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COMPARISON OF ALTERNATIVE PERIPHERAL AND TRANSCATHETER AORTIC VALVE REPLACEMENT: SYSTEMATIC REVIEW

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Abstract

Background: *Transcatheter aortic valve replacement (TAVR) is approved for use in low-to-extreme-risk patients with aortic stenosis, with volumes exceeding those of surgical aortic valve replacement and outcomes continuing to improve. The transfemoral (TF) access route is accepted as the first choice for TAVR and accounts for 95% of cases. However, the use of alternative access remains relevant in many patients with peripheral vascular disease or unfavorable anatomy.*
The aim: *This study aims to show about comparison of alternative peripheral and transcatheter aortic valve replacement.*
Methods: *By comparing itself to the standards set by the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020, this study was able to show that it met all of the requirements. So, the experts were able to make sure that the study was as up-to-date as it was possible to be. For this search approach, publications that came out between 2013 and 2023 were taken into account. Several different online reference sources, like Pubmed and SagePub, were used to do this. It was decided not to take into account review pieces, works that had already been published, or works that were only half done.*
Result: *In the PubMed database, the results of our search brought up 135 articles, whereas the results of our search on SagePub brought up 118 articles. The results of the search conducted for the last year of 2013 yielded a total 56 articles for PubMed and 33 articles for SagePub. The result from title screening, a total 16 articles for PubMed and 10 articles for SagePub. In the end, we compiled a total of 8 papers. We included five research that met the criteria.*
Conclusion: *To compare outcomes among transcatheter aortic valve replacement (TAVR) performed via transaortic (TAo) and subclavian (SCL) approaches. Many patients are not amenable for TAVR via the transfemoral route due to peripheral vascular disease. Limited data exist regarding safety and procedural feasibility of TAVR via TAo and SCL routes.*

Keyword: *Transcatheter aortic., valve replacement, alternative peripheral.*

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) for severe aortic stenosis has demonstrated significant clinical benefit in large randomized trials compared with both medical management and at least equivalent results compared with surgical aortic valve replacement (SAVR) in patients of intermediate or greater risk. TAVR technology has been rapidly adopted across the United States, with comparable results in commercial use and clinical trials. The initial structure of the TAVR clinical trials in the United States and approval from the Food and Drug Administration required that a heart team evaluate each patient as a candidate for a transfemoral (TF) TAVR approach before considering a transapical (TA) or transaortic (TAO).[1,2]

Since its introduction in 2002, transcatheter aortic valve replacement (TAVR) has expanded rapidly as an alternative to surgical aortic valve replacement in patients at high and intermediate procedural risk. Femoral peripheral (FP) access is the most studied and widely used access for TAVR procedures; it allows exclusive percutaneous intervention. However, despite the improvement in device profiles and procedural techniques, FP access cannot be performed in approximately 10% to 15% of patients due to iliofemoral arteriopathy, tortuosity, severe calcifications, aortic aneurysm, mural thrombus, or previous vascular surgery.[3]

Minimally invasive transcatheter aortic valve replacement (TAVR) is a seemingly ideal solution for this high-risk surgical population with correspondingly high-risk disease. In the 20 years since, over 300,000 TAVRs have been performed in 65 countries. In 2010, the first PARTNER B study demonstrated that balloon-expandable TAVR decreased mortality from 50.7 to 30.7% at 12 months when compared with conventional non-surgical treatment. In 2011, balloon-expandable TAVR was shown to be non-inferior to SAVR in high-risk patients. Subsequent studies in 2016 and 2017 demonstrated non-inferiority of both balloon-expandable valves and self-expanding valves with respect to mortality and disabling stroke in intermediate-risk patients when compared to SAVR at 2 years. A recent outcome study demonstrated non-inferiority of TAVR to SAVR, and no structural valve deterioration at 5 years, and even more recently, the PARTER 3 investigators demonstrated a significantly lower rate of the composite outcomes of death, stroke, and rehospitalization at 1 year in low-risk TAVR patients when compared with SAVR patients.[4,5]

METHODS

Protocol

By following the rules provided by Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020, the author of this study made certain that it was up to par with the requirements. This is done to ensure that the conclusions drawn from the inquiry are accurate.

