Sutureless aortic valve replacement with Perceval bioprosthesis: are there predicting factors for postoperative pacemaker implantation?

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Abstract

OBJECTIVES: Aortic valve replacement (AVR) with sutureless bioprostheses has become an alternative to conventional AVR for patients with intermediate to high operative risk. However, this technique is associated with an increased risk of postoperative conduction disorders.

METHODS: We analysed 258 patients who underwent AVR with the Perceval prosthesis from July 2010 to September 2014 at our centre. Electrocardiography were obtained at baseline to record preoperatively the presence of conduction disorders. Preoperative risk factors, intraoperative procedures and complications (61 variables) were compared between patients with permanent pacemaker (PPM group) and without (no-PPM group) need for postoperative PPM implantation.

RESULTS: One hundred and sixty-nine patients underwent isolated AVR with the Perceval bioprosthesis, 89 patients had associated surgery and 23 patients underwent redo operations. The mean age was 77.7 ± 5 years, 139 patients were female (46%) and the mean logistic EuroSCORE was 13.2 ± 11%. At baseline, 8 patients had already an implanted pacemaker. Postoperatively, 27 patients (10.5%) required new PPM implantation due to complete atrioventricular block. On univariate analysis, age (PPM vs no-PPM group: 80 ± 5 vs 77 ± 5 years, $P = 0.009$) and preoperative presence of right bundle branch block (RBBB) [overall $n = 20$ (7.8%); PPM vs no-PPM group: 9 vs 11 (33 vs 4.8%); $P < 0.001$] were identified as independent predictors of postoperative conduction disorders, but only pre-existing RBBB persisted on multivariate analysis (odds ratio 11.3—C-statistic 0.74, error estimate 0.064, confidence interval 0.672–0.801; $P = 0.0002$). Among patients undergoing sutureless AVR, the rate of PPM implantation was high.

CONCLUSIONS: The analysis of the data collected made it possible to identify preoperatively a subset of patients undergoing sutureless AVR at higher risk of postoperative atrioventricular block. Additional surgical precautions should be implemented to prevent the occurrence of conduction disorders after sutureless AVR.

Keywords: Heart valve prosthesis • Pacemaker • Electrophysiology

INTRODUCTION

The Perceval sutureless aortic valve (Sorin Group, Saluggia, Italy) is a collapsible, stent-mounted aortic valve bioprosthesis that can be placed in a sutureless fashion with a conventional surgical technique [1]. This technology includes standard cardiopulmonary bypass, cross-clamping of the aorta and an aortotomy, allowing complete removal of the diseased native valve. Sutureless implantation of heart valves has a significant advantage over the classic technique of suturing the valve in place, because it shortens aortic cross-clamp time and, as a result, myocardial ischaemia time, thus favouring a better clinical outcome [2]. However, this technique is associated with an increased risk of postoperative conduction disorders [3] and high rates of pacemaker implantation, even exceeding 10% in certain subsets of high-risk patients [4]. Such an incidence should not be disregarded because long-term pacing may have deleterious effects on left ventricular (LV) systolic function,

promoting adverse cardiac events [5]. Up to now, the old question 'In patients undergoing aortic valve replacement, what factors predict the requirement for permanent pacemaker implantation?' remains open [6], even more in the setting of sutureless valves.

The aim of this study was to identify the risk factors of postoperative conduction disorders leading to the need for permanent pacemaker (PPM) implantation in patients undergoing aortic valve replacement (AVR) with the Perceval sutureless bioprosthesis.

