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JACC STATE-OF-THE-ART REVIEW

Sutureless Valves, a "Wireless" Option for Patients With Aortic Valve Disease

JACC State-of-the-Art Review

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ABSTRACT

Transcatheter technologies triggered the recent revision of the guidelines that progressively widened the indications for the treatment of aortic stenosis. On the surgical realm, a technology avoiding the need for sutures to anchor the prosthesis to the aortic annulus has been developed with the aim to reduce the duration of cardiopulmonary bypass and simplify the process of valve implantation. In addition to a transcatheter aortic valve replacement (TAVR)-like stent that exerts a radial force, these so-called "rapid deployment valves" or "sutureless valves" for aortic valve replacement also have cuffs to improve sealing and reduce the risk of paravalvular leak. Despite promising, the actual advantage of sutureless valves over traditional surgical procedures (surgical aortic valve replacement) or TAVR is still debated. This review summarizes the current comparative evidence reporting outcomes of "sutureless valves" for aortic valve replacement to TAVR and surgical aortic valve replacement in the treatment of aortic valve stenosis.
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The spectrum of aortic valve disease treatment is rapidly evolving. With technological advances in the design and manufacturing of the devices, and studies demonstrating safety of procedures in low-risk populations, indications for transcatheter aortic valve replacement (TAVR) have progressively widened to embrace lower-risk patients along with high-risk surgical candidates. Still, the main drawbacks of this procedure are thought to originate from the displacement of the native valve by the stent of the device, resulting in potential embolic risks or occlusion of the coronary ostia. In addition, the inability to excise the aortic valve and decalcify the aortic annulus, and the potential partial deployment in the left ventricular outflow tract have raised concerns regarding the long-term durability of the valves, the occurrence of paravalvular leaks, and need for permanent pacemaker implantation.[1]

Regarding surgical treatment, a novel prosthetic valve technology that avoids the need for anchoring sutures, that is, sutureless valves, has been developed to reduce the duration of cardiopulmonary

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HIGHLIGHTS

- The comparative safety and efficacy of sutureless (SuAVR) vs conventional aortic valve replacement surgery is currently under investigation.
- Potential candidates for SuAVR include those undergoing concomitant procedures, complex reoperations in patients with frail aortic root tissue, minimally invasive aortic valve replacement procedures, and high-risk patients for whom TAVR is not suitable.
- The Heart Team should participate in shared decision making with patients in the selection of valve replacement modality for aortic stenosis.

bypass (CPB) and operative time, and to simplify the process of valve implantation. Despite requiring an open surgical implantation, sutureless devices share many similarities with TAVR devices from the design and conceptual perspectives. In addition to a TAVR-like stent that exerts a radial force, these balloon-expandable valves also have cuffs to improve sealing and reduce the risk of paravalvular leak.

Presently, 2 different platforms are available. A totally sutureless device, Perceval (Corcym S.r.l.) and a so-called "rapid deployment device," the Intuity valve from Edwards Lifesciences (Figure 1). The Perceval technology gained U.S. Food and Drug Administration approval in 2016 and is based on bovine pericardium. It has a stent frame similar to self-expanding TAVR devices made of elastic Ni-Ti alloy composed of 2 rings and 9 vertical struts. This supports the valve and maintains it in place without any permanent suture. The elastic properties of the stent allow for increased adaptability to the aortic anatomy, permitting the valve to better comply with the aortic root systo-diastolic movement, a feature thought to relieve the stress on the leaflets. Also, the implantation technique entails collapsing the valve with an atraumatic device before lowering it in the appropriate position and deploying the prosthesis letting it self-expand back to its original diameter and stabilizing it with further balloon expansion. The Edwards Intuity valve gained its U.S. Food and Drug Administration approval in 2016. This valve is a balloon-expandable, rapid deployment device, based on the established Perimount valve platform. The inflow aspect of the valve is equipped with a balloon-expandable stainless-steel cloth-covered frame that is situated within the left ventricular outflow tract. The expandable framework guarantees an optimal positioning and seal between the annulus and the frame and stabilizes the valve at implant. Differently from the Perceval platform, the Intuity valve requires 3 cardinal sutures for fixation of the device to the aortic annulus (Table 1). For the purpose of this review, we refer generally to the use of both the devices in clinical settings for aortic valve replacement (AVR) with the term of "sutureless aortic valve replacement" (SuAVR), but the specific differences in outcomes and characteristics will be separately highlighted and detailed.

SuAVR may have an advantage over TAVR because of the option of excising the diseased native valve, decalcifying the aortic annulus, or debriding chronically infected material. In high-risk patients with aortic stenosis, who are precluded from TAVR for anatomical reasons or requiring concomitant cardiac procedures (such as multivalve or combined coronary procedures), SuAVR could provide the opportunity to reduce the surgical burden by reducing cross-clamp time and operative time. For the same reasons, SuAVR might be a valid option in redo operations with calcified aortic root.[2] In addition, the ease of securing the valve without sutures makes the technology a complementary adjunct to minimally invasive approaches, such as hemisternotomy or minithoracotomy, where access to the annulus may be limited. Whether these characteristics would provide an advantage over traditional surgical aortic valve replacement (SAVR) or TAVR is still debated, and the available evidence remains at the level of observational studies. In addition, the surgical community is divided on the appropriate use of these devices and the supposed clinical advantage of the minimization of CPB time is not widely accepted when weighted against the costs of the devices.[3] This systematic review summarizes the current evidence comparing outcomes of SuAVR with TAVR and/or SAVR in the treatment of aortic valve stenosis and provides an algorithm with practical recommendations to assist decision making as an adjunct to the current guidelines.

ABBREVIATIONS AND ACRONYMS

CPB = cardiopulmonary bypass

MACCE = major adverse cerebral and cardiovascular events

PPMK = permanent pacemaker

PVL = paravalvular leak

RCT = randomized clinical trial

SAVR = surgical aortic valve replacement

SuAVR = sutureless aortic valve replacement

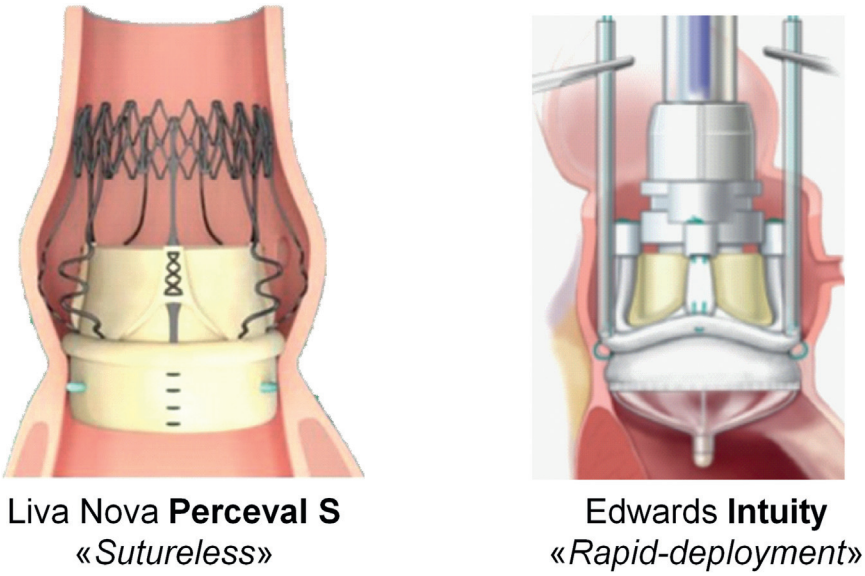
SVD = structural valve degeneration

TAVR = transcatheter aortic valve replacement

METHODS

A systematic review according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement was performed. A comprehensive systematic search was performed to

FIGURE 1 Currently Available Platforms



Perceval ("sutureless," on the left) and Intuity ("rapid deployment," on the right).

identify studies comparing SuAVR with TAVR or SAVR. Details of search strategy, the full PRISMA flow chart outlining the study selection process, characteristics of included studies, and quality assessment are available in the Supplemental Appendix.

SuAVR VS SAVR AND TAVR: DEFINING THE CONTEST. Currently, up to 32% of patients with indications for AVR are deemed too high risk for traditional surgery (SAVR), as prolonged myocardial ischemia and CPB are known factors associated with increased morbidity and mortality.[1] In patients deemed to be inoperable, PARTNER (Placement of AoRTic TraNscathetER Valve) 1 and 2 trials have demonstrated the superiority of TAVR over medical therapy.[4,5] Thereafter, following the promising short and midterm outcomes obtained by TAVR procedures, several randomized studies have investigated the potential advantages of TAVR in intermediate and low-risk patients with aortic stenosis. In addition, a meta-analysis of randomized clinical trials (RCTs), including a total of 8,020 patients, showed that TAVR was associated with reduced all-cause mortality when compared with SAVR.[6] The PARTNER 3 trial further produced compelling evidence with a primary composite endpoint (death, stroke, and rehospitalization) of 8.5% for TAVR vs 15.1% for SAVR at 1 year,[7] 11.5% for TAVR vs 17.4% for surgery at 2 years (HR: 0.63 for TAVR; 95% CI: 0.45-0.88; $P < 0.01$),[8] but there was no significant between-group difference at 5 years (22.8% in TAVR vs 27.2% in SAVR, $P = 0.07$).[9] Although the baseline characteristics were ostensibly the same, nearly one-quarter of patients undergoing SAVR also received concomitant procedures, many of which were other than myocardial revascularization without a complete overlap of indications and risk profile among the 2 groups.[7] In addition, the surgical arm of the group was implanted with various types of prostheses, some of which with known manufacturing defects and variable degrees of performance. The EVOLUT (Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients) trial demonstrated that TAVR was noninferior to SAVR in patients at low surgical risk.[10]

On this basis, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines stated that in symptomatic patients with severe aortic valve stenosis aged older than 80 years or for younger patients with a life expectancy <10 years and no anatomic contraindication, transfemoral TAVR is recommended over SAVR (Class I recommendation, Level of Evidence [LOE]: A).[11]

In patients with severe aortic valve stenosis aged 65 to 80 years and having no anatomic contraindication, either SAVR or transfemoral TAVR is recommended after shared decision making about the

TABLE 1 Sutureless and Rapid Deployment Valves: Technical Aspects

	Perceval S "Sutureless"	Edwards Intuity "Rapid Deployment"
Manufacturer	Corcym(ex Liva Nova)	Edwards
Design	Self-expandable nitinol frame	Ballon-expandable stainless-steel cloth-covered frame
Valve material and design	Bovine pericardium trileaflet	Bovine pericardium trileaflet (Magna Ease platform)
Rinse	Not required	Required (2 times, 60 s each)
Delivery	Collapsed with collapsing tool	Crimped
Implant	No sutures (only for guidance) Self-expandable (+ ballon expansion)	3 fixation sutures Rapid deployment Balloon expansion
Arterial cannulation	Proximal aortic arch	Standard
Aortotomy	High (fat pad)	Standard
Annular decalcification	Not extensive	Complete
Valve position	Intra-annular	Skirt anchored to left ventricular outflow tract

balance between expected patient longevity and valve durability (Class I recommendation, LOE: A).[11]

At the same time, the latest "ESC/EACTS Guidelines for the management of valvular heart disease" recommend performing TAVR in patients older than 75 years, in those at high risk (Society of Thoracic Surgeons Predicted Risk of Mortality [STS-PROM]/ EuroSCORE II >8%) or unfit for surgery (Class I recommendation, LOE: A),[12] whereas SAVR is still recommended for patients younger than 75 years at low risk for surgery (STS-PROM/ EuroSCORE II<4%) or unsuitable for TAVR (Class I recommendation, LOE: B). Finally, SAVR or TAVR are recommended in all other patients according to individual clinical, anatomical, and procedural characteristics (Class I recommendation, LOE: B).[12]

In this panorama, the use of a sutureless valve is rarely mentioned in the guidelines, as most of the evidence for SuAVR relies on single-center and retrospective analyses with scarce long-term follow-up. However, there are some situations in which SuAVR may confer a theoretical advantage over conventional valves or TAVR.

Patient and anatomical factors to consider when deciding among SAVR, SuAVR, and TAVR are summarized in **Table 2** and the **Central Illustration**. **Tables 3 to 5** summarize both mortality and complications.

