



Major Considerations on the Aortic Stenosis and Transapical Valves: Research Article

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Abstract

Background: Aortic valvular stenosis is the most common form of cardiac valvular disease acquired in the Western world, with its calcified degenerative variant being the most frequent. It is estimated that its prevalence is 2.0 - 7.0% in individuals over 65 years of age there are at least 32,000 individuals with the disease on average in Western countries.

Objective: To highlight the main current considerations regarding aortic stenosis and the use of transapical valves, in order to contribute with brief important scientific information to the medical literature, mainly in the world cardiology.

Methods: Following the criteria of literary search with the use of the Mesh Terms that were cited in the item below on "Search strategies", the total of 48 papers that were submitted to the eligibility analysis were cross-checked and, after that, 21 were selected, following the rules of systematic review-PRISMA.

Results: Before only those patients with a prohibitive surgical risk were candidates for TAVI, today we seek to expand the technique to other groups; for example, the bicuspid aortic valve is considered by some authors as a contraindication to transcatheter aortic valve implant (TAVI) and yet several studies point to a benefit of the technique in these patients. Other future TAVI indications will likely include patients with degenerated biological prostheses, TAVI on TAVI, aortic regurgitation, and younger/lower risk patients.

Conclusion: The most recent generations of implantable prostheses seek to minimize the side effects of TAVI, which may be associated with treatment failure, as well as increased morbidity and mortality in patients. Sixteen years after the first percutaneous valve implantation, there is a constant evolution in the sense of providing the total symptomatic relief and better quality of life to patients.

Keywords: Valvular Stenosis; Aortic Stenosis; Transapical Valve; Valvular Calcification

Introduction

Aortic valve stenosis is the most common form of cardiac valvular disease acquired in the Western world, with its calcified degenerative variant being the most frequent [1]. It is estimated that its prevalence is 2.0 - 7.0% in individuals over 65 years of age there are at least 32,000 individuals with the disease on average in Western countries. After the onset of symptoms, the survival of patients with aortic valve stenosis decreased dramatically, approximately 5, 3 and 2 years after the development of angina, syncope and dyspnea, respectively [2,3].

In this context, the gold standard for the treatment of this condition is aortic valve replacement surgery (SAVR) [1,3]. However, it is known that about one-third of the affected individuals are not referred for surgery, either because of the presence of some contraindication or because of the presence of comorbidities that make the procedure at high risk [3,4]. These individuals (inoperable or at high risk) may benefit from transcatheter aortic valve implant (TAVI) and the comparative aspects of both techniques are well documented [4,5].

Since the first aortic valve transcatheter implantation in 2002 by Cribier, *et al* [6]. To date, TAVI has evolved considerably with respect to design and prosthetic components, implantation systems, approaches, among other aspects.

Therefore, the present study aimed to highlight the main current considerations regarding aortic stenosis and the use of transapical valves, in order to contribute with brief important scientific information to the medical literature, mainly in the world cardiology.

Methods

Study Design

Following the criteria of literary search with the use of the Mesh Terms that were cited in the item below on "Search strategies", a total of 48 articles that were submitted to the eligibility analysis were cross-checked and, after that, 21 studies were selected, following the rules of systematic review-PRISMA (Transparent reporting of systematic reviews and meta-analyzes-<http://www.prisma-statement.org/>), according to figure 1.

