

## ICD TECHNICAL AND CLINICAL ISSUES

### OBSERVATIONS OF ATRIAL RHYTHM DURING VF INDUCTION IN DUAL CHAMBER AND CRT ICDS

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**Introduction** Induction of VF during ICD testing at implant of dual chamber devices allows for observation of simultaneous atrial rhythm electrograms. This study was undertaken to observe the possible clinical importance of the atrial mechanism during DFT testing.

**Methods** 104 consecutive patients receiving (initial implant or generator change) dual chamber ICDs (DC) or CRT ICDs with an atrial lead undergoing VF induction, all with T wave shocking, for DFT testing had real time DC electrograms run during testing. The atrial electrograms were reviewed and classified as atrial fibrillation (AF), flutter (AFL), atrial tachycardia (AT), or normal sinus rhythm. Clinical follow-up was 3-24 months (mean 16) after implant.

**Results** 73 men and 31 women were implanted. 77 were DC and 27 CRT devices. Mean age, 67 years. Mean EF, 27%. 22 pts. had a previous history of paroxysmal atrial fibrillation (PAF) or flutter. Of these, 10 were taking amiodarone for this. Another 7 patients were taking amiodarone for recurrent ventricular arrhythmias. During induction of VF, only 3 patients had AF induced. All three pts. had a history of PAF, none on amiodarone. Four pts. had AFL induced, none with a prior history of this. 20 pts. had atrial tachycardia induced, 10 of whom had a history of PAF, and 7 of these were on amiodarone. The remainder had sinus rhythm during VF induction. In follow-up, 6 patients had PAF, 4 of who did not have a prior PAF history.

**Conclusion** Induction of atrial fibrillation during VF induction with T wave shocking is unusual, even in patients with a history of PAF. Amiodarone seems to be protective, though further randomized study looking at this is necessary. The predictive value of induction of AF during VF is unknown in pts. without a history of PAF, and cannot be addressed with these results.

### EVALUATION OF TWO DIFFERENT SHOCK WAVEFORMS WITH A LOW-ENERGY DEFIBRILLATION TEST: THE EFFECTIVE REGISTRY

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**PURPOSE** Comparing the efficiency of a low-energy defibrillation test using two different biphasic shock waveforms (SW): constant tilt (CT) 65% and with a constant pulse duration (CP). **DESCRIPTION:** **EFFECTIVE** is a prospective and multicentric registry that uses St.Jude Medical ICDs with any defibrillation lead. During the implant the physician carries out two low-energy defibrillation tests using the two different SW (sequently 8J, 20J, external DC-shock). Patients are randomized in two groups: in the first a CT is used for the first test, a CP is used in the other one.

**OUTCOMES** 70 patients (65,34±12,97 y.o), 58 male with an average EF of 32,3% and a standard indication for an ICD implant, received respectively 36 (51,4%) single-chamber ICD, 11 (15,75%) dual-chamber ICD and 23 (32,85%) CRT-D. 60 received dual-coil lead, 10 single-coil lead. In 46 (65,7%) a 8J shock ended the VF with at least one of the two SWs and in 39 (55,7%) of these both the SWs succeeded with 8J. Among the other 31 patients, in 19 CT was higher. In 25 (35,7%) the DFT was ≥8J with both SWs: in 15 without difference between the two SWs, but in 7 the CT was higher and in 3 the CP was higher. In 3 (4,28%) the high DFT with both SWs required a high-energy ICD in order to have a safety margin (≥10J). In 12 (17,1%) the programmability of the SW avoided the use of a HE device and in 1 with a right high energy ICD allowed to have a 10J margin.

In **conclusion** the possibility to program different SWs in the same

ICD proves to be an excellent function to have a better defibrillation activity and to manage high DFT cases without using high-energy devices. The DFT proves to be really low in 3 patients out of 4.

### AICD: HOW TO PREDICT HIGH DEFIBRILLATION THRESHOLDS BEFORE IMPLANTATION

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**BACKGROUND:** Successful ventricular defibrillation by an AICD depends on its ability to deliver shocks exceeding defibrillation threshold (DFT). In previous studies, body size, dilated cardiomyopathy, QRS with, QTc interval, left ventricle dilatation, etc, were associated with high DFT (HDFT). However, cut-off points for these variables were not established.

**OBJECTIVE** The aim of the study was to identify pre-implantation parameters which are able to predict HDFT and to determine, if possible, cut-off points for categorical risk stratification.

**METHODS** This was a retrospective study including 171 pts (56.6 ± 17 years, 80% male) evaluated from March 2003 to November 2005. Thirty five parameters were assessed, including standard demographic, electrocardiographic and echocardiographic variables. DFT was considered high when the AICD needed more than 20 Joules, in 2 consecutive shocks, for VF reversion. Pts were divided into 2 groups: Adequate DFT (ADFT) 131 pts and HDFT 40 pts, (23.3%).

Univariate analysis was performed with t test for continuous variables and Chi-square for categorical variables.

Significant variables by Univariate analysis were entered in multivariate analysis to identify independent predictors of HDFT.

**RESULTS** Univariate analysis showed significant differences between ADFT and HDFT groups in: QRS<120 ms (30.8% vs 14.63% p=0.042); QRS>150 ms (30.8% vs 48.8% p=0.035); LVDD>60 mm (50.8% vs 82.9%, p=0.0001); EF<30% (54.6% vs 80.5% p=0.003); Amiodarone administration (last 6 weeks>200mg/day) (53.1% vs 70.7%, p=0.046).

Multivariate analysis showed significant difference in LVDD (OR: 4.11, CI 95%: 1.62-10.38).

**CONCLUSION** In this study population, 23.3% of the pts had HDFT. HDFT was predicted by some clinical, electrocardiographic and echocardiographic parameters. LVDD was found an independent variable to predict HDFT.

### ANTI-ARRHYTHMIC AGENTS DO NOT PREVENT APPROPRIATE ICD THERAPY DELIVERY

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**Purpose** Frequent therapy delivery from Implantable Cardioverter Defibrillator (ICD) may impair quality of life in patients with ICD. The purposes of this study were to determine whether medications that had anti-arrhythmic effect decreased appropriate therapy delivery (ATD) from ICD, and to assess clinical characteristics of patients who experienced ATD.

**Methods** This study consists of 51 patients (37 males, mean age 57.8+/-14.3years) who received ICD. All ICD therapy deliveries including anti-tachycardia pacing and shock delivery for VT and VF but inappropriate therapy delivery for supra-ventricular tachycardia were defined as ATDs. Mean follow-up duration was 27.6+/-20.4 months. Cumulative event free from ATD was compared according to existence of medication of class I and III anti-arrhythmics, beta blockers and ACE inhibitors and/or Angiotensin II receptor blockers (ARB) in whole patients, patients with LVEF<35% (n=25), and patients with LVEF = or >35% (n=26).

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**Result** There were no significant differences in cumulative event free from ATD regardless of class I, III anti-arrhythmics, and beta-blockers in whole patients, patients with LVEF<35% and patients with LVEF = or >35% (p=NS). Cumulative event free from ATD rather tended to be worse in patients with ACE inhibitors and/or ARB (p=0.04 in whole patients). LVEF was lower in patients with class III anti-arrhythmics (36.3+/-15.7% vs 50.7+/-20.9%, p=0.007), beta-blockers (35.6+/-16% vs 49.1+/-20%, p=0.01) and ACE inhibitors and/or ARB (35.1+/-15.4% vs 51.1+/-19.8%, p=0.002) than patients without these medications. Patients with ATD had structural heart diseases more common than patients without ATD (94% vs 67%, p<0.05). **Conclusion** The medications that had anti-arrhythmic effect did not inhibit ATD in patients with ICD. However, this might be associated with underlying heart diseases and heart function. Randomized study will be required to determine actual effect of the medications on suppression of ICD therapy delivery.

**ICD IMPLANT TESTING: APPROPRIATE USE OF 10 JOULE SAFETY MARGIN REQUIRES A STANDARDISED TEST PROTOCOL**

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**PURPOSE** Aim is to study effects of the type of test protocol on outcome of Defibrillation Threshold (DFT) testing and on sensitivity of detecting High Risk patients, defined as requiring a greater than 20 Joule (J) shock to be defibrillated with 80% probability.

**METHODS** A 2-parameter dose-response (DR) curve represented the relation between probability of defibrillation success and shock energy. Computer modeling estimated the parameter distributions of a test population based on 654 Binary Search (BS) DFT's from the Painfree RX II trial. For the individual test patients the model created a DR curve, subjected it to clinically current DFT test protocols and calculated sensitivity and specificity of detecting High Risk patients.

**RESULTS** Simulation showed that 8.7% of the test population were High Risk patients.

Below the tabulated results for a 30(31) J ICD (see Table).

**CONCLUSIONS**

Sensitivity of detecting High Risk patients with E80 > 20 Joule ranged from 14-63% for various protocols with 10 Joule Safety Margin. Standardization of DFT implant test protocol is necessary to obtain a standard sensitivity of detecting High DFT patients.

**SURVIVAL AND COMPLICATION RATE AFTER LONG-TERM FOLLOW-UP OF ICD IMPLANTATION**

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Purpose of the study was to analyze efficacy of ICD during long-term follow-up, to estimate survival of patients with ICD, to evaluate complications rate in early and late postoperative periods.

**Material and Methods.** 240 ICDs were implanted in Bakoulev Center for Cardiovascular Surgery from February 1990 to September 2006. Primary implantations were performed in 164 patients, in 76 cases ICDs were replaced due to battery depletion.

**Results** We evaluated long-term results of 231 III to V generation ICD implantations in 155 patients (117 males, 38 females, mean age 48.0±14.9 years, range 14-78 years). Mean follow-up period was 32.8±30.2 months, range 1-139 months. During this period 91 patients had ICD discharges, time from implantation to first discharge ranging 0.5-70 months. Multifactorial analysis revealed that left ventricular ejection fraction (LVEF) was the only variable influencing the rate of ICD discharges. The mean LVEF was 41.3±16.8% among patients who have already had at least one ICD discharge as opposed to mean LVEF of 57.4% among those who have not had any. Moreover, LVEF appears to be the most important prognostic factor for patient survival, which was 62% in the group of patients with LVEF<40% and 93% in the group of patients with LVEF>40%. Total cumulative proportional survival (Kaplan-Meier) was 79%. Multi-chamber ICDs were shown to improve not only LV pumping function and quality of life (LVEF increasing from 37.3% to 45.0%, NYHA class changing from 2.87 to 2.12) but patient survival as well. Patient survival was 94% among patients with multi-chamber ICD and 67% among those with single-chamber ICD (p<0,001). No intraoperative complications were observed. There was no statistically significant difference for late surgical complications rate between patients with single-chamber and dual-chamber ICDs.

**Conclusion** LVEF and the type of device (single-chamber versus multi-chamber) are two most significant factors influencing patient survival and quality of life.

**MRI ENVIRONMENTS: RESPONSE OF PACEMAKER AND ICD COMPONENTS**

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IN RECENT YEARS, MAGNETIC RESONANCE IMAGING (MRI) HAS BEEN INCREASINGLY USED FOR PERFORMING DIAGNOSTIC MEDICAL IMAGING, AS WELL AS ASSISTING IN NON-INVASIVE MEDICAL PROCEDURES. HOWEVER, THESE SAME MRI

**Table.**

	Test protocol (Test energy/ Implant Criterion)	Probability of failing a test with 10J Safety Margin	Sensitivity of detecting High Risk patients	Safety Margin needed to detect >= 60% of High Risk patients
2/2	(20J)	.090	.63	10J
1*repeated 2/2	(20J)	.045	.45	14J
2*repeated 2/2	(20J)	.030	.33	16J
SD-start at 14J	(21J)	.015	.17	16J
SD+	(21J)	.031	.34	14J
SD++	(21J)	.045	.47	13J
BS-start at 12J	(21J)	.022	.25	18J
SU-start at 5J	(20J)	.012	.14	19J

SYSTEMS UTILIZE VERY STRONG ELECTROMAGNETIC FIELDS WHICH CAN BE DETRIMENTAL TO PATIENTS WITH ACTIVE IMPLANTABLE MEDICAL DEVICES (AIMDS), SUCH AS IMPLANTABLE PACEMAKERS AND ICDs.

ALTHOUGH CONTRAINDICATED BY BOTH THE DEVICE AND MRI SYSTEM MANUFACTURERS, THERE HAVE BEEN A NUMBER OF RECENT REPORTS OF MRI SCANS THAT WERE PERFORMED SUCCESSFULLY ON PACEMAKER PATIENTS. THIS PAPER EXPLAINS IN PART WHY SUCH SCANS WERE PERFORMED WITHOUT APPARENT HARM TO THE PATIENT, AND ALSO WHY SUCH REPORTS ARE ALSO QUITE LIMITED IN SCOPE AND SHOULD NOT BE TAKEN AS SCIENTIFIC EVIDENCE THAT MRI IS GENERALLY SAFE FOR ALL IMPLANT SITUATIONS.

THIS STUDY ADDRESSES THE EFFECTS OF THE THREE MRI FIELDS (B0, B1, RF) ON KEY COMPONENTS WITHIN THE AIMD, INCLUDING THE BATTERY, ICD DISCHARGE CAPACITORS, EMI FILTERS AND OTHER COMPONENTS. BATTERIES AND DISCHARGE CAPACITORS WERE EXAMINED IN A 1.5T MRI SYSTEM USING A VARIETY OF MRI PROTOCOLS. FOR THE BATTERIES, ICD DISCHARGE CAPACITORS AND EMI FILTERS, PROTOTYPES AND PRODUCTION MODELS UTILIZING FERROMAGNETIC AND NON-FERROMAGNETIC COMPONENTS WERE EVALUATED. THE RESULTANT FORCE AND TORQUE WERE ALSO MEASURED. GRAPHS OF TRENDS IN EMI FILTERING IMMUNITY OF AIMDS RELATED TO MRI PULSED RF FIELDS ARE EXPLAINED. THE EXPERIMENTAL BEHAVIOR OF THESE COMPONENTS WAS COMPARED TO THE EXPECTED BEHAVIOR, AS DICTATED BY THE RELEVANT MATERIAL PROPERTIES. DESIGNS THAT MINIMIZE FORCE, TORQUE, AND HEATING, AND IMAGE ARTIFACT IN PARTICULAR, WILL BE PRESENTED. HEATING OF IMPLANTED LEAD WIRES IS ALSO DISCUSSED ALONG WITH THE VARIABLES THAT CAN CONTRIBUTE TO SIGNIFICANT HEATING AT A PACEMAKER DISTAL LEADWIRE TIP.

THIS PAPER WILL INCLUDE A SUMMARY OF CURRENT REGULATORY EFFORTS AND AN MRI WORK ITEM PROPOSAL BY THE ISO STANDARDS BODY FOR ACTIVE IMPLANTS (REF. ISO/TC 150/SC 6).

## IS IT SAFE TO ALLOW PATIENTS WITH ICDs TO DRIVE? LEARNINGS FROM A SINGLE CENTRE EXPERIENCE

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ICD implant indications have widened in recent years, after the publication of the MADIT 2 and the SCD - HeFT trial. On the other hand guidelines on resumption of driving after ICD implant were published almost 10 years ago, when the ICD implant rate was much lower and candidates were generally older. The aim of our study was to evaluate if pts with ICDs have higher risk of having a car accident than the general population.

All patients (612) followed - up in our outpatient clinic were sent a questionnaire in which they were asked about their driving habits before and after ICD implant and, specifically, whether they had been involved in a car accident after the implant.

286 pts (47%) responded to the questionnaire. 71 pts had never driven; 2 pts were forbidden to drive for professional reasons (1 bus and 1 truck driver). 213 (74.5% of all responding) pts (210 male, mean age 62 + 11 yrs) continued to drive after ICD implant. During the follow - up (1430 + 920 days) 11 pts had been involved in car accidents and, importantly, 10 out of 11 were innocent bystanders. Thus, in 996 patient - years, 11 events happened, yielding an annual event rate of 1.1%/patient - years (and only 0.1%, where the driver could had been responsible).

In conclusion, car accidents are infrequent in pts implanted with ICDs, and - in any case - not more frequent than in the general population. The old guidelines need to be updated and specific restrictions on car driving in ICD pts need to be revised to reflect the current data.

## ABLATION FOR ATRIAL FIBRILLATION

### PULMONARY VEIN OCCLUSION: STRUCTURAL AND FUNCTIONAL SEVERITY INDICES

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**Introduction** Pulmonary vein occlusion (PVO) is a rare complication that can develop following radiofrequency ablation (RFA) of AF. Data regarding the number of occluded veins and their clinical course are minimal.

**Methods** Data from 18 patients with complete occlusion of at least one pulmonary vein (PV) following RFA for AF using different ablation strategies were collected. PVO was diagnosed by CT scan and the percent stenoses of the ipsilateral veins were added together to evaluate the total drainage of each lung independently [Cumulative Stenosis Index (CSI) = sum of stenoses/no of ipsilateral veins]. Quantitative lung perfusion was performed and the relative perfusion of each lung was expressed in a percentage of the total perfusion. Patients symptoms were divided into 4 grades according to their severity/number. Relations between the symptoms, CSI and perfusion were analyzed.

**Results** The patients symptoms correlated with the underlying lung findings. In fact, asymptomatic patients had no significant lung disease, while severe symptoms only accompanied pulmonary infarctions, pneumonia, and pulmonary oedema. Patients symptoms also showed a positive correlation with the CSI ( $r = 0.843$   $p < 0.05$ ) and a negative one with the lung perfusion ( $r = -0.667$ ,  $p < 0.05$ ). A lung perfusion  $< 25\%$  indicated a severe lung disease and a CSI  $> 75\%$  correlated well with the impairment of lung perfusion and the presence of severe symptoms.

**Conclusion** Patients with single PVO are mostly asymptomatic. In patients with concurrent ipsilateral PVS/PVO, evaluation of the CSI and pulmonary perfusion may provide an insight into the severity of the condition and prompt early intervention.

### SAFETY OF A SECOND TRANSEPTAL PUNCTURE IN A COMBINED APPROACH TO ATRIAL FIBRILLATION ABLATION

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**Background** A combined approach of left atrial circumferential ablation (LACA) followed by segmental ostial catheter ablation (SOCA) of the pulmonary veins may reduce AF recurrences as compared with SOCA alone. In spite of the potential efficacy of this technique, it is not routinely employed because of concern about performing a second transeptal (TS) puncture on a patient who is systemically anticoagulated. We present our experience with this approach.

**Results** Patients (N=124) who were referred for AF ablation from August 2004 to September 2005 formed the study cohort. Patient characteristics were as follows: mean age 59 years, 97 men, paroxysmal AF (N=91), persistent AF (N=26), chronic AF (N=7), mean EF 60%, and mean left atrial size 4.3 cm. A non-fluoroscopic, 3-dimensional navigation system (Ensite NavX) was used to define left atrial geometry and assist with catheter position. Under hemodynamic and fluoroscopic guidance, a Brockenbrough needle was advanced via a SL-1 or Agilis sheath, and the initial TS puncture was performed in 124 patients. Intracardiac echocardiography (ICE) was used in 54 patients in order to visualize tenting of the septum. Following the first TS puncture, there was one case of tamponade. After completion of LACA,

a second TS puncture was performed in 119 patients with an activated clotting time of 350-370 following a bolus and intravenous infusion of heparin. There was one case of tamponade. Of the total of two cases of tamponade, one procedure included the use of ICE. There were no cases of stroke. The mean time from the second TS puncture to the completion of the procedure was 44 minutes.

**Conclusions** Following LACA, a second TS puncture and segmental isolation of the pulmonary veins may be performed safely and efficiently without an increase in the incidence of tamponade or stroke in a fully anticoagulated patient.

### SELECTIVE APPROACH FOR ABLATION OF PAROXYSMAL AND PERSISTENT ATRIAL FIBRILLATION: IS IT POSSIBLE TO TAILORED ABLATION FOR EVERY SINGLE PATIENT?

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**Background** It is widely accepted that the majority of paroxysmal (PAF) and persistent (PEF) atrial fibrillation (AF) is triggered by foci arising in the pulmonary veins (PVs). Catheter ablation (CA) for PAF and PEF is generally performed creating circumferential lesions around all the pulmonary veins.

**Purpose** Aim of present study was to demonstrate the possibility to address ablation to specific triggers, allowing a reduction of number of the treated PVs and procedure duration.

**Materials and methods** 22 highly symptomatic patients (pz) (17 male; age  $57 \pm 14$  years) underwent CA for PAF (14/22) or PEF (8/22). P wave morphology of the triggering beats were analyzed using 12 leads ECG. A presumable culprit PV was identified in 41% (9/22 pz). During CA in 60% (13/22 pz) one or two culprit PVs was identified, 9/13 was confirm the PV previously identified with 12 leads ECG, in 4/13 pz new single foci was discovered. In 9/22 pz no foci was discovered. CA was targeting to 1 PV in 14% (3/22 pz), 2 PVs in 36% (8/22 pz) and 4 PVs in 50% (11 pz). A second CA was performed in 45% (10/22 pz). On the whole in 50% (11/22 pz) one or two PVs were treated (Gr. A), in 50% all PVs were treated (Gr. B). All CA was performed using both Carto Navigation system and Lasso catheter. We had no complications.

**Results** During a follow-up of  $12 \pm 8$  months we could observed no recurrences of AF or a great improvement of symptoms in 82% (9/11 pz) of Group A and in 73% (8/11 pz) of Gr. B ( $p = ns$ ). There were no late complications.

**Conclusions** In pz with PAF or PEF the identification of triggers allow to perform a culprit PVs selective CA. There were no differences of effectiveness between PVs selective CA and extensive CA.

### RECURRENT ARRHYTHMIAS AFTER ABLATION OF CHRONIC ATRIAL FIBRILLATION AND RESULTS OF THE REPEAT ABLATION

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We report recurrent arrhythmias after ablation of chronic atrial fibrillation (AF) and results of reablation.

**Methods** First ablation consisted of circumferential pulmonary vein (PV) ablation with PV isolation, left atrial (LA) linear lesions and optional focal LA lesions and coronary sinus (CS) ablation. Of 82 patients (pts) with chronic AF (duration  $28 \pm 28$  months, resistant to amiodarone and electric cardioversion), 44 patients have sinus rhythm (SR) since first ablation. Twenty-eight pts (9 F,  $52 \pm 10$  years) underwent second or third (4) ablation for paroxysmal (3) or persistent AF (13), paroxysmal LA tachycardia (LAT) (2), persistent LAT (12), persistent

typical atrial flutter (1) and paroxysmal right atrial tachycardia (1). Results: Paroxysmal AF/LAT was terminated and rendered noninducible. AF (3) was terminated with linear lesion connecting right PVs with mitral annulus, 2 LATs by ablation at septal rim of LA appendage (LAA) mouth. Persistent LATs were terminated at septal (1) or superior rim of LAA mouth (3), Bachmann's bundle (BB) (1), LA roof (1), left PV antrum (2) and CS (4). Of 13 persistent AF, SR was restored from AF in 1 (left PV) and via transitory LAT in 5 pts. Sites of SR restoration were BB (3), septal rim of LAA mouth (1) and LAA roof (1). Right atrial tachycardia was terminated and rendered noninducible in both pts. During  $13 \pm 10$  month follow-up, 21 (75%) pts have stable SR, 5 (18%) pts have persistent AF and 2 (7%) pts have persistent LAT.

**Conclusion** Following ablation of chronic AF using complex LA ablation: 1) proportion of recurrent LATs was high; 2) these LATs were eliminated by reablation; 3) ablation outside posterior LA wall was required to restore SR in majority of patients; 4) recurrent AF occurred if repeat ablation failed to affect the arrhythmia.

### ANTIARRHYTHMIC DRUG THERAPY AFTER RADIOFREQUENCY CATHETER ABLATION IN PATIENTS WITH ATRIAL FIBRILLATION

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**Objectives** In evaluating the efficacy of atrial fibrillation (AF) ablation on AF recurrence prevention a controversial issue is the use of antiarrhythmic drug after ablation. Aim of our study was to compare, in a prospective and randomised study, the impact of antiarrhythmic drug in preventing AF recurrence after AF ablation.

**Methods** From February 2004 to May 2005 one hundred-seven consecutive patients (69 male, mean age  $57 \pm 10$  yrs), with paroxysmal (60%) or persistent (40%) drug refractory AF, were randomized to ablation alone (Group A, 53 patients) or combined with best antiarrhythmic therapy, amiodarone preferred (Group B, 54 patients). All patients underwent cavo-tricuspid and left inferior pulmonary vein (PV)-mitral isthmus ablation plus circumferential PVs ablation, using an electro-anatomical approach, CARTO-guided. Standard ECG, Holter monitoring and transtelephonic ECG monitoring were used to assess AF recurrences. Recurrences during the first month after ablation were excluded from analysis.

**Results** At 12 month follow-up no significant ( $p=0.63$ ) difference was observed in the rate of AF recurrence between Group A (18/53 patients, 34%) and Group B (16/54 patients, 30%). The percentage of patients with at least one asymptomatic AF episode was higher in control group compared with ablation group (10/16 patients, 63%, vs 5/18 patients, 28%,  $p=0.04$ ).

**Conclusions** Continuing antiarrhythmic drug therapy in patients who undergo catheter ablation for AF did not reduced AF recurrences. The use of antiarrhythmic drugs increased the percentage of patients with asymptomatic AF episodes.

### ATRIAL FIBRILLATION TERMINATION MODE COMPARING THREE COMMON ABLATION STRATEGIES FOR PERMANENT ATRIAL FIBRILLATION: RESULTS FROM A RANDOMIZED STUDY

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**Background** Ablation of permanent atrial fibrillation (perm-AF) is typically associated with lower success rate. Recent clinical observations suggested that AF termination during ablation of perm-AF, either by restoring sinus rhythm (SR) or by organization into an atrial tachyarrhythmia (AT), maybe associated with higher long-term maintenance of SR.

**Objectives** We evaluated the mode of AF termination of three common ablation strategies for perm-AF.

**Methods** One hundred and forty four consecutive patients with perm-AF presenting in AF were randomized to:

1. Pulmonary Vein Antrum Isolation (PVAI), N=48;
2. Hybrid approach: initial defragmentation, targeting bi-atrial and coronary sinus (CS) complex fractionated atrial electrograms (CFAE) and started randomly in the right or left atrium, followed by PVAI, N=49;
3. Large area circumferential ablation (LACA) targeting voltage reduction using electroanatomic mapping (CARTO), N=47.

The modes of AF termination were: Conversion to SR, organization into AT or persistence of AF requiring cardioversion following ablation.

**Results** They are shown below:

	PVAI only N=48	Defragmentation +PVAI N=49	LACAN=47	P value
SR	3 (6%)	2 (4%)	1 (2%)	NS
AT	18 (38%)	34 (70%)	5 (11%)	P<0.001
AF	27 (56%)	13 (26%)	41 (87%)	P=0.01

There were no differences in sex, age, AF duration, LA size and LVEF in the three groups. SR was rarely restored with any of the three ablation strategies.

AF organized into AT (cycle length  $246.8 \pm 36.9$  ms) more often in the defragmentation+ PVAI group (70%), less often in the PVAI group (38%) and rarely in the LACA group (11%), ( $p<0.001$ ). However, bi-atrial and CS defragmentation alone, performed initially as part of the hybrid approach, almost never resulted in organization of AF into AT (only 1%).

**Conclusions** Spontaneous conversion to sinus rhythm during ablation is rarely observed during any ablation strategy of perm-AF. The hybrid strategy (defragmentation+ PVAI) had a higher effect on AF termination (74% of cases), whereas the LACA strategy had little impact. Defragmentation alone almost never terminated AF in permanent AF patients.

## EFFICACY AND SAFETY OF RADIOFREQUENCY ABLATION IN THE ELDERLY

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**Introduction** Radiofrequency catheter ablation (RCA) is not frequently used in the elderly, because of the lack of data about its efficacy and safety in this category of patients. The aim of our study is to evaluate the long-term efficacy and the rate of perioperative complications of RCA and to verify if there are any differences in these parameters between elderly and young-adults patients.

**Methods** We evaluated 315 patients with age 61+/-17 years, who underwent RCA from January 2003 to October 2005. The patients have been divided in two groups according to age < 70 (group A, n=201, 63.8%) or >70 (group B, n=114, 36.2%). Within the group B patients have been divided according to age 70-80 (group B1, n=84) and >80 (group B2, n=30). We considered as efficacy end-point the relapse of arrhythmias (RA) during a follow up of 19+10 months. Furthermore, we evaluated as a marker of safety the rate of severe perioperative complications.

**Results** The rate of hospitalization for RA in all patients during a follow up of 19+/-10 months was 4.8%, without significant differences between elderly and young-adults patients (3.5% vs. 5.5%). Within group B this rate was similar between group B1 and B2 (3.6% vs. 3.3%). The period of time between RCA and the first recurrence of arrhythmia was 8.5+/-8 months. The rate of perioperative complications was low (0.6%), with 1 case of pericardial effusion (0.3%) and 1 case of haematoma with secondary anemia (0.3%). There were no significant differences between group A and group B (1% vs 0%).

**Conclusions** Our study demonstrates that there are not significant differences in efficacy and safety of RCA between elderly and young-adults patients. Furthermore, there are no significant differences in postoperative RA and perioperative complications between patients with age > 80 years and age between 70 and 80 years.

## RADIOFREQUENCY ABLATION OF ATRIAL FIBRILLATION: COMPARISON OF THE RESULTS OBTAINED IN THE LEARNING PHASE OF A SINGLE CENTRE WITH WORLDWIDE SURVEY AND LITERATURE REVIEW

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**PURPOSE** The efficacy and safety of segmental ostial isolation in patients with medically refractory atrial fibrillation (AF) is confirmed by recent literature review (Fisher 2006) and worldwide survey (Cappato 2005). Only few studies evaluated the results obtained in the "learning curve" of this technique in a centre with previous large experience. Aim of this observational study was to compare the clinical characteristic, the procedural data, the acute and 6 month follow-up success, and the major adverse effects in consecutive patients treated in our first experience (years 2003-2006) with data reported in two above mentioned reviews.

**MATERIALS AND METHODS** In our series 63 patients underwent AF ablation. We analyzed the success rate free of antiarrhythmic drugs ("cure") and the "improvement" (fewer episodes, no AF episodes in the presence of drug therapy).

**RESULTS** Clinical characteristics in our population were not different from the review (paroxysmal AF 79% vs 83%, heart disease 42% vs 36%; p=ns), while our procedure time was lower (170±35 min vs 278±66 min; p=0.0001). Our total "cure rate" was lower (37% vs 62%; p<0.001), but the "improvement rate" was higher (75% vs 88%; p=0.02); however, our centre required less second procedure rate (9% vs 21%; p=0.03). If we consider the experience of similar-volume centre reported in the worldwide survey, our results showed similar "cure" (35% vs 37%; p=ns) and "improvement" (88% vs 71%; p=0.005) rates. Our major complications were all reversible and consistent with the worldwide survey data (4.6% vs 6%; p=ns).

**CONCLUSIONS** Patients treated in the learning phase of a centre with previous large experience in RF ablation show similar characteristics with literature data. Overall success and complications rate appear also similar. The effects of antiarrhythmic drugs withdrawal on AF recurrences after the first 6 month follow-up should be compared in the future.

## VENTRICULAR AND ATRIAL EVOKED RESPONSE

### EFFECT OF ACUTE EVOKED RESPONSE SIGNAL VARIATIONS ON THE ACUTE PERFORMANCE OF A RIGHT VENTRICULAR AUTOMATIC CAPTURE ALGORITHM

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**Introduction** Automatic capture verification (ACV) is an important component of remote follow-up for implantable defibrillators. The clinically proven reduced pacing output coupling capacitor (RCC) technology for ACV was used in this acute clinical study to evaluate the effect of acute evoked response (ER) variations on the performance of the RVTip-Can algorithm in a heart failure population. **Method** Data from 43 patients (33M/10F, 63.7 ± 11.0 years) were analyzed. The study was performed during CRT-D implant or replacement. Two right ventricular step-down threshold tests were conducted, with an AV delay of 60ms and a starting voltage of 3.5V, immediately following leads implantation and approximately 30 minutes later. Surface ECG and intracardiac electrograms were recorded on a pacing and data acquisition system. Each beat was independently classified by visual examination of the surface ECG morphology and by the ACV algorithm. The capture detection performance was determined by comparison of the algorithm and visual classification. The algorithm performance was evaluated in terms of ER amplitude, artifact, signal-to-artifact-ratio (SAR), capture detection results and threshold accuracy.

**Results** The leads were from four manufacturers (13 dedicated bipolar/30 integrated bipolar; 27 acute/16 chronic). 3093 capture and 797 non-capture beats from 86 threshold tests were examined. The average time between the two tests was 27±6 min. Only the minimum ER amplitude significantly increased between tests (6.5±5.4 vs. 7.0±5.6mV, p<0.01). The sensitivity (99.6% vs. 100%), and specificity (97.2% vs. 97.8%) of the capture detection algorithm was not significantly different between time points, resulting in similar threshold test accuracy at both time points.

**Conclusion** Although a smaller ER amplitude was observed immediately after implant, the signal characteristics were sufficient to maintain capture detection performance at both evaluated time points. In this study the RCC technology-based ACV algorithm was not susceptible to acute signal variations due to lead implantation.

### CHARACTERIZATION OF THE LEFT VENTRICULAR EVOKED RESPONSE WITH AN INDEPENDENT PACE/SENSE VECTOR CONFIGURATION

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**Introduction** The future of Automatic Capture Verification (ACV) technology and remote patient management systems depends on reliable evoked response (ER) signal characteristics. This clinical study evaluated left ventricular (LV) ER signal characteristics in an independent pace/sense (IPS) configuration.

**Methods** Patients with sinus rhythm indicated for CRT-D implantation were enrolled for intraoperative testing. LV stepdown threshold tests in unipolar (LVTip to Can) and extended bipolar (LVTip to RVRing/Coil) pacing vectors were conducted at 0.4ms with an external pacing system (Guidant, St. Paul, MN); unipolar tests were also conducted at 1.0ms. ER signals were sensed LVRing to Can. For each

threshold test the min LV ER (ERmin) and max pacing artifact (ARTmax) amplitudes were assessed offline to calculate the min signal to artifact ratio (SARmin). Signal quality sufficient for capture detection was identified as SARmin>2. Two-sided, paired t-test significance set at p<0.05.

**Results** Data from 16 pts were analyzed. Three different bipolar LV lead types from 2 manufacturers were used. SARmin>2 for both pacing vectors was found in 100% of pts. Pacing threshold was significantly higher for 0.4ms pulse width than for 1.0ms during unipolar pacing; pacing vector had no effect on capture threshold. A significant difference in mean ER peak timing (Tmax) was observed at 1.0ms; all LV ER peaks occurred within the first 70ms after the pacing pulse.

**Conclusion** LV ER signal quality characteristics using the IPS configuration are independent of pacing vector and pulse width and were adequate for signal discrimination in all cases. The flexibility and reliability of the IPS configuration may provide an effective means of implementing ACV technology in the LV.

### EFFECT OF INTERVENTRICULAR PACING TIMING ON CAPTURE VERIFICATION IN THE LEFT VENTRICLE

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**Introduction** Automatic Capture Verification (ACV) technology enables advancement in the areas of automated and remote patient management. The reliability of evoked response (ER) sensing via reduced pacing output coupling capacitor technology has been clinically proven. This technology was applied to the left ventricle (LV) and used in this clinical study to evaluate the effect of interventricular pacing timing or LV Offset (LVO) for the development of a new algorithm for ACV in transvenous LV leads.

**Methods** Data from 43 patients, aged 63.7±11.0 yrs., M/F 33/10, have been analyzed. Patients with sinus rhythm indicated for CRT-D implantation were enrolled for intraoperative evaluation. An external pacing system (Guidant, St.Paul, MN) was used to conduct unipolar (LVTip to Can) LV stepdown threshold tests during biventricular (BiV) pacing at various LVO. During offline analysis, minimum LV ER and maximum pacing artifact (ART) amplitudes were assessed to calculate the minimum signal to artifact ratios (SARmin=ERmin/ARTmax). SARmin>2 was defined as a successful capture discrimination. Negative LVO was defined as LV pacing pulse preceding the RV pacing pulse.

**Results** Five different LV lead types from 3 manufacturers (unipolar/bipolar 14/29) were used with left and right pacemaker pocket locations (41/2). The ERmin was significantly increased at -80ms and -40ms LVO (10.0±5.8mV and 10.5±5.9mV, respectively, p<0.05), and significantly decreased at +40 ms LVO (7.8±5.0mV, p<0.05) when compared to 0ms LVO (8.5±6.6mV). The number of patients with SARmin>2 was significantly greater at -80ms and -40ms LVO (95% and 97%, respectively, p<0.05) and unchanged at +40ms LVO (83%), when compared with 0ms LVO (81%).

**Conclusion** In this study, LV capture detection during BiV pacing using the reduced coupling capacitor technology is sensitive to interventricular pacing timing, suggesting that negative LVO show the greatest potential for capture discrimination.

## LEFT VENTRICULAR EVOKED RESPONSE CHARACTERIZATION DURING BIVENTRICULAR PACING WITH AN INDEPENDENT LV PACE/SENSE CONFIGURATION

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**Introduction** Left ventricular (LV) Automatic Capture Verification (ACV) could be clinically useful for reliable biventricular (BiV) pacing during cardiac resynchronization therapy (CRT). A clinical study was conducted to evaluate LV evoked response (ER) signal characteristics using an independent pace/sense (IPS) configuration.

**Methods** Sinus rhythm patients indicated for CRT-D implantation were enrolled for intraoperative testing using an external pacing system (Guidant, St. Paul, MN). LV unipolar (LVtip to Can) stepdown threshold tests during DDD BiV pacing were performed with various AV Delays (AVD) and LV Offset (LVO) settings. ER signals were obtained with the LVring to Can vector. The following parameters were evaluated: minimum LV ER (ERmin), amplitude stability (AS), mean peak timing (Tmax) and stability (delta Tmax).

**Results** Data from 16 patients were analyzed. Three different bipolar LV lead types were used. A small but significant difference was observed in the paired analysis of AS at different AVD; however, in all cases, the ER amplitude change was <15%. Historically, AS<40% and ERmin>2mV have been identified as sufficient to detect capture. BiV pacing with early LV pacing (LVO = -80ms) and synchronous pacing (LVO = 0ms) at 60ms and 120ms AVD satisfied this criteria in all patients.

**Conclusion** LV ER characteristics with the IPS configuration during BiV pacing are mostly independent of AVD settings. For early LV pacing and for synchronous pacing, the LV ER characteristics were adequate to detect capture. The observed signal consistency over a range of BiV CRT parameter settings may provide an effective means of implementing ACV technology with the IPS configuration.

## ACUTE AUTOMATIC CAPTURE VERIFICATION PERFORMANCE USING LEFT VENTRICULAR PACING LEADS

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**Introduction** Automatic Capture Verification (ACV) technology is an important enabler for new capabilities, such as automated and remote patient follow up and patient management. The clinically proven technology of reduced pacing output coupling capacitor for reliable evoked response (ER) sensing was used in this clinical study to evaluate the effect of pacing vector for the development of a new algorithm for ACV in transvenous left ventricular (LV) leads.

**Methods** Patients (pts) indicated for CRT-D implantation with sinus rhythm were enrolled for intraoperative testing. An external pacing system (Guidant, St. Paul, MN) was used to conduct LV stepdown threshold tests in unipolar (LV to Can), extended bipolar (LVTip to RVCoil) and bipolar (when available) pacing modes. The minimum LV ER and maximum pacing artifact (ART), or polarization, amplitudes were assessed to calculate the minimum Signal to Artefact Ratio (SARmin=ERmin/ARTmax); SARmin was used to evaluate the worst case signal discrimination. SARmin>2 was defined as a successful signal discrimination.

**Results** Data from 15 pts have been analyzed. Seven different LV lead types were used (UP/BP 7/8). SARmin>2 for all pacing vectors was found in 14/15 pts (93%). The offline simulated ACV algorithm showed a capture detection specificity and sensitivity of 99.0% and 100% respectively, in the three tested pacing configurations.

**Conclusion** The novel LV ACV algorithm, which uses the reduced coupling capacitor technology, has shown to have high specificity and sensitivity. The accuracy of the algorithm was independent of the pacing vector, suggesting robust performance that will need to be validated in a future study.

## ATRIAL EVOKED RESPONSE SIGNAL QUALITY IN HEART FAILURE PATIENTS

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**Introduction** Automatic threshold algorithms are widely used in clinical practice to increase device longevity and improve follow-up. The purpose of this clinical study was to evaluate whether right atrial evoked response (AER) sensing in HF patients (pts) can be used as a basis for an Atrial Automatic Threshold (AAT) algorithm.

**Methods** Pts indicated for CRT-D implantation with sinus rhythm were enrolled. An external pacing system (Guidant, St. Paul, MN) was used to conduct RA manual stepdown threshold testing in a unipolar, DDD mode. Surface ECG, atrial and ventricular intracardiac signals, AER, and device timing information were recorded.

**Results** Data was recorded from 33 pts, age 63.8±10.5yrs. Eight bipolar atrial lead types from 3 manufacturers with 21 acute/12 chronic (0.8±1.4 years) were studied. Two pts showed AER peak signals < 0.3 mV and were excluded from the analysis. The data from the remaining 31 pts were analyzed offline by applying a simulation of the AAT algorithm to the recorded data. Measured AER was 1.72±0.93 mV and signal to artifact ratio (SAR) was 57.93±30.06. Manual vs. AAT algorithm classification of atrial paced beats (n=1681) were evaluated for capture/loss of capture (LOC), sensitivity, and specificity.

**Conclusion** Right AER sensing in HF pts can be used as a basis for an AAT algorithm. This technology reliably provides sufficiently large signals and SARs to differentiate capture vs. LOC with sensitivity and specificity greater than 98%.

## AUTOMATIC VERIFICATION OF VENTRICULAR STIMULATION: FUSION MANAGEMENT ALGORITHM

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**BACKGROUND** Ventricular stimulation with automatic control and back-up impulse warrants maximum security for the patient and increase device's longevity.

Fusion's phenomenon may hinder evoked response (ER) detection and cause an unnecessary back-up stimulation.

We evaluated an automatic fusion beat management algorithm, and its relationship with atrioventricular (AV) interval programming in a DDD/R pacemaker.

**METHODS** we analyzed 45 Holter registrations of patients treated with an Insignia Ultra DR.

Fusion beats classification was performed either automatically from the pacemaker by the Fusion Management Algorithm, or manually by the analyzing physician. Fusions were classified as loss of cap-

ture (LOC), true fusions (TF), fusion classified as captured beats (FC). Patients were divided into 2 groups in accordance with AV interval programming : long AV (AVI)( $>150$  msec), short AV (AVs)( $<150$  msec).

**RESULTS** percentage of paced beats was on average 65%. Fusion beats resulted 26% of the total.

No fusion beat was classified like loss of capture (LOC). Misclassification of fusion beats as captured beats (CF) occurred at different rates depending on programmed AV delay, as reported in the table.

**CONCLUSIONS** algorithm's performance of fusion beat's automatic management is improved from AV long interval programming or with automatic search of intrinsic activity. The interaction between automatisms are fundamental for the optimization of the fusion management algorithm.

### WHICH PATIENT EXPERIENCES MARKED PACING THRESHOLD FLUCTUATIONS AFTER PACEMAKER IMPLANT WITH AUTOMATIC CAPTURE? INSIGHTS FROM THE ITACA STUDY

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**Background** Automatic Capture (AC) is an algorithm designed in

permanent pacemakers (PM) (Insignia®, Guidant Corp.) to ensure ventricular pacing with an adequate safety margin, checked on a beat-to-beat basis. Despite the wide use of this algorithm, in clinical practice it is not known how many patients develop a marked threshold rise during the first months from implant requiring maximum energy to ensure safety.

**Aim** Aim of the present analysis is to find, after a PM implant with AC, which patient discharged from hospital with an acceptable ventricular pacing threshold ( $<1.5$  V), develop in the first months a temporary threshold rise requiring backup pacing at 5V.

**Methods and results** 373 patients were discharged after PM implant with a threshold of  $0.56 \pm 0.35$  V and visited at a median of 2.5 months from implant. Daily measurements of ventricular threshold showed that 36 patients (9.6%) experienced at least once a backup pacing at 5V due to a temporary threshold rise. In 33 of this patients a high threshold was not detected neither at discharge nor during the next ambulatory visit. At univariate analysis, considering both patient characteristics (gender, atrial disease, complete AV block, CAD, atrial fibrillation) and lead features (acute/chronic, unipolar/bipolar, active/passive fixation, high/low impedance, steroid/non steroid eluting, threshold  $>1$  V/ $<1$  V at discharge), only patients with threshold  $>1$  V at discharge (23% vs 8%  $p < 0.01$ ) and without steroid eluting leads (71.4% vs 52.7%  $p = 0.02$ ) showed a significantly higher number of cases with threshold rise.

**Conclusion** Up to 10% of patients implanted with PM experience temporary and marked threshold fluctuations over time, most of which cannot be detected at ambulatory follow up or discharge. As clinical or lead variables do not allow to predict completely this behaviour, Automatic Capture algorithm is considered useful to avoid programming of maximum output in the first months from PM implant.

## ATRIAL FIBRILLATION ABLATION: TROUBLES AND TROUBLESHOOTING

### OPEN IRRIGATION CATHETERS GENERATE HIGHER ESOPHAGEAL TISSUE TEMPERATURES THAN STANDARD 8MM TIP CATHETERS WHEN ABLATING WITHIN THE LEFT ATRIUM

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**Introduction** Atrial-esophageal fistula is a devastating complication of catheter ablation of atrial fibrillation probably caused by thermal injury. Both open irrigation catheters (OIC) and large 8mm tip are used for this procedure.

**Objective** To compare the thermal affects on the esophagus (Eso) of the 3.5mm OIC with that of the 8mm during radiofrequency (RF) ablation of the left atrium (LA).

**Methods** Via thoracotomy, 6 dogs underwent placement of a tissue thermocouple onto the anterior surface of the Eso posterior to the LA. An intra-luminal Eso temperature probe advanced to the level of the LA and tissue thermocouple. An ablation catheter advanced into the LA via transseptal puncture. RF lesions were applied to the LA posterior wall near the Eso. In 3 dogs an 8mm delivered lesions at a setting of 50W, 60°C for 90 seconds. In 3 dogs an OIC delivered lesions near the Eso with a setting of 50W, 45°C, 30cc/min flow rate for 90 sec. Simultaneous temperature recordings were obtained from the catheter, tissue thermocouple, and luminal Eso temperature probe.

**Results** An average of 12.6±5 RF lesions were placed in each dog. Anterior Eso tissue temperature significantly increased during each RF application with both the OIC (38.4±0.5°C to 90.7±21.4 °C, p<0.01) and 8mm (38.3±0.5°C to 58.7±7.6 °C, p<0.01). There was also an increase in Eso temperature during RF application with both the OIC (37.3±0.42°C to 40.6±1.2 °C, p<0.01) and the 8mm (37.2±0.1°C to 39.5±0.6 °C, p<0.01). The mean increase in anterior Eso tissue temperature was greater with OIC compared to 8mm (52.3±21.6°C vs 20.4±7.9°C, p=0.01). This was not observed with the luminal Eso temperature when comparing lesions from the OIC and the 8mm (3.3±1.2°C to 2.3±.7 °C, p=NS).

**Conclusion** Lesions delivered with OIC appear to increase Eso tissue temperature more than the 8mm. This is not reflected in intra-luminal Eso temperature measurements.

### OESOPHAGEAL TEMPERATURE MONITORING DURING RADIOFREQUENCY ABLATION IN LEFT ATRIUM

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**Background** Left atrial radiofrequency (RF) ablation in awake patients is often linked to the development of visceral pain.

**Purpose** To investigate the role of oesophageal warming as regard to the development of RF-related pain.

**Methods** An oesophageal probe (OP) capable to measure endoesophageal temperature (Esotherm 4, FIAB) was positioned before starting the procedure. Electroanatomical reconstruction of left atrium was then obtained by using current specific tools. OP position (lateral, central or medial) as regard to the one of the left atrium was evaluated through fluoroscopy imaging. Left atrial surface was then divided into 12 zones (6 anterior and 6 posterior) and maximal oesophageal temperature (OT) was measured at the end of each RF delivery, considering the relative position of the ablator catheter. The patient was asked to define the intensity of the pain experienced dur-

ing each RF delivery by using an intensity score index ranging from 0 (no pain) to 4 (intensive pain requiring immediate interruption of RF).

**Results** 10 patients were studied (7 males). OP insertion was generally well tolerated and no patient asked for its removal during the procedure. Mean OT during RF delivery was 40.9±6.1°C. The location of the OP showed a high correlation to the development of the maximal OT raise (Spearman's rank correlation coefficient 0.64, CI 0,56-0,71). Moreover, the highest values of pain intensity were always reported when RF was delivered at the level of the atrial zones nearby the OP projection (correlation coefficient 0.53, CI 0,53-0,68) and when the highest levels of OT were reached (correlation coefficient 0.61, CI 0,56-0,71).

**Conclusion** Left atrial RF ablation related pain is due (at least partially) to oesophageal warming. Further investigation on short- and long term jeopardizing of oesophageal wall is therefore needed.

### HUMAN HEART-TYPE FATTY ACID-BINDING PROTEIN IS AN EARLY AND SENSITIVE MARKER OF MYOCARDIAL INJURY IN PATIENTS UNDERGOING RADIOFREQUENCY ABLATION

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The application of radiofrequency (RF) energy for ablation of arrhythmias has therapeutical objectives, however it may determine variable degrees of myocardial injury. The human heart-type fatty acid-binding protein (H-FABP) is a cytosolic protein that is released from the cardiomyocyte in response to myocardial damage. It is an early and sensitive marker of injury when compared to cardiac troponin I (TnI) and serum creatin kinase MB (CK-MB). The aim of this study was to evaluate whether serum levels of H-FABP change after RF ablation and whether any relation exists between these levels and duration and mean power of RF applications.

Eleven patients with atrial (n.6) or ventricular (n. 5) tachyarrhythmias who underwent RF ablation were enrolled in the study. Blood samples of H-FABP, TnI and CK-MB were taken before and at 0, 3, 6 and 24 hours after the RF procedure. H-FABP increased from 3.3±.6 to 8.1±2 ng/ml (p<.005) immediately after the procedure while TnI and CK-MB showed a peak at 3 and 6 hrs after ablation (p<.05 versus baseline). Total H-FABP production had a mild (r=.52), not significant relation with the mean power of RF applications but a very significant relation to total RF applications duration in sec (r=.93), p<.0005. No relation between TnI or CK-MB production and the above mentioned ablation parameters could be reported.

These preliminary data show that H-FABP has an important role as an early and sensitive marker of myocardial injury in patients with atrial or ventricular arrhythmias undergoing RF ablation.

### LEFT ATRIAL STRUCTURAL CHANGES AFTER CATHETER ABLATION OF CHRONIC ATRIAL FIBRILLATION USING COMPLEX LEFT ATRIAL ABLATION

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We compared volume and voltage changes of left atrium (LA) obtained from first and repeat electroanatomic mapping in chronic atrial fibrillation (AF) patients (pts), who underwent reablation. Methods: Of 82 pts (chronic AF 28 ± 28 months, resistant to amiodarone and cardioversion), 26 pts (9 F, 52 ± 10 years) underwent reablation in LA. First ablation strategy consisted of circumferential pulmonary vein (PV) isolation, linear lesions including LA septum and

anterior wall and coronary sinus and focal LA ablation. LA volumes (LAV) calculated by CARTO software and volumes related to body surface area (LAV/m<sup>2</sup>) were compared. Points of LA maps were divided into 3 voltage groups (< 0.2; 0.2-1; > 1 mV) and proportions of points were compared. Results: First maps were completed during AF, repeat maps during AF (16) or LA tachycardia (10). Number of first and repeat 3-D map points did not differ (118±19 vs. 113±20; P = 0.2). LAV resp. LAV/m<sup>2</sup> of repeat 3-D maps were smaller (147±26 vs. 120±23 ml; P < 0.01; resp. 72±12 vs. 57±9 ml; P < 0.001). Proportion of LA points < 0.2 mV increased from 35±21 to 42±15%; P = 0.02; proportion of LA points 0.2 - 1 mV decreased from 53±17 to 40±7 mV; P = 0.03; proportion of points > 1 mV increased from 12±8 to 18±15%; P = 0.001. Conclusion: 1) Complex LA ablation led to significant LA volume reduction. 2) Number of LA points exhibiting voltage < 0.2 mV increased, however number of points showing voltage over 1 mV has significantly increased, particularly in LA appendage 3) Results suggest that complex LA ablation may lead to reverse LA structural remodeling even in patients, in whom the arrhythmia was not completely eliminated.

### EARLY DILATION/STENTING OF PULMONARY VEIN OCCLUSION FOLLOWING CATHETER ABLATION FOR ATRIAL FIBRILLATION RESTORES PULMONARY FLOW AND PREVENTS ASSOCIATED LUNG DISEASES

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**Introduction** Pulmonary vein occlusion (PVO) is a rare complication that can develop following catheter ablation (CA) of atrial fibrillation (AF). As a consequence, arterial flow to the affected lung segment may be compromised predisposing to detrimental sequelae. We present the impact of timely intervention for PVO on the corresponding lung.

**Methods** Data from 17 patients with complete occlusion (> 95% stenosis) of at least one pulmonary vein (PV) were prospectively collected after CA for AF using different ablation strategies. PVO was diagnosed by CT scan and the corresponding lung was physiologically evaluated by lung perfusion scans. The percent stenoses of the ipsilateral veins (PVO/PVS) were added together [Cumulative unilat-

eral stenosis (CUS)] and correlations drawn with the quantitative perfusion before and after intervention. Pulmonary intervention was attempted in all patients, and the success was evaluated by the decrease of CUS by CT scan, as well as the improvement of the lung perfusion post intervention.

**Results** Out of the 17 patients, intervention was performed in 15 [7 (46.7%) had dilatation only and 8 (54.3%) had dilation and stents] while restenosis occurred in 46%. The improvement of CUS post intervention was considerable in the successful patients [mean difference 27.5% (95%CI 11.73-43.27) P<0.005]. The number of interventions and the improvement in the CUS correlated with the improvement in lung perfusion (r = 0.765 P<0.001), r =0.929, p<0.01 respectively).

Importantly, following the diagnosis of PVO, the time to intervention was significantly different between the successfully dilated and failed or restenosed patients (2.58±1.88 vs 12.6 ± 10.74 months p<0.05). Moreover, regardless of the degree of improvement in CUS, the improvement in perfusion had a significant negative correlation with the delay in intervention (r =-0.497 p<0.05).

**Conclusion** Patients with concomitant ipsilateral PVO/PVS require early and repeated pulmonary interventions for restoration of pulmonary flow and prevention of associated lung disease.

