

Early outcome of pulmonary valve replacement

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Abstract: Pulmonary valve replacement in the adult population or after repair of congenital heart diseases e.g. Tetralogy of Fallot is an uncommon operation. In our study, we retrospectively and prospectively evaluated the factors associated with mortality and morbidity in patients undergoing pulmonary valve replacement surgery. **Patients and Methods:** an observational prospective-retrospective study aimed to determine the indications, optimal timing and early outcome of patients done pulmonary valve replacement, all patients with the diagnosis of pulmonary valve diseases were identified from the database of Kasr Alainy Pediatric Hospital (Abo Elreish), Kasr Alainy Hospital, Misr University for Science and Technology [MUST] (affiliated by kasr Alainy Hospital). **Results:** There were 12 males (60 %) and 8 females (40%). The mean age was 16.60 ± 8.26 years (range from 8 to 35 years). The mean weight was 43.55 ± 13.99 Kg (range from 25.00 to 70.00 Kg). There was no mortality among the included patients. Postoperative complications occurred in the form of; chest infection in 3 patients (15%), arrhythmia in 3 patients (15%), brain insult in one patient (5%), diaphragmatic paralysis in one patient (5%) and re-opening for bleeding in one patient (5%). **Conclusion:** Surgical pulmonary valve replacement is a safe procedure. Early valve replacement before the development of significant right ventricular dysfunction was associated with low operative mortality. **The Recommendation** is further studies with a larger sample size to obtain statistically significant results.

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1. Introduction

Pulmonary valve incompetence occurs by one of three basic pathologic processes: dilatation of the pulmonic valve ring, acquired alteration of the pulmonic valve leaflet morphology or congenital absence or malformation of the valve. PR leads to right ventricular (RV) volume overload, which will subsequently lead to RV enlargement and RV dysfunction. With time, PR will lead to tricuspid regurgitation (**Kutty et al., 2018**). Pulmonary valve endocarditis is almost always associated with immunosuppressed states, intravenous drug abuse, and/or congenital heart disease. The risk of endocarditis is thought to chiefly depend on two factors: the presence of high-velocity jet that injures the endothelium by shear forces and the exposure to infective organisms (**Seraj et al., 2017**).

Medications are directed according to the specific etiology resulting in pulmonary regurgitation or stenosis in addition to the usual treatment of heart failure (if present) in the form diuretics and maybe vasodilators. Infective endocarditis antibiotic prophylaxis should be considered for patients whose pulmonary valve disease is due to valve leaflet abnormalities (**Nishimura et al., 2014**).

Trancatheter PVR was first reported in humans in 2000 and since then has emerged as an alternative to surgical PVR in patients with a failing RVOT conduit. In addition, case reports are emerging showing successful implantation in the native root, primary in patients with a transannular patch repair for tetralogy of Fallot (**Bonhoeffer et al., 2000**). Although there was an issue of stent fracture, yet altering the implant with bare metal stent reduced this risk significantly (**Cheatham et al., 2015**).

The Food and Drug Administration (FDA) approved its full commercial issue in 2015. The valve comes in two sizes (16 mm and 18 mm) with the 16-mm valve achieving a maximal diameter of 20 mm and the 18-mm valve achieving a maximal diameter of 22 mm. However, Cheatham and associates reported successful maximal dilation of the 18-mm valve up to 24 mm with only mild residual regurgitation (**Cheatham et al., 2013**).

In this study, we are aiming to determine the indications, optimal timing and early outcome of patients received surgical pulmonary valve replacement.

2. Patients and Methods

This study is an observational study aimed at determining the indications, optimal timing and early outcome of patients underwent surgical pulmonary valve replacement. The data of patients who received surgically pulmonary valves were collected from the database of Kasr Alainy Pediatric Hospital (Abo El Reesh), Kasr Alainy Hospital and Misr University for Science and Technology between January 2014 and March 2019.

Inclusion criteria:

Any patient with congenital heart diseases (e.g. after total repair of Tetralogy of Fallot, VSD with pulmonary stenosis, etc.) or acquired pulmonary valve diseases (e.g. infective endocarditis) that underwent pulmonary valve replacement.

