TCAR Hospital Privileges & Credentialing Guidelines

This document provides resources for establishing TCAR (TransCarotid Artery Revascularization) privileges and credentialing in hospitals to ensure patient safety and quality.

Background

- The Joint Commission (JCAHO) is a non-profit organization that accredits and certifies healthcare organizations and programs in the U.S. It was founded in 1951 to set standards for hospital quality and requires hospitals to form credentialing committees to ensure that physicians have the required licenses, certifications, and competence. JCAHO accreditation is required for Medicare and Medicaid reimbursement.[1]
- The Centers for Medicare and Medicaid Services (CMS) also requires healthcare providers to be credentialed to be eligible for Medicare and Medicaid reimbursement.
- Other organizations that set standards for credentialing include:
    - The National Committee for Quality Assurance (NCQA)
    - Utilization Review Accreditation Commission (URAC)
    - The Accreditation Association for Ambulatory Healthcare (AAAHC)
    - Det Norske Veritas (DNV)

Key Resources

Resources for establishing TCAR privileges and credentialing criteria.

Society for Vascular Surgery (SVS) – Credentialing Resources[2]	• Clinical competence statements on training and credentialing in TCAR (June 2020), carotid stenting with multispecialty consensus recommendations (January 2005), vascular medicine and catheter-based peripheral vascular interventions (August 2004). • Guidelines for hospital privileges in vascular surgery and endovascular interventions (May 2018).
CREST-2 Investigators – Factors influencing credentialing of interventionists in the CREST-2 trial[3]	• CREST-2 required substantial oversight and a controlled system to assess current skill level, considering specialty-based practice variability, procedural experience, and periprocedural outcomes to select qualified interventionists.
Society for Cardiovascular Angiography and Interventions (SCAI)/ Society for Vascular Medicine (SVM) – SCAI/SVM expert consensus statement on Carotid Stenting: Training and credentialing for Carotid Stenting[4]	• Summary of carotid artery stenting guidelines, training, competencies, outcome tracking, facility/equipment/personnel requirements, and competency maintenance criteria.
TCAR Physician Credentialing in a Hospital[5]	• Silk Road Medical's guidance on establishing a TCAR credentialing program in a hospital.

TCAR Studies & Publications

Summary of TCAR clinical studies and publications to support credentialing (not an exhaustive list)

ROADSTER 2
Post approval outcomes of TCAR with the ENROUTE® Transcarotid Stent System in a diverse user group with varying levels of TCAR experience.[6]
	• Prospective, multi-center trial that included 692 patients at 43 sites
	• Objective: Evaluate **real world use** of the ENROUTE Transcarotid Stent and Neuroprotection System in a broad user group
	• Results: 30-day outcomes in high surgical risk patients (n=692 intention-to-treat, n=632 per protocol):
	  ○ Intention-to-treat: stroke 1.9%, death 0.4%, MI 0.9%, stroke/death rate 2.3%, stroke/death/MI rate 3.2%
	  ○ Per protocol: stroke 0.6%, death 0.2%, MI 0.9%, stroke/death 0.8%, stroke/death/MI 1.7%
	• Conclusion: **TCAR is a safe and effective procedure in a broad user base with varying TCAR experience levels**. Excellent outcomes are achievable by following the protocol and society guidelines.
	• Key Takeaway: **TCAR stroke rate is 0.6%** in the per-protocol population.

TCAR vs CEA in VQI – High Surgical Risk Real-world comparison of TCAR vs CEA outcomes using Vascular Quality Initiative (VQI) TCAR Surveillance Project (TSP) data.[7]	• Retrospective, propensity-score matched analysis using VQI TSP data • Objective: Compare outcomes after TCAR vs. CEA in high-risk patients • Results: TCAR and CEA had similar rates of in-hospital stroke/death (1.6% vs. 1.6%, P=0.945), stroke (1.4% vs. 1.4%, P=0.881), and death (0.4% vs.0.3%, P=0.662). However, TCAR was associated with lower rates of in-hospital MI (0.5% vs 0.9%, P=0.005) and CNI (0.4% vs 2.7%, P<0.001), and a shorter LOS (≤ 1 day) vs CEA (P<0.001). • Conclusion: **TCAR significantly reduced the risk of in-hospital MI and CNI compared to CEA, with no differences in the rates of stroke/death.** • Key Takeaway: TCAR and CEA had similar rates of in-hospital stroke/ death in high-risk patients.
TCAR vs CEA in VQI – Standard Surgical Risk Real-world comparison of TCAR vs CEA outcomes in standard surgical risk patients using the VQI TSP.[8]	• Retrospective, propensity-score matched analysis of VQI TSP data • Objective: Compare outcomes after TCAR and CEA in standard risk patients • Results: No statistically significant difference in the risk of 30-day stroke, death, or MI*, and 1-year ipsilateral stroke between TCAR and CEA (3.0% vs 2.6%, P=0.34). Conclusion: **TCAR and CEA have equivalent risks of 30-day stroke, death, MI*, and 1-year ipsilateral stroke rate in standard risk patients** undergoing carotid revascularization. • Key Takeaway: TCAR and CEA have similar risks for standard risk patients. This led to FDA approval of TCAR for standard risk patients. • *MI restricted to in-hospital events only.
TCAR vs TF-CAS in VQI Real-world comparison of TCAR vs TF-CAS outcomes using VQI TSP data.[9]	• Propensity-score matched analysis of VQI TSP and Carotid Stent Registry • Objective: Compare outcomes associated with TCAR vs. TF-CAS • Results: TCAR had a significantly lower risk of in-hospital stroke or death (1.6% vs 3.1%, P<0.001), stroke (1.3% vs 2.4%, P=0.001), death (0.4% vs 1.0%), P=0.008). • Conclusion: **TCAR had a significantly lower risk of stroke or death** than TF-CAS, with improved procedural efficiencies (radiation/contrast).

