

Aortic Root Enlargement in patients with small aortic annulus undergoing double valve replacement. A retrospective Comparative cohort study.

Yasser Mubarak¹ and Ahmed Abdeljawad²

¹Minia University Faculty of Medicine

²Cairo University Kasr Alainy Faculty of Medicine

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Abstract

Background: Small Aortic Annulus (AA) is big issue during Aortic Valve Replacement (AVR) necessitating replacement of an undersized prosthetic valve especially with Double Valve Replacement (DVR). Despite that small aortic valve prostheses can lead to Prosthesis-Patient Mismatch (PPM), there remains reluctance to perform aortic root enlargement (ARE) procedures fearing from morbidity and mortality. Objective: To evaluate clinical and echocardiographic outcomes in patients with small aortic annulus undergoing double valve replacement. Methods: The study included 100 consecutive patients underwent DVR for combined rheumatic aortic and mitral valve diseases, between Jan. 2016 and Sept. 2020. Only (50) patients had ARE with DVR. ARE was performed using an autologous or bovine pericardium or Dacron patch by Nick's or Manouguian procedures. The estimated postoperative end-points were mortality, effective orifice areas (EOA), mean aortic pressure gradient and valve-related complications. The least postoperative follow-up period was 6 months. Results: The study included 30 male and 70 female patients with mean age of 35 ± 20 years, body surface area (BSA) of 1.7 ± 0.3 m², aortic annulus diameter was 20 ± 1.4 mm, aortic orifice area was 0.8 ± 0.1 cm², and mean pressure gradient 85 ± 2.5 mmHg. During follow-up period, there was a mild to moderate paravalvular leak (1%) with, (1%) heart block, and residual gradient on prosthetic aortic valve; that was all in DVR alone. Conclusion: Enlargement of aortic root by Nick's or Manouguian technique is safe and effective in patients with small aortic annulus undergoing double valve replacements.

Aortic Root Enlargement in patients with small aortic annulus undergoing double valve replacement. Is it justified? A retrospective cohort study

* Yasser Mubarak, ** Ahmed Abdeljawad.

* Department of Cardiothoracic Surgery, Minia University, Egypt.

Madinah Cardiac Center, King Fahd Hospital, KSA.

** Department of Cardiothoracic Surgery, Cairo University, Egypt. Clinical of Cardiothoracic & Vascular Surgery, Städtisches Klinikum Braunschweig, Germany.

Declarations

Ethics approval and consent to participate : - Patient confirms that have read and understood the information about the research as provided in the participant information sheet inside his file.

The study has got the formal approval and permission from *Minia cardiothoracic surgery department* before to start the study. The study conformed to the principles of "Declaration of Helsinki" and the investigator

followed the appropriate safeguards regarding the rights and welfare of the human participants that have been included in the performed study. *Faculty of Medicine, Research Ethics Committee.*

It should be noted that at the time this research was performed, our research ethics committee was not fully activated. Therefore, the principle investigator has got the formal approval and permission from the relevant department prior to commencement of the study.

Cardiothoracic surgery department section council was 5/2016 and approved NO. 277-5 / 2016.

Consent for publication: - It was obtained written consent from patients.

Availability of data and material: - It is available from recording files and data at cardiothoracic surgery departments and cardiology clinics for follow up.

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Corresponding Author : Yasser Mubarak. Cardiothoracic surgery department, Faculty of Medicine, Minia University. Tel: +966560708223; +201002554078. E-mail: yassermubarak73@gmail.com. ORCID: 0000-0001-8460-2778.

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The key question

In patients with a small AA, implantation of suitable sized prostheses is not possible. So, PPM is the immediate consequence. ARE adds risk on hemodynamics, so there is a debated whether ARE or not to avoid increasing morbidity and mortality.

Key finding

In case of small aortic root, Cardiac surgeons performing AVR even with DVR should enlarge aortic root to allow insertion of appropriate-sized prosthesis to avoid PPM.

Take-home message

DVR with aortic root enlargement is safe and feasible to avoid PPM without increasing morbidity and mortality.

