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Review Article

Mini-Aortic Valve Replacement versus Transcatheter Aortic Valve Implantation: A Propensity-Matched Study

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Background. Total sternotomy for aortic valve replacement has been superseded by less invasive approaches such as mini-sternotomy or transcatheter procedures. There has been an exponential uptake in transcatheter aortic valve implantation (TAVI) in younger and lower risk patients following recent randomized trials. This study aims to compare the outcomes of patients with aortic stenosis treated with minimally invasive approaches: mini-sternotomy for aortic valve replacement (mini-AVR) and TAVI implantation. *Methods*. Between January 2015 and December 2021, a total of 1437 TAVI and 176 mini-AVR patients from 2 tertiary centers fulfilled the criteria and were included in the propensity matching model. *Results*. A total of 256 TAVIs and 146 mini-AVR were included in the matched cohort. There was no significant difference in 30-day mortality in the two groups (TAVI vs. mini-AVR 2.7% vs. 2.8%, $p = 0.935$). TAVI confers slightly lower gradients in the follow-up echo when compared with mini-AVR (peak gradient 20 ± 8.7 mmHg vs. 24.5 ± 10 mmHg, $p < 0.001$; mean gradient 10.9 ± 5.6 mmHg vs. 13.2 ± 5.7 mmHg, $p < 0.001$). On the other hand, mini-AVR exhibits remarkably lower rates of paravalvular leak (mild leak 8% vs. 41.5%, $p < 0.001$; moderate leak 2.8% vs. 0%, $p < 0.001$) and of need for permanent pacemaker implantation (2% vs. 12.2%, $p < 0.001$). Unsurprisingly, TAVI has lower in-hospital stay 3 (2 to 6) days vs. 10 (8 to 13) days, $p < 0.001$). *Conclusions*. For eligible aortic stenosis patients in the 7th decade of life, mini-AVR remains an excellent therapeutic option.

1. Introduction

With the increase in life expectancy and the aging population, aortic stenosis (AS) has become one of the most common heart diseases burdening healthcare systems worldwide [1].

Despite extensive studies in the pathophysiology and risk factors of the nature of calcific aortic valve disease, along with current, potential, and emerging novel medical therapies [2], surgical aortic valve replacement (SAVR) still remains the gold standard in patients with severe symptomatic aortic valve stenosis [3].

Transcatheter aortic valve implantation (TAVI) has rapidly evolved in the last decade as the alternative minimally invasive procedure that could be offered to patients with severe AS. Due to technical improvements in the prostheses and a reduction in the size of delivery systems, procedural risks have decreased, and TAVI has established its role as a minimally invasive technique to treat AS patients who have been considered inoperable [4] or high risk. More

recent studies have established its role in intermediate [5] and indeed lower risk patients [6], even though outcome comparisons only go out to two years so far. SAVR remains the only option with known durable long-term results that extend beyond 10 years [7]. Currently, robust durability data in randomized trials comparing TAVI to SAVR extend to 5, whereas longer-term TAVI durability data are eagerly anticipated [8].

In order to be able to compete with TAVI and avoid the full sternotomy complications, multiple surgical minimally invasive options have emerged. Mini-AVR can be performed via partial sternotomy or anterior right thoracotomy. Its advantages rely on reductions in pain, mechanical ventilation, blood transfusion requirements, sternal wound complications, postoperative incidence of atrial fibrillation, and hospital length of stay when compared to sAVR via complete sternotomy [9]. The evolution of mini-AVR and TAVI has only been feasible, thanks to the technological advances of the implantable valves and their delivery systems [10, 11].

As mentioned previously, TAVI indications have recently been expanded to intermediate and low risk groups [5, 12]. In addition, current American guidelines advocate for the use of TAVI in patients between 65 and 80 years of age despite the lack of long-term (>10 years) durability data [8].

In this retrospective study, we aimed to review the outcomes of propensity-matched patients treated with TAVI and mini-AVR via partial sternotomy.

