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RESEARCH

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Prognostic impact of small size sutureless prostheses: results for 241 patients from an international registry

Giuseppe Santarpino[1,2,3*], Roberto Lorusso[4], Giovanni Concistrè[5], Josè Cuenca Castillo[6], Vincenzo Argano[7], Alistair Royse[8], Angelo Lucas Nobre[9], Patrick Parrino[10], Gianluigi Bisleri[11], Max Baghai[12], Theodor Fischlein[3], Giovanni Troise[13], Generoso Mastrogiovanni[14], Raphael Fontaine[15], Davide Pacini[16], Giuseppe Minniti[17], Aniello Pappalardo[18], George Chad Hughes[19], Philippe Noirhomme[20], Jean-Philippe Grimaud[21], Maximilian Scherner[22], Ignacio Muñoz[23], George Asimakopoulos[24], Antony Walker[25], Daniela Zakova[26], Michele Torella[27], Giorgio Vigano[28], Mark Connolly[29], Christian Dinges[30], Pierre Corbi[31], Loris Salvador[32], Mauro Rinaldi[33], Luis Maroto[34], David Heimansohn[35], Basel Ramlawi[36], Mattia Glauber[37], Jlenia D'Agnano[2], Valeria Cosco[2], Veronica D'Anna[2] and Marco Solinas[5]

Abstract

Background The treatment of aortic valve disease in small annuli remains a debated topic in terms of prosthetic choice - biological or mechanical - and risk of patient prosthesis mismatch.

Methods The clinical data of the 241 patients who received a small size sutureless prosthesis from the Sorin Universal REgistry on Aortic Valve Replacement (SURE-AVR) (NCT02679404) were analysed at 30 days and at follow-up. The mean age was 75.5 ± 7.8 years (89.2% female); the mean Society of Thoracic Surgeons (STS) score was 4.2 ± 3.2%, and the preoperative NYHA class II or III score was 83.8%. A minimally invasive approach was performed in 52.7% of patients; concomitant procedures were performed in 27.8% of patients. Similar aortic clamping and cardiopulmonary bypass times were observed in the overall isolated cohort and the isolated minimally invasive cohort. The mean intensive care unit (ICU) stay was 2.4 ± 2.0 days and the total length of stay was 10.3 ± 6.1 days.

Results Three deaths were recorded at 30 days (1.2%), 2 for noncardiac causes. One patient experienced a myocardial infarction (0.4%) and 2 a nondisabling stroke (0.8%). 2 patients showed intraprosthetic leakage ≥ 2 and one patient para-prosthetic leakage ≥ 2; of these, one patient required reoperation with prosthesis removal. 4.1% of patients required a pacemaker implant. At a maximum follow-up of 8.1 years, 10 cardiovascular deaths, 4 valve related reinterventions (3 structural valve deterioration (SVD) requiring TAVI Valve-in-Valve, 1 endocarditis) occurred.

Conclusions With their good clinical outcomes, sutureless prostheses represent a good alternative for patients with small annuli, who are at high risk for annular enlargement and anticoagulant therapy.

*Correspondence:
Giuseppe Santarpino
gsantarpino@gvmnet.it

Full list of author information is available at the end of the article

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Keywords Biological heart prosthesis, Sutureless aortic valve, Patient–prosthesis mismatch, Follow-up outcome

Background

Aortic stenosis in small annuli presents a distinctive challenge in cardiovascular pathology. In the case of aortic valve replacement in this setting, the selection of an appropriate prosthesis and the surgical approach are crucial to ensure optimal outcomes. This type of patient has a lower body surface area and more comorbidities, resulting in a higher risk of perioperative and postoperative morbidity and mortality. Moreover, the risk of patient-prosthesis mismatch is high [1, 2], a phenomenon that many authors have associated with the risk of heart failure, rehospitalization, reoperation and mortality [3–7].

These are the reasons why the use of aortic valve replacement in patients with small annuli remains an open debate. Numerous strategies, each with a unique set of benefits and drawbacks, have been proposed over the years, including root enlargement, stented valves, stentless or sutureless bioprostheses and, more recently, transcatheter valves. The choice of intervention should be meticulously tailored to individual patient factors, including age, anatomy, and comorbidities.