Exclusion criteria:

Patients with a history of ischemic heart disease e.g. history of myocardial infarction or previous coronary artery bypass grafting.

Preoperative:

All patients were evaluated thoroughly preoperative, intra-operative and postoperative with special attention to preoperative and postoperative echocardiography and Cardiac Magnetic Resonance Imaging (CMRI).

Operative data

All patients were subjected to surgical intervention. A longitudinal incision is made in the RVOT extending out to the pulmonary bifurcation. After sizing for the appropriate valve, it is retained on its "handle," and a continuous suture line is placed along the posterior portion of the right ventricular outflow track (RVOT) and the top part of the valve sewing ring. The valve is oriented "backward," but when the sutures are tightened, the valve will "flip" into its desired orientation. The valve is seated into position, and the posterior suture line is continued to

the edge of the incision in the RVOT. A prosthetic patch is then used as a "roof" over the valve and RVOT incision. This allows the placement of a large valve into the RVOT.

A record was made of the following:

- Ischemic time
- Bypass time
- cardioplegia type
- Type of valve replaced and type of valve implanted.

Postoperative data The following data were recorded:

- Period of mechanical ventilation.
- Duration of inotropic support.
- Duration of hospital and ICU stay.
- Incidence of postoperative complications e.g. low cardiac output syndrome infection, arrhythmia, brain insult, bleeding and diaphragmatic event ration.

Statistical analysis

Data were coded and then entered into the SPSS statistical package (Statistical Package for the Social Sciences) version 21 windows (IBM Inc., Chicago, Illinois, USA). Quantitative data were summarized using the mean \pm standard deviation, median, minimum and maximum while categorical data are presented as the frequency (count) and relative frequency (percentage).

3. Results

Preoperative results

Demographic data

In our study group, there were 12 males (60 %) and 8 females (40%). The mean age was 16.60 ± 8.26 Years with a range from 8 to 35 years. The mean weight was 43.55 ± 13.99 Kilograms with a range from 25.00 to 70.00 Kilograms. Demographic data are shown in Table (1).

Table (1): Demographic features (physical characteristics) of the study group. Data are expressed as mean \pm SD or number (%)

	Mean	Standard Deviation	Median	Minimum	Maximum
Age (years)	16.60	8.26	14.00	8.00	35.00
Weight (kg)	43.55	13.99	40.00	25.00	70.00
				Count	%
Sex	male			12	60.0%
	female			8	40.0%

Clinical data

The preoperative clinical results are reported in Table (2). The results showed that fourteen patients (70%) had a history of Tetralogy of Fallot total repair before, two cases (10%) developed infective

endocarditis, one on a native pulmonary valve and the other on a biological valve in the pulmonary position implanted from 2 years as well as 3 cases (20%) of Lenovo adult Tetralogy of Fallot and one case of adult perimembranous VSD (6mm) with severe PS.

The main presentation was shortness of breath and mild respiratory distress (signs of heart failure) in 10 patients. In patients with pulmonary valve endocarditis (2) the main presentation was fever, shortness of breath and bone aches. One of these patients gave a history of dental procedure 1 month before the appearance of symptoms while the other was an IV drug addict who developed pulmonary valve endocarditis and received a biological valve in pulmonary position 2 years ago. The remaining 8 patients were asymptomatic and accidentally discovered e.g. during routine follow up after Tetralogy of Fallot repair operation.

The mean preoperative oxygen saturation was 95.05% with median 98% ranged from 60% to 100%. Mean preoperative Hemoglobin concentration was 12.85 ± 2.30 gm/dl with a range of 10.50 to 21.0.

In endocarditis patients' blood culture was positive in one patient with Klebsiella species but negative in the other due to the administration of antibiotics before admission and withdrawal of cultures. The mean total leucocytic count (TLC) in these 2 patients was 17,000, while mean CRP and ESR were 200 and 98 respectively.

