Randomized controlled trial between conventional versus sutureless bioprostheses for aortic valve replacement

International Journal of Cardiology xxx (xxxx) xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Randomized controlled trial between conventional versus sutureless bioprostheses for aortic valve replacement: Impact of mini and full sternotomy access at 1-year follow-up

Theodor Fischlein [a,*,1,2], Elena Caporali [b,c,1,2], Thierry Folliguet [d,1], Utz Kappert [e,1], Bart Meuris [f,1], Malakh L. Shrestha [g,1], Eric E. Roselli [h,1], Nikolaos Bonaros [i,1], Olivier Fabre [j,1], Pierre Corbi [k,1], Giovanni Troise [l,1], Martin Andreas [m,1], Frederic Pinaud [n,1], Steffen Pfeiffer [a,1], Sami Kueri [o,1], Erwin Tan [p,1], Pierre Voisine [q,1], Evaldas Girdauskas [r,1], Filip Rega [f,1], Julio García-Puente [s,1], Roberto Lorusso [t,1]

[a] Klinikum Nürnberg, Cardiovascular Center, Paracelsus Medical University, Nuremberg, Germany
[b] Cardiology, Istituto Cardiocentro Ticino, EOC, Lugano, Switzerland
[c] Cardiac Surgery, Istituto Cardiocentro Ticino, EOC, Lugano, Switzerland
[d] Department of Cardiac Surgery, Hôpital Henri Mondor, Université Paris 12, Créteil, Paris, France
[e] Herzzentrum Dresden GmbH Universitätsklinik, Dresden, Germany
[f] UZ Gasthuisberg Leuven, University Hospital, Leuven, Belgium
[g] Hannover Medical School, Hannover, Germany
[h] Heart, Vascular and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA
[i] Medical University of Innsbruck, Innsbruck, Austria
[j] Lens Hospital and Bois Bernard Private Hospital, Lens, France
[k] Poitiers University Hospital, Poitiers, France
[l] Cardiac Surgery, Poliambulanza Foundation Hospital, Brescia, Italy
[m] Medical University of Vienna, Vienna, Austria
[n] Department of Cardiac Surgery, University Hospital Angers, Angers, France
[o] University Heart Center Freiburg, Bad Krozingen, Germany
[p] Catharina Ziekenhuis, Eindhoven, the Netherlands
[q] Division of Cardiac Surgery, Quebec Heart and Lung Institute, Quebec, Canada
[r] University Heart Center Hamburg, Universitätsklinikum Hamburg Eppendorf (UKE), Hamburg, Germany
[s] University General Hospital Virgen de la Arrixaca, Murcia, Spain
[t] Cardio-Thoracic Surgery Department, Heart and Vascular Center, Maastricht University Medical Center (MUMC+), Cardiovascular Research Institute Maastricht (CARIM), Maastricht, the Netherlands

ARTICLE INFO

Keywords:
Aortic valve replacement
Minimally invasive aortic valve replacement
Sutureless aortic valve

ABSTRACT

Background: The present study is a sub-analysis of the multicenter, randomized PERSIST-AVR trial (PERceval Sutureless Implant versus Standard Aortic Valve Replacement) comparing the in-hospital and 1-year results of sutureless versus conventional stented bioprostheses in isolated surgical aortic valve replacement (SAVR) within two different surgical approaches: mini-sternotomy (MS) and full-sternotomy (FS).

Methods: A total of 819 patients (per-protocol population) underwent preoperative randomization to sutureless or stented biological valve at 47 centers worldwide. Sub-analysis on isolated SAVR was performed. Results were compared between sutureless and stented within the two different surgical approaches.

Results: 285 patients were implanted with Perceval (67% in MS) and 293 with stented valves (65% in MS). Sutureless group showed significantly reduced surgical times both in FS and MS. In-hospital results show no differences between Perceval and stented valves in FS, while a lower incidence of new-onset of atrial fibrillation (3.7% vs 10.8%) with Perceval in MS. After 1-year, use of sutureless valve showed a significant reduction of

* Corresponding author at: Klinikum Nürnberg, Breslauer Str.201, 90471 Nuremberg, Germany.
E-mail address: theodor.fischlein@klinikum-nuernberg.de (T. Fischlein).
[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.
[2] T.F. and E.C. contributed equally as senior authors.

https://doi.org/10.1016/j.ijcard.2022.08.012
Received 4 May 2022; Received in revised form 13 July 2022; Accepted 4 August 2022
Available online 6 August 2022

MACCE (5.2% vs 10.8%), stroke rate (1.0% vs 5.4%), new-onset of atrial fibrillation (4.2% vs 11.4%) and re-hospitalizations (21.8 days vs 47.6 days), compared to stented valves but presented higher rate of pacemaker implantation (11% vs 1.6%).