Perceval sutureless pericardial prostheses (Corcym S.r.l., Saluggia, Italy) have demonstrated the ability to significantly reduce invasiveness and surgical times and to improve patient outcomes [8]. Moreover, the lack of sutures and sewing rings can lead to better hemodynamic results than those obtained with a stented biological prosthesis of the same size.

The aim of this study was to report the real-word clinical performance of the Perceval valve size Small (annulus ranging from 19 to 21 mm) in patients who underwent AVR with a small annulus, analysing data from the SURE-AVR registry.

Methods

The Sorin Universal REgistry on Aortic Valve Replacement (SURE-AVR) registry is a real-world, prospective and observational registry that involves 18 countries around the world between 2011 and 2021 and was sponsored by Corcym S.r.l. to monitor its products on the market, collecting preoperative, postoperative and follow-up clinical data. Follow-up visits were performed according to the centers' usual practices (by telephone call, referring physician or clinical visit). For all centers involved, ethics committee and/or institutional review board approval was obtained as required by local regulations. All patients provided informed consent to participate, although it is a register with the use of products already on the market and standardized procedures according to the experiences and habits of the individual centers.

As the goal of a real-world study is to report on the standard of care, the indications/contraindications reported in the "instructions for use" of Perceval were the only inclusion and exclusion criteria applied.

Data from the overall Perceval cohort included in the SURE-AVR registry have been published recently [9], as well as the analysis of the subgroups undergoing sutureless prosthesis surgery in a reoperation setting [10], the MICS approach [11] or in a combined approach for mitral valve surgery [12].

The Perceval valve is a surgical pericardial aortic prosthesis with a sutureless and collapsible design. It comprises two main components: a double-sheet bovine pericardium and a self-anchoring, self-expanding, superelastic Nitinol stent that holds the valve in place without the need for sutures. The prosthesis is available in 4 sizes (Small, Medium, Large, X-Large), covering an annular diameter ranging from 19 to 27 mm.

The implantation technique of the Perceval prosthesis has been described previously [13]: an important step we want to underline is the correct valve sizing, which allows better results in terms of prosthesis functionality [14, 15]. Cerillo et al. demonstrated that oversizing with this valve should be avoided, as it is associated with higher transprosthetic gradients, a higher rate of pacemaker implantation and an increased risk of stent recoil, with subsequent paravalvular leak due to loss of contact between the prosthesis and the annulus.

This study focused on patients who received an "S" size prosthesis. The annulus diameters of the patients were not evaluated through a preoperative CT scan; therefore, we assumed that correct intraoperative sizing had been performed and that being implanted with a size S meant having an annulus ranging between 19 and 21 mm, qualifying as a patient with a small annulus.

Variables are described as means ± standard deviations and as numbers (%) for categorical variables. The outcomes are reported as descriptive statistics. The percentage of early adverse events was calculated as the total number of events divided by the total number of patients. Linearized late complication rates (and 95% confidence intervals) were calculated as the number of late events (> 30 days) divided by the number of late patient-years. Survival and freedom from events were evaluated via the Kaplan–Meier method, with 95% confidence intervals (CIs) around the estimates. The statistical analyses were performed via SAS (Release 9.4, by SAS Institute Inc., Cary, NC, USA).

Table 1 Baseline characteristics.

Baseline data	*N* = 241
Age (years), mean (SD)	75.5 ± 7.8
Female, *N* (%)	215 (89.2)
BSA, mean (SD)	1,7 ± 0.2
Dyslipidemia, *N* (%)	138 (57.3)
Diabetes, *N* (%)	64 (26.6)
Chronic lung disease, *N* (%)	34(14.1)
Renal insufficiency, *N* (%)	19 (7.9)
Peripheral vascular disease, *N* (%)	14(7.8)
Previous cardiac procedures	50 (20.7)
Previous myocardial infarction, *N* (%)	16 (6.6)
Previous CVA, *N* (%)	10(4,1)
Left Ventricular Ejection Fraction, *N*N (%)	58.7 ± 10.4
NYHA class 11–111, *N* (%)	202 (83.8)
Preop sinus rhythm, *N* (%)	202 (83.8)
Endocarditis, *N* (%)	5 (2.1)
Bicuspid valve, *N* (%)	11 (4.6)
STS (%), mean (SD)	4.2 ± 3.2

BSA: body surficial area, SO: standarddeviation, NYHA: New York Heart Association, ST$: society of Thoracic Surgeons

Table 2 Operative characteristics.

