BRIEF ARTICLE

Impact of Cusp-Overlap Technique on Pacemaker Requirement after Transcatheter Aortic Valve Implantation

Impacto de la técnica de Cusp-Overlap en el requerimiento de marcapasos luego de un implante valvular aórtico percutáneo

MATÍAS SZTEJFMAN[1, 2], CARLOS MAXIMILIANO GIULIANI[1, 2], SEBASTIÁN PERALTA[1], EZEQUIEL JOSÉ ZAIDEL[1,]
LUIS CARLOS SZTEJFMAN[1, 2], MARCELO OMAR BETTINOTTI[1]

ABSTRACT

Background: Persistent bradyarrhythmias requiring permanent pacemaker implantation are a common complication after transcatheter aortic valve implantation (TAVI), but high implantation with cusp-overlap technique could prevent conduction system disturbances.
Objective: The aim of this study was to assess the rate of pacemaker use in patients who received TAVI with conventional coplanar technique compared with cusp overlap technique.
Methods: A total of 65 consecutive patients from two centers receiving Evolut-R or Evolut-Pro valve implantation, 50 coplanar and 15 cusp-overlap, were analyzed between 2017 and 2019.
Results: Mean age was 80 years, and there were no differences in risk according to the EuroSCORE. The rate of pacemaker requirement was 0% in cusp-overlap procedures compared with 24.9% in those with conventional implantation (OR=0.0; 95% CI 0-0.89; p=0.041). In addition, cusp-overlap implants presented lower rate of major complications (6.67% vs. 42%; OR=0.09; 95% CI 0.01-0.8; p=0.011).
Conclusions: In this cohort, TAVI procedure with cusp-overlap technique was associated with null pacemaker requirement. Given the potential large-scale impact, external validation of results is needed.

Key Words: Transcatheter aortic valve replacement - Atrioventricular block – Pacemaker, Artificial - Heart Valve Prosthesis Implantation, methods

RESUMEN

Introducción: Las bradiarritmias persistentes que requieren el implante de un marcapasos definitivo son una complicación frecuente tras el implante valvular aórtico percutáneo (IVAP), pero un implante alto con técnica Cusp-Overlap podría evitar las alteraciones del sistema de conducción.
Objetivo: El objetivo fue determinar la tasa de uso de marcapasos en pacientes que recibieron IVAP con la técnica convencional coplanar en comparación con Cusp-Overlap.
Material y métodos: Entre 2017 y 2019 se analizaron 65 pacientes consecutivos de dos centros, que recibieron válvulas Evolut-R o Evolut-Pro: 50 implante coplanar y 15 Cusp-Overlap.
Resultados: La edad promedio era 80 años y no hubo diferencias en el riesgo por puntaje EuroScore. Los procedimientos con la técnica de Cusp-Overlap presentaron 0% de requerimiento de marcapasos en comparación con 24,9% en el implante convencional (OR = 0,0; IC 95% 0-0,89; p = 0,041). También hubo menos complicaciones mayores (6,67% vs 42%; OR = 0,09; IC 95% 0,01-0,8; p = 0,011).
Conclusiones: En esta cohorte el IVAP con la técnica de Cusp-Overlap se asoció con una necesidad de marcapasos nula. Dado el potencial impacto a gran escala se necesita validar externamente los resultados obtenidos.

Palabras clave: Reemplazo de la válvula aórtica transcatéter - Bloqueo atrioventricular – Marcapasos artificial - Implantación de prótesis de válvulas cardíacas, métodos

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is the standard procedure for the management of aortic stenosis (AS), expanding its use from inoperable cases towards low risk patients. (1) Although a significant reduction in periprocedural mortality and morbidity has been observed, some complications are still frequent.

Atrioventricular block (AVB) occurring after TAVI

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Address for reprints: Dr. Ezequiel Zaidel - Acuña de Figueroa 1224 (C1180AAX), Sanatorio Güemes. Department of Interventional Cardiology – e-mail: ezaidel@fsg.edu.ar - Phone/Fax +54 11 4959 8200

[1] Department of Interventional Cardiology, Sanatorio Güemes, Buenos Aires, Argentina.
[2] Department of Interventional Cardiology, Sanatorio Finochietto, Buenos Aires, Argentina.

is a determinant of permanent pacemaker implantation (PPM), ranging from 5% to 50% in different series. (2) Distinctive causes of AVB after TAVI have been classified into previous electrical disturbances, calcification, valve type, and low valve implantation by different groups. (3, 4)

Unlike the conventional radiological technique for TAVI, with left anterior oblique fluoroscopic view and coplanar implantation, Tang suggested the "cusp-overlap" fluoroscopy view to guide implantation of self-expanding valves. (5) With this technique, the catheter is more centered across the aortic valve, and a frontal view of the non-coronary cusp enables higher valve implantation with lower risk of device embolization and contact with the conduction system.

The aim of this study was to establish differences in PPM requirement rates between patients who received TAVI with conventional or cusp-overlap technique. The hypothesis was that the cusp-overlap technique would be associated with lower rate of pacemaker implantation.