Objectives: Small Aortic Annulus (AA) is big issue during Aortic Valve Replacement (AVR) necessitating replacement of an undersized prosthetic valve especially with Double Valve Replacement (DVR). Despite that small aortic valve prostheses can lead to Prosthesis-Patient Mismatch (PPM), there remains reluctance to perform aortic root enlargement (ARE) procedures fearing from morbidity and mortality. We evaluate clinical and echocardiographic outcomes in patients with small aortic annulus undergoing double valve replacement. **Methods:** The study included 100 consecutive patients underwent DVR for combined rheumatic aortic and mitral valve diseases, between Jan. 2016 and Sept. 2020. Only (50) patients had ARE with DVR. ARE was performed using an autologous or bovine pericardium or Dacron patch by Nick's or Manouguian procedures. The estimated postoperative end-points were mortality, effective orifice areas (EOA), mean aortic pressure gradient and valve-related complications. The least postoperative follow-up period was 6 months. **Results:** The study included 30 male and 70 female patients with mean age of 35±20 years, body surface area (BSA) of 1.5 ±0.20 m², aortic annulus diameter was 20±1.4 mm, aortic orifice area was 0.80±0.50 cm², and aortic peak gradient (PG) 80±40 mm Hg. During follow-up period, there was a mild to moderate paravalvular leak (1%) with, (1%) heart block, and residual PG on prosthetic aortic valve; that was all in DVR alone. **Conclusion:** Enlargement of aortic root by Nick's or Manouguian technique is safe and effective in patients with small aortic annulus undergoing double valve replacements.

Introduction

Rheumatic Heart Disease (RHD) is very common in developing countries. It affects mainly mitral and aortic valve. It causes annular fibrosis, may be lead to smaller AA. So, if smaller prosthesis is implanted, there is a PPM, poor Left Ventricle (LV) mass regression, increases overload, and low survival rate. With undersized prosthetic valve, patient can't maintain normal activity; produce symptoms of aortic stenosis (AS) and PPM. Rahimtola first described the issue of PPM, if the EOA of prosthetic valve is very small in relation to patient's BSA[1-2] . Nicks and colleagues first proposed posterior root enlargement in1970. The Nicks technique facilitated placement of a larger size aortic valve prosthesis by extending the aortotomy posteriorly through aortic sinus across the aortic ring and inserting a patch to augment the annulus[3] .

Severe PPM according to the valve's EOA indexed (EOAi) [severe PPM when an EOAI $<0.85 \text{ cm}^2/\text{m}^2$] is associated with worse hemodynamic and clinical outcome [4] . PPM is a predictor of mortality and it can be responsible for postoperative high transvalvular PG. ARE allows for larger prosthesis implantation, consequently avoiding PPM. Despite these potential benefits of ARE, it has not been widely performed by cardiac surgeons, fearing of an increased risk of mortality and morbidity [5-6-7] .

Cardiac surgeons performing AVR should be familiar with techniques of ARE to allow insertion of appropriate-sized prosthesis in case of small AA, and to avoid PPM. Performed properly by an experienced cardiac surgeon, the technique is safe and reproducible [8]. So, nowadays surgeons prefer to do ARE to get rid of PPM and to obtain optimum hemodynamics [1-2].

Methods

Demographic, intraoperative, and outcome data were collected retrospectively cohort comparative study on (100) patients undergoing AVR with or without ARE at a multicenter institutions between Jan. 2016 – Sept. 2020. Those patients with pure or predominant aortic valve stenosis have been included in the study. One-hundred patients with small AA were performed AVR, only (50) patients were underwent ARE with AVR. Mean age was 35 \pm 20 years. Operative death and residual gradient on prosthetic aortic valve (AV) were evaluated. **Inclusion criteria:** Double valve replacement - Small aortic annulus- Rheumatic heart disease - Adult age. **Exclusion criteria:** Valvular heart lesions other than rheumatic disease - Isolated aortic valve replacement – Children - Associated procedures other than AVR - Renal failure- Emergency - Re operation.

A median sternotomy was performed in all patients. Cardiopulmonary bypass (CPB) with systemic cooling to 32degC was routinely used. After the aorta is cross-clamped (Ao.CC) and the heart is arrested by means of intermittent, antegrade cold blood cardioplegia directly delivered into coronary ostia. The decision to maximize EOA was made after intra-operative assessment of AA. After debridement of aorta annulus, it was sized and if it was not admitting 19 mm valve or not suitable to BSA, aortotomy incision is extended into the fibrous trigone between NCC and LCC [Manouguian] or extended into NCC [Nick's] to enlarge AA. This incision reconstructed using a tear drop shaped patch of autologous pericardium [Pericardial patch was harvested and fixed with glutaraldehyde] or bovine pericardium or Dacron patch. Patch was sutured with 4/0 polypropylene starting at the nadir of annular enlargement incision and extending up to 2–3 cm above the plane of annulus. After replacing the mitral valve, AA was resized and appropriate valve was chosen. We use a non-everting, horizontal mattress technique of 2/0 polyester were placed on annulus. Pledged sutures were placed in the plane of annulus where patch enlargement was performed with pledgets resting on outside of the patch. After replacing the valve patch, it was sutured to aortotomy margins using 4/0 polypropylene.

