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Aortic valve replacement using autologous pericardium: single centre experience with the Ozaki technique

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Summary

OBJECTIVE: To assess the clinical implementation and report preliminary results of a novel technique called the Ozaki procedure for stentless aortic valve replacement through reconstruction of the valve leaflets from autologous pericardium.

METHOD: Between September 2015 and May 2017 30 patients (20 males, mean ± standard deviation age 66.83 ± 10.55 years) suffering from aortic stenosis (AS, n = 7), aortic regurgitation (AR, n = 12), or a combination of both (AS/AR, n = 11) were assigned for an Ozaki procedure. The glutaraldehyde-treated autologous pericardium was intraoperatively customised and tailored according to individual sinus measurements and appropriate Ozaki templates (CE marked).

RESULTS: Mean and peak preoperative transvalvular pressure gradients in patients with AS were 46.34 ± 14.71 and 78.00 ± 22.54 mm Hg, respectively and effective orifice area was 0.93 ± 0.26 cm^2. Ejection fraction was preserved at 57.37 ± 10.33%. Twenty-four valves were tricuspid and 6 bicuspid; 13 patients had concomitant cardiac surgery (coronary artery bypass graft, mitral valve repair, replacement of ascending aorta).

: Mean ± SD cross-clamp time for replacement only was 85.18 ± 18.10 minutes and perfusion time 104.76 ± 38.52 minutes. Cusp sizes were 27.76 ± 3.52 mm for the left coronary cusp (CC), 28.20 ± 3.51 mm for the right CC and 29.20 ± 3.34 mm for non-CC. Mean and peak postoperative gradients decreased to 8 ± 3.55 and 14.8 ± 6.21 mm Hg, respectively. Mean length of stay on the intensive care unit was 2.19 ± 2.34 days and in-hospital stay was 8.81 ± 2.04 days after isolated Ozaki procedures. No pacemaker had to be implanted after an isolated Ozaki procedure. Thirty-day mortality was 3.33% (n = 1). After 3 months, no patient presented with aortic stenosis, and regurgitation of the substituted valves was graded nil/trace in 85.71%, mild in 10.71%, and moderate in 3.57% of the patients. Ejection fraction remained unchanged at 58.89 ± 11.29%. No reoperation was required within the first 3 months.

CONCLUSION: This aortic valve replacement technique has become available only recently. In our experience, it can be mastered after a relatively short training period, and has become part of our routine clinical toolbox. The use of autologous pericardium in combination with excellent haemodynamics may have the potential to overcome the structural disadvantages of biological aortic valves, to be beneficial in infective endocarditis, and to represent an alternative for patients with small annuli.

Key words: *Aortic valve replacement, Ozaki, autologous pericardium*

Introduction

Heart valve disease represents a serious and growing public health problem, with aortic valve stenosis being the most common entity [1]. Heart valve disease is frequently caused by degenerative atherosclerotic processes, congenital abnormalities, or rheumatic disease [2, 3]. Open aortic valve replacement remains the gold standard in the treatment of patients with severe aortic stenosis (and aortic regurgitation) [4]. Mechanical valves are preferred in younger patients (<60 years) because of their longer lifetime, whereas biological valves are used for elderly patients in order to avoid the need for oral anticoagulation [4].

Transcatheter aortic valve implantation (TAVI) has become increasingly popular in recent years. To date, this technique has mostly been used in patients for whom conventional aortic valve replacement was considered too risky.

More recently, new surgical approaches, which aim at reconstructing the aortic valve rather than replacing it with a prostheses, have been developed. In 2011, Ozaki et al. published their technique, which involves the use of autologous pericardium and was studied in a large patient cohort with excellent long-term follow-up [5, 6]. Potential benefits of the so-called Ozaki procedure include avoidance of oral anticoagulation, avoidance of foreign material, and suitability for patients with small aortic annuli and in infectious endocarditis. However, excellent long-term outcomes have not yet resulted in widespread use of the technique [7]. Further evidence from short- and long-term studies is

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Oliver Reuthebuch and Luca Koechlin contributed equally to the manuscript.
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needed to prove the efficacy of this technique in the treatment of aortic valve stenosis and regurgitation.
As the first centre for cardiac surgery in Europe, we started performing aortic valve replacement with autologous pericardium in September 2015 after CE certification. The aim of this study was to analyse short-term results from the first 30 patients undergoing aortic valvuloplasty by means of the Ozaki procedure at the University Hospital of Basel.

