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Research Article

Comparison of Alternative Peripheral and Transfemoral Approaches for Transcatheter Aortic Valve Replacement: A Meta-Analysis of Propensity-Matched Studies

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Background. Transfemoral (TF) access is the gold standard for transcatheter aortic valve replacement (TAVR). Alternative peripheral (AP) artery access such as the carotid or axillary artery is considered when the feasibility of femoral access is in doubt. The outcomes comparison of these 2 approaches is unclear due to limited sample sizes in prior studies. Our aim is to compare the clinical outcomes of TF- and AP-TAVR by conducting a meta-analysis of propensity-matched studies. *Methods*. The PubMed, EMBASE, and Cochrane Library databases from inception up to and including February 2022 were searched by 3 separate researchers to identify articles reporting propensity-matched, comparative data on TF vs. AP-TAVR. Clinical outcomes were extracted from the articles and pooled for analysis. *Results*. Seven prior studies, including 9,004 patients, were included in our study, with 6,729 in the TF group and 2,275 in the AP group. In all studies, the baseline characteristics of the patients were highly propensity-matched with the full Newcastle-Ottawa scale. Meta-analysis revealed higher in-hospital/30-day mortality (3.3% vs. 4.4%; OR 0.69; 95% CI (0.51, 0.94); $P = 0.02$) as well as the incidence of stroke (1.9% vs. 3.5%; OR 0.60; 95% CI (0.43, 0.84); $P = 0.003$) for the AP group. There were no significant differences in the incidence of major vascular complications, pacemaker implantation, bleeding, or acute kidney injury. *Conclusions*. Our meta-analysis of propensity-matched studies showed AP-TAVR contains an additional 1.1% risk of early mortality and an additional 1.6% risk of stroke compared to TF-TAVR. These risks should be considered when deciding on access.

1. Introduction

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 [1, 2].

The transfemoral (TF) access route is accepted as the first choice for TAVR and accounts for 95% of cases [3]. However, the use of alternative access remains relevant in many patients with peripheral vascular disease or unfavorable anatomy. Among alternative access routes, alternative peripheral (AP) access via the carotid (transcarotid, TC) or axillary (transaxillary, TAx) arteries is now favored over the older transapical and transaortic techniques due to the poorer outcomes associated with central access [4]. While the safety and efficacy of AP access are established, the comparison of AP versus transfemoral access has not been adequately explored [5]. A better understanding of the relative risks of each approach would allow for a more fully informed decision when choosing an access route.

In the absence of randomized controlled trials, our understanding of this comparison is mostly limited to small retrospective studies. To compare larger cohorts of patients from diverse clinical settings while reducing the risk of bias, we conducted a meta-analysis of propensity-matched studies comparing AP and TF access.

2. Methods

2.1. Search Strategy. This study protocol can be accessed through the PROSPERO International prospective register of systematic reviews by searching ID number CRD42022315182. This study was approved by the Tufts Medical Center Institutional Review Board, and informed consent was not required. An electronic search of the PubMed/MEDLINE, Embase, and Cochrane Library databases from inception to February 2022 was conducted to identify propensity-matched, peer-reviewed articles in English that compare TF-TAVR to TC-TAVR and/or TAx-TAVR. Six sets of search terms across the databases were performed, including "axillary," "transaxillary," "carotid," "transcarotid," "subclavian," and "transsubclavian," combined with "transcatheter aortic valve." Three researchers (D. M., C. S., and Y. Z.) independently performed the search. Inconsistencies among search results were resolved via discussion (D. M., C. S., and Y. Z.) until an agreement was reached. A search for relevant literature was also performed manually. The meta-analysis followed the preferred reporting items for systematic reviews and meta-analyses guidelines [6].

2.2. Study Selection. Eligible studies met the following criteria: (1) randomized controlled trials or propensity-matched observational studies; (2) patient demographics are reported; and (3) sufficient data of outcomes. Studies were excluded if the patient cohorts being compared were not propensity-matched, if there was inadequate or insufficient data for analysis, if the study was a review or a case report, or if the study contained overlapping data from the same institutions, authors, or registries. Each study was assessed independently by 3 researchers (D. M., C. S., and Y. Z.) for quality and bias using the Newcastle-Ottawa scale [7].

