Early outcomes of pulmonary valve replacement after total correction of tetralogy of Fallot

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Introduction
Severe right heart failure with serious consequences may develop after pulmonary regurgitation caused by total correction of tetralogy of Fallot. We performed this thesis to present early outcomes of surgical pulmonary valve replacement (SPVR) in these patients.
Patients and methods
From April 2019 to April 2021, 38 patients, comprising 25 males and 13 females, with a mean age of 15.76 ± 6.24 years, underwent SPVR after 12.63 ± 4.76 years from the first operation. Patients underwent SPVR with either tissue or mechanical valves using the cross-clamp or beating technique. Repair of tricuspid, closure of residual ventricular septal defect, or right ventricle aneurysm resection may be done during the procedure. Follow-up radiograph and transthoracic echocardiography were done after 6 months and 1 year after the procedure. Follow-up cardiac magnetic resonance imaging was done on an average 1 year after the procedure.
Results
Zero mortality was seen in the perioperative period. The mean hospital stay was 6.74 ± 1.08 days. The results of follow-up radiograph, transthoracic echocardiography, and cardiac magnetic resonance demonstrate that after SPVR the right ventricle experiences improvement on its volumes and systolic function.
Conclusion
SPVR seems to be a positive approach and is recommended to be done at the correct time.

Keywords:
pulmonary regurgitation, pulmonary valve replacement, tetralogy of Fallot

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Introduction

Pulmonary regurgitation (PR) is a very common complication after total correction of tetralogy of Fallot (TOF). It accounts for about 50% of repaired TOF patients, and 37% of them will need intervention to correct it [1]. PR is caused by extensive ventriculostomy, infundibulectomy, and also generous transannular patch of the right ventricle (RV) outflow tract [2]. PR is associated with RV enlargement and dysfunction on long terms, so pulmonary valve replacement (PVR) is indicated to prevent permanent dysfunction of RV [3,4].

Aim

This thesis aims to study and determine early outcomes of surgical pulmonary valve replacement (SPVR) after total correction of TOF.

Patients and methods

In this prospective study, 38 patients with moderate to severe PR underwent SPVR in different centers in Egypt. We included totally corrected TOF patients who developed moderate to severe PR with or without tricuspid regurgitation (TR) or residual ventricular septal defect (VSD), and we excluded patients with other cardiac anomalies, pregnant women, and patients with comorbidities such as renal failure, liver failure, or previous stroke. Ethical committee approval of Ain Shams University was obtained. Informed consent from the study participants was taken before operation. The study was performed during the period from April 2019 to April 2021.

Data collection

Preoperatively we collected data about patients such age at the first operation; technique of first operation; age, weight, and height at second operation; preoperative New York Heart Association (NYHA) class; and chest radiograph, transthoracic echocardiography (TTE), and cardiac magnetic resonance (CMR) data.

Intraoperatively, we collected total cardiopulmonary bypass time, cross-clamp time if used, type and size of valve used, need for inotropic support, and associated surgical procedures.

Immediate postoperatively, we collected data regarding duration of ventilation time, ICU stay, hospital stay, major clinical events, perioperative mortality, and first week TTE.

We followed patients after 6 months from operation using chest radiograph and TTE and after 1 year using NYHA class, chest radiograph, TTE, and CMR.

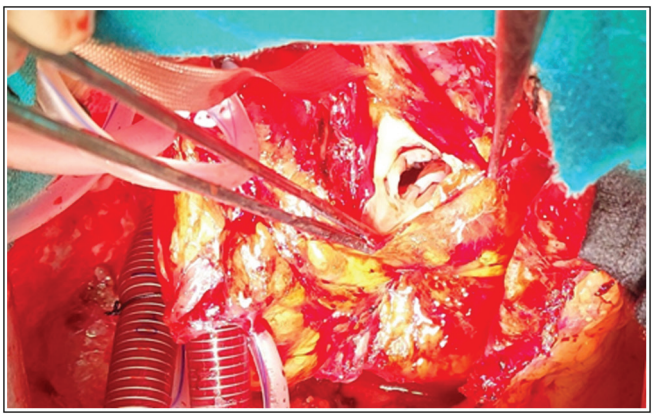
Operative technique

Redo midline sternotomy incision was done using an oscillating saw. Meticulously all adhesions were removed by sharp dissection and electrocautery to achieve a dry field before taking heparin. Standard bicaval to aorta cannulation was done. Cardiopulmonary bypass was then established, and the operation was done using beating heart technique or nonbeating heart according to the case. The main pulmonary artery (MPA) was incised longitudinally and the old patch was excised if we found it. Rudimentary pulmonary leaflets were excised (Fig. 1).

RV aneurysms and remaining subpulmonary muscle bands were resected also. MPA was reconstructed with a large piece of Hemashield patch, where the valve would also be sewn on anteriorly, with the patch covering like a hood the MPA and the newly created right ventricle outflow tract (RVOT) (Fig. 2).