Material and methods

In September 2015, the first aortic valve replacement using autologous pericardium was performed in our clinic. The indication for operation was based on published guidelines [4]. Data were collected between September 2015 and May 2017. The decision whether or not to use the Ozaki procedure was extensively discussed with the patient preoperatively. In our opinion, every patient who is eligible for a biological valve replacement or has a reason for avoiding oral anticoagulation is suitable for an Ozaki procedure. Contraindications were previous thoracic irradiation and re-operation, because of potential damage to the pericardium. All operations were performed by two experienced surgeons. Primary endpoints were in-hospital mortality and thromboembolic events. Intra- and perioperative data, as well as 3-month follow-up data (including echocardiographic results), were also collected.

Surgical technique

All patients were under general anaesthesia and were continuously monitored with two-lead electrocardiography (II, V5), pulse-oximetry, and invasive measurement of arterial blood and central venous pressure by a board-certified cardiac anaesthesiologist, according to our routine protocol for patients undergoing open heart surgery. Transoesophageal echocardiography (TEE) was performed throughout the procedure.
The operative technique has already been described by Ozaki et al. [5]. In brief, after median sternotomy, the pericardium was dissected and treated for 10 minutes with a 0.6% glutaraldehyde solution, before it was rinsed three times for 6 minutes with sterile saline. In the meantime, the ascending aorta and the right atrium were cannulated and cardiopulmonary bypass was established. All operations were performed with use of extracorporeal circulation (ECC). Cardioplegic arrest was accomplished with blood cardioplegia in all cases. After aortotomy, the diseased cusps were resected. The distance between each commissure was measured, using a special measuring device. The pericardium was subsequently cut according to a template that corresponded to the measured size. At this point, the varying thickness of the pericardium had to be considered. The pericardium is usually thicker in vicinity of the diaphragm than in the area of the aortic root. Thus, the larger cusps were usually taken from the diaphragmatic area. Moreover, the inner side of the pericardium (serous lamina) is smoother and therefore this side faces the ventricle. The cusps were then sewn along the annuli with a 4-0 running suture, and commissural coaptation was secured with additional 4-0 sutures. All sutures were knotted and reinforced with an autologous patch outside the aorta. The functionality of the substituted valve was reassessed intraoperatively with water testing, and postoperatively by TEE. A pericardial patch was used to replace the removed pericardium. Postoperatively, the patients were routinely monitored on the intensive care unit (ICU) and lifelong antiplatelet therapy was prescribed (100 mg aspirin per day).

Data collection

Perioperative data were exported from our quality management database. These data were regularly checked for completeness and correctness. An echocardiographic examination was routinely performed prior to the patients' discharge, and resulting data were collected for each patient. Data for the 3 month follow-up analyses were obtained from rehabilitation centres and ambulant cardiologists.

Ethical considerations

The study was approved by the local ethics committee in accordance with the principles of the declaration of Helsinki. All authors had unlimited access to the complete data set and had taken responsibility for its integrity. All authors have read and agreed to the manuscript.

Results

Preoperative demographic data

Between September 2015 and May 2017, a total of 30 patients were operated on by means of the Ozaki technique. Demographic data for these patients are summarised in table 1. The patients' mean ± standard deviation (SD) age was 66.83 ± 10.55 years, and 66.67% (n = 20) of the patients were male. Mean EuroSCORE II score was 2.04 ± 1.39. A combined aortic pathology of stenosis and regurgitation occurred in 11 patients (36.67%). Seven patients (23.33%) had pure aortic stenosis and 12 patients (40%) regurgitation only. One patient (3.33%) had active endocarditis. Eleven patients (36.67%) had concomitant coronary heart disease. Angina pectoris class II was present in 9 patients (30%) and class III in 1 patient (3.33%). Twelve patients (40%) had dyspnoea of New York heart Association (NYHA) class III, and 1 patient (3.33%) suffered from dyspnoea of NYHA class IV. NYHA classes II and I occurred in 12 (40%) and 5 (16.67%) patients, respectively.

