

Early Predictors of Permanent Pacemaker Implantation in Sutureless Aortic Valve Replacement with Perceval Bioprosthesis: A Conduction Disorders Analysis

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Abstract

Context: The innovative Perceval bioprosthesis (Sorin Group S.p.A., Saluggia, Italy) is a surgical sutureless self-expanding valve without a sewing ring. It has recently been introduced as an alternative to conventional surgery to minimize the operative risk in elderly patients. Advantages consist of both shortening the cardiopulmonary bypass time and enhancing the minimally invasive approach.

Objective: Our study has the purpose to analyze the postoperative conduction disorders and identify the associated risk factors in patients undergoing a sutureless aortic valve replacement with the Perceval bioprosthesis.

Methods: This is an observational study including 56 patients who underwent a sutureless aortic valve replacement. The conduction disorders were identified by reviewing the patients' electrocardiograms at baseline, postoperatively, before hospital discharge and at follow-up.

Results: At baseline, five patients (8.9%) presented with pre-operative conduction disorders: two patients (3.6%) had left bundle branch block, one had right (1.8%), one right and left anterior hemiblock, while another showed a Mobitz 1 second-degree atrio-ventricular block. No one had a pre-existing permanent pacemaker. Six patients (10.7%) needed a pacemaker implantation: one for junctional rhythm with an underlying atrial fibrillation, one for second-degree and four for third-degree atrio-ventricular block respectively. Among the 6 patients who implanted a pacemaker, four patients had preoperative conduction disorders ($p < 0.001$) and one patient had anatomical risk factors (small aortic annulus and an off-label concomitant mitral valve replacement).

Conclusions: The presence of preoperative conduction disorders is a statistically significant risk factor for permanent pacemaker implantation following a sutureless aortic valve replacement with the Perceval bioprosthesis.

Keywords: Aortic; Valve; Sutureless; Pacemaker

Abbreviations

AV: Atrio-Ventricular

AVR: Aortic Valve Replacement

LAHB: Left Anterior Hemiblock

LBBB: Left Bundle Branch Block

LPHB: Left Posterior Hemiblock

LVOT: Left Ventricle Outflow Tract

PM: Pacemaker

PPM: Permanent Pacemaker

RBBB: Right Bundle Branch Block

SU-AVR: Sutureless Aortic Valve Replacement

TAVI: Transcatheter Aortic Valve Implantation

THV: Transcatheter Heart Valves

Introduction

Sutureless aortic valve replacement (SU-AVR) with the Perceval bioprosthesis (**Figure 1**) has been developed as an alternative to conventional surgery to minimize the operative risk in elderly patients, shortening the cardiopulmonary bypass time and enhancing the minimally invasive approach [1]. During the deployment of this sutureless prosthesis, the inflation at 4 atm of a balloon catheter-mounted is recommended. As for the transcatheter heart valves (THV), the

implantation procedure could lead to postoperative conduction disorders. The aim of our study is to analyze the postoperative conduction disorders and identify the associated risk factors in patients undergoing SU-AVR with the Perceval bioprosthesis.

Methodology

In this observational study, 56 patients with severe aortic stenosis who underwent the implantation of the Perceval sutureless bioprosthesis at the San Raffaele University Hospital (Milan, Italy) from January 2014 to November 2016 were analyzed. The conduction disorders were identified by reviewing the patients' electrocardiograms at baseline, postoperatively, before hospital discharge and at follow-up. All tracings were analyzed by an independent investigator and an expert cardiac surgeon to record the presence of first-, second- or third-degree AV block, right bundle branch block (RBBB), left bundle branch block (LBBB), left anterior hemiblock (LAHB), left posterior hemiblock (LPHB) and arrhythmias. An experienced cardiologist gave indications whether to implant a permanent pacemaker after surgery. In our center, we wait at least 7-10 days for PM implantation. However, the decision relied on several factors and it is a well-known fact that it varies among centers, depending on the different aggressive/early treatment approach in high risk patients with atrio-ventricular (AV) blocks (**Figure 1**).

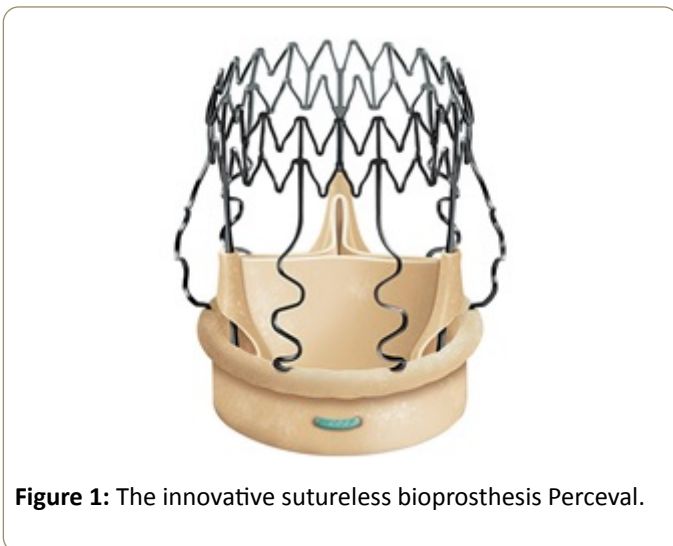


Figure 1: The innovative sutureless bioprosthesis Perceval.

