Operative and ICU Results of Aortic Valve Surgery by Ozaki Technique

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Abstract:

Background: Prosthetic aortic valve replacement is the standard and traditional procedure for aortic valve lesions; however thromboembolic and hemorrhagic events could be associated with the use of prosthetic valves. The purpose of our study is to address the early postoperative results and benefits after aortic valve reconsrtuction using Ozaki technique. **Methods:** 40 patients with aortic valve diseases underwent aortic valve surgery through valve neocuspidization at cardiothoracic surgery department at Cairo university hospitals in the period between March 2020 and November 2020. **Results:** The mean age was 52.23 ± 22.64 years. 32 (80%) patients had severe aortic stenosis while 8 (20%) patients had severe aortic regurge. Postoperatively there was statistically significant decrease in the peak and mean pressure gradients across the valve **(P-value 0.0001)** and increase in effective orifice area **(P-value 0.0001)**. 29 (72.5%) patients had no aortic regurge while the other 11 (27.5%) patients had mild aortic regurge. There was freedom of need to convert to prosthetic valve replacement. There was one in-hospital mortality due to severe impairment of RV systolic function. **Conclusion:** Aortic valve neocuspidization with the use of gluteraldehyde treated autologous pericardium might be a feasible procedure that is associated with good immediate results regarding the valve hemodynamics together with lack of need for lifelong anticoagulation.

Keywords: neocuspidization - gluteraldehyde treated autologous pericardium – Ozaki - effective orifice area

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Introduction:

Prosthetic valve replacement either mechanical or bioprosthesis is the traditional surgical treatment for diseases of the aortic valve. However, there are disadvantages associated with using of the prosthetic valves that include thromboembolic complications together with the need for the lifelong anticoagulation in cases treated with mechanical valves as well as calcification and degeneration in cases treated with bioproshetic valves. [1,2]

The stent structure of the prosthetic valves may result in high pressure gradient across the valves postoperatively and subsequently patient prosthesis mismatch either in surgical aortic valve replacement [(3)] or transcatheter aortic valve implantation (TAVI). [(4)]

Aortic valve repair techniques as annuloplasty and commissurotomy have been performed but could not be applicable for all aortic valve diseases especially calcific stenosis. [(1)] Therefore, the Ozaki procedure, which is a replacement of individual valvular leaflets with treated autologous pericardial patch, finds its place between the repair of the valve and the classic replacement, especially in the cases with small aortic annulus and, possibly, in young patients.[(5)]

Our study aims to describe the early postoperative results after aortic valve reconsrtuction with glutaraldehyde treated autologous pericardium using Ozaki technique.

Patients and methods:

Study design:

40 patients with aortic valve diseases underwent aortic valve surgery by Ozaki technique through valve neocuspidization with the use of gluteraldehyde treated autologous pericardium at cardiothoracic surgery department at Cairo university hospitals in the period between March 2020 and November 2020. Patients below the age of 18 years old were excluded. Informed written consents were obtained from all the patients of the study. Approval of the ethical committee was obtained.

Preoperative preparation:

Transthoracic echocardiography was done for all the patients for assessment of pathology of aortic valve, diameter of aortic annulus, pressure gradients across the valve, effective aortic orifice area and left ventricular ejection fraction (LVEF). Coronary angiography was done if indicated to exclude any coronary lesion.

Surgical Technique:

The patients were placed in supine position. All patients were approached via median sternotomy, at least 7X8 cm of pericardium had been harvested. Care was taken to avoid phrenic nerve injury or damage of the pericardium itself. Pericardium was attached on the plate and stretched with threads to avoid shrinking during treatment. The pericardium was soaked in 0.6% glutaraldehyde solution for 10 minutes, then it was rinsed with saline for 6 minutes and this step was repeated three times.

Full cannulation was done. Aortotomy was made and the distance between the right end of the incision and the left coronary cusp (LCC)-non-coronary cusp (NCC) commissure was 10 mm.

Aortic leaflets were removed completely with careful respect to the integrity of the annulus especially in cases of calcific valves. Each inter-commissural length was measured with the sizers appropriately. The midpoint of the annulus in each sinus was marked. The neocusps

were prepared according to the corresponding window on the template. Guiding dots for every suture site were placed.

