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Review

Sutureless Aortic Prosthesis Valves versus transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients with Severe Aortic Stenosis: A Literature Review

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Abstract: Aortic stenosis continues to be still the most frequently valvular pathology in the elderly population of the Western countries. According to the latest guidelines, the therapeutic choice of aortic stenosis depends on the age of the patient (<75 years or >75 years) and the risk class (STS-Prom/ Euroscore II < o > 4%). Therefore, if the surgical indication is clear in young and low risk patients and percutaneous treatment is the gold standard in older and high-risk patients, the therapeutic choice is still debated in intermediate-risk patients. In this group of patients, the aortic valve stenosis treatment depends on the patient's global evaluation, on the experience of the center and no less important on the patient's will. Two main therapeutic options are debated: surgical aortic valve replacement with sutureless prosthesis versus transcatheter aortic valve implantation. In addition, the progressive development of mininvasive techniques for aortic valve surgery (right -anterior minitoracotomy) has also reduced the peri and post -operative risk in this group of patients. The goal of our review is to analyze the literature evidence of the best therapeutic choice in intermediate risk patients with severe aortic stenosis.

Keywords: aortic stenosis; transcatheter aortic valve implantation; sutureless aortic prosthesis

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1. Introduction

Aortic valve (AV) stenosis is the most frequent cardiac valve pathology in the western world, with a prevalence of 3% for individuals over the age of 75 years [1]. The incidence of AV stenosis is growing, a reflection of the rapid ageing of the population [2]. A multitude of studies have demonstrated the beneficial effects of aortic valve replacement (SAVR) with regard to improvement in quality of life and physical performance in the majority of symptomatic patients.[3]. However, the treatment of aortic valve pathology has been constantly evolving for the last two decades with an increase in the use of transcatheter aortic valve replacement (TAVR) in intermediate and low-risk patients [4]. As TAVR has become more established, newer surgical prostheses have been developed with a variety of anchoring systems that do not rely solely on sutures to hold the valve in the appropriate location [5]. This new aortic prosthesis are called "sutureless prosthesis". By avoiding placement and tying of annular sutures, sutureless aortic prosthesis significantly reduces operative, and more importantly, ischemic times, and may improve outcomes [6–8]. Therefore, sutureless aortic prosthesis should be considered in order to minimize operative times and improve outcomes in high-risk patients in whom a long bypass run would be detrimental, and in those undergoing complex combined procedures. On the other hands, with its compact design and easily handling, sutureless prosthesis facilitates a minimally invasive approach which has been shown to be of comparable

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quality to a full sternotomy for AVR [9–12]. If the surgical indication is clear in young and low risk patients and percutaneous treatment is the gold standard in older and high-risk patients, the therapeutic choice is still debated in intermediate-risk patients. In this group of patients the aortic valve stenosis treatment depends on the patient's global evaluation (evaluation in Heart Team), on the experience of the center and no less important on the patient's will. The goal of our review is to analyze the literature evidence of the best therapeutic choice in the intermediate risk patients with severe aortic stenosis.

2. Material and Methods

2.1. Data Sources and Search Strategy

Current literature investigating severe aortic stenosis, intermediate surgical risk patient, surgical treatment, transcatheter aortic valve replacement, minimally invasive aortic valve replacement with sutureless aortic valve is analyzed and contextualized in this review. Specifically, research was conducted on Medline (Pubmed) and Scopus. To review recent studies , we selected scientific papers published in English in the last ten years . We used the following search terms: severe aortic stenosis, trancatheter aortic valve replacement, minimally invasive surgery, sutureless aortic valve prostheses, cardiac surgery.

2.2. Study Selection

2.2.1. Inclusion Criteria

The inclusion criteria for the included studies in this review were as follows: (1) management of severe aortic stenosis in intermediate surgical risk score patients; (3) comparison between transcatheter aortic valve implantation and sutureless aortic prosthesis valve in intermediate surgical risk patients; (4) role of minimally invasive surgery to improve clinical outcomes in patients undergoing aortic valve replacement with sutureless aortic valve prostheses.

