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TAVR in Low-Risk Patients

FDA Approval, the New NCD, and Shared Decision-Making

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Aortic stenosis (AS) is the most common valvular heart disease requiring intervention in the United States, and over the past decade, there has been a profound and rapid evolution in treatment paradigms. Based on an unprecedented clinical trial effort, transcatheter aortic valve replacement (TAVR) is now approved by the U.S. Food and Drug Administration (FDA) for the treatment of patients with symptomatic AS regardless of surgical risk. Swift adoption of this technology is evident across the country. The availability of evidence-based therapeutic alternatives for AS renews the focus on incorporation of patient values and preferences in a shared decision-making (SDM) approach. SDM for AS originally focused on surgical aortic valve replacement (SAVR), and many of the issues remain salient. These include the avoidance of clinician bias toward one therapy over another, the need for validated risk communication tools such as patient decision aids, and the importance of favorable clinician attitudes and skill sets in SDM. How are recent regulatory and reimbursement changes in TAVR affecting how clinicians partner with their patients in decision making? What is needed to most effectively and efficiently engage patients in these decisions, particularly for low-risk patients? The goal of this paper is to highlight how advances in research and resultant policy changes regarding the treatment of AS are shaping clinician and patient decision making and to recommend future directions to improve patient care.

FDA APPROVAL OF TAVR FOR LOW-RISK PATIENTS

The marked increase in high-quality data regarding the treatment of AS requires policy updates from regulatory agencies and payers; this led to the recent FDA approval of TAVR for low-surgical-risk patients and the reconsideration of the 2012 TAVR National Coverage Determination (NCD). The FDA issued its approval of TAVR in low-surgical-risk patients on August 16, 2019, and was the first regulatory body in the world to do so. The announcement did not address uncertainties being discussed in the cardiology and cardiac surgery communities regarding how TAVR would be utilized in lower-risk patients. Understanding the risks and benefits of TAVR in these patients is challenging given both the relatively short time frame for the existing follow-up in the published data (between 5 and 10 years for patients at high to prohibitive surgical risk [1,2] and 1 to 2 years for low risk), exclusion of bicuspid valve disease in many studies, and the advanced age of patients in the low-surgical-risk trials (an average of 73 to 74 years of age) (3,4). In addition, data is limited in young patients given the small number of patients having completed long-term follow-up with transcatheter bioprosthetic valves and an inability to extrapolate from other populations, due to differences in activity levels affecting bioprosthetic valve durability. Often overlooked, but equally important, is the absence of data on what matters most to low-risk patients with AS. The goals of lower-risk patients are anticipated to be

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distinct from those at higher risk who may favor functionality and quality of life over longevity (5). Thus, even with FDA approval, direction is lacking regarding the best practices for clinicians to guide low-surgical-risk patients through the newly available choice of TAVR versus SAVR.

NATIONAL COVERAGE DETERMINATION FOR TAVR

The Centers for Medicare and Medicaid Services NCDs dictate if and how therapies are made available to Medicare patients. The focus of the recent revision of the 2012 TAVR NCD was on the requirements for clinicians and hospitals offering TAVR: debate surrounded whether these requirements could be less restrictive and thus improve access to therapies. Data was reviewed at a Medicare Evidence Development and Coverage Advisory Committee meeting in July 2018, examining the relationship between procedure volumes and patient outcomes, with stakeholders (including clinicians, patients, industry, researchers, and others) providing presentations to committee members, including data on racial and geographic disparities in care and potential volume-outcome relationships.

The final decision memo was released on June 21, 2019, following 2 public comment periods (6). Notably, the NCD wording does not specify which surgical risks are to be covered, but refers to "the treatment of symptomatic aortic valve stenosis when furnished according to a U.S. Food and Drug Administration (FDA) approved indication" (6), allowing for immediate coverage of low-risk patients following FDA approval. Several controversial sections underwent revision after the public comment period. This included volume requirements for maintaining a program including percutaneous coronary intervention (from 400 to 300 cases/year) and aortic valve replacement (from 20 surgical AVRs per year to a combined requirement of *either* TAVR or SAVR equaling 50 cases/year), effectively expanding the number of hospitals that could offer TAVR. Although a requirement for 2 surgeons with privileges in the hospital was maintained, there was no specification of ongoing surgical requirements among programs seeking to continue to offer TAVR.

Importantly, some of the modifications not only affected where TAVR could be offered, but *how* patients would be presented their therapeutic options and who would be leading these discussions. The proposed memo suggested 1 cardiac surgeon would suffice; the final wording reflected public comments that emphasized a heart team approach to decision making with patients. It required evidence for reimbursement for TAVR that *both* "…a cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis… examined the patient face-to-face, (and) evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy" (6).

With the large randomized trials referenced above demonstrating that TAVR is at least equivalent and has different advantages and disadvantages to SAVR, we believe that a continued emphasis on a heart team approach, complemented by a formalized up-front SDM process, remains essential. Based on the current evidence base and regulatory landscape, it no longer seems appropriate that physicians of any 1 subspecialty control patient access to therapeutic choices; in hospitals without TAVR programs and long-standing referral lines to local surgeons, this provides a need for new health care delivery models. Given that patients referred for SAVR do not face a policy requirement for a heart team approach as those who referred for TAVR do, it is important to step back and examine how the entire cohort of patients with severe AS are being evaluated, engaged, and treated. We believe the NCD could have addressed this in 1 of 2 ways: 1) a broadened scope, mandating a heart team approach to all patients with AS referred for a valve intervention; or 2) setting a precedent with a mandate for SDM in the care of patients with severe AS.

