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Comparable long-term results for porcine and pericardial prostheses after isolated aortic valve replacement

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ADULT CARDIAC

Abstract

OBJECTIVES: Outcome of aortic valve replacement may be influenced by the choice of bioprosthesis. Pericardial heart valves are described to have a favourable haemodynamic profile compared with porcine valves, although the clinical notability of this finding is still controversially debated. Herein, we compared the long-term results of two commonly implanted bioprosthesis at a single centre.

METHODS: All consecutive patients undergoing isolated aortic valve replacement with either a Carpentier-Edwards Magna pericardial prosthesis or a Medtronic Mosaic porcine prosthesis between 2002 and 2008 were analysed regarding preoperative characteristics, short- and long-term survival, valve-related complications and echocardiographic findings.

RESULTS: The Medtronic Mosaic was implanted in 163 patients and the Carpentier-Edwards Magna in 295 patients. The sizes of implanted valves were 22.4 ± 1.5 mm for the Mosaic and 21.8 ± 1.8 mm for the Magna ($P = 0.001$). The long-term survival rate was 76 and 56% after 5 and 10 years for the Medtronic Mosaic, which was comparable with the Carpentier-Edwards Magna (77 and 57%; $P = 0.92$). Overall long-term survival was comparable with an age- and sex-matched Austrian general population for both groups. Valve-related adverse events were similar between groups. The postoperative mean transvalvular gradient was significantly increased in the Mosaic group (24 ± 9 mmHg vs 17 ± 7 mmHg; $P < 0.001$).

CONCLUSIONS: Both types of aortic bioprostheses offer excellent results after isolated aortic valve replacement. Despite relevant differences in gradients, long-term survival was comparable with the expected normal survival for both bioprostheses. Patients with a porcine heart valve had a higher postoperative transvalvular gradient.

Keywords: Aortic valve replacement • Biological heart valves • Bioprosthesis • Survival analysis

INTRODUCTION

Aortic valve replacement is among the most commonly performed procedures in cardiac surgery. The optimal prosthesis for aortic valve replacement has not yet been developed. Bioprostheses do not require a lifelong anticoagulation as opposed to mechanical prostheses and offer a satisfactory haemodynamic profile. However, the risk of structural valve degeneration has to be considered.

The number of biological heart valve implantations significantly increased over the last decades. This is not only due to an increasingly older patient cohort, where biological prostheses are favoured [1, 2]. The higher durability enabled by improved anticalcification treatment and other optimizations of valve design led to a higher implantation rate in a younger patient population. The two most commonly implanted biological prostheses are either stent-mounted native porcine aortic heart valves or bovine pericardial valves [3]. Both prostheses have proven clinical outcome over time [4, 5]. They have undergone modifications in design during the past decades to optimize haemodynamic performance and prolong durability.

Pericardial prostheses are credited to have a favourable haemodynamic profile compared with porcine valves [6, 7]. However, the impact of improved postoperative transvalvular gradients on outcome is still a matter of debate. Furthermore, high transvalvular gradients in porcine heart valves seem to be at least partly caused by an echocardiographic phenomenon [8].

The aim of the current study was to compare two commonly implanted bioprostheses at a single centre in a real-world setting. The Medtronic Mosaic porcine biological aortic heart valve and the Carpentier-Edwards Magna pericardial aortic bioprosthesis were analysed regarding survival, reoperation rate, valve-related complications and echocardiographic data.

MATERIALS AND METHODS

Study population

Data of all consecutive patients undergoing isolated aortic valve replacement with either a Carpentier-Edwards Magna pericardial prosthesis (Edwards Lifesciences, Irvine, CA, USA) or a Medtronic Mosaic porcine prosthesis (Medtronic, St Paul, MN, USA) during the same time period between 2002 and 2008 at a university hospital were prospectively collected and analysed. The surgeon made the decision regarding the type of valve prosthesis according to his or her preference independent of this analysis. There were no strict rules established to guide the decision to one or the other prosthesis. All patients with concomitant surgical procedures except of root and/or annular enlargement were excluded from this analysis. All patients without contraindications received phenprocoumon for 3 months after surgery. Patients were followed by general practitioners and cardiologists without a stringent study protocol.

Data management

The internal review board approved this project (EK 955/2011). Informed patient consent was waived. Patients' characteristics and risk factors were documented prospectively in the electronic documentation system of our institution. Risk scores [additive and logistic European system for cardiac operative risk evaluation (EuroSCORE)] were calculated and stored. The follow-up was performed in accordance with the current guidelines for reporting mortality and morbidity after cardiac valve interventions [9]. All postoperative hospitalizations and outpatient visits in public hospitals of the same city were assessed. In addition, every patient was contacted by telephone to complete follow-up. The databank's closing interval was from mid-February 2013 to end of March 2013 (6 weeks). Furthermore, a second databank search to update survival and adverse event information for final revision was performed in September 2014.

