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The Legenda in Tetralogy of Fallot Repair: Better Short and Mid-term Outcomes

Ahmed Al-Gebaly[1*], **Rania Aboushokka**[2], **Hanan Mohammed**[3] **and Yahia Mahmoud**[4]

[1]*Department of Cardiac Surgery, National Heart Institute (NHI), Giza, Egypt*

[2]*Department of Cardiology, National Heart Institute (NHI), Giza, Egypt*

[3]*Department of Pediatrics, National Heart Institute (NHI), Giza, Egypt*

[4]*Department of Anesthesiology, National Heart Institute (NHI), Giza, Egypt*

[*]**Corresponding author:** Ahmed Al-Gebaly, Department of Cardiac Surgery, National Heart Institute (NHI), Giza, Egypt, Tel: +20223107396; E-mail: ahmadalgebaly@hotmail.com

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Abstract

Aim of the study: To detect the early and mid-term outcome of pulmonary valve sparing technique used with the trans-annular patch implantation in tetralogy of Fallot repair.

Introduction: Since more than half a century, after the successful repair of tetralogy of Fallot, the pulmonary insufficiency became the determinant of long-term outcome regarding: RV function, need for pulmonary valve replacement and post-operative arrythmia. Pulmonary valve sparing (PVS) at the expense of avoidance of trans-annular valve was associated with residual pressure gradient across RVOT.

Patients and methods: A retrospective study done Between Jan 2013 and Jan 2017; on a group of patients diagnosed as Tetralogy of Fallot with Hypoplastic pulmonary annulus (defined as pulmonary valve annulus Z value ≤-3). Those patients were submitted to surgical repair with trans-annular patch to relief the Right Ventricle. There were 33 patients had received a modified pulmonary valve sparing technique and the rest were operated by classic trans-annular patch. The Pressure gradient (PG) across the Right ventricle outflow tract (RVOT) were calculated directly and with Epicardial Echocardiography in the operating room then follow up echo on postoperative outpatients' visits. The Pulmonary Regurgitation was graded by the echocardiographer as (0-3).

Results: In (PVS) group was 23 male and 10 females; and for the control group there were 32 male and 16 females (p-Value: 0.7). The Mean age for Case group were (10.17 ± 2.59) Months and for the control group (10.21 ± 2.89) Months, (p-value: 0.94).

All patients in (PVS) group had pulmonary commissurotomy and anterior release to the pulmonary annulus, follow up Echocardiography for the RVOT gradient revealed; the mean gradient for the case group was 16.00 ± 3.39 and for the control group 14.35 ± 4.51; (p-Value: 0.07).

Evaluation of Pulmonary regurgitation revealed; in the case group 3 had no to trivial, 16 had mild, 14 had mod and no patient had severe pulmonary regurgitation. In contrary to the control group who had 1 patient had mild, 35 patients had mod and 12 patients had severe, (p-Value: <0.0001).

Conclusion: Pulmonary valve sparing techniques include multiple strategies all of them aim to spare the integrity of the pulmonary valve. Adding annular release and transannular patch overcome the fixed part of the Right ventricular outflow. The net result is potentially competent valve with the least gradient.

Keywords: Tetralogy of fallot; Pulmonary insufficiency; Arrythmia

Introduction

Half a century and more since the early reports of surgical repair of tetralogy of Fallot [1,2]. The original concepts were closure of the ventricular septal defect and relief of right ventricular outflow tract obstruction. In the illustrative article done by Sir Lillehei he described direct closure of the VSD, wide opening of the RV and punch excision of the obstructing muscle bundle [1]. Four decades of continuous work on modification of tetralogy of Fallot repair and accompanied that more understanding of the sequalae of the classic repair [3]. At a time, the repair of Fallot was considered rather a palliative surgery, these considerations came after the 2 drawbacks of classic repair of Fallot had established; pulmonary regurgitation with progressive RV remodeling and residual right ventricular outflow obstruction [4-7].

The surgeons were in confusion between complete relief of RVOT obstruction by insertion of trans-annular patch and preserving the pulmonary annulus with some potentials of residual gradient [8-10]. In one of the outstanding technical modification of Fallot repair that invented by a group from Shizouka children hospital; in their

modification they combined transannular patch with valve sparing [11].

This was followed one year later by work done by Vladimiro L Vida et al. as they continued modifications of annular sparing strategies [12].