2. Methods

2.1. Definitions [13, 14]

2.1.1. Cerebrovascular Accident. These were identified as strokes. TIAs and delirium were not classified as cerebrovascular accident as they had a full recovery.

2.1.2. Myocardial Infarction. The VARC-3 endorses the modified SCAI and ARC-2 definition, which provides a common biomarker (troponin or CK-MB) threshold for both PCI and CABG and proposes to use the same definition for periprocedural MI post-SAVR and TAVR. We used troponin as the selected biomarker.

2.1.3. Bleeding. Overt bleeding requires a transfusion of 2–4 units of whole blood/red blood cells[‡] (BARC 3a). Overt bleeding associated with a hemoglobin drop of >3 g/dL (>1.86 mmol/L) but <5 g/d (<3.1 mmol/L) (BARC 3a). Overt bleeding requires reoperation, surgical exploration, or reintervention for the purpose of controlling bleeding (BARC 3b and BARC 4).

2.1.4. Tamponade. Overt bleeding in a critical organ, such as intracranial, intraspinal, intraocular, pericardial (associated with haemodynamic compromise/tamponade and necessitating intervention), or intramuscular with compartment syndrome (BARC 3b, BARC 3c).

Asthma and COPD were identified as different identities in this cohort.

All aortic stenosis patients undergoing TAVI from Harefield Hospital (Uxbridge, United Kingdom) or mini-AVR from La Princesa Hospital (Madrid, Spain) were included in the original database. The relative numbers of each procedure were 256 TAVIs and 141 mini-AVR. Patients with previous cardiac surgery, significant coronary artery disease, more than mild mitral regurgitation, infective endocarditis, and those with interventions before 2015 were excluded (Figure 1).

TAVI was performed either via the transfemoral or transaxillary routes using predominantly either the self-expanding Medtronic Corevalve, Evolut R, PRO, and PRO + valves or the balloon-expandable Edwards SAPIEN, SAPIEN XT, Edwards SAPIEN 3, and Ultra valves. There were also a few patients treated with Lotus (Boston Scientific), Portico (St Jude), and Accurate Neo (Boston Scientific) valves.

Sizing of the valves was performed using CT angiography, and decision on access route and valve selection was discussed in the aortic multidisciplinary meeting, following recent European guidelines [15].

The minimally invasive approach consists of a mini-sternotomy that is performed in a J-shaped fashion, through the third or fourth intercostal space. Both arterial and venous cannulations are performed centrally through the main surgical site (ascending aorta and right atrium with a double-stage cannula). All patients are monitored intraoperatively with transoesophageal echocardiographic guidance.

Follow-up echocardiograms were performed at the first clinic visit, normally 6 weeks from the date of discharge.

Between January 2015 and December 2021, a total of 1437 TAVI and 176 mini-AVR patients from 2 tertiary centers fulfilled the abovementioned criteria and were included in the propensity matching model (Table 1).

2.2. Statistical Analysis. The propensity scores were estimated using a nonparsimonious multivariable logistic regression model with AS treatment (TAVI versus mini-AVR) as the dependent variable and the following variables as covariates: age, gender, BMI, chronic obstructive airways disease, asthma, previous PCI, previous stroke, and LVEF category. Matching was performed with the use of a 2 : 1 (TAVI to mini-AVR matching protocol without replacement (nearest neighbor-matching algorithm), with a caliper width equal to 0.2 of the standard deviation of the logit of the propensity score). The multivariate overall imbalance measure L1 was performed. In the propensity-matched cohort, survival was assessed with the use of the Kaplan–Meier method and compared with the use of the log-rank test.

Following propensity matching, we achieved a good balance L1 of 0.268 with no variables exhibiting a standardized mean difference larger than 0.25 (Figure 2).

A total of 256 TAVI and 141 mini-AVR patients were included in the final analysis.

