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CME

Clinical Outcomes of Electrical Disorders after Transcatheter Aortic Valve Implantation

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ABSTRACT

Introduction
The indication of transcatheter aortic valve implantation in patients considered not suitable candidates for surgery is increasing. Despite acute disorders of the conduction system are common complications, their clinical and electrocardiographic significance is not completely clear.

Objectives
To determine whether acute disorders of the conduction system after transcatheter aortic valve implantation has prognostic implications.

Results
Between March 2009 and February 2012, 47 patients were included in the analysis. Thirty patients (63%) had acute disorders of the conduction system: 19 patients presented isolated complete left bundle branch block (LBBB), 9 patients isolated complete atrioventricular block (CAVB), and 2 patients both conduction disorders, with a total of 21 LBBBs and 11 CAVBs. A definite pacemaker was implanted in 12 patients (25%) before discharge: in 11 due to CAVB and in 1 due to acute LBBB plus atrial fibrillation. Complete AVB reverted in the catheterization laboratory in only one patient. At one month, average ventricular pacing was 90% in patients with persistent CAVB after the intervention, only 3% in the only patient in whom CAVB reverted at the catheterization laboratory and < 10% in the patient with LBB plus atrial fibrillation.
The incidence of postoperative heart failure and hospital stay was greater in patients with acute disorders of the conduction system ($p = 0.007$ and $p = 0.045$, respectively). There were no differences in new hospitalizations and mortality during follow-up.

Conclusions
In this study, the development of acute disorders of the conduction system was associated with increased incidence of heart failure and hospital stay but not with the incidence of major events. A definite pacemaker could be implanted immediately after CAVB develops as the conduction disorder is generally irreversible.

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Key words > Aortic valve stenosis - Heart conduction system - Atrioventricular block –Implantation of heart valve prosthesis

Abbreviations >

CA	Conduction abnormalities	**EF**	Ejection fraction
CAVB	Complete atrioventricular block	**LAH**	Left anterior hemiblock
RBBB	Right bundle-branch block	**HF**	Heart failure
LBBB	Left bundle-branch block	**TAVI**	Transcatheter aortic valve implantation
ECG	Electrocardiogram	**PPM**	Permanent pacemaker

INTRODUCTION
Aortic valve stenosis is the most common valvular heart disease and affects about 3% of people > 75 years. Once symptoms develop, survival is drastically reduced and aortic valve replacement is indicated. Surgical valve replacement was the only option available until 10 years ago. However, transcatheter aortic valve implantation (TAVI) is available in our country

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since 4 years ago and has emerged as an important therapeutic option in high risk patients unsuitable and with contraindications for valve heart surgery.

New conduction abnormalities (CA) are common complications after TAVI, (1) particularly after the implantation of the self-expanding Medtronic CoreValve®, the only valve currently used in our country. The main electrical complications described include complete atrioventricular block (CAVB) requiring permanent pacemaker (PPM) implantation, left bundle-branch block (LBBB) and right bundle-branch block (RBBB). These complications occur in approximately 60% to 70% of cases, according to the different published series, (2, 3). Yet, these percentages have been decreasing over the last years due to technical improvement.

Several predictors of CAVB after TAVI have been described: left-axis deviation, (4, 5), right bundle branch block (RBBB) in the baseline electrocardiogram (ECG), interventricular septal thickness > 17 mm, noncoronary sinus size, (4) mitral annulus calcification and aortic valve area indexed for body surface area after TAVI < 0.86 cm2. Left bundle-branch block is the most common complication (4, 5) and, up to now, the only factor that has been described as predictor for this complication is the depth of prosthesis implantation. (5)

It has already been demonstrated that CA after surgical aortic valve replacement have important clinical implications. Complete atrioventricular block increases mechanical ventilation times, intensive care unit stay, and overall hospital stay, (6) while new LBBB is associated with greater incidence of CAVB, syncope and long-term sudden death. (7) However, the clinical implications of these CA in patients after TAVI have been scarcely evaluated.