Continued on next page

	• Key Takeaways: Not all carotid stenting procedures are the same. TCAR addresses the pitfalls of TF-CAS. VQI data consistently shows best-in-class outcomes for TCAR.
TCAR Learning Curve Learning curve of TCAR surgeons based on data from VQI TSP.[10]	• Objective: Examine the TCAR learning curve using VQI TSP data • Results: 3,456 TCAR procedures were performed by 417 surgeons from 178 centers. Major outcomes were statistically equivalent regardless of experience level, suggesting a short learning curve and no increased risk of inferior outcomes for patients treated by early adopters of TCAR. • Conclusion: TCAR has excellent stroke and mortality rates, even in the early stages of the learning curve. • Key Takeaways: **TCAR is safe and effective for surgeons of all experience levels.**
Impact of Age on Outcomes How age affects outcomes of TCAR, TFCAS, and CEA.[11]	• Multi-center, retrospective review of VQI TSP data • Objective: Comparing the association between age and outcomes after TCAR, TF-CAS, and CEA • Results: TCAR had equivalent stroke and death rates to CEA and significantly lower CNI rates across all age groups. In patients ≥ 80 years of age, TCAR had a 72% lower risk of stroke, 65% lower risk of stroke/death, and 76% lower risk of stroke/death/MI than TF-CAS. • Conclusions: **TCAR is a safe procedure regardless of age,** with advantages over TF-CAS in elderly patients who are at high surgical risk. TCAR had statistically equivalent outcomes to CEA regardless of age, with significantly lower CNI rates. • Key Takeaway: TCAR is a safe procedure for patients of all ages.

1. Credentialing and Privileging - Verifying Practitioner Identification | Ambulatory | Human Resources HR. Jointcommission.org. https://www.jointcommission.org/standards/standard-faqs/ambulatory/human-resources-hr/000002242/
2. Credentialing Resources | Society for Vascular Surgery. Vascular.org. https://vascular.org/vascular-specialists/practice-management/clinical-guidelines/credentialing-resources
3. Lal BK, Meschia JF, Roubin GS, et al. Factors influencing credentialing of interventionists in the CREST-2 trial. J Vasc Surg. 2020;71(3):854-861. doi:10.1016/j.jvs.2019.05.035
4. Aronow HD, Collins TJ, Gray WA, et al. SCAI/SVM expert consensus statement on carotid stenting: Training and credentialing for carotid stenting. Catheter Cardiovasc Interv. 2016;87(2):188-199. doi:10.1002/ccd.26304
5. Silk Road Medical. TCAR Physician Credentialing Proposal Form. https://silkroadmedical.showpad.com/share/cebqEwzGXUbHxAI5ZAL3I
6. Kashyap VS, Schneider PA, Foteh M, et al. Early Outcomes in the ROADSTER 2 Study of Transcarotid Artery Revascularization in Patients With Significant Carotid Artery Disease. Stroke. 2020;51(9):2620-2629. doi:10.1161/STROKEAHA.120.030550
7. Malas MB, Dakour-Aridi H, Kashyap VS, et al. TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2022;276(2):398-403. doi:10.1097/SLA.0000000000004496
8. Liang P, Cronenwett JL, Secemsky EA, et al. Risk of Stroke, Death, and Myocardial Infarction Following Transcarotid Artery Revascularization vs Carotid Endarterectomy in Patients With Standard Surgical Risk. JAMA Neurol. 2023;80(5):437-444. doi:10.1001/jamaneurol.2023.0285
9. Schermerhorn ML, Liang P, Eldrup-Jorgensen J, et al. Association of Transcarotid Artery Revascularization vs Transfemoral Carotid Artery Stenting With Stroke or Death Among Patients With Carotid Artery Stenosis. JAMA. 2019;322(23):2313-2322. doi:10.1001/jama.2019.18441
10. Kashyap VS, King AH, Liang P, et al. Learning Curve for Surgeons Adopting Transcarotid Artery Revascularization Based on the Vascular Quality Initiative-Transcarotid Artery Revascularization Surveillance Project. J Am Coll Surg. 2020;230(1):113-120. doi:10.1016/j.jamcollsurg.2019.09.020
11. Dakour-Aridi H, Kashyap VS, Wang GJ, Eldrup-Jorgensen J, Schermerhorn ML, Malas MB. The impact of age on in-hospital outcomes after transcarotid artery revascularization, transfemoral carotid artery stenting, and carotid endarterectomy. J Vasc Surg. 2020;72(3):931-942.e2. doi:10.1016/j.jvs.2019.11.037