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ORIGINAL ARTICLE

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Examining the typical hemodynamic performance of nearly 3000 modern surgical aortic bioprostheses

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Typical Mean EOAs at 1 Year of Follow-up, 23-mm Surgical Aortic Tissue Valves

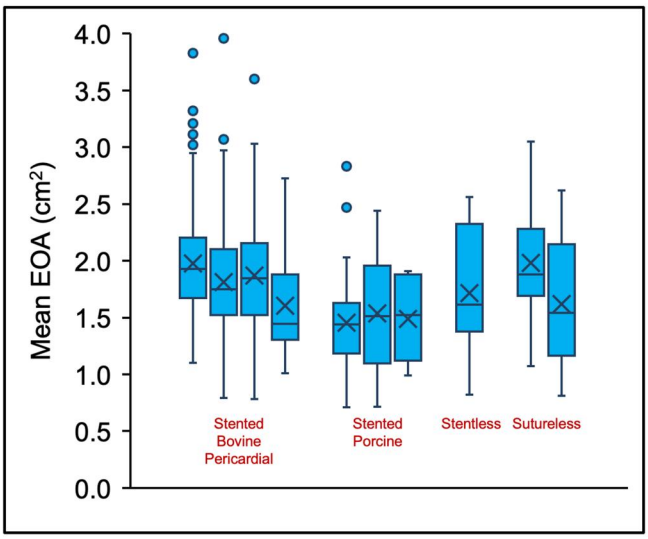
Summary

Population: Adults with moderate to severe AS or AR

Intervention: Surgical aortic valve replacement

Comparison: Hemodynamic performance at 1 year of follow-up

Outcome: Good to excellent hemodynamic performance across surgical valves



Legend: EOAs, effective orifice areas; AS, aortic stenosis; AR, aortic regurgitation.

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Abstract

OBJECTIVES: The objective of this analysis was to assess the normal haemodynamic performance of contemporary surgical aortic valves at 1 year postimplant in patients undergoing surgical aortic valve replacement for significant valvular dysfunction. By pooling data from 4 multicentre studies, this study will contribute to a better understanding of the effectiveness of surgical aortic valve replacement procedures, aiding clinicians and researchers in making informed decisions regarding valve selection and patient management.

METHODS: Echocardiograms were assessed by a single core laboratory. Effective orifice area, dimensionless velocity index, mean aortic gradient, peak aortic velocity and stroke volume were evaluated.

RESULTS: The cohort included 2958 patients. Baseline age in the studies ranged from 70.1 ± 9.0 to 83.3 ± 6.4 years, and Society of Thoracic Surgeons risk of mortality was 1.9 ± 0.7 to 7.5 ± 3.4%. Twenty patients who had received a valve model implanted in fewer than 10 cases were excluded. Ten valve models (all tissue valves; $n = 2938$ patients) were analysed. At 1 year, population mean effective orifice area ranged from 1.46 ± 0.34 to 2.12 ± 0.59 cm^2, and dimensionless velocity index, from 0.39 ± 0.07 to 0.56 ± 0.15. The mean gradient ranged from 8.6 ± 3.4 to 16.1 ± 6.2 mmHg with peak aortic velocity of 1.96 ± 0.39 to 2.65 ± 0.47 m/s. Stroke volume was 75.3 ± 19.6 to 89.8 ± 24.3 ml.

CONCLUSIONS: This pooled cohort is the largest to date of contemporary surgical aortic valves with echocardiograms analysed by a single core lab. Overall haemodynamic performance at 1 year ranged from good to excellent. These data can serve as a benchmark for other studies and may be useful to evaluate the performance of bioprosthetic surgical valves over time.

Clinical trial registration number: NCT02088554, NCT02701283, NCT01586910 and NCT01531374.

Keywords: Surgical aortic bioprostheses • Aortic valve replacement • Valve haemodynamic performance

ABBREVIATIONS

BSA	Body surface area
DVI	Dimensionless velocity index
EOA	Effective orifice area
LVOT	Left ventricular outflow tract
NYHA	New York Heart Association
PERIGON	PERIcardial SurGical AOrtic Valve ReplacemeNt Pivotal Trial of the Avalus bioprosthesis
PPM	Prosthesis–patient mismatch
RCT	Randomized controlled trial
SAVR	Surgical aortic valve replacement
STS	Society of Thoracic Surgeons
VARC-3	Valve Academic Research Consortium

INTRODUCTION

Surgical aortic valve replacement (SAVR) remains an important treatment modality for patients with significant valvular dysfunction, comprising 42% of aortic valve procedures in the USA and 36–64% in western Europe [1–5]. When a decision to implant a surgical aortic valve has been made, the surgeon can choose from a variety of valve types and models with substantial differences in benefits and drawbacks. For example, bioprosthetic valves (stented pericardial, stented porcine, stentless and sutureless valves) have the benefit of not requiring lifelong anticoagulation but the drawback of inevitable degradation in performance over time, whereas mechanical valves require lifelong anticoagulation but are not susceptible to structural valve deterioration. In the USA and Western Europe, the majority (70–83%) of SAVR patients are treated with bioprosthetic valves [4–6] with varying haemodynamic characteristics, durability profiles and primary failure modes. Serial echocardiography is an important tool for monitoring valve performance and ensuring that adequate haemodynamic performance is maintained. However, interpretation may be complicated by variability in expected haemodynamic performance of a given valve model and size, measurement variability, variability between patients and over time, transient changes in valve performance (e.g. due to hypoattenuated leaflet thickening or change in stroke volume) and finally, development of irreversible structural changes resulting in degraded haemodynamic performance.

Reference values from clinical trials are important so that physicians can determine whether a patient's implanted valve is functioning 'normally' after valve replacement and subsequently, over time. Previous studies have provided such information but have been limited by a lack of contemporary valves, limited sample sizes, variability in data collection (e.g. single-centre versus multicentre studies) and variability in echo assessment (i.e. use of different core laboratories or no core laboratory) [7–9].

Ideally normal reference values for valve performance would be based on evaluation of a large number of contemporary surgical valves implanted in multicentre trials and evaluated by a single core laboratory. Such a data set would dramatically improve the validity of comparisons between valve makes and models, comprising a useful tool not only in the surveillance of patients implanted with a valve, but also in the selection of the most appropriate valve model and size. In this analysis, we pooled data from 4 multicentre studies of SAVR [1 nonrandomized and 3 randomized controlled trials (RCTs)] that together included multiple contemporary surgical aortic valves to evaluate haemodynamic performance at 1 year after implant.

PATIENTS AND METHODS

Ethical statement

The Institutional Review Board or Ethics Committee at all sites participating in the individual studies pooled for this analysis provided approval for the specific clinical trial (Supplementary

Material, Tables S1–S4). All patients in all 4 trials provided written informed consent.

