The gray zone is always more dark

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Aortic valve stenosis is a frequent disease in the elderly population, and if it is not treated, it is associated with increased mortality and morbidities.¹ The only treatment option for this disease is valve replacement, and for many decades, aortic valve replacement (AVR) using sutured valves through a median sternotomy has been considered the only solution to improve symptoms and avoid heart failure and death. Nevertheless, in 2003 a European Survey showed that 40% of patients with severe aortic stenosis are denied surgery because they are at prohibitive risk.² In this scenario, transcatheter aortic valve implantation (TAVI) has played an important role for the treatment of this disease in unoperable or at high-risk surgical patients, and now it has been proposed even in the low-risk setting.^{3,4}

TAVI is a minimally invasive solution because it does not require opening the chest or using the cardiopulmonary bypass machine. New alternative strategies for the treatment of high-risk patients have been developed. The combination of minimally invasive AVR surgery with sutureless technology has shown excellent results in terms of postoperative outcomes; therefore, it has been considered an appropriate treatment option for high-risk patients and the real alternative to TAVI in operable patients (Figure 1).⁵

In this issue of the *Journal*, D'Onofrio and colleagues⁶ report the outcomes of patients undergoing AVR with

TAVI sutureless.

Central Message

The role of the heart team is mandatory in the selection of patients for TAVI or surgical sutureless technology.

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TAVI or sutureless prosthesis in a 7-year period. Data extrapolated from the Italian Transcatheter Balloon Expandable Registry were compared with a European dataset of patients who underwent sutureless AVR. As expected, because of the different risk profile of the 2 databases, the overall mortality was higher in the TAVI group; however, these data were not confirmed after propensity matching score analysis. Nevertheless, a well-matched analysis on medium-risk patients with severe aortic stenosis showed that sutureless AVR had better device success and a lower incidence of paravalvular leakage when compared with TAVI.

This article⁶ adds evidence that when a patient is defined as operable, surgery is still the first treatment of choice for the treatment of patients with aortic disease, because the results shown by the authors are still superior to TAVI. Furthermore, the wide use of sutureless technology in combination with any minimally invasive procedure will reinforce this affirmation.

Despite these encouraging conclusions, some considerations are required. According to D'Onofrio and colleagues,⁶ the strength of their study is that the sample analyzed is taken from 2 “real-world,” “all-comers” registries. However, in this study, the proportion of patients undergoing TAVI is 9-fold higher than those patients who underwent surgical sutureless AVR. Real-world means all types of patients, and I would have expected to have a high proportion of patients undergoing surgical AVR and not the contrary. The fact that 6 of 8 cardiac centers have performed less than 50 sutureless AVRs in their experience shows that their sutureless database is only a group of selected patients undergoing cardiac surgery.

FIGURE 1. The TAVI (Sapien; Edwards Lifesciences, Irvine, Calif) and sutureless (Perceval S; LivaNova, London, United Kingdom) valves.

The second consideration regards the definition of “gray zone.” To date, there is no dedicated surgical score to predict operative mortality and morbidity in patients undergoing isolated AVR. Although the European System for Cardiac Operative Risk Evaluation is a useful tool in death prediction, its performance is poor in the setting of a high-risk population. In addition, the European System for Cardiac Operative Risk Evaluation I is out of date, and more updated predictive scores should be considered for identification of a threshold of risk.

Although propensity matching was performed, from a methodological point of view this study still presents several bias. No frailty score has been considered. Furthermore, neither the cardiac center nor the year of the procedure has been forced in the propensity score analysis. Finally, this study ends at 30 days; therefore, we do not have any information regarding the potential adverse effect of paravalvular leakage on midterm outcome.⁷

These thoughts highlight the importance of a heart team, which is mandatory to define and identify the appropriateness of a specific procedure on a specific patient. This is the right way to go for our patients and health care system!

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