Preoperative echocardiographic results

Preoperative echocardiographic results for the 30 patients are summarised in table 2. Mean ± SD preoperative left ventricular ejection fraction (LVEF) was 57.37 ± 10.33% (n = 30). The aortic valve was tricuspid in 24 patients (80%), whereas a bicuspid aortic valve was present in 6 patients (20%). In patients with pure aortic stenosis or combined aortic stenosis and regurgitation (n = 18; 60%), the mean aortic valve pressure gradient was 46.34 ± 14.71 mm Hg (n = 18), and the mean peak gradient was 78.00 ± 22.54 mm Hg (n = 17). The mean aortic orifice valve area was 0.93 ± 0.26 cm^2 (n = 17). Corresponding values for mean and peak velocity were 3.09 ± 0.78 m/s (n = 15) and 4.35 ± 0.94 m/s (n = 16), respectively.

Intraoperative data

Intraoperative data are presented in table 3. Overall, mean ± SD operation time was 230.53 ± 43.78 minutes, aortic

cross clamp time was 95.43 ± 22.96 minutes, and extracorporeal perfusion time was 118.63 ± 40.65 minutes. In isolated Ozaki procedures, the mean operation time was 209.41 ± 35.30 minutes, aortic cross clamp time 85.18 ± 18.10 minutes, and extracorporeal perfusion time was 104.76 ± 38.52 minutes. Mean operation time in combined procedures was 258.15 ± 38.9 minutes, and aortic cross clamp time and extracorporeal perfusion time were 108.85 ± 22.22 and 136.77 ± 36.99 minutes, respectively. Implant sizes for the left and right coronary cusp varied from 23 to 35 mm. For the left coronary cusp, the most frequent sizes were 25 mm (n = 7, 24.14%) and 29 mm (n = 6; 20.69%). For the right coronary cusp, 25 mm (n = 7; 23.33%) and 31 mm (n = 7; 23.33%) were the most frequent sizes. In one patient, the native left coronary cusp could be retained. Sizes for the non-coronary cusp varied from 25 to 35 mm; 8 patients (26.67%) received a 27-mm cusp. In 17 patients (56.67%), an isolated aortic valve replacement was performed, and 13 patients (43.33%) had an additional procedure. These included coronary artery bypass grafting, mitral valve reconstruction or replacement, ascending aortic and aortic hemi-arch replacement, closure of patent foramen ovale, septal resection, and closure of an abscess cavity.

Table 1: Demographic data (n = 30).

Age in years, mean (SD)	66.83 (10.55)
Male Gender, n (%)	20 (66.67)
Body mass index in kg/m^2, mean (SD)	26.36 (5.7)
Diabetes mellitus, n (%)	3 (10)
Dyslipidaemia, n (%)	11 (36.67)
Arterial hypertension, n (%)	17 (56.67)
Active smoker, n (%)	7 (23.33)
Combined aortic valve pathology, n (%)	11 (36.67)
Pure aortic valve stenosis, n (%)	7 (23.33)
Pure aortic valve regurgitation, n (%)	12 (40)
Coronary heart disease, n (%)	11 (36.67)
Active endocarditis, n (%)	1 (3.33)
Angina pectoris CCS I, n (%)	20 (66.67)
Angina pectoris CCS II, n (%)	9 (30)
Angina pectoris CCS III, n (%)	1 (3.33)
Dyspnoea NYHA I, n (%)	5 (16.67)
Dyspnoea NYHA II, n (%)	12 (40)
Dyspnoea NYHA III, n (%)	12 (40)
Dyspnoea NYHA IV, n (%)	1 (3.33)
COPD, n (%)	4 (13.33)
Chronic renal disease, n (%)	1 (3.33)
Dialysis, n (%)	1 (3.33)
Logistic EuroScore in %, mean (SD)	4.54 (2.51)
EuroSCORE II in %, mean (SD)	2.04 (1.39)

CCS = Canadian Cardiovascular Society; COPD = chronic obstructive pulmonary disease; NYHA = New York Heart Association; SD = standard deviation

Table 2: Preoperative echocardiographic results (n = 30).

