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Transcarotid versus transfemoral transcatheter aortic valve replacement: A systematic review and meta-analysis

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ABSTRACT

Background: In the 2021 Transcatheter Valve Therapy (TVT) registry, 8.9 % of patients underwent TAVR via access sites other than the femoral artery. Transthoracic approaches may be contraindicated in some patients and may be associated with poorer outcomes. Therefore other alternative access routes are increasingly being performed. We conducted a systematic review of the literature on transcarotid transcatheter aortic valve replacement (TC-TAVR) and meta-analysis comparing outcomes of TC-TAVR and other access routes.

Methods: We comprehensively searched for controlled randomized and non-randomized studies from 4 online databases. We presented data using risk ratios (95 % confidence intervals) and measured heterogeneity using Higgins' I^2.

Results: Sixteen observational studies on transcarotid TAVR were included in the analysis; 4 studies compared TC-TAVR vs TF-TAVR. The mean age and STS score for patients undergoing TC-TAVR were 80 years and 7.6 respectively. For TF-TAVR patients, mean age and STS score were 81.2 years and 6.5 respectively. There was no difference between patients undergoing TC-TAVR and TF-TAVR in the following 30-day outcomes: MACE [8.4 % vs 6.7 %; OR 1.32 (95 % CI 0.71–2.46 $p = 0.38$) $I^2 = 0$ %], mortality [5.6 % vs 4.0 %; OR 0.42 (95 % CI 0.60–3.37, $P = 0.42$) $I^2 = 0$ %] and stroke [0.7 % vs 2.3 %; OR 0.49 (95 % CI 0.09–2.56, $P = 0.40$) $I^2 = 0$ %]. There was no difference in 30-day major vascular complications [0.7 % vs 3 %; OR 0.55 (95 % CI 0.06–5.29, $P = 0.61$) $I^2 = 39$ %], major bleeding [0.7 % vs 3.8 %; OR 0.39 (95 % CI 0.09–1.67, $P = 0.21$) $I^2 = 0$ %], and moderate or severe aortic valve regurgitation [8.6 % vs 9.9 %; OR 0.89 (95 % CI 0.48–1.65, $P = 0.72$) $I^2 = 0$ %].

Conclusion: There are no significant differences in mortality, stroke MACE and major or life-threatening bleeding or vascular complications when TC-TAVR is compared to TF-TAVR approaches.

1. Introduction

A total of 72,991transcatheter aortic valve replacement procedures were performed in 2019 in the United States, that number is increasing every year and consistently surpassing the annual volume of surgical aortic valve replacement [1]. Since the incidence of aortic stenosis and cardiac surgical risk increase with age, this number is likely to rise as the population ages [2]. Besides, as transcatheter aortic valve replacement is adopted among lower-risk patients, the number of procedures is likely to grow even further [3].

Guidelines recommend transfemoral access during TAVR as the first choice due to its extensive use in clinical trials, minimal invasiveness, ability to be done under sedation, and safety [4]. In the initial TAVR studies, up to 25–30 % of patients were precluded from transfemoral access. Due to an improvement in technology the transcatheter heart valves can be delivered in catheters as small as 14F [5]. This has led to a further decrease in the proportion of patients that need alternative vascular access.

Studies on Transcarotid access for TAVR have reported variable findings and had small sample sizes [6–18]. Despite that transcarotid access is increasingly considered as potentially a preferred approach for alternative

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access. With the recent publication of several controlled observational studies, we performed a systematic review and meta-analysis of observational studies to assess the clinical outcomes of transcarotid approach compared with transfemoral approach.

2. Methods

We followed the QUOROM (The Quality of Reporting of Meta-analyses) and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines throughout the process of performing and reporting this study [19,20].

