

Stentless aortic valve replacement: an update

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Abstract: Although porcine aortic valves or pericardial tissue mounted on a stent have made implantation techniques easier, these valves sacrifice orifice area and increase stress at the attachment of the stent, which causes primary tissue failure. Optimizing hemodynamics to prevent patient–prosthetic mismatch and improve durability, stentless bioprostheses use was revived in the early 1990s. The purpose of this review is to provide a current overview of stentless valves in the aortic position. Retrospective and prospective randomized controlled studies showed similar operative mortality and morbidity in stented and stentless aortic valve replacement (AVR), though stentless AVR required longer cross-clamp and cardiopulmonary bypass time. Several cohort studies showed improved survival after stentless AVR, probably due to better hemodynamic performance and earlier left ventricular (LV) mass regression compared with stented AVR. However, there was a bias of operation age and nonrandomization. A randomized trial supported an improved 8-year survival of patients with the Freestyle or Toronto valves compared with Carpentier–Edwards porcine valves. On the contrary, another randomized study did not show improved clinical outcomes up to 12 years. Freedom from reoperation at 12 years in Toronto stentless porcine valves ranged from 69% to 75%, which is much lower than for Carpentier–Edwards Perimount valves. Cusp tear with consequent aortic regurgitation was the most common cause of structural valve deterioration. Cryolife O’Brien valves also have shorter durability compared with stent valves. Actuarial freedom from reoperation was 44% at 10 years. Early prosthetic valve failure was also reported in patients who underwent root replacement with Shelhigh stentless composite grafts. There was no level I or IIa evidence of more effective orifice area, mean pressure gradient, LV mass regression, surgical risk, durability, and late outcomes in stentless bioprostheses. There is no general recommendation to prefer stentless bioprostheses in all patients. For new-generation pericardial stentless valves, follow-up over 15 years is necessary to compare the excellent results of stented valves such as the Carpentier–Edwards Perimount and Hancock II valves.

Keywords: cardiopulmonary bypass, valves, heart disease, surgery, follow-up studies

Introduction

Homografts for aortic valve replacement (AVR) were the first biologic stentless prostheses used in clinical practice in the 1960s.^{1,2} Binet et al³ introduced a stentless porcine bioprosthesis, but the valve was abandoned because of poor tissue fixation. Due to limited availability and a relatively difficult implantation technique, mechanical AVR became the popular therapeutic option. The disadvantage of life-long anticoagulation therapy in mechanical AVR prompted the development of xenogeneic bioprostheses. Although porcine aortic valves or pericardial tissue mounted on a stent made the

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implantation technique easier, these valves sacrificed orifice area and increased stress at the attachment of the stent, which caused earlier primary tissue failure. Optimizing hemodynamics to prevent patient–prosthetic mismatch and improve durability revived the use of stentless bioprostheses in the early 1990s. The purpose of this review is to provide a current overview of stentless valves in the aortic position.

Various stentless bioprostheses and implantation technique

First-generation stentless bioprostheses were the Freestyle valve⁴ (Medtronic, Minneapolis, MN) and the Prima valve⁵ (Edwards Lifesciences, Irvine, CA) as well as a porcine root and fully scalloped Toronto stentless porcine valve (SPV)⁶ (St Jude Medical, Minneapolis, MN). The O'Brien porcine stentless valve⁷ (CryoLife, Atlanta, GA) and Biocor porcine bioprosthesis (Biocor Industria e Pesquisa, Belo Horizonte, MG, Brazil)⁸ were also introduced to the market, but have not found widespread acceptance. Subcoronary and full-root replacements are major implantation techniques. Mini-root replacement, which is an inclusion technique, has been preferred to avoid bleeding from suture lines at the aortic annulus. The advantage of subcoronary implantation is to avoid the manipulation of coronary arterial ostia. The disadvantages are difficulties occurring in the small aortic annulus and calcified aortic root, and possibilities of valve insufficiency by changing the shape of the stentless valves in a diseased aortic root. The full-root technique requires reimplantation of coronary arteries to the stentless valves. The advantage of this technique is a larger orifice area compared with the subcoronary technique, especially in patients with small aortic annulus. The full-root technique restores the physiological function of the Valsalva sinus and the sinotubular junction, as identified by da Vinci in the 15th century. The disadvantage is the difficulty of reoperation when the aortic wall of the stentless valve calcifies.