Ejection fraction in %, mean (SD)	57.37 (10.33)
Tricuspid aortic valve, n (%)	24 (80)
Bicuspid aortic valve, n (%)	6 (20)
Mean transvalvular aortic pressure gradient in mm Hg (n = 18), mean (SD)	46.34 (14.71)
Peak transvalvular aortic pressure gradient in mmHg (n = 17), mean (SD)	78.00 (22.54)
Effective valve area in cm^2 (n = 17), mean (SD)	0.93 (0.26)
Peak aortic valve velocity in m/s (n = 16), mean (SD)	4.35 (0.94)
Mean aortic valve velocity in m/s (n = 15), mean (SD)	3.09 (0.78)

SD = standard deviation

Postoperative data

Postoperative data are presented in table 4. Overall, patients left the ICU after mean stay of 3.21 ± 6.08 days, and were discharged from hospital after a mean of 9.24 ± 3.16 days. Patients who had undergone an isolated Ozaki procedure left the ICU after a mean of 2.19 ± 2.34 days, and were discharged after 8.81 ± 2.04 days. Patients with combined procedures left the ICU after a mean stay of 4.46 ± 8.74 days, and were discharged after 9.77 ± 4.19 days. A permanent pacemaker implantation was indicated in three patients (10%), in all of whom intraoperative reconstruction of the mitral valve was performed in addition to the Ozaki procedure. In one case, an additional septum

Table 3: Intraoperative data (n = 30).

Operation time in min, mean (SD)	230.53 (43.78)
Operation time in isolated Ozaki procedures in min, mean (SD)	209.41 (35.3)
Operation time in combined procedures in min, mean (SD)	258.15 (38.9)
Aortic cross clamp time in min, mean (SD)	95.43 (22.96)
Aortic cross clamp time in isolated Ozaki procedures in min, mean (SD)	85.18 (18.10)
Aortic cross clamp time in combined procedures in min, mean (SD)	108.85 (22.22)
Extracorporeal perfusion time in min, mean (SD)	118.63 (40.56)
Extracorporeal perfusion time in isolated Ozaki procedures in min, mean (SD)	104.76 (38.52)
Extracorporeal perfusion time in combined procedures in min, mean (SD)	136.77 (36.99)
Implant sizes	
Left coronary cusp (n = 29)	
23 mm, n (%)	4 (13.79)
25 mm, n (%)	7 (24.14)
27 mm, n (%)	5 (17.24)
29 mm, n (%)	6 (20.69)
31 mm, n (%)	3 (10.34)
33 mm, n (%)	2 (6.9)
35 mm, n (%)	2 (6.9)
Right coronary cusp (n = 30)	
23 mm, n (%)	3 (10)
25 mm, n (%)	7 (23.33)
27 mm, n (%)	6 (20)
29 mm, n (%)	3 (10)
31 mm, n (%)	7 (23.33)
33 mm, n (%)	2 (6.67)
35 mm, n (%)	2 (6.67)
Non-coronary cusp (n = 30)	
25 mm, n (%)	6 (20)
27 mm, n (%)	8 (26.67)
29 mm, n (%)	3 (10)
31 mm, n (%)	6 (20)
33 mm, n (%)	4 (13.33)
35 mm (n; %)	3 (10)
Isolated aortic valve replacement, n (%)	17 (56.67)
Combined procedures, n (%)	13 (43.43)

