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Systematic Review

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Brachial Artery Access for Carotid Artery Stenting: A Pooled Analysis

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ABSTRACT

AIM: To examine the potential of transbrachial access (TBA) in carotid artery stenting (CAS).

MATERIAL and METHODS: This systematic review and meta-analysis aimed to comprehensively evaluate the safety and efficacy of TBA for CAS by conducting a thorough search on Medline, Cochrane Library, Embase, and Web of Science databases. Studies reporting TBA for CAS and evaluating primary outcomes such as good neurological results, procedural success, and complications were included. Studies with fewer than 4 patients were excluded.

RESULTS: After a meticulous selection of 1837 literature articles, 11 studies were meticulously chosen for the comprehensive examination, involving a total of 273 patients. The analysis of nine studies revealed a consistent 100% procedural success rate with minimal variability (95% CI: 98% to 100%). In the final assessment of neurological status across eight studies, good neurological outcomes were observed in 99% (95% CI: 98% to 100%). Additionally, nineteen complications were identified, leading to a 1% rate (95% CI: 0% to 9%). Among the 223 patients in eight studies, resulting in a pooled estimate of 0% mortality (95% CI: 0% to 1%), indicating a favorable safety profile.

CONCLUSION: The results of TBA for CAS demonstrate a highly effective and safe procedure. Despite the limitations, TBA can be an option in patients with no other access available, and further comparative studies are required to establish definitive conclusions.

KEYWORDS: Brachial, Carotid, Carotid artery stenting, Stent, Transbrachial

INTRODUCTION

Carotid artery stenting (CAS) involves the passage of a catheter through the skin and into the narrowed blood vessel, in this procedure a stent is placed inside the vessel to open and prevent it from narrowing again (25). Different accesses are used in current practice, the transfemoral approach (TFA) has been widely utilized (9), and is a well-established treatment even in "high-surgical-risk" patients (4). The transradial artery approach (TRA) has gained notoriety due to several potential advantages (10,19,28). While the

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transbrachial approach (TBA) has emerged as an alternative approach (22).

Recent studies demonstrated comparable safety and efficacy outcomes between TFA and TRA (2,19,28). Previous studies dedicated to assessing the safety and efficacy of TBA for CAS emphasize its potential as a valuable alternative. These trials provide essential insights that contribute significantly to broadening our comprehension of optimal access strategies in the context of carotid artery stenting (13,29).

Transbrachial access for CAS consists of gaining access to the carotid artery through the brachial artery in the arm (22). In cases involving anatomical variations in the aortic arch and supra-aortic vessels, significant peripheral artery disease, or severe obesity, radial or brachial access may be the preferred approach. In these scenarios, both TRA and TBA can serve as alternatives to the femoral approach (13). In this context, although randomized studies providing evidence regarding the indications, advantages, disadvantages, safety, and efficacy of TBA for CAS treatment are notably absent in the existing literature, numerous observational studies have emerged, presenting promising and intriguing findings (13,16).

Evaluating the safety and efficacy of employing TBA in CAS becomes an imperative endeavor in light of these considerations. This evaluation establishes synthesized data of TBA as a treatment option, crucial for enhancing patient outcomes and minimizing potential complications, and for enabling objective comparisons with the other approaches utilized for CAS. Therefore, we undertook a systematic review and a pooled analysis to comprehensively examine the potential of TBA in CAS. Through these endeavors, we aimed to elucidate the safety, feasibility, and efficacy of employing TBA in CAS.

MATERIAL and METHODS

Eligibility Criteria

This meta-analysis encompasses all studies that reported TBA for ACS. To minimize bias, studies with fewer than 4 patients or where the primary outcome was not identified were excluded. Additionally, letters, case reports, and comments were also excluded.

Search Strategy

To identify relevant studies, a systematic search was performed across four bibliographic databases: Medline, Cochrane Library, Embase, and Web of Science databases. The search strategy was carefully crafted to conduct a thorough investigation of the topic, utilizing a comprehensive combination of relevant keywords. The specific keywords employed included: “carotid”, “brachial”, “transbrachial”, “TBA”, “stent”, and “stenting”.