2.2.2. Exclusion Criteria

Editorial, case report, letter to editor, conference abstract were excluded from this view.

3. Management of Severe Aortic Stenosis According the International Guidelines

The 2021 ESC/EACTS guidelines [13] form management of valvular heart diseases advocated that: aortic valve interventions must be performed in Heart Valve Centres that declare their local expertise and outcomes data, have active interventional cardiology and cardiac surgical programmes on site, and a structured collaborative Heart Team approach (IC); the choice between surgical and transcatheter intervention must be based upon careful evaluation of clinical, anatomical, and procedural factors by the Heart Team, weighing the risks and benefits of each approach for an individual patient (IC); the Heart Team recommendation should be discussed with the patient who can then make an informed treatment choice (IC); SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/EuroSCORE II <4%) or in patients who are operable and unsuitable for transfemoral TAVI [14]; TAVI is recommended in older patients (≥75 years), or in those who are high risk (STS- PROM/EuroSCORE II>8%) or unsuitable for surgery [15–25]; SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical, and procedural characteristics [26–29]. The 2020 ACC /AHA guidelines for the management of patients with heart valve diseases [30] state the following: for symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended [31–33]; for symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability [31–36]; for symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR [31,32–40]. Both guidelines have highlighted age (surrogate for life expectancy) as the main consideration after accounting for patient preferences, comorbidities, and anatomical characteristics. The age disparities between guidelines and the perceived crudeness of this approach have incited some controversy [41]. The reason of this age disparities is related to the different studies on which the ACC/AHA and the ESC/AHA guidelines are based. The ACC/AHA cites a mix of systematic reviews, RCTs, and observational studies to recommend SAVR for <65 years based on a lack of TAVI follow-up data beyond 5 years; while the ESC/EACTS guidelines cite observational registries which demonstrated a 5-year rate of severe structural valve deterioration of 2.5% and moderate deterioration of 13.3% after TAVI. None of the aforementioned data provides robust evidence for the age thresholds established by the ACC/AHA and ESC/EACTS guidelines. On the contrary, results from the NOTION [42] and UK TAVI trials[43] provided more clarity about low-to-intermediate risk patients ≥70 years of age with a EuroSCORE II <4%. Finally, the 5-year results of the SURTAVI [44] trial also support the durability of TAVI in intermediate-risk patients. These findings, in addition to the 5-year UK TAVI and 10-year NOTION results expected shortly, may provide greater clarity to guidelines and the current uncertainty regarding the optimal age threshold for TAVI and the degree to which age should play a factor in the overall decision-making process after considering patient comorbidities, preferences, and anatomical presentation. Accordingly, in our opinion, the choice of the aortic valve treatment (SAVR versus TAVI) should be based on the risk score classification than on the age theshold.