SD = standard deviation

resection was accomplished. There was no pacemaker implantation after an isolated Ozaki procedure (n = 0; 0%). Postoperative atrial fibrillation occurred in seven patients (23.33%), of whom five had an isolated Ozaki procedure. The postoperative echocardiographic follow-up before discharge (n = 29) showed a mean LVEF of 56.3 ± 10.67% (n = 27). None of the patients had postoperative aortic stenosis. Twenty-three patients (79.31%) had no or only trace aortic regurgitation before discharge. Mild aortic regurgitation was seen in six patients (20.69%), moderate or severe aortic regurgitation was not seen before discharge. In patients with preoperative aortic stenosis, the postoperative mean pressure gradient before discharge was 8.00 ± 3.55 mm Hg, and the peak gradient was 14.8 ± 6.21 mm Hg (both n = 15). Postoperative peak velocity was 2.55 ± 2.36 m/s (n = 15), and mean velocity was 1.67 ± 1.33 m/s (n = 13). Postoperative stroke occurred in two patients (6.67%), one of whom had pronounced stenosis of the intracranial blood vessels on postoperative computed tomographic (CT) angiography. The other patient suffered from generalised arteriosclerosis and had had previous thromboendarterectomies on both carotid bifurcations. The 30-day mortality rate was 3.33% (n = 1). This patient died acutely on the first postoperative day from a transfusion-triggered shock reaction that led to multiorgan failure.

Table 4: Postoperative data (n = 30).

Days on intensive care unit, mean (SD)	3.21 (6.08)
Days on intensive care unit in isolated Ozaki procedure, mean (SD)	2.19 (2.34)
Days on intensive care unit in combined procedures, mean (SD)	4.46 (8.74)
In-hospital days, mean (SD)	9.24 (3.16)
In-hospital days in isolated Ozaki procedure, mean (SD)	8.81 (2.04)
In-hospital days in combined procedures, mean (SD)	9.77 (4.19)
Permanent pacemaker implantation, n (%)	3 (10)
Permanent pacemaker implantation after isolated Ozaki procedures, n (%)	0 (0)
LVEF postoperative in % (n = 27), mean (SD)	56.3 (10.67)
Aortic stenosis (n = 29), n (%)	0 (0)
No or trace aortic regurgitation (n = 29), n (%)	23 (79.31)
Mild aortic regurgitation (n = 29), n (%)	6 (20.69)
Moderate or severe aortic regurgitation (n = 29), n (%)	0 (0)
Mean transvalvular aortic pressure gradient in mm Hg (n = 15), mean (SD)	8 (3.55)
Peak transvalvular aortic pressure gradient in mm Hg (n = 15), mean (SD)	14.8 (6.21)
Peak aortic valve velocity in m/s (n = 15), mean (SD)	2.55 (2.36)
Mean aortic valve velocity in m/s (n = 13), mean (SD)	1.67 (1.33)
Postoperative new atrial fibrillation, n (%)	7 (23.33)
Postoperative new atrial fibrillation after isolated Ozaki, n (%)	5 (29.41)
Postoperative myocardial infarction, n (%)	0 (0)
Postoperative stroke, n (%)	2 (6.67)
Postoperative stroke in isolated Ozaki, n (%)	1 (5.88)
Major bleeding requiring surgical revision, n (%)	0 (0.00)
Major vascular complication, n (%)	0 (0.00)
Postoperative new onset of dialysis or haemofiltration, n (%)	0 (0.00)
Overall mortality after 30 days, n (%)	1 (3.33)

LVEF = left ventricular ejection fraction; SD = standard deviation

Clinical endpoints

Between postoperative day 30 and the 3-month follow-up, one more patient died from aspiration pneumonia. This patient had undergone a combined procedure consisting of Ozaki aortic valve replacement, coronary artery bypass grafting, mitral valve reconstruction and septal resection, and suffered a postoperative stroke due to pronounced stenosis of the intracranial blood vessels. Thus, 28 patients completed the 3 months of follow up (table 5). No patient required reoperation or experienced an additional thromboembolic event within the first 3 months. One patient developed moderate aortic valve regurgitation postoperatively. This was found to be due to valvular endocarditis; the patient underwent reoperation 5 months after the initial operation and a biological valve was implanted.