The size of bioprosthetic valve was calculated using body surface area and indexed pulmonary valve area ($2.65 \pm 0.52\ cm^2/m^2$). Then, valve was sutured to the pulmonary annulus with a continuous polypropylene suture technique or using inverting mattress technique in any patient with 2+ or greater TR. The TV was also repaired using various annuloplasty techniques.

Figure 1



Rudimentary pulmonary leaflets.

Data management and analysis

The collected data were revised, coded, tabulated, and introduced to a PC using the Statistical Package for the Social Sciences (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0.; IBM Corp., Armonk, New York, USA). Data were presented, and suitable analysis was done according to the type of data obtained for each parameter.

Descriptive statistics: Shapiro–Wilk's test was used to evaluate normal distribution of continuous data. Mean, SD, and range were used for parametric numerical data, whereas median and interquartile range were used for nonparametric numerical data. Frequency and percentage were used for nonnumerical data.

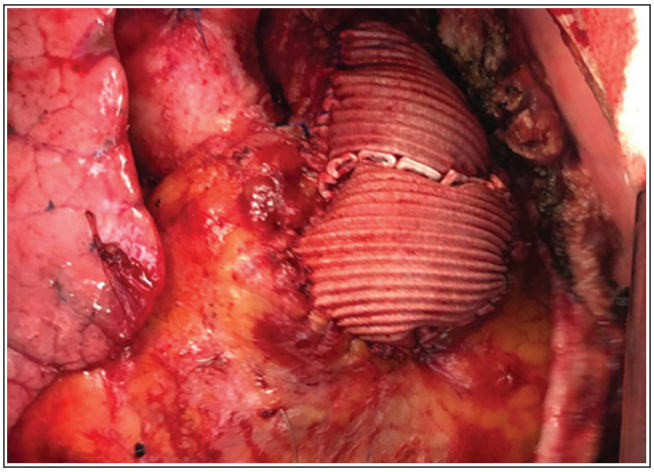
Analytical statistics

Paired *t* test was used to assess the statistical significance of the difference between paired parametric numerical variable. Wilcoxon signed-rank test was used to assess the statistical significance of the difference of a nonparametric numerical or ordinal variable measured twice for the same study group. *P* value was considered significant as follows: *P* value more than 0.05: nonsignificant, *P* value less than 0.05: significant, and *P* value less than 0.01: highly significant.

Results

Between April 2019 and April 2021, 38 patients having history of previous surgical total correction of TOF underwent SPVR. Operations were done in different centers in Egypt such as cardiovascular and thoracic academy of Ain Shams University, Atfal Masr Hospital, 6 October Hospital, and National Heart Institute.

Figure 2



Augmented RVOT and pulmonary artery with patch and PV replaced by tissue valve. PV, pulmonary valve; RVOT, right ventricle outflow tract.

Table 1 shows personal and medical characteristics among study cases:

The mean age at first operation was 3.13 ± 3.21 years, whereas the mean age at the time of PVR was 15.76 ± 6.24 years. Of 38 cases, eight cases were above 20 years old, and the interval between two operations was 12.63 ± 4.76 years. One of our cases was a second redo PVR case. At the time of first repair, the child was 3 years old; at time of first PVR, the child was 9 years old; and at the second PVR, the child was 15 years old. The mean weight at PVR operation was 46.24 ± 15.98 kg, and the mean height was 145.79 ± 16.98 cm. A total of 25 cases were males, whereas 13 cases were female in our sample. A total of four cases on the first operation had made pulmonary valve valvotomy, whereas 34 cases had made transannular patch.

Table 2 shows preoperative clinical assessment, chest radiograph, and TTE data among study cases.

During clinical assessment of patients before operation, one of our cases was NYHA IV, 11 cases were NYHA III, 19 cases were NYHA II, and seven cases were NYHA I. Patients with NYHA I went for operation because of their RVs were progressively dilating. Then mean chest radiograph cardiothoracic ratio was 0.63 ± 0.05. TTE was done before operation. The mean RV size of our patients was 4.05 ± 0.65 cm, and the mean TAPSE was 1.58 ± 0.24 cm. TAPSE was less than 1.5 on 12 cases, in whom their NHYA classification was III and IV. A total of 35 cases had severe PR, and three cases had moderate PR, where two of three cases had residual VSD that required a patch for closure and the third case had residual RVOT obstruction. A total of four cases had severe TR, 12 cases had moderate regurgitation, and 22 cases had mild regurgitation.

Table 3 shows preoperative CMR data among the study cases.

