

● **Special Report from the President of Cardiostim 2010** ●

## Summary of the Abstracts Contents at Cardiostim 2010

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Cardiostim is a congress dedicated to devices, interventional electrophysiology and non-invasive electrophysiology. It was born in 1978, and imagined by Dr Jacques Mugica for educational purposes, and is held traditionally in Nice, French Riviera, on even years. This 2010 edition had 5700 participants coming from 92 countries. A large Japanese attendance was present and two joint sessions were organized with the Japanese Heart Rhythm Society.

The program was divided into three sections: updates, education, and presentations based on selected submitted abstracts.

Following is a summary of these selected abstracts, which does reflect the trends of our specialty, and of technological advances. For devices, telemedicine, MRI compatibility, full automaticity were the main topics. In cardiac pacing, respect of spontaneous AV conduction is confirmed as being essential, and positioning of the right ventricular lead remains an issue. For ICDs, better definition of candidates, utility of DFT testing, and reduction in inappropriate shocks are the main concerns. In CRT, extension of indications toward earlier stages of HF, implementation of hemodynamic sensors, and new approaches to the left ventricle are at the first row.

Ablation techniques benefit from new technologies: interest and limits of cryo-ablation, new radio-frequency catheters, visualization of ablative lesions, contact control, and use of imaging techniques. The goals are: to speed up procedures, make them safer, and more efficient.

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### 1. Device technologies

#### 1.1 Telemedicine for cardiac pacing and ICDs

All manufacturers conceived a remote monitoring system for ICD recipients, but only one proposes such a facility for the whole range of its production.

##### 1.1.1 The COMPAS trial

This study (presented by Mabo) is the first prospective randomized trial including 538 patients:

- One group is active (with telecardiology On), followed up with telemedicine during 18 months;

- In the standard group, with conventional face to face follow-up, telemedicine is passive, the investigator being blind with no accessibility to the transmitted data.

The study demonstrates the non-inferiority of telemedicine compared to conventional follow-up, with a rate of severe adverse events of 17.3% in the active group versus 19.1% in the standard group.

Furthermore, the number of patients' visits is reduced by 27% in the active group. Telecardiology allowed the early diagnosis of various abnormalities, especially persistent atrial fibrillation.

For the first time, COMPAS demonstrates that telecardiology is a reliable alternative to traditional follow-up in paced patients.

### 1.1.2 Centralized telecardiology

Vogtmann presents his original experience of centralized telecardiology, MoniC, in which 9 satellite centers offer their data to a collecting center. A specialized nurse, trained to the use of the system, receives all alerts, and classify them according to a pre-established algorithm in urgent (immediate call to a doctor), relevant (information given to the satellite center), or without subsequent action. Over one year, 121 patients implanted with pacemakers or ICDs were followed up. 1.3 report/patient/an was issued to the satellite center; among these, 36.8% triggered a clinical action (device reprogramming, change in the drug treatment, hospitalization). The nurse workload was 25.6 min/100 days of follow-up per patient, and 7.4 min of communication with the satellite centers.

### 1.1.3 What are the advantages of device remote follow-up?

In the study from Ceb, gathering 267 events in paced patients, the main observed clinical event was atrial fibrillation, detected more rapidly with telemedicine. An earlier visit induced by the diagnosis of AF, led to a change in the drug treatment in 86.5% (antithrombotic agents, antiarrhythmic drugs, reprogramming, cardioversion). Conclusions from Lacopino are comparable in a population of 104 patients implanted with an ICD, followed with the Carelink<sup>®</sup> system: 32% patients with AF during a one-year follow-up (25% of episodes being asymptomatic). AF was managed much earlier (cardioversion, His-bundle ablation, pulmonary vein ablation).

Telecardiology might be an efficient tool for surveys, with early alerts. Any recall means a lot of workload for the implanting center personnel: Schwartz had to manage 13 alerts from 2000 to 2008, in 278 patients out of the 1051 patients implanted with an ICD during that period. A telemonitoring would have been a better option, more efficient, less expensive. These results are confirmed in the subgroup of 40 patients of the E-COST study, who were implanted with the Sprint Fidelis lead. Over 22 months of follow-up, 4 lead failures have been suspected from noise detection and/or abrupt change in lead impedance. The diagnosis was confirmed in 3 cases, leading to the lead replacement before occurrence of inappropriate shocks.