Operative data	*N* = 241
Surgical approach:	
Stemotomy, *N* (%)	113(47.1)
Mini-stemotomy, *N* (%)	82 (34.0)
Mini-thoracotomy, *N* (%)	45 (18.7)
First successful implant, *N* (%)	238 (98.8)
Concomitant procedure, *N* (%)	67 (27.8)
CABG	40 (16.6)
Myectomy	2 (0.8)
AF ablation	2 (0.8)
Thoracic aortic surgery	2 (0.8)
MV repair	8 (3.3)
MV replacement	7 (2.9)
TV repair	7 (2.9)
Other	10(4.1)
CC time (min)-Overall, mean (SO)	59.2 ± 30.2
CPB time (min) - Overall, mean (SO)	85.6 ± 38.7
CC time (min)- Isolated AVR, mean (SO)	50.7 ± 20.3
CPB time (min)- Isolated AVR, mean (SO)	76.0 ± 28.9
CC time (min)- Isolated AVR minimally invasive approach, mean (SO)	51.1 ± 18.6
CPB time (min)- Isolated AVR, minimally invasive approach mean (SO)	76.9 ± 26.5

CABG: Coronary artery bypass grafting; AF: atrial fibrillation; MV: mitral valve; TV: tricuspid valve; CC: Cross Clamp; CPB: cardiopulmonarybypass; AVR: aortic valve replacement

Results

Between March 2011 and June 2021, 1652 patients underwent AVR with the Perceval sutureless valve at 55 international institutions; among them, 241 patients (14.6%) received a size S.

Baseline characteristics

The baseline characteristics are detailed in Table 1. A total of 89.2% of the patients were female, with a mean body surface area of 1.7 ± 0.2. The mean age was 75.5 ± 7.8 years, the predicted risk score (STS) was 4.2 ± 3.2%, and 83.8% of patients had a preoperative NYHA class II or III.

Procedure

Table 2 shows the intraoperative data. Approximately half of the patients (52.7%) received a sutureless prosthesis through a minimally invasive approach, and over a quarter of the patients (27.8%) underwent concomitant procedures, mostly CABG (16.6%), mitral valve repair or replacement (6.5%) and tricuspid valve repair (2.9%).

The Perceval valve was successfully implanted at the first attempt in 238 (98.8%) patients; the remaining 3 patients still received a Perceval size S at the second and successful attempt. The mean overall aortic clamping and cardiopulmonary bypass times were 59.2 ± 30.2 and 85.6 ± 38.7 min, respectively.

Postoperative outcomes

During the postoperative period, the mean ICU stay was 2.4 ± 2.0 days, and the total length of stay was 10.3 ± 6.1 days.

Three deaths were recorded at 30 days (1.2%), two of them for noncardiac causes. One patient experienced a myocardial infarction (0.4%) and two a nondisabling stroke (0.8%). Two patients showed intraprosthetic leakage ≥ 2 and one patient para-prosthetic leakage ≥ 2; among them, only one patient required reoperation with prosthesis removal. 4.1% of patients (10 patients) required a pacemaker implant.

The longest follow-up was 8.1 years (2971 days), and the cumulative follow-up was 406.9 patient-years. The follow-up rate was 99.6% completed at discharge/30 days, 73.6% at 1 year, 71.4% at 5 years and 83.3% at 7 years.

The NYHA class trends up to the 5-year follow-up are shown in Table 3.

The number of deaths at follow-up was 21 (5.2% pts-years): 7 patients died due to unknown causes, 2 due to myocardial infarction, 1 due to worsening of heart failure and 11 due to noncardiac causes. No patient died due to recordable proven "valve-related" causes. Four cases of valve-related reintervention were registered (1.0% pts-years) due to endocarditis (1 case) or structural valve deterioration (3 cases requiring the TAVI Valve-in-Valve procedure). Furthermore, 2 nondisabling cerebrovascular events and 3 bleeding events due to anticoagulant therapy were recorded.

