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

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ARTICLE INFO ABSTRACT Keywords: Background: Transthoracic approaches may be contraindicated in some patients and may be associated with poorer Transcarotid outcomes. Therefore other alternative access routes are increasingly being performed. We conducted a systematic re-Transthoracic Transcatheter aortic valve view of the literature on Transcarotid transcatheter aortic valve replacement (TC-TAVR) and meta-analysis comparing replacement outcomes of TC-TAVR and other access routes. Transaortic 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 180 TC-TAVR patients vs 524 TT-TAVR patients. The mean age and STS score for patients undergoing TC-TAVR were 80 years and 7.6 respectively. For TT-TAVR patients, the mean age and STS score were 79.7 years and 8.7 respectively. TC-TAVR patients had lower 30day MACE [7.8 % vs 13.7 %; OR 0.54 (95 % CI 0.29–0.99, P = 0.05)] and major or life-threatening bleeding [4.0 % vs 14.2 %; OR 0.25 (95 % CI 0.09–0.67, P = 0.006)]. There was no significant difference in 30-day: mortality [5.0 % vs 8.6 %; OR 0.61 (95 % CI 0.29–1.30, P = 0.20)], stroke or transient ischemic attack [2.8 % vs 4.0 %; OR 0.65 (95 % CI 0.25–1.73, P = 0.39)] and moderate or severe aortic valve regurgitation [5.0 % vs 4.6 %; OR 1.14. (95 % CI 0.52–2.52, P = 0.75)]. There was a trend towards fewer major vascular complications in TC-TAVR [3.0% vs 7.8%; OR 0.42 (95% CI 0.16–1.12, P = 0.08)]. Conclusion: Compared with transthoracic TAVR, TC-TAVR patients had lower odds of 30-day MACE and life-threatening bleeding and no differences in 30-day mortality, stroke or TIA, aortic valve regurgitation.

1. Introduction

A total of 72,991 transcatheter 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.

The main contraindications to transfemoral TAVR include unsuitable femoral/iliac artery or aortic size, tortuosity, or anatomy [1]. Alternative access sites that have been studied for TAVR include the transapical, transaortic, Transcarotid, transcaval, transaxillary/subclavian and transeptal routes [1]. In the 2021 annual report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) registry, 8.99 % of patients underwent TAVR via access sites other than the femoral artery [1]. Of these 8.99 % alternative access reported transthoracic access was surprisingly still widely dominant with 5.88 % of cases reported (transapical was 4.11 % and Transaortic 1.77 %). Non transthoracic accesses reported were subclavian 1.88 %, axillary 0.83 %, transcarotid 0.53 %, transeptal 0.01 % and transcaval 0.04 % [1].

While the most commonly used alternative approaches in the US in the 2021 have been transapical and transaortic, these approaches are invasive, require general anesthesia and may not be feasible in some patients with previous thoracic or cardiac surgery [1]. Also, some studies suggest a high morbidity with these routes and higher mortality with transapical access and therefore, there is a need for further research on alternative access for TAVR [6].

Studies on Transcarotid access for TAVR have reported variable findings and had small sample sizes [7-19]. With the recent publication of several

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controlled observational studies, we performed a systematic review and meta-analysis of observational studies to assess the clinical outcomes of Transcarotid approach compared with transthoracic (transapical and transaortic) approaches.

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 [20,21].

2.1. Search strategy

We searched MEDLINE, Cochrane Library, the Web of Science and Google Scholar, for relevant publications since inception until November 25, 2018. We used various combinations of Medical Subject Heading (MeSH) terms and keywords representing the following concepts: "transcatheter aortic valve replacement," "Transcarotid," "transaortic" and "transapical." We also searched ClinicalTrials.gov (November 25, 2018) 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 transaortic or transapical TAVR.
- 2. 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 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 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



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

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Table 1

Characteristics of studies included in systematic review and meta-analysis.

| Study/author, Yr | Study type | Full-text publication? | Request full text from | TC vs TA | TC vs TAo |
|------------------|-------------------|------------------------|------------------------|----------|-----------|
| Kirker, 2017 | Controlled observ | Yes | No | Х | |
| Thourani, 2015 | Controlled observ | Yes | No | Х | Х |
| Damluji, 2018 | Controlled Observ | Yes | No | Х | Х |
| Chamadi, 2018 | Controlled Observ | No | Library | Х | Х |

Collaboration's tool: Risk of Bias in Non-randomized Studies - of Interventions (ROBINS-I tool) [22].