2.1. Search strategy

We searched MEDLINE, Cochrane Library, the Web of Science and Google Scholar, for relevant publications since inception until November 25, 2023. We used various combinations of Medical Subject Heading (MeSH) terms and keywords representing the following concepts: "transcatheter aortic valve replacement," "transcarotid," and "transfemoral." We also searched ClinicalTrials.gov (November 25, 2023) for clinical trials. We reviewed references of the full-text articles that we retrieved for more studies.

2.2. Study selection

Two investigators (C.M and P.N) independently screened the search results and assessed study eligibility. We resolved differences by consensus, and where we could not reach an agreement, a third author (Z.F.) made the decision.

The study inclusion criteria were:

1. Randomized controlled trials (RCTs) or controlled observational studies that compared the outcomes of transcarotid TAVR with transfemoral, transaortic or transapical TAVR
2. Single arm interventional or observational studies on TC-TAVR
3. Studies that reported clinical or aortic valve area and hemodynamic outcomes

Exclusion criteria were:

1. Studies that were not published in English and English translation could not be obtained
2. Case reports

A PRISMA flow diagram [20] summarizing literature search and selection of studies is shown in Fig. 1.

2.3. Data extraction and study quality assessment

The two authors (CM and PN) independently reviewed the included studies and summarized the study characteristics in a data extraction table. The data collected were author, year of publication, number of patients, study design, TAVR access routes, type of transcatheter heart valve, valve size, type of anesthesia, side of carotid artery access (right or left), use of balloon aortic valvuloplasty, use of a carotid shunt, cerebral perfusion monitoring, patient demographic, and clinical characteristics. The

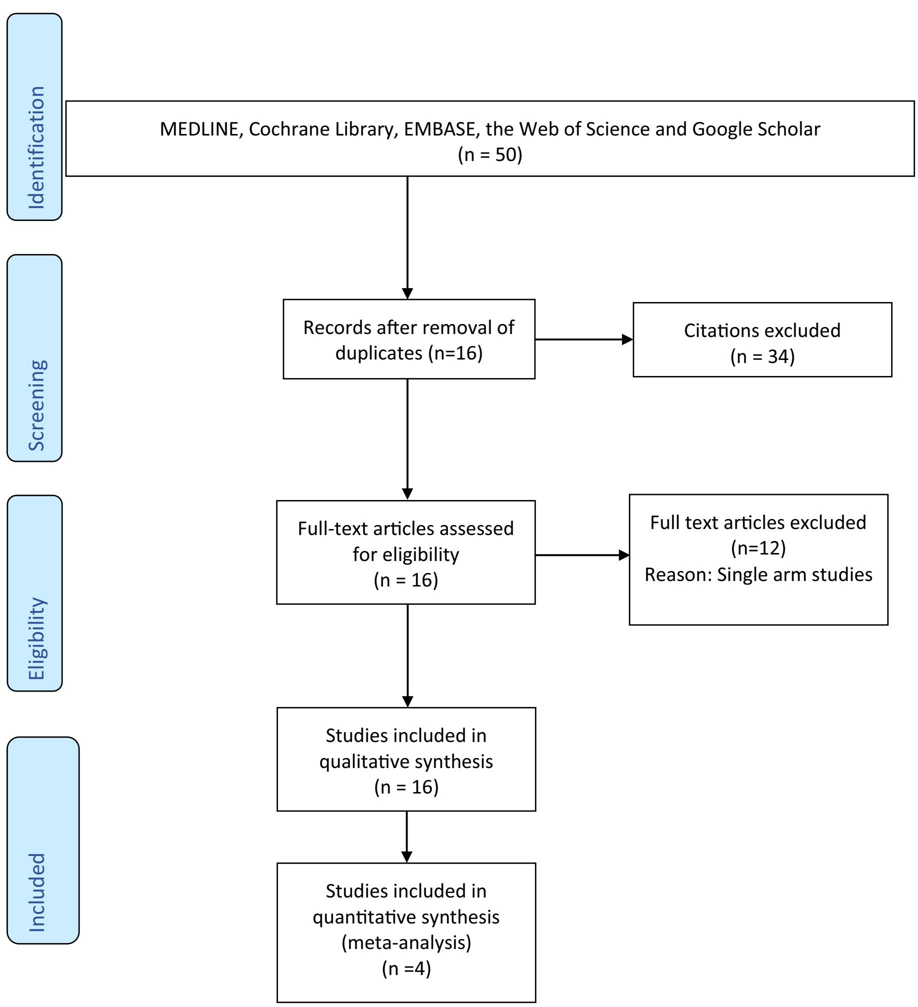


Fig. 1. PRISMA flow diagram of studies included in data search.