The aim of this study is to determine the prognostic implications of new CA after TAVI by comparing the short- and long-term clinical outcomes of patients with new CA versus those without new CA after TAVI.

METHODS

Population

Fifty-seven consecutive patients with severe symptomatic aortic stenosis underwent TAVI with CoreValve® at a single center (Hospital Universitario Fundación Favaloro, Buenos Aires, Argentina) between March 2009 and February 2012. Eight patients with previous PPM and 2 patients who died during the procedure before the prosthesis was implanted were excluded from the study; thus 47 patients were included in the analysis. (Figure 1). The indication for TAVI was based on the high operative risk evaluated by cardiovascular surgeons who considered they were not candidates for surgery due to the presence of comorbidities.

Electrocardiographic data/pacemaker

A baseline ECG was performed in all the patients at admission (before TAVI) and then daily during hospitalization. After TAVI, all the patients were admitted to an intensive care area for the first 48 hours and remained under continuous telemetry monitoring. Patients who underwent PPM were evaluated one month after discharge for pacemaker interrogation of average ventricular pacing and other routine parameters.

Definitions

Complete atrioventricular block was defined as complete dissociation of atrial and ventricular activity in the 12-lead ECG. Left bundle-branch block was defined as the presence of wide QRS complexes > 0.12 s with absence of Q waves in LI, AVL, V5 and V6, small r wave with deep and wide S wave or QS waves in V1 and V2. (8) Heart failure was defined according to the last guidelines of the European Society of Cardiology. (9) Stroke was considered as the acute neurological event defined by the clinical evidence of a new focal neurologic deficit.

Follow-up

Clinical follow-up included the analysis of electronic medical records, evaluation in the cardiology outpatient clinic and telephone calls. Median follow-up was 203 days (range CI 25-75: 51 to 420 days). Two patients were lost to follow-up (and thus pacemaker interrogation could not be done one month after discharge) because they did not live in the country and follow-up was not performed in our institution.

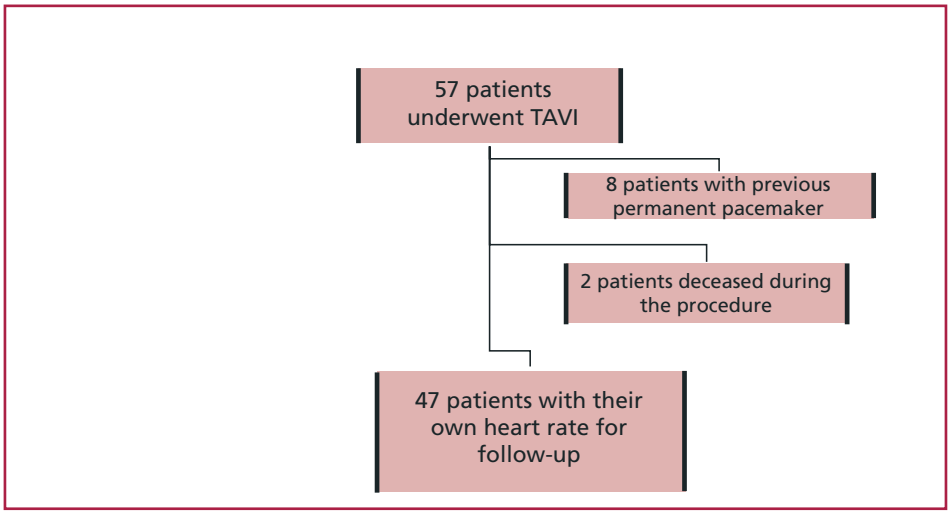

Fig. 1. Study design. Diagram showing patients included and excluded for this study. TAVI: Transcatheter aortic valve implantation. PPM: Permanent pacemaker.

Final endpoints

The final endpoints were all-cause mortality, heart failure, acute myocardial infarction and stroke during hospitalization and follow-up, and all-cause rehospitalizations. The incidence of these events was compared between patients with new CA and those without new CA. The persistence or reversion of the electrical abnormalities was also evaluated with the methods described.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation and were analyzed using Student 's t test or the Mann-Whitney U test for variables with normal or abnormal distribution, respectively. Dichotomous variables were expressed as whole numbers and percentages and were compared using chi square test or Fisher's exact test, as applicable. The variables with significant association with CAVB at univariate analysis were introduced in a multiple logistic regression model (step back method) to determine the independent predictors.

