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EDITOR'S PAGE

TAVR

How Low Should We Go?

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When angioplasty was first applied, the driving consideration was the avoidance of a surgical sternotomy. The patient was 36-years-old, the surgical procedure was known to be safe, and the safety of angioplasty was unknown. When transcatheter aortic valve replacement (TAVR) was first employed, the driving consideration was to avoid a high surgical mortality, and the patient was far advanced in age. The question of how low the aortic stenosis surgical risk can be and still justify the new procedure is a topic of great interest in interventional cardiology, surgery, and medicine in general and is addressed in this issue of *JACC: Cardiovascular Interventions*. A patient I recently encountered focused the question for me. He is 70 years old, suffering from rare brief episodes of atrial fibrillation, and was found to have moderate aortic stenosis with a calculated valve area of 1.2 cm^2. With the exception of his rare bouts of palpitations, he is asymptomatic and maintains a single-digit golf handicap. If next year his aortic valve measures 1 cm^2, should he proceed to surgical aortic valve replacement or hold out for TAVR should it become approved for lower risk individuals?

In this issue of *JACC: Cardiovascular Interventions*, 2 views on the expansion of TAVR to lower risk individuals contrast the opinion of interventional cardiologists and surgeons. Sondergaard (1) briefly reviews the overwhelming evidence for TAVR in inoperable high-risk aortic stenosis patients and points to the noninferiority of TAVR compared with surgical intervention in patients with intermediate risk. He points to very encouraging evidence for sustained durability and improved intermediate outcomes for patients treated percutaneously. He does distinguish between low-risk patients as identified by Society of Thoracic Surgeon (STS) scores and patients who are significantly younger than those who have been studied so far. He sees the likely expansion of TAVR to become the default strategy for patients with significant aortic stenosis.

Nappi et al. (2) raise the concern that interventional cardiology has developed a certain overconfidence in this new technology and wonders whether the physicians and industry with understandable bias toward the noninvasive approach are not moving too fast in considering TAVR for lower risk populations. Of particular concern to him is the long-term durability of these devices compared with surgical valve implantation in patients who have 20 or more years' life expectancy. He also wonders whether all the current surgical technologies have gotten a fair shake. Although low-risk STS scores may be found even in patients in their 80s, he considers this a very different circumstance than applying TAVR in low-risk patients even younger than our 70 year old. Although the conversation between these 2 editorial opinions was designed to achieve contrast, both of them concur on the need for further investigations, and they both raise the same unanswered questions regarding the new technology.

So what are the problems with TAVR that need to be overcome? Randomized trials have identified several different acute outcomes between surgical valve replacement and percutaneous insertion. Prominent among them was the frequency of moderate to severe aortic insufficiency that was more prominent in the TAVR patients. Technology has been making important advances in this area with reduction in aortic insufficiency with improved valve technologies including skirts around the valve ring and repositionable valves so that acute aortic insufficiency has been reduced near to levels found with surgery. The other discriminating feature has been the occurrence of atrioventricular conduction abnormalities resulting in the need for permanent pacing. That issue is addressed by the next 3 papers in this issue. The first of these addresses the incidence,

predictors, and outcomes of permanent pacemaker implantation following TAVR from the U.S. STS/ACC TVT (Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy) registry (3). The second paper details the predictors of permanent pacemaker implantation after TAVR with the SAPIEN 3 valve (Edwards Lifesciences, Irvine, California) (4). This valve, which has significantly reduced the incidence of aortic insufficiency due to its skirt around the prosthesis cage, was also associated with a higher incidence of atrioventricular block and pacemaker requirement. The third paper highlights the importance of right bundle branch block and its relationship to pacemaker requirement and the risk of mortality after TAVR whether a pacemaker is required or not (5). These 3 papers are discussed by Urena and Rodés-Cabau (6) in a comprehensive editorial. Among the issues raised is the question of how detrimental chronic pacing is to left ventricular function and ultimate mortality and how long an observation will be required to evaluate any negative impact? Urena and Rodés-Cabau (6) raise the question of whether the pacemaker implantation is indeed the cause for increased mortality or simply a marker of patients who are more likely to die. Can patients at high risk for permanent pacing (those with right bundle branch block) be better treated with open surgery? The challenge to industry, to develop improvements in the technology that would reduce the need for permanent pacing, was emphasized.

At this time with the expanding enthusiasm for TAVR, the potential advantages and disadvantages of surgical intervention should be considered, especially in the young patients for whom it is now contemplated. The evidence so far might suggest that surgery may be associated with a lower incidence of aortic insufficiency and the need for permanent pacing and with a questionable differential need for chronic anticoagulation. The observation of thrombi on some expandable valves has raised concerns, although the embolic complications of such thrombi have been rare. This observation may be partly due to the greater scrutiny of percutaneous expandable valves compared with those surgically implanted, but the question of application of vitamin K antagonists or new oral anticoagulants is a hotly debated topic in the field. Finally, the question of durability has not been completely put aside. Surprising to many of us, the percutaneously inserted valves have shown remarkable durability comparable to surgical prostheses, but the follow-up is not long enough to completely reassure the 70-year-old patient. Will we have a definitive randomized controlled trial testing TAVR against surgical valve implantation, not only for patients who are at low surgical risk but also for patients of substantially younger age? If such a trial was carried out, what would be a reasonable duration of follow-up? Would it be 10 years, 15 years, 20 years? Undoubtedly there would be major technologic advances in this time frame and therefore whatever devices and procedures were tested the question of whether they applied to the evolved methods would remain. One of the more responsible initiatives in the development of this field has been the requirement in North America for the involvement of surgeons as well as interventional cardiologists. I believe that it is inevitable that less invasive and less expensive therapies will ultimately prevail, and that the experience and collaboration of surgeons, interventional cardiologists, and industry will best ensure that this evolution has the best chance to solve the remaining problems. Meanwhile, the question remains for our "young" and vigorous patient.

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