2.4. Statistical analysis

Seven controlled observational studies were included in the metaanalysis. 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 transaortic TAVR. The total number of patients in the

Table 2

Patient characteristics.

included studies was 180 patients in the transcarotid arm compared with 524 patients in the transthoracic arm. Table 1 summarizes the characteristics of studies included in the systematic review and meta-analysis.

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 cm², and the mean transaortic valve gradient was 58.8 mmHg.

Among patients undergoing transthoracic TAVR, the mean age was 79.7 years, and 55.7 % of the cohort was male. The mean STS score was 8.7. Peripheral artery disease and myocardial infarction were present in

| Study author, yr | Number OF patie transthoracic | nts transcarotid vs | Age | Male gend (%) | er STS risk | Lo | ogistic 1roscore | Euroscore II | NYHA class III/IV | H/O stroke | H/O DM |
|---------------------|----------------------------------|---------------------|-----------------|------------------|-------------|-----------|---------------------|-----------------|----------------------|---------------|-------------|
| Chamadi, 2018 | 101 VS 228 | | 80.4 ± 8.4 | 55 (54.5) | 6.6 ± 5 | .7 | | 8.7 ± 7.5 | | 16 (15.8) | 42 (41.6) |
| Damluji, 2018* | 43 VS 112 | | 81 (72-86) | 27 (63) | 6.9 (4.1- | -8.7) | | | 27 (63) | 3 (7) | 17 (40) |
| Kirker, 2017* | 25 VS 112 | | 77.0 (72.0-8 | 3.0) 13 (52.0) | 6.1 (4.1- | -9.6) | | | 10 (40.0) | 12 (48.0) | 12 (48.0) |
| Thourani, 2015 | 11 VS 172 | | 68.9 ± 23.6 | 5 (45.4) | $17.1 \pm$ | 8.8 | | | 10 (90.9) | 1 (9.1) | 4 (36.4) |
| Study author, yr | H/O hypertension | H/O CABG H/O | D PCI H/O PAD | Creatinine | ON dialysis | A FIB | MI | LVEF | Aortic valve | area Mean | AV gradient |
| Chamadi, 2018 | 82 (81.2) | 24 (23.8) | 67 (66.3) | | | 41 (40.6) | 20 (19.8) | 55 ± 12 | 0.66 ± 0.15 | 5 51 ± | 13 |
| Damluji, 2018* | 34 (79) | | | 1.3 (0.9–1.80) | | 16 (37) | 15 (35) | 55 (35-60) | 0.7 (0.5-0.9 |) 44 (3 | 5–53) |
| Kirker, 2017* | 22 (88.0) | 9 (36.0) | 20 (80.0) | 1.20 (1.06-1.58) | 2 (8.0) | | | 55 (35-60) | 0.7 (0.52-0. | 79) 32 (2) | 7.5–39.25) |
| Thourani, 2015 | 9 (81.8) | 6 (54.6) | 8 (72.7) | 1.72 ± 0.95 | 0 (0.0) | | 2 (18.2) | 45.5 ± 17.4 | 0.62 ± 0.17 | 7 42.0 | ± 18.1 |

Table 3

Procedural data for transcarotid TAVR.

