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Predictors of pacemaker dependency in patients implanted with a pacemaker after Transaortic valve replacement

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ABSTRACT

Introduction and objectives: The development of complete AV block and the need for pacemaker implantation (PM) is the most frequent complication after Transaortic valve replacement (TAVR). In other PM clinical contexts, a higher percentage of ventricular stimulation has been associated with worse prognosis. The objective was to study the existence of predictors of PM dependence.
Methods: We identified 96 consecutive patients who had received a PM post-TAVR (all Core-Valve). We retrospectively analyzed this cohort with the aim of identifying predictors of a high and very high percentage of ventricular pacing (VP), PM dependency and survival.
Results: The mean age was 82.3 years, with a mean logistic EuroSCORE of 17.1, 53% were women and 12% of patients had LVEF < 50%. The indication was complete AV block in 40.5%, and LBBB in 59.5%. Mean survival was 62.7 months, IQR [54.4–71]. The only independent predictor of mortality was the pre-TAVR logistic Euro-SCORE (RR = 1,026, p = 0.033), but not LVEF < 50%, VP > 50%, VP > 85% or PM dependence. In 73 patients PM rhythm was documented at the end of follow-up. Of these, 14 (19.2%) were considered dependent, and 37 (50.7%) presented VP > 50%. The post-TAVR complete AV block recovery rate was 67.8%. In multivariate analysis, female sex (HR = 5.6, p = 0.005), and indication of complete AV block vs. LBBB (HR = 15.7, p = 0.017) were independently associated with PM dependency.
Conclusions: Female sex and indication due to complete AV block were independent predictors of PM dependency during follow up. In our series of patients with mostly normal LVEF, a high percentage of stimulation does not influence prognosis.

1. Introduction

The treatment of Severe Aortic Stenosis (AS) has evolved significantly in recent years. The breakthrough of percutaneous valvular replacement techniques, such as transcatheter aortic valve replacement (TAVR) has significantly increased the number of patients receiving invasive management, compounded by an aging population and thus, by an increase in the prevalence of AS.

Proximity between the aortic valve and the atrioventricular (AV) conduction system [1] explains the frequent appearance f of AV conduction disorders after a TAVR procedure. The incidence of new left bundle branch block (LBBB) and new complete AV block may reach 57% [2] and 20% [3], respectively. As a consequence of the high incidence of new AV conduction disorders [1], the need for pacemaker (PM) implantation is the most frequent complication after TAVR (2–51% according to studies, 28% mean for Core-Valve valves and 6% average for SAPIEN valves) [4]. The main indication is the presence of high-grade AV block followed by severe bradycardia [5]. However, the appearance of new-onset left bundle branch block is an accepted PM indication for some patients [6].

Several predictors of PM implantation after TAVR implantation have been identified: the presence at baseline of complete right bundle branch block (RBBB) [7], calcium in the non-coronary cusp [8], the depth of TAVR implantation [8], male sex [4],

Abbreviations: AS, Aortic Stenosis; TAVR, transaortic valve replacement; AV, atrioventricular; LBBB, left bundle branch block; RBBB, right bundle branch block; PM, Pacemaker; LVEF, Left Ventricular Ejection Fraction.

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intraprocedural AV block [4], prosthesis to LV outflow tract diameter ratio [7] and the LV end-diastolic diameter [7].

PM implantation in this context is performed on many occasions even on the day of TAVR implantation [9], with good results. Although often AV conduction disturbances persist after a year of implantation [10], they do not always appear to be definitive [11], suggesting a certain degree of reversibility of post-TAVR AV conduction disorders.

In addition, in other clinical contexts, a higher percentage of right ventricular stimulation has been associated to worse prognosis. Right ventricular pacing-induced dyssinchrony [12] has been linked to incident atrial fibrillation and heart failure, as well as a lower survival [13–15].

