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REVIEW ARTICLE

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Outcomes of surgical versus transcatheter aortic valve replacement in nonagenarians- a systematic review and meta-analysis

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ABSTRACT

Introduction: Since the approval of transcatheter aortic valve replacement (TAVR), nonagenarian group patients are being increasingly considered for TAVR. Therefore, we compared the clinical outcomes of surgical aortic valve replacement (SAVR) vs TAVR in nonagenarians with severe aortic stenosis.

Methods: A literature search was performed using MEDLINE, Embase, Web of Science, Cochrane, and Clinicaltrials.gov for studies reporting the comparative outcomes of TAVR versus SAVR in nonagenarians. The primary endpoint was short-term mortality. Secondary endpoints were post-operative incidences of stroke or transient ischemic attack (TIA), vascular complications, acute kidney injury (AKI), transfusion requirement, and length of hospital stay.

Results: Four retrospective studies qualified for inclusion with a total of 8,389 patients (TAVR = 3,112, SAVR = 5,277). Short-term mortality was similar between the two groups [RR = 0.91 (95% CI: 0.76–1.10), p = 0.318]. The average length of hospital stay was shorter by 3 days in the TAVR group (p = 0.037). TAVR was associated with a significantly lower risk of AKI [RR = 0.72 (95% CI: 0.62–0.83), p < 0.001] and a lower risk of transfusion [RR = 0.71 (95% CI: 0.62–0.81), p < 0.001]. There was no difference in risk of stroke/TIA[RR = 1.01 (95% CI: 0.70–1.45), p = 0.957]. The risk of vascular complications was significantly higher in the TAVR group [RR = 3.39 (95% CI: 2.65–4.333), p < 0.001].

Conclusion: In this high-risk population, TAVR compared to SAVR has similar short-term mortality benefit but has lower risks of perioperative complications and a higher number of patients being discharged to home.

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Nonagenarians; surgical aortic valve replacement; trans-catheter aortic valve replacement; TAVR; SAVR; elderly; in-hospital outcomes; short-term outcomes

1. Introduction

From 2006–2008, survival among patients older than 85 years has grown steadily in the USA from 720,000 to 1.9 million due to the availability of better healthcare [1]. With improved survival, the prevalence of valvular heart disease is steadily increasing. The most common valvular heart disease encountered in this age group is aortic stenosis with an estimated prevalence of 9.8% [2]. Severe symptomatic aortic stenosis is associated with a worsening of quality of life and functioning [3,4]. Because of the concomitant comorbidities and frailty, this group of patients is considered to be high risk for undergoing surgical aortic valve replacement and is only considered and offered to selective patients. The perioperative risk of mortality associated with surgical aortic valve replacement (SAVR) tends to increase with age up to about 10% in patients aged 85–90 years [5]. Medical therapy often portends a poor prognosis in patients with severe aortic stenosis with patients needing frequent admissions to the hospital with heart failure with progressive decline and eventually death.

Transcatheter aortic valve replacement (TAVR) has demonstrated to be superior to medical therapy and has comparable clinical outcomes to SAVR in patients with high surgical risk. However, the clinical trials have underrepresented patients older than 90 years and therefore the efficacy of TAVR in this group has not been well studied and the data is mostly limited to small retrospective studies. However, TAVR being a minimally invasive procedure presents a great alternative to SAVR in elderly patients. We, therefore, sought to compare the clinical outcomes of SAVR versus TAVR in nonagenarians with severe aortic stenosis through this meta-analysis.

2. Material and methods

The systematic review was conducted according to the PRISMA guidelines and its summary is given in Figure 1. We systematically performed a search of the following databases: PubMed, Embase, Web of Science, and Cochrane library using the medical search terms (MeSH) and their respective keywords with the following search strategy: ‘Nonagenarians’ AND ‘Aortic

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Supplemental data for this article can be accessed here.