CMR was done before operation to assess EF of RV and RV volumes and amount of PR. The mean right ventricle end diastolic volume indexed (RVEDVI) was 196.16 ± 38.04 ml/m^2, the mean right ventricle end systolic volume indexed (RVESVI) was 102.72 ± 23.84 ml/m^2, the mean RVEF was 47.6 ± 7.16, the mean left ventricle end diastolic volume indexed (LVEDVI) was 87.08 ± 19.37 ml/m^2, the mean RV/LVEDV was 2.27 ± 0.34, the mean left ventricle ejection fraction (LVEF) was 56.24 ± 4.13, and the mean pulmonary regurgitation fraction (PRF) was 45.88 ± 7.31%.

Table 4 shows the description of intraoperative assessment among the study cases.

The mean total bypass time was 73.82 ± 19.10 min. A total of four cases were operated on beating heart, whereas the rest of cases had a mean cross-clamp time of 44.06 ± 10.79 min. A total of 19 cases underwent replacement of PV with prothesis size 21, 12 cases used prothesis size 23, four cases used prothesis size 19, whereas three cases used prothesis size 25. A total of 24 cases used porcine tissue valves (Epic supra valve and Hancock II), 12 cases used bovine tissue

Table 1 Description of personal and medical characteristics among study cases

	Mean±SD/%	Minimum	Maximum
Age at first operation	3.13 ± 3.21	1.00	15.00
Age at second operation	15.76 ± 6.24	5.00	32.00
Time between operations	12.63 ± 4.76	3.00	22.00
Weight	46.24 ± 15.98	20.00	85.00
Height	145.79 ± 16.98	104.00	170.00
Sex			
Male	25 ± 65.8		
Female	13 ± 34.2		
Technique of first operation			
Transannular patch	34 ± 89.5		
Valvotomy	4 ± 10.5		

Table 2 Description of preoperative clinical assessment, chest radiograph, and transthoracic echocardiography data among study cases

	Mean±SD/%
NYHA classification	
I	7 ± 18
II	19 ± 50
III	11 ± 29
IV	1 ± 3
Preoperative cardiothoracic ratio	0.63 ± 0.05
RV size	4.05 ± 0.65
TAPSE	1.58 ± 0.24
PR	
Moderate	3 ± 7.9
Severe	35 ± 92.1
TR	
Mild	22 ± 57.9
Moderate	12 ± 31.6
Severe	4 ± 10.5

PR, pulmonary regurgitation; RV, right ventricle.

Table 3 Preoperative cardiac magnetic resonance data among study cases

	Mean±SD
RVEDVI	196.16 ± 38.04
RVESVI	102.72 ± 23.84
RVEF	47.60 ± 7.16
LVEDVI	87.08 ± 19.37
RV/LVEDV	2.27 ± 0.34
LVEF	56.24 ± 4.13
PRF	45.88 ± 7.31

LVEDVI, left ventricle end diastolic volume indexed; LVEF, left ventricle ejection fraction; PRF, pulmonary regurgitation fraction; RV, right ventricle; RVEDVI, right ventricle end diastolic volume indexed; RVESVI, right ventricle end systolic volume indexed.

valve (LivaNova CROWN PRT and Carpentier-Edwards Perimount valve), whereas two cases used mechanical valve (St. Jude Medical). A total of 21 cases of the total cases needed inotropic support during weaning from CP bypass. Moreover, five cases needed tricuspid repair, where two of them were repaired with an annuloplasty ring and three cases were repaired using DeVega's tricuspid annuloplasty technique. In addition, four cases needed closure of residual VSD, three cases needed closure with patch, and one was closed directly. Of 38 cases, five cases needed RV aneurysm resection.

Table 5 shows the description of immediate postoperative assessment among study cases.

The mean ventilation time was 7.29 ± 3.82 h and the maximum ventilation time was 22. The mean ICU stay was 1.89 ± 0.83 days and the maximum was 4 days. The mean hospital stay was 6.74 ± 1.08 days and the maximum was 10 days. Chest tube drainage on the first postoperative day was 430 ± 182 ml^3 and the maximum drainage was 900 ml^3. There was no need for reopening in our patients. Patients with high drainage were controlled medically. A total of two cases complained of superficial wound infection and were resolved with proper antibiotics. No cases complained of heart block after operation. Overall, three cases complained of RV failure in the ICU, who had an RVEF on CMR of less than 40%. They needed aggressive antifailure treatment and then were discharged later to ward. Perioperative mortality was zero.

Figure 3 shows that patients clinically improved, and the NYHA classification improved from one patient with NYHA IV, 11 patients with NYHA III, 19 patients with NYHA II, and seven patients with NYHA I to three patients with NYHA II and 25 patients NYHA I.

Regarding cardiothoracic ratio, Table 6 shows significant improvement in the cardiothoracic ratio from 0.63 ± 0.05 preoperatively to 0.53 ± 0.03 at 6 months to 0.51 ± 0.03 at 1 year, with *P* value less than 0.0001, being highly significant.

