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Early Outcomes after Aortic Valve Replacement by Pretreated Autologous Pericardium versus Metalic Prosthetic Aortic Valve Replacement

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ABSTRACT

Background: Since there is no need for anticoagulation, there is a lower pressure gradient across the valve, and there are better valve hemodynamics, autologous pericardial aortic valve reconstruction is a better option than metallic prosthetic valve replacement.

Objective: Ths study aimed to detect the early outcome differences between aortic valve replacement by pretreated autologous pericardium via Ozaki procedure and metallic prosthetic valves.

Patients and methods: Between November 2019 to August 2021, 40 patients underwent aortic valve replacement in Kasr Alainy and Kasr Alainy-affiliated Hospitals. Patients were divided into 2 equal groups: ***AVR group:*** 20 cases of aortic valve disease requiring metallic aortic valve replacement and ***Ozaki group:*** The Ozaki surgery for aortic valve replacement was necessary in 20 cases of dysfunctional aortic valves. An extensive echocardiographic evaluation was carried out prior to release as well as one, three- and six-months following surgery. Other perioperative factors were also evaluated, including the duration of cardiopulmonary bypass and cross-clamp time, the need for anticoagulation, and the gradient of the aortic valve pressure. **Results:** There were no significant differences between studied groups regards to intraoperative EF% (50.25 ± 7.58 vs 47.95 ± 6.58 %), mean pressure gradient (10.45 ± 1.05 vs 9.75 ± 1.29 mmHg) and peak pressure gradient (20.05 ± 1.92 vs 19.25 ± 2.33 mmHg), duration of ventilation (7.90 ± 1.20 vs 8.65 ± 3.03 hours) and ICU stays (45.25 ± 4.11 vs 51.85 ± 30.43 hours) for mechanical valve replacement and Ozaki group respectively.

Conclusion: With good hemodynamics, no anticoagulation, and maintenance of a smaller pressure gradient across the implanted valve, autologous pericardial aortic valve reconstruction using the Ozaki procedure is a viable option to metallic prosthetic valve replacement.

Keywords: Aortic valve replacement - Ozaki procedure - Metallic valves.

INTRODUCTION

A mechanical valve or a bioprosthetic valve has traditionally been used to replace the damaged valves in the majority of aortic valve diseases. While using a mechanical valve is linked to the unavoidable requirement for lifelong anticoagulation, using a bioprosthetic valve is linked to calcification and accelerating deterioration. None of these valves have hemodynamic performance on par with the aortic valve's natural state [(1).] Because it can prevent these problems that are inherent in prosthetic valve replacement, aortic valve repair is becoming more and more common. It eliminates the requirement for anticoagulation and, for several years, is largely free of significant deterioration and calcification. [(2).]

The use of the natural aortic valve cusps 1, 2, as well as other repair techniques including commissurotomy, annuloplasty, free edge reinforcement, wedge resection, etc. These procedures might not be possible in some aortic valve conditions, particularly calcified aortic stenosis. As a result, the initial goal of aortic valve replacement was to control aortic regurgitation. [(3).]

Similar to the natural aortic valve, improved hemodynamic performance has also been linked to autologous pericardial (auto-pericardial) valve restoration. This ought to be related to improved ventricular performance and quicker ventricular mass shrinkage. Another benefit of the operation is that it can be used on younger patients and those with comparatively smaller aortic roots, in whom it might be difficult to implant a mechanical valve [(4).]

All of these arguments support the idea that, for treating the majority of aortic valve diseases, autologous pericardial aortic valve repair is preferable than replacement. The aim of this work was to detect the early outcome differences between aortic valve replacement by pretreated autologous pericardium and metallic prosthetic valves.

PATIENTS AND METHODS

This comparative descriptive study included 40 adult patients of age group above 18 years old of any sex undergoing aortic valve replacement in Kasr Alainy and Kasr Alainy-affiliated hospitals in the period from November 2019 to August 2021.

Enrolled patients (40 cases) divided to 2 groups: Ozaki group: 20 cases of aortic valve disease needing replacement of the aortic valve with autologous pericardium that has undergone pretreatment. 20 occurrences of aortic valve disease necessitating metallic prosthetic valve replacement belong to the AVR group.

Inclusion criteria: Patients over 18 years old with aortic valve disease requiring aortic valve replacement

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for any of the following pathologies: Rheumatic stenosis or regure, calcific, degenerative and congenital i.e., bicuspid valve.