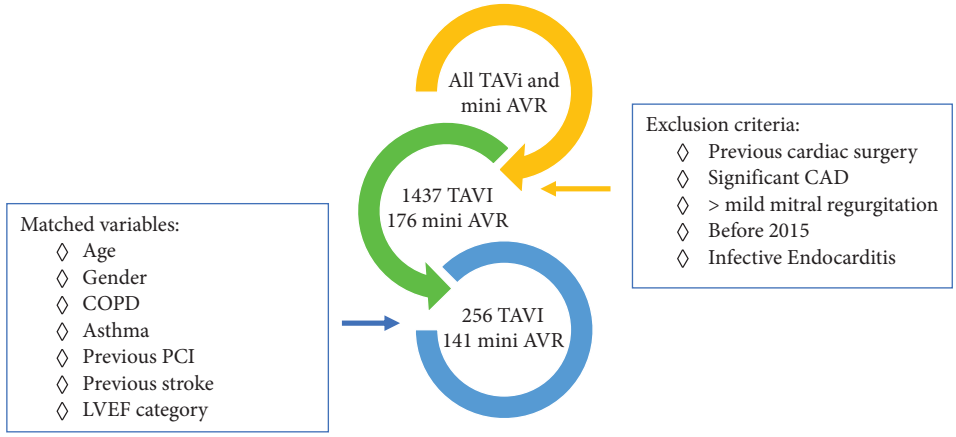

Figure 1: Study recruitment criteria.

Table 1: Baseline characteristics in the total and propensity-matched cohorts.

	Total cohort			Propensity-matched cohort		
	TAVI ($N=1437$)	Mini-AVR ($N=176$)	p value	TAVI ($N=256$)	Mini-AVR ($N=141$)	p value
Age (years)	82.2 ± 6.7	71.7 ± 10.3	<0.001	76.1 ± 7.7	74.8 ± 7.8	0.097
Gender (male) n (%)	733 (51)	86 (48.9)	<0.001	124 (48.4)	72 (51.1)	0.616
BMI	27.4 ± 5.8	28.5 ± 4.3	0.014	30.5 ± 19/2	28.6 ± 4.1	0.225
Type 2 diabetes n (%)						
Diet controlled	68 (4.2)	3 (1.7)	0.105	12 (4.7)	1 (0.7)	0.164
Oral medication	267 (16.5)	32 (17.9)		55 (21.6)	29 (20.6)	
Insulin dependent	76(4.6)	14 (7.8)		18 (7.1)	13 (9.2)	
COPD n (%)	231 (16.1)	17 (9.7)	<0.001	31 (12.1)	17 (12.1)	0.988
Asthma n (%)	127 (8.8)	8 (4.5)	<0.001	11 (4.3)	8 (5.7)	0.539
Previous CVA n (%)	262 (18.2)	7 (4)	<0.001	18 (7.2)	7 (5)	0.380
Previous PCI n (%)	359 (25)	8 (4.5)	<0.001	22 (8.6)	8 (5.7)	0.292
Creatinine (μmol/L)	84 (68 to 107)	84 (70.7 to 99.8)	0.763	83 (68 to 103.5)	84.9 (70.7 to 100.8)	0.825
On haemodialysis n (%)	15 (1)	1 (0.6)	0.597	3 (1.2)	1 (0.7)	0.633
LV function n (%)						
Good	1179 (82)	148 (84.1)	0.017	216 (84.4)	118 (83.7)	0.712
Mild-moderate impairment	183 (12.7)	27 (15.3)		36 (14.1)	22 (15.6)	
Severe impairment	75 (5.2)	1 (0.6)		4 (1.6)	1 (0.7)	
Aortic valve PG (mmHg)	75.2 ± 39	75.3 ± 23.8	0.975	79 ± 48	73.5 ± 23	0.283
Aortic valve MG (mmHg)	45.5 ± 17.4	48.2 ± 13.8	0.102	46.1 ± 16.4	47 ± 13.2	0.633

TAVI: transcatheter aortic valve implantation; AVR: aortic valve replacement; BMI: body mass index; COPD: chronic obstructive pulmonary disease; CVA: cerebrovascular accident; PCI: percutaneous coronary intervention; LV: left ventricular; PG: peak gradient; MG: mean gradient. Data are presented as percentages, mean ± standard deviation, or median (interquartile range).