SUTURELESS VALVES vs SAVR AND TAVR: CLINICAL OUTCOMES AND COMPLICATIONS. 30-day and long-term mortality. The most recent study from the SURD-IR (Sutureless and Rapid Deployment Aortic Valve Replacement International Registry) reported an in-hospital mortality of 2.1% (1.3% in patients who had isolated AVR and 3.7% in those who had concomitant procedures). In the same registry, hospital mortality in the low-risk patient subgroup (logistic EuroSCORE <10%) was 0.8% for isolated AVR and 1.9% in the case of concomitant procedures vs 2.2% and 3.7%, respectively, in higher-risk patients (logistic EuroSCORE >10%).[13]

These results are similar to those reported in large SAVR registries.[14,15] Accordingly, in a large propensity score matching analysis from the Society of Thoracic Surgeons Adult Cardiac Surgery Database, Erfe and colleagues[16] showed a similar mortality rate (3.1% vs 3.1%, $P = 0.98$) between SuAVR and SAVR.

The only prospective randomized trial currently published on SuAVR is the PERSIST (PERceval Sutureless Implant versus STandard Aortic Valve Replacement; NCT02673697) trial. This study included 910 patients who were randomized to AVR with a sutureless or stented valve at 47 centers, using a minimally invasive approach in 50.4% and 47.3%, respectively. The primary outcome was freedom from major adverse cerebral and cardiovascular events (MACCE) and composite of all-cause death, myocardial infarction, stroke, or valve reintervention at 1 year. The study demonstrated noninferiority of MACCE at 1 year and similar 30-day (1% vs 1%) and 1-year mortality (3.7% vs 3.7%).[17] A recent subanalysis[18] included only patients undergoing isolated aortic valve procedure and discussed the 1-year results after index surgery. SuAVR showed a significant reduction in MACCEs (5.2% vs 10.8%, $P < 0.01$) and a significant reduction in stroke rate (1.0% vs 5.4%, $P < 0.01$), but rate of permanent pacemaker implantation was higher compared with SAVR (11% vs 1.6%, $P < 0.01$). This study also attempted to stratify results on the surgical approach (full median sternotomy vs ministernotomy), but data were not statistically significant.

A recent subanalysis of the EVOLUT low-risk randomized trial in which the outcomes of the surgical group were compared according to the treatment with standard SAVR or SuAVR, failed to show a difference in all-cause mortality at 30 days (0.5% vs 1.5%,

TABLE 2 Patient and Anatomical Factors to Consider in the Choice Among SAVR, SuAVR, and TAVR

	SAVR	SuAVR	TAVR
Indications	All patients(especially younger patients)	All patients (especially in case of prolonged procedures or difficult access to annulus)	All patients (especially elderly patients)
Favorable factors in decision making	• Complex endocarditis with annular or aortomitral continuity destruction • Extreme annular sizes (<19 mm or >27 mm) • Preoperative conduction disorders	• Multiple valve surgery or other concomitant procedures • Calcified root or homograft • Redo operation • Fragile aortic wall	• Porcelain aorta • Sequelae of chest radiation • Presence of patent coronary bypass grafts • Redo surgery with cardiac structures adjacent to sternum • Expected patient-prosthesis mismatch • Severe chest deformation or scoliosis (poor surgical exposure)
Unfavorable factors in decision making	• Porcelain aorta • Hostile root • Multi-comorbid patients • Frailty	• Porcelain aorta • Complex endocarditis with annular or aorto-mitral continuity destruction • Extreme annular sizes (<19 mm or >27 mm) • Sinotubular dilation >40mm • Sinotubular:annular ratio >1.3 • Bicuspid valves(relative)	• Poor vascular access • Some concomitant procedures • Endocarditis • Low coronary ostia • Absence of annular calcification • Need for coronary access in the future (relative)
Cost (in-hospital, index procedure)	Reference	Slightly increased (+20%-30%)	Highly increased (+50%-80%)
Ealy mortality	Baseline (~ 2%)	Comparable to conventional	Comparable to conventional
Long-term mortality	Less related to procedure, more related to disease. Actuarial survival rates[15]: at 10 years, 50%-60%; at 15 years, 30%-35%; at 20 years, 15%-20%	Unknown	Unknown
Structural valve deterioration	Low(expected valve durability: 20 years; 10% risk of reoperation at 15 years in a 60-year-old patient)	Unknown	Unknown
Stroke (perioperative)	Rare (1%-2%)	Rare (2%-3%)	Rare (3%-4%)
Pacemaker implantation	Uncommon (1%-2%)	Common(4-6%)	More common (8%-10%)
Bleeding	Common	Common	Rare
Paravalvular leaks	Rare	Rare	Common
Minimally invasive option	Possible	Possible	Yes
Return to usual daily living	2-3 months	2-3 months	2-3 weeks
Patient-prosthesis mismatch	Uncommon	In smaller valves	Rare

SAVR = surgical aortic valve replacement; SuAVR = surgical aortic valve replacement with a sutureless or rapid deployment valve; TAVR = transcatheter aortic valve replacement.

$P = 0.28$) and 1 year (3.3% vs 2.6%, $P = 0.74$) in SuAVR (Table 3).

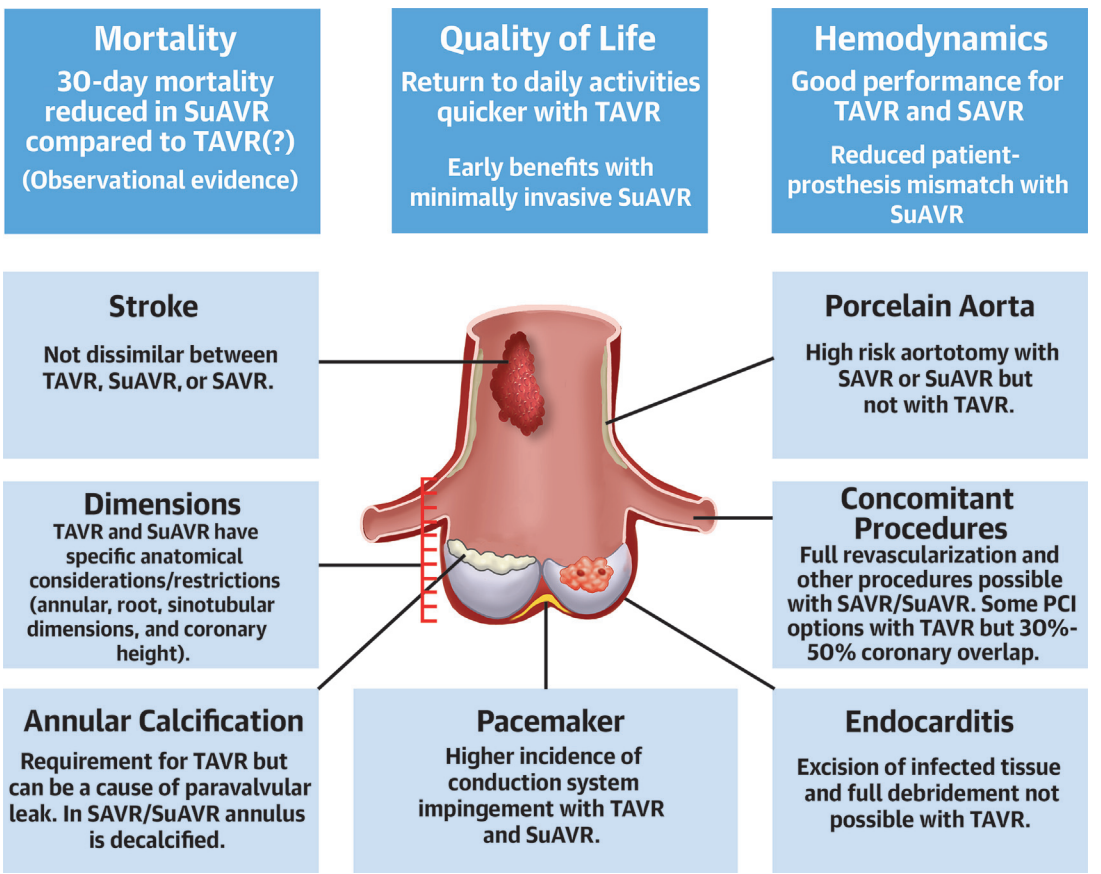
A recent large propensity-matched study comparing rapid deployment valves with conventional prosthesis showed no significative differences in terms of perioperative (2.4% vs 2.3%), 1-year (6.3% vs 5.8%), and 5-year mortality (7.4% vs 12.6%, respectively).[19]

Recently, Bottio et al[20] specifically investigated the role of SuAVR in patients undergoing concomitant myocardial revascularization with coronary artery bypass graft (CABG) surgery. They found a cumulative 30-minute reduction in cardiopulmonary bypass and aortic cross-clamp time in the SuAVR group with lower transvalvular gradient at discharge and follow-up. No differences in early mortality (2.8% in SuAVR+CABG vs 5% in SAVR+CABG, $P = 0.08$), in 5-year survival (93% in SuAVR+CABG vs 91% in SAVR+CABG, $P = 0.784$), and in major adverse events (16.1% in SuAVR+CABG vs 7.3% in SAVR+CABG, $P = 0.067$ when adjusted for revascularization variables) were observed.

Our pooled cumulative analysis of both observational and randomized evidence comparing SAVR and SuAVR showed no difference in mortality at 1 year (OR: 1.01; 95% CI: 0.87-1.16; $P = 0.97$) (Figure 2). Interestingly, when comparing the results of RCTs with retrospective or propensity-matched cohorts we found no statistically significant difference in 1-year mortality.

With regard to the specific differences in outcomes among the 2 available platforms, rapid deployment and totally sutureless valves, most of the literature, including large multicentric registries and meta-analyses, has tended to combine the clinical results of both the devices and compare them with standard SAVR. However, recent head-to-head comparative studies from large multicentric registries complemented by propensity-matched score analysis[21-27] and a metanalysis[24] have confirmed similar hard

CENTRAL ILLUSTRATION **Surgical Aortic Valve Replacement, Surgical Aortic Valve Replacement With a Sutureless Valve, and Transcatheter Aortic Valve Replacement: Procedural Considerations and Postoperative Outcomes**



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PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; SuAVR = sutureless aortic valve replacement; TAVR = transcatheter aortic valve replacement.

clinical outcomes in terms of mortality and cardiovascular events, but differences in transvalvular gradients and surgical timings. Indeed, the rapid deployment valve was associated with better transvalvular gradients and lower incidence of mild aortic regurgitation, whereas the sutureless device was associated with lower cross-clamp, CPB time, and length of stay in hospital (Table 6). In our systematic analysis we found no difference in 1-year mortality among the rapid deployment or totally sutureless groups (test of group difference, $P = 0.82$) (Figure 3).