The technique was started with suturing of the right coronary cusp by using a 4-0 polypropylene suture with 1/2 circle needle. The first suture was passed from the midpoint of the cusp to the midpoint of the annulus. During suturing the smooth surface of the cusp was facing the left ventricle. For the first 3 to 4 stitches on the annulus side, the distance between two stitches must be one third of the corresponding cusp distance, which gave the cusp a bird-nest shape. The last stitch on the annulus had a role in good support of the commissures. The other cusps were sutured in the same manner.

For the commissures, the suture was placed at the midpoint between the free edge and the previous stitch and passed from the same site on the opposing cusp and, then, from the top corner of the wing, and lastly from the aorta. The other end of the suture was passed from the top corner of the other cusp then the aorta. A good reconstruction was obtained with a "windmill" shape. The aortotomy was closed and cross clamp was removed. Weaning from cardiopulmonary bypass was done then intraoperative TEE for assessment of the neovalve competence and gradient across.

Patients were transmitted to cardiac ICU while ventilated. After maintaining the hemodynamic stability, gradual weaning from artificial ventilation and extubation was done.

Statistical Analysis:

Collected data was computed, coded, verified and statistically analyzed using the Statistical Package for Social Sciences (SPSS) version 25. Qualitative variables were represented as percentage and number while quantitative variables were represented as (mean ± SD). Non-parametric Mann-Whitney test was used for qualitative variables and an unpaired Student's t-test was used for quantitative variables. P-value less than 0.05 was statistically significant.

Results:

Preoperative data:

The mean age was 52.23 ± 22.64 years. The study included 27 males and 13 females. Table (1) shows the preoperative data.

Table (1): Preoperative data of the patients

Item	**Value**
Age (years)	52.23 ± 22.64
Gender: -Male -Female	 27 (67.5%) 13 (32.5%)
Body mass index (BMI) (kg/m^2)	29.8 ± 4.3
Comorbidities: - Diabetes mellitus - Systemic hypertension	 8 (20%) 14 (35%)

- Ischemic heart disease - History of rheumatic fever	1 (2.5%) 10 (25%)
Onset of symptoms (years)	2.5 ± 1.13
Echocardiographic findings: -Ejection fraction (EF %) -Aortic valve lesion: 1.Severe aortic regurge 2.Severe aortic stenosis : - Peak pressure gradient (mmHg) - Mean pressure gradient (mmHg) - Effective orifice area (cm^2) - Aortic annulus (cm)	 54.5 ± 6.88 8 (20%) 32 (80%) 84.9 ± 17.3 53.8 ± 9.2 0.8 ± 0.2 2.7 ± 0.88

Perioperative data:

For isolated aortic valve neocuspidization, the mean cardiopulmonary bypass time was 84.1 ± 14.03 minutes and the mean cross clamp time was 68.7 ± 12.43 minutes while for combined procedures, the mean cardiopulmonary bypass time was 115.27 ± 9.33 minutes and the mean cross clamp time was 97.2 ± 10.4 minutes. 36 (90%) patients underwent isolated aortic valve neocuspidization while the other 4 (10%) patients had concomitant surgery. There were 3(7.5%) patients who had all of the three aortic cusps of the same size while the other 37 (92.5%) patients had the non-coronary cusp size larger than the left and right cusps which were of the same size. There was no need for conversion of Ozaki procedure to prosthetic aortic valve replacement in any of the patients of our study (Table 2). The mean time for mechanical ventilation in the postoperative ICU was 9.3 ± 3.87 hours. There was one in-hospital mortality due to severe impairment of RV systolic function in spite of increasing doses of inotropic supports but cardiac function deteriorated and the patient died on first postoperative day (Table 3).

