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RESEARCH ARTICLE

AN EARLY EGYPTIAN EXPERIENCE IN OZAKI TECHNIQUE

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Abstract

Background: The advantage of Ozaki technique for aortic valve replacement surgery over the conventional approach is still debated. This study aimed to evaluate early outcomes after aortic valve replacement using the Ozaki technique

Methods: We prospectively included 20 patients who had aortic valve replacement May 2018 to June 2020. Postoperative bleeding, mechanical ventilation, ICU stay and echocardiographic outcomes were observed.

Results: The mean age was 39.9±14.8 (20-69) years. 13 patients had aortic regurgitation while 7 had aortic stenosis. Aortic cross-clamp (76.2±8.5 (60-100) and cardiopulmonary bypass times (103.8±15.3 (80-125)). One patient (5%) was converted to aortic valve replacement by mechanical valve due to significant aortic regurgitation. Neither significant gradient nor regurgitation was found on one month follow-up echocardiography. Freedom from infective endocarditis was found in all patients. No significant difference was found in the ejection fraction pre and post-operative.

Conclusion: This novel technique seems to have a promising and favorable outcome with no need for anticoagulation and lesser post-operative complication compared to ordinary aortic valve replacement. This technique is associated with low mortality and morbidity

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Introduction:-

Aortic stenosis, being the most common of valvular heart diseases is known to be frequently caused by degenerative Atherosclerosis, congenital abnormalities and rheumatic disease (Nkomo et al 2006).

Aortic valve replacement has been identified as standard method of management of patients with severe aortic valve disease either by mechanical valves in case of young patients (who are less than 60 years old), because of better longevity, or by biological valves for elderly patients to avoid the use of oral anticoagulation (Vahanian et al 2012).

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Trans catheter aortic valve implantation (TAVI) has been greatly used as an effective alternative technique used mostly in patients for whom conventional replacement was considered too risky.

Recently, new surgical approaches, aiming at reconstructing not just replacing the aortic valve, have been developed. In 2011, Ozaki et al. published their technique, which adopts the usage of autologous pericardium a large cohort study with excellent long-term follow-up (Ozaki et al 2015).

Among the possible advantages of the Ozaki procedure is: the evasion of oral anticoagulant usage, copping out using foreign materials, and the appropriateness either for infective endocarditis patients or those with small aortic annulus. However, excellent long-term outcomes are still being assessed before launched for widespread use of the technique. (Narang et al 2008)

Aim of the work:

To evaluate the clinical execution and report early consequences of this novel technique, the Ozaki procedure, aiming at replacing diseased aortic valve leaflets by newly reconstructed leaflets tailored from autologous pericardium

Patients and Methods:-

Design:

This prospective observational study included 20 patients who had AVR between May 2018 to June 2020 in order to find the early and short term (1 month post-operative) outcome of Ozaki technique valve surgery.

Technique:

Surgical access to the heart was through median sternotomy in all cases. The incision started from just below the suprasternal notch to the xiphoid process. Pericardium was harvested and treated with glutaraldehyde, customized intraoperatively and fashioned to meet each sinus measurements guided with the appropriate Ozaki templates. Central cannulation was done with the aortic cannula in the ascending aorta and double-stage cannula in the right atrium. Membrane oxygenator and heart lung machine were used. Myocardial protection is through single dose Custodial Cardioplegia. Research was performed based on medical evidence and observation of patients at the time of weaning from bypass, immediately postoperative and within one month postoperatively.

Table 1:- Basic and preoperative characters of the studied sample. Continuous variables are presented as mean and SD and categorical variables as number and percentages.

Variable	No. (n=20)	%	
Sex	Male	75.0	75.0
	Female	25.0	25.0
Age (ys)	Mean±SD (Range)	39.9±14.8 (20-69)	
Weight (kg)	Mean±SD	78.2±17.9	
	Median (Range)	75.0 (55-125)	
Height (cm)	Mean±SD (Range)	167.3±6.65 (155-178)	
BMI (kg/m ²)	Mean±SD	28.0±6.7	
	Median (Range)	26.0 (20.7-45.9)	
Aortic lesion	AR	13	65.0
	AS	7	35.0
Severity	Severe	20	100.0
Echo findings	LV ED	Mean±SD (Range)	6.0±1.2 (3.7-9.5)
	LV ES	Mean±SD	3.92±1.04
		Median (range)	3.6 (2.2-7.1)
	EF%	Mean±SD (Range)	60.5±6.99 (45-72)
	Posterior wall thickness	Mean±SD	1.17±0.23
Median (range)		1.15 (0.9-1.6)	
Septal wall thickness	Mean±SD (range)	1.22±0.23 (0.8-1.6)	

Table 2:- Intra and post-Operative data. Continuous variables are presented as mean and SD or median (range) and categorical variables as number and percentages.

Variable		n=20
Operative time (h)	Mean±SD	4.7±0.57
	Median (Range)	5.0 (4-6)
Cross clamp time (min.)	Mean±SD (Range)	76.2±8.5 (60-100)
Bypass time (min.)	Mean±SD (Range)	103.8±15.3 (80-125)
Valve sizing using st Jude Epic.	Mean±SD(Range)	21.8±1.2 (19-23)
Any intra operative events of significance	Null	19 (95.0)
	LIM (n. %)	1 (5.0)
Aorta	No regurge	17 (85.0)
	Trivial	2 (10.0)
	Mild	1 (5.0)
Gradient on aorta	Insignificant	20 (100.0)
EF%	Mean±SD (Range)	57.3±6.8 (45-68)
Decision for conversion	No	19 (95.0)
	Yes	1 (5.0)
Inotropic adrenalin	No	11 (55.0)
	Yes	9 (45.0)
Mechanical Ventilation (hr)	Mean±SD	9.25±4.8
	Median (range)	8.0 (4-24)
ICU stay (hr)	Mean±SD	58.1±13.3
	Median (range)	48.0 (34-72)
Postoperative bleeding	Null	1 (5.0)
	Insignificant	14 (70.0)
	Minimal	1 (5.0)
	Moderate (300-1500 ml)	4 (20.0)
Decision to reopen	No	19 (95.0)
	Yes	1 (5.0)

Data:

Each patient underwent full history taking, clinical assessment, and preoperative laboratory, and radiological examinations. The echocardiographic assessment included measurement of the left ventricular ejection fraction (LVEF), left ventricular end diastole diameter (LVED), left ventricular end systole diameter (LVES) and aortic lesion.