When comparing SuAVR and TAVR, no randomized trials are currently available, but the evidence is mainly based on observational and retrospective studies. Gerfer et al[28] in a propensity score matching cohort reported a higher 30-day all-cause mortality in SuAVR with the sutureless valve vs TAVR with ACURATE NEO (Boston Scientific Corporation) (5.1% vs 1.7%, $P = 0.619$). However, a recent meta-analysis including a large cohort of high-risk patients showed an early mortality of 2.5% in the SuAVR group and 5% in the TAVR group ($P = 0.02$).[29] In addition, Meco and colleagues[2] demonstrated in a meta-analysis of propensity-matched studies a lower 30-day mortality and improved 1- and 2-year survival in patients undergoing SuAVR vs TAVR. Long-term benefits with SuAVR have been shown by a recently published metanalysis[30] including propensity-matched studies with reconstructed time-to-event data; in the pooled data from 1,322 patients (661 pairs), TAVR has been associated with a higher risk of mortality during follow-up (HR: 1.74; 95% CI: 1.26-

TABLE 3 Studies Comparing SuAVR vs AVR for Severe Aortic Stenosis

First Author, Year (Study)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Pacemaker	Bleeding
Borger et al, 2015[75] (CADENCE-MIS)	Randomized, multicenter trial	100 patients (51 SuAVR vs 49 SAVR)	4.3 % in SuAVR vs 2.1% in SAVR ($P = 0.53$)	4.3 % in SuAVR vs 2.1% in SAVR ($P = 0.53$)	No significative difference	Higher in SuAVR (4.3 % vs 0.0%; $P = 0.14$)	6.5 % in SuAVR vs 8.3% in SAVR ($P = 0.73$)
Hurley et al, 2015[53]	Systematic review and metanalysis	832 patients were included in the sutureless group and 3,740 in the conventional group	30-day mortality 1.9% in SuAVR vs 3.2% in SAVR ($P = 0.14$)	NR	NR	Higher in SuAVR (9.1% vs 2.4%; $P = 0.025$)	NR
Ensminger et al, 2018[14] (German Aortic Valve Registry [GARY])	Nationwide German experience	A total of 22,062 patients (20,937 SAVR vs 1,125 SuAVR)	In-hospital mortality was similar in SuAVR vs SAVR (1.7% vs 2.2%; $P = 0.22$)	Significantly elevated rates of disabling stroke in SuAVR vs SAVR (2.2% vs 0.9% $P < 0.001$)	NR	Significantly elevated rates of pacemaker implantation in SuAVR vs SAVR (8.8% vs 3.7%; $P < 0.001$)	SAVR 19.4% vs 14.5% SuAVR ($P = 0.004$)
Hanedan et al, 2018[135]	Retrospective study	70 older patients (38 SuAVR vs 32 AVR)	30-day mortality 5.3% in SuAVR vs 15.6% AVR ($P = 0.23$)	NR	NR	NR	5.3% in SuAVR vs 6.3% SARV ($P = 0.999$)
Mujtaba et al, 2018[136]	Retrospective study	763 patients (139 SuAVR vs 624 AVR)	SuAVR 2.1% vs 2.4% SAVR ($P = 0.86$)	SuAVR 2.8% vs SAVR 1.4% ($P = 0.24$)	NR	SuAVR 3.6% vs SAVR 1.9% ($P = 0.23$)	SuAVR group had a lower reopening rate for bleeding (2.1% vs 6.7%; $P = 0.04$)
Woldendorp et al, 2020[49]	Metanalysis on 23 studies	8,718 patients	No significant difference in early mortality (SAVR 2.8%, SuAVR 3.7%, minimally invasive SAVR 1.8%, minimally invasive SuAVR 1.7%)	No significant difference in stroke	NR	SuAVR have greater requirement for postoperative permanent pacemaker (OR 2.27, 95% CI: 1.25-4.14, $P = 0.008$)	No significant difference in major bleeding
Fischlein et al, 2021[17] (PERSIST trial)	Prospective, randomized, adaptive, open-label trial	At 47 centers, 910 patients were randomized to sutureless (n = 453) or conventional stented (n = 457) valves	MACCE at 1 year demonstrated noninferiority of SuAVR vs SAVR (3.7% vs 3.4% SAVR)	Noninferiority was demonstrated for MACCE at 1 year (SuAVR 2.5% vs SAVR 3.2%)	Incidences of perivalvular and central leak were similar (4.2% vs 4.5%)	Use of sutureless valves resulted in a higher rate of pacemaker implantation (11.1% vs 3.6% at 1 year)	SuAVR4.4% vs SAVR 6.3%
Lam et al, 2021[51] (EVOLUT trial)	Evaluate outcomes in patients treated with a sutured (stented or stentless) or sutureless surgical valve from the EVOLUT Low-Risk Trial	680 patients who underwent surgical aortic valve implantation (205 sutureless, 475 sutured)	All-cause mortality between groups was similar between groups at 30 days (0.5% vs 1.5%, $P = 0.28$) and 1 year (3.3% vs 2.6%, $P = 0.74$)	Disabling stroke was similar at 30 days (2.0% vs 1.5%, $P = 0.65$) and 1 year (2.6% vs 2.2%, $P = 0.76$)	NR	Permanent pacemaker implantation at 30 days was significantly higher in SuAVR vs SAVR (14.4% vs 2.9%, $P < 0.001$)	NR

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2.40; $P < 0.001$), even though a dedicate meta-regression to account for baseline age and conditions was not performed (Table 4).

Considering the nature of the available data in the literature on this topic, our pooled cumulative analysis was limited to observational propensity-matched studies comparing TAVR and SuAVR and reporting perioperative 30-day mortality. In this systematic analysis we did not show a statistically significant difference in 30-day mortality among the 2 groups (OR: 0.59; 95% CI: 0.21-1.59; $P = 0.29$) (Figure 4).

Other authors have performed larger combined analyses, including SuAVR, TAVR, and SAVR. Qureshi et al,[31] in a meta-analysis, found in the low- and intermediate-risk population a reduction of at least 30% in 30-day mortality and in the risk for paravalvular leak comparing SuAVR vs TAVR. Takagi et al[32] combined the results of direct-comparison and adjusted indirect-comparison meta-analyses and

TABLE 3 Continued

First Author, Year (Study)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Pacemaker	Bleeding
Erfe et al, 2021[16]	Comparative study with propensity score matching analysis	4,486 SuAVR patients and 13,215 AVR patients	Similar 30-day mortality (3.1% vs 3.1%, $P = 0.98$)	NR	Moderate or greater paravalvular regurgitation (0.2% vs 0.1%, $P = 0.21$) in SuAVR	The SuAVR recipients had more permanent pacemakers (11.4% vs 4.9%, $P < 0.001$) than AVR	NR
Choi et al, 2021[137]	Comparison of clinical outcomes of SuAVR with AVR in a nationwide study. Propensity score-matched analysis	3,173 patients SuAVR and SAVR were performed in 641 and 2,532 patients, respectively	Operative mortality rate was 2.8% without significant differences between the SuAVR (3.4%) and SAVR (2.3%) groups ($P = 0.324$). 1- and 2-year overall survival was 89.1% and 87.5%, respectively, without significant differences between the groups (SuAVR group vs SAVR group 89.9% and 90.5% vs 87.2% and 88.7%, respectively; $P = 0.475$)	SAVR 2.7% vs SuAVR 2.5% ($P > 0.999$)	NR	PPM implantation rate was significantly higher in the SuAVR (3.8%) than in the AVR group (0.9%) ($P < 0.001$)	SuAVR 4.2% vs 3.1% ($P = 0.371$)
White et al, 2022[19]	Retrospective study	2,237 patients, 1,682 SAVR and 295 SuAVR (before propensity matching); 295 couples of patients after propensity score matching	At 30 days, 2.3% in SAVR vs 2.4% in SuAVR ($P = 0.937$). At 1 year, 5.8% in SAVR vs 6.3% in SuAVR ($P = 0.615$). At 5 years, 12.6% in SAVR vs 7.4% in SuAVR ($P = 0.662$)	1.0% in SAVR vs 1.0% in SuAVR ($P = 0.990$)	0.2% in SAVR vs 0.7% in SuAVR ($P = 0.358$)	PPM implantation rate was higher in SuAVR (6.8%) than in SAVR (2.3%) ($P = 0.009$)	NR
Fischlein et al, 2022[18] (PERSIST trial)	Randomized study (subanalysis of PERSIST trial, considering only patients undergoing isolated aortic valve replacement)	578 patients, 285 SuAVR (Perceval, 67% in ministernotomy) and 293 SAVR (65% in ministernotomy)	No in-hospital differences	At 1 year, 1.0% in SuAVR vs 5.4% in SAVR ($P < 0.001$)	No in-hospital differences	At 1 year, PPM implantation rate higher in SuAVR (11.0% vs 1.6%, $P < 0.001$)	No in-hospital differences

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showed improved survival in SuAVR compared with TAVR, but no advantage when compared with conventional SAVR.[32] These results confirm a previous meta-analysis finding in 5,000 high-risk patients in which SuAVR was associated with a reduction in early mortality[33] (**Table 5**). However, this early benefit was not confirmed by another more recent comprehensive metanalysis by Kim et al.[34] Despite the acknowledged significant risk of bias, and the low quality of the evidence, these authors found no difference in the 30-day mortality but a decreased risk of 2-year mortality using SuAVR compared with TAVR (OR: 0.39; 95% CI: 0.17-0.88) and reduced odds of paravalvular regurgitation (OR: 0.11; 95% CI: 0.06-0.21). Interestingly, no differences were found in short-term and 2-year mortality between SuAVR and SAVR.[34]

These findings need to be considered in light of the limitations inherent in the nature of the reported studies. Heterogeneity in baseline patient characteristics or in preoperative risk stratification, differences

TABLE 3 Continued

First Author, Year (Study)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Pacemaker	Bleeding
Berretta et al, 2022[23] (SURD-IR registry)	Comparison of clinical outcomes of SuAVR with AVR in a multicenter registry. Propensity score-matched analysis	5,286 patients, 2,643 SuAVR (minimally invasive approach in 86.2%) and 2,643 SAVR (minimally invasive approach in 62.3%)	No in-hospital differences (1.2% in SuAVR vs 1.4% in SAVR, $P = 0.6$)	Increased risk of stroke in SuAVR (2.3% vs 0.9%, $P < 0.001$)	Residual aortic regurgitation reduced with SuAVR (7.6% vs 13.6%, $P < 0.001$)	Increased risk of PPM in SuAVR (7.9% vs 2.5%, $P < 0.001$)	No in-hospital differences (3.3% in SuAVR vs 3.2% in SAVR, $P = 0.80$)
Lorusso et al, 2022[59]	Randomized study (subanalysis of PERSIST trial, focused of pacemaker implantation)	896 patients (450 SuAVR, 446 SAVR)	NR	NR	NR	In-hospital: Increased risk of PPM in SuAVR (10.4% vs 3.1%, $P < 0.001$). In SuAVR, PPM is related to larger prosthesis dimension (5% in size S, 7% in size M, 7.3% in size L, 21.6% in size XL). At 1 year, no differences (2.3% vs 1.6%)	NR
Salmasi et al, 2022[132]	Metanalysis of 35 studies (1 randomized trial, 1 registry, 6 propensity-matched retrospective study, 28 observational studies)	10,381 patients (3,686 SuAVR, 6,310 SAVR)	No differences ($P = 0.93$)	No differences ($P = 0.28$)	Increased risk of paravalvular leak in SuAVR (OR: 2.52; 95% CI: 1.32-4.79; $P = 0.005$)	Increased risk of PPM in SuAVR (OR: 2.41; 95% CI: 1.92-3.01; $P < 0.001$), consistent in subgroup analysis including Perceval-only (OR: 2.24; $P < 0.01$) or Intuity-only studies (OR: 2.57, $P < 0.001$)	No differences ($P = 0.69$)
Bottio et al, 2022[20]	Retrospective study, 2 centers, all patients undergoing concomitant myocardial revascularization (CABG)	285 patients (144 SuAVR, 141 SAVR), CABG in all patients	No differences (2.8% in SuAVR, 5% in SAVR; $P = 0.09$)	No differences (4% in SuAVR, 1.4% in SAVR; $P = 0.07$)	No differences (4% in SuAVR, 5.9% in SAVR; $P = 0.25$)	Increased risk of PPM in SuAVR (8% vs 3%, $P = 0.018$)	No differences (6% in SuAVR, 7% in SAVR; $P = 0.71$)
D'Onofrio et al, 2022[77]	Retrospective study	375 patients (252 SuAVR, 123 SAVR)	No differences (0.8% in SuAVR, 0.8% in SAVR; $P =$ NR)	No differences (0% in SuAVR, 0% in SAVR; $P =$ NR)	NR	No differences (5.9% in SuAVR, 6.3% in SAVR; $P =$ NR)	NR

CABG = coronary artery bypass graft; NR = not reported; MACCE = major adverse cerebral and cardiovascular events; PPM = patient prosthesis mismatch; SAVR = surgical aortic valve replacement; SuAVR = surgical aortic valve replacement with a sutureless or rapid deployment valve; TAVR = transcatheter aortic valve replacement.