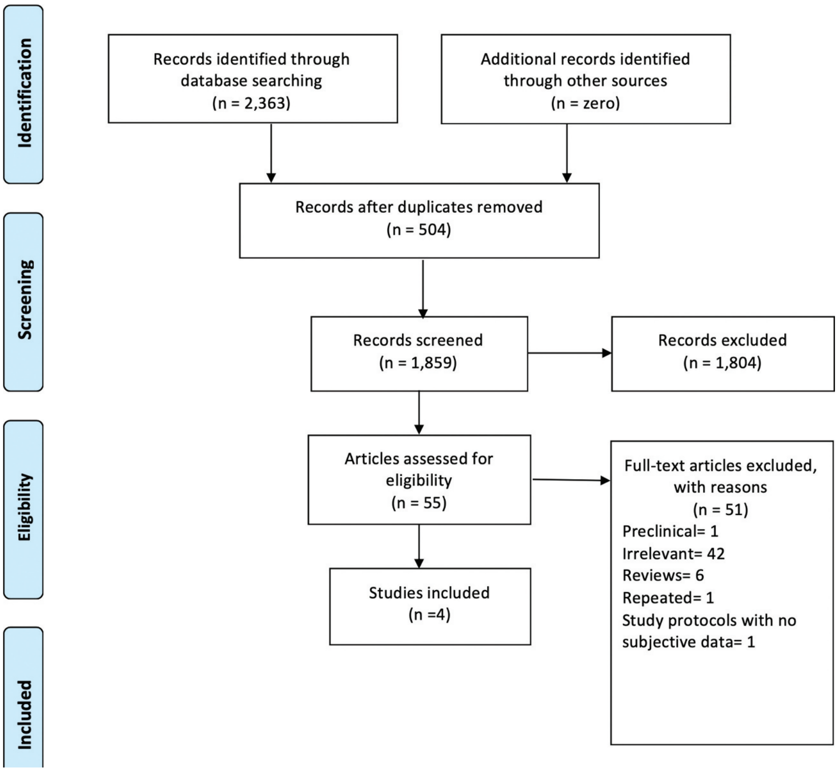

Figure 1. Prisma Flow diagram for study selection.

Valve Stenosis' AND 'Transcatheter Aortic Valve Replacement'. Additionally, unpublished trials were identified from the clinicaltrials.gov website and references of all pertinent articles were also reviewed to ensure the inclusion of all relevant studies.

The following eligibility criteria were used: Original articles reporting the most recent safety or efficacy outcomes for individual studies that comparatively evaluated the use of TAVR and SAVR for elderly severe AS patients. The exclusion criteria were Preclinical studies (1), duplicates (2), irrelevance (3), reviews (4), and other (5).

The quality of the included studies and their risk of inherent bias were assessed using the New Castle Ottawa scale for quality assessment. The bias risk assessment using this tool is mostly subjective. Two independent reviewers performed the risk assessment and the included studies.

The primary endpoint was short-term mortality (in-hospital + 30-day mortality). Secondary endpoints were post-operative incidences of stroke or transient ischemic attack (TIA), vascular access-related complications, acute kidney injury (AKI), transfusion requirement, and length of hospital stay Data on baseline characteristics and clinical outcomes were then extracted and summary tables were created. Summary estimates of the clinical endpoints were then calculated with risk ratio (RR) and 95% confidence intervals using the random-effects model. Statistical analysis was performed using Comprehensive Meta-analysis software (CMA version 3.0, Biostat Inc, Englewood, New Jersey).

2.1. Results: baseline characteristics

The search was completed on 21 January 2020 with no filters applied for language, subjects or time. After removing 504 duplicates, titles and abstracts of 1,859 articles were screened for relevance. Of these, a total of 55 articles were identified and their abstracts and full texts were screened for eligibility. Four studies [6–9] met the inclusion and exclusion criteria. All of the studies were retrospective studies. The reasons for exclusion for the other 51 articles were duplicates (1), preclinical studies (1), irrelevance (42), reviews (6), and other (1). The risk of bias was deemed to be low.