Five patients received additional procedures in the form of VSD closure (one patient), tricuspid repair due to severe tricuspid regurge (two cases), partial anomalous pulmonary venous drainage (PAPVD) repair (one case) and left pulmonary artery (LPA) augmentation due to stenosis (one case). This is in addition to the 3 cases of denovo adult Tetralogy of Fallot that received a total repair.

Table (2): Summary of preoperative clinical results

Preoperative data		Count	%
Distribution of cases	Previously repaired TOF	14	70.0%
	Pulmonary valve endocarditis	2	10.0%
	VSD/PS	1	5.0%
	Adult denovo TOF	3	15.0%
Associated diseases	PAPVD	1	5.0%
	Severe tricuspid regurge	2	10.0%
	LPA Stenosis	1	5.0%
Main presentatin	Dyspnea	10	50.0%
	Fever, dyspnea, bone aches	2	10.0%
	Asymptomatic	8	40%

TOF, Tetralogy of Fallot LPA, Left Pulmonary artery; PAPVD, Partial anomalous pulmonary venous drainage.

Preoperative radiological

The preoperative ECHO parameters in Table (3) showed that The pulmonary valve severe regurge (regurgitant jet $\geq 50\%$ of RVOT) in the 16 patients (80%) with previous repair of Tetralogy of Fallot and pulmonary valve endocarditis as well as severe stenosis (peak systolic gradient ≥ 64 mmHg) in the remaining 4 cases (20%) with adult Tetralogy of Fallot and VSD/PS. Stenotic valves were dysmorphic with thickened leaflets and fused commissures. In endocarditis cases, masses were noted on the ventricular aspects of the valves with a mean size of $6.5\text{mm} \times 13.8\text{mm}$. In the case of native pulmonary valve endocarditis perforation of the nonseptal cusp was noted with small underlying annular abscess cavity of $2\text{mm} \times 3.5\text{mm}$. The mean TAPSE (Tricuspid annular plane systolic excursion) in all cases was $1.86\text{ cm} \pm 0.41$ with a range of 1.2 to 2.5 while the mean sizes of pulmonary annular diameter were $19.35\text{mm} \pm 5.08$ with a range of 7mm to 28 mm.

Moreover, the results from the same Table observed that the preoperative CMRI parameters done in 15 cases (75%) preoperatively. The RVEDI (Right ventricular End-Diastolic Index) was $159.93\text{ ml/m}^2 \pm 24.52$ with a range of 120 ml/m^2 to 230 ml/m^2 while the LVEDI (Right ventricular End-Systolic Index) was $81.53\text{ ml/m}^2 \pm 19.71$ with a range of 50 ml/m^2 to 140 ml/m^2 . The LVEF (Left Ventricular Ejection Fraction) was $56.41\% \pm 5.80$ with a range of 50% to 66 %, while the RVEF (Right Ventricular Ejection Fraction) was $46.33\% \pm 7.68$ (range 40% to 64 %).

Operative data

All patients underwent elective procedures without emergent operations. The median total cardiopulmonary bypass time for all patients was 62.5 minutes (range 50 to 130 minutes) while the median cross clamp duration was 47 minutes (range 40 to 120 minutes) as the results in Table (4).

As mentioned before all patients were approached through full median sternotomy which was for the second time (redo) in 15 cases (75%).

Myocardial protection was achieved through systemic cooling and intermittent antegrade cardioplegia in 19 cases using Breschneider solution (Custodiol) in 15 patients (75%) and cold blood cardioplegia in 4 patients (20%). Only one patient (5%) was done on beating heart according to surgeon preference and no cardioplegia was used.

Nineteen patients (95%) had the pathology at their own native pulmonary valve, while one patient had IE masses on previously implanted pulmonary biological tissue valve. 18 patients received Epic supra valve biological tissue valves with a size range from 19mm to 27mm and one patient received a trifecta biological valve sized 19mm. Only one patient with a native pulmonary valve endocarditis received a mechanical valve **St. Jude Medical™** mechanical valve (size 25mm). There was no need for femoral cannulation in redo cases.