There is very little data on predictors of PM dependence and degree of stimulation, but rates of pacemaker-dependency (defined as asystole at interrogation, persistent complete AV block or > 0% stimulation) rates as low as 33% [16] have been described.

1.1. Objective

The objective of this study is the evaluation of the impact of pacemaker dependency and identification of predictors of pacemaker-dependency following post-TAVR PM implantation.

2. Methods

This is an observational, single center and retrospective study. End-points with potential association with the degree of PM-dependence of PM were evaluated.

2.1. Patients

All patients undergoing a TAVR procedure for severe symptomatic AS between February 2009 and February 2016 were reviewed. The following data were collected for each patient: Indication, Age, Sex, Left Ventricular Ejection Fraction (LVEF), Logistic EuroScore, prior PM implantation, presence of AF, baseline complete left or right bundle branch block, left ventricular outflow tract (LVOT, by echocardiography), interventricular septum thickness (by echocardiography), beta-blocker treatment and renal function.

2.2. Procedures

All patients were admitted to a dedicated acute cardiac care unit, with continuous monitoring, after each TAVR procedure. The indication for a PM was established by the referring physician, after consultation with the cardiac electrophysiology department, according to published international guideline recommendations [17].

The presence of a new LBBB, a complete AV block in the first 24 h and after a week of TAVR implantation was collected for the analysis. The time from the TAVR procedure to PM implantation, as well as pacing mode (with atrial sensing (DDD, DDDR or VDD) or without atrial sensing (VVI or VVIR)) were also collected. PM were programmed according to published international guidelines [17].

2.3. Follow-up

Follow-up was performed at least every 6 months. The following data were collected: PM dependence at one year and at the end of follow-up, vital status at the end of follow-up, degree of stimulation (no stimulation, low stimulation or high (predominant or exclusive) stimulation), presence of stimulation >50%, and reversion of complete AV block after one year. A patient was defined as PM dependent if, after transiently programming the device in VVI mode at 40 bpm, he remained paced.

2.4. Study end-Points

The main end-point was PM dependency at the end of follow-up. As secondary end-point, survival at the end of follow-up, the degree of PM stimulation, and stimulation >85% were evaluated.

2.5. Statistical analysis

Statistical analysis was performed with SPSS 18.0. Categorical variables are expressed as a percentage. Continuous variables are expressed as mean ± standard deviation. Comparisons between categorical variables were performed using the Chi-square test (Fischer test when appropriate). Comparison between continuous variables was performed using the Student *t* test. Survival analysis was performed using the Kaplan-Meier method. The log-rank test was used for survival comparisons. Multivariate analysis using Cox regression analysis was performed in order to identify independent predictors of PM-dependency and survival. A p value < 0.05 was considered significant.

3. Results

During the study period, 96 patients with a TAVR followed by PM implantation were included in the study (Fig. 2). In all cases, a Core-Valve® (Medtronic) prosthesis was implanted. The mean age was 82.3 years, with a mean logistic EuroSCORE of 17.1, and 53% of patients were women. The remaining baseline characteristics are shown in Table 1.

All patients underwent successful PM implantation. An atrial sensing pacing mode with either one (VDD) or 2 (DDD/DDDR) leads was chosen in 31% of patients, with the remaining 69% receiving a single chamber VVI/VVIR device. PM implantation was indicated due to new AV block in 40.5% and new LBBB in 59.5%. The time from the TAVR procedure to PM implantation was longer in those patients with indication due to new LBBB vs new cAVB (2.93 ± 2.2 vs 1.53 ± 1.4 days, p = 0.002). Of the 96 patients, survival data were available in 97%, and complete PM

Table 1
Baseline characteristics.