Exclusion criteria: Re-operations, patients with concurrent heart illness and infective endocarditis, patients with significant comorbidities (such renal failure, etc.), and patients less than 18 years old are among the following:

Methodology in details: Data collected included the following:

Preoperative Parameters: Anthropometric data: age and sex. Pre-operative co-morbidities: Echocardiographic data: Cardiac functions (EF), type of AV disease, left ventricular dimentions and aortic valve annulus.

Anesthesia Management Premedication: Midazolam (0.2 mg/Kg) was injected intramuscularly to premedicate the patients. Sevoflurane was used for inhalational induction on all patients, who then had standard monitoring like an ECG, a pulse oximeter, and a non-invasive blood pressure cuff inserted.

Ozaki procedure: The patients were positioned supine. We approach each patient via a median sternotomy (Figure 1). The Harmonic scalpel was used to remove fat and other surplus tissue from the external surface of the autologous pericardium as the initial step in pericardium preparation (Ethicon Endo-Surgery, Inc, Cincinnati, Ohio). After being separated, the pericardium was immersed in a 0.6% glutaraldehyde solution for 10 minutes, and then it was sterile saline rinsed three times for a total of six minutes. During cannulation of the right atrium and ascending aorta, cardiopulmonary bypass was accomplished. Extracorporeal circulation was used in all procedures (ECC). In every instance, blood cardioplegia was used to achieve cardioplegic arrest. The infected cusps were removed through an aortotomy. Using a specialised measuring tool, the distance between each commissure was measured. The pericardium was then sliced using a template that matched the size that was measured. The pericardium's variable thickness has to be taken into account at this stage. Typically, the pericardium is thicker near the diaphragm than it is at the aortic root. Therefore, the diaphragmatic region was typically used to obtain the larger cusps. Additionally, the smoother inner surface of the pericardium (serous lamina) faces the ventricle.

AVR procedure: The usual surgical technique for aortic valve replacement is via a median sternotomy. After opening the pericardium, cardiopulmonary bypass is instituted with a cannula in the aorta and a two-stage atrial venous cannula through the right atrial appendage.

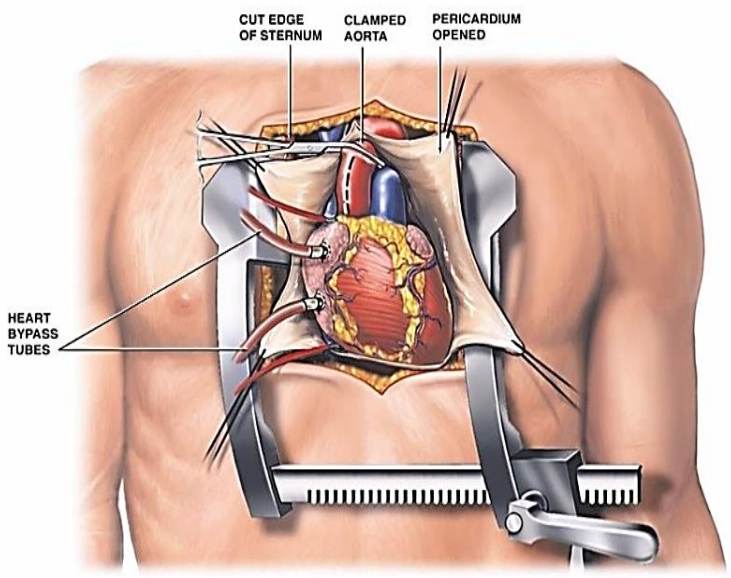

Figure (1): Median sternotomy and CPB tubing

To keep the surgical area dry, an LV vent is placed through the right superior pulmonary vein, the left atrium, the mitral valve, and into the left ventricle. To enhance aortic valve visibility and facilitate aortic closure, the plane between the aorta and pulmonary artery is divided. The patient is cooled to a bladder temperature of 32°C. The aorta is cross-clamped and cardioplegia is administered. Crystalloid or blood cardioplegia can be administered through a retrograde coronary sinus catheter or through an antegrade cannula in the aortic root or, in case of aortic valve regurgitation, directly in the coronary ostia using coronary perfusion cannulas. In the situation of aortic insufficiency and antegrade administration of cardioplegic solution, this will result in backflow of the cardioplegia toward the LV cavity and may cause LV dilation if LV drainage is inadequate. After cross-clamping of the aorta a transverse aortotomy is made approximately 1 cm above the sinotubular junction. It is important to make the aortotomy not too close to the right coronary ostium to avoid injury or distortion during aortic closure. The aorta was opened with a conventional hockey-stick incision extending to the noncoronary sinus of Valsalva stopping 1 cm above the aortic annulus (Figures 2-8).

