REDEFINING RISK DISCUSSIONS: EXPLAINING RISK TO PATIENTS WITH SEVERE AORTIC STENOSIS

Individual risk assessment and shared decision making based on the most up-to-date clinical evidence is an imperative conversation to have in patients with aortic stenosis. Engaging in meaningful risk communication allows patients to understand and participate in their treatment decisions and also helps them monitor for adverse events following their procedure.

CASE #1

Mr. C is an 82-year-old male with previously asymptomatic severe aortic stenosis who is referred to your clinic for further management. The patient reports to you that he has HTN, HLD, IDDM, CKD III, and CAD with prior CABG. He has a prior heavy smoking history but quit after he had a debilitating stroke that left him walking with the assist of a cane.

He reports developing symptoms of dyspnea on exertion and increasing fatigue over the past several months. Additionally, he reports that he has started getting dizzy and lightheaded while mowing the lawn. He became aware of his diagnosis of aortic stenosis several years ago when his PCP ordered a screening echocardiogram for a heart murmur found on his annual physical exam.

He knows that surgery is one option but also heard there is a less invasive procedure with a quicker recovery time. He wants to improve his symptoms, but he is concerned about his risk of having another stroke. He would like to discuss all of his options.

Key Challenges

- Evaluation of patient goals is a key element of any risk communication conversation. This particular patient is focused on his risk of a recurrent stroke.
- Assessment of patients and delivery and communication of information in a multi-disciplinary setting using the expertise of both cardiothoracic surgeons and structural cardiologists is imperative.
- Communication of risk for TAVR requires knowledge of key clinical trial data in order to give an accurate risk assessment to patients.
- In Case 1, explaining the uncommon risk of stroke with this procedure in comparison to the much higher risk of poor outcomes with no treatment can be helpful.

HOW TO IDEALLY PRESENT OPTIONS AND ASSOCIATED RISKS

Begin by explaining transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) as additional options rather than simply continuing medical therapy. Shared decision making is a fundamental component of patient-centered care where clinicians and patients collaborate to make decisions based on the best clinical evidence that balances risks and expected outcomes in conjunction with patient choice, preference, and values. Given his co-morbidities and that this would be a second open heart surgery, this patient is at higher risk for surgical complications. The patient has expressed that his main focus is on any heightened risk of stroke with future procedure(s). While each treatment option has risks and benefits, physician perception of the importance of each risk and benefit may not align with a patient's perception and what matters most to them. In many situations, there is no single "right" healthcare decision since choices about treatment come with pros and cons, and the benefits and harms may affect each patient differently.

Key Challenges

- Recognizing that one of this patient's goals is not to undergo mechanical valve replacement with lifelong anticoagulation is an important part of the discussion.
- Assessment of patients and delivery and communication of information in a multi-disciplinary setting using the expertise of both cardiothoracic surgeons and structural cardiologists is once again imperative.
- Review with the patient what is currently known about surgical and transcatheter valve durability and what is not known yet.
- Be sure they understand and are not simply nodding their head without asking questions or for clarification.

In this scenario, as with all treatment strategies, it is important for the physician to communicate the risks, benefits, and alternatives of a procedure so that the patient understands them. Prior to beginning, explain (in understandable terms) the known risks of having a procedure such as SAVR or TAVR. Reinforce that these procedural risks are likely outweighed by the risks of no treatment at all given aortic stenosis only gets progressively worse with increased morbidity and mortality. From the onset of symptoms and if left untreated, approximately 50 out of 100 people (50%) will die within 2 to 3 years.

MORTALITY OF SEVERE AORTIC STENOSIS

50 out of 100 people will die in 2 to 3 years if severe aortic stenosis is left untreated

50 out of 100 people will still be alive in 2 to 3 years if severe aortic stenosis is left untreated

In discussing the risks of TAVR, it should be acknowledged that while research and clinical trial data can be difficult for patients to understand on their own, it is essential in order for them to make informed decisions. It is the clinician's job to give as simple of an explanation as possible. One of the most recent clinical trials (PARTNER 3) randomized patients with an average STS score of 1.9% (low risk) to TAVR with a third-generation balloon-expandable valve or standard SAVR. The composite endpoint of death from any cause, stroke, or re-hospitalization at one year after the procedure (TAVR 8.5 % vs SAVR 15.1%) suggests superiority of TAVR over SAVR. Mortality rates and stroke rates for TAVR vs SAVR showed 1% vs 2.5% and 1.2% vs 3.1%, respectively. At 30 days, TAVR was also statistically superior to SAVR for the secondary combined endpoint of all-cause mortality or disabling stroke (0.8% vs 2.6%). The prior PARTNER trials demonstrated similar results in intermediate and high-risk patients for surgery.

