

Sizing of Stented Bioprosthesis in Small Aortic Roots

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Whilst lively discussions have continued concerning the size of mechanical valves, the subject of debate, with respect to stented bioprosthetic valves, has focused mainly on durability and hemodynamics. In our clinic we have been searching for a user-friendly stented tissue valve that has the hemodynamic characteristics of a stentless valve, with the ease of implantation of a mechanical valve. This search is particularly pertinent when considering aortic valve replacement in elderly patients with small aortic roots.

In our pursuit, we tested several stented tissue valves produced by different manufacturers and were able to identify differences between them. When using the Epic valve (St. Jude Medical Inc., St. Paul, MN, USA), for example, we found that we were able to implant a valve that was, on average, one size larger than any other stented tissue valve because the St. Jude valves have a flexible stent and a low anatomic profile [1,2]. As a result of this, we decided to test this finding by examining this information within the context of a scientific study.

Material and methods

Between October 2001 and July 2002 the first 54 patients (in whom an aortic valve replacement using a biological valve had been scheduled) were enrolled and a signed informed consent form obtained. To avoid bias arising from personal preference within the surgical team patients were operated on by two different surgeons.

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Table 1. Patient demographics (N=54; Age: 68–82 [mean 77±3.1]).

	Number of patients (%)
Male	20 (37%)
Female	34 (63%)
NYHA class II	23 (43%)
NYHA class III	30 (56%)
NYHA class IV	1 (2%)
Previous aortic surgery	2 (4%)
Previous cardiac surgery	4 (7%)
Associated procedures	22 (40.7%)
ASD closure	1
Mitral valvuloplasty	1
Mitral replacement	1
Replacement ascending aorta	1
CABG	1

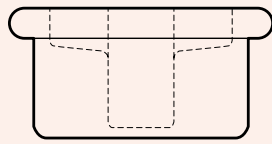
Thirty-four female and 20 male patients, aged from 68–82 years (mean 77±3.1) were included (Table 1). New York Heart Association class was II in 23 patients, III in 30 patients, and IV in one patient. Two patients were admitted for re-operative surgery of the aortic valve, four patients had already experienced cardiac surgery (one previous mitral valve replacement, three previous coronary artery bypass grafts [CABG]), and 22 patients (40.7%) suffered from other cardiac pathologies (one patient had atrial septal defect closure, one had mitral valvuloplasty, one had mitral valve replacement, one had replacement of the ascending aorta, and 18 patients had CABG surgery).

Valve pathology was calcific degeneration in 51 cases, non-coronary cusp prolapse (not repairable) in one case, and failing bioprosthesis due to structural valve deterioration in two cases. In addition, aortic valve stenosis had been diagnosed in 34 cases, aortic

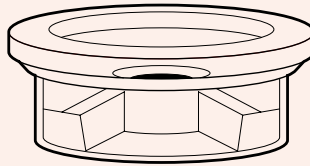
valve insufficiency in three cases and mixed disease in 17 cases.

All patients were operated on via a median sternotomy, while on cardiopulmonary bypass, using antigrade and retrograde cold blood cardioplegia. After removing the valve and carefully decalcifying the annulus, the aortic root was inspected and measured with sizers for either a St. Jude Epic (St. Jude Medical Inc.), Medtronic Mosaic valve (Medtronic, Inc., Minneapolis, MN, USA) or a Carpentier-Edwards S.A.V. Aortic porcine valve (Edwards Lifesciences, Irvine, CA, USA [3,4]). At this point the largest sized valve possible was chosen, but if more than one type of valve of equivalent size was available we chose the valve that best fitted the patient's aortic root. All prosthetic valves were implanted using a continuous running suture of 2–0 polypropylene, in a supra-annular position, and bypass time ranged from 35–146 min (mean 80.9 min),

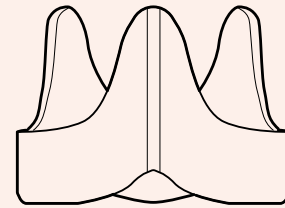
Figure 1. Heart valve sizers manufactured by Carpentier-Edwards (Edwards Lifesciences, Irvine, CA, USA), Medtronic Inc (Medtronic, Inc., Minneapolis, MN, USA) and St. Jude Medical Inc (St. Jude Medical Inc., St. Paul, MN, USA).