Outcomes Definitions

The success of the procedure was determined by the successful insertion of the cannula into the carotid artery and/or by successful dilation using balloons and/or by the placement of stents. Additionally, complications related to the access site were examined. Two criteria were employed to define the outcomes: Good neurological outcomes were attributed to patients with a Modified Rankin Scale (mRs) score between 0 and 2 while patients who either showed improvement or did not experience any change in their neurological status post-procedure were also considered to have achieved favorable outcomes. This criteria was applicable to patients whose neurological condition remained stable without any deterioration. The utilization of these dual criteria enabled a comprehensive evaluation and categorization of patients with favorable neurological outcomes for the purpose of this study.

Statistical Analysis

This systematic review and meta-analysis were performed per the Cochrane Collaboration and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement guidelines (26). Relative risk (RR) with 95% confidence intervals were used to compare outcome treatment effects. I^2 statistics were used to assess for heterogeneity; p-value inferior to 0.05 and $I^2<35\%$ were considered significant. Statistical analysis was performed using the software R (version 4.2.3, R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Study Selection

A total of 1837 articles were found: 558 in Medline, 1234 in Embase, and 45 in Cochrane databases. A total of 963 non-duplicate citations were screened and after a thorough review 914 articles were excluded per title or abstract screen, and 49 articles were selected after reading the abstract for a full-text review. Next, 38 articles were excluded before data extraction. Finally, 11 studies were included in the final analysis. The search is described in Figure 1.

Patient Baseline Characteristics

This systematic review and pooled analysis on carotid artery stenting with transbrachial access included a total of 11 studies involving 273 patients. Out of the 11 studies, eight reported the mean age of the patients, the median of the mean age in years was 72.85. Also, out of the 11 studies, nine reported procedural success, and eight reported neurological outcomes compared to pre-procedural status and stenosis localization. Regarding the duration of follow-up, information on the length of time was available in two studies, both spanning 1 month.

Out of the 11 studies, seven reported the neurological status before and after the procedure. Also, eight reported total mortality and ten reported complications. Five studies reported the stenosis diameter. The measurement of stenosis diameter varied across the studies, with the highest level of occlusion on average reported as 81.5% by Tietke et al. in 2008 and the smallest mean reported as 70% by Mori et al. in 2018.

Based on the studies that reported the information, 58.6% of stenosis were located at the left carotid artery and 41.3% at the right carotid artery. Table I provides comprehensive information on procedural success rate, and neurological out-

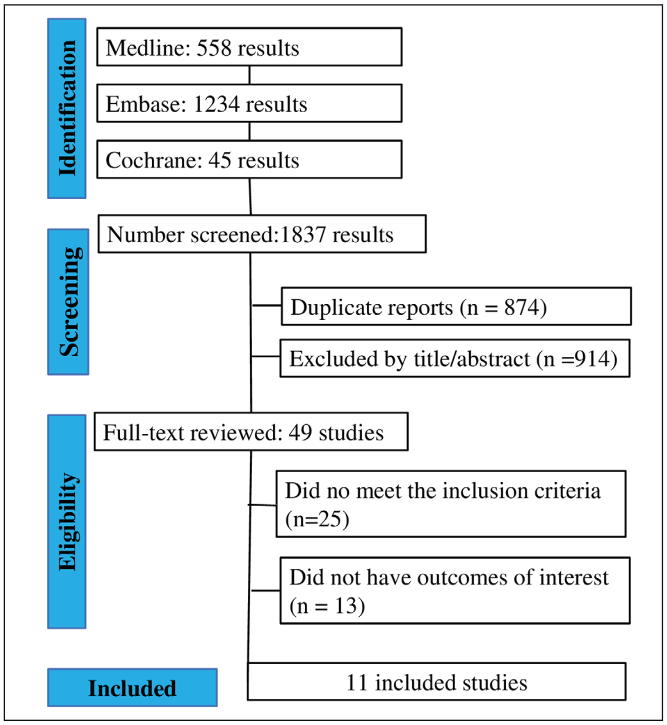

Figure 1: PRISMA flow diagram.

comes compared to the status pre-procedural, stenosis diameter, localization, complications, and mortality.