following outcomes were collected: 30-day major adverse cardiovascular events (MACE) (mortality, stroke or transient ischemic attack), mortality, stroke, transient ischemic attack (TIA), bleeding and major vascular complications. We assessed the study risk of bias using the Cochrane Collaboration's tool: Risk of Bias in Non-randomized Studies - of Interventions (ROBINS-I tool) [21].

2.4. Statistical analysis

Seven controlled observational studies were included in the meta-analysis. Risk ratios (RR) and 95 % confidence intervals (95 % CI) were used to report effect sizes, and the Higgin's I-squared (I^2) statistic was used to measure statistical heterogeneity. We used a fixed effects model in analyses with heterogeneity of ≤25 %. A significance level of 0.05 was used for all analyses. We performed sensitivity analyses by removing one study at a time. We used Cochrane's RevMan 5.3 for meta-analysis. We did not create a funnel plot because of the small number of controlled studies. Among the controlled studies, data were quite homogeneous; therefore we performed a meta-analysis.

3. Results

3.1. Search results and study characteristics

Of sixteen observational studies only four reported outcomes comparing transcarotid with transfemoral TAVR. The total number of patients in the included studies was 143 patients in the transcarotid arm compared with 1134 patients in the transthoracic arm.

3.2. Patient characteristics

All patients had a contraindication to transfemoral access. However, different centers used different algorithms in patients that had a contraindication to transfemoral access. The transcarotid route was considered if patients were not candidates for transfemoral, transapical and transaortic access. In three studies, it was considered a second option after transfemoral access.

The mean age for all patients undergoing TC-TAVR was 80 years, and 53.1 % were males. The mean STS score was 7.6. Three studies reported only EUROSCORE II and the mean was 9.1. Seventy percent and 18.2 % of patients undergoing TC-TAVR had a history of peripheral artery disease of and myocardial infarction respectively. The mean aortic valve area was 0.78 $cm^{2,}$ and the mean transaortic valve gradient was 58.8 mmHg.

Among patients undergoing TF-TAVR, the mean age was 81.2 YEARS, males were 54.3 %, and the mean STS score was 6.5. Peripheral artery disease and myocardial infarction was present in 23.3 % and 15.9 % of patients undergoing TF-TAVR. The pre-procedural echocardiographic characteristics were a mean aortic valve area of 0.76 cm^2, mean transaortic valve gradient of 42.4 mmHg and mean left ventricular ejection fraction of 54.1 %.

Table 1 summarizes study patient characteristics for transcarotid versus transfemoral approach of transcatheter aortic valve replacement.

3.3. Transcarotid TAVR procedural methods

Among patients undergoing transcarotid TAVR, the types of valves used were as follows: Sapien – 11.3 %, SAPIEN XT – 9.6 %, SAPIEN 3–13.3 %, Medtronic CoreValve – 59.2 %, Evolut R – 6.4 % and LOTUS <1 %. General anesthesia was used in 91 % of all TC-TAVR procedures. Table 2 summarizes the procedural data for the trials comparing transcarotid versus transfemoral approach of transcatheter aortic valve replacement.

