Notable Grand Rounds
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Michael & Marian Ilitch
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TRANSCAROTID ARTERY REVASCULARIZATION FOR THE TREATMENT OF CEREBROVASCULAR DISEASE IN HIGH-RISK PATIENTS

About Notable Grand Rounds

These assembled papers are edited transcripts of didactic lectures given by mainly senior residents, but also some distinguished attending and guests, at the Grand Rounds of the Michael and Marian Ilitch Department of Surgery at the Wayne State University School of Medicine.

Every week, approximately 50 faculty attending surgeons and surgical residents meet to conduct postmortems on cases that did not go well. That “Mortality and Morbidity” conference is followed immediately by Grand Rounds.

This collection is not intended as a scholarly journal, but in a significant way it is a peer reviewed publication by virtue of the fact that every presentation is examined in great detail by those 50 or so surgeons.

It serves to honor the presenters for their effort, to potentially serve as first draft for an article for submission to a medical journal, to let residents and potential residents see the high standard achieved by their peers and expected of them, and by no means least, to contribute to better patient care.

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Transcarotid Artery Revascularization for the Treatment of Cerebrovascular Disease in High-Risk Patients

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This paper is based on Dr. Kim's Surgical Grand Rounds presentation on April 20, 2022

Introduction

This paper presents some background and epidemiology regarding carotid artery stenosis. It covers stroke risk, indications and contraindications for carotid artery revascularization, and a brief review of some of the current procedures available. An overview of the transcarotid artery revascularization (TCAR) system then follows, with a short case presentation then a discussion of the learning curve for TCAR, its complications, and post-operative care.

Epidemiology

Nearly 800,000 strokes are reported in the US annually, of which 90% are due to ischemic events. Of these, up to 15% are due to carotid disease. Up to 50% of all patients who have an ischemic stroke have a carotid lesion that would be amenable for treatment as well. Ten percent are hemorrhagic. This accounts for about one out of every 20 American deaths, and is the fourth leading cause of death in the United States. Globally, it is the second leading cause of death (the first being heart disease), with 11% of all deaths.

Risk Factors

Non-modifiable risk factors include age greater than 55, male gender, Asian or African American ethnicity, and genetic predisposition. Modifiable risk factors include strokes that arise from carotid disease. Tobacco smoking, atherosclerosis, hyperlipidemia, hypertension, diabetes, and alcohol are all factors, but the biggest modifiable risk factor is hypertension.

Carotid Artery Stenosis

Symptomatic carotid disease is any type of neurologic dysfunction from an ischemic stroke or transient ischemic attack (TIA) with carotid stenosis ≥50% of the lumen. Asymptomatic carotid disease would be if the patient never had a neurologic event but has >50% and <99% internal carotid artery stenosis.

A stroke is a cerebrovascular accident, cerebrovascular insult, or brain attack resulting from cellular damage to the central nervous system due to compromised circulation with deficits >24 hours. A TIA is a neurologic deficit that lasts <24 hours and has complete resolution.

Pathways for Symptomatic Carotid Disease

The first pathway is embolic, because the most common cause for carotid artery stenosis is atherosclerosis. Plaque can be calcified or soft. Soft plaques tend to be more friable and therefore more dangerous—they can embolize—or (second pathway) they may cause reduced flow due to atherosclerotic disease—flow limitations become serious at >70% stenosis. A third pathway is via fibromuscular dysplasia and a fourth is carotid artery dissections, which are usually iatrogenic or because of trauma.

Indications and Contraindications for Carotid Revascularization

The indication to intervene on asymptomatic carotid disease is when the stenosis is 70-99%. Intervention is also indicated if a patient presents with carotid artery stenosis of greater than 50% and he/she experienced one or more TIA's in the preceding 6 months.

Contraindications really depend on the patient's health status. The benefit of a carotid endarterectomy or carotid revascularization procedure takes five years to come to fruition, so a patient with less than five years of life expectancy would not benefit.

A major devastating stroke with minimal recovery or significantly altered level of consciousness would also be a contraindication, as would chronic occlusion of the ipsilateral carotid artery, because once arteries occlude, they tend to thrombose up to their first branch (ophthalmic artery), to which we do not have access.