Three studies reported the use of pre-stent balloons and the type of guide sheath used. Five studies reported the stent used, with the Wallstent (Boston Scientific, Marlborough, MA) being reported in all five studies and being the most commonly used. Eight studies reported details about the diagnostic sheath while six studies reported on distal protection/embolic protection. For a comprehensive understanding of the procedural details and description, please refer to Table II.

Outcomes

Procedural success

Amongst the 178 studied patients, nine articles indicated that 177 had successful treatments. The success rate was consistently 100% (95% CI: 98% to 100%). When analyzing the combined data using a random effects model, the success rate remained 100% (95% CI: 98% to 100%). It's important to note the consistency in the study results containing minimal variations, as illustrated in Figure 2.

Good neurological outcomes

Of the 203 patients examined, eight studies with significant data revealed that 198 achieved good neurological outcomes

Table I: Baseline Characteristics

Study	Type	N°patients	Mean age (years)	Localization	Stenosis Diameter (%)	Procedural Success rate (%)	Good neurological outcomes (%)	Total complications	Mortality	Follow-up (months)
Ercolini et al., 2009, (6)	N/A	16	N/A	L = 16	N/A	100%	100	1	0	N/A
Fang and Wu, 2012, (8)	N/A	61	71	N/A	N/A	100%	92	7	0	N/A
Iwata et al., 2012, (13)	R	62	74	L = 25 R = 37	78.6	100%	100	9	0	N/A
Kasakura et al., 2016, (14)	R	6	NA	L = 3 R = 3	N/A	100%	N/A	0	0	1
Koge et al., 2018, (15)	R	8	74.87	L = 4 R = 4	N/A	100%	100	2	0	N/A
Mori et al., 2018, (24)	N/A	34	77	N/A	70	100%	N/A	0	N/A	N/A
Sakamoto et al., 2019, (29)	R	27	74.9	L = 12 R = 15	78.4	100%	100	0	0	N/A
Sievert et al., 1996, (31)	N/A	4	70	L = 1 R = 4	77.8	100%	100	0	N/A	N/A
Stankov et al., 2018, (32)	N/A	30	N/A	L = 30	N/A	100%	N/A	0	0	1
Tietke et al., 2008, (33)	N/A	12	67.4	N/A	81.5	92%	100	0	N/A	N/A
Wu et al., 2006, (34)	N/A	13	71.7	L = 7 R = 6	N/A	100%	100	0	0	N/A

***N/A:** Not available; **R:** Retrospective; **L:** Left; **R:** Right.*

Table II: Procedural Description

Study	Pre-stent balloon	Stent (Most common)	Guide sheath	Diagnostic Sheath (cannulating)	Distal protection/ embolic protection
Ercolini et al., 2009, (6)	N/A	N/A	N/A	6F	(16) Embolic protection device
Fang and Wu, 2012, (8)	N/A	N/A	N/A	N/A	N/A
Iwata et al., 2012, (13)	Sterling balloon catheters (Boston Scientific), Rx-Genity (Kaneka Medix or Shiden).	(46) Wallstent (16) Precise	N/A	6F	Angioguard and FilterWire
Kasakura et al., 2016, (14)	N/A	N/A	N/A	N/A	N/A
Koge et al., 2018, (15)	N/A	(8) Wallstent	9F Optimo balloon	3F	(6) Distal filter protection
Mori et al., 2018, (24)	Balloon catheter (Shiden)	N/A	N/A	6F	Spider filter device distal
Sakamoto et al., 2019, (29)	N/A	(26) Wallstent (1) Precise	4F Simmons	6F	(23) Filter; (4) Balloon
Sievert et al., 1996, (31)	N/A	(1) Wallstent	N/A	5F	N/A
Stankov et al., 2018, (32)	N/A	N/A	N/A	6F	N/A
Tietke et al., 2008, (33)	N/A	N/A	N/A	N/A	N/A
Wu et al., 2006, (34)	N/A	(13) Wallstent	6F Kimny	7F	(9) FilterWire; (4) GuardWire

