Shared Decision-Making: Addressing the Medicare Directive and What This Means in a Busy Practice

How are busy vascular practices like the University of Rochester Medical Center proactively engaged in shared decision-making with their patients and families?

BY MICHAEL C. STONER, MD, FACS, DFSVS, AND ALEX AU-YEUNG

Michael C. Stoner, MD, FACS, DFSVS
Professor and Chief, Division of Vascular Surgery
University of Rochester
Rochester, New York
michael_stoner@urmc.rochester.edu
Disclosures: Educational consultant and case proctor for Silk Road Medical.

Alex Au-Yeung
VP, Health Economics & Reimbursement
Silk Road Medical
Sunnyvale, California
aauyeung@silkroadmed.com
Disclosures: None.

Even though Medicare has not mandated shared decision-making (SDM) requirements in all Medicare National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), variations of SDM are already incorporated in a vascular surgeon's everyday practice. The two primary components of SDM in all Medicare coverage guidance involve: (1) scheduling a separate SDM visit with the individual and family; and (2) using an evidence-based decision tool.

The Agency for Healthcare Research and Quality (AHRQ) provides some general guidelines for SDM in their document titled "Shared Decision-Making Tools for Lung Cancer Screening."[1] These include:

- Good communication between clinicians and patients
- Decision aids that provide a structured approach to providing information about options and trade-offs, values related to options and outcomes, and can help foster deliberation
- Tools that provide clinicians with a concise summary of the current clinical evidence and recommendations

CHALLENGES

One of the primary challenges facing vascular surgeons, as well as other providers, is to develop a readable and understandable evidence-based decision tool that can be used during the SDM visit. Based on a 1992 National Assessment of Adult Literacy (NAAL) survey, Medicare beneficiaries read at the 5th grade level.[2] Another updated and more specific 2003 NAAL survey showed that adults aged 65 years and older had a lower average health literacy than adults in younger age groups. As a result, the Centers for Medicare & Medicaid Services developed an 11-part health literacy toolkit (www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit) for making written materials easier to understand and use.

The key takeaways are that written materials must be developed using a reader-centered approach and written from the mindset of the readers.[3] The materials must:

- Attract the intended readers' attention
- Hold their attention
- Make them feel respected and understood
- Help them understand the messages in the material
- Move them to take action

The University of Rochester Medical Center (URMC) Division of Vascular Surgery has developed a solution addressing SDM and authorizing patient consent using a module within their medical record system (Epic Systems Corporation) that can be adopted by other Epic system users.

SHARED DECISION-MAKING IN THE URMC VASCULAR PRACTICE

At URMC, workflow for a patient with a flow-limiting or symptomatic carotid artery stenosis involves a well-established SDM process. After identification of a potential case via ultrasound, patients are screened for both indication (asymptomatic stenosis > 70% or symptomatic

TABLE 1. CONTEMPORARY PERIPROCEDURAL STROKE/DEATH RATES ASSOCIATED WITH VARIOUS CAROTID REVASCULARIZATION STRATEGIES, NON-RISK-ADJUSTED (RAW DATA)

	Symptomatic Patients Stroke/Death/MI (%)	Asymptomatic Patients Stroke/Death/MI (%)
Carotid endarterectomy	2-4	1-2
Transfemoral stent	5-7	3-5
TCAR	2-5	1-2

Abbreviations: MI, myocardial infarction; TCAR, transcarotid artery revascularization.

stenosis > 50%) and physiologic appropriateness for revascularization. All carotid stenosis patients are treated with best medical therapy via cardiovascular risk factor reduction, multimodal antiplatelet therapy, and statin class lipid-lowering therapy. Once a potential has been identified for possible revascularization, a brief discussion regarding the role of risk-reduction procedures is undertaken, including information regarding the need for further axial imaging via CTA, and a return visit to review the data is arranged. The patient is encouraged to bring family members and health care decision-makers to that second visit.