Complications

The most dreaded complication of any carotid revascularization procedure is stroke from emboli. The gold standard, carotid endarterectomy, seeks embolic protection through a distal clamp on the internal carotid artery. There are many other steps in this procedure, including making sure there is no distal dissection flap, that everything is tacked down, that the plaque is removed in its entirety, and that the vessel is flushed copiously to remove any embolic fragments.

After removal of the entire plaque, a patch angioplasty is performed with vein, bovine pericardium, or dacron.

Another method to treat carotid disease is transfemoral carotid artery stenting. This is reserved for high-risk patients who would not be able to tolerate an open procedure. It relies on a distal filter to prevent microembolization. After accessing the common femoral artery, the surgeon must navigate the arch which, along with the great vessels, comes off at a more acute angle as patients age.

It is more difficult to cannulate the common carotid or the innominate. Typically, a reverse curve catheter is used to cannulate these vessels through the arch. That means dragging the catheter along the arch until it hooks into one of the great vessels, a procedure which itself can cause emboli from the arch to the brain. Furthermore, in order to get the filter up distally, the lesion must be crossed and manipulated, which can also cause an embolic event.

A third method is hybrid carotid artery stenting, which has been around for a while but implemented only recently. It requires both an endovascular and an open procedure and relies on flow reversal—on the arterial venous pressure gradient to reverse the flow in the carotid artery and pass it through a filter before returning it into the femoral vein.

TCAR

Historical Background

The first carotid endarterectomy was performed by Dr. DeBakey in 1953. A longitudinal incision on the neck opens up the artery and then the plaque is removed and a patch angioplasty is performed.

The first carotid angioplasty was performed in 1980 by Dr. Matthias on a 68 year old gentleman with COPD, CHF, myocardial infarction, and a recent right hemisphere stroke. He used a transfemoral technique. The result was fairly good, but he did not use any protective device.

The first carotid stent—a wall stent to treat an intimal flap—was placed in 1989. In the early 90s, flow reversal systems came into play with the introduction by Medtronic of Parodi and Bates' first flow reversal system. The early system was a cut down onto the common carotid artery and the distal occlusion device was a balloon fixed to a hypotube. Someone would manually suction using a large syringe. However, the procedure tended to result in strokes because of paradoxical embolization via the external carotid artery through macrocollaterals.

Gore then developed a system with a balloon that included the external carotid artery as well, though due to marketing practices it never really took off.

Patient Case

In 2019, a 78 year-old male presented with a critical right asymptomatic carotid artery stenosis with rapid progression of carotid disease. His RICA was 65% and progressed to 90-95% over the course of a year.

He had a history of laryngeal cancer s/p radiation, and on exam, the skin overlying the neck on that side was taut and thickened, and could not be tented up. His preoperative imaging (Figures 1, below; and 2, next page) shows a very tight stenosis of the internal carotid artery dwindling down to a near string sign.

His first option was carotid endarterectomy, which is invasive and has a high rate of cranial nerve injury for radiated necks. Per AHA Stroke Council guidelines, the combined risk of stroke and death for an asymptomatic patient should be less than 3%. If the patient had a TIA it should be <5%, stroke <7%, and recurrent stenosis <10%.

His second option was carotid artery stenting using the percutaneous transfemoral approach. However, the stroke risk is 4.1 to 15% with this procedure, especially in patients aged over 70.

His third option was hybrid carotid artery stenting (transcarotid artery revascularization—TCAR), whose stroke risk is 1.4% based on the Roadster trial (below). The perioperative MI rate for patients undergoing the hybrid procedure was 0.7 versus 2.3 compared to carotid endarterectomy.