### RISK FACTORS FOR PULMONARY EDEMA FOLLOWING ATRIAL FIBRILLATION ABLATION

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Anecdotal reports suggest that acute pulmonary edema may be a complication of atrial fibrillation ablation. Risk factors for this complication have yet to be identified. DC cardioversion is a rare precipitant of acute pulmonary edema in a general atrial fibrillation population. To address the hypothesis that DC cardioversion at the time of atrial fibrillation ablation may predispose to the subsequent development of pulmonary edema, we examined this association in our cohort of atrial fibrillation ablation patients. In 164 patients who underwent left atrial circumferential ablation with an endpoint of electrical isolation, 7 patients developed acute pulmonary edema within 72 hours. DC cardioversion at the time of atrial fibrillation ablation predicted the subsequent development of acute pulmonary edema (p=0.043). Left ventricular ejection fraction, left atrial size, hypertension and ablation time failed to predict the primary endpoint. All of the patients who developed pulmonary edema were successfully treated with diuresis without subsequent symptoms.

## PHYSIOLOGICAL PACING

### LEFT VENTRICULAR FUNCTION AND ATRIAL FIBRILLATION IN SICK SINUS SYNDROME WITH SINGLE CHAMBER ATRIAL PACING

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Nielsen et.al. in their randomized trial comparing AAIR and DDDR pacing in patients (pts) with Sick Sinus Syndrome (SSS) and normal AV conduction demonstrated that long-term DDDR pacing induces left atrial dilation and, in the case of a high proportion of right ventricular pacing, also reduces left ventricular function (LVF). Furthermore, atrial fibrillation (AF) is significantly less common during AAIR pacing.

Aim of this study was to evaluate during follow-up (FU) the LVF and the presence of AF in pts with single chamber atrial pacing (SCAP) implanted for SSS and normal AV conduction.

19 pts (9 male, 10 female) with SSS and intact AV conduction who received SCAP implanted from 1993 and 2000 were studied. Diagnosis of SSS was based on abnormalities in sinus node recovery time corrected on electrophysiologic study. In all pts the Wenkebach point > 130 /min evaluated with autonomic blockade (atropine 0.04 mg/kg and propranolol 0.2 mg/kg) and carotid sinus massage was carried out. From echocardiographic study were evaluated the left ventricular ejection fraction (LVEF) and the presence of mitral insufficiency. The average of LVEF pre-implantation was 65 +/- 8% and during FU was 58 +/- 9%. One of 19 pts remains in AF from 2003; 6 pts were in treatment with antiarrhythmic drugs. 9 pts were in AAI pacing mode every time of pace-maker check-up. There was no deterioration of mitral insufficiency, except in one case from mild to moderate. In conclusion, this study confirms the benefit of SCAP implanted in pts with SSS and intact AV conduction.

### LONG TERM OUTCOME OF ATRIAL RESYNCHRONISATION PACING FOR THE MANAGEMENT OF DRUG REFRACTORY ATRIAL FIBRILLATION

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**OBJECTIVE** We conducted this study to evaluate long term outcome of patients who underwent atrial resynchronisation with bi-atrial pacemaker implantation in a single centre for management of drug resistant atrial fibrillation (AF).

**METHODS** Patients who were refractory to at least 3 anti-arrhythmic drugs and remained sufficiently symptomatic, were offered either AV node ablation and VVI pacing or bi-atrial pacing without ablation. 31 patients received a bi-atrial pacemaker between 1999 to 2006 (mean duration from AF diagnosis 59 +/- 14 months). During the evaluation period (mean of 3 +/- 2 years), we compared their symptoms, AF duration, AF admissions and anti-arrhythmic drugs for an equal duration pre and post-procedure. Co-morbidities like heart failure, atrial dilatation, left ventricular hypertrophy, valvular heart disease, ischaemic heart disease and sick sinus syndrome were also recorded.

**RESULTS** The study population consisted of 20 male, 11 female patients; mean age 68 +/- 8 years. 21/31 patients (68%) experienced significant reduction in both symptoms and AF duration post-implant (13 i.e., 42% became asymptomatic and 12 i.e., 39% had complete elimination of AF). Significant reductions were seen in mean duration of AF episodes (control period 21.5 days/month and bi-atrial 7.7 days/month; p<0.001), mean number of AF admissions (control 2.7 +/- 3.3 and bi-atrial 0.9 +/- 1.2; p = 0.005) as well as mean number of antiarrhythmic drugs (control 3.5 +/- 1.5 and bi-atrial 1.7 +/- 0.95;

p<0.001). There were 2 re-admissions for left atrial lead repositioning during the study period. Amongst all patient characteristics, only P wave duration on ECG (inter-atrial conduction delay) showed an independent correlation with predicting success (16/17=94% with P wave > 0.12 showing improvement compared to 5/14=36% with P wave < 0.12; p=0.001). 2 patients were referred for ablation due to failure in controlling AF, however 29/31 (94%) were satisfied with their level of symptom control.

**CONCLUSIONS** This study shows that atrial resynchronisation therapy is effective in long term management of drug resistant AF, especially in patients with inter-atrial conduction delay.

### ASYMPTOMATIC ATRIAL FIBRILLATION: THE ROLE OF AN IMPLANTED DEVICE

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**Aim** To evaluate the incidence of asymptomatic episodes of atrial fibrillation (AF) in patients (pts) with pacemaker (PM).

**Methods** Ninety-nine pts (73 +/- 7 years, 59M) implanted with DDD pacemakers (T70, Vitatron) were enrolled and followed up. Each Pt was asked to keep a diary of his symptoms.

PM indications were: 84% SSS; 9% AV block (AVB), 4% SSS+AVB, 2% bradycardia, and 1% neuromediated syncope. 46% of Pts had hypertensive cardiomyopathy, 9% ischaemic cardiomyopathy, 5% dilated cardiomyopathy, 12% valvular disease, 6% ischaemic and hypertensive cardiomyopathy, 1% ischaemic and valvular disease, and 21% had no history of underlying heart disease. Antiarrhythmic drug therapy: 23% amiodarone; 7% flecainide; 17% beta blockers; 8% propafenone; 2% amiodarone+beta blockers; 1% flecainide+beta blockers, 13% Sotalol; 2% Sotalol+Flecainide; 27% no antiarrhythmic drugs. 50% of Pts took Warfarin and 72% had history of AF.

**Results** Till now 198 follow-ups (FUs) have been completed. The mean FU period was 1 year (range: 9-18 months). In 118 cases (59.6%) Pts had at least 1 episode of AF recorded by the PM. 1046 episodes of AF have been recorded and 821 (78.5%) were asymptomatic. Among them 60% of Pts had episodes lasting less than 16 minutes, while the remaining 40% had episodes lasting more than 1 day. In 223 cases (21.3%) pts reported symptoms related to the episodes recorded by PM. In 73 FU (36.9%) pts reported symptoms even if no episodes of AF occurred.

**Conclusions** Our data show a low correspondence between arrhythmic episodes recorded by PM and symptoms reported by Pts. A consistent percentage of Pts have asymptomatic episodes of AF and others report symptoms without having recorded episodes.

### INCIDENCE OF ATRIAL FIBRILLATION IN PATIENTS WITH VENTRICULAR LEAD - RESULTS OF FIFTEEN YEARS FOLLOW-UP

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**Purpose** Atrial fibrillation (AF) appears more frequently in patients with pacemaker (PM) than in general population. Therefore, in patients with PM should be done 12-lead ECG and traced AF presence. When AF appears in patients with PM it is necessary to check up therapy with medicaments and to think about oral anticoagulant therapy.

**Materials and methods** We have analyzed the group of 113 patients with implanted PM. The group consisted of 69 males and 44 females. The average age was 73.4 years (from 35 to 83 years). Time elapsed

from the moment of implanted lead and the first PM was 15.6 years. In the moment of first implantation none of 113 patients had AF. The reason for pacemaker implantation was AV block of the second and the third degree. All the patients were with VVI or VVIR pacing.

**Results** In the examined group 25 patients (22.12%) had AF which they did not have in the moment of implantation of PM. Among them were 9 females and 16 males. The average age was 73.3 years (range from 56 to 79 years) and the time elapsed from the lead implantation and the first PM was 15.1 years. There were no statistically significant differences between the whole group and the patients with AF. However, in the group of patients with AF, three of them had cerebro-vascular insult (CVI). The rest of the group did not have patients with CVI. In correlation with examination five years ago, there was 5% higher incidence of AF in the group.

**Conclusions** Atrial fibrillation have significantly higher incidence in patients with PM in relation to the general population. In these patients the incidence of CVI is significantly increased. Sex, age and time elapsed from lead implantation were not significant for the incidence of AF.

### LONG TERM COMPARATIVE STUDY OF DDD VERSUS AAI PACING IN PATIENTS WITH SICK SINUS SYNDROME AND NORMAL AV CONDUCTION

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**Introduction** One of the controverses of pacing in patients with sick sinus syndrome (SSS) and normal AV conduction is which pacing mode, AAI or DDD, is more favourable.

**Aims:** to evaluate on long term the clinical and economical benefit of AAI unichamber pacing in patients with SSS and normal AV conduction.

**Methods** eighty-four (84) patients implanted with AAI pacemakers, but also with DDD dualchamber pacemakers switched on AAI were compared with ninety-two (92) SSS patients implanted with DDD pacemakers. All patients were followed up at 1 month, and then every 6 months up to 48 months.

**Results** There were no significant differences between the two groups in recurrence of atrial fibrillation (9,5% AAI vs 13% DDD), functional NYHA class, mortality rates at 48 months, incidence of thromboembolic events and perioperative complications. The incidence of high degree AV block was 1,12%/ year and 5,6% at 48 months.

The mean costs in the AAI group were significantly lower ( $P < 0,05$ ).

**Conclusion** AAI pacing in patients with SSS and normal AV conduction is a safe method, with clinical results comparable with DDD pacing, but with lower economical costs.

### NON-APICAL RIGHT VENTRICULAR VDD-PACING: SHORT AND LONGTERM SAFETY AND STABILITY OF THE NOVEL STIMULATION APPROACH

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Standard VDD leads are primarily designed for apical insertion (RVA), actively fixated leads are yet not available due to the electronic complexity. According to current knowledge the RVA pacing may deteriorate cardiac function. VDD pacing in non-RVA localities could be an attractive alternative.

This study sought to determine clinical performance and short-/long-term safety of VDD pacing using non-apical right ventricular lead positions (middle and upper IVS or RVOT). 38 consecutive adults implanted with VDD pacemakers for AV block with normal sinus node function were recruited. Electrodes (Phymos 940; Medico) were positioned randomly to RVA (23pts) and non-RVA site (15pts). In each group, the P- and R-wave amplitudes were determined at implantation, predischarge, 1-month, 6-months and 1-year of follow-up. At each follow-up visit ventricular threshold, P- and R-wave amplitude measurements were performed. Complications (loss of AV-synchrony, micro- and macrodislocations with the need for the lead repositioning and abnormal threshold increase) were recorded and compared among the groups.

Both groups did not differ in their main characteristics (age: 70 vs. 73 y., presence of comorbidities: coronary heart disease, art. hypertension, EF. Diabetes prevailed in the non-RVA group (30% vs. 13%). There were no significant differences among the ventricular thresholds and P-wave amplitudes measured throughout the study visits in both groups (all  $p > 0,05$ ). Atrial undersensing occurred in the predischarge period in 1 patient from the non-RVA group, a lead reposition was performed. No micro- or macrodislocation occurred in studied subjects during the follow-up. No other significant complications (pneumothorax, bleeding, infections) occurred.

Non-apical VDD pacing is an effective strategy for treatment of patients with symptomatic AV block and normal sino-nodal function. Our results suggest that this novel approach of VDD pacing is a viable and safe alternative to standard RV-apical VDD pacing in selected patients despite the passive design of the VDD leads.

## ICD FOR SUDDEN DEATH PRIMARY PREVENTION

### FIRST RESULTS FOR THE PARACOR HEARTNET SUPPORT SYSTEM

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Despite optimal medical treatment, patients (pts) with advanced heart failure (HF) have a high risk of sudden death. Reduction of myocardial wall stress is important to achieve attenuation or reversal of ventricular remodelling. The Paracor HeartNet device is a new epicardially implanted passive ventricular support system, a mesh consisting of elastic nitinol wires coated with silicone (PVSS). To avoid implantation of a separate ICD system, the new HeartNet device has four integrated epicardial defibrillation coils which are connected to a commercially available defibrillator (PVSS-D). Sensing/pacing is performed over a separate pace/sense lead sutured to the apex of the left ventricle. The PVSS/PVSS-D is implanted via a left lateral thoracotomy. The HeartNet Introducer slips the mesh over both ventricles using fluoroscopic control. We report our experience with PVSS and PVSS-D. Ten pts received the PVSS device, two pts the PVSS-D system. Mean age was 52 years, all pts were on optimal medical HF treatment. We report the 12 months follow-up of eight pts with PVSS and the 6 months follow-up of the two PVSS-D pts. There is a trend towards improvement of HF: NYHA class decreased from 2.4 to 1.7, LVEDD from 70.8 to 67.2 mm, BNP from 632 to 368 pg/ml, respectively. LV-EF increased from 25 to 26.7%, 6 minute walking distance from 436 to 471 m and VO<sub>2</sub> max from 17.5 to 18.9 ml/kg/min. DFT's in the two pts with PVSS-D were ≤ 17J. PVSS-D pts did not have ICD discharges during the 6 month follow-up, whereas 3 of the PVSS pts needed ICD implantation during follow-up. One pt received appropriate ICD shocks. No major adverse events occurred during PVSS/PVSS-D implant or during follow-up.

**Conclusion** The Paracor HeartNet (PVSS/PVSS-D) is a promising new approach to prevent further ventricular remodelling and sudden death in pts with advanced HF.

### OUTCOME IN PATIENTS WITH SECONDARY ENDOMYOCARDIAL FIBROELASTOSIS DUE TO CONGENITAL AORTIC VALVE STENOSIS AND IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS

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**Introduction** The endomyocardial fibroelastosis (EFE) is characterized by endocardial hyperplasia due to proliferation of elastic and collagenous fibres. There are primary and secondary forms. Within the secondary form, the EFE due to severe congenital aortic stenosis (CAS) is the most frequent and of greatest importance. EFE in these patients is associated with potential life-threatening ventricular tachyarrhythmias and an increased risk of sudden death. We studied the outcome of two cases of this disease who have been autopsied during a second operation for a 'tumor' of the left ventricle and treated later with an implantable cardioverter-defibrillator (ICD).

**Methods and Results** Both cases underwent aortic valve replacement for CAS at the age of 11 and 8 years old respectively. Eight years later both cases presented with a rapid progressive congestive heart failure and it has been documented a 'tumor' in the left ventricle. The 'tumor' has been extracted as well and we performed a pathologic analysis. It showed endocardial fibroelastosis associated with abnormal intertrabecular spaces. During the follow up both cases presented an episode of aborted sudden cardiac death with documented ventricular flutter. An ICD was implanted in both. During a period of 4 years both cases received a mean of 4.7 (range 2-68) appropriate ICD therapies. The median period between ICD implantation

and the first shock was 6-months. ICD electrical storm was not observed. Inappropriate shocks were seen in both cases due to very frequent atrial tachyarrhythmias. Predictors of appropriate therapy were the 1)left ventricular end-diastolic volume, 2)the volume of remaining maze,3)the frequency of the daily PVCs > 3.500 and 4)severe left ventricular hypertrophy.

**Conclusions** Patients with EFE after aortic valve replacement for CAS have a high arrhythmia rate requiring appropriate ICD therapies. ICD treatment appears to be well tolerated and effective in the management of these patients.

### POST-ISCHEMIC DILATED CARDIOMYOPATHY IS ASSOCIATED TO A HIGH INCIDENCE OF APPROPRIATE ICD THERAPIES, SIGNIFICATIVELY HIGHER IN SECONDARY PREVENTION

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**Purpose** implantable cardioverter-defibrillators (ICD) represent first line treatment in arrhythmic sudden death prevention in patients (pts) with post-ischemic cardiomyopathy and impaired left ventricular function (LVEF). We aim to evaluate incidence of sustained ventricular arrhythmias (VA) in post-ischemic cardiomyopathy affected pts receiving ICD for primary or secondary prevention.

**Materials and Methods** 106 post ischemic cardiomyopathy affected pts who received an ICD and followed up every 6 months were retrospectively analysed. Pts were divided in: primary (group A) or secondary (group B) prevention.

**Results** group A was made of 55 pts (48 males, mean age 68+/-9) while group B of 51 pts (44 males; mean age 68+/-8). Two groups didn't significantly differ for therapy (beta-blockers 91 vs 85%; amiodarone 32 vs 32%; ACE-I or ARBs 80 vs 88%, furosemide and/or anti-aldosterone 73 vs 85%, statins 75 vs 63%, respectively in group A and B, p=NS), diabetes mellitus (19 vs 24%, respectively, p=NS). Group A showed a significantly more impaired left ventricular function (LVEF 28+/-7%) than group B (LVEF 35+/-10%), p= 0.001. At a mean 25+/-14 months follow-up, at least one appropriate ICD therapy was recorded in a significantly higher number of pts in group B than in group A (35 vs 9%, respectively, p=0.001) in a shorter mean time from implantation (14+/-19 vs 21+/-14 months, respectively, p=NS). Non sustained VA were more frequent in group B (33%) than in group A (15%) as well, p=0.02.

**Conclusion** In our experience, in post-ischemic cardiomyopathy affected pts with impaired LVEF, potentially lethal sustained VA show a high incidence. Either sustained than non sustained VA seem to be more frequent in pts who received an ICD in secondary prevention than in primary prevention.

### DO PATIENTS IMPLANTED WITH ICD FOR PRIMARY PREVENTION MATCH THE POPULATION CHARACTERISTICS OF CLINICAL TRIALS? INSIGHTS FROM THE CAMI GUIDE STUDY POPULATION

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Recent primary prevention trials showed that ICD improves survival in post myocardial infarction (MI) patients with left ventricular dysfunction. However, patients implanted with ICD for primary prevention of sudden cardiac death according to current guidelines and daily clinical practice may show different clinical characteristics with respect to the trial population and may be exposed to different risk. Aim of the present analysis is to see if, in post-MI patients with low ejection fraction ( $\leq 30\%$ ) selected for implantation with ICD in the CAMI GUIDE study, clinical characteristics and medical therapy match those of MADIT II and SCD-HeFT trials. 300 post-MI patients with left ventricular dysfunction were enrolled in the CAMI GUIDE study, a multi-center prospective study designed to assess the predictive value for sudden cardiac death of C-reactive protein, and implanted with ICD or CRT-D device. 33% of patients enrolled in the CAMI GUIDE study met the indications for CRT and were implanted with CRT devices with defibrillation backup.

All mean values in the CAMI GUIDE cohort of patients, and subsets implanted with ICD and CRT were reported and compared with respect to MADIT II and SCD-HeFT.

	CAMI GUIDE (ALL)	MADIT II (ICD group)	CAMI GUIDE (ICD)	SCD-HeFT (CRT group)	CAMI GUIDE (CRT)
Age (median)	68	64	67	60	68
Male (%)	88	84	87	77	88
LVEF (median)	26	23	26	25	26
NYHA>II (%)	41	30	40	30	41
Diabetes (%)	28	33	27	31	29
Hypertension (%)	53	53	54	56	52
AF (%)	12	9	11	16	13
Ace inh (%)	64	68	56	83	69
B-Blockers (%)	66	70	70	69	60
Diuretics (%)	85	72	86	82	85
Statins (%)	46	67	39	38	50

Patient characteristics in this cohort match quite well the population of major primary prevention trials, with the exception for patient age, gender and functional class. Despite results of major primary prevention trials have been incorporated into current guidelines, the tendency to implant patients with worse functional class may indicate the need for an effective risk stratification algorithm: the CAMI GUIDE study will provide information on risk stratification for those patients.

### COMBINED RESYNCHRONIZATION AND DEFIBRILLATOR THERAPY IN PATIENTS WITH AND WITHOUT VENTRICULAR ARRHYTHMIAS

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**OBJECTIVES** We attempted to assess the efficacy of cardioverter-defibrillator (ICD) and combined cardiac resynchronization therapy implantable cardioverter-defibrillator (CRT-ICD) in patients with and without ventricular arrhythmias.

**BACKGROUND** Because CRT and ICDs both lower all-cause mortality in patients with advanced heart failure, combination of both therapies in a single device is challenging.

**METHODS** A total of 195 consecutive received a ICD (102 pts) or CRT-ICD (93 pts) if standard criteria were met (left branch block with QRSd  $>120$ ms, NYHA class III or IV). Eighty-seven patients had a history of ventricular arrhythmias (secondary prevention); 108 patients did not have prior ventricular arrhythmias (primary prevention). During follow-up, ICD therapy rate and mortality rate were evaluated.

**RESULTS** During follow-up (593+/-533 days), primary prevention patients experienced less appropriate ICD therapies (AIT) than secondary prevention patients (13.5% vs. 36.8%,  $p < .0001$ ); inappropriate ICD therapies (IIT) were also more frequent in secondary than primary prevention (7.7% vs. 21.8%,  $p=0.005$ ). Also, the mortality (M) rate in the primary prevention group was lower than in the secondary prevention group (3.7% vs. 19.5%,  $p < 0.001$ ). In CRT-ICD group AIT were 9% in primary prevention vs. 48% in secondary prevention ( $p=0.001$ ), IIT 6% vs. 28% ( $p=0.08$ ) and M 4.4% vs. 28% ( $p=.003$ ).

**CONCLUSIONS:** patients that met the standard criteria for CRT showed high appropriate ICD therapies in secondary (48%) prevention. Mortality rate was higher in CRT-ICD patients that had a history of ventricular arrhythmias.

### HEART FAILURE MORTALITY AND SUDDEN DEATH MORTALITY IN THE BOLOGNA DATA BASE OF THE EURO HEART SURVEY ON CHRONIC HEART FAILURE II

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**INTRODUCTION** Acutely decompensated heart failure (ADHF) patients have been enrolled in the EURO HEART FAILURE SURVEY II (EHFII). They had a severe prognosis at discharge and at follow-up (FU).

**PATIENTS AND METHODS** In EHFII 60 patients have been enrolled in Bologna. Clinical characteristics of these patients and the occurrence of heart failure death (HFD), and sudden death (SD), has been evaluated at 3-6-12 months FU. 28% showed a new episode of ADHF, while 72% were decompensated CHF patients. 63% had acute pulmonary edema. The mean age was 77.0 and 51% were males. Cardiomegaly was documented in 83%. 30 showed a concomitant renal failure, and diabetes was present in 20 of them. Almost 58% received a cardiac catheterization and coronary arteriography. 10% had permanent pacing and CRT and 3% had already an ICD. Almost 100% were already on diuretic agents, 62% on ACEi, 88% on beta-blockers, probably not at the maximum tolerated doses. 15/60 had an ACS as the cause of ADHF, the remaining 45/60 were patients with an already known CHF. The best non pharmacological treatment (NPT) was instituted and 4 patients received CRT treatment and two more, ICD therapy. At discharge, we lost 10/60 mainly patients with an ACS, at 3 months, we lost 7 other patients and at 6 months we lost other 8 patients. We lost 26/60 (43.3%) of the patients, at 12 months FU, 3 SD were observed (5.2%) + 2 appropriate ICD shocks (15%).

**CONCLUSIONS** ADHF bears an ominous prognosis, mainly for patients with already documented CHF and for patients suffering ACS. A more aggressive treatment, including primary PTCA and CABG or cardiac surgery, when indicated, is required. For CHF with a new ADHF episodes, a further approach, with an NPT can be required, after stabilisation of the clinical picture.

## ALTERNATIVE PACING SITES

### CIRCADIAN ATRIAL THRESHOLD VARIATIONS AND ATRIAL CAPTURE MANAGEMENT SUCCESS IN PATIENTS WITH SINUS NODE DYSFUNCTION

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**Background** Atrial Capture Management (ACM) is a new algorithm able to automatically measure atrial threshold (AT). Aim of this study was to evaluate the range of variation of AT in patients with sinus node dysfunction.

**Methods** Thirty-one patients (pts) (61% M, mean age 74 ± 8 yy) were implanted with Medtronic EnPulse DDDR pacing system due to sinus node dysfunction. Mean EF was 57 ± 9%. Sixteen pts (52%) had history of atrial arrhythmia and 10 pts (32%) had documented AV block (I° 40%, II° 40%, III° 20%). ACM was programmed to automatically measure threshold every two hours. ACM uses two different methods to measure the AT: Atrial Chamber Reset (ACR) method with sinus rhythm, otherwise AtrioVentricular Conduction (AVC) method. **Results** in a mean follow-up of 9 ± 6 months a total of 42191 measurements was collected, 70% of which successful (ACR 54%, AVC 46%). ACR method was never successful in 4 patients (3%) while AVC in 5 (6%). In all patients at least one of the two methods was successful. Median ACM and AVC success was 84,5% and 83,3%, respectively. History of atrial arrhythmia reduced of 89% the probability to have ACM success >84,5% (OR=0,114, 95% IC(0,022-0,591), p=0,010), while documented AV block reduced of 96% the probability to have AVC success >83,3% (OR=0,056, 95% IC(0,006-0,530), p=0,012). AT showed specific circadian patterns, as already observed in ventricular thresholds: higher thresholds were found in the early morning hours. The difference between the maximum and the minimum threshold recorded over the day was not clinically relevant (0.12 Volts). Higher threshold values were found between 00.00 and 06.00 a.m.

**Conclusions** ACM algorithm showed a good success rate in performing AT measurement in our population of patients. AT showed a circadian variability to ventricle, that does not seem to influence ACM functioning and PM programming.

### PACING IN ATRIAL SELECTIVE SITE: PRELIMINARY DATA FROM THE SOUTH EUROPEAN SELECT SECURE REGISTRY

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**Background** many studies suggest that atrial pacing in selective site results in a reduction of atrial fibrillation due to pre-excitation of left atrium that minimize the total atrial activation time.

**Purpose:** to evaluate the electrical performance of atrial selective site using a new system (Medtronic Select Secure®), composed by a steerable catheter and a 4.1 Fr screw-in lead, specifically designed for selective site pacing

**Materials and Methods** in 70 patients (36M, age 70 ± 9 years) with normal ejection fraction (EF 55 ± 11%) and with normal QRS duration (92 ± 22ms) the Select Secure® lead has been implanted in an atrial selective site (41 patients in inter atrial septum, 21 in coronary sinus ostium and 8 in the Bachman bundle). Three (2.1%) patients had in anamnesis episodes of angina, 29 (41%) palpitations, 4 (5.7%) dyspnea, 7 (10%) dizziness, 13 (18%) syncope while the remaining patients have none of these symptoms.

Fifty-four patients (77%) have paroxysmal or persistent atrial fibrillation. Twenty-two patients (31%) had had one or more cardiovascular hospitalization before the implant.

**Results** the acute data on the leads electrical performance of the whole patients population have been collected: the threshold was of 1.0 ± 0.6V at 0.5ms, the sensing was of 2.4 ± 1.4mV and the impedance was of 750 ± 310 ohm. No adverse events occurred during implant. Eleven patients have already reached the 1 year follow-up; their acute and long term leads electrical performances are respectively: pacing thresholds 1.3 ± 0.8V and 0.9 ± 0.4V (p=NS) and sensing 2.3 ± 1.4mV and 2.6 ± 1.0mV (p=NS). Moreover electrical leads performances did not differ significantly in the different atrial selective sites either acutely and in the long-term follow-up

**Conclusions** atrial selective sites pacing have proved to be easy to reach using this system. Long term electrical data show that atrial selective site pacing performance is safe, reliable and stable in the long term.

### PACING THRESHOLDS VARIATION OVER TIME IN SELECTIVE HIS BUNDLE PACING VS. PARA-HISIAN PACING

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**Background** His Bundle (HB) pacing is a valid alternative to right ventricular (RV) pacing for patients with preserved His-ventricle conduction who are candidates for permanent stimulation. Pacing in the HB area enables either Selective HB pacing (SHBP) or para-Hisian pacing (PHP) to be achieved. SHBP is achieved when the intrinsic QRS is equal, in both duration and morphology, to the paced QRS, the H-V interval is equal to Vp-V and, at low output, only the HB is captured, while increasing the output resulted in both the HB and RV being captured. Conversely, PHP is defined when the intrinsic QRS differs from the paced one and at high output both the RV and HB are captured, while decreasing the output resulted in losing HB capture.

**Purpose** to compare the pacing thresholds variation over time of SHBP vs. PHP.

**Methods** 14 patients (13 males, mean age 72 + 11 years) were identified as candidates for HB pacing, 8 patients were affected by spontaneous supra-Hisian AV block, 5 of whom were in sinus rhythm and the remaining 3 in Atrial Fibrillation; 6 had brady-tachy syndrome. SHBP and PHP were classified, according to the above mentioned criteria. Pacing thresholds were evaluated at implant and at the latest available follow-up (FU)

**Results** SHBP was achieved in 7 pts, while the remaining 7 pts received PHP. The mean FU was 254 + 103 (79-382) days. Acute and chronic pacing thresholds at 0.5 msec were respectively 3.08 V and 2.87 V in SHP (P=NS) and 2.85 V and 4.95 V in PHP (P=0.06). No adverse events occurred either acutely and in the FU.

**Conclusion** SHB shows more stable pacing thresholds over time compared to PHP. Thus it appears quite important to evaluate at implant which type of stimulation is achieved. Further data are needed to confirm these preliminary results.

## COMPARISON OF ELECTRICAL DATA IN DIRECT HIS BUNDLE PACING VS HISIAN ZONE PACING USING THE SELECT SECURE SYSTEM®: DATA FROM THE SOUTH EUROPEAN SELECT SECURE REGISTRY

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**Background** recently some authors have proposed, in patients with preserved his-purkinje system, the hisian region as an alternative pacing site compared to right ventricular (RV) apex, because it preserves the ventricles synchronous contraction.

**Purpose** to evaluate long-term term leads electrical performance in direct his bundle pacing (DHBP) versus pacing in the hisian region (HRP).

**Material and Methods** 163 patients (106 M, age 73 ±10 years), with normal QRS duration (104±23 ms) and no left ventricular dysfunction (LVEF 51.3±11.6%), have been enrolled in 20 Italian centers. DHBP is considered achieved when the paced QRS has the same morphology and duration as the intrinsic QRS in all leads recordings and the Vp-V interval is equal to H-V interval. HRP is considered when the pacing lead is positioned in the His region but DHBP is not reached (i.e. para-His pacing, inflow tract pacing).

**Results** in 68 patients DHBP has been achieved, while the remaining 95 patients received HRP. Twenty-two DHBP patients and 29 HRP patients have reached 1 year follow up. The DHBP patients have shown an acute and a 1 year follow up threshold respectively of 2.0±1.5 V at 0.5 ms and 2.8±3.1 V at 0.5 ms (p = NS). Sensing was respectively of 5.1±4.8 mV and 6.2±6.5 mV (p = NS).

The HRP patients have shown an acute and a 1 year follow up threshold respectively of 1.5±1.3 V at 0.5 ms and 2.3±2.5 V at 0.5 ms (p < 0.05). Sensing was respectively of 6.8±5.7 mV and 5.3±4.2 mV (p = NS).

**Conclusions** patients with DHBP show a higher but stable threshold respect to patients with HRP while sensing shows comparable values between the two groups evaluated.

## FEASIBILITY OF HIGH SEPTUM RVOT PACING USING THE SELECT SECURE SYSTEM®: PRELIMINARY DATA FROM THE SOUTH EUROPEAN SELECT SECURE REGISTRY

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**Background** It is well known that right ventricular apical pacing(RVAP) induces iatrogenic left bundle branch block(LBBB). Recent studies have demonstrated that RVAP may have long term detrimental effects on left ventricular(LV) function. Since pacing from the right ventricular outflow tract(RVOT) does not induce LBBB, septal RVOT can be considered as an alternative more physiological pacing site.

**Purpose** to evaluate the feasibility of septal RVOT pacing using a new system (Medtronic Select Secure®) composed by a steerable catheter and 4.1Fr screw-in lead and specifically designed for selective site pacing

**Materials and Methods:** in 81 patients (49M, age 69±21years) indicated to pacemaker implant according to the current guidelines, the

right ventricular lead was implanted in the RVOT high septum. 7 patients received a single chamber PM, 69pts received dual chamber device and 3 a CRT-P and 2 CRT-D device. The implant indication was Sick Sinus Syndrome in 30pts, AV block in 39pts, both indications in 10pts and VT/VF in 2pts. The mean baseline EF was 45.1±15.3% and 11 pts have previous MI.

**Results** In all patients RVOT pacing has been easily achieved and the mean fluoroscopic implant time was 18.7±15.2minutes. Acute data on the leads electrical performance have been collected: the threshold showed a value of 0.8±0.5V at 0.5ms, the sensing a value of 10.6±5.9mV and the impedance of 830±280ohm. 19 patients have already reached the 1 year follow-up and their acute and chronic leads electrical performances show a threshold respectively of 0.9±0.6 and 0.9±0.6mV(P=NS) and a sensing respectively of 9.7±5.9 and 9.5±6.6mV(p=NS). No adverse events occurred.

**Conclusions** High septum RVOT pacing is feasible and safe using Medtronic Select Secure System®, the leads electrical performances are stable in the long term follow up. Further data are needed to evaluate clinical benefits of this pacing approach compared to traditional one.

## IS THERE A LEARNING CURVE IN ACHIEVING SELECTIVE SITE PACING? DATA FROM THE SOUTH EUROPEAN SELECT SECURE REGISTRY

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**Purpose** to verify if there is a learning curve in approaching atrial and ventricular Selective Site using the Select Secure system composed by a steerable catheter and 4.1 Fr screw-in lead.

**Materials and Methods** 235 implants have been performed in 35 Italian centers. In order to understand if a learning curve in reaching SS exists we considered the total fluoroscopic time needed to perform the implant regardless of it was implanted a single, dual or triple chamber device. Selective sites in the atrium were inter atrial septum, coronary sinus ostium and Bachman bundle, while in the ventricle the selective sites were His bundle, right ventricular outflow tract high septum and low septum.

In each implant center we considered separately the first 5 implants (Group A), the implants from number 6 to 15 (Group B), the implants from number 16 to 25 (Group C) and finally all the other implants (Group D) performed by the same operator.

**Results** Group A consisted of 87 patients, the average implant time is 20.6±14.2minutes; Group B is made of 53patients with an average implant time of 17.3±15.1minutes; Group C has 38 patients and the average implant time is 15.5±9.8minutes; finally, Group D has 57patients with an average implant time of 14.0±9.8minutes.

A t-test has been performed between the first and the last range obtaining a p of 0.001. The percentage of implant success is 98.9%. Only 4 acute failures happened: one patient had a mild perforation without sequel, while three patients had acute dislodgements, one in the atrium and the lead was repositioned, two in the ventricle and one lead was repositioned and the other was replaced.

**Conclusions** there is a learning curve in approaching selective site pacing using Medtronic Select Secure® and implants made by expert personnel required a significant shorter amount of time.

## THE EFFECT OF NASAL CPAP ON CARDIAC ARRHYTHMIAS COMPLICATING WITH SLEEP APNEA SYNDROME

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**Purpose** Sleep Apnea Syndrome (SAS) is frequently associated with cardiovascular comorbidity. The purpose of this study was to investigate existence and frequency of cardiac arrhythmias (CA) associated with SAS and the effect of nasal CPAP (nCPAP) on these CA.

**Methods** This study consists of 43 SAS patients (32males, mean age 51.9+/-13.4years) who had sinus rhythm and underwent nCPAP for Apnea-hypopnea index (AHI) >20 from May 2004 to June 2005. We assessed brady- and tachy-arrhythmias, extra-systoles, and frequency domain analysis of heart rate variability during polysomnography (PSG) at diagnostic study and at nCPAP introduction.

**Result** The number of patients with atrial premature contraction (APC, 35patients vs 35patients), supraventricular tachycardia (SVT, 10patients vs 14patients), ventricular premature contraction (VPC, 20patients vs 16patients), ventricular tachycardia (VT, 1patient vs 2patients), sinus bradycardia <50bpm or heart block >2nd degree (p=NS), and mean number of APC (63+/-202.9 vs 89.4+/-358.0), SVT (1.3+/-3.6 vs 1.3+/-3.2), VPC (160.7+/-1015.5 vs 152.7+/-840.2), VT (0.02+/-0.15 vs 0.19+/-0.88), pause (0.7+/-4.3 vs 2.2+/-14.3) did not decrease during nCPAP introduction compared to the values during diagnostic study (p=NS) despite significant improvement of AHI (64.1+/-26.7 vs 18.4+/-24.0, p<0.0001) and minimum SpO<sub>2</sub> (71.6+/-12.5% vs 84.0+/-9.4%, p<0.0001) during nCPAP introduction. However, number of patients (38patients vs 26patients, p<0.05) with sinus arrhythmia with periodical fluctuation of the heart rate and its duration (207.4+/-155.1 minutes vs 47.2+/-91.9 minutes, p<0.0001) significantly decreased during nCPAP introduction. HF (546.7+/-729.4 msec<sup>2</sup>/Hz vs 336.6+/-473.6 msec<sup>2</sup>/Hz, p=0.04) and LF/HF (2.28+/-1.36 vs 1.91+/-1.06, p=0.03) also decreased during nCPAP introduction.

**Conclusion** Sinus arrhythmia and extra-systoles were frequently seen and fatal arrhythmias were rare in SAS patients. Contrary to expectation, nCPAP failed to decrease arrhythmias during acute phase. Only sinus arrhythmia with periodical fluctuation of the heart rate decreased suggesting decrease of fluctuation of autonomic tone was associated with improvement of SAS.

## CORRELATION BETWEEN SUPRAVENTRICULAR ARRHYTHMIAS RECORDED BY HOLTER-EKG 24 HOURS AFTER ELECTRICAL CARDIOVERSION AND RECURRENCE OF ATRIAL FIBRILLATION

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**Introduction** Efficacy of electrical cardioversion in restoring sinus rhythm (SR) is limited by a high number of atrial fibrillation (AF) recurrences. Maintenance of SR is related to antiarrhythmic therapy, AF duration and atrial size. Among the various parameters analyzed at the Holter-EKG, only heart rate variability and vagal tone depression showed to be related to AF recurrence. In literature data about the correlation between AF recurrence and supraventricular arrhythmias recorded by Holter-EKG 24 hours after cardioversion are poor and controversial.

**Methods** We evaluated 66 consecutive pts underwent to outpatient oesophageal-precordial cardioversion under conscious sedation. All pts were on antiarrhythmic therapy. We performed in all pts Holter-EKG 24 hours after cardioversion. The arrhythmias evaluated were: atrial fibrillation, atrial tachycardia, PACs isolated (rare <1000/24 h, frequent > 2000/24 h) and AV conduction interval modification. One

month follow up was performed. Results. AF relapsed in 15/66 pts (22.7%) at the 1 month follow-up while SR was present in 51 pts (77.3%). At 24 hours after cardioversion Holter-EKG of the 15 pts with AF recurrence, showed SR in 80% (12 pts) and AF in 20% (3 pts). Arrhythmias recorded have been: AT (33.3%), rare isolated PACs (33.3%), frequent isolated PACs (40%) and PAC runs (40%), AF < 1 hour (13.3%); The 12 pts in SR did not present AV conduction interval modification. Arrhythmias recorded in the 51 pts with SR at the 1 month follow up have been: AT (23.5%), rare isolated PACs (54.9%), frequent isolated PACs (21.6%) and PAC runs (21.6%), AF < 1 hour (7.8%); 9 of these 51 pts presented a first degree AV block. No one of the evaluated arrhythmias had a significant correlation with AF recurrence (÷ 2 test).

**Conclusions** Frequency, number of PACs and duration of supraventricular arrhythmias recorded by Holter EKG 24 hours after electrical cardioversion, didn't show to be strong predictors of AF recurrence.

## HIGHER LEVELS OF CRP AND INTENSIVE ALBOUNINOURIA DETECTED AMONG HYPERTENSIVE POPULATION WITH A HISTORY OF PAF

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**Introduction** CRP is an inflammatory index increased in atheromatosis which is the main underlying pathology of hypertension. It is also found to be related with AF. On the other hand micro-albuminuria is related to the severity of hypertension and well correlated with diastolic dysfunction of LV and the general inflammatory process.

**Aim** We try to combine both CRP and albuminuria with the tendency of hypertensive subjects to develop PAF

**Methods** For this purpose, CRP plasma levels and urine albumin levels were measured in 50 hypertensive patients (mean age 58±12 years) with a history of paroxysmal atrial fibrillation (PAF) (group A) and in 50 hypertensive patients (mean age 57,5±10 years) without previous history of PAF (group B). All patient underwent complete echocardiographic study.

**Results** There were no difference between the two groups regarding the clinical data (age, sex -males: 65% vs 60%, body mass index: 27.57±3.2 vs 27.38±4.4kg/m<sup>2</sup>, office systolic BP: 147±12 vs 143±11 diastolic 91±7 vs 90±9mmHg, duration of hypertension: 4.2±2.1 vs 3.9±2.3 years, p=NS for all cases). Patients in group A had increased left ventricular mass index compared to group B (115±27 vs 85±19 gr/m<sup>2</sup> p <0.001), while the left atrial dimension and the left ventricular ejection fraction did not differ (3.72±3.64 vs 3.58±3.64 cm, p=0.092 and 65% vs 67%, p=NS). Both CRP plasma levels (21,2±7,7 vs 0,54±0,42 mg/dl, p=0,0005) and albumin urine levels (49,05±35,7 vs 18,3±16,9 mg/l p=0,005) were found to be significantly higher among hypertensive patient with a history of PAF (group A) compared with hypertensive subjects without a history of PAF. There was no differences regarding the incidence of diastolic dysfunction between the two groups (p>0.05). The data were statistically compared by using Student t-test analysis.

**Conclusion** Hypertensive patient prone to develop PAF present with higher inflammatory indexes as assessed by CRP plasma levels and thereby with intensive albuminuria, declaring that AF increase the inflammatory burden or AF is associated with higher inflammatory burden.

## THE ROLE OF CARDIAC MAGNETIC RESONANCE IMAGING IN PATIENTS WITH VENTRICULAR TACHYCARDIA AND ABSENCE OF CAD

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**Introduction** Cardiac Magnetic Resonance Imaging (CMRI) can identify myocardial infarction (MI) scars. Detection of unrecognized substrate has significant clinical implications

as a most common substrate for reentrant ventricular arrhythmias. In the absence of coronary artery disease (CAD) MI is rare.

**Hypothesis** The use of MRI in patients without CAD after cardiopulmonary resuscitation (CPR) could identify the substrate dependent VT/VF mechanism.

**Methods** Planimetry of gadolinium late enhancement images obtained from CMRI was used to measure scar mass and surface area by two readers blinded to electrophysiological study (EPS) results. The mean scar size was defined as a percentage of left ventricular mass.

**Results** 23 patients without CAD (15 had dilated cardiomyopathy, 6 hypertrophic obstructive cardiomyopathy and 2 normal hearts), mean age  $49 \pm 17$  years, 73% male, mean EF  $0,39 \pm 13$ , underwent CMRI and EPS because documented ventricular arrhythmias.

Parameters	VT/VF non inducible (N=11)	VT/VF inducible (N=12)	p
EF (%)	39±13	37±11	n.s.
Mean scar size (% LV mass)	5±3	11±10	<0.01

**Conclusions** In patients without CAD undergoing EP testing because of documented ventricular arrhythmias, the prevalence of scars is higher in pts with inducible VT/VF than in then in non-inducible population. Cardiac MRI should be considered in patients with no evidence of CAD presenting with unexplained spontaneous or inducible ventricular arrhythmias.

## LONG-TERM REPRODUCIBILITY OF MICROVOLT T WAVE ALTERNANS TESTING IN PATIENTS WITH DILATED CARDIOMYOPATHY AND LEFT VENTRICULAR DYSFUNCTION

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**Background** In patients with left ventricular dysfunction Microvolt T Wave Alternans (MTWA) testing can identify with optimal negative predictive accuracy patients (pts) at low risk of sustained ventricular arrhythmias/arrhythmic death. There are no data about the long-term course of MTWA in pts affected by non-ischemic dilated cardiomyopathy and reduced left ventricular ejection fraction (LVEF).

**Methods** Pts with non-ischemic cardiomyopathy and LVEF < 40% underwent MTWA evaluation using exercise testing to increase heart rate. At  $39 \pm 7$  months follow-up MTWA was reassessed. Exclusion criteria were atrial fibrillation/flutter, required ventricular pacing at

the time of MTWA testing, unstable coronary artery diseases, NYHA class IV heart failure, inability to exercise on a bicycle or treadmill. Clinical and echocardiographic parameters were recorded baseline and at time of second MTWA test.

**Results** This pilot study enrolled 12 pts, mean age  $55 \pm 16$  years, men 83%, LVEF  $32 \pm 5\%$  and NYHA class  $\geq 2$  58%. At baseline a normal MTWA test was documented in 6 pts (50%) and 6 pts (50%) tested MTWA abnormal (indeterminate plus positive). At follow-up 7 pts (54%) confirmed, whereas 5 (46%) changed MTWA results (3 abnormal to normal, 2 normal to abnormal). Normalization of MTWA test was consensual to LVEF improvement ( $34 \pm 5\%$  vs  $47 \pm 7\%$ ), despite same NYHA class score. On the contrary similar LVEF values were recorded baseline and at follow-up in pts with stable MTWA results ( $31 \pm 6\%$  vs  $32 \pm 10\%$ ).

**Conclusions** MTWA evolves over time in pts with non-ischemic cardiomyopathy and moderate to severe left ventricular dysfunction. An increase in LVEF seems to be associated with a higher proportion of MTWA negative tests. These preliminary data might support the serial use of MTWA in pts with persistent LV dysfunction in order to ameliorate clinical path to patient's best treatment.

## VENTRICULAR RHYTHM DISORDERS AND ECG ABNORMALITIES IN PATIENTS WITH DIABETIC CARDIOMYOPATHY - FIVE YEARS AFTER

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**Purpose** Diabetic cardiomyopathy is a very intensive subject of studying in the last years. In greater number of pathoanatomic studies as typical changes in myocardium are stated interstitial fibrosis, myocyt hypertrophy and small vessels disease. We made investigation 5 years ago of changes of ECG and ventricular rhythm disorders in the patients with diabetic cardiomyopathy. Now we repeat this investigation.

**Materials and methods** The original experimental group consisted of 32 diabetics with changes on myocardium, and with absence of hypertension, coronary disease, valvulare disease or alcoholic disease of the heart. We have analyzed 48-hours Holter monitoring and 12-channels ECG. In the meantime, 2 patients died (unknown cause of death).

**Results** Five years ago in the group with diabetic cardiomyopathy 21 patients had normal ECG, while 11 patients had abnormal ECG (left bundle branch block, right bundle branch block, left anterior hemiblock or ST-changes). In the group with diabetic cardiomyopathy 11 patients did not have ventricular rhythm disorders, 19 had unifocal and bifocal VES, while 2 patients had ventricular tachycardia.

Now, five years after this results, only 6 (of 30) patients had normal ECG, while 24 had some abnormality in their ECG (left bundle branch block, right bundle branch block, left anterior hemiblock, left posterior hemiblock, bifascicular block or ST-changes). And the same 6 patients were without ventricular rhythm disorders. In the rest of the group we found 7 patients with VT criteria and 19 with VES. After including amiodaron in the therapy only 1 (of 7) patients had VT (nonsustained).

**Conclusion** Five years after we made the diagnosis of diabetic cardiomyopathy, there is significant progression of ventricular rhythm disorders and ECG abnormalities. Patients with diabetic cardiomyopathy need frequent ECG and Holter monitoring.

## ATRIAL FIBRILLATION: ELECTROPHYSIOLOGY AND CARIOVERSION

### CONDUCTION PROPERTIES OF THE BACHMANN'S BUNDLE IN GOATS IN RELATION TO ITS TISSUE STRUCTURE

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**Introduction** the Bachmann's Bundle (BB) is the main conducting pathways between the right and left atrium. Several studies in both patients and animal models suggested that the BB is an important factor in the perpetuation of atrial fibrillation (AF). The way in which the BB can form a substrate for atrial reentry is not well understood. To this end we have studied the electrophysiological properties of the BB and its relation with fiber bundles orientation and gap junctions (GJ) distribution in the goat.

**Methods** We have studied in 5 control and 4 goats after 10 days of AF: electrical properties of the BB by high density epicardial mapping during slow pacing stimulation from 21 different points of the BB, the distribution of GJ at cellular level by immunohistochemistry of Cx43 and Desmin, and the relation between fibers in the transverse direction by conventional histology (Sirius Red Staining) of the whole BB.

**Results** Electrical stimulation from left or right parts of the BB in both groups revealed uniform conduction across the BB with a high conduction velocity  $103 \pm 18$  cm/sc, while pacing in the middle part of the BB reveals a highly nonuniform anisotropic conduction, with pronounced longitudinal dissociation. Immunohistochemistry revealed that in the BB GJ are more anisotropic at cellular level than other atrial areas, with higher concentration of end-to-end than side-to-side GJ. Histologically, we observed tightly packed strands of myocytes, separated by perimysial connective tissue septa and sparse transversal connections between fibers.

**Conclusion** the BB is a tissue structure characterized by highly nonuniform anisotropic conduction and pronounced longitudinal dissociation during pacing. This behaviour of the BB during pacing is determined by structural characteristics of the tissue and may play a crucial role in the perpetuation of AF.

### ENHANCED DISPERSION OF ATRIAL REFRACTORINESS AS AN ELECTROPHYSIOLOGICAL SUBSTRATE FOR ATRIAL FIBRILLATION VULNERABILITY

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Electrical remodeling plays a part in the recurrences of atrial fibrillation (AF). It has been related to an increase of spatial heterogeneity of refractoriness that favours the occurrence of multiple wavelets of reentry and vulnerability to AF.

**Aim** to examine the relationship between the atrial refractoriness dispersion (Disp\_A) and vulnerability (A\_Vuln) for the induction of non-sustained and sustained AF.

**Methods** 43 pts (63% men;  $56 \pm 12$  yrs) with  $\geq 1$  yr history of paroxysmal AF (PAF) - 27 pts without structural heart disease, 16 with hypertensive heart disease -. They underwent electrophysiologic study while off drugs to analyze sinus node and atrioventricular node function, identify substrates for reentry tachycardias or focally initiated AF. We also studied Disp\_A and A\_Vuln for induction and maintenance of AF. Atrial effective refractory period (AERP) was assessed at five different sites - high (HRA) and low lateral right atrium (LRA), high interatrial septum (IAS), proximal (pCS) and distal coronary sinus (dCS) - during a cycle length of 600 ms. AERP was taken as the longest S1-S2 interval that failed to initiate a propagation response. Disp\_A

was calculated as the difference between the longest and shortest AERP. A\_Vuln was defined as the ability to induce AF with 1-2 extrastimuli or with incremental atrial pacing (600-300 ms) from the HRA or dCS. Pts were separated into three groups: group A - AF not inducible; group B - AF inducible, self-limited (<60 seconds); group C - AF inducible, sustained. Age, hypertension, left atrial size, left ventricular function and hypertrophy, duration of PAF, documentation of atrial flutter/tachycardia, and Disp\_A were analysed to determine any association with A\_Vuln for AF induction.

**Results** There were no significant differences with regard to clinical and echocardiographic data between the groups. AF was inducible in 72% of the pts and noninducible in 28% (group A; n=12). Pts with A\_Vuln showed self\_limited AF in 58% (group B; n=18) and sustained AF in 42% (group C; n=13). The AERP increased from the HRA, LRA, and IAS to the pCS and dCS ( $215 \pm 20$  ms,  $214 \pm 22$  ms,  $230 \pm 30$  ms,  $250 \pm 35$  ms and  $274 \pm 78$  ms respectively; HRA vs dCS,  $p < 0.01$ ), without differences between the values measured in the three groups at any of the five sites. Group A had a lower Disp\_A compared to the group B ( $50 \pm 20$  ms vs  $150 \pm 100$  ms;  $p < 0.05$ ), but not when compared to the group C ( $50 \pm 20$  ms vs  $76 \pm 39$  ms;  $p = NS$ ). There was no significant difference in Disp\_A between group B and group C. Using logistic regression, the only predictor of A\_Vuln was Disp\_A ( $p = 0.05$ ).

**Conclusion** In pts with PAF, Disp\_A is a determinant of A\_Vuln. The increase in Disp\_A facilitates AF induction, whereas the degree of the nonuniformity of AERP appears to be less important in promoting AF maintenance. This suggests that Disp\_A contributes not only for A\_Vuln to AF but also to the type of induced AF.

### INFLUENCE OF I/D ACE GENE POLYMORPHISM ON EFFECT OF TRANSOESOPHAGEAL ELECTRICAL CARIOVERSION IN PATIENTS WITH LONE ATRIAL FIBRILLATION

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**The aim of study** was evaluation of influence of I/D ACE gene polymorphism on early results of transoesophageal electrical cardioversion (OCV) in patents with lone atrial fibrillation (AF).

We observed 30 pts (25 mean 5 woman) aged 47-76 years (mean age 52,3) with lone AF selected from 115 consecutive patients referred to elective electrical cardioversion (CV) due to intolerable symptoms. Left ventricle diameter was assessed by echocardiography examination before OCV in all pts as well as I/D ACE gene polymorphism, rest HR before OCV and mean 24-hour HR assessed based on Holter ECG monitoring.

All patients received effective anticoagulation at least 4 weeks prior to OKV. Any antyarrhythmic medication was stopped at day preceding OKV (for excluding its influence on cardioversion threshold). OKV was done using 6cm2 transoesophageal electrode and biphasic electrical impulse. Effective, mean and total energy of OKV were assessed and compared in relation to type of ACE gene polymorphism.

**Results** Based on evaluation of ACE gene polymorphism, 3 groups of patients were formed -with II (8 pts), ID (14 pts) and DD (8 pts) type of polymorphism. Mean left atrium diameter did not differ significantly in all groups of pts (II-46,0mm; ID-49,0mm; DD-45,5mm) as well as rest HR (II-113,5bpm; ID-99,5bpm; DD-107,8bpm) and 24 hour HR (II-113,5bpm; ID-85,3bpm; DD-87,7bpm)

Effective OKV energy did no significantly differ between studied patients (II-30,1J; ID-35,4J; DD-38,9J) as well as mean OKV energy (II-45,1J; ID-53,3J; DD-48,4J), total OKV energy (II-57,0J; ID-97,5J; DD-61,2J) and mean number of OKV shocks (II-1,6; ID-2,5; DD-1,5).

**Conclusion** Type of ACE gene polymorphism rather do not influ-

ence on energy needed to sinus rhythm restoration by transoesophageal electrical cardioversion in patient with lone atrial fibrillation.

### RELATIONSHIP BETWEEN I/D ACE GENE POLYMORPHISM AND TACHYCARDIOMYOPATHY IN PATIENTS WITH LONE ATRIAL FIBRILLATION

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**The aim of study** evaluation of influence of I/D ACE gene polymorphism and heart rate on development of tachycardiomyopathy in patents with lone atrial fibrillation (AF).