Conclusions: Sutureless bioprosthesis showed significantly reduced procedural times during isolated SAVR in both surgical approaches. Patients with sutureless valves and MS access showed also better 1-year outcome regarding MACCEs, stroke, re-hospitalization and new-onset atrial fibrillation, but presented a higher rate of permanent pacemaker implantation compared to patients with stented bioprosthesis.

1. Introduction

Compared to standard surgical bioprosthesis, sutureless aortic valves feature a shorter operative time and a facilitated implantation, particularly in case of a minimally invasive access [1–5]. However, the actual impact of sutureless bioprostheses on clinical outcome of patients undergoing conventional or minimally invasive surgical aortic valve replacement (SAVR) remains unclear. Results of controlled randomized studies in a large patient population undergoing isolated SAVR by means of minimally invasive or conventional access using sutureless valves in comparison with conventional bioprostheses has been repetitively claimed by clinical and scientific communities to provide objective evidence in these settings. Recently, multicentre, randomized PERSIST-AVR trial has been undertaken to compare sutureless and conventional bioprostheses implanted with full- (FS) or mini-(MS) sternotomy, with overall 1-year results showing no substantial clinical differences between Perceval sutureless valve (Perceval, Corcym S.r.l., Saluggia, Italy) versus conventional stented bioprostheses for isolated or combined SAVR [6,7].

The present study is a sub-analysis of PERSIST-AVR trial aiming at analysing outcomes of patients undergoing isolated SAVR with Perceval sutureless or conventional bioprostheses using a FS or a MS access. In-hospital and 1-year outcomes were collected and analysed within the two surgical approaches.

2. Methods

2.1. Study design

Details about design of PERSIST-AVR trial and primary study outcome have been already published [6,7]. Briefly, PERSIST-AVR trial was a multicentre, prospective, randomized, open-label trial with an adaptive design conceived to demonstrate non-inferiority of Perceval sutureless bioprosthesis compared to standard stented aortic bioprosthesis, in patients with severe symptomatic aortic valve stenosis (ClinicalTrials.gov number NCT02673697). Primary outcome was the freedom from major cerebral and cardiovascular events (MACCEs), with a composite endpoint of death from any cause, myocardial infarction, stroke, or valve reintervention at 1-year. The primary endpoint was met demonstrating non-inferiority of the Perceval valve versus the stented bioprosthesis at 1 year [7]. Study was approved by local Ethic Committees and by Institutional Review Boards of each institution participating. Participants signed informed consent before enrolment in the study. From March 2016 to September 2018, adult patients with severe symptomatic aortic valve stenosis who were deemed good candidates for SAVR were prospectively enrolled in 47 centres across Europe, Canada, United States, Chile, and Israel. In total, 819 patients (per-protocol population) were included in protocol for randomization (1:1 blocked randomization) to Perceval sutureless valve arm or to standard stented aortic bioprosthesis arm. Enrolled patients were randomly assigned, in a 1:1 ratio, to treatment with the sutureless or the stented biological valve. The choice of the surgical bioprosthesis in the stented valve arm was left to the discretion of the surgeon. A blocked randomization list was generated by the sponsor before the start of the study, stratified by country and surgical approach to ensure proportional assignment. To minimize selection bias, randomization was performed after a computed tomography scan confirmed eligibility for the current sutureless valve implantation, suitability for the proposed surgical access (FS or MS), and the decision about an isolated or concomitant procedure was decided. Right anterior minithoracotomy was not allowed due to variable experience among the centers and/or suitability for the comparator standard valve. Only subjects who had undergone standard chest CT-scan to determine if the aortic stenosis can be replaced with an available Perceval valve (size), and is potentially suitable for mini-sternotomy, have been randomized. Details regarding sutureless valve and technical details for implantation have been already published [8–10].

Study protocol was developed in collaboration with Steering Committee and in accordance with principles defined by current guidelines for management of patients with valvular heart disease [11,12]. Details about management of trial and a list of participating centres are provided in Supplemental Material.

2.2. Statistical analysis

Trial design was based on use of a Bayesian adaptive Goldilocks approach, with two planned interim analysis conducted by an independent statistical unit (Berry Consultants, Austin, Texas, United States). Stopping rules were defined a priori empirically through computer-based simulations conducted to optimize study operating characteristics.

Mortality and morbidity rates were assessed using descriptive statistics broken down by adverse event type and timing (intra/perioperative or after intervention according to VARC-2 definitions) [13].

Analyses were conducted on per-protocol population (excluding patients with Major Deviation). A sub-analysis has been performed on isolated AVR to evaluate in-hospital and 1-year outcomes between Perceval and stented both in FS and MS approach.

Serious adverse events (according to VARC-2 criteria) have been assessed using descriptive statistics. Number of events and percentages will be presented in early events ($<$30 days) and late events ($\geq$30 days) divided by treatment arms. A mixed regression analysis was used and Least square (Ls) means and differences of Ls means were generated. Ls means are computed based on ANOVA model with Procedure (Isolated) and Valve type (Perceval sutureless valve, Stented) as independent variables, and surgical timing and ICU management as dependent variable; *p*-values were adjusted by Bonferroni approach to account for multiplicity tests.

