Abstract

Background: Pacing has largely entered its sixth decade. Since the first introduction in 1958, the pacemaker models have evolved. They represent a real breakthrough in terms of technique. The indications for pacing are extensive and cover pathologies different prognoses.

Materials: This study was conducted at the University Hospital Cardiology Service Tlemcen. We are interested in a fringe of 500 patients undergoing cardiac stimulation final.

In our study more than 84% of patients were male, which corresponds to a sex ratio of 5.

In our series 20% of patients underwent stimulation type double room.

The complication rate is estimated at 8% marked by secondary displacement sensor.

Conclusion: The cardiology department of Tlemcen University Hospital is a major center for pacemaker implantation in the western region of the country with encouraging results despite a modest equipment to the standards required.
Feasibility of an New Algorhithm (Acap Confirm) for Automatic Atrial Capture Testing

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Abstract

Introduction: Acap Confirm (ACC) is a new algorithm offered by St. Jude Medical dual chamber pacemakers allowing for automatic atrial threshold determination. The aim of this study is to investigate the feasibility and short-term clinical and technical outcome of this test.

Methods: Patients scheduled for DDD pacemaker implantation (Zephyr XL DR 5820) were enrolled into this prospective evaluation. Set-up test ACC viability and manual step-down (0.4ms) atrial threshold test as well as automatic threshold testing by ACC were performed at implant, 2 weeks and 3 months after implantation. Participants who successfully completed both an automatic and manual capture thresholds test during follow-up were compared.

Results: Data from 79 patients (49M/30F, 70.4 ± 8.5 years old) were analyzed. Bipolar atrial leads (1882T and 1999T) were used. ACC activation rates are shown in the figure below. At 2 weeks and 3 months, threshold results from ACC and atrial manual capture test were: (0.63 ± 0.22 V versus 0.69 ± 0.22 V; r=0.94), and (0.59 ± 0.14 V versus 0.65 ± 0.17 V; r=0.87) respectively. The differences between automatic and manual measurements were ≤0.25V in all patients.

Conclusions: The reliability of ACC is relatively low over a short follow-up. Automatic atrial thresholds measurements (ACC) can be programmed in only 47% of patients at 3 months. There is a good correlation between automatic and manual atrial thresholds. However, long-term clinical outcomes are necessary to confirm these findings.
Correction of Chronotropic Incompetence with Rate-Responsive Device in a Ddd Pacemaker Population: Results from a Pilot Screening Study

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Abstract

Introduction: Chronotropic Incompetence (CI) is a sinus node disease variant. Rate responsive pacemakers (PM) are designed to simulate normal sinus node responsiveness and restore chronotropic competence.

Methods: We report our experience about the incidence of CI in a population of patients implanted with a not rate responsive PM. During the 2012 routine PM follow-up, 18 DDD PM patients (15 m, 3 f; age76±12 years) with battery status in Elective Replacement Indicator (ERI) were identified; they underwent telemetry detection of atrial pacing %, NYHA class, 6 minute walking test (6MWT) or atropine test, pharmacological history (44% was treated with beta-blockers). CI was defined by a sinus rate < 100 bpm at the 6MWT/atropine test, and an atrial pacing > 50%.

Results: In 10/18 patients (55%) a CI was identified (419±136 meters and 76.5±7.8 bpm sinus rate at 6MWT); they were reimplemented with a new DDDR PM; a single or a blended double sensor (accelerometer and/or minute ventilation) was activated.

Conclusion: An appropriate CI detection at the elective PM replacement could improve the physiologic cardiac pacing with implementation of rate responsive algorithms.
Abstract

Introduction: Incidence of pacemaker (PM) implantation after Transcatheter Aortic-Valve Implantation (TAVI) is 6.5%-40%. Most common indications are: complete atrioventricular block (BAV), 1rst degree AV block and left bundle branch block (LBBB), sick sinus rhythm (SSS).