Mortality. Early mortality was defined as all-cause mortality during the first 30 days. In addition to our follow-up, overall mortality was yearly crosschecked with the countrywide database maintained by the national statistical institute (Statistics Austria, Vienna, Austria). All deaths in Austria are registered in the database with the full name, date of birth and date of death. Every Austrian citizen who was operated at our department and died thereafter in Austria could be identified. Therefore, the follow-up for survival is considered as complete except for foreign patients or patients who left the country. The follow-up time ranged from 0 to 11 years in the Mosaic group and from 0 to 12 years in the Magna group, with a mean time of survival follow-up of 6 ± 3 years for both valves ($P = 0.61$).

Morbidity. Reoperations including interventional valve-in-valve procedures were recorded and categorized into reoperations for structural valve disease, non-structural valve disease, valve thrombosis and endocarditis. Furthermore, valve-related adverse events including stroke, transient ischaemic attack, peripheral emboli, endocarditis, valve thrombosis, bleeding and myocardial infarction were assessed during the follow-up. Ten percent of patients were lost to the follow-up for valve-related complications after the early postoperative period with no significant difference between valve types ($P = 0.90$). The follow-up time ranged from 0 to 11 years in the Mosaic group and from 0 to 12 years in the Magna group. The mean time (total amount) of morbidity follow-up was 4 ± 3 (1158) years in the Magna group and 4 ± 3 (626) years in the Mosaic group.

Echocardiography. At least one echocardiographic follow-up with a mean time from surgery to echo of 9 ± 12 months could be performed in 42% of this population. We calculated the projected effective orifice area index (EOAI) according to the implanted valve size using previously published effective orifice area measures and the actual body surface area [7].

Statistical analysis

Descriptive statistical methods were applied to depict the study population regarding preoperative risk factors. The χ^2 test was performed to analyse the frequencies of binary outcomes between treatment groups. Continuous variables were presented as mean and standard deviations and compared by the independent samples *t*-test between valve types. The Kaplan–Meier method with a log-rank test was performed to compare survival. Further, we calculated the average linearized event rates per patient-year by dividing the observed number of events by the number of follow-up years. Cumulative survival of an age- and sex-matched Austrian standard population was computed by the life table method, based on age–sex-specific mortality data of the year 2005 published online by the Austrian Federal Statistical Agency [10]. Cumulative survival and 95% confidence intervals (CIs) for the study population were computed using the product-limit (Kaplan–Meier) method and compared with the standard population according to the methods outlined in Finkelstein *et al.* [11]. In particular, a standardized mortality ratio with 95% confidence limits was calculated, which expresses the ratio of observed number of deaths in the study population and expected number of deaths in an age- and sex-matched reference population with an equal follow-up. This was done for the complete follow-up time as well as separately for the first and the subsequent years. For further survival analysis, a multivariable Cox regression analysis was performed including variables 'valve type', 'year of surgery', $\log_2$ of 'logistic EuroSCORE' and demographic variables with a P-value below 0.2 between groups ('body size in cm'). Non-linear effects of year of surgery, body size and logarithm of logistic EuroSCORE were accounted for by B-splines with three degrees of freedom and tested using likelihood ratio tests against a model assuming only linear effects of these variables. Interactions of the valve type with these four covariables were tested using likelihood ratio tests as well. Finally, the proportional hazards assumption was assessed for all four variables in the model by computing the correlation of scaled Schoenfeld residuals with time [12]. These model extensions did not show any evidence of violation of model assumptions. The two-sided significance level was set to 5%. The R statistical computing software (Version 3.1.1; R Foundation for Statistical Computing, Vienna, Austria) and IBM SPSS Statistics 20 (IBM, Armonk, NY, USA) were used for statistical analysis.

RESULTS

The Medtronic Mosaic was implanted in 163 patients (35.6%) and the Carpentier-Edwards Magna in 295 patients (64.4%). Basic demographic data and risk scores were comparable (Table 1). The mean implanted valve size was 22.4 ± 1.5 mm for the Medtronic Mosaic, which was significantly larger than the Carpentier-Edwards Magna size (21.8 ± 1.8 mm; $P = 0.001$). Procedural characteristics including cross-clamp time and intraoperative risk factors were comparable (Table 2).