MATERIALS AND METHODS

Between July 2010 and September 2014, we collected data of all patients suffering from severe aortic valve stenosis with an indication for surgery at our centre. A specific programme was initiated in our Institution at that time that has involved the Perceval sutureless bioprosthesis. Every week, during an interdisciplinary

conference, we evaluated all patients affected by severe aortic valve stenosis referred to our centre from peripheral hospitals, private practices or our emergency department, considering co-morbidities and surgical risk in order to determine the best therapy. In all patients aged >65 years with an indication for AVR, and compatible echocardiographic findings (symmetric aortic annulus with a diameter between 19 and 27 mm and a sinotubu-lar junction/annulus ratio <1.3), a Perceval sutureless valve was implanted as part of a premarket study (Cavalier Study) and later (after European Community approval in 2011) as routine use. During the premarket study, they also signed an additional informed consent for the experimental use of the new type of prosthesis (not yet CE approved). An informed consent for the use of personal data and follow-up contact was also signed by all patients. The study was approved by the local ethics committee.

Surgical procedure

In the study period, a total of 258 patients were operated on with (n = 65, 25%) or without associated coronary artery bypass grafting (CABG). Twenty-three procedures were redo AVR. In isolated AVR, a partial upper J-sternotomy or a right anterior hemithoracotomy was performed. The Perceval implantation technique has been described previously [7]. Starting from January 2014, the balloon plasty procedure was performed by inflating the balloon catheter to 2 atm rather than 4 atm for 30 s. General anaesthesia with oro-tracheal intubation and standard cardiopulmonary bypass were used in all patients.

Data collection

All baseline data were collected prospectively in a central registry. Electrocardiograms were recorded daily and analysed by two inves-tigators. Heart rhythm, PR interval, QRS duration, morphology and axis as well as the presence and degree of atrioventricular block, RBBB and left bundle branch block (LBBB) were recorded according to the recommendations of the American Heart Association/American College of Cardiology [8]. Briefly, the following electrocar-diography (ECG) parameters were obtained: heart rate, junctional rhythm, paced rhythm, sinus rhythm, atrial fibrillation, LBBB, RBBB, PR interval, QRS duration, QT interval, ST-segment abnormalities, signs of LV hypertrophy, evidence of prior myocardial infarction (pathological Q-waves) and negative T-waves.

At present, given the lack of specific guidelines focusing on the indications for pacemaker implantation after AVR or cardiac surgery [9], the decision whether to implant a pacemaker is based on several factors and varies among centres [6]. In our population, the indication for PPM implantation was established by an experi-enced cardiologist in the presence of atrioventricular conduction block or symptomatic atrial fibrillation and if rate control could not be achieved without antiarrhythmic medication.

The following patient characteristics and major preoperative risk factors were entered into the central database: age, gender, log EuroSCORE, height, weight, body surface area, hypertension, poor mobility, ischaemic cardiomyopathy, extracardiac arteriopa-thy, diabetes, insulin use, Canadian Cardiovascular Society class 4, left ventricular ejection fraction, recent myocardial infarction, New York Heart Association class, renal insufficiency graded as moderate (creatinine clearance >50 to <85 ml/min) or severe (cre-atinine clearance <50 ml/min), pulmonary hypertension graded as

moderate (31–55 mmHg) or severe (>55 mmHg) and chronic ob-structive pulmonary disease.

The following surgical factors with a potential impact on con-duction disorders were also recorded: partial 'J' sternotomy, full sternotomy, right thoracotomy, redo surgery, associated proce-dures (e.g. CABG, catheter ablation, other valve surgery), number of anastomoses, valve size [27 mm (named as XL), 25 mm (or L), 23 mm (or M), 21 mm (or S)], conventional (4 atm) or reduced ballooning (2 atm), cardiopulmonary bypass time, cross-clamp time and bicuspid aortic valve. The results were obtained mainly with the aim to search for any correlation with the rates of post-operative pacemaker implantation.

Statistical analysis

Categorical variables were summarized as frequencies (%) and con-tinuous variables as mean ± standard deviation. Normal distribution of data was assessed with the Shapiro–Wilk test. Continuous vari-ables were compared by the two-tailed paired t-test and categorical variables by the χ^2 test. Variables that demonstrated a statistically significant difference between groups ($P \le 0.05$) were entered into a multivariate logistic regression model to identify independent pre-dictors of the need for PPM implantation.