Figure 1 shows the rates of freedom from death, from reintervention and from reintervention due to SVD, respectively. There were only three cases of structural

Table 3 NYHA class trend up to the 5-year follow-up

NYHA class, *N*(%)	Discharge	1 year	2 years	3 years	4 years	5 years
I	84 (35)	51 (49.5)	22 (38.6)	17 (43.6)	11 (42.3)	11 (44)
II	56 (23.3)	30 (29.1)	31 (54.4)	15 (38.5)	9 (34.6)	9 (36)
III	5 (2.1)	7 (6.8)	2 (3.5)	5 (12.8)	2 (7.7)	4 (16)
IV	2 (0.8)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Not available	93 (38.8)	15 (14.6)	2 (3.5)	2 (5.1)	4 (15.4)	1 (4)

valve deterioration requiring redo at 5.1, 6.2 and 7.3 years.

Discussion

Surgical aortic valve replacement in patients with symptomatic valve stenosis remains the first therapeutic strategy in a large proportion of patients, despite the introduction of transcatheter techniques [16]. The primary purpose of this intervention is to reduce pressure overload on the left ventricle, facilitating its remodelling and improving its function. This is the physiopathological reason why it is preferable to implant a larger-sized valve to improve hemodynamics. However, this is not always anatomically possible and could result in the development of patient–prosthesis mismatch, particularly in patients with small annuli.

A small annulus is not uncommon, especially in the Western world population, where patients are increasingly elderly and often small-sized women [17]. In this context, with multiple comorbidities, the selection of an appropriate prosthesis and the surgical approach are crucial to ensure optimal outcomes.

Different strategies have been proposed over the years: aortic root enlargement, TAVI, mechanical valves and sutureless bioprostheses.

Aortic root enlargement allows expansion of the annular dimensions and enhances hemodynamic performance; however, it is a technically demanding procedure that is not suitable for all patients and has an increased risk of complications [18] and longer operating times [19]. Some authors have studied the mortality risk in cases of annular enlargement in patients older than 80 years, who are likely to have calcified and fragile tissue; the rate of mortality is 10% and the rate of complications is 75%, respectively [20]. It is important to interpret these findings in a modern context where transcatheter technologies are increasingly available [21].

In fact, evidence supporting the use of TAVI in small rings in the literature is increasing [22, 23].

Another option is stented mechanical prostheses, which are known for their durability, allowing rapid and low-risk intervention. Despite the need for anticoagulant therapy for elderly patients, mechanical valves still represent a reasonable choice compared with small biological stent prostheses, allowing a larger effective orifice area and avoiding the risk of early degeneration [24, 25], with good clinical results [26]. In their study, Vicchio et al. demonstrated that mechanical valves in octogenarians are associated with low rates of valve-related complications and similar rates of early mortality and thromboembolic or haemorrhagic complications as biological valves. Recently, a meta-analysis compared the outcomes of small-annuli patients receiving stented biological versus mechanical valves and revealed that there was no difference in terms of mortality, incidence of SVD adverse events at follow-up; however, patients receiving tissue valves had a higher rate of PPM and significantly less left ventricle mass regression [27].

The main issue with biological valves is the risk of structural degeneration, even though it is a result linked to specific biological models, especially small stented bioprostheses [28, 29]. In reality, the pivotal factor leading to the risk of structural valve degeneration is not the design of the prosthesis [30–33] whether the risk of PPM [34], i.e., the small diameter itself in relation to the size of the patient.

Among bioprostheses, one possibility is the use of a sutureless prosthesis: this solution combines good clinical and hemodynamic outcomes - similar to those of stentless prostheses - with rapid implantation, lowering the degree of surgical risk [35].

The experience with the Perceval sutureless technology is 15 years long, with long-term evidence reported by different papers: up to 13 years by Lamberigts et al. [36] and up to 10 years by Pollari et al. [37] and by Concistrè et al. [38]. As mentioned above, the main concern of biological valves is the freedom from SVD and durability: this is not an issue with this type of valve, since Perceval has shown an SVD rate of 0.54%/pt- years [36]. However, in the case of persistent degeneration, valve-in-valve TAVR is a feasible option, as described by the recent publications of Concistrè et al. [39] and Doubois et al. [40], with a low complication rate and excellent hemodynamic performance at midterm follow-up.

The clinical data presented in this study are consistent with those already reported in the literature, both at discharge and during long-term follow-up.