2.3. Data Extraction. Patients' clinical outcomes were extracted from articles manually, and data accuracy was independently verified by 3 researchers (D. M., C. S., and Y. Z.). Data on the TC and TAx approaches were grouped as AP, and data on the TF approach were grouped separately. In-hospital/30-day patient outcomes, including mortality, vascular complications, stroke, new pacemakers, bleeding, and acute kidney injury, were pooled and analyzed. When both in-hospital and 30-day outcomes were reported, 30-day outcomes were used. Within each study, the baseline characteristics of the patients were propensity matched. For each outcome, studies with missing data were excluded from the analysis.

2.4. Statistical Analysis. Categoric variables are indicated by percentages. Meta-analysis was conducted using the Cochrane Collaboration Review Manager 5.4 software. In the forest plots generated, odds ratios (OR) were used as summary statistics. 95% confidence intervals using Mantel-Haenszel (M–H) χ^2 as well as heterogeneity (I^2) were calculated to compare outcomes. The results of the random-effects model were shown, but both the fixed-effects and random-effects models were tested for sensitivity analysis. The numbers of participants and events for each study were available, and no data conversions were necessary. Sensitivity analysis was completed for each outcome by sequentially leaving each study out of the analysis, one at a time ("leave-one-out"). Funnel plots were generated to evaluate the risk of publication bias. Significant heterogeneity was investigated by performing meta-regression with Stata 14.0.

3. Results

3.1. Literature Search. During the initial literature search, 2957 total articles were identified. After the removal of duplicates and review of titles and abstracts, we assessed 103 articles for full-text content. Among those fully assessed, 96 articles were deemed ineligible, and 7 eligible studies were included for meta-analysis [8–14] (Figure 1). An overview of these studies is presented in Table 1. All seven studies compare the clinical outcomes of propensity-matched cohorts undergoing both TF- and AP-TAVR. No randomized controlled trials were identified, and all were single-center or multicenter retrospective studies. The quality assessment of each study was performed as demonstrated in Supplemental Table 1. The studies were of good quality and acceptable for meta-analysis, each with a score of 9 using the Newcastle-Ottawa scale.

3.2. Patient Demographics. The 7 studies include 9,004 total patients, of whom 6,729 underwent TF-TAVR and 2,275 underwent AP-TAVR. Clinical outcomes from these studies were extracted and pooled for analysis, as demonstrated in Supplemental Table 2. Of the seven studies, two articles compare combined AP vs. TF access [9, 14], one article compares TC vs. TF access [8], and four articles compare TAx vs. TF access [10–13].

3.3. Meta-Analysis of Outcomes. Incidence of mortality and stroke were reported by seven studies, with 6,729 TF patients and 2,275 AP patients (Figure 2, Table 2). There were significantly lower rates of mortality (3.3% vs. 4.4%; OR 0.69; 95% CI [0.51, 0.94]; $P = 0.02$) and stroke (1.9% vs. 3.5%; OR 0.60; 95% CI [0.43, 0.84]; $P = 0.003$) in the TF group with low ($I^2 = 5\%$) and no ($I^2 = 0\%$) heterogeneity, respectively. The difference in mortality was not significant on "leave-one-out" analysis when the studies by Alperi et al. were individually excluded [8, 9, 11].

Incidence of new pacemaker implantation was reported by six studies, with 6,689 TF patients and 2,235 AP patients (Figure 3, Table 2). There was no significant different in pacemaker implantation (16.1% vs. 17.7%; OR 1.04; 95% CI [0.79, 1.37]; $P = 0.77$) with moderate ($I^2 = 46\%$) heterogeneity.