Patients and Methods

Patients selection

A retrospective study done Between January 2013 and January 2017 there were 81 patients in the pediatric age group (between 3 months-12 years), who were diagnosed as tetralogy of Fallot with hypoplastic pulmonary annulus (defined as pulmonary valve annulus z-value ≤ -3), had been submitted to surgical repair with trans-annular patch to relief the right ventricle [13-16].

33 patients had received our modified pulmonary valve sparing technique by the same surgeon. The rest of patients were operated with the classic trans-annular patch by other surgeons. The pressure gradient across the right ventricular outflow tract was calculated directly and with epicardial echocardiography.

Demographic data included: age (in months), weight (in kg), height (in cm), body surface area (in m2) and gender distribution. Follow-up echo was done at 6 months post- operative by three dedicated pediatric echocardiographers.

Pulmonary regurgitation was graded as: non-trivial, mild, moderate and severe (0-3). The pulmonary regurgitation was quantitatively evaluated at the post-operative 6 months follow-up echocardiography and graded by the echocardiographer from grade 0 to 3 [17].

Surgical procedures

All patients were pre-medicated with midazolam 0.5 mg/kg orally 15 minutes before transfer to the operating room (OR). On arrival to OR 5-leads electrocardiogram (ECG) and pulse oximeter were connected to the patients and continuously displayed on the monitor (Drager Infinity Kappa, Denvers, USA). The patients received sevoflorane 1% in 2 litre oxygen while inserting peripheral intravascular cannula and an arterial line if possible. Induction of anaesthesia consisted of 2% sevoflurane in 80% oxygen, fentanyl 5 ug/kg and pancuronium 0.1 ug/kg to facilitate endotracheal intubation. After intubation the patients were connected to the anaesthesia machine (Drager Primus, Lubeck, Germany). Patients were ventilated with 60% inspired oxygen in air before cardiopulmonary (CPB) and 80% after bypass. Anaesthesia was maintained by 1% isoflurane in oxygen-air mixture and 1 ug/kg fentanyl every 30 minutes before and after CPB, and during CPB with midazolam 0.1 mg/kg and 1% isoflurane.

Through midline sternotomy, the pericardial cavity was entered after partial thymectomy. A large piece of pericardium was harvested and treated with 2% glutaraldehyde for 5 minutes. The ascending aorta, proximal arch, the root of the neck vessels and both pulmonary artery and its branches were dissected to full mobilization. After going on bypass, a state of moderate hypothermia is maintained during a state of cardioplegic arrest. The state of cardioplegic arrest was achieved by a single dose of Custidiol. The dose is effective for three hours of continuous cardioplegic arrest. The right atrium was entered 0.5-1 cm parallel to the atrioventricular groove starting from the base of right atrial appendage and ending just anterior to the IVC right atrial junction. The internal cardiac structures were evaluated including the degree of over-riding, the morphology of VSD and the right ventricular outflow obstruction. The resection of the obstructing muscle bands was mainly done through the right atrium. The VSD was closed in all patients through the right atrium using a patch of 0.6 mm polytetrafluoroethylene patch. The stage of RVOT reconstruction was done by two techniques, the first was described as group I in which: the main pulmonary artery was opened longitudinally till the pulmonary annulus, then a right-angle clamp had passed through the valve to just below the annulus.

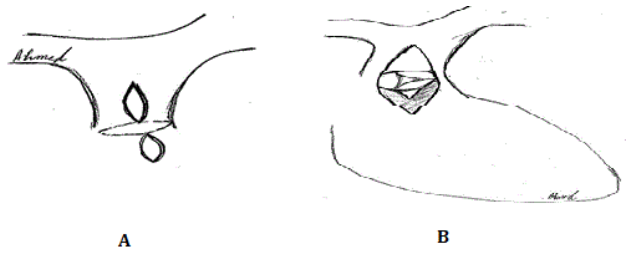

Figure 1: A. this shows the pulmonary arteriotomy and sub-annular right ventriculotomy, B: this shows the anterior annular release and intact valve.

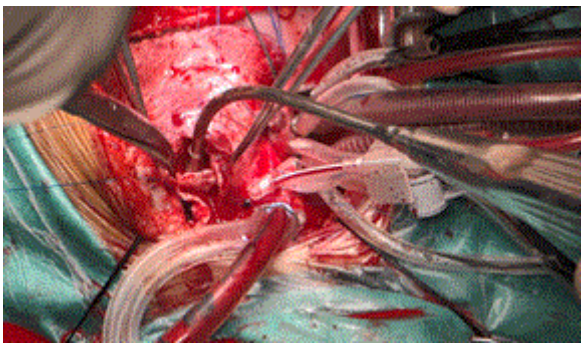

Figure 2: This intraoperative photo of supra-annular pulmonary arteriotomy and anterior annular release and sub-annular right ventriculotomy.

