

# Setting Up A Minimally Invasive Surgery Program: The Sutureless Solution

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**Abstract:** Background and aim of the study: Minimally invasive approaches for aortic valve replacement (AVR) are clinically beneficial for patients but are more technically demanding for surgeons. Sutureless AVR is a new and minimally invasive approach. The study aim was to evaluate initial AVR outcomes in patients aged >75 years after setting up a sutureless minimally invasive surgery program. Methods: Between January 2014 and December 2015, a total of 108 patients aged >75 years with indication of isolated elective AVR received a sutureless bioprosthesis using the minimally invasive approach (sutureless group). The latter group was compared with a second group of patients (n = 115) who received a stented valve through a full median sternotomy (stented group) at the authors' institution between January 2012 and December 2013. After propensity score matching, 95 pairs of patients were available for analysis. Results: Preoperative demographic variables were similar between the matched groups. The aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times were each shorter in the sutureless group (p <0.01). Perioperative mortality was 1% in the stented group, but no mortality occurred in the sutureless group (p = 0.32). Early postoperative extubation, intensive care unit and hospital stays, need for transfusion, and overall hospital stay were lower in the sutureless group. Frequency of pacemaker implantation was higher in the sutureless group than in the stented group (8.3% versus 1.9%; p = 0.05). Aortic transvalvular gradients were lower in the sutureless group (p = 0.01). Conclusion: In the authors' experience, the sutureless aortic valve was a useful tool for establishing a minimally invasive AVR program. The technique was safe, and the shorter ACC and CPB times increased the likelihood of early extubation, reduced the need for blood transfusions, and demonstrated good hemodynamic performance. Patients who underwent sutureless AVR showed an increased need for pacemaker implantation.

**Keywords:** Invasive Surgery, Sutureless Solution, aortic valve replacement, sutureless bioprosthesis

## 1. Introduction

Isolated minimally invasive aortic valve replacement (MI-AVR) has been progressively developed and widely used over the past two decades to provide patients in need of AVR with a less invasive option to conventional full median sternotomy (1,2). Nevertheless, MI-AVR as a technique is more demanding for the surgeon as it involves a considerable reduction in the surgical field and is sometimes associated with prolonged aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times (2). The greater complexity of MI-AVR with a conventional bioprosthesis is clearly a milestone for its widespread use. Benefits of the MI-AVR approach, apart from the aesthetic component, have previously been reported and include safety of the technique, preservation of better ventilatory mechanics, reduced hospital stays, reduced need for transfusion of blood products, a lower incidence of infectious complications, and greater postoperative comfort (1,3). New sutureless aortic valve bioprostheses for surgical implantation have been developed over the past few years, such as the Perceval valve (Sorin Biomedica, Cardio Srl, Saluggia, Italy). The Perceval valve is a bovine pericardial prosthesis that is assembled on a Nitinol stent that does not require sutures for implantation, thus drastically shortening ACC and CPB times (4). This design not only provides an excellent hemodynamic performance but also favors the valve's use in MI-AVR (5).

The present study aimed to evaluate initial AVR outcomes in patients aged >75 years, following the establishment of a program for MI-AVR using sutureless aortic valves.