The second generation of stentless valves improved the technical difficulties related to free-hand implantation with two rows of sutures for subcoronary implantation. The Shelhigh Super Stentless aortic porcine valve (Shelhigh, Inc, Millburn, NJ)⁹ is one of the bioprostheses that require only one row of sutures. The tip of each commissure is attached to the aortic wall. This valve is mounted on a super-flexible ring, preserved with glutaraldehyde, detoxified, and heparin treated with the No-React anticalcification treatment. This valve is easier to implant and possible to use in cases of a calcified aortic wall.

The third generation of stentless valves was pericardial bioprostheses. A bovine Sorin Pericarbon Freedom¹⁰ and an equine 3F heart valve¹¹ are available in the market. These pericardial valves are flexible, easy to implant, and show an extremely good hemodynamic performance.

AVR is the treatment of choice for a vast majority of patients. However, in a subset of patients, ie, elderly patients with various comorbidities such as chronic renal failure, liver cirrhosis, chronic obstructive lung disease, and porcelain aorta, AVR is considered contraindicated because of too high predicted mortality and morbidity rates. Recent advances in valve technology have demonstrated that transcatheter aortic valve implantation is feasible and real. Edwards Sapien¹² and Medtronic CoreValve¹³ are commercially available for transcatheter aortic valve implantation. The concept of these valves is used for new-generation sutureless stentless valves.^{14,15}

Operative outcomes

Reports of the operative mortality of stentless and stented AVR have differed in the literature.¹⁶ Retrospective and prospective randomized controlled studies showed similar operative mortality and morbidity. Although stentless AVR required longer cross-clamp and cardiopulmonary bypass time, it did not impair the postoperative outcomes. In patients with depressed LV function, operative outcomes were better in stentless valves owing to the larger orifice area when the full-root technique was applied to avoid patient–prosthetic mismatch.¹⁶

Luciani et al¹⁷ reported survival rates after stentless and stented xenograft AVR. The stented valve was Hancock II bioprosthesis (Medtronic). Stentless bioprostheses were mainly the Biocor valve, Toronto SPV valve, and O'Brien valve. Hospital mortality was significantly ($P < 0.02$) higher in the stented group (6.2%) than in the stentless group (2.7%). Logistic regression analysis showed smaller aortic annulus, duration of aortic cross-clamp time, and coronary artery disease requiring coronary artery bypass as the predictive risk of hospital mortality. The stented valve was not a risk factor by itself. As a retrospective case match study, Vrandecic et al¹⁸ compared the clinical outcomes of Biocor porcine stented valves and stentless valves implanted between 1990 and 1999. There was no significant difference in hospital mortality (stented 5.4% and stentless 4.4%, $P = 0.79$).

Ali et al¹⁹ compared the Prima Plus stentless valve with the Carpentier–Edwards Perimount valve in a prospective randomized fashion. Although there was no significant difference in the mean aortic annular size, patients in the stentless group received a larger valve prosthesis ($25.3 \text{ mm} \pm 2.0 \text{ mm}$ versus $23.2 \text{ mm} \pm 2.0 \text{ mm}$, $P < 0.001$). Myocardial ischemic

time and cardiopulmonary bypass time was about 30 minutes longer in the stentless group. Thirty-day mortality (2.5% in stented valve and 3.7% in stentless valve) and postoperative morbidity were similar. Chambers et al²⁰ compared the Toronto SPV valve with the Carpentier–Edwards Perimount valve in a prospective randomized fashion. The average labeled size of both valves was 24.7 mm. Thirty-day mortality was 3.5% with the stented valve and 4.0% with the stentless valve, and postoperative morbidity was similar. Dunning et al²¹ also compared the second-generation stentless valve Sorin Freedom with the Sorin More stented valve in a prospective randomized controlled trial. Patients in the stentless group received a larger valve prosthesis (25.7 mm \pm 2.7 mm) than those in the stented group (22.9 mm \pm 2.5 mm) ($P < 0.001$). The bypass time and cross-clamp time were about 10 minutes longer in the stentless group. Thirty-day mortality was 3.2% with the stented valve and 0% with the stentless valve, and postoperative morbidity was similar.

