

The Role of Modification of the Original Ozaki Technique in the Treatment of Aortic Valve Diseases

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SÚHRN

Cieľom tejto pilotnej štúdie je prezentovať naše jedno-ročné skúsenosti s modifikáciou originálnej Ozakiho procedúry pre pacientov so stenózou aortálnej chlopne a pacientov s infekčnou endokarditídou tejto chlopne.

Trinást pacientov vo veku $70,5 \pm 10$ rokov (ženy/muži: 8/5) podstúpilo operáciu aortálnej chlopne použitím autológneho alebo heterológneho konského perikardu. Indikáciou operácie bola stenóza aortálnej chlopne ($n = 10$) alebo regurgitácia chlopne spôsobená infekčnou endokarditídou ($n = 3$). Počas operácie bola vykonaná konkomitantná procedúra MAZE ($n = 2$), aortokoronárny bypass ($n = 1$) a myektómia výtokového traktu ľavej komory ($n = 1$). Jeden pacient odmietol transfúziu krvi z náboženských dôvodov.

Trvanie mimotelového obehu bolo $117,5 \pm 14,5$ minút a dĺžka klemu aorty bola $107,0 \pm 14,4$ minút. Pooperačne bol stredný gradient na aortálnej chlopni $5,1 \pm 1,9$ mm Hg, maximálny gradient bol $5,8 \pm 2,0$ mm Hg, plocha aortálnej chlopne bola $3,3 \pm 0,5$ cm² a regurgitácia aortálnej chlopne bola $0,3 \pm 0,2$. Počas 30-dňového sledovania nebolo zaznamenané žiadne úmrtie, ani reoperácia z dôvodu nálezu na aortálnej chlopni. Jeden pacient umrel tri mesiace po operácii, pričom príčina smrti nebola spájaná s aortálnou chlopňou.

Modifikovaná Ozakiho technika je potenciálne efektívna alternatíva pre mladých pacientov odmietajúcich antikoagulačnú terapiu, ktorí vyžadujú operáciu aortálnej chlopne. Preferovanou cieľovou skupinou pacientov pre použitie tejto techniky sú pacienti s malým aortálnym prstencom, alebo aktívnou infekčnou endokarditídou.

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ABSTRACT

The aim of this pilot study is to present our one-year experience with the modification of the original Ozaki procedure for patients with an aortic valve stenosis and aortic valve infective endocarditis.

Thirteen patients at the age of 70.5 ± 10 (women/men: 8/5) underwent a replacement of the aortic valve using autologous or heterologous equinus pericardium. The indication for surgery was aortic valve stenosis ($n = 10$) or aortic valve regurgitation due to infective endocarditis ($n = 3$). Concomitant MAZE procedure ($n = 2$), aortocoronary bypass ($n = 1$), and left ventricular outflow tract myectomy ($n = 1$) were performed in four patients. One patient refused blood transfusion for religious reasons.

The duration of cardiopulmonary bypass was 117.5 ± 14.5 minutes and the X-clamp time was 107.0 ± 14.4 minutes. The mean gradient after surgery was 5.1 ± 1.9 mmHg; the peak gradient was 5.8 ± 2.0 mmHg; the aortic valve area was 3.3 ± 0.5 cm² and aortic valve regurgitation was 0.3 ± 0.2 . No 30-day mortality and no redo surgery due to valve failure were recorded. One patient died three months after surgery due to non-valve-related reasons.

The modified Ozaki technique is a potentially effective alternative for younger patients rejecting anticoagulant medications and requiring aortic valve surgery. The preferred target group of patients for the use of this technique are those with a small aortic annulus and those with active infectious endocarditis.

Keywords:

Aortic valve stenosis

Infective endocarditis

Ozaki (Benaki) procedure

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Background

Open aortic valve (AV) surgery remains the gold standard for treatment of aortic valve stenosis (AoS) and regurgitation (AoR), the most common contemporary heart valve disease.¹ Aortic valve repair surgery, including an isolated repair or Yacoub/David procedures, shows optimistic results in a long-term follow-up, but in the terrain of infective endocarditis (IE), calcification or vast cusp damage their use is rather limited.² In 2014 Ozaki et al. published a study involving 404 patients who underwent replacement of AV using pericardium.³ The study presented very optimistic results at a 53-month follow-up and the use of the Ozaki technique has begun to be considered as an alternative in AV surgery.

The aim of this pilot study is to present our one-year experience with the modification of the original Ozaki procedure for patients with AoS and AV IE.

Material and methods

All patients (n = 13) undergoing a replacement of AV using autologous or heterologous pericardium from February 2018 to January 2019 at our institution were included in the study. Nearly every patient who is eligible for an AV replacement with the use of a biological prosthesis or has a reason for avoiding oral anticoagulation is suitable for a replacement of AV using some kind of pericardium. All operations were performed by a single-experienced surgeon. Intra- and perioperative data were collected.