***N/A:** Not available; **F:** French.*

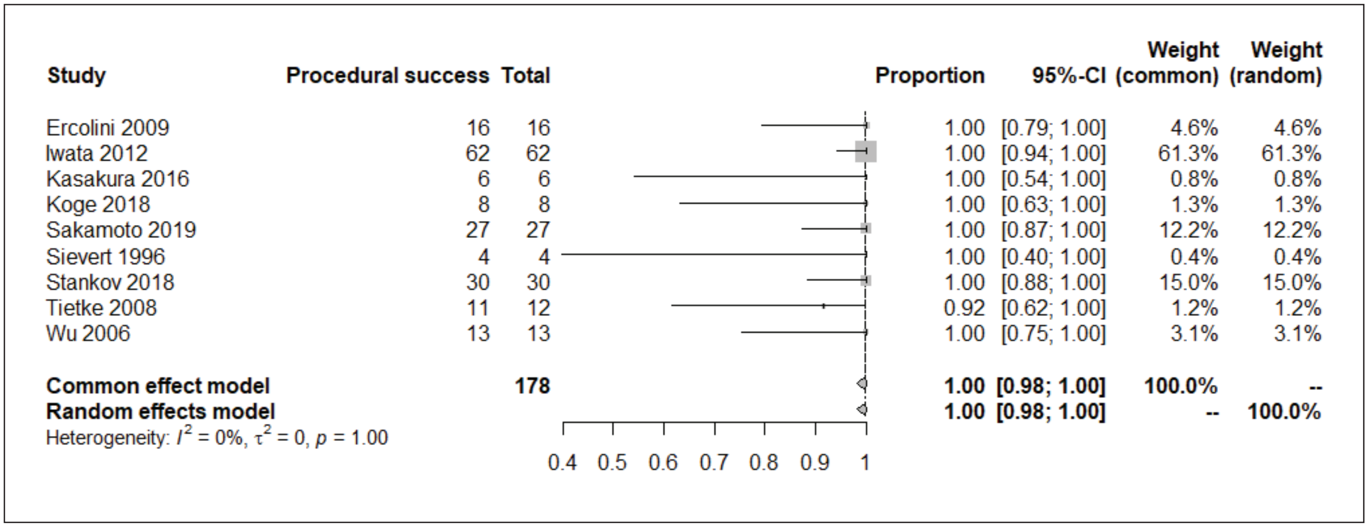

Figure 2: Procedural success.

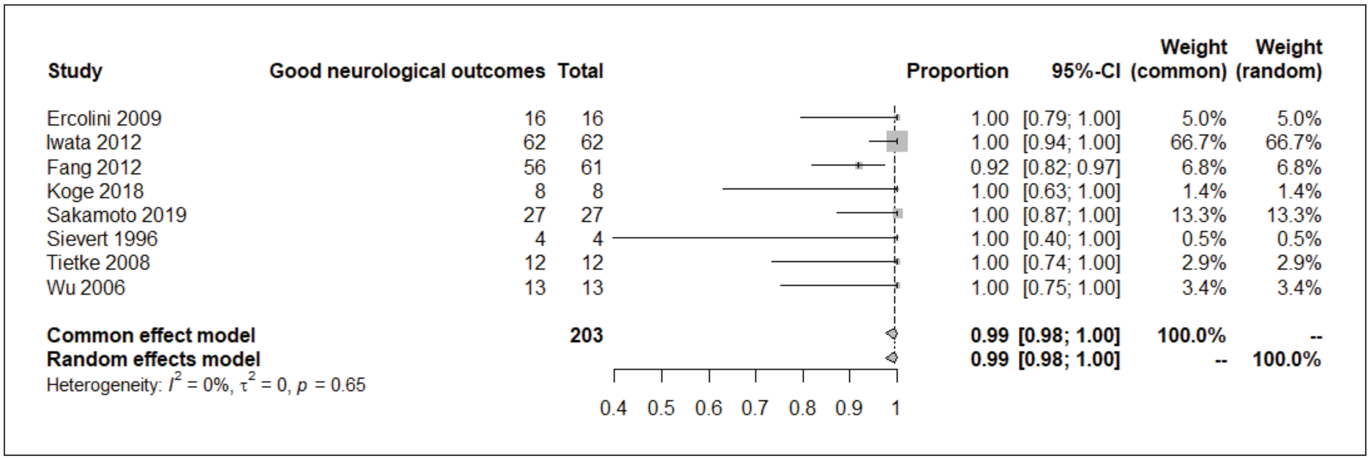

Figure 3: Good neurological outcomes.

after their treatments. Almost all, 99%, experienced good neurological outcomes (95% CI: 98% to 100%). The collective analysis using a random effects model reaffirmed a 99% success rate (95% CI: 98% to 100%). The studies maintained consistency in their findings, with minor discrepancies, as depicted in Figure 3.

