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On behalf of the Society for Vascular Surgery (SVS) Patient Safety Organization (PSO) Vascular Quality Initiative (VQI), we would like to offer comment on the National Coverage Determination (NCD) 20.7: Percutaneous Transluminal Angioplasty (PTA) that provides coverage for carotid artery stenting (CAS).

Executive Summary

The role of Transfemoral Carotid Artery Stenting (TfCAS) is not well defined. Multiple studies have found a prolonged learning curve with adoption of TfCAS raising concern about the generalizability of highly selective clinical trials[1,2,3,4,5,6].

The SCAI/SVMB/SVS credentialing document[7] and the SCAI/SVM expert consensus statement[8] on carotid stenting both require a "quality assurance program specifically designed to assess CAS outcomes". They also recommend "institutional participation in a nationally recognized outcomes database, with mandatory submission of individual operator and institutional outcomes data"[7,8]. VQI agrees with the need for mandatory participation in a national registry as a prerequisite for credentialing and performance of carotid stenting.

Data from the FDA approved SVS VQI TransCarotid Revascularization Surveillance Project[9] has produced the following evidence on TransCarotid Artery Revascularization (TCAR) in comparison to other treatments as well as the impact of different clinical scenarios and risk factors – abbreviated list.

- **TCAR vs Carotid Endarterectomy (CEA)**
  - The perioperative stroke/death rate of TCAR was similar to that of CEA while CNI risk was lower[10]
  - No significant differences in ipsilateral stroke/death-free survival were observed between TCAR and CEA[11]

- **TCAR vs TfCAS**
  - Transcarotid artery revascularization, compared with transfemoral carotid artery stenting, was significantly associated with a lower risk of stroke or death[12]
  - Two nonrandomized studies suggested that TCAR was associated with lower risk of stroke and death as compared with TfCAS.[10]

- **Impact of advanced age**
  - TCAR and CEA can be safely offered to older adults. TfCAS should be avoided in older patients when possible[13]
- **Impact of calcified carotid arteries**

- TCAR demonstrated favorable outcomes compared with TfCAS among patients with calcification greater than 50% of the carotid circumference. Advance burden of carotid artery calcification was associated with worse outcomes in TfCAS but not TCAR[14]

The SVS VQI would propose an effort to better define the role of TfCAS in carotid intervention. *The **VQI TfCAS Surveillance Project** is designed to monitor the safety and effectiveness of stents placed into the carotid artery via a transfemoral (and other) access. The project will compare TfCAS (and other access) with standard carotid endarterectomy in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative. The Primary Outcome Measures would be One-year ipsilateral stroke or death and the Secondary Outcome Measures would be 1). 30-day Stroke or death and 2). 30-day Stroke, death or myocardial infarction.*

The VQI TfCAS Surveillance Project will address the current knowledge gap for carotid intervention and help us better understand the role of TfCAS. The steering committee will include representation from SVS, ACC, SVM and SIR.

SVS VQI Comment

VQI is a clinical registry focused on quality improvement that collects clinical, procedural, and outcome data (out to 1 year) on vascular disease[15]. There are over 1000 participating centers and 6000 participating physicians nationally. Within VQI, less than half of the members identify themselves as vascular surgeons (44%), with strong representation from interventional cardiology (16%), interventional radiology (14%), general surgery (6%), cardiothoracic surgery (5%), neurosurgery (4%), podiatry (3%), orthopedic surgery (2%) and neurology (1%). VQI members come from a broad spectrum of facilities - including academic medical centers (32%), teaching hospitals (32%), and community sites - hospitals and office-based laboratories (37%). The patient population in VQI closely mirrors the United States population of patients with vascular disease. VQI has collaborative relationships with other professional societies including partnerships and endorsements by the American College of Cardiology (ACC), American Heart Association (AHA), Society of Vascular Medicine (SVM), Vascular Access Society of America, American Venous Forum, Society of Vascular Ultrasound, and multiple other vascular and regional vascular societies. VQI was started in 2003 and is a robust source of data for analysis with over 1 million patients in the registries. In 2020, the ACC National Cardiovascular Data Registry merged its Peripheral Vascular Intervention registry with VQI. The AHA was a founding partner in the creation of the VQI Vascular Medicine Consult registry. The CEA registry has almost 200,000 procedures and the CAS registry has almost 100,000 procedures with follow up. VQI registry data has been the basis of over 600 peer reviewed publications as well has hundreds of quality improvement projects. VQI has supported multiple industry post-approval trials and EU MDR reports. VQI data has been used by federal regulatory agencies for device evaluation and label expansion.