Statistical analysis was performed using SPSS 19.0 statistical package for Windows (SPSS Inc, Chicago, IL).

RESULTS

Baseline characteristics of both populations are described in Table 1. Fifty-seven percent of patients were men and mean age was 78 years (61-90). Hypertension was present in 81% of cases, 23.4% had diabetes mellitus and 17% had chronic obstructive lung disease. The average logistic EuroSCORE risk was 16% (percentiles 25-75%: 9-17). All patients had severe aortic stenosis with a mean gradient of 53.1 mm Hg (± 16 mm Hg).

Electrocardiographic parameters

Electrocardiographic characteristics at baseline and immediately after the procedure are shown in Table 2. Baseline ECG showed atrial fibrillation in 9 patients (19%), first-degree atrioventricular block in 10 (21%), LBBB in 6 (12.8%), RBBB in 5 (10.6%) and left anterior hemiblock (LAH) in 6 (12.8%).

New conduction abnormalities immediately after transcatheter aortic valve implantation

There was a significant increase in conduction abnormalities immediately after aortic valve implantation. Thirty patients (63%) presented new CA: LBBB in 21 patients and CAVB in 11, and 2 patients had both disorders. Thus, the prevalence of LBBB increased from 12.8% to 57.4% ($p < 0.0001$) and the prevalence of CAVB from 0% to 23.4% ($p = 0.0005$). Left bundle-branch block was transient in 4 patients (18%) and reverted within the first 24 hours in all the cases. Only one of these patients developed CAVB during hospitalization and required PPM implantation.

Table 1. Comparison between the baseline characteristics of patients with CA and without CA

	With CA (n= 30)	Without CA (n= 17)	p
Male gender, n(%)	17 (56.7)	10 (58.8)	ns
Age, years	79.7 (± 7.5)	77.8 (± 8.5)	ns
Body surface, m^2	1.7 (± 0.18)	1.9 (± 0.2)	0.04
Symptom			
Dyspnea, n (%)	28 (96.6)	16 (94.1)	ns
Angina, n (%)	10 (34.5)	7 (41.2)	ns
Syncope, n (%)	6 (20.0)	3 (17.6)	ns
Hypertension, n (%)	24 (80.0)	14 (82.0)	ns
Dyslipidemia, n (%)	14 (47.1)	8 (46.7)	ns
Current smoker/formers moker, n (%)	12 (40)	6 (35)	ns
Diabetes, n (%)	7 (23.5)	4 (23.3)	ns
Chronic obstructive pulmonary disease (moderate-severe), n (%)	6 (20.0)	2 (11.8)	ns
Creatinine clearence, mg/dl	55 (± 27.549)	70 (± 23.011)	0.08
History			
Unstable angina, n (%)	4 (13)	3 (17)	ns
Acute myocardial infarction, n (%)	5 (16.7)	2 (11.8)	ns
Stroke, n (%)	4 (13.3)	2 (11.8)	ns
Heartfailure, n (%)	3 (10)	4 (23.5)	ns
Aortic valvuloplasty, n (%)	2 (7)	6 (40)	0.016
Echocardiographic parameters			
Moderate to severe mitral regurgitation, n (%)	8 (26.6)	2 (11.8)	ns
LVEF, %	56 (± 9.2)	54 (± 15.3)	ns
Peak aortic gradient, mm Hg	87 (± 24)	78 (± 20)	ns
Mean aortic gradient, mm Hg	55 (± 16)	50 (± 17)	ns
Aortic valvearea, cm^2	0.65 (± 0.2)	0.62 (± 0.1)	ns
LVMI, m^2	127 (± 32)	120 (± 17.6)	ns
Aortic valve annulus, mm	22.7 (± 2.5)	20.5 (± 1.3)	0.005
Interventricular septum, mm	12.9 (± 2.3)	13.6 (± 1.8)	ns
Logarithmic EuroSCORE,%	17.0	14.4	ns

CA: Conduction abnormalities. LVEF: Left ventricular ejection fraction. LVMI: Left ventricular mass index. ns: Non significant.