The total study population from the four studies was 8,389 patients. Of these 3,112 patients underwent TAVR and the remainder underwent SAVR. The baseline characteristics were not uniformly reported making a summary estimate of the baseline characteristics impossible and therefore the baseline characteristics are summarized in Table 1. There was considerable heterogeneity in the baseline characteristics of the two groups. Table 2

2.2. Short-term mortality

The primary outcome of short-term mortality among patients undergoing TAVR was 6.5% while in the SAVR group it was 7.2%. There was no significant difference in short-term mortality between the two groups. [RR = 0.91 (95% CI: 0.76–1.10), $p = 0.318$ $I2 = 0.000$]. (Figure 2,)

Table 1. Baseline characteristics of patients undergoing aortic valve replacement. Abbreviations; N: number of patients, TAVR: Transcatheter aortic valve replacement, SAVR: Surgical aortic valve replacement, NA: not available, NR: not reported.

Author	Number of patients		30-day Mortality		Post-op stroke		Requirement of blood transfusion		Mean length of hospital stay (days)		Discharge to Home from hospital		Post-op Acute Renal Failure		Vascular complications	
	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR
Murashita, T. et al 2014	26	33	1/26 (3.9%)	2/33 (6.1%)	1/26 (3.9%)	1/33 (3.0%)	14/26 (53.9%)	1/26 (3.9%)	Median (IQR) = 5 (1–21)	Median (IQR) = 8 (4–69)	12/26 (48%)	5/33 (21.7%)	1/26 (3.9%)	6/33 (18.2%)	6/26 (23.1%)	0/33 (0%)
Mack, M.C. et al 2015	90	20	10/90 (11.1%)	2/20 (10%)	2/90 (2.2%)	1/20 (5%)	47/90 (52.2%)	7/90 (7.8%)	9.56 ± 8.84	10.35 ± 8.17	63/83 (75.9%)	10/18 (55.6%)	7/90 (7.8%)	2/20 (10%)	NA	NA
Alkhouli, M. et al 2016	1416	4414	88/1416 (6.2%)	326/4414 (7.4%)	29/1416 (2%)	115/4414 (2.6%)	464/1416 (32.8%)	283/1416 (20%)	NA	NA	NA	NA	283/1416 (20%)	1139/4414 (25.8%)	62/4414 (1.4%)	<0.01
Elgendy, I. Y. et al 2019	1580	810	104/1580 (6.6%)	50/810 (6.2%)	90/1580 (5.7%)	35/810 (4.3%)	499/1580 (31.6%)	261/1580 (16.5%)	8.4 ± 5.5	8.4 ± 5.5	860/1580 (54.4%)	180/810 (22.2%)	261/1580 (16.5%)	205/810 (25.3%)	30/810 (3.7%)	0.96

Table 2. Primary and secondary outcomes in nonagenarians undergoing aortic valve replacement. Abbreviations; N: number of patients, TAVR: Transcatheter aortic valve replacement, SAVR: Surgical aortic valve replacement, NA: not available.

