Perspective

Do we need sutureless or self-anchoring aortic valve prostheses?

Malakh Shrestha

Cardiothoracic, Transplantation & Vascular Surgery, Hannover Medical School, Germany

Correspondence to: Malakh Shrestha, MBBS, PhD. Cardiothoracic, Transplantation and Vascular Surgery, Hannover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover, Germany. Email: shrestha.malakh.lal@mh-hannover.de.

Surgical aortic valve replacement (AVR) is the 'gold standard' for the treatment of aortic valve stenosis. Due to the increasing age of the patient population (reflecting the demographic changes), the use of biological valves has increased over the past years. At the same time, a large proportion of these patients require concomitant surgical procedures in addition to AVR. Although trans-apical or trans-femoral aortic valve implantations (TAVI) have been introduced for high risk patients, they are limited to patients with isolated aortic valve pathology. Therefore, strategies for avoiding long ischemia times, as well as long periods of extra-corporeal circulation (ECC) resulting in reduced peri-operative risks should be welcomed among the surgical community. Modern 'sutureless valves' with reduced cross-clamp and cardio-pulmonary bypass times as a result of the absence of sutures, combined with excellent hemodynamics in the short and mid-term, may be an ideal solution for geriatric patients. Additionally, 'self-anchoring' valves will increase the armament of surgeons in treating 'technically difficult' group of patients needing AVR who have small calcified aortic roots and those coming back after aortic root replacement with homografts. These valves should also expand the application of minimally access AVR. Therefore, the question of whether we need 'self-anchoring valves' is not only redundant, but the time may have come for these type of valves to be considered as the 'valve of choice' for higher risk geriatric patients who may be 'high risk' for conventional valves but not ineligible for TAVIs.

Keywords: Aortic valve replacement (AVR); sutureless/self-anchoring heart valve prosthesis

Submitted Aug 15, 2014. Accepted for publication Sep 07, 2014.
doi: 10.3978/j.issn.2225-319X.2014.10.07
View this article at: http://dx.doi.org/10.3978/j.issn.2225-319X.2014.10.07

Introduction

Aortic valve replacement (AVR) continues to be the 'gold standard' for the treatment of severe or symptomatic aortic valve stenosis (1). However, the basic technique has remained similar since 1960 when this operation was first performed. AVR is typically performed through a median sternotomy under extra-corporeal circulation (ECC) and cardioplegic cardiac arrest. The diseased stenotic aortic valve is removed under direct surgical vision and a prosthetic valve (mechanical or biological) is anchored in the aortic annulus with sutures. Regardless of how experienced or 'quick' the surgeon is, the placement of the valve and the tying of sutures prolongs the aortic cross clamp (X-clamp) time. Additionally, the need for sutures also results in minimally invasive AVR being technically more demanding. Theoretically, a reduction of ECC and X-clamp times as well as the increased ease of minimally invasive procedures would be more advantageous, especially elderly patients.

Due to the ageing patient population in the western world, reflecting general demographic changes, the use of biological valves has increased over the past years. In recent years, over 80% of the aortic valves implanted are biological prostheses (2). At the same time, a large proportion of these patients require concomitant surgical procedures in addition to AVR. The German registry data shows that the mortality for isolated surgical AVR in octogenarians is approximately 5% and in combined AVR and coronary artery bypass graft (CABG) is approximately 8% (2). The same registry shows that more than 50% of patients presenting for cardiac surgery in Germany are above 70 years of age, while more

than 15% are octogenarians. For patients deemed as high-risk, trans-apical or trans-femoral aortic valve implantations (TAVI) have been proposed as a suitable alternative (3). However, these procedures are limited to high-risk patients with isolated aortic valve pathology. Additionally, in patients suffering from limited coronary artery disease, a hybrid approach involving TAVI and percutaneous coronary artery angioplasty (PTCA) may be required.

As such, there is a need for new techniques and prostheses for surgical AVR that may reduce cardiac ischemia times and facilitate minimally invasive access surgery, resulting in reduced mortality and morbidity, especially for the ever increasing number of geriatric patients ineligible for TAVIs. It is in this context that the concept of 'self-anchoring/ sutureless valve' was introduced (4).

Sutureless valve

The idea of a 'sutureless' valve implantation is not new. Magovern *et al*. performed the first implantation of a sutureless aortic valve prosthesis in 1963 (5,6). No migration of the valve was observed. Altogether, more than 7,000 such valves were implanted. In those early days of open-heart surgery, ECC was not as safe as it is today and the myocardial protection with cardioplegia was still in early stages of development. Consequently, many of those patients developed paravalvular leaks.

In the following years, advances in cardioplegia reduced the risks associated with conventional techniques that involved suturing of the prosthetic valve to an arrested heart. As a result, the Magovern valve fell out of favour and was no longer implanted. Nevertheless, the Magovern experience was a milestone in cardiac surgery in proving that it was possible to implant valve prostheses without the use of any sutures.

Modern technology and surgical techniques have attempted to solve this problem in present-day self-anchoring valve prostheses by practicing complete decalcification of the annulus under direct surgical vision. The aim is to create a smooth annulus for 'ideal' fitting of the prosthesis into the annulus and utilizing the unique valve designs to prevent valve migration. As a result, 'self-anchoring' valves have the following potential advantages:

(I) Absence of anchoring sutures potentially reduces the X-clamp and ECC times;
(II) Absence of suturing ring results in increased functional valvular diameter;
(III) Minimally invasive access surgery may be technically easier;
(IV) If necessary, concomitant procedures, such as CABG, are possible;
(V) 'Redo' surgery is not a contraindication.