| Study author, yr | Valve type (TC-TAVR) | Valve size (TC-TAVR) (mm) | Anethesia for TC-TAVR | Carotid artery access | Shunt | Cerebral O2 saturation monitoring | BAV | Reason TC chosen | TC access exclusion criteria |
|---------------------|--|---|-----------------------------|-----------------------------|---------------------------------|---|-----------------------|--------------------------------------|--|
| Chamadi, 2018 | Sapien 3–49.5 % Evolut R - 34.7 % CoreValve - 7.9 % Sapien XT - 7.9 % | | GA - 100 % | Left - 97 % | yes - Only when indicated | yes | in 38.5 % cases | | Common carotid artery (CCA) lumen diameter < 7 mm, Contralateral carotid artery occlusion, significant (≥50 %) internal or CCA stenosis, and occlusion or stenosis of vertebral arteries |
| Damluji, 2018 | CoreValve - 49 % Sapien 3–12 % Sapien XT - 10 % | All Valves - 26.8 | GA - 100 % | No data | No | No | Yes | Not clear | |
| Kirker, 2017 | Sapien 3–56 % Sapien XT - 28 % CoreValve 3–12% Sapien - 4 % | Sapien, Sapien XT/3–25.9 Corevalve - 26.5 | 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 |
| Thourani, 2015 | Sapien - 100 % | 23–26 | GA - 100 % | Right - 100 % | Yes | Yes | Yes | Not candidate for TF, TA0 & TA | |

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A 30-day MACE

| | TC-TAVE | R TI | TT-TAVR | | | Odds Ratio | Odds Ratio |
|-------------------------------------|----------------|-------------|---------------------------------|-------|--------|--------------------|--------------------|
| Study or Subgroup | Events T | Total Eve | nts | Total | Weight | M-H, Fixed, 95% CI | M-H, Fixed, 95% CI |
| Chamandi, 2018 | 9 | 101 | 31 | 228 | 54.8% | 0.62 [0.28, 1.36] | |
| Damluji, 2018 | 4 | 43 | 18 | 112 | 28.6% | 0.54 [0.17, 1.68] | |
| Kirker, 2017 | 1 | 25 | 2 | 12 | 8.2% | 0.21 [0.02, 2.57] | |
| Thourani, 2015 | 0 | 11 | 21 | 172 | 8.4% | 0.31 [0.02, 5.39] | |
| Total (95% CI) | | 180 | | 524 | 100.0% | 0.54 [0.29, 0.99] | • |
| Total events | 14 | | 72 | | | | |
| Heterogeneity: Chi ² = (|).83, df = 3 (| (P = 0.84); | | | | | |
| Test for overall effect: | Z = 2.00 (P = | = 0.05) | Favours TC-TAVR Favours TT-TAVR | | | | |

B: 30-day Major Bleeding

| | тс-та | VR | TT-TA | T-TAVR | | Odds Ratio | Odds Ratio |
|-------------------------------------|------------|----------|--------|--------|---------------------------------|--------------------|--------------------|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Fixed, 95% CI | M-H, Fixed, 95% Cl |
| Chamandi, 2018 | 4 | 101 | 32 | 228 | 87.9% | 0.25 [0.09, 0.73] | |
| Kirker, 2017 | 1 | 25 | 2 | 12 | 12.1% | 0.21 [0.02, 2.57] | |
| Total (95% CI) | | 126 | | 240 | 100.0% | 0.25 [0.09, 0.67] | - |
| Total events | 5 | | 34 | | | | |
| Heterogeneity: Chi ² = 0 | 0.02, df = | 1 (P = (| | | | | |
| Test for overall effect: | Z = 2.76 (| P = 0.0 | 06) | | Favours TC-TAVR Favours TT-TAVR | | |