Incidence of major vascular complications and bleeding were reported by six studies, with 6,561 TF patients and 2,219 AP patients (Figure 2 and 3, Table 2). There were no

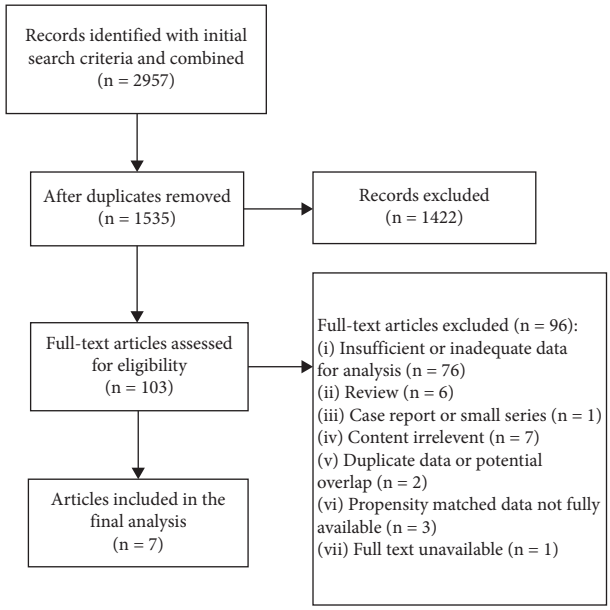


Figure 1: Overview of the systematic literature search and identification of eligible studies for meta-analysis.

significant differences in major vascular complications (8.8% vs. 2.9%; OR 1.22; 95% CI 1.22 [0.88, 1.68]; $P = 0.23$) or bleeding (9.3% vs. 13.2%; OR 0.85; 95% CI [0.71, 1.02]; $P = 0.08$) with low ($I^2 = 2\%$) and no ($I^2 = 0\%$) heterogeneity, respectively.

Incidence of acute kidney injury was reported by six studies, with 6,287 TF patients and 2,190 AP patients (Figure 3, Table 2). There was no significant difference in acute kidney injuries (5.5% vs. 4.8%; OR 1.01; 95% CI [0.59, 1.71]; $P = 0.98$) with moderate ($I^2 = 62\%$) heterogeneity.

The results for stroke, new pacemaker implantation, major vascular complications, bleeding, and acute kidney injury did not change with "leave-one-out" analysis. For all outcomes, the pooled results did not change significantly when a fixed-effects model was used. Meta-regression was performed for pacemaker implantation and acute kidney injury because these outcomes demonstrated moderate-to-high heterogeneity. Meta-regression is demonstrated in Supplemental Table 3, with moderators including the median year of the study period as well as the proportion of AP access patients who received TAx access or a balloon-expandable valve, which did not reveal causes of heterogeneity. Funnel plots demonstrating the risk of publication bias are shown in Supplemental Figure 1.

4. Discussion

In the absence of randomized controlled trials, propensity-matched studies provide the strongest evidence to evaluate access for TAVR. While there is a prevailing assumption that TF TAVR is the gold standard, the evidence base to guide access selection is scarce in the current era when alternative peripheral access has largely replaced thoracic access. Previous meta-analyses included unadjusted studies that individually compared TC and TAx to TF access and demonstrated lower rates of vascular complications and acute kidney injuries for TC and TAx access, respectively [15, 16]. Faroux et al. performed a meta-analysis of 14 studies comparing combined AP access versus TF and reported significantly increased unadjusted mortality and stroke rates with AP access. The difference in stroke risk persisted in their subgroup analysis of four propensity-matched studies [17]. Abusnina et al. reported an unadjusted meta-analysis of 21 studies comparing TF and TAx access, which found increased 1-year mortality as well as a nonsignificant trend towards an increased stroke rate in the TAx group. Given the reliance on nonpropensity-matched studies in their meta-analysis, the TAx population likely had a higher disease burden and shorter life expectancy relative to the TF population [18].

In this meta-analysis of propensity-matched studies comparing AP and TF access for TAVR, we found significantly higher rates of mortality (4.4% vs. 3.3%, $P = 0.02$) and stroke (3.5% vs. 1.9%, $P = 0.003$) with AP access. These differences were not apparent in the individual studies included in the analysis, except for one study which found a higher mortality rate with TAx access [11]. Our analysis found no difference in rates of vascular complications, pacemaker implantation, bleeding, or acute kidney injury.