At the time of the second visit, patients are given information regarding the risks associated with carotid revascularization. Our site is fully vested in the Vascular Quality Initiative (VQI) and closely tracks internal data regarding treatment strategy and outcome. These data are validated and compared with regional and national benchmarks on a continuous basis. National data are used to quote stroke/death risks for each of the three procedural modalities for both symptomatic and asymptomatic patients (Table 1).[4,5]

Upon review of the anatomic data, patients are then offered one of the four possible treatments: (1) continued best medical therapy, (2) carotid endarterectomy, (3) transfemoral stenting, or (4) transcarotid artery revascularization (TCAR). Our institutional preference for minimal-access carotid surgery is toward TCAR based on internal experience and the strong literature supporting its role as a revascularization strategy for high-risk patients. Potential TCAR patients are screened for inclusion and exclusion criteria in the Society for Vascular Surgery VQI TCAR Surveillance Project.[6]

As a tool to assist with the SDM goal, an electronic consent is generated in the Epic medical record system using a standard template. Via modular and separately maintained rich text documents, the generated consent contains general and patient-specific risks and benefits associated with the procedure (Figure 1 on page 10). Several figures are used to illustrate key steps of the case and improve patient understanding. The patient is given both a hard copy and electronic copy of the document. The surgeon fully explains the document to the patient and addresses any questions or concerns with the patient and their representatives. Once a shared decision to proceed with the case is reached, the visit is concluded with the attending surgeon entering a formal case request order into the electronic medical system to ensure fidelity and laterality. ■

1. Agency for Health Care Research and Quality. Is lung cancer screening right for me? Accessed June 11, 2020. https://effectivehealthcare.ahrq.gov/decision-aids/lung-cancer-screening/decisionmaking-tool.html.
2. Aruru M, Salmon JW. Assessment of Medicare Part D communications to beneficiaries. Am Health Drug Benefits. 2010;3:310-317.
3. Centers for Medicare & Medicaid Services. Toolkit for making written material clear and effective. Accessed June 11, 2020. https://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit.
4. Sidawy AN, Zwolak RM, White RA, et al. Risk-adjusted 30-day outcomes of carotid stenting and endarterectomy: results from the SVS vascular registry. J Vasc Surg. 2009;49:71-79. doi: 10.1016/j.jvs.2008.08.039
5. Malas MB, Dakour-Aridi H, Wang GJ, et al. Transcarotid artery revascularization versus transfemoral carotid artery stenting in the Society for Vascular Surgery Vascular Quality Initiative. J Vasc Surg. 2019;69:92-103.e2. doi: 10.1016/j.jvs.2018.05.011
6. ClinicalTrials.gov. SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR). Accessed May 27, 2020. https://clinicaltrials.gov/ct2/show/NCT02850588.

STRONG MEMORIAL HOSPITAL CONSENT FOR MEDICAL OR SURGICAL PROCEDURE SH 419 MR

Patient Name:_____ DOB: _____

- Please read this form or have someone read it to you.
- It's important to understand all parts of this form. If something isn't clear, ask us to explain.
- When you sign it, that means you understand the form and give us permission to do this surgery or procedure.
- I agree for Dr. Stoner, and other members of the Division of Vascular Surgery (Drs. Stoner, Ellis, Doyle, Raman, Glocker, Mix) along with any assistants* they may choose, to treat the following condition(s): Carotid artery blockage
- By doing this surgery or procedure on me: Place a stent in the carotid artery under flow reversal
- This is also known as: TransCarotid Arterial Revascularization (TCAR)
- Laterality: LEFT

*if you'd like a list of the assistants, please ask. We can give that to you.

Patient information regarding TransCarotid Arterial Revascularization (TCAR)

Condition to be Addressed:

You have been diagnosed with a blockage in the carotid artery, which supplies the brain and is a risk factor for a stroke. Your surgeon has recommended fixing this blockage with a small metal tube known as a stent. There are alternatives to TCAR such as using medications, placing a stent from the groin artery to the carotid artery, or a surgical procedure to clean out the blockage directly. Your surgeon feels TCAR is the safest way to deal with this blockage in your case.

About TCAR Procedure:

You will be admitted to the hospital and taken to an operating room. After you are made comfortable with anesthesia, the surgeon will make a small incision just above your collarbone to expose the carotid artery (Figure 1).