Author	**Elgendy, 2019**		**Mack, 2015**		**Alkhouli, 2016**		**Murashita, 2014**	
	TAVR N = 1580	**SAVR N = 810**	**TAVR N = 90**	**SAVR N = 20**	**TAVR N = 1416**	**SAVR N = 4414**	**TAVR N = 26**	**SAVR N = 33**
Age	≥90		91.81 ± 1.79	92.00 ± 1.89	90.31.1	90.31.0	91 (90, 95)	91 (90, 97)
Females	46.8 (39.3–54.6)	43.8 (36.2–51.7)	48.9% (44/90)	60.0% (12/20)	NA	NA	17 (65.4%)	21 (63.4%)
Co-morbidities:								
Hypertensiona	75.6 (69.5–80.9)	74.1 (67.3–79.9)	88.9% (80/90)	80.0% (16/20)	NA	NA	22 (84.62%)	27 (81.8%)
Diabetes mellitusa	18.4 (12.7–26.9)	19.2 (12.8–29.5)	20.0% (18/90)	10.0% (2/20)	NA	NA	6 (23.1%)	5 (15.2%)
Congestive heart failurea	7.9 (5.0–12.2)	3.7 (1.7–8.0)	88.9% (80/90)	50.0% (10/20)	NA	NA	23 (88.5%)	24 (72.7%)
Coronary artery diseasea	51.9 (45.4–58.3)	49.4 (41.7–57.1)	43.3% (39/90)	15.0% (3/20)	NA	NA	13 (50.0%)	6 (18.2%)
Dyslipidemiaa	55.1 (48.3–61.6)	57.4 (50.3–64.2)	NR	NR	NA	NA	NR	NR
Smokinga	20.3 (15.4–26.2)	21.6 (16.2–28.2)	NR	NR	NA	NA	NA	NR
Chronic renal diseasea	22.2 (17.4–27.7)	27.2 (21.2–34.0)	10.4% (7/67)	8.3% (1/12)	NA	NA	NR	NR
Peripheral vascular diseasea	20.6 (15.7–26.4)	21.0 (15.5–27.8)	34.4% (31/90)	20.0% (4/20)	NA	NA	13 (50.0%)	8 (24.2%)
Carotid artery diseasea	5.4 (3.0–9.5)	5.6 (3.0–10.0)	NR	NR	NA	NA		
Atrial fibrillationa	56.3 (49.7–62.7)	59.3 (52.2–66.0)	NR	NR	NA	NA	7 (26.9%)	13 (39.4%)
Cerebrovascular disease	0.6 (0.1–4.4)	0.6 (0.1–4.3)	27.8% (25/90)	40.0% (8/20)	NA	NA	8 (30.8%)	4 (12.2%)
Previous cardiovascular intervention	10.8 (7.6–15.0)	11.7 (7.9–17.0)	70.0% (14/20)	80.0% (72/90)	NA	NA	NR	NR
Previous CABG	4.4 (2.5–7.8)	5.6 (2.9–10.4)	]30.0% (27/90)	25.0% (5/20)	NA	NA	9 (34.6%)	1 (3.0%)

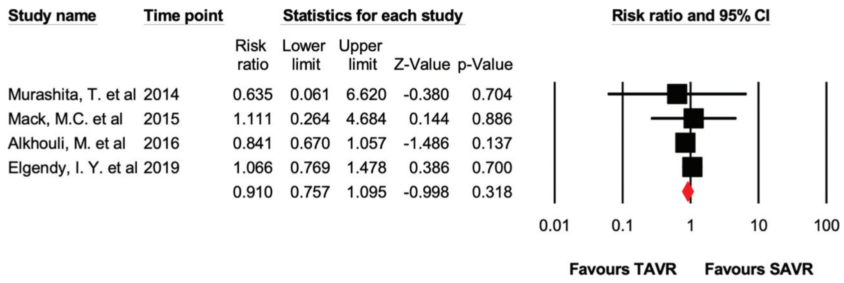

Figure 2. The incidence of short-term Mortality between transcatheter aortic valve replacement versus surgical aortic valve replacement.

2.3. Hospital stay

Only two studies reported hospital length of stay and the length of stay was shorter in the TAVR group by 3 days (p = 0.037). (Figure 2B). Further, in the TAVR group, 55.3% of the patients were discharged directly to home but in the SAVR group, only 22.6% of the patients were discharged home (Figure 3, Table 2).

2.4. Acute renal failure

There was a high incidence of AKI in both groups. The incidence of AKI in the TAVR and SAVR groups was 17.7% and 25.6%, respectively. The relative risk of AKI was 0.72 (95% CI: 0.62–0.83, p < 0.001, I2 = 29.282) between the two groups favoring a lower incidence of AKI in the TAVR group (Figure 4, Table 2).

2.5. Post-operative stroke

The incidence of post-operative stroke/TIA was 3.9% in the TAVR group and 2.88% in the SAVR group. There was no difference in the incidence of post-operative stroke/TIA between the two groups. (RR 1.01 (95% CI: 0.70–1.45), p = 0.957, I2 = 22.081) (Supplementary Figure 1, Table 2).