in the techniques and approaches used in the original studies included in the meta-analyses (ie, transfemoral, trans-apical, trans-carotid), and unmeasured confounding factors related to patient selection, allocation, or operator experience, could have affected the results. In fact, the major RCTs on TAVR showed similar or improved mortality when compared with SAVR, making it difficult to deduce the conclusion that a surgical approach with a sutureless device could introduce a definitive mortality advantage. Differences in patient selection and risk stratification might partially explain these results and tailored studies and registries are warranted to corroborate those findings. In support of this hypothesis, in the large all-comers' GARY (German Aortic Valve Registry), including 1,743 patients receiving SuAVR and 14,730 receiving TAVR, in-hospital mortality was similar 1.6% vs 1.8% before propensity matching, but was significantly higher after SuAVR (1.7% vs 0.65, respectively) after propensity matching.[35]

Paravalvular leaks. The risk of paravalvular leak (PVL) in SuAVR is related to the extent of annular decalcification and the accuracy of sizing. In an initial European multicenter study with the 3F Enable bioprostheses (currently off the market), major paravalvular leaks occurred with a 2.1% rate.[36] The TRITON (Efficacy and Safety of Initial Triple Versus Initial Dual Oral Combination Therapy in Patients

TABLE 4 Studies Comparing SuAVR vs TAVR for Severe Aortic Stenosis

First Author, Year (Study Name)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Permanent Pacemaker	Bleeding
D'Onofrio et al, 2012[39]	Propensity-matched study, multicenter study	468 TA-TAVR (performed in 20 centers) vs 51 SuAVR (performed in 3 centers)	Hospital mortality was 5.3% and 0% in the TA-TAVR and SuAVR groups, respectively ($P = 0.49$) [high-risk cohort]	No perioperative stroke events in both groups	The incidence of paravalvular leak was greater in the TAVR group (44.7% vs 15.8%, $P = 0.001$)	5.3% in TAVR vs 5.3% in SuAVR ($P = 1$)	5.3% in TAVR vs 2.3% in SuAVR ($P = 1$)
Santarpino et al, 2014[138]	Propensity-matched study	122 SuAVR vs 122 TAVR	In-hospital mortalities were 0% in the SuAVR group and 8.1% in the TAVR group ($P = 0.24$). At mean follow-up of 18.9 ± 10.1 months, overall cumulative survival was significantly different between groups SuAVR 97.3% vs TAVR 86.5% ($P = 0.015$)	5.4% in TAVR vs 5.4% in SuAVR $P > 0.999$	Higher paravalvular leak rate in the TAVR group (13.5% vs 0%; $P = 0.027$)	10.8% in SuAVR group and 2.7% in the TAVR group ($P = 0.18$)	NR
Miceli et al, 2016[50]	Comparative study in high-risk patients treated for severe aortic stenosis	178 patients SuAVR vs 91 patients TAVR	The in-hospital mortality rate was 8.1% in the TAVR group and 0% in the SuAVR group ($P = 0.25$) [important absolute difference between groups despite not being statistically significant] 1- and 2-year survival rates were 91.6% vs 78.6% and 91.6% vs 66.2% in patients undergoing SuAVR compared with those undergoing TAVR ($P = 0.1$)	The incidence of stroke was 5.4% vs 0% in the TAVR and SuAVR groups, respectively ($P = 0.30$)	In the TAVR group, 37.8% had mild paravalvular leakage and 27% and 2.7%, respectively, in the SuAVR group ($P < 0.001$)	NR	NR
Biancari et al, 2016[71]	Retrospective multicenter analysis	394 TAVR vs 379 SuAVR	In-hospital mortality 2.6 % after SuAVR and 5.3 % after TAVR ($P = 0.057$)	NR	TAVR was associated with a significantly high rate of mild (44.0% vs 2.1%) and moderate-severe paravalvular regurgitation (14.1% vs 0.3%, $P < 0.0001$) compared with SuAVR	TAVR was associated with a significantly high rate of need for permanent pacemaker implantation (17.3% vs 9.8%, $P = 0.003$) compared with SuAVR	NR
Takagi et al, 2016[33]	Meta-analysis of comparative studies (7 observational comparative studies included)	945 patients	Significant reduction in mortality with SuAVR over TAVR (2.5% vs 7.3%; $P = 0.003$)	NR	Statistically significant reduction in paravalvular aortic regurgitation with SuAVR over TAVR (3.5% vs 33.2%; $P = 0.002$)	NR	No statistically significant difference in bleeding complication
Wang et al, 2016[74]	Meta-analysis of matched studies comparing SuAVR versus TAVR (6 studies included)	741 patients in both the SuAVR and TAVR arm of the study	There was no difference in perioperative mortality. SuAVR patients had significantly better survival rates at 1 ($P < 0.01$) and 2 years ($P < 0.01$)	No significant difference in incidence of stroke and transient ischemic attacks ($P = 0.27$)	SuAVR had a lower incidence of paravalvular leak ($P < 0.01$)	No significant difference in need for pacemaker implantation ($P = 0.86$)	There was a trend toward major bleeding or bleeding requiring re-exploration in patients who underwent SuAVR compared with TAVR ($P = 0.09$)

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TABLE 4 Continued

First Author, Year (Study Name)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Permanent Pacemaker	Bleeding
Meco et al, 2018[2]	Systematic review and meta-analysis of 6 comparative studies using propensity score matching.	1,462 patients (731 SuAVR and 731 TAVR)	In-hospital mortality was lower in the SuAVR group (3.23% vs 5.93%, $P = 0.003$). 1-year survival was better in the SuAVR group ($P = 0.001$), as was the 2-year survival ($P = 0.001$)	In the TAVR group, the incidence of postoperative stroke was higher (1.61% vs 3.64%, $P = 0.01$)	The incidence of moderate or severe paravalvular regurgitation was higher in the TAVR group (2.8 vs 18.19, $P = 0.001$)	There was no difference in the pacemaker implantation (9.31% vs 9.34%, $P = 0.86$)	NR
Shinn et al, 2018[29]	Systematic review and meta-analysis. 7 observational studies included	617 SuAVR and 621 TAVR patients	Early mortality was 2.5% and 5% in the SuAVR and TAVR cohorts, respectively ($P = 0.02$)	Postprocedural stroke was comparable between the 2 cohorts (1.1% and 1.7%, respectively, $P = 0.53$)	Postprocedural significant paravalvular leak was much lower after SuAVR (11% and 1.5%, $P < 0.0001$)	The need for pacemaker insertion was comparable between the 2 cohorts ($P = 0.70$)	NR
Muneretto et al, 2022[72]	Multi-institutional study	967 elderly patients (>75 years) with intermediate risk	The 30-day mortality was significantly lower SuAVR vs TAVR (1.7% vs 5.5%; $P = 0.024$). Multivariable Cox regression identified TAVR as an independent predictor for 5-year mortality and major adverse cardiovascular events at 60 months follow-up, the all-cause death rate was lower in SuAVR than TAVR (SuAVR 16.1% ± 4.1% vs TAVR= 28.9% ± 5.3%, $P = 0.006$)	Stroke/transient ischemic attack cumulative incidence at 5 years was 1.4% SuAVR vs 5.3% in TAVR ($P = 0.010$)	The incidence of perivalvular leak grade II or greater was 1.3% in SuAVR and 9.8% in TAVR ($P < 0.001$)	The rate of permanent pacemaker implantation was 5.5% in SuAVR vs 10.7% in TAVR ($P = 0.032$)	NR
Abdel-Wahab et al, 2020[35] (German Aortic Valve Registry [GARY])	Nationwide German experience	16,743 patients (14,730 TAVR and 1,743 SuAVR) before propensity score matching, 1,605 pairs of patients after propensity score matching	In overall cohort, no differences in in-hospital mortality (1.6% SuAVR vs 1.8% TAVR, $P = 0.62$) but after matching significant decrease in TAVR mortality (1.7% SuAVR vs 0.6% TAVR, $P = 0.003$)	In-hospital stroke rate higher for SuAVR (1.8% SuAVR vs 0.7% TAVR, $P = 0.01$)	In overall cohort, paravalvular leak rate higher with TAVR (0.7% SuAVR vs 2.1% TAVR, $P = 0.001$) but only trend after matching ($P = 0.06$)	PPM implantation rate higher in TAVR (8.5% SuAVR vs 12.8% TAVR, $P = 0.001$)	Vascular complications increased in TAVR (0.8% SuAVR vs 6.3% in TAVR, $P = 0.001$)
Gerfer et al, 2021[28]	Retrospective study	332 patients (119 SuAVR vs 213 TAVR)	Slightly higher rates for 30-day all-cause mortality in SuAVR vs TAVR (1.7% vs 5.1%, $P = 0.619$)	Transient ischemic attack SuAVR= 3.4% vs TAVR= 1.7% ($P = 0.496$) Stroke SuAVR=1.7% vs TAVR= 0.0% ($P = 1$)	Mild SuAVR= 0.0% vs TAVR= 55.9 ($P = 0.001$) and moderate or higher SuAVR = 0.0% vs TAVR = 6.8%, $P = 0.119$)	Comparable PPM rates SuAVR = 10.2% vs TAVR = 8.5% ($P = 0.752$)	NR
Vilalta et al, 2021[54]	Retrospective study	806 patients (325 SuAVR and 481 TAVR) before propensity score matching, 171 pairs of patients after propensity score matching	No differences regarding in-hospital mortality (SuAVR: 4.1%, TAVR: 1.8%, $P = 0.199$)	No differences in stroke (SuAVR: 2.3%, TAVR: 2.9%, $P = 0.736$)	No differences in moderate to severe aortic regurgitation (0.6% SuAVR vs 1.1% TAVR, $P = 0.706$)	PPM implantation rate higher in TAVR (8.8% SuAVR vs 18.1% TAVR, $P = 0.011$)	NR

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TABLE 4 Continued

First Author, Year (Study Name)	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Permanent Pacemaker	Bleeding
Santarpino et al, 2022[83]	Retrospective study	1,445 patients (443 SuAVR and 1,002 TAVR) before propensity score matching, 172 pairs of patients after propensity score matching; low-risk patient cohort	No differences in 30-day mortality (SuAVR vs TAVR: 4% vs 2.9%; $P = 0.7$) At follow-up, SuAVR patients had a significantly higher probability of survival than TAVR patients (no. of fatal events: 22 vs 74; $P < 0.014$)	NR	NR	No differences in pacemaker implantation (SuAVR 5.8% vs TAVR 11.6%; $P = 0.1$)	NR
Sà et al, 2022[30]	Systematic review and metanalysis of 10 studies using matching strategies	5,134 patients (2,567 SuAVR, 2,567 TAVR) in 10 propensity-matched studies	No differences in 30-day mortality ($P = 0.360$). Higher risk of mortality with TAVR (HR: 1.74; 95% CI: 1.26-2.40; $P < 0.001$)	No differences (OR for SuAVR: 1.31; 95% CI: 0.84-2.05; $P = 0.230$)	SuAVR has lower risk of paravalvular leak (OR: 0.09; 95% CI: 0.05-0.17; $P < 0.001$)	No differences but significant trend toward reduced PPM for SuAVR (OR for SuAVR: 0.59; 95% CI: 0.35-1.01; $P = 0.060$)	NR

Abbreviations as in Table 3.

With Newly Diagnosed Pulmonary Arterial Hypertension: A Multi-center, Double-blind, Placebo-controlled, Phase 3b Study - AT) with Edwards Intuity prosthesis demonstrated a paravalvular leak rate at 1 year of 2.3% (1.4% in early stage and 0.9% late).[37] In the first series with the sutureless valve, the incidence of paravalvular leaks was reported as 12.5% to 15%.[38-40]

In a propensity-matched study[36] and pooled results from a meta-analysis,[41] PVL rates ranged approximately 2% to 4%, being higher than in SAVR. The early high occurrence was attributed to inadequate annular decalcification and oversizing of the valves in the initial series. To this extent, it is important to notice that the size of the Perceval device incorporates a degree of oversizing so that further oversizing would be potentially deleterious.

Interestingly, the PERSIST randomized trial demonstrated similar rates of perivalvular (4.2% for SuAVR vs 4.5% for SAVR) and central leak at 1 year (4.8% for SuAVR vs 3.7% for SAVR)[17] (Table 3). Recently, White et al[19] in a large propensity-matched retrospective study including 295 patients per group, also showed no significant differences in the incidence of paravalvular leaks among rapid deployment and standard bioprosthetic valves.

