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# Are Sutureless Aortic Valves Suitable for Severe High-Risk Patients Suffering from Active Infective Aortic Valve Endocarditis?

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Data Interpretation D
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**Background:** Sutureless aortic valves were introduced to facilitate minimally invasive aortic valve surgery. Since sutureless aortic valves are a feasible procedure, we evaluated if any benefits could be identified in severe high-risk patients with active infective endocarditis of the aortic valve.

**Material/Methods:** Between April 2014 and April 2015, a total of 42 patients received a sutureless Perceval® aortic valve (Sorin Biomedica Cardio Srl, Saluggia, Italy) for different indications. Nine of these patients (median age 71 years, range 47–83 years) suffered from active infective endocarditis, including four patients with prosthetic aortic valve endocarditis. Five patients underwent prior cardiac surgery, including transcatheter aortic valve implantation (TAVI). The median EuroSCORE II was 29.5% (range 16.8–87.7%). Post-operatively, data regarding mortality, operative results, and early operative morbidity were collected.

**Results:** There were no cases of 30-day mortality. Four patients needed abscess closure with pericardium. Three patients underwent left atrial appendix closure: one left ventricular thrombectomy, one bypass grafting, and one arch replacement. Median aortic cross-clamp and cardiopulmonary bypass time was 35 minutes (range 26–88 minutes) and 52 minutes (range 40–133 minutes), respectively. The median intubation time was 14 hours (range 1–9 hours). In these high-risk patients, no postoperative morbidity was found except for one re-intubation due to extensive delirium and one re-exploration. No pacemaker implantation was needed. Echocardiographic evaluation showed no central or para-valvular regurgitation, and a median discharge mean gradient of 5.5 mm Hg (range 2.5–10.0 mm Hg).

**Conclusions:** Sutureless aortic valve replacement in very high-risk patients suffering from active infection endocarditis seems to be an option with limited morbidity and appropriate echocardiographic results, however, further studies are needed.

**MeSH Keywords:** Cardiac Surgical Procedures • Endocarditis, Bacterial • Heart Valve Prosthesis Implantation

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## Background

Active infective endocarditis (AIE) has a high mortality rate, especially in patients with previous embolism or abscess formation [1,2]. Mortality rates decreased in the early twentieth century due to implementation of surgical treatment in combination with accurate antibiotic therapy [3]. During the last few decades, AIE mortality rates have not changed, although surgical and postoperative management have further developed through the introduction of new antibiotics against resistant bacteria and minimally invasive surgery for surgical trauma eventually improving overall outcomes. Epidemiologic changes may also play a role. In the past, younger patients were affected by endocarditis due to rheumatic disease, resulting in a well identified valve disease [4]. However, over time, the epidemiological profile has changed. The proportion of patients with healthcare-associated infective endocarditis has increased to up to 30% of all active infective endocarditis cases [5,6]. These patients are generally older and present with multiple morbidities, such as chronic kidney disease, which is exacerbated by intravenous antibiotic therapy, and the afflicted patients are often subjected to home nursing care [7,8]. Another change over time is that *Staphylococcus aureus* has become the primary causative pathogen [9].

In extremely high-risk patients, surgery for aortic valve degeneration has been circumvented using transcatheter aortic valve implantation (TAVI), which has demonstrated excellent results [10]. This is, however, not advisable in cases of endocarditis, leaving conventional surgery the sole option.

Patients with prosthetic valve endocarditis usually require more exhaustive surgery [11]. In addition, since the patient population presents increasingly with a very high-risk profile, alternative treatment choices are needed to allow these patients to be treated with a reasonable operative risk.

Rapid deployment of heart valve prostheses has been introduced to allow surgeons to perform minimal invasive surgery aortic valve replacement (MIS-AVR) [12].

Our team started introducing MIS-AVR in 1996 [13] at the same time as Cosgrove et al. [14]. MIS-AVR has several advantages, such as shorter recovery time, less blood transfusion, shorter ventilation and therefore shorter intensive care unit stay, and improved long-term survival [15], compared with conventional full sternotomy. The disadvantage of MIS-AVR is that it is more demanding and associated with prolonged cardiopulmonary bypass time [16]. Several studies have shown that sutureless aortic heart valves could overcome this problem [12,17].