3.4. Outcomes

3.4.1. Transcarotid vs. transfemoral TAVR

There was no difference between patients undergoing TC-TAVR and TF-TAVR in the following 30-day outcomes: MACE [8.4 % vs 6.7 %; OR 1.32 (95 % CI 0.71–2.46 $p = 0.38$) $I^2 = 0$ %, Fig. 2A], mortality [5.6 % vs 4.0 %; OR 0.42 (95 % CI 0.60–3.37, $P = 0.42$) $I^2 = 0$ %, Fig. 2B] and stroke [0.7 % vs 2.3 %; OR 0.49 (95 % CI 0.09–2.56, $P = 0.40$) $I^2 = 0$ %, Fig. 2C]. There was no difference in 30-day major vascular complications [0.7 % vs 3 %; OR 0.55 (95 % CI 0.06–5.29, $P = 0.61$) $I^2 = 39$ %, Fig. 2D] and moderate or severe aortic valve regurgitation [8.6 % vs 9.9 %; OR 0.89 (95 % CI 0.48–1.65, $P = 0.72$) $I^2 = 0$ %, Fig. 2E]. There was trend towards less bleeding in TC-TAVR compared with TF-TAVR even though it did not reach statistical significance [0.7 % vs 3.8 %; OR 0.39 (95 % CI 0.09–1.67, $P = 0.21$) $I^2 = 0$ %, Fig. 2F].

4. Discussion

Our meta-analysis was done on four studies with outcomes of interest. and the meta-analysis showed no significant difference between TC-TAVR and TF-TAVR in 30-day MACE, mortality, stroke, major vascular complications, and moderate or severe aortic valve regurgitation. It showed a trend towards lower odds of major or life-threatening bleeding.

A higher proportion of patients undergoing TC-TAVR had a history of PAD, myocardial infarction, and a higher mean STS PROM score compared to patients undergoing TF-TAVR.

One of the major concerns about TC-TAVR is the risk of stroke. However, in this analysis, the odds of stroke among the TC-TAVR group were not significantly different from the other two control groups. Most studies did a cross-clamp test and cerebral oxygen saturation monitoring during the procedure and used a carotid shunt when these two tests were abnormal. These procedures might have mitigated the risk of stroke. However, there may be other reasons why the risk of stroke in TC-TAVR is not higher than in TF-TAVR. The carotid artery occlusion is not complete during TAVR since blood flows anterograde around the sheat [7]. Also, retrograde flow from the external carotid artery into the internal carotid artery via the segment of the common carotid artery that is intact may maintain cerebral circulation [7]. Finally, the mid-segment of the common carotid artery that is

Table 1
Study patient characteristics for transcarotid (TC) versus transfemoral (TF) approach of transcatheter aortic valve replacement.

Study	Access	Number	Age (yr)	Male (%)	STS RISK	NYHA CLASS III/IV	Stroke	PAD	Dialysis	Hypertension	Diabetes	LVEF	Aortic valve area	Mean aortic valve gradient
Kirker, 2017	TC	25	77		6.1	40 %	16 %	80 %	8 %	88 %	48 %	55 %	0.7	32
	TF	100	83	51	6	53 %	13 %	39 %	4 %	85 %	34 %	60 %	0.7	37
Paone, 2018	TC	32	79	50	6.9	81 %	*	78 %	6 %	94 %	34 %	56 %	0.89	36.5
	TF	373	80	55	6.1	90 %	21 %	23 %	4 %	91 %	41 %	55 %	0.82	35.9
Thourani, 2013	TC	3												
	TF	18	81	83	13	94 %	28 %	33 %	17 %	100 %	61 %	38 %	0.69	46.3
Watanabe; 2018	TC	83	80	65	6.4	57 %	10 %	61 %		81 %	31 %	52 %	0.8	45
	TF	643	81	54	6.7	52 %	12 %	21 %		75 %	27 %	53 %	0.7	46.7

Abbreviations: STS = Society of Thoracic Surgery; NYHA = New York Heart Association; PAD = Peripheral Arterial Disease; LVEF = Left Ventricle Ejection Fraction.

