

USE OF SUTURELESS AND RAPID DEPLOYMENT PROSTHESES IN CHALLENGING REOPERATIONS

Review of the current evidence

Short Title: Sutureless prostheses in complex reoperations

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ABSTRACT

Background and aim of the study: Sutureless and rapid-deployment bioprostheses have been introduced as alternative to traditional prosthetic valves to reduce cardiopulmonary and aortic cross-clamp times during aortic valve replacement. These devices have been employed also in extremely demanding surgical settings as underlined in the present review.

Methods: A search on PubMed and Medline databases aimed to identify, from the English literature, the reported cases where both sutureless and rapid- deployment prostheses were employed in challenging surgical situations, usually complex reoperations sometimes even performed as a bail out procedures.

Results: We have identified 25 patients in whom a sutureless or a rapid-deployment prosthesis were used in complex redo procedures. In 17 patients a failing stentless bioprosthesis was replaced with a sutureless (n=14) or a rapid deployment valve (n=3). Bioprostheses implanted at first operation were mainly Freestyle (n=11) or Prima Plus (n=3) aortic roots, while Perceval (n=13) and Intuity (n=3) were those most frequently employed at reoperation. A failing homograft was replaced in 6 patients using a Perceval (n=5) or an Intuity (n=1) bioprosthesis while a Perceval was used to replace the aortic valve in 2 patients to treat failure of a valve-sparing procedure. All patients survived reoperation and are reported alive 3 months to 4 years postoperatively.

Conclusions: Sutureless and rapid-deployment bioprostheses have proved effective in replacing degenerated stentless bioprostheses and homografts in challenging redo procedures. In these setting, they should be considered as a valid alternative not only to traditional prostheses but also in selected cases to transcatheter valve-in-valve solutions.

INTRODUCTION

Sutureless bioprostheses (SB) have been introduced in the clinical practice in the early 2000's (1); such devices, by avoiding anchoring sutures, were conceived with the aim of shortening the overall surgical and ischemic times during aortic valve replacement (AVR). With the same goal SB were subsequently followed by rapid-deployment bioprostheses (RDB), which allow to reduce the duration of AVR by using only three guiding sutures tied down after implantation (2). Currently, one SB, the Perceval S (*LivaNova, Saluggia, Italy*) and one RDB, the Intuity valve system (*Edwards Lifesciences, Irvine, CA*) are available for clinical use, while the first SB produced, the 3f Enable (*Medtronic Inc., Minneapolis, MN*) has been withdrawn from the market in 2015 (3).

From the available Literature it appears evident that the initial expectations in terms of consistent reduction of aortic cross-clamp and total cardiopulmonary bypass (CPB) times have been fully met (4,5); moreover, it has also been demonstrated that both SB and RDB provide definite advantages also in terms of hemodynamic performance with a significant reduction of the incidence of severe patient-prosthesis mismatch (6).

Although there are still some concerns on their long-term durability, SB and RDB currently represent an appealing alternative not only to traditional bioprostheses, but also to transaortic valve implantation (TAVI), also in elderly and fragile subjects requiring AVR, in whom shortening of ischemic times may significantly reduce the operative risks. Since SB and RDB have shown satisfactory early and medium-term results, they have occasionally been employed also as possible solution to quite challenging situations, such as complex reoperations, where their use might be still considered as '*off label*'. By analyzing the reported cases, employment of SB and RDB in these scenarios and the results obtained are highlighted in the following review.

BACKGROUND

The concept of a SB was pioneered by Magovern and proposed almost sixty years ago to be applied in AVR (7). In the early years, AVR had a high operative risk mainly due to prolonged duration of CPB, consequent myocardial ischemia and suboptimal techniques of myocardial protection; therefore, a caged-ball prosthesis was devised with the unique feature represented by the possibility of a sutureless implant. The Magovern-Cromie prosthesis was made of a closed stainless steel cage containing a silicone ball; the basal ring contained 9 titanium pins which by rotation could be ejected out and be driven into the aorta securing the device to the aortic annulus. Clinical implants started in 1962 but despite favorable 25-year results, production of this prosthesis ceased in 1980 (8,9). The sutureless concept has been revitalized today in the most recent models of biological prostheses; indeed, reduction of total CPB time is still an important issue as it appears particularly beneficial especially in fragile, elderly patients referred with increasing frequency for AVR. In fact, in this peculiar patient subset the use of tissue valves for AVR has been demonstrated to be advantageous, coupling the benefits of avoidance of chronic anticoagulation and the extended durability of the current generation of bioprostheses (10,11).