There are two procedural registries in VQI for patients undergoing carotid intervention, carotid endarterectomy and carotid artery stenting, (including transfemoral, transcarotid, transradial and transbrachial access) measuring all different forms of neuroprotection (filters and flow reversal)[16].

As CMS is reconsidering the NCD 20.7, VQI would like to offer the following comment. There is significant controversy regarding the efficacy and role of CEA vs CAS. Although carotid artery stenting was initially felt to be beneficial for patients at high-risk for carotid endarterectomy, studies have failed to show the value of high-risk criteria for defining patients who would benefit from CAS[17,18]. Some of the high-risk criteria have not been validated as increasing the risk of CEA. Age greater than 80 years has been cited as a high-risk criterion and as such would be an indication for carotid stenting although studies, including the CREST trial, have shown that the risk of transfemoral carotid stenting in this age group is higher than in younger patients[19,13,20]. It is also unclear whether recurrent stenosis or prior radiation therapy represent high-risk criteria[21].

CEA and CAS have been the source of multiple randomized clinical trials and the interpretation of the trial outcomes has been subject to much controversy. Although it is debatable whether the RCT's have shown CEA or CAS to be superior or non-inferior, there is no debate that the RCT's have been done on carefully selected patients by carefully selected providers (often with a run-in period or certification of providers) at select centers (usually carefully selected). TfCAS is described by its advocates as an advanced endovascular technique that requires advanced training and credentialing[22,8,23] and is subject to a prolonged learning curve[1,2,3,3,4,5,6]. It is not clear whether the randomized trial results represent real world performance and are generalizable to widespread clinical adoption without the restrictions on patients, providers, and centers[24,25,26]. There is concern that community practice would not reflect the current trial outcomes that have strict inclusion and exclusion criteria.
In 2016, CMS approved reimbursement for the FDA approved TransCarotid Artery Revascularization (TCAR) based on participation in the SVS VQI TransCarotid Revascularization Surveillance Project[9]. *The VQI TCAR Surveillance Project is designed to monitor the safety and effectiveness of stents placed directly into the carotid artery while reversing blood flow within the carotid artery to reduce stroke risk. It will compare this less-invasive surgical procedure with standard carotid endarterectomy in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative. The Primary Outcome Measures are One-year ipsilateral stroke or death and the Secondary Outcome Measures are 1). 30-day Stroke or death and 2). 30-day Stroke, death or myocardial infarction.*

Since its inception, the SVS VQI TransCarotid Revascularization Surveillance Project has collected data on 40,000+ TCAR, 120,000+ CEA and 35,000+ TfCAS. During this time, the data has been closely monitored by the SVS VQI TransCarotid Revascularization Surveillance Project steering committee and analyzed by others resulting in over 50 publications in peer reviewed journals reporting on the outcomes of TCAR, CEA, and TfCAS. Analysis of data on standard surgical risk patients has allowed expansion of the SVS VQI TransCarotid

Revascularization Surveillance Project from high-risk patients to include standard surgical risk patients[27].

TransCarotid Revascularization Surveillance Project Findings - Data from the SVS VQI TransCarotid Revascularization Surveillance Project has already produced the following evidence published in peer reviewed journals about TCAR and its outcomes in comparison to other treatments as well as the impact of different clinical scenarios and different risk factors.

- **TCAR vs CEA**
  - Despite a substantially higher medical risk in TCAR patients, in-hospital stroke/death rates were similar between TCAR and CEA[28]
  - The perioperative stroke/death rate of TCAR was similar to that of CEA while CNI risk was lower[10]
  - No significant differences in ipsilateral stroke/death-free survival were observed between TCAR and CEA[11]
  - This propensity-score matched analysis demonstrated significant reduction in the risk of postoperative myocardial infarction and cranial nerve injury after TCAR compared to CEA, with no differences in the rates of stroke/death[29]
  - Although CEA remains the gold standard procedure for patients with carotid stenosis, TCAR appears to be a safe alternative to CEA[30]
- **TCAR vs TfCAS**
  - TCAR, compared with TfCAS, was significantly associated with a lower risk of stroke or death[12]
  - Two nonrandomized studies suggested that TCAR was associated with lower risk of stroke and death as compared with TfCAS.[10]
  - In this propensity score-matched analysis, no significant differences in ipsilateral stroke/death-free survival were observed between TCAR and TfCAS[11]
  - Compared with patients undergoing TfCAS, patients undergoing TCAR had significantly more medical comorbidities but similar stroke/death rates and half the risk of in-hospital TIA/stroke/death[31]
  - TCAR performed favorably compared with TfCAS at both time points[30]