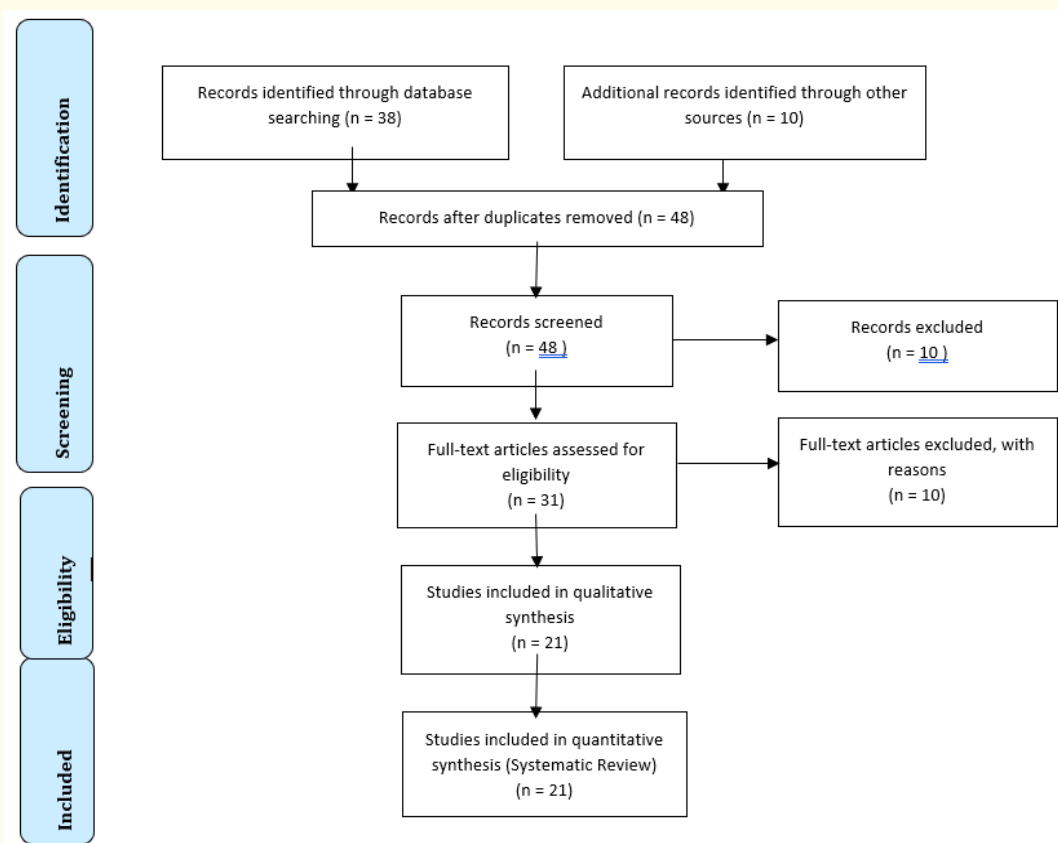


Figure 1: Flowchart showing the screening selection of the scientific works on aortic stenosis and transapical valves that were explored to compose the present study.

Sources of Information

The review protocol was based on the criteria of literary search with the use of mesh terms in the main databases such as Pubmed, Medline, Bireme, EBSCO, Scielo, etc. All references are registered in EndNote by the site: <http://www.myendnoteweb.com/EndNoteWeb.html?cat=myrefs&>.

Search strategy

In general, as an example, the search strategy in MEDLINE / Pubmed, Web of Science, ScienceDirect Journals (Elsevier), Scopus (Elsevier), OneFile (Gale) followed the following steps: - search for mesh terms Valvular stenosis. Aortic stenosis. Transapical valve. Valvular calcification, - use of the bouleanos "and" between mesh terms and "or" among the historical findings.

Major Findings and Discussion

Types of Valves

The balloon expandable valve (Edward SAPIEN) was first introduced in 2000 and consists of a steel structure and three leaflets constructed from bovine pericardium [7]. In high-risk patients, the all-cause mortality rate (33.9% vs. 35%, $p = 0.78$) and the proportion of NYHA class I and II patients after the procedure (83.9% vs. 85.2%, $p = 0.87$) were similar compared to patients undergoing surgical aortic valve replacement (SAVR). In the randomized PARTNER 1B trial [9], this prosthetic valve was superior compared to optimized medical treatment: mortality per year of 30.7%

versus 50.8% ($p < 0.001$) and re-hospitalization rate of 35.0% versus 72.5% ($p < 0.0001$) [9].

The second generation of these valves (SAPIEN XT) [10,12] has a cobalt-chromium structure and presents modifications that allow the introduction of smaller diameter catheters, thus minimizing the vascular complications of the procedure. SAPIEN 3 [11] is a newer model of balloon expandable valves that, while maintaining the same composition as the second generation valve, also allows for a reduction of valve regurgitation due to better fit of the prosthesis, which reduces the space between the valve the prosthetic valve (Figure 2).