METHODS

We have performed an English Literature search on PubMed and Medline databases with the aim of identifying cases where both SB and RDB were employed in challenging surgical situations, usually complex reoperations sometimes performed even as a bail out procedure. Data were supplemented by those obtained from personal files and charts, from archives of the journals present in the CTSNet website, and reference section of published articles. Articles presenting patient or case series and single case reports were included but abstracts related to meeting presentations were not considered.

RESULTS

SB and RDB to replace a failing stentless bioprosthesis

A total of 17 patients were collected in whom a failing stentless bioprosthesis was replaced with a SB (n=14) (12-18) or a RDB (n=3) (19,20); in fact, one patient has been reported twice (12,17). There were 11 males and 6 females with an age ranging from 29 to 84 years at reoperation. A Freestyle porcine aortic root (*Medtronic Inc., Minneapolis, MN*) was employed in 11 cases, a Prima Plus porcine aortic root (*Edwards Lifesciences, Irvine, CA*) in 3 (Fig. 1), a Freestyle stentless aortic valve in subcoronary position in 1 and an Elan stentless aortic valve (*Vascutek Ltd., Inchinnan, UK*) in subcoronary position in 1; in 1 patient the type of stentless aortic root implanted was not specified. Failing stentless bioprostheses were replaced with a Perceval SB in 13 cases (size S in 7, M in 2 and L in 4) (Table 1), with an Intuity RDB in 3 (19, 21 and 23 mm) (Table 2) and with a 23mm 3f Enable SB in 1 (Table 1); one patient required also an associated mitral valve repair with a ring annuloplasty. Reoperation was required from 11 to 17 years; chest reentry was performed through a repeat median sternotomy in 13 cases while this information was not available in 4 patients. Follow-up after reoperation ranges from 3 months to 4 years. There were no operative deaths and all patients are reported alive at last follow-up interval with normally functioning prostheses at echocardiographic controls.

SB and RDB to replace a failing homograft

A failing homograft was replaced in 6 patients using a Perceval SB (n=5, size S) or an Intuity RDB (n=1, 21mm) (21-26) (Table 3); in 4 patients the homograft was implanted as full root replacement and in 2 as free-hand AVR. There were 4 males and 2 females, with an age ranging from 39 to 70 years; reoperation was required 7 to 21 years after initial homograft implant. In 5 patients reoperation was performed through a repeat median sternotomy while in 1 the approach utilized was not indicated. In 2 patients combined mitral valve replacement was also performed. All patients survived reoperation and 5 are

reported alive 3 to 44 months postoperatively and with normal prosthetic function while in one follow-up data are not available.

SB to replace a failing aortic valve sparing procedure

This complication has been reported in 2 male patients, 63 and 73-year-old, to treat failure of a valve-sparing operation. In one, reoperation with implantation of a Perceval XL was required after 3 months; in another, in whom immediate failure of an aortic valve-sparing procedure occurred intraoperatively, with persistent significant aortic regurgitation, a Perceval L was implanted. Both patients are asymptomatic at 3 and 4-year follow-up (27,28).

DISCUSSION

The recent introduction in the surgical armamentarium of SB clearly demonstrates that old ideas can be effectively turned into modern concepts in the manufacture of cardiac valve prostheses (29). SB have demonstrated in large series and multicenter studies that they provide satisfactory results with low operative mortality, constantly improving outcomes, even when associated procedures are performed, and promising medium-term data (30-32). Similar results have been reported with RDB with regard to safety, hemodynamic performance and favorable outcomes (33-36). Based on the current available data both RB and RDB are considered a valid alternative to conventional prostheses for AVR; in particular, when compared to surgical AVR these devices also allow for shorter CPB and cross-clamp times (4,5). However, RB and RDB provide clearcut advantages beyond the reduction of operative times such as improved hemodynamic performance, and facilitation of mini-invasive approaches, which renders these devices competitive in specific cases also in comparison with TAVI (3,6,37-39).