- **Impact of advanced age**
  - TCAR and CEA can be safely offered to older adults. TfCAS should be avoided in older patients when possible[13]
  - The advantages of TCAR become more pronounced in elderly patients, with significant reductions in in-hospital stroke compared with TfCAS in patients ≥77 years old[20]
  - TCAR had similar outcomes relative to CEA among octogenarians with respect to 30-day and 1-year rates of stroke/death[32]

- **Impact of calcified carotid arteries**

- TCAR demonstrated favorable outcomes compared with TfCAS with calcification greater than 50%. Advance burden of calcification had worse outcomes in patients undergoing TfCAS but not TCAR[14]
- While increased calcification increased rates of adverse events after TfCAS, this trend was not observed after TCAR, which also had lower rates of death and stroke/death with severe calcification. TCAR had lower risk of mortality than TfCAS in calcified arteries[33]

- **Impact of sex**
  - No sex differences in in-hospital or 1-year stroke/death following TCAR. TCAR appears to be safe as for women as for men with both symptomatic and asymptomatic carotid artery disease[34]
  - Stroke/death and stroke/death/MI rates were similar in symptomatic and asymptomatic males and females treated by CEA or TCAR. TCAR may be a safe alternative to CEA particularly in women while TfCAS is associated with substantial adverse outcomes[35]
- **Impact of contralateral carotid artery occlusion**
  - TCAR has lower odds of in-hospital stroke or death compared to TfCAS, independent of symptomatic status (in patients with contralateral carotid occlusion). Compared to CEA, TCAR seems to be a better option in asymptomatic patients[36]
  - TCAR seems to be safe in patients with contralateral carotid occlusion[36]

- **Impact of symptom status**
  - Findings suggest that classifying patients undergoing TCAR - that patients' specific preoperative neurologic symptoms should instead be used in risk assessment[37]
  - Patients with a remote history of TIA/stroke have increased risk of in-hospital death after TfCAS and may benefit from TCAR[38]
  - TCAR and CEA can be safely offered to symptomatic patients[13]

- **Impact of timing**
  - CEA remains the safest method within the urgent period. Outside of 48 hours, TCAR and CEA have comparable outcomes[39]
  - TCAR within 14 days of a neurologic event resulted in higher ipsilateral postoperative stroke rates compared with CEA, especially when performed within 48 hours after a stroke[40]
  - TCAR had a reduced incidence of stroke when performed after 48 hours. Urgent TCAR within 48 hours of the onset of stroke was associated with a threefold increased risk of in-hospital stroke/death[41]

- **Standard risk patients**

  - TCAR and CEA have equivalent risk of perioperative stroke, death, or myocardial infarction and ipsilateral stroke through 1 year in standard risk patients (compared to high risk patients)[42]
  - TfCAS was associated with an increased risk of perioperative stroke compared to CEA in standard-risk patients[43]

- **Impact of lesion length**
  - Carotid lesion length appears to negatively impact in-hospital outcomes for TCAR and TfCAS. In lesions longer than 25 mm, TCAR appears to be safer than TfCAS with regard to the risk of in-hospital stroke, stroke/TIA, death, stroke/death, and extended length of stay[44]
- **Treatment of restenosis**
  - TCAR was associated with decreased odds of 30-day TIA compared with TfCAS. However, the two treatment approaches were similarly safe in terms of the remaining perioperative outcomes, including stroke and death and stroke, death, and MI[45]
  - TCAR was associated with significantly lower odds of in-hospital stroke, MI, stroke/transient ischemic attack, stroke/death, and stroke/death/MI when compared with redo-CEA and lower odds of in-hospital stroke/transient ischemic attack when compared with TfCAS[46]

- **Treatment of radiation induced lesions**
  - Radiation induced carotid stenosis treated by TCAR had the lowest risk of the composite of stroke, death, and MI and CNI. Therefore, TCAR might be the preferred treatment modality[47]

- **Treatment of patients with a "hostile neck" including radiation**
  - TCAR experienced an increased risk of access site complications; however, the risk for technical failure and postoperative stroke/death, stroke, TIA, MI, or death was similar among both groups. TfCAS was associated with significant increase in the risk of death and technical failure compared with TCAR in this group of patients. These results confirm that TCAR should be the preferred minimally invasive revascularization procedure for patients with hostile neck anatomy[48]