Statistics

For the data analysis the IBM SPSS Statistic Version 22 software was used (Armonk, NY, USA). Continuous variables are reported as mean \pm SD or in median and interquartile range [Q1-Q3] considering the normality of the distribution, while categorical variables are expressed by frequency (%). For continuous variables, the normality of distribution was assessed with the Kolmogorov-Smirnov test. Differences between groups are calculated using Student's T test or Mann-

Whitney's U test for normal and skewed variables respectively, while Fisher's exact test was used for categorical variables. A p-value $<0,05$ was considered to indicate statistical significance.

Results

All patients (n = 56) who underwent a SU-AVR with the Perceval bioprosthesis were included. Preoperative characteristics are shown in **Table 1**. The mean \pm SD age of the patients was 76.9 ± 4.8 y.o., while the median Logistic EuroSCORE I was 7.7% [5.9-9.5%] and STS mortality score was 2.8% [1.9-3.7%]. At baseline, five patients (8.9%) presented with pre-operative conduction disorders: two patients (3, 6%) had LBBB, one had RBBB (1.8%), one RBBB+LAHB, while another showed a Mobitz 1 second-degree atrio-ventricular block. All the patients showed a preoperative sinus rhythm, except 3 cases of chronic atrial fibrillation. No one had a pre-existing Permanent PaceMaker (PPM).

Table 1: Preoperative patients characteristics (COPD=Chronic Obstructive Pulmonary Disease, NYHA=New York Heart Association, STS=Society of Thoracic Surgeon).

Study population	n = 56
Age (years)	76.9 \pm 4.8
Male pts	24 (42.9%)
Logistic EuroSCORE I	7.7% [5.9-9.5%]
STS mortality score	2.8% [1.9-3.7%]
BMI	27.7 \pm 4.7
Diabetes	13 (23.2%)
COPD	13 (23.2%)
NYHA III-IV	16 (28.7%)

One patient with permanent AF received a concomitant radiofrequency ablation. Six patients (10.7%) needed a PPM implantation: one for junctional rhythm with an underlying atrial fibrillation, one for second-degree and four for third-degree AV block respectively. Among the 6 patients who implanted a PPM, four patients had preoperative conduction disorders (type 1 II AV block, LBBB, RBBB and RBBB+LAHB respectively; $p<0.001$) and one patient had anatomical risk factors (small aortic annulus and an off-label concomitant mitral valve replacement).

The PM implantation procedure was performed 7-40 days after surgery (median: 18 days). Of the 6 patients requiring a PPM implantation, an arithmologic follow-up was available in 4 patients (66.7%), while one subject with PPM died after 9 months from surgery for senile marasmus.

The median follow-up duration was 5.9 months (2.9-13.7). Of the 4 patients, 3 (75%) were pacemaker dependent and 1 (25%) was nonpacemaker dependent (**Table 2**).

Table 2: PPM rate in SU-AVRs with Perceval in literature.

Author	Center	No. of pts	PPM (%)
Flameng et al. [3]	Leuven, Belgium	32	3.10%
Folliguet et al. [4]	Paris, France - Hannover, Germany	208	7.70%
Mazine et al. [5]	Canadian multicenter study	215	17%
Van Boxtel et al. [6]	Eindhoven, Germany	30	13.30%
Konig et al. [7]	Jena, Germany	14	28.50%
Vogt et al. [8]	Nuremberg - Münster, Germany	258	10.50%
Shresta et al. [1]	European multicenter study	731	7.40%
Belluschi et al. 2016	Milan, Italy	56	10.70%

Discussion

The identification of risk factors associated with a PPM implantation after aortic valve surgery is still an open issue, even more in the setting of sutureless valves [2].

The exact mechanism of atrioventricular conduction disorders in SU-AVRs with Perceval remains to be clearly elucidated. Some hypothesis include: the decalcification process, the large annular sealing coil of the inflow ring, the balloon inflation at 4 atm (3040 mmHg) and the high profile of the nitinol stent. The patients who mostly benefit by using a sutureless procedure are at intermediate/high surgical risk, with higher rates of surgical complications. However, our idea is that the surgeon's sutureless experience plays a pivotal role. New recommendations for implant by LivaNova, to avoid any interference with the conduction system, consist of both the undersizing approach and the evaluation of the guiding sutures depth. The four Perceval dedicated sizers (size S for annuli 19-21 mm; M for 21-23 mm; L for 23-25 mm; XL for 25-27 mm; **Figure 2**) are used to assess the corresponding prosthesis size: in case of doubt between two sizes the best choice is the smaller size. This precaution could reduce the development of paravalvular leaks, intra-aortic regurgitation, high gradients and postoperative PM need. Furthermore, the surgical procedure required the application of three 4-0 Prolene guiding sutures. New recommendations suggest their insertion at 1-2 mm below the nadir of each aortic cusps into the LVOT (previous manufacturer's guidelines reported 3-4 mm). In addition, a normal bite of the stitches has to be considered to reduce a possible trauma of the His bundle.