Table 4 Description of intraoperative assessment among study cases

	Mean±SD	Minimum	Maximum
Bypass time	73.82 ± 19.10	50.00	130.00
Cross-clamp time	44.06 ± 10.79	30.00	80.00
Size of prosthesis			
19	4 ± 10.5		
21	19 ± 50		
23	12 ± 31.6		
25	3 ± 7.9		
Type of prosthesis			
Bovine	12 ± 31.6		
Mechanical	2 ± 5.3		
Porcine	24 ± 63.2		
Inotropic support			
No	17 ± 44.7		
Yes	21 ± 55.3		
Associated surgical procedures			
No	24 ± 63.1		
Repair of tricuspid	5 ± 13.2		
Closure of residual VSD	4 ± 10.5		
RV aneurysms resection	5 ± 13.2		

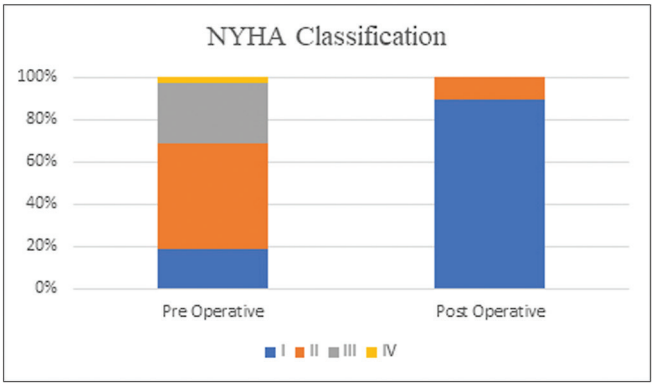
RV, right ventricle; VSD, ventricular septal defect.

Table 5 Description of immediate postoperative assessment among study cases

	Mean±SD/%	Minimum	Maximum
Ventilation time	7.29 ± 3.82	4	22
ICU stay	1.89 ± 0.83	1	4
Hospital stay	6.74 ± 1.08	5.00	10.00
Bleeding drainage on 1st day	430 ± 182	200	900
Infection and wound dehiscence	2 ± 5		
Heart block	0 ± 0		
RV failure	3 ± 8		
Perioperative mortality	0 ± 0		

RV, right ventricle.

Figure 3



Comparison between NYHA classification preoperatively and 1 year postoperatively.

Table 6 Comparison between cardiothoracic ratio on chest radiograph at baseline and at different follow-ups

	Mean±SD	*P**	Significance
Preoperative cardiothoracic ratio	0.63 ± 0.05	0.0001	HS
6-month cardiothoracic ratio	0.53 ± 0.03		
Preoperative cardiothoracic ratio	0.63 ± 0.05	0.0001	HS
1-year cardiothoracic ratio	0.51 ± 0.03		
6-month cardiothoracic ratio	0.53 ± 0.03	0.001	HS
1-year cardiothoracic ratio	0.51 ± 0.03		

*Paired *t* test.

Regarding RV size, Table 7 shows that the RV size significantly improved from 4.05 ± 0.65 to 3.87 ± 0.59 cm postoperatively, with *P* value less than 0.001, to 3.03 ± 0.41 cm at 6-month follow-up echo, with *P* value less than 0.0001, and further improved to 2.91 ± 0.41 cm at 1-year follow-up echo, with *P* value less than 0.0001.

Regarding TAPSE, Table 8 shows that there is a slight decrease in TAPSE from 1.58 ± 0.24 to 1.40 ± 0.27 cm postoperatively and a significant improvement to 1.80 ± 0.19 cm at 6-month follow-up, with *P* value less than 0.001, and to 1.92 ± 0.18 cm at 1-year follow-up, with *P* value less than 0.0001.

Regarding the peak P gradient on pulmonary valve, Fig. 4 shows that the mean peak P gradient postoperatively was 17.39 ± 6.49 and was 22 ± 6.73 mmHg after 6 months and was 25.53 ± 7.05 mmHg after 1 year. Patients in whom the implanted prothesis size was 23 or 25 (15 patients), the mean peak P gradient was 18.53 ± 4.13 mmHg, whereas in whom the implanted prothesis size was 19 or 21 (23 patients), the mean peak P gradient was 30.08 ± 4.19 mmHg.

Table 7 Comparison between right ventricle size at baseline and at different follow-up echo

	Mean±SD	*P**	Significance
RV size	4.05 ± 0.65	0.001	HS
Postoperative RV size	3.87 ± 0.59		
RV size	4.05 ± 0.65	0.0001	HS
6-month RV size	3.03 ± 0.41		
RV size	4.05 ± 0.65	0.0001	HS
1-year RV size	2.91 ± 0.41		
Postoperative RV size	3.87 ± 0.59	0.0001	HS
6-month RV size	3.03 ± 0.41		
Postoperative RV size	3.87 ± 0.59	0.0001	HS
1-year RV size	2.91 ± 0.41		
6-month RV size	3.03 ± 0.41	0.001	HS
1-year RV size	2.91 ± 0.41		

RV, right ventricle.