- **Impact on center outcomes**
  - Availability of TCAR at a hospital was associated with a decrease in the likelihood of perioperative major adverse cardiac events after carotid revascularization[49]

- **Impact of protamine**
  - Protamine can be safely used in TCAR to reduce the risk of perioperative bleeding complications without increasing the risk of thrombotic events[50]
  - The optimal ratio of protamine/heparin dosing regimen for the reversal of heparin during TCAR is 1:1[51]

- **Role of antiplatelet agents**
  - Despite a substantially higher medical risk in patients undergoing TCAR with ticagrelor, 30-day rates of stroke, major bleeding events, and combined stroke/MI/death were similar between patients on ticagrelor and clopidogrel[52]
  - The use of perioperative P2Y12 inhibitors seems to markedly decrease the perioperative neurological event rate with TCAR and Tf-CAS in both symptomatic and asymptomatic patients[53]
  - These findings support current guidelines recommending DAPT prior to CAS but also suggest that P2Y12-monotherapy may confer similar thromboembolic benefits[54]
  - Patients not maintained on DAPT after TCAR experienced increased risk of stroke and death in the perioperative and follow-up periods[55]
  - Compared with aspirin/clopidogrel, aspirin/ticagrelor was associated with a potentially lower risk of stroke/death and bleeding complications after CAS in cases in which protamine was used[56]

- **Impact of arch anatomy**
  - TfCAS was associated with increased risk of stroke/death with complex aortic arch anatomy, however, rates of stroke/death after TCAR were similar regardless of arch complexity[33]
  - TCAR has improved outcomes of TIA/stroke/death compared with TfCAS in both simple and complex aortic arch anatomy[57]

- **Impact of alternative access sites**
  - Compared with TfCAS or TCAR, transbrachial/transradial CAS was associated with a higher risk of in-hospital stroke/death[58]

- **Impact of anesthesia type**
  - The choice of anesthesia for TCAR does not appear to have any effect on clinical outcomes[59]
  - TCAR confers a lower risk of MI compared with CEA. No differences in MI rates when performed with local/regional anesthesia[60]

- **Impact of balloon inflation**
  - Post-stent balloon inflation seems to be safe without an increase in the odds of postoperative in-hospital stroke/death[61]
  - There is no difference in neurological complications owing to balloon dilation strategy during TCAR[62]
- **Impact of completion cerebral angiography**
  - Routine performance of CCA was not beneficial. The detection of new lesions on CCA was rare[63]

- **Impact of postoperative hypotension**
  - Hypotension after CAS is associated with adverse neurologic and cardiac events[64]

- **Mechanism of cerebral protection**
  - Compared with TfCAS-Distal Embolic Protection, TCAR was associated with a lower risk of perioperative stroke or death. Dynamic flow reversal might provide better neuroprotection.[65]

- **Impact of frailty**
  - Modified Frailty Index is a reliable tool that can be used to identify high-risk patients for TCAR prior to intervention[66]

- **Risk prediction models**
  - TCAR risk score calculator can be used to estimate the risk of stroke or death within 30 days of the procedure[67]
  - A symptomatic carotid lesion, and to a lesser extent cardiac arrhythmia, are strong predictors of 30-day stroke/death[68]

- **Impact of learning curve**
  - TCAR is being performed with excellent stroke and mortality rates in the TSP, even in the early stages of the surgeons' learning curve[69]

- **Cost effectiveness**
  - TCAR does not meet a traditional cost-effectiveness threshold to replace CEA. TfCAS is the least cost-effective strategy[70]
  - CEA cost $7,821 for 2.85 quality-adjusted life years (QALY), whereas TCAR cost $19,154 for 2.92 QALYs[71]

- **Temporal trends in the performance of TCAR**
  - TCAR has become the dominant carotid revascularization approach, surpassing TfCAS and CEA in patients at high-risk[72]

SVS VQI TransCarotid Revascularization Surveillance Project data and findings have resulted in a number of commentaries, reviews, and editorials on TCAR.