In the ALTITUDE study, using the Latitude<sup>®</sup> system, Gillian retrospectively analyzed the data from 15991 patients and showed that programming of a high VF zone and of a VT zone is associated with a low risk of inappropriate shocks.

## 1.2 MRI and pacemakers/ICDs

MRI use is contraindicated in PM/ICD recipients. The risks are the following: over/under sensing, device dysfunction, life-threatening arrhythmias. However, manufacturers are now able to provide MRI compatible devices.

Sommer gives the results of a multicentric study about 464 randomized patients and followed over 1 year. Among them, 258 underwent a 1.5 Tesla MRI (spinal chord, brain). No complication occurred during the examination. Anelli Monti also reports a study of 41 pacemaker patients who underwent an MRI without any complication. The MRI compatible leads are stiffer, and a higher rate of complication has been noticed, leading to reintervention in 14.6% cases.

MRI compatibility is a step forward, but the system should be used under special conditions:

- Manual pre- and post-reprogramming is necessary, a procedure which might be practically difficult;
- Only new patients are concerned. The whole system should be compatible: pacemaker and leads.

The 3 tesla MRI will soon be the standard: will our PMs be still compatible?

## 1.3 The new standard of connection: IS4 connector

The IS4 standard was announced since years but is still not available. This connection is supposed to replace the IS1/DF1 connection. Doshi reports a primary experience of 53 mono- and dual-coil ICD leads according to the IS4 draft from June 2009. The complication rate and the electrical characteristics are not different from the IS1 standard. Eckardt evaluated the performances of mono- and dual-coil leads, with active or passive fixation in 419 patients. Nothing special was noticed when leads are tested with high energy shocks (41 joules), sensing of ventricular arrhythmias is normal as pacing thresholds and impedances are. No sensing abnormality was observed during manipulations of the can through the skin.

To implant a pacemaker and to avoid ventricular pacing may look paradoxical. But preservation of AV conduction algorithms are appropriate when AV conduction is normal or subnormal. However, post-operative prescription of antiarrhythmic drugs and long PR intervals, longer than 300 ms, are two conditions where AV conduction may impair rapidly in the mid-term follow-up (Mabo).

## 1.4 Anticoagulation and device implantation

Patients who require implantation of a device,

who are at risk of hemorrhage or thrombosis because of their pathologies, and who need antiplatelet or anticoagulant therapy, are very numerous. Rodriguez-Manero compared the continuation of anticoagulation (INR between 1.7 and 2.3) with the use of low-weight heparin in 175 consecutive patients. No thrombo-embolic complication occurred. A lower rate of hemorrhagic complications was observed (16.3% versus 26.5%) in the anticoagulated group, especially major hemorrhages (3.2% versus 6.1%) with shorter hospitalizations (1.3 days versus 1.8).

To decrease the rate of hemorrhagic complications, Ohlow tested the D-Stat flowable haemostat, an association of collagen and thrombin in the form of a powder, placed in the device pocket at the end of implantation in 156 patients under antiplatelet or anticoagulation treatment. The rate of complication was not modified, but a trend for more reinterventions (7.3 versus 2.7%), and more infections (4.9 versus 1.4%) was noticed.

## 2. Defibrillation

Presentations are mostly devoted to ICDs complications, and the search for solutions. However, one must not forget the main benefit of ICDs: they save lives everyday!

### 2.1 Benefits are obvious

In a meta-analysis gathering results from 8 clinical trials and 5343 patients with EF less than 35%, Theuns shows a 60% reduction in arrhythmia related deaths, and 28% reduction in total mortality, in patients with (−29%) or without ischemic cardiomyopathy (−26%). The LOHCAT trial from Van Rees demonstrates that the majority of the 750 patients surviving from sudden cardiac death received an appropriate therapy from their device, whatever their ejection fraction was: 65% if EF < 40% versus 63% if EF > 40%. However, patients with very low EF are not good candidates for ICD therapy as recalled by Van Rees: among 900 ischemic patients, EF less than 25% and high age are associated with a bad prognosis. Wakslak, in a multivariate analysis of the 1232 patients of the MADIT II trial, reports a 37% reduction in mortality when renal function is normal. However, the benefit is not significant in patients more than 75 years of age, and when the renal function is impaired (uremia > 2.5 g/l). In the ACT register, Deering gathered data from 6129 patients, followed over 2 years, and found a mortality rate of 8.9%, with 4.9% of non cardiac deaths and 1.1% of sudden cardiac deaths. The highest mortality

rate was found in the oldest patients with low EF, large QRS, presence of AF, high NYHA class, and implantation of a CRT device.