Echocardiographic characteristics after 3 months

The echocardiographic 3-month follow-up was performed in 28 patients (93.33%), a mean of 106.68 ± 63.66 days after the initial operation (table 6). Mean LVEF was 58.89 ± 11.29% (n = 27). None of the patients had evidence of aortic valve stenosis. Moderate aortic valve regurgitation was seen in one patient (3.57%). Mild aortic regurgitation was seen in three patients (10.71%), whereas no or only trace aortic regurgitation was seen in the majority of patients (n = 24; 85.71%). The mean transvalvular pressure gradient was 6.57 ± 3.53 mm Hg (n = 22); peak gradient was 13.51 ± 8.88 mm Hg.

Discussion

The aim of this study was to evaluate the feasibility, transferability and short-term performance of the Ozaki procedure using data from the first 30 patients operated on with this method at the University Hospital of Basel. Despite very promising results published by the inventor of the procedure, to date only limited and unpublished data are available from other centres [5, 6]. To the best of our knowledge, these are the first data from a cohort of patients undergoing the Ozaki procedure from a centre other than

Table 5: Clinical endpoints after 3 months (after in-hospital period).

3-month follow-up completed, n (%)	28 (93.33)
Follow-up (days), mean (SD)	106.68 (63.66)
All- cause mortality, n (%)	1 (3.33)
Reoperation, n (%)	0 (0)
Thromboembolic event, n (%)	0 (0)

SD = standard deviation

Table 6: Echocardiographic characteristics after 3 months (n = 28).

3-month follow-up completed, n (%)	28 (93.33)
Follow-up (days), mean (SD)	106.68 (63.66)
LVEF in % (n = 27), mean (SD)	58.89 (11.29)
Aortic valve stenosis, n (%)	0 (0)
No or trace aortic regurgitation, n (%)	24 (85.71)
Mild aortic regurgitation, n (%)	3 (10.71)
Moderate aortic valve regurgitation, n (%)	1 (3.57)
Mean aortic valve gradient in mm Hg (n = 22), mean (SD)	6.57 (3.53)
Peak aortic valve gradient in mm Hg (n = 18), mean (SD)	13.51 (8.88)

LVEF = left ventricular ejection fraction; SD = standard deviation

Toho University Ohashi Medical Centre, Tokyo, Japan. After its CE certification in September 2015, we started using the Ozaki technique, one of the first cardiosurgical centres in Europe to do so. Obvious advantages of this new technique, beside the excellent postoperative echocardiographic outcomes that were published earlier, include avoidance of oral anticoagulation, avoidance of foreign material, lower gradients, a larger orifice area and the feasibility of anatomical reconstruction [5, 6].

Aortic valve replacement with a mechanical or biological prosthesis is a safe and established procedure, and considered the gold standard in the treatment of aortic valve stenosis or regurgitation [4]. Therefore, we strived to maintain high safety standards when we introduced the Ozaki technique in our institution. The 30-day mortality rate was 3.33% (n = 1), and the rate of reoperation due to structural valve failure within 3 months was 0%, which underlines the safety of this procedure. There were two thromboembolic events (6.67%); this rate was lower in the study by Ozaki et al. [6]. However, one of our patients underwent a combined procedure consisting of aortic valve replacement, myocardial revascularisation, mitral valve reconstruction, and septal resection, and the postoperative CT angiography showed pronounced stenosis of the intracranial blood vessels. Thirteen patients (43.33%) had a concomitant procedure. Mean ± SD operation time in isolated Ozaki procedures was 209.41 ± 35.30 versus 258.15 ± 38.9 minutes in combined procedures. Aortic cross clamp time in combined procedures was 108.85 ± 22.22 minutes, and extracorporeal perfusion time was 136.77 ± 36.99 minutes. In pure aortic replacements, the operation time was shorter (aortic cross clamp time: 85.18 ± 18.10 minutes; extracorporeal perfusion time: 104.76 ± 38.52 minutes), and comparable to the data of Ozaki et al. [6]. Nevertheless, after 30 operations (performed by two surgeons) there is still a certain learning curve to consider.