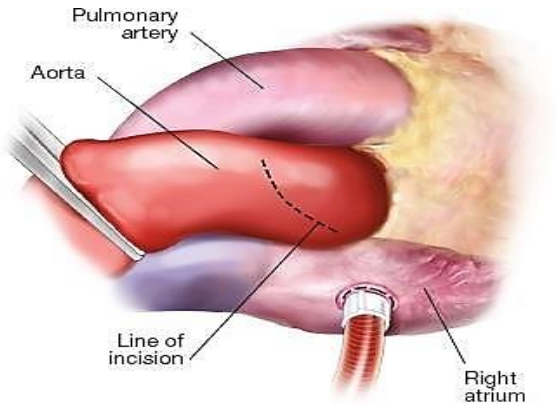

Figure (2): Aortotomy through hockey-stick incision

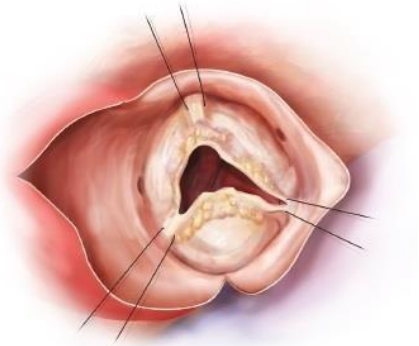

Figure (3): Calcified aortic valve with stay sutures in commissures.

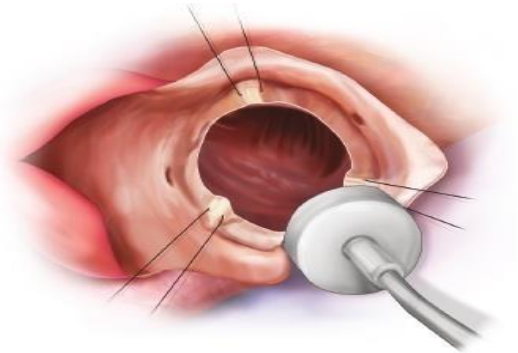

Figure (4): The valve cusps are excised with removing as much of the calcium as possible.

Figure (5): The annulus is calibrated, with a sizer that corresponds to the specific prosthesis.

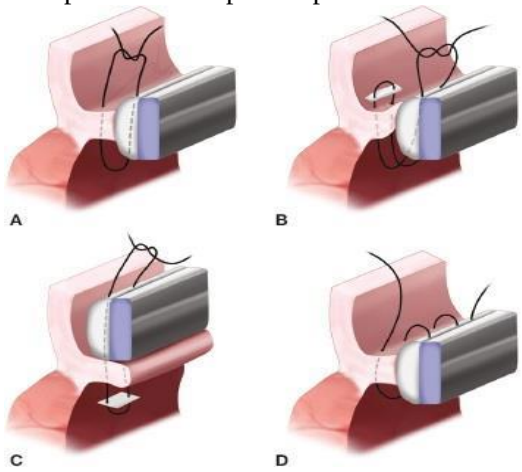

Figure (6): The valve is sewn to the aortic annulus with either pledgeted sutures (below [c] or above [d] the annulus) or non-pledgeted double needle 2-0 Ti-Cron sutures (a+d).

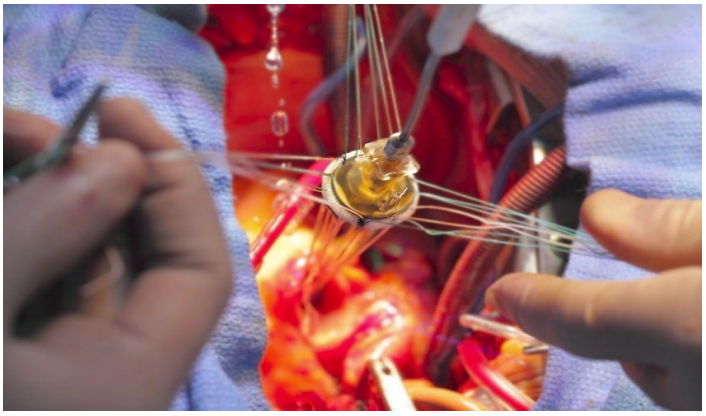

Figure (7): The valve sutures are passed through the valve sewing ring and the prosthesis slides over the sutures toward the supra-annular position

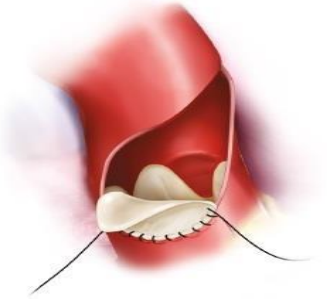

Figure (8): Patch enlargement of the aortotomy when strut is protruding.