It seems to be interesting to investigate the percentage of patients who are still pacemaker dependent at follow-up and whether rhythm disorders recover over time. In our population, 75% of the PM receivers were pacemaker dependent at the available arithmologic follow-up.

The majority of PM was implanted after hospital discharge: the median interval of the arrhythmological procedure from surgery was 18 days (5 subjects received a PM>10 days from operation), while the median postoperative hospital stay was 6 days.

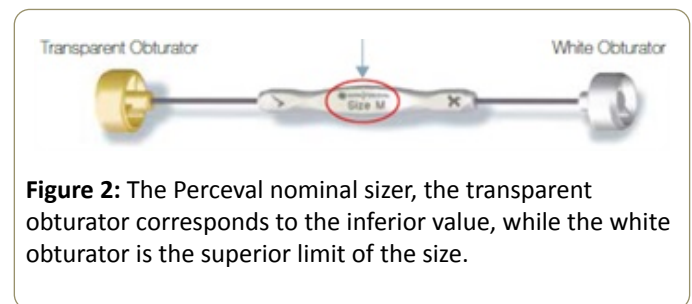


Figure 2: The Perceval nominal sizer, the transparent obturator corresponds to the inferior value, while the white obturator is the superior limit of the size.

Our results are quite similar to those provided by other groups using Perceval, even if there is a great variability. The Belgian group of Flameng first reported in 2011 a very low PPM rate of 3.3% [3], while the beginning experience of 208 patients treated with Perceval in France and Germany showed a rate of 7.7% [4]. In the Canadian multicenter study the rate was 17% [5]. In the series of Van Boxtel, 4 patients needed a PPM implantation (13.3%) [6], while the group of Konig reported a rate of 28.5%, the highest described about Perceval, but in a very small series, therefore maybe affected by the learning curve [7]. The group directed by Santarpino in Germany published a percentage of 10.5% [8], while the largest series belonged to the European multicenter study (Pilot, Pivotal, CAVALIER trials) of 731 patients with a rate of 7.4% [1].

These results are comparable to the conventional AVRs with sutured bioprosthesis. As reported by Huynh et al. [9] and Elahi et al. [10] the PPM implantation rates varies from 8.7-9.1% to 8.3-18% for stented and stentless AVRs respectively. Small aortic annulus, pre-operative rhythm disorders (OR=12.5) and concomitant mitral valve replacement (OR=11.5) were identified as risk factors.

The need of PPM implantation for other sutureless devices seems to be lower than Perceval. Borger et al. [11] showed a rate of 5% in their AVRs with the rapid deployment system Edwards Intuity (7/141). A similar percentage was obtained in the series of Eichstaedt et al. [12] in which 120 patients were treated with the 3f Enable valve: among them, only 8 patients needed a PM (6.7%). In a meta-analysis published in 2011 by Bates et al. [13] the mean PPM implantation rate following a TAVI procedure was 14.2%, even if it appeared higher in case of Medtronic CoreValve (20.8%), while the Edwards Sapien device showed a percentage of 5.4%.

In their serie of 258 SU-AVRs with Perceval, Vogt et al. identified age and preoperative RBBB as independent predictors of PPM implantation [8]. In our study, the presence of preoperative conduction disorders (II-degree AV block, LBBB, RBBB and RBBB+LAHB) was found to be a risk factor for PPM implantation [overall n= 5 (8.9%), PPM vs no-PPM group: 4 vs 1 (66.7% vs 2%); p<0,001].

The main limit of this study was the small number of patients. In addition, our population includes the first 56 patients who underwent a SU-AVR with the Perceval bioprosthesis at our center; therefore these results could be affected by the surgeon's learning curve. So, further investigations and randomized clinical trials are mandatory to identify other risk factors and the impact of the SU-AVR implantation technique on the rate of PPM implantation.

In conclusion, the presence of preoperative conduction disorders is a statistically significant risk factor for PPM implantation following a SU-AVR with the Perceval bioprosthesis. Therefore, despite Perceval's optimal hemodynamic results, an accurate analysis of the preoperative rhythm has to be considered.

A written consent was obtained from each patient after full explanation of the purpose and nature of the procedures used.

Disclosure

Dr. Stefano Moriggia has a financial relationship with Sorin Group S.p.A. as proctor for Perceval.

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