N = 96	mean ± SD or %
PM indication	
cAVB	40.5%59.5%
LBBB	
Female sex	53%
Age (years)	82.3 ± 6.3
Weight (Kg)	71.2 ± 12.2
Height (cm)	159.3 ± 8.2
BMI (Kg/m2)	44.5 ± 7.2
Charlson C.I.	4.1 ± 2.9
LVEF	58.5 ± 10.2
Logistic EuroSCORE	17.1 ± 12.8
Patients with previous PM	2.1%
Baseline LBBB	7.6%
Baseline RBBB	16.7%
IV Septum Thickness (mm)	12.7 ± 2.5
Atrial Fibrillation	17%
Creatinine Clearance (mL/min)	60.7 ± 27.8
Beta-blockers treatment	33%

PM: Pacemaker, IV: interventricular, LBBB: Left Bundle Branch Block, RBBB: Right Bundle Branch Block, LVEF: Left Ventricular Ejection Fraction, cAVB: complete atrioventricular block, mm: millimeters. C.I.: comorbidity index, BMI: Body Mass Index.

follow-up data in 76% of the patients. The mean follow-up time was 24.4 months (median: 20, IQR: [8–43]). Survival after 1 year and at the end of follow-up was 92.5% and 74.4%, respectively. The mean survival time was 62.7 months (IQR: [54.4–71], Fig. 1).

3.1. PM dependency

Of the 73 patients in whom device interrogation was performed at the end of follow up, 14 (19.2%) were considered dependent, and 37 (50.7%) presented a percentage of stimulation above 50%.

Patients with PM due to complete AV block showed more frequently PM dependency at the last evaluation (33.3%) than those patient with PM due to LBBB (10%, p = 0.016).

A total of 28 (38.3%) presented complete AV block in the first 24 h post-TAVR. Of these, in 20 (71.4%) the PM was implanted in the first 24 h after the procedure. As of their last available device interrogation, 19 (67.8%) were not dependent and 12 (42.9%) presented a percentage of stimulation<50%. Only 11 (39.3%) showed VP ≅ 100%.

After 7 days, 29 patients showed complete AV block. Of the 28 with complete AV block at 24 h, 1 (3.6%) experienced reversion before 1 week, but was nonetheless PM dependent at the end of follow-up. 2 of 41 (4.1%) without complete AV Block after 24 h, developed complete AV block during the next 6 days.

After 1 year, 17 (60.7%) of the 28 patients who had complete AV block < 24 h post-TAVR were not dependent (p = 0.008); and 12 (42.9%) showed a degree of PM stimulation > 50% (p = 0.291). Among patients who did not develop complete AV block during the first 24 h (n = 45), 5 (12.5%) were PM dependent at their last follow-up.

3.2. Determinants of PM dependence

After 1 year of follow-up, 51% of patients showed either no pacing or a low pacing percentage. At univariate analysis, female sex, indication due to complete AV block vs LBBB, a complete AV block < 24 h, a new LBBB post-TAVI, time from TAVR to PM implantation, and PM implantation > 24 h post-TAVR were associated with PM dependency at last follow-up (Table 2).

After a multivariate analysis (Table 3), only female sex (HR = 5.6, p = 0.005), and indication of PM due to complete AV block Vs LBBB (HR = 15.7, p = 0.017) were independently associated with PM dependency. All 19 male patients with PM implanted due to LBBB showed no PM dependency at last evaluation.

None of the variables studied predicted a degree of stimulation > 50% in the last evaluation, although indication of PM due to complete AV block Vs LBBB almost reached statistical significance (HR = 1.856 [CI-95: 0.941, 3.661], p = 0.074).

3.3. Determinants of survival

A higher degree of pacing was not predictive of reduced survival rates (log-rank = 0.61), whether defined as no pacing vs. any pacing (log-rank = 0.281), as VP < 50% vs. VP > 50% (log-rank = 0.684), or > 85% stimulation (log-rank = 0.353). Furthermore PM dependency status did not significantly impact survival (log-rank = 0.383). After multivariate analysis, only the Logistic EuroSCORE was significantly associated with mortality at the end of follow-up (per 1 unit, HR = 1026, p = 0.033).