2.2.1. Endpoints. The primary endpoint was mortality within 30 days.

Secondary endpoints included haemodynamic data including mean and peak gradients (measured at 6 weeks follow-up), paravalvular leak, stroke, renal failure requiring dialysis, permanent pacemaker implantation, periprocedural MI, major and life-threatening bleeding, and in-hospital stay.

3. Results

A total of 256 TAVI and 141 mini-AVR patients were included in the final analysis.

In the surgical group, the average EuroScore I was 6.3, and the average EuroScore II was 2.68. This was not available for the TAVI cohort. However, most of the main variables have been propensity matched for.

The TAVI patients were treated predominantly with Evolut R 78 (30.6%), Evolut PRO 60 (23.5%), and SAPIEN 3/Ultra 102 (40%) valves. There were also 2 (0.8%) patients treated with Direct Flow, 3 (1.2%) with old generation Corevalve, 5 (2%) with SAPIEN XT, 1 (0.4%) with SAPIEN, 1 (0.4%) with Lotus, 2 (0.8%) with Portico, and 1 (0.4%) with Accurate Neo valves.

The mini-AVR patients were treated predominantly with Perceval 37 (26.2%), and Trifecta 51 (36.2%), 7 (5%) with St Jude, 17 (12.1%) with Carpentier, 6 (4.3%) with ON-X, 10 (7.1%) with ATS, 9 (6.4%) with Crown, 3 (2.1%) with Mitroflow, and 1 with other mechanical valve manufacturer. In total, 121 (85.8%) patients were treated

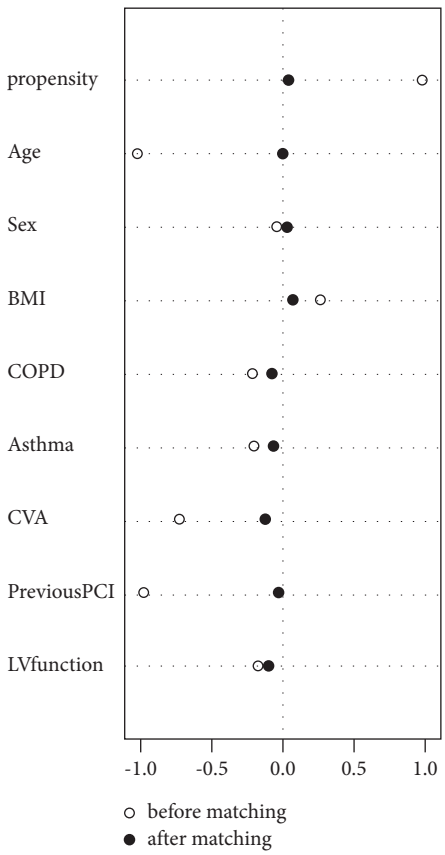

Figure 2: Standardized mean differences in the propensity-matched variables before and after matching.

with bioprosthetic valves and 20 (14.2%) with mechanical.

Overall, 87.9% of surgical patients were treated with valves sized 23 mm or less, whereas in the TAVI cohort, only 19.5% of patients were treated with prostheses sized 23 mm or less (Supplementary table). In the mini-AVR group, 32(22.8%) of patients had a valve that was 19 mm or smaller.

As shown in Table 1 in the propensity-matched cohort patients, the two groups have similar age, gender, and comorbidities including diabetes, COPD, previous stroke, previous PCI, renal function, LV function, and aortic valve haemodynamics.