The present review has underlined that RB and RDB are effective, not only for standard AVR, but also extremely useful when dealing with complex surgical scenarios. These are mainly represented by the need to perform redo procedures following previous total aortic

root replacement with stentless bioprostheses or aortic homografts implanted according to a modified Bentall technique. In such patients, after many years, either the porcine aortic root or the aortic wall of the homograft usually become heavily calcified, rendering a second Bentall operation extremely hazardous even if not technically impossible (16,22,40); indeed, in such instances, a valve-in-valve procedure has been considered as less hazardous when compared to an aortic root re-replacement (41). In fact, excision of the calcified root and detachment of the coronary buttons may result in injury to such structures, complicating an already cumbersome and demanding procedure; furthermore, also the annulus of the porcine or homograft aortic valve is often severely calcified, stiff and narrowed preventing positioning of anchoring stitches or a traditional stented prosthesis of adequate size (40). In these situations, both SB or RDB have proved effective with no reported operative deaths, even when the procedure was performed as a bailout option (16), and with favorable late outcomes in all cases.

Owing to the limited durability of the first generations of bioprosthetic valves, many centers have acquired considerable experience with reoperation in recipients of degenerated porcine and pericardial bioprostheses (42,43). It is a general experience that, especially in elective cases, reoperation to replace a failing bioprosthesis is in most cases not too technically demanding and can be performed with substantially low operative mortality. Despite this in recent years the use of TAVI as a valve-in-valve procedure has acquired increasing popularity, particularly owing to its limited invasiveness (44). This review demonstrates that SB and RDB can be used as effectively as TAVI in complex redo procedures, in critically ill subjects and even in cases where TAVI was considered not technically feasible (16,22). Furthermore, it is noteworthy to consider that SB have been used at reoperation even in patients with chronic aortic dissection or endocarditis with pseudoaneurysm formation; occasionally, AVR with a SB has been associated to graft replacement of the ascending aorta to reconstruct an adequate sino-tubular junction to

provide a proper anchoring for the SB cage (14,16,18,26). A Perceval valve was also employed in combination to mitral valve replacement or repair indicating feasibility and stability of AVR with a SB also after insertion of a rigid prosthesis or a ring in the mitral annulus (15,25,26).

Currently, a mini-invasive approach, through a mini-sternotomy or mini-thoracotomy incision, is advocated when surgical redo-AVR is planned with SB and RDB (37,45). Interestingly, in all patients considered in this review reoperation was performed through a standard repeat median sternotomy; it is likely, however, that with increasing experience minimally invasive approaches will be preferred also in complex redo cases using SB or RDB.

SB was employed in 2 patients to correct intraoperative failure of a valve-sparing procedure with unsatisfactory repair due to recurrent or intraoperative persistent aortic regurgitation (25,26). TAVI in the presence of aortic regurgitation is generally still considered an '*off-label*' procedure and not yet a standard of care in this setting (46,47). However, the fact that SB implanted in patients with aortic regurgitation maintained normal function up to 4 years after implantation could stimulate prospective studies aimed to extend the use of percutaneous valves, by using specifically designed devices, to aortic pathologies other than calcific aortic stenosis.

Besides complex reoperations, and even if beyond the scope of this review, some unusual, often challenging situations, where SB or RDB were employed, must also be considered. The Perceval SB has been successfully used for AVR in patients with a porcelain aorta when alternative options such as a TAVI were not feasible (48-50).

Recently, an Intuity RDB has been used in a 59-year-old woman with extensive endocarditis of the aortic valve. The complex repair included reconstruction of the aortic outflow by closing a large abscess with a double pericardial patch and AVR with a RDB (51). In this patient the use of a RDB allowed to shorten a complex procedure, but it should

be underlined that in similar settings favorable results have been obtained with alternative techniques validated on larger patient series (52).

Stenotic bicuspid aortic valves (BAV) have represented in the past a contraindication to SB implant which, nevertheless, has been performed with a Perceval prosthesis as another '*off-label*' procedure in a patient with BAV (53). In recent years, however, it has been demonstrated that a Perceval SB can be deployed safely in patients with stenotic BAV without increasing the risk of paravalvular leaks and that BAV should not be currently considered an absolute contraindication to AVR with SB (54). This has been confirmed also by the data from an international registry demonstrating that implantation of either SB or RDB in BAV is more technically demanding but not a contraindication '*per se*' to the use of such devices (55). However, important prerequisites for success have been recognized in a detailed analysis of aortic root geometry and in some technical details, particularly correct decalcification of the aortic annulus and proper sizing (55).

