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INNOVATIVE VALVE DISEASE THERAPIES, A POTENTIAL BENEFIT FOR PATIENTS BUT CALLING FOR MORE CLINICAL EVALUATION

Reply to the Editor:

Although we did not take their letter as a critique of our recent study comparing transcatheter aortic valve implantation with surgical aortic valve replacement,¹ we read with great interest the commentary by Santarpino and colleagues² and welcome the opportunity to reply.

The treatment of aortic valve disease has been the theater of outstanding progress during the last 2 decades, with the emergence of such breakthrough health technologies as transcatheter aortic valve implantation. The same tends to be observed for mitral valve therapies, with promising approaches such as percutaneous repair³; however, higher-level evidence remains to be generated.⁴

There is no doubt that the growing number and the wider diversity of health technologies represented by innovative medical devices and surgical approaches should be welcomed. These have the potential to improve survival and other clinical outcomes, as well as quality of life, and to provide alternatives in clinical situations with high unmet needs.

The expansion of therapeutic armamentarium can become such that the medical decision making is complexified, however, unless it is guided by evidence from various sources of clinical effectiveness and safety data. This is why scientific publications reporting clinical evaluation of health technologies, here used for aortic valve therapy, should be encouraged rather than been seen as putting various approaches in competition.

Clinical evaluation of new health technologies using comparative methods is crucial to generate evidence and can be complemented by systematic review methods that synthesize the best available evidence. This process, together with individual clinical expertise and patient preference, contributes to evidence-based medicine,⁵ which should be consistently promoted because it strengthens the choice for an optimal tailored approach to the individual patient as advocated by Santarpino et al.² The need for more clinical evaluation should be even further emphasized for medical devices, because they are generally less evaluated than medicines as a result of less stringent regulation, especially in Europe.

Randomized, controlled trials are the most robust design, offering the major advantage of generating strictly comparable groups, thus allowing the best measure of a new treatment

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efficacy. The disadvantage of randomized, controlled trials is that often the evidence is based on a highly selected population, which can raise issues of generalizability. This is why complementary sources of data, such as those from observational “real-world” studies, are worthy of being considered. Our recent study that compared clinical outcomes of transcatheter aortic valve implantation and surgical aortic valve replacement with a nationwide database is one such example.¹ Unlike theoretically based randomized, controlled trials, “real-world” studies provide a comprehensive view of the effectiveness of a new intervention in a more representative population, yet with a slightly higher risk of generating groups of patients that are not strictly comparable.

Irrespective of the design chosen to generate evidence, we fully agree with Santarpino and colleagues² that follow-up durations of patients in these studies should be sufficient to capture long-term clinical outcomes. Similarly, as emphasized by Santarpino and colleagues,² economic evaluation conducted alongside clinical studies should be promoted because of the substantial costs of some of these new health technologies.

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TAILORED APPROACH FOR SEVERE AORTIC STENOSIS Reply to the Editor:

We thank Dr Santarpino and colleagues for their insightful comments on our article.¹ Today, transcatheter aortic valve implantation (TAVI) has evolved as the standard treatment for severe aortic stenosis in patients with high surgical risk. Decision-making for TAVI or surgical aortic valve replacement (SAVR) should be performed by a heart team consisting of cardiologists, cardiac surgeons, and anesthesiologists. The European guideline recommends that in the patients with intermediate surgical risk (Society of Thoracic Surgeons or European System for Cardiac Operative Risk Evaluation II >4% or logistic European System for Cardiac Operative Risk Evaluation I >10%), the decision between SAVR and TAVI should be made by the heart team.² Other risk factors not included in these scores, such as frailty, calcified aorta, sequelae of chest radiation, hostile chest, and chest deformity, should be also taken into consideration.

In their letter, Santarpino and colleagues state that patients undergoing transapical (TA) TAVI are generally at greater risk than those who are treated with transfemoral (TF) TAVI, and that patients undergoing SAVR are less frail than patients undergoing TAVI. We agree with the authors of the letter and that is the one of the reasons that the TA group had a greater mortality than the minimally invasive aortic valve replacement (MIC-AVR) and TF groups in our study, although the difference did not reach statistical significance. Although each group had comparable perioperative risks after propensity score matching with 23 perioperative factors, we did not analyze other factors, such as

porcelain aorta, frailty, the history of thorax radiation therapy, or chest deformity. These factors also have an impact on mortality and morbidities.

Considering the use of cardiopulmonary bypass for SAVR and comparing it with the invasiveness of each approach, it could be expected that bleeding complications occur more in the MIC-AVR and the TA groups than the TF group. In our study, there was no significant difference in the incidence of bleeding complications.

As recommended by the authors, we analyzed the costs in the propensity score-adjusted groups. The median costs for the patients undergoing TAVI, at 36,889 € TA and 33,884 € TF, are nearly twice as high as in the MIC group, at 17,350 €. This was also found by Osnabrugge and colleagues,³ and they pointed out that the difference was mainly caused by the greater costs of prostheses and devices.

Although the clinical outcomes of TAVI have improved and devices are steadily evolving, uncertain clinical issues still exist, such as the durability of valves. The long-term influence of silent stroke and hemodynamic influence of conduction abnormalities after TAVI are also still unclear. In addition, TAVI is significantly more expensive than MIC-AVR. These issues should be clarified and resolved before expanding the TAVI indication to low-risk patients with longer life expectancy.

We agree completely with the authors' concept of "different patients = different procedures," and cardiac surgeons should be able to offer SAVR, TA-, and TF-TAVI procedures and tailor the approach to the individual patient.

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