It is important to note that rate of PVL is also linked to the learning curve of operators in implanting these devices, as pointed out in an international expert consensus statement on the topic,[42] and in a more recent review on health risk management.[43] This idea is supported by the progressive decrease in the incidence rate of PVL across historical series along with surgeons' experience.[41,44,45] Design improvements and associated technique adjustments have played a role in the reduction of the reported incidence of this complication.[44,46] Multidetector-row computed tomography has been also proposed to aid sizing and adequate prosthesis selection.[47]

As opposed to TAVR, SuAVR enables removing the diseased valve with an adequate calcium debridement of the annulus. This allows optimal valve deployment and a reduction in paravalvular leak that could impact survival.[48] In fact, the reported average incidence of PVL with SuAVR is lower than that reported with TAVR (6.9% and 34%, respectively) (Table 4). Nonetheless, as both technologies mature, PVL rate with TAVR and SuAVR are likely to both reduce further in the foreseeable future.

Importantly, SuAVR performed via a minimally invasive approach (hemi-sternotomy) has been associated with a significantly reduced rate of paravalvular leakage in comparison with TAVR but also improvement in survival at 2 years in retrospective studies, suggesting that minimally invasive SuAVR could be considered as a treatment approach for patients in the "gray zone" between TAVR and conventional surgery (ie, such as intermediate-low risk), either due to aortic root anatomy or an unfavorable peripheral vasculature that precludes the transfemoral approach for TAVR.[2,49] Similarly, a comparison between right anterior thoracotomy SuAVR and TAVR showed significant reduction in paravalvular

TABLE 5 Studies Comparing SuAVR, TAVR, and AVR for Severe Aortic Stenosis

First Author, Year	Type of Study	Study Size	Mortality	Stroke	Paravalvular Leak	Pacemaker	Bleeding	Major Vascular Complication
Takagi et al, 2017[32]	Meta-analyses and an adjusted indirect-comparison meta-analysis (IDC-MA) on randomized controlled trials and propensity score-matched studies	6 RCTs and 30 PSM studies included 15,887 patients	Lower 30-day or in-hospital all-cause mortality after SuAVR than after TAVR (OR: 0.48; 95% CI: 0.28-0.80; $P = 0.005$) and no significant differences between SuAVR and SAVR (OR: 1.07; 95% CI: 0.60-1.94; $P = 0.81$) and between TAVR and SAVR (1.07; 95% CI: 0.90-1.27; $P = 0.45$).	NR	NR	NR	NR	NR
Qureshi et al, 2018[31]	Meta-analysis of SuAVR vs SAVR and TAVR	12 studies included	SuAVR was associated with at least 30% reduction in 30-day mortality vs TAVR (OR: 0.40; 95% CI: 0.25-0.62; $P < 0.001$) primarily in the low- and intermediate-risk population. No reduction in the risk for 30-day mortality SuAVR vs SAVR (OR: 1.03; 95% CI: 0.56-1.88; $P = 0.93$).	Absence of either benefit or harm about stroke	SuAVR was associated with a reduction in the risk for paravalvular leak vs TAVR (OR: 0.13; 95% CI: 0.09-0.17; $P < 0.001$).	Evidence in favor of SAVR with at least 50% risk reduction in pacemaker implantation against SuAVR. Absence of evidence to support or refute that SuAVR is associated with reduction of relative risk of PPM implantation vs TAVR	NR	NR
Kim et al, 2021[34]	Meta-analysis of SuAVR vs SAVR and TAVR	1 randomized and 78 observational studies (n = 60,689; SuAVR vs SAVR = 39,171, vs TAVR = 21,518)	Compared with TAVR, SuAVR demonstrates no significant difference in mortality at 30 days (OR: 0.52; 95% CI: 0.85-1.16), but decreased odds at 2 years (OR: 0.39; 95% CI: 0.17-0.88). Compared with SAVR, SuAVR was associated with a similar mortality at 30 days (OR: 0.99; 95% CI: 0.85-1.16) and 2 years (OR: 0.99; 95% CI: 0.43-2.30)	NR	SuAVR has reduced odds of mild paravalvular regurgitation compared with TAVR (OR: 0.11; 95% CI: 0.06-0.21)	SuAVR significantly increased odds of permanent pacemaker implantation (OR: 2.5; 95% CI: 2.25-2.77)	NR	NR

AVR= aortic valve replacement; PSM = propensity score matched; other abbreviations as in Table 3.

leaks and a trend toward improved immediate and midterm outcomes and survival.[50]

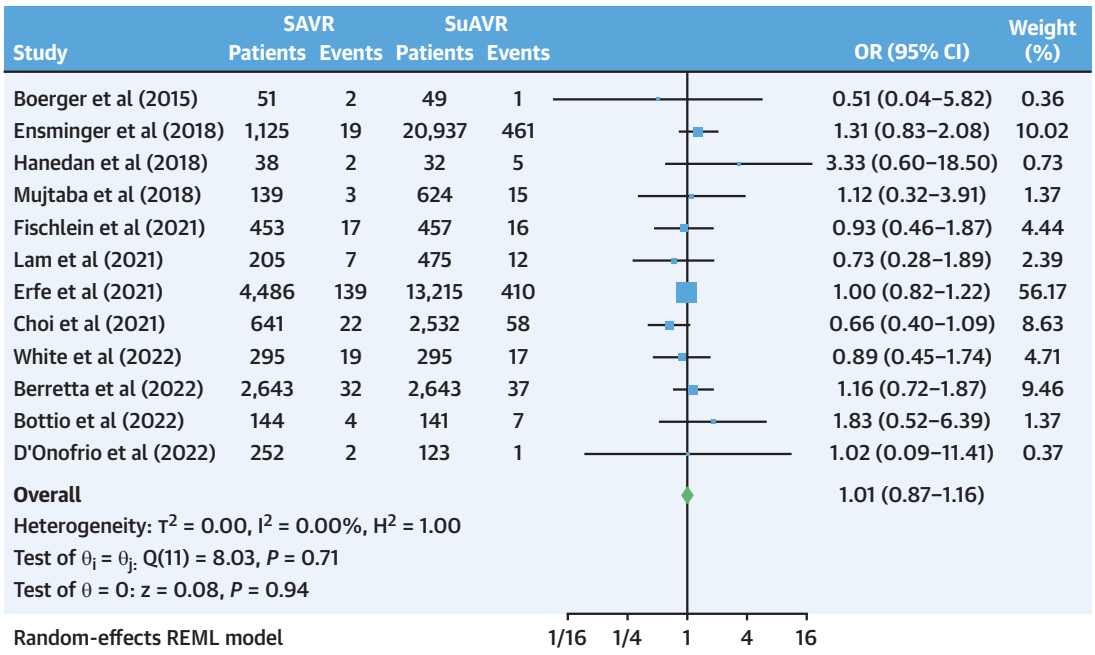
Stroke rates. As noted in the largest report from GARY, neurological events (transient ischemic attack or disabling stroke) with SuAVR are similar to conventional SAVR (1.9% incidence).[14] The PERSIST trial showed noninferiority for MACCEs at 1 year with similar rate of stroke at 30 days (1.5% vs 1.9%) and 1 year (2.5% vs 3.2%) for SuAVR and SAVR, respectively.[17] Similar findings were shown in the subanalysis of the EVOLUT low-risk trial in terms of all-cause mortality (0.5% vs 1.5% at 30 days and 3.3% vs 2.6% at 1 year)[51] (Table 3).

A recent meta-analysis of propensity-matched studies indicated that surgically implanted sutureless valves had a lower stroke rate than matched TAVR patients.[2] However, in another meta-analysis including a large cohort of high-risk patients, postoperative neurological events were similar among SuAVR and TAVR groups[29] (Table 4).

Permanent pacemaker implantation rate. The reported incidence of permanent pacemaker (PPMK) implantation for SuAVR is approximately 5.6% to 9.1%[52-55] but it has been reported to be as high as 17% in some series[48] compared with 3.6% to 6.9% for SAVR, and 8.5% to 16.6% for TAVR.[4,29,56,57]

The PERSIST trial confirmed the higher rate of pacemaker implantation in SuAVR with totally sutureless devices when compared with SAVR (11.4% vs 3.6% at 1 year).[17] These results were recently echoed by a subanalysis of the EVOLUT low-risk trial showing PPMK implantation rate at 30 days of 14.4%

FIGURE 2 SAVR vs SuAVR: 1-Year Mortality



SAVR = surgical aortic valve replacement; SuAVR = surgical aortic valve replacement with a sutureless valve.

in the SuAVR group and 2.9% in the SAVR group[51] (Table 3).

In a recent propensity-matched retrospective study on 2,237 patients (295 per group after matching), the rapid deployment valve group had a significantly higher incidence of pacemaker implantation when compared with standard biological valves (6.8% vs 2.3%) and a consequent longer length of stay in hospital (9.8 days vs 8.9 days).[19]

The need for pacemaker implantation in SuAVR is mainly related to the position of deployment of the valve within the annulus and the impact of the radial anchoring forces. Avoidance of oversizing in sutureless valves may help to reduce the incidence of this complication because of its effect on the conducting tissue.[42] Shorter left ventricular outflow tract "skirt" of the prosthesis would probably translate in reduced pacemaker rates. Interestingly, a recent meta-analysis comparing the sutureless (Perceval) valve with rapid deployment (Intuity) valves showed a lower incidence of pacemaker implantation in the latter group (RR: 0.69; 95% CI: 0.50-0.94).[58] Potential risk factors for PPMK have been investigated in retrospective series, and prior right bundle branch block appears to be a strong predictor of PPMK implantation (OR: 2.60; 95% CI: 1.15-5.81; P = 0.022).[55] The role of preoperative conduction disorders in predicting PPMK has been confirmed by the recent subanalysis of the PERSIST-AVR (Perceval Sutureless Implant vs Standard Aortic Valve Replacement) randomized study,[59] which also suggested that PPMK incidence correlates with larger valve size (eg, size XL in Perceval sizer, equals to 27-mm valve) even though a clear size-dependent effect has not been shown.[59] Similarly, an Intuity valve size ≥23 mm was found to be an independent predictor of new onset of persistent left bundle branch block (P = 0.02).[60]

The direct comparison between the 2 available devices for SuAVR in terms of pacemaker implantation has been recently reported by the SURD-IR (Sutureless and Rapid Deployment Aortic Valve Replacement International Registry).[61] The analysis of >4,000 SuAVR patients concluded that in the totally sutureless prosthesis the rate of PPMK implantation decreased over time (10.8% in procedures up to 2016, 6.3% in procedures after 2017), probably because of surgical improvements and a more accurate sizing. In fact, cardiopulmonary bypass time was reduced, and the use of smaller prostheses was increased, as a reflection of the cumulated learning curve. The reduction in PPMK as well as in the previously mentioned incidence of PVL might also pertain to the modifications in design of the updated version of the prosthesis. The so-called Perceval Plus features

TABLE 6 Sutureless and Rapid Deployment Valves: Clinical Outcomes

	Perceval S (Sutureless)	Edwards Intuity (Rapid Deployment)
Years follow-up	Similar (10+ years)	Similar (10+ years)
Device success	Similar (>99%)	Similar (>99%)
Cardiopulmonary bypass time	**Reduced, 20 min less (~55-60 min isolated AVR)**	(~75-80 min isolated AVR)
Cross-clamp time	**Reduced, 15 min less (~40 min isolated AVR)**	(~55 min isolated AVR)
Paravalvular leak	Similar (0%-1%)	Similar (0%-1%)
Mild aortic regurgitation	(8%-10%)	**Reduced (4%-5%)**
Transvalvular mean gradient	(14-15 mm Hg)	**Reduced, 3-5 mm Hg less (10-11 mm Hg)**
Pacemaker rate	Similar (6%-9%)	Similar (6%-9%)
Postoperative stroke	Similar (1%-2%)	Similar (1%-2%)
In-hospital mortality	Similar (1%-3%)	Similar (1%-3%)
Structural valve degeneration at 1 year	Similar (0%-1%)	Similar (0%-1%)
Use in minimally invasive approach	**Similar (favored in right anterior thoracotomy)**	Similar
Use in combined procedures	**Similar**	Similar
Use in redo procedures	Similar (favored in calcified root)	Similar

Bold indicates clinical differences in terms of outcomes or efficacy.
AVR = aortic valve replacement.

a valve stent with reduced protrusion in the left ventricular outflow tract, which is thought to mitigate the risk of conductance blocks, as shown in the most recent series.[61,62] Surgical adjustments,[63-65] increased operator experience,[13,21,46,49,66,67] and multidetector-row computed tomography aid in avoiding oversizing[68,69] and have also been claimed to be at the basis of the improved Perceval outcomes.

