

AORTIC VALVE RECONSTRUCTION SURGERY USING AUTOLOGOUS PERICARDIUM: THE EXPERIENCE IN VIETNAM

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October 18, 2021

Abstract

Objective: The study aimed to evaluate the indications and describe the aortic valve reconstruction techniques by Ozaki's procedure in Vietnam and report mid-term outcomes of this technique in Vietnam. **Methods:** Between June 2017 and December 2019, 72 patients diagnosed with isolated aortic valve disease, with a mean age of 52.9 (19 – 79 years old), and a male:female ratio of 3:1 underwent aortic valve reconstruction surgery by Ozaki's technique at Cardiovascular Center, E Hospital, Vietnam. **Results:** The aortic valve diseases consisted of aortic stenosis (42%), aortic regurgitation (28%), and a combination of both (30%). In addition, the proportion of aortic valves with bicuspid morphology and small annulus (≤ 21 mm) was 28% and 38.9%, respectively. The mean aortic cross-clamp time was 106 ± 13.8 minutes, mean cardiopulmonary bypass time was 136.7 ± 18.5 minutes, and 2.8% of all patients required conversion to prosthetic valve replacement surgery. The mean follow-up time was 26.4 months (12- 42 months), the survival rate was 95.8%, the reoperation rate was 2.8%, and rate of postoperative moderate or higher aortic valve regurgitation was 4.2%. Postoperative valvular hemodynamics was favorable, with a peak pressure gradient of 16.1 mmHg and an effective orifice area index of 2.3 cm^2 . **Conclusions:** This procedure was safe and effective, with favorable valvular hemodynamics and a low rate of valvular degeneration. However, more long-term follow-up data are needed.

Introduction

Aortic valve disease (AVD) is the most common valvular heart disease in developed countries which accounts for more than 50% of open-heart surgeries in Europe.^{1,2} In Vietnam, AVD is also a common valvular heart disease. Worldwide, aortic valve replacement surgery using a prosthetic valve remains the standard method to treat patients with aortic valve disease who have indications for surgery.³ However, there are several limitations related to a prosthetic valve, such as lifelong administration of anticoagulants, premature degeneration of biological valve, and pannus formation in sub-valvular area.^{4,5,6} Therefore, aortic valve repair or reconstruction surgery has been increasingly considered.

Tuffier performed the first surgical commissurotomy of the aortic valve in 1913.⁷ Since cardiopulmonary bypass was invented and developed in 1954, many repair or reconstruction techniques have been reported with favourable outcomes.^{8,9} One method that has been applied in many countries with a plethora of successful operations is Ozaki's procedure.¹⁰ This technique reconstructs individual cusps and was firstly performed in April 2007, Tokyo, Japan.¹¹ In Vietnam, aortic valve reconstruction surgery has just been implemented recently with early results of feasibility and advantages have been reported.^{12,13} Therefore, we conducted this

study with 02 objectives: (1) To evaluate the indications of aortic valve reconstruction surgery by Ozaki's procedure at our hospital, (2) To report the mid-term outcomes of this method.

Material and methods

Study subjects : all patients diagnosed with isolated aortic valve disease, had indications for surgery according to AHA guidelines, underwent aortic valve reconstruction surgery using autologous pericardium by Ozaki's procedure at Cardiovascular Center, E Hospital from June 2017 to December 2019.

Study design : an observational study of all patients with isolated aortic valve disease undergoing aortic valve reconstruction surgery by Ozaki's technique.

Surgical procedures : All surgical procedures were performed by surgeons who received direct hands-on training and training certificate from Prof. Ozaki. This surgery was performed via a sternotomy, therein the pericardium was elaborately dissected and harvested in a minimum size of 8x8 cm by ultrasonic scalpel. Then, the pericardium was treated with glutaraldehyde 0,6% solution in 10 minutes before being rinsed with normal saline for 6 minutes (repeatedly three times). The establishment of the cardiopulmonary bypass system utilized 03 cannulas inserted respectively in ascending aorta, superior vena cava, and inferior vena cava. After opening the ascending aorta, diseased cusps were resected entirely. The measured distance of 2 commissures indicated the size of the reconstructed cusp using autologous pericardium. The constructed cusps were then sutured to the respective annulus. The aortic valve should be tested before closing the incision of the aorta. After aortic cross-clamp was release and the return of beating heart, transesophageal echocardiography was performed to evaluate valvular morphology and hemodynamics following termination of cardiopulmonary bypass.

Data collection and statistical analysis : preoperative variables (clinical features, subclinical parameters, echocardiography), intraoperative variables (aortic annulus size, the number of constructed cusps, aortic cross-clamp time, cardiopulmonary bypass time, ...), short and mid-term outcomes (clinical features, echocardiography, complications, survival rate) were collected during a minimum of 12 months follow-up. Data were analyzed by R 4.0.0 software using t-test and ANOVA test to compare the means of different groups.