SDM IN SEVERE AS FOR LOWER-RISK PATIENTS

The TAVR NCD fell short of requiring SDM or the use of an evidence-based decision aid (often used as a proxy for measuring SDM). SDM is an evidence-based approach to decision making, shown to improve patient outcomes, including patient knowledge, decisional conflict, and satisfaction. There is less evidence that decision aids or SDM steers patients to one decision over another; instead, data suggests that informed decisions are more likely to reflect patient values and preferences (7). SDM, with use of decision aids, is widely seen as a measure of high-quality decision making and is increasingly recommended in expert consensus statements and reimbursed by payers (8). The Centers for Medicare and Medicaid Services has several precedents for mandating SDM in NCDs: lung cancer screening, left atrial appendage closure, and implantable cardioverter-defibrillators. These contemporary examples further demonstrate

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

FDA = U.S. Food and Drug Administration

NCD = national coverage determination

SAVR = surgical aortic valve replacement

SDM = shared decision-making

TAVR = transcatheter aortic valve replacement

TABLE 1 Key Aspects of a Shared Decision-Making Process for Low-Risk Patients With Symptomatic Aortic Stenosis

	Details	Examples
Step 1: team talk	*Identify the problem* and confirm that there is >1 reasonable treatment option.	"I would like to share with you the options of SAVR and TAVR and how they differ."
	Justify the choice, emphasizing respect for individual preference and the role of uncertainty in outcomes	"There are unknowns about valve durability, and everyone feels differently about this."
	Defer closure. Support the process of deliberation by deferring closure (i.e., the patient says "you decide, doc" before information exchange)	"I will help you make a decision about how to treat your valve problem. Before I do, may I describe the options so I can understand how you value the differences?"
Step 2: option talk	*Check knowledge.* Learn what patients already know, and identify misconceptions.	"What have you heard about aortic valve replacement?"
	Describe options. Review pros and cons, using effective risk communication	"Using a decision aid for aortic stenosis, let us review the pros and cons of how to fix the valve now, and in the future."
	Summarize. Use teach back to clarify patient understanding	"Tell me what you understand about the main differences between SAVR and TAVR for you."
Step 3: decision talk	*Focus on preferences.*	"What matters most to you when considering valve replacement?"
	Check the need to defer or make a decision. This may include deferring the decision if more time is needed and offering an opportunity to meet again	"Are there more things we need to discuss before deciding how to treat your valve problem?"

Adapted with permission from Elwyn et al. (9).
SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

how policies have evolved following stakeholder input, including through broader inclusion of team members, from nonimplanting physicians *only* in left atrial appendage closure to inclusion of advanced practice providers in the implantable cardioverter-defibrillator NCD.

SDM is a process in which clinicians perform 3 distinct tasks with their patient: 1) identify that there is a choice to be made; 2) present information on all reasonable options; and 3) listen to informed patient preferences, deliberate with patients and families, and come to consensus on a decision (9) (**Table 1**). Although heart team clinicians often feel they already use an SDM approach, research suggests that basic patient education is often confused with this process (10); decision aids and values clarification exercises are infrequent in real world practice. Currently, there are at least 4 publicly available decision aids for AS developed using rigorous standards: a series of decision aids on the American College of Cardiology's patient-facing Cardiosmart web site; ValveAdvice, a Patient Centered Outcomes Research Institute-sponsored online risk calculator and educational tool; the Severe Aortic Stenosis Decision Aid, created with American College of Cardiology support; and BMJ Rapidrecs' tool for TAVR versus SAVR. These decision aids currently cover intermediate-, high-, and prohibitive-risk patients (all are available at the Shared Decision Making Web site under "Tools" [11]). Although decision aids are important, clinician skill sets in SDM are even more critical, and favorable clinician attitudes surpass both for successful implementation of SDM (12).

Even as the current TAVR NCD requires involvement of a multidisciplinary team in decision making, there is no evidence that heart team clinicians have the interest or skill sets to lead patients and their families in an SDM process. In fact, the published data suggest that individual physicians continue to fall short when it comes to SDM, bolstering the importance of additional training, tools, and policies that encourage favorable attitudes toward SDM (12).

We believe that it is now incumbent on the cardiology and cardiac surgery communities to embrace the existing evidence demonstrating that SDM is limited in real-world practice, and identify tools and implementation strategies to bring SDM to patients with severe AS (an example of an SDM process for severe AS is shown in **Table 1**) Complex aspects of decision making will include learning how diverse patients value the differences between SAVR (with mechanical or bioprosthetic valves) and TAVR. These may be distinct, and even contrary, to local physicians' assessments of the differences. These include stroke risk, pacemaker rates, paravalvular leak, the potential for atrial fibrillation, role of anticoagulation, future ease of additional procedures (i.e., coronary access), uncertainties regarding durability in all bioprosthetic valves, mode of valve reintervention, and short-term benefits such as rapid return to activities with minimal burden on others. Through this approach of positioning the patient as an expert in his or her own values, perspectives, and goals, we can hope to experience improvements in the quality of care delivery and patient-centered outcomes seen in other areas of medicine and surgery with SDM (7) and match the rapid innovation in therapeutic choices with state-of-the-art health care delivery.

CONCLUSIONS

The option of TAVR has expanded to low-risk patients because of robust clinical evidence and resultant policy changes. In this context, we recommend an SDM approach for *all* patients considering aortic valve replacement, with implementation of best practices to ensure incorporation of patient goals and preferences into final decision making, leading to improved patient outcomes.

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