We observed 30 pts (25 mean 5 woman) aged 47-76 years (mean age 52,3) with lone AF selected from 115 consecutive patients referred to elective electrical cardioversion (CV) due to intolerable symptoms. Echocardiography examination was made before and 1 month after CV.

I/D ACE gene polymorphism evaluation, rest HR before CV and mean 24-hour HR based on Holter ECG were performed in all pts.

All pts were divided into 2 groups: group I - 14 pts with depressed left ventricle ejection fraction during AF and its normalization after sinus rhythm restoration;

group II - 16 patients with normal LVEF during AF.

**Results** Mean LVEF in gr.I pts before CV was 34,5% and 1 month after - 57,5%. In gr. II this LVEF values were 56,8% and 56,9% respectively. Patients with II type of ACE polymorphism had the lowest values of LVEF before CV (II-38,8%, ID-46,6% and DD-50,1%,  $p < 0,03$ ) whereas there were no differences of LVEF one month after CV (II-57,8%, ID-50,1% and DD-52,5%)

Rest HR before CV was higher in gr.I (116,4 vs 92,5 bpm,  $p < 0,03$ ) as well as mean 24-hour HR (96,8 vs 81,7 bpm,  $p < 0,02$ ). Type II of ACE gene polymorphism were more frequent in patients with tachycardiomyopathy (35,7% vs. 18,8%), whereas type DD was more frequent in pts with normal LV function during AF (31,3% vs. 21,4%).

#### Conclusions

1. Type II ACE gene polymorphism is more frequent in patients who develop the tachycardiomyopathy during lone atrial fibrillation thus it might take a part in tachycardiomyopathy pathogenesis.
2. Higher values of rest (incidental) HR and mean 24-hour HR were observed in patients with lone atrial fibrillation who developed tachycardiomyopathy, in comparison to subjects with normal left ventricle function.

### SAFETY AND EFFICACY OF OESOPHAGEAL-PRECORDIAL ELECTRICAL CARADIOVERSION IN PATIENTS WEARING PACEMAKERS

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**Introduction** Electrical cardioversion is widely used for the termination of atrial fibrillation (AF) which is very common in pacemaker (PMK) patients. Dysfunction of the cardiac stimulator, acute loss of capture or chronic increase in stimulation thresholds have been reported in literature following electrical defibrillation.

**Methods** We evaluated the effects of a low energy electrical cardioversion in 30 patients with AF with dual chamber PMK underwent to oesophageal-precordial cardioversion under conscious sedation. Adhesive patch were placed in an anterior-lateral position as

far as possible from the pulse generator and all ten electrodes of the oesophageal catheter were connected to the positive pole of a biphasic defibrillator. Before cardioversion the higher voltage output was programmed. Patients received a single 50J shock, increased directly to a maximum of 100 J if the first shock was unsuccessful. PMK was checked before and after cardioversion, at the discharge and 8 weeks after.

**Results** In 29 of 30 patients (96,6%) oesophageal-precordial cardioversion restored sinus rhythm (SR) with a mean effective energy of  $55 \pm 15$  J. The mean midazolam dosage was  $3,4 \pm 1$ mg. No complications were observed. None of the 30 patients developed exit block or a significant increase in pacing threshold immediately after cardioversion. The 8 weeks follow-up showed a 37% AF recurrence rate; no modification of the pacemaker function neither of the stimulation and sensing thresholds were reported.

**Conclusions** Oesophageal-precordial electrical cardioversion of AF in patients with PMK showed to be effective. It didn't cause PMK malfunctions, acute loss of capture or chronic increase in stimulation thresholds. It uses less energy, and less of the pacing lead lies in the electrical field produced by the shock, reducing the probability of delivering a substantial amount of energy to the lead tip or the generator.

### SIMPLIFIED INTERNAL CARADIOVERSION OF ATRIAL FIBRILLATION WITH A NOT-IMPLANTED STANDARD ICD SYSTEM. CONTINUING EXPERIENCE

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**Background** internal cardioversion (ICV) is a routine procedure to interrupt persistent atrial fibrillation (AF) with reported high success rates in selected patients. It is commonly performed with specific leads and devices, often with coils in the coronary sinus, and/or adapting an external defibrillator.

**Purpose of the study:** to assess feasibility and safety to use a standard ICD system for routine ICVs.

**Methods** in 25 consecutive pts (7F, mean age  $67 \pm 7$ ) with persistent, long-lasting, symptomatic AF we performed ICV using standard dual coil defibrillation leads (Medtronic Sprint Fidelis® or Guidant Reliance®) inserted through antecubital veins (except 2 subclavian and 1 cephalic) connected to an externally placed, standard ICD (Medtronic InSync III Marquis®) programmed with passive can. Pts were mildly sedated with midazolam (median dose 3.5 mg i.v.). Three synchronized shocks at 10 (7 for very thin patients), 15 and 30 J, delivered between the two coils (right ventricle and superior vena cava) were foreseen. Sensing and pacing was warranted through the same standard lead.

**Results** At the moment of ICV, 15 pts were in therapy with amiodarone, 1 with sotalolol, 6 with ACE-inhibitors and 10 in chronic anticoagulation therapy. Sinus rhythm (SR) was restored uneventfully in all patients except two, with a median of 1.8 shocks and a median energy of 16.8 J. A 30 J shock was required in eight cases. No patient complained any discomfort. Mean time needed for ICV was  $40 \pm 25$  min. Fluoroscopy time was  $5 \pm 4$  min, including the time for additional procedures (3 PM and 1 ICD implants, and 1 EP study) contextually performed.

**Conclusions** we safely performed ICV, restoring SR in the vast majority of patients utilizing low shock energy, without anaesthesiologist support, with satisfactory procedure duration and good acceptance by patients. We are continuing our experience and expanding our population, in view of adopting this approach as clinical routine.

## CARDIAC PACING LEADS

### EPICARDIAL PACING: A SINGLE-CENTER STUDY ON 321 LEADS IN 138 PATIENTS

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**Objective** This study presents the long-term outcome of 321 epicardial leads in 138 patients.

**Methods and results** All leads were Medtronic CapsureEpi model 4965 steroid eluting leads. The 1-, 3-, and 5-year patient survival was 91%, 83% and 77%, respectively. Twenty-seven patients died. In 25/27 deaths a pacing-related death could be excluded. Strangulation of the heart by an abandoned epicardial lead was the cause of death in one child. One other patient died suddenly at the age of 3 years. Failures occurred in 57 of 321 epicardial leads (18%). For all 321 leads, the 1-, 3- and 5-year freedom from failure was 91%, 85% and 71%, respectively. The cumulative proportion of patients without any lead defect was 85% after 1 year, 76% after 3 years and 62% after 5 years. The percentage of patients without serious adverse events at 1, 3, and 5 years was 97%, 91%, 85%, respectively.

Lead fracture was the cause of failure in 15 leads of 9 patients. An important increase in pacing threshold occurred in 35 leads of 30 patients. Other failures were: diaphragmatic stimulation, infection, excessive traction and strangulation. Eighteen failures were repaired by 11 surgical interventions in 9 patients. Thirty-nine defects were corrected non-invasively in 31 patients.

**Conclusions** The use of steroid-eluting epicardial leads has proven to be an adequate option. In paediatric cardiology, the epicardial approach remains an indispensable tool for achieving a lifelong pacing.

### LONG-TERM OUTCOME OF TRANSVENOUS LEADS IN CHILDREN WITH VVIR PACEMAKER (PM)

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**Purpose** the implantation of PM in children has still many complications mainly related to leads or infections. Aim of the study is the evaluation of long-term outcome of VVIR PM with transvenous leads in children.

**Methods** retrospective analysis of pts  $\geq 15$  years of age at VVIR PM implantation in our Center. All leads were implanted by transcatheter subclavian vein puncture and placed in the RV apex with PM generator in prepectoral pocket. Data are expressed as mean  $\pm$  SD (range).

**Results** between 1990 and 2005, 117 children (47 girls) underwent VVIR PM implantation with transvenous leads placed in the RV apex at  $5 \pm 4$  years of age (2 days-15 years), for complete AVB (105 pts, 89%, postoperative in 37) and sinus node dysfunction (SND) in 12. Other congenital heart defects (CHD) were present in 63 pts (54%). The leads implanted were: unipolar (n.78, 67%)/bipolar (n.39), screw-in (n.6)/tined (n.108, 94%), steroid-eluting (SE, n.86, 76%)/nonsteroid (nonSE, n.28), and were fixed to subcutaneous tissues by absorbable suture alone (AS, 100 pts, 88%) or by AS and the addition of atrial loop (AS and AL) in the last 17 pts.

Follow-up (FU) duration is  $7 \pm 4$  (0.1-16) years. Complications were divided in early (<3 months: hemothorax 3%, device infections 3%, lead dislocation 5%) and late (lead failure= 20 pts, 17%, device infections 3%). Of the variables evaluated (age at implantation, FU duration, SE vs. non-SE, lead fixation, polarity, AS vs. AS and AL) only the use of AS and AL was significantly associated with lead failure (0% vs. 20% for AS,  $p=0.04$  Fisher exact test). LV dysfunction and subclavian vein occlusion occurred in 5% of patients.

**Conclusions** VVIR PM in pediatric age have good results in long-

term FU but also frequent complications that may require device revision. The use of AS and AL showed better results.

### BACTERIOLOGICAL ASSESSMENT OF INFECTIOUS PM/ICD LEADS

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**PURPOSE** Facing a high incidence of infections in patients underwent leads extraction of cardiac stimulation devices at our Centre, we decided to proceed with a microbiologic assessment to identify the prevalent strains of bacteria responsible for these infections. We especially focused on assessing the sensitivity of bacteria to antibiotics, so as to delineate an effective therapeutic protocol.

**MATERIALS AND METHODS** Between May 2003 and June 2006, at our Centre, 72 leads were extracted from 39 patients, of which 87.5% had indication of infection. After extraction, samples of the suspected infected leads (the tip, the intravascular part of the lead in direct contact with the endocardial tissue and the pin, extravascular, joining the lead to the stimulation device) were sent to the laboratory.

**RESULTS** Staph. epidermidis was the most frequently isolated bacterial strain (37.5%), followed by Gram + flora (16.1%), Staph. aureus (14.3%), Candida parapsilosis (5.4%), Staph. schleiferi (5.4%), Corynebacterium species and Staph. hominis (3.6%). Retained sensitivity to antibiotics was the following: teicoplanin/vancomycin 100%; doxycyclin 96%; amikacin 94%; piperacillin-tazobactam 58%; co-trimoxazole 78%; gentamycin 65%; quinolones 47%; rifampicin 44%; cephalosporins 25% and oxacillin 25%. The sub-analysis of resistance in various clinical indications showed that in case of sepsis, sensitivity for glycopeptides and amikacin was retained (about 100%); to a lesser degree, that also applies to doxycyclin (80%).

**CONCLUSIONS** A very high percentage of the germs responsible for device infections are oxacillin-resistant (75%). Remarkably, our data point out a poor susceptibility to antibiotics of the bacteria associated with pacemaker-related infections, and show that also local infection not healing with usual antibiotics are often sustained by methicillin-resistant strains. Therefore, systemic antibiotics, preferentially glycopeptides, in full-regimen doses, must not be delayed in such patients, having in mind that, however, the mainstay of the management of relapsing infections is the complete removal of the implanted system.

### BACTERIOLOGICAL POCKET AND PIN/TIP CULTURE OF INFECTED PACEMAKER AND DEFIBRILLATOR LEADS

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**Purpose** Infection of PM/ICD is becoming a more and more frequent occurrence. Despite its lack of systemic symptoms of infection, chronic draining sinus rarely heals with local interventions. We performed a microbiologic assessment on samples from blood, pocket, lead pin and tip in suspected infections.

**Material and methods** Between May 2003 and June 2006, at our Centre, 72 leads were extracted from 39 patients (87.5% with an infective indication). Before explant, patients with local infection, chronic drain-

ing sinus or sepsis underwent a blood culture and a bacteriological examination of the device pocket. After extraction, both device tip and pin were also examined.

**Results** Lead cultures were more sensitive than pocket ones, with 81.1% of culture positives as compared to the 63.9% recorded for pocket sample cultures ( $p=0,001$ ). Cultures on blood samples were positive only in 27.8% of cases. Lead pins cultures were positive in 85% of the chronic draining sinus cases, while cultures on pocket samples were positive only in 50% of these patients. Lead tips cultures were positive in 73.3% of pocket infections and in 57.7% of chronic draining sinus cases.

**Conclusions** Lead cultures are more sensitive than cultures from pocket samples for infection diagnosis. It is therefore necessary that they are always carried out, so that an appropriate antibiotic therapy can be defined. Our results demonstrate that chronic draining sinus is often sustained by an infection. This emphasises the need for awareness of the limited efficacy of reparative operations and justifies a less conservative approach about resorting to extraction procedures. The high percentage of positive tip cultures in local infection and chronic draining sinus cases demonstrates that there is a chance for propagation of infection from the pocket to the tip. This further reiterates that the infection can only be treated through complete extraction of the lead.

#### **PACE-MAKERS AND ICDs LEAD EXTRACTION WITH LASE TECHNIQUE: A SINGLE CENTRE EXPERIENCE**

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The increase in implant rates, especially of ICDs, has subsequently increased the absolute number of leads' malfunctioning or lead/device infection. The longer the time past from the implant, the thicker the fibrotic reaction that occurs around the lead body or between the lead and the vessels' wall; for this reason, in the majority of cases, simple manual traction is not sufficient to allow lead removal and alternative techniques are needed. The laser sheath uses optical fibers, delivering pulsed ultraviolet excimer laser light, to vaporize fibrotic tissue binding intravenous cardiac leads to the vein or heart wall during lead extraction. Since April 2004 to August 2006, 74 PM or ICD leads in 41 pts were extracted. Leads had been implanted since 79 + 15 months. Indication for extraction was infection in 63 leads and malfunctioning in 11 leads. There were 25 (33%) atrial lead, 44 (59%) ventricular lead, 10 (12%) ICD leads and 5 (6%) coronary sinus leads. 20 leads (27%, 3 atrial, 15 ventricular and 3 coronary sinus leads) were extracted by simple manual traction; in the remaining 54 (73%) leads the laser sheath was used. Of the latter, 48 (93%) were completely removed, whilst 4 (2%) were incompletely removed (3 atrial

and 1 ventricular leads). 2 leads were removed surgically. Major perioperative complications needing surgical intervention (cardiac tamponade) were observed in 2 pts. The only factor predicting possibility of simple manual traction removal was time from implant: 6 + 3 months vs. 87 + 31 months.

In conclusion, leads extraction with laser sheath is a safe and effective procedure. Major complication incidence rate is lower than 5%. The only factor predicting efficacy of manual traction is time from implant. In young pts fibrosis seems to be thicker.

#### **PM/ICD LEADS EXTRACTION: A NEW SINGLE-CENTRE EXPERIENCE**

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**PURPOSE** Over the last few years, an increasingly widespread use of permanent cardiac stimulation devices for the therapeutic treatment of rhythm disturbances has been closely followed by an increase in the number of device-related complications which due to leads extractions. This study reports our experience in leads extraction.

**MATERIALS AND METHODS** Between May 2003 and June 2006, at our Centre, 72 leads were extracted from 39 patients (27 male, age 26-85, mean 70.9 ± 13.5 years, age of implant range 1-312 months, mean 48.9 ± 49.4, n. of reparative operations prior to the extraction procedure 1.6 ± 1.5, range 0-5, active anchoring 16%, 28 atrial, 35 ventricular, 2 VDD and 7 defibrillator leads). Clinical indications to extraction were sepsis (25%), pocket infection (26.4%), chronic draining sinus (36.1%), PM/ICD malfunction (6.9%) and interference with other systems (2.8%). Manual traction with a locking stylet was performed in 52.8% of leads and dilation/countertraction through polypropylene sheaths in 47.2%. Success was completely achieved in 97.2% and partially in 1.4%. Only one lead (1.4%) was not extracted. Manual traction alone was effective in 52.8% of leads and dilation in 96.9%, so achieving a total success rate of 97.2% through the sequential use of traction followed by dilation technique. Local anaesthesia was effective in 80.6%, while sedation by an Anaesthetist was necessary only in 19.4%. Acute complications were non-sustained ventricular tachycardia (6.9%), asymptomatic (11.1%) and symptomatic hypotension (5.6%), and the perioperative treatments were volume expansion (40.3%), drugs (22.2%) and transfusions (13.9%).

**CONCLUSIONS** The results obtained show that the choice of carrying out this delicate procedure was rewarded by a high success rate both in terms of a high percentage of successful operations and a limited number of recorded complications. The methods utilized, involving manual traction and dilation, were able to treat and resolve even the most complex cases.

## SUDDEN DEATH RISK STRATIFICATION

### EFFECT OF BEPRIDIL ON ARRHYTHMOGENESIS IN HEARTS FROM DILATED CARDIOMYOPATHY MODEL MICE AND GUINEA-PIGS

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Bepridil is a multiple ion-channel (Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>) blocker, and has anti-arrhythmic effects. However, only a small number of basic studies have reported regarding the anti-arrhythmic mechanism of bepridil. Therefore, we examined the effect of bepridil on automaticities and Ca<sup>2+</sup> dynamics in dilated cardiomyopathy (DCM)-model-mice (mutation deltaK210 in cardiac troponin T) papillary muscles and guinea-pigs atrial muscles treated with isoproterenol. Ventricular papillary muscles and atrial trabeculae were dissected from their hearts, and attached to a tension transducer. The muscles were usually conditioned by field stimulation. Isometric tensions were recorded during stimulation and after stoppage of the stimulation. When isoproterenol was administered to the guinea pigs atrial muscles in low potassium Krebs-solution, spontaneous high frequency twitches were observed in the absence of field stimulation. Bepridil (5–30 μM) suppressed these automaticities with concentration dependent manner without any significant change in the twitch responses to field stimuli. In the DCM-model-mouse ventricular muscles, spontaneous high frequency twitches were observed without field stimulation. When bepridil was administered, these spontaneous twitches also were suppressed. Similar anti-arrhythmic effects were observed with pilsicainide (pure Na<sup>+</sup> channel blocker), but not with nifekarant (pure K<sup>+</sup> channel blocker) in DCM-model-mice. Moreover, similar preparations were loaded with Rhod-2, a Ca<sup>2+</sup> indicator or Di4-ANEPPS, a membrane potential indicator. Sequential two-dimensional images of surface cells were acquired using a confocal-microscope. In both type of muscles, spontaneous Ca<sup>2+</sup> transients and action potential signals were detected, and they were suppressed by bepridil. On the other hand, Ca<sup>2+</sup> waves, which correspond to after-contraction, were not suppressed by bepridil. These results suggest that bepridil has a strong anti-arrhythmic effect with little suppression of tension, and that the arrhythmogenic factor in those muscles may not directly relate to DAD, to which Ca<sup>2+</sup> waves relate.

### IMPACT OF COMPLETENESS OF REVASCULARIZATION AND Q WAVE EVOLUTION ON QT DYNAMICITY AFTER MYOCARDIAL INFARCTION WITH ST ELEVATIONS

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**Background** QT dynamicity is a marker of ventricular repolarization used in risk stratification of cardiac death. The aim of this study was to correlate QT dynamicity parameters with completeness of revascularization and Q wave evolution after myocardial infarction with ST elevations (STEMI).

**Methods** A 24-hour ECG monitoring was performed in 133 patients 48–72 hours after acute STEMI. All these patients were treated with direct percutaneous coronary intervention (dPCI). The QT dynamicity (assessed by slope of linear QT/RR regression line) was automatically analysed from 24-hour ECG recordings using QT Guard software of MARS Unity Workstation, GE Medical. Occurrence of pathologic Q wave was assessed on 12-lead ECG 48 hours after STEMI.

**Results** Complete revascularization was achieved in 68 patients

(group A), in 64 patients multivessel disease was present (group B). The QT/RR slope of the groups A and B was not different (0.2±0.117 vs 0.225±0.109, p=0.1). Pathologic Q wave evolved in 86 patients (group C), in 46 patients no Q wave was observed (group D). The QT/RR slope was significantly steeper in the group C compared to the group D (0.229±0.118 vs 0.181±0.099, p=0.007).

**Conclusions** No simple relationship between completeness of revascularization and the QT dynamicity was found probably due to different times from STEMI beginning to artery opening. The QT/RR slope is steeper in patients with Q wave evolution after STEMI confirming that they are high risk individuals.

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### PREVALENCE AND PROGNOSTIC SIGNIFICANCE OF SHORT QT-INTERVAL IN MIDDLE-AGED FINNISH POPULATION

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**PURPOSE** Short QT syndrome is an inherited disorder characterized by a short QT interval and increased risk of sudden cardiac death (SCD). The significance of a short QT interval in a random population is unknown. Therefore, we assessed the prevalence and prognostic significance of short QT interval in a middle-aged population with a long follow-up.

**MATERIALS AND METHODS** We screened the 12-lead electrocardiograms (ECG) of 10826 randomly selected middle-aged subjects (5658 males, mean age 44+/-8.4 years, range 30–59 years) enrolled in a population study during the years 1966–1972. The mean follow-up period was 21+/-5.8 years. All-cause mortality and cardiovascular mortality were the end-points. In addition to Bazett's correction method (QTc), Fridericia equation (QTf) and nomogram method (QTnc) were used to correct QT interval for heart rate. The cut of value for short rate corrected QT intervals were 320 msec (very short) and 340 msec (short).

**RESULTS** The prevalence of very short QT interval (<320 msec) based on QTc, QTnc and QTf was 0.10%, 0.06% and 0.06%, and the prevalence of short QT interval (<340 msec) was 0.4%, 0.3% and 0.3%, respectively. All-cause mortality or cardiovascular mortality did not differ between the subjects with very short (<320 msec) or short (<340 msec) from those with normal QT interval. None of the deaths of subjects with QT interval shorter than 340 msec were classified as sudden and none of the subjects had a medical history of aborted SCD, syncope or ventricular tachyarrhythmia.

**CONCLUSIONS** Short QT interval is not very uncommon in middle-aged population. It does not indicate an increased risk for SCD or cardiovascular mortality in a random population.

### SUDDEN DEATH IN ATHLETES: TWO PROSPECTIVE DATABASE IN THE EMILIA-ROMAGNA REGION

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Sudden death (SD) in young subjects and competitive athletes has been frequently reported, but no recent prospective epidemiological surveys have been proposed or reported so far.

**PATIENTS AND METHODS** A ten years data base of the Emilia-

Romagna Region has been organized to assess the prevalence, the incidence and the causes of SD in athletes and young subjects, practicing both competitive and non competitive sportive activities. Data have been collected from referring or team physicians, newspapers, and anatomic-pathological reports and necroscopies, when available. A new prospective database has been started in 2005, including 5 new cases.

**RESULTS** The use of illicit drugs had been documented in 12 cases. 56 observations are reported, with a mean age of  $24 \pm 15$  years (range 12-45 years). 47 were male and 9 were female. The practiced sport activities were as follows: 21 soccer, 15 basket, 4 cyclism, 2 volleyball, 3 tennis, 5 athletics and 6 other sports. Necroscopies were available in 36/56 (64%). Data from these necroscopies are reported: 11 cases apparently negative findings (+6 with early occurring atherosclerosis +2 primary cardiomyopathy, cardiomegaly and reduced thickness of the myocardial wall); 6 arrhythmogenic right ventricular displasia cardiomyopathy and Brugada syndrome; 4 Marfan syndrome or other connective tissues disorders; 4 myocarditis; 4 acute myocardial infarction; 3 viral infectious disease of the lungs; 2 previous unrecognized rheumatic heart disease; 2 cerebral hemorrhages.

**CONCLUSIONS** SD is still relatively frequent, mainly in young subjects, practicing sport activities without an adequate non invasive or invasive cardiovascular evaluation. In the majority of the reported cases, and underlying heart disease could be easily identified at necroscopy. A more complete cardiovascular evaluation should be performed, including a strict control of illicit drugs use, by tissue, blood and urine samples evaluation. A preventive or post-mortem genetic screening can be today performed for genetic cardiovascular diseases.

### RISK OF SUDDEN DEATH IN CHILDREN WITH ANTIDROMIC TACHYCARDIA IN WPW SYNDROME

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**PURPOSE** We evaluated a real risk for sudden death in 11 (8,5%) children with antidromic tachycardia from 130 symptomatic children with WPW syndrome.

**METHOD** All of them have had EKG during and after tachycardia and echocardiographic finding. They were followed up from 5 to 13 years. Electrophysiological examination and treatment with radiofrequency catheter ablation were made in all 11.

**RESULTS** There were 5 of 11 children with the antidromic tachycardia before ten years (two at 6 years and three at 8 years) as the first tachycardia in WPW syndrome. Others 6 have had antidromic tachycardia and previously orthodromic tachycardia, and all were in teenage. From five younger group 4 have had atrial fibrillation in adolescent age with the shortest RR intervals shorter than 220 msec. The last one

have had atrial fibrillation at 17 years with shortest RR interval 320 msec, and in 21 year the EKG without preexcitation. By electrophysiological examination in 10 (91%) of 11 children with antidromic tachycardia there were multiple pathways.

**CONCLUSION** The younger children with antidromic reciprocating tachycardia in WPW syndrome are in great risk for more serious tachycardia during teenage and need the electrophysiological investigation and treatment with radiofrequency catheter ablation before teenage. Antidromic reciprocating tachycardia are the clinical sign of multiple pathways in most cases during childhood.

### IDIOPATHIC DILATED CARDIOMYOPATHY IS ASSOCIATED TO A HIGH INCIDENCE OF APPROPRIATE ICD THERAPIES INDEPENDENTLY FROM SUSTAINED VENTRICULAR ARRHYTHMIAS IN ANAMNESIS

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**Purpose** implantable cardioverter-defibrillators (ICD) represent first line treatment in arrhythmic sudden death (SD) prevention in patients (pts) with impaired left ventricular function (LVEF). Recent data suggest an important benefit in idiopathic dilated cardiomyopathy (DC). We aim to evaluate incidence of potentially lethal sustained ventricular arrhythmias (VA) in DC affected pts who underwent ICD implantation according to current guidelines.

**Materials and Methods** 45 DC affected pts who received an ICD and followed up every 6 months were retrospectively analysed. Pts were divided in: primary (group A) or secondary (group B) prevention.

**Results** group A was made of 24 pts (20 males, mean age  $62 \pm 10$ ) while group B of 24 pts (17 males; mean age  $62 \pm 11$ ). Two groups didn't significantly differ for therapy (beta-blockers 94 vs 92%; amiodarone 24 vs 25%; ACE-I or ARBs 88 vs 90%, furosemide and/or anti-aldosterone 83 vs 91%, respectively in group A and B,  $p=NS$ ), diabetes mellitus (12 vs 10%, respectively,  $p=NS$ ). Group A showed a significantly more impaired left ventricular function (LVEF  $25 \pm 7\%$ ) than group B (LVEF  $35 \pm 10\%$ ),  $p=0.002$ . A significantly higher number of pts in group A (62%) received a biventricular ICD than group B (24%),  $p=0.04$ . At a mean  $18 \pm 12$  months follow-up, at least one appropriate ICD therapy was recorded in 7% for group A and 11% for group B,  $p=NS$ . Number of non sustained ventricular tachycardia was similar in 2 groups (group A: 32% vs group B: 40%,  $p=NS$ ). Inside each group, LVEF, diabetes or drug therapy didn't match with presence of VA.

**Conclusion** In our experience, in DC affected pts with impaired LVEF, potentially lethal sustained VA are present in 10% of pts independently by primary or secondary prevention indication, after 2 years from implantation.

## CARDIAC RESYNCHRONIZATION THERAPY: TECHNIQUE, RESULTS AND COMPLICATIONS

### INCIDENCE OF ATRIAL FIBRILLATION IN PATIENTS WITH CARDIAC RESYNCHRONIZATION THERAPY, A CASE CONTROL STUDY

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**Background** Prevalence of atrial fibrillation (AF) in patients with heart failure (HF) increases along NYHA class, reaching up 50% for class IV. Resynchronization therapy (CRT) improves cardiac performance and accordingly NYHA class. The aim of this study was to determine retrospectively the effects of CRT in the incidence of AF

**Methods** We studied 28 patients recipients of CRT-ICD systems comparing them with a group of 29 dual chamber ICD patients matched by gender, age, NYHA class and LV ejection fraction. No previous sustained AF was recorded before the implant. Mean follow-up period was 8.5 months. Clinical and echocardiographic variables were reviewed, and the AF episodes stored by the devices.

**Results** In the CRT group, 57.6% of the patients had idiopathic dilated cardiomyopathy and 42.2% ischemic cardiomyopathy. Two patients died during follow-up (1 cardiovascular). Three patients (11.5%) were readmitted because of HF symptoms. Four patients presented AF during follow-up (15.4%) but only one episode of AF longer than 12 hours. In the ICD group, 5 patients died during follow-up (3 cardiovascular deaths) and 4 patients were readmitted because of HF. Eight patients presented AF(23.2%) and there were 6 episodes longer than 12 hours ( $p < 0.05$ ). Regarding echocardiographic data, in the CRT group the left atrial diameter remained unchanged. The mean ejection fraction raised from  $22.8 \pm 8.8$  to  $32.5 \pm 13.3\%$  ( $p < 0.001$ ). In the dual chamber ICD group there were no differences.

**Conclusions** CRT was associated to lower AF incidence being statistical significant the reduction of the longer episodes. Based on the lack of significant changes in the atrial dimension observed, our data support a beneficial effect in the atrial electrical remodeling derived from the CRT.

### ATRIAL AND VENTRICULAR ARRHYTHMIAS IN CRT-PATIENTS IN THE FIRST 7 MONTHS

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Bifocal right (BRIGHT) stimulation in congestive heart failure is set up as a randomized cross-over study in candidates with an indication for CRT. BRIGHT pacing was achieved by simultaneous pacing of the apex and the outflow tract.

**METHODS** after a run in period of 1 month the patients were blindly randomized for 3 months either to therapy or control (VVI 40 bpm pacing). The STRATOS LV pacemaker has a memory for recording arrhythmia counters and additionally it stores intracardiac electrograms (IEGM). In 33 out of 42 pts follow up was complete. Incomplete follow up was due to 4 deaths, 1 refusal, 1 protocol violation and 2 lead problems.

**RESULTS** CRT pacing was reached in  $98.5 \pm 3.2\%$  (range 85 to 100). Automatic mode switch (AMS) was in most pts programmed at 160 bpm (avg  $158 \pm 4$  bpm). In 2 pts the AMS number was corrupted by frequent far field sensing in the bipolar mode and myopotentials oversensing in the unipolar mode. In the other pts AMS was mean  $6.8 \pm 10.7$ . The burden of atrial fibrillation was less than 1 minute/3 months in 37 pts, between 1-and 10 minutes in 3 pts and in 3 pts atrial fibrillation was either persistent necessitating cardioversion or converted spontaneously after > 3 hours. VES  $2177 \pm 3172$  day, V couplet  $256 \pm 463$  /day; V triplet  $53 \pm 120$  /day; V run  $51 \pm 114$  /day; V run (> 8beats)  $25 \pm 114$  /day. 4 pts died due to progressive heart failure. V arrhyth-

mias may be overestimated due to the pm-preference to mark fast arrhythmias as ventricular. However, the intracardiac ecg confirmed shortlasting VTs for 2,5 seconds in 5 pts.

**CONCLUSION** Supraventricular and ventricular arrhythmias are very infrequent during the first 7 months follow up. The stored intracardiac electrogram is very useful to correct arrhythmia diagnosis.

### HEART RATE VARIABILITY MONITORED BY AN IMPLANTED CARDIAC RESYNCHRONIZATION DEVICE PREDICTS CARDIOVASCULAR EVENTS IN PATIENTS WITH NYHA CLASS II AND III/IV HEART FAILURE

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**Introduction** There are initial evidences that cardiac resynchronization (CRT) increases parameters of heart rate variability (HRV). However, data on long-term changes of HRV in heart failure pts treated with CRT are still lacking. We analyzed the long-term changes of HRV, monitored by CRT devices, to assess the role of such changes in predicting CRT efficacy and cardiovascular events (CvE).

**Methods** The study included 509 pts, 112 in NYHA class II and 397 in NYHA class III/IV, enrolled in the InSync/InSync ICD Italian Registry and implanted with CRT devices capable of continuous assessment of a time-domain parameter of HRV (SDANN). Baseline value of SDANN was considered the average of the first week after implantation.

**Results** At baseline, SDANN was comparable in NYHA II and III/IV pts ( $71 \pm 21$  and  $68 \pm 22$ ms), it increased significantly in both groups after 6 months ( $91 \pm 29$  and  $85 \pm 27$ ms,  $p < 0.05$  Vs baseline) and the improvement persisted until 1 year ( $94 \pm 30$  and  $84 \pm 26$ ms). SDANN values were significantly higher in NYHA II than in III/IV pts at 1 year ( $p < 0.05$ ). During follow-up (median 12 months), 97/509 (19%) pts, 14 (13%) in NYHA II and 83 (21%) in NYHA III/IV, had a CvE (death, heart transplantation or HF hospitalization). The baseline characteristics identifying pts experiencing CvE were: a shorter echo-measured aortic-to-pulmonary pre-ejection interval ( $31 \pm 44$  Vs  $48 \pm 25$ ms,  $p = 0.01$ ), as well as a lower SDANN at baseline ( $64 \pm 22$  Vs  $72 \pm 22$ ms,  $p = 0.02$ ) and after 1 month of CRT ( $74 \pm 29$  Vs  $84 \pm 26$ ms,  $p = 0.01$ ).

**Conclusions** CRT determines long-term sustained changes of HRV profile. The greater improvement of HRV in NYHA II pts suggests that even pts with mild HF may benefit from CRT. Higher values of SDANN at baseline and early after CRT, as well as larger baseline mechanical dyssynchrony, permit to identify patients at lower risk for CvE.

### CARDIAC RESYNCHRONIZATION THERAPY IN PATIENTS WITH A NARROW QRS AND EVIDENCE OF LV DYSSYNCHRONY

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**Background** Cardiac resynchronization therapy (CRT) is beneficial in selected patients with advanced heart failure and QRS complex > 120 ms. Patients with QRS < 120 ms are according current guidelines not indicated for CRT. The outcome and potential benefit are not known.

**Objective** To evaluate the effects on CRT in heart failure patients with QRS complex < 120 ms and evidence of significant left ventricular dyssynchrony using tissue Doppler imaging (TDI) in a prospective study.

**Methods** 27 consecutive patients with heart failure, NYHA class III/IV,

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LV EF<0.30, QRS complex duration < 120 ms, all with LV dyssynchrony (> 60 ms on TDI) were included. Control group (31 pts) with same criteria with exception of QRS duration > 120 ms.

**Results** All baseline characteristic were comparable between patients with QRS duration <120 ms (mean 115 + 7 ms) and patients with QRS duration > 120 ms (mean 163 +21 ms). No significant relation between baseline QRS duration and LV dyssynchrony was observed (R =0.27, ns.) The change of clinical data, echocardiographic parameters and QoL 12 month after implant were comparable in both groups with exception of QRS shortening.

change of parameter	QRS <120 ms	QRS>	120ms p
QRS (ms)	-10 +- 5	-43 + 12	<0.01
6 min VT (m)	+112 +- 27	+127 +- 24	ns
LV EF (%)	+9 +-8	+7 +- 11	ns
LV EDD (mm)	-6 +- 5	-9 +- 7	ns
QoL score	-21 +-11	-17 +- 9	ns

**Conclusions** CRT therapy is beneficial in patients with a narrow QRS complex (<120 ms) and evidence of LV dyssynchrony measured by TDI. The improvement of clinical symptoms, LV EF, reverse LV remodeling and the change in QoL was comparable to patients with QRS complex duration > 120 ms.

**PRE-OPERATIVE MULTISLICES COMPUTED TOMOGRAPHY IMPROVES SUCCESS RATE OF BIVENTRICULAR DEVICE IMPLANTATION**

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Clinical and haemodynamic benefits of cardiac resynchronization therapy mainly depend on achieving an optimal pacing site in the left ventricle, with respect to improvement of left ventricular dyssynchrony. Cardiac multislices computed tomography (cMCT) is a new, reliable technique that allows an effective spatial three-dimensional reconstruction of CS and its tributaries. An accurate knowledge of anatomy of coronary sinus (CS) and of its veins is of major importance to place the left lead over the echocardiographically desynchronized segments. Aim of this study was to compare usefulness of a pre-operative study of CS anatomy gained by cMCT (20 pts, Group 1) with that of CS study obtained by conventional retrograde venography (RV) performed during CRT procedure (20 pts, Group 2). Time to CS incannulation, time to reach the target vein, total procedural times and implant success rate were compared between the two groups.

**Results** in 5 pts (25%) of Group 1, cMCT showed a CS anatomy unsuitable for a proper left lead implantation, with consequent shift of these pts to a surgical approach. Success transvenous implant rate was 19\20 (95%) in Group 1 and 15\20 (75%) in Group 2. Total procedural times, time to CS incannulation and time to place the lead in the target vein were significantly lower in Group 1 vs Group 2 (139±31 vs 137±33, p<0.03, 9±4 vs 16±4, p<0.04 and 23±13 vs 46±14 minutes, p<0.04, respectively).

**Conclusions** the pre-operative awareness of unsuitable CS anatomy may guide the decision to withheld a tranvenous procedure in favour of a first-line surgical epicardial approach to attain proper lead positioning. Moreover, pre-operative study of CS tributaries allows more accurate choice of guide-catheter and of shape and size of left lead, increasing success rate of CRT procedure and reducing procedural times.

**IS THERE ANY ROOM FOR REMOTE FOLLOW-UP OF CRT-ICD PATIENTS? DATA FROM THE INSYNC ICD ITALIAN REGISTRY**

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**Introduction** With expanding indications for ICD and CRT, the burden of post-implant follow-up(F/U) is growing. Launch of remote F/U systems in Europe is currently underway to provide remote device interrogations (INT) capability (device reprogramming is not allowed). We analyzed device-stored data from patients implanted with CRT-ICD and enrolled in the InSyncICD Italian Registry, to characterize the management of CRT-ICD patients in current clinical practice.

**Results** 217CRT-ICD patients (190males;65±14years) were identified, all with complete device-data for at least 1year. Over a mean F/U period of 570±158days, 1959INT occurred. Of these, the majority (1280,65%) involved the reprogramming of device parameters. The mean time interval between all INT was 70±25days. Overall, a marked reduction in INT requiring reprogramming was observed from the first 6months of F/U compared to the following period (from 3.6±1.8 to 1.1±1.0INT/6months).

A mean of 6.0±5.9device parameters were reprogrammed during the first 6month F/U, versus 4.4±5.6(p=0.000) during the subsequent F/U period. In particular, the number of reprogrammed parameters decreased from 3.9±4.2 to 2.5±3.5(p=0.000).

At multivariate analysis, a higher-than-median number of INT resulted significantly associated to each additional shock delivered (OR:2.51;95%CI:1.42-4.42).

A total of 133INT in 60 patients were performed following a device shock, with 80% of these occurring within 5days of the shock, and 60 of these INT occurring within 1day after the shock. 65INT(49%) did not require device reprogramming.

**Conclusions** Frequent INT with reprogramming were observed during the first 6months of F/U, due to a need to optimize parameters, in particular for CRT delivery. This may preclude, in this period, use of remote F/U systems that, on the contrary, may play a critical role afterwards.

As frequent shocks predict an elevated INT frequency and a considerable portion of post-shock INT dot not involve reprogramming, patients with many shocks may benefit from remote F/U, preventing many ER and clinic visits and burdensome patient travel.

**CRT OPTIMIZATION : CLINICAL VALIDATION OF A NEW ALGORITHM BASED ON PEAK ENDOCARDIAL ACCELERATION**

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**Background** the recent clinical experience confirms the need and benefits of long-term CRT reprogramming, showing that the optimal parameters for CRT, in particular VV and AV delays, could change over the time. As demonstrated by experimental and clinical studies an accelerometer sensor, inserted in the tip of a right ventricle (RV) lead and based on assessment of Peak Endocardial Acceleration (PEA), gives information on heart contractility non only in normal hearts but also in failing ones.

A new CRT optimization algorithm is based on PEA measurements

during AVD scanning (the PEAarea is estimated as the average of PEA values), for each pacing configuration: a wider PEAarea corresponds to a greater improvement of cardiac function.

**Aim of this study** validation of the new PEAarea method to optimize CRT, comparing results with LVdP/dtmax.

**Methods** 15 patients ( $72 \pm 8$  years) in sinus rhythm with impaired LV function (NYHA class III or IV, QRS  $170 \pm 17$ ms) were implanted with a biventricular pacemaker (Sorin Living CHF) connected to a RV pacing lead (BEST) equipped with PEA sensor. At follow-up, AVD scanning ranging from 60 to 220 ms was automatically performed at different pacing configurations (LV, BiV0, LR12, LR40, RL12, RL40). A pressure catheter (CD-Leycom) inserted in the LV was used for LVdP/dtmax measurements at each pacing configuration.

Hemodynamic responders to CRT were defined by change in LVdP/dtmax greater or equal to 10%.

For each patient the Student-Newman-Keuls test ( $\alpha=0.05$ ) was performed on LVdP/dtmax values to determine optimal CRT configurations.

**Results** 12/15 pts were classified as responders to CRT. In 9/12 responders the optimal pacing configuration determined using PEAarea method corresponds to the greatest hemodynamic improvement indicated by LVdP/dtmax.

**Conclusions** The consistent results of PEAarea with indications given by a contractility index (LVdP/dtmax) are the basis to introduce this new operator-independent and cost-effective method for CRT devices optimization.

### TRIPLE SITE VENTRICULAR PACING FOR CARDIAC RESYNCHRONISATION USING TWO CORONARY SINUS LEADS: INITIAL EXPERIENCE AND FEASIBILITY

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**Background** Cardiac resynchronisation therapy (CRT) is an established adjunctive treatment for patients with heart failure and electromechanical dyssynchrony. Approximately 30% of patients do not derive clinical benefit from CRT with biventricular pacing. Implantation of alternative or additional ventricular leads may improve clinical response.

**Methods** Since January 2006 a series of patients have been implanted with a TriVentricular (TriV) pacing system, using 3 ventricular leads for CRT. Standard introducers, guide sheaths and pacing leads were used. Patients received a defibrillator where clinically indicated. We examined the baseline characteristics, procedure details and complications in these patients.

**Results** Transvenous implantation of 2 coronary sinus (CS) leads for TriV pacing was attempted in 22 patients (17M,5F), mean age  $68(\pm 12)$  years. Aetiology of heart failure was ischaemic in 13 (59%) patients. Mean ejection fraction was  $26(\pm 6)\%$  and left ventricular end-diastolic diameter  $67(\pm 10)$ mm. Median procedure and screening times were 149 and 36 mins respectively. All patients had a lead positioned at the right ventricular (RV) apex. In 14 (64%) patients, 2 CS leads were successfully implanted; the first in a lateral or postero-lateral coronary vein and the second in an anterolateral branch (12 patients) or middle cardiac vein (2 patients). Leads were positioned to produce maximal orthogonal separation between the 3 pacing sites. Placement of a second CS lead proved impossible in 7 patients due to anatomy (5 pts), unacceptably high thresholds (1 pt) and CS dissection (1 pt). In one patient, it proved impossible to implant any CS lead. There were no pneumothoraces, haematoma or deaths relating to the procedures. One patient developed an infection requiring system explant. Two patients experienced intermittent phrenic nerve stimulation which was overcome by device reprogramming.

**Conclusions** TriV pacing using transvenous implantation of 2 CS leads is feasible with an acceptable complication rate. The potential clinical benefits of TriV pacing need to be elucidated.

## ABLATION FOR ATRIAL FIBRILLATION: NEW TECHNOLOGY AND OUTCOME

### IMPACT OF INTEGRATION OF MULTISLICE COMPUTED TOMOGRAPHY IMAGING INTO 3D ELECTROANATOMIC MAPPING ON CLINICAL OUTCOME, SAFETY AND EFFICACY OF RADIOFREQUENCY ABLATION OF AF

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**AIMS** Circumferential radiofrequency catheter ablation around the orifices of the pulmonary veins is a curative catheter-based therapy of paroxysmal, persistent and permanent atrial fibrillation. Integration of multislice computed tomography into three-dimensional electroanatomic mapping to guide radiofrequency catheter ablation has been shown to be accurate and feasible. This study investigated whether the use of such sophisticated imaging technology translates into better clinical outcomes, procedural efficacy and safety in comparison with a control group treated with conventional 3D electroanatomic mapping.

**METHODS** One hundred consecutive patients (85 male, mean age  $55 \pm 9$  years) with multi-drug-resistant atrial fibrillation underwent radiofrequency catheter ablation. In this study we used a wide area circumferential approach with confirmed pulmonary vein isolation (requiring additional ablations at the ostial level) and further lines as needed.

**RESULTS** Comparison of outcome data between the conventional electroanatomic mapping (Carto XP) and the image integration technology (Carto MERGE) resulted in a significant improvement in procedural success for the image integration group (85.1% vs. 67.9%;  $p=0.018$ ). No single case of significant pulmonary vein stenosis occurred in the Carto MERGE group versus three significant stenoses in the conventional group (trend to significance;  $p=0.098$ ). Both procedure and fluoroscopy times remain unchanged.

**CONCLUSION** Multislice computed tomography image integration into electroanatomic mapping significantly improves the success of wide area circumferential ablation with confirmed isolation of the pulmonary veins and additional lines. In addition, the safety of radiofrequency ablation with regard to the occurrence of pulmonary vein stenosis is increased in comparison with a control group using conventional electroanatomic mapping alone. Procedural efficacy remains unchanged.

### INTEGRATION OF CT SCAN WITH ELETTOANATOMIC MAPPING TO PERFORM RADIOFREQUENCY ABLATION OF ATRIAL FIBRILLATION

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Accurate visualization of left atrial (LA) anatomy and location of the ablation catheter within the chamber, along with image fusion within one single system may facilitate and improve success and safety of radiofrequency ablation (RFCA) of atrial fibrillation (AF).

We studied the feasibility and the safety of fusion of multislice CT scan with electroanatomic mapping (EAM) of LA to guide RFCA of AF. Between June 2005 and May 2006 a retrospective analysis was performed in 39 patients (pts, mean age 56, 35 male) with symptomatic paroxysmal (25), persistent (4), permanent (10) AF resistant to 2 antiarrhythmic drugs. All pts underwent catheter mapping using a Multislice cardiac tomography image integration into an EAM (CartoMerge). Ablation consisted in electrical LA circumferential isolation of pulmonary vein (PV) and whenever indicated linear lesions of high and low posterior wall, left isthmus, complex fractionation, coronary sinus and right isthmus. Procedure and fluoroscopy time were  $194 \pm 36$  and  $29 \pm 2$  mn whereas ablation time was  $86 \pm 14$  mn. The number of mapping points was  $103.5 \pm 12$ . CT Registration used

a mid roof point as a landmark preceding synchronisation by visual alignment. Fusion of CT with EAM was achieved with a mean error of  $2.003 \pm 1.37$  mm. The mean range of distance between mapping points and CT images varied between 0.014 mm and 7.18 mm. **Conclusion** CT image integration to EAM system can be successfully and safely performed in pts underwent RFCA of AF. This new technique allows use of real surface anatomy to guide anatomy-based catheter ablation procedures thus guiding precise RF delivery in selected areas and may potentially reduce fluoroscopy time.

### SPECTRAL MAPPING GUIDED AF-NESTS ABLATION OF PAROXYSMAL AND PERMANENT AF: IMPLICATIONS OF AUTOMATIC FIRING DURING RF DELIVERY AND PROCEDURAL OUTCOMES

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**Background** PVI at its antrum level (PVAI), combined with isolation of the superior vena cava (SVCI) has improved long-term ablation success of paroxysmal (PAF) and persistent/permanent (PS/PM-AF). Real time spectral mapping (SM) in sinus rhythm (SR) identifies sites with disorganized frequencies, namely fibrillar atrial myocardium or AF-Nest (AFN). The spectral characteristics of AFNs may be an expression of regional clusters of autonomic nervous system (ANS) possibly creating different degrees of anatomical and/or functional abnormalities that could lead to focal cellular disarray, anisotropic conduction and triggering atrial automaticity (firing).

**Purposes** To assess if automatic firing (possibly due to direct stimulation of nerve terminals) could result from RF current delivery at AFN sites localized in atria and within the coronary sinus (CS). To determine if adjunctive AFN ablation improves outcome.

**Methods and Results** 140 consecutive pts underwent ablation of PAF (N=84) and PS/PM-AF (N=56). Following PVAI, spectral mapping and ablation of AFN was performed in SR. The AFNs ( $29 \pm 13$  AFN sites per pt) were found in the low crista terminalis and adjacent low lateral right atrium (CT-RA), left atrial appendage (LAA), RA inferior to the CSos, RA-SVC junction (septal aspect) and CS (middle and distal). Firing (short, fast and irregular atrial bursts) during AFN ablation along the CT-RA was virtually present in all pts. Firing was often seen with AFN ablation in the CS, LAA and RA-SVC. Success following single procedure (defined as freedom of AF or Atrial Tachycardia (AT) recurrences during F/U= $193 \pm 46$  days): PAF (AF 92%, AT 97%); PS/PM-AF (AF 95%, AT 84%).

**Conclusions** Automatic firing is commonly induced during RF delivery at AFN sites, particularly at CT-RA, LAA and CS. This hybrid ablation strategy has favorably improved long-term AF ablation outcome. Whether AFN ablation modulates an unbalanced ANS potentially responsible for initiation and maintenance of AF remains to be demonstrated.

## RADIOFREQUENCY CATHETER ABLATION OF COMPLEX ARRHYTHMIAS GUIDED BY TWO DIFFERENT TYPES OF NON-FLUOROSCOPIC CARDIAC MAPPING SYSTEM: A PROSPECTIVE STUDY

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**Purpose** non-fluoroscopic cardiac mapping systems are useful for the study and ablation of arrhythmias reducing X-ray exposure. Aim of this non randomized study was to evaluate the usefulness and limitations of two non-fluoroscopic cardiac mapping systems (CARTO and NavX) in different complex arrhythmias.

**Materials and methods** Between Jan and Jul 06, 67pts (53M/14F, age54.1±12.8 range15-78) underwent an electrophysiologic study (EPS) followed by radiofrequency catheter ablation (RFCA). These patients showed different arrhythmias: 50 atrial fibrillation (AF), 10 ventricular tachycardia (VT), 5 atrial flutter (AFL), 2 ectopic atrial tachycardia (EAT). The electro-anatomic mapping has been performed with CARTO system in 13pts and with NavX system in 54pts.

**Results** The ablation was successful in 63/67 pts. The procedure failed in 3pts: in 2 pts (VT) for the probable epicardial localization of the circuit, in 1 (AF) for the onset of pericardial effusion, and was not performed on 1 pt (VT due to congenital heart disease) because the EPS results suggested a surgical procedure. Acute pericardial effusion was diagnosed on 2 AF whose mapping had been carried out through NavX. No other complications were observed. No significant differences were observed between CARTO and NavX systems in terms of procedure time and X-ray exposure. Considering 1 unit (U) equal to the cost of a diagnostic tetrapolar catheter, the cost of AF ablation procedure was 18.7U for CARTO vs 24.7U for NavX, while for VT ablation the cost was 18.7U for CARTO vs 12.1U for NavX.

**Conclusions** Despite a higher procedural cost regarding the ablation of VT and with a lower outlay in the ablation of AF, the CARTO system offers the same reliability and effectiveness as the NavX system. Thus both systems can be equally employed in ablative procedures concerning different types of complex arrhythmia, offering the possibility to select the most appropriate system.

## VIDEO-ASSISTED EPICARDIAL PULMONARY VEIN ISOLATION OFF-PUMP AND ABLATION OF GANGLIONIC PLEXI IN PATIENTS WITH ATRIAL FIBRILLATION. OUR FIRST 24 PATIENTS

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The objective of this study is to assess the feasibility and safety of our initial experience of video-assisted thoracoscopic epicardial pulmonary vein isolation in our first 24 patients with atrial fibrillation.

**Method** Since Nov -05, twentyfour patients (8 women, 16 men, 39-70 years) with persistent (20 pats) or permanent (4 pats) AF underwent video-assisted thoracoscopic epicardial pulmonary vein isolation (VAPV). Twelve of the 24 patients had previously undergone two unsuccessful endocardial catheter pulmonary vein (PV) isolations.

The epicardial approach included two intercostally 10 mm ports and one working port on each side of the thorax and VAPV was performed "off pump" bilaterally on a beating heart. A bipolar radiofrequency device (Atricure) was used to achieve transmural linear lesions and isolation of the PVs. The left atrial appendage (LAA) was excised using a surgical stapler. Vagal ganglionic plexi (GP) were identified

using high frequency stimulation 800 bpm, pulse width 9,9 msec, in specific predetermined sites around the PVs. During stimulation, a decrease exceeding 50% of the ventricular rate identified a GP with predominantly vagal innervation. Vagal denervation was confirmed by repeating the GP stimulation after the RF application(s).

**Results** PV isolation confirmed by pacing, ablation of vagal GP, and excision of the LAA were successful in each patient. Eight of the ten patients (80%) followed for 6 months are in SR and of 10 patients followed for 3 months all are in SR. Complications included bleeding requiring thoracotomy in 2 pats and cerebral infarction in one pat with permanent AF and DCMF.

**Conclusions** VAPV including vagal denervation and excision of LAA is feasible and well tolerated in AF patients. Our initial experience offers promising results in AF patients who cannot be cured with endocardial catheter ablative technique. The long term safety and efficacy of the method needs to be evaluated.

## PROSPECTIVE STUDY OF SURGICAL CRYOABLATION

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ATRIAL FIBRILLATION (AFIB) IS THE MOST COMMON ARRHYTHMIA. THE NATURAL HISTORY LEAD PATIENT TO PERMANENT AFIB DESPITE PHARMALOGICAL TREATMENT. THE PROGRESS IN COMPREHENSION OF PHYSIOPATHOLOGICAL MECHANISMS AND THE DEVELOPMENT OF DIFFERENT SOURCES OF ABLATION, PERMIT NEW TERAPEUTIC APPROACH LIKE SURGICAL CRYOABLATION.

WE INCLUDED IN A PROSPECTIVE STUDY 37 PATIENTS WHO UNDERWENT THORACIC SURGERY FOR MITRAL VALVE REPAIR OR BYPASS REVASCULARIZATION, BETWEEN FEB 04 AND DEC 05. THEY ARE ALL IN AFIB FOR MONTH (PERSISTENT) OR YEAR (PERMANENT).

**RESULT** PERIOPERATIVE MORTALITY IS ABOUT 11%, ALL IN THE FIRST WEEK.

THESE DEATH ARE RELATED TO AN ELEVATED EUROSORE AND NOT TO THE COMPLEMENTARY PROCEDURE OF ABLATION.

AT 6 MONTH 65% ARE IN SINUS RHYTHM, WITH AMIODARONE OR SOTALOL COVER BY WARFARINE.