In conclusion, this review has shown that SB and RDB represent a clear technological advancement and an important adjunct in prosthetic valve replacement surgery. Current evidence suggests that SB and RDB are of great help in extremely challenging situations, such as complex reoperations, particularly when undertaken for stentless valves and homografts failures. In these settings such devices allow a limited surgical approach avoiding complex aortic root re-replacement and significantly reducing the risk of reoperation. Based on the results of the present review, and once evidence will be provided on consistent medium and long-term durability, it will be possible to consider unusual or even '*off label*' employment of both SB and RDB in future recommendations.

AUTHOR'S CONTRIBUTION

Igor Vendramin, MD: Concept/design, drafting article

Daniela Piani, MD: Data collection

Matteo Meneguzzi, MD: Data collection

Giovanni Benedetti, MD: Data analysis/interpretation

Daniele Muser, MD: Data analysis/interpretation

Uberto Bortolotti, MD: Drafting article

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LEGEND

Fig 1. Preoperative computed tomography scan of a 79-year-old man who had undergone a modified Bentall procedure using a 27mm Prima Plus stentless bioprosthesis, showing the extensively calcified porcine aortic root after 11 years. The porcine aortic valve was replaced with a Perceval M sutureless bioprosthesis.

Table 1: Use of sutureless bioprosthesis in challenging reoperations. Summary of reported cases.

Author	Year	Age,sex	Operation	Reoperation	Outcome, FU
Villa et al ¹²	2013	63,F	21mm Freestyle aortic root	Perceval S	Alive, NA
Kim et al ¹³	2015	78,M	25mm Prima aortic root	Perceval S	Alive, 3 months
Lio et al ¹⁴	2016	72,F	25mm Freestyle aortic root	Perceval S	Alive, 7 months
		83,F	27mm Freestyle aortic root	Perceval L	Alive, 1 year
Götte et al ¹⁵	2016	83,M	25mm stentless aortic root*	Perceval M, MVr	Alive, NA
Marzouk et al ¹⁶	2016	78,M	23mm Freestyle subcoronary	Perceval S	Alive, 6 months
Chiariello et al ¹⁷	2017	3M,2F** Mean age, 69±6 years	21mm Freestyle aortic root (n=1); 27mm Freestyle aortic root (n=2); 23mm Prima aortic rot (n=1); 25mm Prima aortic root (n=1)	Perceval S (n=2), M (n=1), L (n=2)	Mean, 27±16 months
Stoker et al ¹⁸	2018	44,F	21mm Freestyle aortic root	Perceval S	Alive, NA
		29,M	27mm Freestyle aortic root	Perceval L	Alive, NA
		76,M	23mm Freestyle aortic root	23mm Enable	Alive, NA

FU= Follow-up; NA= Not available; S= Small; M= Medium; L= Large; MVr= Mitral valve repair.

*The Stentless bioprosthesis model is not specified

**One of these patients was previously reported (see reference #12) and therefore was excluded from the Table.

Table 2: Use the Intuity rapid deployment bioprosthesis in challenging reoperations. Summary of reported cases.

Author	Year	Age,sex	Operation	Reoperation	Outcome, FU
Gariboldi et al ¹⁹	2013	50,M	Freestyle aortic root	Intuity 21mm	Alive, NA
Martinelli et al ²⁰	2015	69,M	Freestyle 25mm aortic root	Intuity 23mm	Alive, 6 months
		84,F	Elan SB subcoronary	Intuity 19mm	Alive, 6 months

FU= Follow-up; NA= Not available; SB= Stentless bioprosthesis

Table 3: Reoperation for failed homografts using Perceval of Intuity bioprostheses.
Summary of reported cases.

Author	Year	Age,sex	Operation	Reoperation	Outcome, FU
Folliguet et al ²¹	2013	62,M	23mm homograft aortic root	Perceval S	Alive, 6 months
Čanádiová et al ²²	2015	70,F	AVR, freehand homograft	Perceval S	Alive, NA
Dohmen et al ²³	2016	61,F	21mm homograft aortic root	Perceval S	Alive, 1 year
Folesani et al ²⁴	2016	50,M	AVR, 24mm freehand homograft	21mm Intuity	Alive, 6 months
Akca et al ²⁵	2017	55,M	Homograft aortic root	Perceval S, MVR	Alive, 3 months
Hammond et al ²⁶	2020	39,M	Homograft aortic root	Perceval S, MVR	Alive, 44 months

FU= Follow-up; S= Small; AVR= Aortic valve replacement; NA= Not available; MVR= Mitral valve replacement.