3. Results

Among the 819 randomized subjects included in PERSIST-AVR trial, 285 patients have been implanted with Perceval (67% in MS) and 293 with stented (65% in MS); all of them underwent isolated AVR. Preoperative patients' characteristics are listed in Table 1. Patients implanted with Perceval had similar pre-operative risk profile of the ones implanted with stented, in both full-sternotomy and minimally invasive approach (Table 1). Sutureless valve showed significantly shorter cardiopulmonary bypass (CPB) and aortic cross-clamping times, in both the surgical approaches (Fig. 1). Mean intensive care unit stay and hospital stay did not differ among the two types of bioprostheses (Table 2). Clinical outcomes at 30 days showed significantly reduced new-onset of atrial fibrillation episodes and higher rate of permanent pacemaker

Table 1
Patients' characteristics.

	Full-sternotomy (n = 202)		Mini-sternotomy (n = 376)	
	PERCEVAL (n = 94)	STENTED (n = 108)	PERCEVAL (n = 191)	STENTED (n = 185)
Age	75.2 ± 6.0	75.0 ± 5.8	75.4 ± 5.7	74.0 ± 6.9
Female gender	50 (53.2%)	46 (42.6%)	114 (59.7%)	87 (47.0%)
Hypertension	75 (79.8%)	85 (78.7%)	156 (81.7%)	150 (81.1%)
Dyslipidaemia	54 (57.4%)	59 (54.6%)	93 (48.7%)	116 (62.7%)
Diabetes	24 (25.5%)	37 (34.3%)	42 (22.0%)	42 (22.7%)
Smoker	21 (22.3%)	36 (33.3%)	29 (15.2%)	48 (25.9%)
COPD	12 (12.8%)	11 (10.2%)	21 (11.0%)	16 (8.6%)
Malignancy	10 (10.6%)	9 (8.3%)	14 (7.3%)	12 (6.5%)
Peripheral Artery Disease	6 (6.4%)	12 (11.1%)	14 (7.3%)	11 (5.9%)
Coronary Artery Disease	27 (28.7%)	25 (23.1%)	56 (29.3%)	42 (22.7%)
Angina (CCS score III-IV)	7 (7.4%)	9 (8.3%)	23 (12.0%)	17 (9.2%)
Heart Failure	3 (3.2%)	8 (7.4%)	10 (5.2%)	7 (3.8%)
Myocardial infarction	4 (4.3%)	3 (2.8%)	8 (4.2%)	4 (2.2%)
TIA	7 (7.4%)	2 (1.9%)	1 (0.5%)	3 (1.6%)
Stroke	3 (3.2%)	3 (2.8%)	7 (3.7%)	6 (3.2%)
Endocarditis	0 (0.0%)	1 (0.9%)	0 (0.0%)	0 (0.0%)
Previous cardiac surgery	1 (1.1%)	1 (0.9%)	0 (0.0%)	0 (0.0%)
STS score	2.6 ± 2.4	2.1 ± 1.5	2.0 ± 1.3	1.8 ± 0.9
EuroSCORE II	2.0 ± 1.4	1.9 ± 1.6	1.9 ± 1.6	1.5 ± 0.8

Values are expressed as mean ± standard deviation, n (%). COPD=Chronic Obstructive Pulmonary Disease, CCS=Canadian Cardiovascular Society Angina Grade, TIA = Transient Ischemic Attack.

implantation in Perceval vs stented; these results are valid in case of a minimally invasive access but not with a full sternotomy approach (Table 3).

3.1. 1-year outcome

Similar results between Perceval and stented valves have been reported in case of FS approach. On the contrary, in patients undergoing sutureless valve implantation through a MS access, there was a significantly reduction of MACCE events, stroke rate, new onset of atrial fibrillation, but a higher rate of permanent pacemaker implantation (Table 3). Furthermore, sutureless groups implanted through MS showed a significant reduction of re-hospitalizations after hospital discharge (Fig. 2). Cause for re-hospitalizations and number of events are reported in Table 4.

4. Discussion

This is a sub-analysis of the first randomized, controlled study (PERSIST-AVR trial) comparing sutureless versus conventional stented bioprostheses focusing on isolated SAVR either with a FS or MS access. This study demonstrated a significantly reduction in cross-clamp time and CPB time using Perceval in both FS and MS surgical approaches. Moreover, SAVR with sutureless valve in MS cohort demonstrated a significantly reduction in MACCEs, new-onset of atrial fibrillation episodes and re-hospitalizations at 1-year follow-up, mainly due to the lower number of hospital accesses for neurological events. Regarding the incidence of permanent pacemaker implant Perceval showed a higher value vs stented in the MS approach, but not in the FS one.