RESULTS

A total of 258 patients received a Perceval sutureless aortic valve prosthesis between July 2010 and September 2014. Pacemaker implantation was performed 5–19 days after AVR (mean 9.2 days). Twenty-seven (10.5%) patients required new PPM implantation after sutureless AVR due to complete atrioventricular block (PPM group). At baseline, 8 patients had already an implanted pace-maker and were therefore excluded from the analysis. The remaining 223 patients represent the no-PPM group.

Preoperative characteristics and ECG findings of the two study groups are presented in Tables 1 and 2. Patients from the PPM group were older (80 ± 5 vs 77 ± 5 years, P = 0.009) and had a higher prevalence of RBBB (33 vs 4.8%, P < 0.001). As for surgical factors, there were no significant differences between groups, in-cluding annular size and bicuspid aortic valve (Table 3).

Logistic regression analysis was used to predict the need for postoperative PPM implantation. The C-statistic for the fitted lo-gistic regression model was 0.06 (P = 0.0002), with an area under the receiver operating characteristic curve of 0.74, indicating good model fit. On multivariate analysis, preoperative RBBB was found to be an independent predictor of postoperative PPM implant-ation [odds ratio (OR) 11.3, P < 0.001].

At our centre, approximately 90% of AVR procedures were per-formed by two experienced surgeons (124 and 106 operations, re-spectively, out of a total of 258 AVRs). A significant difference in the rate of postoperative PPM implantation was observed among patients who were operated on by these two surgeons (4.8 and 17.9%, respectively; P = 0.001). On multivariate analysis, surgeon 'B' was found to be an independent predictor of postoperative PPM implantation (OR 3.2, P = 0.03).

DISCUSSION

The aim of this study was to identify preoperative and periopera-tive predictors of conduction disorders leading to the need for

Table 1: Preoperative characteristics of the study population

	Total (*n* = 258)	PPM group (*n* = 27)	No-PPM group (*n* = 231)	*P*-value
Pacemaker preoperatively	8 (3.1)	0	8 (3.5)	
Age (years)	77.7 ± 5	80.07 ± 5	77.4 ± 5	0.009
Age >70 years	97 (37)	14 (52)	83 (36)	0.08
Male sex	119 (46)	9 (33)	110 (48)	0.11
Log EuroSCORE	13.2 ± 11	14.24 ± 11	13 ± 11	0.61
Height (m)	166 ± 10	161.23 ± 21	166 ± 8	0.25
Weight (kg)	77 ± 15	76.12 ± 21	77 ± 14	0.74
BSA (kg/m^2)	1.87 ± 0.2	1.82 ± 0.2	1.88 ± 0.2	0.14
Hypertension	209 (81)	24 (89)	185 (80)	0.13
Poor mobility[a]	45 (17)	4 (15)	41 (18)	0.45
Ischaemic cardiomyopathy	75 (29)	10 (37)	65 (28)	0.23
Extracardiac arteriopathy	57 (22)	8 (30)	49 (21)	0.23
Diabetes	71 (27)	6 (22)	65 (28)	0.32
IDDM	16 (6)	2 (7.4)	14 (6.1)	0.52
CCS 4	3 (1.2)	0	3 (1.3)	0.71
LVEF (%)	58.8 ± 8.7	60.73 ± 8.3	59 ± 8.7	0.27
LVEF ≥50%	205 (79)	22 (82)	183 (79)	0.54
LVEF 30–50%	37 (14)	4 (15)	33 (14.3)	0.56
Recent AMI	3 (1.2)	2 (7.4)	1 (0.4)	0.29
NYHA class	2.8 ± 0.5	2.85 ± 0.4	2.8 ± 0.5	0.81
Renal insufficiency	45 (17)	3 (11)	42 (18)	0.25
Moderate (CrCl >50 to <85 ml/min)	69 (27)	10 (37)	59 (25)	0.15
Severe (CrCl <50 ml/min)	30 (12)	2 (7.4)	28 (12)	0.36
Pulmonary hypertension	40 (15)	3 (11)	37 (16)	0.34
Moderate (31–55 mmHg)	66 (26)	8 (30)	58 (25)	0.37
Severe (>55 mmHg)	33 (13)	2 (7.4)	31 (13)	0.29
COPD	40 (15)	4 (15)	36 (16)	0.76