## 2. Clinical Materials And Methods

### 2.1. Patients

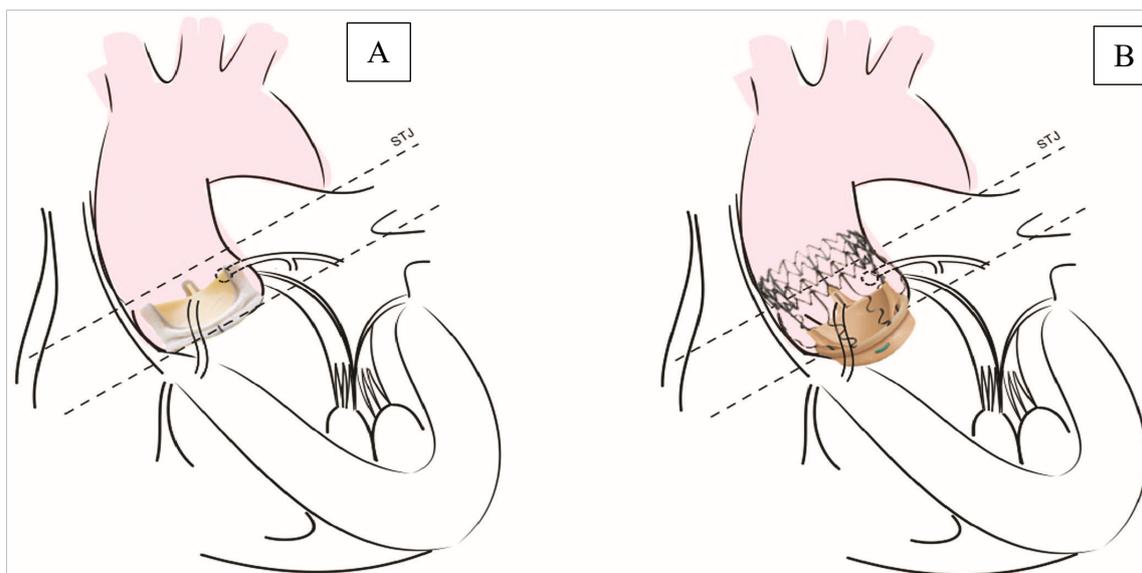
The study was a single-center, observational, retrospective investigation. Clinical data were collected from the department database and the regional electronic health record

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system. Between January 2014 (the start of the sutureless MI-AVR program) and December 2015, a total of 108 consecutive patients aged >75 years who were undergoing sutureless MI-AVR were included; these patients formed the sutureless group. Any patients who had previously undergone heart surgery, had active endocarditis, a history of emergency surgery, or had undergone a concomitant cardiac procedure (in addition to AVR) were excluded. A case-matched control group of 115 patients was assembled from the department's surgical database that consisted of patients treated using a conventional aortic valve bioprosthesis and a full sternotomy approach between January 2012 and December 2013; these patients formed the stented group (Fig. 1). After propensity score matching, 95 pairs were available for analysis. The decision to contraindicate conventional surgery and refer the patient for transcatheter aortic valve implantation (TAVI) during the study period was made by a cardiac team that considered candidates for TAVI to be those with large comorbidity indices or who met inoperability criteria for anatomical reasons. Approval to conduct the study was granted by the regional and local ethics committees, and all patients provided their informed consent to participate.



**Figure 1:** A) Stented bioprosthetic aortic valve (conventional). B) Sutureless aortic valve (Perceval).STJ: Sinotubular junction

## 2.2. Surgical technique

Both groups underwent the same anesthetic and monitoring protocols, as well as carbon dioxide use via continuous infusion throughout the procedure to reduce the possibility of air embolism.

For the sutureless group, a longitudinal incision of 7-8 cm was made along the presternal midline, forming an upper J-ministernotomy from the sternal manubrium to the third or fourth intercostal space. Central cannulation was performed in all cases using the superior vena cava for venous drainage (multiperforated 29 Fr venous cannula) and mild hypothermia. A single dose of cold hematic cardioplegia was administered by antegrade infusion. After performing a transverse aortotomy and complete excision of the calcified annulus, measurements were performed to determine the size of the prosthesis. The Perceval bioprosthesis was collapsed with the compressor device and released in the aortic annulus with the aid of three reference points located at the lowest point of the annulus between each commissure. The position of the prosthesis was verified by direct visualization and then expanded by pressurization of a balloon at 3-4 atm for 30 s, after which the three guide sutures were removed.

For the stented group, after a conventional full median sternotomy, CPB was established with central cannulation and mild hypothermia (34°C). An initial dose of cold hematic cardioplegia was administered by antegrade infusion and continuous retrograde infusion. After partial aortotomy and excision of the calcified native valve, the largest possible conventional bioprosthesis was implanted, depending on intraoperative measurement of the aortic annulus.

