Aortic valve replacement with sutureless prosthesis: better than root enlargement to avoid patient-prosthesis mismatch?*

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Abstract

OBJECTIVES: Aortic valve replacement in patients with a small aortic annulus may result in patient-prosthesis mismatch (PPM). Aortic root enlargement (ARE) can reduce PPM, but leads to extended cardiac ischaemia times. Sutureless valves have the potential to prevent PPM while reducing cardiac ischaemia times.

METHODS: Between January 2007 and December 2011, a total of 128 patients with a small aortic annulus underwent surgery for aortic valve stenosis at our centre. Thirty-six (17% male, n = 6) patients received conventional valve replacement with ARE and 92 (16% male, n = 18) subjects received sutureless valve implantation (Sorin Perceval). We conducted a comparative, retrospective study with follow-up.

RESULTS: The sutureless group showed a significantly higher age (79 years) than the ARE patients (62 years, P < 0.001) and received significantly more concomitant cardiac procedures (33%, n = 30 vs 6%, n = 2, P = 0.001). The mean operation, cardiopulmonary bypass and cross-clamp times were significantly lower in sutureless patients (147 ± 42, 67 ± 26 and 35 ± 13 min, respectively) than in ARE patients (181 ± 41, 105 ± 29 and 70 ± 19 min, respectively, P < 0.001). The mean postoperative effective orifice area (EOA) indexed to the body surface area was 0.91 ± 0.2 cm²/m² in ARE patients and 0.83 ± 0.14 cm²/m² in sutureless patients (P = 0.040). The rate of patients with severe PPM was 6% (n = 2) in ARE patients and 11% (n = 8) in sutureless patients (not significant, n.s.). The 30-day mortality rates were 2% (n = 2) in sutureless patients and 6% (n = 2) in ARE patients (n.s.). The 1- and 5-year survival rates of the sutureless group were 92 and 54% years, respectively, whereas the 1- and 5-year survival rates of the ARE group were 76% (n.s.).

CONCLUSIONS: Although the sutureless valve patients received significantly more concomitant procedures, all operation-associated times were significantly shorter. Despite sutureless valve patients being older, the 30-day mortality and survival rates were comparable in the two groups. Since the indexed EOA was only slightly lower and the incidence of severe PPM was not significantly higher in the sutureless valve patients, we conclude that sutureless valve implantation is an alternative to conventional ARE to treat a small aortic annulus and avoid PPM, especially in geriatric patients who benefit from the quick implantation process.

Keywords: Aortic valve replacement • Patient-prosthesis mismatch • Aortic root enlargement • Sutureless valves • Sorin Perceval

INTRODUCTION

Aortic valve replacement (AVR) for aortic valve stenosis is one of the most commonly performed procedures in cardiac surgery [1]. However, especially in patients with a small aortic annulus, the implantation of a relatively small-sized prosthesis may result in patient-prosthesis mismatch (PPM) with increased pressure gradients [2]. Moderate PPM is defined as a prosthetic valve effective orifice area (EOA) indexed to the body surface area of 0.65–0.85 cm²/m² and severe PPM as 0.65 cm²/m² or less [3]. PPM can lead to adverse postoperative outcome with persistent symptoms, less left ventricular mass regression and poor mortality [4].

One of the most commonly applied surgical techniques to avoid PPM is aortic root enlargement (ARE) at the time of the procedure [5]. Although some reports suggest that ARE is safe [6], other reports suggest that the risk may be higher. Furthermore, ARE is more time-consuming and technically challenging, thus leading to prolonged cross-clamp times and the potential risk of adverse outcome.

While common aortic valve prostheses usually narrow the EOA due to their suturing ring, sutureless valve prostheses are basically ‘stentless’ and offer the advantage of a larger EOA, thus potentially

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avoiding PPM [7]. Another benefit of sutureless valve prostheses is their self-anchoring delivery and application mechanism, which reduces cardiopulmonary bypass (CPB) and cross-clamp times [8]. In this study, we set out to compare the perioperative and mid-term outcome of patients undergoing surgery for aortic valve stenosis with a small annulus who received either conventional tissue valve replacement with ARE or implantation of a sutureless valve (Sorin Perceval®).

