Six month outcomes after leadless pacemaker implantation and comparison with a historical cohort: a single center study

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Background/Introduction: Despite a wealth of experience, cardiac pacemakers are associated with a substantial number of complications. Recently approved leadless cardiac pacemakers (LCP) are fashioned to avoid lead and pocket-related complications while providing single chamber ventricular pacing.

Purpose: Evaluation of six-month safety and efficacy after LCP implantation, as well as comparison of complication rate with Standard Pacemaker (SPM) recipients using propensity score matching.

Methods: New LCP recipients were followed in a single center. Patients received both currently available LCP systems. Single or dual chamber pacemaker recipients were identified before the first LCP implantation. Propensity score matching was used to pair LCP and SPM recipients with regards to sex, age, weight, renal failure class, history of diabetes, usual medication with anticoagulants and indication for pacing as covariates.

Results: There were 79 LCP implantation attempts in 78 patients, and 76 were successfully delivered (96.2%). Mean procedural time was 46.12±35.4 minutes. There were 5 device or procedure related serious adverse events (6.4±2.8%). 73 LCP recipients reached 6 months of follow-up and 95.5±2.5% of them reached a combined efficiency endpoint of low capture threshold (<2 Volts) and acceptable R-wave sensing (<±4 mVolts). 168 SPM recipients were enrolled as controls, and 72 of them were matched with 72 leadless pacemaker recipients who reached 6 months of follow-up. Absolute standardized mean differences of the selected covariates were less than 0.20 after matching, suggesting balance between groups. The 6-month complication ratio difference with 90% confidence intervals was -2.8 [-10.3; 4.8]% thus LCP met our criterion for noninferiority versus SPM regarding complications at 6 months. Kaplan Meier survival curves showed a trend toward a lower complications rate after LCP implantation but the results did not reach statistical significance (Figure 1).

Conclusion: Our results confirm the safety and efficacy of LCP as well as a trend towards lower complications when comparing with SPM. To the best of our knowledge, this study is the first to include both the 2 leadless systems available to date. Further studies are needed to clarify the specific risks associated and to assess the retrievability and the lifespan of these systems in the long run.

Abstract P408 Table. Patients’ characteristics (N=88)

Table 1. With anti-coagulation

<table>
<thead>
<tr>
<th>With anti-coagulation</th>
<th>36 (40.9%)</th>
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<tbody>
<tr>
<td>AV block</td>
<td>27 (30.7%)</td>
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<tr>
<td>Atrial fibrillation and bradycardia</td>
<td>22 (25.0%)</td>
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<tr>
<td>Sick Sinus Syndrome Tachy-Bradycardia</td>
<td>26 (29.5%)</td>
</tr>
</tbody>
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Abstract P407 Figure. 6-month freedom from complications

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Leadless pacemaker: initial experience of two centres in Portugal

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Introduction: Leadless pacemakers have emerged as alternative to conventional pacemakers. Early studies showed a high rate of implantation success and low rate of complications in the procedure. The long-term performance of these devices remains uncertain.

Objective: To evaluate the efficacy and safety of a series of consecutive patients submitted to implantation of leadless pacemaker.

Methods: Prospective observational registry from two centers including 51 consecutive patients undergoing implantation of leadless pacemaker Micra™ between June 2015 and June 2017. The endpoints were the effectiveness and safety of the procedure, as well as the electrical performance in the implantation and follow-up.

Results: The population had a mean age of 77±9 years and 73% were male. The main indication for implantation was bradycardia associated with atrial fibrillation (77%), followed by complete atrioventricular block and sinus node disease. The Micra pacemaker was successfully implanted in all patients. During the first 30 days, the complication rate was low (1.9%) with only one femoral pseudo-aneurysm requiring surgical correction; there was no pericardial effusion or displacement of the device. The parameters remained stable over the mean follow-up of 7 months (Table).

Conclusions: In our experience, implantation of Micra was an effective and safe procedure and the parameters remained stable over time.

Abstract P409 Table.

Table 1. Implantation Follow-up

<table>
<thead>
<tr>
<th>Threshold</th>
<th>0.59±0.25 ms (0.24 ms)</th>
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<tbody>
<tr>
<td>Impedance</td>
<td>717±144 ohms (590±105 ohms)</td>
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<tr>
<td>Sensing</td>
<td>10.7±4.7 mV (13.9±5.1 mV)</td>
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