**CONCLUSION** SURGICAL CRYOABLATION IS SAFE AND EFFICACE IN ADDITION OF THORACIC SURGERY.

THE FINAL INDICATION OF THIS TECHNIQUE AND THE PLACE OF THE ANTICOAGULANT TREATMENT AT TERM NEED TO BE EVALUATE.

## HYBRID ABLATION AND PREVENTIVE PACING THERAPY FOR PERSISTENT OR PERMANENT ATRIAL FIBRILLATION: THE HAPPI-AF TRIAL

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**INTRODUCTION** Foci located in the pulmonary veins initiate AF in many patients and can be treated by catheter ablation (ABL) of the peri- or extra-ostial regions. However, in patients with chronic AF, ABL has a high recurrence rate. Preventive pacing therapies (PPT) may be effective in preventing AF recurrence and reduce AF burden. The prospective HAPPI-AF trial was conducted to evaluate the effectiveness of the combination (hybrid) therapy of ABL and PPT.

**METHODS** Patients with symptomatic, drug refractory, persistent or permanent AF were implanted with a pacemaker providing PPT algorithms as well as extended AF diagnostic and monitoring capa-

## ABLATION FOR ATRIAL FIBRILLATION: NEW TECHNOLOGY AND OUTCOME

bilities (Selection 9000, Vitatron). Patients were subsequently randomized to three groups: only PPT, only ABL, and hybrid therapy (ABL+PPT). Patients were cardioverted at device implantation and/or after ABL as required. Follow-up visits were scheduled at 3, 6, 12, and 15 months. Primary endpoints were AF burden and freedom from AF-recurrence at 15 months based on the pacemaker memory and clinical evaluation.

**RESULTS** 150 patients were included; 72% were male; mean age was 64 years; LVEF was 63+/-14%; mean AF history was 85 months. Complete data was available from 110 patients. The mean AF burden was 32.9+/-43.5% in the PPT group, 18.4+/-28.8% in the ABL group, and 15.2+/-33.6% in the ABL+PPT group. The median AF burden was reduced to 0.0% in the ABL+PPT group, compared to 0.2% in the ABL group and 8.8% in the PPT group. 63% of the ABL+PPT group were free from AF at 15 months, compared to 45% of the ABL group and 29% of the PPT group.

**CONCLUSION** Continuous monitoring is essential to accurately measure AF. The data suggest better results in the hybrid group (ABL+PPT). Pulmonary vein isolation is important but not sufficient to treat patients with chronic AF.

### **RADIOFREQUENCY ABLATION IN THE TREATMENT OF ATRIAL FIBRILLATION- WHO SHOULD BE CONSIDERED FOR THE NEURAL ABLATION?**

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Complete vagal denervation during circumferential PV ablation in humans significantly reduces the recurrence of atrial fibrillation (AF).

On the other hand hypertension complicated by structural heart changes, the main cause of AF, is also related to altered autonomic activity. Aim of the study: to show how different range of parasympathetic activity could initially be observed in hypertensive patients depending on left ventricular (LV) structure and function. Methods: Middle-aged untreated hypertensive patients (HP) on sinus rhythm were enrolled. Exclusion criteria: CAD, CHF, diabetes, valvular heart disease. Pts were divided into 3 groups: -30 healthy controls, -40 HP without LV hypertrophy (LVH), -45 HP with LVH (LVMI>125g/m<sup>2</sup>). Low and high frequency components of heart rate variability (lnLF, lnHF), reflecting autonomic activity, were derived from the 5-min periods before, during, and after 30-min tilting/60o. LV structure and transmitral diastolic function indices (LVMI, peak velocity of the early-E and atrial-A inflow, IVRT, and DT) were assessed by echocardiography. Results: HP with LVH had significantly lowered heart rate variability, and significantly blunted increase in the lnHF value in the 5-min period just after tilting, compared to HP without LVH, and to healthy controls (p<0.01 and p<0.001, respectively). There was a significant negative correlation between LVM/H2.7 and the lnHF change values (pooled data, r=-0.32, p=0.002). In a multiple regression analysis (pooled data, 115 patients) heart rate variability (lnLF) as a dependent variable was significantly influenced (R<sup>2</sup>=0.45) by A (peak atrial velocity, partly reflecting left atrial force, beta=-0.24, p=0.04), average value of systolic blood pressure measurements obtained from ABPM (beta=-0.31, p=0.0036), gender (beta=-0.26, p=0.0038), and by age (beta=-0.22, p=0.05). Conclusion: Many factors modulating AF occurrence also significantly blunt parasympathetic activity, so neural ablation during RF procedure in patients with AF and structural heart disease should be considered after the individual assessment of autonomic balance and its influence on AF.

## CARDIAC RESYNCHRONIZATION THERAPY: TECHNOLOGICAL ASSESSMENT

### ACUTE AND SHORT-TERM EFFECT OF MYOCARDIAL SCAR TISSUE ON ELECTROPHYSIOLOGICAL, HEMODYNAMIC AND CLINICAL PARAMETERS IN CARDIAC RESYNCHRONIZATION THERAPY

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**Background** Presence of scar tissue can influence the electrophysiological myocardial properties, acute and chronic hemodynamic effects of cardiac resynchronization therapy (CRT).

**Aim of the study** To investigate the effect of scar tissue identified by gadolinium-enhanced magnetic resonance imaging (MRI) on stimulation, sensing parameters, and the acute and chronic hemodynamic effect in patients undergoing CRT.

**Methods** 53 pts (43 males) with heart failure NYHA III-IV, fulfilling the criteria for CRT implantation, underwent gadolinium-enhanced MRI prior to implant, to locate and quantify myocardial scar tissue. Scar tissue was considered transmural if hyper enhancement involved more than 50% of wall thickness. Patients were divided into 3 groups: group I (n=14 pts): transmural scar tissue in the area of the left ventricular (LV) lead; group II (n=12 pts) transmural scar tissue remote from the LV lead; group III (n=27 pts) no transmural scar tissue. Stimulation and sensing thresholds were measured for all LV leads and the optimal atrioventricular and interventricular (V-V) interval were derived invasively by LVdP/dt max measurement.

**Results**

Acute measurement of electrophysiological and hemodynamic parameters in relation to scar (see Table).

**Conclusion**

Scar tissue has no significant effect on electrophysiologic parameters. The increase in LVdP/dtmax is significantly lower when transmural scar tissue is present at the location of the LV pacing lead compared to remote or no scar. The optimal V-V interval is significantly longer in the patients with scar tissue, independently of the location of the scar. LV dP/dt increase is a predictor of short term outcome.

### EFFECTIVENESS OF LEFT VENTRICLE PRESSURE DERIVATIVE ANALYSIS IN PATIENTS WITH HEART FAILURE AND NARROW QRS

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**BACKGROUND** Currently, heart failure (HF) patients are selected for resynchronization therapy (CRT) mainly on ECG criteria. However, in previous reports CRT determined clinical benefit also in HF patients with narrow QRS. One of the essential point in CRT is improvement of left ventricle pressure derivative (dP/dt).

**PURPOSE** We assessed the maximum dP/dt before CRT in patients with narrow QRS and HF.

**METHODS** Ten patients (69.3±11.3 y; 6 male) with left ventricle ejection fraction < 40%, NYHA class II-III refractory HF, narrow QRS interval (< 130 msec) and intraventricular dyssynchrony proved by standard echo were selected for CRT. Intraventricular dyssynchrony were defined as more than 140 msec of septal to posterior wall motion delay (SPWMD). All patients were studied by cardiac catheterization to evaluate acute effect of resynchronization. Maximum dP/dt was measured during atrial pacing and atrial-biventricular sequential pacing at the rate of 80 beats per minute before CRT. Atrial-ventricular delay was fixed at 100 msec. Brain natriuretic peptide (BNP) was measured before and after CRT to determine responder to CRT.

**RESULTS** At baseline, HF patients showed LV ejection fraction of 33.1±7%, intraventricular (185±30.8 msec) delay by SPWMD and maximum dP/dt of 708±230 mmHg/sec. Eight patients whose BNP decreased after CRT were defined as responders while two cases whose BNP increased in spite of CRT was defined as non-responders. In eight responders maximum dP/dt during biventricle stimulation increased more than 15% compared with baseline data during atrial stimulation. The mean percent increase of maximum dP/dt was 23.5%. By contrast, two non-responders had only 7% and 9% rise of dP/dt by pre-procedure pacing study although echo showed intraventricular dyssynchrony.

**CONCLUSIONS** More than 15% rise of dP/dt during simulative biventricle pacing may represent a valid means for improving the selection of HF patients without wide QRS suitable for CRT.

### OUR EXPERIENCE IN THE USE OF TWA, BNP, HRV, CONVENTIONAL ECHO AND TDI TO INCREASE THE ACCURACY IN INDICATIONS TO CRT-D

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**AIM OF THE STUDY** is to evaluate if the data coming from TWA, BNP, HRV and conventional ECHO and TDI, in addition to those validated by clinical trials on CRT and CRT-D (EF, NYHA class, ECG) can be useful in increasing the accuracy in indication to CRT-D in clinical practise and are able to guide to an appropriate use of time and resource-consuming exams.

**METHODS** from October 2003 to September 2006, 35 CHF pts. received CRT-D and underwent clinical and instrumental evaluation at baseline, at 3 months and every 6 months after implantation. The evaluation included: NYHA class, echocardiographic parameters (+ TDI), BNP plasma values, HRV and recurrence of ventricular tachyarrhythmias conditioning ICD shocks. 26 pts. underwent TWA analysis at baseline and at 6 months.

**RESULTS** in the whole, pts. showed: improvement in NYHA class and in EF, reduction in BNP values, increase in HRV and maintenance

**Table.**

	V threshold	I threshold	EGM (mV)	% dP/dt	V-Vopt (ms)
Group I	0.98±1.02	1.59±1.47	16.0±8.2	14.5±10.4	50.3±26.3
Group II	0.73±0.52	1.20±0.89	17.5±8.4	27.5±16.4	51.7±21.7
Group III	1.01±0.76	1.63±1.50	18.0±7.6	32.0±20.0	34.8±22.2
After 3 months follow-up					
	% dP/dt (mmHg/s)	NYHA Class	6 MWT fraction	Ejection ESV	LV
Group I	+14.5%	-13%	+13%	+5%	+0.6%
Group II	+27.5%	-23%	+16%	+19%	-11.8%
Group III	+32.0%	-30%	+19%	+40%	-20.3%

## CARDIAC RESYNCHRONIZATION THERAPY: TECHNOLOGICAL ASSESSMENT

of a stable positive TWA. Only 2 pts. developed ventricular arrhythmias during follow-up. So, no relationship between TWA and shocks was showed. The evaluation of inter/intraventricular asynchrony, both at baseline and at 3 months, showed disomogeneous data.

**CONCLUSIONS** the improvement of the arrhythmic pattern expressed by the reduction in BNP values, the increase in HRV and the very low incidence of ventricular arrhythmias seems to be related to the favorable effect of CRT. The behaviour of TWA analysis differs from that of the other parameters.

The echocardiographic indexes have not showed data useful either in the selection of pts., or in the evaluation of the results.

So, also in our data, a high NYHA class and the severe left ventricular dysfunction are valuable criteria for patients' selection and are predictive of favorable results; the evaluation of the other indexes wouldn't seem useful to change the therapeutical strategy based on the data coming from the current guidelines.

### VECTOR-CARDIOGRAPHY PREDICTS ACUTE HEMODYNAMIC IMPROVEMENT BY CARDIAC RESYNCHRONIZATION THERAPY

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Cardiac resynchronization therapy (CRT) is an accepted treatment for congestive heart failure (NYHA III to IV), but a substantial number of patients does not respond to therapy. LBB, QRS width and echo-cardiographic measurements are parameters for indication, but are not consistent with hemodynamic response. A new method, based on Vector-Cardiogram (VCG)-Analysis can deliver additional information on areas with late excitation, with slow or fast depolarization speed, to identify responder. The aim of this study is to validate the effectiveness of VCG-based analysis in predicting the CRT Responders and compare the results with hemodynamic data.

**Methods** 70 pts (50 male, 61.5 years, QRS width 158ms ± 20.9, EF 22.5%, LVEDD 72.2mm) received a CRT pacing system. The VCG (Sema 200, Schiller CH) was obtained at baseline (CRT off) and the evaluation of the VCG were blinded and performed offline. Hemodynamic parameters such as pulse pressure (PP) and contractility (dp/dt) were intraoperatively measured. Hemodynamic improvement was measured after CRT therapy was initiated and the patients were subsequently divided into two responder groups (RG) and one non-responder group (NR). RG 1: PP >10%, dp/dt >20%, RG 2: PP 5-10%, dp/dt 10-20%, NR: PP <5%, dp/dt <10%.

**Results** In all 70 pts we were able to perform the VCG analyses. In 59 out of 70 pts (84.3%) we found a good correlation between the hemodynamic improvement and the predicted classification drawn from the VECG. 11 pts did not respond to therapy, 10 pts out of this 11 were identified by VCG analyses.

**Conclusions** Preliminary results of the VECG show a good correlation with the invasive hemodynamic parameter in 84.3% of pts. A further evaluation with a larger group of pts could help to make the VCG-method a standard procedure.

### COMPARISON BETWEEN NOVEL RADIONUCLIDE ANGIOGRAPHY SYNCHRONY INDEXES AND TISSUE DOPPLER IMAGING FOR THE EVALUATION OF INTRA-LEFT VENTRICULAR ASYNCHRONY

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**AIM** To evaluate the reliability of two novel radionuclide angiography (RNA) phase analysis indexes of cardiac asynchrony, - synchrony (S) and entropy (E), when compared to tissue Doppler imaging (TDI) indexes.

**METHODS** 10 p, mean age 68 years, with symptomatic CHF undergoing resynchronization therapy underwent RNA planar studies (Siemens e-cam dual-head camera, best-septal LAO 99mTc-labelled red blood cells, 740 MBq i.v., 64x64 matrix size, 24 frames/cycle, 6000 KCounts). TDI was performed following the American Society of Echocardiography criteria, and asynchrony was defined as the electromechanical delay (EMD) in a left ventricular (LV) 12-segment model > 20 ms. Phase images were generated on first Fourier harmonic fit of the time-activity curve of the cardiac cycle, drawing a region of interest on the end-diastolic frame for right ventricle (RV) and LV. Analysis of the phase histogram was performed with a commercial software calculating the LV and RV standard deviation (SD). S and E, according to the information theory, were calculated with a home-made software, considering complete synchrony when S equals 1 and E equals 0, while dyssynchrony is marked by the opposite values.

**RESULTS** Mean RNA LV ejection fraction was 29,8±9% and ultrasound ejection fraction was 28± 4% (r=0,85; p=0,004). Phase analysis showed a mean LV SD of 46± 26°. Mean S was 0,93±0,06 and mean E was 0,52±0,14. EMD significantly correlated with S (r=-0,72; p=0,01) but not with E (r=0,61; p=0,06). SD significantly correlated with S but not with E (r=-0,69; p=0,02 vs r=0,79; p=0,06). There was no correlation between SD and LV EMD (r=0,56; p=0,09).

**CONCLUSIONS** S and E may be considered valuable tools for the detection of intra-left ventricular asynchrony whereas TDI evaluation may be cumbersome in specific clinical settings. Moreover, S and E may overcome many of the intrinsic limitation of phase analysis SD.

### EVALUATION OF INTERVENTRICULAR DELAY IN PATIENTS SELECTED FOR RCT

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**POPULATION** 34 PTS (27 MALES) IMPLANTED FROM NOV 02 TO MAY 06. 23 NICM WITH 22 IN CLASS III AND 12 IN CLASS IV WITH OPTIMAL MEDICAL THERAPY, MEAN AGE 68 YEARS, MEAN LEVF 22%. THEY ARE ALL IN SINUS RHYTHM WITH LARGE LEFT BUNDLE BRANCH BLOCK (189 MSEC).

**METHOD** THIS IS A RETROSPECTIVE STUDY WITH TTE PRE AND POST IMPLANTATION OF PACEMAKER OR ICD AND INTER-VENTRICULAR DELAY MESUREMENT BEFORE AND AFTER DEVICE ADJUSTMENT. THE DATA ARE COMPLETED FROM IMPLANTATION TILL JULY 06 WITH TOTAL MORTALITY, CARDIAC MORBIMORTALITY, NYHA AND QOL. ALL DEVICE ARE FROM MEDTRONIC COMPANY, TRUE TRIPLE CHANEL. THE RV LEADS ARE SCREWED IN THE SEPTUM AND LV LEAD ARE IN POSTERIOR OR LATERAL VEIN.

**RESULTS** THE TTE CRITERIA (INTERVENTRICULAR DELAY) IS 58 MSEC BEFORE, 18 MSEC AFTER IMPLANTATION, WITH QRS WIDTH 148 MSEC. AT MEAN SURVEY OF 521 DAYS, THE TOTAL MORTALITY IS 19% WITH 4 CARDIAC DEATH. WE SHOW AN NYHA AMELIORATION IN 90% AND QOL IMPROVMENT IN 96%. 3 PTS ARE CONSIDERED AS NON-RESPONDER AND FINALY 81% ARE FREE OF HOSPITALIZATION FOR HF.

**DISCUSSION** RATE OF NON-RESPONDER AND CARDIAC MORBIMORTALITY IS LOWER THAN GENERALLY DESCRIBED. THE INTERVENTRICULAR DELAY IS SUPERIOR IN NON-RESPONDER BUT EQUAL AFTER IMPLANTATION. THE GLOBAL MANAGEMENT WITH TTE AND POSTOPERATIVE DELAY ADAPTATION ARE MORE RELIABLE TO THE IMPROVMENT AND THE BEST RESULT THAN THE ONLY CRITERIA OF INTERVENTRICULAR DELAY.

**CONCLUSION** RCT IMPROVE QOL, CARDIAC MORBIMORTALITY OF OUR PATIENTS, BUT THE RETROSPECTIVE DATA DON'T ALLOW US TO AFFIRM THE RESPONSABILITY OF ONLY THIS TTE CRITERIA IN THE AMELIORATION.

### PROGNOSTIC SIGNIFICANCE OF PRO BNP TEST IN PATIENTS WITH CHF AND DEVICES THERAPY. HIGH VALUES ARE RELATED TO PROGNOSIS, ICD DISCHARGES AND BETTER DEVICES THERAPY

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**INTRODUCTION** ProBNP is applied in the management and risk stratification of patients with CHF, and in the efficacy evaluation of devices therapy (DT).

**PATIENTS AND METHODS** In the SHAPE project, three group of CHF patients were evaluated: Group A) 160 consecutive non selected patients, Group B) of 19 patients with CHF and an ICD, and Group C) 7 patients, with VVI or CRT therapies.

**RESULTS** In Group A, in the 20 patients with a proBNP of more than 2500-3000 pg/ml, we observed 5 episodes of HF and two CD in the following 3 months, 4 recurrences of minor CHF, in the group with a proBNP value between 2500 and 1500. No problems or clinical recurrences, were observed below 500 or less of proBNP. In the range between 501 and 1500 pg/ml, all the patients had history of cardiac disease, CHF or abnormal EF%, but no clinical episodes were observed. In Group B, 6/19 with appropriate discharges or ATP treatments, were observed with a mean value of proBNP of 2000 +/- 560 pg/ml. In one patient, with a reduced value of proBNP, a severe hypokalemia

was the cause of the arrhythmic storm and of ICD discharges. Conversely, no discharges were observed in 13/19, with a mean value of 450+/- 550.

In Group C), 7 patients in VVI pacing, showed a mean value of 2016+/- 751 pg/ml, while 6 patients, in CRT, showed a mean value of 633+/- 389 ml of proBNP, respectively.

**CONCLUSIONS** Patients, with appropriate DT, show higher mean value of proBNP. Thus, patients with unstable CHF, as documented by high blood peptide values, are at high risk of ventricular arrhythmias. Moreover, the benefits of CRT versus VVI pacing, in CHF patients, can be assessed by proBNP evaluation.

### BIVENTRICULAR EPICARDIAL PACING CONCOMITANT WITH CARDIAC SURGERY IN HEART FAILURE PATIENTS

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**PURPOSE** Biventricular pacing can be carried out by epicardial approach when it is not possible to obtain it through an endocavitary way. Often epicardial implants are performed as single procedures. We try to evaluate left ventricular epicardial lead positioning as first-choice procedure, in heart failure patients undergoing concomitant cardiac surgery.

**MATERIALS AND METHODS** 13 consecutive epicardial PM implanted by first intention in patients with NYHA IV and EF<35%. These patients underwent surgery for CABG, mitral valve reconstruction, mitral valve replacement and combined operations. Pacing thresholds, sensing parameters and lead impedances were assessed during surgery (Intra-Operative assessment, IO) and during follow-up (control visit C1: mean time from implant 35 days; C2: 116 days; C3: 186 days).

**RESULTS** Testing atrial lead, IO threshold resulted  $3.6 \pm 0.6$  V, while at C1 it was  $1.5 \pm 1.7$  V. IO sensing was  $0.5 \pm 0.3$  mV, but at C1 it came up to  $1.5 \pm 0.3$  mV. IO assessment of right ventricle lead threshold was  $3.6 \pm 0.7$  V, while at C1 it was  $0.9 \pm 0.8$  V. Its IO sensing was  $2.9 \pm 0.3$  mV, while at C1 it was  $11.9 \pm 6.2$  mV. Left ventricle IO threshold was  $4.9 \pm 1.0$  V, but at C1 it became  $1.2 \pm 0.9$  V. IO sensing was  $3.5 \pm 0.8$  mV while at C1 it was  $13.5 \pm 2.5$  mV. Mortality at follow-up was very high, approaching 70%, and many deaths were sudden.

**CONCLUSIONS** IO electrical check often show not optimal values, both for LV, RV and atrial leads, but these parameters strongly improve at 30 days and remain stable at follow-up. However, LV epicardial lead positioning seems to be reliable, concomitantly with cardiac surgery procedures. The high mortality of our study population may pose strong argument supporting ICD implantation in such patients.

## CARDIAC RESYNCHRONIZATION THERAPY

### SYMPTOMS OF HEART FAILURE DURING LONG-TERM RIGHT VENTRICULAR APEX STIMULATION AFTER AV JUNCTIONAL CATHETER ABLATION

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Patients with pharmacologically resistant atrial fibrillation (AF) experience improvement after AV junctional catheter ablation (AVCA) in spite of subsequent 100% right ventricular pacing. Recent reports have shown that right ventricular stimulation leads to electrical and/or mechanical dyssynchrony and deterioration of the left ventricular function.

**Methods** 270 patients underwent AVCA during a period of 11 years, from January 1994 to December 2004. A pacemaker was implanted before or on the day of ablation. Two hundred and thirteen patients (111F:102M), 73±9 years old, were clinically followed during a period of 6±2.9 years (range 1 to 11).

**Results** Fifty-one patients (24%) were known to have symptoms of heart failure (HF) before the AVCA and were on pharmacological treatment for HF. All 213 patients were in persistent or permanent AF at the time of AVCA. Pre-ablation left ventricular ejection fraction was 55±12% (range 19 to 76%), while the left ventricular diastolic diameter was 53±7.5 mm.

At the time of follow-up (FU), 23/162 pat (14%) had developed new symptoms of HF in a period of more than three years after ablation, while 13/51 pat (25%) with previously known HF showed an exaggeration of HF, detected more than three years after procedure. Thirty-eight (18%) deaths occurred during FU, at 51±32 months (range 1-120) after the AVCA. Eight patients died of worsened HF and four died suddenly at home.

**Conclusions** Long-term 100% right ventricular pacing following AVCA resulted in worsening of previously known heart failure in 25%, while the incidence of new symptoms was 14%. Patient selection seems to play a significant role as may other, unknown, factors.

### CONVENTIONAL DUAL CHAMBER APICAL PACING IN PATIENTS WITH ADVANCED ATRIO-VENTRICULAR BLOCK AND PRESERVED BASAL LEFT VENTRICULAR FUNCTION: A PROSPECTIVE LONG TERM STUDY

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**Background** Permanent right ventricular apical pacing (RVAp) can deteriorate synchrony of ventricular function and cardiac performance. However is not completely elucidated in which patients (pts) the long term effects of RVAp leads to adverse changes in myocardial contraction and decreases hemodynamics.

**Purpose** The aim of this study was to prospectively determine the effects of permanent RVAp on clinical course and cardiac parameters (both systolic and diastolic) in pts with preserved basal left ventricular ejection fraction (LVEF).

**Population** We prospectively selected 26 pts (16M, 10F, mean age 69±6 years) with advanced atrio-ventricular block and clinical indication for conventional DDD pacing. Basal QRS amplitude was 105±9 ms.

**Methods** Echo/Doppler and pacemaker/clinical follow-ups were performed post implantation and after 12, 24, 36 months respectively. The optimization of the AV interval was obtained by Doppler. By telemetric interrogation percentage of ventricular paced beats and of atrial synchronous beats was determined. The following parameters were collected: diastolic left ventricular dimensions (LVDD), LVEF, myocardial performance index (MPI), NYHA functional class and Quality of life (QoL).

**Results** At telemetry % of paced beats was more or equal than 95% and of atrial synchronous beats more or equal than 93%. All collected data are reported in Table I.

**Conclusions** In pts with preserved basal left ventricular function chronic RVAp does not decrease significantly systolic parameters. Also in such pts diastolic impairment is weakly correlated with clinical findings, therefore its significance has not practical relevance. Our data suggest that at this time, with such a low impact on cardiac performance in the long term period, RVAp still should remain the first therapy in this population. Caution is needed in the selection of pts for alternative modalities of pacing.

### HEART RATE CONTROL: SIGNIFICANCE, PROBLEMS AND OUTCOMES IN CARDIAC RESYNCHRONIZATION THERAPY RECIPIENTS WITH FIXED ATRIAL FIBRILLATION

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It has been proofed that cardiac resynchronization therapy (CRT) improves survival, exercise tolerance, quality of life. For beneficial effect to achieve it is essential to maintain programmed pattern of myocardial activation. In some patients with fixed atrial fibrillation (FAF) it is sometimes difficult because of tendency to tachyarrhythmia

**Purpose** To evaluate significance and methods of heart rate control and its influence on heart function and clinical presentation of patients with FAF and CRT.

**Methods** 20 patients with heart failure and FAF was implanted with biventricular stimulator. One month after implantation and then every 6 month we evaluated systolic function, NYHA class, exercise tolerance by 6-minute walk test distance (6MWT), heart rate. We considered good heart rate control if less than 30% of beats were above the programmed lower rate. Mean follow-up was 12 months (6-18 months).

**Outcomes** Mean NYHA class at implant was 3,2 and ejection fraction (EF) 24,9 and 6MWT 293m. In 10 patients (group 1, G1) we were able to obtain good rate control with pharmacological agents and in 9 not (group 2, G2). In 2 patients it was not possible to achieve sufficient heart rate control with drugs and in these patients we performed A-V node ablation (group 3, G3) Results in G1: after 1 month: NYHA 2, 6MWT 487,5m, EF 32,3%; 12 months: 2, 425m, 29,6%; 18 months: 2, 500m, 33%.

Tabella I.

	BASELINE	12 MONTHS	p	24 MONTHS	p	36 MONTHS	p
LVEF%	53±9	52±6	NS	51±9	NS	50±12	NS
MPI	0.41±0.06	0.41±0.1	NS	0.44±0.3	0.1	0.47±0.3	0.001
LVDD	57±3	58±6	NS	58±5	NS	59±2	NS
QoL	10±4	11±6	NS	11±8	NS	11±5	NS
NYHA class	1.4±0.4	1.42±0.6	NS	1.6±0.1	NS	1.7±3	NS

In G2: after 1 month NYHA 3, 6MWT 400m, 34,3%; 12 months: 2,2, 420m, 33,3%;  
18 months: 2,3, 378m, 27,5%.

IN G3: 1 month: 2,7, 230m, 23%; 12 months: 1,5, 550m, 40%.

**Conclusions** The better rate control and the higher percentage of fully captured biventricular stimulation the better clinical outcome. A-V node ablation may be desirable in patients in whom it is difficult to obtain good rate control with drugs.

### INSULIN TREATED DIABETES AND RENAL INSUFFICIENCY INDEPENDENTLY REDUCE SURVIVAL IN HEART FAILURE PATIENTS AFTER CARDIAC RESYNCHRONIZATION THERAPY

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**Background** Cardiac resynchronization therapy (CRT) improves left ventricular function and outcome in patients (pts) with heart failure (HF). Prior observations suggest that diabetes and renal insufficiency increase the mortality risk in pts with HF; the influence of insulin treatment on outcome is less well established.

**Aim of the study** To investigate the effect of diabetes and renal insufficiency on the outcome of a cohort of HF pts after CRT.

**Methods** We studied 447 consecutive pts with advanced HF who underwent CRT in a single institution (males 80.8%, mean age 65.7±9.7 years, ejection fraction 29.9±6.11%); the mean follow-up was 23.8±16.4 months. Pts were stratified in 3 groups: non diabetic pts, non insulin treated diabetic pts, insulin treated pts.

**Results** Three hundred fifty six (79.6%) pts had no diabetes, 62 (13.9%) had non insulin treated diabetes, 29 (6.5%) had insulin treated diabetes. After Cox multivariate analysis, insulin treated diabetes (HR 2.69, 95% C.I. 1.24; 5.81, p = 0,012) and renal insufficiency (HR 2.61, 95% C.I. 1.49; 4.55, p = 0.001) were independent predictors of total mortality, while non insulin treated diabetes was not (HR 1.45, 95% C.I. 0.67; 3.14, p = 0.345). However, only renal insufficiency was an independent predictor of cardiac mortality (HR 2.86, 95% C.I. 1.49; 5,51, p = 0.002), while non insulin treated diabetes (HR 0.85, 95% C.I. 0.30; 2.43, p = 0.762) and insulin treated diabetes (HR 1.99, 95% C.I. 0.77; 5.16, p = 0.158) were not.

**Conclusions** After CRT insulin treated diabetes and renal insufficiency independently affect survival in HF pts. Whether insulin use is a risk factor per se or a marker of a more advanced disease warrants further investigations. Only renal insufficiency predicts cardiac mortal-

ity, suggesting that insulin treated diabetic pts mainly die from non cardiac causes.

### FIRST EXPERIENCE WITH A WIRELESS TELEMETRY FEATURE IN A CRT-D DEVICE

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**Introduction** Distance telemetry based on radio frequency data transmission is a desired feature for cardiac rhythm management devices. The Guidant CONTAK RENEWAL 4RF ZIP Wandless Telemetry (ZIP) is designed to increase interrogation speed compared to inductive telemetry, it eliminates the wand in the sterile field, programming can occur while physician is closing the pocket and it is designed for seamless remote transmission of device data from patients. The system operates in the bandwidth for Short Range Devices at 869.85 MHz. In order to avoid pocket heating the system emits a maximum power of 0.75mW.

**Method** 58 patients (65.4 + 9.6 yrs., NYHA II-IV) were enrolled and evaluated during implant, pre-discharge and at one month FU. During implant and at one month FU both the distance between programmer and device and ZIP stability were assessed. Distance was assessed in normal routine equipment settings, and not set up to test maximum achievable distance. At pre-discharge interrogation time was measured with both ZIP and inductive telemetry.

**Results** At pre-discharge the mean interrogation time with inductive and ZIP Wandless Telemetry was 31+118 seconds and 13+45 seconds respectively. In 4 out of 165 procedures ZIP was disturbed. In 3 out of 4 cases, the programmer detected noise and suggested the use of the wand. In 1 out of those 4 cases the wand was used to continue communication between programmer and device. The mean distance between programmer and device at implant and one month was 2.04m (1.1-3.1m) and 1.44m (0.5-2.4m) respectively.

**Conclusion** During this Registry, ZIP Wandless Telemetry showed a good performance. The speed of interrogation was more than two times faster compared to inductive telemetry, ZIP showed good stability and worked well at distances used in normal clinical settings. ZIP Wandless Telemetry represents a next step into wireless remote advanced patient management system.

## RELATION BETWEEN THE SERUM LEVEL OF NT PRO BNP AND RESULTS OF HEAD-UP TILT TEST IN PATIENTS WITH SYNCOPE - THE PRELIMINARY STUDY

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The increased myocardial contractility occurring after decreased venous return due to standing position is the most common triggering factor for vaso-vagal syncope.

The level of brain natriuretic peptide is related to myocardial contractility.

The aim of study was the analysis of the relationship between the level of NTproBNP and the results of head-up tilt test (HUTT) in patients with syncope.

We observed 39 pts (15 men, 24 women) aged 17-38 yrs (x 28,1 yrs) with syncope referred to HUTT.

All pts underwent standard HUTT (HUTT-S) acc. to Westminster protocol. Additional tilt test with nitroglycerine administration (HUTT-NTG) was performed in pts with negative HUTT-S. Before HUTT blood sample was collected in each patients for NTproBNP serum level measurement

**Results** Positive HUTT (both standard or NTG-induced) were in 27 pts (75%). Mixed type was observed in 33% of pts, cardioinhibitory in 44%, and vasodepressive in 23% of pts.

NTproBNP level was significantly lower in pts with tilt-induced syncope 21,1 vs 81,5 pg/ml,  $p < 0,03$ . There were no differences of NTproBNP level between pts with different types of vaso-vagal response. Similarly there were no differences of NTproBNP levels between standard HUTT and NTG-induced HUTT syncope.

**Conclusions** Rest serum level of NTproBNP correlate with head-up tilt test results in patients with vaso-vagal syncope. Rest serum level of NTproBNP seems to be a predictor of head-up tilt test outcome in patients with syncope

## A COMPARISON OF IMPLANTABLE LOOP RECORDER VERSUS CONVENTIONAL DIAGNOSTIC TESTING. RESULTS OF THE RUP (RECURRENT INFREQUENT UNEXPLAINED PALPITATIONS) STUDY

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**Background** The current diagnostic pathway for patients with palpitations sometimes fails to establish a diagnosis. The aim of the study, a multicentre, prospective, randomized trial, was to compare the diagnostic yield of conventional diagnostic testing (CDT) with that of prolonged monitoring strategy using an implantable loop recorder (ILR), in patients with infrequent unexplained palpitations.

**Methods** We studied 50 consecutive patients (mean age 47±18 years, 33 females) without, or with only mild, heart disease, and with infrequent (= 1 episode per month) sustained (>1 minute) palpitations. Before enrolment, patients had a negative initial evaluation, including clinical history, physical examination, ECG and blood chemistry examinations. Patients were randomized either to conventional strategy (24-hour Holter recording, a period of monitoring of at least 4 weeks with an external recorder, and electrophysiological study) (n=24) or to ILR (Reveal Plus., Medtronic) implantation with 1-year monitoring (n=26). Full hospital costs of the two strategies were calculated.

**Results** There was no difference in baseline clinical characteristics

between groups. The median number of palpitations in the last year was 6 in the CDT group, and 8 in the ILR group. In the CDT group a diagnosis was obtained in 5 patients (atrial fibrillation 1 case, supraventricular tachycardia 4 cases), palpitations did not recur in 13 patients, 5 patients failed to activate the external recorder, and there was 1 case of device malfunction. In the ILR group a diagnosis was obtained in 19 pts (sinus rhythm 2 cases, supraventricular tachycardia 6 cases, sinus tachycardia 4 cases, atrial fibrillation 4 cases, atrial flutter 2 cases, paroxysmal AV block 1 case), palpitations did not recur in 6pts, and 1 pt failed to activate the device. Thus, the diagnostic yield of ILR was significantly higher respect to CDT (73% vs 21%,  $p < 0.001$ ). Nine of 19 pts with negative CDT consented to ILR implantation: a diagnosis was obtained in 6 pts (supraventricular tachycardia 1 case, sinus tachycardia 4 cases, paroxysmal AV block 1 case), and symptoms did not recur in 3 pts. No significant adverse event was observed during the study.

Despite the higher initial cost, the cost per diagnosis in the ILR group was lower than in the conventional strategy group ( $3,056 \pm 363$  vs  $6,768 \pm 6,672$ ,  $p = 0.012$ ).

**Conclusions** In subjects without severe heart disease and with relatively infrequent palpitations, ILR is a safe and more cost-effective diagnostic approach than conventional strategy.

## ANALYSIS OF THE RHYTHM VARIATIONS DURING SPONTANEOUS CARDIOINHIBITORY NEURALLY-MEDIATED SYNCOPE. IMPLICATIONS FOR RDR PACING OPTIMISATION. AN ISSUE 2 SUBSTUDY

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**Background** Little is known of the variations of the heart rhythm during spontaneous cardioinhibitory neurally-mediated syncope. Their knowledge has both academic and practical implications for the optimisation of rate drop response (RDR) pacing mode

**Method and results** We describe variations of the rhythm occurring during 48 syncopal episodes documented by Implantable Loop Recorder. The presyncopal phase, of 18 s (interquartile range 9; 65) was characterized by a fall in heart rate from  $83 \pm 20$  bpm to maximal bradycardia or (multiple) asystolic pauses which lasted a median of 19 s (10; 30). The recovery phase lasted 22 s (7; 52). The total duration of the cardioinhibitory reflex was 85 s (47; 116). We then calculated the potential increase in benefit that an optimally programmed Drop Rate detection could provide compared with a reference Lower Rate detection. Compared with Lower Rate detection (defined as 2 consecutive beats at 40 bpm), Drop Rate detection (assumed to be Drop Size = 20 bpm, Detection Window = 1 min and Drop Rate = 50 bpm) would have been able to introduce Intervention Pacing a median of 5.7 s (interquartile range 5.1; 10.4) earlier in 28 cases (58%).

**Conclusion** Cardioinhibitory neurally-mediated reflex varies widely from a few seconds to some minutes. In our data the total duration was <2 min. Optimal RDR programming, being potentially able to anticipate the detection of the cardioinhibitory reflex by a few seconds, could provide an increase in benefit for cardiac pacing therapy in prevention of syncope.

## LOWER LIMB AND ABDOMINAL COMPRESSION BANDAGES PREVENT PROGRESSIVE ORTHOSTATIC HYPOTENSION IN THE ELDERLY. A RANDOMIZED SINGLE BLIND CONTROLLED STUDY

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**Background** Progressive orthostatic hypotension can occur in elderly people during standing.

**Aim** To assess the efficacy of compression bandage of legs and abdomen in preventing hypotension and symptoms.

**Methods** Twenty-one patients (70±11 years) affected by symptomatic progressive orthostatic hypotension underwent two tilt test procedures, with and without elastic bandage of the legs (compression pressure 40-60 mmHg) and of the abdomen (compression pressure 20-30 mmHg) in a randomized cross-over fashion. Leg bandage was administered for 10 minutes and followed by additional abdominal bandage for further 10 minutes. Symptoms were evaluated by a 7-item Specific Symptom Score (SSS) questionnaire before and after 1 month of therapy with elastic compression stockings of the legs (prescribed in all patients irrespective of the results of the tilt study).

**Results** In the control arm, systolic blood pressure decreased from 125±18 mmHg immediately after tilting to 112±25 mmHg after 10 minutes of sham leg bandage and to 106±25 mmHg after 20 minutes despite the addition of sham abdominal bandage. The corresponding values with active therapy were 129±19 mmHg, 127±17 mmHg (p=0.003 vs control) and 127±21 mmHg (p=0.002 vs control). In the active arm, 90% of patients remained asymptomatic, versus 53% in the control arm (p=0,02). During the month before evaluation, the mean SSS score was 35.2±12.1 with dizziness, weakness and palpitations accounting for 64% of total score. SSS score decreased to 22.5±11.3 after 1 month of therapy (p=0.01).

**Conclusion** Lower limb compression bandage is effective in avoiding orthostatic systolic blood fall and reducing symptoms in elderly patients affected by progressive orthostatic hypotension.

## UTILITY OF NON INVASIVE ECG EXAMINATION (12 LEAD ECG AND HOLTER MONITORING) IN DEFINING ATRIO VENTRICULAR NODE CONDUCTION DEFECT AMONG PATIENTS PRESENTING WITH SYNCOPE

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**Objectives** To compare abnormal non-invasive ECG (N I ECG) markers on 12-lead ECG or/and 24-hour Holter monitoring (HM) with Electrophysiology study (EPS) findings suggesting Atrio-Ventricular Node Conduction Defect (AVNCD) in patients presenting with syncope of unknown origin (SUO).

**Methods** A total of 156 patients (age 61.71 ±15.42) suffering from SUO with concurrent findings of different conduction defects on N-I ECG evaluation (ECG or HM or both) consisting of : 1.complete RBBB, 2.complete LBBB, 3.LAHB, 4.LPHB, 5.1stAV block, 6.bifascicular block (1stAV block with LAHB or LPHB), 7.trifascicular block (1stAV block and RBBB with LAHB or LPHB), 8.1stAV block with LBBB, 9.episodes of 2ndAVBlock (type-I or type-II), 10.blocked atrial beats, underwent EPS. We compared the abnormal findings on the N-I ECG evaluation with those on EPS defined as:1.His-Ventricular interval>60msec, 2.Weckenbach and 2:1 AV block CL>500 and 400msec respectively, 3.Effective Refractory Period of the AV-node>450msec, 4.split His activity, 5.sub-Hisian block on atrial stimulation, 6.bi or trifascicular block on atrial stimulation.

**Results** Of 156 patients with any form of ECG or HM derived conduction defect (Any AVNCD), 90 (57.69%) had at least one abnormal finding on the EPS suggesting AVNCD (Positive predictive value 68.70%). After logistic regression analysis, adjusted for age, sex, ejection fraction and evidence of organic heart disease, patients with SUO and any AVNCD, 1stAVB, LBBB, bi or trifascicular block had 6.06, 3.07, 2.83, 4.63 and 8,63 odds ratios (OR) respectively, of finding AVNCD on EPS (all p<0.05). Apart from age (OR:1.022, p=0.002) no other clinicolaboratory parameter was predictive of AVNCD on EPS.

**Conclusion** A significantly high proportion of patients with SUO and most forms of N-I ECG derived conduction abnormalities, had EPS evidence for AVNCD.

## INHERITED TACHYARRHYTHMIAS

### RIGHT VENTRICULAR HISTOLOGICAL FINDINGS IN PATIENTS WITH BRUGADA SYNDROME

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**Background** the relation between structural heart disease and electrical instability in patients with Brugada Syndrome (BS) is still unknown. Recent works showed that endomyocardial biopsy in patients with BS and ventricular arrhythmias was of value in detection of structural alterations.

**Purpose** to investigate the role of inflammation in BS subjects with ventricular arrhythmias.

**Methods** we studied 7 consecutive patients (5 males) with history of arrhythmic events (2 with syncope, 5 with family history of sudden death and nonsustained ventricular tachycardia recorded on Holter ECG) and ECG diagnosis of BS (type 1 morphology or type 2 converted to type 1 after infusion of flecainide). All the patients were studied for ventricular vulnerability and underwent endomyocardial biopsy. The study for ventricular vulnerability was performed by pacing right ventricular apex and outflow tract with 2 different drives (600-400 msec) and delivering up to 3 extrastimuli (minimal coupling interval 200 msec). Endomyocardial biopsies were performed at the level of right ventricular septal-apical wall. Myocardial specimens were fixed in 10% buffered formalin; after preparation they were observed by two different expert pathologists. The diagnosis of myocarditis was established in the presence of inflammatory infiltrates associated with necrosis of adjacent myocytes, according to the Dallas criteria

**Results** No evidence of inflammatory infiltrates was detectable in any myocardial specimen. There was no evidence of histologic changes. All patients had evident ventricular vulnerability: programmed electrical stimulation induced VF in 6 patients and NSVT in 1 patient. All the patients underwent implantation of automatic internal cardioverter defibrillator and are currently under clinical follow-up.

**Conclusion** In our study no evidence of cardiac inflammatory pattern was seen in patients with BS. Further investigation is needed to better characterize the ultrastructural abnormalities attached to this clinical setting.

### USEFULNESS OF RPM SYSTEM IN THE DIAGNOSIS OF ARRHYTHMOGENIC RIGHT VENTRICULAR CARDIOMYOPATHY/DYSPLASIA (ARVC/D)

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ARVC/D is a heart muscle disease, characterized by right ventricular (RV) myocardial atrophy with fibrofatty replacement and electric instability. Three-dimensional electroanatomic voltage mapping offers the potential to identify low-voltage areas.

After a noninvasive clinical evaluation, twelve consecutive patients (10 men and 2 women; mean age, 32.6±12 years) underwent further invasive study including RV electroanatomic voltage mapping with RPM System. Multiple RV endocardial, bipolar electrograms (155±18) were sampled during sinus rhythm. Eight patients (group A; 66,7%) had an abnormal RV electroanatomic voltage mapping showing 1 area (mean 3.15±0.9) with low-voltage values (bipolar electrogram amplitude <0.5 mV), surrounded by a border zone (0.5 to 1.5 mV) that transitioned into normal myocardium (>1.5 mV). Low-voltage

electrograms appeared fractionated with significantly prolonged duration and delayed activation. In 4 patients (group B; 33,3%), electroanatomic voltage mapping was normal, with preserved electrogram voltage (5.4±1.7 mV) and duration (41.5±1.8 ms) throughout the RV. Low-voltage areas in patients from group A corresponded to echocardiographic/MRI RV wall motion abnormalities and were associated with familial ARVC/D. Patients from group B had echocardiographic/MRI RV wall motion abnormalities but were not associated with familial ARVC/D. During the time interval from onset of symptoms to the invasive study, 3 patients (37,5%) with electroanatomic low-voltage regions received an implantable cardioverter/defibrillator because of life-threatening ventricular arrhythmias, whereas all patients with a normal voltage map remained stable on antiarrhythmic drug therapy.

The RPM System enhanced the accuracy for diagnosing ARVC/D by demonstrating low-voltage areas. The predictive accuracy of voltage mapping to identify those patients more prone to sudden death remain to be assessed by a prospective follow-up study.

### HETEROGENITY OF BRUGADA SYNDROME: CLINICAL AND PROGNOSTIC IMPLICATIONS IN ELDERLY SUBJECTS

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**Background** The impact of Brugada syndrome (Bs) in the general population appears not limited to the mid to late thirties but it is also recognizable in people of more advanced age with co-morbidities. In these old patients the prognosis is still to be defined.

**Methods** Patients (pts) were evaluated for Bs in presence of an electrocardiographic (EKG) pattern of Brugada and/or syncope of unknown origin, familial history of Bs or sudden death. A test with Flecainide (F) (2mg/Kg) or Ajmaline (A) (1 mg/Kg) were utilized for diagnosis. F/A test was positive in presence of a J-wave amplitude >2 mm in lead V1-3. An electrophysiological study (EPS), was indicated for proper risk stratification when appropriate. A high resolution EKG and an echocardiogram (Echo) were also obtained.

**Results** From 11/ 2001 to 7/2006, 74 pts suspected for Bs were admitted for F/A test. In 31/ 74 pts (20 male) F/A test resulted positive. Object of the study were 17 out of 31 pts (6 male) older than 50 yrs (mean age 59). All pts but 2 had recurrent syncope or were symptomatic for dizziness, palpitations and thoracic pain. 1 pts had a completely normal resting EKG. Left ventricular function (echo) was normal in all. 12 pts had one or more co-morbidities (cancer in 3; chronic hepatitis (2); diabetes (2); ischemic heart disease (2); systemic hypertension (6). 5 pts had no associated diseases. 3 pts had an automatic cardioverter defibrillator (ICD) implanted. During a mean follow-up (FU) of 17 mths all pts are still alive. ICD telemetry documented no VA.

**Conclusion** Brugada syndrome appears to be not a very rare condition in a unselected population. The presence of Bs in older pts is consistent with the hypothesis of a genetic heterogeneity. Prognosis in elderly also depends from cardiac disease and co-morbidities frequently associated

## THE COVERED TYPE AND THE EXTENT OF FAMILY DISTRIBUTION OF SUDDEN DEATH OR CARDIAC ARREST SHOW THE HIGHEST PROGNOSTIC SIGNIFICANCE IN BRUGADA SYNDROME PATIENTS

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**INTRODUCTION** The prognostic significance of family distribution of cardiac arrest (CA) or sudden death (SD) in Brugada syndrome patients is still debated. We verified the importance of the ECG aspect (covered versus saddle back type) in association to family distribution (FD) and the extent of FD of CA and SD, in our families of BS.

**PATIENTS AND METHOD** We evaluated, in our thirteen families, the ECG pattern (spontaneously or drug induced covered type), the FD and the extent of FD of CA and SD, in relation to new episodes of CA or appropriate ICD shocks (AIS) in a 11+/-7 years cumulative follow up.

**RESULTS** The covered ECG type was documented in 8/13 families, 6/8 had new CA or AIS, while other patterns were documented in 5/13 in whom, only a new CA was documented.

FD was observed in 7/13 and new CA or AIS were observed in 6/7 families. Considering the extent of FD, more than 4 episodes of CA and SD were observed in 4/13 families associated with 8 new episodes in all 4. Conversely, 2-4 episodes were observed in 3/13 families associated with 2 new episodes of CA or SD. In the third group less than 2 episodes in the FD were observed in 6/13, associated with no new episodes.

**CONCLUSION** Further evidence has been provided in our patients population suffering from BS, showing that the covered type (spontaneously occurring or after drug test), FD and the extent of FD of more than 4 episodes of CA or SD are strongly associated with a poorer prognosis or more frequent AIS. We suggest to follow the present indication for ICD implantation in symptomatic BS patients, to avoid medico-legal controversies as reported in cases of SD, in whom and adequate diagnosis and risk stratification for SD were not performed.

## INTRACARDIAC ECHOCARDIOGRAPHY IN NONCOMPACTED LEFT VENTRICULAR MYOCARDIUM

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**Background** Noncompaction of the ventricular myocardium (NCVM) is a rare disorder of myocardial morphogenesis characterized by prominent trabecular meshwork and deep intratrabecular recesses in the absence of other structural heart defects.

**Purpose** We describe the use of intracardiac echocardiography (ICE) within the diagnostic process in a case of NCVM.

**Methods** A 61 year-old asymptomatic caucasian man presented with ventricular bigeminism and nonsustained ventricular tachycardia recorded on Holter ECG. No history of spontaneous syncope or dizziness was collected. Transthoracic echocardiography showed: small left ventricular dilatation and hypokinesis of middle inferior and septal walls, trabeculations at the middle septum and on the middle lateral walls, ejection fraction 48%. Coronary angiography showed normal coronary arteries; left ventricle angiography showed diffuse left ventricular hypokinesis with prominent meshwork of trabeculations. Programmed right apical ventricular stimulation (drive 600 msec, triple extrastimulus) induced monomorphic sustained ventricular tachycar-

dia degenerating into ventricular fibrillation. ICE was then performed.

**Results** ICE showed a prominent meshwork of trabeculations, mainly at the level of right ventricular apex with a noncompaction/compaction ratio >2. Moreover, color-Doppler study showed typical forward and reversed blood flow from the ventricular cavity into the spaces between the trabeculations throughout the cardiac cycle; no thrombi were observed. The patient underwent internal cardioverter defibrillator implantation and is currently in good conditions under clinical follow-up.

**Conclusion** ICE allowed the diagnosis of NCVM by mean of the very high imaging resolution.

## INTRACARDIAC ECHOCARDIOGRAPHY AND ELECTROANATOMICAL MAPPING IN ARRHYTHMOGENIC RIGHT VENTRICULAR DYSPLASIA

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**Background** Arrhythmogenic right ventricular dysplasia (ARVD) is characterized by fatty or fibro-fatty replacement inside the right ventricular myocardium and developing of electrical instability. Several imaging tools can be used to validate the diagnostic hypothesis. The diagnosis of early and mild forms of disease is often difficult.

**Purpose** We describe the use of combined diagnostic tools to investigate a very likely case of ARVD in a subject who could not undergo standard cardiac MRI for availability issue.

**Methods** A 28-year old Caucasian male patient presented with a syncope episode during the recovery after a basketball match. Physical examination was normal. ECG showed sinus rhythm with narrow QRS complex and negative T waves from V1 to V4 with evidence of e wave. Trans-thoracic echocardiography revealed mild enlargement of the middle right ventricular cavity. Holter ECG revealed several brief and asymptomatic episodes of nonsustained monomorphic ventricular tachycardia. Programmed stimulation in right ventricular apex induced a fast monomorphic (left bundle branch block, inferior axis) ventricular tachycardia rapidly degenerating into ventricular fibrillation. We utilized a combination of intra-cardiac echocardiography (ICE) and electroanatomical mapping (EM) to validate the diagnostic hypothesis of ARVD.

**Results** ICE confirmed mild right ventricular enlargement and micro-aneurysms were detected below the tricuspid ring, mainly in the posterior-inferior aspect. Right ventricular EM showed a circumscribed low potentials area at the same level of the micro-aneurysms, in the right ventricular area corresponding to the so-called 'triangle of dysplasia'. No hemodynamically stable monomorphic tachycardia could be induced and mapped to validate its focus originating in the same area. The patient insisted on immediate implantation of a cardiac defibrillator before appointment for cardiac MRI in another center. Currently he is under clinical follow up.

**Conclusion** ICE and EM could be considered part of the diagnostic path in patients with suspected ARVD. Systematic studies are needed to validate this hypothesis.

## PHARMACOLOGICAL TREATMENT OF ATRIAL FIBRILLATION

### ATRIAL FIBRILLATION IN CHF. CLINICAL FEATURES, THERAPEUTICAL STRATEGIES AND PROGNOSIS IN THE BOLOGNA REGISTRY OF THE INTERNATIONAL STUDY AF-CHF

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**INTRODUCTION** Atrial fibrillation (AF) and chronic heart failure (CHF) are recognized as the two major epidemics in the 21st century. The treatment of AF in CHF patients remains to be determined. **PATIENTS AND METHODS** We enrolled 40 consecutive patients, in the Bologna registry, similarly to the Canadian AF-CHF study. The patients were randomly assigned to the two therapeutical strategy of AF in CHF patients: rate control (RAC) or rhythm control (RHYC). Clinical features, associated therapeutical strategies (TS) and prognosis, are reported.

**RESULTS** Etiology was CAD (55%), followed by DCM (15%), and valvular diseases (VD) (12.5%).

21/40 were randomized to RHYC and 19/40 to RAC. EF% was 30%, in the entire group, 31% and 28% in the RHYC versus RAC groups. The majority of patients were in NYHA class 3 (57.5%) and NYHA class 4 (22.5%).

B-blockers and ACEi were administered in 85% and 82% of both groups. Electrical ablation (EA), pacing or CRT, CABG and valvular operations were more frequently applied in RHYC versus RAC. The one year prognosis showed a significant higher mortality in RAC 6/19 (39.5%) versus RHYC 2/21 (9.5%). Only 9/21 (42.8%) were in SR and 0/19 in RAC. 38/40 received OAT.

**CONCLUSIONS** CHF patients with AF are characterized by a severely reduced EF%, advanced NYHA classes. The optimal drug therapy should be instituted, including non-anti-arrhythmic agents and OAT. Of the two available therapeutical strategies, RHYC is justified in patients, in whose AF is associated with severe hemodynamic deterioration. Frequently, non pharmacological treatment, including cardiac surgery (CS), and/or EA should be applied to maintain SR. Conversely, RHYC control should be used when EF% is not clearly associated with symptoms worsening. Only, by applying these guidelines, including CS and/or EA, RHYC seems to be superior to RAC. in the long term prognosis of AF-CHF patients.