Methods: We evaluated the follow-up (device interrogation) of 14 patients that underwent PM implantation after TAVI (reason of implantation was: 7 pts for BAV, 5 pts for 1rst degree AV block and LBBB, 2 for left and right bundle branch block alternance, 1 pts for 2:1 AV block).

Results: Patients with preexisting right bundle branch block (RBBB) that underwent Corvalve implantation, patients with RBBB+LBBB alternance and with 2:1 AV block had 100% of ventricular pacing during follow-up. Patients with BAV that underwent Edwards Sapien valve implantation, with restoration of conduction 24 hours after the procedure and pts with 1rst degree AV block and LBBB had 0% of ventricular pacing during follow-up.

Conclusions: Implantation of PM after TAVI is performed too early in the post operatory period. The preexisting RBBB and the Corvalve implantation determine irreversible AV block. The presence of reversible AV block after TAVI with the Edwards Sapien valve and the presence of 1rst AV block with LBBB do not require pacing over time.
Longevity of Medtronic Sprint Fidelis ICD Lead During Over 5-Year Long-Term Follow-Up

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Abstract

Introduction: Medtronic Sprint Fidelis ICD Lead (FL) has been withdrawn from the market because of frequent conductor failure. The survival rate was estimated at approximately 85%, however, over 5 years longevity has not been well discussed.

Methods: Study subjects were 67 cases (mean 61 year-old, 51 males) in whom FL was implanted. Cephalic venous access was dominant (57 cases). Capture/sensing threshold and lead impedances were measured every 3-6 months. The mean follow-up periods was 5.6±0.5 (range: 5-6.9) years.

Results: Conductor failure occurred in 5 (7%) cases (Table 1). Regarding to these cases, younger age, preserved LVEF and female gender were considered to be high risk. Patient alert worked promptly to avoid inappropriate shock therapies in 2 of them.

Conclusions: FL functioned normally in 93% during over 5 years follow-up in our institution, and it was higher comparing with previous studies. Cephalic venous access may have reduced the risk of conductor failure. However, patient alert must be activated in FL cases, and careful observation, e.g. using remote monitoring should be recommended, especially in high risk cases.

Table 1: Cases with Conductor Failure

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age (year-old)</th>
<th>Underlying Disease</th>
<th>LVEF</th>
<th>Time to Failure (years)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>59</td>
<td>Sarcoidosis</td>
<td>0.36</td>
<td>4.4</td>
<td>Artificial Noise</td>
</tr>
<tr>
<td>Female</td>
<td>50</td>
<td>CAD</td>
<td>0.55</td>
<td>3.5</td>
<td>Impedance↑↓Patients Alert</td>
</tr>
<tr>
<td>Male</td>
<td>35</td>
<td>HCM</td>
<td>0.40</td>
<td>4.3</td>
<td>Impedance↑↓Patients Alert</td>
</tr>
<tr>
<td>Male</td>
<td>54</td>
<td>CAD</td>
<td>0.58</td>
<td>2.8</td>
<td>Impedance↑↓Patients Alert</td>
</tr>
<tr>
<td>Female</td>
<td>69</td>
<td>HCM</td>
<td>0.70</td>
<td>3.5</td>
<td>Artificial Noise ↓Inappropriate Shock</td>
</tr>
</tbody>
</table>
Abstract

Background: Low EF patients have more risk factors than normal EF patients needing lead extraction. However, the safety of lead extraction for low EF patients remains unclear.

Methods: Between 2005 and 2012, we collected data of 199 consecutive patients who underwent percutaneous transvenous lead extraction and compared incidence of major adverse events (MAE; death, myocardial infarction, stroke, cardiac tamponade, PE, blood transfusion or pneumohemothorax) between patients <35 EF and patients ≥35 EF. The endpoint of this study was incidence of major adverse events (MAE; death, myocardial infarction, stroke, cardiac tamponade, PE, blood transfusion or pneumohemothorax) after procedure.

Results: There were 38 patients (19.1%) with low EF and 161 patients (80.9%) with normal EF. All patients underwent successful transvenous removal of endocardial leads. One of 38 patients (2.6%) had evidence of MAE in low EF patients. No significant difference of MAE was found in the low EF group (2.6 vs. 3.7%, P = 0.221).