Permanent pacemaker / ventricular pacing

Twelve of the 30 patients with new CA required PPM before discharge: 11 due to CAVB and 1 for new LBBB associated with atrial fibrillation with 3-second pauses during telemetry. Complete atrioventricular block reverted at the catheterization laboratory during hospitalization in only one patient, after PPM had been implanted. Pacemaker interrogation of ventricular pacing time was achieved in 10 of the 12 patients. In patients with persistent CAVB after the intervention, mean ventricular pacing was 88% (53-100). In the patient in whom CABV reverted in the catheterization laboratory, mean ventricular pacing was only 3% and < 10% in the patient with LBBB plus atrial fibrillation. Two patients who did not live in Buenos Aires were lost to follow-up. Table 3 shows the clinical and electrophysiological characteristics of the 12 patients who required PPM during hospitalization.

Clinical parameters

No hospital deaths or deaths at 30 days were reported in both groups. The incidence of postoperative HF was 30% and was more common in patients with new CA (43% vs. 6%; p = 0.007). After evaluating which echocardiographic parameters following implantation could have influenced in the development of this complication, we did not find statistically significant differences in the presence of aortic regurgitation, except for mild perivalvular leak which was slightly greater in patients with new CA vs. those without new CA (42% vs. 42.8%, p = 0.75). In the same sense, ejection fraction (EF) before and after implantation measured by Doppler echocardiography was similar in the group of patients with new CA (EF before implantation 56.3% ± 10.8% vs. EF after implantation 55.65% ± 9.7%; p = 0.56). Finally, the presence of moderate to severe mitral regurgitation was similar between both groups before implantation (new CA 26.6% vs. without new CA 11.8%; p = 0.28) and after implantation (new CA 30% vs. without new CA 17.6%; p = 0.49). Hospital stay was longer in patients with conduction abnormalities (8.67 ± 12.2 days vs. 3.93 ± 1.1 days; p = 0.0088). At long-term follow-up, the rate of rehospitalization was 30%, with a tendency to be greater in patients with new CA compared to those without new CA (44% vs. 14%; p = 0.089) (Figure 2). Mortality rate was 8.5% (4 patients) in both groups, and there were no differences between those with new CA vs. patients without new CA (10% vs. 7%; p = 0.75). Only one patient presented stroke during hospitalization and 2 (4.2%) during follow-up; all these patients belonged to the group with new CA.

Table 2. Changes in the electrocardiographic parameters after transcatheter aortic valve implantation

	Baseline ECG (n=47)	ECG immediately after TAVI (n = 47)	p
AF, n (%)	9 (19.0)	13 (27.6)	ns
LBBB, n (%)	6 (12.8)	27 (57.4)	<0.0001
RBBB, n (%)	5 (10.6)	5 (10.6)	ns
LAH, n (%)	6 (12.8)	6 (12.8)	ns
1st-degree AVB, n (%)	10 (21.0)	11 (23.4)	ns
CAVB, n (%)	0 (0.0)	11 (23.4)	<0.0005

ECG: Electrocardiogram. TAVI: Transcatheter aortic valve implantation. AF: Atrial fibrillation. LBBB: Left bundle-branch block. RBBB: Right bundle-branch block. LAH: Left anterior hemiblock. 1st-degree AVB: First-degree atrioventricular block. CAVB: Complete atrioventricular block. ns: Non significant.

Predictors of complete atrioventricularblock

Univariate analysis identified body mass index (p = 0.017), RBBB (p = 0.008) and LAH (p = 0.002) before implantation to be associated with the development of CAVB. However, after performing multiple logistic regression analysis, only LAH (OR 13.1; 95% CI 1.03-166) and RBBB (OR 9.2; 95% CI 1.01-140) in the baseline ECG showed an independent association.