Simplified Manouguian which was allowed ARE without opening LA, without distorting the mitral annulus, and decreased incidence of potential bleeding. Also, modified Nick's procedure was allowed ARE without extended to mitral annulus , and can be performed in AVR.

In cases of small AA accepted small prosthetic AV without ARE, we have started to implant AV after put pledgets along the mitral annulus before implanting AV. So, AA gets the size of the valve that it deserves. Then one can easily implant mitral valve. For better hemodynamic effect, we prefer to implant prosthetic AV in anteroposterior direction. We prefer to implant prosthetic mitral valve in anatomical position, so that

struts of mitral valve do not impinge upon AV, which is already in position.

Figure (1,2,3)

The statistical analysis was performed using the SPSS software package (version 20.0; SPSS Inc., Chicago, IL, USA). The analyzed data were expressed as number (N), percentage (%), mean (M) and standard deviation (SD) or as proportions. P-value < 0.05 was considered statistically significant.

Results

Table (1), Table (2)

Post-operative Echocardiogram (Echo) before discharge showed acceptable gradients across aortic valve in all cases with ARE, however there are PPM with different levels on aortic valve in all cases without ARE.

Table (3)

The duration of aortic cross clamp is slightly longer by approximately 10 min compared to routine DVR; it didn't make a significant difference in over-all management of patient. There is no incidence of intra-operative or post-operative bleeding, no excessive requirement of blood products. There was mild o moderate paravalvular leak in 1% and heart block in 1% in DVR without ARE.

Table (4)

With root enlargement one- two size bigger was replaced in 50 patients and PPM was eliminated in all patients. Nick's was performed in (45) cases and Manouguian in (5) cases. Type of patches were used autologous pericardium in (35) cases, Dacron in (12) cases, and Bovine in (3) cases. There were no operative or in hospital mortality.

Discussion

Patient's age and activity can be considered for calculating cardiac output demand; young people with active life style will require larger prosthesis for a higher cardiac demand. Since implanting a small-sized valve can worsen outcome due to increased preload [2]. This study was undertaken to review our strategy and feasibility of ARE in patient undergo DVR to avoid PPM without increase in morbidity or mortality especially in young patients (age = 35+- 20).

In patients with a small AA, it is difficult to implant large valve prostheses. PPM is the immediate consequence of this situation[6] . We observed high variable pressure gradient across aortic prosthesis with DVR alone (postoperative PG 25.9 +- 5.8).

Rheumatic heart diseases usually affect left heart valves requirement DVR. Small aortic annulus is a big problem facing cardiac surgeons in AVR and more with DVR. Most of the patients also have tricuspid valve disease, atrial fibrillation and severe LV dysfunction, that add risk factors on hemodynamics if ARE did not performed. So, there is still debated whether implant small prosthesis or ARE to avoid increasing morbidity or mortality. [9] . In our study, preoperative risk factors were not obstacles to do ARE, however, these factors may be worse with PPM.

ARE techniques can be performed simply and modified without complexity to get benefit and avoid complications. So, that is an alternative to implantation of too small prosthesis, ARE may actually reduce mortality[10] . Our study used to perform modified Nick's procedure to implant larger prosthesis without increasing risk of technique even in junior surgeons.

There have been only a few studies on DVR with ARE. Some with only small number of patients of non-Rheumatic etiology and most are case reports. ARE in DVR is enlarging AA without increase in operative mortality but at expense of prolonged CPB time [10] . That is encouraging us to collect data for comparison between two groups of DVR with/out ARE, and motivate cardiac surgeons to ARE, if needed to avoid PPM. ARE itself does not increase operative risk. Surgeons should not be reluctant to enlarge the aortic root to permit implantation of adequately sized valve prostheses.

ARE requires some technical skills, and should not increase operative risk. So, it is possible to implant valve 2 sizes larger than the native annulus [4] . We observed in the study no incremental risk in mortality or adverse events after surgical ARE compared with AVR alone.

Most surgeons prefer to use a small aortic prosthesis instead of expanding the annulus. Yet the use of a small aortic prosthesis may be associated with obstruction of left ventricular output, resulting in a higher PG and PPM. Studies have demonstrated that mortality was higher in patients receiving a small aortic prosthesis [11] . So, ARE is a safe procedure with expert surgeon and should be considered at the time of AVR even with DVR to avoid PPM.

Surgical ARE has not been widely performed by cardiac surgeons, because of concerns regarding the possible increased risk of early mortality and morbidity [4] . In our study, ARE was safe and did not increase morbidity and mortality.