Use of sutureless bioprostheses has been widely reported to reduce procedure times, both with FS and MS approaches [7,14–16]. Ease of implantation enhances MS approaches, as recently confirmed by STS Registry data and other series, demonstrating that use of sutureless or rapid deployment bioprostheses allow a wider application of minimally invasive procedures [17,18]. Previously, reduced procedure times achieved with sutureless valve implantation in some series have not consistently translated into clinical benefits [19–22]. Indeed, in a recent large series, Erfe and colleagues found no significant difference in 30-day outcomes, when sutureless or rapid deployment valves were compared to SAVR with conventional stented tissue valves, despite

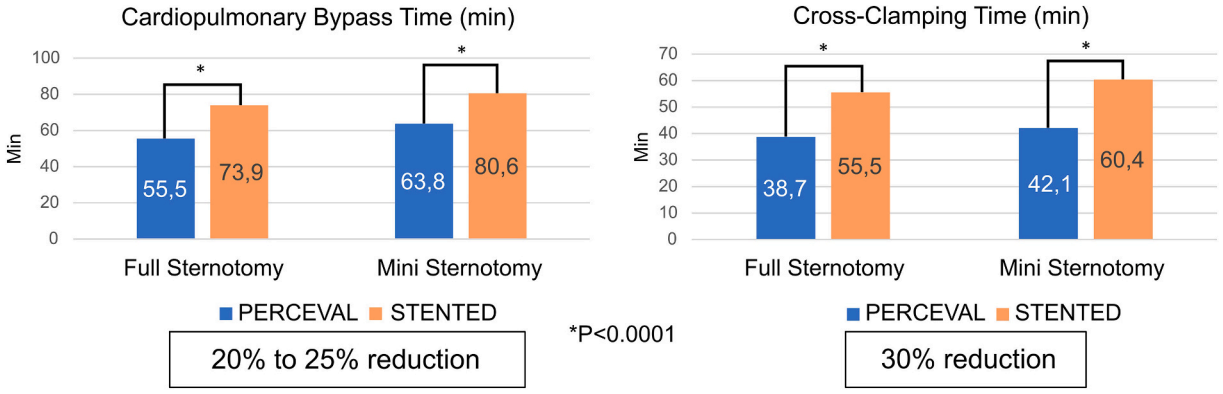

Fig. 1. Surgical times for Perceval and conventional stented bioprostheses in both full sternotomy and minimally invasive approach. Use of sutureless valve for aortic valve replacement surgery had shorter procedure times for cardiopulmonary bypass or cross-clamping times in both full-sternotomy and mini-sternotomy.

Table 2
Intensive care unit and hospital length-of-stay by surgical approach and study groups (estimates and standard error).

	Full-sternotomy (n = 202)				Mini-sternotomy (n = 376)			
	PERCEVAL (n = 94)	STENTED (n = 108)	Ls mean difference	p-value (Bonferroni adjusted)	PERCEVAL (n = 191)	STENTED (n = 185)	Ls mean difference	p-value (Bonferroni adjusted)
ICU stay (days)	6.3 (0.8)	5.8 (0.8)	0.54	0.642	3.6 (0.7)	3.6 (0.7)	−0.07	0.937
Length of stay (days)	12.6 (1.9)	15.1 (1.9)	−2.49	0.359	13.3 (1.6)	13.5 (1.5)	−0.20	0.927

Values are expressed as mean ± standard deviation.

Table 3
Clinical outcomes at 30 days and outcomes at 1-year in patients undergoing isolated aortic valve replacement with sutureless or conventional stented tissue valves.

