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ORIGINAL ARTICLE

Short- and long-term need for permanent pacemaker after transcatheter implantation of the Edwards Sapien aortic valve prosthesis

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KEYWORDS
Pacemaker;
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Abstract
Introduction: A permanent pacemaker is frequently needed after transcatheter aortic valve implantation, but the available data are mainly on the CoreValve system.
Objective: To evaluate the need for new permanent pacemaker after implantation of the Edwards Sapien device, as well as related factors.
Methods: We included the first 100 patients treated with the Edwards Sapien device at our institution. Of these, 12 had a permanent pacemaker before the procedure, and thus our study population was the remaining 88 patients.
Results: A permanent pacemaker was indicated in eight patients (9.1%) during hospitalization or at 30 days. After discharge, another four patients needed a pacemaker (at 42 days and three, 18, and 30 months). Two variables were associated with the need for pacemaker during hospitalization: previous dialysis (13% vs. 1%, p=0.042) and complete right bundle branch block before the procedure (25% vs. 5%, p=0.032). More than one month after the procedure, the characteristics associated with the need for pacemaker were plasma creatinine level (2.5±1.7 vs. 1.3±0.6 mg/dl, p=0.001) and previous myocardial infarction (50% vs. 10%, p=0.013).
Conclusion: The rate of pacemaker implantation with the Edwards Sapien device was 9.1%. Right bundle branch block and dialysis were associated with this complication.

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PALAVRAS-CHAVE
Pacemaker;
Implantação valvular aórtica percutânea;
Longo prazo

Necessidade a curto e a longo prazo de implantação de *pacemaker* permanente após implantação percutânea da válvula prostética aórtica *Edwards-Sapiens*

Resumo
Introdução: A necessidade de um *pacemaker* permanente após implantação percutânea da válvula aórtica é frequente, embora os dados disponíveis estejam principalmente associados ao sistema *CoreValve*.
Objetivos: O objetivo foi avaliar o índice do novo *pacemaker* permanente, bem como todos os fatores relacionados, após a implantação do dispositivo *Edwards-Sapiens*.
Métodos: Incluímos os primeiros 100 doentes tratados com o dispositivo *Edwards-Sapiens* no nosso hospital. Destes, 12 já tinham *pacemaker* permanente antes do procedimento, pelo que a população do estudo corresponde aos restantes 88 doentes.
Resultados: O *pacemaker* permanente foi indicado em oito doentes (9,1%) durante o internamento ou a 30 dias. Após a alta hospitalar, outros quatro doentes necessitaram de colocar o *pacemaker* (aos 42 dias e aos três, 18 e 30 meses). Duas variáveis foram relacionadas com a necessidade de colocação de *pacemaker* durante o internamento: diálise prévia (13 *versus* 1%, p=0,042) e bloqueio completo do ramo direito antes do procedimento (25 *versus* 5%, p=0,032). Mais do que um mês após o procedimento, as características, que foram relacionadas com a necessidade de colocação de *pacemaker*, foram os níveis da creatinina plasmática (2,5±1,7 *versus* 1,3±0,6 mg/dl, p=0,001) e enfarte do miocárdio prévio (50 *versus* 10%, p=0,013).
Conclusão: A necessidade de colocação de *pacemaker* após a implantação do dispositivo de *Edwards-Sapiens* foi de 9,1%. O bloqueio completo do ramo direito e a diálise foram associados a esta complicação.

Introduction

The need for pacemaker (PM) secondary to severe atrioventricular (AV) conduction abnormalities is a relatively common complication after transcatheter aortic valve implantation (TAVI).[1–12] This is apparently due to mechanical compression of the conduction system by the device, as the His bundle and left branch are anatomically very close to the aortic annulus and aortic valve.[13,14]

The need for PM implantation after TAVI is especially frequent with the self-expanding CoreValve (CV) prosthesis (Medtronic Inc., Minneapolis, MN), and therefore information about this complication is mainly available on patients treated with this device.[1,2,5–11] By contrast, there are fewer data on the need for PM with the balloon-expandable Edwards Sapien (ES) valve (Edwards Lifesciences Inc., Irvine, CA).[12,15]

Furthermore, data on the need for PM implantation after TAVI are mainly related to the periprocedural period, whereas there is less information on longer follow-up. This is important, because patients referred for TAVI are frequently of advanced age, and may require PM implantation unrelated to TAVI.

The objective of this study was to evaluate the need for PM implantation, as well as related factors, both short- and long-term, after ES device implantation. For this purpose, we performed a long-term follow-up of the first 100 patients treated with the ES at our institution.

Methods

Study population

The first 100 patients treated with the ES at our institution were included in the study. In all cases, the indication was established by the heart team, with the participation of clinical cardiologists, interventional cardiologists and cardiac surgeons. Briefly, patients had symptomatic severe aortic stenosis (valve area <1 cm^2) with high surgical risk and an estimated survival >1 year. Initially, a EuroSCORE >20% was required, but subsequently patients with EuroSCORE <20% and with other situations (e.g., patent left internal mammary artery grafts and porcelain aorta were accepted).

Of the 100 patients, 78 underwent TAVI by transfemoral access and 22 by transapical access. The transfemoral approach was the first choice, but transapical TAVI was performed when the iliac anatomy did not allow a safe procedure by a transfemoral approach.

Technique

In all cases, the procedure was performed under three-dimensional transesophageal monitoring and general anesthesia.

A femoral vein was punctured to advance a temporary pacemaker into the right ventricle, and a femoral artery was used to advance a pigtail catheter into the ascending