On the other hand, in the rapid deployment cohort, the rate of PPMK was stable over time (8.8% in the early group, 9.3% in the late group), with no significant differences in patient characteristics, but an increased rate of concomitant septal myectomy.[61] The reasons underlying the stable results with rapid deployment valves are probably multifactorial. The new generation of the rapid deployment valve, the Elite valve (introduced in 2014-2016), has been designed with the main aim to facilitate deliverability in minimally invasive surgery and improve hemodynamics via the subvalvular expansion of the stent in the left ventricular outflow tract. Differently, from the Perceval Plus with a thinner more intra-annular ring, the changes applied to the original design of the Intuity valve and the geometrical distribution of the radial forces at the subannular level might have not been adequate to reduce the entity of tissue damage and pressure overload of the membranous septum. More importantly, a plethora of different factors related to the nature of the evidence currently available might have played an even stronger role. Patient selection, concomitant procedures increasing the susceptibility to arrhythmia (ie, CABG, septal myectomy[61]), and learning curve effect are only some of the potential factors influencing the results.

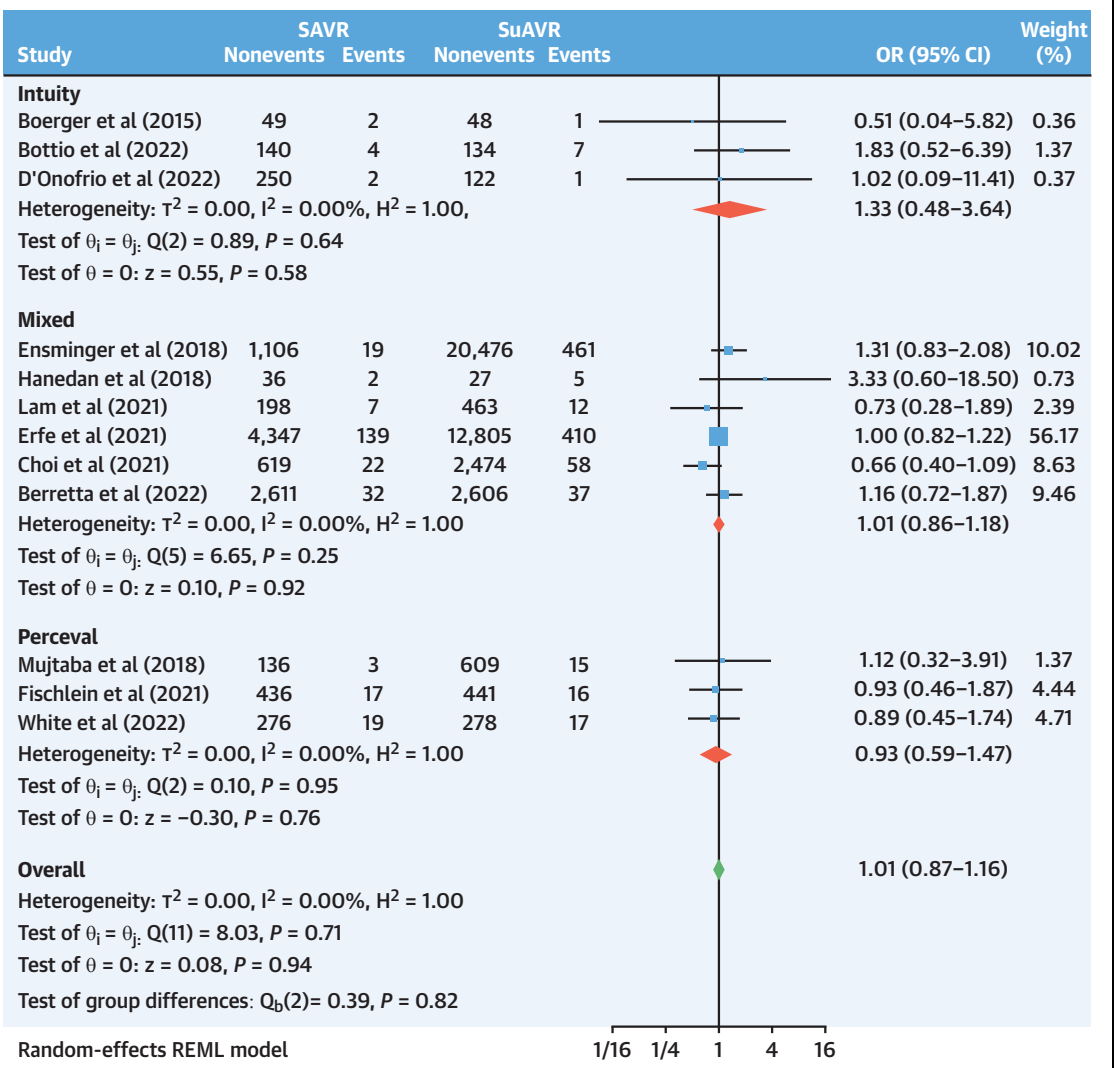
The differences and risk factors for PPMK implantation between sutureless and rapid deployment prosthesis should be adequately addressed in future studies.

The consequences of PPMK implantation after SuAVR have been investigated by retrospective studies. Notably, at 3-year follow-up, PPMK after SuAVR was not associated with a higher risk of mortality or rehospitalization for heart failure.[55] In another recent 9-year follow-up retrospective analysis, 50% of patients implanted with PPMK after rapid deployment SuAVR remained pacemaker dependent in the long-term, while the rest needed only temporary pacemaker support.[70]

When compared with TAVR, SuAVR has been associated in many large retrospective multicenter studies with a reduced need for permanent pacemaker. Biancari et al[71] showed that TAVR was associated with a 17.3% incidence of permanent pacemaker implantation vs 9.8% in SuAVR. These results were echoed by Muneretto et al[72,73] in another recent multi-institutional experience and by Vilalta et al[54] in a recently published retrospective study. However, the results of 3 meta-analyses concurred in showing no significant difference in pacemaker implantation in TAVR or SuAVR[2,29,74] and a more recent retrospective analysis showed equal rates of incidence of this complication[28] (Table 4). These results are most likely the effect of a progressive improvement in TAVR technologies.

Prosthesis mismatch and hemodynamic performance. A multicenter randomized study (CADENCE-MIS [A Randomized Comparison of the EDWARDS INTUITY Valve System anD commErcially Available Aortic

FIGURE 3 SAVR vs SuAVR, Subanalysis for Sutureless/Rapid Deployment: 1-Year Mortality

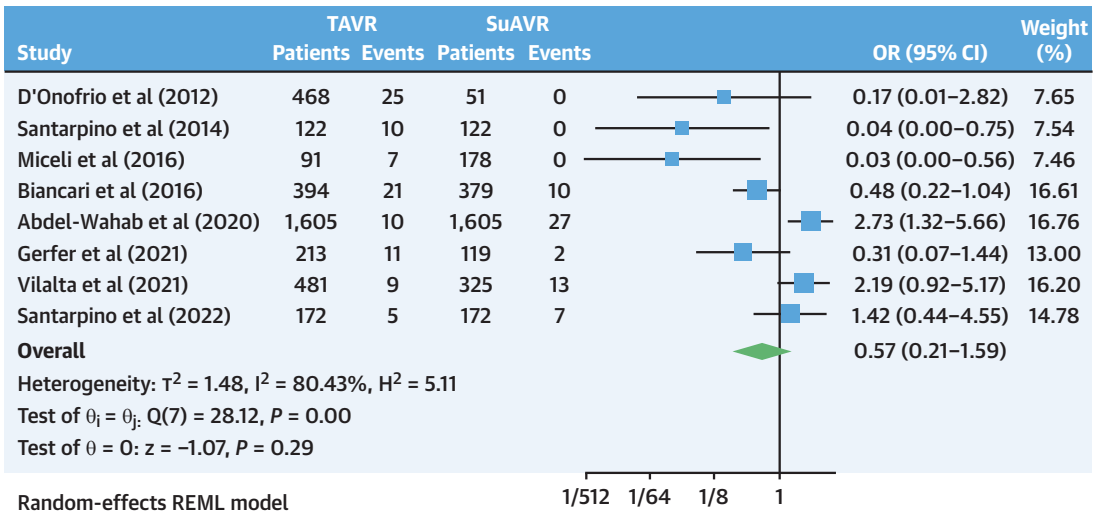


Abbreviations as in Figure 2.

Bioprostheses in Subjects uNdergoing surgiCal Aortic Valve Replacement Using Minimally InvaSive Techniques]) that compared the short-term outcomes of upper hemi-sternotomy AVR with a rapid deployment device vs SAVR with full sternotomy showed lower mean transvalvular gradient and rate of patient-prosthesis mismatch (0% vs 15.0%, $P = 0.013$) at 3 months in the rapid deployment group compared with the SAVR patients.[75]

Similarly, in the subanalysis of the EVOLUT low-risk trial, SuAVR conferred a hemodynamic benefit with respect to SAVR with lower 1-year mean gradients (9.9 ± 4.2 mm Hg vs 11.7 ± 4.7 mm Hg).[51] This has been confirmed by a recent propensity-matched comparison between sutureless and Perimount prostheses in which the sutureless valve exhibited lower postoperative gradients (15 vs 17 mm Hg, $P = 0.002$).[76] Another recent retrospective propensity-matched study comparing Intuity valve with Carpentier Magna Ease prosthesis showed postoperative gradients 5 mm Hg lower in SuAVR ($P = 0.001$) and a significantly lower incidence of patient-prosthesis mismatch (7.1% in SuAVR vs 22.8% in SAVR, $P = 0.006$).[77] However, data about late structural valve degeneration (SVD) and SVD-related reoperation were not reported in these studies. Previous

FIGURE 4 TAVR vs SuAVR: Perioperative Mortality



SuAVR = sutureless aortic valve replacement with a sutureless valve; TAVR = transcatheter aortic valve replacement.

observational studies have also shown advantages with SuAVR in terms of hemodynamic outcomes in elderly or high-risk patients and in those requiring multiple procedures (such as double valve replacements, coronary artery bypass grafting, or atrial fibrillation ablation), even in the context of active endocarditis.[14,40,41,78,79] The TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement trial; NCT01700439) study, a recent prospective nonrandomized multicentric single-armed trial reporting 7 years of follow-up of SuAVR with rapid deployment valves showed a mean gradient and effective orifice area of 11.1 ± 5.3 mm Hg and 1.6 ± 0.3 cm^2, respectively.[80]

The direct comparison between the 2 available types of sutureless devices has been recently investigated in a meta-analysis by Sohn et al.[58] This study showed a greater hemodynamic benefit with rapid deployment SuAVR with lower mean transvalvular gradient but longer cross-clamp times and CPB times with respect to totally sutureless devices.[58]

When comparing SuAVR and TAVR, in a propensity-matched study by Kamperidis et al,[81] the authors demonstrated that TAVR valves have a significantly larger effective orifice area than the SuAVR and as a result, lower incidence of patient-prosthesis mismatch.