Surgery was performed under general anaesthesia with continuously monitored electrocardiography, pulse-oxymetry, and invasive measurement of central venous and arterial pressure. Transoesophageal echocardiography (TEE) was conducted throughout the procedure. Standard midline sternotomy was performed. If autologous pericardium was used, the pericardium was dissected and treated in 0.6% glutaraldehyde solution for 10 minutes and subsequently rinsed three times for 6 minutes in sterile saline. Afterwards, cardiopulmonary bypass (CPB) was established in the standard fashion, with the left ventricle venting via the right upper pulmonary vein and the heart was arrested using standard antegrade cardioplegia. The ascending aorta was opened at the level of sinotubular junction and explantation of the native valve was performed. The autologous or heterologous (equinus) pericardium was subsequently cut out according to a template size corresponding to the aortic annulus. The

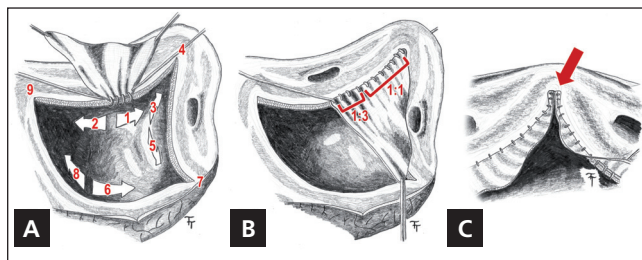


Fig. 1 – Sketch of the Ozaki procedure. (A) Steps of cusps and commissures suturing; (B) ratios of stitching the cusps; (C) final additional stitch in commissure.

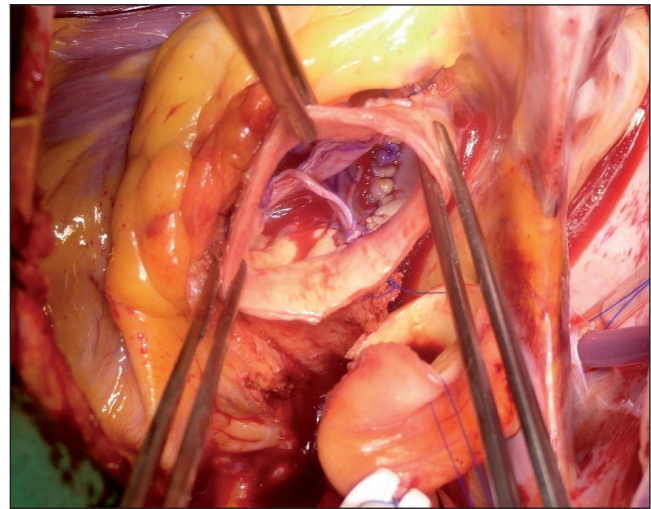


Fig. 2– Perioperative depiction of the new constructed AV.

cusps were then sewn along the annuli with a 4-0 monofilament running suture, and commissural coaptation was secured with an additional 4-0 suture (modification of original Ozaki technique) (Fig. 1). Implantation of each additional cusp was begun from the centre of the new cusp and annular centre between the commissures. The first three stitches were strictly applied in a 1 : 3 ratio (the gap between the stitches in the cusp was three times greater than in the corresponding annulus). Finishing of the suture was applied in a 1 : 1 ratio (Fig. 1). After all the cusps had been implanted, the commissure between the new right and left cusps was secured with additional 4/0 Prolene. Creation of the other two commissures was done after performing coaptation of the cusps applying a triple-foot forceps (Trifeet®, Asanus Medizintechnik, Neuhausen, Germany). After completing the other two commissures, the Triffeet® forceps was released and final appearance of the valve was checked (Fig. 2). After closing aortotomy an X-clamp was released. Intraoperative transoesophageal echocardiography following CPB was used to examine the neo-valve performance. The aortotomy was then sutured and circulation restored. Postoperatively, the patients were monitored at an intensive care unit (ICU). Antiplatelet therapy (100 mg of aspirin per day) was prescribed.

Echocardiographic parameters were collected preoperatively and on the day of patient discharge. Survival was determined at the time of manuscript preparation using the registry of portal of the Health Care Surveillance Authority.

Results

The ratio of women/men in the patient cohort was 8 : 5. The age of the patients at the time of the surgery was 70.5 ± 10 years. Ten patients underwent surgery because of degenerative AoS (73.9 ± 4.8 years old) and three patients because of IE and AoR (59.2 ± 15.7 years old). The peak and mean aortic valve gradient of the patients with AoS were 78.9 ± 3.2 and 46.1 ± 14.4 mmHg, respectively. The aortic valve area of the patients with AoS was 0.7 ± 0.2 cm². The

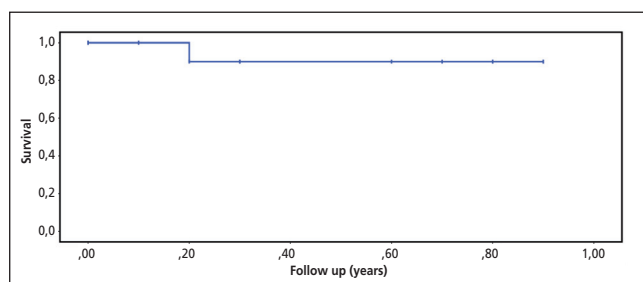


Fig. 3 – Cumulative survival of patients.