Criteria for Eligibility

For the purpose of this literature review, we show comparison of alternative peripheral and transcatheter aortic valve replacement. It is possible to accomplish this by researching or investigating the risk factor for physical disability in patients with leprosy. As the primary purpose of this piece of writing, demonstrating the relevance of the difficulties that have been identified will take place throughout its entirety.

In order for researchers to take part in the study, it was necessary for them to fulfil the following requirements: 1) The paper needs to be written in English, and it needs to determine the best time to perform emergency surgery for congenital diaphragmatic hernia. In order for the manuscript to be considered for publication, it needs to meet both of these requirements. 2) The studied papers include several that were published after 2013, but before the time period that this systematic review deems to be relevant. Examples of studies that are not permitted include editorials, submissions that do not have a DOI, review articles that have already been published, and entries that are essentially identical to journal papers that have already been published.

Search Strategy

We used " alternative peripheral and transcatheter aortic valve replacement" as keywords.The search for studies to be included in the systematic review was carried out using the PubMed and SagePub databases by inputting the words: *(("Valve replacement"[MeSH Subheading] OR "procedure of valve replacement"[All Fields] OR "transcatheter aortic"[All Fields]) AND ("alternative peripheral valve replacement"[All Fields] OR "procedure transcatheter aortic"[All Fields]) AND ("alternative peripheral and transcatheter aortic "[MeSH Terms] OR ("procedure alternative peripheral valve replacement"[All Fields]))* used in searching the literature.

Data retrieval

After reading the abstract and the title of each study, the writers performed an examination to determine whether or not the study satisfied the inclusion criteria. The writers then decided which previous research they wanted to utilise as sources for their article and selected those studies. After looking at a number of different research, which all seemed to point to the same trend, this conclusion was drawn. All submissions need to be written in English and can't have been seen anywhere else.

