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ORIGINAL ARTICLE

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Minimally invasive aortic valve replacement: short-term efficacy of sutureless compared with stented bioprostheses

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Abstract

OBJECTIVES: Sutureless aortic valve prostheses have been introduced to facilitate the implant process, speed up the operating time and improve haemodynamic performance. The goal of this study was to assess the potential advantages of using sutureless prostheses during minimally invasive aortic valve replacement in a large multicentre population.

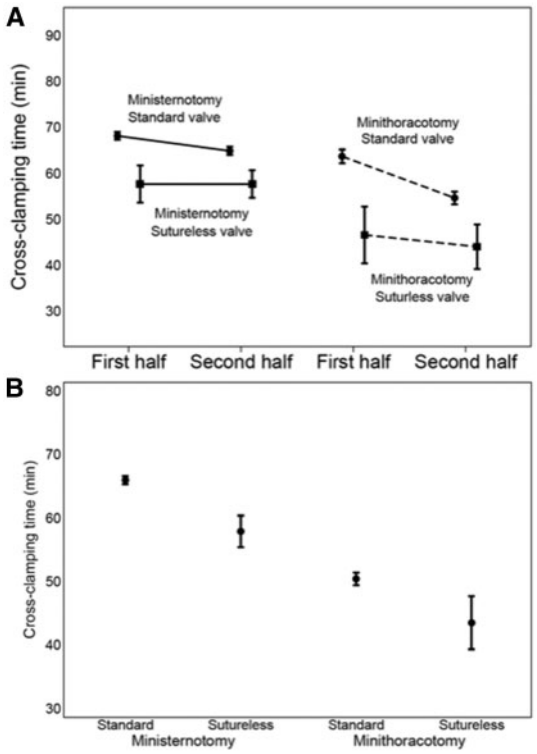
METHODS: From 2011 to 2019, a total of 3402 patients in 11 hospitals underwent isolated aortic valve replacement with minimal access approaches using a bioprosthesis. A total of 475 patients received sutureless valves; 2927 received standard valves. The primary outcome was the incidence of 30-day deaths. Secondary outcomes were the occurrence of major complications following procedures performed with sutureless or standard bioprostheses. Propensity matched comparisons was performed based on a multivariable logistic regression model.

RESULTS: The annual number of sutureless valve implants increased over the years. The matching procedure paired 430 sutureless with 860 standard aortic valve replacements. A total of 0.7% and 2.1% patients with sutureless and standard prostheses, respectively, died within 30 days ($P = 0.076$). Cross-clamp times [48 (40–62) vs 63 min (48–74); $P = 0.001$] and need for blood transfusions (27.4% vs 33.5%; $P = 0.022$) were lower in patients with sutureless valves. No difference in permanent pacemaker insertions was observed in the overall population (3.3% vs 4.4% in the standard and sutureless groups; $P = 0.221$) and in the matched groups (3.6% vs 4.7% in the standard and sutureless groups; $P = 0.364$).

CONCLUSIONS: The use of sutureless prostheses is advantageous and facilitates the adoption of a minimally invasive approach, reducing cardiac arrest time and the number of blood transfusions. No increased risk of permanent pacemaker insertion was observed.

Keywords: aortic valve, replacement • heart valve prothesis, biological • minimally invasive surgery

[†] The first two authors contributed equally to this work.



INTRODUCTION

The treatment of aortic valve diseases has undergone a rapid change in recent years. Although strong data support the use of transcatheter aortic valve implants in high-risk surgical candidates [1], the best treatment for intermediate [2] and low-risk [3] patients requiring aortic valve replacement (AVR) is still a matter of debate. Both transcatheter and surgical procedures are evolving with the implementation of new techniques, new prostheses and new deployment devices. To have a good reference to compare to transcatheter aortic valve implants, it is important to define the best strategy for patients undergoing surgical treatment. Despite the lack of definitive randomized trials, retrospective studies and meta-analyses have shown that a reduction in postoperative morbidity is almost invariably observed with minimally invasive surgical approaches (mini-AVR) compared to a full sternotomy [4, 5], and a survival advantage was recently demonstrated in propensity matched cohorts [6, 7].

