

Initial Experience with Transcarotid Artery Revascularization (TCAR) Demonstrates its Safety and Efficacy in Elderly High-Risk Patients

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Categories: General Surgery

Keywords: stenting, stent, balloon angioplasty, enroute transcarotid neuroprotection system®, contralateral femoral vein, carotid artery, tcar, transcarotid artery revascularization

How to cite this poster

Ghamraoui A K, Ricotta J J (2018) Initial Experience with Transcarotid Artery Revascularization (TCAR) Demonstrates its Safety and Efficacy in Elderly High-Risk Patients. *Cureus* 10(10): e.

Abstract

Stroke is the leading cause of long-term disability and third leading cause of death in the United States, with 20-30% of ischemic strokes caused by carotid artery disease. Although carotid endarterectomy has been performed for over 50 years, there remains an inherent risk of perioperative stroke and cardiac mortality. Transcarotid artery revascularization (TCAR) is a novel method in the surgical management of carotid disease, where blood flow in the common carotid artery is temporary reversed away from the brain to confer protection from intraoperative stroke. Recent investigational studies reveal a 1.1% risk of perioperative stroke and 0% cardiac mortality. Described herein is a case series of the first four TCAR procedures performed in the South Florida region.

The procedures were performed by creating an incision over the common carotid artery, which was dissected free and controlled. The contralateral femoral vein was then accessed percutaneously. The common carotid artery was then punctured under direct visualization and the ENROUTE Transcarotid Neuroprotection System® was then connected between carotid artery and femoral vein to reverse flow through the carotid artery. Balloon angioplasty and stenting of the internal carotid artery was then performed.

Of the four TCAR procedures performed, three were for symptomatic and one for asymptomatic high-grade carotid artery stenosis. There was no incidence of peri-operative stroke or mortality. Three of the patients were discharged on post-operative day one, one on post-operative day three due to adrenal insufficiency.

Transcarotid Artery Revascularization (TCAR) represents the next step in minimally invasive surgical management of high-risk patients with severe carotid artery disease. The above cases represent a single institution experience with the first TCAR procedures to be performed in South Florida.

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Published 10/17/2018

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Initial Experience With Transcarotid Artery Revascularization (TCAR) Demonstrates its Safety and Efficacy in Elderly High-Risk Patients

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Objectives
 Stroke is the leading cause of long-term disability and third leading cause of death in the United States.¹
 • 20-30% of ischemic strokes are caused by carotid artery disease.¹

There is inherent risk of perioperative stroke and cardiac mortality with carotid endarterectomy (CEA) and transarterial carotid artery stenting (CAS). Carotid revascularization, both CEA and CAS, is associated with an increased risk of adverse outcomes in patients >80 years of age.²

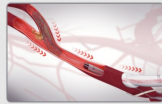
Figure 1: Transcarotid artery revascularization (TCAR) is a novel technique that combines surgical principles of neuroprotection with less invasive endovascular techniques to treat severe carotid artery stenosis.

TCAR investigational studies reveal:
 1.4% 30-day stroke rate and 0% cardiac mortality³

The first TCAR procedure in South Florida was performed at our institution in May 2018 on a symptomatic 89-year-old female.

Since that time, we have successfully treated a number of high-risk elderly patients.

We present our initial experience with TCAR in patients ≥80 years of age.



Methods
 Clinical data of patients undergoing TCAR for symptomatic (≥50%) or asymptomatic (≥80%) carotid stenosis between May 31, 2018 and September 14, 2018 was prospectively collected.

Primary Outcomes:
 • Stroke
 • Myocardial infarction
 • Mortality

Secondary Outcomes:
 • Postoperative length of hospital stay
 • Procedure time
 • Fluoroscopy time
 • Clamp/flow reversal time
 • Mortality

Subgroup analysis was performed on patients ≥80 years of age to examine effect of symptomatology and patient's hospital admission status.
 • Variables compared using Student's t-test.

Figure 2: TCAR procedures were performed utilizing the ENROUTE[®] (Sitek Road Medical Inc, Sunnyvale, CA) Transcortical Neuroprotection and Sheath System as follows: 1) Transverse incision made above the clavicle to expose the common carotid artery (CCA); 2) which is then directly punctured and sheath inserted and secured; 3) Contralateral femoral vein accessed and venous return sheath secured; 4) Flow controller sheath line is connected to arterial and venous sheaths; 5) Reversal of flow is then initiated, pulling blood away from the brain; 6) CCA is then clamped and the transcarotid stent delivered under reverse flow.

Results

Table 1: Composite primary and secondary outcomes

	All age (n=17,756)	Age < 80 (n=14,433)	Age > 80 (n=3,323)	P-value
Carotid artery stenosis (%)	89.9 ± 6.8	89.7 ± 7.0	89.3 ± 8.0	0.825
Stroke (%)	0	0	0	1
MI (%)	0	0	0	1
Cardiac mortality (%)	0	0	0	1
Mortality (%)	0	0	0	1
Procedure time (mins)	58.6 ± 36.9	57.3 ± 35.1	63.5 ± 25.7	0.499
Clamp/flow reversal time (mins)	5.1 ± 0.9	5.0 ± 0.9	5.5 ± 1.0	0.290
LOS (days)	2.5 ± 1.5	2.6 ± 1.6	2.3 ± 1.0	0.088
Fluoroscopy time (mins)	5.6 ± 2.0	5.5 ± 1.9	5.9 ± 2.6	0.744

MI: myocardial infarction; LOS: postoperative length of hospital stay; Age: age group in years. Data presented as mean ± SD.

Subgroup Analysis

Table 2: Effect of symptomatology on outcomes

	Asymptomatic (n=10,978)	Symptomatic (n=6,778)	P-value
Carotid artery stenosis (%)	86.1 ± 7.7	89.8 ± 5.5	0.078
Procedure time (mins)	56.0 ± 35.8	64.7 ± 35.4	0.008
Clamp/flow reversal time (mins)	5.0 ± 0.9	5.0 ± 0.8	1
LOS (days)	2.0 ± 1.0	2.0 ± 0.9	0.906
Fluoroscopy time (mins)	5.4 ± 1.9	5.5 ± 2.1	0.796

Data presented as mean ± SD.

Table 3: Effect of admission status on outcomes

	Inpatient (n=10,978)	Outpatient (n=6,778)	P-value
Carotid artery stenosis (%)	89.9 ± 6.8	89.3 ± 8.0	0.397
Procedure time (mins)	58.6 ± 36.9	63.5 ± 25.7	0.026
Clamp/flow reversal time (mins)	5.1 ± 0.9	5.5 ± 1.0	0.106
LOS (days)	2.5 ± 1.5	2.3 ± 1.0	0.086
Fluoroscopy time (mins)	5.6 ± 2.0	6.0 ± 2.1	0.401

Data presented as mean ± SD.

Conclusions

- Transcarotid artery revascularization (TCAR) can be performed successfully and safely in both symptomatic and asymptomatic patients older than 80 years of age.
- Procedure and clamp times are short, as is length of stay (LOS).
- TCAR may represent a safe and effective alternative to CEA and CAS for high-risk elderly patients.

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