	Full-sternotomy (n = 202)			Mini-sternotomy (n = 376)		
Outcomes at 30 days	PERCEVAL (n = 94)	STENTED (n = 108)	Difference (95% Cred Int)	PERCEVAL (n = 191)	STENTED (n = 185)	Difference (95% Cred Int)
MACCE	3 (3.2)	3 (2.8)	0.7 (−4.1;5.1)	3 (1.6)	8 (4.3)	2.2 (−1.5;5.9)
Death	0 (0.0)	1 (0.9)	0.9 (−1.8;3.4)	2 (1.0)	1 (0.5)	−0.5 (−2.5;1.6)
IMA	1 (1.1)	1 (0.9)	−0.1 (−3.6;3.1)	0 (0.0)	2 (1.1)	1.1 (−0.7;2.9)
Stroke	2 (2.1)	1 (0.9)	−1.2 (−5.2;2.6)	1 (0.5)	5 (2.7)	2.2 (−0.6;4.9)
Reintervention	0 (0.0)	0 (0.0)	0.0 (−2.1;1.8)	1 (0.5)	0 (0.0)	−0.5 (−1.9;0.9)
TIA	0 (0.0)	1 (0.9)	0.9 (−1.8;3.4)	0 (0.0)	0 (0.0)	0.0 (−1.0;1.0)
Surgical bleeding	5 (5.3)	6 (5.6)	0.2 (−6.3;6.6)	5 (2.6)	7 (3.8)	1.2 (−2.5;4.8)
New-onset AF	3 (3.2)	5 (4.6)	1.4 (−4.3;6.9)	**7 (3.7)**	**20 (10.8)**	**7.1 (1.8;12.3)**
PM implantation	12 (12.8)	8 (7.4)	−5.4 (−13.8;3.1)	**20 (10.5)**	**2 (1.1)**	**−9.4 (−13.9; −4.6)**
Paravalvular leak (moderate/ severe)	0 (0.0)	0 (0.0)	0.0 (−2.1;1.8)	1 (0.5)	0 (0.0)	−0.5 (−1.9;0.9)
Outcomes at 1-year	**PERCEVAL (n = 94)**	**STENTED (n = 108)**	**Difference (95% Cred Int)**	**PERCEVAL (n = 191)**	**STENTED (n = 185)**	**Difference (95% Cred Int)**
MACCE	6 (6.4)	5 (4.6)	−1.8 (−8.3;4.7)	**10 (5.2)**	**20 (10.8)**	**5.6 (0.0;11.1)**
Death	2 (2.1)	3 (2.8)	0.7 (−4.1;5.1)	8 (4.2)	7 (3.8)	−0.4 (−4.2;3.4)
IMA	1 (1.1)	1 (0.9)	−0.1 (−3.6;3.1)	0 (0.0)	3 (1.6)	1.6 (−0.5;3.7)
Stroke	3 (3.2)	1 (0.9)	−2.3 (−6.7;2.0)	**2 (1.0)**	**10 (5.4)**	**4.4 (0.7;8.0)**
Reintervention	1 (1.1)	1 (0.9)	−0.1 (−3.6;3.1)	2 (1.0)	3 (1.6)	0.6 (−1.9;3.1)
TIA	2 (2.1)	2 (1.9)	−0.3 (−4.6;3.9)	0 (0.0)	0 (0.0)	0.0 (−1.0;1.0)
Surgical bleeding	5 (5.3)	8 (7.4)	2.1 (−4.9;8.8)	8 (4.2)	7 (3.8)	−0.4 (−4.4;3.7)
Endocarditis	0 (0.0)	2 (1.9)	1.9 (−1.5;4.8)	3 (1.6)	6 (3.2)	1.7 (−1.6;4.9)
New-onset AF	3 (3.2)	10 (9.3)	6.1 (−0.8;12.5)	**8 (4.2)**	**21 (11.4)**	**7.2 (1.7;12.5)**
PM implantation	12 (12.8)	9 (8.3)	−4.4 (−13.0;4.1)	**21 (11.0)**	**3 (1.6)**	**−9.4 (−14.1; −4.4)**
Paravalvular leak (moderate/ severe)	0 (0.0)	0 (0.0)	0.0 (−2.1;1.8)	2 (1.0)	1 (0.5)	−0.5 (−2.5;1.6)

Values are expressed as n (%). MACCE: major acute cardio-cerebral events, IMA: myocardial infarction, TIA: transient ischemic attack, AF: atrial fibrillation, PM: pacemaker, Reintervention: valve substitution for severe paravalvular leak. 1-year outcomes include outcomes at 30 days. There are no patients lost to follow-up.

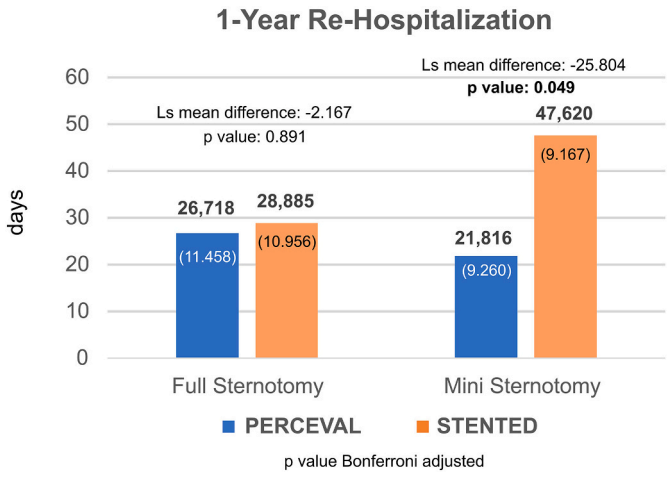

Fig. 2. 1-year re-hospitalization in stented versus sutureless groups according to surgical access. Minimally invasive approach showed a significant reduction of re-hospitalization after hospital discharge (Ls: least square).

significantly reduced CPB and cross-clamp times [17]. On the contrary, the results of this study showed not only a significant reduction in the operative times with Perceval vs stented valves but also some clinical advantages linked to the use of Perceval in a minimal invasive approach [23,24].