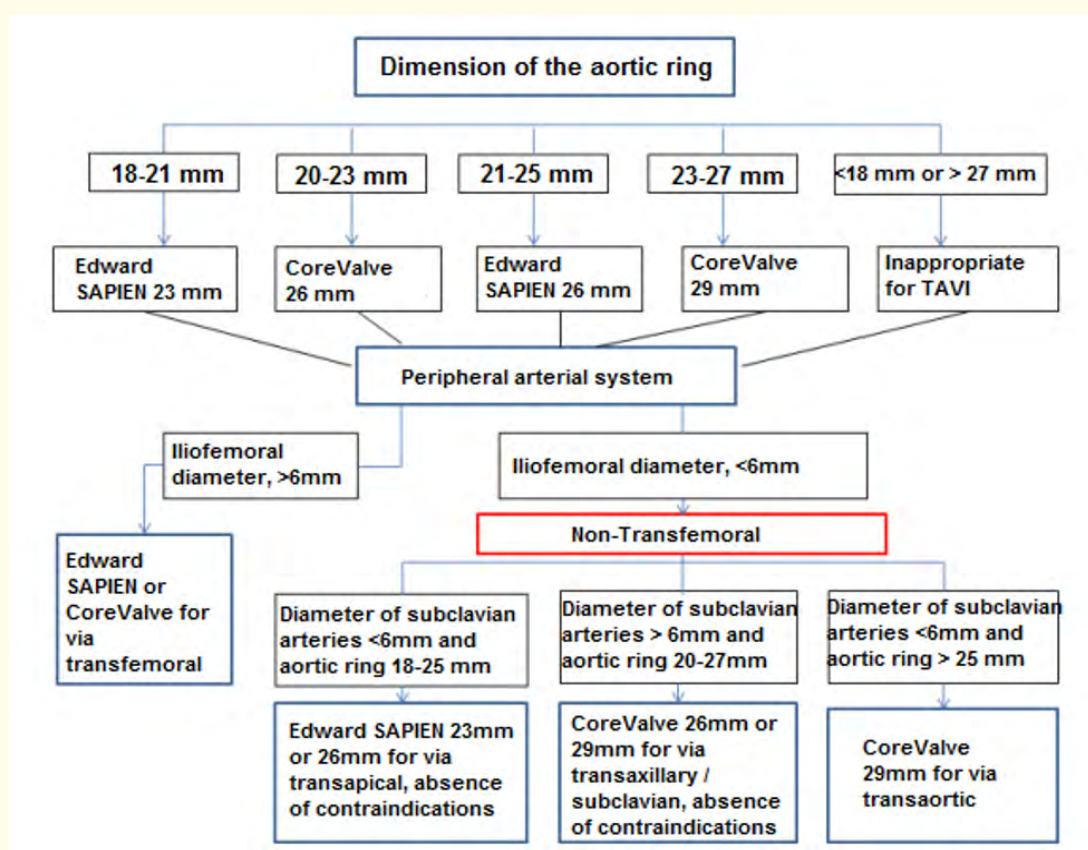


Figure 2: Algorithm to choose the appropriate prosthesis as a function of the diameter of the aortic orifice.

Currently

In general, TAVI improves the quality of life and the functional status of patients. Kala, *et al.* (2013) [16] studied the quality of life at 30, 90 and 360 days after the intervention using an EQ-5D questionnaire; At 30 and 90 days, the quality of life of TAVI and

SAVR patients is comparable, and at 360 days, only the anxiety/depression score was better in patients submitted to ARVS (83.3% versus 59.1%; $p = 0.046$). Functional status improved in all patients (NYHA class I-II at 13.3% baseline vs. 78.9% at 360 days) and overall health status improved significantly in patients undergoing TAVI with a positive patient trend submitted to SAVR.

Mortality

TAVI is associated with a reduction in overall and cardiovascular mortality in patients when compared to medical treatment. Kapadia, *et al.* [17] obtained a 3-year mortality rate of 54.1% in TAVI vs. 80.9% in medical treatment ($p < 0.001$), as well as a significant improvement of NYHA functional class in the TAVI group. In this study, although the incidence of stroke was higher in the TAVI group (cumulative 3-year stroke incidence of 15.7% vs. 5.5% with medical treatment, $p = 0.012$), the mortality rate or stroke in these groups patients was significantly lower when compared to patients undergoing medical treatment (57.4% vs. 80.9%, $p < 0.001$).

There was no statistically significant difference in mortality in the TAVI group. The SAVR group, however, there are some studies where the results are not the same. Considering only cardiovascular mortality, the results are similar, i.e. TAVI is comparable to SAVR and both procedures are superior to medical treatment, with severe heart failure and sudden death accounting for 2/3 of the causes of cardiovascular death.

Future Perspectives

Since its initial application by Cribier, *et al.* (2002) [6], there is a constant evolution in TAVI. The new prosthetic designs seek to improve the performance of the technique, either by obtaining better results/optimization of the functional status of the patient or by reducing the complications inherent to the procedure [13-15]. If only patients with prohibitive surgical risk were once candidates for TAVI, today it is sought to expand the technique to other groups; as an example, the bicuspid aortic valve is considered by some authors as a contraindication relative to TAVI and yet several studies point to a benefit of the technique in these patients [18-21].

Other future TAVI indications will likely include patients with degenerated biological prostheses, TAVI on TAVI, aortic regurgitation, and younger/lower risk patients. Kondur, *et al.* (2016) [21] compared the outcomes of aortic valve replacement in a meta-analysis involving 1618 patients who underwent TAVI and 1581 patients who underwent SAVR (5 trials). The authors concluded that TAVI presents survival and infarction rates that are surpassing those of SAVR, as well as lower rates of major hemorrhage, in patients with low or intermedical surgical risk. However, in these patients, SAVR is associated with less need for pacemaker implan-

tation (7.5% vs. 21.6%, $p < 0.001$) and lower rate of paravalvular regurgitation (1.5% vs. 7.8%, $p < 0.001$) [21].

Conclusion

Increasingly TAVI is seen as an option for the treatment of aortic valve stenosis in patients classified as having a high surgical risk. The indications for this procedure are constantly being revised, due to the evidence extrapolated from the numerous clinical trials in this area, so it is expected the future expansion of the target population of the technique. The most recent generations of implantable prostheses seek to minimize the side effects of TAVI, which may be associated with treatment failure, as well as increased morbidity and mortality in patients. Sixteen years after the percutaneous valvular implantation, there is a constant evolution in the sense of providing the total symptomatic relief and better quality of life to the patients.

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