Two cases of the adult Fallot's Tetralogy were associated with severe tricuspid regurge which was

repaired during the surgery by band annuloplasty through right atriotomy and one case was associated with partial anomalous pulmonary venous drainage (PAPVD) which was also repaired during the surgery through right atriotomy using a pericardial patch to close an ASD and direct the right pulmonary veins into the left atrium. In addition, one case of the patients with previously repaired Tetralogy of Fallot had stenosis of the left pulmonary artery (LPA) which was augmented by upward extension of the pericardial patch to the stenotic pulmonary artery and one case with VSD/PS had the VSD closed through right atriotomy by Polytetrafluoroethylene (PTFE) patch. This is in addition to the 3 cases of denovo adult Tetralogy of Fallot that received a total repair in the form of VSD closure through right atriotomy and resection of any obstructing bands through the RVOT incision with the pulmonary valve replacement as the results in Table (5).

Table (3): Summary of preoperative radiological results

Preoperative data		Mean	Standard Deviation	Median	Minimum	Maximum
ECHO	TAPSE (cm)	1.86	0.41	1.80	1.20	2.50
	P annulus (mm)	19.35	5.08	20.00	7.00	28.00
CMRI	EDRVI (ml/m2)	159.93	24.52	155.00	120.00	230.00
	EDLVI (ml/m2)	81.53	19.71	80.00	50.00	140.00
	LVEF (%)	56.41	5.80	55.00	50.00	66.00
	RVEF (%)	46.33	7.68	45.00	40.00	64.00

TAPSE Tricuspid annular plane systolic excursion; P, pulmonary; EDRVI, End-Diastolic Right Ventricular Index; EDLVI, End-Systolic Right Ventricular Index; LVEF, Left Ventricular Ejection Fraction, RVEF, Right Ventricular Ejection Fraction.

Table (4): Showing intraoperative time parameters

	Mean	Standard Deviation	Median	Minimum	Maximum
CPB time (min)	62.50	33.85	55.00	25.00	180.00
ACC time (min)	47.35	26.06	45.00	0.00	120.00

CPB, cardiopulmonary bypass; ACC, aortic cross clamp

Table (5): Showing the summary of operative results

Operative data		Count	%
Approach	Median sternotomy	20	100.0%
	Custodiol cardioplegia	15	75.0%
Cardioplegia type	Cold blood cardioplegia	4	20.0%
	No cardioplegia	1	5.0%
Type of valve implanted	Mechanical valve (St. Jude Medical™)	1	5.0%
	Epic supra biological valve	18	90.0%
	Trifecta biological valve	1	5.0%

Postoperative results:

The median duration of mechanical ventilation in all patients was 1.50 day (range 1 to 3 days). All patients needed postoperative inotropic support in the form of Dobutamine in 7 patients (35%), Dobutamine +Milrinone in 9 patients (45%) and Epinephrine +Norepinephrine +Milrinone in 4 patients (20%) with a median duration of inotropic support of 2 days.

Three patients (15%) developed postoperatively chest infection (*Pseudomonas* and *Klebsiella* species) and were managed with antibiotics according to culture and sensitivity. 3 patients (15%) had arrhythmia in the form of atrial fibrillation (AF) which was managed medically with Amiodarone and one patient (5%) was reopened due to post-operative bleeding where bleeding from sternal wires was found and dealt with properly. One patient (5%) of the denovo TOF suffered from cerebrovascular stroke with left-sided hemiparesis.

MRI showed a lacunar infarction in the territory of the right middle cerebral artery mostly embolic in nature. The patient was managed neurologically and discharged home after the improvement of his general condition. One patient (5%) showed diaphragmatic paralysis on the left side postoperatively and received diaphragmatic plication through left lateral thoracotomy. Superficial wound infection complicated 2 patients and was managed conservatively with antibiotics according to culture and sensitivity and frequent dressings. Swab wound cultures were taken and showed Staph species in these cases.

The median postoperative total hospital stay was 9 days with a range of 3 to 39 days while median postoperative ICU stay was 3.5 days (2 to 12 days). In our study, there was no operative mortality as the results in Table (6).

Table 6: Summary of postoperative time parameters.