<u>Perspectives</u>

- **Transcarotid Artery Revascularization: Is It Better than Carotid Endarterectomy?** -Studies have shown a lower risk of stroke or death compared with the transfemoral carotid stenting approach, and an equivalent risk of stroke or death compared with traditional carotid endarterectomy.[73]

- **Introduction of Transcarotid Artery Stenting and the Inherent Responsibilities for a Vascular Surgeon** - Transfemoral carotid stenting has not been successful in reducing the risk of stroke or death in patients with high anatomical risk factors compared with endarterectomy. TCAR has been found to be associated with a reduced risk of intra-operative stroke compared with transfemoral carotid artery stenting. Carotid stenting will become more widely accepted as TCAR technology becomes universally available, and patients will continue to expect treatment options using minimally invasive techniques.[74]

- **Outcomes of Carotid Revascularization in Patients with Contralateral Carotid Artery Occlusion -** TCAR has lower odds of in-hospital stroke or death compared to TfCAS, independent of symptomatic status. Compared to CEA, TCAR seems to be a better option in asymptomatic patients.[75]

- **Application of Transcarotid Artery Revascularization for Carotid Bifurcation Atherosclerosis-the preferred stent-angioplasty option for vascular surgeons** - Transcarotid artery revascularization (TCAR) with flow reversal offers a less invasive option for high-risk patients and has the lowest reported overall stroke rate for any prospective trial of CAS.[76]

- **Current evidence for transcarotid artery stenting with flow reversal as the preferred carotid artery stenting approach** - TCAR appears to be the safest method for carotid stenting, given the significantly lower risk of stroke or death compared with other methods of carotid stenting[77]

- **Recent advances in the treatment of carotid artery disease** - TCAR has a strong potential to become the preferred method of carotid stenting in the future and may challenge carotid endarterectomy as the preferred method.[78]
- **Transfemoral vs Transcervical Carotid Artery Stenting** - The current available data certainly stimulate further research on TCAR appearing as the bright light in the future of CAS.[79]

- **TCAR Results in Low Rates of Periprocedural Neurologic Events, Myocardial Infarction, and Death** - Non-randomized comparisons suggest that TCAR may offer a novel solution to reducing periprocedural stroke, death, and MI in patients with carotid stenosis. A well-controlled randomized trial should be prioritized to obtain level 1 evidence.[80]

<u>Choice of anesthesia</u>

- **Anesthetic considerations in transcarotid artery revascularization** - There are inadequate data to support the superiority of either monitored anesthesia care or general anesthesia as the anesthetic technique of choice. [81]

Operative technique

- **Technical tips for success in transcarotid artery revascularization** - ENROUTE reverse flow cerebral protection affords the opportunity to aggressively predilate carotid artery lesions with relative impunity before stent insertion.[82]

Learning curve

- **Learning curve and proficiency of transcarotid artery revascularization compared to transfemoral carotid artery stenting** - TCAR was not associated with an increased rate of stroke or death during operator's early experience. These data suggest that TCAR is readily learned and patients are not at increased risk during a surgeon's early experience.[83]

The VQI TCAR Surveillance Project has provided and will continue to provide real-world evidence on the role of TCAR in carotid intervention.

Potential path forward

The SVS VQI would therefore propose a similar effort to define the role of TfCAS in carotid intervention.

*The **VQI TfCAS Surveillance Project** is designed to monitor the safety and effectiveness of stents placed into the carotid artery via a transfemoral (and other) access. The project will compare TfCAS (and other access) with standard carotid endarterectomy in centers that participate in the Society for Vascular Surgery Vascular Quality Initiative. The Primary Outcome Measures would be One-year ipsilateral stroke or death and the Secondary Outcome Measures would be 1). 30-day Stroke or death and 2). 30-day Stroke, death or myocardial infarction.*

SVS VQI will ensure that the steering committee will have representatives from SVS, ACC, SVM, and SIR.

Conclusion

The VQI CEA and CAS registries are a combined effort of the SVS and the ACC NCDR to better understand and improve the care of patients with carotid disease. Current evidence derived from this database has changed clinical practice and improved the care of vascular patients[84,85,42,9]. The current role of TfCAS is not well defined and the rationale for its application is based on selective trials with strict inclusion/exclusion criteria raising concerns about the generalizability of clinical outcomes. Multisocietal credentialing documents recommend a quality assurance program and national registry participation. Similar to the VQI TCAR Surveillance Project, the VQI TfCAS Surveillance Project is designed to capture the real-world experience of TfCAS. The project will collect the real-world data and outcomes of TfCAS including all users, all sites, and all patients without exclusion criteria, run-in period, or restrictions on credentialing. The VQI TfCAS Surveillance Project will provide real world evidence on TfCAS regarding indications, advantages, limitations, and disadvantages. The VQI TfCAS Surveillance Project will allow us to better define the role of different carotid interventions in the treatment of carotid stenosis.

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