### PREVENTION OF ATRIAL FIBRILLATION RECURRENCE WITH RAA INHIBITORS TREATMENT AFTER SUCCESSFUL ELECTRICAL CARADIOVERSION

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**Introduction** ACE inhibitors and AT2 blockers have a IIa class of recommendation with a level of evidence B as non antiarrhythmic pharmacological treatment for prevention of recurrences.

Many studies have shown a lower atrial fibrillation recurrence rate in patients treated with RAA blockers in addition to traditional antiarrhythmic therapy. RAA inhibitors therapy contrasts the electrical and mechanical remodelling of the atria and results in reducing the AF recurrences.

**Methods** We evaluated the efficacy of therapy with ACE inhibitors or AT2 blockers in addition to traditional antiarrhythmic treatment for prevention of AF 8 weeks after successful DCS. 59 consecutive patients affected by persistent AF underwent to oesophageal electrical cardioversion. All patients were treated with amiodarone before and after DCS, while only 29 patients received flecainide. Moreover

24 patients received ACE inhibitors, 11 AT2 blockers and 25 did not receive any RAA inhibitor. Follow up was performed 8 weeks after DCS.

**Results** At the 8 weeks follow up AF relapsed in 24 patients (40,6%) while SR was still present in 35 patients (59,3%). In the group of patients receiving therapy with ACE inhibitors, 12/24 (50%) had AF recurrence; in the group treated with AT2 blockers 10/11 (91%) were in SR while 1/11 (9%) had AF recurrence. In patients that without any RAA inhibitor therapy 14/25 (56%) patients were in SR while in 11/25 (44%) recurred AF. X<sup>2</sup> test was used to compare data of ACE vs. no therapy group (p = N.S.), AT2 blockers vs. no therapy (p = 0,02) and ACE vs. AT2 blockers (p = 0,04).

**Conclusions** Efficacy of electrical cardioversion is limited by the high rate of AF recurrence nevertheless the use of traditional antiarrhythmic therapy. In our series AT2 blockers showed to be more effective in preventing AF recurrences compared to ACE inhibitors or no therapy.

### EFFECT OF INTRAVENOUS VERAPAMIL LOADING ON LEFT ATRIAL APPENDAGE FUNCTION IN PATIENTS WITH PERSISTENT ATRIAL FIBRILLATION

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**Purpose** Although verapamil is currently used to control ventricular rate in patients with atrial fibrillation (AF), there are only few data on the relationship between this drug and left atrial appendage (LAA) function. Aim of this study was to evaluate the change of LAA velocities and spontaneous echo contrast (SEC) after intravenous administration of verapamil.

**Materials and Methods** The study group consisted of 25 consecutive patients scheduled for electrical cardioversion of persistent AF. Left atrial and LAA mechanical function were assessed by changes of pulsed Doppler measurements of LAA velocities and SEC before and after intravenous verapamil administration at dose of 0,1 mg/kg.

**Results** Heart rate significantly decreased from 103 ± 16 bpm to 92 ± 16 bpm after verapamil administration (p = 0,014). Similarly, LAA mean peak velocities decreased from 37±0,19 cm/s to 24 ± 0,12 cm/s (p = 0,004). A significant positive association was observed between heart rate reduction and decreased LAA flow velocities (r = 0,44; p = 0,025). SEC increased after verapamil administration in 12 patients (48%). In six of them (24%) the increase was to grade 3-4. A significant negative association was observed between left atrial dimensions and LAA velocities (r = - 0,58; p = 0,002). No other clinical and echocardiographic variable was associated with LAA velocities.

**Conclusion** The present results suggest that verapamil administration before electrical cardioversion might impair LAA function. This effect may be greater and clinically relevant in patients with enlarged left atrium. These findings also suggest the possibility that the thromboembolic risk may be increased by negative inotropic agents, such as verapamil, used to control ventricular rate.

### EFFICACY AND SAFETY OF A COMBINATION THERAPY WITH AMIODARONE AND FLECAINIDE IN THE PREVENTION OF ATRIAL FIBRILLATION RECURRENCE AFTER SUCCESSFUL ELECTRICAL CARADIOVERSION

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**BACKGROUND** The efficacy of electrical cardioversion of persistent atrial fibrillation (AF) is limited by a high relapse rate. Amiodarone

treatment before electrical cardioversion, especially when continued after a successful procedure, may reduce AF recurrence incidence, nevertheless it still remains very high in the first two months, as high as an average of 50% at two months according data reported in literature. Very poor reports about the association of amiodarone and flecainide after a successful electrical cardioversion are present in literature.

**METHODS** We performed outpatient oesophageal electrical cardioversion in 56 consecutive patients (mean age:  $67.1 \pm 8.7$  years, weight:  $78.7 \pm 16$  kg, left atrium diameter:  $45.8 \pm 6.6$  mm, LVEF:  $54 \pm 16\%$ ) with persistent AF (mean duration:  $6.8 \pm 8.2$  months). All patients received effective anticoagulant therapy for at least 20 days before the procedure and for at least 8 weeks afterward. 49 patients were pre-treated with amiodarone 200 mg daily before electrical cardioversion and 7 patients underwent DCS without antiarrhythmic therapy. In 21 of those patients receiving amiodarone, flecainide at a dosage of 150 mg/die was added soon after the cardioversion, while in the other 28 amiodarone alone was continued. In all 7 patients not receiving amiodarone, flecainide alone was started after the cardioversion. All patients were seen two months after the cardioversion.

**RESULTS** In the group receiving both amiodarone and flecainide 71,5% (15/21) of pts remained in SR at 8 weeks after DCS compared to the 57,2% (16/28) of pts taking amiodarone alone (P=NS, Fischer's exact test), and 57% (4/7) of pts receiving flecainide mono-therapy. No adverse drug reaction was reported.

**CONCLUSIONS** The combination of flecainide and amiodarone proved safe in the treatment of patients cardioverted from atrial fibrillation. The combination showed a non-significant trend toward greater efficacy compared to either agent alone.

### EFFECT OF AMIODARONE ON ELECTRICAL REMODELING IN PATIENTS WITH PERSISTENT ATRIAL FIBRILLATION

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Pre-treatment with low-dose Amiodarone (Am) has been associated to increased cardioversion efficacy and reduced atrial fibrillation (AF) recurrence, suggesting a preventive effect on atrial electrical remodeling. This hypothesised was tested in a group of pts with persistent AF undergoing internal electrical cardioversion (IC).

**METHODS** In 19 pts with persistent AF (mean duration:  $3.4 \pm 1.5$  months) a subgroup of 10 pts was pre-treated with Am 4 weeks before IC (7 M,  $67 \pm 5$  years; 400 mg/day) while the remaining 9 pts were pre-treated with digoxin (control group: 5 M,  $68 \pm 4$  years; 0.25 mg/day). In each patient IC (Rhythm Technologies USA) was applied at incremental energy levels (from 0.5 to 20 J) and the defibrillation threshold was determined. After IC atrial refractory period (ERP) was evaluated by MAP catheter (EP Technologies, USA) in three different right

atrial sites (antero-septal, postero-septal, and lateral wall) and at four pacing cycle lengths (300 to 600 ms).

**RESULTS** Am pre-treated pts showed a lower dispersion of refractoriness ( $18 \pm 10$  ms vs.  $31 \pm 10$  ms; P=0.01) and a higher ERP ( $189 \pm 10$  ms vs.  $178 \pm 10$  ms; P=NS) in comparison with controls. While control group showed a poor refractory period rate adaptation with a mean slope of  $0.05 \pm 0.021$ , Am pts showed a preserved rate adaptation of refractoriness with a mean slope of  $0.09 \pm 0.007$  (P<0.05). In addition, a lower but not significant defibrillatory threshold ( $8.2 \pm 2.3$ J vs.  $9.1 \pm 2$ J) was found in Am pre-treated pts.

**CONCLUSION** In pts with persistent AF, pre-treatment with Am before IC reduces dispersion of refractoriness and exerts a protection against the fibrillation-induced maladaptation of refractory period suggesting a preventive effect on electrical remodeling.

### ACE INHIBITORS IN THE PREVENTION OF ATRIAL FIBRILLATION IN PATIENTS WITH TACHY-BRADY SYNDROME TREATED BY RATE ADAPTIVE DUAL CHAMBER PACEMAKER

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**Aim** This study was performed to evaluate whether ACE inhibitors prevent atrial fibrillation (AF) in patients with brady-tachy syndrome treated by rate adaptive dual chamber (DDDR) pacemaker.

**Methods** Fifty consecutive patients with brady-tachy syndrome who underwent implantation of DDDR pacemaker were enrolled and retrospectively evaluated. Regarding to treatment with ACE inhibitors, the patients were divided in the two groups: treated (n=29) and non-treated (n=21) group. The primary end point was the development of permanent AF.

**Results** At baseline evaluation there was no difference in age, gender, underlying heart disease and antiarrhythmic drug therapy between the two groups. During the mean follow-up period of 24 months, permanent AF developed in 10 patients with overall incidence of 20%, while paroxysmal AF occurred in 15 (30%) patients. The incidence of permanent AF at 1-year and 2-years was lower in patients treated with ACE inhibitors, as compared with those not taking these drugs. However, this difference was not statistically significant (6.8% vs. 14.2%, p=0.700, and 7.4% vs. 16.7%, p=0.567 respectively). On the other side, the incidence of paroxysmal AF was significantly lower in patients treated with ACE inhibitors (10% vs. 57%, p=0.001).

**Conclusion** The results of this study suggest that ACE inhibitors may have a beneficial effect in the prevention of AF in patients with brady-tachy syndrome treated by DDDR pacemaker. However, larger prospective studies are required to confirm these results

## TRANSCATHETER ABLATION OF TACHYARRHYTHMIAS

### LEFT ATRIAL FLUTTER AFTER RF ISOLATION OF THE PULMONARY VEINS

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Purpose of study was to evaluate of electrophysiological mechanisms of left atrial flutter (LAF) developing after RF isolation of the pulmonary veins (PV) or endocardial RF-Maze procedure in the left atrium (LA) in patients with atrial fibrillation (AF).

From February 2000 to September 2006 in 329 patients (259 males, 70 females) RFA procedures in PVs were performed (average 1,36 per 1 patient). Left atrial flutter (LAF) was detected as a concomitant arrhythmia after PV or RF-Maze procedure in LA for persistent and chronic AF treatment in 20,7% patients (57 males and 11 females, mean age 47,9 years). Mean cycle duration of LAF was 228±45 msec.

85% of pts with refractory to antiarrhythmic therapy LAF were entered in the RF study. Unstable LAF was registered in 7 patients (15,2%) – additional RFA in the area of PV orifices were effective in these cases. In another category of patients (n=15; 32,6%) left isthmus-block was created. 24 patients (52,2%) underwent LAF mapping with CARTO system with determination of the “slow conduction zone” (SCZ). RF ablation lines created on the roof and the posterior wall together with left isthmus isolation proved sufficient for LAF termination. SCZ were located between the LPV trunk or collector and the LA appendage (12), on the LA anterior wall (3), between RPV collector and atrial septum (6) and between RIPV and MV (3).

In the postoperative period (12±8 months) these pts, including 41% of pts in whom previous AAT was not effective, had no LAF paroxysms.

18% of patients with paroxysmal, persistent or permanent AF had atypical - left atrial flutter in early or long term follow-up period after PV RF isolation and endocardial RF-Maze type procedure in left atrium. Electroanatomic mapping and entrainment allow precisely characterize re-entrant circuits in LA and to guide catheter ablation of atypical left atrial flutter.

### COMPARISON OF 8-MM-LARGE-TIP VERSUS CLOSED COOLED-TIP CATHETERS (CHILLI II) FOR RADIOFREQUENCY ABLATION OF CAVOTRICUSPID ISTHMUS-DEPENDENT ATRIAL FLUTTER

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Radiofrequency (RF) ablation of cavotricuspid isthmus (CTI)-dependent atrial flutter (AFL) can be performed using different types of ablation catheters. 8-mm-Large-tip and closed Cooled-tip catheters are capable of creating larger lesions, resulting in greater efficacy.

The aim of this study was to compare the efficacy and safety of single-sensor 8-mm-Large-tip and a new 4-mm closed Cooled-tip (Chilli II, Boston Scientific) catheters for AFL ablation in non-randomized, prospective study.

In 50 consecutive patients referred for ablation of CTI-dependent AFL, CTI ablation was performed with a 8-mm-Large-tip catheter (n=30) or an 4-mm closed Cooled-tip catheter (Chilli II) (n=20). RF current was applied for 60 to 120 seconds in a temperature-controlled mode (60 °C/70 W) with the 8-mm-Large-tip catheter and at maximum power output of 50 W and temperature limit of 50 °C with the 4-mm closed Cooled-tip catheter. The endpoint was the achievement of a bidirectional isthmus conduction block. The number of applications for 8-mm-Large-tip catheter was 13.3±7.6 and for 4-mm closed Cooled-tip catheter 7.5±3.2 (P<0.001) at powers between 35 and 50 W and at a tip temperature range of 38-43 °C. Ablation duration and fluoroscopy time were 20.4±14.4 and 26.4±13.5 min for 8-mm-Large-tip catheter, respectively. In contrast, for 4-mm closed Cooled-tip catheter, abla-

tion duration and fluoroscopy time were 9.8±5.6 (P<0.0001) and 25.3±10.7 min, respectively. In 100% of the patient bi-directional block was obtained. In a mean follow-up of 6-months, recurrence rates of AFL were 1 in the closed Cooled-tip group and 3 in the control group, corresponding to 5% and 10%, respectively. No major complications were observed.

Use of the 8-mm-Large-tip and 4-mm closed Cooled-tip (Chilli II) catheters have high efficacy for RF ablation of CTI-dependent AFL. When compared to 8-mm-Large-tip catheter, the 4-mm closed Cooled-tip (Chilli II) catheter requires lower application numbers and AFL recurrence rates are reduced.

### SHORT- AND LONG-TERM EFFICACY OF RADIOFREQUENCY AND CRIO-ABLATION OF CAVO-TRICUSPID ISTHMUS

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**Background** Cryo-ablation is a recent method of ablation, safer than radiofrequency.

**Purpose** to compare radiofrequency (RF) ablation with cryo-ablation.

**Methods** we studied 17 patients (PT), 9 males, mean age 66.41, 11 PT with hypertensive cardiomyopathy, 3 with coronary artery disease, 2 with 1C flutter and 1 with dilated cardiomyopathy. Radiofrequency ablation was performed with a Blazer catheter 8 mm, and cryoablation with Cryocath freezer 8 mm. 3 months after ablation, the persistence of cavo-tricuspid (CT) isthmus block status was reassessed during a control electrophysiological study (ES). The following parameters were evaluated after the ablation and at the control ES: sequence of activation along the Halo catheter and presence of a line of double potentials along the block during pacing from the coronary sinus (CS), evaluation of the time interval between double potentials along the line of block and of the time interval between spike and last Halo component during pacing from the proximal CS.

**Results** All the PT were asymptomatic during the 3 months period preceding the control study. No statistically significant difference was found between RF and Cryo groups as regard to the number of PT recovered isthmus conduction (22% vs 37% respectively, P=ns). A statistically significant reduction of the interval between double potentials and of the interval between the spike and the last Halo electrogram was found in both groups. In the RF group the basal double potential interval of 117±11.29 msec decreased to 112.571±9.015 while the spike-last Halo component interval decreased from 184±9.18 to 170±179.8 msec. In the Cryo group the basal double potential interval of 116±15.21 msec decreased to 110.5±13.08 while the spike-last Halo component interval decreased from 190.3±12.01 to 185.8±11.35 msec.

**Conclusion** Patients with typical atrial flutter undergoing RF or cryo ablation have similar results in terms of arrhythmia recurrences and persistence of CT isthmus block.

### COMPARATIVE STUDY OF RESULTS OF CATHETER ABLATION OF VENTRICULAR TACHYCARDIA FROM DIFFERENT AETIOLOGIES

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**Background** In selected cases, radiofrequency catheter ablation of ventricular tachycardia is considered an alternative therapeutic option to implantable defibrillator. The aim of the study was to assess long-

term results and adverse events in patients with ventricular tachycardia from different aetiologies.

**Patients and methods** The recurrence rate of tachycardia, consequent further therapies (other catheter ablation procedures, drug therapy and implantable defibrillator) and clinical events have been assessed in 60 consecutive patients undergoing ventricular tachycardia catheter ablation between January 2000 and December 2004.

**Results** During a median follow-up of 20 months, (interquartile range 13-36), tachycardia recurred in 27 patients (45%) after a median of 3 months (interquartile range 1 to 30). A second procedure was performed in 11 patients; it was successful in 8 patients. Four patients underwent pharmacological therapy which was successful in all cases.

Overall, after ablation (1 or more procedures) and pharmacological therapy, tachycardia was cured in 75% of cases. All the 20 patients without structural heart disease were cured with ablation vs 62% of patients with heart disease ( $P=0.001$ ).

Patients with dilated cardiomyopathy reported worst results (33% success,  $P=0.03$ ).

Recurrences were predicted by acute failure of procedure ( $P=0.05$ ), presence of heart disease ( $P=0.006$ ) and history of atrial arrhythmias ( $P=0.02$ ). On a multivariate analysis, only structural heart disease continued to be independent predictor of ventricular tachycardia recurrence.

**Conclusion** Catheter ablation of ventricular tachycardia has high percentage of recurrences in patients with heart disease, while is curative in subjects without structural heart disease.

### USEFULNESS OF RPM SYSTEM IN THE ABLATION OF VENTRICULAR TACHYCARDIAS AND REPETITIVE MONOMORFIC VENTRICULAR ECTOPIES OF RIGHT VENTRICULAR OUTFLOW TRACT

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**Aim** To test the usefulness of RPM System in the ablation of ventricular tachycardia (VT) and repetitive monomorphic ventricular ectopies (RMVE) of right ventricular outflow tract (RVOT).

**Methods** Out of Twenty-two patients (15 men; aged 57+ 15 years), three with sustained VT like left bundle branch block and lower axis, and nineteen patients with RMVE like left bundle branch block and lower axis have undergone an electrophysiological study with RPM. The burden of RMVE has been quantified with Holter ECG. The anatomical and voltage maps of the right atria, ventricle and its outflow tract have been reconstructed. A stimulation protocol has been performed with up to three extra stimuli from the right ventricle apex and from the outflow tract in basal conditions and after the infusion

of isoprenaline. The ablation site has been confirmed with pace-mapping. The ablation procedure has been done by using a maximum power of 50 W and a maximum temperature of 60 °C for less then 60 seconds. The targets considered are the following: discontinuation of VT and suppression of the RMVE during ablation and persistence of this result for 30 minutes in basal conditions and with the infusion of the isoprenaline.

**Results** The procedure has been successful for 21 patients out of 22. During a follow-up of 12 months without any antiarrhythmic drug, no VT relapse has been documented and Holter ECG executed three months later documented an improvement in the occurrence of VEs (from 17.859±13.488 BEV/24 hours to 507±722 BEV/24 hours;  $p=0.028$ ).

**Conclusions** By using RPM, it has been possible to obtain a specific individuation of the good site of ablation with the help of electrical and voltage activation maps. Therefore, the use of RPM, must be considered safe and effective in the ablation of the VT and RMVE which originate from the RVOT.

### CATHETER ABLATION OF VENTRICULAR TACHYCARDIAS IN PATIENTS WITH CORONARY ARTERY DISEASE AND PRESERVED LEFT VENTRICULAR FUNCTION: LONG-TERM RESULTS

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**Introduction** Patients with coronary artery disease (CAD), hemodynamically tolerated ventricular tachycardias (VTs) and preserved left ventricular function ( $EF>40\%$ ) may benefit from catheter ablation without the necessity of cardioverter-defibrillator (ICD) implantation. The aim of the study was to retrospectively analyze the long-term outcome of this patient cohort.

**Methods and Results** From January 2001 to May 2006, a total number of 11 patients (all men, mean age of 71±7let) with CAD, LV  $EF>40\%$  underwent in our institution ablation for tolerated VT. Mean LV  $EF$  was 47±8%, mean rate of clinical VT was 175±30bpm. Ablation was performed using the electroanatomical mapping system (CARTO, Biosense Webster, Israel). The clinical VT was successfully abolished in all but one patient. After the procedure, two patients were implanted with an ICD for inducibility of other hemodynamically nontolerated VTs. During follow up of 26±17months no arrhythmias recurred, only one patient underwent successful reablation. No sudden deaths occurred, one patient died of non cardiac cause two years after the procedure. No arrhythmias were noted in patients with implanted ICD.

**Conclusions** Catheter ablation of tolerated ventricular tachycardias in patients with coronary artery disease and preserved left ventricular function is highly efficient and has long lasting effect. Selected patients may still require ICD back-up, however, its role in this patient population is to be determined.

## CARDIAC PACING AND SLEEP APNEA

### PREVALENCE OF SLEEP DISORDERED BREATHING AND EFFECT OF ATRIAL PACING IN PATIENTS WITH SICK SINUS SYNDROME

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**Purpose** We investigated the prevalence of sleep disordered breathing (SDB) in patients diagnosed with sick sinus syndrome (SSS) and evaluated the efficacy of atrial pacing during sleep in those patients. **Methods** Thirty-five consecutive patients (mean age, 67±11:27 men) who were diagnosed with SSS were studied prospectively in this study. All patients received polysomnographic evaluations before implantation of permanent pacemaker (PPM). Heart rate variability was analyzed in patients with maintain sinus rhythm during polysomnography. After implantation of PPM, SDB patients (apnea-hypopnea index (AHI)>5) received polysomnographic evaluations during AAI 70 per minutes setting.

**Results** Prevalence of SDB were 83% (AHI >5), 60.0% (AHI >15), 26.7% (AHI >30) in patients with SSS. 60% of SDB patients had hypertension (0% of normal patients, p=0.085). There were no significant difference between SDB patients and normal patients with diabetes mellitus, hyper-lipidemia, history of ischemic heart disease, history of heart failure. In the heart rate variability analysis, pNN50 (29.8 vs 9.6%: p=0.0394) and HF power (8251 vs 859ms<sup>2</sup>: p=0.0337) were smaller in patients with SDB than those without SDB before implantation of PPM. polysomnographic evaluations were performed in 25 cases of SDB group before and after implantation of PPM. Central type apnea were significantly reduced after implantation of PPM (3.6 vs 1.2: p=0.0075). There were no significant difference in AHI (23.4 vs 20.0: p=0.2631) and obstructive type apnea (5.4 vs 6.1: p=0.5130).

**Conclusion** Our results indicate that it is high incidence of SDB in patients with SSS. In SSS patients with SDB, atrial pacing significantly reduces the number of episodes of central type sleep apnea. However obstructive sleep apnea. Atrial pacing dose not reduce those of obstructive type sleep apnea.

### EFFECT OF CLOSED LOOP STIMULATION IN PATIENTS AFFECTED BY SLEEP APNEA SYNDROME

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In the last years atrial stimulation at higher frequency than mean nocturnal rate has been considered an alternative in the treatment of patients affected by Sleep Apnea Syndrome (SAS) and refractory or no-compliant with the CPAP therapy. In fact SAS episodes may be provoked by a destabilization of the simpato-vagal tone that it could be restored through the cardiac pacing so decreasing the incidence and the entity of sleep disorders. A pacing modality called Closed Loop Stimulation (CLS), that use the indirect measure of ventricular contractility, allows a physiological pacing rate tightly related to the variations of autonomous central system. We hypothesize that a pacemaker which supply CLS would be more effective than constant atrial overdrive pacing at fix rate in reducing sleep apnea number and gravity. In fact, during the various stage of sleep, rapid fluctuations in heart rate are present and cardiac stimulation to a fixed rate cannot answer to the request of the autonomous central system to reach higher rates.

We performed two polysomnography recording in a patient affected by severe obstructive SAS and brady-tachy syndrome: one basal recording the day before pacemaker implant and second recording one week after, with pacemaker programmed in CLS mode. A 50% of decrease

of Apnea Index (AI) (46.2 basal vs 23.9 CLS) and Apnea/Hypopnea Index (AHI) (65.5 basal vs 31.7 CLS) was observed during CLS. Polysomnography recording during CLS showed an higher mean heart rate (68 bpm vs 57 bpm basal). The mean O<sub>2</sub> saturation didn't changed between two recordings (92% basale vs 90% CLS). From this case report we can hypothesize that CLS may have beneficial effect on sleep apnea episodes number but not on intensity of episode. These results could be useful for the development of clinical study design to assess the real impact of CLS on number and severity of sleep apnea episodes.

### CAN MESSAGES GENERATED BY THE THERAPY ADVISOR HELP THE PHYSICIAN DURING FOLLOW-UP? FINAL RESULTS OF THE EUROPEAN T-STAR REGISTRY

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Modern pacemakers (PMs) store much data which influence the patient (pt) management. PMs also provide a wide array of algorithms for rate and rhythm control in atrial fibrillation (AF). Analyzing all data and optimizing AF therapy prolongs the follow-up visit (FUP) and requires specific knowledge. A solution can be the expert system Therapy Advisor (TA) which analyzes all data during interrogation and indicates which diagnostics need further attention using Main Observations (MOs) and Detailed Information Messages (DIMs). It also provides Programming Advices (PAs) to optimize PM therapy. The aim of the prospective multi-center T-STAR registry was to evaluate the frequency of the messages and their impact on AF management.

**METHODS** Pts with class I/II indication for a DDDR PM (Vitatron T70 DR) were included. At the 1st and 2nd FUP (1-3 months, 4-7 months) pts complaints, PM diagnostics, analysis and recommendations of the TA and the physicians were assessed.

**RESULTS** The final analysis included 199 pts (72±9 years; 56% male, mean FU: 4.7±2.4 months). Pacing indications were SSS (56%), advanced AV block (31%) and others (14%); 70% had a history of AF. Nine of 54 pts (17%) with FUP data and no history of AF had AF; five of them did not have any symptoms. At the 2nd FUP 45% reported about symptoms. The TA generated 375 AF messages in 69 pts. More pts (n=48; 66%) with symptoms had 289 AF messages than pts (n=21; 24%) without symptoms (86 AF messages). The physicians considered 93% of all messages as appropriate (99% of MOs, 97% of DIMs, 81% of PAs). The physicians had not thought of a TA advice in 17 cases (5%).

On this basis the physicians changed in 55 pts 99 PM settings (64% with, 36% without symptoms; p<0.05), 47 were AF therapy related. They made 28 changes in AF medication in 22 pts (77% with symptoms, 23% without; p<0.05). Changes in AF therapy were based on PM diagnostics in 98%, on pt symptoms in 13%, on clinical examination in 4% and others in 27%.

**CONCLUSIONS** The TA generated frequently MOs during FUP which were considered by the physicians as appropriate in most cases. The PM diagnostics were often used to optimize AF treatment. The TA support seems to help the management of symptomatic pts during FUP.

### HOME MONITORING TECHNOLOGY. PACEMAKER- AND ICD-PATIENT MANAGEMENT IN CLINICAL PRACTICE

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Home Monitoring (HM) technology allows a real-time transmission of diagnostic data stored in the pacemaker and defibrillators memory to physicians. Its cost-effectiveness for optimal treatment of

paced patients still remains a debated issue. In this study the impact of HM technology on patient medical treatment and on health care resource utilization in a high volume pacemaker and ICD clinic was evaluated. From May to September 2006, 49 patients (mean age  $69,9 \pm 9,9$  years) received HM devices (41 pacemakers, 7 ICD, 1 CRT-D). For each patient, a nurse consulted the cardioreports on the website either weekly or daily when alerts were received. Critical cases were submitted to the physician. During a mean follow-up of  $78 \pm 46$  days (12-165 days), 4396 reports were transmitted (3954 scheduled and 442 event related), resulting in 85% of HM controlled days. On the whole, 20 hours and 50 minutes were spent for HM data analysis (18h 23min by the nurse and 2h 26min by the physician). For each patient follow-up, 2min and 55sec were spent (2min 30sec by the nurse and 4min 42sec by the physician,  $p < 0,01$ ). Due to critical cases analysis, 9 patients (18%) received transtelephonic instructions and 14 patients (28%) were called for an additional follow-up. In 5 patients (10%) previously unknown paroxysmal atrial fibrillation episodes were detected, in 1 (2%) unsustained ventricular tachycardia runs and in 2 (4%) atrial oversensing and undersensing, respectively. During the additional follow-up, in 5 patients (10%) the pharmacological treatment was modified, in 3 (6%) the device was reprogrammed, in 4 (8%) further tests were planned and in 2 (4%) the HM diagnosis was confirmed without additional actions taken. In conclusion, in our experience HM technology allowed optimal medical treatment and device programming with low consumption of health care resource.

#### TELE-CARDIOLOGY HOME MONITORING: ANALYSIS OF PATIENT'S ACCEPTANCE

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**PURPOSE** Between October 05 and April 06, a survey was submitted to patients, in order to determine their acceptance of S.Filippo

Neri Hospital (Rome) Tele-cardiology Service, a remote EKG control service for Post MI with palpitation symptoms or undiscovered arrhythmias identification. The scope of such survey was to find whether there exists any correlation between patients' acceptance and variables such as age, gender.

**MATERIALS AND METHODS** A survey was submitted to 107 patients followed for two weeks by the Home Monitoring Service. The survey was composed of 12 questions on the acceptance of the EKG monitoring from patients' home through a common phone line transmission. The acceptance was determined based on user-friendly technology, pleasure to be followed staying comfortably at home, enhancement of treatment and diagnosis, usability in mobility, frequency of contacts with the physician, patients' willingness to pay for the service. The answers were organized by a multiple choice of five levels. Patients were clustered in classes depending on age (<30, 30-50, 50-70, >70 years old), education level, working activity, gender, family composition (1 to >4 components). The comparison between two groups was performed using the Student t-analysis or ANOVA statistic with Bonferroni's correction for multiple comparisons in case of more than two categories for the variables.

**RESULTS** The analysis of answers based on age showed statistically meaningful results: 'I learned rapidly to use the device' patients <30 'Completely agree' vs. patients >70 'Almost agree',  $p=0.015$ ; 'The remote service allows enhancing the interaction with the physician' patients 30-50 vs. 50-70 agreed less with the sentence,  $p=0.010$ . Considering the education level: 'The remote control could substitute the in-office visit' secondary school degree 'Almost agree' vs. Master degree 'Neutral',  $p=0,033$ . Considering the working activity, gender and family composition there isn't any significant difference between answers.

**CONCLUSION** Patients are generally satisfied with remote monitoring, though there are some differences in the perception of remote monitoring as a clinical treatment enhancement and in technology acceptance. It is useful to tune the training depending on the patient.

## SUDDEN DEATH NON INVASIVE RISK STRATIFICATION

### ASSESSMENT OF QT DYNAMICITY IN SUBACUTE AND CHRONIC PHASE OF MYOCARDIAL INFARCTION

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**Background** QT dynamicity is a marker of ventricular repolarization used in risk stratification of cardiac death. The aim of this study was to compare QT dynamicity parameters in subacute and chronic phase of myocardial infarction (MI).

**Methods** In 42 patients a 24-hour ECG monitoring was performed 48-72 hours after acute MI. The monitoring was repeated after 4-6 weeks. The QT dynamicity (assessed by slope of linear QT/RR regression line) was automatically analysed from 24-hour ECG recordings using QT Guard software of MARS Unity Workstation, GE Medical.

**Results** The QT/RR slope in subacute phase compared to chronic phase was not different ( $0,2\pm 0,117$  vs  $0,225\pm 0,109$ ,  $p=0,1$ ).

**Conclusions** Holter monitoring after MI is an important examination for risk stratification of cardiac death. Our study shows that prognostic information is comparable if the examination is performed anytime later than 48 hours after MI.

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### NON-LINEAR ANALYSIS OF ECG SIGNALS IN SUDDEN DEATH RISK STRATIFICATION

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The aim of the study is to evaluate the possibility to correctly classify the ECG signals among patients (pts) with inducible (ind) or non inducible (no-ind) ventricular tachyarrhythmias (VTs) at electrophysiologic study (EES) and healthy pts.

**METHODS** We studied 50 arrhythmic and 50 healthy pts, using a clustering algorithm applied to the results of different methods of non-linear analysis, in particular mutual information, recurrence, determinism, entropy, ratio and trend, i.e. parameters derived by the analysis of the temporal series reconstructed with "embedding dimension" techniques. Another predictive method has been developed, consisting of the analysis of the dynamic attractors derived by the ECG signals. A third method has been tested using a self-organized artificial neural network called ITSOM (Inductive Tracing Self-Organizing Map), that allows to classify the patients by means of the chaotic attractors formed by the series of winning neurons generated by the network.

**RESULTS** All the three methods have shown a correct classification of the pts in three classes. The healthy pts present a chaotic dynamic behavior more similar to that of no-ind pts, whereas the ind pts present a higher dynamic stability. As the existence of an automated classification technique could constitute in the future a non-invasive method to predict the development of VTs, with less uneasiness, costs and risks in comparison with the invasive EES. We found out that the healthy pts present a dynamic chaotic organization very similar to that of the no-ind pts, whereas the ind pts' ECGs show a higher dynamic stability. The results have confirmed that the attractors formed by the healthy and no-ind pts generated codes similar each others and different from those generated by the ind pts.

**CONCLUSIONS** Our study suggests that non-linear analysis of ECG signals could constitute a non-invasive method to predict the development of VTs.

### T-WAVE ALTERNANS FOR SUDDEN DEATH RISK STRATIFICATION IN ATHLETES WITH VENTRICULAR ARRHYTHMIAS

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**Introduction** Aim of our study is to evaluate the role of TWA to stratify the risk of sudden cardiac death in athletes (Ath) with complex ventricular arrhythmias (VA), and to document a possible correlation between TWA and electrophysiological testing (EPS) results.

**Methods** We studied 43 Ath with VA (31 M, mean age  $34 \pm 12$  years). In all cases a cardiological evaluation was performed, including TWA and EPS. The patients were evaluated during a follow-up of  $30 \pm 22$  months: The end-point was the occurrence of Sudden Death (SD) or malignant ventricular tachyarrhythmias (VT).

**Results** TWA was negative in 28 Ath (65%), positive in 8 (19%) and indeterminate in 7 (16%). All subjects with negative TWA did not show induction of VT at EPS, with significant correlation between negative TWA and negative EPS ( $p<0.001$ ). All Ath with positive TWA also had VT induced by a EPS, with significant correlation ( $p<0.001$ ). In 2 Ath with undetermined TWA (29%) VT were induced at EPS. Our data did not show significant correlation between indeterminate TWA and positive or negative EPS. However, there was significant correlation between abnormal TWA test (positive or indeterminate) and inducibility of VT at EES ( $p<0.001$ ). During follow-up we observed a significant difference in end-point occurrence (VT or SD) between Ath with negative or positive TWA (0% vs 37.5%) and between Ath with negative or positive EPS (0% vs 30%).

**Conclusion** TWA confirm its role as a simple and non-invasive test, and it seems useful for prognostic stratification of Ath with VA. Furthermore, there is a significant correlation between TWA and EPS results.

### PROGNOSTIC ROLE OF NON SUSTAINED VENTRICULAR TACHYCARDIA IN PATIENTS WITH DILATED CARDIOMYOPATHY AND DIFFERENT DEGREE OF LEFT VENTRICULAR DYSFUNCTION

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**Background** The prognostic value of non sustained ventricular tachycardias (nsVT) in patients with dilated cardiomyopathy (DC) is not well defined.

**Aim of the study** To evaluate the role of nsVT and their characteristics (frequency, length and rate) for the prediction of major ventricular arrhythmias (MVA) in patients with DC on tailored medical treatment.

**Methods and Results** Among 351 consecutive patients with DC, 319 were evaluated 1 year after diagnosis on optimal medical treatment (ACE-inhibitors 88%, beta-blockers 82%) to predict the risk of MVA during the following  $94\pm 48$  months. Thirtytwo patients were excluded because of heart transplantation or death, sudden in 11 (3.1%), occurred before the evaluation. From diagnosis to evaluation median left ventricular ejection fraction (LVEF) increased from 0.29 to 0.41 ( $p<0.001$ ) and the proportion of patients with nsVT decreased from 47% to 26% ( $p<0.02$ ). In patients with  $LVEF\leq 0.35$  at evaluation, the occurrence of MVA (4/100 patient-years) was not correlated with nsVT. NsVT were associated with a higher rate of MVA only in patients with  $LVEF>0.35$  ( $3.4$  vs  $1.8/100$  patient-years in patients with and without nsVT;  $p=0.003$ ); in this group, 2 or more nsVT/day (HR=5.33; CI 1.59-17.85) and longer nsVT (HR for every 2-beat increase

1.81; 95% CI 1.13-2.92) were correlated with a higher risk of MVA at multivariate analysis.

**Conclusions** After medical stabilization, nsVT were less frequent in patients with DC and did not increase the risk of MVA in the subgroup with LVEF  $\leq$  0.35. The number and the length of nsVT runs were significantly related to MVA only in subjects with LVEF  $>$  0.35.

### EVALUATION OF HRV AND REPOLARIZATION DISTURBANCES AS A POTENTIAL SUDDEN CARDIAC DEATH PREDICTORS IN CHILDREN WITH HYPERTROPHIC CARDIOMYOPATHY

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The aim of study was evaluation of the HRV parameters and duration of QRS complexes, QT and transmural QT as sudden death predictors in children with hypertrophic cardiomyopathy (HCM).

Study population consisted of 8 children: 5 boys and 3 girls aged from 1,5 to 18 years (mean 12,3 years) with hypertrophic cardiomyopathy and increased risk of SCD. Control group consist of 18 children sex and age matched to the studied group.

Based on 12-lead ECG recorded in all pts, the following parameters were evaluated:

- duration of QRS complex, maximal duration of QTc interval and dispersion of QTc intervals (dQT)

- transmural QT dispersion (t-QTd) - mean duration of T wave, measured from peak to end (in leads V5 and V6).

The following HRV parameters were evaluated based on 24-hour ECG: standard deviation of RR intervals (SDNN), root mean square of successive differences (rmsSD) power spectrum of low (LF) and high (HF) frequencies as well as HF/LF balance.

**RESULTS** Children with HCM revealed significantly prolonged QTc intervals (542,5 vs. 408,3 ms,  $p < 0,001$ ) as well as dispersion of QTc (134,8 vs 42,5 ms,  $p < 0,001$ ), transmural dispersion of repolarization - tQTd (91,4 vs 59,8 ms,  $p < 0,02$ ) and LF/HF HRV balance (3,48 vs 1,19,  $p < 0,001$ ). Parasympathetic-related HRV parameters were significantly depressed in pts with HCM (rmsSD - 22,3 vs 46,1 ms;  $P < 0,02$ ; HF power spectrum (0,08 vs 0,301s<sup>2</sup>  $p < 0,001$ ) whereas SDNN (147,3 vs 125,5) and sympathetic-related LF power spectrum did not differ significantly. Mild prolongation of QRS was observed in pts with HCM (98,5 vs 77,6 ms,  $p < 0,06$ )

### CONCLUSIONS

1. Children with hypertrophic cardiomyopathy presents significant disturbance of repolarisation
2. Changes of HRV observed in children with hypertrophic cardiomyopathy are mainly related to lack of parasympathetic drive.
3. Both HRV and ventricular depolarization parameters seems to be useful in risk stratification in children with hypertrophic cardiomyopathy.

### VAGAL TONE MEDIATED IDIOPATHIC VENTRICULAR FIBRILLATION

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**Background** Some cases of idiopathic ventricular fibrillation (VF) triggered by premature ventricular complex (PVC) from the right ventricular outflow tract (RVOT) have been reported. However, the autonomic tone precipitating development of such VF has been rarely elucidated.

**Case** A 25-year-old female experienced 3 episodes of syncope with seizure for 2 years. No structural heart disease was pointed out. Holter ambulatory monitoring revealed 81 monofocal PVCs from RVOT per day occurring at night. The tilt table test could not induce neurally-mediated syncope, however, immediately after tilt down accompanied by decrease in heart rate, PVCs occurred with bigeminal cycle followed by 8 beats of nonsustained polymorphic ventricular tachycardia. Another episode of syncope was triggered by severe pain during veno-puncture. The ECG monitoring showed that PVCs occurred after the prolongation of RR interval leading to polymorphic ventricular tachycardia degenerating into ventricular fibrillation, which terminated spontaneously in 30 sec. No ventricular arrhythmias were induced by programmed electrical stimulation. Beta-blockade or adenosine triphosphate could not induce PVCs, however, edrophonium administration induced couplets or triplets of PVCs from RVOT. Brugada syndrome or long QT syndrome was excluded by administration of pilsicainide or K channel blockade. Catheter ablation for the culprit PVCs from RVOT induced by edrophonium prevented the occurrence of VF. Although an implantable cardioverter-defibrillator was implanted, neither VF nor nonsustained VT has been recorded over 3 years of follow up.

**Conclusion** Idiopathic VF triggered by PVC from RVOT contains a clinical entity in which the VF develops exclusively under high vagal tone.

## PACING, ICD AND PATIENTS QUALITY OF LIFE

### ECHO VALIDATION OF SERIAL AV DELAY OPTIMIZATION BY ELECTRICAL VELOCIMETRY

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Changes in thoracic electrical conductivity can be analyzed by Electrical Velocimetry (EV) in order to determine hemodynamic parameters and to optimize individual AV delay.

**Aims** To validate utilization of EV to individualize optimal AV delay (AVD) in AV block (AVB) and congestive heart failure (CHF) pacing by echo.

**Methods** Pacemaker related interatrial conduction intervals (IACT) in VDD and DDD pacing were measured in 35 pacemaker patients (17 AVB, 18CHF, mean age 66,7±7,2years) by oesophageal left atrial electrogram of the Biotronik ICS3000 programmer (Biotronik, Berlin). Using the new AESCULON cardiovascular monitor (Osypka Medical, Berlin and San Diego), we performed serial AVD scan by 30s EV recordings to determine optimal AVD in VDD pacing by maximal cardiac index. Optimal AVD for DDD pacing was calculated by adding individual difference between IACT in DDD and VDD operation. Results were compared by echo.

**Results** In all patients, EV recordings during right and simultaneous biventricular VDD pacing resulted in optimal AVD. Comparing EV and echo optimization, we found significant ( $p=0,01$ ) correlation ( $k=0,92$ ) with mean difference of 3,8±17,5ms.

**Conclusions** 1. Electrical Velocimetry is a valid serial method to individualize AVD in AVB and CHF pacing. 2. Results significantly correlate with echo. 3. Individual IACT measurement can be utilized to reduce every serial AVD optimization to either VDD or DDD pacing.

### COMPARISON OF DDD-CLS RATE ADAPTIVE PACING VERSUS FIXED DDD PACING: EFFECT ON AUTONOMIC BALANCE

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Evidences exists the artificial pacing may induce short and long term modification of the parasympathetic and sympathetic autonomic function. We compared the heart rate, blood pressure and heart rate variability changes with respect to spontaneous activity, resulting from atrial paced beats occurring either at fixed rate (DDD) or at a physiological-like rate (DDD-CLS). We simultaneously and continuously measured beat-to-beat heart rate and blood pressure for 24 hours in patients implanted with Inos2+ (Biotronik GmbH, Berlin, Germany). A randomized cross-over comparison of DDD-CLS and DDD pacing was done by short- (5 min) and long-term (24h) time domain analysis, and by frequency domain analysis (low frequency and high frequency spectral power of spontaneous RR intervals). The DDD-CLS pacing mode had no influence on systolic pressure, while it resulted in lower diastolic pressures (3.7%), probably expression of the longer RR intervals of the paced beats. This behaviour was observed also in the comparison between DDD paced and spontaneous beats, where a 9.6% decrease in diastolic pressure was obtained. During DDD pacing mode, systolic pressures of spontaneous beats were higher (7.9%) than paced values, which were instead comparable to the values measured during DDD-CLS. Low Frequency power was higher after DDD fixed rate pacing, compared to CLS (173.0 vs 84.9 msec<sup>2</sup>); high frequency power was similar in the two stimulation modes. An increased spontaneous systolic pressure during DDD and an increase of the RR interval low frequency power could be expression of a shift toward sympathetic predominance. We may hypothesise that long-

term fixed rate DDD pacing results in compensatory mechanisms that might exert blood pressure control in the absence of heart rate modulations.

### QUALITY OF LIFE IN PATIENTS WITH ICD AND BIVENTRICULAR ICD

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**Background** Implantable Cardioverter Defibrillator (ICD) is an important tool in reducing mortality of patients (pts) with malignant arrhythmias. Biventricular-ICD (BIV-ICD), moreover, can resynchronize ventricular contraction in pts with left bundle branch block and ventricular dissynchrony. But the quality of life of these pts could be deteriorated.

**Aim** Investigate the degree of psychophysical well-being in pts with ICD and BIV-ICD and monitor the effects of the device on quality of life.

**Methods** Our population is composed of 27 pts (24 male), mean age 66±9 years, 4 in NYHA class II and 23 in NYHA class III, submitted to ICD implant (15) or BIV-ICD (12). All of them compiled, before and one month after the implant of the devices, 2 questionnaires: the AD/Rehabilitation card, which evaluates state anxiety and mood score, and the Short Form 36 (SF 36), useful for the evaluation of bodily and mental health. They were also submitted to a psychological interview.

**Results** Before the implant the scores of state anxiety is statistically significant greater (21±5) than after the implant (16±6; $p=0.01$ ). As regard mood, mean scores worse after the implant (6±2 vs 5±2) and this has a negatively effect on the quality of life, particularly on physical role (29±3vs21±3), emotionalism (32±3vs63±4 $p=0.029$ ) and mental health (67±2vs64±2). Improvement in quality of life was observed as regard the scores of physical activity (48±3vs53±3), pain perception (32±3vs63±4), general health (39±2vs8±2 $p=0.034$ ) and vitality (55±3vs57±2). No changes as regard social activities (68±3vs68±3). The changes in the scores of health change scale (3.6±0.8vs2.8±1.2 $p=0.018$ ) indicate that most of the pts perceive their health status as improved.

**Conclusions** In our experience ICD and BIV-ICD have beneficial effects on physical aspects, but increase the degree of anxiety and depression. These effects could be an adaptation to the devices and a psychological support could facilitate this process from the pts.

### MONITORING OF THE INTRATHORACIC IMPEDANCE IN PATIENTS WITH CHRONIC HEART FAILURE

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**Background** Prevalence of patients (pts) with chronic heart failure (CHF) worldwide is increasing. CHF is a major cause of mortality and hospitalization.

Several studies showed that intrathoracic impedance decreases during intrathoracic fluid accumulation.

**Aim:** To assess intrathoracic impedance monitoring in ambulatory pts with CHF.

**Methods** 60 pts (15% female, age 68+/-9, FE=27%+/-7) with CHF eligible for CRT-ICD implantation according to current guidelines, were enrolled in the study and divided into two clinically comparable groups. Group-A (30pts) received a Medtronic InSync Sentry™

system with OptiVolTM-Fluid-Status-Monitoring and Patient-Alert. Group-B received a conventional CRT-ICD system. Pts underwent every 4 months a complete follow-up, including clinical assessment and device functionality test. Hospitalizations due to CHF and other visits due to CHF-symptoms or device alert were tracked. Modifications in drugs administration were recorded, including those resulting from the analysis of the device diagnostics, the Cardiac-CompassTM (i.e. thoracic-impedance-index, heart-rate, heart-rate-variability, level of exercising from the rate responsive sensor). Average FU was 11+/-6 months.

**Results** All-cause hospitalizations:3 in group-A vs 9 in group-B;CHF-hospitalizations:0 vs 5 (p=0,02). Further visits:2 in group-A vs 1 in group-B (p=0,6);drug therapy modifications:7 vs 10 (p=0,39), 4 vs 10 of those from symptoms occurrence and 3 vs 0 from device diagnostics indices. Deaths:2 in group-B.

Analysis of Cardiac-CompassTM in group-A showed a significant increase of the OptiVolTM index in 10 cases:5 due to CHF-symptoms, 1 due to temporary suspension of therapy, 1 due to influence, and 3 false positives.

**Conclusions** OptiVolTM could be a useful tool to reduce hospitalizations, allowing an early modification of the therapy before symptoms occurrence. Nevertheless, an evaluation of clinical and Cardiac-CompassTM data is needed, as intrathoracic impedance rise alone, following cardiogenic pulmonary congestion or other causes, is poorly specific.

Sensitivity and Specificity of the OptivolTM cannot be assessed, as population size and follow-up period duration are not sufficient to infer general conclusions.

### HEART RATE VARIABILITY AND QUALITY OF LIFE IN ELDERLY PATIENTS WITH SINUS BRADYCARDIA PACED WITH CLOSED LOOP STIMULATION OR CONVENTIONAL ACCELEROMETRIC-SENSOR-BASED DDDR

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Close Loop Stimulation (CLS) bases heart rate modulation principle on an indirect analysis of contractility determined by autonomic nervous system. Therefore, a wider sampling of paced heart rates is expected as compared with a standard accelerometric sensor. Our aim was to assess whether this results in an advantage for a selected elderly patients in terms of quality of life (QoL) score.

**Methods and results:** 23 elderly patients (age 77 ± 8; 10 male) with severe sinus bradycardia received a Biotronik Protos DR/CLS pacemaker and were randomized to CLS or conventional DDDR pacing mode. Follow-ups were scheduled at 1 month, for pacemaker programming optimization, and at 3 month for data collection. Quality of life were assessed at baseline and 3 months after implantation by means of a recently introduced Aquarel questionnaire, specifically

designed for pacemaker patients (Cronbach's alpha: 0.73 - 0.92). Also at 3-month follow-up long-term standard deviation of atrial rate (ASD) was collected. 6 patients presenting with an atrial pacing percentage <90% and 4 with frequent and/or sustained atrial tachyarrhythmias (burden >5%), were ruled out. Baseline Aquarel QoL scores and their increment at 3-month follow-up in the CLS and the DDDR groups are *in the table*.

At three months, ASD was higher in the CLS group (9.5 ± 3.5 bpm), than in the DDDR group (8.7 ± 3.8 bpm; p=0.041, unpaired t-test).

**Conclusions** Both CLS and DDDR increased Aquarel QoL scores, although CLS trended better. It is not clear whether this trend is clinically relevant and correlate with the wider long-term ASD observed. Further investigation and larger population are need and expected.

### VALIDATION OF ATRIAL TACHYARRHYTHMIA BURDEN AS REPORTED IN HOME MONITORING TRANSMISSIONS BY 24 HOURS HOLTER RECORDING. A METHOD TO EFFICIENTLY COLLECT DATA

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Daily atrial tachyarrhythmia (AT) burden, expressed as percentage of 24 hours spent in Mode Switch (MS) by a pacemaker patient, is part of the information reported by Home Monitoring (HM) every day. We have elaborated a HM-based method to clinically validate the AT burden data transmitted by HM through standard 24 h Holter recording.

We analyzed 3-months follow-up data from 196 brady-tachy syndrome (BTS) patients (48% male, age 73 ± 6) with at least one documented AT episode within 3 months prior to implant of a Biotronik HM-pacemaker. 74 patients had at least one MS episode within 24 h before follow-up, therefore the overall probability to document a MS episode in a 24 h Holter performed 3 months after implant in that patients is 38 ± 4% (95% CI: 31-45%). This estimate increased up to 76 ± 7% (95% CI: 60-87%), considering only those 41 patients (21%) with >20% pacemaker AT burden. Furthermore, we tested two logistic models to predict a MS occurrence within 24 h before follow-up. The first model, including age, gender, NYHA class, left atrium size, antiarrhythmic drugs, did not reach statistical significance (p=0.32). The second logic model, including number of MS within 48 h (p=0.32), 72 h (p=0.01), 96 h (p=0.94) before follow-up, number of MS (p=0.003) and duration of the longest MS episode (p=0.44), resulted statistically significant (p<.0001). The probability estimate reaches 53 ± 8% (95% CI: 38-69%), selecting patients with at least 3 MS episodes, of which at least 1 occurring within 72 h before follow-up.

Basing on these results, we propose to immediately recall HM patients for Holter recording whenever HM reports indicate >20% AT burden, or at least 1 MS episode for two consecutive days, disregarding other clinical variables. This method is being tested and should result in a success rate > 40%.

Table.	CLS		DDDR	
	Baseline	3-month increment	Baseline	3-month increment
Chest discomfort	80.1	5.2%	82.4	4.1%
Dyspnoea and exertion	51.7	21.6%	53.9	19.5%
Arrhythmias	63.7	19.7%	66.7	16.2%

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### INESSANT VENTRICULAR TACHYCARDIA BRADYCARDIA DEPENDENT - 3 YEAR FOLLOW-UP

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**CASE PRESENTATION** A 45-year old patient has idiopathic dilated cardiomyopathy (IDCM) (LVEF 10%, QRS 110 msec, NYHA III). He has often episode of the IVT refractory to antiarrhythmic drugs. Last RF ablation and often DC electroconversions are unsuccessful. Duration of the VT was permanent in days and spontaneously stopped. The longer episode has 21 days.

We performed electrophysiology study and located 3 focus of VT with different fr (120, 140 i 180 bpm). Repetitive RF ablation was unsuccessful. During the hospitalisation VT was 8-time converted with DC shock and i.v. infusion of the Amiodaron. Because the patient has incessant VT we concluded that the implantation of the implantable cardioverter-defibrillator (ICD) was not convenient solution. In the intensive care unit (I.C.U.) patient was on the continued ECG monitoring; he has often the synus bradycardia and sometime has pause > 3.0 sec, after them appears VT. We implanted temporary pacemaker.

For the 15-days period spontaneous fr was < 50 bpm and we implanted Affinity DDDR P.M. (of the St. Jude Medical). During the implantation of the P.M. patient appears VT (fr 140 bpm). VT was stopped with ventricular overdrive pacing. In the I.C.U. for next 2 weeks and on the follow up control (6-th, 12-th, 24-th and 36-th months), patient was haemodynamically stable (last measure LVEF 20% and NYHA II). He was all time with pacing rhythm (AP-VP 9%, and AP-VS 91%) and without new attacks of the VT.

**CONCLUSIONS** IVT in this patient onset with bradycardia. P.M. protects patient of the bradycardia, and in the prevention of the IVT he has Amiodaron. He is candidate for the heart transplantation and we included them at the transplant list.

### VT SURGERY NAVIGATED BY CARTO SUBSTRATE MAPPING

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**Objectives** Aim of this retrospective analysis was to study effect of surgical remodeling and cryoablation of the arrhythmogenic and severely dysfunctional LV in the patients after myocardial infarction (MI).

**Background** The main indication for ICD therapy is to reduce the risk of sudden cardiac death due to life threatening ventricular tachyarrhythmias (VTA). One possibility is to map arrhythmogenic substrate before the surgical procedure.

