The Use of Sutureless and Rapid-Deployment Aortic Valve Prosthesis in Patients with Bicuspid Aortic Valve: A Focused Review

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Abstract

The use of sutureless and rapid-deployment prostheses is generally avoided in patients with BAV due to anatomical concerns and the elevated risk of para-prosthetic leaks. Multiple studies have reported the use of these prostheses in patients with BAV with varying degrees of success. The focus of this review is to consolidate the available evidence on this topic. A scoping review was conducted using a comprehensive search strategy within Medline, Embase, and Cochrane Central Register of Controlled Clinical Trials for relevant articles. All abstracts and full texts were screened by two independent reviewers according to predefined inclusion and exclusion criteria. Of 1052 total citations, 44 underwent full text review and 13 (4 case reports, 6 retrospective analyses, and 3 prospective analyses) were included in the scoping review. Across all 13 studies, a total of 314 patients with BAV were used for data analysis. In sutureless and rapid-deployment prostheses, the mean postoperative aortic valvular gradients were less than 15mmHg in all studies with mean postoperative aortic valvular areas all greater than 1.3cm. There were 186 total complications for an overall rate of 59%. Individual complications included new onset atrial fibrillation (n=65), required pacemaker insertion (n=24), intraprosthetic aortic regurgitation (n=20), new onset atrioventricular block (n=18), and new onset paravalvular leakage (n=10). The use of sutureless and rapid deployment prostheses in patients with BAV showed comparable intraoperative and implantation success rates to patients without BAV. Various techniques have been described to minimize complications in patients with BAV receiving sutureless or rapid-deployment prostheses.

Introduction

Bicuspid aortic valve (BAV) is a common congenital heart condition affecting approximately 0.5% of the population.[1] In its pure form, a Type 0 BAV results from two aortic cusps without any raphes whereas BAV Type 2 occurs with two raphes. Type 1 BAV is the most common form with one raphe and is particularly associated with fusion of the right and left cusps.[2] The need for surgery of the aortic valve and/or aorta is increased in patients with BAV, with one study showing a 27% incidence of a surgical event over a 20-year period.[3] Additionally, up to one third of patients undergoing aortic valve replacement may also require aortic root surgery.[4]

The advent of sutureless and rapid-deployment valves has facilitated surgery for patients who would otherwise not be a surgical candidate due to frailty or prolonged surgical procedures. Sutureless valves (*Perceval Sorin* (LivaNova group) *Sutureless Aortic Heart Valve* (Perceval) and *3f Enable* (ATS Medical) *Aortic Bioprosthesis* (3f Enable)) consist of three biological pericardial leaflets mounted within a self-expanding Nitinol frame.[5] Upon expansion, these prostheses are stabilized in place by radial outward force without relying on permanent suturing to the patient's aortic annulus.[6] The Perceval valve is inserted using a transverse aortotomy with temporary guiding sutures at the nadir of each sinus in the annulus and passed through the eyelets of each

valve.[7] Commissural traction sutures are removed following visual confirmation of correct valve placement, and the balloon is then inflated at 4 atm for 30 seconds.[8] Following deflation, the catheter is removed. The 3f Enable valve is also inserted using a transverse aortotomy, although its implantation is slightly different. When inserting the 3f Enable valve, its commissural tabs are attached to the aorta (near the level of the native aortic annulus) and spaced at 120-degree intervals. The commissural tabs are fixated using three mattress sutures with pledgets, two lateral sutures, and one horizontal suture once the inner holder has been removed.[9] It should be noted that this device was discontinued in May 2015 for safety concerns. The rapid-deployment valve (*Intuity* (Edwards Lifesciences) *valve* (Intuity)) consists of three biological pericardial leaflets anchored to a balloon-expandable, stainless steel cloth-covered frame that is incorporated into the valve inflow.[10] For Intuity rapid deployment valve insertion, a hockey stick aortotomy should be performed and extend obliquely across the sinotubular junction to the middle of the noncoronary sinus. Similar to the Perceval sutureless valve insertion, the native leaflets should be excised and debridement of the annulus should be conducted. Three equidistant guiding sutures should be placed at the nadir of each coronary cusp, and exit 2-3 mm above the annulus. Using the guiding sutures, the valve should be parachuted using the associated delivery system perpendicularly into the annulus. Once the valve has been determined to be correctly positioned, the balloon is inflated to 4.5-5 atm and maintained for 10 seconds prior to deflating it. Following deflation, the delivery system is removed and the three guiding sutures are cut and serially tied.