Sutureless and rapid deployment aortic valve prostheses have been introduced to facilitate the implant process, reduce the operating time and improve the haemodynamic performance. Several studies have documented the safety and efficacy of using these prostheses [8, 9] also with the minimally invasive approach [10]. However, few studies have specifically addressed the potential advantages of using sutureless prostheses during mini-AVR in comparison with standard stented prostheses [11, 12].

The goal of this report was to compare in a large multicentre recent population the short-term surgical outcomes of patients undergoing minimally invasive AVR using sutureless or standard bioprostheses.

MATERIALS AND METHODS

All patients signed an informed consent form to allow clinical and administrative data storage and utilization for scientific purposes according to the General Data Protection Regulation. Because of the retrospective nature of this study, the local ethics committees waived the need for patient consent. Prospectively collected data from 11 Italian cardiac centres were analysed retrospectively. All consecutive patients operated on from January 2011 through December 2019 who received a first-time isolated AVR with a bioprosthesis through a minimal access approach (partial hemisternotomy or right anterior minithoracotomy) were considered for the analysis. Patients undergoing combined procedures and a full sternotomy and patients receiving a mechanical aortic prosthesis were excluded.

The primary outcome of the study is the incidence of 30-day deaths following a mini-AVR performed with a standard stented prosthesis compared with a sutureless bioprosthesis. Secondary outcomes are the occurrence of major complications following the replacement with both types of prostheses: stroke, worsening of kidney function, inserting a permanent pacemaker, reopening for bleeding, postoperative atrial fibrillation and low cardiac output. Postoperative complications have been reported according to the Valve Academic Research Consortium-2 definitions [13]. Low cardiac output was defined as the need for postoperative inotropic support for more than 48 h in the intensive care unit and/or from an intra-aortic balloon pump.

The choice and the type of minimally invasive approach were based on the surgeon's preference. The choice of the valve also depended on the surgeon's preference and the availability of the prosthesis. The techniques have been described previously [14].

For the upper hemisternotomy approach, a 6- to 7-cm skin incision is made, and the sternum is partially opened in a J-shaped fashion, up to the third/fourth intercostal space. Arterial and venous cannulas are usually inserted through the main surgical site. If the right atrium is difficult to expose, then a percutaneous venous cannula is advanced through the right femoral vein into the right atrium using the Seldinger technique under transoesophageal echocardiographic guidance. The right anterior minithoracotomy is performed through a 5- to 7-cm incision at the second or third intercostal space without rib resection. The right internal mammary artery is not routinely cut off. The ascending aorta or the femoral artery is used for cannulation, depending on the patient's anatomy. Venous drainage is achieved in the fashion described for ministernotomy. A preoperative computed tomography scan without contrast enhancement is sometimes performed to evaluate the anatomical relationship between the intercostal spaces, the sternum, the ascending aorta and the aortic valve [15]. Vacuum-assisted cardiopulmonary bypass is established; a left ventricular vent is placed through the right superior pulmonary vein or the pulmonary artery. The ascending aorta is clamped, and anterograde cardioplegic solution is delivered into the aortic root or selectively into the coronary ostia. Different stented (porcine: Hancock II and Mosaic, Medtronic, Minneapolis, MN, USA; pericardial: Carpentier-Edwards, Edwards Lifesciences, Irvine, CA, USA, Mitroflow and Crown PRT, LivaNova/Sorin, London, UK) and a single sutureless (Perceval, LivaNova/Sorin, London, UK) aortic valve bioprosthesis have been implanted. All patients underwent postoperative transoesophageal echocardiography, and no more than trace/mild paravalvular regurgitation was tolerated in either group.