DISCUSSION

In our study, the incidence of electrical disorders after transcatheter implantation of the self-expandable CoreValve® was 63%; the most frequent conduction

Patient	Age	Gender	Baseline rhythm	Previous conduction abnormality	Indication of PM	Type of PM	VP% at 1 month
4	82	M	SR	RBBB, LAH	CAVB	DDD	100
7	83	M	AF	LBBB	CAVB	DDD	-
15	71	F	AF	None	AF + LBBB	VVI	<10
18	86	M	SR	1st-degree AVB, LAH	CAVB	DDD	72
24	73	M	SR	RBBB, LAH	CAVB	DDD	100
25	81	M	AF	1st-degree AVB, IRBBB, LAH	CAVB	VVI	53
29	90	F	SR	RBBB, LAH	CAVB	DDD	90
31	69	M	SR	None	CAVB	DDD	-
37	85	F	SR	1st-degree AVB	CAVB		96
41	66	M	AF	None	CAVB		96
49	82	F	SR	RBBB	CAVB		99
51	84	F	SR	None	Transient CAVB		3

PM: Pacemaker. VP%: Ventricular pacing percentage. AF: Atrial fibrillation. SR: Sinus rhythm. RBBB: Right bundle-branch block. LAH: Left anterior hemiblock. LBBB: Left bundle-branch block. 1st-degree AVB: First degree atrioventricular block. IRBBB: Incomplete right bundle-branch block. DDD: Dual chamber pacing and sensing pacemaker. VVI: Ventricular pacing and sensing pacemaker.

Table 3. Clinical and electrophysiological characteristics of the 12 patients who required permanent pacemaker during hospitalization

abnormality was LBBB, followed by CAVB. No other conduction abnormality occurred immediately after the procedure and during follow up (4 patients presented de novo atrial fibrillation after implantation, but the difference between atrial fibrillation before and after implantation was not significant). Left bundle-branch block reverted in 1 out of 5 patients within 24 hours. During long-term follow-up, only one patient with LBBB required PPM as decided by the primary care physician.

Complete atrioventricular block occurred during the procedure in all cases, except for one patient in whom LBBB developed 24 hours after TAVI. In only one patient CAVB reverted in the catheterization laboratory and then presented LBBB; in the rest of the patients, CABV persisted until discharge. Average ventricular pacing one month after discharge was > 50%, demonstrating that CAVB is generally irreversible. The only case in which ventricular pacing was < 50% belonged to the patient who presented heart block reversion in the catheterization laboratory after PPM.

The rate of CAVB and LBBB observed in our study was lower than the one reported by previous publications using CoreValve®. (1, 3, 4) This might be explained by the technique used for implantation. At our center, we performed balloon aortic valvuloplasty (predilation) in the catheterization laboratory before TAVI in only 9 of the 47 patients, as this technique is now seldom used mainly due to its association with the development of conduction system complications. Presence of LAH or RBBB in the baseline ECG was identified as an independent predictor of CAVB and of PPM requirement after TAVI. These findings are in agreement with those reported by previous studies. (3)

The development of electrical disorders significantly increased the incidence of HF immediately after implantation and of hospital stay, but was not associated with higher long-term mortality or new all-cause hospitalization after a median follow-up of 203 days. Of importance, the development of HF after implantation seems to be related only with PPM but not with aortic regurgitation due to periprosthetic leakage or with the severity of mitral regurgitation, as the incidence of these variables was similar in both groups. Previous studies showed that the incidence of stroke was 5% with the Sapiens valve (10) and 3% to 4% with the CoreValve®. (1) In this study, only one among the 47 patients presented stoke immediately after the procedure and 2 (4.2%) during follow-up. All these patients belonged to the new CA group; however, no conclusion can be drawn due to the low number of events.

Up to the moment of performing this study (from March 2009 to February 2012), the indication for PPM was based on the preference of the interventional cardiologist due to the scarcity of information about the outcome of electrical disorders after aortic CoreValve® implantation. We consider that our study provides valuable information as, based on the results described, CAVB would be the only conduction disorder with indication of PPM before discharge. This can be implanted in the catheterization laboratory if CAVB develops immediately after the procedure as the conduction disorder is apparently irreversible.