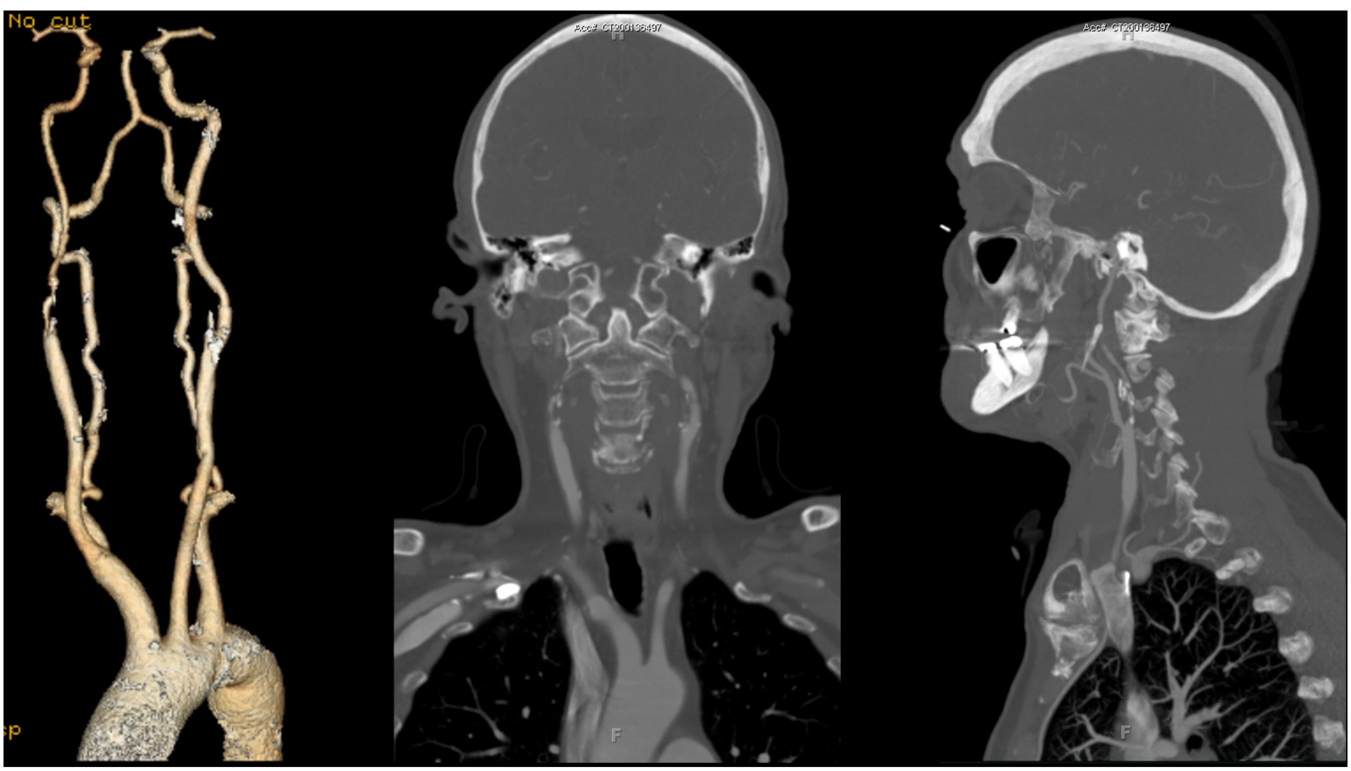

Figure 1. Cervical CTA with 3D reconstruction, coronal, and sagittal views of right carotid artery stenosis of 90-95%