Statistical analyses

Data are reported as mean ± standard deviation, median (interquartile range) or percentage for categorical variables. We used the *Student's t-test* to compare continuous variables; associations between categorical were evaluated using the χ^2 or Fisher exact test, as appropriate (expected count of <5). Because several preoperative variables were different between the conventional and sutureless valve groups, we evaluated a propensity score matched cohort using an automated procedure to select similar patients stratified by surgical approach. The propensity score was based on a backward stepwise logistic regression model (*P*-value > 0.10 to remove) for sutureless valves, including gender, age, arterial hypertension, diabetes mellitus, hypercholesterolaemia, renal dysfunction, respiratory or lung disease, previous disabling stroke, history of cancer, atrial fibrillation, peripheral vascular disease, coronary artery disease, ejection fraction category, previous surgery, urgency of procedure and EuroSCORE II. Model calibration was verified by the Hosmer–Lemeshow test. Discrimination evaluation was based on the area under the receiver operating curve. Matching was performed at a 1:2 ratio, selecting for each patient who had an AVR with a sutureless prosthesis 2 patients who had the conventional one. Selection was stratified by surgical approach on the basis of the lowest absolute difference in propensity scores within a maximum calliper width of 0.25 of the standard deviation of the linear predictor of the propensity score [16]. Absolute standardized differences in the distribution of patient characteristics before and after matching were depicted. Post-matching standardized differences <10% indicate a successful balance. Mixed regression models with matched patients as random effects were used to evaluate the data of paired patients (linear for continuous variables and logistic for binary data). Odds ratios with 95% confidence intervals were estimated. Mixed regression models with the operators as the random effect were used to estimate the relationship between the cross-clamp time and the surgical approach, implanted valve and surgical experience. The intraclass correlation coefficient was used to quantify the proportion of cross-clamp time variability explained by the operator. The temporal trend over 2 years in the proportion of procedures with sutureless and conventional valves are displayed graphically. To assess cross-clamping time in the most recent procedures (50% of operations, second half) compared to the earlier procedures (50% of operations, first half), we graphically reported the mean value and standard error within the operators. All analyses were conducted using STATA software, version 14 (Stata-Corp LP, College Station, TX, USA). The *P*-value was 2-sided, and the level of statistical significance was 0.05.

RESULTS

A total of 3402 patients received isolated aortic replacement valves with minimal access approaches. A total of 475 patients had sutureless valves, and 2927 had conventional bioprostheses. The yearly number of sutureless valve implants increased over the years: Fig. 1 shows the proportion of patients receiving the 2 types of prostheses. In the last 2 years, there were ∼1000 interventions, one-third of them involving a sutureless valve (Fig. 1). Table 1 shows patient characteristics by study group. In comparison to conventional AVR, patients receiving sutureless prostheses were more frequently women and older with a greater prevalence of atrial fibrillation but a lower prevalence of diabetes, hypercholesterolaemia, peripheral vascular disease and coronary artery disease.

The matching procedure paired 430 sutureless with 860 conventional AVRs. The logistic multivariable model, used to generate the propensity score, included in the final step of backward stepwise selection the following variables: sex, age, coronary artery disease, diabetes, hypercholesterolaemia, atrial fibrillation, left ventricular ejection fraction and previous surgery. The model had good discrimination and calibration in predicting the surgical approach (area under the receiver operating curve = 0.75 and Hosmer–Lemeshow test *P* = 0.542). No differences in demographic

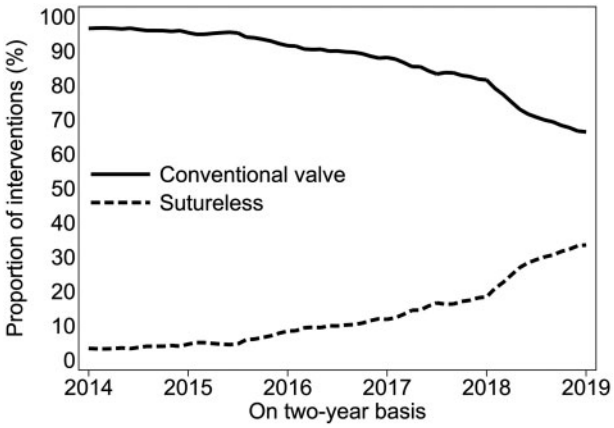


Figure 1: On a 2-year basis, proportion of procedures with sutureless and conventional valves.

Table 1: Characteristics of patients by prostheses in the overall population and in the subgroups paired by propensity score