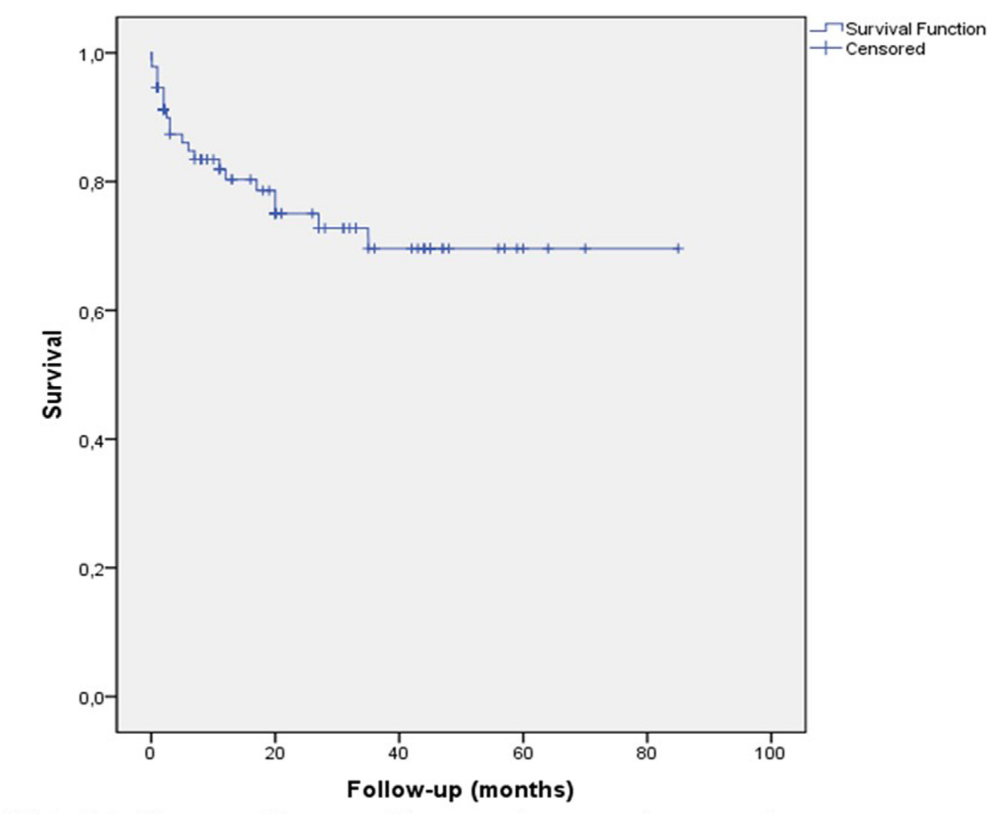

Fig. 1. Survival Curve. Abscissa axis: follow-up in months. Ordinate axis: proportion of patients alive.