Stroke represents a serious complication that contributes to morbidity and mortality [19]. The etiology of stroke with AP access is unclear. With TF access, stroke is thought to be related to traumatic passage of the delivery device through the aortic structures, leading to dislodgement of calcific and atheromatous debris and embolization [20]. AP access transverses a lower percentage of the aortic arch compared to TF and should theoretically be associated with a lower stroke risk. One possibility is that the aortic arch segment bypassed during AP access (left-sided AP access in particular) is less relevant given its distal location. Dislodgement of debris directly at the access site in poorly selected patients, or temporary occlusion of the ipsilateral carotid or subclavian arteries by the delivery device, may also be implicated. Further, patients may be selected for AP access because of atheromatous disease affecting the iliofemoral arteries. Therefore, atheromatous disease may be generally more severe in AP patients and contribute to an increased risk for stroke. There exists radiological evidence to corroborate the increased stroke rate seen with AP access. Patients undergoing TC-TAVR have been shown to carry greater ipsilateral ischemic burden on postprocedural MRI [21]. For TC access in particular, strategies that may possibly mitigate the risk of stroke include careful preoperative evaluation of the cerebral vasculature, periprocedural monitoring of cerebral oximetry, and distal clamping of the carotid artery [15].

The reasons for increased mortality with AP access are unclear. Our data suggests that a higher stroke rate with AP access could be a contributor. Further, the invasiveness of AP access, typically including general anesthesia and a surgical cutdown, can contribute additional risks. Importantly, AP access is typically chosen for patients with underlying severe peripheral vascular disease that makes femoral access suboptimal. The AP-TAVR patient population is expected to

Table 1: Summary of studies included in the meta-analysis.

Study	Year published	Country	Study period	Transfemoral (*n*)	Alternative peripheral (*n*)	Type of study
Alperi et al. [8]	2021	Europe/North America	2015–2020	442	85	Prospective, retrospective review
Beurtheret et al. [9]	2019	France	2013–2017	1613	1613	Prospective, retrospective review
Gleason et al. [10]	2018	United States	2011–2015	202	202	Prospective, retrospective review
Jiménez-Quevedo et al. [11]	2021	Spain	2009–2019	4123	138	Prospective, retrospective review
Kindzelski et al. [12]	2021	United States	2006–2019	168	56	Retrospective review
Petronio et al. [13]	2012	Italy	2007–2011	141	141	Prospective, retrospective review
Villecourt et al. [14]	2020	France	2015–2018	40	40	Retrospective review

