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ORIGINAL RESEARCH

Ozakis procedure and transesophageal echocardiography

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ABSTRACT

Background: Aortic valve disease is a major cause of cardiovascular morbidity and mortality globally. Surgical aortic valve replacement has traditionally been the definitive treatment for advanced aortic stenosis and regurgitation. Anticoagulation, prosthesis durability, and poor hemodynamics have created interest in the use of other techniques. The Ozaki procedure, an aortic valve reconstruction with autologous pericardium, has become an acceptable surgical choice in several etiologies, such as rheumatic disease, bicuspid valves, and calcific degeneration. Perioperative transesophageal echocardiography (TOE) is essential in the assessment and management of this new procedure. **Methods:** We retrospectively studied 17 patients who had the Ozaki procedure from January to December 2024 at a tertiary care center. Information was gathered from clinical records, operating reports, and perioperative echocardiographic data. All operations were by the same surgical team, and intraoperative TOE evaluation was uniform before and after cardiopulmonary bypass. **Results:** Seventeen patients (14 men, 3 women) were admitted with aortic diseases, of whom 8 had aortic stenosis and 9 aortic regurgitation. Mean preoperative valve area was 2.08 ± 0.84 cm^2 with a mean gradient of 20 ± 21 mmHg. Trivial aortic regurgitation after surgery was present in 3 patients. Mean gradient was profoundly reduced to 6 ± 5 mmHg (p=0.004). Three patients needed reoperation for moderate or severe regurgitation on postoperative day one. No other significant complications were observed. **Conclusion:** Our experience indicates that the Ozaki procedure can provide satisfactory early hemodynamic results and eliminates the need for long-term anticoagulation. Intraoperative TOE provides invaluable information in assessing cusp geometry, validating valve competence, and determining the necessity for urgent revision. Multicenter studies with larger numbers of patients are needed to confirm long-term durability and optimize patient selection criteria for this novel approach.

Keywords: Ozaki procedure, aortic valve reconstruction, transesophageal echocardiography, cardiac surgery, autologous pericardium

INTRODUCTION

Aortic valve disease, including stenosis and regurgitation, is an expanding worldwide health burden [1]. The cause is varied with congenital defect (e.g., bicuspid aortic valve), atherosclerotic disease, and rheumatic fever contributing largely to disease load [2]. Among them, stenosis continues to be the most prevalent valvular malady and comes with substantial morbidity and mortality if not addressed [3]. Until now, the conventional surgical strategy has been either mechanical or bioprosthetic valve replacement. Although mechanical valves provide durability, they require lifelong anticoagulation; bioprosthetic valves, while exempting the patient from strict anticoagulation, are subject to structural deterioration with time [4]. Both these valves can fall short in simulating the optimal hemodynamic performance of the native valve, especially with elevated cardiac outputs.

Given these constraints, there is increasing interest in alternative techniques that more closely resemble normal physiology. Aortic valve repair has become popular but is frequently constrained by the degree of calcification and the integrity of the native leaflets [5]. The Ozaki procedure, also known as aortic valve neo-cuspidization (AVNeo), is designed to reconstruct the aortic valve with autologous pericardium. Initially described by Ozaki et al., the technique has proven to be efficacious in terms of gradient reduction and anticoagulation avoidance [6]. It is said to be available

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for use across a variety of aortic pathology, such as rheumatic disease, bicuspid or tricuspid aortic valve, and infective endocarditis [7].

Despite the advancement of minimally invasive transcatheter aortic valve replacement (TAVR), open surgical procedures are still advised in various patient populations like younger patients and in patients with complex valvular anatomy [2]. TAVR is also not widely accepted for the treatment of isolated aortic regurgitation because of issues in anchoring the valve and its durability. Therefore, the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) currently advise surgical repair of severe aortic regurgitation, especially in non-calcified valves [4].

Within this shifting landscape, imaging in the perioperative period holds prominence. TOE has found itself as a powerful tool for surgeons in performing complex valvular reconstruction by enabling accurate analysis of aortic valve geometry and function pre-and post-cardiopulmonary bypass [8]. It has the potential to impact surgical planning, guarantee appropriate leaflet coaptation, and immediately identify valvular disease or paravalvular leaks.

The purpose of this study is to summarize the initial echocardiographic and clinical outcomes of the Ozaki procedure in one institution experience. Of special interest, we comment on the intraoperative application of TOE for evaluation of newly constructed autologous pericardial leaflets and correct positioning. Our retrospective study evaluates safety and feasibility of this method both in aortic stenosis and aortic regurgitation, contributing to the limited but growing evidence in support of this new surgical procedure.