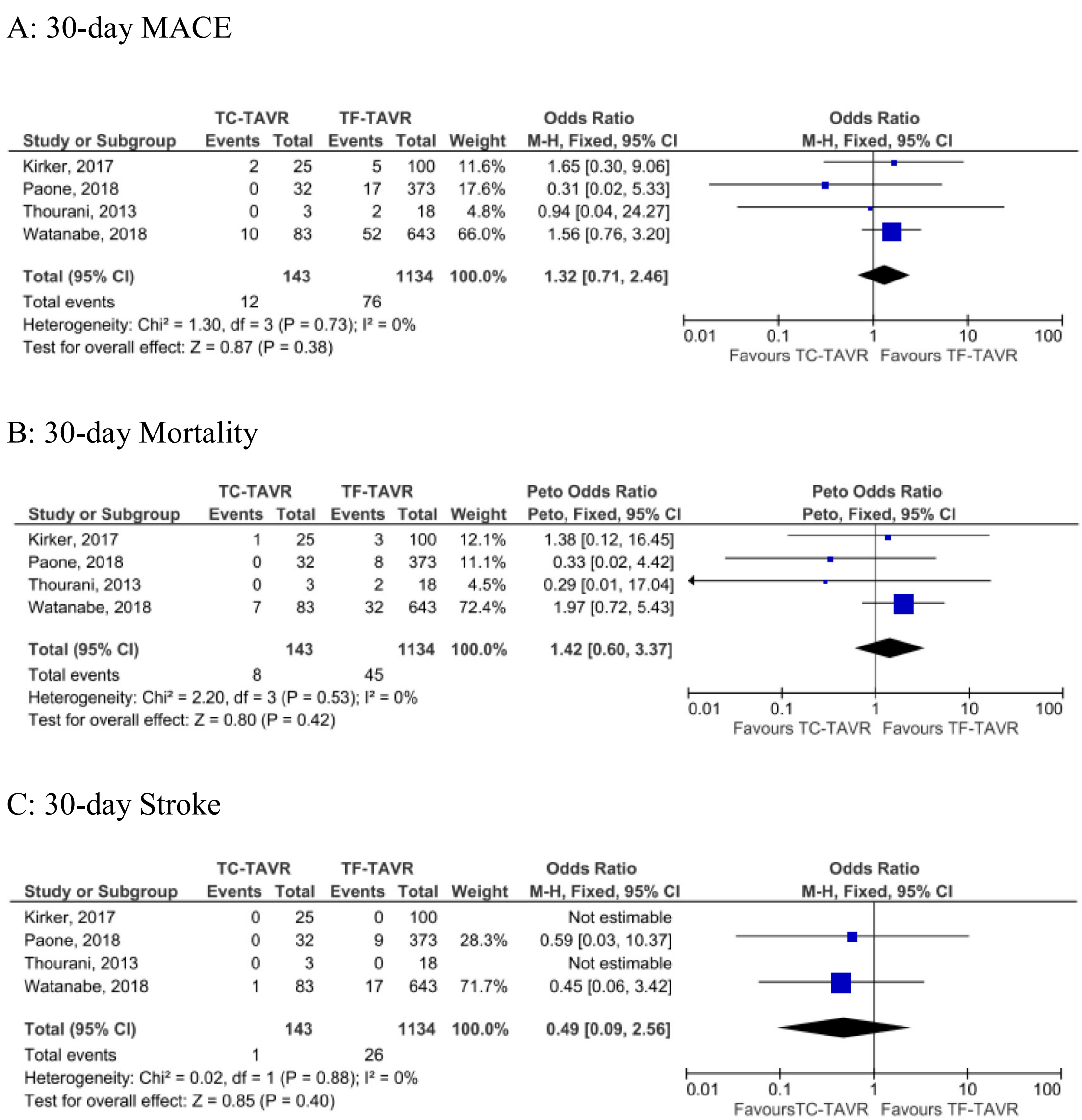
Table 2
Procedural data in the Transcarotid arms of the studies comparing Transcarotid (TC) versus Transfemoral (TF) Approach of transcatheter aortic valve replacement (TAVR).

