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STUDY OF SERIAL CHANGES IN RIGHT VENTRICULAR OUTFLOW TRACT GRADIENT IN IMMEDIATE & EARLY POST-OPERATIVE PERIOD AFTER TETRALOGY OF FALLOT REPAIR

Cardiothoracis

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ABSTRACT

Aim: To evaluate the changes in Right ventricle outflow tract residual gradient in the Immediate & early postoperative period following Intracardiac repair for Tetralogy of Fallot (ToF). **Methods:** An observational study was conducted in the Department of CTVS at ABVIMS & Dr. RML Hospital, New Delhi from April 2023 to Sept 2024. The inclusion criteria were patient of weight >6kg with a confirmed diagnosis of ToF who underwent intracardiac repair. Patient who underwent intracardiac repair with other cardiac procedure, re-exploration, and those <6kg were excluded. Total 50 patients with preoperative diagnosis of ToF were included. Right ventricular outflow tract (RVOT) gradients were measured intraoperatively post-cardiopulmonary bypass and compared with measurements taken post-operatively using echocardiography. Paired t-test were used for statistical comparison with $p<0.05$ as level of significance. **Results:** The mean age was 7.8 years, there were 30 males. The mean preoperative RVOT gradient was 85.93 mmHg. The mean intraoperative RVOT gradient was 32.6±2.3 mmHg, which decreased to 27.7 ±3.1 mmHg post-operatively. The decrease was statistically significant ($p<0.0001$). The mean cardiopulmonary bypass time was 118.98 minutes. **Conclusion:** In conclusion, there was a significant reduction in RVOT gradients in the early postoperative period following intracardiac repair for ToF on serial monitoring.

KEYWORDS

right ventricular outflow tract, tetralogy of Fallot, intracardiac repair

INTRODUCTION

Tetralogy of Fallot (ToF) is the most frequent cause of cyanotic heart disease, accounting for 3%-5% of all congenital heart diseases, and has an incidence of 0.28-0.34 per 1000 live births.[1]

Pathophysiologically, it is characterized by deviation of infundibular septum anteriorly and in the cephalad direction which causes obstruction of the right ventricular outflow tract (RVOT).[2] This was first described by Arthur Fallot in 1888.[3] It primarily occurs during development of the heart wherein there is failure of fusion of infundibular septum with the ventricular septum resulting in a defect in the ventricular septum. Moreover along with this there is overriding of the aorta and crowding of the RVOT, and secondary right ventricular hypertrophy into pulmonary stenosis.[2]

The identification and surgery remains the key to the management of the patients. Surgical approach has come a long way which involves palliation in the initial stages by creating an arterial shunt systemic to pulmonary with secondaries involving primary repair.[4]

Among the surgeries, first successful operation was performed in 1950 by Kirklin et al with the use of pump oxygenator.[5] Over the period of decades, it has improved resulting in longer outcomes and survival rates of the patients. However, despite surgery the obstruction may not be completely cured and residual cardiac lesion may remain.[2]

A definitive gradient in the form of RVOT gradient has been used a measurable tool to determine the obstruction to the RVOT. Studies continue to determine the cut-off levels which may be achieved during the intraoperative stage and in the postoperative stage.[1,2,6]

It has been seen that <30 mm Hg of RVOT in the postoperative stage after weaning from cardiopulmonary bypass (CPB) can be a good cut-off indicator and reinstitution of CPB has been advised if the pressure ratio (pRV/pLV) is more than 75% and the residual RVOT intraoperative is >40 mm Hg. But still a gap remains in between these two readings where decision may have an enigma but follow-up studies recently have shown that there is further decline in RVOT gradient in the postoperative stage as compared to intraoperative stage and thus patients may not need reinstitution of CPB, which may allow decrease in the CPB time and complications associated with it.[1,2]

Not many Indian studies have been conducted in this regard. Thus, the present study was conducted to assess the improvement in the RVOT gradient as compared to the baseline preoperative stage in the intraoperative stage and in the postoperative stage.

METHODS

An observational study was conducted in the Department of CTVS at ABVIMS & Dr. RML Hospital, New Delhi from April 2023 to Sept 2024. The inclusion criteria were patient of weight >6kg with a confirmed diagnosis of ToF who underwent intracardiac repair. Patient who underwent Intracardiac repair with other cardiac procedure, re-exploration, and those <6kg were excluded. Patients were informed about the study and a written informed consent was obtained before enrolling them in the study.

Sample Size

Based on study of Toshkhani D et al [7] who observed that mean RVOT gradient on TTE was 12.53±7.11 mmHg pre-operatively and 9.23±4.92 post-operatively 1 month.

Under: 95% power of study and 5% level of significance – Minimum sample size needed was 45 patients. To reduce margin of error, total sample size taken was 50.

Formula Used Is:

For Comparing Mean Of Pre And Post

$$N >= \frac{(\text{standard deviation})^2 * (Z_\alpha + Z_\beta)^2}{(\text{mean difference})^2}$$

Where Z_α is value of Z (normal variate) at two sided alpha error of 5% and Z_β is value of Z (normal variate) at power of 95% and mean difference is difference in mean values of pre and post.