Research ethics : Our study was approved by Hanoi Medical University Institutional Ethical Review Board with approval number NCS06/HMUIRB (the most prestigious medical university of Vietnam) and the Ethics Committee of E hospital (approval number 1018/BB-BE). Patients were provided full information about different surgical methods for aortic valve disease and the advantages or disadvantages of each method before making decision.

Results

Between June 2017 and December 2019, a total of 72 patients with isolated aortic valve disease underwent aortic valve reconstruction surgery using Ozaki's procedure at our hospital. We obtained the following results after a mean follow-up time of 26.4 months (range 12-42 months).

Table 1 depicts preoperative characteristics of the study cohort. The mean age was 52.9 (19 – 79 years old), male/female ratio was 3/1, and the most common clinical symptoms were dyspnea (95.8%), angina (62.5%). In addition, the bicuspid aortic valve accounted for 28%.

Table 2 represents intraoperative parameters. The proportion of patients with small aortic annulus ([?] 21mm) was 38.9%. The number of patients with one, two, or three reconstructed cusps was 03, 07, and 62, respectively. The mean aortic cross-clamp time was 106.3 minutes, and the bicuspid-morphology group needed shorter time than the tricuspid-morphology group (94.7 minutes versus 109.7 minutes, $p = 0.03$). Two patients required conversion to prosthetic valve replacement due to occlusion of left coronary arterial ostium caused by a reconstructed cusp.

Thirty-day postoperative results are shown in Table 3. There was one in-hospital death due to acute cardiac tamponade caused by bleeding in postoperative day 1, and two patients required reoperation due to postoperative bleeding and infection of the sternum.

The mid-term results showed a survival rate of 95.8% at a mean follow-up time of 26.4 months (Figure 1A). A total of three patients died during following, including one patient had acute cardiac tamponade on post-operative day 1 and two patients had rupture of pseudoaneurysm at 3 and 8 months after surgery. The cumulative incidence of reoperation related to the reconstructed aortic valve was 2.8% (02 patients had reoperation due to endocarditis at 6 and 24 months after surgery) (Figure 1B). The cumulative incidence of moderate or higher aortic regurgitation was 4.2% (one patient had moderate regurgitation immediately after surgery, and 02 patients had severe regurgitation due to endocarditis that required reoperation) (Figure 1C). The peak pressure gradient was stable during follow-up (16.1 to 17.1 mmHg), and the effective orifice area index was 2.3-2.5 cm² (Figure 2).

Discussion

Indications of aortic valve reconstruction surgery by Ozaki procedure

The mean age of our study cohort was 52.9 with the youngest was only 19 years old and 38.9% was under 50. These patients would have been indicated to receive mechanical aortic valve replacement according to AHA recommendations.¹⁴ However, we decided to perform the Ozaki procedure due to the following reasons: (1) In developing countries including Vietnam, it is difficult to administer and monitor anticoagulants especially for patients in remote areas and ethnic minorities. (2) The studies reported by Ozaki and Lida suggested that the group of young patients had a low rate of reconstructed valve impairment during a mid-term follow-up.^{15,16}

The advantage of Ozaki's technique was the total resection of the diseased cusps; therefore, it could be implemented to different types of aortic valve disease including stenosis, regurgitation, and a combination of both.¹¹ The previous approaches such as cusps expansion all have some limitations in the case of aortic stenosis.

Other authors (Ozaki et al.¹¹ and Krane et al.¹⁷) performed aortic valve reconstruction in cases of both isolated aortic valve disease and in combination with other surgeries such as coronary artery bypass graft (CABG), mitral valve repair or replacement. Nevertheless, our study enrolled only patients with isolated aortic valve disease because (1) With a new technique, the selection of isolated AVD would reduce surgical and aortic cross-clamp time; (2) Outcomes evaluation would not be influenced by various factors.

Aortic valve reconstruction in bicuspid aortic valve

In patients with bicuspid aortic valve, the choice to reconstruct 02 cusps or 03 cusps depended on the type of bicuspid valve. In true bicuspid aortic valve (type 0) with 02 equal-sized cusps, we performed a reconstruction surgery preserving bicuspid morphology (Figure 3). In contrast, we reconstructed the bicuspid aortic valve with 03 cusps in cases of type I (one raphe and a third commissure). Ozaki et al. implemented reconstruction for all types of the bicuspid aortic valve with 03 cusps because the authors believed that the area formed by 03 cusps was more optimal than 02 cusps.¹⁸ As reported by Aicher et al., the long-term outcomes of aortic bicuspid valve reconstruction in 316 patients were excellent after ten years.¹⁹ In our view, tricuspid morphology was physiological to patients; however, in type 0 bicuspid aortic valve, the preservation of bicuspid morphology was a proper solution to avoid dividing up the aortic annulus as well as direct suturing to the aortic wall which could lead to complications such as aortic dissection and postoperative bleeding. Besides, since the cusps sizes were measured by the distance between 02 commissures, the reconstructed valve would open in a circular shape with greater effective orifice area; therefore, valve hemodynamics were comparable to that of 3-cusp reconstruction (Table 4).