Long-term outcomes

Long-term outcomes of various stentless bioprostheses have been reported (Table 1).^{22–30} Several studies showed an improved survival after stentless AVR, probably due to better hemodynamic performance and earlier LV mass regression compared with stented AVR.^{31–38} However, there was a bias of operation age and nonrandomization. A randomized trial supported improved survival of patients with stentless valves. Lehman et al³⁹ compared the Freestyle or Toronto valves with Carpentier–Edwards porcine valves. Eight-year survival was significantly ($P = 0.04$) better in

the stentless group (78.1% \pm 3.8%) than in the stented group (66.0% \pm 4.9%). On the contrary, another randomized study did not show improved clinical outcomes for up to 12 years. Cohen et al⁴⁰ compared the Toronto SPV valve with the Carpentier–Edwards Perimount valve. Freedom from valve-related morbidity at 12 years was 82% \pm 7% in the stented group and 55% \pm 7% in the stentless group ($P = 0.05$). The actuarial survival rate at 12 years was 35% \pm 7% in the stented group and 52% \pm 7% in the stentless group ($P = 0.37$). Although improved hemodynamic outcomes were obtained in patients with a Toronto SPV valve, clinical outcomes were similar in both groups.

The long-term results over more than 10 years were excellent with the Freestyle valves.²³ However, the degeneration was still present in the Toronto SPV valves more than 10 years after implantation.²⁴ Regarding structural valve deterioration and survival benefit, longer follow-up is necessary to compare the excellent results of stented valves such as the Carpentier–Edwards Perimount and Hancock II valves.

Hemodynamic advantages

LV hypertrophy and increased LV mass were highly correlated with sudden death, congestive heart failure, stroke, myocardial infarction, coronary artery disease, and other cardiovascular events.⁴¹ Incomplete regression of LV mass and LV function after AVR was also related to poor long-term survival.⁴² Therefore, pressure gradient across the implanted valve is one of the most important issues in AVR.

Early postoperative hemodynamic performance was not different between stentless and stented valves, though implanted valve size was larger in stented AVR.^{43–46} The hemodynamic advantage of stentless AVR is not unanimous, though stentless valves one size larger could be implanted if the aortic annulus has the same size. Subcoronary implantation of stentless prostheses does not necessarily allow for larger valve selection compared with stented valves, because the LV outflow suture line is within the aortic annulus. The stented valves can be placed in a supra-annular position, upsizing from the true aortic annular size. New-generation Carpentier–Edwards Perimount Magna (Edwards Lifesciences, Irvine, CA) valves had a better hemodynamic performance compared with stentless Edwards Prima Plus (Edwards Lifesciences) valves regarding pressure gradient and effective orifice area.⁴⁷ No difference was found when the Prima Plus valve was compared with the Perimount pericardial valve.^{37,48,49} Compared with porcine stented valves, hemodynamic performance was better with stentless valves.^{39,50,51} A faster and better recovery of LV function and mass

Table 1 Comparison of stented and stentless valves

| Criteria | Result |
|---------------------|--|
| Operative mortality | Similar |
| Early outcomes | Similar (cohort and RCT study) |
| Late outcomes | Stentless group better (Cohort study) Similar or slightly better in stentless group (RCT study) |
| Hemodynamics | |
| Mean PG and EOA | Stentless better than porcine valve Similar to pericardial valve Stented C–E Magna valve better than stentless Freestyle valve |
| LV mass regression | |
| <6 months | Better in stentless group (most cohort and RCT study) |
| >12 months | Similar (cohort and RCT study) |
| Durability and SVD | Better in stented group ^a |

Note: ^aCompared with the first-generation stentless valves.

Abbreviations: C–E, Carpentier–Edwards; EOA, effective orifice area; LV, left ventricular; PG, pressure gradient; RCT, randomized controlled trial; SVD, structural valve deterioration.

has been reported after stentless AVR.^{36,52–57} Implantation technique was also related to the improved hemodynamics. A full-root technique can implant a larger stentless valve in the supra-annular position, allowing upsizing, compared with the original aortic annulus.^{58,59} There may be a bias in the selection of stentless or stented valves by surgeons, because more complicated aortic root anatomy leads to the more frequent selection of stented valves in the learning curve period.