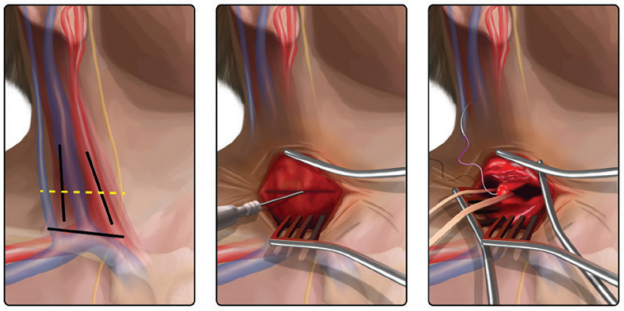

Figure 1. The carotid artery is exposed just above the collarbone.

After that, the surgeon will place a small catheter in your femoral (groin) vein (Figure 2). This catheter will be used to setup the flow-reversal which diverts blood from the carotid artery to the vein to keep any debris from getting dislodged and traveling to the brain.

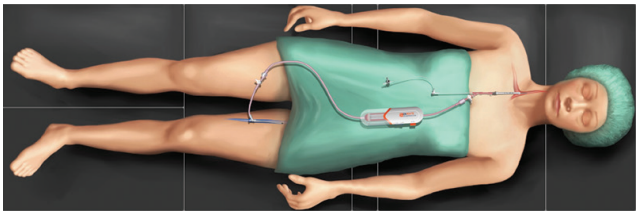

Figure 2. A catheter is placed in the carotid artery and femoral (groin) vein. This causes blood flow to temporarily flow away from the brain while the surgeon is working on the carotid artery. Any debris that is released is caught in a filter.

Once the catheters are in place, the blockage in the neck artery will be stretched with a balloon, and then covered with a small mesh metal tube called a stent (Figure 3). When this is complete, flow is restored to the brain. The catheters are then removed and the incision is closed up with sutures.

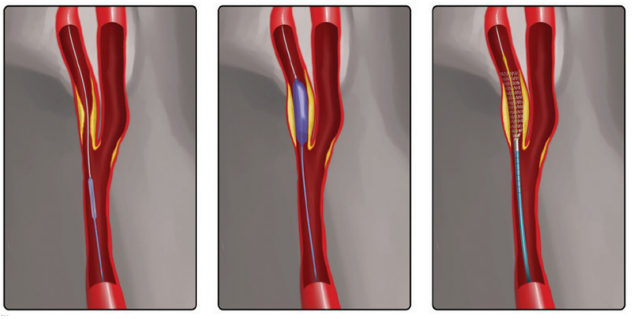

Figure 3. While blood is being diverted away from the brain, a small wire is used to cross the blockage. A balloon is temporarily inflated to push the blockage out of the way, then a stent is placed.

Alternatives:

There are several ways to treat a carotid artery blockage which include:

1. Medical treatment with blood thinners and drugs to improve cholesterol level
2. Placement of a stent routed from the femoral (groin) artery to the carotid artery
3. Carotid endarterectomy, which is a surgical procedure to open the carotid artery and clean out the blockage directly.

Risks and Discomforts:

Stroke: During the procedure there is a risk of stroke if material from your blood vessels should break off and travel to the brain. It is important to understand that while this procedure is designed to reduce your risk of stroke, there is a small risk of stroke associated with the surgery. Your surgeon feels that the risk of stroke is higher without surgery than with the surgery.

Bleeding: There is a risk during or after the procedure that either the carotid artery or femoral vein could bleed. This may result in the need for further surgery, blood transfusions or other procedures.

Nerve Injury: Temporary or permanent injury to nerves that lie next to the carotid artery could result in changes to your voice (hoarseness), difficulty swallowing or difficulty breathing. Nerve injury may require further surgery or procedures to address in some cases.

Infection: There is a risk that the incision or even stent could get infected. This could require additional medications or procedures to address.

Need for a Prolonged Stay in the ICU: This procedure is complex and as with any complex surgery there is a risk for you to become ill requiring prolonged complex medical care including, antibiotics, need for ventilator support, or need for a tracheostomy/feeding tube. Your family should know your wishes related to these treatments prior to your surgery.

Figure 1. Informed consent document used at the URMC to facilitate SDM in patients undergoing TCAR procedure.