## 2.3. Postoperative care

Patients of both groups were subjected to the same postoperative intensive care unit (ICU) protocol. Patients were considered eligible for extubation when they met the following criteria: responded to command, pulse oximetry oxygen saturation (SpO<sub>2</sub>) exceeding 95% at a fraction of inspired oxygen (FiO<sub>2</sub>) less than 0.5; PaCO<sub>2</sub> less than 50 mmHg, pH exceeding 7.30, and adequate respiratory mechanics. Criteria for ICU discharge were: no acute neurological disorder; SpO<sub>2</sub> exceeding 90% at a FiO<sub>2</sub> of less than 0.5; no uncontrolled arrhythmia; no active chest tube drainage; hourly urine output exceeding 0.5 ml/kg, and no vasopressors or inotropic agents. A restrictive threshold (hemoglobin <7 g/dl) was considered for packed red blood cells (RBC) transfusion. Hospital discharge was considered in those patients with good functional recovery and without postoperative complications requiring in-hospital treatment. All patients received antiplatelet therapy (aspirin; 150 mg/24 h). Preventive doses of

anticoagulation agents with low-molecular-weight heparin were administered as indicated over the duration of hospitalization. Clinical and transthoracic echocardiography (TTE) follow-up was performed for all patients (at three months postoperatively).

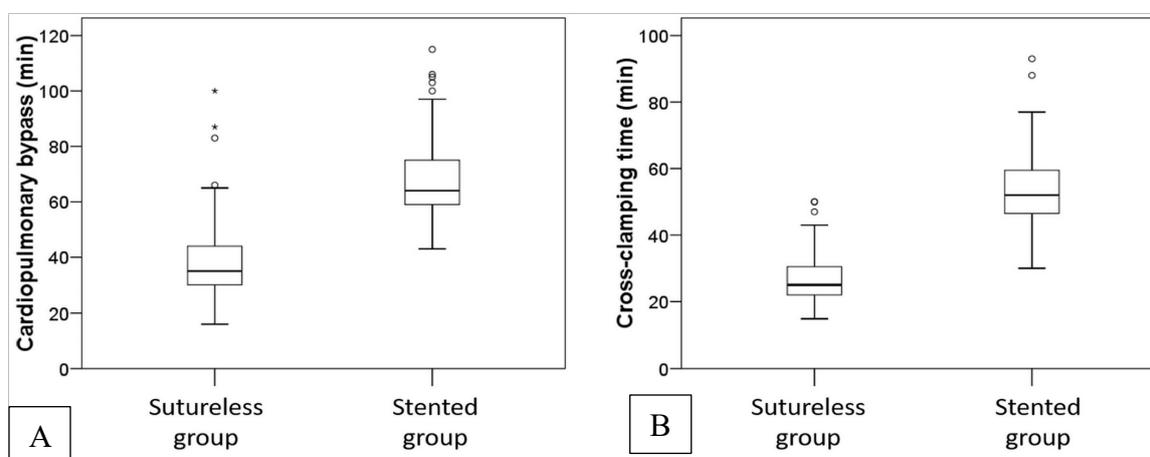
## 2.4. Statistical analysis

All statistical analyses were conducted using SPSS software (version 22; IBM SPSS Inc., Chicago IL, USA). A descriptive analysis of all variables included in the study was performed. Quantitative variables were expressed as mean  $\pm$  SD, and qualitative variables as absolute values and percentages. Normal distribution of data was assessed using the Shapiro-Wilk test. Continuous variables were compared using two-tailed paired *t*-tests, and categorical variables using the chi-squared test. Non-normally distributed variables were tested using the Mann-Whitney test. A *p*-value  $<0.05$  was considered to be statistically significant. Propensity score matching (1:1) was performed to control for selection bias as a result of the use of nonrandom sutureless group assignment.

The following patient characteristics and major preoperative risk factors were entered into the model: age, gender, body surface area, hypertension, hyperlipidemia, diabetes mellitus, history of previous myocardial infarction, left ventricular ejection fraction, pulmonary hypertension  $>50$  mmHg, renal disease (estimated glomerular filtration rate  $<30$  ml/min/1.73 m<sup>2</sup>), chronic obstructive pulmonary disease, peripheral vascular disease, and NYHA functional class. Subsequently, the postoperative outcomes of the resulting 95 matched pairs of both groups were compared.

