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EDITOR'S PAGE

A Rose by Any Other Name: A Valve by Any Other Method

The interest in catheter-based treatment of aortic stenosis is at a fever pitch, as indicated by the standing-room crowds packing the presentations at the recent ACC Scientific Sessions in Chicago. We, at *JACC: Cardiovascular Interventions*, have also been overwhelmed by the large number of submissions on the subject. There are so many important papers that we decided to dedicate this issue exclusively to transcatheter aortic valve intervention (TAVI). Is that excitement driven by the dramatic results of the PARTNER (Placement of AoRTic TraNscathetER Valve) trials or by the worldwide adoption of this technology outside the United States? My view is that the main driver of the current interest in the United States is the pending Center for Medicare and Medicaid Services (CMS) action which will approve reimbursement for TAVI (or is it TAVR?). But what is in a name? Maybe not much, but an interesting linguistic divide has emerged in naming the procedure. You will notice that TAVI, the original designation, has morphed into "TAVR" in the United States but remains TAVI in the world where it is already approved. Is that because authors from outside North America need a native English speaker to edit their manuscripts? Hardly, since in England it remains "TAVI", and on last check, English is widely spoken there. Is the change because the valve is "replaced" rather than simply "implanted"? Certainly not. Perhaps one could make the point that the valve function is being replaced, although in common parlance, "replaced" indicates that something is removed and another is put in its place. "Placed" would work but who could pronounce "TAVP"? Implantation seemed okay, and of note, most papers in this focused issue used the designation "TAVI". The selected papers for this issue reflect the dominance of the international experience with this technique. So, why has the name been changed in the United States? Is it because TAVR has a throaty, more macho sound than TAVI? Perhaps not, but we are getting close. The role of CMS and other insurance carriers should be considered. There are codes existing for aortic valve surgery which use the current language of aortic valve replacement since the old valve is removed and a new one is put in. Perhaps the more "macho" name can engender a more robust reimbursement. Do not get me wrong—I have been involved with a few percutaneous and minimally invasive transcatheter valve procedures and they are demanding and technically complex and deserve reimbursement that is appropriate. Ahhh, but what is in a name?

Perhaps I should move to a more serious topic concerning this potentially revolutionary technology. As the CMS approval is pending, the question of who will be performing the procedures is of great interest. The CMS will mandate institutional and operator experience or at least the performance of other structural heart disease procedures that can make the mastering of these procedures likely. What kind of experience will serve as qualification to become an aortic valve implanter? Is a high volume of percutaneous coronary interventions (PCIs) helpful? Is "structural heart" experience helpful if it is predominantly closure of patent foramen ovale? Cardiothoracic surgery will play a prominent gatekeeper role since approval for reimbursement will be only for those patients judged to be at prohibitive operative risk by 2 surgeons. How many hospitals will be launching this activity? There is speculation that 200 to 400 sites may be approved. If PCI is any indicator, there will be enormous political pressure to expand the number of sites with the argument for enhanced patient access. Until and unless this technology becomes completely user-friendly, restriction to centers that can provide high volumes of

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Another issue that will not be resolved in the short term is who should have the procedure. Current approval is for extremely high-risk patients who are not only Medicare recipients (ergo: the importance of CMS in this discussion) but on average are over 80 years of age, and many over 90 years of age. Although the PARTNER results dramatically favored the treatment group, mortality from other causes remains high in this population. Identification of which patients are likely to have a sustained benefit and which ones are not is an important area for investigation. The ethical debate about distributive justice related to technologies that consume large amounts of healthcare resources will be intensifying in years to come.

Although approval will be for inoperable patients, the PARTNER cohort A trial 2-year results reported at the ACC Scientific Session continued to show parity with surgical approaches in high-risk but operable patients, and the PARTNERS II trial of intermediate-risk patients and the CoreValve trials are under way. These necessary, randomized, controlled trials, emanating largely from the United States, and vast observations from countries with approval, will likely lead to widespread use of these technologies and those that grow from this innovation. It was a wise decision for the sponsors and the Food and Drug Administration to insist on a collegial involvement of surgeons and cardiologists. Hopefully, for the sake of patients, the "heart team" will survive after wider dissemination of the method.

This year in Rouen, France, many pioneers celebrated with Alain Cribier the 10th anniversary of TAVI. Whether we call this "rose" TAVI or TAVR, for the patients who will benefit, it is truly "sweet"!

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