The RVOT is opened to a maximum 1 cm downwards as shown in Figures 1 and 2. The pulmonary annulus is released from the pulmonary trunk in a process called anterior release till the lateral wall of the pulmonary trunk. The pathway from the RVOT was thoroughly evaluated for any residual obstruction which was released. According to the predicted annular size, a trans-annular patch was prepared and sized. The starting point of the sutures was at the distal pulmonary end to permit later completion of the trans-annular patch with beating heart. When reaching the pulmonary valve area, the commissurotomy was done on all commissures of the pulmonary valve. In a subgroup of patients, we suspended the anterior pulmonary annulus to the reconstructed RVOT patch. This process decreased the pulmonary regurge as shown in Figure 3.

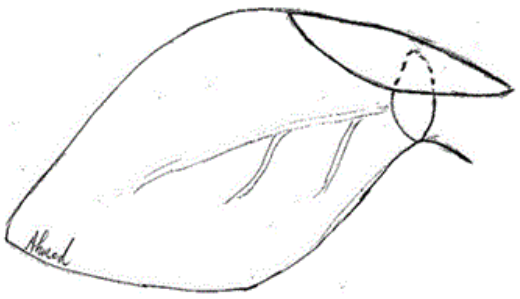

Figure 3: This shows the (TAP.PVS) and the valve without re-suspension.

In group II, the tetralogy of Fallot was repaired by the classic trans-annular patch and trans-atrial closure of VSD. After weaning of the bypass and removal of the cannula, pressures were obtained from cardiac chambers and were correlated to the hemodynamic state as well as the epicardial echocardiographic findings.

Statistical analysis

Statistical analysis of the obtained data was performed in SPSS version 17, variables were checked for distribution of normality, using: a) normal plots, b) Kolmogorov Smirnov tests and c) Shapiro Wilks tests. The data were presented as numbers and percentages for the qualitative data. Means, standard deviations and ranges for the quantitative data with parametric distribution and median with interquartile ranges (IQR) for the quantitative data with non-parametric distribution. Chi-square test was used for the comparison between two groups with qualitative data and Fisher exact test was used instead of the Chi-square test when the expected count in any call was found to be less than 5.

Independent t-test was used for the comparison between two groups with quantitative data and parametric distribution, while Mann-Whitney's test was used for the comparison between two groups with quantitative data and non-parametric distribution. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant when less than 0.05.

Results

This cohort study was done on 81 patients diagnosed as Tetralogy of Fallot with hypoplastic pulmonary annulus, they were categorized into two groups according to the technique of trans-annular patch insertion the group one in whom patients received trans-annular patch with pulmonary valve sparing technique and re-suspension of the valve and group two in whom the patients received classic trans-annular patch repair. In group one there were 23 male and 10 females while in group two there were 32 males and 16 females, there was no statistical difference among the studied groups regarding gender distribution, p value was 0.7.

The range was 4-42 months while in group (TAP), the range was 5-96 months. There was no statistical difference among the studied groups regarding age distribution, P value was 0.98. This data is summarized in Table 1.

Variable	Group I (n=33)		Group II (n=48)		test	p
Age (months)					MW 790.5	0.988 NS
-Median -Range	10 4-42		10 5-96			
BSA (m2)					MW 632.5	0.123 NS
-Median -Range	0.37 0.31 – 0.54		0.36 0.29 – 0.80			
	N	**%**	**N**	**%**	**χ2**	**P**
Gender					0.082	0.774
Male Female	23 10	70 30	32 16	67 33		
BSA: Body Surface Area						

Table 1: Comparison of demographic data of the studied group cases and control.

The range was 0.31-0.54 M2 while in group (TAP), the range was 0.29-0.80 M2. There was no statistical difference among the studied groups regarding gender distribution, P value was 0.12.

The preoperative echocardiographic analysis of the pulmonary annulus and the RVOT pressure gradient is summarized in Table 2.

