Minimally invasive aortic valve replacement with sutureless valve is the appropriate treatment option for high-risk patients and the “real alternative” to transcatheter aortic valve implantation

Mattia Glauber, MD, and Antonio Miceli, MD, PhD

From the Centro Cardiotoracico, Istituto Clinico Sant’Ambrogio, Gruppo Ospedaliero San Donato, Milan, Italy. Disclosers: M.G. has financial interest in Sorin. The other author has nothing to disclose with regard to commercial support.

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Address for reprints: Antonio Miceli, MD, PhD, Centro Cardiotoracico Istituto, Clinico Sant’Ambrogio, Gruppo Ospedaliero San Donato, Via Faravelli 16 20149, Milan, Italy (E-mail: antoniomiceli79@alice.it).

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Mattia Glauber, MD, and Antonio Miceli, MD, PhD

Central Message

Minimally invasive aortic valve replacement with a sutureless valve is the first-line treatment option for operable high-risk patients.

See Articles page 735, page 833 and 841 in the October issue, and page 1570 in the December issue.

See Editorial Commentary page 743.

Aortic valve replacement through a full sternotomy is the conventional approach for the treatment of aortic valve stenosis, and clinical outcomes have significantly improved in the last decade, despite gradual increases in patient age and overall risk profile.¹ Nevertheless, new alternative treatment options have been introduced into the clinical practice with the aim of reducing the “invasiveness” of the surgical procedure while maintaining the same quality and safety as a conventional approach.² Currently, there are controversies regarding the definition of minimally invasive aortic valve replacement (MIAVR). The Society of Thoracic Surgeons database defines as minimally invasive any procedure not performed with a full sternotomy and cardiopulmonary bypass support and specifically refers to the transcatheter aortic valve implantation (TAVI).³ Conversely, a scientific statement of the American Heart Association defines minimally invasive cardiac surgery as a procedure done with a small chest incision that does not include the conventional full sternotomy, distinguishing between the percutaneous and surgical approaches.⁴ We prefer the latter definition, because it highlights the concept that MIAVR is an operation-specific strategy aiming at reducing the surgical invasiveness.²

The most common MIAVR approach is the ministernotomy, followed by the right anterior minithoracotomy. Compared with conventional surgery, MIAVR has shown excellent outcomes in terms of mortality, morbidities, and patient satisfaction while providing faster recovery, shorter hospital stay, and better cosmetic results. Several meta-analyses have shown that MIAVR has the advantage of reducing bleeding and blood transfusions, atrial fibrillation, wound infection, and ventilation times, and it improves the respiratory function and reduces the time to return to normal activities.⁵⁻⁹ As consequence, MIAVR is associated with fewer rehabilitation resources and reduces costs. These benefits seem to be more evident in patients undergoing right anterior minithoracotomy.^{10,11} Despite

these results, MIAVR is performed in a minority of heart centers, and traditionalists claim that it is not “surgeon friendly” because it is technically more complex and requires a long learning curve.^{12,13} The reduction in working space for the exposure and implantation of a sutured valve is more challenging and reflects longer operative times associated with this procedure. Prolonged cardiopulmonary bypass and crossclamp times are associated with adverse outcomes, raising some concerns regarding MIAVR’s safety in elderly and high-risk patients.^{14,15} In this setting, the drawback of increasing operative times could be avoided by the adoption of sutureless technology, which facilitates the MIAVR approach.

In recent years, 3 different sutureless and rapid-deployment aortic valves have been introduced in Europe as alternatives to conventional biologic sutured valves for the treatment of medium- to high-risk patients undergoing aortic valve replacement. The Perceval S valve (Sorin Biomedica Cardio srl, Salluggia, Italy), Enable valve (Medtronic, Inc, Minneapolis, Minn), and Edwards Intuity valve system (Edwards Lifesciences, Irvine, Calif) have been designed to avoid passing the stitches through the annulus and suture knotting to simplify the surgical procedure and minimize the ischemic time. All these sutureless valves have shown excellent clinical and hemodynamic outcomes, no structural valve deterioration, and high freedom