		Overall			Paired by matching criteria		
	All *n* = 3402	Standard *n* = 2927	Sutureless *n* = 475	*P*-value	Standard *n* = 860	Sutureless *n* = 430	*P*-value
Male gender	51.5%	53.7%	37.9%	<0.001	40.7%	40.2%	0.842
Age (years)	76 (70–80)	75 (69–80)	77 (73–82)	<0.001	77 (72–81)	77 (72–82)	0.547
Body mass index (kg/m^2)	26.8 (24.2–29.8)	26.8 (24.3–30.0)	26.3 (23.9–29.1)	0.161	26.7 (24.2–29.7)	26.4 (23.7–29.3)	0.338
Arterial hypertension	74.2%	74.3%	73.3%	0.629	74.9%	73.3%	0.512
Diabetes mellitus							
Oral antidiabetic drugs	11.9%	12.6%	7.6%	0.002	9.9%	7.9%	0.248
Insulin	3.4%	3.3%	4.0%	0.420	4.9%	4.2%	0.564
Hypercholesterolaemia	51.2%	52.1%	45.3%	0.005	46.2%	44.9%	0.653
Renal dysfuntion	3.4%	3.6%	2.7%	0.365	4.1%	3.0%	0.345
Respiratory or lung disease	8.1%	8.3%	6.5%	0.187	6.2%	7.2%	0.437
Previous disabling stroke	1.5%	1.5%	1.3%	0.687	1.5%	1.4%	0.870
History of cancer	6.4%	6.7%	4.4%	0.060	4.7%	4.7%	>0.999
Atrial fibrillation	9.6%	8.8%	14.3%	<0.001	12.6%	14.4%	0.327
Peripheral vascular disease	6.8%	7.3%	4.0%	0.009	5.3%	4.4%	0.472
Coronary artery disease	12.3%	13.2%	7.4%	<0.001	8.1%	8.1%	>0.999
Left ventricular ejection fraction				0.347			0.967
LVEF >50%	80.3%	80.4%	78.4%		78.3%	78.3%	
LVEF 30–50%	19.2%	19.1%	20.3%		20.9%	20.7%	
LVEF <30%	0.6%	0.5%	1.3%		0.7%	0.9%	
Previous surgery	1.3%	1.2%	1.9%	0.211	1.9%	1.9%	>0.999
EuroSCORE II (%)	1.6 (1.1–2.8)	1.6 (1.1–2.7)	1.8 (1.3–3.1)	0.387	1.7 (1.2–2.9)	1.8 (1.3–3.1)	0.247
Urgent procedure	6.6%	6.4%	8.2%	0.139	7.4%	7.0%	0.762

Median (interquartile range) or percentage. Renal dysfunction: dialysis or creatinine >2 mg/dl. Body mass index available for 2213 patients (175 sutureless) and left ventricular ejection fraction for 2655 patients (231 in sutureless).
LVEF: left ventricular ejection fraction.

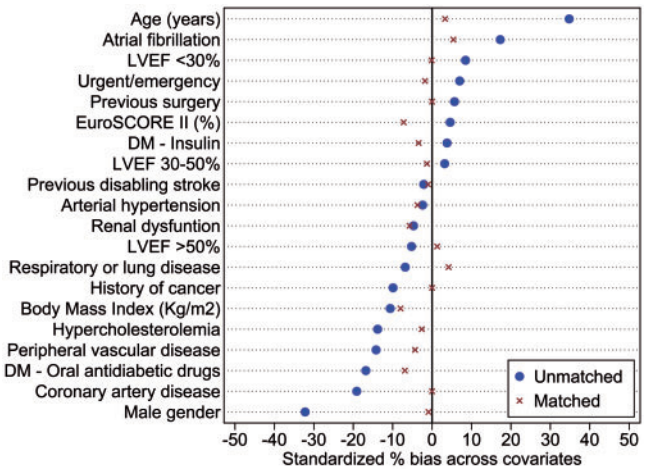


Figure 2: Absolute standardized differences between preoperative data before and after matching. DM: diabetes mellitus; LVEF: left ventricular ejection fraction.

and preoperative data were observed between the 2 matched groups (Table 1). Absolute standardized differences between groups of preoperative data before and after matching were reduced in the matched sub-sample compared with the overall population (Fig. 2).

Table 2 reports intra- and postoperative data in both overall study groups and matched sub-samples. About one-third of procedures were performed as thoracotomies and two-thirds as partial hemisternotomies without differences between groups. Cross-clamp times were significantly longer in the conventional valve replacement than in the sutureless group, both in the overall population and in subjects paired by propensity score. No statistically significant difference in major complications was observed with the exception of fewer blood transfusions (also in paired procedures) and fewer cases of atrial fibrillation in patients receiving sutureless valves that showed also a slightly shorter postoperative period in the overall cohort (mean difference 1 day, standard error 0.4; $P = 0.013$). A total of 47 patients died (1.4%), 4 in the sutureless group (0.8%) and 43 in the conventional valve replacement group (1.5%). Figure 3 shows observed and expected deaths in the overall population and in the matched patients. No difference in permanent pacemaker insertion was observed in the overall population (3.3% vs 4.4% in the standard and sutureless groups, respectively; $P = 0.221$) and in the matched groups (3.6% vs 4.7% in the standard and sutureless groups, respectively; $P = 0.364$).