Variable	Group I (n=33)	Group II (n=48)	test	p

RVOT-GR- (mmHg)			MW 790.5	0.988 NS
-Median -Range	70 55-85	75 65-85		
P-Z value			t-test -0.509	0.612 NS
-Mean ± SD -Median -Range	-4.481 ± 0.467 -4.51 -5.32-3.20	-4.433 ± 0.375 -4.45 -5.12-3.42		
RVOT-GR: Right Ventricular Outflow Gradient				

Table 2: Comparison of preoperative Echo data of the studied groups cases and control.

Variable	**Group I (n=33)**		**Group II (n=48)**		**test**	**p**
AXC Time (min)					MW 271.5	0.000 **
-Median -Range	70 55-90		60 55-80			
CPB (min)					MW 937.5	0.158 NS
-Median -Range	98 85-112		100 80-115			
ICU/Hrs.					MW 592.5	0.052 NS
-Median -Range	72 69-78		70 (68- 78			
Mortality	**NO**	**%**	**NO**	**%**		
No Yes	33	100	47	98	0.696	0.404 NS
	0	0	1	2		
AXC: Aortic Cross Clamping CPB: Cardiopulmonary Bypass Time ** highly significant						

Table 3: Comparison of input and output data of the studied groups cases and control.

The intraoperative data of both groups are summarized in Table 3 and it showed a statistical difference in Aortic cross clamp time among both groups, P value was <0.001 and there was no statistical difference among the studied groups regarding total bypass time, P value was 0.158.

The Post bypass quality control of our repair included intra-cardiac monitoring of RVOT pressure gradient, RV/LV ratio, also epicardial echocardiographic evaluation of the RVOT and the pulmonary valve and the results are summarized in Table 4.

Variable	**Group I (n=33)**	**Group II (n=48)**	**test**	**p**
Direc-GR			MW 816	0.800 NS
-Median -Range	5 0 -30	5 0-30		
RV-LV			MW 853	0.554 NS
-Median	0.412	0.428		

-Range	0.33-0.58	.03-0.53		
Echo-post-Gr			MW 631.5	0.106 NS
-Median -Range	15 10-30	15 5-23		
Direc-GR: Direct Intracardiac Pressure Reading of RVOT-GR RV/LV ratio: Right Ventricle to Left Ventricle Pressure Ratio Echo-Post-Gr: Postoperative Echo RVOT-GR				

Table 4: Comparison of Echo data of the studied groups cases and control.

Variable	**Group I (n=33)**		**Group II (n=48)**		**test**	**p**
ICU/Hrs.					MW 592.5	0.052 NS
-Median -Range	72 69-78		70 68 -(-78)			
Mortality	**NO**	**%**	**NO**	**%**		
No	33	100	47	98	0.696	0.404 NS
Yes	0	0	1	2		

Table 5: Comparison of postoperative short-term outcome data of the studied groups cases and control.

The postoperative outcome showed no statistical difference among both groups regarding the ICU stay time as the P value was 0.052. There was no statistical difference in mortality on both groups as the p value was 0.404; the detailed results are summarized in Table 5.

The serial echocardiographic evaluation of those patient revealed that; in group (TAP-PVS) group there were 11 patients who have no-trivial pulmonary regurgitation, 17 patients who have mild pulmonary regurgitation, 5 patients who have moderate pulmonary regurgitation and no patient have severe pulmonary regurgitation; in contrary to group two who submitted to classic trans-annular patch repair (TAP), there were no patient who have (no-trivial) pulmonary regurgitation, 1 patients who have mild pulmonary regurgitation, 35 patients who have moderate pulmonary regurgitation and 12 patients have severe pulmonary regurgitation; there was a significant statistical difference among both groups as the P value was <0.001. These data are illustrated in Table 6 and Figure 4.

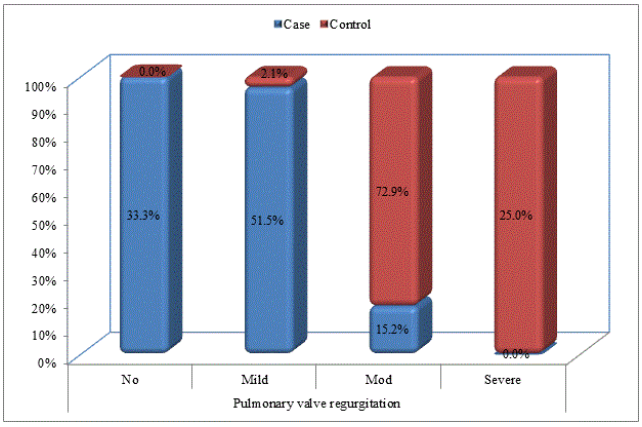

Figure 4: Bar chart between case and control according to pulmonary valve regurgitation.