Table 8 Comparison between TAPSE at baseline and at different follow-ups with echo

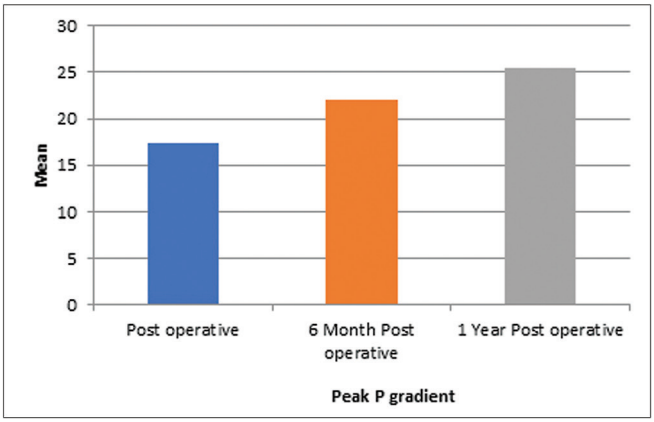
	Mean±SD	*P**	Significance
TAPSE	1.58 ± 0.24	0.0001	HS
Postoperative TAPSE	1.40 ± 0.27		
TAPSE	1.58 ± 0.24	0.001	HS
6-month TAPSE	1.80 ± 0.19		
TAPSE	1.58 ± 0.24	0.0001	HS
1-year TAPSE	1.92 ± 0.18		
Postoperative TAPSE	1.40 ± 0.27	0.0001	HS
6-month TAPSE	1.80 ± 0.19		
Postoperative TAPSE	1.40 ± 0.27	0.0001	HS
1-year TAPSE	1.92 ± 0.18		
6-month TAPSE	1.80 ± 0.19	0.001	HS
1-year TAPSE	1.92 ± 0.18		

*Paired *t* test.

A, B, C (pre vs. immediate post *P*=0.001, pre vs. 6 months *P*=0.001, pre vs. 1 year *P*=0.001, respectively) E, F (immediate post vs. 6 months *P*=0.317, immediate post vs. 1 year *P*=0.08, respectively), and G (6 months vs. 1 year *P*=0.157).

Regarding PR, Table 9 shows that PR improved significantly postoperatively from moderate and severe to no or mild PR.

Figure 4



Comparison between peak P gradient postoperatively and at follow-up echo.

Table 9 Comparison between pulmonary regurgitation at baseline and at different follow-ups with echo

	Pre [A,B,C] [*n* (%)]	Immediate post PR[E, F] [*n* (%)]	6-month post-PR[G] [*n* (%)]	1 year post-PR [*n* (%)]
PR*				
No	0	35 (92.1)	34 (89.5)	32 (84.2)
Mild	0	3 (7.9)	4 (10.5)	6 (15.8)
Moderate	3 (7.9)	0	0	0
Severe	35 (92.1)	0	0	0

PR, pulmonary regurgitation.
*Wilcoxon signed-rank test.
Superscript letters show that PR improved significantly postoperatively from moderate and severe to no or mild PR.

Table 10 Comparison between TR at baseline and at different follow-ups with echo

	Pre [A,B,C] [*n* (%)]	Immediate post TR[E, F] [*n* (%)]	6-month post-TR[G] [*n* (%)]	1 year post-TR [*n* (%)]
TR*				
Mild	22 (57.9)	25 (65.8)	31 (81.6)	35 (92.1)
Moderate	12 (31.6)	13 (34.2)	7 (18.4)	3 (7.9)
Severe	4 (10.5)	0	0	0

*Wilcoxon signed-rank test.
Superscript letters show significant improvement on TR from 16 cases having moderate and severe TR to 13 cases having moderate TR postoperatively to seven cases having moderate TR after 6 months to three cases having moderate TR after 1 year. The patients who had severe TR were repaired during operation, and their TR degree became trivial to mild TR.

Table 11 Comparison between cardiac magnetic resonance parameters at baseline and at follow-up

	Mean±SD	*P*	Significance
Pre-RVEDVI	196.16±38.04	0.0001*	HS
FU RVEDVI	131.36±25.81		
Pre-RVESVI	102.72±23.84	0.0001*	HS
FU RVESVI	61.96±15.22		
Pre-RVEF	47.60±7.16	0.0001*	HS
FU RV EF	52.92±7.21		
Pre-LVEDVI	87.08±19.37	0.0001*	HS
FU LVEDVI	98.04±20.63		
Pre-RV/LVEDV	2.27±0.34	0.0001*	HS
FU RV/LVEDV	1.35±0.19		
Pre-LVEF	56.24±4.13	0.0001*	HS
FU LVEF	61.52±3.98		
Pre-PRF	45.88±7.31	0.0001**	HS
FU PRF	4.16±4.47		

LVEDVI, left ventricle end diastolic volume indexed; LVEF, left ventricle ejection fraction; PRF, pulmonary regurgitation fraction; RV, right ventricle; RVEDVI, right ventricle end diastolic volume indexed; RVESVI, right ventricle end systolic volume indexed.
*Paired *t* test.
**Wilcoxon signed-rank test.