The national Swedish registry (Gadler) has 3997 implanted patients with a survival rate of 80% at 5 years, and 58% at 10 years. But the survival rates of the implanted ICD and leads are respectively 63% and 96% at 5, and 8%/87% at 10 years. Lifetime of the battery is shorter in case of a CRT device (3.5 years). Devices with autcapture feature should have a longer lifetime. Today, the automatic threshold measurement functions properly as demonstrated by Beau, who analyzed the manual and automatic results of atrial, RV, and LV threshold tests in 107 ICD patients.

Nageh shows that the prognosis of patients implanted for secondary prevention (before or after heart surgery) is less favorable: 37% total mortality rate at 50 months, and 27% in the 95 patients who received appropriate therapies.

### 2.2 Type of leads

Debate is still on-going about the use of mono- and dual-coil leads. Shah shows that dual coil leads should be avoided in infants and teenagers (78 patients): efficacy is not different but the risk of deterioration is higher.

The same debate is about the location of the lead within the right ventricle. The SEPTAL trial (Mabo) compared the medioseptal (n = 97) versus the apical ICD lead position (n = 98). Over a 3-year follow-up, no difference was observed between the two groups in terms of therapy efficiency and complication rate.

### 2.3 Should we perform a defibrillation test at implant?

The tradition is to test defibrillation at two attempts with a 10 Joule safety. However, the test gives a probability of efficacy, and does not guarantee shock efficiency afterwards, and on the other hand, leads have improved and maximal energy shock available has been increased (40 joules instead of 31 Joules). Chances of success are enhanced.

In the observational PANORAMA study (Sweidan), 43% of the 1377 patients were not tested at implant, especially CRT devices (63% versus 24% for the single chamber devices, and 44% for the dual chamber). Primary prevention implants were less tested (50% versus 72% tested in secondary prevention implants). When a test was performed, the shock was unique in 81% cases, with a safety margin less than 10 joules in 78%. The FIRST registry (Mansourati) brought similar conclusions, with 29% not tested among 298 patients, and in 63% cases,

with only one test. The SAFE-ICD study (Brignole) including 2096 patients have similar results with 59% not tested, the main reason being the NYHA class (II) in a multivariate analysis.

Does it change the prognosis?

Greenberg (ACT registry) included 4680 ICD recipients, and 24.3% patients were not tested. These patients have a higher mortality but due to non cardiac over mortality. The sudden cardiac death rate is not different. The same conclusions are given by Kusnitz, in 231 patients with the same mortality rate at 20 months of follow-up (9.6% if tested versus 9.6% if not tested). Hojgaard recalls that an efficient shock is not a warranty of shocks efficacy during follow-up: among the 216 patients of the COGENT-4 study, 3 had inefficient shocks although high energy shock devices with short charge times were used. In these 3 recipients, tests at implant were efficient.

Some medications may influence efficacy unfavorably, like amiodarone which decreases safety margin. As a matter of fact, under amiodarone, Stiller demonstrates a mean increase of 4 joules in 38 patients, superior to 10 joules in 7, and a not warranted efficacy in 4 (10%).

#### 2.4 Achilles' heels of ICDs

In 787 patients, El-Damaty reports 18% of inappropriate shocks over a 3.6-year follow-up, and Grimma, a 12% rate in 805 patients over 49 months. After 5 years, Van Rees gives a cumulative incidence of 18%, favored by previous AF, age less than 70 years, and absence of statine treatment. Inappropriate shocks are associated with an over mortality in multivariate analysis (RR: 1.6). In 699 patients studied by Contractor, treated (412) or not (287) with statines, there is a reduction in the number of shocks (OR:1.64) with statines. The misclassification of atrial arrhythmias is higher with single chamber devices. Analysis of atrial signals between the superior vena cava and the ICD can be an option.