Conclusions: In low EF patients, percutaneous transvenous lead extraction could be performed safely without prolonged hospital stay.
Abstract

Background: Removal of infected endovascular leads has often required for cure of systemic infection, but the perceived risk of embolic in the presence of large (> 10 mm) vegetations has been considered a relative contraindication to transvenous removal.

Methods: Between 2005 and 2012, 119 patients who extracted due to infection (256 leads) were enrolled in this study. The primary endpoint of this study was incidence of pulmonary embolism (PE) after procedure in patients with and without large vegetation. The secondary endpoints were major adverse events and hospitalization period in each group.

Results: Large vegetation (range 12-25mm) was found in 9 (15.1%) patients. All patients underwent successful transvenous removal of endocardial leads. In entire group, two patients had developed PE (11.1% vs 0%, p=0.005). There was no difference in hospitalization periods and MAEs between those with or without large vegetation (47.8±21.3 days vs 37.9±26.1 days, P value 0.13) (22.2% vs 7.92% , P value 0.09).

Conclusions: Incidence of PE after procedure was significantly higher in patients with large vegetation. However, no significant difference of MAE and hospital stay was found.
Abstract

**Background:** Lead dependent infective endocarditis (LDIE) is a major complication of the treatment with the electronic devices. The diagnostic process in LDIE patients is very difficult because of nonspecific symptoms delays of proper management.

**Methods:** We analyzed the clinical data of 320 LDIE (mean age 66.3 ±15.0; 98 women) consecutive patients admitted to single Reference Center for transvenous leads extraction (TLE) procedure in years 2006-2012. The main symptoms, laboratory markers and echocardiographic findings were assessed.

**Results:** 35.7% LDIE patients were determined by local pocket infection. The main symptoms of LDIE were nonspecific: 58% patients complained of recurrent fever with shiver, 22% were treated from recurrent pulmonary infection; in 42% patients only weakness, dizziness and periodically dyspnoea were observed. The maximum number of hospitalization due to LDIE symptoms reached 5/year with the mean 1.5±0.83/year. Average time from first symptoms to TLE was 7.3±11.8 months. Antibiotics before TLE admission were intermittently applied in 82% LDIE patients. Laboratory inflammatory parameters showed high variability: mean ESR value: 43.6 ±29.2, CRP 48.5± 65 mg/l, procalcitonin: 1.2 ng/ml ±3.6 with normal leucocytes level: mean 8.9 K/ul ±5.7. Blood culture (all excluding 3 pts received antibiotic before admission for TLE) detected bacteraemia only in 36.6% patients, periprocedural extracted leads culture indicated pathogens in 47.2% cases. Echocardiography demonstrated vegetations in 66.9% CDRIE patients; in 40.2% of them vegetations were visible only in transesophageal echo.

**Conclusions:** Lead dependent infective endocarditis is a very serious disease with large diagnostic problem. The symptoms and laboratory results are nonspecific, echocardiographic findings are authoritative in about 67% cases. LDIE patients need the comprehensive diagnostic process to accelerate proper treatment.
Abstract

Background: Transvenous leads extraction (TLE) consists the key-procedure in management of lead dependent infective endocarditis (LDIE). The assessment of TLE safety and effectiveness in this particular group of patients seems to be very important.

Methods: Analysis of data 1220 patients treated by TLE in single Reference Center in years 2006-2012 was conducted with separated of 320 LDIE patients. The comparative assessment of factors influencing to proceeding and effectiveness of TLE in LDIE and remaining patients was performed with evaluation of complete procedural success and clinical success in both groups of patients.