Study author, year	Valve type (TC-TAVR)	Anesthesia for TC-TAVR	Carotid artery access	Shunt	Cerebral O_2 saturation monitoring	Balloon aortic valvuloplasty	Reason TC chosen	TC access exclusion criteria
Kirker, 2017	Sapien 3–56 % Sapien XT - 28 % CoreValve 3–12 % Sapien - 4 %	GA - 100 %	Right - 85 %	No	Yes	Yes		Carotid diameter < 6.5 mm, >50 % contralateral carotid stenosis, vertebral artery stenosis with contralateral vertebral retrograde flow consistent with steal at rest
Paone, 2018	Sapien XT/3–93.8 % CoreValve Evolut R - 6.2 %	GA - 100 %	Right - 78 %	No	No	Unknown	Not candidate for TF	Carotid diameter < 6 mm, significant tortuosity or calcification, >50 % stenosis in contralateral carotid artery
Thourani, 2013	Sapien - 100 %	GA - 100 %	Right −100 %	Yes	Yes	Yes	Not candidate for TF, TA0 & TA.	Common carotid artery diameter of ≤8 mm and evidence of common carotid stenosis
Watanabe, 2018	Sapien - 54 % CoreValve 47 %	GA - 100 %	Either but right - preferred	No	No	Yes	Heavily calcified or tortuous iliac artery, iliac diameter < 5 mm	Massive calcification of carotid, carotid <5.5 mm, >50 % stenosis of contralateral common carotid, High risk malformation of circle of Willis

Abbreviations: TC = Transcarotid; TAVR = Transcatheter Aortic Valve Replacement; TF = Transfemoral; TAO = Transaortic; TA = Transaxillary.

usually used for access in TC-TAVR usually doesn't have atherosclerosis [7]. The initial risk of stroke among TC-TAVR patients was relatively high, ranging from 5.7 % to 7 % [10,12]. This risk has declined in recent studies due to the use of smaller delivery catheters [22]. Some recent studies have also used local anesthesia which might reduce hypotensive episodes and consequently watershed stroke events [6,10,23].

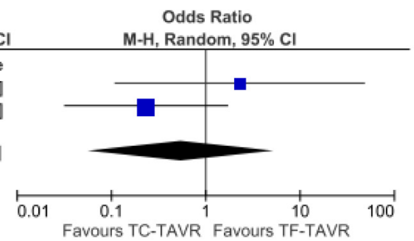
Even though the TF-TAVR cohort had a lower comorbidity burden and STS score, there was no significant difference in the reported clinical



D: Major Vascular Complications

Study or Subgroup	TC-TAVR Events	TC-TAVR Total	TF-TAVR Events	TF-TAVR Total	Weight	Odds Ratio M-H, Random, 95% CI
Kirker, 2017	0	25	0	100		Not estimable
Paone, 2018	0	32	2	373	37.7%	2.29 [0.11, 48.63]
Watanabe, 2018	1	83	32	643	62.3%	0.23 [0.03, 1.73]
Total (95% CI)		**140**		**1116**	**100.0%**	**0.55 [0.06, 5.29]**
Total events	1		34			

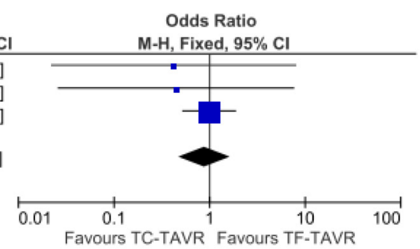
Heterogeneity: Tau² = 1.09; Chi² = 1.63, df = 1 (P = 0.20); I² = 39%
Test for overall effect: Z = 0.52 (P = 0.61)