Postoperative time parameters	Mean	Standard Deviation	Median	Minimum	Maximum
Duration of mechanical ventilation (day)	1.55	0.60	1.50	1.00	3.00
ICU stay (days)	4.55	2.78	3.50	2.00	12.00
Hospital stay (days)	12.85	10.25	9.00	3.00	39.00

Postoperative echocardiography was done to the patient before discharge and showed: well-functioning well seated implanted valves with no paravalvular leak in all patients. The median pressure gradient across the

implanted valve was 10 mmHg (range 6-18mmHg). No residual septal defects and no more than mild tricuspid regurge in repaired tricuspid valves were detected in Table (7).

Table 7: Summary of postoperative results.

Postoperative data	Count	%	
Inotropic support	Dobutamine	7	35.0%
	Dobutamine + Milrinone	9	45.0%
	Epinephrine+norepinephrine+Milrinone	4	20.0%
Mortality	0	0%	
Postoperative complications	Diaphragmatic paralysis	1	5.0%
	Chest infection	3	15.0%
	Arrythmia	3	15.0%
	Brain insult (infarction)	1	5.0%
	Reopening for bleeding	1	5.0%
	Superficial wound infection	2	10.0%

4. Discussion

Longstanding PR and PS have been recognized to have deleterious effects on RV function. Exercise limitation, right and left ventricular dysfunction, and

electrocardiographic abnormalities are the most common complications. It seems that the main cause of sudden death in these patients is fatal arrhythmias resulting from RV dysfunction and therefore

preservation or restoration of RV function may reduce the risk (**Warner et al., 2003**).

Pulmonary valve replacement, whether surgical or interventional, is consequently considered for the preservation of the jeopardized RV function. Trans-catheter implanted valves in the pulmonary position are recently FDA-approved starting from 2015. However, due to their high costs, they are not yet available over a wide range in developing countries. Therefore, surgical PVR is still the standard approach for treating non-repairable pulmonary valves in these countries. Although the importance of avoiding the chronic RV volume and pressure overload is well recognized, yet the ideal time for PVR remains a debatable issue (**Buechel et al., 2005**).

In our study, there were 12 males (60%) and 8 females (40%). Comparing these results with other studies we found that gender prevalence was variable and depended mainly on the included study cohort. For example, male patients represented 47% while female patients represented 53% in the study done by (**Jain et al., 2012**).

In our study, the mean age was 16.60 ± 8.26 years ranging from 8 to 35 years, while the mean weight was 43.55 ± 13.99 Kilograms ranging from 25.00 to 70.00 Kilograms. When comparing these results to other studies representing cases of PVR we find that the timing of surgical intervention is variable according to each institute's policy. For example, older mean ages and higher body weights are detected in the series published by (**Jain et al. 2012**) where the median age was 33 years and the median weight was 73 kg.

On the other hand, in our study the right ventricular end-diastolic volume index (RVEDI) was $159.93 \text{ ml/m}^2 \pm 24.52$ with a range from 120 ml/m² to 230 ml/m² and the left ventricular end-diastolic volume index (LVEDI) was $81.53 \text{ ml/m}^2 \pm 19.71$ with a range from 50 ml/m² to 140 ml/m². While the LVEF was $56.41 \% \pm 5.80$ with a range from 50% to 66 % and the RVEF was $46.33 \% \pm 7.68$ with a range from 40% to 64 %.

Owing to the fact of the accuracy of MRI measurements for the LV and RV as evidence of ventricular function in chronic pulmonary valve diseases we find lower values in other series presenting results of PVR. For instance in the study done by (**Kogon et al. 2009**) of 107 patients, chamber measurements revealed a median RVEDI of 148 mL/m² (range, 74–308 mL/m²), a median right ventricular end-systolic volume index (RVESI) of 82 mL/m² (range, 28–195 mL/m²) and a LVEDI of 69 mL/m² (range, 38–147 mL/m²). The median RV/LV end-diastolic volume ratio was 1.98 (range, 0.94–3.5). Functional measurements revealed a median RV ejection fraction of 45% (range, 24%–52%) and an LV

ejection fraction of 59% (range, 29%–65%). The median pulmonary regurgitant fraction was 39% (range, 10%–76%) (**Kogon et al., 2009**).