Pooled study design

This analysis pooled data from the PERIcardial SurGical AOrtic Valve ReplacemeNt (PERIGON) Pivotal Trial of the Avalus bioprosthesis (Medtronic, Minneapolis, MN, USA; clinicaltrials.gov registration ID: NCT02088554) and the surgical arms of the Evolut Low Risk study (NCT02701283), SURTAVI study (NCT01586910) and CoreValve US High Risk Pivotal Trial (NCT01531374). The studies were conducted at 172 sites in the USA, Canada, Japan, Europe, Australia and New Zealand (Supplementary Material, Table S5), with enrolment between February 2011 and November 2018. The PERIGON Pivotal Trial was a prospective interventional study of a single aortic valve (Avalus), and the Evolut Low Risk, SURTAVI and CoreValve High Risk studies were RCTs in which surgeons were allowed to implant a commercially available surgical valve of their choice in patients assigned to SAVR. Valve models implanted in fewer than 10 patients were excluded. All four studies were sponsored by Medtronic, and details about study design and primary results have been published [10–14]. Supplementary Material, Table S6 provides additional information about the individual studies.

Echocardiograms were evaluated by an independent core laboratory. The core laboratory for the PERIGON Pivotal Trial was MedStar Research Institute (Washington, DC, USA), whereas the core laboratory for the CoreValve High Risk, SURTAVI and Evolut Low Risk studies was the Mayo Clinic (Rochester, MN, USA). To ensure consistency between the echocardiographic measurements in the RCTs and the PERIGON Pivotal Trial, the one-year echocardiograms from the latter were over-read by the Mayo Clinic core laboratory.

Echocardiographic assessment

Aortic prosthetic valve effective orifice area (EOA) was calculated by the continuity equation:

$$\text{EOA} = 0.785 \times (\text{LVOT diameter})^2 \times \text{LVOT VTI} / \text{Aortic Valve VTI}$$

where LVOT = left ventricular outflow tract and VTI = velocity–time integral. The LVOT diameter was measured from the outer-to-outer edges of the sewing ring as recommended by the guidelines [15]. Mean aortic valve gradient was obtained by averaging values obtained from tracing 3–5 aortic velocities. Peak velocity and mean gradient were acquired from all transducer positions to obtain the highest values [16].

Echocardiographic parameters

The analysis was designed to characterize the haemodynamic performance of contemporary surgical aortic valves at one-year postimplant. Patient characteristics and procedural details of the cohort were analysed and stratified by valve model and by study.

Echocardiographic end-points included mean aortic gradient, dimensionless velocity index (DVI), EOA, peak aortic velocity and stroke volume (SV). Transvalvular and paravalvular aortic regurgitation were also assessed. The proportions of patients with no, moderate and severe prosthesis–patient mismatch (PPM), defined according to the Valve Academic Research Consortium (VARC-3) [17], were calculated, as was indexed EOA (EOAi) by body surface area (BSA).

Statistical analysis

The analysis cohort consists of patients who underwent a successful SAVR. Categorical variables are reported as counts and frequencies. Continuous variables are presented as mean ± standard deviation. For selected echocardiographic end-points, the mean, median, minimum and maximum values, and quartiles 1 and 3 are illustrated with box and whisker plots. Mean values for mean aortic gradient, DVI and EOA are stratified by valve size for each valve model. EOAi by BSA and valve size are presented. Statistical comparisons were not performed due to the heterogeneity of the 4 study populations that were pooled and the differences between valve types. The analyses were performed to determine the haemodynamic functioning of contemporary surgical aortic valves at 1 year and not to compare prior iterations or valve types. Statistical analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

A total of 2958 patients underwent SAVR in the 4 studies: PERIGON, $n = 1129$; Evolut Low Risk, $n = 682$; SURTAVI, $n = 793$; and CoreValve High Risk, $n = 354$. There were several differences among the studies in patient age, Society of Thoracic Surgeons (STS) risk of mortality and functional status [New York Heart Association (NYHA) class] at baseline, with patients in the PERIGON and Evolut Low Risk studies being younger, more frequently male and having fewer comorbidities than patients in the SURTAVI and CoreValve High Risk studies (Supplementary Material, Table S7). Hemisternotomy and right thoracotomy were more frequently used in the PERIGON and Evolut Low Risk studies. Aortic stenosis was the primary indication for valve replacement in the RCTs. In the PERIGON Pivotal Trial, 952 (84.3%) of patients had a primary indication of aortic stenosis; 65 (5.8%) had an indication of aortic regurgitation; 106 (9.4%) had mixed stenosis and regurgitation; and 6 (0.5%) had a failed prosthesis. A congenital bicuspid valve was an exclusion criterion in the 3 RCTs but was present in 337 of 1111 patients (30.3%) in the PERIGON Pivotal Trial. Table S8 presents additional procedural data by study. Twenty patients received a surgical valve that had been implanted in fewer than 10 patients (in all studies combined) and were excluded from further analyses (Supplementary Material, Fig. S1).

Data for 10 models of 4 surgical valve types are reported here. The 10 models included 4 stented bovine pericardial valves (Avalus, $n = 1134$; Perimount series, $n = 741$; Trifecta, $n = 394$; Mitroflow, $n = 53$); 3 stented porcine valves (Mosaic, $n = 232$; Hancock, $n = 67$; Epic, $n = 39$), 1 stentless valve (Freestyle, $n = 67$); and 2 sutureless valves (Intuity, $n = 116$; Perceval, $n = 95$). Supplementary Material, Fig. S2 shows the number of each valve model that was implanted in each study. Table 1 lists the baseline characteristics of patients who received each valve model. Baseline characteristics varied among the valve models (Table 1), although BSA was similar, ranging from 1.9 ± 0.2 to 2.0 ± 0.2 m^2.