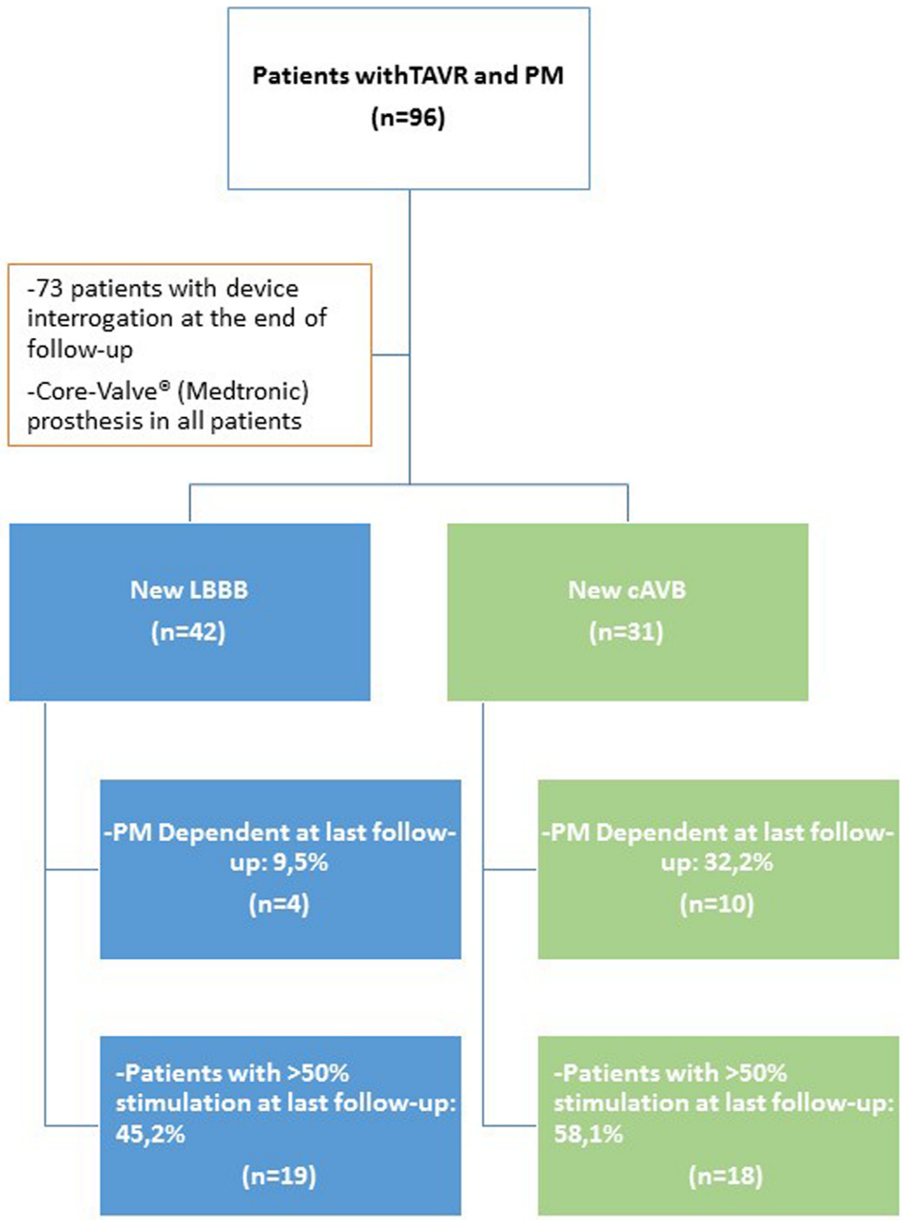

Fig. 2. Consort Diagram. TAVR: Transaortic valve replacement, PM: Pacemaker, LBBB: Left Bundle Branch Block, cAVB: complete atrioventricular block.

3.4. Very high PM stimulation

14 patients (18.9%) showed very high degree of stimulation at last follow-up. In a univariate analysis, only a new LBBB after TAVR (HR = 0.321 [CI-95: 0.119, 0.861], p = 0.024), and PM due to complete AV block Vs LBBB (HR = 2.682 [CI-95: 1.01, 7.118], p = 0.048), were predictors of PM stimulation > 85%.

4. Discussion

In our retrospective experience, female sex and indication of complete AV block Vs LBBB were independently associated with pacemaker mid-term dependency.

4.1. Survival

In this cohort of elderly patients undergoing TAVR and PM implantation, mostly with LVEF > 50% and adequate PM programming, survival at one year was 92.5% (74.4% at last patient follow-up). Such high survival rates have also been described in other published series [18,19]. The only predictor of mortality in our series was baseline logistic Euro-SCORE, which has also been the case in other studies [20].