Of 66 surgeons, 16 performed more than 60 procedures (third quartile of operators' number of interventions, top-volume group). Minithoracotomies and sutureless valves were significantly more common among the top-volume surgeons (37.7% vs 16.1% and 14.1% vs 7.9%) whose operations required shorter cross-clamp times (62 ± 23 vs 73 ± 34 min). About one-third of the cross-clamp time variability was explained by the surgeon (intraclass correlation coefficient 0.335). Among the less experienced surgeons (<60 interventions), cross-clamp time was not related to the surgical approach, but it was lower for sutureless valve implants (-16 ± 6 min; $P = 0.010$). The cross-clamp time decreased as surgical experience increased (6 ± 2 min saved for each 10 interventions previously performed; $P = 0.002$). Figure 4 depicts cross-clamp times in operators with at least 10 interventions according to surgical approach, type of valve implanted and period of surgery (first and second half of similar procedures chronologically performed). The mean cross-clamp time was

Table 2: Intra- and postoperative data by type of prosthesis in the overall population and in the subgroups paired by propensity score

		Overall			Paired by matching criteria		
	All *n* = 3402	Standard *n* = 2927	Sutureless *n* = 475	*P*-value	Standard *n* = 860	Sutureless *n* = 430	*P*-value
Intraoperative							
Surgical approach							
Minithoracotomy	35.1%	35.2%	34.7%	0.859	33.5%	33.5%	–
Ministernotomy	64.9%	64.8%	65.3%	0.859	66.5%	66.5%	–
Cardiopulmonary bypass time (min)	76 (59–93)	77 (60–94)	65 (55–83)	0.053	78 (61–91)	65 (54–84)	0.281
Cross-clamp time (min)	61 (46–75)	63 (47–76)	48 (40–63)	<0.001	63 (48–74)	48 (40–62)	<0.001
Postoperative							
Blood transfusion	33.4%	34.7%	25.1%	<0.001	33.5%	27.4%	0.022
Renal function worsening	5.1%	5.3%	3.6%	0.107	4.9%	4.0%	0.446
New-onset atrial fibrillation	23.9%	25.0%	17.1%	<0.001	20.3%	18.6%	0.435
Permanent pacemaker insertion	3.5%	3.3%	4.4%	0.221	3.6%	4.7%	0.364
Wound infection	0.5%	0.5%	0.4%	>0.999*	0.5%	0.5%	>0.999
Reopening bleeding/complications	3.4%	3.5%	2.9%	0.573	2.8%	3.0%	0.814
Pulmonary complication/reintubation	3.1%	3.3%	2.1%	0.162	3.4%	2.3%	0.303
Tracheostomy	0.9%	1.1%	0.2%	0.117*	0.8%	0.2%	0.239
Confusion/delirium	1.5%	1.5%	1.3%	0.687	1.6%	1.2%	0.507
Stroke	0.5%	0.5%	0.4%	>0.999*	0.2%	0.5%	0.488
Low cardiac output	2.3%	2.5%	1.5%	0.186	2.8%	1.6%	0.202
Sepsis	0.6%	0.7%	0.4%	0.759*	1.0%	0.5%	0.297
Cardiac arrest	0.4%	0.4%	0.4%	>0.999*	0.6%	0.5%	0.788
Urinary tract infection, length of stay (days)	1.9 (1.2–2.0)	1.9 (1.1–2.0)	1.9 (1.7–2.7)	0.561	1.9 (1.6–2.1)	1.9 (1.7–2.7)	0.070
Postoperative days	8 (7–13)	8 (7–13)	8 (7–11)	0.013	8 (7–11)	8 (7–11)	0.531
Deaths	1.4%	1.5%	0.8%	0.278	2.1%	0.7%	0.076

Median (interquartile range) or percentage. Low cardiac output: intra-aortic balloon pump and/or inotropic use for >2 days.
**P*-value by using the Fisher exact test.