Complications related to access

Table III: Complications

Study (year)	Complications
Ercolini et al., 2009, (6)	(1) Thrombosis
Fang and Wu 2012, (8)	(2) Brachial pseudoaneurysm
Iwata et al., 2012, (13)	(1) Transient hemiparesis
Kasakura et al., 2016, (14)	0
Koge et al., 2018, (15)	Embolic; (1) Pseudoaneurysm
Sakamoto et al., 2019, (29)	0
Sievert et al., 1996, (31)	0
Stankov et al., 2018, (32)	0
Tietke et al., 2008, (33)	0
Wu et al., 2006, (34)	0

N/A: *Not available.*

Analysis of the Complications

In the analysis of 239 patients, 6 experienced complications related to the procedure. The combined data from ten studies revealed a complication rate of 1% (95% CI: 0% to 3%). By employing a random effects model, the complication rate was consistently estimated at 1% (95% CI: 0% to 3%). It is noteworthy that the studies exhibited moderate variability in their outcomes, with Figure 4 and Table 3 providing additional information.

Mortality

In Figure 5, it's worth noting that zero of the 223 patients included in the study experienced mortality. When the data from thirteen studies were pooled, a mortality rate of 0% (95% CI: 0% to 1%) was reported. Employing a random effects model for the analysis, the mortality rate consistently remained at 0% (95% CI: 0% to 1%). The studies demonstrated consistent results with minimal disparities, as depicted in the figure.

DISCUSSION

This systematic review and meta-analysis are dedicated to exploring the safety and effectiveness of the use of TBA for CAS. A comprehensive and thorough literature search was conducted to collect data from studies on this subject, aiming to provide a comprehensive understanding of this significant approach for carotid artery stenosis. This analysis incorporates data from 11 studies, focusing on procedural success, clinical results, adverse events, and mortality associated with TBA for CAS.

The key discoveries of this study were: 1) TBA for CAS displayed an exceptionally high rate of procedural success, with a 100% success rate; 2) favorable neurological outcomes were attained in 99% of the cases treated through TBA; 3) the rate of complications was minimal, with only 1% of cases experiencing issues; 4) There were no documented procedure-related fatalities. The chosen studies exhibited low heterogeneity, with an I^2 of 0% for most analyses, except for the complications analysis, which showed significant heterogeneity, with I^2 = 48%. These findings indicate that TBA for CAS is associated with favorable results, including a high rate of procedural success and favorable clinical outcomes, with low rates of complications and no procedure-related deaths. The low heterogeneity among the chosen studies adds further credibility to our findings, making a compelling case for the safety and effectiveness of TBA for CAS.

Despite the favorable results of this study, TBA for CAS is not as commonly used for carotid revascularization as other techniques (24), as it is viewed as an alternative stenting pro-