Values are expressed as mean ± standard deviation or numbers (%).
AMI: acute myocardial infarction; BSA: body surface area; CCS: Canadian Cardiovascular Society; COPD: chronic obstructive pulmonary disease; CrCl: creatinine clearance; IDDM: insulin-dependent diabetes mellitus; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PPM: permanent pacemaker.
[a]Defined as severe mobility impairment due to musculoskeletal or neurological dysfunction.

Table 2: Preoperative ECG findings in the study population

	Total (*n* = 258)	PPM group (*n* = 27)	No-PPM group (*n* = 231)	*P*-value
Heart rate (bpm)	74 ± 14	71 ± 18	74 ± 14	0.33
Junctional rhythm	3 (1.2)	0	3 (1.3)	0.72
Paced rhythm	7 (2.7)	0	8 (3)	0.46
Sinus rhythm	219 (85)	25 (92)	194 (84)	0.19
Atrial fibrillation	27 (10)	1 (3.7)	26 (11)	0.18
LBBB	21 (8)	3 (11)	18 (7.8)	0.39
RBBB	20 (7.7)	9 (33)	11 (4.8)	<0.001
PR interval (ms)	164 ± 27	173 ± 30	163 ± 27	0.12
QRS duration (ms)	96 ± 22	104 ± 30	95 ± 21	0.06
QT interval (ms)	401 ± 39	414 ± 45	399 ± 38	0.89
ST-segment abnormalities	24 (9)	2 (7)	22 (9.5)	0.53
Signs of LV hypertrophy	46 (18)	4 (15)	42 (18)	0.45
Prior AMI	21 (8)	1 (3.7)	20 (8.6)	0.33
Negative T-wave	25 (10)	3 (11)	22 (9.5)	0.51

Values are expressed as mean ± standard deviation or numbers (%).
AMI: acute myocardial infarction; LBBB: left bundle branch block; LV: left ventricular; PPM: permanent pacemaker; RBBB: right bundle branch block.

pacemaker implantation in patients undergoing sutureless AVR. The achievement of a reduction in the incidence of conduction disturbances with subsequent pacemaker therapy is of utmost importance. Prolonged QRS duration was found to be associated with increased mortality in the general population, with intraventricular conduction delay being most strongly associated with an increased risk of arrhythmic death [10]. In addition, LBBB weakly predicted arrhythmic death, whereas RBBB was not associated with increased mortality [10]. Intraventricular conduction abnormalities also carry a poor prognosis: patients with bundle

Table 3: Surgical factors

	Total (*n* = 258)	PPM group (*n* = 27)	No-PPM group (*n* = 231)	*P*-value
Partial 'J'-sternotomy	159 (61)	15 (55)	144 (62)	0.31
Full sternotomy	90 (35)	11 (41)	79 (34)	0.32
Right thoracotomy	9 (3.5)	1 (3.8)	8 (3.5)	0.64
Redo procedure	23 (8.9)	1 (3.8)	22 (9.5)	0.28
Associated procedure	89 (34)	12 (44)	77 (33)	0.73
CABG	65 (25)	10 (37)	55 (24)	0.11
Catheter ablation	5 (1.9)	0	5 (2.2)	0.76
Other valve surgery	4 (1.5)	0	4 (1.7)	0.63
No. of anastomoses	0.4 ± 0.8	0.6 ± 0.9	0.4 ± 0.7	0.23
Valve size				
27 mm (XL)	29 (11)	3 (11)	26 (11)	0.63
25 mm (L)	116 (45)	14 (52)	102 (44)	0.29
23 mm (M)	95 (37)	8 (30)	87 (38)	0.27
21 mm (S)	18 (7)	2 (7.4)	16 (6.9)	0.57
Conventional (4 atm) ballooning	206 (80)	24 (89)	182 (79)	0.15
Reduced (2 atm) ballooning	49 (19)	3 (11)	46 (20)	0.19
Cardiopulmonary bypass time (min)	73 ± 26	70 ± 23	74 ± 26	0.52
Cross-clamp time (min)	44 ± 18	41 ± 14	44 ± 18	0.39
Bicuspid aortic valve	28 (11)	2 (7.4)	26 (11)	0.45