4. State of the Art in the Management of Intermediate Surgical Risk Patients with Severe Aortic Stenosis

If the surgical indication is clear in young and low risk patients and percutaneous treatment is the gold standard in older and high-risk patients, the therapeutic choice is still debated in intermediate-risk patients. In this group of patients the AV stenosis treatment depends on the patient's global evaluation, on the experience of the center and no less important on the patient's will. Two main therapeutic options are debated: surgical aortic valve replacement (SAVR) with sutureless prosthesis versus transcatheter aortic valve implantation (TAVR). The introduction of the new guidelines certainly expands the category of patients to be subjected to TAVR [13–30]. However, the evaluation of the hemodynamic aspects, the durability of the prosthesis as well as the rate of complications (mortality and major cerebrovascular events) still remains to be clarified. On the other side, “sutureless prosthesis”, by avoiding placement and tying of annular sutures, significantly reduces operative, and more importantly, ischemic times, and may improve outcomes [45,46]. Furthermore, sutureless aortic prosthesis should be considered in order to minimize operative times and improve outcomes in high-risk patients in whom a long bypass run would be detrimental, and in those undergoing complex combined procedures. Finally, with its compact design and easily handling, sutureless prosthesis facilitates a minimally invasive approach which has been shown to be of comparable quality to a full sternotomy for AVR [47,48]. In addition to the better results compared to traditional surgery, minimally invasive treatment of the aortic valve has been seen to have a better trend than TAVR even in intermediate-risk patients. In fact, Miceli et al. demonstrated a lower rate of mortality and stroke in patients undergoing suturless aortic valve replacement surgery as well as a better hemodynamic performance linked to the lower rate of perivalvular leaks (5.4% vs 81.1%, p value < 0.001) [49]. Referring to the most recent data present in the literature, we analyzed the results of the two procedures (SAVR with sutureless and TAVR) by comparing echocardiographic data such as peak and mean transvalvular gradients, presence of perivalvular leaks, pace-maker implantation and clinical data such as 30-day mortality, onset of stroke and acute kidney injury.

4.1. Peak and Mean Transvalvular Gradients

Munuretto et al, in their multicenter study on elderly patients at intermediate risk, demonstrated how patients undergoing suturless surgery had a mean and peak transvalvular gradient of 12.2±5.7

and 22.3±9-0 respectively at 60 months of follow-up, while patients undergoing TAVI had a mean and peak transvalvular gradient of 13.27±6.3 and 23.51±9.5. Furthermore, a statistically more significant finding, a severe (≤ 0.65 cm2 /m2) Patient-Prostheses Mismatch (PPM) emerged in 12 (4.1) patients undergoing suturless surgery and in 19 (6.5%) patients undergoing TAVI [50]. Furthermore, this result overturns what was previously demonstrated by the same author in the previous multicenter study in which the average and maximum transvalvular gradients in patients undergoing TAVI were lower than those in patients undergoing suturless surgery, however analyzed in the peri- and immediate post-operative period [51]. Similarly, other authors, in comparing the hemodynamic performance of sutuless and TAVI, had highlighted a lower mean and maximum transvalvular gradient in patients undergoing a percutaneous procedure [52]., as well as a lower number of PPMs [53]. However, even in this case the data related to the patient's discharge and not related to further follow-up. Therefore, we believe that attention should be paid to the long-term (>24 months) evaluation of maximum and mean transvalvular gradients.

4.2. Perivalvular Leaks

The removal of the aortic cusps, the decalcification of the annulus and the subsequent implantation of the prosthesis guarantees greater adherence of sutureless aortic prosthesis to the aortic root. For this reason, the presence of perivalvular leaks is always greater in the TAVI group compared to the group of patients undergoing suturless as demonstrated by recent numerous meta-analyses [54–56]. Having established that the presence of severe perivalvular leaks that generate aortic insufficiency with grade >2 constitutes the strongest independent predictor of 1-year mortality [57], attention was placed on the development of techniques that can reduce the degree of aortic insufficiency post TAVR. Landes et al conducted a retrospective study on the techniques used in patients with aortic insufficiency with grade > 2 which involved the use of: redo-TAVI, plug, or balloon valvuloplasty, demonstrating that the degree of reduction of aortic insufficiency and mortality were more favorable in redo-TAVI than with the other two methods. However, redo-TAVI can increase the risk for patient–prosthesis mismatch, coronary obstruction or access difficulties [58]. Although technological progress will lead to greater refinement of the techniques as well as greater adhesion of the percutaneous prostheses to the native aortic valve, currently the results in terms of perivalvular leaks of TAVI are lower than those of sutureless ones.

