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Original article

Transradial Carotid Artery Stenting: A Comprehensive Registry Analysis and Comparative Evaluation of Access Routes for Improved Outcomes

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Abstract

Introduction. Carotid artery stenting via the radial route is being investigated as a potential strategy to mitigate access-related bleeding in carotid artery interventions. Ongoing trials and procedural initiatives seek to enhance the overall efficacy of these interventions. The utilization of transradial access (TRA) for Carotid Artery Stenting (CAS) holds promise in reducing bleeding incidents compared to the traditional transfemoral approach (TFA).

Methods. Clinical trials are currently examining the comparative benefits of carotid revascularization versus exclusive reliance on best medical therapy for asymptomatic patients. Our interventions primarily targeted symptomatic or high-grade carotid stenosis. A comprehensive five-year registry analysis of carotid artery stenting was conducted, encompassing a comparison of outcomes between transfemoral and trans-radial interventions, as well as inter-operator and patient subset analyses.

Results. Over the five-year period from 2018 to 2022, a total of 573 CAS procedures were performed. The majority of patients (77%, or 442) underwent TRA, with a predominant male representation (68%). Four operators exhibited varying proportions of TRA/TFA utilization, and the choice of approach was at the operator's discretion. The interventions predominantly involved the use of embolic protection (EP). The primary outcome measure, encompassing major events such as stroke, death, or bleeding, occurred more frequently in the TFA group, with rates of 6.2% (8/131) compared to 2.5% (11/442) in the TRA group, resulting in an overall incidence of 3.3% major adverse events in the entire registry. Notably, the majority of major adverse events were attributed to bleeding, with rates of 3.8% in the TFA group and 1.6% in the TRA group.

Conclusions. While our findings suggest superior outcomes for TRA CAS compared to TFA CAS, it is important to acknowledge the presence of real and significant confounding factors associated with operator variability and the absence of randomization between groups. Consequently, statistical comparisons are deemed neither fair nor scientifically robust in this context. This observational analysis of registry data serves as a hypothesis-generating exercise, underscoring the necessity for further investigations into the impact of access route on CAS outcomes.

Kew words carotid artery stenting, trans-radial approach

Introduction

Carotid artery stenting via the radial route is being explored as a potential strategy to minimize access-related bleeding in carotid artery interventions.[1] Minimally invasive percutaneous endovascular neurointerventions have rapidly evolved and gained more popularity over the past three decades, overshadowing conventional surgical repair.[2] Ongoing trials and procedural initiatives aim to enhance the overall efficacy of these interventions. The utilization of transradial access (TRA) for Carotid Artery Stenting (CAS) holds promise in reducing bleeding incidents compared to the traditional transfemoral approach (TFA).[3] CAS has become an accepted alternative to carotid endarterectomy for revascularization of the internal carotid artery (ICA) among high-risk patients. The femoral approach in CAS can present challenges due to access site complications, technical difficulties related to peripheral vascular disease (PVD), and anatomical variations of the aortic arch.

Traditionally, transfemoral arterial access is the preferred approach for CAS due to broad operator experience, ease of navigating the carotid vasculature from the aortic arch femorally, and the larger vessel size allowing for a wide range of devices. However, anatomical variations, advanced atherosclerotic disease, severe iliac artery tortuosity, peripheral arterial disease, and morbid obesity can complicate selective catheterization of the carotid arteries via the femoral route. This complexity may lead to a higher risk of access site complications, prolonged multiple catheterization attempts, and potentially in-

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crease the risk of cerebral embolization and stroke.[1,2,3,4] Our interventions primarily targeted symptomatic or high-grade carotid stenosis, with all cases having CA stenosis greater than 80% and comorbid conditions increasing the risk of carotid endarterectomy. A comprehensive five-year registry analysis of carotid artery stenting was conducted, comparing outcomes between transfemoral and transradial interventions, as well as inter-operator and patient subset analyses.