Pulmonary valve regurgitation	**Case**		**Control**		**Total**		**Chi-square test**	
	No.	**%**	**No.**	**%**	**No.**	**%**		
No	11	33.3%	0	0.0%	11	13.6%	58.967	<0.001**
Mild	17	51.5%	1	2.1%	18	22.2%		

Mod	5	15.2%	35	72.9%	40	49.4%		
Severe	0	0.0%	12	25.0%	12	14.8%		
Total	33	100.0%	48	100.0%	81	100.0%		
**Highly Significant This table shows statistically significant difference between case and control according to pulmonary valve regurgitation.								

Table 6: Comparison between case and control according to pulmonary valve regurgitation.

Follow up Transthoracic Echocardiographic evaluation were done in outpatient follow up clinic at serial checkup revealed insignificant RVOT gradient and PR as shown in Figure 5.

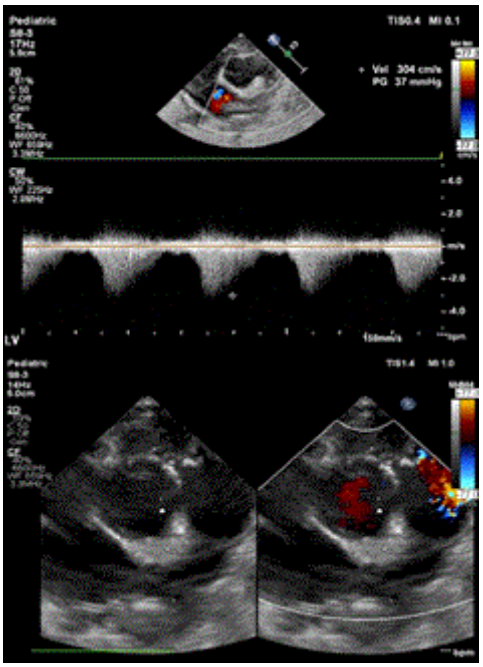

Figure 5: Transthoracic echocardiography of ROVOT in a patient submitted to TOF repair with (TAP/PVS).

Kaplan-Meier survival curves in mid-term follow up for occurrence of significant pulmonary regurgitation. There was highly statistically significant difference among the two survival curves (Log-rank chi-squared=32.961, p-value ≤ 0.001 HS) (Figure 6).

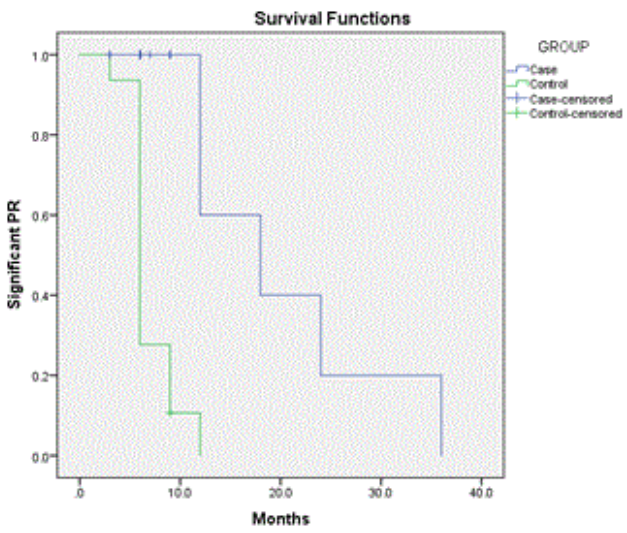

Figure 6: Kaplan-Meier survival curves in short term follow up of occurrence of Significant pulmonary regurgitation in 11 cases & the median time for significant PR in (TOF-TAP/PVS) was 18 months vs. 6 months in (TOF-TAP). There was highly statistically significant difference among the two survival curves (Log-rank chi-squared=48.8, p-value ≤ 0.001 HS).

