Predicting the Ideal Valve Size During Aortic Valve Replacement with Rapid Deployement Bioprosthetic Valves. Is Intraoperative Transesophageal Echocardiogram Reliable?

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Abstract

Objective: To describe experience with using intraoperative Transesophageal Echocardiography to reliably predict the size of the rapid deployment prosthetic valve by measuring the native aortic annulus Methods: Retrospective review of single institution series of patients undergoing Aortic Valve Replacement with Rapid Deployement Bioprosthetic Valves. Included were patients that had their native aortic valve replaced either isolated or as part of any additional procedure. Aortic annulus was measured prior to initiation of the operation using transesophageal echocardiography (TEE). Correlation analysis was conducted between Echocardiographic annular measurements and actual implanted valve sizes. Results: Twenty five patients underwent rapid deployment valve implantation in the aortic position. Of these, 36% of patients had the same size valve as the measured aortic annulus, 48% of patients had a valve implanted that was 1 mm different, and 16% of patients had 2 mm difference. The mean annular size based was 22.4 mm (range: 21-28 mm). The mean valve size implanted was 23.3 mm (range: 21-27 mm). There was no statistically significant difference between the mean annular measurement and the valve size selected (0.9 mm , p = 0.8). Conclusion: TEE can further enhance valve sizing and guidance through a proper and safe deployment. Although evident in our experience, larger scale studies are needed to further elucidate conclusions on the importance of avoiding under-sizing valves.

Introduction

Sutureless/rapid deployment valves provide the surgeon with a new tool for aortic valve

replacement (AVR) therapy, which can simplify the procedure. The main concern about

sutureless/rapid deployment valves is the development of paravalvular leak. The incidence varies between 1-7%, and is associated with detrimental sequelae for the patient (1,2,3). In this series we would like to share our experience with using intraoperative Transesophageal Echocardiography to reliably predict the size of the rapid deployment prosthetic valve by measuring the native aortic annulus. This will hopefully provide the surgeon with extra assurance on valve sizing during rapid deployment Aortic valve replacement and minimize the possibility of paravalvular leak.

Methods

We retrospectively reviewed our Aortic Valve Replacement database. We were able to identify 25 rapid deployment aortic valves (INTUITY Valve System, Edwards Life Sciences LLC,

Irvine, Calif) that had documented intraoperative Transesophageal Echocardiographic Annular

measurements. Written consent was obtain from participants in the study. All of those valves were implanted in the Aortic position. In this cohort, we only included patients that had their native aortic valve replaced either isolated or as part of any additional procedure. Patients that underwent Intuity valve implantation for Redo Aortic valve replacement were excluded from this study.

Follow up was immediately post-operatively (1-3 weeks) and also at different intervals during the post-operative course (minimum 1 month) at which time an echocardiogram was performed. The mean age of our patient cohort was 68.3 (range: 55-75) years. Patients baseline characteristics are summarized on table 1. (age, concomitant procedures- cabg, mitral valve, tricuspid etc, approach sternotomy, upper sternotomy, right thoracotomy). Our Cardiac Anesthesiology team measured the aortic annulus prior to initiation of the operation using transesophageal echocardiography. Measurements were performed both in the long and short axis views. All measurements were appropriately documented, the implanted valve sizes were reviewed, and a correlation was concluded between Echocardiographic annular measurements and actual implanted valve sizes.

Results

We reviewed 25 patients that underwent rapid deployment valve implantation in the aortic position. For all patients we used the same valve system, INTUITY Valve System (Edwards Life Sciences LLC, Irvine, Calif). Overall, 36% of patients had the same size valve as the measured aortic annulus, 48% of patients had a valve implanted that was 1 mm different, and 16% of patients had 2 mm difference. (Figure 1) The mean annular size based on intraoperative TEE was 22.4 mm (range: 21-28 mm). The mean valve size that we implanted was 23.3 mm (range: 21-27 mm). (Graphic 1) There was no statistically significant difference between the mean annular measurement and the valve size selected (0.9 mm , $p = 0.8$). Echocardiograms were performed on postoperative visits at various intervals that were at least 1 month postoperatively. We identified 5 patients (20%) with trivial paravalvular leak at >1 month postoperative echocardiogram. There were no patients with moderate or severe paravalvular leaks. There was one patient (4%) who required pacemaker implantation.

Discussion

Rapid deployment valves, such as the Intuity Valve, have allowed easier replacement through a simplified procedure with shorter cardioplegic arrest and cardiopulmonary bypass times. (1,4) In this study we would like to share our experience with the value of intraoperative

echocardiography in predicting the size of rapid deployment valves in the aortic position. One of the main concerns of the so-called sutureless or rapid deployment valves is the theoretical possibility of paravalvular leak given the fact that only 3 guiding sutures are needed for this type of bioprosthesis. When done correctly the risk of the above is small. In the TRANSFORM study, the investigators reported a 6.9%, 1.2%, and 0.4% incidence of mild, moderate and severe paravalvular leak respectively at 1 year follow up echocardiography. (table 1)