A, B, C (pre vs. immediate post P=0.08, pre vs. 6 months P=0.006., pre vs. 1 year P=0.001, respectively), E, F (immediate post vs. 6 months P=0.014, immediate post vs. 1 year P=0.02, respectively), and G (6 months vs. 1 year P=0.046).

Regarding TR, Table 10 shows significant improvement on TR from 16 cases having moderate and severe TR to 13 cases having moderate TR postoperatively to seven cases having moderate TR after 6 months to three cases having moderate TR after 1 year. The patients who had severe TR were repaired during operation, and their TR degree became trivial to mild TR.

Regarding CMR, Table 11 shows significant improvement on RV and LV function and volumes and reduction on pulmonary valve regurgitation. The mean RVEDVI improved from 196.16±38.04 to 131.36±25.81 ml/m^2 with P value less than 0.0001. The mean RVESVI improved from 102.72±23.84 to 61.96±15.22 ml/m^2, with P value less than 0.0001. The mean RV EF improved from 47.60±7.16 to 52.92±7.21, with P value less than 0.0001. The mean LVEDVI increased from 87.08±19.37 to 98.04±20.63 ml/m^2, with P value less than 0.0001. The mean RV/LVEDV improved from 2.27±0.34 to 1.35±0.19, with P value less than 0.0001. The mean LVEF improved from 56.24±4.13 to 61.52±3.98, with P value less than 0.0001. The mean PRF improved from 45.88±7.31 to 4.16±4.47 with P value less than 0.0001.

Discussion

This literature is investigating SPVR in TOF patients including a heterogenous group of patients of different age groups and different types of prothesis such as tissue or mechanical valves.

We aimed to further investigate this condition focusing on early outcome during the first year after SPVR. We limited restrictions on patients' age to include ages ranging from 5 to 32 years to determine the time of maximum benefit from the procedure. We also included patients who underwent SPVR using metallic or bioprosthetic valves to differentiate between beneficial outcomes of different prostheses. A meticulous approach was used for investigation using chest radiograph and TTE immediate postoperative and follow-up. We further confirmed the results using follow-up CMR. Routine follow-up visits were conducted in the outpatient setting by a consultant every 6 months and were documented and evaluated separately to decrease the risk of bias.

This study was conducted on 38 patients experiencing PR after total correction of TOF who were selected randomly from many cardiac surgery centers in Egypt.

Preoperative assessment

In our study, the mean age at first operation was 3.13±3.21 years, whereas the mean age at the time of PVR was 15.76±6.24 years, and the interval between two operations was 12.63±4.76 years. Our patients made PVR earlier than other studies. Babu-Narayan *et al*. [5] reported that the mean age at PVR was 32 years, and also Vliegen *et al*. [6] reported that the mean age at PVR was 29 years. However, the results were near to our mean age in the study by Quail *et al*. [7] where the mean age at PVR was 19.6 years. Moreover, the study by McKenzie *et al*. [8] reported that the median age was 15.9 years, which was very near to our mean age. The younger mean age in our series may be attributed to earlier tendency to do PVR in our centers to avoid irreversible RV failure.

The mean weight at SPVR in our study was 46.24±15.98 kg and the mean height was 145.79±16.98 cm, whereas the median weight in the study by McKenzie *et al*. [8] was 55.3 kg.

Regarding sex, 65.8% of patients were male. This shows that the male affection is more than female affection. Babu-Narayan *et al*. [5] agreed with us, as males were 58% of total patients, and also Mitropoulos *et al*. [9] reported that males were 72% of total patients.

In our study, 89.5% of patients made a transannular patch on the first operation, whereas 51% made a transannular patch in the study by Babu-Narayan *et al*. [5] and 86% in the study by Quail *et al*. [7]. It means that transannular patch increases the risk for need of PVR later.

Intraoperative assessment

In our study, the mean bypass time was 73.82 ± 19.10 min, four (10.5%) cases were operated on beating heart, whereas in the rest of cases, the mean cross-clamp time was 44.06 ± 10.79 min. In the study by Babu-Narayan *et al*. [5], the mean bypass time mean was 113 ± 59 min, 45% of cases were operated on beating heart, whereas in the rest of cases, the mean cross-clamp time was 42 ± 45 min. However, Mitropoulos *et al*. [9] performed all cases using beating heart with bypass time of 47.5 ± 12 min, meaning that there is general tendency in our centers to operate under usage of cross-clamp, and the cross-clamp time was near to other studies' time.