## 3. Results

No significant between-group differences were noted in the baseline characteristics of the study population (Table 1). The intraoperative variables are listed in Table 2. Notably, the ACC and CPB times were lower in the sutureless group than in the stented group ( $27.1 \pm 7.4$  min versus  $53.7 \pm 10.9$  min and  $38.5 \pm 14.3$  min versus  $68.7 \pm 14.3$  min, respectively;  $p < 0.001$ ) (Fig. 2). On one occasion, it was necessary to revert to full sternotomy while treating a patient from the sutureless group. Intraoperative TEE showed moderate to severe paravalvular leak in seven patients. Since the prosthesis appeared to be positioned too high in the supraannular position (in three patients) or incomplete annular decalcification was observed (in four patients), repositioning of the Perceval bioprosthesis was required on seven occasions. Although longer ACC and CPB times were observed in these seven patients ( $46.2 \pm 9.3$  min and  $63.8 \pm 12.2$  min, respectively), they had an uneventful postoperative course, and TTE showed good results at follow-up.



**Figure 2:** Comparison of cardiopulmonary bypass (A) and aortic cross-clamp (B) times in matched groups.

The postoperative variables are listed in Table 3. Perioperative mortality was observed in one patient in the stented group (1%) secondary to cardiogenic shock. There were no cases of perioperative mortality among patients in the sutureless group ( $p = 0.32$ ). Early postoperative extubation ( $<6$  h) was performed in 68% of patients in the sutureless group and in 57% of patients in the stented group ( $p = 0.03$ ). In the sutureless group, 55% of patients required less than 24 h postoperative ICU care compared with 40% of patients in the stented group ( $p = 0.02$ ).

The overall postoperative stay was shorter for the sutureless group than for the stented group ( $7.2 \pm 4.0$  days versus  $8.9 \pm 6.9$  days, respectively;  $p = 0.03$ ). In the sutureless group, 51% of patients required a concentrated transfusion of RBCs, compared with 69% of patients in the stented group ( $p < 0.01$ ). There were no significant differences between the two groups for

**Table 1:** Preoperative parameters of the propensity matched groups.

Parameter	Sutureless group (n = 95)	Stented group (n = 95)	p-value
Age (years)*	$78.7 \pm 3.5$	$78.5 \pm 2.2$	0.63
Female gender	58 (61)	53 (56)	0.46
BMI (kg/m <sup>2</sup> )*	$28.9 \pm 4.3$	$29.4 \pm 4.0$	0.40

Parameter	Sutureless group (n = 95)	Stented group (n = 95)	p-value
Obesity (BMI >30)	34 (36)	39 (41)	0.45
BSA (m <sup>2</sup> )*	1.73 ± 0.16	1.76 ± 0.17	0.21
Preoperative creatinine (mg/dl)*	1.10 ± 0.41	1.14 ± 0.35	0.46
eGFR <30 ml/min/1.73 m <sup>2</sup>	7 (7)	6 (6)	0.77
Preoperative hemoglobin (mg/dl)*	12.6 ± 1.4	12.9 ± 1.6	0.17
Hypercholesterolemia	63 (66)	58 (61)	0.45
COPD	8 (8)	12 (13)	0.34
Diabetes mellitus	17 (18)	20 (21)	0.58
Arterial hypertension	78 (82)	72 (76)	0.28
Peripheral vascular disease	5 (5)	4 (4)	0.73
Functional class (NYHA)			
I	3 (3.1)	2 (2.1)	0.65
II	39 (41.0)	35 (36.8)	0.55
III	53 (55.7)	58 (61.0)	0.46
IV	0	0	
EuroSCORE I (%)*	8.4 ± 3.4	7.9 ± 2.8	0.26
EuroSCORE II (%)*	2.8 ± 1.7	2.6 ± 1.6	0.40
Preoperative LVEF (%)*	60 ± 12	63 ± 13	0.43
Left ventricular dysfunction (LVEF <55%)	19 (20)	16 (17)	0.57
Preoperative aortic valve peak gradient (mmHg)*	80 ± 21	84 ± 23	0.21
Preoperative aortic valve mean gradient (mmHg)*	47 ± 14	50 ± 16	0.17
Preoperative cardiac rhythm			
Sinus rhythm	75 (79)	70 (74)	0.39
Heart block (first degree)	13 (14)	15 (16)	0.68
Left bundle branch heart block	9 (9)	12 (13)	0.48
Atrial fibrillation	16 (17)	22 (23)	0.27
Pacemaker	2 (2)	3 (3)	0.65

\*Values are mean ± SD.