COMPOSITE ENDPOINT AT 1 YEAR WITH TAVR

8.5 out of 100 people experience a composite endpoint of death from any cause, stroke, or re-hospitalization at 1 year with TAVR

91.5 out of 100 people don't experience a composite endpoint of death from any cause, stroke, or re-hospitalization at 1 year with TAVR

COMPOSITE ENDPOINT AT 1 YEAR WITH SAVR

15 out of 100 people experience a composite endpoint of death from any cause, stroke, or re-hospitalization at 1 year with SAVR

85 out of 100 people don't experience a composite endpoint of death from any cause, stroke, or re-hospitalization at 1 year with SAVR

CASE #2

Mrs. L is a 59-year-old female with no known medical problems who was in her usual state of health until recently when she had a syncopal event while playing tennis. On further prompting, she reports feeling more fatigued over the past few months. An echocardiogram reveals critical aortic stenosis and a CT scan confirms her anatomy is amendable to TAVR with adequate transfemoral vascular access. She has undergone left heart catheterization with no evidence of obstructive CAD.

She is aware of SAVR and TAVR as potential therapeutic options and wishes to discuss the best individualized option for her. She is not interested in a mechanical valve that would require lifelong anticoagulation. She asks about surgical and transcatheter bioprosthetic valve durability given her relatively young age.

Begin by explaining TAVR versus SAVR. Based on the PARTNER 3 trial, TAVR has proven to be superior to SAVR in low-risk patients based on a combined endpoint of death from any cause, stroke or re-hospitalization at one year after the procedure as well as regarding individually both mortality and stroke rates.

Currently, the known long-term TAVR durability is excellent with the majority of patients remaining free of SVD between 5 and 10 years with fewer than 1 out of 100 patients having valvular failure. However, longer term data on valve durability are still lacking, which should be explained to the patient. Several studies have reported encouraging data on surgical bioprosthetic valve performance following implantation with more than 85 out of 100 people free from SVD at 10 years. However, the lack of standard definition for bioprosthetic valvular dysfunction up until recently has not allowed for effective comparison between various studies.

MAKING RISK MEANINGFUL

- It is important for physicians to engage in meaningful discussions with patients to best determine their needs. Inviting patients to participate lets them know that their voice is essential.
- Start by reviewing a patient's goals for care, which can deepen your connection and inform risk discussions. You can try saying: "Let's take a moment to better understand your healthcare goals today," to emphasize that their needs and concerns are being valued and heard. Reinforcing the concept that "Our goals are your goals" conveys mutual respect between the care team and patient and establishes that this is a collaborative partnership in helping them to meet their healthcare needs.
- Explain the diagnosis to the patient and how symptoms are related to that diagnosis. Help put into perspective in a simple way what can generally be expected in terms of outcomes if the illness progresses and were to go untreated.
- Provide information on the benefits and risks of treatment options in an easy-to-understand, non-threatening but direct way. In the first case, explain to the patient that he is high risk for a repeat open-heart surgery, and share with him the risk of stroke based on the most recent TAVR data. In the second case, emphasize that while current research suggests excellent and comparable durability for transcatheter and surgical bioprosthetic valve replacements, the data past 5-10 years for transcatheter valve durability is still unknown.
- Ask the patient to repeat back their understanding of their diagnosis and clarify as needed. "After talking today, I'd like to gauge what your understanding of your illness is. Can you explain it to me?" Be sure to make them feel comfortable to ask questions.
- Guide the patient through the use of any available risk assessment tool and then discuss the treatment options based on their goals and preferences. Make sure to also discuss the morbidity and mortality associated with no treatment, which can assist in highlighting potential benefits of treatment. Ask that they verbalize understanding of the risks. "Can you repeat back to me your understanding of the risks of this procedure?" This will actively engage them allowing for further processing and understanding of the procedure as well as prompting them to ask questions.
- Facilitate decision making and next steps, letting the patient know that they have some time to think things over. Provide information and resources such as shared decision making tools for the patient on the diagnosis and various treatment options, and schedule follow-up. Help your patient verbalize what further tests are being ordered or medications are being prescribed. "So what are the next steps we will be taking after your visit today?"

Core Essentials for Effective Risk Communications in the Current Era of TAVR vs SAVR

- As with all risk communication discussions, discern what the patient's healthcare goals are during the visit.
- Explain the diagnosis of aortic valve stenosis in understandable terms. Gauge the patient's level of understanding by using communication confirmation methods such as the teach-back method.
- Provide the most up-to-date information about the risks and benefits of surgical and transcatheter treatment options compared to getting no treatment or continuing on medical therapy only.
- Facilitate decision making and next steps. Provide information and resources (using up-to-date technology) for patients to reference as they strive to make an informed decision.
- Leave time for questions.