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EDITORIAL

Percutaneous Aortic Valve Replacement: Current Status and Future Perspective

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ABSTRACT

Surgical valve replacement is the definitive therapy for patients with critical aortic stenosis (AS). However, the risk of surgery may be higher in elderly patients with significant comorbidities. Six years after the first in man, percutaneous aortic valve implantation (PAVI) for the treatment of AS currently represents a dynamic field of research and development. Two devices have a CE marked and are under clinical investigation for PAVI, the Edwards-Sapien valve mounted within a balloon-expandable stent and the self-expanding CoreValve. Since the first in-man PAVI by Alain Cribier in 2002, well over 1000 high-risk patients with severe symptomatic AS have been treated using PAVI (as of January 2008). The currently available results suggest that the technique is feasible and provides hemodynamic and clinical improvement for up to two years in patients with critical AS at high risk or with contraindications for surgery. Pending questions concern mainly safety and long-term durability.

KEY WORDS: *aortic stenosis; aortic valve replacement; aortic valvuloplasty; percutaneous aortic valve implantation; transapical aortic valve implantation*

INTRODUCTION

Valve disease is an important public health problem as it carries a poor prognosis and its prevalence is strongly linked to the phenomenon of population ageing. The most frequent native valve disease in Europe is currently aortic stenosis (AS), which is most often seen in elderly patients with comorbidities. Valve replacement is the definitive therapy for patients with severe AS who have symptoms or objective consequences such as left ventricular (LV) dysfunction.[1] Operative mortality is quite low, even in elderly patients when properly selected, and long-term results have been shown to be satisfactory. However, the risk of surgery may be higher in elderly patients with significant comorbidities. In addition, several registries show that referring physicians often do not propose surgery, as was the case in the Euro Heart Survey with 33% of patients with severe valve disease and severe symptoms not being considered for surgery.[2] Thus, despite the good results of valve surgery there may well be a role for less invasive alternatives. Balloon aortic valvuloplasty (BAV) is now rarely used, mainly due to its limited long-term efficacy.

Six years after the first in man,[3] percutaneous aortic valve implantation (PAVI) for the treatment of AS currently represents a dynamic field of research and development: two devices have been CE marked and are being commercialised.[4-8] These two devices

List of Abbreviations:
AS = aortic stenosis
BAV = balloon aortic valvuloplasty
CE = *conformitu europienne*, French for «European conformity» (product conformance mark)
LV = left ventricle
PAVI = percutaneous aortic valve implantation
TEE = transesophageal echocardiography

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are under clinical investigation for PAVI. One device is the Edwards-Sapien valve (Edwards Lifesciences Inc, California, USA), which consists of 3 pericardial leaflets mounted within a tubular, slotted, stainless-steel, balloon-expandable stent. The other device is the CoreValve Revalving System (CRS TM, CoreValve Inc, Irvine, California, USA), which has 3 pericardial leaflets, initially bovine and currently porcine, mounted in a self-expanding, nitinol frame. Since the first in-man PAVI by Alain Cribier in 2002,[3] well over 1000 high-risk patients with severe symptomatic AS have been treated using PAVI (as of January 2008).

TRANSFEMORAL APPROACH

Over 400 cases have been performed using the balloon expandable and another 500 using the self-expandable prosthesis (Company sources January 2008). Reports originate from a number of centres worldwide.[4-7] The patients treated were mostly over 80 years old, at high risk (e.g. Logistic EuroScore >20% in most cases), or with contraindications for surgery.

The overall results can be summarised as follows:

Procedural success is closely linked to experience, and is about 90% in experienced centres. A learning curve can also be observed resulting in better patient selection and outcomes. Valve function is good with a final valve area ranging from 1.5 to 1.8 cm^2.

Mortality at 30 days ranges from 5 to 18%. Acute myocardial infarction occurs in 2 to 11%. Coronary obstruction is rare (<1%). Mild to moderate aortic regurgitation, mostly paravalvular, is observed in around 50% of cases. However, the availability of larger prostheses and their more careful matching with the size of the aortic annulus led to the decrease in the incidence of severe aortic regurgitation to around 5%. Prosthesis embolization is rare, around 1%.

Vascular complications, with an incidence ranging from 10 to 15%, remain a significant cause of mortality and morbidity. Stroke ranges from 3 to 9%. Finally, atrioventricular block occurs in 4 to 8%, necessitating pacemaker implantation in up to 24% with self-expandable devices.