Methods

Patients undergoing CAS are generally at higher risk for vascular access-related complications and bleeding. This is due to the use of larger-bore catheters compared to coronary procedures, and carotid atherosclerosis is often associated with lower-limb arteriopathy. Carotid artery stenting is typically performed through femoral vascular access using 6–9 Fr guiding catheters. [5]Transradial CAS (TRCAS), though performed routinely in very few centers worldwide, is reserved for selective cases. Thorough imaging of the aortic arch and supra-aortic vessels with computed tomography or magnetic resonance is considered helpful in meticulous planning for this approach. TRCAS is indicated for cases like a Type 2 bovine arch with left internal carotid artery (LICA) stenosis, while right ICA (RICA) stenosis with Type 2 or 3 aortic arch is considered favorable for transradial access. Lack of other viable peripheral vascular access becomes an obligatory indication for TRCAS. [6]Short hemostasis time could potentially allow operators to perform these procedures without discontinuation of oral anticoagulation. Radial access has been shown to reduce acute kidney injury (AKI) compared to femoral access due to a reduction in bleedings, vascular complications, and renal cholesterol embolization. Early mobilization of patients treated with CAS transradially may also reduce post-procedural hypotension, a determinant of contrast-induced AKI. Clinical trials are currently examining the comparative benefits of carotid revascularization versus exclusive reliance on the best medical therapy for asymptomatic patients.[1,3]

Artery Approach

Transfemoral CAS was performed according to standard clinical practice with the same 6 F guiding sheath choice as radial procedures. For the femoral approach, after local anesthesia, the femoral artery was punctured with a 19-gauge needle through which a J-wire was advanced into the femoral artery. In all cases, a 5 Fr short sheath was introduced initially, and then the procedure was performed using a 6 Fr 90 cm long sheath. The sheath was removed immediately after the procedure, and a closure device (Angio-Seal™; St. Jude Medical, St. Paul, MN, USA) was used. A mechanical compression bandage was used for four hours, and the patients were mobilized afterward.[2,6]

For the radial approach, the wrist is hyperextended, and local anesthesia (1 mL lidocaine 2%) is administered. The optimal access site is 1-2 cm proximal to the styloid processus of the radius bone along the axis with the most powerful pulsation of the radial artery (RA). A 20-G plastic cannula-over-needle (Glidesheath insertion kit, Terumo, Tokyo, Japan) is inserted at a 30” to 60” angle along the vessel axis using the single-wall puncture or, if not possible, counter puncture technique. When good arterial back-bleed is obtained, the 0.021” hydrophilic guidewire is advanced, and the hydrophilic 5-Fr sheath (Radifocus, Terumo, Tokyo, Japan) is introduced over the guidewire.[2,5,6]

Medication

Intra-arterial vasodilator (5 mg verapamil) is injected to reduce RA spasm (RAS). Sedation is only administered to anxious patients because circulating catecholamines can precipitate RAS. Immediately after sheath insertion, intravenous unfractionated heparin (50–70 m/kg, up to 5000 units) weight-based dosage for obese patients is administered. RA angiography is performed through the cannula or sheath before catheter insertion. This crucial step defines the RA anatomy from midforearm to brachial/axilar anastomosis and provides a roadmap for secured access. A diluted solution of 3 mL of contrast mixed with 7 mL of blood is injected briskly and recorded. In cases with RAS, tortuosity, and/or radial loops and high takeoff RA, a careful advancement is attempted under fluoroscopy guidance. In most cases, these anatomic variations may be negotiated for diagnostic carotid arteriography. However, patients with unfavorable RA anatomy (severe tortuosity, significant 360” RA loops, and high-takeoff, small-caliber RA) should not be considered for the use of large-bore devices. All patients were pre-treated with Clopidogrel and Aspirin. Those who were naive to antiplatelet therapy were loaded with 300 mg of Clopidogrel o.d. and/or 250 mg of Aspirin i.v. 12–24 h before the procedure. Oral anticoagulation with Apixaban or Rivaroxaban was not suspended before the procedure when indicated for any patient in any group. After the completion of the procedure, hemostasis was obtained using a TR Band (Terumo Corporation, Japan). After discharge, the majority received DAPT for 1 month, and a minority of patients in need of anticoagulation received triple antithrombotic therapy.[6]