This study was performed to evaluate the use of sutureless aortic valves in very high-risk patients suffering from active infective prosthetic aortic valve endocarditis.

## Material and Methods

Between April 2014 and July 2015 a total of 42 patients received a Perceval sutureless aortic valve (Sorin Biomedica Cardio Srl, Saluggia, Italy) for different indications. Nine patients had been diagnosed with active infective endocarditis (AIE). Five of those patients suffered from native valve endocarditis, and four patients suffered from active infective prosthetic valve endocarditis, including TAVI patients (according to the modified Duke criteria to diagnose aortic infective endocarditis [18]). Prospective collection of data for this study was anonymized and approved by the medical ethical committee of the University of Berlin.

Statistical analyses were done with SPSS (version 17, SPSS Inc., Chicago, IL, USA). Continuous variables were presented as median (range) and categorical variables as frequency (%). Operative mortality was defined as death occurring within 30 days of surgery or during hospitalization.

### Surgical technique

Implantation of the Perceval sutureless aortic valve has been previously described [19]. In brief, all patients required median sternotomy. Normothermic cardiopulmonary bypass was established in three patients and one patient needed hypothermic perfusion at 32°C due to additional aortic arch surgery. All patients received central cannulation except the patient undergoing arch surgery; in this case, arterial cannulation of the right axillary artery was performed. In all patients, the left ventricle was vented through the right superior pulmonary vein. Warm blood cardioplegia was used to arrest the heart and transverse aortotomy was performed 3.5 cm above the right coronary ostium. Radical debridement of infected tissue and aortic root abscess cavity was performed. Autologous or xenogeneic pericardium was used for stabilization of the infected area and aortic annulus. Subsequently, three guiding polypropylene 3-0 sutures were placed at the deepest point of the native sinus for placing the previously prepared and correctly sized Perceval sutureless aortic valve. The prosthesis was released and the valve balloon was expanded for 30 seconds at a pressure of 4 atm. Sterile saline fluid was added at 37°C allowing the nitinol stent to adapt to the intra-aortic wall. The prosthesis was controlled for correct position and the aortotomy closed in a standard fashion.

## Results

### Patient characteristics

The median age of the patients was 63 years (mean, 68.4±8.2 years; range, 47–83 years). Three patients were female (33%).





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**Table 1.** Patient's characteristics.

| Patient number | Age (years) | LVEF (%) | NYHA Class | Logistic EuroSCORE II | Previous cardiac surgery | Prosthetic valve endocarditis | Abscess | Embolism |
|---|---|---|---|---|---|---|---|---|
| 1 | 61 | 31 | IV | 87.7 | Yes | Elan | Yes | Yes |
| 2 | 62 | 35 | III | 12.4 | No | No | No | No |
| 3 | 74 | 60 | III | 24.5 | Yes | 3F | Yes | No |
| 4 | 73 | 60 | III | 21.8 | No | No | No | No |
| 5 | 67 | 55 | III | 71.0 | Yes | No | No | No |
| 6 | 71 | 50 | III | 56.1 | Yes | Dokimos | Yes | No |
| 7 | 78 | 55 | II | 16.8 | No | No | No | Yes |
| 8 | 83 | 70 | III | 36.7 | No | No | No | No |
| 9 | 47 | 45 | IV | 17.5 | Yes | Autograft | Yes | No |

NYHA – New York Heart Association; yrs, years.