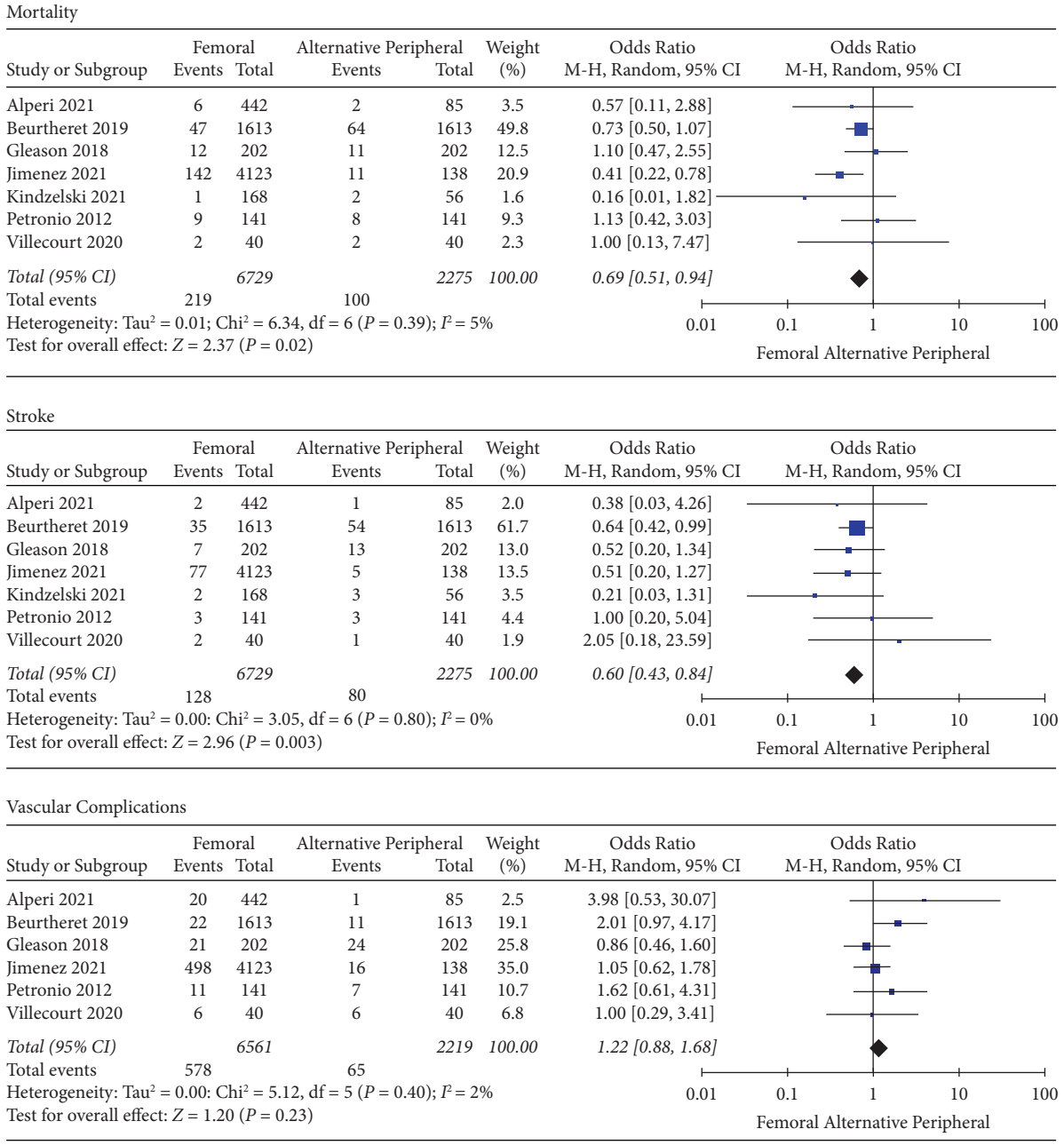


Figure 2: Forest plots comparing mortality, stroke, and vascular complications for patients undergoing transfemoral versus alternative peripheral transcatheter aortic valve replacement.

Table 2: Comparison of outcomes between transfemoral and alternative peripheral access.

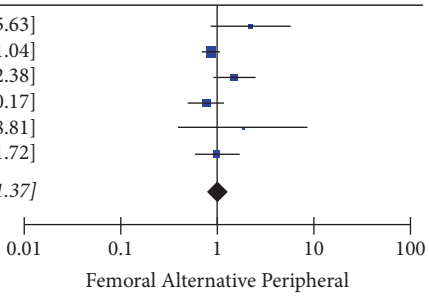
Outcomes	No. of studies	No. of patients (TF)	No. of patients (AP)	No. of events (TF)	No. of events (AP)	Odds ratio, M-H random, 95% CI	*P* value	I^2 (%)
Mortality	7	6729	2275	219 (3.3)	100 (4.4)	0.69 [0.51, 0.94]	0.02	5
Stroke	7	6729	2275	128 (1.9)	80 (3.5)	0.60 [0.43, 0.84]	0.003	0
Vascular complications	6	6561	2219	578 (8.8)	65 (2.9)	1.22 [0.88, 1.68]	0.23	2
Pacemaker implantation	6	6689	2235	1079 (16.1)	396 (17.7)	1.04 [0.79, 1.37]	0.77	46
Bleeding	6	6561	2219	607 (9.3)	294 (13.2)	0.85 [0.71, 1.02]	0.08	0
Acute kidney injury	6	6287	2190	348 (5.5)	105 (4.8)	1.01 [0.59, 1.71]	0.98	62

Values are number, percentage (in parentheses) AP, alternative peripheral; CI, confidence interval; M-H, Mantel-Haenszel; TF, transfemoral.

Pacemaker Implantation

Study or Subgroup	Femoral Events	Femoral Total	Alternative Peripheral Events	Alternative Peripheral Total	Weight (%)	Odds Ratio M-H, Random, 95% CI
Alperi 2021	53	442	5	85	6.9	2.18 [0.84, 5.63]
Beurtheret 2019	254	1613	287	1613	34.8	0.86 [0.72, 1.04]
Gleason 2018	53	202	39	202	18.7	1.49 [0.93, 2.38]
Jimenez 2021	673	4123	28	138	20.8	0.77 [0.50, 0.17]
Kindzelski 2021	11	168	2	56	2.9	1.89 [0.41, 8.81]
Petronio 2012	35	141	35	141	15.8	1.00 [0.58, 1.72]
Total (95% CI)		*6689*		*2235*	*100.00*	*1.04 [0.79, 1.37]*
Total events	1079		396			