METHODS

We reviewed our hospital database for patients undergoing surgery for aortic valve stenosis with a small annulus between January 2007 and December 2011. A small aortic annulus was defined as a projected indexed EOA of ≤0.89 cm²/m² intraoperatively. The indexed EOA was calculated by the published ‘real life’ echocardiographic data [9] since EOA derived from in vitro experiments tends to be not reliable [10]. Patients, who received a root enlargement procedure due to impeded closure of the aortotomy, were excluded. Patients who received a root patch plasty because of an abscess/endocarditis were excluded, too. We identified a total of 36 patients who received conventional biological AVR and concomitant ARE at our centre. We compared the conventional group with patients undergoing AVR with a sutureless valve prosthesis (Sorin Perceval®).

Retrospective analysis of the chart and operation report was performed to analyse 36 (83% female, n = 30) patients who received a conventional tissue valve replacement with ARE and 92 (82% female, n = 75) subjects who received a sutureless Sorin Perceval valve. We compared these two groups and conducted a retrospective study with follow-up.

Surgical technique: aortic valve replacement and root enlargement

Access was established either via a standard median sternotomy or an upper mini-j-sternotomy. After systemic heparinization, CPB was initiated with direct cannulation of the ascending aorta and the right atrium. After aortotomy incision, the aortic valve was resected and the annulus decalcified. Next, the size of the aortic annulus was measured. The indication for ARE was a small aortic valve orifice area to patient’s body surface area. The decision to perform an ARE was made by the operating surgeon, depending on the patient’s age, size, weight, comorbidities and the anatomy of the aortic root. The ARE was performed according to the techniques of Nicks et al. [5] using either autologous pericardium or Dacron patches. The ARE technique enabled the insertion of a prosthetic valve at least one size larger than the original annulus could accommodate. Valve sizing and selection were performed with the sizers provided by each respective prosthetic valve manufacturer. The prostheses were anchored using pledgeted threads.

Surgical technique: sutureless valve implantation

Access and CPB were established as described above. The aortotomy incision is performed at the distal portion at the sinotubular junction. The aortic valve is resected and the annulus decalcified. After sizing of the aortic annulus, three guiding suture threads were positioned at the nadir of each sinus. The Sorin Perceval S® prosthesis was introduced into the aorta using the three guiding threads. Postdilatation of the prosthesis was done according to the manufacturer’s recommendation. After implantation of the prosthesis and removal of the guiding threads, the aorta was closed and CPB was ended.

Anticoagulation therapy

After surgery, patients were anticoagulated with coumadin for the first 3 months only. Thereafter, unless no other indication existed for further coumadin treatment, the patients received a life-long therapy with aspirin.

Echocardiography

Echocardiography was performed using a Philips Healthcare ultrasound machine (Philips GmbH Market DACH, Hamburg, Germany). M-mode, two-dimensional and Doppler transthoracic echocardiogram was recorded. The EOA was determined and divided by the patient’s body surface area at the time of examination to obtain the indexed EOA. Severe PPM was defined as an indexed EOA of 0.65 cm²/m² or less [3]. Paravalvular leakage was defined as functional, moderate aortic regurgitation or more.

Follow-up

All patients were contacted for follow-up, which was done according to common guidelines [11]. We also acquired and reviewed the most recent medical data from the primary care physicians and/or cardiologists.

Statistical analysis

Data analysis was performed using the SPSS 22 Statistics software (IBM, Herrenberg, Germany). Normal distribution of variables was analysed with the Kolmogorov–Smirnov test. Normally distributed continuous variables are stated as mean ± standard deviation, whereas continuous variables without normal distribution are stated as median + range. The t-test and the Mann–Whitney test were used for the analysis of continuous variables depending on normal distribution. Categorical variables are stated as absolute numbers and proportions. Differences in categorical variables were analysed using the Fisher’s exact test due to the sample size. Kaplan–Meier analysis was used for the evaluation of survival and the log-rank test was used to test for differences. Multivariate analysis was performed using a binary logistic regression model to discriminate independent risk factors for 30-day mortality. Further evaluation of survival was performed using multivariate Cox regression analysis. A value of P < 0.05 was considered statistically significant.