Postoperatively, the patient was transferred to the intensive care unit (ICU). We reported the duration of mechanical ventilation (MV), blood loss, and ICU stay duration.

Follow up was carried out in the outpatient clinic postoperatively. The one month postoperative TTE was routinely done to assess the aortic valve integrity and gradient across the valve.

Statistical analysis:

The collected data were tabulated and analyzed using SPSS version 20 software (SpssInc, Chicago, ILL Company). Categorical data were presented as number and percentages, quantitative data were tested for normality using Shapiro test, assuming normality at $P > 0.05$. They were expressed as mean±SD, range if parametric; median was added for non-parametric variables. Parametric matched variables were analyzed by Paired “t” test. $P \leq 0.05$ was considered significant.

Results:-**Preoperative and operative data**

The mean age was 39.9±14.8 years, 13 patients had aortic regurge and 7 had aortic stenosis. The mean ejection fraction was 60.5±6.99 (Table 1).

The mean operative time was 4.7 ± 0.57 h. The mean clamping time was 76.2 ± 8.5 mins. The mean bypass time was 103.8 ± 15.3 mins. One patient (5%) was converted to aortic valve replacement by mechanical valve due to significant aortic regurgitation (Table 2).

Postoperative outcomes:

Four patients (20%) had moderate post-operative bleeding with one patient (5%) needed reopening for exploration (Table 2). Observing the one month post-operative echographic findings, we detected no significant regurgitation or gradient across the aortic valve and there were no significant change in the ejection fraction (Table 2, 3).

Table 3:- Comparing EF before and after intervention. Continuous variables are presented as mean and SD.

EF %	Mean±SD (Range)	Paired t	P
Pre intervention	60.5±6.99 (45-72)	1.93	0.068 (NS)
Post intervention	57.3±6.8 (45-68)		

Discussion:-

Several advantages of the Ozaki procedure are present including no foreign body insertion, no warfarin needed. The reconstructed aortic valve has significantly less pressure gradients, compared to conventional aortic valve replacement cases and it can be applied to almost all aortic valve pathologies.

In this study, we observed the short outcomes of Ozaki procedure for Stentless Aortic valve replacement. While in comparison with a study done by Reuthebuch et al. 2018 the mean age was relatively older, the mean age was 66.83 ± 10.55 years. Our study had similar preoperative and echocardiographic parameters comparable with other studies.

In this study the cross clamp time and Cardiopulmonary bypass time were significantly longer than aortic valve replacement. Similar results were found in other studies and that could be attributed to the more technically demanding and time-consuming technique, but this could be reduced by experience.

The need for conversion was needed in one patient (5%) intra-operative due to significant regurgitation found on transthoracic echography.

In this study there were no cases of operative mortality. The mean mechanical ventilation time was 9.25 ± 4.8 hours and the ICU stay was 58.1 ± 13.3 hours. One patient was re-operated on due to significant bleeding (5%). Reuthebuch and associates found similar results.

In the current study neither significant gradient nor regurgitation was found on one month follow-up echography. Freedom from infective endocarditis was found in all patients. No significant difference was found in the ejection fraction pre and post-operative.

In a study done by Rosseikin et al, 2018 comparing Ozaki Mini with Ozaki Full (which is the same procedure as in the current study), the median duration of operation was 260 minutes, cross clamp time ranged from 88.26 to 123.75 minutes, blood loss in ICU around 600 ml with no need for blood transfusion in ICU, No renal failure was noticed during 30 days follow up.

In a similar study done by Nguyn et al., 2018 they found that the mean age was 47.4 years most of patients were female. The main pathology was chronic rheumatic valve disease (66.7%). The mean aortic cross-clamp time and CBP time were 106.8 and 153.6 minutes, respectively. Mean ventilation time was 8.4 hours, and the mean intensive care unit time was 1.6 days. No mortality was recorded in their study. Intraoperative transesophageal echocardiography showed competent valves with trivial regurgitation in three valves with no stenosis detected. TTE three months postoperatively showed the same result.

Also, Nguyn and his colleagues, 2019 in another study recommended that Ozaki procedure is easy, safe and is an alternative to conventional sternotomy surgery. In their center, this approach was associated with low mortality and morbidity and a high rate of success of repair.

Also, Rene and Tornike, 2018 successfully introduced the Ozaki procedure into their institute and achieved nice results. The procedure could provide excellent and superior consequences for many diseased aortic valves but they insist that it is not equivalent to a well-performed valve repair

Limitations:

This study was limited by small sample size, short-term follow-up and inter-observer variability in interpreting the echocardiographic findings.

Conclusion:-

This novel technique seems to have promising and favorable outcomes with no need for anticoagulation and lesser post-operative complication compared to ordinary aortic valve replacement. This technique is associated with low mortality and morbidity.

Conflict of interest:

Authors declare no conflict of interest.

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