Table 1 – Echocardiographic parameters

	Before surgery	After surgery
Aortic annulus	21.4 ± 1.6 mm	22.2 ± 2.5 mm
Peak gradient	78.9 ± 23.2 mmHg	5.8 ± 2.0 mmHg
Mean gradient	46.1 ± 14.4 mmHg	5.1 ± 1.9 mmHg
Aortic valve area	0.7 ± 0.2 cm ²	3.3 ± 0.5 cm ²
Aortic regurgitation	–	0.3 ± 0.2

annulus of the aortic valve and left ventricle ejection fraction of all patients was 21.4 ± 1.6 mm and $50.2 \pm 6.4\%$, respectively. Twelve patients had a tricuspid AV and one patient had a bicuspid valve. Autologous pericardium was used in two patients and equinus pericardium in eleven patients. The time of the CPB was 117.5 ± 14.5 minutes, and the aortic clamping time was 107.0 ± 14.4 minutes. Two times concomitant MAZE procedure was performed. One concomitant aortocoronary bypass and left ventricle outflow tract myectomy were performed. One patient refused blood transfusion for religious reasons.

The time spent at the ICU was 4.3 ± 2.1 days and the hospitalization time from surgery to discharge from the hospital was 13.0 ± 8.9 days. The echocardiographic parameters of the valve at the time of patient's discharge are shown in Table 1. Two patients needed temporary continuous veno-venous haemodialysis because of renal failure. Two patients underwent pleural puncture because of pleural effusion. In two patients the postoperative period was complicated by temporary atrial fibrillation with conversion to the sinus rhythm. No atrioventricular block was recorded. One death because of unreported reasons was recorded three months after surgery (Fig. 3). At the time of the manuscript preparation, the patient follow-up was at 0.4 ± 0.4 years.

Discussion

The Ozaki procedure begins to be increasingly used in the treatment of AV disease. There are more studies of original authors presenting optimistic short- and medium-term follow-up results with a follow-up of 25.2 and 34.2 months.^{3,4} Additional studies have presented acceptable results, without long-term follow-up data.^{1,5} Reuthebuch et al. present the first cohort of patients undergoing the Ozaki procedure from a centre other than Toho University Ohashi Medical Center, Tokyo, Japan.¹ The authors present optimistic perioperative data with 30-day mortality

of 3.3%. This work includes 43% of patients with concomitant procedures, and the mean CPB time and aortic cross clamp time were 118 and 108 minutes, respectively. These data are comparable with 118 minutes (CPB time) and 107 minutes (aortic X-clamp time) in the presented group of patients with 31% of concomitant procedures.

Despite progress in antibiotics therapy, approximately one third of patients with IE require surgical therapy, and in-hospital mortality remains at about 20%.^{6,7} Because of heterogeneity of patients with IE, no standard therapy has yet been established, and implantation of any prosthesis means a higher risk of disease recurrence.⁷ There are no randomized studies definitively investigating two aspects of reconstructive surgery in the field of AV IE, including durability and resistance to infections.⁶ Solari et al. presented a paper focusing on the use of a pericardial patch in reconstructive surgery of the mitral valve in the field of IE. The study included 155 patients who underwent repair surgery with a follow-up of 122.5 months. The authors effectively state that patch repair techniques offer durability that is similar to that obtained with no-patch reconstructive techniques.⁸ Okada et al. also present the Ozaki technique as a useful strategy for aortic valve IE treatment.⁶

In 2018 Nguyen et al. published a study including nine patients who underwent a minimally invasive Ozaki procedure.⁹ The authors present no mortality and no conversion to full sternotomy, a shorter ventilation time (8.4 hours), a shorter time at the ICU (1.6 days) and a shorter hospitalization time (5.8 days) in comparison with other studies.⁹ The minimally invasive Ozaki procedure is probably the next step in making aortic valve therapy more effective.

Conclusion

According to our short-term experience in correlation with the published data, the Ozaki technique is a potentially effective alternative for younger patients who are reluctant to anticoagulant medications and require AV surgery. The preferred target group of patients for the use of this technique are patients with a small aortic annulus and patients with an active IE.

Conflicts of interest

The authors declare no conflict of interest.

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Ethical statement and consent to participate

An Independent Ethics Committee confirmed that this study is in compliance with the principles of the Declaration of Helsinki and ICH Guidelines for Good Clinical Practice and applicable regulatory requirement.

Informed consent

Informed consent for the use of patients data was obtained and the consent records are available for review by the editor.

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