In fact, this is the first study showing a significant reduction at 1 year of MACCEs events in the Perceval cohort vs the stented ones, when a minimal surgical invasive approached was used [25]. Potential explanation for this observed positive clinical impact might be linked to a significant reduced rate of new onset of atrial fibrillation episodes [26]. Decreased rates of atrial fibrillation might have reduced risk of embolic episodes following sutureless valve implantation with a consistent observed reduction in stroke rates and other cardiac-related complications [27]. From these 1-year results, it seems that MS approach might become the procedure of choice with sutureless isolated SAVR.

A higher incidence of pacemaker implantation rate in MS cohort with sutureless valve was, however, observed in the present study. Higher perioperative pacemaker implantation rate in patients receiving a sutureless valve was also observed in similar series comparing conventional stented tissue valves with sutureless and rapid deployment valves [17,28]. However, reduced pacemaker rate after sutureless valve implantation has also been observed and reported in association with a more careful attention to valve sizing and implanting technique [29–32]. The mechanisms for higher pacemaker rate compared to standard valves are likely due to compression of conduction system caused by prosthetic stent below the annulus, particularly in case of valve oversizing [24,33]. These shortcomings have been recently addressed by a next generation design of sutureless valve and by implant refinements [34,35]. Nonetheless, it is also worth underlying that FS approach was not associated with higher pacemaker implantation rate, indicating another aspect to be further investigated.

Continued investigations are warranted to further explain these outcomes and more thoroughly in sutureless valve cohort.

4.1. Limitations of the study

This study presents some limitations. The choice of the stented valve was at the discretion of the operating physician and the impact of the surgical implantation technique or the type of the tissue valve was not considered in this sub-analysis. Moreover, the decision to implant a pacemaker was driven by local policies and procedures at each study hospital, and this might have impacted the homogeneity of the results. Finally, the original study was not powered for this sub-analysis.

5. Conclusion

Perceval sutureless valve improves surgical times in both FS and MS

Table 4
Cause of re-hospitalization and number of events by surgical approach and study group.

	Full-sternotomy (n = 202)		Mini-sternotomy (n = 376)	
Cause of re-hospitalization	PERCEVAL (n = 94)	STENTED (n = 108)	PERCEVAL (n = 191)	STENTED (n = 185)
Access site complications	2	1	4	7
Mean sternal dehiscence	2	–	2	4
Deep sternal wound infection	–	1	2	3
Blood disorders	2	8	6	–
Cardiac disorders	20	27	32	37
Arrhythmias and conduction disorders	14	21	23	27
Heart failure	1	3	3	3
Cardiac tamponade	1	1	1	2
Pericardial effusions	3	1	2	3
Pericarditis	–	1	–	1
Intracavitary thrombosis	1	–	3	–
Coronary artery disease with angioplasty	–	–	–	2
Infections	4	4	10	12
Endocarditis	1	2	4	6
Respiratory infections	2	2	1	5
Sepsis	1	–	5	1
Neurologic disorders	7	3	5	12
Stroke	3	–	1	6
TIA	2	1	2	2
Confusion/ Delirium	2	1	–	4
Syncope	–	1	2	–
Kidney failure	2	5	2	1
Respiratory disease	5	4	9	12
Vascular disease	1	–	1	5

TIA: transient ischemic attack; Respiratory disease: pulmonary oedema, pleural effusion, pneumothorax, respiratory distress/insufficiency. Vascular disease: thrombosis arterial or deep vein, pulmonary embolism, vessel occlusion/ obstruction/pseudoaneurysm.

approaches during isolated SAVR for severe aortic stenosis. Moreover, in comparison to stented valves, the sutureless valves, used in a minimally invasive setting, shows significantly better clinical outcomes after 1 year, including lower rate of MACCEs, re-hospitalizations and new onset of atrial fibrillation. Sutureless valve is affected by a significant higher incidence of permanent pacemaker implantation at 30 days with a MS access, but not with a FS approach.

Funding

PERSIST-AVR Trial was funded by Corcym S.r.l..

Declaration of interest

Theodor Fischlein: consultant CORCYM and BioStable; Thierry Folliguet: consultant CORCYM (Steering Committee); Bart Meuris, Malakh L. Shrestha: consultant CORCYM (Steering Committee and Proctor); Eric E. Roselli: consultant CORCYM (Steering Committee and Proctor), speaker for Abbott, consultant, speaker and investigator for Edwards and Medtronic; Nikolaos Bonaros: Educational grants: Edwards Lifesciences, CORCYM, Speaker Honoraria: Edwards Lifesciences, CORCYM, Medtronic; Olivier Fabre, Giovanni Troise, Steffen Pfeiffer, Sami Kueri, Julio García-Puente: consultant CORCYM (Proctor); Martin Andreas: consultant Abbott and Edwards (Proctor), advisor Medtronic; Filip Rega: consultant CORCYM and AtriCure (Proctor), Research Support Recipient Medtronic; Roberto Lorusso: Consultant Medtronic, LivaNova, CORCYM and Getinge (honoraria paid to the Maastricht University) and Member of the Medical Advisory Board for Eurosets (honoraria paid to the Maastricht University). Elena Caporali, Utz Kappert, Pierre Corbi, Frederic Pinaud, Erwin Tan, Pierre Voisine, Evaldas Girdauskas have no relationships with industry and other entities.