Table 1: Baseline characteristics by valve model

Characteristics	Valve model									
	Stented bovine pericardial				Stented porcine			Stentless	Sutureless	
	Avalus ($n=1134$)	Perimount ($n=741$)	Trifecta ($n=394$)	Mitroflow ($n=53$)	Mosaic ($n=232$)	Hancock ($n=67$)	Epic ($n=39$)	Freestyle ($n=67$)	Intuity ($n=116$)	Perceval ($n=95$)
Age (years)	70.1 ± 8.9	77.6 ± 7.0	78.7 ± 7.2	82.1 ± 7.6	79.5 ± 6.6	81.8 ± 6.3	80.5 ± 6.4	80.8 ± 5.8	73.7 ± 6.0	74.0 ± 6.2
Female	279 (24.6%)	279 (37.7%)	182 (46.2%)	30 (56.6%)	89 (38.4%)	21 (31.3%)	24 (61.5%)	35 (52.2%)	43 (37.1%)	43 (45.3%)
Male	855 (75.4%)	462 (62.3%)	212 (53.8%)	23 (43.4%)	143 (61.6%)	46 (68.7%)	15 (38.5%)	32 (47.8%)	73 (62.9%)	52 (54.7%)
BMI (kg/m^2)	29.4 ± 5.4	29.5 ± 5.9	29.6 ± 5.9	29.4 ± 7.0	29.3 ± 5.1	28.6 ± 5.2	30.2 ± 6.7	29.1 ± 6.1	32.6 ± 6.4	30.7 ± 5.5
BSA (m^2)	2.0 ± 0.2	1.9 ± 0.2	1.9 ± 0.2	1.9 ± 0.3	1.9 ± 0.2	1.9 ± 0.2	1.9 ± 0.2	1.9 ± 0.2	2.0 ± 0.2	2.0 ± 0.2
NYHA class										
I	125 (11.0%)	25 (3.4%)	6 (1.5%)	1 (1.9%)	7 (3.0%)	3 (4.5%)	0 (0.0%)	0 (0.0%)	12 (10.3%)	9 (9.5%)
II	535 (47.2%)	353 (47.6%)	175 (44.4%)	17 (32.1%)	66 (28.4%)	24 (35.8%)	16 (41.0%)	21 (31.3%)	78 (67.2%)	47 (49.5%)
III	452 (39.9%)	319 (43.0%)	191 (48.5%)	28 (52.8%)	134 (57.8%)	33 (49.3%)	21 (53.8%)	42 (62.7%)	26 (22.4%)	39 (41.1%)
IV	22 (1.9%)	44 (5.9%)	22 (5.6%)	7 (13.2%)	25 (10.8%)	7 (10.4%)	2 (5.1%)	4 (6.0%)	0 (0.0%)	0 (0.0%)
STS risk of mortality (%)	2.0 ± 1.4	3.9 ± 2.6	4.3 ± 2.5	6.4 ± 3.2	4.9 ± 2.7	5.5 ± 4.2	5.8 ± 3.2	5.4 ± 2.9	2.0 ± 0.7	2.1 ± 0.8
Chronic obstructive lung disease	133 (11.7%)	220/726 (30.3%)	111/390 (28.5%)	18 (34.0%)	64/230 (27.8%)	20 (29.9%)	13/37 (35.1%)	37 (55.2%)	19 (16.4%)	27/89 (30.3%)
Diabetes	302 (26.6%)	250 (33.7%)	140 (35.5%)	24 (45.3%)	100 (43.1%)	21 (31.3%)	15 (38.5%)	23 (34.3%)	31 (26.7%)	32 (33.7%)
Hypertension	864 (76.2%)	644/740 (87.0%)	358 (90.9%)	49 (92.5%)	216 (93.1%)	57 (85.1%)	36 (92.3%)	61 (91.0%)	93 (80.2%)	83 (87.4%)
Myocardial infarction	99 (8.7%)	89 (12.0%)	54 (13.7%)	5 (9.4%)	42 (18.1%)	4 (6.0%)	10 (25.6%)	16 (23.9%)	7 (6.0%)	3 (3.2%)
Peripheral vascular disease	82 (7.2%)	169/740 (22.8%)	97/393 (24.7%)	14 (26.4%)	35.3% (82/232)	23 (34.3%)	10 (25.6%)	20 (29.9%)	10 (8.7%)	4 (4.2%)
Prior coronary artery bypass	25 (2.2%)	100 (13.5%)	66 (16.8%)	5 (9.4%)	49 (21.1%)	11 (16.4%)	10 (25.6%)	10 (14.9%)	3 (2.6%)	1 (1.1%)
Percutaneous coronary intervention	160 (14.1%)	147 (19.8%)	75 (19.0%)	16 (30.2%)	69 (29.7%)	13 (19.4%)	12 (30.8%)	23 (34.3%)	20 (17.2%)	10 (10.5%)
Implanted cardiac device[a]	40 (3.5%)	67/740 (9.1%)	38 (9.6%)	10 (18.9%)	29 (12.5%)	8 (11.9%)	5 (12.8%)	8 (11.9%)	6 (5.2%)	5 (5.3%)

Values are mean±SD (n) or n (%).

BMI: body mass index; BSA: body surface area; NYHA: New York Heart Association; SD: standard deviation; STS: Society of Thoracic Surgeons.

[a]Pacemaker or defibrillator.

Table 2: Procedural characteristics by valve model

Characteristic	Valve model									
	Stented bovine pericardial				Stented porcine			Stentless	Sutureless	
	Avalus ($n=1134$)	Perimount ($n=741$)	Trifecta ($n=394$)	Mitroflow ($n=53$)	Mosaic ($n=232$)	Hancock ($n=67$)	Epic ($n=39$)	Freestyle ($n=67$)	Intuity ($n=116$)	Perceval ($n=95$)
Surgical approach										
Median sternotomy	905 (79.8%)	592 (79.9%)	354 (89.8%)	50 (94.3%)	190 (81.9%)	55 (83.3%)	33 (84.6%)	62 (92.5%)	46 (39.7%)	61 (64.2%)
Hemisternotomy	146 (12.9%)	75 (10.1%)	24 (6.1%)	3 (5.7%)	28 (12.1%)	3 (4.5%)	1 (2.6%)	4 (6.0%)	11 (9.5%)	15 (15.8%)
Right thoracotomy	69 (6.1%)	66 (8.9%)	14 (3.6%)	0 (0.0%)	11 (4.7%)	8 (12.1%)	4 (10.3%)	0 (0.0%)	59 (50.9%)	19 (20.0%)
Other	14 (1.2%)	8 (1.1%)	2 (0.5%)	0 (0.0%)	3 (1.3%)	0 (0.0%)	1 (2.6%)	1 (1.5%)	0 (0.0%)	0 (0.0%)
Aortic root replacement	3 (0.3%)	2 (0.3%)	0 (0.0%)	1 (2.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	13 (19.4%)	0 (0.0%)	0 (0.0%)
Total bypass time (min)	105.6 ± 41.4 ($n=1133$)	98.7 ± 37.7 ($n=730$)	96.6 ± 37.7 ($n=390$)	103.8 ± 36.5 ($n=53$)	94.2 ± 34.1 ($n=228$)	99.3 ± 47.0 ($n=66$)	87.2 ± 49.7 ($n=39$)	150.4 ± 64.9 ($n=65$)	73.4 ± 27.9 ($n=115$)	83.5 ± 41.8 ($n=95$)
Total aortic cross-clamp time (min)	79.4 ± 31.3 ($n=1134$)	73.8 ± 27.2 ($n=723$)	70.8 ± 27.8 ($n=386$)	76.3 ± 23.5 ($n=53$)	68.6 ± 23.8 ($n=222$)	75.5 ± 32.1 ($n=64$)	64.1 ± 43.3 ($n=39$)	120.2 ± 43.2 ($n=65$)	55.9 ± 21.5 ($n=115$)	56.1 ± 28.3 ($n=95$)

Values are mean±SD (*n*) or *n* (%).

SD: standard deviation.