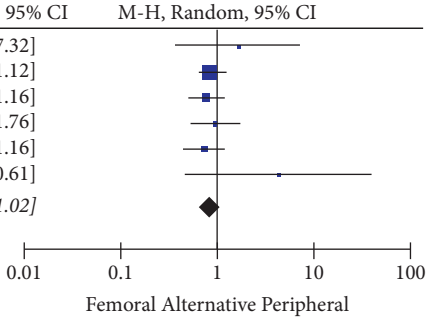
Heterogeneity: Tau² = 0.05 : Chi² = 9.25, df = 5 (P = 0.10); I^2 = 46%
Test for overall effect: Z = 0.29 (P = 0.77)



Bleeding

Study or Subgroup	Femoral Events	Femoral Total	Alternative Peripheral Events	Alternative Peripheral Total	Weight (%)	Odds Ratio M-H, Random, 95% CI
Alperi 2021	17	442	2	85	1.6	1.66 [0.38, 7.32]
Beurtheret 2019	121	1613	138	1613	52.8	0.87 [0.67, 1.12]
Gleason 2018	67	202	79	202	20.6	0.77 [0.51, 1.16]
Jimenez 2021	347	4123	12	138	9.4	0.96 [0.53, 1.76]
Petronio 2012	51	141	62	141	14.9	0.72 [0.45, 1.16]
Villecourt 2020	4	40	1	40	0.7	4.33 [0.46, 40.61]
Total (95% CI)		*6561*		*2219*	*100.00*	*0.85 [0.71, 1.02]*
Total events	607		294			

Heterogeneity: Tau² = 0.00: Chi² = 3.67, df = 5 (P = 0.60); I^2 = 0%
Test for overall effect: Z = 1.73 (P = 0.08)



Acute Kidney Injury

Study or Subgroup	Femoral Events	Femoral Total	Alternative Peripheral Events	Alternative Peripheral Total	Weight (%)	Odds Ratio M-H, Random, 95% CI
Beurtheret 2019	45	1613	62	1613	28.7	0.72 [0.49, 1.06]
Gleason 2018	29	202	20	202	23.6	1.53 [0.83, 2.80]
Jimenez 2021	257	4123	16	138	25.3	0.51 [0.30, 0.87]
Kindzelski 2021	1	168	0	56	2.5	1.01 [0.04, 25.20]
Petronio 2012	14	141	6	141	15.7	2.48 [0.92, 6.65]
Villecourt 2020	2	40	1	40	4.2	2.05 [0.18, 23.59]
Total (95% CI)		*6287*		*2190*	*100.00*	*1.01 [0.59, 1.71]*
Total events	348		105			

Heterogeneity: Tau² = 0.22: Chi² = 12.99, df = 5 (P = 0.02); I^2 = 62%
Test for overall effect: Z = 0.02 (P = 0.98)

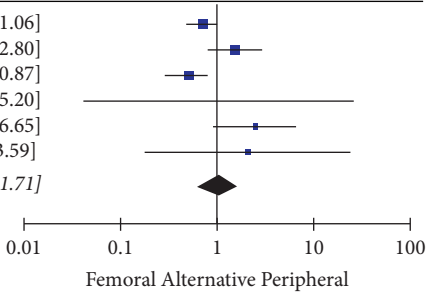


Figure 3: Forest plots comparing pacemaker implantation, bleeding, and acute kidney injury for patients undergoing transfemoral versus alternative peripheral transcatheter aortic valve replacement.

be inherently sicker and more prone to mortality and serious complications. We attempted to account for this underlying difference by including only propensity-matched studies, but unmeasured differences between the AP and TF populations are still likely to influence outcomes in the absence of randomization. Notably, the difference in mortality was dependent on the inclusion of 3 studies and did not persist on "leave-one-out" analysis [8, 9, 11].