Carpentier-Edwards valve sizer



Medtronic Mosaic valve sizer



St. Jude Medical valve sizer

Table 2. Type and size of valves implanted.

Number of patients receiving valve (% of total study group)	Type of valve implanted*	Valve size/mm
14 (26%)	St. Jude Epic	21
15 (28%)	St. Jude Epic	23
14 (26%)	St. Jude Epic	25
7 (13%)	St. Jude Epic	27
4 (7%)	St. Jude Epic	29

* Carpentier-Edwards S.A.V. Aortic (Edwards Lifesciences, Irvine, CA, USA); St. Jude Epic (St. Jude Medical Inc., St. Paul, MN, USA); Medtronic Mosaic valve (Medtronic Inc., Minneapolis, MN, USA)

and cross-clamp time ranged from 25–111 min (mean 65 min).

Results

Perioperative mortality was seen in three patients (5.5%). None of the deaths were valve related and all occurred between the 9th and the 16th post-operative day. All three patients had an echo on the 7th post-operative day while in stable hemodynamic conditions, thus enabling us to include their data in this study.

Table 2 shows the valve type, size, and the number of recipients during the course of the study and Fig. 1 shows the differences between the manufacturer’s sizers. It is evident from Table 2 that when choosing the valve best suited to the patient’s aortic root, a St. Jude Epic valve was selected in all cases operated on within this period. In two cases, however, both the Carpentier-Edwards S.A.V. or the St. Jude Epic could have been implanted, but the St. Jude valve was chosen as the stent height of the Epic valve ensured coronary clearance in patients with small aortic roots. These data also demonstrated that in 25 patients we were able to implant a valve size of 25 mm or higher, which is

unusual in a population of mainly (62%) elderly women close to the age of 80 years. The postoperative gradients through the St. Jude Epic valves were similar to those described in previous papers, and in line with those of other stented biological valves implanted at our institution [1,2]. In two cases we experienced a patient/valve mismatch, with a significant mean gradient that was reduced by half after 6 weeks of appropriate medical treatment.

Conclusion

This study arose whilst considering the different approaches available for aortic valve replacement in elderly patients with small aortic roots. Our preference was for a stented tissue valve with good hemodynamic characteristics. When testing the St. Jude Epic valve we noted that we could use a valve, on average, one size larger than any other tissue valve. This is significant because the size of the biological stented valve incorporates valve height, as well as outer diameter, and the entire valve has to comfortably fit in the aortic root.

When we compared the valves produced by a range of manufacturers we found that whilst they were identical

in outer diameter, the Epic valve was better able to ‘adapt’ to the patient’s aortic root. When examining this valve we found that the difference in size was due to a combination of elements: stent height and flexibility, cuff thickness and the supra-annular position of the cuff. In addition, the valve was found to have an extremely low implantation profile; thus preventing compromising the coronary ostia, in spite of the supra-annular position. At no point in our study did we need to use a patch to close the aorta, and in all cases an Epic valve was used as it was the ‘largest implantable valve’.

We believe it is important to bring this issue to the attention of the cardiac surgical community.

This study has completely changed our attitude in favor of expanding the use of biological stented valves as a substitute to the aortic valve. We are therefore planning to follow up all the patients in this study by means of a medical examination, plus echocardiographic control, at 1 year and include all the findings in a further research paper.

References

1. Myken P, Beach-Hanssen O and Pippis B et al. Fifteen years follow up with the St Jude Medical Biocor Porcine Bioprosthesis. *J Heart Valve Dis*, 2000;**9**:415–22.
2. Bottio T, Rizzoli G, Gerosa G et al. Mid-term follow-up in patients with Biocor porcine bioprostheses *Cardiovasc Surg*, 2002;**10**:3:238–44.
3. Bonchek LI, Burlingame MV, Vazales BE. Accuracy of sizers of aortic valve prosthesis. *J Thorac. Cardiovasc. Surg.* 1987;**94**:632–4.
4. Cochran RP, Kunzelman KS. Discrepancies between labelled and actual dimension of prosthetic valve sizers. *J Cardiac Surg.* 1996;**11**:318–24.