Several 'sutureless or self-anchoring valve' prostheses have been introduced for clinical use in recent years. So far, there is clinical experience with three different self-anchoring prostheses: the ATS 3f Enable™ Sutureless Bioprosthesis (ATS, Minneapolis MN, USA), the Perceval sutureless aortic valve prosthesis (Sorin Group, Saluggia, Italy) and the Edwards Intuity self-anchoring valve system (Edwards Life sciences, CA, USA). To date, more than 10,000 patients have undergone AVR with 'self-anchoring' prostheses with follow-up of up to seven years.

More than 60 peer reviewed academic papers have been published to date about these valves (6-13). These studies have shown that self-anchoring valves not only 'work' but also compare well against conventional sutured valves. These publications have shown the following:

(I) The results of AVR with these valves in geriatric patients are promising, with mortality of approximately 3% for isolated AVR and under 5% in combined AVR and CABG (7,8). This compares favorably against results published with conventional sutured valve prostheses (2);
(II) Isolated AVR with self-anchoring valves can be performed with X-clamp time under 20 minutes (9);
(III) Absence of sutures makes minimally invasive AVR possible even in patients with small calcified aortic roots (10).

Ranucci *et al*. reported that the aortic cross clamp time is an independent predictor of severe cardiovascular morbidity, with an increased risk of 1.4% per one minute increase (13).

Therefore, self-anchoring valves may be especially advantageous in the following group of patients:

(I) Elderly patients with indication for combined CABG and AVR;
(II) Patients with small and calcified aortic annulus;
(III) For broader application of minimally invasive AVR.

However, some concerns still remain, particularly with regard to the following:

(I) Implantation: although implantation of these valves is technically 'simple', the 'sizing' has to be 'ideal', otherwise paravalvular leaks or in root dehiscence may occur;
(II) All the modern 'self-anchoring' valve prostheses are latest generation valves. They have to be further 'refined/modified' to make the 'sizing' and

implantation simpler;

(III) 'Stent fatigue': the longest follow-up is more than seven years for the Perceval and Medtronic Enable valves and more than four years for Edwards Intuity valves. Although no such problem has been observed till date, longer follow-up is needed before these prostheses are routinely implanted in younger patients.

Conclusions

Therefore, the question of whether we need 'self-anchoring valves' is not only redundant, but the time may have come for these type of valves to be considered as the 'valve of choice' for higher risk geriatric patients who may be 'high risk' for conventional valves but ineligible for TAVIs. Additionally, 'self-anchoring' valves will increase the armament of surgeons in treating 'technically difficult' group of patients needing AVR with small calcified aortic roots and those coming back after aortic root replacement with homograft. These valves should also help in broadening the application of minimally invasive AVR.

Acknowledgements

The author has a consultant (Speaker, Proctor) agreement with Sorin Biomedica and Edwards Life Sciences.
Disclosure: The author declares no conflict of interest.

References

1. Schwarz F, Baumann P, Manthey J, et al. The effect of aortic valve replacement on survival. Circulation 1982;66:1105-10.
2. Beckmann A, Funkat AK, Lewandowski J, et al. Cardiac surgery in Germany during 2012: a report on behalf of the German Society for Thoracic and Cardiovascular Surgery. Thorac Cardiovasc Surg 2014;62:5-17.
3. Cribier A, Eltchaninoff H, Bash A, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation 2002;106:3006-8.
4. Wendt D, Thielmann M, Pizanis N, et al. Sutureless aortic valves over the last 45 years. Minim Invasive Ther Allied Technol 2009;18:122-30.
5. Magovern GJ, Cromie HW. Sutureless prosthetic heart valves. J Thorac Cardiovasc Surg 1963;46:726-36.
6. Totaro P, Nicolardi S, Zattera G, et al. Old prosthesis with a modern concept: 41-year survival with a sutureless Magovern-Cromie aortic valve prosthesis. Eur J Cardiothorac Surg 2011;39:789.
7. Shrestha M, Folliguet T, Meuris B, et al. Sutureless Perceval S aortic valve replacement: a multicenter, prospective pilot trial. J Heart Valve Dis 2009;18:698-702.
8. Folliguet TA, Laborde F, Zannis K, et al. Sutureless perceval aortic valve replacement: results of two European centers. Ann Thorac Surg 2012;93:1483-8.
9. Flameng W, Herregods MC, Hermans H, et al. Effect of sutureless implantation of the Perceval S aortic valve bioprosthesis on intraoperative and early postoperative outcomes. J Thorac Cardiovasc Surg 2011;142:1453-7.
10. Shrestha M, Maeding I, Höffler K, et al. Aortic valve replacement in geriatric patients with small aortic roots: are sutureless valves the future? Interact Cardiovasc Thorac Surg 2013;17:778-82; discussion 782.
11. Martens S, Sadowski J, Eckstein FS, et al. Clinical experience with the ATS 3f Enable® Sutureless Bioprosthesis. Eur J Cardiothorac Surg 2011;40:749-55.
12. Kocher AA, Laufer G, Haverich A, et al. One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial: a prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY Valve System. J Thorac Cardiovasc Surg 2013;145:110-5; discussion 115-6.
13. Ranucci M, Frigiola A, Menicanti L, et al. Aortic cross-clamp time, new prostheses, and outcome in aortic valve replacement. J Heart Valve Dis 2012;21:732-9.

Cite this article as: Shrestha M. Do we need sutureless or self-anchoring aortic valve prostheses? Ann Cardiothorac Surg 2015;4(2):175-177. doi: 10.3978/j.issn.2225-319X.2014.10.07