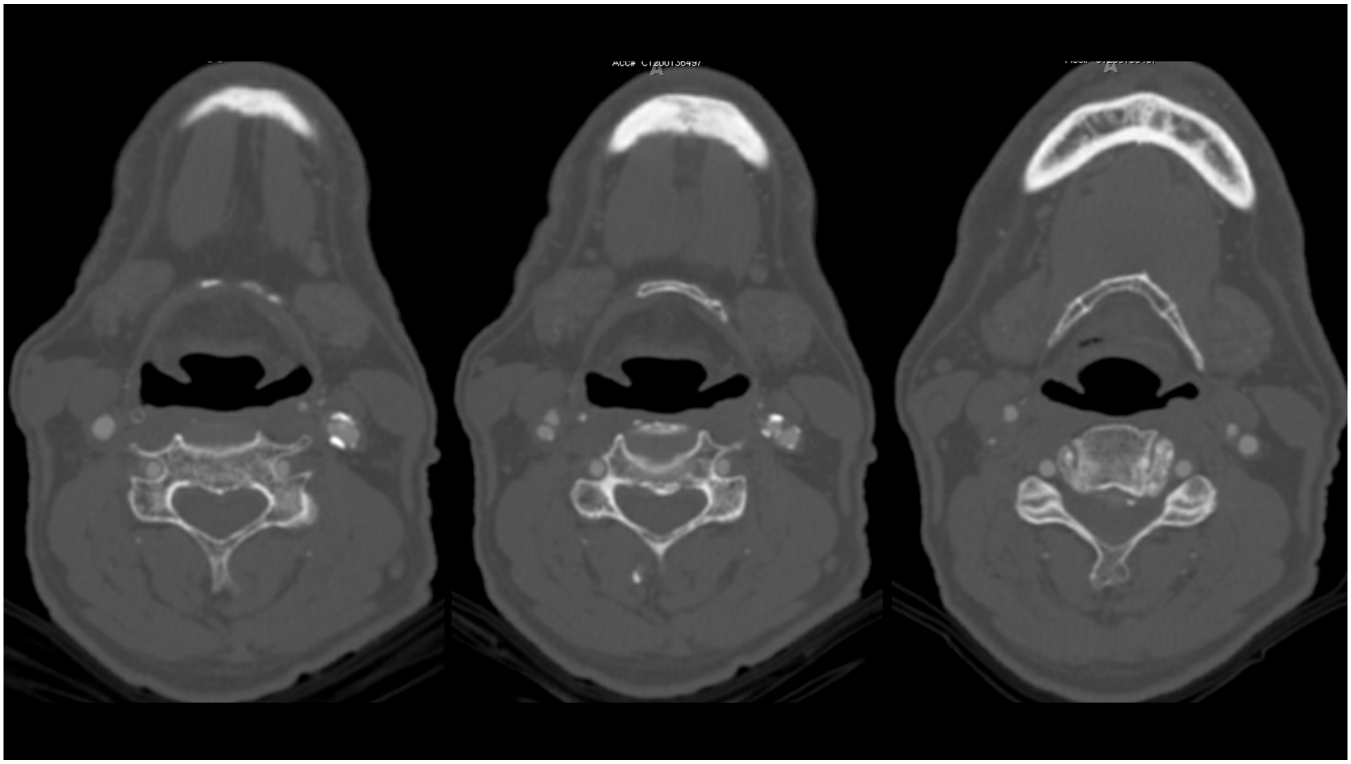

Figure 2: Cervical CTA with progressive axial views revealing right carotid artery stenosis 90-95%

Thus, TCAR is the hybrid approach to carotid stenting. It requires surgical exposure to the common carotid artery at the base of the neck for stent deployment and it uses dynamic flow reversal for cerebral protection.

The Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER) Trial

The Roadster Trial aimed to assess the safety and efficacy of this approach. It used a TCAR registry. It was a prospective single-armed trial involving 18 centers and 141 patients, both symptomatic and asymptomatic. The endpoint was a stroke, MI, or death within 30 days post-operatively.

The study found that the death rate from TCAR was 1.4%, stroke 1.4%, and MI 0.7%. The stroke rate is significantly lower than what was shown in the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST), and the Mi rate was lower than carotid endarterectomies. So they concluded that reverse flow is safe.

Anatomical and Medication Requirements

Anatomical requirements to perform the TCAR procedure are:

- 5cm working length of common carotid artery (clavicle to bifurcation) by ultrasound in surgical positioning
- ≥6mm CCA for 8 Fr sheath
- No severe disease at CCA puncture site (minimal disease in CCA)
- Vessel diameter ≥4mm and <9mm

Medication requirements:

All TCAR patients are loaded seven days prior with the loading dose and started on Plavix, aspirin, and a statin. In cases where the procedure needs to be performed on an acute basis, the patient can be loaded up with Plavix prior to the procedure.

Indications and Contraindications

The indications for TCAR are the same as for patients with cerebrovascular disease; however, this is specifically designed for patients at high

Physiologic Risks	Anatomic Risks
Age ≥75	**Prior head/neck surgery or irradiation**
CHF	Spinal immobility
LVEF ≤35%	Restenosis post CEA
≥2 diseased coronaries with ≥70% stenosis	**Surgically inaccessible lesion**
Unstable angina	**Laryngeal palsy; laryngectomy; permanent contralateral cranial nerve injury**
MI within 6 weeks	Contralateral occlusion
Abnormal stress test	Severe tandem lesions
Need for open heart surgery	Bilateral stenosis requiring treatment
Need for major surgery (including vascular)	
Uncontrolled diabetes	
Severe pulmonary disease	

Figure 3. CMS definition of high surgical risk (1 or more)

risk for adverse events. So who's at risk? CMS defines who's at risk and splits it into physiologic risks and anatomic risks. (See Figure 3 above)

Contraindications for TCAR are:
- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated
- Patients in whom the ENROUTE Transcarotid NPS is unable to be placed
- Patients with uncorrected bleeding disorders
- Patients with known allergies to nitinol
- Lesions in the ostium of the common carotid artery

The first ROADSTER trial was conducted in the early 2010s. ROADSTER 2 is an ongoing investigation of long term results of TCAR.