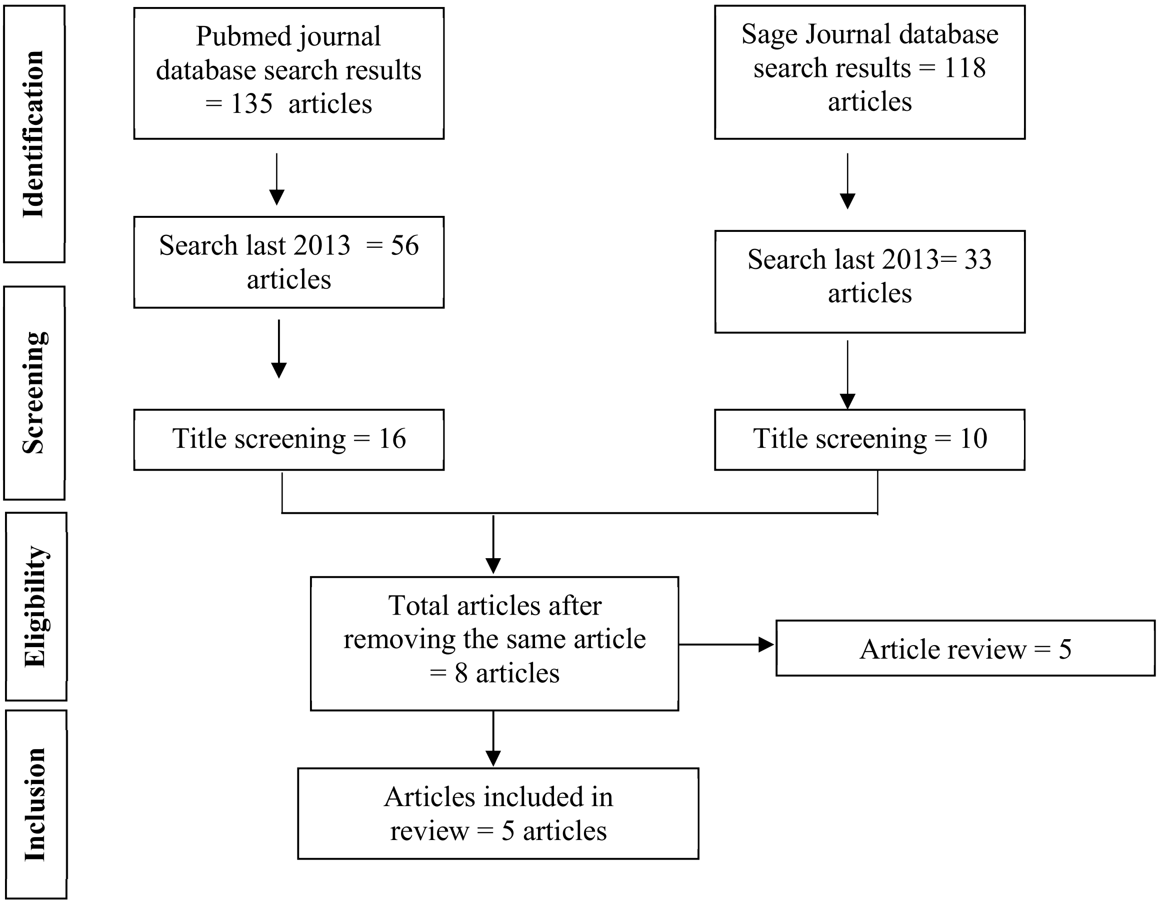

Figure 1. Article search flowchart

Only those papers that were able to satisfy all of the inclusion criteria were taken into consideration for the systematic review. This reduces the number of results to only those that are pertinent to the search. We do not take into consideration the conclusions of any study that does not satisfy our requirements. After this, the findings of the research will be analysed in great detail. The following pieces of information were uncovered as a result of the inquiry that was carried out for the purpose of this study: names, authors, publication dates, location, study activities, and parameters.

Quality Assessment and Data Synthesis

Each author did their own study on the research that was included in the publication's title and abstract before making a decision about which publications to explore further. The next step will be to evaluate all of the articles that are suitable for inclusion in the review because they match the criteria set forth for that purpose in the review. After that, we'll determine which articles to include in the review depending on the findings that we've uncovered. This criteria is utilised in the process of selecting papers for further assessment. in order to simplify the process as much as feasible when selecting papers to evaluate. Which earlier investigations were carried out, and what elements of those studies made it appropriate to include them in the review, are being discussed here.

RESULT

In the PubMed database, the results of our search brought up 135 articles, whereas the results of our search on SagePub brought up 118 articles. The results of the search conducted for the last year of 2013 yielded a total 56 articles for PubMed and 33 articles for SagePub. The result from title screening, a total 16 articles for PubMed and 10 articles for SagePub. In the end, we compiled a total of 8 papers. We included five research that met the criteria.

Isogai, T *et al* (2023)[6] showed The need for PVI during TF-TAVR is not uncommon, mainly due to the bailout treatment for vascular complications. PVI is not associated with worse outcomes in TF-TAVR recipients. Even when PVI is required, TF-TAVR is associated with better short- and intermediate-term outcomes than non-TF-TAVR.

Pineda, AM *et al* (2019) showed AA-TAVR is associated with an increased incidence of postoperative adverse events, including mortality, when compared with those undergoing TF access.