In randomized studies, better hemodynamic results were obtained with Freestyle,^{57,60} Sorin Freedom,²¹ Prima Plus,^{48,61,62} and Toronto SPV valves^{20,43} compared with stented valves. Although Freestyle valves showed a greater reduction in peak velocity and a greater increased effective orifice area than Mosaic porcine valves, there was a similar reduction in LV mass index and clinical outcomes at 6 months and 12 months after the operation.⁵⁷ Narang et al⁶⁰ compared the Freestyle valves with Carpentier–Edwards Perimount valves. LV ejection fraction, LV mass, New York Heart Association scale, and mean pressure gradient were similar in both groups. However, in patients with LV ejection fraction less than 50% and implanted valve less than 19 mm, there was a significant difference in LV mass index and mean pressure gradient. Sorin Freedom stentless valves had a better pressure gradient and effective orifice area than Sorin More stented valves.²¹ However, there was no significant difference in LV mass index at 12 months after the operation. Ali et al⁴⁸ compared Prima Plus valves with Carpentier–Edwards Perimount valves. There was no difference in mean pressure gradient and LV mass 8 weeks postoperatively. Similar results were obtained by Doss et al⁶¹ and Risteski et al⁶² in patients over the age of 75 years. Chambers et al²⁰ and Cohen et al⁴³ compared Toronto SPV valves and Carpentier–Edwards Perimount valves in a randomized fashion. The effective orifice area, mean pressure gradient, and LV mass index were similar 12 months after the operation.

Stentless valves showed no pressure gradient during dobutamine stress echocardiography in comparison with elevated transvalvular gradient in mechanical valves.⁴⁵ Several studies demonstrated superior hemodynamics under exercise with stentless valves compared with mechanical valves after AVR.^{63,64} Fries et al⁴⁴ compared 23 mm Freestyle valves implanted by the full-root technique with native aortic valves and 23 mm Carpentier–Edwards Perimount valves. There was a significant increase of pressure gradient in the stented valve group under exercise, though the native valve group and the stentless valve group showed no increase in pressure gradient under exercise.

An improved hemodynamic performance resulted in faster LV mass reduction in patients with aortic stenosis and LV hypertrophy.⁶⁵ A meta-analysis showed a faster LV mass reduction in patients with stentless AVR than in those with stented AVR.⁵² However, some studies showed no differences in LV mass reduction.^{57,60–62} Although faster LV mass regression has been reported after stentless AVR, it was obtained by larger valve implantation, and final LV mass regression was not significant 1 year after AVR.²¹

Degeneration and durability

Primary tissue failure is an important issue after biological valve implantation (Table 2). Theoretically, xenogenic stentless aortic valves have better durability by avoiding stress at the stent sites.⁶⁶ The hypothesis that durability is improved by avoiding tissue stress as far as the treatment method is the same as the stented counterparts cannot be proved yet. The freedom rate from structural valve deterioration of the Freestyle valves was 97% at 10 years after AVR,²³ which was similar to stented AVR.⁶⁷ A major cause of structural valve deterioration was cusp tear.⁶⁸ Toronto SPV valve demonstrated significant degeneration and an increase in LV mass at 10-year follow-up after AVR.⁴⁰ Freedom from reoperation at 12 years was 75%, which is much lower than with the Carpentier–Edwards Perimount valve (92%). Cusp tear with consequent aortic regurgitation was the most common cause of structural valve deterioration. Urgent or emergent reoperation was necessary due to hemolytic anemia and congestive heart failure. The Toronto valve group also reported that 12-year freedom from reoperation AVR was as low as 69%.²⁴ The Carpentier–Edwards Perimount valve deteriorated with sclerosis and calcification rather than cusp tear by pathological study,⁶⁹ which could permit the elective reoperation in patients of stable condition. The first-generation Cryolife O'Brien valve also has shorter durability compared with stent valves. Actuarial freedom from reoperation was 94% at 5 years and 44% at 10 years.⁷⁰ Early prosthetic valve failure was also reported in patients who underwent root replacement with the Shelhigh stentless valve and composite graft.⁷¹

The information of durability of xenogenic stentless valves in younger patients is absent because the majority of these valves are replaced in patients older than 50 years. Only Vrandecic et al¹⁸ reported the better durability of Biocor stentless bioprostheses than of its counterparts in patients with a mean age of 48.1 years and 46.1 years. Although long-term results of homograft aortic valves are excellent, faster calcification in homografts has been reported compared with Freestyle stentless valves in a younger age group.⁷²