Long-term results up to 2 years (though only 1 year in most studies) are reported in a limited number of patients. They show a survival rate of 70-80% with a significant improvement in clinical condition in most cases. The majority of late deaths are due to comorbidities. Serial echocardiographic studies have consistently shown good prosthetic valve function with no structural deterioration of valve tissue.

TRANSAPICAL APPROACH

The total experience with transapical aortic valve implantation[9,10] comprises over 300 patients, also at high risk for conventional surgery, even more so because of concomitant peripheral arterial disease, in most cases. Experience currently reported only relates to the balloon-expandable prosthesis.

The implantation success rate of the transapical procedure is around 90%. Over 70% of cases are done off pump, the figure being 90% in experienced centres, and the rate of peri-operative conversion is 9-12%. Mortality rates range from 9-18%. The incidence of stroke is 0-6%. The quality of the results seems closely related to experience as well as to the availability of high quality imaging in the operating theatre. There are currently no direct comparative studies available of the two approaches.

PERSPECTIVES

Progress in delivery systems and valve manufacturing could lead to lower-profile, repositionable, retrievable, and more durable devices, as well as a wider range prosthetic valve dimensions. Furthermore, improved imaging, such as online 3D reconstruction and stereotaxis, could facilitate valve placement.

PENDING QUESTIONS

In the light of the current experience, bearing in mind the previously-mentioned, inherent limitations of any conclusions, PAVI using both balloon and self-expandable devices can be said to be feasible. Short- and mid-term hemodynamic results are good up to two years. However, the technique remains challenging, in particular, with regards to vascular access, device sizing, and positioning.

The major concerns with regards to safety are:

- Vascular complications with the transfemoral approach, which should decrease with smaller devices.
- Stroke rate.
- Long-term consequences of paravalvular leaks, even if mild to moderate regurgitation is considered not to have significant clinical consequences in the short-term.
- Atrioventricular block, the incidence, timing, and predictors of which have to be identified more precisely.

Mid- (short-) term clinical outcome is encouraging; however, long-term durability of these bioprostheses remains a key question, especially if considering lowering the threshold for the indication.

- The feasibility of subsequent aortic valve intervention is not known.

Selection of candidates for PAVI, especially risk assessment, should involve multi-disciplinary consultation between cardiologists and surgeons.

PAVI is indicated in patients with calcified pure or predominant aortic stenosis. At the present stage, PAVI should only be proposed in patients with severe symptoms that can definitely be attributed to valve disease. The procedure should currently be restricted to patients at high-risk or with contraindications for surgery. It is premature to consider using it in patients who are good surgical candidates. PAVI should not be performed in patients whose life expectancy is less than 1

year, who should be managed conservatively.

General *contraindications* for PAVI are:

- Aortic annulus <18 mm or >25 mm for balloon expandable and <20 or >27 for self expandable devices.
- Bicuspid valves because of the risk of incomplete deployment of the stented valve.
- Presence of asymmetric heavy valvular calcification, which may compress the coronary arteries during PAVI. The risk of coronary compression can be anticipated during BAV.
- Presence of bulky atherosclerosis of the ascending aorta and arch detected by TEE.
- Aortic root dimension >45 mm at the aorto-tubular junction for self-expandable prostheses.
- Presence of apical LV thrombus.

The performance of PAVI, even more so *ab initio*, should be restricted to a limited number of high volume centres, which have both cardiology and cardiac surgery departments. The procedure requires the close cooperation of a team of specialists in valve disease including clinical cardiologists, echocardiographers,[11] interventional cardiologists, cardiac surgeons and anaesthesiologists.[8] A hybrid suite is ideal as it fulfils the role of both an operating room and a catheterization laboratory.

The currently available results obtained with PAVI suggest that these techniques are feasible and provide hemodynamic and clinical improvement for up to two years in patients with severe symptomatic AS at high risk or with contraindications for surgery. Pending questions concern mainly safety and long-term durability. Surgeons and cardiologists must work as a team to select the best candidates, perform the procedure, and, finally, evaluate the results. Today these techniques are targeted at high-risk patients but they may be extended to the lower risk group in the future, if the initial promise holds true after careful evaluation. We are currently at the stage of evaluation, and a careful commercialisation process including training and post-market surveillance is crucial to avoid the risk of uncontrolled diffusion.

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