Values in parentheses are percentages.

BMI: Body mass index; BSA: Body surface area; COPD: Chronic obstructive pulmonary disease; eGFR: Estimated glomerular filtration rate; EuroSCORE: European System for Cardiac Operative Risk Evaluation; LVEF: Left ventricular ejection fraction.

**Table 2:** Intraoperative parameters in matched groups (mean ± SD).

Parameter	Sutureless Group (N = 95)		Stented Group (N = 95)		P-Value
Cross-clamp time (min)*	27.1 ± 7.4		53.9 ± 11.2		<0.01
CPB time (min)*	38.2 ± 14.2		68.1 ± 14.2		<0.01
Prosthetic aortic valve	Perceval	(100)	Carpentier Magna Mitroflow	21 (22) 74 (78)	
Dimensions	S	22	19	8	
	M	32	21	40	
	L	25	23	39	
	XL	16	25	8	
Conversion to full sternotomy	1		---		
Sutureless valve repositioning	7		---		

\*Values are mean ± SD.

Values in parentheses are percentages. CPB: Cardiopulmonary bypass.

**Table 3:** Comparison of postoperative short-term clinical outcomes in matched groups.

Variable	Sutureless Group (N = 95)	Stented Group (N = 95)	P-Value
30-Day mortality	0	1 (1)	0.31
Early extubation (<6 h)	65 (68)	51 (54)	0.03
ICU LOS (<24 h)	55 (58)	40 (42)	0.02
Reoperation for bleeding	2 (2)	4 (4)	0.40
<b>Blood transfusions</b>			
RBC	48 (51)	66 (69)	<0.01
FFP	13 (14)	21 (22)	0.12

Variable	Sutureless Group (N = 95)	Stented Group (N = 95)	P-Value
Platelet transfusion	15 (16)	20 (21)	0.34
<b>Respiratory complications</b>			
Pleural effusion	2 (2)	4 (4)	0.40
Pneumothorax	0	1 (1)	0.31
Respiratory infections	3 (3)	5 (5)	
<b>Hemodynamic complications</b>			
Cardiogenic shock	0	1 (1)	0.31
IABP or VAD	0	0	
Perioperative MI	1 (1)	2 (2)	0.56
Cardiac tamponade	2 (2)	2 (2)	1
<b>Neurological complications</b>			
Type I	0	2 (2)	0.15
Type II	2 (2)	5 (5)	0.24
<b>Renal complications</b>			
AKI	4 (4)	8 (8)	0.23
Renal failure requiring temporary dialysis	0	1 (1)	0.31
CVVH			
<b>Surgical wound complications</b>			
Superficial wound infection	1 (1)	4 (4)	0.17
Deep wound infection	0	1 (1)	0.31
<b>Heart rhythm disorders</b>			
Atrial fibrillation	16 (17)	22 (23)	0.27
New pacemaker implantation	8 (8)	2 (2)	0.053
Hospital LOS (days)*	7.2 ± 4.0	8.9 ± 6.9	0.03
Readmission post discharge home	3 (3)	5 (5)	0.46
<b>NYHA class (3 months' follow up)</b>			
I	58 (61.0)	52 (54.7)	0.37
II	37 (38.9)	42 (44.2)	0.46
III	0	0	
IV	0	0	

\*Values are mean ± SD.

Values in parentheses are percentages.

AKI: Acute renal injury (AKIN criteria); CVVH: Continuous venovenous hemofiltration; FFP: Fresh-frozen plasma; IABP: Intra-aortic balloon pump; ICU: Intensive care unit; LOS: Length of stay; MI: Myocardial infarction; RBC: Red blood cell; VAD: Ventricular assist device.

The transfusion of other blood products. Pacemaker implantation for complete heart block was required in 8% of patients in the sutureless group compared to 2% of patients in the stented group ( $p = 0.05$ ). The preoperative and postoperative echocardiographic variables are listed in Table 4. Postoperative peak and mean aortic gradients were significantly lower in the sutureless group than in the stented group, but there were no statistically significant between-group differences for paravalvular leaks (Table 4).