Early mortality was 2.8% and comparable between groups (Table 2). During the follow-up, 54 (33%) of porcine valve patients and 100 (34%) of pericardial valve patients died ($P = 0.87$). The long-term survival rate was 76 and 56% after 5 and 10 years for the Medtronic Mosaic, which was comparable with the Carpentier-Edwards Magna (77 and 57%; $P = 0.92$). Multivariable Cox regression analysis revealed significant association with survival of the logistic EuroSCORE [hazard ratio (HR) = 1.67 per doubling, 95% CI: 1.45–1.91, $P < 0.001$] and body height (HR = 1.02 per cm, 95% CI: 1.004–1.038, $P = 0.015$), but not of the type of valve (HR = 1.067 of Carpentier-Edwards Magna versus Medtronic Mosaic valve, 95% CI: 0.76–1.49, $P = 0.71$) or year of surgery (HR = 0.96 per calendar year, 95% CI: 0.86–1.079, $P = 0.50$).

Overall survival of our study population was compared with expected survival of an age- and sex-matched Austrian reference population for both groups (Fig. 2). The Medtronic Mosaic valve had no decreased survival compared with the standard population in the first year [standardized mortality ratio (SMR) = 1.57, 95% CI: 0.76–3.26, $P = 0.17$]. Survival over the whole study period and survival after the first year was also comparable with the standard population, respectively [SMR: 1.08 (0.80–1.47); $P = 0.56$ and SMR: 1.02 (0.73–1.42); $P = 0.89$]. The Carpentier-Edwards Magna valve showed a decreased survival in the first year [SMR: 2.48 (1.57–3.90), $P < 0.001$], but similar survival as the standard population over the whole period and after the first year, respectively [SMR: 1.10 (0.88–1.38); $P = 0.35$ and SMR: 0.93 (0.72–1.21); $P = 0.54$].

The observed valve-related complications were similar in both groups (Table 3). One patient in the Mosaic group and 1 patient in the Magna group received a valve-in-valve procedure. One patient in the Magna group died after admission but prior to the valve-in-valve procedure and 1 patient in the Magna group was still on the list for a valve-in-valve procedure during the final follow-up (both events were not included in the analysis).

The postoperative mean transvalvular gradient was significantly higher in the Mosaic group (24 ± 9 mmHg vs 17 ± 7 mmHg; $P < 0.001$; Fig. 1). The calculated percentage of moderate (EOAI ≤0.85 cm^2/m^2 and >0.65 cm^2/m^2) and severe prosthesis patient mismatch (EOAI ≤0.65 cm^2/m^2) was significantly worse for the Medtronic Mosaic prosthesis (moderate: 57 vs 19%; severe: 2 vs 0%; $P < 0.001$).

DISCUSSION

Herein, we present a single-centre, direct, non-randomized comparison of two bioprostheses currently implanted in the majority of surgical aortic valve replacements in an elderly patient cohort [3]. In contrast to other recent publications, we evaluated a very distinct patient group, which was limited to isolated aortic valve replacements [13–15]. Thereby, we avoided possible confounding factors such as concomitant coronary artery bypass grafting or other surgical procedures. This resulted in a higher survival rate

Table 1: Preoperative patient characteristics

Factor	Porcine	Pericardial	*P*-value
Age (years)	74 ± 8	73 ± 9	0.70
Sex (f/m)	93 (57%)/70 (43%)	160 (54%)/135 (46%)	0.56
Height (cm)	167 ± 9	166 ± 12	0.095
Weight (kg)	77 ± 14	78 ± 18	0.75
Body surface area (m^2)	1.92 ± 0.21	1.91 ± 0.23	0.69
NYHA III and IV	80 (62%)	133 (63%)	0.82
Additive EuroSCORE	8 ± 3	7 ± 3	0.15
Logistic EuroSCORE	12 ± 12	10 ± 10	0.21
Ejection fraction >50% (%)	104 (72%)	202 (75%)	0.64
Heart rate (bpm)	70 ± 15	72 ± 13	0.35
Systolic blood pressure (mmHg)	131 ± 24	131 ± 22	0.99
Diastolic blood pressure (mmHg)	69 ± 13	71 ± 16	0.34
FVC (l)	2.7 ± 0.9	2.7 ± 0.8	0.76
FEV1 (%)	86.1 ± 23.8	87.7 ± 23.6	0.64
Haemoglobin (g/dl)	12.8 ± 1.5	13.0 ± 1.8	0.24
Platelets (G/l)	228 ± 73	227 ± 69	0.98
Creatinine (mg/dl)	1.2 ± 0.8	1.2 ± 0.7	0.62
Mean preoperative gradient (mmHg)	61 ± 22	59 ± 24	0.42

Porcine: Medtronic Mosaic; Pericardial: Carpentier-Edwards Magna; Continuous data are presented as the mean ± standard deviation; categorical data as total number and percentage;
bpm: beats per minute; FVC: forced vital capacity; FEV1: forced expiratory volume in 1 second; EuroSCORE: European system for cardiac operative risk evaluation.