Several abstracts reveal the failure rate of the Sprint Fidelis lead. The Danish registry (Johansen) gathers 601 leads, with a 15.8% failure rate after 54 months for the single coil leads, and 12.7% for the dual coil leads. Only 1.7% leads were not functional at the end of follow-up. In 196 patients, Patwala reports a 16% lead fracture rate, which increases over time. The largest series comes from Hauser on 1039 leads, with an increasing failure rate over time, up to 14% at 50 months. Young age, female gender, high EF, and presence of a cardiomyopathy (hypertrophic especially), are factors of higher failure rate in an univariate analysis. Medtronic has developed

an algorithm capable of reducing the inappropriate rate due to oversensing of artifacts, without delaying the detection of the true arrhythmias (Meijer). The Lead integrity Alert has been tested by Kallinen showing a reduction in occurrence (18% versus 69%) and number of inappropriate shocks (0.5% versus 8.4%).

#### 2.5 Arrhythmic storms

They impose an urgent hospitalization. Pastor found 7% storms in 632 patients during a 40-month follow-up. The predictive factor revealed by a multivariate analysis was implantation for secondary prevention.

### 3. Cardiac resynchronization therapy

The last part of year 2009 is characterized by the publications of MADIT-CRT and REVERSE (European cohort), that triggered the new CRT guidelines, with extension of indications to NYHA class II patients. This Cardiostim edition focused on the subgroups analysis of MADIT-CRT.

#### 3.1 Come back on MADIT-CRT

These studies revealed, for MADIT-CRT, a reduction in the adverse HF events by CRT-D devices in mildly symptomatic patients (NYHA class I or II), with LV dysfunction (EF < 30%), and large QRS (>120 ms), and for REVERSE, a beneficial effect of CRT (and not defibrillation) on LV remodeling in a similar population (NYHA class I or II, EF < 40% and QRS > 110 ms).

Zareba shows the superiority of CRT when LBBB is present, and QRS > 160 ms, in the 1820 patients of MADIT-CRT. Arshad observed a better effect of CRT in women, who demonstrate a lower all cause mortality. In ischemic patients, Barsheshet shows that the beneficial effect of CRT increases over time in patients with prior infarction, and is better in ischemic patients without infarction. Last but not least, occurrence of atrial arrhythmias is associated with a bad prognosis (mortality and HF events). Among 1089 patients followed for 2.4 years, 16.5% patients experienced atrial arrhythmias.

Eyal Nof reveals that the proportion of paced patients requiring an upgrading to CRT is low, around 5% during a 26-month follow-up. Lesaux shows that in the 60 patients presenting with mild LV dysfunction, receiving a primary prevention ICD, none of them had to be upgraded to CRT after 3 years. For Scott, the upgrading rate to CRT in ICD patients with EF < 35% is 7%, with rates of 0.5%, 3.6%, and 10.1% at 1, 3 and 5 years respectively.

### 3.2 Factors influencing the outcome of CRT patients

The higher the grade of mitral insufficiency, the poorer the prognosis for Kenji Ando. However reduction of moderate to severe MI is a factor of good prognosis.

As already reported in MADIT-CRT, occurrence of atrial arrhythmias had a poor prognosis. Santini reports the results of the Italian registry gathering 1193 patients from 77 centers. After a follow-up of 13 months, the incidence of atrial arrhythmias was 30%. Their occurrence was correlated with higher rates of death, heart transplant, and HF hospitalizations. Results of the ACTION-HF registry, reported by Botto have similar results.

Chronic obstructive pulmonary disease is a factor of poor prognosis in CRT patients.

In 611 patients included over a 10-year period, with a follow-up of 40 months, Lunati reports a 5% mortality rate. Eyal Nof, showing similar results, found that the clinical response at one year is predictive of the long term survival, but not the echographic response.

For Muto, the presence of a contractile reserve at stress echo is predictive of the CRT response. In 271 patients, 78% responders are observed when there is a contractile reserve versus 54%. In 126 patients of Neja's study, rates are respectively 75% and 35%.

### 3.3 And the super responders?!

Foster observed 25% super responders in MADIT-CRT. Factors of super response are: Female gender, non-ischemic cardiomyopathy, and very large QRS. However, Stefan found only 5% of super responders with similar favorable factors. Defaye had 18% super responders in his cohort of 340 patients, with a survival rate of 65% at 5 years.

### 3.4 A lot of excitement about hemodynamic sensors

- Peak endocardial acceleration

The results of the CLEAR study given by Ritter are now available. When the Peak Endocardial Acceleration sensor (SonR<sup>®</sup>) is used to set AV and VV intervals, the response rate is 86% versus 62% in conventional practice. Mabo demonstrates that analysis of the two components of SonR (PEA1 and PEA2) allow prediction of the patient's HF status, and Donal shows a good correlation between systolic time intervals given by SonR in comparison with echo. Bordachar shows in a pig experiment, that dP/dt max can be well analyzed from a SonR lead placed in the atrium. Last but not least, Klug

suggests the appropriateness of the SonR amplitude changes during VTs for analysis of their tolerance.