MATERIALS AND METHODS

Study Design and Setting

This retrospective analysis was done at Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi, for a period of one year. Seventeen consecutive patients who had undergone the Ozaki procedure in this period were enrolled. Eight of these patients had a preponderance of diagnosis of aortic stenosis, and nine had aortic regurgitation.

Patient Population and Data Collection

Data were gathered from hospital medical records, operation notes, and detailed perioperative echocardiographic results. Inclusion criteria were patients diagnosed with either severe aortic stenosis or significant aortic regurgitation necessitating surgical correction. Patients with inadequate data or other valve replacement surgeries were excluded.

All patients had standard preoperative transthoracic echocardiography (TTE) done to evaluate valvular disease, chamber size, left ventricular function, and valve area. Intraoperative TOE was done after induction as a baseline study, and following weaning from cardiopulmonary bypass (CPB).Postoperative echocardiography was repeated on day one to identify any residual or emerging valvular abnormalities.

Surgical Technique

All operations were performed under general anesthesia with standard monitoring, including invasive arterial pressure, end-tidal CO_2, pulse oximetry, urine output, and core temperature. After a median sternotomy, the pericardium was carefully harvested and treated with 0.6% glutaraldehyde for pliability and strength. Concurrently, a separate surgeon undertook cannulation of the aorta and vena cavae for CPB. Systemic anticoagulation was achieved with intravenous heparin at 400 IU/kg, targeting an activated clotting time (ACT) $\geq$ 480 seconds.

Once on CPB, an aortotomy was performed, and the diseased aortic valve leaflets were excised. Using dedicated sizing instruments specific to the Ozaki procedure, the distance between each commissure was measured to tailor the new cusps. The autologous pericardium was trimmed according to the measured template, creating three cusps of appropriate size. These custom-made pericardial leaflets were then sutured onto the aortic annulus, reconstructing the valve. After careful inspection, the aorta was closed, and patients were weaned from CPB, with immediate postoperative TOE verifying adequate leaflet coaptation and ruling out significant regurgitation.

Postoperative Management

All patients were transferred to the intensive care unit (ICU) for hemodynamic monitoring and supportive care. Follow-up echocardiographic assessments were performed routinely on postoperative day one and subsequently as indicated. A detailed review of complications, particularly bleeding, thromboembolism, and valve dysfunction, was undertaken.

This standardized protocol was applied to all 17 cases, with the same surgical and anesthetic team performing the procedure and intraoperative echocardiographic assessments.

RESULTS

Overall Findings

A total of 17 patients (14 males, 3 females) underwent the Ozaki procedure. The majority of patients were under 20 years of age (47.2%), reflecting a younger demographic with significant valvular pathology. The remaining patients were distributed across the age groups of 21–40 years (17.6%), 41–60 years (17.6%), and 61–80 years (17.6%). Etiologically, rheumatic heart disease (41.2%) was the most common cause, followed by calcific degeneration (23.5%), bicuspid aortic valve (17.6%), congenital origin (11.8%), and infective endocarditis (5.9%). Four patients had mixed aortic valve lesions (both stenosis and regurgitation),

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and two patients required concomitant coronary artery bypass grafting (CABG).

Demographics and Operative Data

- Table 1 and Table 2 summarize the age and sex distribution, respectively.
- Among 17 patients, 8 had predominant aortic stenosis, and 9 presented with predominant aortic regurgitation.
- The average CPB time was 181 ± 20 minutes, and the cross-clamp time was 150 ± 17 minutes.

Perioperative Echocardiographic Outcomes

Preoperative Assessments

- Mean gradient: 20 ± 21 mmHg
- Mean end-systolic volume (ESV): 39.34 ± 7.17 mL
- Mean end-diastolic volume (EDV): 90.28 ± 11.93 mL
- Ejection fraction (EF): 55% ± 5%
- Aortic valve area by planimetry: 2.08 ± 0.84 cm^2

Postoperative Assessments

- Immediate TOE revealed trivial aortic regurgitation in 3 patients and acceptable cusp coaptation in the remainder.
- Mean gradient significantly decreased to 6 ± 5 mmHg (p=0.004).
- Postoperative EDV was 90.67 ± 11.68 mL, and ESV was 39.38 ± 6.93 mL, both showing minimal change from baseline but without statistical significance.
- EF remained stable (54% ± 6%), indicating no significant compromise in left ventricular function.
- The reconstructed valve area increased to 2.57 ± 0.55 cm^2 ($p<0.05$).

Three patients, however, developed moderate or severe aortic regurgitation within the first postoperative day. They underwent early reoperation, which entailed conventional aortic valve replacement with a mechanical prosthesis. No other major complications, including stroke, permanent pacemaker requirement, or significant bleeding, were encountered in the study cohort. The length of ICU stay ranged from 7 to 27 days, with a median of 7–8 days in most cases.