Table 2: Procedural specifications and early follow-up

Factor	Porcine	Pericardial	*P*-value
Duration of anaesthesia (min)	274 ± 57	275 ± 64	0.84
Cross-clamp time (min)	60 ± 19	57 ± 14	0.12
Red blood cell units (packs)	2.5 ± 1.5	2.8 ± 2.2	0.28
Valve size (mm)	22.4 ± 1.5	21.8 ± 1.8	0.001
Revision for bleeding	7 (4.3%)	21 (7.1%)	0.23
Early mortality	5 (3.1%)	8 (2.7%)	0.83

Porcine: Medtronic Mosaic; Pericardial: Carpentier-Edwards Magna; Continuous data are presented as the mean ± standard deviation; categorical data as total number and percentage.

Table 3: Valve-related long-term outcome regarding adverse events

Factor	Porcine	Pericardial	*P*-value
Structural valve dysfunction (reoperation/reintervention)	3 (0.5%)	3 (0.3%)	0.46
Non-structural dysfunction (reoperation)	1 (0.2%)	3 (0.3%)	0.66
Embolism			
Stroke	16 (2.6%)	21 (1.8%)	0.88
Transient ischaemic attack	5 (0.8%)	8 (0.7%)	0.83
Emboli	2 (0.3%)	7 (0.6%)	0.40
Myocardial infarction	2 (0.3%)	4 (0.3%)	0.54
Valve thrombosis	2 (0.3%)	2 (0.2%)	0.55
Bleeding event	1 (0.2%)	2 (0.2%)	0.16
Endocarditis	2 (0.3%)	9 (0.7%)	0.22
Endocarditis (reoperation)	0 (0%)	1 (0.1%)	0.46

Total number of events and (%/year) are reported; Porcine: Medtronic Mosaic; Pericardial: Carpentier-Edwards Magna.

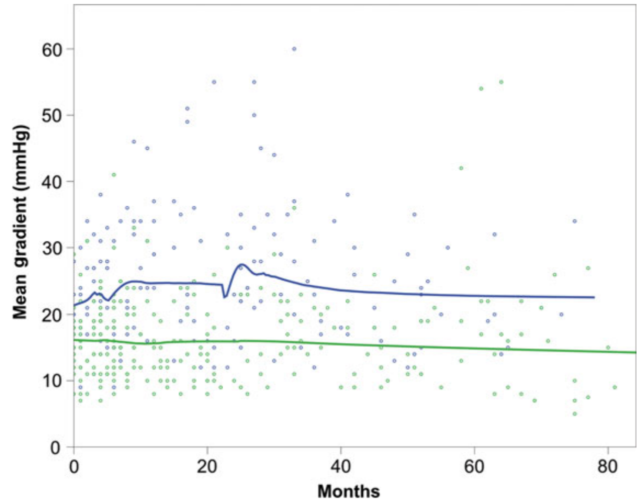

Figure 1: Postoperative transvalvular gradients. Blue: porcine valve; green: pericardial valve; a smoothing line for each group was obtained by a local regression function. Multiple measurements of each patient available were included.

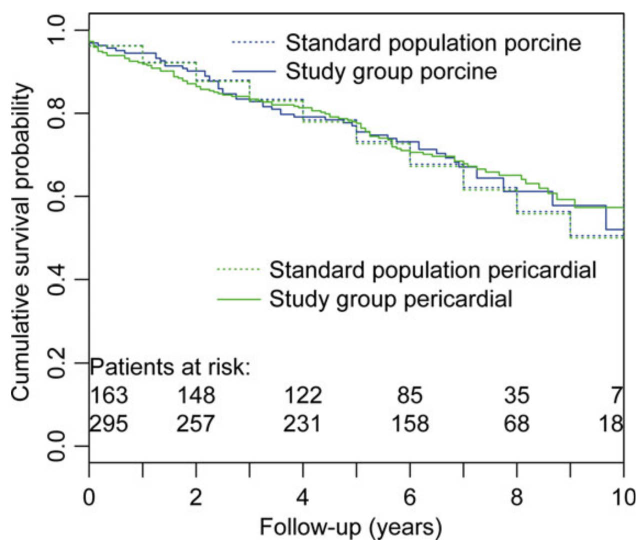

Figure 2: Cumulative survival compared the age- and sex-matched population. The age- and sex-matched standard population represents the expected overall Austrian survival for the year 2005.