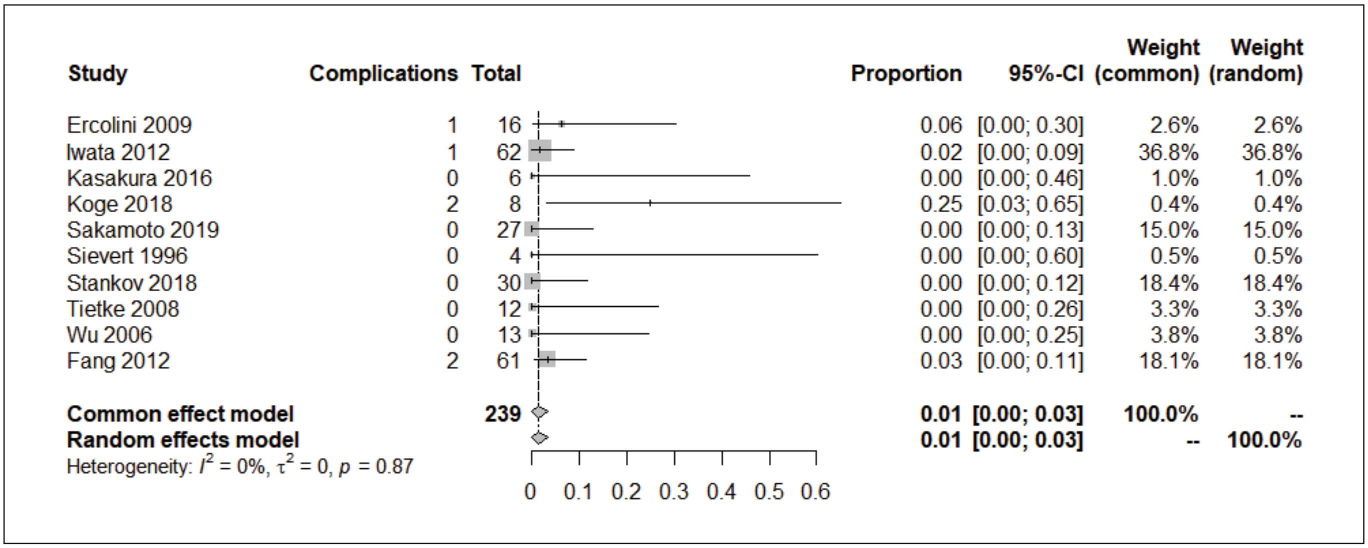

Figure 4: Complications.

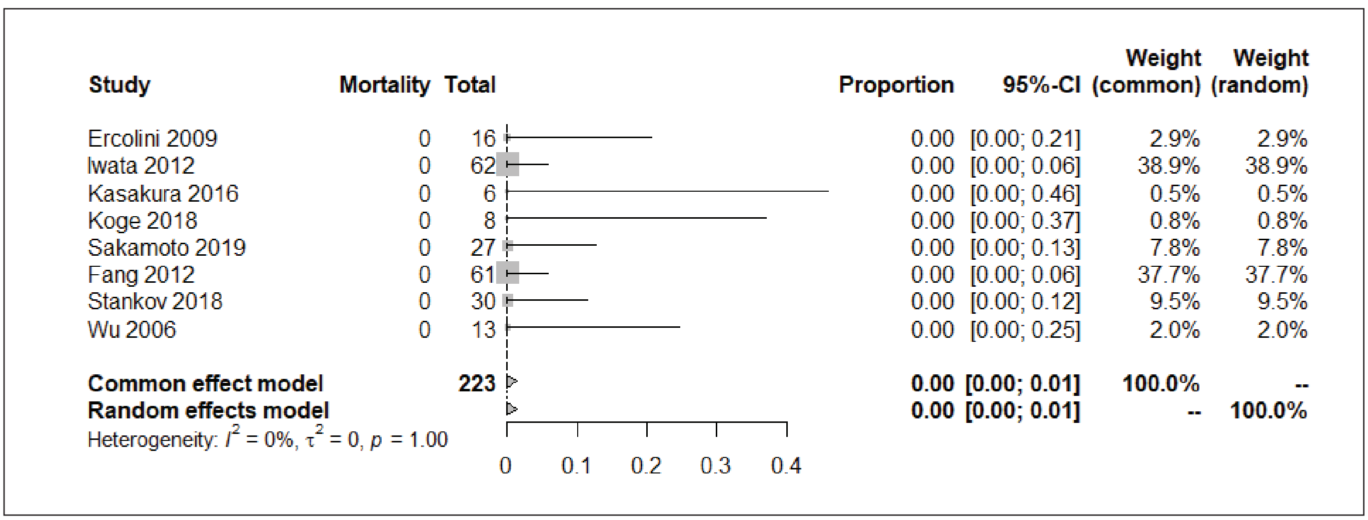

Figure 5: Mortality.