In technical terms, it is described as a prospective, single arm, multicenter, postapproval registry for patients undergoing TCAR.

Data analyzed from 692 patients at 43 sites between 2015 - 2019 showed a 99.7% success rate for the procedure. Early postoperative outcomes (30 day) were:

- Stroke: 1.9%
- Death: 0.4%
- MI: 0.9%

Issues

Despite these encouraging results, TCAR is not without issues. It's long-term performance has not yet been established. It has not been on the market for very long and many surgeons are still learning to adopt it. Also, it suffers from problems that come along with transfemoral stenting or endarterectomy—infection secondary to contamination of the stent, which can lead to thrombosis, pseudo aneurysm (PSA) formation, or rupture.

A stent can also thrombose, cause distal embolization, or it can even migrate. An oversized stent can cause overstretching of the artery, which can rupture and cause life threatening bleed.

There are issues, too, with Plavix resistance as well as malabsorption. If patients are taking h2 antagonists, it can affect the absorption of their aspirin.

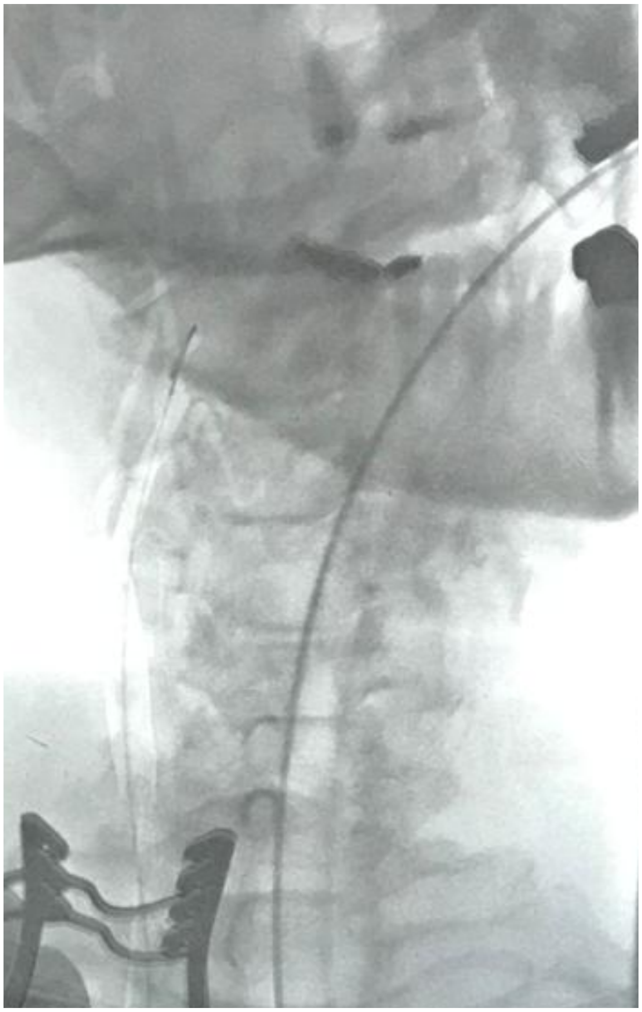

Figure 4. Wire placed in right external carotid artery prior to arterial sheath placement