C: 30-day Mortality

| | TC-TAVR | TT-TAVR | | Odds Ratio | Odds Ratio |
|----------------------------|------------------|---------------------------------|--------|-------------------|--------------------|
| Study or Subgroup | Events Tota | Events Total | Weight | M-H, Fixed, 95% C | M-H, Fixed, 95% CI |
| Chamandi, 2018 | 5 10 | 14 228 | 42.7% | 0.80 [0.28, 2.27] | - |
| Damluji, 2018 | 3 43 | 12 112 | 32.4% | 0.63 [0.17, 2.33] | |
| Kirker, 2017 | 1 2 | 2 12 | 13.6% | 0.21 [0.02, 2.57] | |
| Thourani, 2015 | 0 1 | 17 172 | 11.4% | 0.39 [0.02, 6.84] | |
| Total (95% CI) | 180 | 524 | 100.0% | 0.61 [0.29, 1.30] | • |
| Total events | 9 | 45 | | | |
| Heterogeneity: Chi2 = 1 | .05, df = 3 (P = | | | | |
| Test for overall effect: 2 | Z = 1.27 (P = 0. | Favours TC-TAVR Favours TT-TAVR | | | |

D: Stroke or TIA

| | TC-TAVR | TT-TA | TT-TAVR | | Odds Ratio | Odds Ratio |
|-------------------------------------|-----------------|-----------------------------|---------|--------|--|--------------------|
| Study or Subgroup | Events To | tal Events | Total | Weight | M-H, Fixed, 95% Cl | M-H, Fixed, 95% CI |
| Chamandi, 2018 | 3 1 | 01 11 | 228 | 59.6% | 0.60 [0.16, 2.21] | |
| Damluji, 2018 | 1 | 43 6 | 112 | 29.6% | 0.42 [0.05, 3.60] | |
| Kirker, 2017 | 1 | 25 0 | 12 | 5.7% | 1.53 [0.06, 40.37] | |
| Thourani, 2015 | 0 | 11 4 | 172 | 5.1% | 1.63 [0.08, 32.12] | |
| Total (95% CI) | 1 | 80 | 524 | 100.0% | 0.65 [0.25, 1.73] | - |
| Total events | 5 | 21 | | | | |
| Heterogeneity: Chi ² = (| 0.80, df = 3 (F | P = 0.85); I ² = | : 0% | | | |
| Test for overall effect: | Z = 0.85 (P = | 0.39) | | | 6.01 0.1 1 10 100 Favours TC-TAVR Favours TT-TAVR | |

E: Aortic Valve regurgitation

| | TC-TA | VR | TT-TA | VR | Odds Ratio | | | Odds | Ratio | |
|--|-----------|----------|-------------------------|-------|------------|--------------------|------|-----------------|-----------------|-----|
| Study or Subgroup | Events | Total | Events | Total | Weight | M-H, Fixed, 95% C | I | M-H, Fixe | ed, 95% CI | |
| Chamandi, 2018 | 3 | 101 | 9 | 228 | 48.0% | 0.74 [0.20, 2.81] | | | | |
| Damluji, 2018 | 6 | 43 | 11 | 112 | 47.0% | 1.49 [0.51, 4.31] | | _ | | |
| Kirker, 2017 | 0 | 25 | 0 | 12 | | Not estimable | | | | |
| Thourani, 2015 | 0 | 11 | 4 | 172 | 5.0% | 1.63 [0.08, 32.12] | | | | |
| Total (95% CI) | | 180 | | 524 | 100.0% | 1.14 [0.52, 2.52] | | | | |
| Total events | 9 | | 24 | | | | | | | |
| Heterogeneity: Chi ² = 0 | .69, df = | 2 (P = 0 | 0.71); l ² = | 0% | | | 0.01 | 0.1 | 10 | 100 |
| Test for overall effect: Z = 0.32 (P = 0.75) | | | | | | | | Eavours TC-TAVR | Favours TT-TAVR | 100 |

F: Major Vascular complications





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52 % and 36.2 % respectively. The echocardiographic characteristics were as follows: mean aortic valve area of 0.7 cm², mean transaortic valve gradient of 40.7 mmHg and mean left ventricular ejection fraction of 51.2 %.

Table 2 summarizes the patient demographic and clinical characteristics of the different studies.

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 % and Evolut R – 6.4 % General anesthesia was used in 91 % of all TC-TAVR procedures.

Table 3 summarizes the methods and materials used in the transcarotid TAVR procedure.