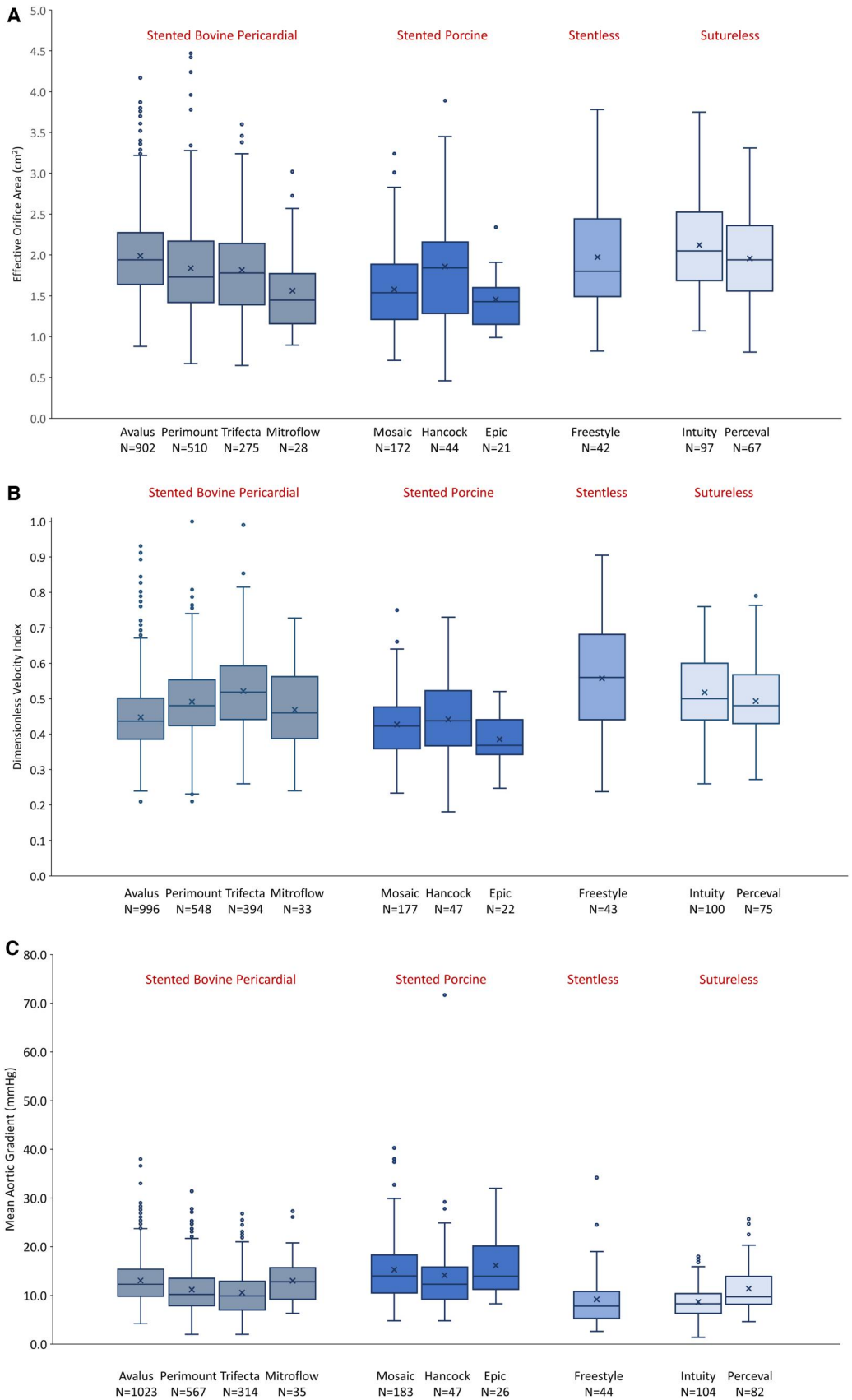

Figure 1: Box and whisker plots illustrating haemodynamic performance at 1 year in 10 contemporary surgical valve models: (**A**) effective orifice index, (**B**) dimensionless velocity index, (**C**) mean aortic gradient, (**D**) peak aortic velocity and (**E**) stroke volume. In each plot, x indicates the mean; capped vertical bars, minimum and maximum values; horizontal line, median; and boxes, quartiles 1 and 3. The circles represent outliers. Data for each valve model are based on all valve sizes combined.