2.6. Transfusion requirement

There was a high incidence of post-procedure transfusion in both the groups with 32.9% and 47.05% of the patients needing transfusion in the TAVR and SAVR groups, respectively. The risk of the need for post-procedure transfusion was lower in the TAVR group. (RR 0.71 (95% CI: 0.62–0.81), p < 0.001 I2 = 63.60) (Supplementary Figure 2, Tables 2).

2.7. Vascular access site complication

Among the patients undergoing TAVR, the incidence of vascular complications was 5.9% while in the SAVR group it was 1.7%. The risk of vascular access complications was significantly higher with the TAVR group as compared to the SAVR group. [RR 3.39 (95% CI: 2.65–4.333), p < 0.001, I2 = 95.7] (Supplementary Figure 3, Tables 2).

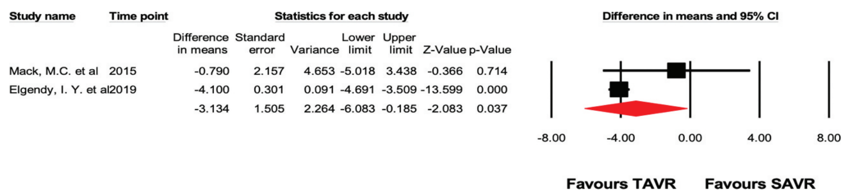

Figure 3. Overall hospital stay in the patients undergoing transcatheter aortic valve replacement versus surgical aortic valve replacement.

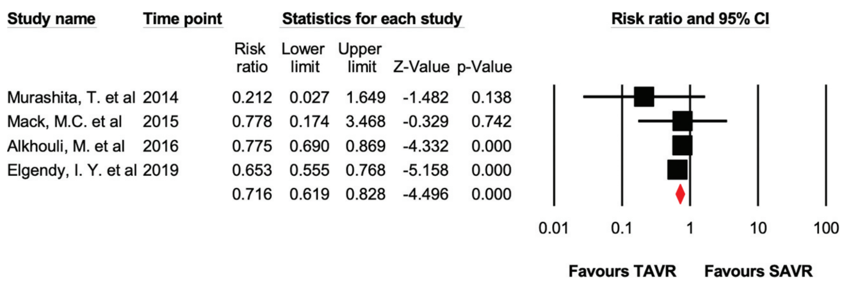

Figure 4. The incidence of post-operative acute kidney injury in the patients undergoing transcatheter aortic valve replacement versus surgical aortic valve replacement.

3. Discussion

Given the high morbidity/mortality risk associated with valvular heart disease in the older population, consideration of pretreatment risk stratification prior to and long-term survival benefits/quality of life is critical when making clinical recommendations.

The incidence of critical AS is estimated to be present in >5% of patients aged 85 years and older [10]. With improved survival, the burden of AS is expected to rise with age-related degeneration of the aortic valve. Further competing mortality risks from their associated comorbidities with poor rehab potential make them challenging candidates for valve replacement and constitute a high-risk group. When opting for choice of therapy, most nonagenarians prefer medical therapy over SAVR owing to high mortality and morbidity associated with SAVR; however, medical therapy is associated with poor prognosis with a median survival of 18 months [11,12]. The placement of aortic transcatheter valve (PARTNER-B) trial which evaluated TAVR in high-risk patients with a mean age of 83 (n = 358) reported a mortality rate of 31% with TAVR versus 51% with medical therapy at 1 year follow-up ($p < 0.001$) [13].

In our study, the short-term mortality rates were not different among patients undergoing TAVR or SAVR, although there was a trend towards lower mortality in the TAVR group. The lack of significant clinical benefit with the TAVR in the short term compared to the surgical group could be due to the selection of clearly operable patients in the surgical group. The lack of long-term mortality data from the studies enlisted for our meta-analysis limits further assessment if nonagenarians undergoing TAVR have a long-term mortality benefit which would be a true marker of benefit in this group of patients that has extensive comorbidities.