Table 1. Age-wise Distribution of Patients

Age (years)	n	%
0–20	8	47.2
21–40	3	17.6
41–60	3	17.6
61–80	3	17.6
Total	17	100.0

Table 2. Sex-wise Distribution of Patients

Sex	n	%
Male	14	82.4
Female	3	17.6
Total	17	100.0

Table 3. Etiology of Aortic Valve Disease

Etiology	n	%
Bicuspid	3	17.6
Calcific Degeneration	4	23.5
Congenital	2	11.8
Infective Endocarditis	1	5.9
Rheumatic Heart Disease	7	41.2

Table 4. Pre- vs. Postoperative Aortic Valve Area

Time Point	Mean ± SD	p-value
Pre-op	2.08 ± 0.84	
Post-op	2.57 ± 0.55	<0.05 (*)

(*) Statistical significance obtained by paired t-test.

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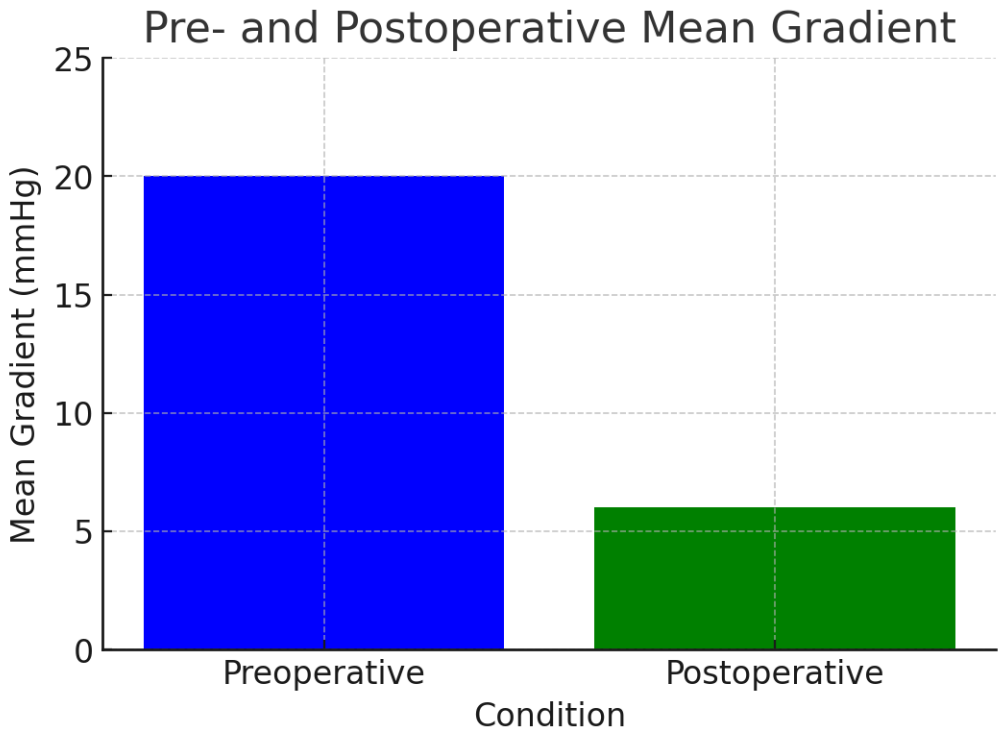

Figure 1. Pre- and Postoperative Mean Gradient (mmHg)

(A bar chart comparing the drop from preoperative mean gradient of 20 ± 21 mmHg to postoperative 6 ± 5 mmHg.)