CRediT authorship contribution statement

Theodor Fischlein: Conceptualization, Writing – original draft, Supervision. **Elena Caporali:** Conceptualization, Writing – original draft, Supervision. **Thierry Folliguet:** Data curation, Writing – review & editing. **Utz Kappert:** Investigation, Validation. **Bart Meuris:** Methodology, Validation. **Malakh L. Shrestha:** Investigation, Visualization. **Eric E. Roselli:** Data curation, Validation. **Nikolaos Bonaros:** Writing – review & editing, Resources. **Olivier Fabre:** Investigation, Resources. **Pierre Corbi:** Methodology, Investigation. **Giovanni Troise:** Validation, Resources. **Martin Andreas:** Writing – review & editing. **Frederic Pinaud:** Methodology. **Steffen Pfeiffer:** Data curation, Investigation. **Sami Kueri:** Investigation, Resources. **Erwin Tan:** Data curation, Investigation. **Pierre Voisine:** Investigation, Validation. **Evaldas Girdauskas:** Writing – review & editing. **Filip Rega:** Data curation. **Julio García-Puente:** Writing – review & editing. **Roberto Lorusso:** Project administration, Conceptualization, Writing – original draft, Supervision.

Acknowledgments

PERSIST-AVR Investigators reported in Supplemental Material.

Complete list of PERSIST investigators and contributors provided in Supplemental Material.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2022.08.012.

References

[1] A. Ihsan Parlar, M. Onur Hanedan, I. Mataraci, et al., Immediate outcomes of aortic valve replacement with sutureless versus stentless bioprosthesis, J. Heart Valve Dis. 25 (2016) 21–27.
[2] J. Forcillo, D. Bouchard, A. Nguyen, et al., Perioperative outcomes with sutureless versus stented biological aortic valves in elderly persons, J. Thorac. Cardiovasc. Surg. 151 (2016) 1629–1636.
[3] M. Dalén, F. Biancari, A.S. Rubino, et al., Ministernotomy versus full sternotomy aortic valve replacement with a sutureless bioprosthesis: a multicenter study, Ann. Thorac. Surg. 99 (2015) 524–530.
[4] S. Pfeiffer, A.M. Dell'Aquila, F. Vogt, et al., Efficacy of sutureless aortic valves in minimally invasive cardiac surgery: an evolution of the surgical technique, J. Cardiovasc. Surg. 58 (2017) 731–738.
[5] M. Hassan, Y. Miao, A. Maraey, et al., Minimally invasive aortic valve replacement: cost-benefit analysis of ministernotomy versus minithoracotomy approach, J. Heart Valve Dis. 24 (2015) 531–539.
[6] R. Lorusso, T. Folliguet, M. Shrestha, et al., Sutureless versus stented bioprostheses for aortic valve replacement: the randomized PERSIST-AVR study design, Thorac. Cardiovasc. Surg. 68 (2020) 114–123.
[7] T. Fischlein, T. Folliguet, B. Meuris, et al., Sutureless versus conventional bioprostheses for aortic valve replacement in severe symptomatic aortic valve stenosis, J. Thorac. Cardiovasc. Surg. 161 (3) (2021 Mar) 920–932.
[8] V. Vasanthan, W. Kent, A. Gregory, et al., Perceval valve implantation: technical details and echocardiographic assessment, Ann. Thorac. Surg. 107 (2019) e223–e225.
[9] S. Pfeiffer, T. Fischlein, G. Santarpino, Sutureless sorin perceval aortic valve implantation, Semin. Thorac. Cardiovasc. Surg. 29 (2017) 1–7.
[10] M. Glauber, A. Miceli, L. Di Bacco, Sutureless and rapid deployment valves: implantation technique from a to Z-the perceval valve, Ann. Cardiothorac. Surg. 9 (4) (2020 Jul) 330–340.
[11] A. Vahanian, O. Alfieri, F. Andreotti, et al., Guidelines on the management of valvular heart disease (version 2012): the joint task force on the management of Valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS), Eur. J. Cardiothorac. Surg. 42 (2012) S1–44.