4.3. Pace-Maker Implantation

While the results relating to perivalvular leaks appear quite clear between the two groups, the same cannot be said regarding the incidence of pacemaker implantation. A meta-analysis of six comparative matched studies using propensity score matching (identified 1462 patients in that 731 patients underwent sutureless and 731 patients underwent a TAVI) conducted by Meco and others revealed no differences in pacemaker implantation between the two groups (OR 1.06, 95% CI 0.54–2.08; P = 0.86) [59]. More recently Zubarevich et al. analyzed the results of 248 consecutive patients who underwent either suturless or TAVI at our institution treated between April 2018 and June 2021 and, although the TAVI group had a numerically larger sample (169 vs 79) no differences were highlighted between the two groups [60]. On the contrary, Munuretto et al in their recent meta-analysis conducted on patients with isolated aortic stenosis at intermediate risk demonstrated a statistically higher rate of pacemaker implantation in patients undergoing TAVI [50]. However, in none of the more or less recent manuscripts on this topic, is the sutureless prosthesis associated with a greater risk than TAVI for pacemaker implantation. Furthermore, the variability relating to the TAVI group seems to be explained by the technique and choice of device used. In fact, Edwards Sapiens prostheses have been associated with a lower incidence of pacemaker implantation, as well as not performing balloon-dilation of the aortic valve before balloon-expansion of the prosthesis, or positioning it slightly towards the coronary artery, which may extrude the calcified native cusps less toward the region of least resistance, causing structural damage and edema within the conduction system[61].

4.4. Clinical Outcomes

A recent metanalysis performed by Barili et al. [62] including seven trials showed that TAVI had a lower incidence of composite of death or stroke in the first 6 months, with an HR reversal after 24 months favouring SAVR. This was confirmed for all cause death. TAVI was also associated with an increased incidence of rehospitalization after 6 months that got worse after 24 months. Although it could appear that there is no difference between TAVI and SAVR in the 5-year cumulative results, TAVI shows a strong protective effect in the short term that runs out after 1 year. TAVI becomes a risk factor for all-cause mortality and the composite end point after 24 months and for rehospitalization after 6 months. Surgical aortic valve replacement (SAVR) has an intrinsic increased risk of complications in the first months related, for example, to extracorporeal circulation and surgical incisions, risks that decrease soon after surgery. This result is in contrast with those of single randomized controlled trials (RCTs) and other published metanalyses that use summary data [63]. The relatively short follow- up time in RCTs on intermediate- and low-risk groups limited results between 2 and 5 years, because only the 2 trials on high risk and 1 small trial on low risk reached the 5-year follow-up [64–66] The PARTNER 2A trials and the PARTNER 3 increased the 5-year follow-up population from 1776 patients to 3808 [67,68]. The PARTNER 2 A trial enrolled 2032 intermediate-risk patients with severe, symptomatic aortic stenosis at 57 centers. Patients were stratified according to intended transfemoral or transthoracic access (76.3% and 23.7%, respectively) and were randomly assigned to undergo either TAVR or surgical replacement. Among patients with aortic stenosis who were at intermediate surgical risk, there was no significant difference in the incidence of death or disabling stroke at 5 years after TAVR as compared with surgical aortic-valve replacement. The PARTNER 3 trial randomly assigned 1,000 patients (1:1) to transfemoral TAVR with the SAPIEN 3 valve versus surgery (mean Society of Thoracic Surgeons score: 1.9%; mean age: 73 years) with clinical and echocardiography follow-up at 30 days and at 1 and 2 years. This trial concluded that at 2 years, the primary endpoint remained significantly lower with TAVR versus surgery, but initial differences in death and stroke favoring TAVR were diminished and patients who underwent TAVR had increased valve thrombosis.