Postoperative care: Patients who were ventilated and receiving inotropic support were transferred to the cardiac ICU. Every patient in the ICU underwent invasive blood pressure monitoring, direct CVP measurement, continuous ECG monitoring, hourly urine output monitoring, and eight-hourly checks of their vital signs. Chest tubes are monitored and potential reopening is considered if they are removing more fresh blood than 3-5 ml/kg/hr.

Ethical considerations: The study was approved by The Local Ethics Committee of Cairo University,it was in accordance with the principles of the declaration of Helsinki.

Statistical analysis:

The Statistical Package for the Social Sciences (SPSS), version 24.0 for Windows-10, was used to conduct all statistical analyses. Categorical variables are displayed as percentages and absolute values. For categorical data between groups, a Chi-square test (also known as a Fisher's correction test) was utilised. The appropriate means, standard deviations, or medians with minimum and maximum ranges are used to express continuous variables. To compare groups with normally distributed data, an independent sample t-test was employed, while the Mann-Whitney test was utilised for variables that weren't normally distributed. Findings will be presented in tables and graphs as appropriate. P-value ≤ 0.05 will be considered statistically significant at 95% level of confidence.

RESULTS

Our study was carried out on 40 patients divided into 2 groups: **AVR group**: 20 cases of aortic valve disease requiring aortic valve replacement by metallic prosthetic valve and **Ozaki group**: 20 cases of aortic valve disease requiring aortic valve replacement by pretreated autologous pericardium.

Table (1) showed no significant differences between studied groups regarding demographic and comorbids risk factors.

Table (1): Demographic and risk stratification among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
Age (Years)	51.05±11.86	50.35±14.22	0.169	0.866
Weight (kg)	68.0±10.87	71.10±11.35	0.882	0.383
	No (%)	No (%)		
Sex Males Females	10 (50%) 10 (50%)	12 (60%) 8 (40%)	0.101	0.750
Comorbiditeies DM HTN DM+HTN Smoking No Comorbiditeies	 3 (15%) 2 (10%) 1 (5%) 2 (10%) 12(60%)	 2 (10%) 1 (5%) 0 (0%) 3(15%) 14(70%)	1.887	0.756

Table (2) showed no significant differences between studied groups as regards baseline echocardiographic findings.

Table (2): Pre-operative echo findings among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
EF %	64.20±6.50	60.20±7.62	1.786	0.082
Aortic annulus (cm)	2.22±0.15	2.36±0.28	1.971	0.056
End diastolic (ED)	5.32±0.38	5.50±0.70	1.011	0.318
End systolic (ES)	3.70±0.70	3.74±0.54	0.202	0.840
	No (%)	No (%)		
Lesion AS AR	12 (60%) 8 (40%)	11 (55%) 9 (45%)	0.0	1.00

Table (3) showed significant shorter bypass and aortic cross clamp times in AVR group compared to ozaki groups with p value < 0.01.

Table (3): Operative CPB and cross clamp times among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
CPB time (minutes)	59.25±6.54	75.00±9.31	6.191	<0.001
Cross clamp time (minutes)	44.50±3.94	57.750±8.80	6.146	<0.001

Table (4) showed no significant differences between studied groups regarding intraoperative TEE data.

Table (4): Intraoperative TEE data among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
EF %	50.25±7.58	47.95±6.58	1.025	0.312
Mean pressure gradient (mmHg)	10.45±1.05	9.75±1.29	1.882	0.067
Peak pressure gradient (mmHg)	20.05±1.92	19.25±2.33	1.185	0.243
Effective OA	-----	2.65±0.19		

Tables (5) showed no significant differences between studied groups as regards one-month post-operative follow up of studied groups by echocardiography. Three cases in AVR group had cardiac tamponade compared to no case in Ozaki group.