[12] R.A. Nishimura, C.M. Otto, R.O. Bonow, et al., 2014 AHA/ACC guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association task force on practice guidelines, J. Am. Coll. Cardiol. 63 (2014) 2438–2488.
[13] A.P. Kappetein, S.J. Head, P. Généreux, et al., Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research Consortium-2 consensus document, J. Thorac. Cardiovasc. Surg. 145 (1) (2013 Jan) 6–23.
[14] M. Andreas, P. Berretta, M. Solinas, et al., Minimally invasive access type related to outcomes of sutureless and rapid deployment valves, Eur. J. Cardiothorac. Surg. 58 (5) (2020) 1063–1071.
[15] M. Glauber, L. Di Bacco, J. Cuenca, et al., Minimally invasive aortic valve replacement with sutureless valves: results from an international prospective registry, Innovations 15 (2020) 120–130.
[16] M.A. Borger, V. Moustafine, L. Conradi, et al., A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement, Ann. Thorac. Surg. 99 (2015) 17–25.
[17] J.M. Erfe, S.C. Malaisrie, A.C. Andrei, et al., Outcomes of sutureless/rapid deployment valves compared to traditional bioprosthetic aortic valves, Ann. Thorac. Surg. 111(6) (2020) 1884–1891.
[18] B. Meuris, W.J. Flameng, F. Laborde, et al., Five-year results of the pilot trial of a sutureless valve, J. Thorac. Cardiovasc. Surg. 150 (2015) 84–88.
[19] G.R. Barnhart, K.D. Accola, E.A. Grossi, et al., TRANSFORM (multicenter experience with rapid deployment Edwards INTUITY valve system for aortic valve replacement) US clinical trial: performance of a rapid deployment aortic valve, J. Thorac. Cardiovasc. Surg. 153 (2017) 241–251.
[20] B. Gersak, T. Fischlein, T.A. Folliguet, et al., Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an international expert consensus panel, Eur. J. Cardiothorac. Surg. 49 (2016) 709–718.
[21] T. Fischlein, B. Meuris, K. Hakim-Meibodi, et al., The sutureless aortic valve at 1 year: a large multicenter cohort study, J. Thorac. Cardiovasc. Surg. 151 (2016) 1617–1626.
[22] T.A. Folliguet, F. Laborde, K. Zannis, et al., Sutureless perceval aortic valve replacement: results of two European centers, Ann. Thorac. Surg. 93 (2012) 1483–1488.
[23] F. Pollari, G. Santarpino, A.M. Dell'Aquila, et al., Better short-term outcome by using sutureless valves: a propensity-matched score analysis, Ann. Thorac. Surg. 98 (2014) 611–616.
[24] M. Meco, A. Montisci, A. Miceli, et al., Sutureless perceval aortic valve versus conventional stented bioprostheses: meta-analysis of postoperative and midterm results in isolated aortic valve replacement, J. Am. Heart Assoc. 7 (2018).
[25] M. Shrestha, T. Folliguet, B. Meuris, et al., Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial, J. Heart Valve Dis. 18 (2009) 698–702.
[26] M. Shrestha, T. Fischlein, B. Meuris, et al., European multicentre experience with the sutureless Perceval valve: clinical and haemodynamic outcomes up to 5 years in over 700 patients, Eur. J. Cardiothorac. Surg. 49 (2016) 234–241.
[27] G. Hindricks, T. Potpara, N. Dagres, et al., 2020 ESC guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS): the task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) developed with the special contribution of the European heart rhythm association (EHRA) of the ESC, Eur. Heart J. 42 (5) (2020) 373–498, https://doi.org/10.1093/eurheartj/ehaa612.
[28] S. Ensminger, B. Fujita, T. Bauer, et al., Rapid deployment versus conventional bioprosthetic valve replacement for aortic stenosis, J. Am. Coll. Cardiol. 71 (2018) 1417–1428.
[29] P. Berretta, S. Arzt, A. Fiore, et al., Current trends of sutureless and rapid deployment valves: an 11-year experience from the sutureless and rapid deployment international registry, Eur. J. Cardiothorac. Surg. 58 (5) (2020) 1054–1062.
[30] M. Lazkani, C. Yerasi, S. Prakash, et al., Permanent pacemaker implantation and paravalvular leak rates following sutureless aortic valve operations, J. Card. Surg. 33 (2018) 808–817.
[31] V. Chauvette, A. Mazine, D. Bouchard, Ten-year experience with the Perceval S sutureless prosthesis: lessons learned and future perspectives, J. Vis. Surg. 4 (2018) 1–8.
[32] S.S. Mujtaba, S.M. Ledingham, A.R. Shah, et al., Aortic valve replacement with a conventional stented bioprosthesis versus sutureless bioprosthesis: a study of 763 patients, Braz. J. Cardiovasc. Surg. 33 (2018) 122–128.
[33] M. Dalén, F. Biancari, A.S. Rubino, et al., Aortic valve replacement through full sternotomy with a stented bioprosthesis versus minimally invasive sternotomy with a sutureless bioprosthesis, Eur. J. Cardiothorac. Surg. 49 (2016) 220–227.
[34] F. Vogt, M. Moscarelli, A. Nicoletti, et al., Sutureless aortic valve and pacemaker rate: from surgical tricks to clinical outcomes, Ann. Thorac. Surg. 108 (2019) 99–105.
[35] B. Yanagawa, J. Cruz, L. Boisvert, et al., A simple modification to lower incidence of heart block with sutureless valve implantation, J. Thorac. Cardiovasc. Surg. 152 (2) (2016 Aug) 630–632.