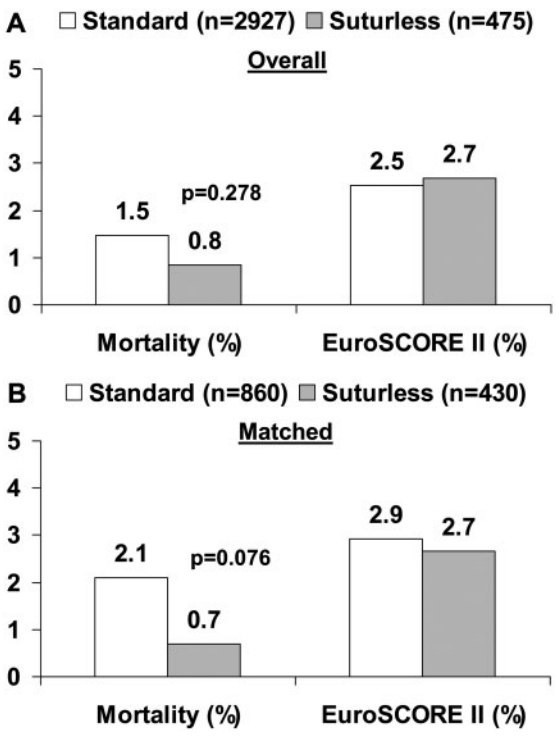


Figure 3: Observed (**A**) and expected (**B**) deaths with sutureless and conventional valves in the overall population and in the matched patients.

reduced by 5 ± 1 min ($P = 0.002$) in the second period (greater experience) and for sutureless compared to standard valve (-11 ± 2 min; $P < 0.001$) with lower values associated with a minithoracotomy, especially in the second period (Fig. 4A). Surgeons who implanted both types of valves using the same surgical approach had lower cross-clamp times with sutureless than with conventional prostheses, especially for those interventions performed via a minithoracotomy (Fig. 4B).

DISCUSSION

The results of our study show that sutureless prostheses facilitate the adoption of a minimally invasive approach, thereby reducing cardiac arrest time and the number of blood transfusions.

We recently demonstrated in a large multicentre study that a minimally invasive AVR improves postoperative outcome by reducing hospital deaths compared to conventional surgery [7]. The goal of the present study was to further evaluate the potential benefit of this technique by analysing clinical outcome in patients undergoing minimally invasive AVR using sutureless or standard stented bioprostheses.

The results obtained are positive in terms of hospital deaths and postoperative morbidity in both groups; they confirm that minimally invasive AVR is a safe and reproducible technique and should also be considered in light of the fact that many of these patients would have been offered a transcatheter procedure only because of their age.

It is usually accepted that 'short' aortic clamping times are associated with better clinical results [17, 18].This is the first multicentre study involving many surgeons (over 20 surgeons implanted both the sutureless and conventional models) that shows the reproducibility as well as the effectiveness of lowering the cross-clamp time during minimally invasive AVR using sutureless valves rather than

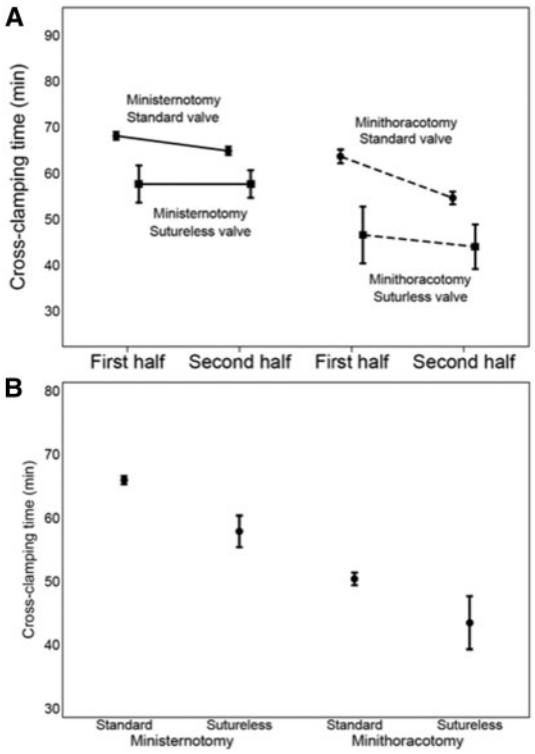


Figure 4: Cross-clamp time by surgical approach and valve type in the first and second halves of the procedures (**A**) and its mean value and standard error for operators who inserted both sutureless and conventional valves using the same surgical approach (**B**). Operators who performed fewer than 10 procedures were excluded.