**Table 4:** Preoperative and postoperative (three months' follow-up) echocardiographic findings for matched groups.

Parameter	Baseline Sutureless Group	Stented Group	P-Value	Follow Up Sutureless Group	Stented Group	P-Value
LVEF (%)*	60 ± 12	63 ± 13	0.10	61 ± 9	63 ± 14	0.24
LVEDD (mm)*	51 ± 5	52 ± 6	0.21	51 ± 4	52 ± 5	0.12
LVESD (mm)*	33 ± 6	33 ± 7	0.99	31 ± 4	32 ± 8	0.27
IVST (mm)*	14.5 ± 3.0	14.2 ± 2.1	0.42	14.1 ± 2.9	13.9 ± 2.2	0.59
PWT (mm)*	13.2 ± 2.5	13.5 ± 2.4	0.40	13.0 ± 2.2	13.3 ± 2.3	0.12
Peak gradient (mmHg)*	80 ± 21	84 ± 23	0.21	20 ± 6	26 ± 8	<0.01
Mean gradient (mmHg)*	47 ± 14	50 ± 16	0.17	9 ± 3	13 ± 7	<0.01
Paravalvular leak <sup>3</sup> 2				2 (2)	1 (1)	0.56

\*Values are mean ± SD.

Values in parentheses are percentages. IVST: Interventricular septum thickness; LVEDD: Left ventricular end-diastolic diameter; LVEF: Left ventricular ejection fraction; LVESD: Left ventricular end-systolic diameter; PWT: Posterior wall thickness.

#### 4. Discussion

The experiences of the authors are reported after establishing a program of sutureless elective MI-AVR in patients aged >75 years. The observed outcomes in this population were excellent, with no in-hospital mortality and good hemodynamic performance. Compared to patients in the stented group who underwent conventional stented AVR,

surgical times, blood transfusion frequency, postoperative mechanical ventilation duration, and hospital length of stay were significantly reduced among patients in the sutureless group. However, an increased rate of permanent pacemaker implantation was observed in the sutureless group.

New guidelines for the management of valvular heart disease recommend surgical AVR for low-risk patients and TAVI for patients in whom surgery is not indicated (6). With regard to intermediate-risk patients, it is important to consider patient comorbidities and operative risk, vascular access, experience of each medical center, and patient preferences prior to settling on an intervention strategy. However, most studies have focused on surgical AVR with full sternotomy and implantation of a sutured prosthesis, making this invasive procedure the 'gold standard'. The impact of the newly introduced sutureless technology has not yet been widely evaluated.

Sutureless valves favor minimally invasive surgical approaches; thus, the choice of isolated MI-AVR has increased over recent years, with J-ministernotomy being one of the most frequently used approaches (7). As minimally invasive surgery reduces surgical invasion, the benefits reported are mainly derived from better ventilatory mechanics and postoperative comfort, less need for the transfusion of blood products, and lower incidences of infectious complications (1,8). Unfortunately, MI-AVR is a more demanding technique and is associated with longer ACC and CPB times (1), potentially increasing the risk of side effects (9,10). Lehmann et al. (3) highlighted better short- and long-term survival with MI-AVR compared with full sternotomy, despite slightly longer surgery times. These findings could be attributed to less trauma produced by MI-AVR as well as a selection bias, as MI-AVR was performed only by more experienced surgeons. At the present authors' center, MI-AVR with stented bioprostheses was also performed by more experienced surgeons in selected cases.

New sutureless prostheses have simplified the surgical implantation technique, favoring and expanding use of the minimally invasive approach (5,7,11). Thus, at the authors' center, sutureless MI-AVR has been the standard approach for patients aged >75 years (sutureless group) since January 2014. The results of the present study show that it is a safe technique in terms of hospital mortality (0% for the sutureless group versus 1% for the stented group,  $p = 0.31$ ). Since the study involves a selected population (patients with elective procedures, without previous heart surgery, without associated procedures, and without endocarditis), the hospital mortality rate for both groups was lower than had been reported in other similar series (12,13). Furthermore, there is evidence of a drastic reduction of ACC and CPB times, despite the minimally invasive approach.