Results: The results were demonstrated in the table

Conclusions: The LDIE patients represented more TLE risk factors: older age, more number of the leads- particularly abandoned and loop of the leads. Despite that the present study demonstrated a very high safety and effectiveness of TLE procedure in the large group of LDIE patients with low number of major complications and periprocedural mortality, comparable with non-infective TLE group. This observation confirms that TLE should be the basic of the treatment this very serious disease.
A Novel Method to Manage ICD Lead Fracture in a Very High Risk Patient. Case Report

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Abstract

Objective: To describe a novel method to deal with ICD lead fracture in very high risk patients with deep vein thrombosis.

Case Report: We describe the case of a 71-year-old man, with a CRT-D device (Biotronik Lumax 340 HF-T) implanted for 28 months, presenting with inappropriate ventricular arrhythmia detection on home monitoring report.

The patient had a medical history of long lasting systemic arterial hypertension, insulin dependent diabetes mellitus, two coronary stents implanted for two years, severe peripheral arterial disease with no palpable limbs pulses, Acute Myocardial infarction at the age of 27 and femoral vein stent implanted for 2 months due to deep vein thrombosis. During this last hospitalization, left subclavian vein thrombosis was also found. The patient was in use of aspirin, clopidogrel and warfarin.

Device interrogation showed 5 episodes of high frequency noise in the right ventricular sense/pace channel interpreted as ventricular tachycardia (VT) or Ventricular Fibrillation (VF). Two of these episodes led to capacitor charge, which was aborted prior to shock delivery. HV1 and HV2 channels showed no abnormalities. Echocardiogram showed severe left ventricular dysfunction and LVEF = 27%. Left ventricular lead sensing and impedance were normal.

Due to the high complication risk, oral anticoagulant and dual antiplatelet therapy regimen, deep venous thrombosis and the advanced heart failure clinical status, we decided not to put another ICD lead on. The strategy planned was to do a less invasive procedure under local anesthesia.

Procedure description: With the patient under local anesthesia the ICD pulse generator was exposed with minimum dissection. The Left and Right ventricular leads sense/pace channels were then switched in the pulse generator inlet and the generator was put back in place. Total procedure time was 30 minutes and the telemetry at the end showed good ventricular sensing at the right ventricular channel (left ventricular lead). The postoperative course was uneventful and the patient was discharged in postoperative day 1. Thirty three days after the procedure the patient had episodes of ventricular arrhythmia (VT and VF) promptly detected and treated by the device, returning to normal synus rhythm. The patient had no sequela after this appropriate shock delivery.

Discussion: CRT-D patients tend to be high risk and with multiple comorbidities. Any medical intervention on them is accompanied by high morbidity/mortality risk. This patient had previous interventions indicating that deep venous access to put another ICD lead in would not be possible. There were no palpable peripheral pulses and an invasive arterial pressure line was not feasible, making general anesthesia a very high-risk approach. The surgical strategy adopted gave a secure path to fix the device problem. As long as the ventricular arrhythmia diagnosis are made by the right ventricular channel readings, the switch with the left ventricular lead provided a noise free tracing with safe diagnosis, that led ultimately to appropriate shock delivery in a life threatening episode.

Conclusion: This unique and novel approach was possible even in this very high-risk patient and turned into a life saving procedure as demonstrated by the subsequent arrhythmia episode. We think that all the ICD manufacturers should make it possible to make this ventricular channel switch during a outward electronic evaluation by device telemetry. If this change were made many patients with sensing/pacing right ventricular lead fractures would benefit from this.
Figure 1: Noise detection in the right ventricular channel

Figure 2: Appropriate VT/VF detection and shock delivery with normal sinus rhythm following the shock
Abstract

Background: Cardiovascular implantable electronic devices (CIEDs) are frequently inserted while patients are on anticoagulant or anti-aggregant therapy. As a result, the probability for hematoma formation and its consequences is higher.

Objective: To evaluate the effectiveness of TopClosure® 3S System in preventing local hematoma formation following implantation of CIEDs in patients prone to bleeding complications due to anticoagulant or potent anti-aggregant treatment.