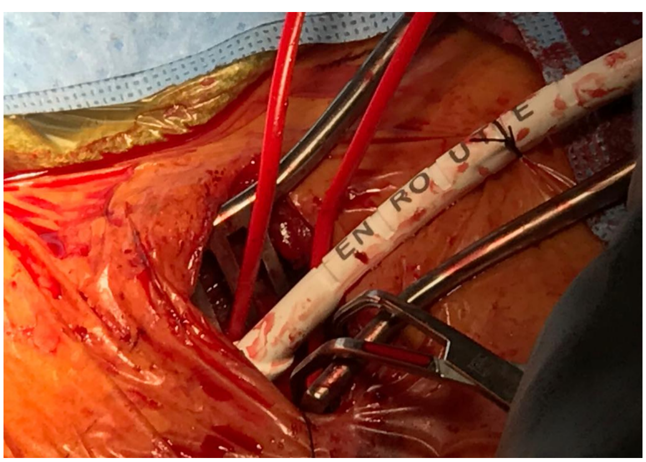

Figure 5. Arterial sheath placed in right common carotid artery

The TCAR Procedure

Pre-procedure Imaging: Carotid ultrasound should be routine for all patients with carotid disease. It provides a lot of information: The degree of stenosis, the length of disease, the plaque morphology, degree of calcification, and it also measures proximal, mid, and distal ICA (internal carotid artery). But specific for TCAR is the evaluation of the common carotid artery.

Positioning: The neck should be extended via a scapular and/or spine roll with the head turned to the side, the shoulders pulled down for floor visual, and all radiopaque objects around and behind the head removed. Prep from the ear to below the nipple. Expose and prep the contralateral groin for the percutaneous venous sheet placement.

Anesthesia: General anesthesia can be done but TCAR favors local anesthesia with conscious sedation. Continuous monitoring of blood pressure with an arterial line should be done for all patients undergoing carotid revascularization. Hypotension and bradycardia should be avoided.

BP/Heart Rate: The foundation of the mechanism where the flow gets reversed and embolic fragments are captured relies on the difference between arterial and venous blood pressure. For this, blood pressure needs to be 140 to 160 mmHg systolic and vasopressors should be available in case of need. Heart rate should be 70 bpm or higher. Prophylactic use of atropine or glycopyrrolate is recommended in all patients unless unnecessary or hazardous.

Central Venous Access: Percutaneous access to the contralateral common femoral vein is the easiest way for the device to lay. An 8 French venous sheath is inserted. The common carotid is exposed about two finger breadths above the clavicle, between the clavicular and sternal heads of the sternocleidomastoid.

Common Carotid Artery (CCA) Exposure: The right CCA is more superficial than the left, and the recurrent laryngeal nerve travels posteriorly at the common carotid level, but the lymphatic structures are less prominent. The CCA arches more posteriorly. The thoracic duct enters the left internal jugular vein at this level and will be avoided by keeping the dissection anterior to the jugular vein. A very short transverse incision of about 2-4 cm in length, along the anterior edge of the clavicular head of the SCM muscle and 1-2 cm superior to the upper edge of the clavicle. The initial muscle to encounter will be the platysma, beyond which an avascular plane leads directly to the common carotid.

Pre-suture Artery: With the common carotid artery exposed, a U-stitch using 5-0 Prolene is used to pre-close. This will close the arteriotomy once the sheath is pulled out. This should be in the mid-CCA and the patient should be anticoagulated, usually with 100 units of IV Heparin per kilogram, allowed to circulate systemically for about five minutes to raise ACT to the target of >250.

Arterial Traction: Retraction of the umbilical tape on the CCA provides about an extra 1-2 cm working length for access with a micro puncture needle. It is important not to use the same needle that that was used to access the femoral vein because a dull needle can invaginate and back-wall. As well, pulling too hard on the umbilical tape can ovalize the vessel and at the same time back-wall the artery.

Microsheath Insertion: A micro sheath with 1 cm markings is placed 2-3 cm inside the artery, staying proximal to the bifurcation and the disease. It is very important to have good help during the procedure to stabilize the wire and sheath.

Initial Imaging: A cervical angiogram is obtained to allow delineation of anatomy and to engage the external carotid artery with the wire and micropuncture sheath. J-wire is then advanced, microsheath is removed, and the transcarotid arterial sheath is inserted. (See Figures 4 and 5.)

Line Prep: Flow is now allowed to fill the filter and the line. To confirm reversal flow, the line is locked then flushed with heparinized saline until clear. When the stopcock is reopened, the reverse flow can be observed traversing the flow controller.

TCAR Timeout: At this point, another timeout is needed prior to establishing active flow reversal to confirm blood pressure = 140 - 160 mmHg, heart rate ≥70, and devices are prepped and ready. Once the common carotid artery is clamped proximally, flow reversal is active.

Balloon and Stent: Another carotid angiogram shows the lesion, which can now be crossed and pre-dilated with a balloon. The stent is then deployed and a completion angiogram made. (See Figures 6 and 7, next page.)