Aortic valve reconstruction in patients with small aortic annulus

Aortic valve replacement using a prosthetic valve could lead to prosthesis-patient mismatch (PPM) in patients with small aortic annulus. Hoffman et al. reported the surgical outcomes in 632 patients who had small aortic annulus and revealed that PPM occurred in 45.1% to 92.8% of patients, and about 4.0% to 22.8% had severe PPM.²⁰ There was no PPM observed in our study 12 months surgery in the group with small aortic annulus (Table 5). It was consistent with Sho A et al.'s study which reported no patients who underwent the Ozaki procedure had PPM condition.²¹ The Ozaki technique does not utilize artificial annulus, in addition, the

cusps are sutured directly to the natural annulus, which prevented pannus formation in prosthetic valve and PPM condition after surgery.

The technical failure of surgical aortic valve reconstruction using Ozaki's procedure

We had 02 patients who required conversion to prosthetic valve replacement, and the reason was post-operative occlusion of left coronary arterial ostium caused by the cusps. Ozaki et al. conducted the study in 850 patients in which no case was converted to surgical valve replacement.¹¹ On the other hand, Krane et al. operated on 103 patients with aortic valve reconstruction by Ozaki's procedure showed that 01 patient suffered from left coronary arterial ostium occlusion caused by the left coronary cusp.¹⁷ Coronary arterial ostium occlusion by cusps could occur as a consequence of the abnormally large cusps resulting in asymmetric condition; therefore, the precise measurement of the distance between 2 commissures plays a critical role in achieving technical success of surgical reconstruction using the Ozaki procedure.

Mid-term results

The survival rate was 94.8% at a mean follow-up time of 26.4 months in our study. In comparison to Ozaki's study, the survival rate of 850 patients was 85.9%,¹¹ at a mean follow-up time of 53.5 months, and it was 98.1% at a mean follow-up time of 14 months after surgery according to Krane et al.¹⁷ In our study, 02 patients died from ascending aortic pseudoaneurysm rupture at 3 and 8 months after surgery, respectively. These patients were admitted to the hospital with a diagnosis of postoperative sternitis and both underwent an operation for stainless steel suture removal and debridement. However, the infection progressed to spread into the mediastinum and caused a pseudoaneurysm at the aorta incision site and then rupture. During Ozaki's procedure, the extensive dissection and harvest of the anterior pericardium could be a risk factor infection from the sternum to spread into the anterior mediastinum.

The cumulative incidence of reoperation was 2.8%, including 02 patients who required reoperation for endocarditis. As reported by Ozaki in 850 patients, there were 13 patients reoperated due to endocarditis.¹¹ The incidence of reoperation due to degeneration and calcification was extremely low. In our study, no patient had valvular degeneration during follow-up despite the relatively low mean age (52.9). The procedure of harvesting the pericardium, treatment with glutaraldehyde, and rinsing all required absolute sterility.

The cumulative incidence of aortic regurgitation was 4.2%, including 01 patient who had moderate regurgitation immediately after surgery without progression at 42 months follow up and 02 patients who had severe regurgitation due to endocarditis that underwent reoperation after 03 and 06 months, respectively. In comparison, the incidences of moderate or higher aortic regurgitation reported by Ozaki and Krane were 7.3% (the follow-up of 53.6 months) and 3% (the follow-up of 14 months), respectively.^{11,17} In Ozaki's procedure, the height of the cusps are elevated to the level of the sinotubular junction in the aorta which increases the aortic cusp coaptation than that with the natural valve, thus limiting the risk of cusp prolapse and subsequent aortic regurgitation.

Aortic valve hemodynamics were favorable, with a post-operative peak gradient pressure of 16.1 to 17.1 mmHg. All patients have been prescribed aspirin 100 mg only if in sinus rhythm after surgery and no bleeding or thromboembolic complications were observed.

In conclusion, aortic valve reconstruction surgery by Ozaki procedure was a safe approach, with a low mortality rate and a high technical success rate. This technique could be implemented in various types of aortic valve diseases and morphology. Hemodynamics of reconstructed valves were favorable with a low cumulative incidence of aortic regurgitation without prosthesis-patient mismatch. However, this technique is limited by a longer aortic cross-clamp time, cardiopulmonary bypass time than in prosthetic valve replacement. The longest follow-up time was 42 months; therefore, it is necessary to continue the follow-up to evaluate long-term outcomes.

Acknowledgements

We would like to thank the patients who trusted us and agreed to undergo the Ozaki procedure and vo-

luntarily participated in this study. Thank you to the anesthesiologists, cardiologists, and nurses of the Cardiovascular Center, E Hospital, for participating in the diagnosis, treatment, and surgery of the patients.

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