**Methods** In our retrospective study we analyzed 15 patient after MI (9 men, 6 women, 63,8 ± 7,6 years) who were indicated for open heart surgery. The mean LV EF was 32%. In all patients we documented monomorphic ventricular tachycardia (VT) during electrophysiological programmed stimulation (EPS) and they were indicated for open heart surgery. Before surgery we mapped substrate with CARTO system and define VT substrate for surgeon. We put RF lesions in certain spots for identification critical sites. Encircling cryoablation was used to eliminate arrhythmogenicity according the CARTO map either with or without aneurysmectomy. After one month after surgical procedure EPS was performed again to indicate VT induction.

**Results** We finished successfully surgical procedure in all 15 patients with previous CARTO LV mapping. We could identify specific arrhythmogenic substrate with dense scar surrounding by border zones in all patients. In only 5 patients we mapped post MI scar or aneurysm in the inferior wall. In 11 patients complete aneurysmectomy was performed together with cryoablation. CABG was not performed in

only 4 patients. RF lesions were identified in all cases we used RF during CARTO mapping (7 patients). During EPS after surgery we induced VT in only one patient and he got ICD. During follow up of 16 months we didn't observe any VT recurrence.

**Conclusions** We conclude that CARTO might be used when VT surgery is planned to help eliminate inducibility of VT. This complex approach is feasible safe

### THE BRUGADA SYNDROME REGISTRY OF THE PIEMONTE REGION: MANAGEMENT AND FOLLOW-UP

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**Purpose** The issue of risk stratification in Brugada syndrome is still unanswered. In this study the data of the Registry of the Piemonte Region are reported. A standardized approach was adopted, especially regarding the electrophysiologic study (EP). Follow-up data was obtained.

**Materials and methods** Patients had Brugada type 1 ECG spontaneously or after flecainide or ajmaline test. Clinical and familial history were collected. Programmed stimulation was performed from two right ventricular sites, at two pacing cycle lengths with up to two extrastimuli to the ventricular refractory period. ICD was implanted in patients with previous cardiac arrest and in those with sustained ventricular arrhythmias induced at EP study.

**Results** 118 patients were included: 100 males (85%) and 18 females (15%). Fifty-nine patients were asymptomatic (50%) and 59 symptomatic (50%): 4 patients with aborted sudden death and 51 patients with syncope (syncope without prodromes in 40%). The first symptom occurred at a mean age of 45±14 years.

EP study was performed in 95 patients (50 symptomatic and 45 asymptomatic) (81%). Sustained ventricular arrhythmias were induced in 33 patients, 35%: 46% of 23 symptomatic patients and 21% of asymptomatic (10 pts) (p=0.02). Fifty patients (42%) underwent ICD implant. At a mean follow-up of 24±18 months, 7 events occurred. Six patients received an appropriate ICD shock and an asymptomatic patient who had refused EP study died suddenly during sleep. Six ICD shocks occurred in symptomatic patients (10%), but none in the asymptomatic: 2 occurred in the group with syncope with prodromes, 2 in the group of syncope without prodromes and 2 in the group with previous cardiac arrest. No event was observed in the patients not induced at EP study.

**Conclusions** In this study the high risk patients were correctly identified by EP study. Apparently vaso-vagal syncope does not imply a good prognosis.

### PROPORTION OF PATIENTS WITH IDIOPATHIC DILATED CARDIOMYOPATHY AND AICD INDICATIONS AT DIAGNOSIS AND DURING FOLLOW-UP

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**Background** Recently published trials on ICD defined the characteristics of patients (pts) with idiopathic dilated cardiomyopathy (DC) who should be treated with these devices; however, trials involving pts with a recent diagnosis failed to show a benefit from ICD implant-

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tation, probably because a significant improvement on optimal medical therapy is possible in many cases, with consequent risk reduction.

**Methods** Patients with idiopathic DC enrolled in our Registry from 1988 to 2006, april were evaluated at diagnosis and after 6, 12, 24 months (mo) and after 6 years to analyse the number of candidates to ICD implantation according to SCDHeFT criteria (LVEF <= 0.35, NYHA class II-III).

**Results** 605 patients (age 45±14, LVEF 0,32 ± 0.11, 23% in III-IV NYHA class) were evaluated at diagnosis and during follow-up. During this period 80% were treated with beta-blockers and 86% with ACE-inhibitors. The proportion of patients who satisfied SCDHeFT criteria dropped from 47% (at diagnosis) to 20% after 6 months. During this period all cause mortality was 6% and 4% in pts with and without SCDHeFT characteristics, while SD rate was respectively 1.8% and 1.9%. For the period of follow-up, the proportion of pts with SCDHeFT characteristics remained stable (20% at 12 mo, 18% at 24 mo and 20% after 6 years). The presence of higher LVEF considered at enrolment was associated with lower probability of maintaining indications to AICD after 6 mo (for interquartile range increase OR 0.43, 95% CI 0.27-0.69, p<0.001).

**Conclusions** The proportion of patients with DC meeting criteria for ICD implantation according to SCDHeFT criteria diminished significantly after 6 months on optimal medical treatment; during this period, total and especially sudden mortality rate were similar in patients with and without SCDHeFT characteristics; this should be considered for the choice of timing of implantation.

### RULE OF ICD IN PRIMARY PREVENTION: MULTICENTER STUDY (AURA PILOT STUDY)

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**Aim** To evaluate the impact of recent guidelines on prevention of sudden death in clinical practice.

**Methods.** Fifty five patients (male 86%, mean age 64±11.6 years, left ventricular ejection fraction (LVEF) 29±6%, New York Heart Association functional class 2.7±0.6, ischemic 57%, primitive dilated cardiomyopathy 43%) received an implantable cardioverter defibrillator (ICD) for sudden death primary prevention due to LVEF<35%. ICD were programmed with Ventricular Tachycardia (VT) (160-200 bpm) and Ventricular Fibrillation (VF) (> 200 bpm) zones. Shock therapy was programmed in VF zone and anti-tachy pacing (ATP) (Schaumann protocol) and shock therapies were programmed in VT zone. Each patient was followed-up on three month bases and a final device report was collected after 18 months.

**Results** An appropriate ICD intervention was reported in 19/51 (37%) patients. Seven patients had at least one intervention in VF zone (13.7%) and fifteen had at least one intervention in VT zone (29.4%). Four patients died during the follow-up.

**Conclusion** In clinical practice mortality is quite comparable with the most important trials, instead the percentage of patients with appropriate ICD intervention in VF and VT zones is slightly superior than expected from clinical trials. Our observations support the wide ICD implantation in patients with reduced LVEF.

### CAN WE SOLVE THE AESTHETIC PROBLEMS RELATED TO DEFIBRILLATOR IMPLANT IN YOUNG WOMEN?

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Dimensions of Implantable Cardioverter Defibrillators (ICD) are relevant. Also in subpettoral position, a swelling is often appreciable and the cut dimension is considerable, with important aesthetic problems.

To solve this problem, we planned a new implant technique. 3 women (age 36, 38 and 41 years) have been implanted with a dual chamber ICD for Long QT Syndrome (1) and with a dual chamber biventricular ICD for Idiopathic Dilated Cardiomyopathy (2). After the percutaneous pick of the subclavian vein, the leads were introduced (by a peel-away introducer), opportunely positioned and finally fixed on the pectoral muscle. The cut necessary to get the muscle and fix the leads was about 1.5 cm in subclavicular position. Successively, a second cut was performed in sub mammalian position and then the sub pectoral muscle was stripped in order to prepare the pocket. The leads have been allocated in the pocket by tunnelling (using a portex thoracic catheter 32 F) and connected to the device, which has been fixed to the muscle. The two cuts have been closed, using Dexon 0 size for the muscle and the subcutaneous tissue and Nylon 00 size for the skin. The defibrillation test have been successfully performed in all three patients. The pocket preparation and closure, in general anaesthesia by Propofol, reached 23±8 minutes and the patients have been discharged, as usually, after 24 hours. At the first follow-up, after 12 days, the two breasts were perfectly proportioned and the only cut visible was in subclavicular position. At 3 months follow-up no dislodgment of the device was observed and the patients complained no symptoms related to the device position.

In conclusion, this technique should be used in all young patients, where the aesthetic problem surely contributes to worsening of the procedure psychological impact and to declining the acceptability of the device implant.

### ROLE OF EARLY CPR IN OUT-OF-HOSPITAL CARDIAC ARREST - TRIDENTE VITA ROMA PROJECT

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**Purpose** Sudden cardiac death is caused in 80-90% of cases by ventricular tachycardia and/or ventricular fibrillation. Early use of external defibrillators (AED) is essential to improve the number of survivors. Our aim was to evaluate the impact on survival of cardiopulmonary resuscitation (CRP) performed by witness to cardiac arrest in a regional project of early defibrillation.

**Material and Methods** We delivered 37 AED to volunteers from traffic police, railway police and firemen: 24 were placed in movable positions (police vehicles), and 13 in fixed positions. We trained, and re-trained every six months, 512 volunteers (first responders). The time required for intervention was counted from the time of the first call to the emergency services to the time the AED was switched on.

**Results** During 3 years, we registered 15 witnessed cardiac arrests, 11 of whom were treated at fixed positions and 4 from movable positions. In 8 cases victims received CRP from witnesses before first responders arrived (CPRy), in 7 cases (CPRn) cardiopulmonary resuscitation was performed only after the arrival of the first responders, when appropriate. Survival to hospital discharge was significantly more frequent in those patients who had received bystander CPR than in those whose CPR began with the arrival of emergency services (5/8

vs. 1/7,  $p < 0.05$ ). There were no significant differences between the two groups in the time required for intervention or in the subjects characteristics.

**Conclusions** In accordance with the ILCOR 2005 guidelines, our data show a considerable improvement in survival in subjects who underwent early CRP. Most interventions were performed at fixed positions (11/4 vs 4/24) because the current organisation of the emergency response service does not permit the prompt assignment of an appropriately equipped vehicle to an arrest situation.

### PRELIMINARY EXPERIENCE OF THE IMPLEMENTATION OF AUTOMATED EXTERNAL DEFIBRILLATORS IN A LARGE BOLOGNA CONDOMINIUM

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**INTRODUCTION** The highest incidence of cardiac arrest (CA) has been observed at patient's house.

Automated external defibrillators (AED) have been implemented in large malls, airports, schools, but not in condominiums.

**PATIENTS AND METHODS** In collaboration with Italian

Physiocontrol Medtronic we implemented two AEDs (and one with Leardal) in three buildings of a large Bologna condominium, in which 120 families live. **RESULTS** For two years, we monitored with the AEDs, 5 patients with an acute coronary syndrome (ACS), chest pain or dizziness, while waiting for a 118 Bologna Soccorso ambulance, at the patient's house. In 2006 we monitored 2 patients, one with a stroke and one with a total AV block, while waiting for a 118 Bologna Soccorso ambulance. All patients were later transferred to the emergency department for primary PTCA.

Recently, in January and May 2006, in both cases, together with one son of the patients we took care of subjects suffering from CA. In the first case, the subject experienced CA due to VF. He was adequately monitored and cardioverted according to AED voice informations. The second case, suffered from recurrent VT. The patient was defibrillated 14 times. Both were later admitted to the hospital and received an ICD implantation.

**CONCLUSIONS** AED can be easily implemented in a large condominium, where many subjects are ready to take the CPR course and certificate in the local 118-Bologna Soccorso school.

A direct telephone connection should be made available with the local 118-Bologna Soccorso, to simultaneously alert the emergency ambulance. Many patients have been successfully monitored for 20 minutes, while waiting for an emergency ambulance. CA can be adequately treated by relatives and family members when AED are available close to the patient's house

## ATRIAL FIBRILLATION ABLATION

### ATRIAL FIBRILLATION TERMINATION MODE DURING ABLATION WITH DIFFERENT STRATEGIES: COMPARISON BETWEEN PAROXYSMAL AND PERMANENT ATRIAL FIBRILLATION

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**BACKGROUND** Whether different ablation strategies affect atrial fibrillation (AF) termination depending on the paroxysmal or permanent nature of the arrhythmia is unclear. AF termination during ablation was either conversion to SR or organization into atrial tachyarrhythmia (AT).

**OBJECTIVES** We compared the effect of AF ablation on the AF termination for parox-AF versus perm-AF using two common AF ablation strategies.

**METHODS** One hundred and forty four consecutive scheduled for AF ablation presenting in the lab in AF were parox-AF (n=47) or perm-AF (n=97). Each group was randomized to PVAI only (21 with parox-AF and 48 with perm-AF) versus bi-atrial ablation of the complex fractionated atrial electrograms (defragmentation) including the coronary sinus followed by a PVAI (24 patients with parox-AF and 49 patients with perm-AF). Modes of AF termination were: conversion to SR, organization into AT or persistence of AF requiring cardioversion following ablation.

**RESULTS** are summarized in table.

There was no significant difference between the groups in term of sex, age, AF duration, LA size and EF. AF conversion to SR was significant for parox-AF (38%), but rare for perm-AF (5%). Defragmentation alone, performed before PVAI either for parox-AF or perm-AF, terminated the AF only in three patients (2%).

**CONCLUSION** Ablation performed during AF terminated AF in more than 80% of parox-AF independently of the ablation strategy. Defragmentation associated with PVAI had a higher effect on AF organization into AT for perm-AF compared to parox-AF. Defragmentation alone had no impact on AF termination both in paroxysmal and permanent AF.

### RECURRENCE OF ATRIAL FIBRILLATION AFTER EFFICACIOUS RADIOFREQUENCY TRANSCATHETER ABLATION OF REGULAR SUPRAVENTRICULAR TACHYCARDIA. LONG-TERM FOLLOW-UP

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Radiofrequency transcatheter ablation (RFTCA) of the focal AF, even when associated with antiarrhythmic drug treatment, has a success

rate of no more than 88%, and an early recurring rate as high as 35%. Among the triggers, regular supraventricular tachycardia (SVT) such as atrioventricular re-entry nodal tachycardia (AVRNT) and atrioventricular re-entry tachycardia (AVRT), atrial flutter (AFL), atrial tachycardia (AT) have been reported.

**Aim** To verify the usefulness and the safety of RFTCA for regular SVT in a selected study group with associated episodes of AF paroxysmal or persistent, as well as the recurrence of AF after efficacious RFTCA.

**Methods** The study population is represented by 189 patients of whom 109 males with an average age of 54±20 years who underwent electrophysiological studies (ES) and RFTCA for regular SVT with associated episodes of AF (AVRNT/AF 91/12, AVRT/AF 28/3, AFL/AF 68/22, AT/AF 4/1) and with an pre-RFTCA average recurrence of paroxysmal AF of 5+6 episodes per year. All the patients filled in the questionnaire on the quality of life (SF-36), had echocardiograms and underwent ES and RFTCA.

**Results** Out of the total of RFTCA procedure for regular SVT with associated AF, a complete success was obtained at the first procedure in all patients. Clinical follow-ups were programmed at 1, 3, 6 and 12 months and telephone follow-ups at 16 and 24 months. At the follow-up of 20+6 months no recurrence of AVNRT and AT was verified, three recurrences of AFL and one of TRAV, and no recurrence of AF was documented.

**Conclusion** RFTCA for regular SVT has shown to be a safe procedure with good long-term results. The absence of recurrence of AF, during the limited observation and study periods in this selected population, can most likely be attributed to the elimination of the trigger represented by regular SVT.

### EXTENSIVE LINEAR APPROACH IN ABLATION OF ATRIAL FIBRILLATION

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**Purpose** Atrial fibrillation (AF) is the most common supraventricular arrhythmia, nevertheless its therapy is far to be considered definite. Ablation of AF has been proposed both in absence and in presence of structural heart disease. Surgical ablation of AF showed good results even in structural heart disease due to multiple linear lesions. Little is known about the feasibility and effectiveness of transcatheter linear approach.

**Materials and Methods** Two hundred and fifty pts with (115) and without (135) structural heart disease were submitted to ablation of atrial fibrillation (AF) with left atrial linear lesions, with irrigated tip radiofrequency catheter, including encircling of pulmonary veins, roof, left isthmus, posterior wall between the two encirclings. If AF was still inducible with a 5 sec 250 bpm atrial burst a septal line (mitral annulus- right inferior pulmonary vein) and if still inducible anterior line (mitral annulus right superior pulmonary vein) were added. Visit, ECG and Holter were performed after a month and once every three months.

**Results** After a follow up of 400 +/-230 days, success rates were 84%, and 88% with drugs. A three months echocardiographic evaluation showed a preserved atrial contractility and mitral flow.

Recurrences were left atrial flutter in 23,1% and AF in 76,9%. In

**Table.**

	PVAI in parox-AFN=21	PVAI in perm-AFN=48	P value	PVAI+defrag in parox-AFN=24	PVAI+defrag in perm-AFN=49	P value
SR	6 (29%)	3 (6%)	0.019	12 (50%)	2 (4%)	P=0.002
AT	11 (52%)	18 (38%)	NS	8 (33%)	34 (70%)	P=0.001
AF	4 (19%)	27 (56%)	0.004	4 (17%)	13 (26%)	NS

patients with recurrences the burden of AF was significantly decreased. The presence of structural heart disease was not predictive of the outcome, whereas the presence of permanent vs persistent vs paroxysmal AF was predictive ( $p=0,01$ ). Procedures were complicated by tamponade in 2% of cases.

**Conclusions** Transcatheter multiple linear lesion approach is feasible and highly effective in the ablation of atrial fibrillation even in presence of structural heart disease.

### NON INDUCIBILITY OF ATRIAL ARRHYTHMIAS AFTER LINEAR ABLATION OF ATRIAL FIBRILLATION

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**Purpose** Ablation is an effective tool in the treatment of paroxysmal atrial fibrillation. The achievement of non inducibility of sustained atrial flutter and fibrillation has been reported to improve pulmonary veins isolation late results. Aim of the study was to establish the usefulness of non inducibility even after linear ablation of paroxysmal atrial fibrillation.

**Materials and methods** A hundred and twenty patients (pts) with paroxysmal atrial fibrillation were submitted to ablation of atrial fibrillation with irrigated tip radiofrequency catheter applying left atrial linear lesion including encircling of pulmonary veins, roof, left isthmus.

In 48 pts (40%) no further procedures were performed (group 1) In 72 pts (60%) a 5 sec 250 bpm atrial burst was performed. In 48 pts (66%) non sustained (> 5 minutes) atrial arrhythmias were induced (group 2). In 24 (33%) pts sustained atrial arrhythmias were induced and 12 (50%) of them were ablated (group 3) whereas 12 were not (group 4).

**Results** After a follow up of 300+/- 145 days later recurrences rates of atrial flutter and fibrillation were evaluated: 13% in group 1, 12,5% in group 2, 17% in group 3 and 14% in group 4.

No statistically significant differences were found among the four groups. The ablation of the induced arrhythmias required a mean procedure time prolongation of 1 +/- 0,5 hours.

**Conclusions** In paroxysmal atrial fibrillation after linear ablation including encircling of pulmonary veins, roof, left isthmus, the achievement of non inducibility of sustained atrial arrhythmias is time consuming and seems not to predict the late outcome.

### TIME COURSE ANALYSIS OF THE NEUROHORMONAL PROFILE BEFORE AND AFTER LEFT ATRIAL ABLATION IN PATIENTS WITH ATRIAL FIBRILLATION

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**Background** left atrial ablation is a new and growing therapy to face atrial fibrillation; results seem good, despite ablation techniques are quite different. Little is known about the real benefit of the rhythm restoration on haemodynamic and neurohormonal profile in patients with atrial fibrillation treated with left atrial ablation.

**Methods and results** one hundred-eleven patients affected by paroxysmal or persistent atrial fibrillation were treated with circumferential pulmonary-vein ablation and additional lines in the posterior left atrial

um, roof and mitral isthmus. All patients were studied with clinic examination, echocardiography and neurohormonal profile (BNP, endothelin, TNF alpha, aldosterone, epinefrine) before ablation and 2, 6 and 12 months after. Results are depicted in table 1.

**Conclusions** in atrial fibrillation patients treated with left atrial ablation we observed significant improving in the ejection fraction and reduction in BNP plasma level during the first year after ablation.

**Table 1.**

	baseline	2 months	6 months	12 months	p
EF %	51±8,4	53,4±7	56±5	58±4	0,001
BNP pg/ml	54,9±75	42,8±51,2	44,2±60	27,6±39	0,013

### ATRIAL RESYNCHRONIZATION THERAPY IN PATIENTS UNSUITABLE FOR LEFT ATRIAL ABLATION PROCEDURES FOR THE MANAGEMENT OF ATRIAL FIBRILLATION

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**OBJECTIVE** To determine whether patients who are unsuitable for left atrial (LA) ablation, would respond to treatment of their atrial fibrillation (AF) with atrial resynchronization by bi-atrial pacing.

**METHODS** We analyzed the outcome of bi-atrial pacing in our atrial resynchronization program according to whether the patients were deemed suitable or unsuitable for LA ablation and compared their outcome with regard to symptoms, antiarrhythmic drug requirement, AF episodes and hospital admissions. 17 patients were considered unsuitable for ablation therapy due to co-morbidities like heart failure (8/17), left atrial dilatation (10/17), valvular heart disease (7/17), left ventricular hypertrophy (7/17) and severe chronic lung disease (2/17). 9 patients also had co-existent ischaemic heart disease. 14 patients were considered suitable for ablation as they demonstrated no contraindication. Mean follow-up was 32+/-20 months (unsuitable group) and 36+/-22 months (suitable group).

**RESULTS** 13/17 of the unsuitable group and 8/14 of the suitable group demonstrated significant improvement in both symptoms and AF, the difference between the 2 groups was not significantly different ( $p=0,44$ ). There was a significant improvement in mean AF episodes/month following bi-atrial pacing in both groups (suitable group pre 19.5+/-9.2, post 8.3+/-11.7,  $p=0,009$ ; unsuitable group pre 23.2+/-7.9, post 7.2+/-9.6,  $p<0,001$ ), no significant difference between the groups ( $p=0,33$ ). There was a reduction in mean number of AF admissions in both groups (suitable group pre 2.2+/-1.9, post 0.9+/-1,  $p=0,03$ ; unsuitable group pre 3+/-4.2, post 0.9+/-1.4,  $p=0,045$ ), difference between the groups not significant ( $p=0,70$ ). The mean number of anti-arrhythmic drugs was reduced in both groups (suitable group pre 3.5+/-1.3, post 1.8+/-0.9,  $p<0,001$ ; unsuitable group pre 3.5+/-1.7, post 1.5+/-0.9,  $p<0,001$ ), difference between the 2 groups not significant ( $p=0,56$ ).

**CONCLUSIONS** The efficacy in reduction of both AF and symptoms was similar in both groups. This study shows that atrial resynchronization therapy with bi-atrial pacing is effective in suppressing both symptoms and AF, thus providing an alternative for patients unsuitable for left atrial ablation procedures.

## AV AND INTRAVENTRICULAR DELAY OPTIMIZATION

### AAISAFER MODE PREVENTS VENTRICULAR PACING IN NON-SELECTED PATIENTS

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Clinical data indicate that 'ADI' pacing modes such as AAIsafeR prevent ventricular (V) pacing in patients not presenting with Atrio-Ventricular (AV) block. We report our clinical experience in consecutive non-selected patients.

**Methods** At each visit, the percentage of A and V pacing and the number of Endless-Loop Tachycardias (ELT) detected by the device were retrieved. All data collected from patients implanted with a Symphony DR 2550 pacemaker (Sorin Group/ELA Medical, France) programmed in AAIsafeR or DDD were retrospectively analyzed and compared with non-paired Student test or Fisher test as appropriate. Results were considered as significant if  $p < 0.05$ .

Our center recruited 168 patients from April 2004 to March 2006. Main pacing indication was AV block (49%), sinus node dysfunction (48%) or other indication (3%). Mean age at implant was  $80 \pm 9$  years old, and 54% of patients were males. AAIsafeR(R) was programmed in 114 patients and DDD(R) in 54. In DDD mode, mean resting AV delay was set to  $150 \pm 17$  ms.

**Results** Mean follow-up was  $8 \pm 5$  months (1-24). The table summarizes the results.

	AAIsafeR	DDD	p
Mean A pacing ± STD [Median], %	83±20 [92]	81±23 [91]	NS
Mean V pacing ± STD [Median], %	9±21 [0]	95±13 [100]	<0.00001
% of patients with 0% V pacing	61	0,3	<0.0001
Mean Nb of ELT ± STD [Median]	4±19 [0]	46±85 [1]	<0.00001

**Conclusions** In non-selected pacemaker patients, AAIsafeR significantly prevents V pacing compared to standard DDD mode. Furthermore, maintaining spontaneous AV conduction protects the patients against ELT episodes.

### LONG TERM EVALUATION OF CONVENTIONAL DUAL CHAMBER PACING IN PATIENTS WITH ADVANCED ATRIO-VENTRICULAR BLOCK AND DIFFERENT HEMODYNAMIC CONFIGURATIONS

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**Background** Conventional dual chamber right ventricular apical pacing (RVAp) decreases cardiac performance. However long term sequelae of RVAp are not widely investigated in different subgroups of patients (pts).

**Aim** Prospectively assess the long term effects of RVAp on clinical course of pts with different basal hemodynamic configurations and parameters of cardiac function.

**Population** We studied 32 selected pts (20 M, 12 F, age  $69 \pm 6$  years) with advanced atrio-ventricular block and indication for conventional DDD pacing. At enrollment post implantation pts were divided in 2 groups. Group I: left ventricular ejection fraction (LVEF)  $< 55\%$ , right ventricular ejection fraction (RVEF)  $> 45\%$ ; Group II: LVEF  $< 55\%$ , RVEF  $< 45\%$ .

**Methods** Pts were paced with echo optimized atrio-ventricular delay. Echo/Doppler was performed at baseline and after 12, 24, 36 months from implantation. At the end of each period the parameters collected were: LVEF, RVEF, left ventricular myocardial performance index (MPI), NYHA functional class and quality of life (QoL), telemetric interrogation.

**Results** At telemetry the % of ventricular paced beats was  $> 97\%$  and of atrial synchronous beats  $> 93\%$ . Multivariate analysis identified only RVEF as predictor of adverse clinical evolution ( $p < 0.001$ ). Data are reported in Table I.

**Conclusions** In pts with reduced left ventricular function MPI presented progressive worsening, however this finding alone has not clinical implication especially if RVEF is preserved. By other end RVEF strongly predicts clinical course and has a central role in the selection of pacing modality. Our data suggest that in pts with reduced LVEF particularly those with right ventricular dysfunction need an integrated/alternative pacing modality when pacemaker is indicated.

	POST IMPLANT	12 MONTHS	p	24 MONTHS	p	36 MONTHS	p
<b>GROUP I</b>							
LVEF %	50±9	49±10	NS	48±5	NS	48±7	NS
MPI	0.41±0.06	0.42±0.3	NS	0.44±0.4	0.08	0.46±0.1	0.001
QoL	10±4	11±8	NS	12±4	NS	12±6	NS
NYHA	1.6±0.4	1.7±0.8	NS	1.8±0.5	NS	1.9±0.4	NS
RVEF %	49.±7	48±5	NS	48±8	NS	47±5	NS
<b>GROUP II</b>							
LVEF %	47±6	46±7	NS	44±4	NS	44±5	0.05
MPI	0.42±0.04	0.43±0.1	NS	0.45±0.09	NS	0.46±0.1	0.01
QoL	16±6	17±4	NS	18±7	NS	18±5	NS
NYHA	1.5±0.7	1.8±0.3	NS	2.2±0.5	0.01	2.6±0.6	0.001
RVEF %	43±5	40±4	0.1	38±6	0.01	36±7	0.001

## EFFECTS OF RIGHT VENTRICULAR PACING ON INTRA-LEFT VENTRICULAR ELECTROMECHANICAL ACTIVATION IN PATIENTS WITH NATIVE NARROW QRS

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**Background** some patients with right ventricular (RV) apical pacing show contractile asynchrony of the left ventricle. Whether the asynchrony is due to RV pacing or it was a pre-existent condition remains unknown.

**Aim** to evaluate how much pacing from the RV apex affects left ventricular (LV) electromechanical activation, and to assess if the extent of LV asynchrony during RV pacing can be predicted by clinical, electrocardiographic or echocardiographic parameters obtained during spontaneous rhythm.

**Methods** we evaluated 56 patients with narrow QRS and preserved atrio-ventricular conduction who received a permanent back-up RV pacing. Intra-LV electromechanical activation was assessed during spontaneous rhythm and during pacing using tissue Doppler echocardiography.

**Results** an abnormal intra-LV electromechanical delay (defined as >41 ms difference between the faster and the slower activated LV wall) was found in 15 patients (27%) during spontaneous rhythm and in 28 patients (50%) during RV pacing ( $p<0.001$ ). Among 9 baseline variables (age, sex, history of heart failure, QRS duration in spontaneous rhythm and during pacing, LV end-diastolic and end-systolic diameters, LV ejection fraction, intra-LV electromechanical delay in spontaneous rhythm), an abnormal baseline intra-LV electromechanical delay and QRS duration >85 ms were independent predictors of abnormal intra-LV delay during RV pacing.

**Conclusion** RV apical pacing induces asynchrony of LV contraction in a substantial percentage of patients but not in all. While normal baseline intra-LV electromechanical activation cannot exclude the development of significant asynchrony during RV pacing, presence of pre-implant LV asynchrony predicts worsening of this detrimental effect.

## LEFT VENTRICULAR ELECTROMECHANICAL ACTIVATION TIME IN PATIENTS WITH HEART FAILURE AND NORMAL QRS DURATION, AND IN PATIENTS WITH WIDE QRS COMPLEXES

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**OBJECTIVES** We sought to define the reference values of the intra-left ventricular (LV) electromechanical delay (EMD), and to assess

the sequence of electromechanical activation and the prevalence of intra-LV dyssynchrony in heart failure (HF) patients with normal QRS complex and in patients with wide QRS complex (both right [RBBB] and left [LBBB] bundle branch block).

**BACKGROUND** Little is known about electromechanical activation sequence in patients with HF and normal QRS (= 100 ms), and in patients with RBBB.

**METHODS** We studied LV electromechanical activation sequence using tissue Doppler imaging echocardiography and a six LV wall model in 103 patients (41 with HF and normal QRS, 22 with RBBB, and 40 with LBBB), and in 59 controls.

**RESULTS** In controls, intra-LV EMD was 17 ms, (interquartile range 13-30); 95% of controls had a value =41 ms. Compared to controls, the patients showed a longer intra-LV EMD: 33 ms (20-57) in patients with normal QRS, 32 ms (23-50) in RBBB patients, and 50 ms (30-94) in LBBB patients. Intra-LV dyssynchrony (defined as intra-LV EMD >41 ms) was present in 40%, 36% and 60% of the patients, respectively.

**CONCLUSIONS** Since LV dyssynchrony was present in several patients with HF and normal QRS, and in patients with RBBB, and conversely 40% of LBBB patients showed values of LV electromechanical activation within the normal range, the assessment of LV synchronicity with imaging techniques may be more important than QRS duration or morphology in selecting patients for cardiac resynchronization treatment.

## USEFULNESS OF INTRATHORACIC FLUIDS ACCUMULATION MONITORING WITH AN IMPLANTABLE BIVENTRICULAR DEFIBRILLATOR IN REDUCING HOSPITALIZATIONS IN PATIENTS WITH HEART FAILURE

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**Introduction** patients(pts) with advanced heart failure(HF) are frequently hospitalized for fluid overload. In some of them, the implantation of biventricular pacing device with back-up ventricular defibrillator(B-ICD) is indicated. In a available B-ICD model(InSync Sentry Medtronic Inc.), measurement of intrathoracic impedance has been integrated. This parameter is strictly related, with an inverse linear correlation, to the pulmonary fluid overload. Purpose of our work is to evaluate the clinical usefulness of this device in the reduction of hospitalization rates for HF.

**Materials and methods** in a case-control study, we have compared the number of hospital admissions for congestive HF during same follow-up period in two homogeneous groups of pts. each (one) composed of 27 consecutive pts undergoing B-ICD device implantation in our center. The first group of pts was implanted with a B-ICD device with Optivol system for monitoring the intrathoracic fluid accumulation with activated acoustic alarm(Group I Optivol) and the second group was implanted with B-ICD device(InSyncIII Marquis Medtronic Inc.), with similar features except for the absence of Optivol monitoring system(Group II NoOptivol). Follow-up visits and device controls were periodically performed at 3 months interval or in case of acoustic alarm or hospitalization for congestive HF.

**Results** the clinical characteristics of the two groups of pts were not statistically different. In 12 of the 27 pts in Group I, in a follow-up of 359+/-98 days, 18 Optivol alarms were observed and only one hospital admission for congestive HF occurred in a pt ignoring the device alarm for 13 days. In the Group II pts, 8 hospitalizations for HF decompensation were observed ( $p<0.05$ ).

**Conclusions** InSync Sentry device is a useful tool for the clinical management of HF pts., it can result in early treatment during the pre-clinic stage of HF decompensation and in a significant reduction of hospital admissions for congestive HF.

## AV AND INTRAVENTRICULAR DELAY OPTIMIZATION

### CHARACTERISTICS OF SUPER-RESPONDER PATIENTS TO CARDIAC RESYNCHRONIZATION THERAPY

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Aim of our study was to analyze the characteristics of pts that showed the greater clinical and functional improvement after CRT.

**Methods** After a mean follow-up of  $19 \pm 16$  months, a total of 114 consecutive pts (31 female, 83 male, mean age  $70 \pm 8$  years) that underwent CRT for advanced heart failure (NYHA III or IV, ejection fraction (EF)  $< 35\%$ , QRS  $> 120$  msec) were evaluated. Pts that showed a functional improvement of at least two NYHA classes and an EF increase of at least 20 percentage points were defined as super-responders (SR). Clinical, electrocardiographic and echocardiographic characteristics and predictive variables of SR patients were analyzed.

**Results** 16 pts (14%) (5 female, mean age  $65 \pm 8$  years) were identified as SR pts. Four pts (25%) had ischemic cardiomyopathy, four pts (25%) had atrial fibrillation (AF) and underwent AV node ablation, 2 pts (12.5%) were previously paced for complete AV block. After CRT the EF increased from  $30 \pm 4\%$  to  $56 \pm 5\%$  and NYHA decreased from  $3.2 \pm 0.3$  to  $1 \pm 0.1$ . SR pts were younger ( $65 \pm 8$  vs  $71 \pm 8$  years,  $p < 0.01$ ), had better baseline EF ( $30 \pm 4\%$  vs  $27 \pm 7\%$ ,  $p < 0.05$ ) and more prolonged interventricular mechanical delay ( $61 \pm 32$  msec vs  $21 \pm 36$  msec,  $p < 0.05$ ). Baseline QRS interval was similar in both group ( $171 \pm 20$  msec vs  $172 \pm 33$  msec; after CRT, SR pts showed a shorter QRS interval ( $135 \pm 18$  msec vs  $152 \pm 23$  msec,  $p < 0.01$ ).

**Conclusions** CRT SR pts seem to be affected by less advanced cardiomyopathy but more desynchronized ventricles. QRS reduction after CRT could be a predictive variable of better outcome. AF does not seem a contraindication to complete reverse remodelling.

### PERFORMANCE EVALUATION OF PERMANENT CONVENTIONAL VERSUS BIFOCAL STIMULATION IN PERMANENT ATRIAL FIBRILLATION AND ATRIO-VENTRICULAR BLOCK PATIENTS USING PEAK ENDOCARDIAL ACCELERATION

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**INTRODUCTION** Permanent atrial fibrillation (PAF) associated with permanent high-degree AV block is one of the current most common ACC\AHA indications for VVIR(R) pacemaker implant, with the goal of restore physiological rhythm.

In patients with PAF and high-degree AV block, atrial arrhythmia plays an important role in worsening haemodynamic condition, making pacing configuration optimisation mandatory. For these patients with medium-high haemodynamic damage for the lack of atrial contribution to ventricular refilling, it's still not known which is the optimal pacing configuration. Moreover, the detrimental effect due to RV stimulation acts in a faster way. Some authors are now considering biventricular stimulation an alternative to conventional stimulation, able to prevent detrimental effect.

Although a long history, it is not well understood the mechanical antidromic RV stimulation long-term effect and how it can induce morphologic and electrical alterations in both ventricular chambers. TDI has been recently used for studying mechanical desynchronisation but the results are controversial.

In order to evaluate this issue, continuous contractility analysis can join standard echocardiography.

In the past few years simultaneous stimulation of RV in apex and in a region close to interventricular septum root (bifocal stimulation), in

patients with heart failure and wide QRS complex, has been demonstrated to improve LBBB and make duration normal.

One of the more reliable contractility index is LV dP/dt. This index can be evaluated in PM implanted patients through a sensor imbedded in RV catheter. This catheter (MiniBest) is provided in the tip with a micro-accelerometer able to measure beat-by-beat mechanical acceleration generated by isovolumetric contraction phase by the myocardium. This peak-to-peak acceleration (Peak Endocardial Acceleration, PEA) well correlates with global contractility measured by LV dP/dt.

**AIM OF THE STUDY** The aim of this pilot study is to demonstrate the haemodynamic advantages of bifocal stimulation versus conventional VVIR stimulation in patients with PAF and high-degree block AV and, in HF patients, it leads to a ventricular resynchronization, as a reliable alternative to biventricular stimulation.

PEA will provide an unequivocal and continuous determination of ventricular contractility; PEA temporal analysis will provide information on haemodynamic performance and detrimental effect due to RV stimulation.

Standard echocardiography and TDI will join PEA data to better understand resynchronisation effect of bifocal stimulation.

For the study purpose, each patients will be tested to three different pacing configuration: conventional VVIR, septal single RV catheter VVIR, bifocal configuration.

As this is a pilot and pure observational study, the intention is to treat 20 patients.

**PRIMARY GOAL** The primary goal is to evaluate if bifocal stimulation is better than standard VVIR stimulation and septal stimulation in term of PEA and echocardiography data.

**STUDY DESIGN** This is a pilot, single-centre, longitudinal, prospective, 1 arm, 5 months duration study.

Patient require: PAF, high-degree AV block, implantation of a PEA provided PM.

All will undergone 4 follow-up, the first after PM implantation or immediately before hospital dismissal, the second after 1 month, the third and fourth after 3 and 5 months.

First 30 days are only observational for system stabilisation and PM will be programmed in VVIR configuration.

In each follow-up (implant or baseline, standard VVIR, septal VVIR and bifocal stimulation) will be measured: PEA (mean of the last 24 hours), LVEF, ventricular dissynchrony through TDI.

Following the first 30 days in conventional VVIR, patients will be stimulated from the septum for 2 and after that for 2 months in bifocal stimulation.

**CONCLUSION** With this pilot study we aim to clarify the role of bifocal stimulation in a sub-population of patients candidated to VVIR PM implantation.

In particular, we will evaluate the possible protective effect of this type of stimulation, taking into consideration it does not require LV catheter implantation, leading to an easy and short time procedure. If this configuration will show a better performance than standard VVIR, it will be to be considered as a valid therapeutic alternative to biventricular stimulation, able to prevent detrimental effect and desynchronisation, factors responsible in the long-term of induced HF.

The use of PEA, joined with TDI and standard echocardiography will avoid misunderstanding about data interpretation, giving an absolute value during time on cardiac contractility.

## ICD TESTING BY A COMBINED USE OF DEFIBRILLATION AND VULNERABILITY METHODS

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**Background** a standard method for implantable cardioverter defibrillator (ICD) testing has not been identified so far. Aim of our study was ICD testing by a combination of upper limit of vulnerability (ULV) and defibrillation threshold (DFT) tests.

**Methods** 30 pts (age range 35-79 years, 28 males) receiving ICD for sudden cardiac death (SCD) primary prevention (22 pts) and secondary prevention (8 pts) were enrolled. All pts had left-sided pectoral active-can ICDs with transvenous right ventricular, apical dual-coil defibrillation leads. 20 pts (67%) had coronary artery disease and 10 pts (33%) not ischemic dilated cardiomyopathy. ICDs were tested by

a combination of ULV and DFT methods. T-wave scan was performed at 17-18 J with a 4-shock sequence. If VF was not induced a single DFT test at 17-18 J was then performed. Success terminated the protocol, while failure required two successful DFT test at 21-22 J. If T-wave scan induced VF, a rescue shock at 21-22 J was tested. Failure terminated the protocol, while success required a second VF conversion test at 21-22 J.

**Results** 22 pts (73%) had a negative 17-18 J ULV test and a successful 17-18 J DFT test (group A). In 8 pts (27%) T-wave scan induced VF subsequently terminated by a 21-22 J rescue shock in 6 pts (group B) and by a further 31 J shock in 2 pts (group C). In all group B pts a second 21-22 J DFT test was successful. Both pts of group C, requiring SCD primary prevention, obtained a 10-J safety margin with reversal of shock polarity (1 pt) or with an high energy ICD (1 pt).

**Conclusions** combined ULV and DFT testing at 17-18 J demonstrated appropriate ICD function with 1 VF induction in 73% of cases and with 1-2 VF inductions in 93% of cases.

## HEART FAILURE: PHARMACOLOGICAL AND NON PHARMACOLOGICAL TREATMENT

### HEART RATE TURBULENCE (HRT) IN PATIENTS (PTS) WITH DILATED NONISCHAEMIC CARDIOMYOPATHY (DCM), VENTRICULAR TACHYARRHYTHMIAS (VT) AND IMPLANTED CARDIOVERTER DEFIBRILLATOR

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**Introduction** The aim of this study was to explain if HRT were different in pts with DCM with and without VT. There were not strong data suggesting the value of HRT as a risk factor of VT in DCM.

**Method and material** 58 pts in age 18-71 with DCM (NYHA II-III, mean 2,2±0,4) with left ventricular ejection fraction (LVEF) 15-50% and ventricular premature beats and sinus rhythm had 24-hour Holter recording.

15 pts had VT and ICD. Pts with ICD were older and had lower LVEF then pts without ICD. Characteristic of pts:

Group	Age (year) mean	Gender SD	male (no)	female (no)	LVEF %	SD
all pts	47,5	14,9	42	16	34,4	11,3
pts without VT+ICD	44,7	14,5	33	10	36,3	11,1
pts with VT+ICD	55,4	13,5	9	6	8,9	10,4

24-hour Holter recordings were performed using digital recorders and analyzed using the Oxford Medilog System. HRT were calculated using free software from www.h-r-t.com. We estimated the turbulence onset (TO) and the turbulence slope (TS). TO<0% and TS>2.5ms/beat were considered as normal. We standed apart categories: HRT0 - TS+TO were normal, HRT1 - TS or TO were abnormal, HRT2 - TS+TO were abnormal.

#### Results

Group	TO mean n. %	TS SD	HRT0 mean n. %	HRT1 SD	HRT2 n. %
all pts	-0,0090 27,6	0,0281 11	5,0599 19	5,2140	31 53,4
pts without VT+ICD	-0,0101 12	0,0302 27,9	5,4201 6	5,1018 14	25 58,1
pts with VT+ICD	-0,0061 4	0,0216 26,7	4,9091 5	5,7122 33,3	6 40

**Conclusions** Abnormal HRT (one or two) were found more frequent in pts with VT. TO was lower in pts with VT, but difference was not statistical significant. TS did not differ between pts with and without VT.

### ELECTROPHYSIOLOGICAL EFFECTS OF CARVEDILOL ADMINISTRATION IN PATIENTS WITH DILATED CARDIOMYOPATHY - A PROSPECTIVE, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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**Background** Several studies suggest the clinical efficacy of carvedilol in reducing atrial and ventricular arrhythmias in patients with left ventricular dysfunction (LVD) due to congestive heart failure (CHF) or following myocardial infarction. However, the mechanisms supporting its antiarrhythmic efficacy have been derived from experimental studies. In this prospective, placebo-controlled trial we examined the electrophysiological effects of a high oral dose of carvedilol in patients with CHF and LVD due to non-ischemic dilated cardiomyopathy.

**Methods and Results** Thirty one patients underwent electrophysiological study and were randomly assigned to treatment with carvedilol or placebo. After two months of treatment the study was repeated. Carvedilol prolonged almost all conduction times. In the same group atrial and ventricular effective refractory periods were significantly prolonged, while the parameters of repolarization remained virtually unchanged. The prolongation of refractoriness was most pronounced in the atrium. The change in ventricular refractoriness was correlated with ejection fraction (r=0.94, p<0.01) suggesting that patients with more preserved left ventricular function responded to treatment with greater prolongation.

**Conclusion** Even after a short period of administration carvedilol has marked and diffuse electrophysiological effects that would be beneficial for patients with CHF and may contribute to the positive outcome of clinical trials.

### ARE ALL PATIENTS WITH A GOOD EJECTION FRACTION REALLY AT LOW RISK OF CARDIAC DEATH AFTER MYOCARDIAL INFARCTION ? USFULNESS OF NONINVASIVE TESTS

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**Background** A preserved LVEF is a marker of a good prognosis after myocardial infarction (MI). However, sensitivity of LVEF is far to be optimal, thus a high proportion of patients (pts) who will die have a LVEF > 35-40%, the "cut-off" values currently used to identify high risk pts.

**Aim** To assess the prognostic value of noninvasive tests in the prediction of cardiac death/nonfatal arrhythmic events in pts with a preserved or only slightly impaired LVEF.

**Methods** Of 538 pts included in our database because of e tests for ventricular late potentials (LP) detection, heart rate variability and ventricular arrhythmias on Holter monitoring were performed in all pts. End-point of the present analysis was cardiac death/non fatal arrhythmic events at 2 years.

**Results** 31 pts (6%) showed cardiac death/non fatal arrhythmic events, 16 (46%) of 45 pts with LVEF ≤ 35% and 15 (3%) of 493 with LVEF > 35%. Sensitivity of LVEF ≤ 35% was 52%. In the group of patients with LVEF > 35% (age 55 ± 9 yrs, men 86%, LVEF 50 ± 9%, anterior MI 45%, non-Q wave MI 9%, previous MI 9%, ventricular fibrillation in the acute phase 9%, thrombolysis 54%), age (60 ± 9 vs 54 ± 9 yrs, p=0.01), heart rate at ECG (77 ± 13 vs 67 ± 11 bpm, p=0.001), PVC/hour at Holter monitoring (88 ± 225 vs 13 ± 52, p=0.000) and LP (5% vs 2%, p=0.002) were significantly associated with cardiac death/non fatal arrhythmic events. Survival Cox analysis identified PVC frequency per hour (p=0.002) and ventricular late potentials (p=0.01) as independent predictors of poor outcome. Incidence of cardiac death/nonfatal arrhythmic events was significantly (p=0.002) different among the 287 patients without any marker among PVC/hour ≥ 10 and LP (Group 0), the 143 with only 1 marker (Group 1) and the 22 with both markers (Group 2): 1% in Group 0, 3% in Group 1 and 14% in Group 2. Sensitivity, specificity, positive and negative predictive value were 25, 96, 14 and 98%, respectively.

**Conclusion** The present analysis confirmed a low sensitivity of LVEF in the identification of patients at high risk of cardiac death/non fatal arrhythmic events after a MI. Thus, approximately 50% of patients

with a poor prognosis cannot be treated with a specific therapeutic option such as an ICD. The use of noninvasive tests may be useful to identify a subgroup of patients (5% of our study population) who may have an incidence of adverse events not different from that observed in the control arm of an ICD trial like the SCD-HeFT (15%), despite a preserved LVEF.

## ELECTROPHYSIOLOGICAL EFFECTS OF LEVOSIMENDAN IN NON- ISCHEMIC DILATED CARDIOMYOPATHY

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**Purpose** The purpose of the present study was to evaluate in humans the effects of levosimendan, a calcium sensitizer inotrope on cardiac electrophysiological properties.

**Methods** In 6 stable patients with non-ischemic dilated cardiomyopathy and reduced left ventricular ejection fraction (<30%), two electrophysiological studies were performed, before and 24 hours after the infusion of levosimendan. Patients were free of antiarrhythmic drugs for five half-lives before their entry into the study.

Before and after infusion of levosimendan, we measured AH and HV intervals, corrected sinus node recovery time (SNRT) and the Wenckebach point. Effective refractory period (ERP) at 3 cycle lengths (CL: 600,500,400ms) in right ventricular apex and inducibility of ventricular tachycardia, were also tested in both studies.

**Results** After the infusion of levosimendan, corrected SNRT, AH, HV interval and Wenckebach point were not affected. ERP in ventricular myocardium showed a non statistical significant reduction.

In 4 of the 6 patients, sustained monomorphic ventricular tachycardia was inducible at baseline. After infusion of levosimendan, sustained monomorphic ventricular tachycardia was still inducible in these 4 patients although a less aggressive stimulation (two vs three extra stimuli) was required. In the remaining 2 patients non-sustained ventricular tachycardia not presented at baseline study was induced after levosimendan administration.

**Conclusions** Induction of sustained ventricular tachycardia was increased after levosimendan infusion showing increase of myocardial excitability.

## PREVENTION OF HF HOSPITALIZATIONS BY THORACIC IMPEDANCE MONITORING (OPTIVOLTM SYSTEM) IN PATIENTS IMPLANTED WITH A CRT-ICD

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**Introduction and Methods** Patients (pts) with heart failure (HF) are frequently hospitalized for fluid overload. New available CRT and ICD devices (InSync Sentry<sup>TM</sup>, Concerto<sup>TM</sup> and Virtuoso<sup>TM</sup> Medtronic Inc.) provide a measurement of intrathoracic impedance by means of the Optivo<sup>TM</sup> Thoracic Fluid Status Monitoring that is capable to identify potential fluid overload before HF hospitalization.

The Optivo<sup>TM</sup> System collects and stores intrathoracic electrical impedance data measured from the right ventricular lead coil. The feature also calculates the reference impedance, a slow-moving average used to detect decreases in the daily impedance, and calculates the cumulative difference from the daily impedance value. The concept is that lower impedance equates to fluid accumulation and decompensation and can lead to a drug therapy modification. After exceeding a programmable threshold value, the device can alert the pts with a warning system that includes audible and luminous signals.

This work describes the clinical experience at S. Filippo Neri Hospital with the Optivo<sup>TM</sup> System in HF patients treated with CRT.

**Patients and Results** To date, 30 patients with chronic refractory HF and CRT indications, 70% male, age 70,7±8,3 years, 60% NYHA class III, FE=29,2%±4,6%, were implanted with an InSync Sentry<sup>TM</sup>, mean follow-up 9,9±7,1 months.

Only one hospitalization due to HF occurred, and Two Optivo<sup>TM</sup> events were recorded, both with an appropriate activation of the alarm, that led to an unscheduled follow-up visit, in which the drug regimen was modified (i.e. diuretic dose was increased). This determined a prompt reversion of the fluid accumulation process that avoided the hospitalization of the patients.

**Discussion** In this experience, the Optivo<sup>TM</sup> System demonstrated to be a useful tool for the clinical management of HF pts, as it can result in early treatment during the pre-clinic stage of HF decompensation and in a significant reduction of HF hospitalizations.

## REVERSE REMODELING AND REDUCTION OF INFLAMMATORY MARKERS ARE RELATED TO THE ABSENCE OF MAJOR ADVERSE CARDIAC EVENTS IN PATIENTS ON CARDIAC RESYNCHRONIZATION THERAPY

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**Introduction** Cardiac remodeling, interleukin-6 (IL-6) and high-sensitivity C-reactive protein (hsCRP) are involved in heart failure (HF) pathophysiology. However it has not been evaluated if they are linked to major adverse cardiac events (MACE: HF death, sudden death and unplanned cardiac rehospitalizations) in HF patients on cardiac resynchronization therapy (CRT).

**Methods** We recorded MACE of 140 HF pts (on optimized medical therapy, EF 29±3, III-IV NYHA class, with intraventricular dyssynchrony) who underwent CRT (enrolled since April 2004). Moreover we evaluated before and after 6 months of CRT: IL-6 (pg/mL), hsCRP (mg/L), NYHA class, quality of life (QoL), 6' walking test (6'WCT,m), left ventricular end-diastolic (LVEDV) and endsystolic (LVESV) volumes (ml).

**Results** (see table below). MACE were observed in 40 pts (28,6%): 22 deaths and 18 unplanned rehospitalizations. Only pts without MACE showed a clear significant reduction of inflammatory markers and of left ventricular volumes (reverse remodeling), while all patients (with and without MACE) showed a significant improvement of clinical status (table).

**Conclusions** 1) Reverse remodeling and reduction of IL-6 and of CRP are linked to the absence of MACE in CRT pts; 2) Clinical improvement after CRT does not seem useful to predict outcome

## PERSISTENCE OF INTRINSIC CONDUCTION IN PATIENTS WITH ATRIAL FIBRILLATION TREATED WITH CARDIAC RESYNCHRONIZATION THERAPY: THE INSYNC ITALIAN REGISTRY

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In patients with atrial fibrillation (AF) and treated with cardiac resynchronization therapy (CRT), the lower rate (LR) of the device is usually programmed to minimize persistent intrinsic conduction and guarantee therapy delivery. We investigated the role of the ventricular pacing percentage (VP) on the clinical effectiveness of CRT.

**Methods** 88 patients with CRT indications and permanent AF (68 male, 31 ischemic, ejection fraction (EF) 29±8, NYHA Class 3.1±0.6) received a system for biventricular pacing and were enrolled in the

HEART FAILURE: PHARMACOLOGICAL AND NON PHARMACOLOGICAL TREATMENT

**Table.**

	MACE patients (n=40)		No MACE patients (n=100)	
	Baseline	6 months after	Baseline	6 months after
IL-6	11.8 ± 11	9.7 ± 11.1	11.2 ± 11.8	9.2 ± 13.8**
CRP	6.9 ± 3.5	14 ± 28.2	6 ± 4.5	4.7 ± 6.1**
NYHA	3.2 ± 0.6	2.4 ± 0.9***	3.2 ± 0.5	1.9 ± 0.7***
QoL	40.9 ± 18.4	21.5 ± 16.7***	40 ± 17.4	13.7 ± 15.6***
6'WCT	278.3 ± 87.5	379.6 ± 67.9***	301.8 ± 93.6	379.3 ± 76***
LVEDV	195 ± 66.2	187.2 ± 67.2	182.9 ± 65.7	153.4 ± 65.9***
LVESV	139.8 ± 58.5	127.3 ± 55.8*	128.3 ± 58.5	107.7 ± 59.9***

\*p<0.05 vs. baseline; \*\* p<0.01 vs. baseline: \*\*\* p< 0.001 vs. baseline

InSync/InSync ICD Italian Registries. Ventricular pacing mode was programmed and LR was set to minimize intrinsic conduction.

**Results** At a mean follow-up of 15±10 months the mean VP during the entire device lifetime was 88±16%, as documented by the device memory. Either patients with VP>88% (n=56) or with VP=88% (n=32) improved at follow-up, however end-systolic diameter decreased only in VP>88% patients (from 57±11mm to 50±13mm, p<0.05) and their mean increase of EF was higher than VP=88% (10±11% vs. 4±9%, p=0.035). Among VP>88% patients, 18 subjects had ablated AV node or stable AV block while 38 had intact AV conduction (programmed LR: 64±7% vs. 69±6%, p=0.021). Both groups significantly improved, but the former group showed a higher increase of EF (16±13% vs. 7±8%, p=0.010).