Table (5): One-month post-operative echo data among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
EF %	51.50±6.49	48.25±7.08	1.513	0.138
Mean pressure gradient (mmHg)	9.15±1.13	8.25±1.29	2.347	0.024
Peak pressure gradient (mmHg)	19.10±2.12	18.10±1.94	1.556	1.279
Cardiac tamponade	No (%)	No (%)		
	3 (15%)	0 (0%)		

Tables (6) showed no significant differences between studied groups as regards 3-month post-operative follow up of studied groups by echocardiography.

Table (6): Three-month post-operative echo data among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
EF %	54.30±5.22	51.25±5.51	1.797	0.080
Mean pressure gradient (mmHg)	7.55±0.82	7.85±0.93	1.437	0.158
Peak pressure gradient (mmHg)	14.95±1.46	15.25±1.25	0.698	0.489

Tables (7) showed no significant differences between studied groups regarding 6-month post-operative follow up of studied groups by echocardiography.

Table (7): Six-month post-operative echo data among studied groups

	AVR group	Ozaki group	test	P value
	Mean ± SD	Mean ± SD		
End diastolic (ED)	5.22±0.41	5.16±0.65	0.349	0.728
End systolic (ES)	3.37±0.70	3.43±0.49	0.314	0.755
EF %	63.85±2.39	62.25±3.09	1.832	0.074
Mean pressure gradient (mmHg)	6.50±0.60	6.90±0.85	1.719	0.093
Peak pressure gradient (mmHg)	13.05±1.14	12.40±1.46	1.569	0.124

Tables (8) showed no significant deteriorate of 6-month post-operative echo findings compared to those in preoperative echo.

Table (8): Pre operative and 6-months post-operative echo among studied groups

		Pre op echo	6 month Post operative Echo	test	P value
		Mean ± SD	Mean ± SD		
AVR	EF	64.20±6.50	63.85±2.39	0.226	0.822
	ED	5.32±0.38	5.22±0.41	0.800	0.428
	ES	3.70±0.70	3.37±0.70	1.491	0.144
OZAKI	EF	60.20±7.62	62.25±3.09	1.115	0.271
	ED	5.50±0.70	5.16±0.65	1.592	0.119
	ES	3.74±0.54	3.43±0.49	1.901	0.064

EF%= Ejection fraction, ED= End diastolic, ES = End systolic.

DISCUSSION

In Europe and North America, aortic valve disease affects 2-7% of those over 65, making it the most prevalent valvular disease type. With a median survival of fewer than two years in those with heart failure symptoms, symptom development is swift and fatal when left untreated. Aortic valve replacement is still the basis of therapy in patients with an acceptable risk profile because conservative treatment is mostly ineffectual for the long-term management of aortic valve disease [(5)].

In current study, mean age was 50.85 years old ranged from 20 to 72 years and mean weight was 69.55 kg. The study included 22 males (55%) and 18 females (45%) with male predominance. 23 (57.5%) of enrolled patients had aortic stenosis (AS) while, 17 (42.5%) of patients had aortic regurgitation (AR). No significant differences between studied groups regarding demographic, comorbidies risk factors and baseline echocardiographic findings. Compared to current study, **Nguyn *et al.*** [(6)] found that the mean age was 47.4 years, most of patients were females. **El-badawy *et al.*** [(7)] studied 20 patients with younger mean age (39.9±14.8 years), 13 patients had AR and 7 had AS. The mean ejection fraction was 60.5±6.99. Also, in a series by **Krane *et al.*** [(8)] on 103 patients, AS was the primary diagnosis in 80 patients (77.7%), followed by AR in 23 patients (22.3%). The average age was 54 ± 16.4 years (range, 13.8-78.5). 436 individuals who had AVR were investigated by **Khatchatourov *et al.*** [(9)] with a mean age of 62.11 years, they included 70 patients (31 women and 39 men) who had autologus intervention. 18 patients (26%) had AR, 7 patients (10%) had both AS and AR, and 45 patients (64%) had AS. Regarding mechanical ventilation and ICU stays, they were longer in Ozaki group compared to AVR group with no significant differences between them (duration of ventilation was 7.90±1.20 vs 8.65±3.03 hours), (ICU stays was 45.25±4.11 vs 51.85±30.43 hours) for mechanical valve replacement and Ozaki group respectively. Similar to current study **El-badawy *et al.*** [(7)] study, found that the mean mechanical ventilation time and ICU stay for the autologus reconstruction group, respectively, were 9.25 hours and 4.8 hours. Also, **Nguyn *et al.*** [(6)] in 2018 published a study including nine patients who underwent a minimally invasive Ozaki procedure. The authors reported 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)].