Carotid Angiography

First, an aortography was performed in LAO 30 projection with a small contrast volume (15 ml at 10 ml/s) to visualize the aortic arch. Then, the non-symptomatic or non-severely stenotic carotid artery was cannulated. Secondly, the diseased common carotid artery (CCA) was deeply engaged with the Simmons 1 catheter.[5,6] There are two simple methods of utilizing the natural reversed curve of the Simmons catheters within the aortic arch. The first involves passing the catheter over a standard 0.035” wire previously positioned into the descending thoracic aorta. The shape is reformed by withdrawing the guidewire into the primary curve and furthermore to prolapse the catheter into the ascending aorta with a quarter up to half rotation. The second is a loop in the ascending aorta using a hydrophilic Glidewire or another extra support wire in patients with a

very tortuous and dilated aortic arch. In any case, the catheter should be withdrawn and directed to engage the left carotid and then into the right common carotid.[2]

Carotid Intervention

The target common carotid artery (CCA) was initially cannulated via the radial artery using a 5F Simmons 1 or 2 diagnostic catheter, which was then advanced to the external CA (ECA) over an extra support 0.014" coronary guidewire. After removing the coronary guidewire, a 0.035" guidewire was advanced into the ECA, and the Simmons 1 was exchanged for a 5F or 6F shuttle sheath and positioned in the distal CCA. The diagnostic catheter is removed, keeping the position of the super stiff wire constant in the distal branch of the ECA (i.e., the superficial temporal branch). When a severe stenosis of the ECA was also present, the tip of the stiff wire was shaped as a pigtail to increase support and positioned in the distal CCA.[1,2,6] The 6 Fr × 90 cm introducer sheath (DestinationTM, Terumo, Japan; Flexor ® Shuttle Select®, Cook Medical, Bloomington, IN, USA, sometimes Flexor Shuttle Guiding Sheath 6 Fr × 110 cm) was positioned in the CCA. The wire and dilator are then removed slowly, leaving the sheath in a secure position in the mid-CCA. CAS was performed under local anesthesia without sedation. Blood pressure, pulse, and oxygen saturation were continuously monitored throughout the procedure, and neurological assessment was performed by experienced nursing staff.[6]
Transfemoral CAS was performed according to standard clinical practice with a guiding sheath, and the same embolic protection and stents in both groups.

Definitions

A successful angioplasty was defined as no more than 30 percent post-intervention stenosis and an improvement of at least 20 percent in the degree of stenosis. Access-site bleeding was considered major if associated with a hemoglobin loss of at least 2 mmol/l, administrations of blood transfusions, vascular repair, and prolonged hospitalization, and minor if bleeding at the vascular access site only resulted in hematoma formation and did not require specific therapy or interruption of antiplatelet or anticoagulation regimen.[6,7] Major Adverse Cardiovascular and Cerebrovascular Events (MACCE) were assessed as the composite of stroke, death, non-fatal acute myocardial infarction, repeated revascularization of the target vessel by percutaneous transluminal angioplasty (PTA), or vascular operation during the hospital stay and at 30 days. Stroke was defined as an acute neurological event with focal symptoms and signs lasting >24 hrs and was considered a complication of carotid revascularization if it occurred within 30 days of the procedure. Independent certified personnel performed baseline and post-procedure neurological assessments on all patients.[4,7]

Results

Over the five-year period in a single center, a total of 573 CAS procedures were performed. The majority of patients (77%, or 442) underwent TRA, with a predominant male representation (68%). Four operators exhibited varying proportions of TRA/TFA utilization, and the choice of approach was at the operator's discretion. The interventions predominantly involved the use of embolic protection (EP). The primary outcome measure, encompassing major events such as stroke, death, or bleeding, occurred more frequently in the TFA group, with rates of 6.2% (8/131) compared to 2.5% (11/442) in the TRA group, resulting in an overall incidence of 3.3% major adverse events in the entire registry. Notably, the majority of major adverse events were attributed to bleeding, with rates of 3.8% in the TFA group and 1.6% in the TRA group.
Two of the operators contributed to the TFA group far more than the other two who performed over 96% of CAS via radial or ulnar artery. This creates bias in the data regarding access and complications. Thus, the 27 percent of attempted radial and switched towards femoral is biased and not reliable for all operators. This is the reason we only count frequencies and simple proportions without any statistical comparison between the radial and femoral group.