- Transvalvular and intra-thoracic impedance

Neri found a nice correlation between transvalvular impedance and hemodynamic variations in patients implanted. Pandozi evaluated impedance variations during rhythm disorders, and found a correlation between signal changes and hemodynamic tolerance. Its use could avoid inappropriate shocks in ICD patients. Transvalvular impedance could also allow detection of aggravation of heart failure. Wiegand reported the results of the InSync Sentry registry including 896 patients: 78% patients who had an alert from their device, presented signs of heart failure. Inappropriate alerts were otherwise corrected by reprogramming of the alert threshold.

### 3.5 Technological advances

Implantation of a LV lead in the coronary sinus network remains challenging. Gutleben and Goetze suggest that 3D reconstruction could help the implant procedure. In addition smaller leads were developed (Exner, Wong) to facilitate the catheterization of small diameter veins, as well as new tools (Giannola). The interest of the electronic repositioning was reported by several presentations (Defaye, Gold, Huizar): choice is directed by the best threshold, the absence of phrenic nerve stimulation, or better sensing capability. Introduction of quadripolar leads will even enhance the reprogramming capabilities (Danschel, Thibault).

Last but not least, new approaches to the left ventricle are under development. Mihalez reports the endocardial LV trans-apical approach in 14 patients. A conventional active fixation lead is placed endocardially after puncture of the LV apex at the laterobasal wall. These techniques allow endocardial pacing that has been demonstrated as being hemodynamically more efficient and less dependent from the position of the lead in animal experiments. Strik report an experiment on 6 dogs with a significant improvement of electrical activation, and systolic and diastolic function compared to epicardial pacing.

## 4. Electrophysiology, ablation techniques

Atrial fibrillation ablation is still the main topic of this section. However, ventricular ablation techniques becomes a major issue in this field.

### 4.1 Management of syncopes

It remains difficult and patients undergo many examinations ending up with a transfer to the cardiology department with the diagnosis of unex-

plained syncope. Special syncope units should improve the management of syncope in our hospitals. The multicentric PICTURE study (Edvardsson) is the typical example of what's going on: the majority of patients were visited by 3 different specialists and underwent a mean number of 13 examinations. This fact enhances the role of the REVEAL system that demonstrates the cardiac origin of syncope in 84% leading to the implantation of a pacemaker or an ICD.

Favale analyzed the interest of the tilt test. In 20% cases, the test was positive. Independent risk factors were found: female gender, more than 3 syncope episodes before diagnosis, and a positive tilt test.

#### **4.2 Management of sudden cardiac death: a status quo**

A Swiss registry (Katz) reveals a survival rate of 6.4% only. The majority of survivors presented sudden cardiac death in presence of witnesses who started CPR. This CPR was especially beneficial when witnesses had been trained to it (52% of survivors), and when the origin of SCD was arrhythmic (82% of survivors).

The early repolarization syndrome was studied by 3 groups. A Greek registry (Dilaveris) revealed this syndrome in 5% of the overall population. The Bordeaux team, which has been the pioneer, analyzed the QRS fragmentation to predict the occurrence of ventricular arrhythmias in 44 patients with abnormal EKG, and prior SCD. Over a 5.5-year follow-up, a recurrence of ventricular rhythm disorders occurred in 71% patients presenting with QRS fragmentation versus no recurrence when QRS fragmentation was absent. Last but not least, a Fin team (Tikkanen) found that early repolarization found in lateral leads, was frequently associated with hypertrophic cardiomyopathy and metabolic syndrome.

#### **4.3 Research and new techniques**

Several groups study the use of stem cells in various conditions.

In the dilated cardiomyopathy, Vrtovec studied the effects of the intra-coronary injection of stem cells on ventricular repolarization: results are encouraging, with a significant improvement in functional, biological, and echographic criteria, without modification of the QT interval.

In the ischemic heart disease, Krause evaluated the effect of cellular transplant in patients with myocardial infarction that occurred 10 days earlier, with impaired EF. EF improved without occurrence of ventricular arrhythmias during a 6-month follow-up.