BAV has traditionally been considered a relative contraindication for the use of sutureless and rapid-deployment prostheses due to anatomic concerns surrounding valve implantation. These concerns were primarily due to how uneven alignment of the two cusps and aortic root asymmetry in BAV may result in paraprosthetic leak.[11] In recent years, numerous studies have attempted to expand sutureless and rapid-deployment valves to the BAV patient population. The purpose of this scoping review is to describe the outcomes and complication rates of patients BAV undergoing aortic valve replacement with the Perceval sutureless prosthesis, 3f Enable sutureless prosthesis, or Edwards Intuity rapid-deployment prosthesis.

Review Questions

To investigate the outcomes and complications of sutureless (Perceval and 3f Enable) and rapid-deployment (Edwards Intuity) prostheses in patients with BAV, major questions to be addressed in this scoping review include:

What are the postoperative outcomes and complications in patients with BAV that undergo sutureless or rapid-deployment valve replacement?

Do the intraoperative outcomes, postoperative outcomes, and complications for sutureless or rapid-deployment valves differ between patients with and without BAV?

Methods

Study Design

A scoping review was conducted to assess outcomes in patients with BAV who underwent aortic valve replacement using sutureless or rapid-deployment prostheses. The literature search included studies published before June 2021 from MEDLINE, Embase, and Cochrane Central Register for Controlled Trials databases. Full texts and associated references were also manually searched for further citations.

Inclusion Criteria

This scoping review considered studies that included adult (>18 years of age) patients with any category (0, I, or II) of BAV who underwent BAV replacement using sutureless (Perceval or 3f Enable) or rapid-deployment (Edwards Intuity) prostheses. Qualitative studies, quantitative studies, and case reports/series were considered for inclusion. Exclusion criteria included: non-English studies, patients <18 years of age, editorials, commentaries, review articles, and studies with mixed patient populations that lacked outcomes specific to BAV patients.

Search Strategy

A database search was conducted using Medline, Embase, Cochrane Library, and Google

Scholar to identify relevant citations in June 2021. The following keywords and subject

headings were used: "exp bicuspid aortic valve" OR "bicuspid aortic valve.mp" OR "BAV.mp" OR "exp aortic valve" OR "aortic valve.mp" AND "sutureless.mp" OR "exp aortic valve replacement" OR "aortic valve replacement.mp" OR "rapid deployment.mp" OR "perceval.mp" OR "intuity.mp" OR "exp aortic valve prosthesis" OR "aortic valve prosthesis.mp".

Results were restricted to adult populations. There were no date restrictions. Language was

restricted to citations published in English. There were a total of 1052 citations that were identified using this strategy. All citations were uploaded to Covidence for abstract and full text screening, with duplicates being removed. Conference abstracts, oral presentations, and progress reports overlapping with identified peer-reviewed studies were manually excluded by the authors. An overview of the PRISMA study selection is outlined in **Figure 1** .

Study Selection

Two independent reviewers (TS and MK) screened all citation titles and associated abstracts using the inclusion and exclusion criteria above. Following a consensus being reached on citations subject to the initial screening criteria, a full text review was performed. Citations that did not meet inclusion criteria after full text review were excluded. Those that were included underwent manual data extraction by TS and MK.

Results

Of 1052 total citations captured using the described search strategy, 44 underwent full text review, and 13 (4 case reports, 6 retrospective analyses, and 3 prospective analyses) (**Table 1**) were determined to be relevant to the scoping review. For each citation, baseline characteristics data, postoperative parameters, and complications (**Tables 2-4**) were extracted.

Discussion

To the author's knowledge, this is the first review looking at outcomes and complications of sutureless (Perceval and 3f Enable) and rapid-deployment (Edwards Intuity) prostheses in patients with BAV. Upon collation of the data, it was determined that the parameters under study were similar in nature between the sutureless and rapid-deployment valves.