4.5. Minimally Invasive AVR versus TAVI

A lot of study assessed the benefit of minimally invasive surgery AVR when compared with convetional AVR [69,70]. lmeida et al. [69], in an excellent meta-analysis and meta-regression on 1303 patients, showed that minimally invasive aortic replacement is a valid alterantive to conventional AVR, reducing hospital stay and incidence of hemorrhagic events. Despite significantly greater aortic cross-clamp and cardiopulmonary bypass time in patients underwent minimally invasive surgery, this is not associated to increasing of adverse clinical effects. Accordingly, Angelini et al. [70], in an interesting multicenter, international, randomized controlled trial titled COMICS including patients aged cluding patients aged ≥18 and <85 years undergoing elective or urgent isolated coronary artery bypass grafting (CABG), isolated aortic valve replacement (AVR) surgery, or CABG + AVR surgery, showed that minimally invasive surgery reduces the relative risk of primary outcome events by about 25%. They defined as primary outcomes events the following 12 post-operative serious adverse events: death, myocardial infarction (MI; suspected events were documented by serum troponin concentrations and electrocardiograph recording (ECG) but the latter were not provided), stroke (report of brain imaging by CT or MRI, in association with new onset focal or generalized neurological deficit), gut infarction (diagnosed by laparotomy or post mortem), stage 3 AKI or need for haemofiltration, reintubation, tracheostomy, mechanical ventilation >48 h, reoperation, percutaneous intervention, sternal wound infection with dehiscence, septicaemia confirmed by microbiology. The right anterior thoracotomy (RAT) showed excellent results in terms of mortality and rate of post-operative complications when compared with different surgical technique [49]. The association between RAT and sutureless appear to be better even than TAVI although there are still few comparison studies available. Doyle et al developed a propensity-matched meta-analysis studies in which they demonstrated that with the same surgical risk, patients undergoing minimally invasive surgical treatment had a lower rate of pacemaker implantation (OR 0.2; 95% CI 0.09-0.51), aortic insufficiency linked to the presence of periprosthetic leaks (OR 0.05; 95% CI 0.01-0.19), while a higher

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rate of acute renal failure was highlighted in patients undergoing minimally invasive surgical treatment with a consequent negative impact on the length of hospital stay (OR 3.15; 95% C.I. 2.07-4.80). However, the mortality rate between the two groups was comparable (OR 0.90; 95% CI 0.35-2.26) [71]. Therefore, what emerges is the substantial difference in terms of better clinical and hemodynamic outcomes in patients undergoing minimally invasive surgery compared to traditional surgery and completely comparable, and in some respects superior, to those of patients undergoing TAVI [49]. Even more recently, a retrospective Korean study has demonstrated better results of minimally invasive surgery (particularly in the right minithoracotomy approach) in elderly patients at high surgical risk by comparing length of hospital stay, in-hospital mortality, all-cause mortality, and other major postoperative complications [72]. It is hoped, therefore, that comparison studies between the two groups can be increasingly numerous so as to be able to define with ever greater accuracy the therapeutic treatment suitable for the clinical and anatomical characteristics of the patients.

4.6. Structural Durability of TAVAR versus SAVAR

Both SAVR and TAVR use bioprosthetic valves, with the SAVR valve being a fixed stent with an estimated life span of 15 years and the TAVR valve being capable of expanding and collapsing [73]. However, TAVR being the newer procedure, with the first valve implanted in 2002 by Alan Criber , and developments in the technique and valves having spanned only just under 20 years, the life span of the TAVR valve is still uncertain. Most studies that compare TAVR to SAVR valves report data of only up to 5 or 6 years, making an assessment of valve durability beyond that time frame difficult to determine. In an interesting study Ler et al. showed that TAVR valves appear to be more susceptible to structural valve deterioration and thus potentially less structurally durable than SAVR valves, therefore they may be associated with higher rates of moderate or severe aortic regurgitation, paravalvular regurgitation and reintervention in the 1-year-, 2–3 year, and 5-year period [74].

5. Conclusions

In intermediate risk patients with severe aortic stenosis, aortic valve replacement with sutureless prostheses seem to be the better treatment in particular in patients with morphological predictors of paravalvular leak after TAVI (asymmetrical distribution of calcium and /or massive and bulky annular calcification). The sutureless aortic valve prostheses implantation is associated with shorter extracorporeal circulation and aortic cross clamp time that traditional prosthesis; at the same time allowed a minimally invasive surgical approach that provide better postoperative recovery.

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