Essential pre-operative characteristics are summarized in Table 1. The predicted mortality was calculated by the EuroSCORE II (median, 29.5% (range 16.8–87.7%). Two patients were obese (body mass index >30 kg/m$^2$) and two patients showed severe pulmonary hypertension (>55 mm Hg). All patients had arterial hypertension. Four patients presented with severe peripheral vessel disease. Diabetes mellitus was diagnosed in seven patients, of which one patient was insulin dependent. All patients suffered from compensated renal failure except one patient who was on chronic dialysis. Five patients underwent reoperation, one of which had undergone coronary bypass surgery 15 years earlier. Active infective prosthetic aortic valve endocarditis was found in four patients. Prior prosthesis implantations were: 3F (Medtronic, Minneapolis, MN, USA) in combination with double coronary bypass surgery 12 years ago, Ross procedure (autograft) four years ago, Elan (Vascutek Deutschland GmbH, Hamburg, Germany) three years ago, and transfemoral TAVI and afterwards surgical aortic valve replacement (SAVR) (Dokimos plus; Labcor Laboratorios LTDA, Belo Horizonte, MG, Brazil) four months ago. The pathogen was known in all patients: streptococci species (n=2), enterococci species (n=2), and staphylococci species (n=5) of which three were *Staphylococcus aureus* infections. The main operative indication was abscess formation in the aortic root area.

## Operative details

Surgical details are presented in Table 2. All Perceval sutureless aortic valve prostheses were implanted successful. Redeployment of the Perceval sutureless aortic valve was not necessary in any patient. Seven patients received a 25 mm (Perceval L) sized sutureless aortic valve and two patients received a 27 mm (Perceval XL) sized sutureless aortic valve. Two patients underwent minimally invasive surgery by partial upper-sternotomy. Five re-operations were performed: four patients suffered from aortic valve prosthetic infection and one patient underwent previously coronary bypass surgery. Annulus reconstruction and abscess cavity closure were needed in four patients. Next to the Perceval sutureless aortic valve implantation, additional procedures were performed in eight patients: two patients had coronary bypass surgery (single and triple bypass), two patients had aortic surgery, two patients had mitral valve repair, two patients had left atrial appendix ligation, one patient had left atrial ablation, and one patient had left ventricle thrombectomy. One patient required aortic arch reconstruction in which case aortic surgery was performed prior to sutureless aortic valve implantation. The median skin-to-skin operation time was 139 minutes (mean 166±61 minutes; range 98–255 minutes), with a median cardiopulmonary bypass time of 52 minutes (mean 63.9±30.0 minutes; range 26–88 minutes) and a median cross-clamping time of 55 minutes (mean 42.9±21.0 minutes; range 40–133 minutes). Intra-operative transesophageal echocardiography showed absence of para- and trans-valvular leakage in all patients.

## Post-operative outcomes

There was 100% survival at 30 days after surgery. The median respiration support was 14 hours (range 1–19 hours), with one patient receiving ongoing support. One patient needed re-intubation due to severe delirium. During this period of respiratory weaning, the patient developed sternal instability, yet without infection. Sternal revision was successfully performed. One patient was re-explored for pericardial effusion. None of the patients received a permanent pacemaker during follow-up. One patient needed temporary hemodialysis until





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**Table 2.** Surgical details.

| Patient number | Perceval prosthesis size (mm) | Concomitant procedure | MIS-AVR | CC Time (min) | CPB Time (min) |
|---|---|---|---|---|---|
| 1 | 25 | Triple bypass, annulus reconstruction, abscess closure, TV thrombectomy | No | 64 | 87 |
| 2 | 25 | – | No | 36 | 56 |
| 3 | 25 | Ligation LAA, atrial ablation, annulus reconstruction, abscess closure, AAR | No | 35 | 69 |
| 4 | 25 | Ligation LAA | Yes | 27 | 41 |
| 5 | 25 | Single bypass | No | 26 | 40 |
| 6 | 25 | Ascending aorta, aortic arch reconstruction, annulus reconstruction, abscess closure | No | 88 | 133 |
| 7 | 27 | Mitral valve repair | No | 50 | 58 |
| 8 | 27 | – | Yes | 30 | 43 |
| 9 | 25 | Mitral valve repair, annulus reconstruction, abscess closure | No | 30 | 52 |

AAR – ascending aorta repair; CC – cross clamping; CPB – cardiopulmonary bypass; LAA – left atrial appendix; LV – left ventricle; min – minutes; MIS-AVR – minimal invasive surgery aortic valve replacement.

renal function had recovered. The median intensive care unit (ICU) stay was four days (range 1–16 days) with an additional intermediate-care unit stay of six days (range 3–10 days). Echocardiographic evaluation at discharge demonstrated absence of central- or para-valvular leakage in all patients, with correct position of the sutureless aortic bioprosthesis. The average median pressure gradient was 5.5 mm Hg (range 2.5–10 mm Hg). During a median follow-up period of seven months (range 1–11 months), none of the patients underwent reoperation or experienced reinfections, structural or nonstructural prosthetic dysfunctions, thromboses, embolisms, or bleeding events. One patient died during follow-up due to multi-organ failure.