Table 2 Characteristics of various stentless valves

| Bioprosthesis | Company | Material and treatment | Key remarks |
|---------------------------------|----------------------|---|---|
| O'Brien valve | CryoLife | Porcine valve with GAH low-pressure fixation | Actuarial freedom from SVD 91% at 5 years and 44% at 10 years ⁷⁰ |
| Toronto SPV valve | St Jude Medical | Porcine valve with GAH low-pressure fixation | Freedom from reoperation 75% ± 5% at 12 years ⁴⁰ |
| Freestyle valve | Medtronic | Porcine aortic root with GAH zero-pressure fixation with amino oleic acid treatment | Actuarial freedom from SVD 97.0% ± 2.2% (subcoronary), 96.0% ± 4.5% (full root), and 90.9% ± 11.2% (root inclusion) at 10 years, ²³ but deteriorate thereafter ⁶⁸ |
| Prima Plus valve | Edwards Lifesciences | Porcine aortic root with GAH low-pressure fixation and XenoLogiX anticalcification treatment | Actuarial survival rate 71.5% at 8 years and freedom from SVD 97.8% at 8 years ²⁵ |
| Biocor stentless valve | St Jude Medical | Porcine valve sutured to a GAH-treated bovine pericardial conduit | Freedom from reoperation 98.9% ± 0.7% at 9 years ¹⁸ |
| Pericarbon freedom valve | Sorin Biomedica | Bovine pericardial valve composed of two sheets sutured together, GAH treated, and detoxified with homocysteic acid | Freedom from valve-related death and reoperation 91% ± 4% and 94% ± 4% at 7 years No structural valve deterioration observed ¹⁰ |
| Super-stentless valve | Shelhigh | Porcine valve mounted on a superflexible ring with GAH and No-React anticalcification treatment | Possible contamination and malfunction warning by the US Food and Drug Administration ⁷¹ |
| 3F Therapeutics stentless valve | ATS Medical | Equine pericardial tubular valve treated with buffered formulation of GAH fixation | Large effective orifice area (1.7 cm ²) ¹¹ |

Abbreviations: GAH, glutaraldehyde; SVD, structural valve deterioration.

Recommended indication of stentless valves

Homografts have been believed to be the substitute of choice in patients with active infective endocarditis. However, there was no difference in susceptibility to infection between homografts and mechanical valves.⁷³ Several reports of cures for infective endocarditis with stentless valves have been demonstrated as the substitute of the homograft,^{74–76} which is not easily available in many countries.

Stentless bioprostheses were thought to replace stented biological valves by better hemodynamic performance and longer durability when they were introduced in the early 1990s. In 2008, less than 12% of all aortic valve prostheses implanted in Europe were stentless.⁴⁹ The low percentage of stentless valves was attributed to similar hemodynamic performance and easier implanting technique of new-generation bioprostheses such as Carpentier–Edwards Perimount Magna valve and Medtronic Mosaic Ultra valve. The durability of long-term outcomes was not better than expected. A demanding, cumbersome technique prolongs cardiac ischemic and bypass time and increases risk to the patient. Most surgeons now tend to implant stented valves in complicated cases and octogenarians, knowing that operative mortality and durability are not worse than with stentless AVR. Stentless valves with an easier implantation technique (one suture line or

sutureless) may increase the market of stentless bioprostheses in the future.

There was no level I or IIa evidence of better hemodynamic performance, LV mass regression, surgical risk, durability, and late outcomes. At present, stentless bioprostheses are recommended in relatively young and active patients with impaired LV function and small aortic annulus. There is no general recommendation to prefer stentless bioprostheses in all patients.

Bioprostheses for transcatheter aortic valve implantation does not have long-term outcomes.^{12,13} Following the previous literature on stentless valves, modification of stentless bioprostheses used in the transcatheter technique should be restricted to patients with serious comorbidity or octogenarians contraindicated to standard AVR. Autologous pericardial stentless valves should also be limited to younger age groups of patients aged less than 50 years.⁷⁷

Disclosure

The author discloses no conflicts of interest.

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