None of enrolled patients in current study complaining of early postoperative complications, conduction abnormalities and none of them required anticoagulation. After one month and during follow up of enrolled patients, only three cases in AVR group had cardiac tamponade requiring drainage compared to no case in Ozaki group. Compared to current findings, **El-badawy *et al.*** [(7)] reported that four patients (20%) had moderate post-operative bleeding. The frequency of endocarditis and thromboembolic events was greater in aortic valve restoration utilising autologous pericardium, according to several investigations. [(10)]. Aortic valve repair patients in the **Vijayan *et al.*** [(2)] study had mild aortic regurgitation in 2 out of 20 patients (10%; not statistically significant) after 6 months.

Khatchatourov *et al.* [(9)] observed mild problems in 43 individuals (61%), which is higher than the current data. A pacemaker was implanted in two (3%) patients, a tamponade required drainage in one (1%), and a stomach ulcer caused significant gastrointestinal bleeding in one patient (1%). Five patients (7%) sustained acute renal failure with eventual full recovery of renal function, and two patients (3%) had transient ischemia episodes with complete recovery. Atrial fibrillation was the benign consequence that occurred most frequently in 25 cases (36%). 9 patients experienced a complete left bundle branch block, 7 in the AS group and 2 in the AR group. Throughout the hospital stay, there were no myocardial infarctions, significant arrhythmias, or resuscitations. Mortality at 30 days was 1.4%. Comparable to recent research, **Ozaki *et al.*** [(11)] and **Krane *et al.*** [(8)] reported a lower incidence of conduction abnormalities.

Regarding post operative echocardiographic findings; EF%, mean and peak pressure gradients were equivalent in the AVR and ozaki groups at one, three-, and six-months postoperative echocardiography, with no significant differences between them. In all approaches, there was no significant deterioration of 6-month postoperative echo results (EF percent, ED, and ES) compared to those in preoperative echo. **El-badawy *et al.*** [(7)] in a line with current findings, detected no significant regurge or gradient across the aortic valve and there was no significant change in the ejection fraction pre- and post-operative. Against current findings, **Krane *et al.*** [(8)] bioprosthesis valves showed a substantially reduced mean pressure gradient when compared to autulogous nearly (8.5 ± 3.7 mm Hg vs. 10.2 ± 2.0 mm Hg, P 0.001, respectively). However, similar to the current study, they discovered that 93.8% of patients had access to echocardiography six to twelve months after surgery, and that it did not reveal any change in hemodynamic parameters from the time of discharge. Furthermore, in patients with isolated aortic stenosis, **Iida *et al.*** [(12)] reported a mean peak pressure gradient of 19.2 mmHg after 20 months and 22 mmHg one week after the treatment, with a substantial difference between the two. ($p<0.05$).

The ongoing review found no death rate or frequency of reoperation during the subsequent period. The greatest distributed series by **Ozaki *et al.*** [(11)] approves these benefits in 850 patients with a mean development of roughly 4 years with genuine liberated from death and total rate of reoperation, discoveries that are reliable with current discoveries. An examination with nine patients who got a negligibly obtrusive Ozaki treatment was accounted for in 2018 by **Nguyen *et al.***

[6] no mortality or transformation to a full sternotomy is accounted for by the creators.

No 30-day mortality or in-medical clinic mortality was noted in the preliminary by **Khatchatourov *et al.*** [9] nor was resuming vital. No instances of careful mortality were accounted for by **El-badawy *et al.*** [7]. Because of impressive dying, one patient required a subsequent activity (5%).

Death rates at 30 days range from 0% to 3.3%, as per other distributed examinations. This is very equivalent to the careful AVR casualty rate [13]. Our examination showed that the Ozaki approach is a basic, secure, and viable substitute for customary metallic aortic valve substitution medical procedure. It has a positive relationship with low mortality and grimness as well as a high pace of fruitful fix. One more issue with the prosthetic valves that is every now and again noticed shows restraint prosthesis bungle and the rising tension inclination that outcomes across the valve. [2, 14, 15, 16].

CONCLUSION

The Ozaki procedure will fit between the valve repair and its traditional replacement, especially in the case of a tiny annulus and, presumably, in young patients, given the characteristics of all approaches. The Ozaki treatment is simple and safe, and it can be used instead of traditional metal aortic valve replacement surgery. It's linked to reduced mortality and morbidity, as well as a high rate of repair success.

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