In the ischemic cardiomyopathy with heart failure, Romanov succeeded in reducing cardiac mortality at one year, with improvement of ventricular function. Salvarani studied the arrhythmogenicity induced by stem cells transplantation, a drawback that limits the expansion of the technique so far. The TGF- $\beta$ 1 growing factor seems to be part of the phenomenon.

So far, trials are small sized, but are the start of larger studies, which are mandatory for the development of this new line of techniques.

#### **4.4 Ablation of ventricular rhythm disorders**

Three abstracts are of interest in this field.

Amin evaluated the effect of the infarct zone size on the success of VT ablation. When the fibrotic zone is small (defined as  $<35\text{ cm}^2$  on a CARTO voltage map), the chances of success are important and the risk of recurrence minimal.

Maury prefers the VT ablation (versus ICD) in patients with recurrent VTs, severe cardiomyopathy, and multiple comorbidities. This discussion will occur frequently in the future with the ageing of the population.

Jadidi characterizes the arrhythmogenic substrate of VF: heterogeneous tissular abnormalities were found in the Purkinje network, but also dispersion of action potential durations, triggering reentry phenomena.

#### **4.5 Atrial fibrillation is everywhere**

##### **4.5.1 Some genetics**

Boldt studied in atrial fibrillation the implication of the GATA4 factor mutations, known for being responsible for congenital heart diseases. In 96 patients with idiopathic AF, two mutations of the GATA4 factor were found.

##### **4.5.2 AF and medical treatment**

Several meta-analyses followed AFFIRM, and confirmed that ventricular rate control was as good as maintenance of sinus rhythm as far as mortality is concerned. However, Bonanno, who included the most recent studies in his meta-analysis demonstrates that maintenance of sinus rhythm offers a reduction in cardiovascular mortality. In the same way, a Japanese study (Matsuda) confirms the superiority of sinus rhythm on LV EF and absence of dyssynchrony (2D speckle tracking).

##### **4.5.3 A new predictive tool of AF recurrence: atrial Doppler tissue imaging (PA-TDI)**

Two teams evaluated this new parameter, which seems to be a good independent predictive parameter

of the recurrence of AF in HF patients and in the acute phase of myocardial infarction. Management of AF is crucial in this patient population as the increased risk of mortality is well known in case of AF occurrence during follow-up.

#### 4.5.4 Which ablation strategy for which AF?

Ablation of persistent AF is feasible but with less success than for paroxysmal AF. In the former population, isolation/disconnection of pulmonary veins is not sufficient. Patients should be better stratified as suggested by Barker, because they compose a heterogeneous group of patients.

The most frequent procedure is to apply additional left atrial lines of ablation to the pulmonary vein isolation; It increases the success rate: 44% versus 49% in a series of 142 patients (Berkowitch). 66% of patients without recurrence of AF during follow-up went back to sinus rhythm during the ablation procedure. These lines were done at the LA roof, septum, along the coronary sinus, and in the mitral isthmus. The drawback is that those lines may be incomplete, and thus, responsible for occurrence of left atrial flutters (fourfold more than without lines (Berkowitch)).

The other possible technique is to locate the LA zones where fragmented potentials are recorded (complex atrial fractionated electrograms, CAFE), and that may trigger AF recurrence. Seitz reports a correlation between these zones, revealed by CARTO, and zones of fibrosis analyzed by late enhancement MRI. Their surface area are correlated with the rate of early recurrence of AF (Daccarett). However, these latter findings are contradictory with those of Jadidi. The MRI fibrotic zones would correspond to low voltage electrograms in sinus rhythm, and not to CAFE that would be functional only.

Four presentations (Yamane, Yao, Matsuo, Maeda) deal with the use of ATP for testing the reconnection of pulmonary veins at the end of the ablation procedure (10 to 20%). Last but not least, in order to avoid the rare but catastrophic complication of esophageal fistula, Rolf and Fürnkranz propose the use of a temperature probe placed in the esophagus during the ablation procedure, for the permanent monitoring of esophageal temperature and to modulate the energy of applications.