RESULTS

The preoperative patient characteristics are given in Table 1. The median age was significantly lower in the ARE group (62 years) than in the Perceval group (79 years, P < 0.001). While height and weight were evenly distributed between the two groups, the mean...
body mass index was higher in the ARE group (34 ± 7) compared with the Perceval group (28 ± 5, P < 0.001). The body surface area was 1.8 ± 0.2 in both groups (n.s.). The preoperative echocardiography parameters were distributed relatively equally in both groups.

The intra- and perioperative data are given in Table 2. The Perceval group (33%) showed a significantly higher rate of concomitant cardiac procedures than the ARE group (6%, P < 0.001). Furthermore, the majority of isolated AVR in the Perceval group was performed minimally invasive (53%), whereas only three procedures in the ARE group were carried out this way (8%, P < 0.001). The mean operation, bypass and aortic cross-clamp times were significantly shorter in the ARE group. Although the 30-day mortality rate was slightly higher in the ARE group (6%) compared with the Perceval group (2%), this difference was not statistically significant (n.s.). The rate for postoperative pacemaker implantation was significantly higher in Perceval patients (15%) than in ARE patients (6%, n.s.).

The results of the discharge echocardiography examinations are given in Table 3. While we observed no paravalvular leakages in the ARE group, 3% of the Perceval patients showed a paravalvular leakage. The Kaplan–Meier survival curves are shown in Figure 1. The follow-up was 81% complete for the ARE group and 91% complete for the sutureless valve group. The mean follow-up times were 4.4 ± 2.8 years for the ARE group and 2.9 ± 1.6 years for the sutureless valve group. Both the 1- and 5-year survival rates of the ARE group were 76%. The 1- and 5-year survival rates of the Perceval group were 92 and 54% years, respectively. There was no significant difference in survival (n.s.).

We also performed a multivariate analysis using a binary logistic regression model. However, in our model, we did not find an independent risk factor predicting 30-day mortality.

We used a multivariate Cox regression model to identify independent risk factors for mid-term mortality. We found that age was an independent risk factor predicting mid-term mortality. We also found that the presence of concomitant procedures, the type of operation, and the use of a minimally invasive approach were significant risk factors for mid-term mortality.
was the only risk factor predicting mid-term mortality (hazard ratio = 1.122, CI = 1.017–1.238, \( P = 0.022 \)).

**DISCUSSION**

PPM is a complication after AVR leading to adverse postoperative outcome with persistent symptoms [4]. For many decades, ARE has been performed to implant a larger prosthetic valve into a small aortic annulus [5]. The sutureless aortic valve prostheses, being also ‘stentless’, offer the potential advantage of a larger EOA, thus avoiding PPM [7]. This study is the first one comparing small aortic annulus [5]. The sutureless aortic valve prostheses, has been performed to implant a larger prosthetic valve into a.

While some patient characteristics were distributed equally in the two groups, some were differently distributed. This has to be taken into account when interpreting the results of the study. The age was significantly higher in the sutureless valve group. Sutureless valves have been on the market only for a very limited period of time and the first trials had strict inclusion and exclusion criteria including a minimum patient age of 75 years or more. Our study involves also patients from this early period, explaining the higher age in this group when compared with the ARE group.

The ARE group showed a higher BMI and a higher incidence of redo cases. On the other hand, the sutureless valve group showed a higher age and a higher incidence of patients of NYHA classes III and IV. These factors indicate that the patients of the latter group were in a more morbid condition before surgery. Despite the higher age and NYHA class, the sutureless valve group received more concomitant surgical procedures. Interestingly, although the sutureless valve group was in a more morbid condition and received more concomitant procedures, all operation-associated times were significantly shorter. This might be explained by the self-anchoring delivery and application mechanism, which can reduce CPB and cross-clamp times [8].

The postoperative outcome was similar in both groups in terms of the rethoracotomy rate, the mean stay on the intensive care unit and the 30-day mortality rate. Given that the sutureless valve group showed a significantly higher age and NYHA class, but still showed an outcome comparable to the ARE group, we believe that sutureless valve implantation is a safe alternative to conventional valve replacement with ARE to reduce PPM.