compared with the publication by Said *et al.* [13]. Overall long-term survival was equal in both groups of our study. A multivariate Cox regression analysis corrected for the potential effect of EuroSCORE and demographic parameters did not show any difference regarding the valve type or year of surgery. Moreover, the long-term survival was also comparable with the age- and sex-matched Austrian population (Fig. 2). Our data are inline with previous publications reporting favourable survival with these valves in an elderly population [4, 5, 15, 16]. We previously demonstrated that older patient cohorts are more likely to achieve the predicted survival after aortic valve replacement compared with younger patients [17].

The observed operative mortality led to a decreased survival compared with the matched population in the first year after surgery for the Magna valve, but this effect could be overcome thereafter. A similar number of patients in the Mosaic group would have probably also resulted in a significantly decreased survival in the first year.

The valve-related complication rate was low and comparable with other reports (Table 3) [15]. Valve-in-valve procedures were applied in recent reoperations. This may reduce the threshold for reinterventions in the near future and avoid death due to structural valve deterioration, which was observed in one of our patients. A recent meta-analysis by Yap *et al.* [14] described a lower rate of valve-related adverse events for pericardial valves. It may require a higher sample size to find similar differences of adverse events in our population. On the other hand, our report describes only recent and currently available types of pericardial and porcine prostheses, which may have improved results regarding adverse events due to new tissue preservation protocols.

The central question, which is always addressed in the literature regarding porcine heart valves, is the presence, cause and effect of high transvalvular gradients [7, 14]. As expected, transvalvular gradients were also increased in our postoperative echocardiographic follow-up of the Medtronic Mosaic valve. However, long-term survival did not differ between groups. A potential explanation may be that the observed differences in gradients as such do not affect long-term outcome in this elderly patient cohort. Otherwise, the observed higher gradients measured in the Mosaic valve could also be caused by an echocardiographic phenomenon [8]. The concept of this phenomenon, called pressure recovery, was previously published and advocates that the majority of the observed gradient in the Medtronic Mosaic group is again transferred to aortic pressure after the aortic prosthesis due to the laminar flow pattern [18].

Another aspect has to be addressed in the discussion regarding postoperative transvalvular gradients. Previous publications highlighted the variable labelling of valve sizes and also reported a difference in the inner diameter of size-matched prostheses up to 2 mm [19, 20]. Therefore, studies comparing different aortic valve prostheses according to the labelled implanted valve size have to be interpreted with caution. Our department introduced the Medtronic Mosaic early and previously published a randomized analysis comparing implanted valve sizes in relation to the real annular diameter measured with a hegar dilator [21]. The implanted Carpentier-Edwards Magna labelled sizes were smaller compared with the Medtronic Mosaic valve for a standardized annular measurement. This was observed again in the current analysis. Not one 19 mm Medtronic Mosaic valve was implanted in this patient population and the average diameter according to the labelled size was 0.6 mm higher in the Medtronic Mosaic group.

The size of the implanted prosthesis is a major determinant for prosthesis-patient mismatch [22]. A severe mismatch below 0.65 cm^2/m^2 has been identified as a potential risk factor for long-term mortality [23]. Severe prosthesis -patient mismatch may induce turbulent flow in the ascending aorta, which would theoretically diminish the pressure recovery effect. The Mosaic group had a higher number of patients suffering from prosthesis patient mismatch. The analyses regarding survival were not included in this paper due to a low number of patients with severe prosthesis patient mismatch.

Limitations

The current study is retrospective in nature. Although the follow-up for survival was complete due to the crosscheck with the statistical institute, the follow-up for valve-related adverse events was based solely on a database research and telephone follow-up. Restoration of normal life expectancy in elderly patients should not be extrapolated to younger age groups, as death from competing causes obscure valve-related mortality. Furthermore, elderly patients accepted for cardiac surgery at a given age may be in a better general health condition compared with the general population.

Only routine echocardiographic studies without a distinct time schedule were available. Therefore, the projected rather than the measured EOAI was used for prosthesis patient mismatch grading.

CONCLUSION

In conclusion, both types of aortic bioprostheses offer excellent long-term results as documented by comparison with the Austrian standard population. Differences in transvalvular gradients had no impact on long-term survival.

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