Bleeding and other adverse outcomes. General outcomes of SuAVR are similar to conventional SAVR with 1.2% rate of kidney failure, 2.2% of prosthetic endocarditis, and 1.4% incidence of reoperation for bleeding.[52] Another recent large analysis confirmed similar rates of VARC-2 30-day safety composite endpoints, but demonstrated an increased rate of valve-related rehospitalization in the SuAVR group (9.1% vs 5.1%).[51]

TAVR is associated with a higher rate of major vascular complications, but the sutureless valve group has increased transfusion requirements compared with TAVR.[2] However, SuAVR with minimally invasive approaches such as hemi-sternotomy and right anterior thoracotomy have been associated in observational studies with reduced bleeding and blood transfusions, atrial fibrillation, wound infection, ventilation times, and time to return to normal activities.[78,82]

A recent large multicenter propensity-matched analysis comparing TAVR and SuAVR showed no difference in 30-day mortality and pacemaker implantation rate, but costs were significantly lower in the SuAVR group.[83] Another cost-effectiveness analysis showed that both in-hospital and long-term costs are lower for SuAVR when compared with TAVR (total savings ranging from $4,158 in France to $20,930 in the United States). This was accompanied by a parallel significant gain in raw and quality-adjusted life expectancy.[84]

The cumulative incidence of SVD in SuAVR was 0.4% in a systematic review, and valve embolization

is a rare complication of sutureless valves, occurring in 0.9% of cases.[41,52] The recently published TRANSFORM study on rapid deployment valves confirmed a 97.5% freedom from SVD and similar rates of reinterventions or valve explantation at 7 years.[80] In the longest available follow-up data for the Perceval valve by the UZ Leuven group including 784 patients at 13 years, freedom from reintervention at 1, 5, and 10 years were respectively 99%, 97%, and 94%, with very low instances of SVD.[25,85] These results were corroborated in other multicentric series with a 0.4% rate of valve degeneration at 5 years.[62] Importantly, the introduction of an innovative phospholipid-reduced and aldehyde-neutralizing tissue treatment, the so-called FREE, in the more modern iteration of the Perceval device (Perceval Plus) might have played a significant role in these results.[86] In this context, it is important to note that correct implantation of these devices has an impact on valve function and hemodynamics, and the progressive experience cumulated by the operators, so-called "learning curve effect," has been claimed to play a role in several reports.[13,66] Design improvements in both the rapid deployment and totally sutureless devices aimed at avoiding oversizing have been implemented with the aim to reduce leaflet overcrowding or "pin-wheeling," which might contribute to early degeneration. The issue of surgical learning curve has also been advocated to explain the higher rates of stroke observed in the earlier series. Multiple deployment attempts following erroneous implantation might be responsible for embolic phenomena.[87]

SVD is unfortunately still poorly understood in the TAVR realm. However, a recent report from the UK TAVI (United Kingdom Transcatheter Aortic Valve Implantation) registry demonstrated good valve durability with freedom of SVD of 91% at 5 to 10 years, 8.7% incidence of moderate SVD and <1% of severe SVD at 5 to 6 years average.[88] Recent data from the EVOLUT trial showed increased SVD risk with SAVR than with TAVR at 5 years (4.38% vs 2.57%, $P = 0.0095$), and SVD carried a doubled risk of death and rehospitalization for aortic valve disease or heart failure. The risk of developing SVD was found to be higher in younger patients, women, and patients with a higher body surface area. Also, this difference in SVD was more pronounced in patients with smaller (≤23 mm) annuli (5.86% SAVR vs 1.39% TAVR, $P = 0.049$).[89] Interestingly, recent advances in the understanding of aortic flow, wall shear stress, and flow displacement in the aortic root during the cardiac cycle will provide valuable data for the design of new-generation prosthetic valves to reduce SVD.[90]

DISCUSSION AND FINAL CONSIDERATIONS. The potential roles of SuAVR. In meta-analyses of observational evidence, the sutureless devices seem to show some advantages in comparison with both conventional SAVR and TAVR. As with TAVR, the midterm results of sutureless valves are satisfactory, but long-term data are still awaited.[3,91]

The perceived principal advantage of sutureless valve technology is the reduction in the ischemic surgical time compared with conventional sutured valves.[64] However, conclusive evidence to suggest that the reduction in aortic cross-clamp time, as allowed by using the sutureless valve, may lead to improvements in morbidity or mortality is missing.[3,19,41,91-94] Data from the CADENCE-MIS, a randomized trial comparing minimally invasive SuAVR with rapid deployment valves with full sternotomy SAVR, has showed significantly reduced cross-clamp times in the SuAVR group, but similar cumulative CPB time and no significant differences in clinical outcomes.[75] Another small non-industry-sponsored RCT on older patients with small root implanted with the totally sutureless prosthesis, confirmed reduced operative times and no differences in mortality, but was underpowered to detect differences in hard clinical outcomes.[95] However, several retrospective observational studies have suggested an association between prolonged cross-clamp or CPB times with increased risk of postoperative complications (including renal failure, respiratory failure, low-output syndrome, postoperative atrial fibrillation, higher transfusion requirements, and longer postoperative hospital stay) and trends in mortality.[96-98] A meta-analysis of randomized and propensity-matched comparative studies tailored to investigate the impact of reduced operative times on clinical outcomes showed similar 1-year survival rates but reduced postoperative complications as atrial fibrillation and blood product transfusions in the SuAVR group, at the cost of increased PPMK implantation.[99] Whether the appetite for the use of SuAVR is more driven by the ease of implant and by the surgeon's perception of reduced operative time in high-risk patients rather than an effective impact on clinical outcomes is difficult to demonstrate at present and would require ad hoc studies. However, it is plausible to think that in selected high-risk patients requiring multiple or long procedures, SuAVR might confer a potential advantage in terms of postoperative complications.

Therefore, based on the current literature and in consideration of the theoretical benefits and surgical ease, sutureless valves might be considered a potential

option for patients who require concomitant procedures with expected high surgical burden[92,100-102] and could have a role in minimally invasive AVR.[20]

Also, as recommended in the latest International Expert Consensus Panel, patients with a small aortic annulus or those who require a redo operation, have a fragile aortic wall, or have hostile aorto-vascular disease (eg, calcified homografts, small aortic root) could benefit from SuAVR.[103-106]

Complex reoperative aortic valve surgery represents a niche in which sutureless devices might play a significant role and provide a theoretical advantage over SAVR. The design of the devices could in fact allow for achieving larger effective orifice areas[107] and might simplify the surgical implant, especially in patients with anatomical small root and significantly calcified annuli or in previous root replacement with homograft performed according to modified Bentall technique. In fact, excision of the calcified root and detachment of the coronary buttons may result in injury to such structures, complicating an already cumbersome and demanding procedure. Furthermore, the annulus of the porcine or homograft aortic valve is also often severely calcified, stiff, and narrowed, preventing the positioning of anchoring stitches or a traditional stented prosthesis of adequate size. Vendramin et al[104] showed low mortality rate and complications in a retrospective series of challenging reoperation for failed or degenerated stented bioprosthesis and homografts implanted with sutureless and rapid deployment valves. These results were corroborated by Dhanekula et al[87] in their series of redo AVR and redo root replacement in which the authors interestingly showed lower gradients and larger effective orifice area of the newly implanted Perceval when compared with the explanted valves. Last, a real-life retrospective study comparing redo AVR surgery with either sutured or sutureless valves showed significantly lower cross-clamp ischemic time and pacemaker implantation rate in SuAVR when compared with SAVR.[108]

On these grounds, high-risk patients, as redo patients, who would otherwise be considered for TAVR, or low-intermediate-risk patients in the "gray zone" between SAVR and TAVR may have some of their operative risk obviated by use of sutureless valve technology, especially if performed via a minimally invasive approach.[2,109]

To this regard, a recent report from the Society of Thoracic Surgeons database including 122,474 patients and comparing minimally invasive and standard SAVR concluded on similar mortality and complications for all the Society of Thoracic Surgeons risk categories. Taking from the very low mortality in low-risk patients treated with minimally invasive surgery, the authors intriguingly concluded that minimally invasive SAVR should be considered as a benchmark against TAVR in low-risk patients and it is plausible to speculate that SuAVR could play a role also in this context.[110] A very recent network meta-analysis showed similar early postoperative outcomes to SAVR in both SuAVR and minimally invasive SuAVR with the potential for reduction in ventilation time, hospital stay, and postoperative atrial fibrillation.[49] The results of the PERSIST trial confirmed noninferiority in clinical outcomes at 1 year.[17] Nevertheless, SAVR can be performed via minimally invasive access using standard sutured prosthesis too, and currently there is no consistent evidence investigating differences in outcomes between sutureless and sutured valves in minimally invasive settings. Therefore, the perceived benefit of the use of sutureless valves in minimally invasive surgery currently only relies on the surgical ease of handling and implantation.

The "cons" and pitfalls in SuAVR. A potential for increased risk of stroke and pacemaker implantation compared with SAVR has been noted in the most recent large registry study[14] and should be considered in the decision-making process.

Also, the surgeon should be mindful of the constraints of sutureless valves in the preoperative planning. These limitations include size availability (from 19 to 27 mm); active endocarditis with annular destruction, which may preclude a stable valve implantation; significant dilation of the ascending aorta exceeding 4 cm in the sinotubular junction; or a ratio between the sinotubular diameter and the aortic annulus >1.3. The latter 2 contraindications are particularly relevant for the sutureless valve, as the stent maintaining the valve in position relies on the anatomy of the sinotubular junction. However, the rapid deployment valve is not affected by this issue.

For similar reasons, bicuspid valves with asymmetrical sinuses of Valsalva are not ideal for SuAVR because of anatomical concerns and the elevated risk of para-prosthetic leaks. However, since the original reports in 2014 on the feasibility of sutureless implantation in bicuspid valves,[111] more data have become available in this regard.[112,113] Type 0 Sievers valves are associated with higher rate of complications, including aortic regurgitation, need for second cross-clamp and PPMK implantation.[114-116] The geometric aberrancy adds a degree of complexity requiring additional techniques aimed at restoring annular circularity and supporting the symmetric expansion of the prosthesis.[117] Similarly, in type 2, the use of commissural plication stitches or inter-

commissural compressive mattress sutures has been reported to assist correct valve deployment.[113] Type 1 Sievers with true raphe are instead generally addressable similarly to a tricuspid valve. A recent review specifically evaluated this topic investigating 314 patients in 13 published studies[118] and concluded that SuAVR in patients with bicuspid valves has comparable implantation success to patients with tricuspid aortic valve, with similar PPMK implantation rate (8%-10%) and paravalvular leak (3%-5%). However, a rate of overall complication of approximately 60% was noted in the pooled cohort and the quality of the evidence was low, as many studies included were case reports or retrospective unmatched analysis.[118] Therefore, the routine use of SuAVR in patients with bicuspid aortic valve still requires adequate validation and future studies will elucidate those points to trigger technological improvements.

Another recurrent pitfall regards the risk of intraoperative misplacement of the device with need for subsequent reimplantation. This instance has been reported in approximately 2% of the cases but constitutes an important element of consideration mandating for adequate anatomic preoperative and intraoperative evaluation.[119] The Heart Team should therefore play a pivotal role in determining indications for sutureless valves, and the technicalities of the procedure should be discussed among the experts.[120] To this regard, a recent Canadian survey among cardiac surgeons concluded that SuAVR is still perceived as a procedure for patients with hostile root or small annular size, and its use in minimally invasive procedures, in redo operation, and in younger patients is still not shared by the surgical community.[121] The fear of pacemaker implantation, uncertain data about SVD, and (above all) high costs remain significant perceived limitations to SuAVR widespread use. In addition, the increasing introduction of automated knotting systems derived from minimally invasive surgery platforms could mitigate the "time factor" in the implantation of surgical bioprostheses, further limiting the appetite for a sutureless device in SAVR on cost/benefit balance.

SuAVR: a proposed guide and decisional algorithm. Although the patients currently best suited for consideration of sutureless valve technology seem to be those whose optimal management is uncertain in the spectrum between TAVR and conventional surgery, existing risk stratification tools, such as EuroSCORE, lack the discriminating factors of surgical anatomy (ie, aortic annular pathology), frailty, and other relevant comorbid conditions. Frailty, in particular, is an overall marker of impaired functional, cognitive, and nutritional status and is associated with increased morbidity and mortality after surgery and TAVR.[122] These parameters were recently introduced in the European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines for the management of valvular disease in the choice between SAVR and TAVR, but a potential role of SuAVR in decision making could be also hypothesized.