As shown in Table 2, there was no significant difference in 30-day mortality between the two groups (TAVI vs. mini-AVR 2.7% vs. 2.8%, $p = 0.935$). Amongst bioprosthetic valves, TAVI confers slightly lower gradients in the 6-week follow-up echo when compared with mini-AVR (peak gradient 20 ± 8.7 vs. 24.5 ± 10 mmHg, $p < 0.001$; mean gradient 10.9 ± 5.6 vs. 13.2 ± 5.7 mmHg, $p < 0.001$). On the other hand, TAVI is associated with significantly higher rates of paravalvular leak (mild leak 41.5% vs. 8%, $p < 0.001$; moderate leak 2.8% vs. 0%, $p < 0.001$) and new permanent pacemaker implantation (12.2% vs. 2%, $p < 0.001$). There appears to be a higher incidence of periprocedural stroke amongst TAVI patients (4.5% vs. 0.7%, $p = 0.039$). TAVI had a lower in-hospital stay (3 (2 to 6) days vs. 10 (8 to 13) days, $p < 0.001$) (Table 2).

4. Discussion

In our propensity-matched study, we report similar 30-day mortality between patients treated with mini-AVR or TAVI (2.8% vs. 2.7%, p 0.935). Mini-AVR was associated with less periprocedural stroke and pacemaker implantation compared to TAVI. However, TAVI valves exhibited slightly lower peak and mean gradients, at the expense of significantly higher rates of paravalvular leak. As expected, TAVI was associated with significantly lower in-hospital stay.

It is well established in the literature that TAVI valves have larger orifice areas for certain aortic annulus dimensions compared to surgical valves, hence lowering the incidence of prosthesis-patient mismatch [16, 17].

When severe, prosthesis-patient mismatch is known to be associated with reduced survival in both surgical AVR [18] and TAVI patients [19]. In this study, amongst patients treated with bioprosthetic valves, we have shown lower gradients in the TAVI group which also accommodated much larger valve sizes compared to the surgical one.

Registries on minimally invasive approaches for AVR have reported a reduction in ICU length of stay, mechanical ventilation time, and postoperative blood loss [20]. In our cohort, we only report one major bleeding requiring reintervention and one major stroke, with a 30-day mortality of 2.8%, demonstrating that a minimally invasive approach via mini-sternotomy is safe and feasible in a selected population.

30-day mortality occurred in 2.8% of the mini-AVR patients and in 2.7% of the TAVI patients, which is slightly lower than the mortality observed in the PARTNER II trial (4.1% vs. 3.9%) and in line with the results of the SURTAVI trial (3.9% vs. 2.8%), the major trials involving intermediate-risk patients [5, 21]. However, in our data, stroke and at least moderate paravalvular leak were significantly higher in the TAVI cohort. These differences, albeit significant, should be considered within the limitations of a retrospective study design and targeted propensity matching. TAVI outcomes are in line with other previously published studies [22]. We observed a significantly higher percentage of permanent pacemaker insertion (12.2%) when compared with mini-AVR (2.1%). It should be noted however that a large proportion of the TAVI population was treated with an older-generation self-expanding TAVI valve which was associated with higher pacemaker rates.

Recently, the 2 years follow-up of the PARTNER 3 trial reported that with regards to the primary endpoint (death, stroke, or rehospitalization at 1 year), initial differences in death and stroke favoring TAVI were diminished, and patients who underwent TAVI showed a signal towards increased incidence of structural valve degeneration [6].

Current updates in the American guidelines advocate for the "at will" use of TAVI or sAVR in patients between 65 and 80 years old [8]. Our data, however, suggest that mini-AVR could potentially reduce rates of pacemaker and paravalvular leak and offer a well-established durable result. European guidelines are towards the side of caution when advocating the use of TAVI in younger populations (<75).

Table 2: Outcomes between TAVI and mini-AVR.