cedure. More popularly used approaches include the novelty of transcarotid artery revascularization (TCAR), CAS done by other accesses, and carotid endarterectomy (CEA); a more established technique besides its extensive adoption, often attributed to its safety as there is an elevated risk of stroke associated with stenting (2,3,8,9,23,30), CEA presents higher risks of myocardial infarction (9). Regarding CAS, TRA has gained notoriety as a substitute for TFA, since it shows to be more comfortable for the patient, has faster recovery times, and causes fewer bleeding-related complications when compared to the more established TFA for CAS (10,19,28). This may happen given that the radial artery is a more compressible site, thus presenting a lower risk of puncture-related complications when compared to TFA. As a result, it has gained broader acceptance, particularly with the advancements in navigational catheters and devices. Recent research shows that there is no significant difference between the two access techniques in terms of complications and length of hospital stay. However, a significant difference is observed in the rate of cross-over, with the TRA (24) being more frequently involved. This is expected, as TRA is often considered a complementary technique with higher success rates in certain patients, such as those with unfavorable aortic arch morphology (9).

In turn, TBA has also been gaining notoriety as an effective alternative when TFA for CAS is unsuitable due to anatomical anomalies or diseases of the aorta or peripheral arteries (5,11,31,32), which is the common motivation for TRA use (1,7,21). Nevertheless, due to anatomical characteristics of the brachial artery, such as the fact that it is a more proximal and deeper artery, TBA is normally considered after TRA is first deemed unfavorable, as complications involving the brachial artery may have worse outcomes. The preference for TBA may arise when navigating the aortic arch through TRA pose challenges or in specific patient cases. Patients with stenotic lesions secondary to peripheral atherosclerotic disease, with increased vasospasm risk, with concerns for dissections or presenting anatomical irregularities may hinder the use of TRA. In such patients, TBA emerges as a viable, efficient, and secure alternative. However, in the sense that these both approaches are used as substitutes for the more habitual TFA, these accesses are typically put in the same category when comparative clinical studies are done. Therefore, the lack of such studies and even case series reporting the use of TBA specifically leaves room for investigations such as the one presented in this pooled analysis, revealing the need for studies that actively compare TBA with other approaches in suitable patients. This compromises an important investigation because, although both TBA and TRA can be used as alternatives to TFA, TBA still commonly represents a secondary strategy when TRA is not suitable.

In the analysis of the circumstances favoring TBA over TRA, certain recurring criteria have surfaced. TBA was frequently preferred to when employing larger guiding catheters, such as a 7-French or larger arterial sheaths, due to the smaller diameter of the radial artery compared to the brachial artery, rendering TBA access to be considerably superior in that matter. In instances involving taller patients, TRA often became unfeasible due to constraints in guiding catheter length, thus leading to a preference for TBA. Notably, Yip et al. utilized a 175 cm height threshold as a determinant for TBA suitability (35). Furthermore, TBA was also favored over TRA when patients presented with a weak or absent radial pulse, an assessment typically carried out through palpation. In Montorsi et al. study of 2016, when both arteries were deemed viable, the radial approach was the top choice, especially in cases requiring filter protection. However, when proximal embolic protection was needed, either the radial or brachial approach was considered as such devices usually request larger catheters. In their subsequent assessment in 2021, they mentioned the preference for TBA in patients who had undergone multiple previous catheterizations of the radial artery for CAS. Additionally, in the context of female patients, particularly those with a history of prior radial artery catheterization or a weak radial pulse, TBA was the initial preference in Montorsi et al. practice. Yip et al. also utilized Allen's test to determine the chosen access — if it produced positive results in both hands, TBA was selected (35).