Table 1. The litelature include in this study

Author	Origin	Method	Sample Size	Result
Isogai, T *et al*., 2023[6]	USA	Retrospective study	2386 patients	Review of 2386 patients who underwent TAVR with a balloon-expandable valve at a single institution from 2016 to 2020. The primary outcomes were death and major adverse cardiac/cerebrovascular event (MACCE), defined as death, myocardial infarction, or stroke. Of 2246 TF-TAVR recipients, 136 (6.1%) required PVI (89% bailout treatment). During follow-up (median 23.0 months), there were no significant differences between TF-TAVR with and without PVI in death (15.4% versus 20.7%; adjusted HR [aHR], 0.96 [95% CI, 0.58–1.58]) or MACCE (16.9% versus 23.0%; aHR, 0.84 [95% CI, 0.52–1.36]). However, compared with non-TF-TAVR (n=140), TF-TAVR with PVI carried significantly lower rates of death (15.4% versus 40.7%; aHR, 0.42 [95% CI, 0.24–0.75]) and MACCE (16.9% versus 45.0%; aHR, 0.40 [95% CI, 0.23–0.68]). Landmark analyses demonstrated lower outcome rates following TF-TAVR with PVI than non-TF-TAVR both within 60 days (death 0.7% versus 5.7%, P=0.019; MACCE 0.7% versus 9.3%; P=0.001) and thereafter (death 15.0% versus 38.9%, P=0.014; MACCE 16.5% versus 41.3%, P=0.013).
Pineda, AM *et al*., 2019[7]	USA	Retrospective study	600 patients	TAVR was performed in a total of 600 patients, of which 78 (13%) had AA and 522 (87%) had TF access. Patients undergoing AA were younger, and had higher prevalence of chronic obstructive pulmonary disease, peripheral vascular disease, prior myocardial infarction, and prior sternotomy. Greater than mild paravalvular regurgitation (4.2% vs 0.0%; P=.04) and unplanned vascular surgery (5.4% vs 1.3%; P=.09) were more frequent in the TF group. However, patients who underwent AA had longer hospital stay (median 4 days [interquartile range, 3-7 days] vs 3 days [interquartile range, 3-4 days]; P<.001) and an increased incidence of prolonged ventilation (5.1% vs 1.3%; P=.06), 30-day all-cause (5.1% vs 1.7%; P=.08), and cardiovascular mortality (5.1% vs 1.3%; P=.04). The 6-month (15.7% vs 5.7%; P<.01) and 12-month (16.7% vs 10.2%; P=.07) mortality rates were higher for patients undergoing AA. The usage of AA significantly decreased over time (P=.01), primarily driven by a decrease in transapical (P<.001) and direct aortic access (P=.02).
Choi, CH *et al*., 2018[8]	USA	Retrospective study	40 patients	The primary mode of bioprosthetic valve failure for ViV implantation in the stentless group was aortic insufficiency (78%, 25/32), while in the stented group was aortic stenosis (75%, 6/8). The ViV procedure success was 96.9% (31/32) in stentless group and 100% in stented group (8/8). There were no significant differences in all-cause mortality at 30 days between stentless and stented groups (6.9%, 2/31 versus 0%, 0/8, P = 0.33) and at 1 year (0%, 0/25 versus 0%, 0/5). In the stentless group, 34.4% (11/32) required a second valve compared to the stented group of 0% (0/8). There was a significant difference in the mean aortic gradient at 30-day follow-up (12.33 ± 6.33 mmHg and 22.63 ± 8.45 mmHg in stentless and stented groups, P < 0.05) and at 6-month follow-up (9.75 ± 5.07 mmHg and 24.00 ± 11.28 mmHg, P < 0.05), respectively.
Hoover, NE *et al*., 2022[9]	USA	Retrospective study	2064 patients	Matched TC versus TF cohorts did not differ with respect to in-hospital mortality (0.0% vs 1.4%, p = 0.380), stroke (2.3% vs 2.5%, p = 0.917), major vascular complications (0.8% vs 2.2%, p = 0.268), composite bleeding complications (4.6% vs 6.4%, p = 0.647), requirement for permanent pacemaker (14.6% vs 12.9%, p = 0.426), postoperative hospital length of stay (3.3 ± 3.4 vs 3.1 ± 3.3 days, p = 0.467), or direct hospital costs ($52,899 ± 9,560 vs $50,464 ± 10,997, p = 0.230). Similarly, at 1-year, patients who underwent TC versus patients who underwent TF did not differ with respect to all-cause mortality (7.6% vs 6.4%, p = 0.659), hospital readmission (20.0% vs 23.9%, p = 0.635), or quality of life as measured by the Kansas City Cardiomyopathy Questionnaire score (84.0 ± 17.1 vs 88.4 ± 13.9, p = 0.062).
Mach, M *et al*., 2021[10]	Austria	Retrospective study	692 patients	Postprocedural adverse event data showed higher rates of newly acquired atrial fibrillation (6.9% vs. 19.4%; p = 0.049), prolonged ventilation (2.8% vs. 25.0%; p < 0.001) and multi-organ failure (0% vs. 6.9%) in the surgical cohort. The in-hospital and 30-day mortality was significantly higher for iSAVR (1.4% vs. 13.9%; p = 0.012; 12.5% vs. 2.8%; p = 0.009, respectively). The long-term survival (median follow-up 5.0 years (2.2–14.1 years)) of patients treated with the surgical approach was superior to that of patients undergoing TAVR (p < 0.001).