## Discussion

Sutureless heart valves were first implanted in 1962 [20]. This so-called "ball-and cage" value or Magovern-Cromie value was a sutureless valve, fixed by multiple spikes protruding at its base; several hundreds of prostheses were successfully implanted with the longest published case having 42 years of follow-up [21,22].

Today, the concept of sutureless heart valve implantation has been revived after tremendous modifications of the implantation tools and annulus fixation [12,23,24]. The purpose of these newer bioprostheses was to increase the number of patients undergoing MIS-AVR rather than SAVR by full sternotomy with all advantages including improved survival [15,25]. Prospective randomized trials were initiated to collect validated data to demonstrate favorable hemodynamic behavior and significant left ventricular mass regression [26].

Due to these promising results, further indications have been evaluated to improve the outcomes of inpatients in need of concomitant cardiac procedures. Shrestha et al. [27] showed a 30-day mortality rate of 2.1% in patients undergoing AVR with additional concomitant procedures. The operative risk was predicted by the logistic EuroSCORE, which showed a mean value of 12.1%, including 15.2% (37/243) with an EuroSCORE above 20%. Since the Shrestha et al. study was done in an older patient population with a mean age of 79.9±5.1 years; it was proposed that it could be beneficial in elderly patients suffering from combined aortic valve and coronary vessel disease. In an earlier study, Minh et al. [28] demonstrated the advantages of these sutureless bioprostheses during double valve treatment. There were no cases of 30-day mortality, limited comorbidity, and good quality of life during early follow-up.

Other studies have shown that sutureless bioprostheses are a viable alternative to transcatheter valve treatment [29,30]. Santarpino et al. [31] showed that para-valvular leakage occurred significantly more frequently in patients undergoing TAVI than after sutureless valve implantation (34% and 7% respectively), which resulted in a significantly lower mortality ($p$=0.001). The Santarpino et al. study showed that TAVI technology was significantly more expensive in overall hospital





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costs: 32,877±6,148 € and 22,451±11,704 € ($p$<0.001) for TAVI and sutureless prosthesis, respectively.

Active infective aortic valve endocarditis is still a serious disease with high mortality [32]. As previously mentioned, today's patients suffering from AIE are older and the proportion of patients with healthcare-associated AIE has increased to up to 30% of all active infective endocarditis patients [5,6]. Though the introduction of TAVI treatment for inoperable patients or patients with high risk showed excellent results [10], the potential risk for TAVI-AIE also increased, resulting in another patient cohort in need of treatment. Amat-Santos et al. [33] showed an incidence of 0.67% (53/7944) in their study register, which was much lower than a previous study that reported a rate of 3.4% at one year [34].

In general, patients with AIE need early extensive surgery and possible root replacement or even double valve replacement with reconstruction of the left ventricular outflow tract and atrial roof. However, since the aging patient population presents with severe risk for operative complications, alternative treatments with reasonable operative risk are needed [35–37]. In our patient population, the EuroSCORE II was extremely high, however, morbidity was acceptable and no mortality was recorded. Furthermore, these patients showed no reinfection during follow-up, although this follow-up period was limited.

Other studies have shown that patients who underwent TAVI could also experience AIE, and alternative surgical options are needed in these patients. In our study we included one patient who had received TAVI and had developed endocarditis. Extensive surgery was performed; however, the cardiopulmonary bypass time was limited, which may be important as bypass time is an independent predictor for early mortality in elderly patients, as is reducing time-dependent inflammatory response [38].

This study showed that sutureless bioprostheses can be successfully used in high-risk patients even if concomitant procedures were needed.

## Conclusions

Sutureless aortic valve replacement in severe high-risk patients suffering from AIE seems to be a suitable option with limited morbidity and appropriate echocardiographic results, however, further studies in larger patient cohort are needed.

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