Intraoperative Parameters

Minimally invasive surgical approaches to implant sutureless and rapid deployment prostheses were used in most studies. Cardiopulmonary bypass times and cross-clamp times are consistent with sutureless and rapid-deployment valve replacement techniques in patients without BAV.[16, 24] However, in studies including non-BAV patients treated with sutureless[16] or rapid-deployment[24] valve replacement compared to conventional valve replacement, the hypothesized benefit of reduced CBP and cross-clamp times on postoperative mortality was not statistically significant. Across studies reporting complications specifically for patients with BAV, 1 case involving sutureless (Perceval) implantation failed and required a sutured valve to be substituted.[18] In an additional 5 BAV patients treated with sutureless (Perceval) prostheses[11, 14, 17, 22]redeployment was necessary for correct positioning. Although Tsai et al[22] reported redeployment in 2 out of 5 patients treated with sutureless prostheses, they reported increased success with subsequent surgeries as additional techniques for valve implantation were utilized. Of note, no redeployment was reported from any studies using Edwards Intuity rapid deployment valves in BAV patients. For studies that did not specify between patients with and without BAV, Suri et al[20] reported a 96.3% success rate for deployment of sutureless (Perceval) prostheses in 300 patients and Szecel et al[21] reported 2 cases (0.4%) where a standard stented valve was substituted due to failure of effective sutureless (Perceval) valve implantation. These intraoperative findings suggest that implanting sutureless and rapid deployment prostheses in BAV patients has a low incidence of failure

requiring conversion to sutured valves or redeployment, with comparable implantation success to patients without BAV.[20, 21]

Postoperative Parameters

Outcomes

In all reporting studies, postoperative mean aortic valvular gradients were less than 15mmHg and postoperative mean aortic valve surface areas were 1.4cm^2 or greater. These findings suggest preliminary successful hemodynamic parameters in both sutureless and rapid-deployment valves in BAV patients. The absence of an outer sewing ring on sutureless prostheses may benefit aortic transvalvular gradients by limiting the external surface area.

Complications

The overall complication rate was 59% and included new onset atrial fibrillation (n=65), requisite pacemaker insertion (n=24), and regurgitant flow (encompassing both central aortic regurgitation (n=20) and paravalvular leakage (n=10)). New onset atrioventricular block is more common after sutureless aortic valve replacement (5-17%) than conventional surgical aortic valve replacement (2-4%) (25). Other studies in non-BAV patients with sutureless or rapid-deployment prostheses have shown increased requirement for postoperative pacemaker implantation.[17] In a systematic review of 12 studies on the use of sutureless valves including Perceval S, 3F Enable, Trilogy, and Edwards Intuity in patients without BAV, the proportion of patients with postoperative permanent pacemaker insertion, stroke, paravalvular leak, and endocarditis were 5.6%, 1.5%, 3.0%, and 2.2% respectively.[26] These findings are comparable to the complications noted in our review for postoperative permanent pacemaker insertion (7.6%), stroke (3.5%), paravalvular leak (3.2%), and endocarditis (0.6%)**.** Meco et al[27] suggested that the outward force during balloon dilatation with Perceval sutureless valves on the aortic annulus may cause atrioventricular conduction disorders leading to new onset atrial fibrillation. Additionally, the positioning of the Perceval valve below the aortic annulus may lead to conduction system compression causing atrioventricular block.[11] Valve size and BAV asymmetry have also been shown to be associated with heart conductivity (atrial fibrillation, atrioventricular block, and requisite pacemaker insertion) and flow (intraprosthetic aortic regurgitation and paravalvular leakage) problems. Smaller valve sizes have been shown to cause paravalvular leakage in the Edwards Intuity valve and new onset aortic regurgitation in the Perceval valve.[11] Larger valve sizes have been shown to increase pacemaker implantation rates in both the Edwards Intuity valve and the Pereceval valve, as well as hemodynamic turbulence in the Perceval valve.[10] This can be further complicated by asymmetric expansion of the replacement valve owing to irregular annular space.[17] Included studies have demonstrated techniques to address these issues. For Type I BAV, the semicircular annulus and true raphe allows for repair akin to tricuspid aortic valve replacement.[20] However, Durdu et al[14] reported additional techniques for Type 0 and Type II BAV suggesting that one inter-commissural U-mattress suture was sufficient for elliptical-to-circular remodeling in Type 0 BAVs, but additional mattress sutures and commissural plications may be required in Type II BAVs. The purpose of suture placement is to create otherwise-absent structural integrity that supports symmetric expansion, as well as maintains form amidst fluctuations in pressure consistent with the cardiac cycle.

Conclusions

This scoping review demonstrates preliminary efficacy of sutureless and rapid-deployment valves in BAV replacement. The use of sutureless and rapid deployment prostheses in patients with BAV showed comparable intraoperative and implantation success rates compared to patients without BAV. Postoperative complications from using these prostheses in patients with BAV included new onset atrial fibrillation, new onset aortic regurgitation, new onset atrioventricular block, and required pacemaker insertion. The onset of these complications is due to an array of contributing factors, such as annular size, annular preparation, valve size, valve expansion, and underlying cardiac pathology. The rates of these complications decrease with the use of alternative surgical techniques contingent upon the anatomical defect.