During “sutured” aortic valve replacement, the surgeon places 12-15 or sometimes even more sutures around the annulus. This is a form of “annuloplasty”, because the prosthesis is circumferentially “pulling” the annulus towards itself and as a result a small undersize of a prosthesis is much more forgiving compared to rapid deployment valves. In rapid deployment valves, sizing the valve appropriately is of paramount importance. A critical step here is meticulous decalcification of the aortic annulus. Inappropriate decalcification will lead to valve under-sizing. The calcium will prevent the “barrel” end of the sizer to advance to the intra-annular plane and this will be misinterpreted as “too big of a valve”, when what really happens is that an eccentric piece of calcium inhibits the sizer to advance to the appropriate level. This is more common in minimal access cases where visibility can sometimes be inadequate. TEE is a very useful tool that Cardiac

Surgery teams have at their disposal. It is in fact a quality measure that should be applied during valve surgery. Although at the beginning of our experience with Intuity valves we skipped documenting intraoperative annular measurements, now we always measure the annulus. We found this to be very helpful in predicting the valve size to be used. 27 % of our patients received a valve that was smaller than the annular measurement. Most of these operations were performed during our early experience with rapid deployment valves. Currently, time we tend to place valves that are equal or larger than the annular measurement. In fact, the mean size valve implanted was 23.3 mm which is 0.9 mm greater compared to the mean annular size of 22.4 mm. When the annulus measures between valve sizes, i.e 24 mm, we always try to implant a size up which in this case would be 25 mm. There was one case of new pacemaker implantation. This patient had an annulus measured at 26 mm and we placed a 27 mm Intuity valve. The patient did not have preoperative bundle branch block and perhaps one should be less aggressive with oversizing when implanting a bigger Intuity valve. Overall however the incidence of pacemaker implants in this series was 4% which is favorable. The Intuity Valve system uses the well-proven performance and longevity of the Carpentier-Edwards Perimount Magna Ease (Edwards Life Sciences LLC, Irvine, Calif) Bioprosthesis and the newly developed rapid deployment technology. This combination provides surgeons with a novel tool that may minimize operative times and simplifies the procedure. There is a learning curve and some important steps that are critical for successful deployment. TEE is perhaps one of our greatest allies in this process: it can further enhance valve sizing and guidance through a proper and safe deployment. Although evident in our experience, larger scale studies are needed to further elucidate conclusions on the importance of avoiding under-sizing valves.

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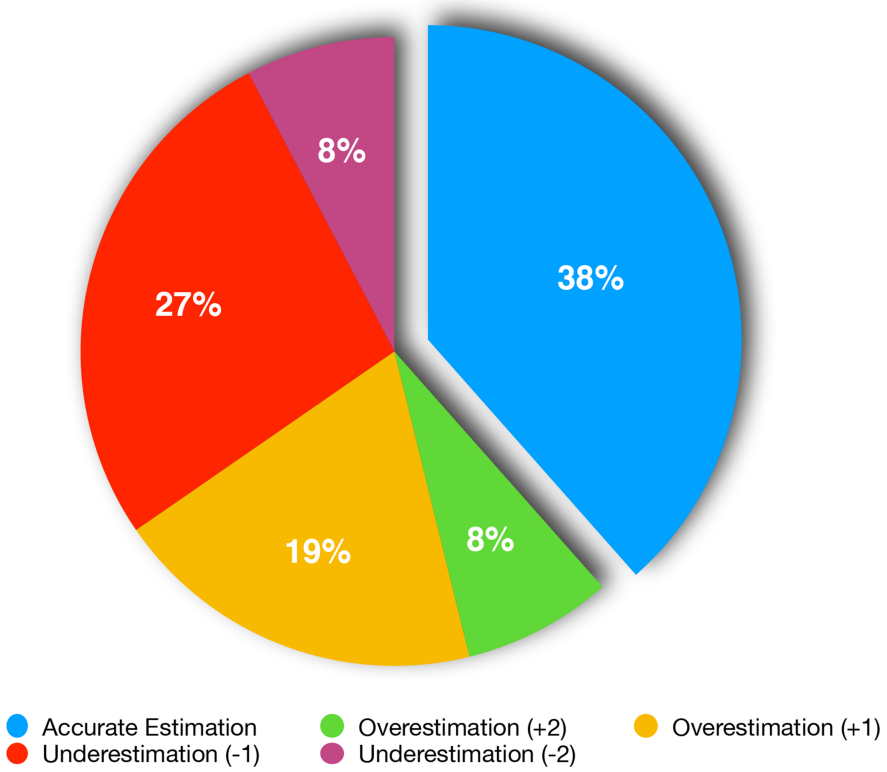
Figure Legends:

Figure 1: graphic representation of estimations recorded during the study.

Table 1: Demographics of patient population used in study.



Age
➢ **55-75 (68.3)**
Diagnosis
AS 11/25
AS+CAD 9/25
AI+ATAA 2/25
AS+MR 1/25
AI+CAD 1/25
Approach
Sternotomy 21/25
Upper sternotomy 2/25
Rt thoracotomy 2/25
Procedure
Isolated AVR 11/25
AVR+CABG 11/25
AVR+MVR 1/25
AVR+ Ascending root replacement 2/25
Outcomes
30 days Mortality 0/25
30 days stroke 0/25
Major bleeding 0/25
Valve thrombosis 0/25
Valve explant 0/25
Major post op PVL 0/25
Trace post op PVL 5