Restore Antegrade Flow and Remove Transcarotid Sheath: After a pause of about five minutes to allow any embolic fragments to go through the filter, the common carotid is unclamped, returning flow to passive reversal. The arterial flow lone is disconnected, the sheath removed, and the arteriotomy closed with the pre-placed U stitch.

Last Steps: The platysma is re-approximated close to the skin and manual pressure applied to the groin.

The patient may be interested to see the debris in the filter that could have potentially embolized his or her brain.

The Learning Curve for TCAR

Since it is a fairly new procedure, several studies of the learning curve have been conducted. One of them, which looked at 188 consecutive patients, showed that after about 15 cases the operators decreased their procedural time from 79 to 71 minutes (for a carotid endarterectomy it is usually about 90 minutes) and duration of flow reversal, which would be essentially clamp time for carotid endarterectomy, went from 13 to nine

A. Carotid angiogram B. Carotid angioplasty C. Post dilatation

Figure 6. Stent deployment

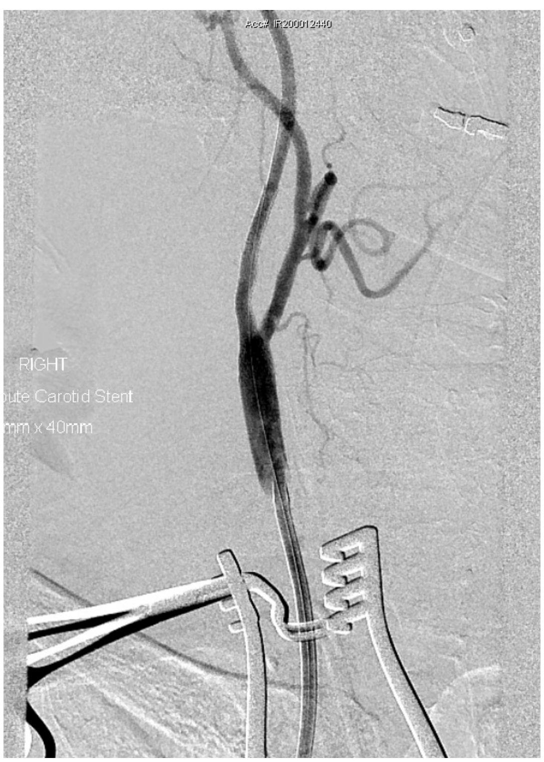

Figure 7: Completion right carotid angiogram following deployment of 9 mm Enroute stent

minutes. The low rate of stroke, death, and combined stroke rate / death was similar for the early and late experience, suggesting that this technique can be adopted quickly by vascular surgeons experienced with carotid intervention.

A review of data from the TCAR Surveillance Project (TSP) divided clinician experience into Novice, Intermediate, Advanced, and Expert. The study included 3456 procedures performed by 417 unique surgeons from 178 centers between September 2016 and December 2018. Overall, the data showed low stroke and mortality rates, even among operators in the early stages of the learning curve. There were no significant differences in major in-hospital outcomes, including stroke, death, and stroke/death/myocardial infarction between groups.

The study also found that increased experience was associated with lower operative, fluoroscopy, flow reversal times, and decreased bleeding.

TCAR for Supra-aortic Lesions

TCAR has been used to treat lesions in the supra-aortic of the great vessels. Instead of going antegrade, after cutting the common carotid artery cut down, the catheter is placed retrograde and the common carotid artery clamped distal to where the sheath is placed. Innominate artery lesions and common carotid lesions have also been treated in this way, with technical success.

Complications

The biggest complications for this procedure—2% of all cases—are access-related: 1- 2% due to arterial dissection (snowplowing, ovalization, etc.) and 2% due to bleeding. The use of protamine has been found to drastically reduce significant bleeding complications.

Post-operative Care

The main requirements of post-op care are:

- Maintain SBP 110-160 mmHg
- Monitor neck for expanding hematoma
- Frequent neuro checks
- Plavix for 30 days
- ASA and statin lifelong
- Surveillance duplex in 30 days, 6 months, 1 year

Conclusions

TCAR is a valuable procedure for the treatment of extracranial carotid artery stenosis in high risk patients.

The 30-day stroke rate is lower than transfemoral stenting and the stroke and MI rates are lower than carotid endarterectomy.

The procedure seems to be easily adopted by surgeons with existing endovascular and open skills.

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