We included patients who underwent PVR using tissue or mechanical valves. Porcine valves were 63.2%, bovine valves were 31.6%, and mechanical 5.3%. In other studies such as Babu-Narayan *et al*. [5], mechanical valves were not used, and 70% of patients with tissue valves were porcine. So, the usage of porcine tissue valves is preferable among surgeons. However, the study by Dehaki *et al*. [10] used mechanical valves in all cases. They provided long-term outcomes of SPVR with mechanical valves and showed excellent durability and low thrombosis risk when patients were adequately anticoagulated.

Overall, 50% of patients used valve size of 21 in our study, whereas in the study by McKenzie *et al*. [8], the median valve size was 23. There is general tendency to put a bigger valve as possible as to avoid gradient on it during growth of patients.

A total of 21 (55.3%) cases needed inotropic support for weaning from bypass, which is acceptable.

At the time of operation, five (13.2%) cases needed tricuspid repair, four (10.5%) cases needed closure of residual VSD, and five (13.2%) cases needed RV aneurysm resection. In the study by Babu-Narayan and colleagues, 4.5% of cases needed tricuspid repair, and 9% needed closure of VSD. However, in the study by Mitropoulos *et al*. [9], 37% needed RV aneurysm resection, and 36% needed tricuspid repair. The need for additional procedures varies according to the case disease.

Immediate postoperative assessment

Our patients needed mechanical ventilation support for 7.29 ± 3.82 h, whereas in the study by McKenzie *et al*. [8], the median mechanical ventilation was less than 1 day. Patients needed to stay in ICU for about 1.89 ± 0.83 days, which was similar to the needs of patients for ICU stay in the study by McKenzie *et al*. [8]. The mean hospital stay was 6.74 ± 1.08 days. Babu-Narayan *et al*. [5] and Mitropoulos *et al*. [9] reported almost a near mean length of hospital stay of 7 days, which is nearly similar to other procedures. Perioperative mortality was zero in our study. Babu-Narayan *et al*. [5] reported 2% mortality in the first 30 days postoperatively. Mitropoulos *et al*. [9] also reported 2% mortality. This indicates that this procedure is a low-risk procedure. However, in one of our cases during sternotomy and freeing RVOT patch that was heavily calcific and attached to sternum, a tear occurred in the patch indicating the use of femorofemoral canulation, and SPVR was done without using a cross-clamp. The patient is fine with good health till now from this situation. We learned that we must review computed tomography chest of patients carefully before operation and take all precautions if there is a risk of bleeding during sternotomy.

Postoperative follow-up studies

NYHA classification

Significant improvement in NYHA status was noticed in our patients, where only three patients become NYHA II and rest of patients became NYHA I. Moreover, Mitropoulos *et al*. [9] and meta-analysis by Ferraz Cavalcanti *et al*. [11] noticed this significant improvement in NHYA status.

Chest radiograph

In our study, we used chest radiograph to follow-up patients calculating cardiothoracic ratio every 6 months. We found significant improvement on cardio thoracic ratio from 0.63 ± 0.05 preoperatively to 0.53 ± 0.03 on 6 months to 0.51 ± 0.03 on 1 year, with *P* value of 0.0001. Chest radiograph is a cheap, fast, and accessible utility, which is a good indicator for improvement of cardiomegaly caused by RV dilatation.

Echocardiography

RV size: we compared RV size across follow-up echo immediate postoperative and every 6 months. We noticed an improvement from 4.05 ± 0.65 to 3.87 ± 0.59 cm postoperatively and further improvement to 3.03 ± 0.41 cm on 6-month follow-up echo and to 2.91 ± 0.41 cm on 1-year follow-up echo. Mitropoulos *et al*. [9] reported an improvement on RV size from 3.75 ± 0.028 to 3.09 ± 0.28 cm postoperatively, and also Yim *et al*. [12] reported an improvement on mid-term follow-up on RV size from 4.4 ± 1.3 to 2.6 ± 1.2 cm. So, it is obvious that RV size reduced markedly after SPVR.

TAPSE: we noticed a slight drop of TAPSE from 1.58 ± 0.24 to 1.40 ± 0.27 cm immediately postoperatively, which then significant improvement to 1.80 ± 0.19 cm on 6-month follow-up and to 1.92 ± 0.18 cm on 1-year follow-up. In the study by Mitropoulos and colleagues, TAPSE improved

from 1.46 ± 0.05 to 1.7 ± 0.1 cm. Yim *et al*. [12] also reported an improvement of TAPSE from 1.6 ± 2.5 to 1.71 ± 0.3 cm. On the contrary, Selly *et al*. [13] reported that TAPSE decreased from 1.72 ± 0.29 to 1.62 ± 0.29 cm after surgery, but they recommended to use real-time 3D echocardiography to measure RVEF as they found an improvement on RVEF from 40.2 ± 10.3 to 44.1 ± 11.4 postoperatively, which correlated to the improvement they found on CMR. So, it is clear that the function of RV improves by time, and usage of 3D TTE will show this to us.