Values are expressed as mean ± standard deviation or numbers (%).
CABG: coronary artery bypass grafting; PPM: permanent pacemaker.

branch block (especially LBBB) and bifascicular block have a higher mortality risk than sex- and age-matched control subjects [11]. In the study of van Boxtel *et al.* [3], sutureless AVR with the Perceval bioprosthesis was frequently complicated by new LBBB, but this phenomenon remains to be clearly elucidated. Although we did not observe a higher incidence of LBBB, cardiac surgeons should be aware of this possible perioperative complication. In particular, 3 patients (1.2%) developed LBBB immediately after Perceval S implantation. Of these, 1 patient experienced an episode of asystole 6 days postoperatively requiring PPM implantation, whereas no other conduction disorders occurred during follow-up in the remaining 2 patients.

Conversely, Pellicori *et al.* reported a higher mortality in patients with RBBB. Compared with patients with LBBB, those with RBBB had more signs of peripheral congestion, especially in combination with higher plasma levels of N-terminal of pro hormone brain natriuretic peptide (NT-proBNP) [12]. In addition, the need for pacemaker therapy also increased with age, with QRS prolongation being more common in the elderly. In a large cohort of 780 consecutive elderly patients (≥70 years) undergoing isolated AVR for severe symptomatic aortic stenosis, pre-existing bundle branch block predicted the need for PPM implantation [13].

Our study is among the few ones that focused on the postoperative need for pacemaker implantation following sutureless AVR. In the same observation period, among 1673 patients who underwent conventional AVR at our centre, the incidence rate of pacemaker implantation was 6.8% (*n* = 113, *P* = 0.026). Such a lower incidence in this population could be related, on one hand, to the fact that a proportion of patients underwent emergency surgery because of endocarditis and combined procedures and, on the other hand, to the decalcification strategy used. However, we hypothesize that the sutureless population is sicker, and it is likely that higher risk patients may suffer higher rates of PPM implantation. A multicentre, randomized prospective study (PERSIST-AVR Study) has already been designed to test this hypothesis by comparing sutureless with stented bioprostheses.

The classical mechanisms of atrioventricular conduction disorders are often triggered by surgical interventions. Mild decalcification may also be the causal mechanism behind the occurrence of conduction disorders because of the high pressure at the level of the membranous septum that may damage the His bundle and the atrioventricular conduction. However, at our centre, the same decalcification strategy is used for both stented and sutureless prosthetic valves, and so it cannot account for our results. A major limitation in understanding this phenomenon and to the generalizability of our results derives from the fact that several operative factors can be hardly standardized. For instance, the definition of 'complete' or 'partial' annular decalcification is difficult to compare as it depends on the surgeon's experience and type of calcification (symmetrical or asymmetrical, protruding into the aortic root or spreading to the LV outflow tract, less extensive at the leaflet level or more pronounced in the aortic wall or interventricular septum). This variability in evaluation, description and treatment may partially account for the varying PPM implantation rates in the case series reported by different cardiac surgery centres. However, results concerning surgeon experience and learning curve are the main focus of ongoing studies from our group, addressing differences in prosthesis placement (e.g. even just a few millimetres: upward or downward), positioning of guiding sutures or holder orientation during valve deployment. All these factors may affect the procedure outcome. In our opinion, the surgeon's experience plays a key role, as also suggested by our results, but at present any inferences would be speculative. Also the effect of the learning curve remains to be clearly elucidated. In the last 2 years, a reduced postoperative PPM implantation rate was observed in our series, but this was paralleled by more favourable patient characteristics, given that the Perceval valve is nowadays implanted also in younger and lower risk patients.