	TAVI ($N = 256$)	Mini-AVR ($N = 141$)	p value
30 day mortality n (%)	7 (2.7)	4 (2.8)	0.935
Paravalvular regurgitation n (%)			<0.001
Mild	103 (41.5)	11 (8)	
Moderate	7 (2.8)	0	
Severe	0	0	
Bioprosthetic valve PG (mmHg)*	20 ± 8.7	24.5 ± 10	<0.001
Bioprosthetic valve MG (mmHg)*	10.9 ± 5.6	13.2 ± 5.7	<0.001
Permanent pacemaker n (%)			
Preprocedure (existing)	13 (5.7)	1 (0.7)	<0.001
Postprocedure	28 (12.2)	3 (2.1)	
Cerebrovascular accident n (%)	11 (4.5)	1 (0.7)	0.039
Periprocedural myocardial infarction n (%)	0	0	N/A
New renal replacement therapy n (%)	3 (1.4)	4 (2.8)	0.335
Tamponade n (%)	3 (1.2)	2 (1.4)	0.840
Bleeding (major/life threatening) n (%)	4 (1.9)	1 (0.7)	0.369
Death (30 day) n (%)	7 (2.7)	4 (2.8)	0.935
In hospital stay (days)	3 (2 to 6)	10 (8 to 13)	<0.001

TAVI: transcatheter aortic valve implantation; AVR: aortic valve replacement; PG: peak gradient; MG: mean gradient. Data are presented as percentages, mean ± standard deviation, or median (interquartile range). *Gradients were calculated only for bioprosthetic surgical valves; mechanical prostheses were excluded.

Previous publications on the comparison of TAVI vs. mini-AVR show similar results to ours, however, at the cost of higher rates of acute kidney injury [23, 24] amongst the mini-AVR groups.

Cardiac surgeons should adopt minimally invasive techniques in order to allow for faster recovery, reduced hospital length of stay and improved patient experience. The option of minimally invasive aortic valve replacement ensures prostheses' durability and rapid recovery, which is advantageous and appealing for those patients in the "grey zone."

5. Limitations

As with any retrospective study, this one is not without its limitations. Despite optimal balance between the parameters that were chosen for propensity matching, as with any nonrandomized study, it is impossible to account for selection bias and unaccounted confounding. However, in the absence of randomized evidence, propensity matching is the next best in class demonstrating that both TAVI and mini-AVR are viable options to treat aortic stenosis in those eligible patients. Results, therefore, should be interpreted with care and used as hypothesis generating rather than conclusion drawing.

6. Conclusions

Mini-AVR remains an excellent option in the treatment of eligible patients with aortic stenosis with very low 30-day mortality, paravalvular leak, and pacemaker rates. With 30-day mortality similar to TAVI and the established durability of the devices used, mini-AVR where feasible remains an excellent option for patients in the 7th decade of life (age 70–80). A review of all cases by the heart team is fundamental to direct patients to the most appropriate and safe approach.

Data Availability

The data underlying this article will be shared upon reasonable request to the corresponding author.

Ethical Approval

Following consultation with our local research ethics committee, a consent waiver was issued because the study was part of an ongoing retrospective audit, and all data were anonymized.

Conflicts of Interest

Dr. VP has received honoraria from Medtronic.

Authors' Contributions

(i) MMV collected the relevant clinical information, wrote the first draft, and reviewed the article. (ii) EMS collected data and assisted with editing. (iii) NAA collected data. (iv) FA collected data. (v) BBG collected data. (vi) GRC performed final review and validated the study. (vii) VP performed final review, validated the study, and supervised the writing-up of the study as the senior author.

Supplementary Materials

Figure 1. Kaplan–Meier curves for primary outcome—all cause mortality up to 30 days. Tables 1 and 2: TAVI (transcatheter aortic valve implantation) and surgical prostheses types and sizes. (*Supplementary Materials*)

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