Table 1: Outline of Included Studies

Author	Publication Medium	Study Design	Number of Patients (N=314)	Prosthesis
Chiariello et al. (12)	Journal	Case Report	1	Perceval
Corici et al. (13)	Journal	Case Report	1	Edwards
Durdu et al. (14)	Journal	Retrospective Case Series	13	Perceval
Grant et al. (15)	Journal	Case Report	1	Edwards
Mashhour et al. (16)	Journal	Case Report	8	Perceval
Miceli et al. (11)	Journal	Prospective Case Series	191	Edwards and
Nguyen et al. (17)	Journal	Prospective Case Series	25	Perceval
Roumy et al. (18)	Journal	Retrospective Case Series	17	Perceval
Santarpino et al. (19)	Conference Abstract	Case Report	1	Perceval
Suri et al. (20)	Journal	Retrospective Cohort Study	20	Perceval
Szecel et al. (21)	Journal	Retrospective Case Series	11	Perceval
Tsai et al. (22)	Journal	Retrospective Case Series	5	Perceval
Vola et al. (23)	Journal	Prospective Case Series	20	3f Enable

Table 2: Baseline Characteristics of Included Studies

Citation	Mean Age (years)	Sex (%F/%M)	Surgical Approach	Pre-operative Peak/Mean Valvular Gradient (mmHg)	Pre-operative Aortic Valve Area (cm^2)	Cardiopulmonary Bypass Time (minutes)	Cross-Clamp Time (minutes)
Chiariello et al.	67	100%/0%	Mini-sternotomy	8/-	-	-	-
Corici et al.	67	100%/0%	Median sternotomy	-/-	-	-	-
Durdu et al.	72.8 ± 2.26	46%/54%	Right anterior mini-thoracotomy	-/46.4 ± 13.8	-	54.5 ± 4.4	40.3 ± 3.1
Grant et al.	53	0%/100%	Mini-sternotomy	-/29	1	75	-
Mashhour et al.	80	-/-	-	-/-	-	-	-
Miceli et al.	70.7 ± 9.8	52%/48%	47% Mini-sternotomy; 26% median sternotomy; 26% right anterior mini-thoracotomy; 1% conversion	Perceval: 28.3 ± 10.9/14.8 ± 5.8 Edwards: 19.2 ± 7/10.9 ± 4.4	-	80 (58-104)*	55 (35.5-72)*

Nguyen et al.	77.8 ± 5.4	32%/68%	52% Median sternotomy; 28% right anterior minithoracotomy; 20% ministernotomy	-/49.4 ± 15.7	0.78 ± 0.18	62.2 ± 16.6	49.9 ± 14.5
Roumy et al.	-	35%/65%	-	69 ± 28.14/44 ± 18.2	-	-	-
Santarpino et al.	-	-/-	-	-/50.4 ± 10.9	0.7 ± 0.2	-	28
Suri et al.	67.9 ± 7.1	50%50%	-	-/-	-	70.2 ± 27.8	52.3 ± 19.6
Szecel et al.	-	-/-	-	-/-	-	-	-
Tsai et al.	-	-/-	-	-/-	-	-	-
Vola et al.	74.7 ± 5.4	55%/45%	55% Right anterior minithoracotomy; 25% ministernotomy; 10% median sternotomy; 10% thorascopy	79 ± 20/53.5 ± 12.6	0.55 ± 0.15	113 (82-145)*	85 (66-102)*

*Median (Range)

Table 3: Postoperative Outcomes of Included Studies

Citation	Follow-Up (months, unless otherwise specified)	Prosthesis Size	Postoperative Peak/Mean Valvular Gradient (mmHg)	Postoperative Aortic Valve Area (cm^2)	Hospital Length of Stay (days)	Intensive Care Unit Length of Stay (days)
Chiariello et al.	22	-	8/-	-	6	-
Corici et al.	6 days	23mm	-/-	-	6	-
Durdu et al.	15.1 ± 6.3	10 large (24-25mm) 3 XL (26-27mm)	-/13.6 ± 4.4	1.81 ± 0.38	8.2 ± 2.4	3.1 ± 1.4
Grant et al.	12	23mm	-/-	-	-	-
Mashhour et al.	-	-	-/-	-	-	-