Moreover, several additional questions remain unanswered. These pertain to interindividual variability and the precise mechanisms underlying the development of conduction disorders with subsequent need for PPM implantation. Of the 27 patients who received a

Table 4:   Rate of PPM implantation after sutureless aortic valve replacement with the Perceval bioprosthesis in different centres

Article	Centre	No. of patients	PPM (%)	Special features
van Boxtel *et al.* [3]	Eindhoven, Netherlands	31	13.3	19.4% concomitant CABG
Meuris *et al.* [18]	Pilot trial	30	3.3	5-year follow-up
Miceli *et al.* [19]	Massa, Italy–Nuremberg, Germany	281	4.2	Minimally invasive
Mazine *et al.* [20]	Canadian multicentre study	215	17	6 Canadian centres
Laborde *et al.* [21]	Cavalier Trial	658	11.6	25 European centres
Rubino *et al.* [22]	European multicentre study	314	8	5 European centres
König *et al.* [23]	Jena, Germany	14	28.6	Comparison with a stented model
Flameng *et al.* [1]	Leuven, Belgium	32	3.1	Conventional approach

CABG, coronary artery bypass graft; PPM: permanent pacemaker.

PPM, only 7 developed bradycardia while in the operation theatre, requiring temporary Dual-Dual-Dual (DDD) pacing. In a similar way, the variability among cardiologists in the indications for PPM implantation is another factor that deserves consideration. Of the 27 patients implanted with a pacemaker, 10 (37%) were in sinus rhythm at the follow-up visit. We collected these data as a further stimulus for future research and discussion. However, we do not know whether patients required periods of active pacing during the interval between follow-up visits, and this is a limitation of our study.

Several explanations may be considered for the observed rate of new PPM implantations following sutureless AVR. It is likely that the development of atrioventricular conduction disorders may be due to the large intra-annular sealing coil of the Perceval bioprosthesis. The prosthesis frame delivers an outward force affecting the aortic annulus during balloon dilatation. The force used for dilatation was reported as 4 atm, which is a pressure equal to 3040 mmHg [14]. The effects of the force on the annulus were not temporary by means of the acquired constant shape of the prosthesis. This may be the reason for PPM requirement, as suggested also by others [14]. In our experience, a lower inflation pressure (2 vs 4 atm) did not significantly affect the incidence of pacemaker implantation, also considering our current institutional population [up to May 2015: overall 306 patients; 4 atm in $n = 201$ (2010–2013) −25 pacemakers implanted (12.4%), and 2 atm in $n = 105$ (2014–2015)−11 pacemakers implanted (10.5%); $P = 0.38$]. Another possible explanation is the sutureless profile of the Perceval bioprosthesis. By comparing our results with those obtained by Eichstaedt *et al.* in 120 patients using another sutureless Nitinol device (3f Enable), a higher rate of PPM implantation was observed in our population (10.5 vs 6.7%) [15]. Similarly, the need for postoperative PPM was also higher in our series compared with that recorded by Borger *et al.* in 69 patients using a sutureless valve not made of Nitinol (Edwards Intuity) (10.5 vs 4.3%) [16].

With regard to the prostheses used for transcatheter aortic valve implantation (TAVI), also the lack of valve decalcification may have caused the occurrence of conduction disorders, because of the high pressure at the region of the membranous septum. By comparing patients who underwent TAVI at our centre during the same observation period, the rate of PPM implantation was not significantly different from that of our sutureless population [$n = 26$ (7.1%) out of 368 TAVI procedures; $P = 0.088$]. However, it is well known that the prosthesis profile/model may have an impact on the rate of PPM implantation, as testified by the higher incidence of pacemaker implantation reported by Bates *et al.* using the CoreValve prosthesis compared with the Edwards-Sapien transcatheter heart valve [17].