METHODS

This was a retrospective analysis of a continuous database where all TAVI procedures were registered in two tertiary care centers of the city of Buenos Aires, Argentina, between January 2017 and December 2019. Follow-up was carried out during hospitalization and at 30 days. Two authors prospectively collected information from each procedure and included it into a database.

The team of interventional cardiologists began performing TAVI in 2009, but as all patients received Evolut-R or Evolut Pro self-expanding valves since January 2017, this was the date chosen as study initiation. Thus, the learning curve was overcome and new-generation valves were used in all cases. Transfemoral access was used in 100% of cases.

All TAVI patients were eligible for this study; however, patients with previous pacemaker implantation were excluded from the analysis of the primary endpoint, and patients with left bundle branch block were excluded from the analysis of new bundle branch blocks at 30 days. Follow-up was performed using information from medical records and by phone calls.

The primary endpoint was need for PPM implantation during hospitalization and at 30-days. Other endpoints included the incidence of complete left bundle branch block at 30 days, and the composite endpoint of major complications (PPM implantation, more-than-mild paravalvular leak, acute obstruction of a coronary artery, shock, major bleeding, and death). Variable definitions and assignment were based on the VARC-2 classification, (6) and the information was retrieved from the procedural registries, complementary tests, and medical records.

As this was an ongoing registry of patients from two centers, exclusion or allocation biases were avoided through review of the information by the researchers Giuliani and Peralta.

Statistical analysis

Sample size was limited by the time interval of the study and the number of patients who received TAVI in both hospitals; therefore, adequate sample size calculation was not possible. Qualitative variables were expressed as numbers and percentages and quantitative variables were described as mean (standard deviation) or median (interquartile range) according to their distribution. Bartlett's method was used to define the normal distribution of results. Comparisons were made using conventional statistical analyses (chi-square test, Fisher's exact test, Student's t-test, and analysis of variance, according to the type of variable distribution). In the absence of information on any variable, the case was excluded from the analysis and no imputations were made. There were no losses to follow-up. Patients with previous pacemakers were excluded from the analysis of new pacemakers. The Epi Info V7.0® software was used for statistical analysis, and $p < 0.05$ was considered statistically significant.

Ethical considerations

The study procedures were in compliance with the Declaration of Helsinki. The group of authors analyzing the data had no access to patient confidential information.

RESULTS

A total of 65 patients underwent TAVI with Evolut-R or Evolut-Pro self-expanding valves at both centers between 2017 and 2019. Among them, 50 patients received conventional coplanar implantation, while the cusp-overlap high implantation technique was used in all cases (15 patients) since November 2019.

Mean age was 80 years, with a higher proportion of women in the cusp-overlap group (66% vs. 33% in the coplanar group, $p < 0.01$). No differences were found in patient risk stratification by the Society of Thoracic Surgeons score: 5.75 (IQR 4-8.4) and 6.8 (IQR 5-8.9), respectively (p=NS); however, 85% of the patients from both groups had class III or IV heart failure symptoms (Table 1).

Once the cases with previous pacemaker implantation (9 patients in the conventional group and 1 case in the cusp-overlap group) were excluded, a 0% rate of pacemaker implantation could be established in the cusp-overlap group compared with 24.9% (10 patients) in the conventional implantation group (OR=0; CI 95%: 0-0.89; p=0.041). The composite endpoint at 30 days was also lower in the cusp-overlap group (7.14% vs. 43.9%; OR=0.09; CI 95%: 0.01-0.82; p=0.001) (Table 3).

The incidence of transient left bundle branch block at 30 days was 21.4% in the cusp overlap group and 17% in the conventional group (p=NS), with only one case of permanent left bundle branch block with cusp overlap technique (7.14% vs. 0%, p=0.08). There were no differences in fluoroscopy time, contrast volume, or mortality (Table 2).

DISCUSSION

The main finding of this study was the complete absence of pacemaker requirement in the cusp-overlap group without increased risk of other complications in patients undergoing TAVI.

Complications after TAVI, such as AVB, not only modify patients' prognosis but also have significant economic consequences, accounting for 25% of the

Table 1. Baseline population characteristics

	CUSP-OVERLAP (n = 15)	CONVENTIONAL (n = 50)	OR (IQR)	P
Proportion of patients	23.08%	76.92%		
Men	33%	66%	0.25 (0.27-0.87)	0.02
Women	66%	34%		
Age (±SD)	80.07 (6.31)	79.46 (6.80)		0.76
EuroSCORE II (±SD)	6.32 (4.66)	8.95 (7.68)		0.19
STS (IQR)	5.75 (4-8.4)	6.8 (5-8.9)		0.32
NYHA 3 or 4	87%	84%		0.25
COPD	33.3%	32%		0.92
Coronary heart disease	53.3%	58%		0.74
Angioplasty	33.3%	42%		0.54
CABG	13.3%	18%		0.67
Peripheral vascular disease	6.67%	28%	0.18 (0.02-1.5)	008
Stroke	13.3%	8%		0.61
Atrial fibrillation	13.3%	16%		0.80
Previous pacemaker	6.67%	16%		0.67
Right bundle branch block	0%	14%		0.18
Left bundle branch block	6.67%	20%		0.43
EF (±SD)	59 (187)	55.3 (13.9)		0.40
Maximum gradient, mmHg (±SD)	76.8 (27.6)	70.4 (25.5)		0.41
Mean gradient, mmHg (±SD)	52.5 (18.2)	42.3 (16.3)		0.046
Aortic valve area (IQR) cm^2	0.60 (0.5-0.8)	0.79 (0.68-0.8)		0.03
Minimum annulus by CT, mm (±SD)	20.4 (2.7)	22.4 (2.4)		0.018
Maximum annulus by CT, mm (±SD)	26 (3.4)	26 (3.4)		0.99
Annulus area by CT, mm^2 (±SD)	434 (107)	488 (86)		0.07
Bicuspid	0%	4.4%		0.40
Porcelain	13.3%	6.3%		0.58