Methods: During 10-11/2012 we identified 20 patients prone to bleeding among our patients requiring CIED implantation. Patients were assigned alternately to TopClosure® 3S therapy, or to usual pressure dressings, the latter served as the control group. Ten days following surgery, wound dressings were removed and an independent surgeon evaluated healing stage prior to staple removal. Therapy outcome was assessed by permission to extract staples, need to continue antibiotics, or requiring further TopClosure® application.

Results: Only one patient of the treatment group required additional antibiotic therapy and TopClosure® application (10%) compared to 6 patients in the control group (60%), who required additional antibiotic administration, deferral of staple removal, or further pressure dressing application.

Conclusions: The use of the TopClosure®, following CIED implantation in cardiac patients on active anticoagulant and/or intense anti-aggregant therapy, proved in this ongoing study to be safe and efficacious.
Abstract

Introduction: The choice between active vs passive fixation leads at the time of pacemaker implantation is primarily based on operators experience. However, there is a paucity of data on the clinical benefits such as device longevity and complication rate of using either type of lead fixation system.

Methods: Consecutive patients who received a pacemaker at our academic center over a 6 month period were retrospectively analyzed. Either a passive or active ventricular lead chosen based on operators preference. Pacing threshold and impedance were collected 3 weeks post implant and used to calculated device longevity based on pacing at 60 beats per minute with pulse width of 0.4ms in a single chamber St. Jude Accent device. Longevity calculation also included safety margin at twice and three times pacing threshold, and pacing at 50% and 100%. Lead dislodgment rate was also collected.

Results: Overall, 362 patients underwent pacemaker implantation (197 passive). At 3 weeks, 311 patients (167 passive) had complete follow up. Patient characteristics in both groups were similar in terms of age, gender and pacemaker indication. Both mean pacing threshold and impedance were significantly lower in the passive lead group compared to active lead group. Depending on percentage of pacing and safety margin parameters, Passive fixation lead could potentially save up to 2 years in battery life compared to active fixation lead (P< 0.001) (Table 1). Lead dislodgment rate was not significantly different among groups (2.5% vs 4.2%, p=NS).

Conclusions: Passive ventricular leads have significantly lower pacing thresholds and may potentially prolong estimated battery life by 2 years. Passive ventricular leads did not have an increased risk of dislodgment.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Passive Fixation lead (n=167)</th>
<th>Active fixation lead (n=144)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean threshold at 3 weeks (SD)</td>
<td>0.6mV ± 0.2</td>
<td>1.0mV ± 0.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean impedance at 3 weeks (SD)</td>
<td>564Ω ± 11</td>
<td>640Ω ±103</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean years of longevity (SD) at 50 % pacing with safety margin twice the pacing threshold</td>
<td>17.8 ± 0.6</td>
<td>16.7 ± 0.7</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean years of longevity (SD) at 100 % pacing with safety margin twice the pacing threshold</td>
<td>17.2 ± 0.9</td>
<td>15.3 ± 1.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean years of longevity (SD) at 50 % pacing with safety margin three times the pacing threshold</td>
<td>12.8 ± 2.9</td>
<td>11.2 ± 3.5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean years of longevity (SD) at 100 % pacing with safety margin three times the pacing threshold</td>
<td>10.3 ± 3.9</td>
<td>8.7 ± 4.5</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
Abstract

Introduction: The 5 Fr Sorin Hepta 4B lead is a bipolar transvenous pacemaker lead. We observed an unexpected high failure rate of this pacemaker lead. The aim of this study was to determine the performance of the Hepta 4B lead.

Methods: In the Medisch Spectrum Twente, a total of 98 Sorin Hepta 4B right ventricular pacemaker leads were implanted. Analysis of the pacemaker database and patients' charts was performed to assess the rate of lead-related complications of all implanted Hepta 4B leads, requiring lead replacement.

Results: Median time of follow up was 5.5 (4.2 - 6.4) years. Of the 98 implanted Hepta 4B leads, 21% (21/98) were replaced. A total of 18% (18/98) of the leads showed electrical malfunction, leading to symptoms in 5% (5/98) of the patients. Electrical malfunction included impedance change, threshold rise and sensing problems. The Kaplan-Meier curve of lead failure free survival during follow-up is shown in figure 1.