standard prostheses. Cardiopulmonary bypass times were not significantly shorter in the sutureless group despite a downwards trend. Recently published multicentre data on sutureless and rapid deployment mini-AVR demonstrates mean cross-clamp times and cardiopulmonary bypass times similar to those that we report [19]. The analysis made in 4 separate subgroups (sutureless or standard bioprosthesis via ministernotomy and sutureless or standard bioprosthesis via minithoracotomy) shows the same efficacy in each of them (Supplementary Material). The operations were also performed by surgeons without extensive experience with the minimally invasive approach. The times of cardiac ischaemia were shortened by reducing surgical complexity, which might have contributed to improved outcomes in patients who received sutureless valves.

What has the greatest influence on the 'lengthening' of operating times? In our study, the average times for thoracotomies were lower than those for ministernotomies, which goes against the trend observed in previous studies indicating that a ministernotomy is faster than a minithoracotomy [20]. Our result is probably explained by the skill and experience with the minithoracotomy of some of the surgeons, some of whom have been using this procedure for years [21, 22]. This fact also explains the results shown in Fig. 4: The cross-clamp time decreased more significantly between the first and second phases of the experience in the 'standard + minithoracotomy' patients since, '*per se*', the Perceval prosthesis does not have a 'real' learning curve. On the other hand, less experienced surgeons approaching a minithoracotomy have reduced surgical times that were initially high. In other words, the most difficult thing to learn is not the Perceval implant but the minithoracotomy approach '*per se*', which requires a more demanding and dedicated training.

The occurrence of rhythm disorders and of permanent pacemaker insertions did not differ between patients treated with a sutureless and a standard prosthesis. Compared to the initial experiences with sutureless and rapid deployment valves, multicentre reports have described a significant reduction in the insertion of permanent pacemakers [20.6% (2009–2010) to 5.6% (2017–2018)] due to the learning curve and the refinement in implant techniques [10]. After adjustment for preoperative rhythm disturbances, no increased risk of permanent pacemaker insertion has been described for sutureless and rapid deployment valves [23].

Our study has a number of limitations due to the retrospective design. The centralized database includes a large amount of information but some may be missing either by omission during the collection process or due to the absence of the collection field. An example is the lack of information regarding transvalvular gradients and the site of arterial cannulation (antegrade aortic or retrograde femoral). Another drawback is the lack of objective criteria for patient selection for a particular procedure and/or valve choice. These drawbacks obviously can contribute to study bias, and propensity matching can only partially address this issue. Being retrospective, the study lacks protocol-based transfusion criteria; therefore these data should be interpreted with caution. Follow-up data are beyond the scope of this study, but they would add important information regarding survival, systemic embolism and structural valve deterioration.

In conclusion, the use of a sutureless prosthesis facilitates minimally invasive AVR, allowing a significant reduction in the operating time and a better postoperative outcome compared to the use of a 'standard' prosthesis. Future comparisons between AVR and transcatheter aortic valve implants should be performed with the minimally invasive approach and sutureless valve in the surgical arm of the study.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *ICVTS* online.

Conflict of interest: Dr Alberto Albertini and Dr Mauro Del Giglio received proctoring fees from LivaNova.

Author contributions

Domenico Paparella: Conceptualization; Methodology; Supervision; Writing—original draft; Writing—review & editing. **Giuseppe Santarpino:** Conceptualization; Data curation. **Marco Moscarelli:** Conceptualization; Data curation; Methodology. **Pietro Guida:** Data curation; Formal analysis; Software. **Adriano De Santis:** Data curation; Methodology. **Kahlil Fattouch:** Conceptualization; Data curation; Methodology. **Luigi Martinelli:** Conceptualization; Data curation; Methodology; Writing—review & editing. **Roberto Copppola:** Data curation; Investigation; Methodology. **Elisa Mikus:** Conceptualization; Data curation; Methodology. **Alberto Albertini:** Conceptualization; Data curation; Supervision. **Mauro Del Giglio:** Data curation; Methodology; Supervision. **Renato Gregorini:** Conceptualization; Data curation; Writing—review & editing. **Giuseppe Speziale:** Conceptualization; Data curation; Methodology; Writing—original draft.

Reviewer information

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