It is worth mentioning the results achieved also in other centres that implanted the Perceval sutureless bioprosthesis. In a pilot trial reporting the 5-year clinical and haemodynamic outcome, only 1 of 30 patients needed a new PPM [18]. In another series from two European centres, the incidence rate of conduction disturbances requiring PPM was 4.2% (12/281 patients) [19]. In a Canadian multicentre trial including 215 patients, a total of 37 patients (17%) underwent postoperative PPM implantation [20]. Finally, in the study of van Boxtel *et al.* [3], 4 patients (13.3%) required PPM because of complete atrioventricular block and new-onset LBBB developed in a high proportion of patients (39.3%). It is therefore clear that there is substantial variability among centres in the reported PPM implantation rate, ranging from 3.1 to 28.6% (Table 4) [1, 3, 18–23].

The heterogeneity of our study population, along with the limited number of PPMs implanted, does not allow us to establish the exact mechanisms implicated in the development of conduction disorders. This represents a limitation of our study, as no management strategy can be suggested to avoid or reduce the risk of this complication.

CONCLUSION

Among patients undergoing sutureless AVR at our centre, the rate of PPM implantation was high. The analysis of the data collected made it possible to identify preoperatively a subset of patients undergoing sutureless AVR at higher risk of postoperative atrioventricular block. Additional surgical precautions should be implemented to prevent the occurrence of conduction disorders after sutureless AVR. Notwithstanding this, the question remains open as to how the PPM implantation rate can be lowered. It is likely that an excessively extensive decalcification may account for the high prevalence of postoperative PPM in our study population. The traction on the commissural and/or guiding sutures may also play a role in the occurrence of conduction disturbances. It would be worthy to investigate whether conduction disorders recover over time and if PPM recipients are still pacemaker-dependent at long-term follow-up [24].

The identification of RBBB as a risk factor for postoperative conduction disturbances requiring PPM may provide the future direction for sutureless AVR, but further studies are warranted to confirm our results. Whether additional surgical precautions should be implemented to prevent the development of conduction disorders and the effects of new-onset conduction disorders

on the clinical outcome after conventional and/or sutureless AVR are also the subject of ongoing studies.

Conflict of interest: Theodor Fischlein is a consultant for Sorin Group.

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eComment. The importance of choosing a proper predictor variable selection method in logistic regression analyses

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In their recently published manuscript Vogt et al. investigated factors associated with permanent pacemaker implantation after sutureless bioprosthetic aortic valve replacement [1]. In the statistical analysis section of the manuscript, authors reported that they included only the variables, which are significantly different among groups. We think that a delicately chosen predictor variable selection method will make this study more precise. In logistic regression analysis, selection of predictor variables in a regression model can influence the outcome. To overcome the problems in selecting predictor variables, there are some methods available in statistical software programmes. The purpose of multiple logistic regression is to define the functional relationship between predictor variables and outcome.

During statistical model building variables are minimized as much as possible so that the most parsimonious model that describes the data is found. Commonly used variable selection methods are hierarchic selection, forced entry, and stepwise methods. In hierarchic selection researcher determines the possible variables entering into the model based on previous studies. Variables which have already proven to be a predictor enter the model first; other variables are incorporated subsequently. Forced entry is a method in which all predictors forced into the model. This method is not suitable for high number of variables like Vogt et al.'s research (they described 61 variables). Stepwise regression predictor variable selection is based on mathematical criteria. There are two different stepwise selection methods: forward and backward. In forward selection, which involves starting with no variables in the model, chi-square statistic is computed for each effect and the largest of these statistics is determined. The computer adds the variable if it improves the model. In backward elimination, which involves starting with all candidate variables, testing the deletion of each variable using the results of the Wald test for individual variables are examined. The variable that does not improve the model is removed. As a result, the validity and quality of research rely heavily on statistical methodology. In logistic regression analyses, researchers must select a suitable predictor entry method for their studies.

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Reference

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