In this regard, there is also less variability in surgery times, which reflects a greater reproducibility of the surgical technique. Only one patient required conversion to full median sternotomy for hemostatic control, and on seven occasions, the sutureless prosthesis had to be repositioned intraoperatively, with good subsequent results. Those events occurred at the beginning of the MIS program and might be related to the procedural learning curve. Early extubation (<6 h) and ICU stays of less than 24 h were more common in the sutureless group, most likely because of the minimally invasive approach that preserves better ventilatory mechanics.

Overall, postoperative stays were shorter, and the need for RBC concentrate transfusions was lower for the sutureless group. In a multicenter study that used propensity score matching, Dalén et al. (12) compared 171 patients who underwent ministernotomy surgery with a sutureless bioprosthesis implant with 171 patients who underwent a full sternotomy with a stented bioprosthesis. Even though no differences were noted in perioperative mortality at 30 days or two years postoperatively, these authors reported that patients treated with sutureless prostheses showed a significant reduction in ACC and CPB times, less need for the transfusion of blood products, and a higher risk of postoperative permanent pacemaker implantation.

Likewise, in the present study, postoperative permanent pacemaker implantation was higher in the sutureless group than in the stented group (8% versus 2%, respectively;  $p = 0.05$ ). Earlier studies reported an incidence of between 5% and 23% (11,14) of complete heart block with the use of these new prostheses, compared to 3% to 7% for stented prostheses in a similar population (15,16). Several factors are likely associated with the increased complete heart block, including the existence of preoperative conduction disorders, anatomical factors (intense calcification of the aortic annulus), and those arising from the surgical technique used (17,18).

In the present series, the technique for implanting sutureless prostheses was slightly modified. In concert with the recommendations of other centers, towards complete decalcification of the aortic annulus, fully intra-annular prosthetic implant, and shorter or no intra-prosthetic balloon times (10s) were performed (19). Although no factors associated with the need for postoperative pacemaker implantation were detected (most likely due to the limited cohort size), these changes in valve implantation technique could explain why most complete heart blocks occurred during the initial phase of the study. In this regard, Yanagawa et al. (20) reported a considerable reduction in the need for postoperative pacemaker implantation, in line with the experience of the surgical team.

Excellent short- and medium-term hemodynamic performance of sutureless prostheses has already been described (11). In the present series, the echocardiographic control at two months showed significant improvement in valve gradients. Other groups have reported similar results in patients with small aortic roots, provoking a discussion of the need for aortic annulus extension in this age of the sutureless prosthesis (21). The incidence of significant paravalvular leak (grade  $\geq 2$ ) was 2% in both groups, although no exhaustive decalcification of the aortic annulus was performed in the initial phase of sutureless prosthesis implantation, and this could favor the appearance of periprosthetic leaks.

## 5. Study Limitations

The main limitations of the study were its single-center, observational, non-randomized nature that involved a selected population with isolated aortic stenosis, and short-term follow-up. The reduced sample size did not afford sufficient statistical power for detecting between-group differences in certain clinical and echocardiographic events. Further randomized studies with a larger number of patients are required to make short- and long-term comparisons of new sutureless prostheses versus conventional prostheses and TAVI, as well as their application in combined surgery or reoperations.

## 6. Conclusion

In conclusion, the sutureless aortic valve was a useful tool for establishing a successful program for MIAVR. Compared to a propensity-matched population of patients undergoing conventional stented AVR, the technique was safe and enabled a reduction of ACC and CBP times, favored early extubation, reduced the need for blood transfusions, and demonstrated good hemodynamic performance at the three-month follow-up. However, there was an increased need for pacemaker implantation among patients who received sutureless aortic valves.

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**CRedit Author contribution statements:** F. Estevez-Cid and V. Bautista-Hernández contributed to the conception and design of the study. C. Velasco-García de Sierra, L. Fernandez-Arias, and M. Garcia-Vieites contributed to the drafting of the manuscript. A. Bouzas-Mosquera and E. Barge-Caballero provided critical revision of the manuscript for important intellectual content. J. Cuenca-Castillo supervised the project and approved the final version. All authors read and approved the final manuscript.

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