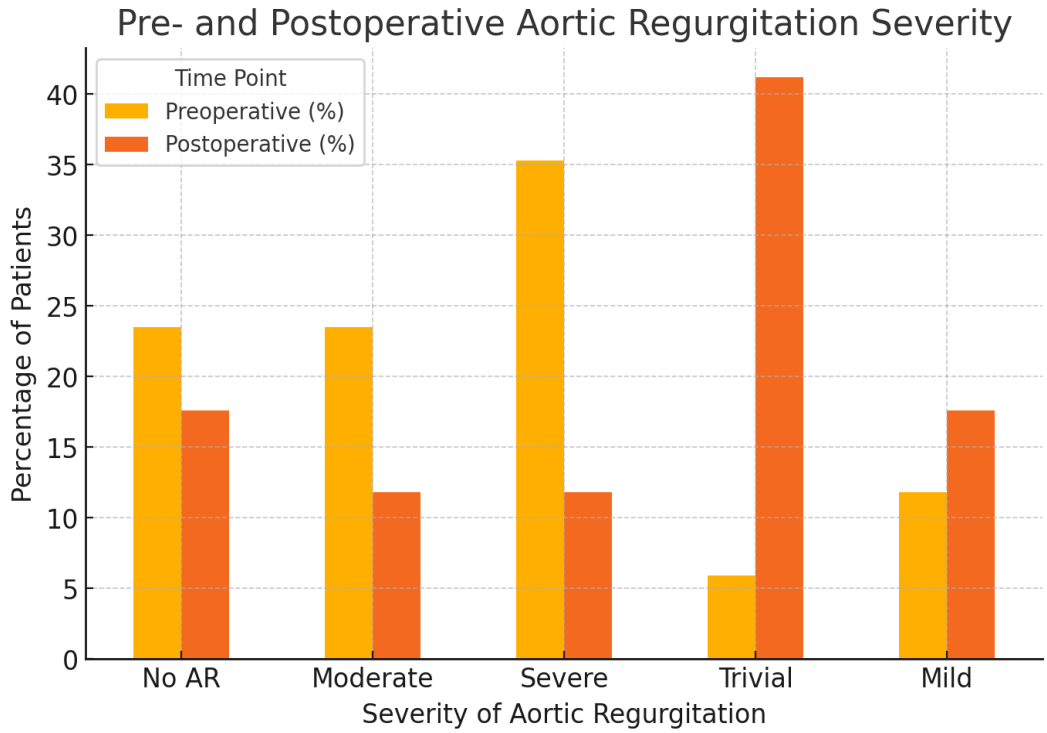

Figure 2. Distribution of Aortic Regurgitation Severity Pre- and Post-Ozaki

(A pie chart or bar graph showing changes in AR severity from moderate/severe to trivial/mild.)

DISCUSSION

The Ozaki procedure, or aortic valve neo-cuspidization with autologous pericardium, is a promising alternative for patients with aortic stenosis or regurgitation in various etiologies [6,7,9]. Our experience underscores the viability of this procedure in a younger population, with nearly half the patients being less than 20 years of age. These results support prior literature to the effect that this method is most useful in younger or middle-aged patients in whom otherwise prolonged effects of anticoagulation and structural degeneration of the valve can ensue [10].

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From the hemodynamic view, our study illustrates a significant decrease in mean gradient, from 20 ± 21 mmHg at preoperative level to 6 ± 5 mmHg immediately after procedure (p=0.004). This reduction is in keeping with the principle that autologous pericardial leaflets are better able to reproduce native valve motion than standard prosthetic valves [9]. Mean aortic valve area also improved significantly, potentially indicating preserved or even increased cardiac output under physiological conditions. Equivalently comparative studies by Krane et al. and Lida et al. demonstrated consistent effective orifice areas and pressure gradients up to two years following surgery [11,12]. Furthermore, Ozaki et al. reported long-term durability of eight years, reporting a stable peak gradient of approximately 15.2 mmHg [6]. These results support our finding of acceptable early hemodynamics.

The intraoperative role of TOE cannot be overstated. Through real-time visualization of leaflet coaptation and annular geometry, TOE enables surgeons to make immediate adjustments, which may avoid early postoperative complications [8]. Three of our patients exhibited moderate or severe regurgitation on day one postoperatively, requiring conversion to a mechanical valve. This highlights the necessity for careful operative technique and high-resolution intraoperative imaging. Improvements in future pericardial preparation or leaflet size may further decrease these early failures.

Lack of significant adverse effects like stroke or arrhythmic complications is reassuring and concordant with the previous reports elucidating the good safety profile of the Ozaki procedure [6,9,13]. No permanent pacemaker was also not needed, an issue that has been raised for transcatheter procedures in association with disruption of the conduction system [14]. Although the follow-up interval in our experience was brief, our observations point towards good early to mid-term results consistent with other series presented [7,10].

Regardless of these encouraging results, there are several limitations in this study, including single-center design, retrospective data, and small sample size. More prolonged follow-up is required to determine longevity of the reconstructed leaflets and risk of late regurgitation or calcification. Prospective multicenter trials with uniform protocols will better define the complete clinical utility, patient selection criteria, and long-term durability of this surgical technique.

In conclusion, the Ozaki procedure appears to be a safe and effective option for the surgical management of aortic valve disease in selected patients. The incorporation of intraoperative TOE not only ensures precise sizing and placement of neocusps but also aids in early detection of any technical errors, improving overall surgical outcomes.

CONCLUSION

In summary, our experience in a single center indicates that the Ozaki procedure yields good early hemodynamics, especially in lowering aortic valve gradients and preserving ventricular function. The use of intraoperative TOE is critical in ensuring accurate leaflet sizing and positioning with resultant early complication reduction. In spite of the requirement of reoperation by a small minority of patients, the overall results were encouraging, supporting the role of this technique as a valve replacement alternative. Larger prospective trials with longer follow-up will be needed to further establish its longevity, determine the best candidates, and optimize surgical techniques for wider clinical use.

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