The need for PM implantation after TAVR has been associated with poor outcomes [21,7,22], but there are contradictory data regarding excess mortality[21,23]. Conceivably, significant RV stimulation (>40%) [13] could negatively influence prognosis [24]. However, our data suggest that the degree of ventricular stimulation does not impact mid-term survival, even those with > 85% stimulation, as showed in other series with LVEF > 50% [25,26], and contrary to series of patients with reduced LVEF [27,28,29]. We consider that the low rate of patients with LV dysfunction (12.1%) in our series explains the lack of impact of a significant RV stimulation in the prognosis. However, the population with preserved LVEF is adequately represented in our series, and this supports that a high percentage of stimulation does not affect the prognosis in these patients.

Table 2
Determinants of PM dependency. Univariate analysis.

	HR	95%-CI	P value
PM due to cAVB Vs. LBBB	4.425	1.369;14.302	**0.013**
Female sex	10.333	1.269;84.146	**0.029**
Age (for 1 year)	1.025	0.922;1.139	0.65
LVEF (per 1%)	1.036	0.98;1.095	0.214
LVEF < 50%	0.408	0.05;3.337	0.403
IV septum (per 1 mm)	0.983	0.768;1.258	0.889
Logistic EuroSCORE (per 1 unit)	1.014	0.959;1.073	0.621
Cr Clearance(per 1 mL/min)	1.001	0.981;1.021	0.949
Beta-blockers treatment	0.653	0.141;3.025	0.586
Baseline LBBB	1.045	0.745;2.14	0.801
Baseline RBBB	1.205	0.323;4.493	0.782
Atrial Fibrillation	2.524	0.738;8.631	0.14
Complete AV block < 24 h	3.353	1.11;10.127	**0.032**
New LBBB post-TAVI	0.193	0.059;0.635	**0.007**
PM without atrial sense	0.446	0.155;1.283	0.134
TAVR-PM Time (for 1 day)	0.458	0.217;0.964	**0.04**
TAVR-PM Time > 1 day	0.118	0.015;0.924	**0.042**

HR: Hazard Ratio, CI: Confidence Interval, PM: Pacemaker, IV: interventricular, LBBB: Left Bundle Branch Block, RBBB: Right Bundle Branch Block, LVEF: Left Ventricular Ejection Fraction. CR: Creatinine.

Table 3
Determinants of PM dependency. Multivariate analysis.

	HR	95%-CI	P value
Female sex	15.772	1.622;153.322	**0.017**
PM due to cAVB Vs. LBBB	5.634	1.667;19.041	**0.005**
TAVR-PM Time (for 1 day)	0.577	0.248; 1.344	n.s.
TAVR-PM Time > 1 day	0.265	0.031; 2.235	n.s.

HR: Hazard Ratio, CI: Confidence Interval, PM: Pacemaker.

4.2. Recovery of AV conduction

Recovery of AV conduction after complete AV block has been described, and is generally related to the cause of AV block [17]. Post-TAVR AV conduction disturbances can have variable clinical course and thus the indication of a pacemaker should be tailored to each specific patient [17].

In the case of PM implantation after aortic valve replacement surgery, guideline recommendations are ambiguous [17], based on limited series [30] with high dependency rates (59.3%), that also showed that AV block within the first 24 h was a strong predictor of dependency [31].

PM Dependency is not a clearly defined situation [32]. Of the patients in our series, only 19.2% were PM-dependent at last follow-up, and only half (50.7%) had a percentage of stimulation less than 50%. Even among those with evidence of complete AV block in the first 24 h (n = 28), 67.8% were not dependent, 42.9% had a stimulation percentage of less than 50%, and only 39.3% presented continuous pacing. If we compare the percentage of patients with PM dependency in our series with those published by Glikson et al (TAVR: 18.9 vs. Surgery: 59.3%, OR = 0.319 [CI-95% = 0.19–0.53], $p < 0.001$), in spate of methodological limitations, our data would suggest that recovery of AV conduction is more likely after TAVR than after surgical aortic valve replacement.