E: Aortic Valve regurgitation

Study or Subgroup	TC-TAVR Events	TC-TAVR Total	TF-TAVR Events	TF-TAVR Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Kirker, 2017	0	25	4	100	8.1%	0.42 [0.02, 8.07]
Paone, 2018	0	32	12	373	9.0%	0.44 [0.03, 7.69]
Watanabe, 2018	12	83	94	643	82.9%	0.99 [0.52, 1.89]
Total (95% CI)		**140**		**1116**	**100.0%**	**0.89 [0.48, 1.65]**
Total events	12		110			

Heterogeneity: Chi² = 0.57, df = 2 (P = 0.75); I² = 0%
Test for overall effect: Z = 0.36 (P = 0.72)



F: 30-day bleeding

Study or Subgroup	TC-TAVR Events	TC-TAVR Total	TF-TAVR Events	TF-TAVR Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Kirker, 2017	1	25	11	100	51.7%	0.34 [0.04, 2.74]
Paone, 2018	0	32	12	373	24.4%	0.44 [0.03, 7.69]
Watanabe, 2018	0	83	8	643	23.9%	0.45 [0.03, 7.83]
Total (95% CI)		**140**		**1116**	**100.0%**	**0.39 [0.09, 1.67]**
Total events	1		31			

Heterogeneity: Chi² = 0.04, df = 2 (P = 0.98); I² = 0%
Test for overall effect: Z = 1.27 (P = 0.21)

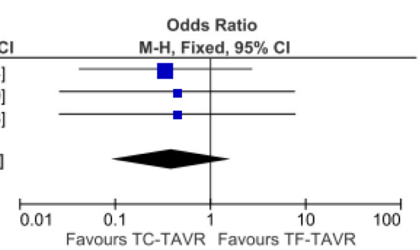


Fig. 2. Forrest plots for transcarotid versus Transfemoral transcatheter aortic valve replacement outcomes.
A: 30-day MACE.
B: 30-day mortality.
C: 30-day stroke.
D: Major vascular complications.
E: Aortic valve regurgitation.
F: 30-day bleeding.

outcomes between TC-TAVR and TF-TAVR. The short direct access to the aortic valve and minimal manipulation of the aortic arch in TC-TAVR likely reduced the risk of thromboembolic and bleeding complications [5].

With data showing worse outcomes with transthoracic TAVR compared with TC-TAVR, [24] TC-TAVR, transaxillary and subclavian TAVR are increasingly considered the preferred routes for alternative access.

Transaxillary and subclavian access may be contraindicated in some patients with arterial tortuosity, calcification, and coronary artery bypass graft (CABG) with a patent left internal mammary artery (which can lead to myocardial hypoperfusion during Transaxillary TAVR) [12]. Unfortunately there no studies that compares transaxillary and subclavian access outcomes to those of TC-TAVR.

Despite the limitation of this meta-analysis being based on observational data and the fact that patients who will be candidates for transfemoral access are unlikely to undergo transcarotid access; we still believe that these facts make our results more compelling as it shows that transcarotid access can still yield outcomes close to transfemoral access even in the patients who are not candidates for the later. Another limitation is it still unclear based on our data whether right or left carotid approach leads to better outcomes.

5. Conclusion

This meta-analysis suggests that there are no significant differences in mortality, stroke MACE and major or life-threatening bleeding or vascular complications when TC-TAVR is compared to TF-TAVR approaches. However, compared with transthoracic TAVR, TC-TAVR patients had lower odds of 30-day MACE and major or life-threatening bleeding.

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CRediT authorship contribution statement

Cyrus Munguti: Writing – original draft, Investigation. **Paul M. Ndunda:** Writing – review & editing, Methodology, Investigation, Formal analysis. **Abdullah Abukar:** Writing – review & editing, Validation, Methodology, Conceptualization. **Mohammed Abdel Jawad:** Writing –

review & editing, Validation. **Mohinder R. Vindhyal:** Writing – review & editing, Validation, Conceptualization. **Zaher Fanari:** Writing – review & editing, Validation, Supervision, Project administration, Investigation.

Declaration of competing interest

All the authors have no declarations to make.

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