3.4. Outcomes

3.4.1. Transcarotid vs. transthoracic TAVR

Compared with transthoracic TAVR, TC-TAVR patients had lower odds of 30-day MACE [7.8 % vs 13.7 %; OR 0.54 (95 % CI 0.29–0.99, P = 0.05) $I^2 = 0$ %, Fig. 2A] and major or life-threatening bleeding [4.0 % vs 14.2 %; OR 0.25 (95 % CI 0.09–0.67, P = 0.006) $I^2 = 0$ %, Fig. 2B]. There was no significant difference in 30-day: mortality [5.0 % vs 8.6 %; OR 0.61 (95 % CI 0.29–1.30, P = 0.20) $I^2 = 0$ %, Fig. 2C], stroke or transient ischemic attack [2.8 % vs 4.0 %; OR 0.65 (95 % CI 0.25–1.73, P = 0.39) $I^2 = 0$ %, Fig. 2D] and moderate or severe aortic valve regurgitation [5.0 % vs 4.6 %; OR 1.14. (95 % CI 0.52–2.52, P = 0.75) $I^2 = 0$ %, Fig. 2E]. There was a trend towards fewer major vascular complications in TC-TAVR compared with TT-TAVR [3.0 % vs 7.8 %; OR 0.42 (95 % CI 0.16–1.12, P = 0.08) $I^2 = 0$ %, Fig. 2F].

4. Discussion

Our meta-analysis was done on four studies with outcomes of interest. Compared with transthoracic TAVR, TC-TAVR patients had lower odds of 30-day MACE and major or life-threatening bleeding. There was no significant difference in the odds of mortality, stroke, major vascular complications, and moderate or severe aortic valve regurgitation.

A higher proportion of patients undergoing TC-TAVR had a history of PAD but lower proportion with myocardial infarction and their STS scores were lower than in transthoracic 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 control group. 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 TT-TAVR. The carotid artery occlusion is not complete during TAVR since blood flows anterograde around the sheath [11]. 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. [8] Finally, the mid-segment of the common carotid artery that is usually used for access in TC-TAVR usually doesn't have atherosclerosis [8]. The initial risk of stroke among TC-TAVR patients was relatively high, ranging from 5.7 % to 7 % [11,13]. This risk has declined in recent studies due to the use of smaller delivery catheters. [23]. Some recent studies have also used local anesthesia which might reduce hypotensive episodes and consequently watershed stroke events [7,11,24].

The outcomes following the use of alternative access sites in TAVR have been variable between studies [25]. According to the STS/ACC TVT registry 2021 data, 4,4 % of TAVR procedures were done through the transapical route which is decline when compared to the 2016 data because it is more invasive and high-risk leading to higher morbidity and mortality [1,26]. this higher morbidity and mortality can be explained by its higher rate of

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complications include major bleeding, accidental coronary artery injury, ventricular apex aneurysm, arrhythmias, and acute kidney injury [25,27–30]. Transaortic access is also invasive and may not be feasible in patients with a history of a sternotomy, chest radiation therapy or patients with coronary artery bypass grafts that overlie the aorta [25]. The higher MACE, major or life-threatening bleeding and major vascular complications with transthoracic TAVR compared with TC-TAVR in this analysis, show a similar pattern to previous studies comparing transthoracic TAVR with TF-TAVR [31–33].

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) [13].

Whether right or left carotid approach leads to better outcomes remains unclear and requires further study.

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: Conceptualization, Formal analysis, Writing – original draft. **Paul Ndunda:** Formal analysis, Writing – review & editing. **Mohinder R. Vindhyal:** Data curation, Writing – review & editing. **Abdullah Abukar:** Conceptualization, Data curation, Writing – review & editing. **Mohammed Abdel-Jawad:** Data curation, Writing – review & editing. **Zaher Fanari:** Writing – review & editing, Investigation, Project administration, Validation.

Declaration of competing interest

All the authors have no declarations to make.

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