Our study shows the clinical results with the Perceval sutureless bioprosthesis in 241 patients who underwent AVR patients with a small size Perceval valve were enrolled in the SURE-AVR registry. Our data demonstrate that the implantation of Perceval bioprosthetes is

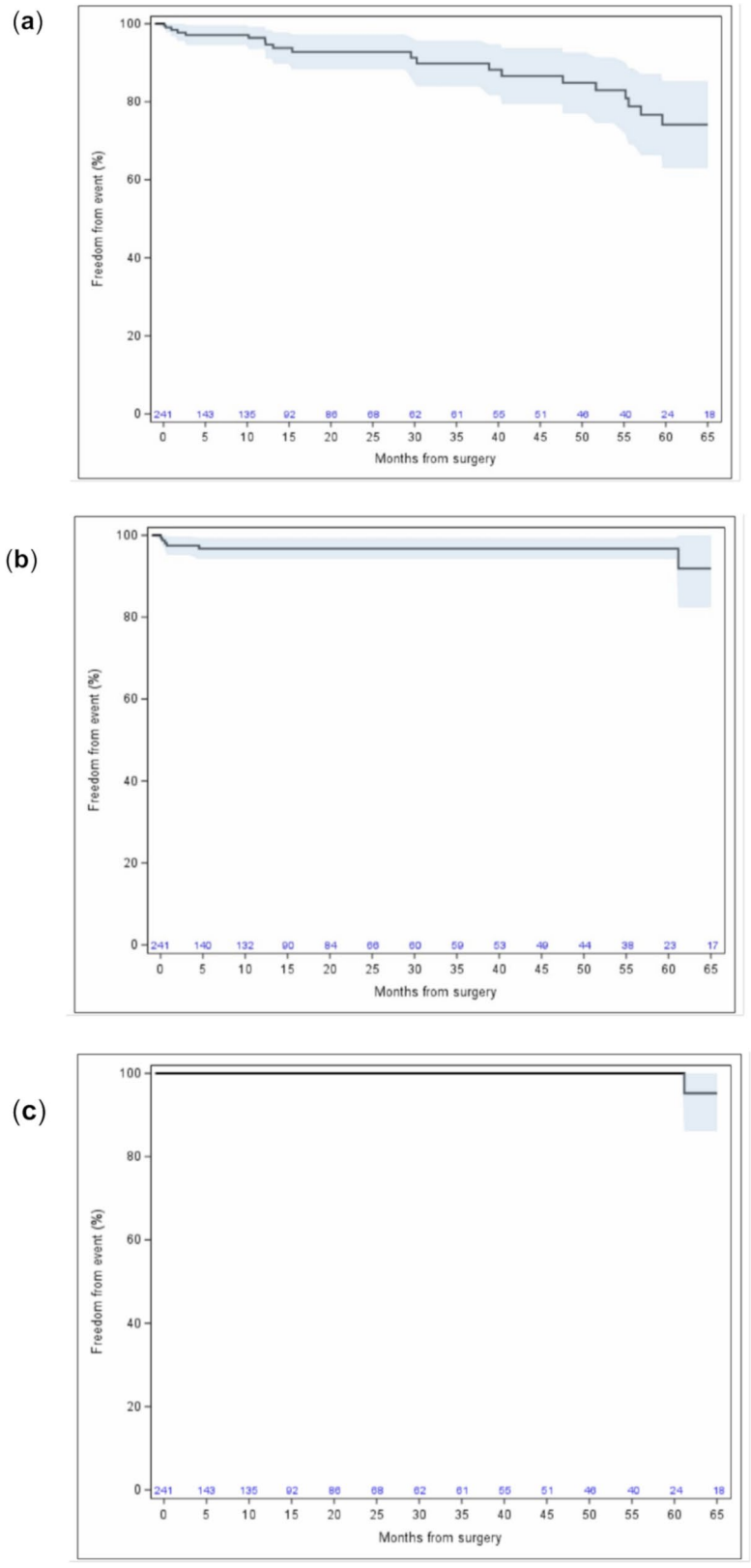

Fig. 1 Kaplan-Meier Curves: (**a**) Freedom from death; (**b**) Freedom from reintervention; (**c**) Freedom from reintervention due to SVD

a safe and feasible procedure associated with good early and late clinical outcomes in a population with a high risk of PPM, symptom recurrence and long-term mortality.