While there was a trend towards fewer major vascular complications in AP access, this difference was not significant. Direct visualization of the target artery via surgical cutdown, which is commonly done for AP access, could theoretically mitigate the risk for vascular complications. Previous meta-analyses featuring unmatched studies found a lower rate of vascular complications with TC access [15, 22]. Percutaneous access can be used for transaxillary access and may increase the risk for vascular complications. An analysis of the Society of Thoracic Surgeons and American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry found that percutaneous access was pursued in 27% of all TAx-TAVRs and was associated with a significantly higher rate of major vascular complications compared to surgical cutdown [23]. The overwhelming majority of transaxillary access in the studies included in our analysis appear to have been done with a surgical cutdown, although this was not always explicitly

stated. Overall, the numerically higher rate of vascular complications in the TF group (8.8% vs. 2.9%) suggests AP access may reduce vascular complications if patients are well selected.

Differences between the two techniques included within the AP group are possible and may affect the interpretation of our analysis. A propensity-matched analysis of the STS/ACC TVT Registry found a higher stroke rate with TAx access compared to TC [24]. More recently, a meta-analysis of 5 observational studies, which included the aforementioned study, reported no significant differences between TC and TAx-TAVR for mortality, stroke, bleeding, or vascular complications [25]. A propensity-matched study from a multicenter French registry similarly found no difference in major outcomes [26]. At this time, the evidence suggests the two approaches are fairly comparable. In practice, the first-line choice for alternative peripheral access is left to the expertise and comfort of individual centers [5].

Alternative access has important implications for clinical practice, particularly for patients with potentially suboptimal iliofemoral vasculature. While enthusiasm for AP access has grown in recent years, this study represents what is arguably the best comparison to date of AP and TF access and reinforces the status of TF as the gold standard. While there may be slightly elevated risks of stroke and mortality with its use, AP access appears to have outcomes that are similar to TF access overall. The additional 1.1% and 1.6% risks of mortality and stroke, respectively, are relatively minor, particularly in the setting of an AP population that is expected to be more prone to complications. Given these considerations, we suggest that operators may approach alternative access fairly liberally when there are concerns about the iliofemoral vasculature. However, these findings should serve as a word of caution against an overly aggressive approach and to encourage careful consideration of the risks and benefits in a given patient.

4.1. Study Limitations. There is insufficient data to perform similar comparisons of TAx or TC against TF access. Therefore, outcomes of the AP group as a whole may not accurately represent the outcomes of a particular subset of AP access. Further, despite propensity-matching, selection bias may lead to unmeasured patient characteristics that disproportionately influence the outcomes of either group. Similarly, information regarding procedural techniques is not consistently reported but may be relevant to outcomes. Publication bias may have influenced the availability of data for meta-analysis and may limit the generalizability of our findings.

5. Conclusions

TF access remains the preferred technique for TAVR due to superior outcomes. Compared to TF, AP access is associated with slightly higher rates of short-term stroke and mortality. This supports careful consideration of a patient's risk factors and anatomy before opting to perform TAVR via AP access. AP access should be used when there are doubts about the safety or feasibility of TF-TAVR.

Abbreviations and Acronyms

AP:	Alternative peripheral
MH:	Mantel-Haenszel
OR:	Odds ratio
STS/ACC TVT:	Society of thoracic surgeons and American college of cardiology transcatheter valve therapy
TAVR:	Transcatheter aortic valve replacement
TAx:	Transaxillary
TC:	Transcarotid
TF:	Transfemoral.

Data Availability

Underlying data will be made available upon reasonable request.

Ethical Approval

This study was approved by the Tufts University IRB on 7/11/2022

Consent

The requirement for informed consent was waived.

Disclosure

This study was presented at the annual Transcatheter Cardiovascular Therapeutics (TCT) Conference, Boston, MA, Sept 16–19.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Supplementary Materials

Supplemental Table 1. Quality assessment of each study included in the meta-analysis is presented according to the Newcastle-Ottawa scale. Supplemental Table 2. For each study included in the meta-analysis, the total number of patients and events in both the transfemoral and alternative peripheral groups are presented. Supplemental Table 3. Meta-regression is demonstrated for pacemaker implantation and acute kidney injury, including the moderator, coefficient, 95% confidence interval, and *P*-value. Supplemental Figure 1. Funnel plots to demonstrate the risk of publication bias for each outcome are presented. (*Supplementary Materials*)

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