Choi, CH *et al* (2018)[8] showed ViV in the stentless bioprosthetic aortic valve has excellent procedural success and intermediate-term results. Our study shows promising data that may support the application of TAVR in stentless surgical aortic valve. However, further and larger studies need to further validate our single center's experience.

Hoover, NE *et al* (2022)[9] showed Patients who underwent TC and TF did not differ with respect to in-hospital complications, length of hospital stay, and direct hospital costs, as well as 1-year mortality, readmission, and quality of life. These data add to ongoing support for the TC approach as the optimal alternative access for patients with transcatheter aortic valve replacement deferred from a transfemoral approach.

Mach, M *et al* (2021)[10] showed Although the survival analysis revealed a higher in-hospital and 30-day survival rate for high-risk patients aged ≤75 years who underwent TAVR, iSAVR was associated with a significantly higher long-term survival rate.

DISCUSSION

Transcatheter aortic valve replacement has been increasingly performed worldwide and is commonly performed using transfemoral access. Nevertheless, a large proportion of patients also have concomitant peripheral arterial disease (PAD), which increases the risk of peri-procedural vascular complication, as well as precluding the possibility of transfemoral TAVR owing to inadequate luminal size for delivery system deployment.[11,12]

Aortic stenosis is the most prevalent valvular cardiovascular disease, affecting approximately 2%–9% of the population over the age of 65 years. Aortic stenosis is a progressive disease that is relatively asymptomatic in its early stages. With worsening valvular stenosis and left ventricular pressure overload, a latent period gives way to symptomatic disease. Symptomatic disease has a prevalence of 2%–5% in patients over the age of 75 years. Symptomatic aortic stenosis has a poor prognosis with medical (nonsurgical) treatment alone, with 50% of patients not surviving after 1 year. TAVR is a minimally invasive procedure used to treat patients with severe aortic stenosis at increased risk for surgical complications. Currently, there are two U.S. Food and Drug Administration (FDA)–approved devices used for TAVR: the balloon-expandable Sapien valve (Edwards Lifesciences, Irvine, Calif) and the CoreValve Revalving System (Medtronic, Minneapolis, Minn). The Sapien valve is available in multiple sizes ranging from 20 mm to 29 mm. The CoreValve Revalving System is available in sizes ranging from 23 mm to 34 mm.[13]

Transcatheter aortic valve implantation (TAVI) for the treatment of symptomatic and severe aortic valve stenosis (AS) has rapidly evolved during the last decade. TAVI has proven superior or non-inferior against surgical aortic valve replacement (SAVR) for patients at high, intermediate or low surgical risk. Because of superior results on procedural and clinical outcome, the transfemoral technique has been the preferred access for TAVI as compared to transapical access. Safe application of transfemoral access for TAVI is, however, precluded in patients with underlying obstructive peripheral atherosclerotic disease and/or tortuosity of the iliofemoral route. Alternative, non-femoral and non-transapical access approaches for TAVI have thus been developed, such as a transapical, transcaval, direct aortic, transcarotid or transaxillary approach. In recent years, the transaxillary approach has gained popularity in favour of other alternative access sites. This review aims to provide a summary of data available on TAVI performed through transaxillary access.[14,15]

CONCLUSION

To compare outcomes among transcatheter aortic valve replacement (TAVR) performed via transaortic (TAo) and subclavian (SCL) approaches. Many patients are not amenable for TAVR via the transfemoral route due to peripheral vascular disease. Limited data exist regarding safety and procedural feasibility of TAVR via TAo and SCL routes.

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