**Conclusions** These observations illustrate the necessity to assess and ensure full biventricular capture in this population. The AV node ablation seems associated to a better clinical outcome, probably because it allows permanent therapy delivery without requiring elevated LR and precludes the fusion of paced and residual spontaneously conducted beats.

**RADIATION BURDEN AND ASSOCIATED RISKS IN PATIENTS UNDERGOING FLUOROSCOPICALLY GUIDED IMPLANTATION OF CARDIAC RESYNCHRONIZATION DEVICES**

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**BACKGROUND** Cardiac resynchronization therapy (CRT) may be associated with extended fluoroscopic exposure. We evaluated radiation risks for patients undergoing fluoroscopically- guided cardiac resynchronization device implantation.

**METHODS** The fluoroscopy time, dose-area product (DAP), exposure parameters, and percentage contribution of the fluoroscopic projections commonly used were recorded in a series of 14 consecutive patients referred for cardiac resynchronization device implantation and compared to corresponding data obtained from a control group of 20 patients who underwent a conventional rhythm device implantation operation. The DAP to peak skin dose, DAP to effective dose, and DAP to gonadal dose conversion factors were determined for biventricular pacing and conventional rhythm device implantation using a humanoid phantom and thermoluminescence dosimetry.

**RESULTS** The mean total fluoroscopy time and DAP values were 35.2 min and 4,765 cGy cm2, respectively, for biventricular pacing and 8.2 min and 1,106 cGy cm2, respectively, for conventional rhythm device implantation. Patient skin dose from biventricular pacing pr

## CARDIAC RESYNCHRONIZATION THERAPY: CLINICAL ISSUES

### CRT WITH OR WITHOUT CARIOVERTER DEFIBRILLATION BACK-UP: EFFECT OF PRIMARY PREVENTION TRIALS ON CLINICAL PRACTICE, THE INSYNC ITALIAN REGISTRY

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**Background and Aim** Primary prevention trials (Madit II, Companion, SCD-HeFT) showed the effectiveness of ICD to reduce mortality in ischemic and non ischemic patients with poor ejection fraction. Aim of the study was to evaluate how these trials influenced medical choice for biventricular defibrillator (CRT-D) implant in current clinical practice.

**Methods** 2341 patients, implanted with a CRT device (1369 CRT, 972 CRT-D) in 117 centers and enrolled in the Italian InSync/InSync ICD Registries between 1998 and 2005, were divided in 3 different groups: Group A (703 patients implanted before 2001), Group B (1050 patients implanted during 2002-2003, Madit II publication), Group C (588 patients implanted from 2004, Companion and SCD-HeFT publications).

**Results** (\*:  $p < 0.05$  vs A; #:  $p < 0.05$  vs B). In the overall population, 26% of patients received a CRT-D device in group A, 45%\* in group B and 55%\*# in group C.

According to NYHA Class distribution (NYHA II/III/IV), the functional status improved: 15%/66%/19% in group A, 18%/69%/13%\* in group B, and 24%/65%/11%\* in group C. QRS progressively decreased from  $173 \pm 33$ ms (group A), to  $165 \pm 31$ ms\* (group B), and  $157 \pm 30$ ms\*# (group C).

In CRT-only population the mean age was  $68 \pm 9$  years in group A,  $70 \pm 10$ \* in group B and  $72 \pm 9$ \*# in group C; in group A, 42% of patients were ischemic versus 34%\* in group B and 30%\* in group C.

In CRT-D population, 58% of patients in group A were ischemic, versus 72%\* in group B and 66% in group C. The NYHA Class distribution (NYHA II/III/IV) was 19%/63%/18% in group A, 23%/68%/9%\* in group B, 26%/65%/10% in group C.

**Conclusions** In clinical practice, results from primary prevention efficacy trials increased the rate of CRT-D implants in ischemic patients and subjects with better functional status. CRT devices without defibrillator back-up are nowadays considered especially for elderly or non-ischemic patients.

### ON THE CORRELATION BETWEEN MINOR VENTRICULAR ARRHYTHMIAS AND VENTRICULAR FIBRILLATION IN PATIENTS IMPLANTED WITH BIVENTRICULAR ICD

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**Introduction** Implantable cardioverter defibrillators (ICD) are usually implanted in patients with malignant ventricular tachyarrhythmias. The purpose of the present study was to investigate the recurrence and distribution of minor ventricular arrhythmias to predict the occurrence of ventricular fibrillation episodes in patients with ICD.

**Material and Methods** Our analysis concerned data relatives to 237 ICD implanted patients, from a larger database of 841 patients, over an observation period of one year. These 237 patients were selected as those whose ICD whose programmed to deliver electrical therapy only for ventricular fibrillation (VF) but not for ventricular tachy-

cardia (VT). Patients with an history of Ischemic Aetiology had a lower incidence of VF.

**Results** The percentage of patients who experienced at least one VT episode was higher in the no-VF than in the VF group (54.0% vs. 33.3%). The mean VT episodes duration was higher in VF patients than in patients free from ventricular fibrillation ( $40.6 \pm 99.5$  sec vs.  $4.9 \pm 12.9$  sec). In addition, the ventricular cycle length resulted to be significantly shorter in VF patients ( $433.1 \pm 112.2$  ms vs.  $312.5 \pm 47.6$ ). Literature data on the correlation between VT and VF are controversial. It has been claimed that VT may trigger VF, so that an increased number of VT episodes is expected in patients suffering from VF episodes. On the other hand, evidences have been collected that VT and VF may have different electrophysiological mechanisms. In our population, characterized by  $EF < 35\%$ , we found that the higher occurrence of VF characterizes the No-VF patients, but the duration of VT episodes is higher in those patients who experienced at least one VF episodes.

### PACING RIGHT VENTRICLE WITH RIGHT BUNDLE BRANCH BLOCK ECG PATTERN REDUCES INTERVENTRICULAR DYSSINERGY?

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**BACKGROUND** typical left bundle branch block (LBBB) superior axis ECG pattern of right ventricular apical pacing generates deleterious effects on left ventricular (LV) function caused by an asynchronous interventricular and intraventricular activation.

**PURPOSE** We investigated the possibility to pace the right ventricle (RV) from alternative sites, in order to avoid deleterious effect due to right ventricular apical pacing.

**METHODS and RESULTS** 96 consecutive patients were referred to our Institutions to undergo pacemaker (PM) implantation, from January to September 2006. We obtained a right bundle branch block (RBBB) superior axis ECG pattern in 7 patients who underwent dual chamber PM implantation (5 M and 3 F, mean age 69 years, range 56, 83). Such ECG pattern remained stable after at least a 3 months follow-up. This pattern resulted from pacing the posterior septum in the mid-apical region with a tined lead pacing lead. M-mode, 2D echocardiography and PW-TDI confirmed lead tip position, showing that the RBBB pattern was not associated to paradoxical interventricular septum motion and that it truly generate an earlier LV contraction.

**CONCLUSION** Pacing the mid-apical portion of the posterior septum generates a RBBB-superior axis ECG pattern that remains unmodified over the time. Such ECG pattern might produce a beneficial effect on LV performance avoiding the paradoxical septum motion and the occurrence of interventricular dyssinergy.

### ROLE OF TISSUE DOPPLER IN THE SELECTION OF PATIENTS WITH STANDARD INDICATION TO CRT

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**Purpose** utility of tissue Doppler imaging (TDI) to select patients who could benefit of CRT.

Two-dimensional color TDI in 20 patients with heart failure (middle age  $68.4 \pm 8.3$  years, 95% males, 55% ischemic, 2 with permanent atrial fibrillation, 18 with left bundle branch block, 2 with pacemaker) and standard indication to CRT (ejection fraction  $EF > 35\%$ , QRS  $> 120$  ms, NYHA functionla class 3-4) was performed. Traditional evaluation with physical examination, ECG and standard echocardiography was done. With a Vivid 7 General Electric TDI was acquired as digital loops in the apical four-chambers view. During off-line analy-

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sis a time to peak systolic velocity was measured in the basal septal and basal lateral segment. A difference among the two times > 60 ms was considered index of intraventricular dyssynchrony. The atrioventricular interval was optimized using Doppler echocardiography on the first day after implantation of the biventricular device. At least 3 months after CRT new clinical evaluation and color TDI were performed. In the whole group of patients after CRT an improvement of the mean NYHA functional class (from 3+–0,4 to 1,9+–0,4 p<0,001) and of EF (from 26,1+–5,5 to 35,8+–8,1 p<0,001) was observed. The index of intraventricular dyssynchrony varied from 78,3+–48,9 to 27,6+–27,9 p<0,01. The mean duration of the QRS varied from 169,1+–28,1 to 145+–22,9 ms (p<0,05). In 5 patients (25%) an improvement of at least 5 percentage points of the EF was not observed (not responder). Age, etiology, NYHA functional class, EF, mean QRS of these patients before CRT didn't differ from responders. Only the degree of intraventricular dyssynchrony measured with TDI was different among the 2 groups (103,4+–38,8 ms responder vs 42+–41,1 ms not responder p <0,05). 4 of the 5 patients not responder had not intraventricular dyssynchrony.

**Conclusion** TDI is able to select patients with marked intraventricular dyssynchrony that can benefit of CRT.

**COMPARISON AMONG DIFFERENT METHODS OF TDI IN IDENTIFICATION OF INTRAVENTRICULAR DYSSYNCHRONY AFTER CRT**

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**Purpose** compare different methods of TDI to identify the degree of LV synchronism obtained after CRT. A group of 37 patients with heart failure received a biventricular device and TDI was performed at least 3 months after CRT. With a Vivid 7 General Electric TDI was acquired as digital loops in the apical four and two-chambers. During off line analysis the time to peak systolic velocity was measured in 8 segments of the LV. We have compared (1) an analysis performed on 2 basal segments (septal and lateral) with 60 ms of difference among the 2 times as index of intraventricular dyssynchrony with (2) an evaluation on 4 segments (basal and middle septal and lateral walls) with a cut off of 65 ms and with (3) an analysis performed on 8 segments (basal and middle septal, lateral, inferior and anterior walls) with a cut off of 100 ms of difference among 2 any times. Only in 20 patients (55%) the methods gave homogeneous results showing absence of LV dyssynchrony. With the method of 2 segment (1) it was synchronous the 94,5% of the patients, appraising 4 segments (2) it was synchronous the 64,8% and with the analysis of 8 segments (3) was synchronous 71,4% (p NS). The feasibility of the analysis and the reliability of the curves was different among the three methods for the presence of not optimal visualization especially of the middle anterior wall. In the analysis of 8 segments good curves are obtained only in 55% of the patients.

**Conclusion** different methods of analysis with TDI can show not univocal results. Greater the numbers of segments considered and smaller can be the degree of feasibility and accuracy of the examination.

**ENDOCARDIAL ELECTRIC PARAMETERS OF CARDIAC RESYNCHRONIZATION THERAPY IN NORMAL HEARTS AND DILATED CARDIOPATHY**

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**Aim** of our study was to compare the electrical conduction differences between a group of heart failure patients candidate to CRT and

a group of patients with standard indication for ventricular pacing in normal hearts.

**Methods** Group 1 was composed by 69 patients (20 female, 49 male, mean age 70 ± 8 years) undergoing CRT therapy for advanced heart failure (NYHA class III or IV, ejection fraction ≤ 35%, QRS interval >120 msec). The control group was composed by 8 patients without cardiomyopathy and with standard indication for ventricular pacing, implanted with biventricular device.

**Results** All patients were implanted with left endocardial lead positioned in anterolateral, lateral or posterolateral segment. We measured the interval between spontaneous electrical signal obtained by Right and Left ventricular lead (Rsensed-Lsensed), the interval between spike and opposite ventricular signal (Rpaced-Lsensed and Lpaced-Rsensed), and the correspondent 12 leads QRS width. Echocardiographic resynchronization data were collected too.

	CMP	CONTROL	P
AGE (y)	70±9	75±10	0.090
SEX (female %)	28.9	25	0.859
NYHA class	3.1±0.5	1.4±0.5	0.0001
ISC CMP (%)	29	37	0.928
AF (%)	18.8	25	0.956
LVEF (%)	27.5±5.6	61.6±9	0.0001
LVEDVi (ml/mq)	104.8±28.2	53.7±30.6	0.0001
LVEDD (mm)	67.9±7	52.1±12.1	0.0001
PQ (msec)	213.6±32	178.5±30.6	0.004
QRS (msec)	161±26.1	112±32	0.0001
IEGM Rsen-Lsen (msec)	86.6±44	27.1±14.1	0.0001
QRS left paced (msec)	191.2±40	189.9±30.5	0.933
IEGM Lpac-Rsen (msec)	123.3±34.4	86.4±18.7	0.006
QRS right paced (msec)	206±34.9	185±13.7	0.107
IEGM Rpac-Lsen (msec)	130.2±38.6	93.6±21.1	0.014
QRS biventricular (msec)	140.7±23.6	138.3±25.9	0.802
Q-Po (msec)	94.3±43.6	58.7±2.3	0.027
Q-Ao (msec)	131±41.1	65.7±1.2	0.0001
Q-Ao - Q-Po (msec)	36.7±38.2	7±3.5	0.035
Q-PL (msec)	181.5±54.7	67.7±6.4	0.0001
Q-Siv (msec)	124.4±59.8	63.3±5.8	0.007
Q-PL - Q-Siv (msec)	57±50.9	4.3±1.2	0.006

**Conclusions** Patients affected by symptomatic dilated cardiopathy, with severe impaired left ventricular systolic function, intraventricular and interventricular desynchronization with prolonged QRS duration, present a significative prolongation of spontaneous intraventricular conduction time measured with endocardial leads, and a significative prolongation of paced conduction time not revealed by surface QRS.

**ELECTRICAL PERFORMANCE ON MID TERM FOLLOW UP OF LV LEADS**

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**Materials and Methods** 52 consecutive patients (39M, age 76.6±7.2years, 33.1±9.6%EF, 26 with Ischemic cardiomyopathy and 26 with Idiopathic cardiomyopathy), with standard indication to CRT have been enrolled. Patients have been implanted using LV leads pro-

duced by 3 different companies: Medtronic, Guidant, St Jude; 16pts have been implanted with bipolar leads, while 36 with unipolar leads. 6 patients were affected by diabetes; 14 by hypertension. 12 patients have been treated with Cordarone and 32 with Furosemide.

**Results** In all patients the biventricular pacing has been achieved. LV lead acute and 1 year follow up mean threshold at 0.5 msec are respectively  $1.3 \pm 1.4V$  and  $1.2 \pm 0.9V$ , with impedance respectively of  $846 \pm 358$  ohm and  $648 \pm 168$ ohm. Patients have been divided into 2 groups: Ischemic (n=21) and Idiopathic (n=8) and the pacing thresholds have been compared; at implant the threshold for ischemic group is  $1.7 \pm 1.9V$ , while the threshold for idiopathic is  $0.9 \pm 0.6V$ ; at 1 year FU, the values are  $1.4 \pm 1.2V$  for ischemic and  $0.8 \pm 0.4V$  for idiopathic. Patients have been then divided in 2 groups: those with bipolar (n=11) and those with unipolar (n=25) leads. Pacing thresholds were  $0.8 \pm 0.5V$  for bipolar leads and  $1.3 \pm 1.4V$  for unipolar leads at implant and  $1.1 \pm 0.7V$  for bipolar leads and  $1.2 \pm 1.0V$  for unipolar leads at 12 months FU.

Finally, Pts have been grouped according to the drug (CORDARONE) treatment. At implant the threshold was  $1.7 \pm 1.97V$  in pts treated with Cordarone, while  $1.41 \pm 1.89V$  in the others. After 1 year, the values were  $1.44 \pm 1.39V$  in the Cordarone group, while  $1.14 \pm 0.88V$  in the other one.

All threshold measurements has been taken at a pulse width of 0.5ms. **Conclusions** LV leads electrical performances are stable in the mid term follow up and comparable with endocardial traditional leads. No statistically significant differences have been found according to patients HF etiology, drug treatment and according to pacing lead configurations.

## REIMPLANTATION OF LEFT VENTRICULAR PACING LEAD VIA CORONARY SINUS IN PATIENTS PREVIOUSLY TREATED BY CARDIAC RESYNCHRONIZATION DEVICE REMOVAL

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**BACKGROUND** In the era of Cardiac Resynchronization Therapy (CRT), the necessity to remove left ventricular pacing lead introduced via coronary sinus (CS) progressively increased. CS adherences may complicate left ventricular (LV) pacing lead extraction and make challenging the following reimplantation.

We described efficacy and feasibility of LV pacing lead reimplantation via CS in patients previously treated with lead extraction from the same CS venous branch.

**METHODS AND RESULTS** Since March 2000 until June 2005, 303 patients were submitted to a CRT device implant at our Institute. Among these, 34 patients (28 male, median age  $68.5 \pm 9.4$  years, range 52-82) had been previously treated with a complete CRT device removal (because of local infection in 14, sepsis in 11, device malfunction in 9). Pacing period was 19.4 months (range 2-84). Lead removal was performed in 24 patients by manual extraction and in 10 patients by transvenous mechanical dilation. Reimplantation procedure was successful in all patients; in 33 patients the implant was performed by conventional equipment immediately after the extraction (device malfunction) or 48h later (in case of local infection/sepsis). In 1 patient CS venous angioplasty was performed in order to overcome a venous stenosis and to reach the target vessel. During follow-up (median 17 months), we observed local haematoma in 3 patients, phrenic nerve pacing in 1, non cardiac death in 1.

**CONCLUSIONS** Our experience confirms that CS lead reimplantation after previous extraction may be performed successfully and safely in a large amount of patients. Sometimes, venous adherences and/or stenosis may arise difficulties and the use of non conventional equipment can be required.

## SUPRAVENTRICULAR TACHYARRHYTHMIAS

### DIFFERENT TRANSOESOPHAGEAL PACING METHODS IN TREATMENT OF ATRIAL FLUTTER

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**The aim** of study was to observe optimal pacing methods in patients treatment with paroxysmal atrial flutter[PAF]. 448 pts were hospitalised in Latvian Center of Cardiology 2002 to 2005 with PAF in intensive care.

**Methods** In all pts were transoesophageal pacing (TEP) performed. Pts were divided in two groups: I.group 220 pts - PAF were treated with [TEP] with mode 3 to 5 impulsis (IMP) with ramp minus 10 msec. II.group 228 pts were paced with long burst 25 to 30 IMP. All TEP were performed in intensive care, treatment was started in first 30 min. After hospitalisation. 273 pts were II NYHA class, 175 III NYHA. Higher PAF activities were observed in NYHA III.

**Results** In I.gr. TEP (UHS 20 Biotronik with special module and PC based EP system) sinus rhythm (SR) was restored immediately in 158 pts (70.5%), short Afib were observed 10 to 120 sec after TEP 38 pts, in 22 pts PAF changed to fast atrial tachycardia(FAT). In II.g. SR was restored immediately in 121 pts (53%). In 72 pts was observed FAT, converted to SR in 45 pts, in 35 pts PAF was converted to Afib. In I.gr. SR was restored in 89% (p<0.01), in other cases we used DC or antiarrhythmic drugs (AAD). In II.g. SR was restored in 72.8% (p<0.01), DC or AAD was performed in 27.2%. Pts in II. gr. had mostly subjective complaints as I.gr. in TEP procedure.

**Conclusions** 1. TEP has evident advantages in atrial flutter treatment 2. Short pacing mode is previously for immediately sinus rhythm restoration, does not cause on increased risk on atrial fibrillation. 3. Long pacing mode mostly converted atrial flutter to atrial fibrillation. 3. We prefer antiarrhythmic drugs in combination with TEP. 4.Method is simple, does not cause on increased possibility of risk

### INTRA-ATRIAL REENTRANT TACHYCARDIA IN PATIENTS WITH CONGENITAL HEART DISEASE: ELECTRO-STRUCTURAL CORRELATION

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**Background** Intra-atrial reentrant tachycardia (IART) is a frequent complication in patients with congenital heart disease who had undergone surgical repair. At the moment, factors that can predict the onset of intra-atrial reentrant arrhythmias are unknown. The purpose of this study is to evaluate Strain/Strain Rate (S/SR) in a population of GUCH patients with IART after surgical repair of the congenital heart disease.

**Methods:** We studied 11 GUCHpts with IART (age:30±13years, range 11-54yaers, 5M/ 6F) at our GUCH UNIT and we compared them with 11 GUCHpts without IART after the same surgical repair, comparable for age, sex, congenital heart disease and age at surgery. Atrial functional evaluation has been performed by analysis of atrial Strain/Strain Rate (S/SR).

**Results** The mean age at surgery was 12±11years. The congenital cardiopathies who had surgical repair of the 11 pts were: Atrial septal defect(2pts); Tetralogy of Fallot(2pts); Complete Transposition of Great Arteries (2pts); Partial atrioventricular canal defect(2 pts); Megalic right atrium(1 pt); Pulmonic valve Stenosis(1 pt); Double in-let ventricle (1 pt). The onset of the arrhythmia occurred 15±10years after the surgical repair. At the ecardiographic evalu-

ation of atrial function, GUCHpts with IART had comparable values to pts with the same cardiopathy without arrhythmia and higher values than people without cardiopathy.

At S/SRimaging evaluation GUCHpts with IART had a significant reduction of atrial S and SR values, when compared with atrial S and SR values of GUCH patients without IART and with the ones of normal people (table).

**Conclusions** The found modifications of S and SR of lateral and anterior wall of left atrium and of right atrium support the hypothesis that S and SR reflect the fibrosis of the atrium subjected to surgical and functional insult. These parameters could predict the onset of re-entrant arrhythmias related to this anatomic condition determined by fibrosis.

### WHAT SHOULD WE CONSIDER AS THE END POINT OF RADIOFREQUENCY SLOW PATHWAY MODIFICATION IN PATIENTS WITH TYPICAL AVNRT?

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**Aim** to assess differences between patients (pts) with dual anterograde AVN pathways but without spontaneous/inducible reentrant arrhythmia and those with dual AVN physiology and typical AVNRT, and to transmit this observations to changes in AVN characteristics due to the effective RF slow pathway (SP) modification.

**Methods** 57 pts with AH jump up phenomenon and AVNRT referred to RF ablation (SP ablation in 34 pts, and SP modification in 24 pts) and 45 pts with AH jump but without history of, and without inducible AVNRT, were enrolled. In EP study there were assessed: Wenckebach block cycle length (WCL), ERPfast, ERPslow, AH jump, SPAH, SPAH max, presence of V-A conduction, and cycle length of pacing-induced ventriculo-atrial block (VABCL).

**Results** Pts with AVNRT had better anterograde AVN conduction properties (WCL=356±67 vs 399±108 ms, p=0.04), shorter ERPslow (245±47 vs 287±73 ms, p=0.001), greater difference between ERPfast and ERPslow (97±43 vs 68 ±45 ms, p=0.0026), and more frequently maintained and qualitatively better retrograde V-A conduction (91% vs 46%, p<0.001, VABCL=338±74 vs 468±100 ms, p<0.0001, respectively) in comparison with patients with dual AVN pathways but without AVNRT. Analysis confined to the cases with maintained retrograde conduction revealed approximate to the mentioned above differences between groups. The effective SP modification (24pts, no recurrence of arrhythmia during 33.52±19.8 months follow-up) resulted in the increase in the WCL (from 348±92 to 400±134 ms, p=0.04), significant increase in ERPslow (from 250±60 to 307±59 ms, p=0.006) and increase in SPAH (from 262±62 to 344±99 ms, p=0.03).

**Conclusions** Differences in AVN characteristics that were observed between pts with dual AVN conduction properties without and those with typical AVNRT were similar to changes in SP characteristics due to the effective RF slow pathway modification. Analysis of larger populations would help to establish more precise AVN electrophysiological criteria necessary for prediction of AVNRT occurrence.

### DISTRIBUTION OF THE ATRIAL FRAGMENTED POTENTIALS IN PATIENTS WITH PERMANENT ATRIAL FIBRILLATION

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**Purpose.** Fragmented potentials are recently considered a new useful target for atrial fibrillation (AF) ablation. The aim of this study

was the evaluation of the right (RA) and the left atrium (LA) electroanatomic maps using the fragmentation index (FI). The 3D reconstruction of both atria was carried out during AF rhythm by using a function of an electroanatomic mapping system known as "cycle length mapping", available on the Unix version.

**Methods** The study considered 16 patients who underwent biatrial electroanatomic mapping for permanent AF ablation. An average of 123 points were acquired for a biatrial map, 47 for the RA and 76 for left LA. Each point of the maps was the result of recording 10 seconds of electrograms. Reanalysis of the measures was performed offline. FI was calculated as the ratio between the number of the peaks in the intracardiac channel and the number of the annotation in the same channels.

**Results** The FI recorded in the LA was on average higher than in the RA (6,5 vs 5,5). The ratio between right/left median FI was 0,89 supporting the highest fragmentation of the LA. The sites of the highest FI were on the roof of LA (7 pts), on the posterior wall of the LA (5 pts) and on the inferior wall of LA (4 pts.) In 3 cases the highest FI was localized in the proximal portion of the coronary sinus. The sites of the lowest FI were frequently localized around the pulmonary veins, atrial appendages, cava veins and RA free wall.

**Conclusions** In patients with permanent AF the fragmentation of potentials is higher in the LA than in the RA. The roof and the posterior wall of the LA are the more common sites of high fragmentation but a high variability between patients were observed.

## TIME BETWEEN THE FIRST DETECTION OF HYPERTENSION AND ATRIAL FIBRILLATION APPEARANCE AND THE INFLUENCE OF SEVERAL FACTORS ON IT

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The estimated prevalence of atrial fibrillation (AF) is 0,4% to 1% in the general population, increasing with age. Hypertension, ischemic heart disease, heart failure, valvular heart disease, and diabetes are the prominent conditions associated with AF.

Aim of this study was to evaluate the time between the first detection of hypertension and AF appearance and the influence of several factors on it. 61 patients (pts) (44 male, age 54-86 years) were included in this study. The pts were treated with calcium-antagonist, ACE-inhibitors, angiotensin antagonist and betablockers. The pts underwent the echocardiographic (ECHO) study and electrocardiographic (ECG) study. From the ECHO, in accordance with the American Society of Echocardiography, were measured the following parameters: left ventricular end-systolic (LVES) and end-diastolic (LVED) diameters, septal (SIV) and posterior wall (PW) thickness, ejection fraction (EF), left atrial diameter (LAD). On ECG were evaluated the presence and the type of biphasic P-wave in V1 and duration of P-wave. As the results, AF appeared in 10 of 61 pts (16,4%, group 1) before 5 years, in 33 pts (54,1%, group 2) 5-10 years and the remaining 18 pts (29,5%, group 3) after 10 years. These pts were treated with ACE-inhibitors or angiotensin receptor antagonist, respectively 88,8% in group 1, 83,9% in group 2 and 88,1% in group 3. There was no statistically significant difference between three groups regarding echocardiographic and electrocardiographic parameters.

In conclusion, the appearance of AF occurs at variable times and it is difficult to predict the time interval between the first detection of hypertension and AF appearance.

## THE VERY EARLY EFFECTS OF PROPAFENONE AND AMIODARONE ON ATRIAL VULNERABILITY FOR ATRIAL FIBRILLATION

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**Background** Atrial fibrillation (AF) is the most frequent SVT, and the treatment of it, is addressed to both targets cardioversion and maintenance of sinus rhythm (SR). The onset of AF has been related to the existence of atrial premature beats. Propafenone (Pr) and Amiodarone (Am) have been successfully used for both targets of AF therapy, with Am been superior for the maintenance of SR and Pr superior for rapid cardioversion. The purpose of this study was to define the effects on the electrophysiological background related to atrial vulnerability for AF, of these two clinical effective pharmaceutical agents.

**Methods** In 25 patient with a history of lone AF while they were in sinus rhythm, an EPS was performed before and after the administration of iv Pr (group A, 13p: effusion: 2mg/kg Pr in 3-5 min) or Am (group B 12p: effusion: 5mg/kg in 20 min). The Interatrial conduction time (ICTAFRP) of the last conducted in the atrial premature beat and the atrial functional refractory period (AFRP) were estimated, during basic rate and pacing rates of 100,120,140 b/min.

**Results** In group A the AFRP is prolonged at all heart rates but significantly and more profound at the rate of 120b/min ( $p < 0,05$ ), whereas the ICTAFRP is depressed strongly at all pacing rates especially the higher ones. In group B Am prolonged AFRP during intrinsic rhythm and pacing rates of 100, 120b/min, not for the rate of 140b/min whereas it did not affect the ICTAFRP at all. In both groups AF was not inducible after both antiarrhythmic administration even in patient with inducible AF before the administration.

**Conclusion** The alterations of ICT and atrial FRP in combination might allow the suggestion that both antiarrhythmic agents partially suppress the vulnerability for AF via different electrophysiological ways taking into account that they are both suppressed the inducibility of AF.

## P-MIN EVALUATED ON ECG REPRESENTS A RELIABLE PREDICTOR FACTOR FOR THE DETECTION OF HYPERTENSIVE PATIENTS PRONE TO PAROXYSMAL ATRIAL FIBRILLATION

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**Background-Aim** Hypertension is a well known common cause of atrial fibrillation. It is significant to identify risk-prognostic factors among hypertensive patients prone to develop paroxysmal atrial fibrillation (PAF). Measurements of P-min from signal-averaged ECG is a predictor of PAF. Whether P-measurements based on ECG or 24h-ambulatory ECG (24h-ECG) may be used for detection of hypertensive patients at high risk for developing PAF while in sinus rhythm is not well defined.

**Methods** Towards this end, we performed ECG and 24h-ECG in 50 hypertensive patients with a history of PAF (group A) and in 50 hypertensive patients without a history of PAF (group B). We measured Pmin, Pmax, P dispersion (=Pmax-Pmin) from both ECG and 24h ECG recordings. Also our patients underwent an echocardiographic study for determination of left atrial dimensions (LA) and left ventricular ejection fraction (EF).

**Results** There were no differences between the two groups, A and B regarding the clinical data. Patients in group A had increased both left ventricular mass index and LA dimension compared to group B (115±27 vs 85±19 gr/m<sup>2</sup> and 3,77±0,3 vs 3,51±0,4 cm respectively  $p < 0,05$

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for both cases) while left ventricular EF did not differ (65% vs 67%). By applied a Student t-test analysis of the data, it was revealed that P min measured on ECG was significantly and statistically shorter (135,5±49,04 vs 163,53±54,07 ms p=0,004) among patient of group A compared with group B, whereas Pmax in the same group was longer but of borderline regarding the statistical significance (231,84±58,3 vs 214,9±52,74 ms p=0,06). There were no differences in P dispersion (96,33±25,71 vs 50,98±16,64 ms p>0,05) measured on ECG and also for all these parameters measured from the 24h ECG recording (p>0,05) as follow: Pmin 56,33±19,76 vs 76,6±10,37ms, Pmax 136,94±24,34 vs 113,21±12,37 and P dispersion 83,88±21,2 vs 36,6±12,08 ms

**Conclusion** Hypertensive patients predisposed to PAF could be detected by manual measurements of Pmin on surface ECG while in sinus rhythm.

**INFLUENCE OF THE GENDER ON RESULTS OF HEAD-UP TILT TEST IN PATIENTS WITH SYNCOPE**

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The aim of study was evaluation of results of head-up tilt test (HUTT) in patients with syncope in relation to their sex.

We observed 227 pts (88 men, 139 women) aged 18-58 yrs (x 38,2 yrs) with syncope referred to HUTT.

All pts underwent standard HUTT (HUTT-s) acc. to Westminster protocol. Additional tilt tests with isoproterenol infusion or sublingual nitroglycerine administration were preformed in pts with negative HUTT-s. HUTT was assessed as positive if reproduced symptoms referred by patients.

**Results**

The prevalence of syncope in women was observed, whereas vaso-vagal syncope was observed in comparable frequency between men and women in studied group (82,9 vs 82,1%)

Positive HUTT-s was in 96 pts (42,3%). Among 139 pts with negative HUTT-s 80 pts (35,2%) underwent HUTT with isoproterenol infusion (HUTT-I) and 51 (22,5%) pts with NTG administration(HUTT-NTG). HUTT-I was positive in 46 pts (57%), whereas HUTT-NTG was positive in 36 pts (70,5%). At least positive HUTT was in 78,4%pts. Mixed type of vaso-vagal response (VVR) to HUTT was the most frequent during HUTT-I whereas cardioinhibitory type of VVR was the most frequent during HUTT-NTG. There were no significant differences in the frequency of VVR between men and women in standard and isoproterenol HUTT. Mixed type of VVR was more frequent and vasodepressive less frequent in men than in women during HUTT-NTG

	Type of VVR			HUTT - STD +			HUTT - ISO +			HUTT - NTG +		
	All pts	W	M	All pts	W	M	All pts	W	M	All pts	W	M
	96*	54*	42*	46*	28*	18*	36*	32*	13*			
1	54%	56%	52%	63%	61%	67%	44%	35%	62%			
2 A	5%	4%	7%	9%	7%	11%	11%	13%	8%			
2B	13%	11%	14%	4%	7%	0%	28%	30%	23%			
3	28%	30%	26%	24%	25%	22%	17%	22%	8%			

W, Woman; M, Man; \*, pts

**Conclusions**

1. Vaso-vagal syncope induced by standard head-up tilt test did not more frequently occurs in women that in men
2. The method of induction of syncope during HUTT not a sex of patient has influence on the type of vaso-vagal response to tilt.

## PACING LEADS EXTRACTION TECHNIQUES AND OUTCOME

### PACEMAKER AND ICD LEAD REMOVAL USING RF AND NON RF EXTRACTION SYSTEM

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**Objectives** Aim of this prospective randomized single center study was to evaluate safety and efficacy of pacemaker and implantable defibrillator (ICD) lead extraction using electro-surgical dissection sheaths (EDS).

**Background** Implanted leads are encapsulated by fibrotic tissue and transvenous removal technique using simple polytetrafluoroethylene (PTFE) sheaths becomes to be less effective and more risky.

**Methods** In the last three years 120 patients (161 leads) were randomized for either radiofrequency current supported EDS extraction or countertraction lead removal procedure using standard PTFE sheaths. There were 60 patients in each arm, 96 men and 24 women included in the study. The mean age of randomized patients was  $62.7 \pm 9.6$  years. In 16 patients we explanted 17 ICD leads. The average time from the date of implantation to the extraction procedure was  $73.4 \pm 15.7$  months. We defined success as a complete lead removal or partial success when less than 40 millimeters of the lead remained in the site of previous insertion.

**Results** Complete extraction rate was 78 leads (93%) in the RF group and 56 leads (73%) with standard transvenous lead extraction system for contraction ( $p < 0.01$ ). Among these leads we removed successfully 9 from 10 ICD leads (90%) in RF group and only 4 from 7 ICD leads (57%) in standard group. We observed also significant reduction of time to get successful removal of pacemaker and ICD leads using radiofrequency system ( $9.6 \pm 6.2$  min versus  $21 \pm 9$  min,  $p < 0.01$ ). Partial success was reached in 6 patients with RF system and in 11 with standard sheaths.

Serious complications were associated with standard system in two patients: septical embolizations to the lungs in both patients.

**Conclusions** We proved EDS extraction system to be significantly more effective and associated with less procedure time. We didn't observe life threatening complications in this study.

### TRANSVENOUS REMOVAL OF PACING AND DEFIBRILLATING LEADS: A SINGLE CENTER RESULTS AND COMPLICATIONS IN OVER 2000 CONSECUTIVE LEADS

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**BACKGROUND** Transvenous extraction of Pacing (PL) and Defibrillating Leads (DL) is today an effective technique showing low incidence of serious complications. Results and complications of this complex technique are strongly affected by the experience of the operators and by the availability of different approaches for difficult cases. This report analyses the longstanding experience performed in a single Center in over 2000 leads.

**MATERIALS AND METHODS** since December 1989, we managed 1263 patients (923 men, mean age 66.9 years, range 6-95) with 2122 leads (mean pacing period 67.4 months, range 1-336). PL were 1910 (1127 ventricular, 732 atrial, 51 CS leads), DL were 212 (196 ventricular, 4 atrial, 12 SVC leads). Indications to removal were class I in 34.6% and class II in 65.4% of the leads. We performed mechanical dilation using the Cook Vascular (Leechburg PA, USA) extraction kit and other intravascular tools (Catchers and Lassos, Osypka, Grentzig-Whylen, G). Since 1996 a Jugular Approach (JA) through the internal jugular vein was performed in case of free-floating or difficult exposed leads.

**RESULTS** 2046 leads (1834 PL, all the 212 DL) were completely

removed (96.42%), 22 (1.04%) partially removed and 37 (1.74%) not removed; in 17 PL (0.8%) the technique was not applicable. Since 1996, 1809 leads were submitted to removal. The JA was performed in 54 free-floating and 150 difficult exposed leads, we completely removed 196/204 (96.07%) leads and partially removed 6/204 (2.94%). In this period, 1779/1809 (98.34%) leads were completely removed. Serious complications occurred in 9 cases: cardiac tamponade (8 cases, 2 death), hemotorax (1 death).

**CONCLUSIONS** our experience shows that success rate and complications of transvenous lead removal using mechanical dilation are highly affected by the experience of the staff. The use of the JA allows high effectiveness and safety in case of free-floating or difficult exposed leads

### USEFULNESS OF MECHANICAL TRANSVENOUS DILATION AND LOCATION OF THE ADHERENCES IN PATIENTS UNDERGOING CORONARY SINUS LEAD EXTRACTION

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**Aims** Few data are currently reported on the outcome of coronary sinus (CS) lead removal, particularly using mechanical dilation (MD). We aimed to evaluate feasibility, safety and effectiveness of CS lead extraction, focusing on MD usefulness, in the event that lead traction (LT) was ineffective.

**Methods** We studied 37 consecutive patients (30 male, mean age 68.1, range 52-80), who underwent left ventricle (LV) pacing lead removal; the indication for extraction was local infection in 16 patients (43.3%), sepsis in 11 patients (29.7%) and lead malfunction in 10 patients (27%). The procedure was first attempted by LT, followed, if unsuccessful, by MD using polypropylene sheaths.

**Results** All CS leads (time from implant  $19.5 \pm 16.5$ , range 2-84 months) were successfully removed; LT was effective (LT group) in 27 patients (73%) and ineffective in 10 patients (27%), for whom MD was necessary (MD group). There were no major complications. Binding sites were found to be in the CS in only one patient. No differences were noted on the data analyzed between LT and MD group; in particular, time from implant was similar in both groups (MD vs LT group:  $17 \pm 8.9$  vs  $20.4 \pm 18.6$  months;  $p = ns$ ).

**Conclusions** Our study suggests that CS leads, after mid-term pacing, can be effectively and safely removed using MD with polypropylene sheaths, in case of unsuccessful LT. No preoperative elements predictive of LT failure could be identified. Adherences were rarely located in the CS vein.

### DUAL APPROACH FOR TRANSVENOUS LEAD EXTRACTION IN PATIENTS WITH POCKET INFECTION OR UPGRADE TO AN ICD

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The dual approach for transvenous lead extraction in patients will be described

**Methods** Lead removal was performed in a following order: lead was removed from the fibrous tissue in the pocket, sleeve was removed, and gentle but progressive manual traction was performed with a simple guide wire inserted to the lead tip. Intracardiac ECG and fluoroscopy are used. In some cases strong fibrous tissue surrounds the lead and then from the femoral vein a standard angiography catheter, JR4 or AL1, were used in combination with a long snare to grab the distal lead part or the Needle Eye was used.

**Results** in 26 pts with a mean age of  $64 \pm 16$  years 40 leads were

## PACING LEADS EXTRACTION TECHNIQUES AND OUTCOME

removed. 2 procedures were done in one pt for two different leads: pacing lead exchanged for shock lead and a spontaneous dislocation of an atrial lead. Indications: 9 pts infection and in 2 pts dislocation, 1 pt radiation and in 14 pts an upgrade from a pacemaker to an ICD. Dwell in time is 4.5 +/-3.8 years. In 1 pt lead removal failed. Additional tools were used in 3 pts Needle Eye, in 1 pt a long sheath over the lead, and in 8 pts also the inferior approach with a snare. Complications were low blood pressure due to pain and manipulation of the entangled lead in the right ventricle in 2 pts. There no early or late death.

**Conclusion** Removal of redundant leads in case of a pacemaker upgrade to an ICD or in case of an infection can be handled successfully with standard tools for lead extraction, such as a snare and Needle eye. However, we recommend strongly the dual approach for complete and complication free removal of the leads, in case of adhesions in the upper tract of the venous system.

## CHRONIC EVALUATION OF A PASSIVE-FIXATION INTRAPERICARDIAL PACING LEAD IN CANINES

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**Introduction** Conventional epicardial pacing leads are active-fixation and require surgical procedures for their placement, causing trauma and complications to the patients. A non-surgical percutaneous subxiphoid approach, similar to that for epicardial mapping or ablation, offers an alternative for placing epicardial leads. However the active-fixation epicardial leads impose significant safety concern. A novel passive-fixation intrapericardial lead (IP Lead), the first of its kind to our knowledge, has been designed for safe placement using the subxiphoid procedure under fluoroscopy. This study is to investigate ease of implant, the mechanical stability and electrical performance of the IP leads using chronic canine models.

**Methods** Upon access to the pericardial space via the percutaneous subxiphoid puncture, a specially designed introducer was used to place IP leads over LV region. A total of 6 canines were implanted with one lead per model. In a series of post implant follow-up, the lead position was carefully examined under fluoroscopy, and the electrical measurements were taken and compared to those from a standard transvenous LV lead in similar models. Histology analysis of the explants was conducted to characterize underlying tissue reactions to the intrapericardial leads.

**Results** All six implants were successful with no complications. Throughout 90 days post implant all leads were stable without noticeable position changes. Their electrical performance was basically similar to the standard transvenous LV leads. Histology analysis indicated that the tissue-electrode interfaces were typical of pacing leads and the coronary arteries underneath the electrode did not exhibit any injury over the 90 day chronic study.

**Conclusions** A novel passive-fixation intrapericardial pacing lead can be safely placed via a subxiphoid procedure to pericardial space achieving excellent mechanical stability. The electrical performance was well acceptable over the course of 90-day study. The leads did not cause unusual tissue reactions or any damage to the underlying coronary arteries.

## MAJOR DETERMINANTS OF PACEMAKER ELECTRODE IMPLANTATION: THE RULE OF 6

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Implantation of a pacemaker lead has to follow 6 simple fist rules for proper functioning of the lead in bradycardia pacing. We use these 6 important characteristics during the pacemaker lead implantation:

stability of the tip, ST elevation on the intracardiac ecg, sense values (P/R value), slew rate of the signal, stimulation threshold, and as 6th phenomenon the lack of remote signals, which especially is important for the atrial electrode.

**OBJECTIVES** implant of 52 leads (37 ventricular and 15 atrial) in 40 pts were studied with respect to above mentioned parameters, after fixation of the lead. These parameters were also used for attempts to implantation without fluoroscopy.

**METHODS** The ST elevation was recorded on 12 lead ECG recorder (Siemens, CathCor) on a scale of 1cm/1 mV. ST elevation as an average of 5 complexes is expressed in mm. The other parameters were measured with the ERA 300B (Biotronik).

**RESULTS** P/R wave amplitude(Mv) Atrium vs Ventricle respectively  $2.8 \pm 1.3$  vs  $16.0 \pm 8.9$ ,  $P < 0.0001$ ; Slew rate (V/sec)  $0.5 \pm 0.2$  vs  $1.6 \pm 0.9$ ,  $P < 0.0001$ ; ST Elevation (mm, 1V= 10mm)  $21 \pm 13$  vs  $80 \pm 48$ ,  $P < 0.001$ ; Threshold (@0.5 msec)  $0.8 \pm 0.2$  vs  $0.6 \pm 0.2$ ,  $P < 0.02$ .

There is no strong correlation between the 4 parameters, except for a correlation of the P/R wave amplitude with the slew rate, regression coefficient for P wave/slew rate is 0.78 and the R wave/slew rate is 0.61. Far field signals were seen in 3 cases with amplitudes of  $\pm 0.3$  mV. In 2 cases fluoroscopic blind implantation was successful.

**CONCLUSIONS** The rule of 6 or the 6 parameters give all the information needed for a proper lead implantation. Only the slew rate is not an independent parameter and is directly related with the amplitude of the P or R wave.

## ONE YEAR CHRONIC PERFORMANCE OF FAR FIELD SIGNAL REDUCTION (FRS) PACING LEADS IN RIGHT ATRIUM

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**Introduction** The Far Field Signal Reduction Lead (FSR) has demonstrated its efficacy in minimizing the detection of the far field ventricular signal in the atrium up to 90 days post implant in patients. Since the tip-to-ring spacing is only 1.1 mm, there was a concern about the fibrosis effects on the bipolar electrode performance stability over the long term. This study investigates the FSR leads' electrical performance at one-year versus 90 day post implant, with an additional comparison of the 360-day Far Field sensing threshold between a standard lead and the FSR lead.

**Methods** 25 patients (11 females, and an average age of  $69 \pm 10$  years) were randomized at implant to receive either the new SJM Tendril® FSR pacing lead (n=14) or a SJM Tendril® ST Model 1688T (n=11), and were followed through 360 days. In addition to the standard follow-up, a FF sensitivity threshold test was performed with PVAB programmed to 60ms.

**Results** The data from the 90 and 360-day follow-up among a paired group of FSR patient showed no statistical significant change in impedance, pacing, or sensing amplitudes. At the 360-day follow-up, the far field sensing thresholds for 67% FSR leads versus only 30% control group were maintained below 0.1mV, the minimal measurable level by the pacemakers. None of the patients with FSR leads had FF sensing threshold at or above 0.3mV, while 30% of patients with the control leads did.

**Conclusion** FSR leads consistently demonstrated significantly lower FF sensing amplitudes than conventional pacing leads throughout the one-year follow-up after implant. Other electrical measurements were maintained robust and acceptable between the two follow-up periods with no statistical significant differences. Therefore, the efficacy of far field reduction along with other electrical performance of the FSR leads remains stable and reliable in the long term post implant.

## PREVENTION OF POCKET RELATED COMPLICATIONS WITH FIBRIN SEALANT IN PATIENTS UNDERGOING PACEMAKER IMPLANTATION RECEIVING ANTICOAGULANT TREATMENT

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**Purpose** The aim of our study was to establish the efficiency of fibrin sealant in the prevention of pocket related complications in patients undergoing pacemaker implantation receiving anticoagulant treatment.

**Materials and methods** The study was performed upon 40 and 41 patients prospectively randomized into treatment and control groups

who underwent pace maker implantation procedure during the period from January 2002 to July 2004 at the Pacemaker Center - Clinical Centre Nis, Serbia. Patients in both groups were receiving anticoagulant treatment with heparin or warfarin. Surgical procedures between both groups differed only by the application of fibrin sealant prior to wound closure in the treatment group.

**Results** In the treatment group, there were no pocket related complications while in the control group 6 patients (14.63%) had minor hematomas that did not need any treatment. Four patients (9.76%) had significant hematomas (2 patients were treated conservatively and other 2 patient needed reintervention). In the follow up period (2-27 months) no late complications were registered in both groups.

**Conclusion** Fibrin sealant is an effective adhesive and hemostatic agent. The results obtained in our study show that the administration of fibrin sealant in patients receiving anticoagulant treatment eliminates postoperative hematomas after pacemaker implantation procedures.

## ICD AND HEART FAILURE

### INTRAVENTRICULAR CONDUCTION DISTURBANCES MIGHT CAUSE VENTRICULAR DYSFUNCTION: THE THEORY OF THE EGG AND THE CHICKEN

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**Introduction** The severity and the prognosis of heart failure has been combined with the development or the presence of LBBB. It has not clearly been defined if the development of intraventricular conduction disturbances themselves without overt heart failure, with normal EF can be the substrate or the cause of ventricular dysfunction. Although lately it has been some debate about this issue and some investigators support that these conduction disturbances can cause such a dysfunction.

**Aim** The study was conducted to elucidate this field.

**Methods** We studied 81 patients with a history of essential hypertension normal EF. From those patients 43 of group A presented with LBBB, QRS duration equal or more than 120 ms (mean age 57,4±12,4 years) and 38 of group B with normal duration of QRS (mean age 57,1±11,2 years). BNP plasma levels were measured for all patients and all of them undergone an echocardiographic study to estimate the EF.

**Results** There were no differences regarding the clinical data (age, history of hypertension, levels of BP). The EF of all patients was normal range but it was statistically and significantly higher in group B (65,54±5,76 vs 67,86±5,09% p= 0,036). BNP levels were found to be statistically and significantly higher in group A (27,65±33,34 vs 12,9±15,38 p=0,045). In a subgroup analysis among patients of group A, comparing patients with LBBB who additionally had a history of PAF (21p) with those who did not (22p) we found that the BNP levels were higher in those patients with LBBB and PAF (40,78±37,9 vs 15,11±22,77 p=0,005). Doing the same in group B also patients with PAF had higher levels of BNP (24,34±13,88 vs 1,46±2,43 p=0,024). Finally we compared also patients without PAF of group A and group B and we found that only the presence of LBBB increased the levels of BNP (15,11±22,77 vs 1,46±2,43 p=0,006).

**Conclusion** The presence of LBBB and thereby intraventricular conduction disturbances consist a cause of ventricular dysfunction as it is assessed by BNP plasma levels. The history of PAF consist an additional burden for ventricular function. Further investigation is needed to define if the egg begets the chicken or the way around.

### CLINICAL CHARACTERISTICS OF PATIENTS WITH REVERSE REMODELLING AFTER CARDIAC RESYNCHRONIZATION THERAPY (FROM NORTH-EAST ITALIAN REGISTER)

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**Objective** To analyze the characteristics of pts that showed the greater clinical improvement and reverse remodeling after CRT in a large multi-center registry.

**Methods** Mean follow-up of 34 ± 18 months, a total of 353 consecutive pts (75 female, mean age 70 ± 8 years) whose underwent CRT for advanced heart failure (NYHA III-IV, LVEF<35%, QRS>120msec.) were evaluated. Pts who were alive, that showed a functional improvement of at least two NYHA classes, an EF increase of at least 20 absolute percentage points and reached an EF > 45% during the follow-up, were defined as super-responders (SR).

**Results** 37 pts (10.4%), mean age 68 ± 7 years, 15 female (41%) were identified as SR. Nine pts (24%) had ischemic cardiomyopathy, 7 pts

(18.9%) had atrial fibrillation (AF), 10 pts (33%) were previously paced for high degree AV block.

After CRT the EF increased from 28 ± 6% to 54 ± 6%, NYHA decreased from 3.0 ± 0.1 to 1.0±0.0. SRpts were more often female (41% vs 20%, p<0.01), with non-ischemic cardiomyopathy (77% vs 51%, p=0.005) and had better baseline EF (27.9 ± 6% vs 25.5 ± 6.1%, p<0.024). Baseline QRS interval was similar in both group (175 ± 26 msec vs 178 ± 31 msec), however after CRT, SRpts showed a shorter QRS (146 ± 26 msec vs 163 ± 28 msec, p=0.004). SRpts with an AICD did not have any ventricular tachyarrhythmia in the follow up.

**Conclusions** SRpts after CRT seem to be female affected by non ischemic cardiomyopathy, have not major ventricular arrhythmias. QRS reduction after CRT seems to be a predictive variable of good outcome. Permanent AF does not seem a contraindication to complete reverse remodeling. In this subgroup of patients ventricular desynchronization seems the major cause of heart failure and CRT could be curative.

### ASSESSMENT OF THE VARIATIONS IN NEUROHORMONAL PROFILE, HAEMODYNAMICS AND FUNCTIONAL CAPACITY IN HEART FAILURE PATIENTS TREATED WITH CARDIAC RESYNCHRONIZATION

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**Background** Cardiac Resynchronization Therapy (CRT) has been shown to improve the clinical status and survival in congestive heart failure (CHF) patients, but little is known about its influence on neurohormonal status.

**Methods and results** We studied the changes of the functional state, echocardiographic data, cardiopulmonary testing and neurohormonal situation in patients treated with CRT for moderate to severe heart failure. This study comprised 120 NYHA II to IV patients, all indicated to CRT; one hundred consent to be implanted (gr.A), whereas 20 refused (gr.B). All patients were studied with Echocardiography (Echo), Cardiopulmonary test (CPX), and repeated evaluation of Brain Natriuretic Peptide (BNP), Endotelin (END), big Endotelin (big-END), epinephrine (EPI), alfa tumor Necrosis Factor (alfa TNF) before and 1 year after CRT implant. In gr.A patients all clinical, Echo, CPX parameters significantly improved between basal and follow-up whereas only BNP and big-END changed significantly. On the contrary, none of these parameters significantly changed in grB

**Conclusions** This study showed an echocardiographic, cardiopulmonary and neurohormonal profile improvement in a consistent heart failure population treated with CRT on top of optimal medical therapy.

### CARDIAC RESYNCHRONIZATION THERAPY INDUCES SIMULTANEOUS AND IDENTICAL (INCREASE OR DECREASE) CHANGES OF HS-CRP AND NT-PROBNP

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**Purpose** High sensitivity C-reactive protein (hs-CRP) and N-terminal pro-brain natriuretic peptide (NT-proBNP) are increased during heart failure (HF) and are considered important prognostic markers for HF patients. However it is unknown the effect of cardiac resynchronization therapy (CRT) on both markers simultaneously evaluated.

**Methods** Thus we studied 66 HF pts (mean age 72 ± 8.9 yrs, EF = 29.9 ± 9.6%, III-IV NYHA class, on optimized medical therapy, with intraventricular dyssynchrony) who underwent CRT. CRP and NT-

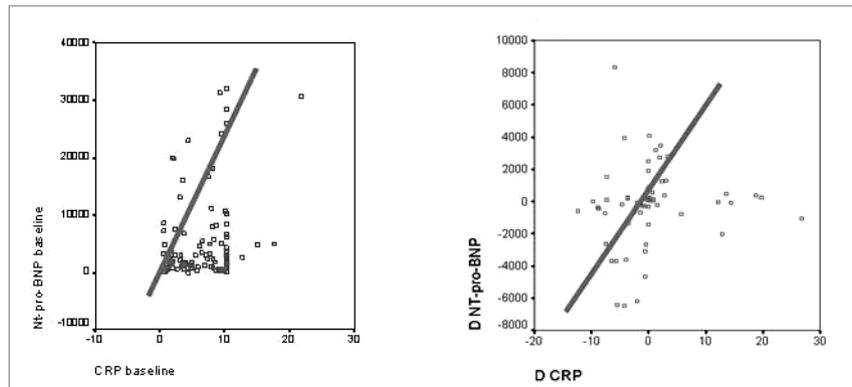


Fig. 1

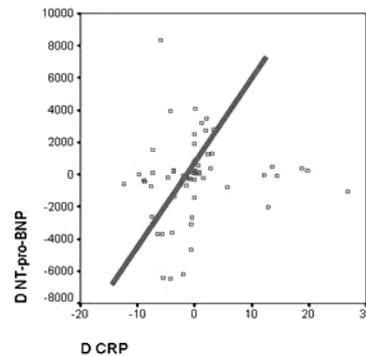


Fig. 2

proBNP were measured immediately before CRT and six months after. **Results** A significant correlation between these two parameters ( $R=0.23$ ;  $p=0.02$ ) before CRT was found (fig. 1). In addition, by evaluating differences of both CRP and NT-pro-BNP between pre-implantation and 6-months after CRT a significant correlation was observed ( $R=0.36$ ;  $p=0.005$ ) (fig. 2).