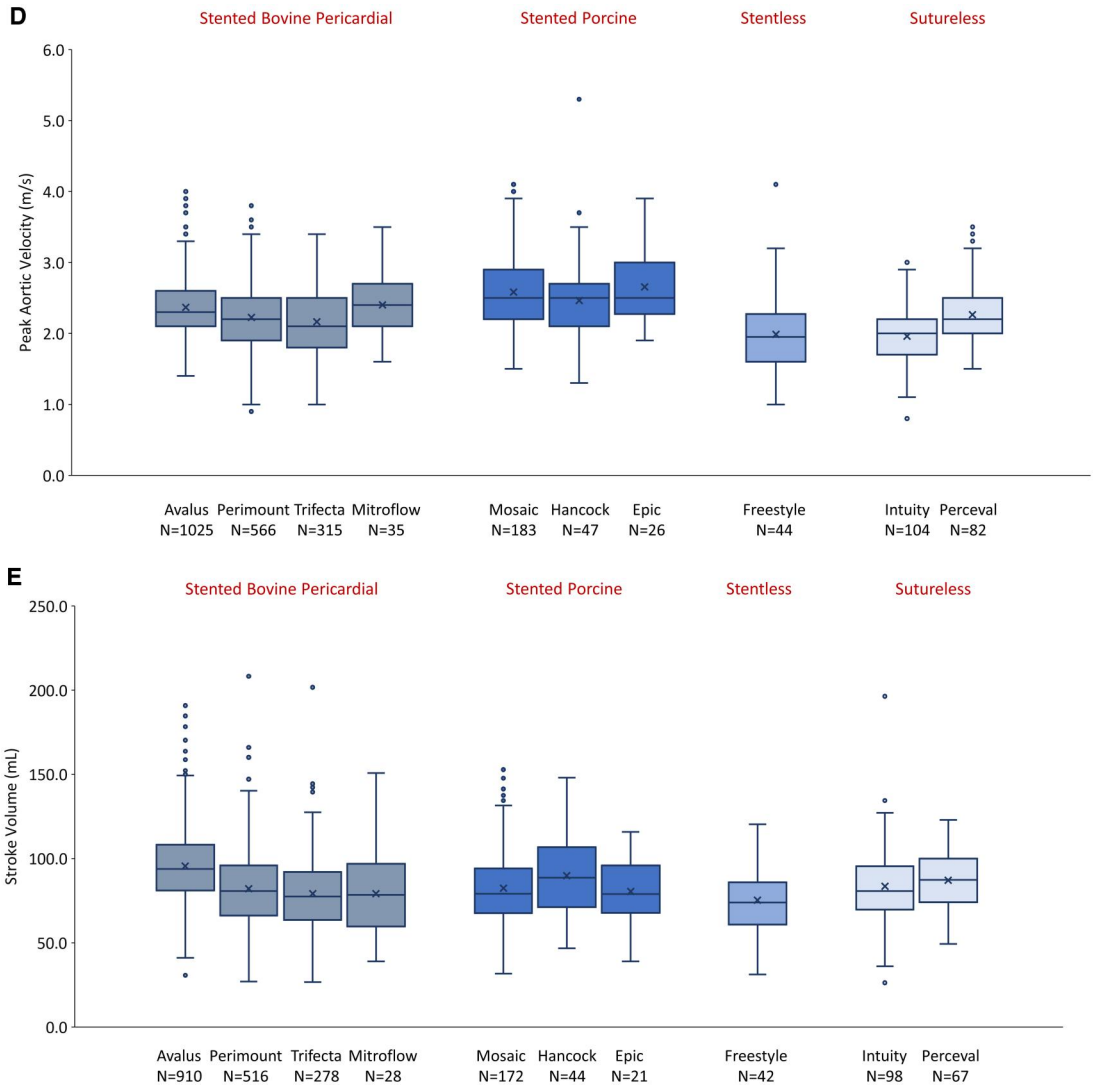

Figure 1: Continued

Table 2 shows the procedural details for each valve model. Median sternotomy was the most common surgical approach for patients who received all valve models except the Intuity sutureless valve; 50.9% of patients who received the Intuity sutureless valve underwent a right thoracotomy. The most frequently implanted valve size in each study was 23 (Supplementary Material, Fig. S3) [The Perceval valve is a sutureless, expandable bioprosthesis that is available in sizes small (corresponding to a measured annular diameter of 19–21 mm), medium (21–23 mm), large (23–25 mm) and extra-large (25–27 mm) [18]. In the Evolut Low Risk study, small Perceval valves ($n = 89$) were categorized as 21 mm; medium valves as 23 mm; large valves as 25 mm; and extra-large valves as 27 mm. In the SURTAVI study, investigators entered the valve size in mm ($n = 6$)] [18].

Figure 1 illustrates the haemodynamic performance of each valve model at 1 year, grouped by valve type. Among the 10 valve models, EOA values ranged from 1.46 ± 0.34 to 2.12 ± 0.59 cm^2, and DVI ranged from 0.39 ± 0.07 to 0.56 ± 0.1. Mean gradient ranged from 8.6 ± 3.4 to 16.1 ± 6.2 mmHg. Tables 3–5 further stratify those data by labelled valve size. At 1 year, peak aortic velocity ranged from 1.96 ± 0.39 to 2.65 ± 0.47 m/s, and SV, from 75.3 ± 19.6 to 89.8 ± 24.3 ml. Supplementary Material, Fig. S4 shows EOAi by BSA for the valve models.

The rates of PPM at 1 year among the valve models were as follows: none, 42.9–79.5%; moderate, 13.6–33.3% and severe, 2.1–23.8% (Fig. 2). Most patients had no transvalvular regurgitation at 1 year (70.6–85.9%), and rates of moderate and severe transvalvular regurgitation were low (moderate, 0–0.3%; severe, 0–3.8%) (Fig. 3). Similarly, most patients had no paravalvular regurgitation at 1 year (81.5–95.7%), and there were no cases of severe paravalvular regurgitation at this timepoint (Fig. 3).

DISCUSSION

The studies pooled for this analysis yielded 2938 patients who underwent SAVR with a contemporary surgical aortic valve, making it the largest surgical valve series that includes multiple global centres, a wide variety of surgical valves and echocardiograms evaluated by a single core laboratory. This data set provides a unique opportunity to examine haemodynamic performance of multiple surgical aortic valves in a very large number of patients. The use of a single core lab to assess all

Table 3: Mean effective orifice area (cm^2) at 1 year by valve model and labelled valve size

	Labelled valve size[a,b]							
	All sizes	17 mm ($n=1$)	19 mm ($n=146$)	21 mm ($n=674$)	23 mm ($n=1029$)	25 mm ($n=812$)	27 mm ($n=239$)	29 mm ($n=36$)
Stented bovine pericardial								
Avalus ($n=1134$)	1.99 ± 0.51 ($n=902$)	1.16 ($n=1$)	1.40 ± 0.24 ($n=31$)	1.57 ± 0.31 ($n=162$)	1.97 ± 0.43 ($n=313$)	2.12 ± 0.43 ($n=302$)	2.50 ± 0.54 ($n=83$)	3.00 ± 0.51 ($n=10$)
Perimount ($n=741$)	1.84 ± 0.59 ($n=510$)	NA	1.29 ± 0.49 ($n=19$)	1.49 ± 0.42 ($n=132$)	1.81 ± 0.45 ($n=199$)	2.13 ± 0.61 ($n=128$)	2.58 ± 0.61 ($n=31$)	3.78 ($n=1$)
Trifecta ($n=394$)	1.81 ± 0.53 ($n=275$)	NA	1.28 ± 0.34 ($n=27$)	1.61 ± 0.42 ($n=93$)	1.87 ± 0.47 ($n=96$)	2.18 ± 0.41 ($n=43$)	2.50 ± 0.49 ($n=15$)	3.46 ($n=1$)
Mitroflow ($n=53$)	1.56 ± 0.55 ($n=28$)	NA	1.01 ($n=1$)	1.46 ± 0.42 ($n=13$)	1.60 ± 0.53 ($n=8$)	1.82 ± 0.81 ($n=6$)	NA	NA
Stented porcine								
Mosaic ($n=232$)	1.58 ± 0.49 ($n=172$)	NA	1.07 ± 0.23 ($n=3$)	1.24 ± 0.38 ($n=29$)	1.46 ± 0.39 ($n=65$)	1.79 ± 0.48 ($n=64$)	1.99 ± 0.34 ($n=10$)	2.75 ($n=1$)
Hancock ($n=67$)	1.86 ± 0.75 ($n=44$)	NA	NA	1.10 ± 0.36 ($n=7$)	1.54 ± 0.51 ($n=12$)	1.97 ± 0.67 ($n=16$)	2.50 ± 0.51 ($n=6$)	3.03 ± 0.38 ($n=3$)
Epic ($n=39$)	1.46 ± 0.34 ($n=21$)	NA	1.04 ($n=1$)	1.37 ± 0.26 ($n=9$)	1.49 ± 0.35 ($n=7$)	1.69 ± 0.46 ($n=4$)	NA	NA
Stentless								
Freestyle ($n=67$)	1.97 ± 0.66 ($n=42$)	NA	1.38 ($n=1$)	2.12 ($n=1$)	1.71 ± 0.52 ($n=18$)	2.15 ± 0.64 ($n=16$)	2.51 ± 0.99 ($n=4$)	2.04 ± 1.03 ($n=2$)
Sutureless								
Intuity ($n=116$)	2.12 ± 0.59 ($n=97$)	NA	1.51 ± 0.36 ($n=6$)	1.80 ± 0.39 ($n=17$)	1.98 ± 0.44 ($n=31$)	2.35 ± 0.55 ($n=30$)	2.65 ± 0.69 ($n=13$)	NA
Perceval[c] ($n=94$)	1.95 ± 0.57 ($n=66$)	NA	NA	1.38 ± 0.38 ($n=3$)	1.62 ± 0.55 ($n=17$)	1.95 ± 0.45 ($n=27$)	2.35 ± 0.51 ($n=19$)	NA

Data are mean±SD (n).