Pressure gradient on pulmonary valve

There is a slight increase on pressure gradient through newly replaced pulmonary valve by time on first year. P gradient postoperatively was 17.39 ± 6.49 and was 22 ± 6.73 mmHg after 6 months and was 25.53 ± 7.05 mmHg after 1 year. Bokma *et al*. [14] reported on early follow-up for pressure gradient on valve was 17 ± 9 mmHg. This is an acceptable value but needs long-term follow-up to see durability of types of valves and risk of valve thrombosis on mechanical valves. One of our cases was second redo PVR, where pressure gradient was 70 mmHg. This was 6 years from first PVR, so long-term follow-up is needed to see durability of tissue valves on pulmonary position.

Pulmonary valve regurgitation

There is significant improvement to PR from moderate and severe to no or mild PR through our follow-up echo on 6 months and 1 year. Mitropoulos *et al*. [9] reported only 11% of cases developed mild PR and rest of cases had no PR on follow-up.

Tricuspid valve regurgitation

In our study, we noticed there was a significant improvement on TR from 16 cases having moderate and severe TR to 13 cases having moderate TR immediately postoperatively to seven cases having moderate TR after 6 months to three cases having moderate TR after 1 year. Mitropoulos *et al*. [9] and Bokma *et al*. [14] also reported a significant improvement on TR after usage of proper technique for tricuspid repair if needed.

Cardiac magnetic resonance imaging

CMR is essential for evaluation of RV function preoperatively and postoperatively. In our study, the mean RVEDVI improved from 196.16 ± 38.04 to 131.36 ± 25.81 ml/m^2. In the study by Vliegen *et al*. [6], the mean RVEDVI improved from 166.8 ± 40.3 to 114.3 ± 35.0 ml/m^2, and in the study by Selly *et al*. [13], the mean RVEDVI improved from 152.1 ± 38.5 to 111.7 ± 31.7 ml/m^2.

The mean RVESVI decreased from 102.72 ± 23.84 to 61.96 ± 15.22 ml/m^2. In the study by Vliegen *et al*. [6], it decreased from 99.0 ± 35.9 to 66.3 ± 35.2 ml/m^2, and in the study by Selly *et al*. [13], it decreased from 91.6 ± 32.5 to 66.2 ± 27.6 ml/m^2.

In our study, the mean RVEF improved from 47.60 ± 7.16 to 52.92 ± 7.21, which is near to the improvement in the study by Selly *et al*. [13], where the mean RVEF increased from 41.1 ± 12.5 to 44.4 ± 10.3, and also in the study by Vliegen *et al*. [6], there is a slight improvement in the mean RVEF from 41.7 ± 9.7 to 42.1 ± 11.1.

We found that the mean LVEDVI increased from 87.08 ± 19.37 to 98.04 ± 20.63 ml/m^2, which is very near to the results of Bokma *et al*. [14], as LVEDVI increased significantly from 89 ± 22 to 98 ± 22 ml/m^2, but the study by Vliegen *et al*. [6] mentioned no significant change in LVEDVI.

In our study, the mean RV/LVEDV decreased from 2.27 ± 0.34 to 1.35 ± 0.19. In the study by Frigiola *et al*. [15], it also decreased from 2.2 ± 0.5 to 1.4 ± 0.5. The meta-analysis by Ferraz Cavalcanti *et al*. [11] showed significant reduction after PVR, indicating significant improvement of RV volumes.

The mean LVEF improved from 56.24 ± 4.13 to 61.52 ± 3.98. In the study by Bokma *et al*. [14], the mean LVEF increased from 51 ± 11 to 53 ± 9, and also the meta-analysis by Ferraz Cavalcanti *et al*. [11] confirms there is an improvement on LVEF after PVR, and this confirms the interventricular interaction.

The mean PRF improved significantly from 45.88 ± 7.31 to 4.16 ± 4.47, as mentioned also by the studies by Vliegen *et al*. [6], Bokma *et al*. [14], and meta-analysis by Ferraz Cavalcanti *et al*. [11].

CMR shows improvement on RV volumes and systolic function and also cleared to us that LV improves with the improvement of RV. So, CMR is a mandatory tool for long-term follow-up of TOF patients.

The study limitations and shortcomings

This study had some limitations like the small number of patients, high cost of serial follow-up investigations, and short period of postoperative follow-up of nearly 1 year, which does not present the durability of various types of valves, need for redo PVR, and long-term mortality.

Conclusions

SPVR after total correction of TOF has been associated with low operative risk with perioperative zero mortality,

significant decreases in RV volumes, and significant improvement on RV and LVEF. However, choosing the timing for PVR is very important, so as not to be very early to expose patients to multiple operations and not very late that impairments of RV are irreversible.

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Conflicts of interest
No conflict of interest.

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