2021

Carotid artery dissections from TCAR as reported by the Food and Drug Administration

Dongjin Suh BS
Virginia Commonwealth University School of Medicine

Yuchi Ma BS
Virginia Commonwealth University School of Medicine

Daniel H. Newton MD
Virginia Commonwealth University Health System

Michael F. Amendola MD
Central Virginia VA Health Care System

Kedar S. Lavingia MD
Central Virginia VA Health Care System

Carotid Artery Dissections from TCAR As Reported by the Food and Drug Administration

Dongjin Suh, B.S.[1], Yuchi Ma, B.S.[1], Daniel H. Newton, M.D.[1,2,3], Michael F. Amendola, M.D. FSVS FACS,[3] Kedar S. Lavingia, M.D.[1,2,3]

Virginia Commonwealth University School of Medicine[1], Virginia Commonwealth University Health System[2], Central Virginia VA Health Care System, Richmond, VA[3]

INTRODUCTION

- **Transcarotid Artery Revascularization (TCAR)**: reverses blood flow away from the brain while placing a stent through a direct, surgical access of the carotid artery.
- Carotid artery stenosis is a major cause of ischemic stroke.[1] TCAR provides an alternative to carotid endarterectomy (the current gold standard for treatment).
- TCAR demonstrated the lowest perioperative stroke rate when compared to other similar methods of stent placement.[2]
- Carotid artery dissection (CD) is the most common TCAR complication, but its management has not been well characterized.[3]

OBJECTIVE

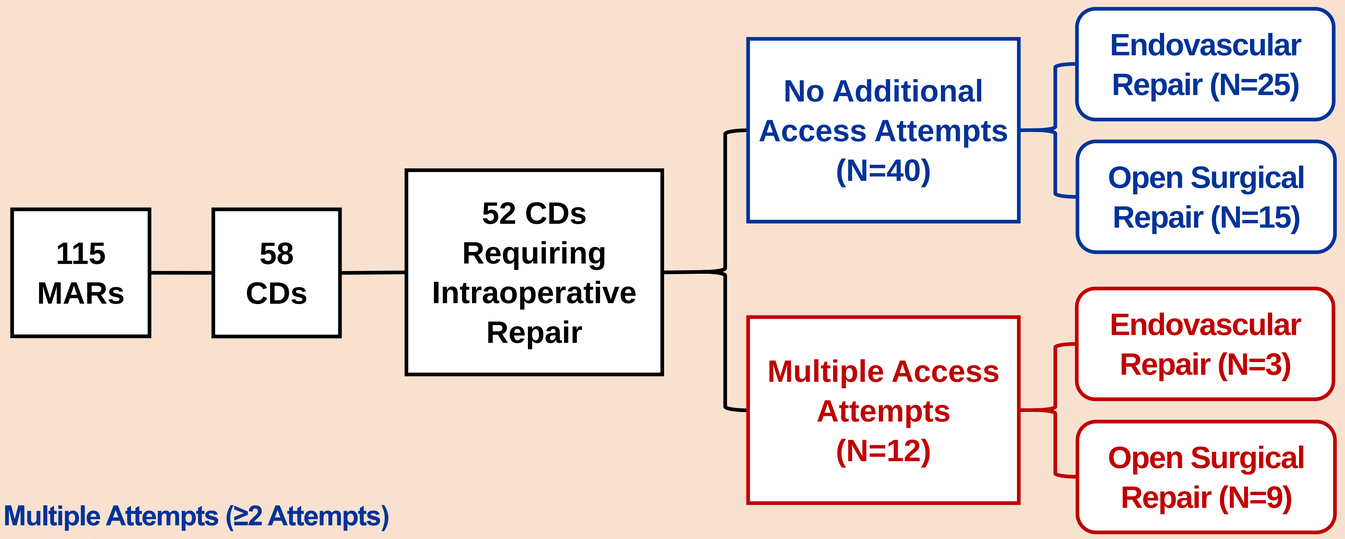
To characterize carotid artery dissections that result from TCAR procedure and their course of intraoperative management.