[a]Durko *et al.* [26] recommend a minimum of 30 patients for each valve size when reporting haemodynamic performance data. Results for a specific valve size based on <30 patients should be interpreted in light of this recommendation.

[b]The size 17 Avalus valve is approved for use in Japan only.

[c]The Perceval valve is a sutureless, expandable bioprosthesis that is available in sizes small (corresponding to a measured annular diameter of 19–21 mm), medium (21–23 mm), large (23–25 mm) and extra-large (25–27 mm) [18]. In the Evolut Low Risk study, small Perceval valves ($n=89$) were categorized as 21 mm; medium valves as 23 mm; large valves as 25 mm; and extra-large valves as 27 mm. In the SURTAVI study, investigators entered the valve size in mm ($n=6$).

SD: standard deviation.

Table 4: Dimensionless velocity index at 1 year by valve model and labelled valve size

	Labelled valve size[a,b]							
	All sizes	17 mm ($n=1$)	19 mm ($n=146$)	21 mm ($n=674$)	23 mm ($n=1029$)	25 mm ($n=812$)	27 mm ($n=239$)	29 mm ($n=36$)
Stented bovine pericardial								
Avalus ($n=1134$)	0.45 ± 0.09 ($n=996$)	0.37 ($n=1$)	0.42 ± 0.07 ($n=35$)	0.42 ± 0.08 ($n=187$)	0.46 ± 0.09 ($n=356$)	0.45 ± 0.09 ($n=317$)	0.46 ± 0.11 ($n=88$)	0.54 ± 0.13 ($n=12$)
Perimount ($n=741$)	0.49 ± 0.10 ($n=548$)	NA	0.43 ± 0.08 ($n=19$)	0.47 ± 0.10 ($n=144$)	0.49 ± 0.10 ($n=215$)	0.51 ± 0.11 ($n=136$)	0.54 ± 0.11 ($n=33$)	0.66 ($n=1$)
Trifecta ($n=394$)	0.52 ± 0.11 ($n=304$)	NA	0.46 ± 0.09 ($n=32$)	0.51 ± 0.10 ($n=103$)	0.53 ± 0.12 ($n=105$)	0.56 ± 0.09 ($n=48$)	0.58 ± 0.08 ($n=15$)	0.65 ($n=1$)
Mitroflow ($n=53$)	0.47 ± 0.13 ($n=33$)	NA	0.32 ($n=1$)	0.48 ± 0.11 ($n=16$)	0.43 ± 0.11 ($n=10$)	0.52 ± 0.18 ($n=6$)	NA	NA
Stented porcine								
Mosaic ($n=232$)	0.43 ± 0.09 ($n=177$)	NA	0.37 ± 0.08 ($n=4$)	0.39 ± 0.08 ($n=30$)	0.42 ± 0.09 ($n=65$)	0.45 ± 0.09 ($n=65$)	0.44 ± 0.05 ($n=12$)	0.52± ($n=1$)
Hancock ($n=67$)	0.44 ± 0.12 ($n=46$)	NA	NA	0.35 ± 0.09 ($n=7$)	0.41 ± 0.14 ($n=14$)	0.47 ± 0.11 ($n=16$)	0.50 ± 0.09 ($n=6$)	0.53 ± 0.08 ($n=3$)
Epic ($n=39$)	0.39 ± 0.07 ($n=21$)	NA	0.37 ($n=1$)	0.38 ± 0.07 ($n=9$)	0.39 ± 0.07 ($n=7$)	0.39 ± 0.09 ($n=4$)	NA	NA
Stentless								
Freestyle ($n=67$)	0.56 ± 0.15 ($n=43$)	NA	0.69 ($n=1$)	0.75 ($n=1$)	0.54 ± 0.19 ($n=19$)	0.58 ± 0.12 ($n=16$)	0.57 ± 0.10 ($n=4$)	0.41 ± 0.05 ($n=2$)
Sutureless								
Intuity ($n=116$)	0.52 ± 0.10 ($n=100$)	NA	0.52 ± 0.13 ($n=6$)	0.53 ± 0.08 ($n=17$)	0.51 ± 0.10 ($n=32$)	0.51 ± 0.10 ($n=32$)	0.54 ± 0.12 ($n=13$)	NA
Perceval ($n=94$)[c]	0.49 ± 0.12 ($n=75$)	NA	NA	0.52 ± 0.12 ($n=5$)	0.46 ± 0.10 ($n=19$)	0.48 ± 0.11 ($n=31$)	0.52 ± 0.13 ($n=20$)	NA

Data are mean±SD (n).
[a,b,c]See footnotes in Table 3.
SD: standard deviation.

Table 5: Mean aortic gradient (mmHg) at 1 year by valve model and labelled valve size

	Labelled valve size[a,b]							
	All sizes	17 mm ($n=1$)	19 mm ($n=146$)	21 mm ($n=674$)	23 mm ($n=1029$)	25 mm ($n=812$)	27 mm ($n=239$)	29 mm ($n=36$)
Stented bovine pericardial								
Avalus ($n=1134$)	13.1 ± 4.5 ($n=1023$)	21.9 ($n=1$)	17.1 ± 4.9 ($n=37$)	15.6 ± 5.1 ($n=195$)	12.7 ± 4.0 ($n=363$)	12.4 ± 3.9 ($n=324$)	10.3 ± 3.5 ($n=91$)	9.5 ± 3.3 ($n=12$)
Perimount ($n=741$)	11.2 ± 4.6 ($n=567$)	NA	14.4 ± 4.7 ($n=20$)	12.6 ± 4.8 ($n=151$)	11.2 ± 4.1 ($n=221$)	9.9 ± 4.3 ($n=139$)	8.0 ± 3.2 ($n=33$)	6.6 ± 4.7 ($n=3$)
Trifecta ($n=394$)	10.6 ± 4.7 ($n=314$)	NA	15.5 ± 5.3 ($n=33$)	11.4 ± 4.5 ($n=106$)	10.1 ± 4.1 ($n=108$)	7.8 ± 3.0 ($n=51$)	7.0 ± 2.3 ($n=15$)	5.7 ($n=1$)
Mitroflow ($n=53$)	13.0 ± 5.3 ($n=35$)	NA	21.1 ± 7.1 ($n=2$)	11.6 ± 3.9 ($n=17$)	15.9 ± 5.7 ($n=10$)	9.5 ± 2.6 ($n=6$)	NA	NA
Stented porcine								
Mosaic ($n=232$)	15.3 ± 6.2 (n=183)	NA	22.8 ± 5.4 ($n=4$)	18.7 ± 5.5 ($n=30$)	16.0 ± 7.0 ($n=68$)	13.5 ± 4.6 ($n=66$)	11.4 ± 4.0 ($n=14$)	7.2 ($n=1$)
Hancock ($n=67$)	14.1 ± 10.1 ($n=47$)	NA	NA	24.8 ± 20.8 ($n=7$)	16.0 ± 6.6 ($n=15$)	11.0 ± 3.4 ($n=16$)	9.4 ± 2.1 ($n=6$)	6.4 ± 1.4 ($n=3$)
Epic ($n=39$)	16.1 ± 6.2 ($n=26$)	NA	32.0 ($n=1$)	17.2 ± 6.0 ($n=11$)	11.6 ± 2.2 ($n=9$)	18.8 ± 4.1 ($n=5$)	NA	NA
Stentless								
Freestyle ($n=67$)	9.2 ± 6.0 ($n=44$)	NA	10.3 ($n=1$)	5.2 ($n=1$)	12.2 ± 7.7 ($n=19$)	6.9 ± 2.6 ($n=17$)	5.9 ± 1.3 ($n=4$)	8.4 ± 5.2 ($n=2$)
Sutureless								
Intuity ($n=116$)	8.6 ± 3.4 ($n=104$)	NA	9.4 ± 2.3 ($n=7$)	9.9 ± 3.2 ($n=18$)	8.6 ± 3.5 ($n=34$)	8.6 ± 3.6 ($n=32$)	6.6 ± 2.3 ($n=13$)	NA
Perceval[c] ($n=94$)	11.4 ± 4.6 ($n=81$)	NA	NA	9.3 ± 2.5 ($n=5$)	13.3 ± 4.8 ($n=20$)	11.3 ± 4.4 ($n=33$)	10.5 ± 4.9 ($n=23$)	NA