Conclusions: We report an extreme and unexpected failure rate of the Sorin Hepta lead. The most common complication was electrical dysfunction.

The reason for this phenomenon has to be analyzed, but the co-radial multifilar design, allowing a smaller diameter of the lead, may explain this finding. (figure 2)
Use of Chest Computer Tomography (CT) Scan in Patient Undergoing Laser Lead Extraction

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Abstract

Introduction: The need for infected device extraction has been rising. There is no clinical information on the use of Chest CT scan before lead removal.

Methods: From a prospective registry at a tertiary referral center from October 2008 to October 2012, 410 patients were studied. All patients had gated chest CT scans without contrast before laser lead extraction. Three-dimensional reconstructions were done to enhance diagnostic abilities.

Results: Among 410 patients 74% were males and average age was 67±16 years. Mean EF was 35±14, NYHA 3.0±0.7. Comorbidities were Coronary Artery Disease 53%, Diabetes Mellitus 38%, Hypertension 86% and Hemodialysis 8%. Indications for extraction were infection 54%, malfunction 41%. Devices extracted were pacemaker 32.9%, ICD 41.2%, CRT 25.8%. There were 16 patients (3.9%) with extracardiac leads. There were 32 patients (14.4%) with septic pulmonary emboli among 222 patients with device endocarditis.

Conclusions: Gated CT scan of the chest is helpful in patients undergoing laser lead extraction in detecting leads in extracardiac location. Septic pulmonary emboli was identified in patients with device infection.
Is the Transvenous Extraction of Cardioverter-Defibrillator Leads And Left Ventricular Leads More Risky than that of Pacemaker Leads?

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Abstract

**Background:** Although there are reports showing that the extraction of implantable cardioverter-defibrillator (ICD) leads and cardiac resynchronization therapy (CRT) leads may be hazardous, clinical evidence suggests that such procedures are safe. We evaluated the safety of transvenous lead extraction of ICD or CRT-D, compared with that of pacemaker.

**Methods:** Between August 2009 and September 2012, we collected data prospectively of 210 consecutive patients who underwent percutaneous transvenous lead extraction and compared incidence of major adverse events (MAE; death, myocardial infarction, stroke, cardiac tamponade, PE, blood transfusion or pneumothorax) between PM and ICD or CRT implanted patients.

**Results:** There were 129 patients (42.3%) with PM and 81 patients (57.7%) with ICD or CRT. All patients underwent successful transvenous removal of endocardial leads. Two of 81 patients (2.5%) had evidence of MAE in ICD or CRT group. No significant difference of MAE was found between two group (4.0 vs. 2.5%, P = 0.57).

**Conclusions:** In patients with ICD or CRT, percutaneous transvenous lead extraction could be performed safely compared with PM lead extraction.
Clinical Significance of Collateral Superficial Vein Across the Clavicle in Patients with Transvenous Permanent Device


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Abstract

Introduction: Obstruction of the access vein is a well-known complication after transvenous permanent device implantation. In that case, well-developed collateral superficial veins are frequently observed. We assessed the relationship between the venous obstruction and development of the superficial veins.

Methods: A total of 100 patients scheduled for generator replacement were enrolled. The skin surface around the device was photographed. Contrast medium was injected into the peripheral arm vein, and venography was performed before generator replacement.

Results: Venous obstruction was defined as a luminal diameter narrowing of > 75%. Venography showed the venous obstruction in 26 (26.0%) patients. We focused on a collateral superficial vein across a clavicle, because main routes of collateral circulation were through jugular veins. Of 100 patients, 42 (42.0%) had the superficial vein across the clavicle. Sensitivity of the presence of the superficial vein across the clavicle in the diagnosis of the venous obstruction was 96.2% and specificity was 77.0% (p<0.001).

Conclusions: The presence of the superficial vein across the clavicle is useful for the prediction of the venous obstruction in patients with transvenous permanent device.