METHODS

- **Manufacturer And User Device Experience (MAUDE)**: FDA database designed for surveillance of all FDA-approved medical devices.
- This database was queried for Medical Adverse Reports (MARs) on Silk Road Medical's ENROUTE Transcarotid Neuroprotection System (Oct. 2016 – Oct. 2020).
- All CDs identified intraoperatively were analyzed for:
  - Number of access attempts for CD repair
  - Type of repair (endovascular, surgical)

RESULTS I

Figure 1. Query of medical adverse reports related to TCAR from MAUDE database

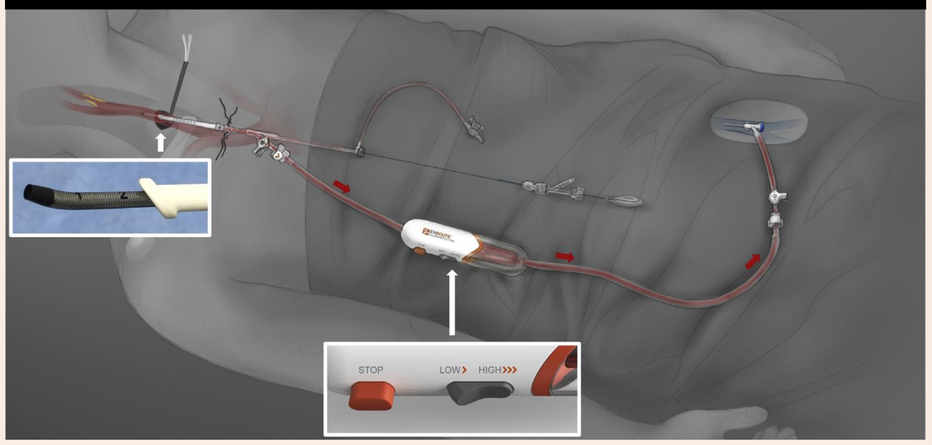


Multiple Attempts (≥2 Attempts)
Medical Adverse Report (MAR), Carotid Artery Dissection (CD)

Table 1. Comparison of CD repair methods based on number of access attempts needed to reach the true lumen

Intraoperative CD Repair	Endovascular Repair (N=28)	Open Surgical Repair (N=24)	p-value (Fisher's Exact)
No Additional Access Attempts	25/40	15/40	0.044
Multiple Access Attempts	3/12	9/12	0.039

Image 1. TransCarotid Artery Revascularization [2]



RESULTS II

- Of the 58 CDs, sheath placement was the most common procedural event attributed to CDs (N=34)
- Rate of endovascular repair was significantly higher in CDs requiring no additional access attempts
- Rate of open surgical repair was significantly higher in CDs with persistent failure to obtain true lumen despite ≥2 access attempts
- Rate of stroke from either endovascular repair (N=1) or open surgical repair (N=1) was similar (p=1.00).
  - 1 stroke from a hypotensive episode 7 hours after endovascular CD repair
  - 1 stroke during conversion to CEA
- No deaths were associated with CD and subsequent repairs

CONCLUSION

- **Sheath placement** was the most common procedural events associated with CD
- **Rate of endovascular repair** was significantly higher if no additional access attempts were needed
- **Rateof open surgical repair** was significantly higher for cases requiring multiple access attempts

LIMITATIONS

MARs collected from the MAUDE database do not account for all TCAR procedures performed in the U.S.

1. Luk Y, Chan YC, Cheng SW. Transcarotid Artery Revascularization as a New Modality of Treatment for Carotid Stenosis. Ann Vasc Surg. 2020;64:397-404.
2. Malas MB, Leal J, Kashyap V, Cambria RP, Kwolek CJ, Criado E. Technical aspects of transcarotid artery revascularization using the ENROUTE transcarotid neuroprotection and stent system. J Vasc Surg. 2017 Mar;65(3):916-920.
3. Nana PN, Brotis AG, Spanos KT, Kouvelos GN, Matsagkas MI, Giannoukas AD. A systematic review and meta-analysis of carotid artery stenting using the transcervical approach. Int Angiol. 2020 Oct;39(5):372-380.