In our study of 20 patients' good early outcome with nil operative mortality and low postoperative morbidities could be achieved (3 patients with a chest infection, 3 patients with arrhythmia, 1 patient with reopening due to post-operative bleeding, 1 patient with brain insult and 1 patient with diaphragmatic paralysis). This may be partly due to our policy of early PVR and partly due to the low number of included patients. The median postoperative total hospital stay was 9 days with a range of 3 to 39 days while the median postoperative ICU stay was 3.5 days (range 2 to 12 days). In addition, as there were no deaths in our series, no risk factors for operative mortality could be elicited.

In the study done by (**Jain et al., 2012**) of the 153 patients, 22 (14.4%) experienced one of the Major Adverse Event after PVR. The only significant risk factor in the multivariable analysis for an adverse event was concomitant surgery. In this study, 31 patients (20.3%) remained in the hospital for longer than 7 days. The significant risk factors for a prolonged hospital stay included the presence of preoperative arrhythmias, New York Heart Association class 3 and concomitant surgery. The patients in the mortality group were significantly older (median 48 vs 33years; p-value =0.0001). The significant risk factors for mortality in the multivariable analysis included age older than 40 years (9.89%) and concomitant surgery (6.65%).

In study done by **Discigil et al. (2001)**, morbidity included prolonged ventilatory support (>48 hours) in 7patients (17%), sternal wound infection in 2 patients (5%) as well as cerebrovascular stroke, lower extremity compartment syndrome, exploration for bleeding, and partial gastrectomy for gastrointestinal bleeding in 1 patient each (2%). The mean length of hospital stay was 14.5 days.

In our study, all patients received biological valves except one which received a mechanical valve due to surgeon preference. Mechanical valves are superior regarding the durability but possess the drawback of lifelong anticoagulation which might be problematic in the pulmonary position. Biological valves have the advantage of lack of anticoagulation in the long run but with lower durability when compared to mechanical valves. However, newer generations of biological valves with longer durability as well as the evolution of catheter-implanted valve-in-valves have changed the algorithm in choosing the appropriate valve for surgical PVR.

When considering options for surgical PVR the risk of valve failure should also be considered. All valves inserted in the pulmonary position apart from

mechanical valves have a limited life expectancy, with wide variations in rates of freedom from valve failure and re-operation, depending on the type of valve and patient age (**Waterbolk et al., 2006**).

In a study done by (**Waterbolk et al., 2006**) of 27 surgical pulmonary valve replacements by mechanical prostheses with early mortality in one patient and late fatal anticoagulation-related pulmonary hemorrhage in another patient. One mechanical prosthesis had to be replaced 14 years after insertion as a result of fibrous tissue overgrowth. The mean follow-up was 5.5 years in their series and ranged from 2 months to 18 years. This study has demonstrated that pulmonary valve replacement can be performed safely using a mechanical prosthesis. They have also shown that thrombo-embolic events and prosthetic thrombosis do not occur when a proper anticoagulation regimen is maintained. (**Waterbolk et al., 2006**)

Our series included only early results regarding mortality and morbidity which represent a limitation to the study. In general, surgical PVR can be done with good long term results concerning survival and freedom from reoperations.

Therrien et al. (2000) reported 92% survival at 5 years and 86% at 10 years in 70 adult patients after pulmonary valve replacement. In addition, **Discigil et al. (2001)** reported a 95% survival rate at 5 years and 76% at 10 years in 42 patients. While, **Caldarone et al. (2000)** reported freedom from re-operation in 81% of patients after 5 years, 58% at 10 years, and 41% at 15 years. These authors, as well as many others, have shown that young age at pulmonary valve placement is associated with a higher rate of valve failure and early re-operation.

Conclusion and Recommendations

According to our study surgical pulmonary valve replacement is safe with a good early outcome. Early valve replacement before the development of significant right ventricular dysfunction was associated with low operative mortality.

Our recommendation is doing further studies of both surgical and interventional pulmonary valve replacement with larger sample sizes and longer follow up periods to determine the best option and timing to replace the pulmonary valve.

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