The sutureless valve group showed a higher rate of pacemaker implantation after surgery than the ARE group. In the latter group, we observed a pacemaker implantation rate of 6%, which is comparable with the results of other studies [12]. The higher risk for postoperative atrioventricular conduction disorders after sutureless valve implantation is a previously described issue [13]. We believe that the self-expanding stent frame of the Perceval® prosthesis and its postdilatation with a balloon might apply intense pressure on the aortic annulus, thus inhibiting conduction of the atrioventricular junction. We observed a higher rate of atrioventricular conduction disorders in the early learning phase of sutureless valve implantation. Nowadays, we apply less pressure during postdilatation and observe a lower pacemaker implantation rate after sutureless valve implantation. The benefit of the quick implantation process, which allows more morbid patients to be treated in shorter operation times, has to be weighed carefully against the potential need for postoperative pacemaker implanta-

The mean and maximum gradients of the discharge echocardiography examinations were slightly higher in the sutureless valve group compared with the ARE group. Nonetheless, this difference was only marginal and one has to question whether this difference has any clinical relevance. Furthermore, we observed a decline of the mean gradients in the sutureless valve group and an incline in the ARE group during follow-up examinations, leading to basically comparable numbers without any statistically significant difference.

The mean EOA was slightly higher in the ARE subjects. Although these differences were statistically significant, one has to question whether this subtle difference has any clinical relevance. Also, the EOA indexed to the body surface area of patients was slightly higher in the ARE group. This difference was not statistically significant. The mean indexed EOA is only slightly below 0.85 cm²/m², which indicates gentle PPM [3]. Clearly, the EOA results of the sutureless valve group are far away from the criteria for severe PPM, which is defined as an indexed EOA of 0.65 cm²/m² or less [3]. The small benefit of a slightly higher indexed EOA of the ARE group has to be weighed carefully against the quick implantation process of the sutureless valves. The incidence of patients with severe PPM was slightly higher in the sutureless valve group;
however, this difference was not significantly higher. We believe that sutureless valve implantation is an alternative for patients with a small aortic annulus to avoid PPM.

The long-term performance of sutureless aortic valve prostheses is not yet available. This might lead surgeons to reserve the sutureless valves for older patients. However, with increasing experience, the future will show how they perform also in younger patients. We performed one redo AVR in a patient with previous implantation of a Sorin Perceval valve that showed sudden, rapid leaflet degeneration during the fifth year post-implantation, most likely caused by infection. The surgery could be performed with ease and the further postoperative course of this patient was completely uneventful. This indicates that sutureless valve implantation might also be an option in younger patients with a small aortic annulus. Since the Sorin Perceval valves were implanted only in patients of 75 years or older during the initial trial, the median age of the sutureless valve group in the present study is higher than in the ARE group. Because of the limited experience with sutureless valves and the relatively high age of the sutureless valve group, one might assume that this prosthesis was reserved only for older patients.

The incidence of paravalvular leakages was higher in the sutureless valve patients without being statistically significant. Sutureless valve implantation might lead to paravalvular leakage due to sub-optimal decalcification. The cohort in our study comprises first patients who received sutureless valve implantation at our centre and there is a learning curve. The incidence of paravalvular leakages was higher in the sutureless valve group during follow-up without being statistically significant.

The mid-term survival was comparable in both groups. In the ARE group, we observed some deaths within the first postoperative year, followed by no further deaths. The sutureless valve group showed a continuous decline of living patients. This is explained by the significantly higher patient age of this group. The Cox regression analysis showed that age was the only significant variable predicting mortality during follow-up.

Limitations

One limitation of this study is its retrospective character. The different distribution of some variables including age represents a selection bias and has to be taken into account when interpreting the results of the study.

CONCLUSION

Although the sutureless valve patients received significantly more concomitant procedures, all operation-associated times were significantly shorter. Despite sutureless valve patients being older, the 30-day mortality and survival rates were comparable in the two groups. We conclude that sutureless valve implantation is an alternative to conventional ARE to treat a small aortic annulus and avoid PPM, especially in geriatric patients.

Conflict of interest: none declared.