Data are mean±SD (n).

[a,b,c]See footnotes in Table 3.

SD: standard deviation.

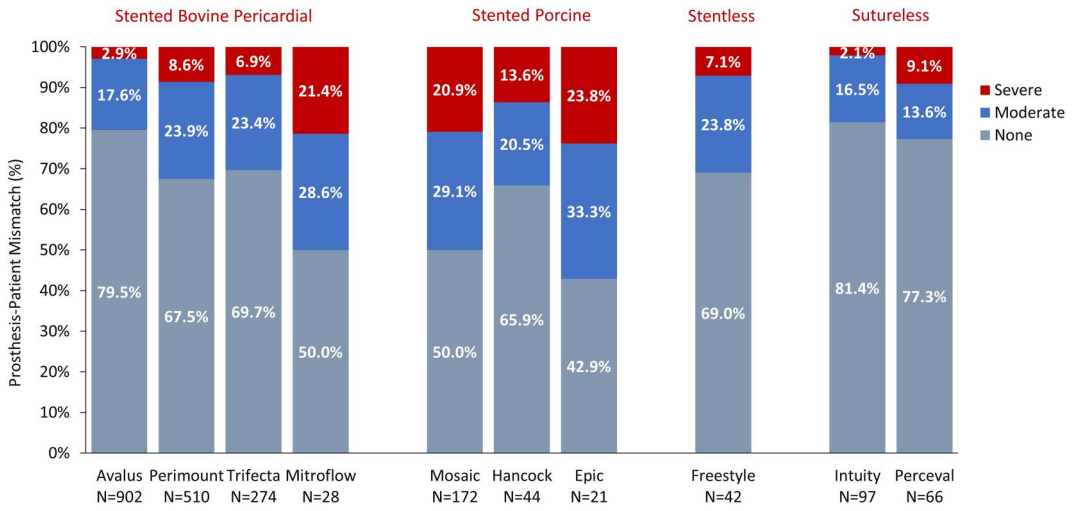

Figure 2: Prosthesis–patient mismatch at 1 year.

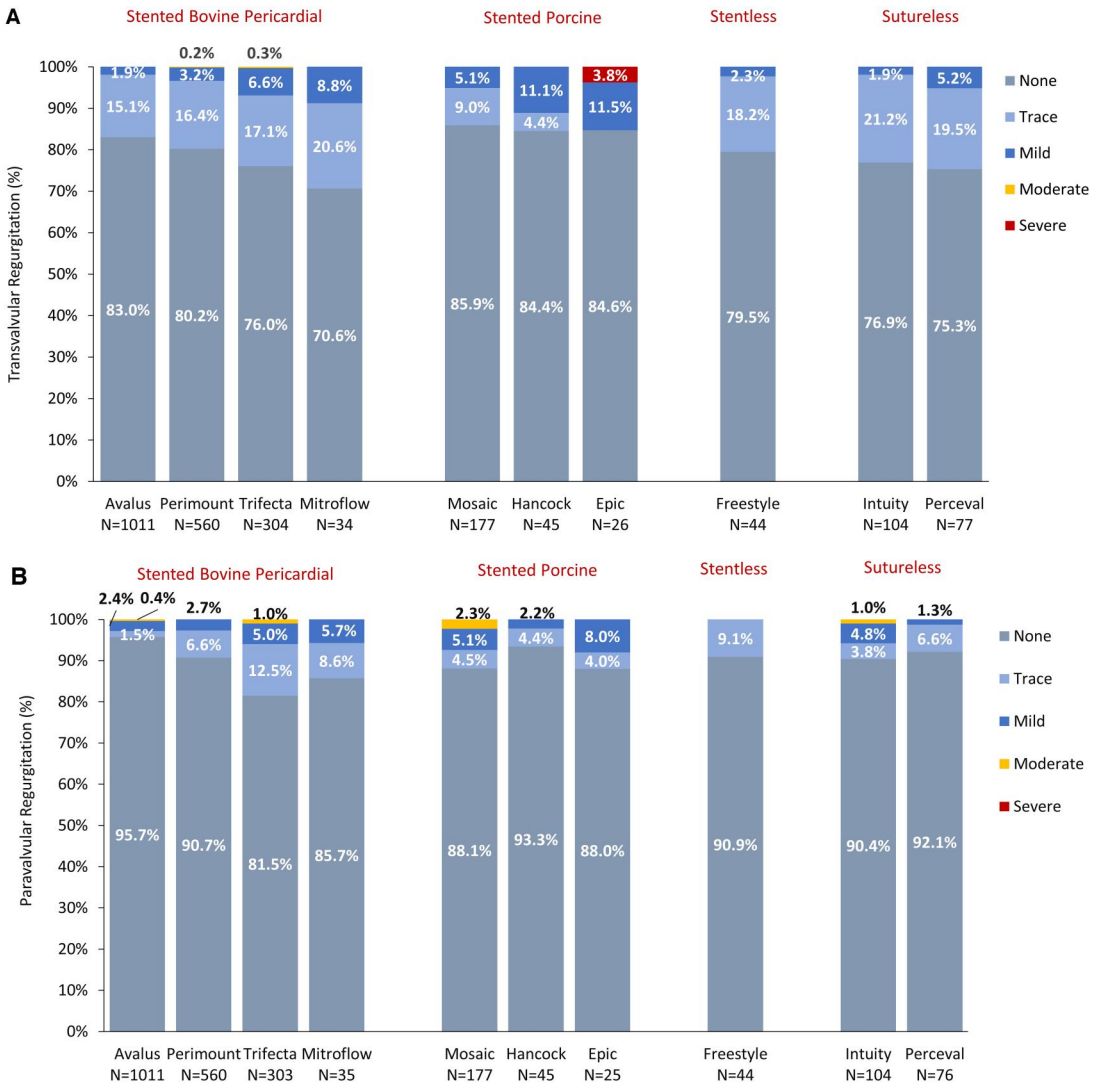

Figure 3: Aortic regurgitation 1 year postimplant: (**A**) transvalvular and (**B**) paravalvular.

echocardiograms using a common methodology increases the robustness of the data set, overcoming an important limitation of previous, similar analyses and allowing for a more comparative assessment between valve models.