Discussion

This study has various limitations. It is a prospective single-center, single-arm observational registry, with the intrinsic shortcomings of potentially limited external validity and intrinsic bias. The sample size was relatively small. Nevertheless, this study represents the real-life report on the use of radial access for carotid artery stenting. While our findings suggest superior outcomes for TRA CAS compared to TFA CAS, it is important to acknowledge the presence of real and significant confounding factors associated with operator variability and the absence of randomization between groups. Consequently, statistical comparisons are deemed neither fair nor scientifically robust in this context. Data suggested comparable procedural outcomes between the transradial and transfemoral approaches when performing carotid stenting; however, high-level evidence regarding postoperative brain images and the risk of stroke are lacking.[1,7] Therefore, it is reasonable for interventionists to weigh up the risks of neurological events and potential benefits, including fewer access site complications, before choosing the radial or femoral arteries as access sites. Future large-scale randomized controlled trials are imperative.[1,3,7]

Conclusion

TRA showed less access bleeding than femoral. This observational analysis of registry data serves as a hypothesis-generating exercise, underscoring the necessity for further investigations into the impact of access route on CAS outcomes.

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Sažetak

Trans-radijalno stentiranje karotidne arterije: Sveobuhvatna analiza i komparativna evaluacija pristupnih mesta za poboljšani ishod

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Uvod. *Stentiranje karotidne arterije radijalnim putem se istražuje kao potencijalna strategija za ublažavanje krvarenja vezanog za pristup u intervencijama na karotidnoj arteriji. Tekuće proceduralne inicijative nastoje da poboljšaju ukupnu efikasnost ovih intervencija. Korišćenje trans-radijalnog pristupa (TRA) za stentiranje karotidne arterije (CAS) obećava smanjenje incidenata krvarenja u poređenju sa tradicionalnim transfemoralnim pristupom (TFA).*

Metodi. *Klinička ispitivanja trenutno ispituju komparativne prednosti karotidne revaskularizacije u odnosu na isključivo oslanjanje na najbolju medicinsku terapiju za asimptomatske pacijente. Naše intervencije su prvenstveno bile usmerene na simptomatsku ili karotidnu stenozu visokog stepena. Sprovedena je sveobuhvatna petogodišnja analiza stentiranja karotidnih arterija, koja je obuhvatala poređenje ishoda između trans-femoralnih i trans-radijalnih intervencija.*

Rezultati. *Tokom petogodišnjeg perioda od 2018. do 2022. godine obavljene su ukupno 573 CAS procedure. Većina pacijenata (77% ili 442) je podvrgnuta TRA, pri čemu je dominantna zastupljenost muškaraca (68%). Četiri operatera su pokazala različite proporcije korišćenja TRA/TFA, a izbor pristupa bio je na diskreciji operatera. Intervencije su pretežno uključivale upotrebu embolijske zaštite (EP). Primarna mera ishoda, koja obuhvata glavne događaje kao što su moždani udar, smrt ili krvarenje, javljala se češće u TFA grupi, sa stopama od 6.2% (8/131) u poređenju sa 2.5% (11/442) u TRA grupi, što je rezultiralo sa ukupnom incidencom od 3.3% velikih neželjenih događaja u celom registru. Značajno je da je većina velikih neželjenih događaja pripisana krvarenju, sa stopama od 3.8% u TFA grupi i 1.6% u TRA grupi.*

Zaključci. *Dok naši nalazi ukazuju na superiorne rezultate za TRA CAS u poređenju sa TFA CAS, važno je istaći prisustvo značajnih dodatnih faktora povezanih sa ekspertizom operatera i odsustvom randomizacije između grupa. Shodno tome, statistička poređenja se u ovom kontekstu ne smatraju naučno robusnim. Ova opservaciona analiza podataka iz registra služi za stvaranje hipoteze, naglašavajući neophodnost daljih istraživanja uticaja pristupne rute na ishode CAS-a.*

Ključne reči: *stentiranje karotidne arterije, trans-radijalni pristup*