Conclusion: - Aortic root enlargement can be safely done in patients undergoing double valve replacement with benefit of bigger size prosthesis without additional mortality and morbidity.

Abbreviations:- **ARE** : aortic root enlargement, **DVR** : double valve replacement, **AV** : aortic valve, **AVR** : aortic valve replacement, **AA** : Aortic Annulus, **NCC** : Non Coronary Cusp, **LCC** : Left Coronary Cusp, **LV** : Left Ventricle, **RHD** : rheumatic heart disease, **PPM** : Prosthesis Patient Mismatch, **EOA/i** : Effective Orifice Area/ indexed, **RHD** : Rheumatic Heart Disease, **BSA** : Body Surface Area, **PG** : Pressure Gradient, **EF** : Ejection Fraction, **CPB** : Cardio Pulmonary Bypass, **Ao. /CC time**: Aortic Cross Clamp/ time, **MV** : Mechanical Ventilation, **HB** : Heart Block, **LCO** : Low Cardiac Output, **COPD** : Chronic Obstructive Pulmonary Disease, **CAD** : Coronary Artery Disease, **DM** : Diabetes Mellitus, **HTN** : Hypertension, **AF** : Atrial Fibrillation, **AS** : Aortic Stenosis.

Table (1):- Demographic data, pre-operative risk factors.

Variable	DVR alone (N=50)	DVR with ARE (N=50)
Age	Mean 32±24	Mean 35±20
Gender	65% female	70% female
BSA	1.7±0.5 m ²	1.5±0.2m ² [average 1.37 m ²]
NYHA class I II III VI	5.9% 19.8% 60.4% 13.9%	4.1% 15.9% 68.5% 11.5%
AF	20%	30%
Bicuspid aortic valve	1%	2.5%
PVD	No	No
COPD	No	No
LCO	No	No
HTN	No	0.5%
DM	No	2.5%
s/p MI or CAD	No	No
Smoking	5%	10%
Stroke and TIAs	No	No
Aortic lesion Stenosis Insufficiency Mixed	18.4% 10.8% 70%	34% P-value [?]0.0001 3.7% 0.0002 61.6% 0.0069

Table (2):- Pressure gradient and EF.

Variable	DVR alone.	DVR with ARE
Preop. PG (mmHg)	75±3.5	85 ± 0.5
Postop PG (mmHg)	25.9 ± 5.8	15 ± 2.3
EF (%) Postop.	45 ± 4.7	55 ± 5.9

Table (3):- Postoperative data

Variable	DVR alone	DVR with ARE
CPB time (minutes)	117±43	133±49
CC time (minutes)	92±35	105±39
Postop. LCO	No	4%
Bleeding and re-exploration	No	No
Blood product requirement	2±1.5	3±2.3
Duration of MV (hr.)	12 ± 6	18 ± 6.4
Infection SSWI Pneumonia	1.5% No	3% 0.5%
Heart Block (HB)	1%	No
Paravalvular Leak (PVL)	1%	No
ICU Stay (days)	3 ± 1.8	4 ± 2.3
Total Hospital Stay (days)	10 ± 5.1	12 ± 7.2

Table (4):- size of prosthetic valves

Variable	AVR alone	AVR with ARE
Prosthetic aortic valve	19	21 – 23 - 25
Prosthetic mitral valve	25- 27	27 – 29

Figure Legend

Figure (1):- Nick's procedure by incision of non-coronary cusp

Figure (2):- Patch suture started at angle of incision

Figure (3):- Complete patch suture and suture for valve taken

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Figure (1)

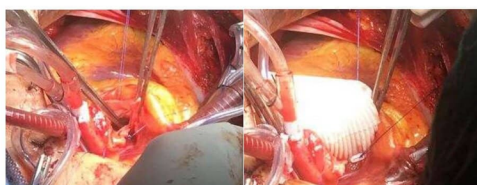


Figure (2)

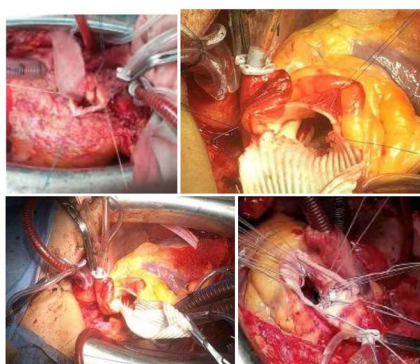


Figure (3)

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table.pdf available at <https://authorea.com/users/376324/articles/493308-aortic-root-enlargement-in-patients-with-small-aortic-annulus-undergoing-double-valve-replacement-a-retrospective-comparative-cohort-study>