While this analysis revealed a relatively low complication rate, with only 19 out of 239 patients experiencing any complication, it is important to acknowledge the potential risks associated with TBA for CAS. Three potential risks associated with the approach include the development of a pseudoaneurysm in the brachial artery, median nerve palsy, and brachial artery occlusion. Of all the included articles, only the study by Fang and Wu presented a detailed comparison between TBA and TRA complications. In their analysis, sheathless TRA had only one transient ischemic attack (TIA) as a neurological complication and none puncture-site complications, while TBA had five neurological complications and two pseudoaneurysms that required surgical repair as a puncture-site complication (8). Besides the articles presented in this review, the current literature still lacks more comprehensive reports or reviews of complications related to TBA for CAS, and there are even fewer comparisons with other accesses for CAS or other techniques for treating carotid artery stenosis. However, insights from cardiac angiography can be used to extrapolate potential risks associated with brachial access. In this regard, a recent meta-analysis by Mele et al. reported complication rates ranging from 0.4% to 6.2% for bleeding at the access site in TBA, with a significantly higher range of 0.6% to 25% for TFA; importantly, the relative risk did not show statistically significant differences in the case of any site complications (18). Another review, conducted by Mantripragada et al., assessed the major access site complications rate of TBA in a more broadly way, which was done including studies that investigated its use in different endovascular procedures (17). In this study, the authors stated that TBA access complications, with a rate of 5.27%, appear to be more frequent than those of TFA and TRA.

Finally, it is important to show that TBA holds the expected results for stenting techniques. In terms of good neurological outcomes, TRA and TFA have both shown high success rates in previous studies, with a rate of 98% to 100% (1,2,19,20). Similarly, our analysis demonstrated a 99% success rate. Complication rates also followed a consistent pattern, with TBA showing similar results to TFA and TRA (12,20,27). Furthermore, it is noteworthy to mention that zero of the included studies reported procedure-related deaths, consistent with findings from previous research on TRA and TFA. Likewise, some studies reported low mortality rates, such as 0.79% for TFA and 0.94% for TRA (1,12,19,28). Therefore, the current study and the broader literature affirm the overall safety of these procedures, but further investigation is still needed to better differentiate the risks and benefits of each approach.

Limitations

It is crucial to acknowledge the limitations of the present study. Initially, the inclusion of observational studies introduces bias into the analysis. Furthermore, while most studies did not report the study design, and those that did, were predominantly retrospective, contributing to a biased analysis. Other factors to consider include the lack of available and consistent eligibility criteria for brachial access across all studies. The analysis is based on a relatively small number of studies and patients, indicating the need for additional research with larger sample sizes to validate our findings. Therefore, while the current pooled analysis synthesizes all the useful scientific literature found in the selected databases, it does not determine the benefits and drawbacks of TBA for CAS compared to other accesses. Prospective studies could enhance our understanding of this technique, which is still lacking in the literature, increasing the risk of bias in our analysis and limiting the level of evidence presented in this review. Additionally, bias related to the expertise and experience of each operator and their center may arise, especially when analyzing TBA, a less common approach for CAS compared to TFA and TRA.

CONCLUSION

This systematic review and meta-analysis aimed to assess the safety and effectiveness of TBA for CAS based on data from 11 studies. Despite the observed favorable results, TBA is not as widely adopted for carotid revascularization compared to other techniques, being considered a secondary strategy after TRA when anatomical challenges or complications arise. Preferences for TBA over TRA are influenced by factors such as guiding catheter size, patient height, radial pulse strength, and previous catheterization. The study acknowledges potential risks such as pseudoaneurysm and median nerve palsy associated with TBA for CAS, despite a relatively low complication rate. While TBA shows promise as an alternative, especially for patients unsuitable for TFA or TRA, further research is crucial to comprehensively understand the risks and benefits, considering the limitations of this study, including biases introduced by observational studies and the need for larger sample sizes.

Declarations

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Availability of data and materials: Not applicable.

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AUTHORSHIP CONTRIBUTION

Study conception and design: MPS

Data collection: SB, GMS, LBO, JVDS, RMB, FFA, ACP

Analysis and interpretation of results: MPS

Draft manuscript preparation: MPS, SB, GMS, MYF, LBO, JVDS, RMB, FFA, ACP, RB, JAAF

Critical revision of the article: RB, JAAF

Other (study supervision, fundings, materials, etc...): MPS, SB, MYF, LBO, JVDS, RMB, FFA, ACP, RB, JAAF

All authors (MPS, SB, GMS, MYF, LBO, JVDS, RMB, FFA, ACP, RB, JAAF) reviewed the results and approved the final version of the manuscript.

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