REFERENCES


Dr E. Beckmann: Actually we took notice of your earlier comments and reedit the whole statistical analysis and the inclusion and exclusion criteria. So what I just presented is data with the annulus indexed to the body surface area and we had to remove eight patients from the initial group that would have shown no PPM. What you see here is all indexed to the body surface area? So that can offer some selection bias, and so the conclusions that we can get from that, maybe we have to be careful.

My major criticism to the paper is that you may be dealing with two different populations. One is in terms of age; they are different. The one that got the aortic root enlargement is a younger population. Also, then there are more additional procedures done on the population that received a stentless valve, plus a major approach through a ministrotomy in patients with sutureless valves. So that can offer some selection bias, and so the conclusions that we can get from that, maybe we have to be careful.

I have two questions for you. The first one is, in the manuscript, you set a threshold of 23 mm as an annulus size to go for a root enlargement. Can you comment on why you picked that number instead of going for an indexed to surface body annulus?

Dr Quintana: Excellent. So then I have another question that whenever you are deciding to go for a sutureless valve in this middle age population, so if you have a patient around a 60-65-year-old who wants a tissue valve, for example, are deciding to go for a sutureless valve in this middle age population, so if you...
be even difficult if you have a sutureless valve? Is there a threshold where your institution says from this age we would rather do a root enlargement or we prefer to go for a stentless valve?

**Dr Beckmann**: I think that is an important question. The major issue is that there is not much long-term experience with sutureless valves. They have not been on the market for such a long time, so it maybe makes you hesitate when you consider sutureless valves for younger patients. When you have somebody who is maybe 60 or 65 years old you would rather go for a conventional valve that has been on the market for 30 years since you know that there will be good results over the long term. I think when we have more experience with sutureless valves it might also be an option for younger patients. At the moment there is no formal threshold, but the tendency seems to be sutureless valves for patients of 60 to 70 years of age. But I think there is no real data supporting this.

**Dr M. Shrestha** (Hannover, Germany): I just want to answer some of your comments. Your first comment was that in this study we had two different groups of patients. The reason was that this is a retrospective study, first. The second is that the time period was 2007 onward, and in this time period we had the Perceval study, and the inclusion criteria was above 75. So we could not include any younger patients. If we had to do it now, of course, as a prospective study, then of course, like he said, I would go down to 60, 65, because this clearly shows that either you can do a root enlargement and spend, I don’t know, additional 20–30 minutes of cross-clamp time or you just put in this valve with more or less the same results.

**Dr Quintana**: A quick remark here. You or the audience, what do you think about reoperations with this type of prosthesis? Do you think they are more challenging than regular redo aortic valve replacement after a tissue valve, for example?

**Dr Shrestha**: No, it is easier than with the classical valves. Luckily in the last eight years there were only two cases that I had to redo aortic valve replacement after Perceval implantation, both were endocarditis, and one was after five years post-implant. It is easy. You don’t need to take out any sutures. You have to be careful, of course; you cannot just pull it out and with the Perceval, supraavalvar stent, does not press into the aorta. It is not like the endo-vascular stents that we are seeing, it is different, because here the fixation is done by the inflow side. So that’s the only part that you have to take it out, and it’s quite easy; takes you about 10 seconds I think.

**Dr A. Kaya** (Amsterdam, Netherlands): The damage to the root, is that different than during a conventional valve?

**Dr Shrestha**: No, less, because you don’t need to take out any sutures. You just need to peel it out. You don’t use force, but it’s very easy actually.

**Dr Kaya**: But it is based on nitinol, and you do use lowering of the temperature, like ice water? Does that help?

**Dr Shrestha**: No, because if you look at the Perceval valve, the outer part of the inflow part, is covered with pericardium, so it sticks already to the patient’s native root. So thus using cold water, it may shrink the upper part of the stent but not the lower part, (the inflow part). What I used was not a knife, scissors just to peel out. It takes you 10 seconds and the root is not damaged. It’s not like in the classical valves that if you are not careful taking out the sutures and the sewing ring, you can really end up with a Bentall procedure.

eComment: Aortic-root enlargement procedures: an invaluable surgical technique

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References