Table (2): Intraoperative data

Item	**Value**
Operative time parameters: *1-Isolated Ozaki* Cardiopulmonary bypass duration (min) Aortic cross clamp time (min) *2-Concomitant procedures:* Cardiopulmonary bypass duration (min) Aortic cross clamp time (min)	 84.1± 14.03 68.7 ± 12.43 115.27 ± 9.33 97.2 ± 10.4
Concomitant surgery: -Coronary artery bypass grafting (CABG) -Mitral valve surgery	 1 (2.5%) 3 (7.5%)
Need for inotropes	18 (45%)

Table (3): Postoperative data

Item	**Value**

Mechanical ventilation (hours)	9.3 ± 3.87
ICU stay (days)	2.28 ± 1.2
Postoperative events: -Reopening for high blood drainage -Heart block needed permanent pacemaker	 1 (2.5%) 1 (2.5%)
Postoperative Echo: -Ejection fraction (EF %) - Peak pressure gradient (mmHg) - Mean pressure gradient (mmHg) - Effective orifice area (cm^2) - Aortic regurge: -None -Mild	 51.8 ± 5.93 14.8 ± 1.29 7.3 ± 0.98 2.6 ± 0.18 29 (72.5%) 11 (27.5%)
Mortality	1 (2.5%)

Postoperative echocardiographic findings:

Postoperative echo revealed that the peak and mean pressure gradients across the aortic valve significantly decreased and the effective orifice area of the aortic valve significantly increased in comparison to preoperative echo findings as shown in table (4). Postoperatively, 29 (72.5%) patients had no aortic regurge while the other 11 (27.5%) patients had mild aortic regurge.

Table (4): Comparison between preoperative and postoperative echo findings

Item	Preoperative Echo	Postoperative Echo	P-Value
Peak pressure gradient (mmHg)	84.9 ± 17.3	14.8 ± 1.29	**0.0001**
Mean pressure gradient (mmHg)	53.8 ± 9.2	7.3 ± 0.98	**0.0001**
Effective orifice area (cm^2)	0.8 ± 0.2	2.6 ± 0.18	**0.0001**
Ejection fraction (EF %)	54.5 ± 6.88	51.8 ± 5.93	0.063

Discussion:

For several decades, aortic valve replacement (AVR) had been the standard surgical treatment of different valve lesions. However, the lifelong need of anticoagulation with mechanical valves and progressive degenerative and calcific changes with bioprosthetic valves had created the need for using alternative methods for management of aortic valve lesions. [2,6]

Early results of aortic valve neocuspidization with the use of autologous pericardium had their impact in gaining popularity especially with the absence of many adverse effects that are known to be associated with classic AVR.[6]

The aortic valve neocuspidization technique preserves the aortic annulus and allows the physiological systolic annular diltation of the aortic valve, which results in increasing the effective orifice area and eventually improving the postoperative hemodynamic results. This is particularly important in cases with small aortic annulus. [1,7,8,9]

According to our study, the postoperative results regarding the hemodynamics and postoperative outcome were good. This could be achieved through the statistically significant decrease in the peak and mean pressure gradients and increase in the effective orifice area after neocuspidization technique as evident by postoperative echocardiography. There was no need for conversion to prosthetic AVR or reintervention of the valve in our study. There was 1 (2.5%) patient needed reopening for bleeding control and 1 (2.5%) patient had complete heart block needed permanent pacemaker insertion, also there was one in hospital mortality (2.5%) due to severe RV impairment.

There was a study demonstrated that the mean preoperative peak pressure gradient was 89 ± 32.9 mmHg and decreased to 22 ±10.7 mmHg one week postoperatively with freedom of conversion to AVR. [10] In another study, there were 2 (2.6%) patients had moderate to severe aortic regurge after the procedure and both were managed with conversion to prosthetic AVR. [11]

Ozaki technique is associated with long duration of bypass and cross clamp when compared with the time needed for traditional prosthetic valve replacement. [12] This could be explained by the steep learning curve of the procedure in addition to the surgical technical complexity during the reconstruction of the valve leaflets. [9]

Limitations:

The main limitations of our study were the relatively small number of patients included in the study and the short term follow up of the postoperative outcome. So, we recommend performing future studies with mid and long term follow ups for better assessment of the efficacy and durability of the neovalve reconstruction technique.

Conclusion:

Ozaki technique through aortic valve neocuspidization with the use of gluteraldehyde treated autologous pericardium might be a feasible and effective procedure that is associated with good immediate results regarding the valve hemodynamics and freedom of need to convert to prosthetic valve replacement and thus the lack of need for lifelong anticoagulation.

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