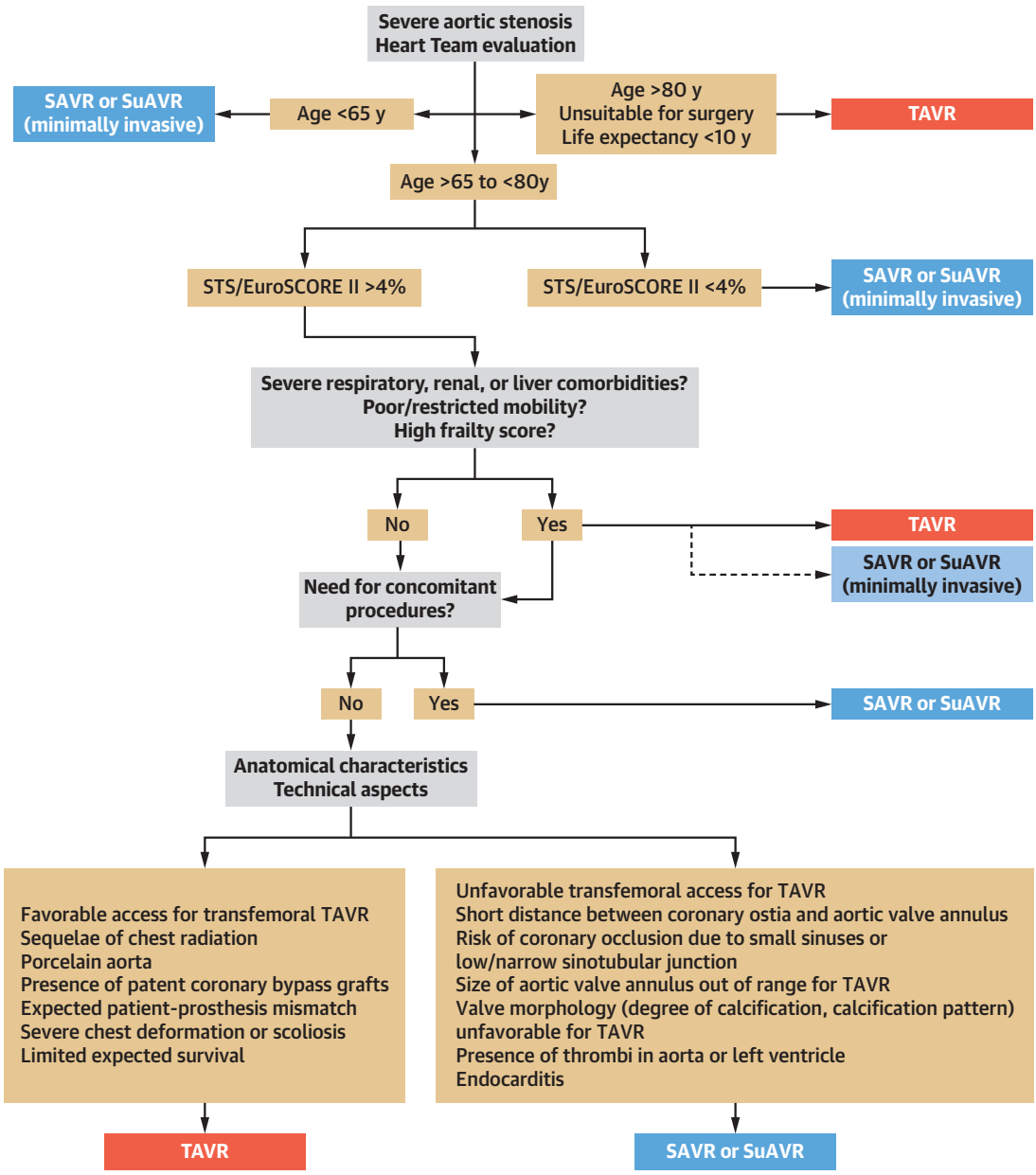
Based on the currently available evidence, we suggest the following decision algorithm when approaching a patient with aortic stenosis based on 3 main factors: the patient's clinical characteristics (including risk scoring, comorbidities, frailty, likelihood of quality-of-life improvement after intervention), the presence of concomitant cardiac pathology amenable to intervention, and technical and anatomical aspects of the procedure proposed (**Figure 5**). Anatomical and clinical features that should be considered when choosing between SuAVR or SAVR are summarized in **Figure 6**.

Anatomical considerations are paramount in guiding decision making between sutureless and conventional AVR. As shown in **Table 2**, calcification of the ascending aorta or the aortic root or a small aortic root would favor SuAVR. Whereas, in cases of high risk of atrioventricular block (preexisting atrioventricular block I or II, right bundle branch block, severe calcification of the annulus, or the interventricular septum or pure aortic regurgitation), conventional AVR is preferred over SuAVR. Also, extremely large anulus sizes mandate for a conventional implantation considering the lack of available sutureless devices of adequate sizes.

SuAVR with a minimally invasive approach, if performed in centers with high volume and expertise,[123,124] might be considered an alternative to TAVR and an available surgical option in low-risk patients. In patients at high surgical risk requiring multiple procedures, SuAVR might constitute a valid adjunct to reduce timing and possibly postoperative complications, as shown for double aortic and mitral procedures, or in cases of concomitant CABG when a percutaneous option is not available.[92,100-102] However, it should be noted that at present there is no conclusive demonstration of a mortality clinical benefit related to reduced CPB or cross-clamp time in sutureless or rapid-deployment AVR. Also, currently no comparative study was specifically designed to investigate the impact of SuAVR and procedural timings in patients undergoing concomitant procedures.

It is also important to consider the increasingly recognized issue of impaired coronary access after TAVR (up to 38% of the cases) in patients with coronary disease that might need revascularization

FIGURE 5 Decisional Algorithm for Treatment of Aortic Stenosis

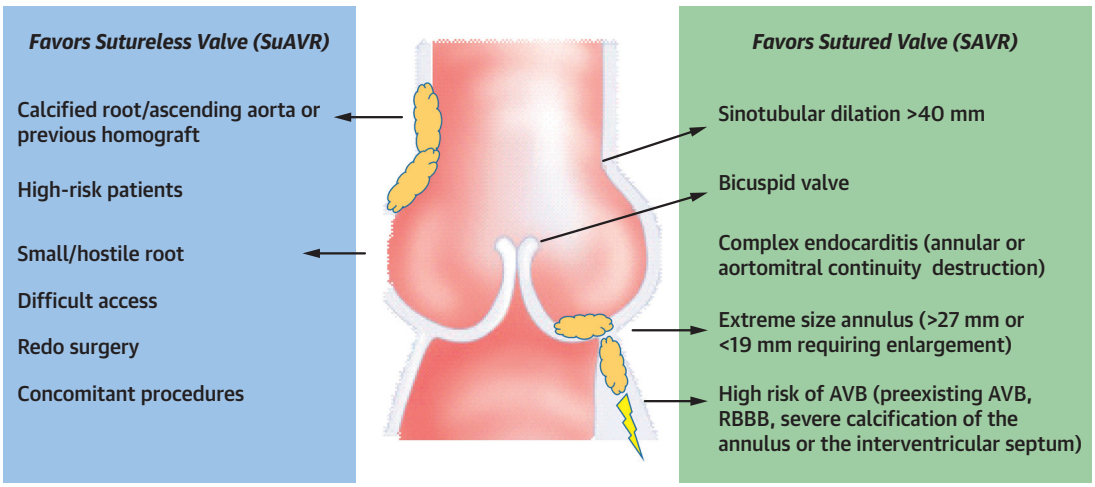


Abbreviations as in Figures 2 and 4.

interventions in the future.[125-129] These data would encourage a careful evaluation of TAVR candidates with known coronary heart disease susceptible for future treatment. In these cases, minimally invasive surgery with SuAVR might also represent a viable option.

More evidence is, however, needed to confirm this proposed algorithm. Nevertheless, with the advent of TAVR in the arena of aortic valve disease, it is clear that the discussion on the technical approach to be adopted for valve replacement should involve all the members of the Heart Team. In this regard, as recently pointed out by Batchelor et al[130] in an expert consensus paper on the role of the multidisciplinary heart team, the centrality of the patients in the shared decision making remains paramount, and active engagement of the

FIGURE 6 Anatomical Guidance and Clinical Factors Between SuAVR and SAVR



AVB = atrioventricular block; RBBB = right bundle branch block; other abbreviations as in Figure 2.

patients should be pursued ensuring their understanding and respecting their wishes.

SuAVR: open questions. Despite the mentioned benefits of SuAVR and its potential introduction in the decision-making process for the management of aortic valve stenosis, it is intriguing to note that the surgical community has still not expressed a univocal consensus about the role of sutureless valves, and their routine use is debated.[3,91,131] Reasons underlying the surgical skepticism are multifaceted and inevitably influenced by nonmeasurable confounding factors, such as surgeon experience or predilection. Also, the evidence in support of SuAVR is mainly observational and might be affected by publication biases relative to the experience of a single expert, particularly in minimally invasive surgery. Even the most recent metanalyses include heterogeneous studies[132] and this could undermine the translatability of the results in the real-life scenario, discouraging a larger-scale adoption of these devices. Also, the comparability among TAVR and SuAVR studies is also affected by the proportion of patients requiring additional procedures (ie, CABG or mitral valve surgery) in the sutureless group. Randomized evidence on the use of SuAVR as well as large real-life studies are warranted to elucidate these points, although almost 25% of surgeons are reluctant to participate in an RCT comparing SuAVR with TAVR.[121] Of note, the only randomized trial on the use of the sutureless valve has up to now produced results only for the first-year follow-up. Also, in light of the recent result of the COMMENCE (ProspeCtive, nOn-randoMized, MulticENter Clinical evaluation of the Edwards Pericardial Aortic & Mitral Bioprostheses [Models 11000A & 11000M] with a new tissue treatment platform) trial with Resilia technology,[133] surgical AVR still provides excellent outcomes with solid long-term results and this increases the complexity of clinical comparisons. The results of the CAVALIER (Safety and Effectiveness Study of Perceval S Valve for Extended CE Mark; NCT01368666) trial are awaited.

In most studies, minimally invasive aortic valve surgery and the use of a sutureless valve are combined concepts. Despite being separate topics, the current literature tends to produce aggregated results, introducing another potential source of bias. In fact, both conventional prosthesis and sutureless valves are used in these studies and it is difficult to establish differences in the outcomes of these 2 types of prostheses within the field of minimally invasive surgery. Ad hoc studies would be necessary to elucidate these points.

Another unanswered question is the feasibility of valve-in-valve TAVR after SuAVR considering the design differences of the rapid deployment and sutureless prostheses. The current literature lacks tailored studies in this regard but current registries (such as the post-market MISSION registry, "Assessing clinical outcomes using the Edwards Intuity Elite Valve System in isolated AVR using Minimally Invasive Surgery In a EurOpean multi-ceNter"[134]) might answer this question in the near future.

It is also interesting to note a difference in the use-rate of SuAVR in Europe and the United States with most of the clinical results being published from European centers. Fewer studies belong to the American literature including a single-armed clinical trial on the sutureless device as a U.S. Food and Drug Administration Investigational Device Exemption trial confirming both safety and effectiveness of the valve with mortality lower than expected.[112] The geographical delocalization of the use and scientific production on SuAVR could further explain the lack of consensus in the surgical community at present.

Although the sutureless prostheses and TAVR devices share some similarities from the technological design standpoint, the intrinsic clinical impact on patients of the 2 procedures is significantly different (recovery time, postsurgical complications). This might have further contributed to the current skepticism on SuAVR and to the failure to reach the same degree of widespread consensus and use in the "surgical counterpart" of aortic valve disease management.

STUDY LIMITATIONS. The retrospective nature of the retrieved studies, the heterogeneity of the data, mainly deriving from observational low-sized cohort studies, and the potential reporting and publication biases are the main methodological limitations of this study. Although a pooled analysis of the hard outcomes as perioperative and 1-year mortality was possible within the mentioned limitations, other outcomes such as neurological events, pacemaker implantation, and complications were affected by more significant biases also related to heterogeneity in definitions and diagnostic criteria among the singles studies. These and other issues prevented a meaningful statistical analysis of these variables. Last, we performed a thorough and extensive literature search without any language, publication date, or publication status restrictions; however, it is possible that relevant unpublished data were not identified.

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KEY WORDS aortic stenosis, aortic valve replacement, outcomes, rapid deployment, sutureless, transcatheter

APPENDIX For supplemental Methods, tables, and figures, please see the online version of this paper.