In our experience, the described cohort was, on average, 75 years old, at low-to-intermediate risk (STS score 4.2 ± 3.2%), and almost 90% were female. 53% of patients were implanted through a minimally invasive approach (mini-sternotomy or mini-thoracotomy), with an overall implantation success of 98.8%, demonstrating the suitability of the Perceval for minimal procedures owing to its unique collapsible profile. Moreover, the sutureless design allows for shorter procedural times. In our study, both the aortic cross clamp and cardiopulmonary bypass times were low, and in isolated procedures, there was no difference in procedural times when median sternotomy was compared with the minimally invasive approach (ACC time: 50.1 ± 23.8 vs. 51.1 ± 18.6, respectively; CPB time: 74.4 ± 33.8 vs. 76.9 ± 26.5, respectively).

The incidence of pacemaker implantation (4.1%) was comparable to that of conventionally stented valves, and early intra- and paravalvular leak rates were low (0.8% and 0.4%, respectively), as were 30-day cardiovascular death rates (0.4%). Survival at the 5-year follow-up was 86.1%. Unlike previous reports, this study was prospective and analysed the largest multicentric cohort of patients implanted with a Perceval bioprosthesis.

To the best of our knowledge, this is the first study that records the results of a large number of patients with a small aortic annulus receiving a Perceval "Small".

Even if we were not able to report the hemodynamic results, we can rely on previous studies that demonstrated satisfactory outcomes and performances up to midterm follow-up, regardless of the prosthesis size [41, 42]. Villa et al. [41] compared the performance of small size sutureless prostheses with that of larger models and reported similar hospital outcomes and no influence of prosthesis size on early-to mid-term survival. Aldea et al. [42] analysed the impact of valve size on hemodynamic and LV mass regression and reported that the mean and peak gradients remained low and stable up to 5 years across all valve sizes, as did significant and similar LV mass regression.

The limitations of this study are the same as those of any observational, prospective, nonrandomized registry: no monitoring and no adjudication of patients' inclusion and adverse events, no core laboratory review of the images, and no comparative arm.

The main limitation of this study is the lack of hemodynamic data. Since follow-up visits were performed according to the site's routine practice, echocardiographic follow-up data were not available for most of the patients. Therefore, we decided to report only clinical data.

The definition of "small annuli" is not based on a CT-scan sizing but rather on intraoperative sizing and subsequent implantation of a Perceval size S that is designed to fit an annulus ranging from 19 to 21 mm and adapts to it. Given the absence of leaks and migration in our data, we can reasonably conclude that the annuli analysed were up to 21 mm long. The lack of CT-based sizing may have reduced the precision in annular classification; however, the absence of paravalvular leaks or prosthetic dysfunction suggests that intraoperative sizing and surgical technique were appropriate. This observation aligns with the findings of Margaryan et al. [15], who emphasized the importance of accurate sizing to prevent prosthesis–patient mismatch or complications, and with Pfeiffer et al. [43], who showed that improper positioning of the prosthesis may result in paravalvular leaks.

The definition of structural valve deterioration is based on the Akins guidelines and not on the hemodynamic criteria.

Moreover, the absence of a control group precludes any direct comparison between the Perceval valve and other bioprostheses.

It should also be noted that the data presented derive from an observational registry sponsored by Corcym S.r.l., the manufacturer of the Perceval valve. Nevertheless, data collection and management were conducted by independent clinical centers, each following their own standard clinical procedures. Although no formal external adjudication was performed, the autonomy of the participating centers is considered sufficient to support the robustness and reliability of the results presented.

Conclusion

In conclusion, in our study, the use of sutureless prostheses proved to be a useful weapon in the treatment of patients with small annuli, with good clinical results, both at discharge and during long-term follow-up. The therapeutic alternatives in the hands of cardiac surgeons and hemodynamists in the case of "small annuli" are numerous, and our described strategy may be particularly indicated, in our opinion, in patients judged to be operable but at high risk for annular enlargement techniques and for subsequent anticoagulant therapy.