#### 4.5.5 A constellation of new technologies

##### - Cryoablation: where are we?

This is the first alternative technique to “hot” AF ablation. Results are comparable in ablation for paroxysmal/persistent AF. In series from 55 to 776 patients, Heintz, Nadji, Schumacher, Kane, and

Haldass report short term success rates of 85–95%. After 3 to 12 months of follow-up, 52 to 97% patients remain without symptomatic AF. The anatomical approach of the cryoablation for AF can be combined with the traditional electrical check of pulmonary vein disconnection. In that case, the success rate increases at 6 months (86% versus 53%, Koch). Compared to the “hot” technique, procedure duration is close to 150 min, but X-Ray exposure is increased (35 min, mean value). The main complication is a reversible phrenic nerve standstill (7–10%). Risks of thrombo-embolism and tamponade are comparable. Long term vein stenosis is not absent (Langbein), and the cryo-balloon should be kept at the antrum of the veins, and not placed within veins. However in case of complementary radio-frequency ablation within the veins, this risk goes up to 4% (Mouquet). In conclusion, cryoablation for ablation of paroxysmal AF is an efficient technique that is proposed at first row by Kane. However, there is no reliable data supporting its indication in persistent/permanent AF.

##### - New ablation catheters

Ablation Frontiers has catheters designed for an anatomical and electrophysiological approach. They are multipurpose, circular, linear or star shaped (PVAC, MAAC, and MASC), and allow application of radiofrequency at several spots in mono or bipolar mode. Their clinical efficacy looks similar to the traditional catheter designs. After a 6- to 12-month follow up, 50 to 85% patients remain in sinus rhythm, depending on the type of AF, persistent or paroxysmal (Mulder, Zeb, Bünz, Bulava). Type and rate of complications are also the same as in the conventional approaches. Procedure duration is much shorter (Klein, Chung), similar to the duration of cryo-ablation procedures, but X-ray exposure is more important as fluo is the only tool to guide navigation.

A better contact of the catheter tip on the myocardial wall creates a more complete and transmural lesion, but with a higher risk of perforation. Endosense has developed the TactiCath<sup>®</sup>, which enables real-time measurement of the force applied by the catheter to the tissue. In the TOCCATA study, Neuzil showed the inverse relationship between the measured contact force and the AF recurrence rate. The dynamic systolic and diastolic variability of contact depends on the ablation site within the left atrium, the catheter orientation, and the possible use of steerable sheaths (Herrera, Shah). This feature is also essential to prevent perforations. The Therapy Cool Flex from St Jude Medical is an irrigated catheter with a flexible tip. In experiments, it has

been demonstrated that this catheter allows a larger contact surface with the myocardial wall, with an identical contact force (Byrd), and a better and deeper dispersion of energy within the tissue, with a lower surface temperature (Narciso). Voyage Medical developed the IRIS catheter, with a new irrigation system (saline bridge), and allows the direct visualization of the ablated endocardium. The continuity of the ablation lines can be controlled in real-time, as shown by Sacher in 10 patients with an indication of cavo-tricuspid isthmus ablation. In experiments, Chik observed larger and deeper lesions, obtained with less energy power. Last but not least, the EAS balloon (Cardiofocus) has been tested in 21 patients (Schmidt) in a feasibility and safety study. It has a variable diameter with an endoscope that allows visualization of venous ostia. The laser energy is used for ablation. Fluo times are similar to conventional procedures, 98% veins are isolated, one tamponade was reported.

- Robotic magnetic navigation

Stereotaxis proposes the NIOBE system, including a very flexible, non-traumatic and irrigated catheter that can be controlled remotely. This system allows the parallel use of electro-anatomical maps (Biosense, Carto). In a series of 446 patients, randomized in 2 groups (magnetic versus manual

navigation), Bauerfeld shows that, whatever the indication for ablation can be, the remote magnetic navigation offer similar success rates, with much less X-ray exposure, and a significantly lower complication rate (0.5 versus 2.6%). However, Arya reports less enthusiastic results as far as AF ablation is concerned: a complete pulmonary vein deconnection is obtained in only 79% cases versus 87% with the manual procedure. At 6 months, 58% patients have no AF recurrence versus 66%. Carmo suggests that the catheter tip might be too flexible, and as a matter of fact, the application time of energy to achieve deconnection of pulmonary veins is significantly shorter when a more powerful magnetic field of 0.1 T (instead of 0.08 T) is used.

#### 4.6 Some nice case reports

The one from Borbola evaluating the benefits of ivabradine in inappropriate sinus tachycardias, that has not the side effects of beta-blockers, nor the complications of ablation.

The one from Cantu, who describes a VT ablation via a trans-apical approach in a patient with mitral and aortic mechanical valves.

The one from Maury, who ablated an atrial flutter/AF in a patient having a Heart Mate II, but without any navigation system to avoid interferences.