**Conclusion** CRT induces simultaneous and identical (increase or decrease) changes of hs-CRP and NT-proBNP. Thus both markers appear potentially useful to assess effects of CRT.

### VENTRICULAR TACHYARRHYTHMIA INITIATION IN ICD PATIENTS

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The initiation of Ventricular tachyarrhythmia (VT) is studied by reviewing spontaneous intracardiac electrograms from patients with implantable cardioverter-defibrillators (ICD). We separate patients in two groups: coronary artery disease (CAD) and dilated cardiomyopathies (DCM). Modes of VT onset are divided into: (i) premature ventricular contraction (PVC); (ii) PVC preceded by a short-long-short cycle (SLS); (iii) PVC preceded by a pacing beat after a post-ectopic escape interval (PM). Coupling interval (CI), prematurity index (PI), median sinus rate of 20 sec immediately before VT initiation (Last20sRR), and VT rates are analysed. Significant differences are assessed by Student T-test with  $p < 0.05$ .

A total of 165 VT episodes (79 CAD and 86 DCM) from 37 patients (26 CAD and 11 DCM) are analysed. PVC onset is the most frequent initiation pattern (110 VTs; 67% - 59 CAD and 51 DCM) followed by SLS (35 VTs; 21% - 13 CAD and 22 DCM) and PM (20 VTs; 12% - 7 CAD and 13 DCM).

DCM patients have more VT episodes and a greater variability of the VT initiation patterns, ( $p < 0.02$ ). CAD and DCM groups do not show significant difference in CI, PI, LastRR or VT rate of SLS and PM onsets. The analysis of the other features showed that PI is significantly higher in PVC than SLS and PM ( $p < 0.03$ ) for CAD and DCM. Unexpectedly we also observed that Last20sRR is significantly lower in PM than in PVC or SLS ( $p < 0.001$  for both CAD and DCM groups). In conclusion a greater number and a more heterogeneous initiation of VTs is observed in DCM patients. The unexpected observation that

patients with PM onset have basal cardiac rhythm slower immediately before VT onset should be more deeply investigated.

### EVALUATION OF ATRIAL SENSING PERFORMANCES IN A SINGLE-LEAD ICD SYSTEM AT IMPLANT AND DURING FOLLOW-UP

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Even though introduction of algorithms for discrimination between ventricular and supra-ventricular arrhythmias in dual-chamber ICD has significantly increased specificity of detection, inappropriate therapy delivery still remain a problem for single-chamber ICD. The first clinical experiences, have been reported. The aim of this study is to evaluate the atrial signal amplification capability and long-term stability of atrial signals of a new single-lead ICD system.

We compared P wave amplitude measured at implant with a conventional PSA device (unfiltered P wave) with the measure provided telemetrically by the ICD (filtered P wave). Filtered/unfiltered P wave ratio (amplification factor) was evaluated at implant and during follow-up.

43 patients (mean age  $64 \pm 16$  years) received a Biotronik Lexos A+ and Kainox A+ single-lead ICD system. 23 patients (53%) were implanted for primary prevention and 33 (78%) presented ischemic disease. At implant the mean filtered P wave amplitude was significantly higher than the mean unfiltered signals ( $3,85 \pm 0,81$  mV vs  $2,02 \pm 1,49$  mV,  $p < 0,00001$ ). The mean P wave amplification factor was  $2,77 \pm 1,62$  (range 0,68-7,98) and was linearly correlated with the inverse of unfiltered P wave value ( $R=0,82$ ;  $p < 0,0001$ ). Excluding 5 patients presenting with permanent atrial fibrillation at implant, the correlation coefficient increased up to 0,96 ( $p < 0,0001$ ). However, also in this 5 patients undersensing of atrial signal was never observed. In 25 patients who performed follow-up of  $384 \pm 244$  days, the mean P wave was  $3,80 \pm 0,69$  mV with no significant difference detected as compared with implant data ( $3,68 \pm 0,93$  mV;  $p=0,41$ ).

The single-lead ICD system studied reliably amplified P wave amplitudes by a factor of about three, maintaining this performance during the observed follow-up. Also in patients with atrial fibrillation the device was able to amplify low and unstable P waves providing a continuous arrhythmia detection.

## IMPLANTATION OF CARDIAC DEFIBRILLATORS WITHOUT INDUCTION OF VENTRICULAR FIBRILLATION. DEFIBRILLATION THRESHOLD TESTING

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**Background** Even though the intraoperative threshold testing of the implantable cardioverter defibrillator (DFT) may cause haemodynamic impairment or might be unfeasible, it is still considered a standard and required practice at the time of implantation. Given this issue and the recent improvement of defibrillator technology, we compared the outcome of ICD recipients who underwent DFT with those who had no testing.

**Methods** Enrolled in this retrospective analysis were 291 subjects with chronic heart failure secondary to ischaemic dilated cardiomyopathy who received transvenous ICDs between January 2000 and December 2004. 137 patients (81% men; mean age 69±9 years; mean ejection fraction 26±4%) had DFT (DFT-Group) and 154 (90% men; mean age 69±9 years; mean ejection fraction 27±5%) had no testing (No-DFT Group). All patients were taking standard medications for heart failure. We compared total mortality, total cardiovascular mortality, sudden death cases and spontaneous ventricular arrhythmias (sustained ventricular tachycardia, VT, and ventricular fibrillation, VF) episodes between these groups at two year after implantation.

**Results** No differences were found in general characteristic of two study groups. There were no differences in total mortality (DFT Group Vs No-DFT Group: 20% Vs 16%) and in total cardiovascular mortality (DFT Group Vs No-DFT Group: 13% Vs 10%). DFT Group showed a higher rate of sudden cardiac deaths than No-DFT Group (DFT Group Vs No-DFT Group: 6% Vs 0.6%,  $p < 0.05$ ). VT and VF episodes were both significantly larger in No-DFT than in DFT Group.

**Conclusion** Our data seems support the idea that ICD implantation without DFT is as safe and has the same mortality benefits as implantation with testing. Furthermore the higher incidence of sudden death in DFT-Group seem to suggest that this procedure could further worsen myocardial damage and elevate the defibrillation threshold, thus leading to unsuccessful cardioversion and death. Nevertheless, this hypothesis should now be tested in a larger randomized prospective study.

## AV-DELAY OPTIMIZATION USING LEFT VENTRICULAR IMPEDANCE IN HEART FAILURE PATIENTS

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**Purpose** The selection of an optimal left ventricular (LV) atrio-ventricular delay (AVD) has gained increased attention for cardiac resynchronization therapy (CRT). The optimization is usually performed using echocardiography or invasive hemodynamic measurements. LV impedance has shown to reflect LV volume changes. This study evaluates the feasibility of optimizing AVD using LV impedance measurement.

**Material and Methods** At CRT implant, ten patients (9 male, 9 NYHA III, 1 NYHA II, EF: 26.5±6.7%, QRS: 165 ±35 ms, age: 70.4±5 y) underwent an AVD variation pacing protocol. For each AVD, the pacing mode was switched several times between AAI and BiV DDD at sinus rate+10 ppm. Aortic and LV pressure were measured using a dual-sensor micromanometer catheter. The parameters SV, LV dP/dtmax, stroke admittance (SY) were determined. The best AVD setting was determined by the maximum differences of the SV, dP/dtmax and SY at BiV and AAI pacing.

**Results** The optimum AVD was 130±11 ms for SV, 130±15 ms for dP/dtmax, and 126±19 ms for SY. The maximum observed AVD-difference between SY and hemodynamic methods was 40 ms (in one patient only). The range between maximum and minimum values during AVD-variation was 70±34 mmHg/s (8.7±4.8%) for dP/dtmax, and 7.8±3.8 ml (12.2±4.7%) for SV. If AVD was optimized with SV, the SV for BiV pacing was 64±17 ml, if optimized by SY 63.3±17 ml (NS). If optimized with dP/dtmax, the dP/dtmax for BiV pacing was 804±194 mmHg/s, if optimized by SY 808±186 mmHg/s (NS).

**Conclusions** The differences between the AVD-values selected by impedance and by hemodynamic methods were not significant. The achieved SV and dP/dtmax values during BiV pacing were not significantly different when AVD was selected by impedance or by hemodynamics. A method for automatic AVD-optimization by an implantable device can be achieved by LV impedance.

## CARDIAC RESYNCHRONIZATION THERAPY: PROGRAMMING, OPTIMIZATION AND FOLLOW-UP

### PATIENTS WITH DDD OR VVI STIMULATION: WHO WILL BENEFIT MORE AFTER UPGRADE TO BIVENTRICULAR SYSTEM?

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Risk factors of heart failure and conduction disturbances and other indications for pacemaker (PM) implantation are similar. Therefore it is not uncommon that patients with PM have or develop heart failure symptoms. Moreover most widespread right ventricle apex stimulation may be the reason of worsening or may lead to heart failure. It is now proofed that biventricular stimulation is more beneficial for the patients.

**Purpose** Evaluation of effect of upgrade to cardiac resynchronization therapy (CRT) in patients with previously implanted DDD or VVI pacemaker.

**Method** 19 patients with DDD (4) or VVI (15) with drug resistant heart failure were implanted with left ventricle lead. 3 patients with VVI was upgraded to BiV-DDD. After implantation after 1 month and then every 6 month we evaluated exercise tolerance by 6-minute walk test distance (6MWT), NYHA class and we performed echocardiography. The mean time of follow-up was 8 months (3-13months).

**Results** At implant mean NYHA class was 3,1, 6MWT 370 meters, EF 24,7%, ESD 59,3mm, EDD 71,3mm, MR 2,1. In patients with VVI pacemaker mean NYHA class 3,2, 6MWT 360m, EF 24,4%, ESD 59,5mm, EDD 71,8mm, MR 2,1. In patients with DDD NYHA 3, 6MWT 390, EF 25,7%, ESD 58,7mm, EDD 69,2mm, MR 2.

After 1 month: VVI group: NYHA 2,2, 6MWT 488m, EF 37,6%, ESD 50,6mm, EDD 69,7mm, MR 1,4. DDD group: NYHA 2,5, 6MWT 456m, EF 30%, ESD 46mm, EDD 56mm, MR3.

After 12 months: VVI group: NYHA 1,8, 6MWT 440m, EF 33%, ESD 60,6mm, EDD 72,4mm, MR 2,25. DDD group: NYHA 2,5, 6MWT 275m, EF 29,5%, ESD 51,5mm, EDD 64,5mm, MR 2.

**Conclusions** Clinical improvement is significantly better in patients upgraded to CRT from single-chamber stimulation (VVI) than from dual chamber stimulation (DDD). Improvement can be observed one month after implantation and lasts at least for 12 months.

### VENTRICULAR ELECTRICAL DELAY IN CONGESTIVE HEART FAILURE PATIENTS CAN BE PREDICTIVE FOR CARDIAC RESYNCHRONIZATION RESPONDERS

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The cardiac resynchronization therapy (CRT) has been demonstrated to be effective in improving functional parameters such as New York Heart Association functional class (NYHA) and hemodynamics parameters such as left ventricle ejection fraction (LVEF); nevertheless in many studies and publications there are a consistent number of non-responders patients.

**Aim** The objective of this study has been to evaluate an electrical index as a possible method to predict responders.

**Methods and Results** From October 2004 to June 2005, 29 patients (16 male, mean age 67+/-10 years, mean NYHA functional class 3.0+/-0.3, mean LVEF 26.8+/-5.4%) with dilated cardiomyopathy (primitive 41%, ischemic 48%, other 11%) underwent implantable cardioverter defibrillator biventricular implant (CRT-D) with distinct sensing channels (Guidant Contak Renewal IV®).

During the procedure the electrical delay (ms) between right ventricular and left ventricular leads (VVD) was measured assessing the different timing of the sensing response of the leads.

We positioned the left leads in lateral branch of coronary sinus (64%),

anterior (24%) and posterior (12%) and we have mean VVD of 84 +/- 41 ms.

During a 12 months follow-up we define responders the patients that improve the NYHA class at least of one unit (RESP A) and that improve the LVEF at least of 30% (RESP B). In the whole population we have 48% of RESP A, 62% of RESP B and 21% of non responders (neither RESP A nor B).

If we consider the patients with VVD>=90 ms (15 pts, 52%) we have 67% of RESP A, 87% of RESP B and only 6% of non responders (neither RESP A nor B).

**Conclusions** VVD assessment, during implant procedure, can be a valid and helpful tool to improve the rate of responders suchlike the positioning in the lateral branch.

### REGULAR VV DELAY OPTIMIZATION IS NECESSARY TO MAINTAIN OPTIMAL HEMODYNAMICS IN CRT-D PATIENTS

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**Background** Atrio-ventricular delay (AV delay) and inter-ventricular pacing delay (VV delay) are critical parameters in Cardiac Resynchronization Therapy (CRT) devices, which optimization improves cardiac hemodynamics. However, data on the respective benefits of these 2 parameters and the need for their regular optimization is limited.

**Study objectives** The aim of this retrospective analysis was to evaluate the respective acute hemodynamic benefits of AV and VV delay optimization at baseline and 6 months post-implantation, in the patients enrolled in the RHYTHM II study. All p-values <0.05 were considered significant.

**Methods** RHYTHM II was a randomized trial evaluating the benefit of VV delay optimization in patients implanted with a CRT-D device. 73 patients underwent echocardiographic AV and VV delay optimization both at baseline and at 6 months.

Optimal AV delay provided the widest separation between E and A waves, preventing early closure of the mitral valve. Optimal VV delay maximized the LV outflow tract velocity time integral (LVOT VTI). **Results** At baseline, when compared to default programming (AV=150ms and VV=0ms), AV delay optimization did not improve significantly LVOT VTI, but VV delay optimization did (p<0.0001), both compared to default programming and optimized AV delay.

6 months post implantation, the optimal AV delay was not different from baseline. However, the optimal VV delay was significantly different from baseline (p=0.0479). The values of the LVOT VTI at the new optimized programmings (AV and AV & VV delays) were not different from baseline (p=0.5034 and p=0.6344 respectively).

**Conclusions** VV delay optimization improves acute cardiac hemodynamics in CRT-D patients. Maintenance of optimal hemodynamic performance at 6 months requires re-optimization of VV delay.

## AV OPTIMIZATION IN PATIENTS WITH DDD AND CRT DEVICES. A SIMPLE METHOD NOT REQUIRING DOPPLER ECHOCARDIOGRAPHY

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Although the value of AV interval optimization (AVopt) is unquestionable, the methods used are controversial and complex. AVopt is needed because DDD and CRT devices introduce delays affecting mechanical left heart AV (LtAV). Because of these, normal right heart AVs (RtAV) may result in an abnormal LtAVs, causing atrial and ventricular contraction overlap. A previously described AVopt equation (US Pat 5,179,949) was used in this study:  $RtAV = ATt + IAEMD - PSO - IVD$ , where ATt= atrial transport time, PSO= P-sensing lag time, IAEMD= interatrial electromechanical delay and IVD= interventricular delay. With equation, RtAV is adjusted so that ATt ends before LV contraction. Aims: 1. To demonstrate that constituents of equation are predictable from ECG. 2. To develop a software AVopt requiring only ECG measurements. Methods: Thirty-three patients with DDD and 7 Pts with CRT were included for validation of the method. P-wave duration (PWd): measured using ECG lead-II. ATd: measured from the mitral flow A wave. IAEMD: from the onset of right atrial P wave to onset of A wave. PSO: difference measured-programmed AVs. IVD: extension of left prejection interval by RV pacing. Regression analyses were done between IAEMD and PWd and between IVD and paced QRS duration. Results: 1. Correlation coefficient between PWd and IAEMD was  $R=0.82$ ,  $P<0.001$  and between IVD and paced QRS duration was  $R=0.8$ ,  $P<0.002$ . 2. Mean ATd was  $73 \pm 4$  ms. Regressions and ATd were loaded into the computer. For optimization the following inputs are needed: PWd, RV-paced QRS and PSO. At the press of a key suggested AV delays for all pacing modes are then available. Conclusions: AVopt of DDD and CRT is feasible by compensating for PSO, interatrial and interventricular delays. Delays can be easily predicted from surface ECG and calculations done by custom software with no need of Doppler echocardiography.

## COMPARISON OF THE IMPACT ON QUALITY OF LIFE AND DEVICE RELATED ANXIETY OF PATIENTS RECEIVING CARDIAC RESYNCHRONIZATION THERAPY AND THAT PERCEIVED BY CAREGIVERS

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**Introduction** Randomized studies have found significant improvement in quality of life (QOL) using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) in patients receiving CRT. However, none have explored how QOL is perceived by the patients' caregivers. Furthermore, other QOL instruments have shown worsening QOL in some ICD patients that was not reflected in CRT-D studies. This study investigated QOL from perspectives of both patients and caregivers, and the possible influence of device-related anxiety on MLHFQ QOL.

**Methods** The MLHFQ was administered to 46 consecutive patients and their caregivers receiving CRT devices at PinnacleHealth Hospitals immediately after implant and at one month follow-up. At the follow-up, they also answered the device-specific questionnaire (SDQ). Changes in QOL were computed for both groups and stratified by level of device anxiety according to SDQ. Within-group QOL scores were tested with a paired t-test and between-group scores with an unpaired t-test.

**Results** Patients had a mean age 71 years (range 45-86), with 65% male, and 35% female. CRT was associated with a QOL improvement of the patient (-31 pts,  $p<0.0001$ ) and that perceived by the caregiver (-30 pts,  $p<0.0001$ ). Although the mean QOL changes were virtually identical, the correlation between individual patients and their

specific caregivers was poor ( $r^2=0.042$ ). Device-related anxiety was expressed in 21/46 (46%) patients. QOL improvement in those patients was less than those without device-related anxiety (-28 vs. -35 pts, respectively) not statistically significant ( $p=0.22$ ).

**Conclusions** There was a significant improvement in QOL and patient caregivers also discern a similar degree of improvement. While nearly half of patients expressed anxiety about their device, this factor did not appear to impede the ability of CRT to improve QOL. Further study is required to clarify the differences in QOL from different perspectives and to evaluate the validity of MLHFQ in assessing device-related outcomes.

## THE USE OF THE QRS MORPHOLOGY IN THE DETERMINATION OF THE OPTIMAL SENSED AV INTERVAL

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**Background** In cardiac resynchronization therapy (CRT) the optimal paced atrio-ventricular (PAVopt), optimal sensed atrio-ventricular (SAVopt) and optimal interventricular (V-V) has to be determined in order to achieve maximal benefit.

**Hypothesis** We hypothesized that the morphology of the paced QRS complex during measurement of the PAVopt interval can be used to determine the SAVopt interval, in patients with intrinsic AV conduction.

**Methods** In 13 patients (2 females) with normal AV conduction and LBBB, with heart failure fulfilling the criteria for implantation of a CRT device, PAVopt and V-V interval were determined by invasive measurement of LV dP/dt max. The corresponding 12 lead ECG was recorded, followed by LVdP/dt measurement with a PAV interval 20 ms longer and shorter than the PAVopt. Subsequently the lower rate was decreased below the sinus rate creating atrial sensing ventricular pacing. In this setting the SAV interval was changed till the QRS morphology was identical to the morphology at the optimal paced AV interval. At this setting LV dP/dtmax was measured and compared to LVdP/dt at an AV interval 20 ms longer (SAVopt+20ms) and 20 ms shorter (SAVopt-20ms), than S-AVopt.

**Results** By optimization of the PAV and V-V interval the LVdP/dtmax increased from  $613 \pm 298$  to  $748 \pm 213$  mmHg/s (+22%;  $p=0.0009$ ). The PAVopt was  $146 \pm 19$  ms. The SAVopt was  $97 \pm 14$  ms and the corresponding LVdP/dt max at this interval was  $736 \pm 194$  mmHg/s (+20%;  $p=0.002$ ). LVdP/dtmax at S-AVopt-20ms and SAVopt+20ms was  $711 \pm 192$  mmHg/s ( $p=0.003$ ) and  $707 \pm 203$  mmHg/s ( $p=0.0009$ ) respectively. The mean difference in PAVopt and SAVopt was  $50 \pm 15$  ms ( $p=0.0004$ ) ranging from 20 to 80 ms.

**Conclusion** In CRT there is a wide individual spread in the difference between PAVopt and SAVopt, necessitating determination of both. Once PAV opt is determined, the corresponding QRS morphology can be used as a template to determine the SAV opt and vice versa..

## IS THERE ANY IMPORTANCE OF A RIGHT VENTRICULAR SEPTAL LEAD IMPLANTATION IN THE CARDIAC RESYNCHRONIZATION THERAPY?

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**Background** The cardiac resynchronization therapy (CRT) has become the admirable treatment for heart failure (HF) but an ideal lateral vein is sometimes absent.

**Objectives & Methods** The aim of this study is to know whether the right ventricular (RV) septal lead implantation in cases without suitable lateral veins was an appropriate procedure or not. Thirty-one cases (17 males, 71 years old) underwent CRT as of this August in

our hospital. Average NYHA classification was 3.1, QRS width was 150msec and ejection fraction was 33%. The optimal left ventricular (LV) lead implantation in a lateral or an antero-lateral vein could be done in 23 cases (74%) and the RV septal lead implantation was necessary to get enough electrical separation time (over 100msec.) between RV and LV lead in 6 cases (19%). In 2 cases with much dilated left ventricle, tri-ventricular pacing was done. Atrial septal lead implantation was also done in later cases.

**Results** Twenty-four responders (77%) could have kept the improvement of their complaints without any re-hospitalization at 12 months follow-up period. Four of 6 cases (66%) with RV septal lead implantation could become responders.

**Conclusion** This study showed RV septal lead implantation might be an appropriate procedure for cases without optimal lateral veins. Even in the use of the cardiac resynchronization therapy defibrillators, this procedure still might be necessary in cases which a tri-ventricular pacing is needed.

### CAN CARDIAC RESYNCHRONIZATION THERAPY CAUSE REVERSE REMODELLING OF THE RIGHT VENTRICLE?

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**Objectives** Cardiac resynchronization therapy (CRT) can improve symptoms and left ventricular (LV) function in patients with end-stage

heart failure and LV dyssynchrony. It has been reported that CRT also causes reverse remodelling of the LV. It is still unclear if CRT also leads in reverse remodelling of the right ventricle (RV). The aim of this study was to evaluate RV remodelling after 8 months of CRT.

**Methods** Fifteen consecutive patients (66;± 11 years; 10 male,) with end-stage heart failure (9 with coronary artery disease (CAD) and 6 with dilated cardiomyopathy (DC)), EF < 30%, QRS duration > 120 ms, and left bundle branch block underwent CRT-implantation. LV volumes and RV chamber size were assessed at baseline, and after 8 months of CRT. Simpson's technique was used for LV volumes calculating. For assessing RV chamber size we measured the following parameters in the apical four chamber view: 1) RV long axis, from tricuspid annulus to RV apex (RVLA) 2) RV short axis, from ventricular septum to RV free wall at the middle of the RV (RVSA) and 3) tricuspid annulus diameter (TVAN).

**Results** CRT led to significant remodelling of the LV after 8 months (end-diastolic volume from 267;±98ml to 240;±76 ml, p<0.001, and end-systolic volume from 218;±91 to 167;±81 ml, p<0.001).

RV chamber size also presented a significant decrease at 8 months of therapy. RVLA from 93 to 88 mm, p<0.001, RVSA from 31 to 29 mm, p<0.01 and TVAN from 39 to 35mm, p<0.01. Patients with end-stage heart failure due to DC presented the highest level of RV remodelling.

**Conclusions** CRT can cause significant reverse remodelling of the left and the right ventricle after 8 months of therapy. For RV remodelling most benefit was observed in patients with heart failure due to Dilated cardiomyopathy.

## CARDIAC ARRHYTHMIAS: CLINICAL ASPECTS

### UNCOMMON ETIOLOGY FOR HEART BLOCK IN ADULTS

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**Purpose** A variety of diseases, besides the common Lev-Lenegre disease, can cause heart conduction system abnormalities. This includes: acute rheumatic fever, Sarcoidosis, connective tissue disorders, neoplasm and bacterial endocarditis.

The purpose of the study is to raise awareness to these rare conditions.

**Method** We present eight adult patients with various rare causes for heart block, who needed pacemaker therapy (temporary or permanent):

- I. A 33-year-old female who suffered acute rheumatic fever and transient complete atrio-ventricular block (CAVB).
- II. A 19-year-old soldier with a history of acute rheumatic carditis, who presented with recurrent syncope. Serial ECG recordings demonstrated inappropriate sinus bradycardia, and AV dissociation.
- III. A 43-year-old female suffering Wegener granulomatosis, proved by nasal mucosa biopsy and intermittent CAVB.
- IV. A 68-year-old female, known with metastatic breast cancer with pericardial involvement, presented with syncope and CAVB.
- V. A 69-year-old female presented with CAVB was diagnosed as having bacterial endocarditis, with abscess formation along the conduction system.
- VI. A 43-year-old male, presented with and Stokes-Adams syndrome. On chest X-ray, CT and Gallium-scan, there is an evidence for hilar lymphadenopathy, being evaluated for Sarcoidosis.
- VII. A 42-year-old man presented with intermittent 2:1 AV Block. The patient was treated with Radiotherapy to the Mediastinum for Lymphoma, 25 year previously, and on a CT scan of chest, there is evidence of heavy calcifications of the 3 coronary arteries, the root of Aorta, Aortic valve and Mitral Annulus.
- VIII. A 49-year-old male, presented with CAVB. This young patient has quadriplegia and syringomyelia, following a road accident, 11 years ago.

**Conclusion** It is suggested that patients with these disorders should be followed periodically, thus allowing early detection and treatment of heart conduction disturbances.

### INDICATION CRITERIA FOR ELECTROPHYSIOLOGICAL STUDY IN PATIENTS AFFECTED BY MYOTONIC DYSTROPHY TYPE 1

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**Purpose** Cardiac involvement in Myotonic Dystrophy type 1 (MD1) is characterized by arrhythmias causing an high incidence of sudden death (SD). Our aim is to evaluate sinus node (SN), atrio-ventricular (AV) node alterations and ventricular tachyarrhythmias inducibility at electrophysiological study (EPS).

**Materials and Methods** 172 MD1 patients (pts) were evaluated. Patients with symptoms as palpitations, pre-syncope or syncope, family history of SD, pacemaker (PM) or implantable cardioverter-defibrillator (ICD) implantation, ECG evidence of PQ interval > 240 ms,

2nd/3rd AV block, left bundle branch block (LBBB) or fascicular block associated right bundle branch block (RBBB), RR pauses > 3s at Holter ECG or frequent ventricular arrhythmias underwent EPS.

**Results** an EPS has been proposed in 86 pts (50%); 36 (21%) for family history, 45 (26%) for symptoms, 38 (23%) for AV block or LBBB/RBBB, 3 (1.8%) for RR pauses and 13 (7.6%) for frequent ventricular arrhythmias. EPS was performed in 67 pts (mean age 44+/-13 years; 36 males). Intracardiac recordings showed a mean AH interval of 116+/-39 ms and a mean HV interval of 64+/-19 ms (HV >55 ms in 59% of pts). Corrected SN recovery time was 368+/-173 ms, with a sinus node impairment detected in 15% of pts. AV conduction was evaluated by incremental atrial pacing that showed a mean AV Wenckebach of 430+/-111 ms and a pathological AV Wenckebach in 21% of pts. Sustained atrial arrhythmias were induced in 13% of pts, while sustained ventricular arrhythmias in 25%. As a consequence of EPS results a device implantation was indicated in 44 (66%) pts; a loop-recorder in 12 (27%) pts, a PM in 22 (50%), and an ICD in 10 (23%).

**Conclusions** When widened to symptoms and family history for arrhythmias, EPS is indicated in 50% of MD1 population bringing to device implantation in 2/3 of pts.

### MYOCARDITIS IN ATHLETES: EPIDEMIOLOGY, PROGNOSIS AND MEDICO-LEGAL ASPECTS

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**INTRODUCTION** Infective myocarditis (I M) is one cause of sudden death (SD) in athletes. Thus, a protocol including non invasive cardiology tests (NICT), laboratoristic profile (LP) has been set-up.

**PATIENTS AND METHODS** 119 young athletes (SA) were selected for frequent ventricular arrhythmias (VA), worsening of pre-existing VA, with or without evolutive STT changes. They received NICT and a LP, including IgM, IgA and IgG versus the most common viral and bacterial infections (AI).

**RESULTS** 56 of the 119 subjects (47%) showed LP compatible with AI. 28 of the 56 subjects (50%), with positive LP had also clinical signs of an acute systemic illness (SI) with a concomitant myocardial involvement (MI). In 26 of 28, SA has been discontinued and resumed in 20, after 6-9 months. In 28 with LP, in 12 case IM was due to Echo Cocksackie B, Enterovirus, in 4 cases to Toxoplasmosis, of which 1 lethal and 1 evolving in dilated cardiomyopathy, in 4 cases to infectious mononucleosis, in 2 cases to flu virus or Adenovirus, in 2 cases to Mycoplasma Pneumoniae, in 2 cases to Herpes Virus or Herpes Zoster infections, 1 case to borelliosis or Lyme' s syndrome and 1 case to Legionellosis. We observed 2 death in the acute phase, and 1 death in the follow-up.

**CONCLUSIONS** The signs of a SI could be identified in SA (47%). Clinical picture of an upper respiratory tract o low bowel infection, in association with a typical LP, can be regarded as SI. Signs of pericarditis and or ST changes, frequent VA or worsening of VA can be considered highly indicative of MI involvement. SA should be discontinued for 6-9 months.

A strict adherence to guidelines and to the proposed protocol for screening and follow-up of suspected myocarditis in athletes, is worthwhile in eliminating medico-legal controversies.

## REVERSIBILITY OF PJRT-RELATED TACHYCARDIOMYOPATHY

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**Purpose** Sustained chronic-incessant tachyarrhythmias often cause left ventricular dysfunction defined as tachycardiomyopathy. Permanent junctional reciprocating tachycardia (PJRT), a re-entrant tachycardia, is an infrequent form of chronic supraventricular tachycardia that occurs primarily in young people. The arrhythmia is usually refractory to drug therapy, therefore radiofrequency ablation should be considered as the first choice treatment.

**Materials and Methods** A 22-year old man with a diagnosis of dilated cardiomyopathy associated to permanent junctional reciprocating tachycardia was referred to our hospital for radiofrequency (RF) ablation. No drugs had been tested in order to control the arrhythmia. The echocardiogram demonstrated left ventricular dilatation (EDV 178 ml) with severe deterioration of the EF (31%) and mild mitral regurgitation. The patient underwent an endocardial electrophysiological study. Two quadripolar catheters were inserted percutaneously through the right femoral vein and positioned in the region of the His Bundle and in the right ventricle. A decapolar catheter was placed into the coronary sinus. A 4 mm tip Celsius ablating was used to map the tricuspidal annulus and perform RF ablation. This catheter was connected to a Medtronic Atakr RF generator. Endocardial signals were recorded on a LAB System DUO EP. Patient entered the EP lab in PJRT, the tachycardia having a cycle length of 400 msec. The accessory pathway was recorder at the posteroseptal aspect of the coronary sinus orifice. RF energy was delivered at this site, obtaining termination of the arrhythmia. Following catheter ablation, PJRT could no more be induced, even during isoproterenol infusion.

**Results** At 3 months control, patient was asymptomatic and the echocardiogram demonstrated improvement of ventricular function.

**Discussion** This report confirms that catheter ablation should be the first choice treatment for permanent junctional reciprocating tachycardia and should be performed as soon as possible, to improve or normalize the cardiac function.

## COMPARISON BETWEEN ELECTROANATOMIC MAPPING VS CARDIAC MAGNETIC RESONANCE IMAGING IN MYOCARDIAL SUBSTRATE STUDY IN MYOTONIC DYSTROPHY TYPE 1

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**Purpose** In Myotonic Dystrophy type 1 (MD1) affected patients an altered cardiac substrate is present that clinically presents with conduction abnormalities and arrhythmias. Aim of this study is to evaluate early myocardial alterations detection using electroanatomic mapping and cardiac magnetic resonance (cMRI) in MD1 population without evidence of bradi- or tachy-arrhythmias.

**Materials and Methods** Fourteen MD1 patients underwent electrophysiological study (EPS) and right ventricular (RV) electroanatomic mapping with CARTO system. RV unipolar voltage (UNI-v), bipolar voltage (BI-v) (normal value > 1,5 mV) and bipolar potential duration (Bi-dur) were misured; RV was divided in 4 regions: apex, septum, free wall and outflow tract. All patients underwent cMRI with

RV structural alterations analysis (edema, fibroadipose infiltration and delayed enhancement).

**Results** CARTO mapping analysis evidenced at least one altered potentials region (BI-v < 1,5 mV) in a statistically significant greater number of patients (8/14) than cMRI did (2/14) (p=0.046). Comparing altered myocardial substrate presence at CARTO mapping vs cMRI in the 4 RV regions a statistically significant difference was found for outflow tract (p=0.033). No statistically significant differences were found for apex, septum and free wall.

**Conclusions** CARTO electroanatomic mapping seems to be more accurate in detecting presence of altered electrical substrate in RV outflow tract than cMRI in MD1 patients without evidence of bradi- or tachy-arrhythmias. Such electrical alterations presence could help in identifying a pre-clinical stage in MD1 related myocardopathy.

## IMPORTANCE OF IDENTIFYING FASCICULOVENTRICULAR PATHWAYS

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**Objective** To describe the electrophysiologic findings of fasciculoventricular pathways (FVP) and the results of adenosine administration to achieve their diagnosis.

**Method and Results** Six out of 1354 pts, referred for WPW syndrome, were found to have FVP.

1. Four pts with isolated FVP exhibited only anterograde decremental conduction with subtle preexcitation. As the AH prolonged the HV and degree of preexcitation were unchanged. No tachycardia was induced.
2. During programmed atrial stimulation (PAS), a 26 years old woman showed an AV nodal reentrant tachycardia with a FVP serving as a bystander. After ablation of the slow AV pathway (SAVP) no tachycardia could be induced.
3. A 15 year old girl showed subtle preexcitation. PAS revealed a left AV pathway (LAVP). An AV reentrant tachycardia with 2 cycle lengths was induced showing variations of 50 ms in the AH interval. Retrograde conduction occurred through the LAVP. When the cycle length was 240 ms, AH was 60 ms and HV 35 ms (normal QRS). Conduction may have occurred through the fast AV pathway and a FVP might have been refractory. When the cycle length was 290 ms, AH was 110 ms and HV 25 ms (preexcited QRS). Conduction may have occurred through a SAVP and a FVP. After ablation of the LAVP, minimal preexcitation persisted. AV conduction was decremental demonstrating constant HV intervals and dual AV node physiology. No arrhythmia was induced.

In all cases, administration of adenosine resulted in gradual prolongation of the AH interval and transient AV block while HV and preexcitation remained constant.

**Conclusions** FVP did not participate in the tachycardia circuits, serving as bystanders. As FVP may simulate antero-septal or mid-septal AV pathways their identification is important to avoid catheter ablation in the septal zone, with the potential risk of AV block. Adenosine administration is a helpful tool for noninvasive diagnosis.

## FETAL ARRHYTHMIAS: FROM ECHOCARDIOGRAPHIC DIAGNOSIS TO CLINICAL MANAGEMENT

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**Background** Fetal arrhythmias are serious conditions sometimes requiring treatment. An early diagnosis and a correct assessment of the hemodynamic consequences of the arrhythmia play a critical role in a correct management of this condition.

**Methods** We studied 36 consecutive fetuses with cardiac arrhythmia. Rhythm diagnosis was based on M-mode, pulsed wave Doppler and tissue Doppler imaging (TDI). Only fetuses with: 1) incessant tachycardia (>12 hours) and mean ventricular rate >200/min, 2) signs of left ventricular dysfunction, or 3) hydrops, were treated using oral maternal drug therapy.

**Results** The mean gestational age at diagnosis was 24.3±4.5 weeks. Twenty-one fetuses had tachycardia with a 1:1 AV conduction. Based on ventricular-atrial interval, prenatal diagnosis was: permanent junctional reciprocating (n=6), atrial ectopic (n=6) or AV reentry tachycardia (n=9). One had atrial flutter, 1 ventricular tachycardia and 4 congenital AV block. Nine showed premature atrial or ventricular beats. Fifteen fetuses with incessant tachycardia, left ventricular dysfunction or hydrops were prenatally treated with maternal administration of digoxin, sotalol or flecainide. The total success rate (sinus rhythm or rate control) was 14/15 (93%). Seven fetuses were hydropics. Three of these died (1 at 28 weeks of gestation, 2 in the first week of life). The prenatal diagnosis of arrhythmia was confirmed at the birth in 31/35 live-born. No misdiagnosis was made using TDI. At a 3±1.1 year follow-up 33/35 children are alive and well.

**Conclusion** Fetal echocardiography could clarify the electrophysiological mechanism of fetal cardiac arrhythmias and guide the therapy.

## ANALYSIS OF THE COST OF THERAPY IN PATIENTS WITH ATRIAL FIBRILLATION IN THE CZECH REPUBLIC

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We have calculated medical costs in patients with atrial fibrillation (AF). Methods: Using a retrospective inquiry sent to local cardiologists, data from 306 patients (94 women, 64 ±11 years) was obtained. Patients undergoing AF ablation were not included. Total expenses at treatment of AF patients were calculated as costs spent on hospital stay, medical investigations, diagnostic tests, therapeutic interventions, drugs, and transportation. The calculated items were the following: complex and targeted examination by local cardiologists and general practitioners, prothrombin time evaluation, Holter ECG monitoring, transthoracic and transesophageal echocardiography, electrical and pharmacological cardioversion, hospital stays for AF or embolic complication, coronary angiography, atrial flutter I ablation, pacemaker implantation, emergency medical service, pre-paid medical care, spas, stomatology, and transportation. Results: Total expenditure per patient was 42 406.60 Czech crowns (1 413 Euro) per year. Of the individual items, the cost of therapeutic interventions amounted to 50%. Catheter ablation of type I atrial flutter was the most expensive intervention employed to reduce the arrhythmic burden (410 EUR). Hospital stays followed as the second largest item of the overall cost (27%). If flutter ablation was not calculated, hospital stay would represent the highest cost (327 EUR). Expenditures on antiarrhythmic and anticoagulation therapy amounted to 9% of the total costs. Conclusion: Similar studies from other European countries showed yearly expenditures on the medical care of AF patients of around 3 100 EUR, which is roughly double of the burden of 1 413 EUR in the Czech Republic. This difference is caused mainly by lower price of work and by global economic situation in the Czech Republic. In addition to the atrial flutter ablation, hospital stays represented the major expenditure, which is in concord with previous studies.

## CARDIAC PACING: TECHNICAL AND CLINICAL ISSUES

### A FEASIBLE APPROACH FOR INTERATRIAL SEPTUM PACING USING A NEW STEERABLE CATHETER TO FACILITATE PRECISE LEAD PLACEMENT

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**BACKGROUND** There are a variety of pacing techniques to the prevention of atrial fibrillation (AF). The interatrial septum (IAS) pacing has been reported to be effective to reduce the frequency of paroxysmal AF.

The MEDTRONIC 3830 Select Secure system is a new generation steerable catheter and active fixation lead useful to facilitate precise lead placement. We report our experience in IAS pacing using 3830 in order to evaluate feasibility and safety.

**METHODS** IAS pacing superiorly to the coronary sinus by Medtronic 3830 system was performed in 11 patients (6 males 5 females) with standard indication for permanent dual-chamber pacing and a history of recurrent paroxysmal AF. After hospital discharge, clinic visit, ECG, device system performance and evaluation of arrhythmic events was scheduled at 6, 12, 18, 24 months.

**RESULTS** The mean time for implantation skin to skin was 67 minutes. We had one acute dislocation that required repositioning and no other adverse events. At implant the mean pacing threshold was 1.6 +/- 0.4 V, the impedance 700 +/- 208 Ohm, and the p wave amplitude 2.3 +/- 1.5 mV. At 6 months the mean pacing threshold was 1.1 +/- 0.6V the impedance 509 +/- 74 Ohm and the p wave amplitude 1.9 +/- 1.3 mV. During a 484 +/- 195 days mean follow up we observed: 3 patients AF totally free, 4 patients had AF recurrence but very short (< 1 minutes), 3 patients had AF recurrence but with lowering of the symptoms, and only one patient had AF recurrence that has necessitated DC cardioversion.

**CONCLUSIONS** Our experience suggests that Medtronic 3830 Select Secure system is safe and useful to reach and pace IAS. The lead performance improves by time. The IAS pacing may prevent and markedly reduce the frequency of paroxysmal af.

### A DEDICATED LEFT ATRIAL PACING AND SENSING LEAD IMPROVES THE OUTCOME OF ATRIAL RESYNCHRONISATION PACING FOR ATRIAL FIBRILLATION

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**PURPOSE** To compare the outcome of patients who underwent atrial resynchronisation for drug resistant atrial fibrillation (AF) using a new bi-atrial pacemaker with a dedicated coronary sinus lead for permanent left atrial pacing and sensing versus patients who were treated with a conventional bi-atrial pacemaker with left and right atrial leads connected in tandem to a single atrial port by use of a splitter device.

**METHODS** 18 patients were implanted with the new bi-atrial pacemaker with dedicated left atrial pacing (LA group) and 13 patients were implanted with a conventional splitter type bi-atrial pacemaker (conventional group). We compared the 2 groups with regard to symptoms, AF duration, AF admissions and antiarrhythmic drug requirement for an equal period of time pre and post-pacemaker implant (29 +/- 18 months for LA group and 41 +/- 20 months for conventional group).

**RESULTS** The conventional group (mean age 68 years) consisted of 9 males, 4 females and the LA group (mean age 69 years) consisted of 11 males, 7 females. There was a significant improvement in both symptoms and AF duration in 15/18 (83%) of the LA group versus 6/13 (46%) of the conventional group (p=0.03). The improvement in

median AF episodes was a reduction of 26 days/month (range -9 to 30) in the LA group compared to 2.5 days/month improvement (range -7.5 to 22.5) in the conventional group (p<0.001). There was an 80% reduction in mean number of admissions in LA group (2.2 +/- 2.2 pre-implant and 0.4 +/- 0.8 post; p<0.001) compared to a 48% reduction in conventional group (3.3 +/- 4.4 pre and 1.7 +/- 1.5 post; p=0.05). Improvement in mean number of antiarrhythmic drugs was similar in the 2 groups (LA group 1.9 +/- 1.1 and conventional group 1.7 +/- 1.8; p=0.7).

**CONCLUSIONS** Atrial resynchronisation for AF using a bi-atrial pacemaker with a dedicated coronary sinus lead which enables more effective left atrial pacing, produces a better result than conventional bi-atrial pacing.

### SECOND GENERATION OF FRACTAL-COATED PACEMAKER SCREW-IN LEADS WITH STEROID

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**Background** Screw-in leads traumatize the endomyocardium, resulting in increase of stimulation thresholds after implantation, whereas steroid-elution has demonstrated improved thresholds in active-fixation leads. The performance of the 2nd generation of fractal-coated screw-in leads with steroid has been compared with the 1st generation.

**Methods** We investigated atrial pacing threshold, impedance, and P-wave amplitude at Pre-Hospital Discharge (PHD) and at the 1-, 3-, and 6-month (mth) follow-up (FU) of the Setrox S lead with those of the predecessor Selox SR lead (both Biotronik). Setrox S is similar to Selox SR, except for the pacing surface (4.5 mm<sup>2</sup> vs. 2.0 mm<sup>2</sup>) and the thinner and more flexible body. The data were derived from 2 international multicentric prospective studies, carried out to demonstrate efficacy and safety of the leads: 127 pts implanted with Setrox S (71±10 yrs, 55% males, FU-time 5.5±1.8 mths) were compared with 58 pts implanted with Selox SR (68±9 yrs, 60% males, FU-time 5.4±1.7 mths). P-values < 0.05 were stated as significant, results are represented as mean ± SD.

**Results** Atrial threshold at 0.4 ms was significantly lower for Setrox S at PHD and similar for later FUs (0.6±0.2, 0.7±0.3, 0.8±0.4, 0.8±0.4 V vs. 0.8±0.6, 0.7±0.3, 0.8±0.5, 0.8±0.5 V; at PHD, 1-, 3-, 6-mth FUs, resp.). Atrial impedance at 0.4 ms and 3.6 V was significantly higher for Setrox S at each FU (520±63, 534±64, 539±68, 545±69 Ohm vs. 477±93, 463±63, 476±63, 471±52 Ohm). P-wave amplitude was higher (n.s.) for Setrox S at PHD and similar for later FUs (3.7±1.7, 4.0±1.8, 4.1±1.8, 4.1±1.7 mV vs. 3.4±1.9, 4.1±1.8, 4.2±1.7, 4.2±1.9 mV).

**Conclusions** The active-fixation, fractal-coated and steroid-eluting lead Setrox S showed better performances acute after implant compared to Selox SR lead. The results at follow-ups are similar so the performance of the Setrox S corresponds to the state-of-the-art active-fixation leads with steroid.

## THE CHOICE OF VDD PACEMAKER AT REPLACEMENT IS LIMITED BY THE PREVIOUSLY IMPLANTED LEAD?

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Theoretically, replacement of a VDD device requires using a similar pacemaker to provide the best match between the filtering characteristics of the pacemaker and the atrial dipole of the lead. This study evaluated the performance of newly implanted Vitatron VDD pacemakers connected to dedicated leads and compared the results with those of the same Vitatron pacemakers used as replacement but connected to a variety of nondedicated leads.

**Methods** 23 consecutive patients (15 M, 8 F, 78±6 years) in Group 1 underwent pacemaker replacement with a VDD(R) Saphir 3 (Vitatron BV, Arnhem, The Netherlands) device designed for an 8.6 mm atrial dipole. Atrial dipoles of the previously implanted leads ranged from 5 to 30 mm. Another 22 consecutive patients (14 M, 8 F, 80±7 years) in Group 2 received a Saphir 3 pacemaker with the related dedicated lead.

**Results** P-wave amplitude measured by the same Pacing Sensing Analyzer (PSA) at the first implantation was 1.7±0.8 vs. 1.7±0.5 mV (P=NS) in groups 1 and 2 respectively. P-wave amplitudes measured at 1 month follow-up after replacement in Group 1 and at 1 month follow-up after implantation in Group 2 were 0.69±0.5 vs. 0.85±0.3 mV (P=NS) respectively. The percentage of atrial sensing at the same follow-up was 97±3 vs. 95±5% (P=NS) in groups 1 and 2 respectively.

**Conclusions** Replacement of VDD pacemakers with the Saphir 3 model designed for a short dipole is safe and reliable when used in combination with previously implanted nondedicated leads.

## IMPROVEMENT OF CONGESTIVE HEART FAILURE BY UPGRADING OF PERMANENT RIGHT VENTRICULAR APICAL PACING (DDD) TO CARDIAC RESYNCHRONIZATION THERAPY

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Right ventricular apical (RVA) pacing induces chronic LV remodeling, including asymmetric hypertrophy and redistribution of cardiac mass, mitral regurgitation, increased left atrial diameter, reduced EF, and may explain the increased risk for heart failure (HF) hospitalization.

**Aims** To evaluate the clinical response of patients with RVA pacing upgraded to cardiac resynchronization therapy (CRT).

**Methods** Twenty-eight consecutive patients (mean age 68, mean EF 0.28) with RVA pacing (DDD) and a very high-risk substrate (low EF, MI, a history of symptomatic HF) were upgraded to CRT-D. Eighteen patients (64.3%) had DDD/Cum%VP >= 40 and 10 patients (35.7%) had DDD/Cum%VP <= 40. All patients had a wide paced QRS (226 ± 34 ms). Clinical and echocardiographic parameters were recorded prior to, at 3 and at 6 months after CRT upgrading.

**Results** Upgrading of RVA pacing to CRT resulted in a significant improvement in EF, mitral regurgitation degree, and in measures of electrical and mechanical synchrony. NYHA functional class was also significantly improved (from 3.1 ± 0.7 at 2.3 ± 0.6, p<0.0001). The 6-minute walking distance increased from 202 ± 107 m to 354 ± 115 m (P < 0.005). No fatal event (death due to MI or HF, and SCD) occurred during the follow-up. 9 patients (32.2%) received an appropriate treat-

ment for SVT, no ventricular fibrillation was documented.

**Conclusions** CRT has become a routine option for patients with drug refractory HF and intraventricular conduction delay. Patients with prior RVA pacing (DDD) and a very high-risk substrate had a dramatically increased risk of HF hospitalization that could be attributed to ventricular and AV desynchronization. Upgrading to CRT by the addition of a coronary sinus lead is now considered a valid option for patients with intractable HF and wide QRS with permanent RVA pacing.

## DILATED CARDIOMYOPATHY (DCM) IN INFANTS WITH PACEMAKER (PM).

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**Purpose** evaluation of DCM occurring in infants with isolated complete congenital AVB (CCAVB) after PM implantation.

**Methods** retrospective analysis of infants with CCAVB who implanted PM at age <1 year to analyse DCM development. Data reported as median (range). Pts with (group, G, 1) and without (G2) DCM were compared with Mann-Whitney/Fisher exact tests.

**Results** 21 pts with CCAVB and normal left ventricular function (LVF) pre-implantation, underwent DDD (12 pts) or VVIR PM implantation with epicardial (14 pts) or endocardial leads, placed in the RV apex. DCM occurred in 6 pts (29%) after 3 (3-13) months. G 1 pts showed significant lower implantation age, 3 (1-85) days vs. 90 (1-355) (p=0.01) and more frequent DDD pacing (100% vs. 40%, p=0.03). Female sex (67% vs 20%, p=0.06) and higher heart rate (HR, >160 bpm) in the first month after implantation from PM stored data (19% vs. 3%, p=0.06) seem more frequent. The differences of HR pre-implantation [G1, 57 (39-74) vs. G2, 51 (35-80) bpm], broad QRS escape rhythm (33% vs. 14%), autoantibodies (33% vs. 27%), pacing rates (100-180 vs. 90-180 bpm) were not statistically significant. Follow-up was 5 (0.3-12) years. One pt died of heart failure (HF) after 3 months, 4 are medically treated. In 1 pt with drug-refractory severe HF, LVF normalized in 6 months after PM downgrading (VVI 50 bpm) to obtain spontaneous narrow QRS junctional rhythm (JR) although the low HR.

**Conclusions** pts with CCAVB develop frequently DCM perhaps because of early DDD pacing. We suspect a tachycardiomyopathy caused by RV pacing and high paced HR (sinus rhythm tracking ventricular pacing) in pts with bradycardia during fetal life. Pts with VVIR PM, although the RV pacing, show lower paced HR and no DCM. After switch from PM rhythm to JR, LV normalized in 1 pt.

## LEARNING CURVE IN LEAD EXTRACTION: EXPERIENCE OF A NEW SINGLE DEDICATED CENTRE AND COMPARISON BETWEEN EXTRACTION OUTCOMES IN THE FIRST 6 MONTHS AND AFTER

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**PURPOSE** As we recently started PM and ICD lead explants, we believed it was appropriate to proceed with a quality assessment of the procedures carried out at our Centre, comparing extraction outcomes in the first six months and after.

**MATERIALS AND METHODS** Between May 2003 and June 2006 we extracted 72 leads from 39 patients (27 male, age 26-85 years, mean 70.9).

**RESULTS** While comparing the first six months and the following ones, as for continuous variables, no significant differences were detected for patients' age (72.3 vs 70.7 years old), number of explanted leads

per patients (2.3 vs 2.2), number of reparative operations prior to extraction (1.4 vs 1.5), manual traction time (58 sec vs 56 sec) or number of required sheaths per lead (2.0 vs 2.5). Differences found in other variables were instead statistically significant: time from implant (15.7 vs 54.3 months,  $p=0.022$ ), lead mobilization time (0h:19m vs 0h:50m,  $p=0.001$ ), extraction time (0h:07m vs 0h:29m,  $p=0.011$ ), dilation time (0h:01m vs 0h:22m,  $p=0.004$ ) and fluoroscopy time (0h:05m vs 0h:15m,  $p=0.030$ ). Considering nominal variables, values such as patient sex, venous access, lead characteristics (type, polarity, insulation, fixation), operative results, acute and chronic complications and its treatment did not show significant differences. On the contrary, we found significant differences for other variables: need for temporary PM after procedure (20 vs 98.4%,  $p=0.000$ ), drugs administration (0 vs 25.8%,  $p=0.000$ ), effectiveness of traction alone (80 vs 48.4%,  $p=0.037$ ).

**CONCLUSIONS** In the first six months, procedural difficulty was lesser, for a priori selection of patients explanted. However, the comparison between the first six months and the following months returned positive results, both in terms of operating success and limited number of complications. These positive results lasted despite the operating conditions becoming more complex in the later months, due to increased implant age and not-selected indications for extraction.

## FEASIBILITY AND SAFETY OF THE EXTRACTION OF PERMANENT LEADS FOR PACING AND DEFIBRILLATION BY RADIOFREQUENCY APPLICATION. A SINGLE CENTRE EXPERIENCE

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**Background** The incidence of lead-related complications, both in early and late phase, is increasing over years owing to the increased number of implanted systems. The stabilization of the leads is a continuous process involving fibrous tissue growth along the interface between lead and venous endothelium, the so called adherence. During extraction the troubling problem is the adherence lysis: several methods have been developed to get it (mechanical, laser). We started to use radiofrequency, a system based on the combination of an expanding wire inserted in the lead lumen, a mechanical sheath surrounding the energy delivering sheath.

**Methods** In a 24 months period 25 patients (pts), age  $79\pm 4.24$ , 18 pacemakers (PM) and 7 ICD, 18 male, underwent extraction for relapsing pocket infection (10), sepsis/endocarditis (14), mechanical obstacle (1). The mean persistence of the leads was  $167\pm 137.17$  months. The pts required local and/or general anesthesia with the assistance of an anesthesiologist.

**Results** 1 pts (80, female, with endocarditis) died during the procedure for pulseless activity without echo evidence of cardiac tamponade. 1 pt required emergency vascular surgery due to tearing of the subclavian vein. The pt recovered uneventfully. In 1 pt radiofrequency was ineffective (tight adherence between proximal coil and endothelium). In 2 more pt the removal was partial due to anatomical abnormalities. All but one the pts with sepsis/endocarditis healed uneventfully. No more major side effects were observed. Complete success was achieved in 80%; partial success in 8%. All the treated pts are doing well and are actually followed-up by our centre.

**Conclusion** In our experience the use of radiofrequency was feasible allowing a success rate close to 90%. The safety was comparable to the other techniques. A higher number of procedures and a direct comparison could allow the clarification of the relative merits of radiofrequency with regard to other techniques.