Abbreviations

SURE-AVR	Sorin Universal Registry on Aortic Valve Replacement
AVR	Aortic Valve Replacement
NCT	National Clinical Trial
STS	Society of Thoracic Surgeons
NYHA	New York Heart Association
ICU	Intensive Care Unit
SVD	Structural Valve Deterioration
TAVI	Transcatheter Aortic Valve Implantation
CT	Computed Tomography
CABG	Coronary Artery Bypass Grafting
MICS	Minimally Invasive Cardiac Surgery
ACC	Aortic Cross-Clamp

CPB	Cardiopulmonary Bypass
PPM	Patient-Prosthesis Mismatch
LV	Left Ventricle
CVA	Cerebrovascular Accident
BMI	Body Mass Index

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Author contributions
GS made substantial contributions to the conception, methods, data acquisition and interpretation, and writing and reviewing of the manuscript. RL, GC, JCC, VA, AR, ALN, PP, GB, MB, TF, GT, GM, RF, DP, GM, AP, GCH, PN, JPG, MS, IM, GA, AW, DZ, MT, GV, MC, CD, PC, LS, MR, LM, DH, BR, MG, MS participated in the data acquisition and interpretation and in the writing, reviewing and editing of the manuscript. The authors read and approved the final submitted manuscript and agreed to be personally accountable for their own contributions and to ensure that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved. JD, VC, VD participated in the review and contributed to the editorial process.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
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Competing interests
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Author details
[1]Department of Clinical and Experimental Medicine, Magna Graecia University, Catanzaro, Italy
[2]Department of Cardiac Surgery, Città di Lecce Hospital, GVM Care & Research, Lecce, Italy
[3]Paracelsus Medical University, Nuremberg, Germany
[4]Cardiothoracic Surgery Department, Heart and Vascular Centre, Maastricht University Medical Centre, Cardiovascular Research Institute Maastricht, Maastricht, The Netherlands
[5]Heart Hospital Pasquinucci Hospital of Massa, Massa, Toscana, Italy
[6]Complejo Hospitalario Universitario de A Coruña, A Coruña, Spain
[7]Unit of Cardiac Surgery, Policlinic Giaccone, University of Palermo, Palermo, Italy
[8]The Royal Melbourne Hospital, Parkville, Australia
[9]Santa Maria Hospital, Lisbon, Portugal
[10]Oschner Clinic Foundation, New Orleans, USA
[11]Kingston General Health Research Institute, Ontario, Canada
[12]King's College Hospital, London, UK
[13]Fondazione Poliambulanza Brescia, Brescia, Italy
[14]Ospedali Riuniti San Giovanni di Dio e Ruggi d'Aragona, Salerno, Italy
[15]Centre Hospitalier Régional de Namur, Namur, Belgium
[16]Policlinico Sant'Orsola– Malpighi, Bologna, Italy
[17]Azienda U.L.S.S n.9 Ospedale di Treviso Ca' Foncello, Treviso, Italy
[18]Az. Ospedaliero-Universitaria "Ospedali Riuniti" di Trieste, Trieste, Italy
[19]Duke University, Durham, USA
[20]UCL Saint Luc, Brussels, Belgium
[21]Clinique Saint Augustin, Bordeaux, France
[22]Universitätsklinikum Magdeburg, Magdeburg, Germany
[23]Hospital Reina Sofía de Córdoba, Córdoba, Spain
[24]Royal Brompton Hospital, London, UK
[25]Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, UK
[26]Centre of Cardiovascular Surgery and Transplantations, Brno-střed, Czech Republic
[27]Azienda Ospedaliera dei Colli - Ospedale Monaldi, Naples, Italy
[28]University Medical Center Groningen, Groningen, The Netherlands
[29]St.Joseph's Regional Medical, Paterson, USA
[30]LandesKrankenha us Salzburg, Salzburg, Austria
[31]Chu Poitiers, Poitiers, France
[32]Ospedale San Bortolo, Vicenza, Italy
[33]AOU Città della Salute e della Scienza di Torino - Ospedale Molinette, Torino, Italy
[34]Hospital Clínico San Carlos, Madrid, Spain
[35]St.Vincent Heart Center of Indiana, Indianapolis, USA
[36]Valley Health System, Ridgewood, USA
[37]Sant'Ambrogio Clinic, Milano, Lombardia, Italy

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