Discussion

The repair of tetralogy of Fallot was considered tell the early years of this new century as a palliative surgery as the classic repair is associated with two detrimental drawbacks the PR and RVOTO [18-20]. Evolving techniques in TAP/PVS had erupted especially in this decade [21].

in the study done by Takaya Hoashi, et al. [22] on 222 patients who had tetralogy of Fallot, 84(37%) had annular preservation without ventriculotomy. 5-year freedom from moderate or greater pulmonary regurgitation was 50%, RV/LV pressure ratio after CPB, Mean, SD 0.56 ± 0.15, Range 0.22-0.92. in our study we were able to obtain a lesser RV/LV ratio among most of our studied patients in the sitting with acceptable integrity of pulmonary competence.

in a study done by Robert D. Stewart, et al. [23] on 102 patients who had tetralogy of Fallot repair they were able to do pulmonary valve sparing in 82 patients. The mean age in PVS group was 9.4 ± 19 and in trans-annular patch group was 11 ± 8.4 the mean BSA in both groups were 0.35 ± 0.15 and 0.36 ± 0.11 respectively. The mean pulmonary

annulus z-score -1.7 ± 1.2 -4.8 ± 1.7 in both groups. The postoperative results in both groups the mean p RV/LV 0.53 ± 0.13 0.56 ± 0.11

In PVS and TAP groups respectively, the incidence of significant PR in PVS group was 15% and in TAP group was 70% in comparison to our study we ensured a good relief of the constricting part of the RVOT which is an integral part of the F4 morphology, hence our group of patients who had TAP/PVS obtained a lesser RV/LV ratio

Two studies of PVS that are landmark in this era are; one from Vladimiro L. Vida, et al. [12] and Hiroki Ito, et al. [11].

In Vida et al. 69 patients who underwent early trans-atrial TOF repair were enrolled in the study. The patients were divided into 2 groups: PV preservation by PV annulus balloon dilation (group 1) and PV cusp reconstruction after annular incision (group 2).

In our study we considered that precise use of fine surgical instruments to reconstruct and enlarge the annulus is better than the use of inflating balloons which carries a higher risk for incompetence of the pulmonary valve. In their study the Median follow-up time was 580 days which allowed better evaluation of their repair.

While in our study no patient required redo surgery for significant RVOTO in Vida, et, al Two patients were re-operated for residual right ventricular outflow tract (RVOT) obstruction (1 in group 1 and 1 in group 2).

As we mentioned before that fine surgical reconstruction offer better handling of the pulmonary valve and annulus so less distortion of the morphology of the pulmonary leaflets in the same time opening the annulus relief the fixed element in the RVOT. When we compared our results regarding the postoperative RVOT gradient we had better results as in their series them median peak RVOT gradient was 25 mm Hg (range, 8-60 mm Hg). The degree of PV regurgitation in group 1 was none/mild in 24 patients (80%) and moderate in 6 (20%) and was none/mild in 8 patients (25%), moderate in 11 (34.4%), and severe in 13 (28.6%) in group 2 (P ¼ .001).

While in Ito, et, al Sixty-eight consecutive patients who underwent complete repair of a tetralogy of Fallot in whom There were 19 (28%) patients with a pulmonary (z-score <-4)

They were able of Valve preserving in 11 of 19 (58%) of the z <-4 group, while we had a higher limit in the pulmonary valve Z score this may be related to our new experience in this TAP/PVS strategies.

They were able to avoid trans-annular patch in 98% of subgroup of patients who had z value >-4. In this subgroup, residual right ventricular outflow tract velocity was 2.4 ± 0.6 m/s at discharge from the hospital. During a mean follow-up of 2.6 ± 2.4 years, no re-intervention was necessary. Late right ventricular outflow tract velocity was 2.2 ± 0.6 m/s, and there was no severe pulmonary regurgitation. Similar to our results the presence of severe PR was nil in the group 2 who had TAP/PVS.

Limitations

This study is a single surgeon experience with this new modality of tetralogy of Fallot repair combining TAP and PVS, this may need to be evaluated with a larger study to denote if this procedure is reproducible or not. This short-term follow up was optimistic regarding the competency of the new pulmonary root complex those results will be more prognostic if longer periods in another study.

Conclusion

Pulmonary insufficiency begets more pulmonary insufficiency, when we keep the integrity of the pulmonary leaflets; we have the potentials of growth and development of the pulmonary valve. In the classic form of Fallot releasing the fixed part ensure low postoperative pressure gradient across the RVOT. The evolving techniques for PVS offers the potentials for better short, mid and long-term outcomes.

Conflict of Interest

We have no disclosures, no refunds or personal interest direct or indirect for this research.

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