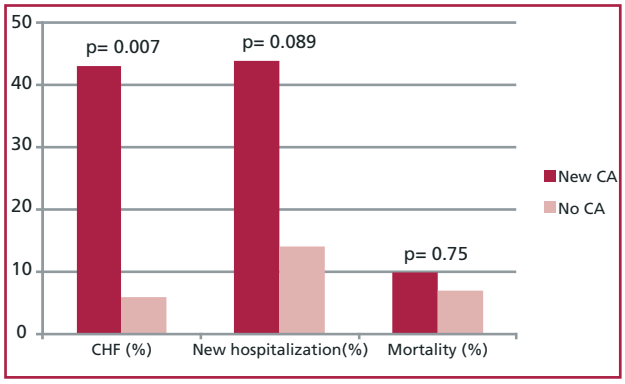

Fig. 2. Incidence of events in the two groups analyzed. New CA: New conduction abnormalities. No CA: No conduction abnormalities. * Congestive heart failure (CHF) during hospitalization. ** Long-term mortality.

Study limitations

The small number of patients is the main limitation of our study, although this is the largest case series published in our country up to the present. It is essential to enlarge the sample by including new cases, and if possible, perform a multicenter trial that would add valuable information. Finally, the short follow-up time could have influenced the absence of differences between the two groups analyzed.

CONCLUSIONS

Conduction abnormalities are common complications after TAVI, with higher incidence of HF during hospitalization and longer hospital stay, and no significant effect on the development of long-term events. A permanent pacemaker should be implanted immediately after CAVB develops as the conduction disorder is generally irreversible.

RESUMEN

Complicaciones eléctricas posimplante de válvula aórtica percutáneo: evolución clínica y eléctrica

Introducción

El implante valvular aórtico percutáneo es una opción terapéutica cada vez más utilizada en pacientes en los que se descarta la cirugía. A pesar de que las alteraciones agudas de la conducción son una de las complicaciones más frecuentes, su significado clínico y electrocardiográfico no es del todo claro.

Objetivos

Determinar las implicaciones pronósticas del desarrollo de alteraciones agudas de la conducción luego del implante valvular aórtico percutáneo.

Resultados

Entre marzo de 2009 y febrero de 2012 se incluyeron para el análisis 47 pacientes; de ellos, 30 (63%) presentaron alteraciones agudas de la conducción: 19 pacientes solo bloqueo completo de rama izquierda (BCRI), 9 pacientes solo bloqueo auriculoventricular completo (BAVC) y 2 pacientes presentaron ambos trastornos, los que totalizaron 21 BCRI y 11 BAVC. A 12 (25%) se les implantó un marcapasos definitivo previo al alta: en 11 por BAVC y en 1 por BCRI agudo más fibrilación auricular. En solo un paciente el BAVC revirtió en hemodinamia. Los pacientes que persistieron con BAVC posintervención presentaron una media de estimulación ventricular en la intervalometría al mes del 90%, mientras que en el paciente con BAVC que revirtió en hemodinamia fue de solo el 3% y en el paciente con BCRI más fibrilación auricular fue <10%.

La incidencia de insuficiencia cardíaca en el posoperatorio fue mayor en los pacientes con alteraciones agudas de la conducción (p= 0,007), al igual que la estadía hospitalaria (p=0,045). En el seguimiento no hubo diferencias en la tasa de reinternación ni en la mortalidad.

Conclusiones

En el presente estudio el desarrollo de alteraciones agudas de la conducción mostró un aumento en la incidencia de insuficiencia cardíaca y en los días de internación, sin incremento en la tasa de otros eventos mayores. La colocación de un marcapasos definitivo luego del BAVC podría realizarse en forma inmediata, ya que el trastorno generalmente es irreversible.

Palabras clave > Estenosis de la válvula aórtica - Sistema de conducción cardíaco - Bloqueo atrioventricular - Implantación de prótesis de válvulas cardíacas

Conflicts of interest

None declared.

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