The significance of the Ozaki procedure in aortic valve surgery remains to be determined, and the question of who benefits most from this form of aortic valvuloplasty remains open. Our study cohort was very diverse, exemplified by an age range of 39 to 83 years. Ozaki et al. emphasised the lack of TAVI devices for patients with small aortic annuli [6]. In their series, 309 (75.7%) of 416 patients undergoing the Ozaki procedure had a small aortic annulus, which is suggestive of the importance of this issue [6]. The literature suggests favouring stentless biological aortic prostheses over stented biological prostheses in patients with small aortic annuli, which results in improved left ventricular function and functional class [7]. Similar benefits can be expected from the Ozaki procedure as a result of the anatomical replacement (rather than prosthetic replacement) of the aortic valve and the larger resultant orifice area. However, to date no mid- and long-term echocardiographic data are available to prove these assumptions. Shultz et al. recently published the, to date, largest propensity-matched study comparing stented and stent-less biological prostheses [8]. Compared to these results, 30-day mortality was lower in patients treated with the Ozaki procedure in the original publication (2.7% stented, 2.9% stentless, 1.9% Ozaki) [6, 8]. However, in our study cohort, the 30-day mortality was slightly higher (3.3%); this might be the result of the limited statistical power of our study, with only 30 patients, and because we performed other procedures concomitantly in some cases. As for long-term outcomes, the follow-up survival rate was 83.3% at 73 months after the Ozaki procedure in the original publication (215 concomitant procedures, 201 isolated Ozaki aortic valve replacements), which is slightly higher than the follow-up survival rates of 80.5 and 80.7% at 5 years after implantation of stent-less prostheses and stented prostheses, respectively, published by Shultz et al. [6, 8] Unfortunately, Shultz et al. provided no long-term echocardiographic data or information about reoperation [8]. In 2016, Repossini et al. published data from a cohort of 565 patients undergoing isolated (n = 350) or combined (n = 215) aortic valve replacement with the stentless Freedom Solo (FS) bovine pericardial valve (Sorin Group, Milan, Italy) [9]. After a mean ± SD follow-up time of 6.9 ± 3.7 years, 28 patients (5.2%) underwent reoperation, for several reasons: endocarditis in 9 patients, blunt trauma in 1, and structural valve deterioration in 18 [9]. No reoperation due to structural valve deterioration was required within 73 months of follow-up after Ozaki aortic valve replacement in the cohort of Ozaki et al. [6]. Sponga et al. recently published their long term echocardiographic data on the FS valve in 109 patients [10]. They observed a deterioration in echocardiographic findings in the long term: at discharge, 3–5, and 7–9 years postoperatively, the mean ± SD gradients were 8 ± 4, 12 ± 11, and 19 ±19 mm Hg, respectively [10]. Mean ± SD peak pressure gradient 5.5 years after Ozaki aortic valve replacement was 14.3 ± 5.0 mm Hg and echocardiographic follow-up showed no signs of any structural valve deterioration [6].

On this basis and the combination of our results with the excellent mid-term results Ozaki et al. [6] published, we consider the Ozaki procedure a potentially effective alternative for younger patients requiring aortic valve surgery for whom a mechanical valve is not an option. Also, the avoidance of artificial material makes the technique favourable in infective endocarditis.

Study limitations

This was a nonrandomised, retrospective single centre study. Because the study protocol was finalised at the end of the observation period, 3-month echocardiographic follow-up data were not complete in all patients and echocardiography was performed by various examiners. Moreover, we present only short-term data. Therefore, a standardised 12-month echocardiographic and clinical follow-up study to confirm our preliminary results is currently being implemented. Due to the fact that the glutaraldehyde substance is not available on the market in a pharmacopeia quality, the preparation of the glutaraldehyde soaking solution is a high-risk procedure and can be restricted by health authorities.

Conclusion

With our short-term results on aortic valve replacement with use of the Ozaki technique, we were able to confirm the excellent results that Ozaki et al. had published before [5, 6]. Further evidence from long-term studies and randomized clinical trials are required to guide the treatment and to assess the degree of degeneration of the treated pericardium.

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