

defined by the authors as “a worrying trend,” might actually represent an intriguing revolution in aortic stenosis management considering the benefit in terms of length of stay in hospital demonstrated by the study (1) and the relative consequences on perioperative costs. Is this just a “worrying extreme” or could something be done to make it happen? We believe that besides resolving the still-known daunting issues affecting TAVI outcomes (2), there are some hidden players. First, keep in mind that the concept of transcatheter valve replacement was initially ideated by Bonhoeffer et al. as a transvenous placement of a pulmonary valve prosthesis. However, none of the current devices used for TAVR considers in detail the anatomic characteristics of the aortic root, which, differently from the pulmonary valve, is an anatomic-functional unit composed by the annulus, the sinuses of Valsalva, and sinotubular junction with peculiar geometrical features.

Second, the majority of TAVI candidates have extremely calcified valves and annuli that are factors known to expose the patient to increased risk of conduction blocks or paravalvular leaks (3). The possibility of surgically decalcifying the annulus and guaranteeing better hemodynamics and thus enabling larger effective orifices might constitute an advantage over TAVI, as shown in clinical studies, especially for poorly functioning left ventricles. Indeed, a recent study demonstrated superiority in terms of in-hospital mortality, incidence of paravalvular leaks, and need for pacemaker of surgical sutureless valve implantation over TAVI in an age- and risk-matched large cohort of patients (4). On the other hand, outcomes of conventional surgical aortic replacement in elderly patients with high Society of Thoracic Surgeons scores are considered more than satisfying (3), and Indraratna et al., in a systematic analysis of cost-effectiveness in aortic valve treatment, showed that TAVI expense might be justified in comparison to medical therapy for patients deemed not to be surgical candidates, but there is not sufficient evidence to economically justify the use of TAVI in preference to surgical aortic replacement in the high-risk surgical patients (5).

On this basis, what would be the selection criteria to offer TAVI in lower risk categories? Should particular features of aortic disease, such as heavy valve calcifications, unsuitable annulus geometry, or aortic configuration, be considered as a deterrent for TAVI in lower risk candidates and instead move these patients to a conventional procedure, maybe through a minimally invasive approach, with a high surgical risk but more secure results? Conversely, would an even younger patient with an amenable anatomy and moderate valve disease benefit from the rapid

recovery provided by TAVI over conventional surgery in light of the increasingly positive results shown by the past trials?

We are convinced that TAVI will be a fundamental revolution in aortic stenosis, but should we stop and rethink on the selection criteria to achieve this TAVI revolution?

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REPLY: TAVI in Lower Risk Patients

Revolution or Nonsense? Keep Calm and Select Patients



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We read with interest the comments by Dr. Spadaccio and colleagues regarding the results of the OBSERVANT (Italian Observational Multicenter Registry) study, and we thank them for giving us the opportunity to clarify some of the issues raised in their letter. First, we would like to emphasize that OBSERVANT is a prospective observational study that enrolled consecutive patients with severe aortic stenosis treated with either surgical aortic valve replacement (SAVR) or transcatheter aortic valve implantation (TAVI) at 93 Italian centers between December 2010 and June 2012 (1). Therefore, it represents a “screen shot” depicting the adoption rates of SAVR and

TAVI in Italy during the study period. After having acknowledged that most of patients treated with TAVI were at low or intermediate risk, we therefore labeled this finding as “worrying,” in light of the lack of evidence supporting the role of TAVI in this particular population up to mid-2012. However, growing evidence coming from randomized controlled trials (2) and first reports of new-generation transcatheter valves (3) have created many expectations for the future of TAVI.

We respectfully disagree with Dr. Spadaccio and colleagues when they state that none of the current devices used for TAVI consider in detail the anatomic characteristics of the aortic root. Besides the fact that the authors of the letter do not provide any explanation for this statement, we believe that transcatheter valves have been accurately designed and developed to fit well to the aortic root and calcified valves. In addition, new-generation TAVI devices have incorporated features to address the limitations of the first-generation devices (i.e., outer skirt, easier positioning, repositionability, and retrievability).

We concur that annular calcification represents an important issue of TAVI, being usually responsible for paravalvular regurgitation or annular injury after valve deployment. However, with increased understanding of mechanisms associated with such complications and integration of new devices and tailored prosthesis sizing, clinical outcomes of TAVI have shown to compare favorably with the latest surgical series (–2-4). In fact, according to our knowledge, all the current evidence indicates that TAVI is at least noninferior compared with SAVR (–2-4). The study by Biancari et al. (4) included TAVI procedures performed in a single center at a very early stage of the local program and with first-generation devices, thus justifying the suboptimal results reported in the TAVI cohort. Indeed, the most recent TAVI series report (3) on in-hospital mortality of 1% to 2%, and significant paravalvular regurgitation rate of less than 5%.

In terms of valve hemodynamics, Dr. Spadaccio and colleagues indicated better performances of surgical bioprostheses, obtained thanks to valve decalcification. However, previous reports are all consistent in stating that patient-prosthesis mismatch is more frequent and more often severe after SAVR than TAVI (5).

In conclusion, in light of the promising results of TAVI in high-risk populations and the expected reduced rates of complications related to the increased operators' experience and the improved designs of the devices, future exploratory trials should investigate the reproducibility of TAVI results

achieved in the high-risk patients also in those not completely fulfilling a strict definition of “high-risk.”

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Nitrites/Nitrates in Heart Failure With Preserved Ejection Fraction



With great interest, we read the carefully performed study by Borlaug et al. (1) on the beneficial effect of sodium nitrite on invasive exercise hemodynamics in patients with heart failure with preserved ejection fraction. We appreciate their findings and suggest a complementary explanation: Although organic