from valve reoperation as late as 5 years.¹⁶⁻¹⁸ A recent meta-analysis of more than 1000 high-risk patients with an expected mortality of 10% reported that overall early and 1-year mortalities were 2.1% and 4.9%, respectively, while the 1-year incidences of stroke, valve deterioration, and endocarditis were 1.5%, 0.4%, and 2.2%, respectively. Finally, the overall rate of major paravalvular leakage (>2+) was 3%. Only 40% of patients, however, benefited from a minimally invasive approach.¹⁹ We have described the largest case series of patients undergoing a minimally invasive approach either through ministernotomy or right anterior minithoracotomy with sutureless valves and reported outstanding results. Operative mortality was 0.7%, and relative to our previous studies with stented valves, we found an overall 40% reduction in the crossclamp and cardiopulmonary bypass times, suggesting that sutureless valves facilitate the MIAVR approach and standardize the surgical technique.²⁰ Finally, the rate of major paravalvular leakage was 1.8%, similar to the Placement of Aortic Transcatheter Valves (PARTNER) 1A trial for stented valves.²¹ The reduction of ischemic time was confirmed in comparative studies between sutureless and conventional stented valves.²²⁻²⁴ These results have raised the hypothesis that the MIAVR approach with sutureless valves might be considered an alternative procedure to TAVI for high-risk patients.

TAVI was originally designed to treat a group of patients with severe aortic stenosis who would be at prohibitive risk when undergoing a standard open procedure, and nowadays it is increasingly performed for high-risk patients. Despite the great enthusiasm for this new technology, however, the PARTNER trial failed to show any potential advantage of TAVI relative to the conventional surgery.²¹ Furthermore, several studies and recent meta-analyses of more than 8000 patients have concluded that TAVI is likely ineffective in reducing early and midterm all-cause of mortality versus surgical aortic valve replacement in high-risk patients.²⁵⁻³¹ Nevertheless, subanalysis of randomized trials has shown TAVI to be associated with higher incidences of neurologic events, vascular complications, pacemaker requirement, and moderate or severe aortic regurgitation.²⁵ In this regard, TAVI is a palliative solution that leaves the native valve in situ; this might explain the higher rates of stroke, atrioventricular block, and paravalvular leakage. Conversely, the surgical approach has the advantage of removing the diseased valve and allows an accurate débridement of the calcified aortic annulus, resulting in a lower incidence of postoperative complications, especially in terms of paravalvular leakage. It has been shown that paravalvular leakage is a predictor of poor survival and should be avoided.³² The main limitation of these studies is that the

surgical outcomes are related to conventional surgery, consisting of full sternotomy and sutured aortic prosthetic valves. To date, there have been only 2 studies that rely on MIAVR and sutureless technology. In a propensity-matched analysis, Santarpino and colleagues³³ have shown better outcomes in patients undergoing ministernotomy and sutureless aortic valve replacement than in those treated with a TAVI approach, suggesting that this combination of these new technologies may be considered the first-line treatment for high-risk patients considered in the gray zone between TAVI and conventional surgery. Our group reported similar results when outcomes were compared between the right anterior minithoracotomy approach with sutureless and TAVI procedures.³⁴ Interestingly, Jahangiri and co-workers³⁵ found that 42% of patients referred for TAVI underwent conventional surgery and did well. This finding supports our hypothesis that a minimally invasive approach associated with a sutureless valve would be the real treatment option for high-risk patients considered to be operative candidates.

Finally, an analysis of cost-effectiveness of these procedures should be considered. A cost-utility analysis of TAVI concluded that it is not recommended to reimburse TAVI for high-risk patients who are operative candidates, because these patients had no survival benefit after 1 year with TAVI, their risk of stroke was double, and their costs were higher.³⁶ In addition, a systematic review and a large Society of Thoracic Surgeons study concluded that TAVI is a potentially cost-effective alternative to medical therapy for patients not considered to be operative candidates; however, it is not the most cost-effective strategy for medium- and high-risk patients who are operative candidates, because evidence is currently insufficient to justify economically the use of TAVI in preference to conventional surgery.^{37,38} These studies focus on patients undergoing conventional surgery; no study has yet focused on the cost-utility of MIAVR with sutureless technology.

In light of these considerations, we strongly believe that the presence of a heart team is mandatory for the treatment of high-risk patients undergoing aortic valve replacement. Although we recommend a TAVI procedure for patients who are not candidates for a surgical procedure, a tailored approach should be considered for high-risk patients considered to be operative candidates, taking into account the patient's morbidities, the frailty conditions, and the life expectancy. In this setting, a minimally invasive approach with a sutureless valve might be considered a treatment option for high-risk patients and the "real alternative" to a TAVI procedure. A well-designed randomized trial, however, is required to confirm our hypothesis.

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