Miceli et al.	-	Perceval: 7 small, 26 medium, 32 large, 23 XL Edwards: 12 19mm, 14 21mm, 33 23mm, 26 25mm, 18 27mm	Perceval: 28.3 ± 10.9/14.8 ± 5.8 Edwards: 19.2 ± 8.4/10.9 ± 4.4	-	12 (9-16)*	2 (1-4)*
Nguyen et al.	12 ± 8	4 medium (23mm), 9 large (25mm), 12 XL (27mm)	-/12.7 ± 6.4	1.86 ± 0.6	9.48 (4-50)	3 ± 2
Roumy et al.	Until discharge	-	22 ± 9.18/12 ± 4.36	-	-	-
Santarpino et al.	Until discharge	23mm	9/5	-	7	1
Suri et al.	12	3 small, 6 medium, 9 large, and 2 XL	-/10.3 ± 3.7	1.4 ± 0.3	-	-
Szecel et al.	31.2	-	22/10	1.6	-	-
Tsai et al.	34**					
Vola et al.	13.8 ± 10.7	3 19mm, 9 23mm, 4 25mm, 4 27mm	Discharge (n=20): 17.1 ± 7.3/10.0 ± 4.2 12 Months (n=17): 17.4 ± 10.1/9.2 ± 5.2	1.6 ± 0.6	-	3 (1-5)*

*Median (Range) **Median

Table 4: Postoperative Complications

Postoperative Complication	Observances
New-onset atrial fibrillation	65 (21%)
Required pacemaker insertion	24 (7.6%)
Intraprosthetic aortic regurgitation	20 (6.4%)
New-onset atrioventricular block	18 (5.7%)
Acute kidney injury	12 (3.8%)
Cerebrovascular incident	11 (3.5%)
Paravalvular leakage	10 (3.2%)
Excessive bleeding	7 (2.2%)
Wound complications	7 (2.2%)
Ventilatory support >72 hours	4 (1.3%)
30-day mortality	4 (1.3%)
Endocarditis	2 (0.6%)
New-onset left bundle branch block	1 (0.3%)

New-onset sick sinus syndrome	1 (0.3%)
Total	186

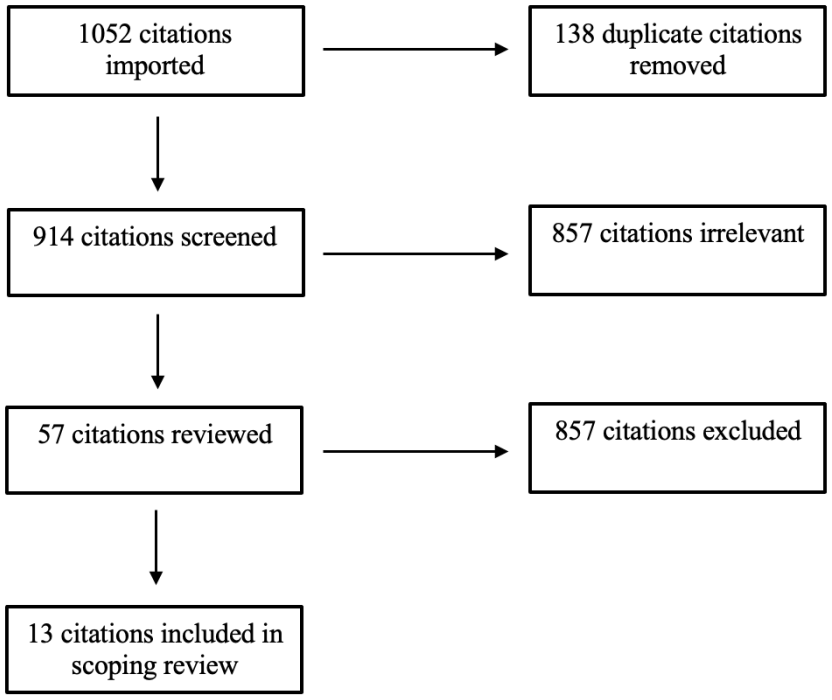

Figure 1 . Prisma study selection flowchart

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Morgan King - Search, study selection, data extraction, writing of manuscript

Thomas Stambulic - Search, study selection, data extraction, writing of manuscript

Darrin Payne - Editing manuscript

Angel Luis Fernandez - Writing manuscript, editing manuscript

Mohammad El-Diasty - Search, writing manuscript, editing manuscript

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