Reaction to the Intravenous Contrast Dye: There is also a risk that you could have a reaction to the IV contrast dye given during the procedure. Sometimes this reaction is life threatening and could require that your breathing tube be kept in for a prolonged period of time. Sometimes the contrast dye can decrease your kidney function requiring need for temporary or permanent dialysis.

Death: This procedure is complex and involves changing the blood flow to your brain. Given the nature of this procedure there is a risk of death during the procedure related to the procedure itself or complications of the procedure. It is important to understand that the purpose of carotid repair is to prevent stroke and death but the procedure itself places you at risk for death. Your doctor has offered this procedure because he/she believes that the risk of not treating your carotid is greater than the risk of the surgery.

1. The care provider has explained my condition to me. They have told me how the procedure can help me. They have told me about other ways of treating my condition. I understand the care provider cannot guarantee the result of the procedure. If I don't have this procedure, my other choices are: No surgery with continued observation.
2. The care provider has told me the risks (problems that can happen) of the procedure. I understand there may be unwanted results. The risks that are related to this procedure include: Need for future revisions of implant due to leaks into aneurysm, excessive bleeding, infection of implant, paralysis, access site infection and/or wound break down in groins or neck, allergic reaction to contrast dye, kidney failure with potential need for temporary or lifelong dialysis, lung failure requiring dependence on ventilator or need for tracheostomy, heart attack, stroke, lowered or loss of blood flow to legs, blood clots in legs, pulmonary embolism, need for additional future or emergent procedures, death.
3. I understand that during the procedure, my care provider may find a condition that we didn't know about before the treatment started. Therefore, I agree that my care provider can perform any other treatment which they think is necessary and available.
4. I understand the care provider may remove tissue, body parts, or materials during this procedure. These materials may be used to help with my diagnosis and treatment. They might also be used for teaching purposes or for research studies that I have separately agreed to participate in. Otherwise they will be disposed of as required by law.
5. My care provider might want a representative from a medical device company to be there during my procedure. I understand that person works for: Representative from device company The ways they might help my care provider during my procedure include: providing information and support to hospital staff regarding the device, helping the OR staff prepare and other, including any hands on assistance (describe)
6. Here are my decisions about receiving blood, blood products, or tissues. I understand my decisions cover the time before, during and after my procedure, my treatment, and my time in the hospital. After my procedure, if my condition changes a lot, my care provider will talk with me again about receiving blood or blood products. At that time, my care provider might need me to review and sign another consent form, about getting or refusing blood.

I understand that the blood is from the community blood supply. Volunteers donated the blood, the volunteers were screened for health problems. The blood was examined with very sensitive and accurate tests to look for hepatitis, HIV/AIDS, and other diseases. Before I receive blood, it is tested again to make sure it is the correct type.

My chances of getting a sickness from blood products are small. But no transfusion is 100% safe. I understand that my care provider feels the good I will receive from the blood is greater than the chances of something going wrong. My care provider has answered my questions about blood products.

My decision about blood or blood products	Yes
My decision about tissue Implants	N/A
I understand this form. **My care provider or his/her assistants have explained:**	What I am having done and why I need it. What other choices I can make instead of having this done. The benefits and possible risks (problems) to me of having this done. The benefits and possible risks (problems) to me of receiving transplants, blood, or blood products. There is no guarantee of the results. The care provider may not stay with me the entire time that I am in the operating or procedure room. My provider has explained how this may affect my procedure. My provider has answered my questions about this.

I give my permission for this surgery or procedure.	_____ My signature (or parent or other person authorized to sign for you, if you are unable to sign for yourself or if you are under 18 years old)	_____ **Date**	_____ **Time**

Electronic Signatures will display at the bottom of the consent form.

Care provider's statement: I have discussed the planned procedure, including the possibility for transfusion of blood products or receipt of tissue as necessary; expected benefits; the possible complications and risks; and possible alternatives and their benefits and risks with the patients or the patient's surrogate. In my opinion, the patient or the patient's surrogate understands the proposed procedure, its risks, benefits and alternatives.

Electronically signed by: Michael C Stoner, MD	5/19/2020 **Date**	8:50 AM **Time**

Electronically signed by Stoner, Michael C, MD at 5/19/2020 8:50 AM
Note shared with patient