Our dependency and stimualtion rates are similar to most published Core-Valve series [21,33], yet lower than others [34]. The type of prosthesis is related to the incidence of post-TAVR AV block [4]. Core-Valve prosthesis, such as those implanted in our series, have been linked to a higher incidence of new complete AV block and need for PM implantation, compared to Sapiens prosthesis [4]. In the study by Naveh et al. [34], of 38 patients with post-TAVR PM, 26 (68.4%) were considered PM-dependent. Both types of valves were used in this study (the percentage of each type is not detailed), and this could explain the lower recovery rate of AV block found in the study. Therefore, the rate of AV conduction recovery could be different in Sapiens valves, and thus our findings may not be applicable to patients implanted with other prostheses.

4.3. Predictors of PM dependency

The best predictor of PM dependency was an indication due to complete AV block vs LBBB. In our series, AV block was observed mostly in the first 24 h, and this led to an early PM implantation. A late (>24 h) PM implantation predicted a low PM dependency rate, likely because most "late" PM implants were performed in patients exhibiting LBBB, in whom the decision to implant a PM was not made as urgently as with cAVB, probably due to a perceived potential reversibility of AV conduction disturbance. Probably, the appearance of a new cAVB reflects a more severe and durable damage in the conduction system than in the case of a new LBBB. Female sex was also identified as an independent predictor, specifically independent of the LVOT diameter. A cause for this finding is not evident and deserves an in-depth study. Although these predictors should be confirmed in larger series, our findings could be helpful in order to select the device type and programing modes in those patients receiving a PM after TAVR implantation.

The baseline PR interval, presence of RBBB, or the interventricular septum thickness have been associated with PM dependency at follow-up in some series [34,35] but, in our study, neither septal thickness nor baseline RBBB were predictive of dependency.

LBBB after TAVR was predictive of not presenting a very high degree of PM stimulation.

4.4. Strategies and recommendations

The need for a PM should be carefully evaluated after TAVR [1]. Early and severe damage (evidenced by a new complete AV block) seems to be the only clear clinical scenario in which early PM implantation is warranted. When damage to the conduction system is not as early (<24 h) or is not as severe (i.e., new LBBB showing a QRS complex < 160 ms, as opposed to complete AV block), the decision to implant a PM should be delayed, especially in male patients, considering the high rate of reversibility of the damage at the level of the left branch of the His bundle, especially with SAPIENS valves. In those patients, the use of an implantable cardiac monitoring device may be appropriate [6].

In those patients in whom PM implantation is considered indicated on the basis of findings other than early (<24 h) complete AV block, we would recommend implantation of a single-chamber PM in VVI mode and a lower frequency limit of 40 bpm [27], especially in male patients, in order to minimize ventricular stimulation and to avoid complications associated with a second lead. However, some patients may benefit from an additional atrial lead, and the decision should be individualized. Additionally, PM programming has an impact on clinical endpoints [24,13,27,36,37,38], mainly minimizing ventricular stimulation. In those patients in whom a PM with atrial sensing is implanted, programming a long AV interval (220–300 ms), preferably using one of the available dynamic/adaptive algorithms [24], should be considered. Finally, it would be desirable to agree on a definition of the concept of pacemaker dependence.

4.5. Limitations

The main limitation of the study is its retrospective nature, which limits the availability of some clinical variables and follow-up data. The decision to implant a PM was made at the discretion of the attending physicians, although in all cases a standard criterion was followed, according to published clinical practice guidelines. Another limitation is that only Core-Valve prostheses were implanted in our series. Finally, despite being a single-center study, homogeneous accepted guideline-based criteria regarding PM indication were employed by all involved physicians.

5. Conclusions

- Female sex and PM implantation due to complete AV block Vs LBBB were independently associated with pacemaker dependency.
- Post-TAVR complete AV-block recovery rate (67.8%) with Core-Valve prosthesis is higher than the rate published after aortic valve surgery, and probably higher than Sapiens prosthesis.
- In this series of patients with mostly normal LVEF, a high percentage of stimulation was not associated with worse prognosis.

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