Beyond mortality there appear to be at least short-term benefits with TAVR among nonagenarians and these include shorter hospital length of stay, which was noted to be 3 days shorter compared to the SAVR in our meta-analysis. The shorter duration of stay would invariably decrease hospital-acquired complications such as infections in the TAVR group. In addition, about 55% of the patients were discharged to home compared to only 22.6% of the patients in the SAVR group. Further, the risks of AKI and the need for transfusion were also significantly lower in the TAVR group. This further demonstrates the lower morbidity associated with TAVR and has potential cost savings to the patients, insurers and health systems. Zack et al. reported an average cost of 228633–135218 US $ in TAVR patients versus 202920–151681$ in SAVR patients [14]. The costs of TAVR appear to be higher because of the higher cost of the implant device which is a fairly new technology and also the higher use of pacemakers in the TAVR group. The risk of permanent pacemaker implantation with TAVR is about 11–12.5% compared to 9–10% with the SAVR group [8].

The only complication that was predictably higher in the TAVR group was the risk of vascular complications which can be expected by the presence of peripheral vascular disease in the age group. This outcome cannot be directly compared to the SAVR group because these patients do not undergo large bore vascular access for the surgery. However, patients undergoing SAVR can have sternal wound infections and the risks of deep sternal wound infections are estimated to be in the range of 1–5% after median sternotomy [15]. Further, the risk of post-operative atrial fibrillation is also significantly higher in the SAVR group compared to TAVR (45% vs 20%) [6].

Annually 67, 500 SAVR are performed in the US and this number has been rapidly declining with the advent of TAVR and clinical trials have demonstrated that TAVR has similar outcomes to SAVR in low and intermediate-risk patients. Since the advent of TAVR, a sevenfold increase has been seen in the total number of nonagenarians undergoing TAVR. This being a minimally invasive procedure has become the procedure of choice for the management of nonagenarians with AS who are deemed to have intermediate and high operative risk. Studies have reported that afterload reduction after TAVR results in marked hemodynamic improvement. This reduction in afterload markedly improves aortic valve area from 0.6 to 1.8cm2 and reduced mean pressure gradient from 60 to 8.3 mmHg, thus, leading to a significant reduction in NYHA class by a mean of 1.8 grades with immediate symptomatic relief with similar hemodynamic performance as SAVR [16–19].

There are technical challenges to the use of TAVR in the elderly, especially those with severe peripheral vascular disease and needing alternative access such as subclavian, transaortic, transapical or more recently the trans-carotid approach. The procedural and mortality rates are elevated with the alternative access approach as observed in the PARTNER-1 trial, the 30-day mortality rate with transfemoral vs transapical approach was 4% vs 12%. The choice of prosthesis use also affects outcomes such as the need for permanent pacemaker implantation and paravalvular regurgitation. The risks of both of these are increased with the use of self-expanding compared to the balloon-expandable valve [20–24].

There are several limitations to our analysis. First, there are very few studies that evaluated the outcomes of TAVR in the nonagenarian population. Second, outcomes reported were not uniform, and therefore, performing meta-analysis with variable outcomes makes it extremely challenging. Third, SAVR is rarely performed among nonagenarians and those patients undergoing this procedure may have been carefully selected with those who are likely to have a good clinical outcome and who have good rehab potential and therefore the risk profile of the patients undergoing TAVR and SAVR may not be similar. Further, we were unable to evaluate the effects of race, gender and ethnic background on the measured outcomes. Lastly, most of the included studies were retrospective and publication bias could not be assessed.

4. Conclusion

In conclusion, in this high-risk population of nonagenarians who were treated for severe symptomatic AS, TAVR compared to SAVR has similar short-term mortality but has lower risks of perioperative complications, shorter length of stay and a higher number of patients being discharged to home. Although the evidence is limited, the current literature suggests that TAVR has the potential to become the choice of therapy among nonagenarians with severe aortic stenosis considering the above benefits. Future studies should focus on the long-term benefits of TAVR among nonagenarians.

Disclosure statement

The authors declare no conflict of interest.

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