STS: Society of Thoracic Surgeons. NYHA: New York Heart Association. COPD: Chronic obstructive pulmonary disease. CABG: Coronary artery bypass grafting. EF: Ejection fraction. CT: Computed tomography.

Table 2. Events during and after percutaneous aortic valve implantation

	CUSP-OVERLAP (n = 15)	CONVENTIONAL (n = 50)	OR (IQR)	P
Transfemoral access	100%	100%		0.23
General anesthesia	0%	26%	0 (0-0.73)	0.028
Conversion to open surgery	0%	0%		1
Post-maximum gradient, mmHg (±SD)	10.5 (4.2)	12.4 (6.7)		0.30
Post-mean gradient, mmHg (±SD)	5.7 (2.1)	5.9 (3.4)		0.81
Severe paravalvular leak	0%	2%		0.079
Moderate paravalvular leak	0%	22%		0.079
Major bleeding	0%	2%		1
Major vascular complication	0%	4%		1
Stroke or TIA	0%	2%		1
Major stroke	0%	0%		1
AKI	0%	4%		1
Fluoroscopy time (min)	12.06 (1.1)	12.34 (2.8)		0.72
Contrast volume (ml)	91 (12.5)	99.5 (24)		0.19
In-hospital mortality	0%	0%		1
30-day moderate or severe paravalvular leak	0%	28.5%		0.07
30-day stroke	0%	0%		1
30-day death	0%	2%		1
New PPM	0%	20%	0 (0-1.09)	0.056
Composite endpoint	6.67%	42%	0.09 (0.01-0.8)	0.011

TIA: Transient ischemic attack. AKI= acute kidney injury. PPM: Permanent pacemaker.

Table 3. Outcomes after excluding patients with previous artificial pacemaker implantation (9 cases in the conventional group, 1 in the cusp-overlap group)

	CUSP-OVERLAP (n = 14)	CONVENTIONAL (n = 41)	OR (IQR)	P
New PPM	0.14 (0%)	10/41 (9%)	0 (0-0.89)	0.041
New transient CLBBB	3/14 (21.4%)	7/41 (17%)		0.70
New permanent CLBBB	1/14 (7.14%)	0%		0.08
Composite endpoint	1/14 (7.14%)	18/41 (43.9%)	0.09 (0.01-0.82)	0.001

PPM: Permanent pacemaker. CLBBB: Complete left bundle branch block

cost of the procedure. (7) In this regard, AVB rate was lower with the self-expanding valves used in this cohort than in the initial TAVI series (24.9%), but it was 0% using the cusp-overlap technique. If these results are validated in other cohorts, the cost-effectiveness analyses of TAVI could be modified, mainly in countries with limited financial resources.

Although coronary sinus occlusion and paravalvular leak have been described as potential risks for the technique, no such complications were observed in this series. Furthermore, fluoroscopy time and iodinated contrast volume were not increased with this new technique, possibly due to an appropriate procedural planning before the patient enters the operating room. (8) In this sense, the previous CT scan used in our series, with annulus, coronary sinus, left ventricular outflow tract and coronary height measurements, and planning a right caudal oblique projection, may have contributed to the results.

In recent clinical trials, the use of TAVI for lower-risk patients makes post-TAVI complications more relevant, so we consider that proper planning, prosthesis selection, access and risk assessment of electrical complications are now essential.

The study limitation was the impossibility to perform a subgroup analysis due to the low number of patients. Since all the procedures were performed by the same medical team, which had already overcome the learning curve (more than 10 years since the first implantation), results cannot be extrapolated to less experienced centers. Finally, decision for PPM implantation was limited to 30 days after the procedure. However, the rate of further AVB with these valves is <3.3% beyond day 30 (9) compared with other valves presenting risk of later blocks. (10) Due to the low number of patients, the impossibility to carry out a sensitivity analysis was also a study limitation.

CONCLUSIONS

In this series of patients, TAVI using the cusp-overlap technique was safe and associated with null rate of PPM implantation at 30 days. These results should be externally validated, given the potential benefit of avoiding pacemaker implantation after TAVI.

Conflicts of interest

None declared.

(See authors' conflicts of interest forms on the website/ Supplementary material)

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