Overall haemodynamic performance at 1 year was generally good, with low mean gradients across all valve models (8.6 ± 3.4 to 16.1 ± 6.2 mmHg), including single-digit gradients for the Intuity and Freestyle models. EOAs ranged from 1.46 ± 0.34 to 2.12 ± 0.59 cm^2 at 1 year, with 4 valves (Intuity, Perceval, Freestyle and Avalus) having a mean 1-year EOA $\geq$2.0 cm^2. DVI, which ranged from 0.39 ± 0.07 to 0.56 ± 0.1, was numerically similar among the stented pericardial, stentless and sutureless valves and slightly lower among the porcine valves. SV for the 10 valves ranged from 75.3 ± 19.6 to 95.4 ± 20.7 ml with high SVs among some bovine pericardial, porcine and sutureless valves. It is important to note, however, that the purpose of this analysis was not to directly compare valve models but to evaluate each model individually to determine its typical haemodynamic performance at 1 year.

PPM (moderate or severe) was present at 1 year in 21–50% of patients who received a stented pericardial valve, 34–57% of patients who received a stented porcine valve, 31% of patients who received a stentless valve and 19–23% of patients who received a sutureless valve. Although moderate PPM might not be clinically relevant for some patients in this analysis considering the mean ages in the pooled studies (70–82 years), for younger patients, these findings highlight the importance of considering durability, the need for lifelong anticoagulation, the potential for thrombogenicity and other factors, including lifetime management, when choosing a valve type for AVR.

Notably, the population mean EOA and rates of PPM reported in this manuscript for Avalus differed substantially from what was reported previously from the PERIGON Pivotal Trial [10, 11]. In this analysis, the mean EOA at 1 year for the Avalus valve was 1.99 ± 0.51 cm^2 compared with the previously reported 1-year EOA of 1.5 ± 0.4 cm^2 [10, 11]. The proportion of patients with no PPM at 1 year in this analysis was 79.5% compared with 24.5% reported earlier. The values reported here correspond well with what has been reported from real-world studies of this valve [19, 20]. The variations in EOA and PPM predominantly arise from variances in the measured LVOT diameter between core labs. The differences in measured EOA and PPM rates for the Avalus valve highlight the need for methodological standardization in echocardiographic assessment [21, 22] as well as the need for caution when making cross-study comparisons, particularly when multiple non-standardized core labs are used. Because of the standardization offered by this data set, haemodynamic comparisons across valve models and sizes are more reliable, although limitations remain. EOAi charts using measured EOA from this study are provided in the Supplementary Material, Fig. S4. While we recognize the significant limitations of EOAi charts in predicting PPM that have been well documented in the literature from this group as well as others [23, 24], we have decided to publish EOAi charts from this analysis in the supplement in order to provide a standardized reference as we acknowledge that in current practice, some surgeons do reference these charts despite their inaccuracy in forecasting PPM. It is important to note that these charts should not be the sole tool used in valve selection and sizing [25, 26].

Representative data on the normal haemodynamic function of surgical valves at specific timepoints can serve as a resource to physicians to evaluate the performance of an individual patient's implanted valve at follow-up and to guide management. However, it is critical to recognize the limitations of haemodynamic measurements, including variability in measurements of the LVOT diameter and the potential for measurement errors [21, 27]. For this reason, physicians should use these haemodynamic performance data in combination with other parameters, such as functional status, LV function, LV hypertrophy and valvular calcification, when determining whether a patient needs an intervention [28, 29].

Limitations

In addition to the potential shortcomings of echocardiographic measurements, this study had several limitations that must be considered when interpreting the results. There were differences in the patient population of each study with the SURTAVI and CoreValve High Risk studies having older, frailer patients with a higher operative risk and more comorbid conditions. In addition, the inclusion and exclusion criteria differed between PERIGON and the RCTs. The number of each valve model, and each valve size of a particular model, varied widely, which may have impacted the results. Multiple iterations of the Perimount bovine pericardial valve were implanted in the RCTs, but the specific model (e.g. Perimount, Perimount Magna Ease) was not consistently reported. For this reason, we were unable to stratify those data by valve subtype. Annulus size was measured differently in the RCTs and PERIGON, so assessing haemodynamic outcomes by annulus size and valve type was not possible. Although echocardiograms were assessed at a single core laboratory, multiple sonographers performed the assessments, introducing the possibility of interobserver variability. However, the assessments were reviewed by 2 of the authors (Jae K. Oh and Saki Ito) before data were entered into the database, and the entered data were then approved. The valves evaluated in this study were implanted by several different surgeons with various levels of experience and different implantation techniques, which may have impacted haemodynamic performance. On the other hand, for this exact reason, the data presented in this study reflect the real-world haemodynamic performance of these valves.

CONCLUSION

This analysis demonstrates the haemodynamic performance that can generally be expected at 1 year with currently available surgical tissue valves. Overall performance ranged from good to excellent for the individual valve models, sizes and haemodynamic parameters. These data can serve as a benchmark for other studies and may be a useful resource to help guide patient management following SAVR.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

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DATA AVAILABILITY

The data underlying this article are owned by the study sponsor and will not be made available to other investigators for research purposes.

Author contributions

Robert J.M. Klautz: Conceptualization; Investigation; Methodology; Resources; Supervision; Visualization; Writing—original draft. **Vivek Rao:** Conceptualization; Investigation; Resources; Writing—review and editing. **Michael J. Reardon:** Conceptualization; Investigation; Resources; Writing—review and editing. **G. Michael Deeb:** Investigation; Resources; Writing—review and editing. **Francois Dagenais:** Conceptualization; Investigation; Resources; Writing—review and editing. **Michael G. Moront:** Conceptualization; Investigation; Resources; Writing—review and editing. **Stephen H. Little:** Investigation; Resources; Writing—review and editing. **Louis Labrousse:** Investigation; Resources; Writing—review and editing. **Himanshu J. Patel:** Investigation; Resources; Writing—review and editing. **Saki Ito:** Investigation; Resources; Writing—review and editing. **Shuzhen Li:** Data curation; Formal analysis; Methodology; Software; Validation; Writing—review and editing. **Joseph F. Sabik III:** Conceptualization; Investigation; Methodology; Resources; Supervision; Writing—review and editing. **Jae K. Oh:** Conceptualization; Investigation; Resources; Writing—review and editing.

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