Total 50 patients with preoperative diagnosis of ToF were included. Patient details noted were age, gender and CPB time. Trans-atrial approach was used for surgery.

A standardized surgical approach was followed which involved Aorto-Bicaval cannulation and moderate systemic hypothermia, ductus arteriosus was ligated. Myocardial protection was achieved using del Nido cardioplegia and Ice slush. A Right atriotomy was performed to access the Infundibular septum and Pulmonary valve. Obstructing tissue, including Parietal bands and Trabeculations, was excised to relieve stenosis. The pulmonary valve was inspected, tethering released, and commissurotomy performed if necessary. Hegar dilators were used to determine pulmonary annulus size. JIRAAT technique used to assess adequacy of resection. Complete visualization of pulmonary valve was considered adequate resection. RVOT gradients were measured intraoperatively post-CPB using TEE & post-operatively (with in 24hr) using TTE.

RVOT gradients were measured intraoperatively post-cardiopulmonary bypass which were compared with measurements taken post-operatively using echocardiography.

After repair, all the patients were assessed by TEE for adequacy of repair.

Follow Up And Outcomes

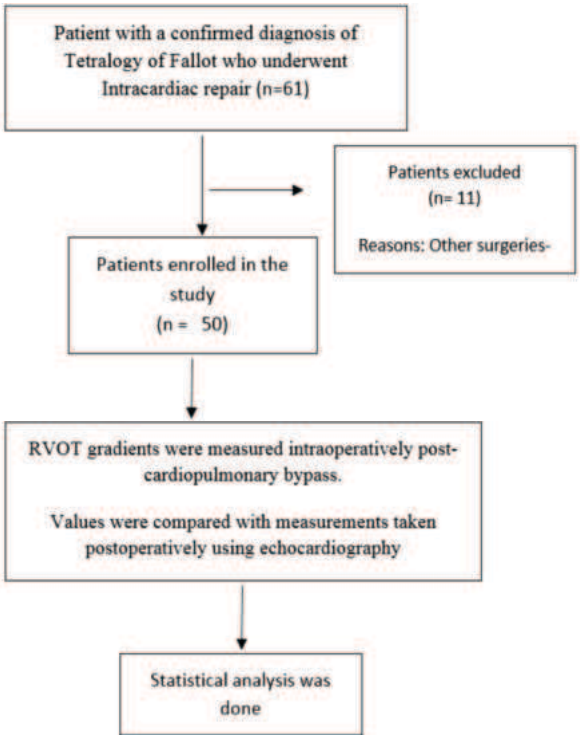
RVOT gradients were measured intraoperatively post-cardiopulmonary bypass. RVOT measurement findings were compared with measurements taken post-extubation using echocardiography. Patients were followed up in the operation theatre for any complications or mortality. The outcome measures were post-operative RVOT gradient.

Statistical Analysis

Statistical Package for Social Sciences (SPSS) version 21.0 was used. Paired t-test were used for statistical comparison. $p<0.05$ was taken as level of significance.

RESULTS

The Study Was Done As Per The Flow Chart Figure 1.



Mean ± SD age of the study population was 7.8 ± 2.6 years. Distribution of gender was as follows: Male in 30 (60%) cases and Female in 20 (40%) cases (Table 1, Figure 2).

Table 1:- Demographic Characteristics Distribution.

Demographic characteristics	n (%)	Mean ± SD
Age (years)	-	7.8 ± 2.6
Gender		
Male	30(60%)	-
Female	20(40%)	

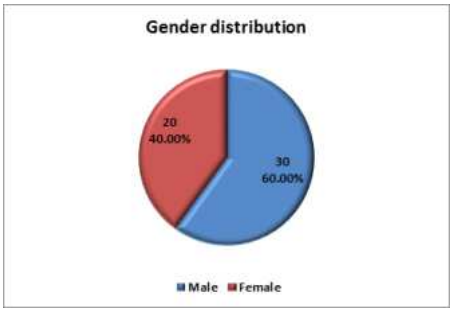


Figure 2:- Gender Distribution.

Mean ± SD cardiopulmonary bypass (CPB) time was 118.98 ± 7.59 minutes (Table 2).

Table 2:- Descriptive Statistics Of Cardiopulmonary Bypass (CPB) Time.

Variable	Mean ± SD	Range
Cardiopulmonary Bypass (CPB) Time	118.98 ± 7.59	60-164

Compared to pre-operative RVOT gradient (85.93 ± 5.73 mmHg), it significantly decreased to 32.6 ± 2.3 mmHg intraoperatively (p value < 0.0001) and 27.7 ± 3.1 mmHg post-operatively (p value < 0.0001) (Table 3, Figure 3).

Table 3:- Comparison of Pre-operative RVOT Gradient with Intraoperative and Post-Extubation RVOT Gradient.

Variable	Mean ± SD	Range	P value
RVOT Gradient (Pre-operative)	85.93 ± 5.73	37-98	-
RVOT Gradient (Intraoperative)	32.6 ± 2.3	22-45	<0.0001*
RVOT Gradient (Post-operative)	27.7 ± 3.1	15-38	<0.0001*

* Paired T Test

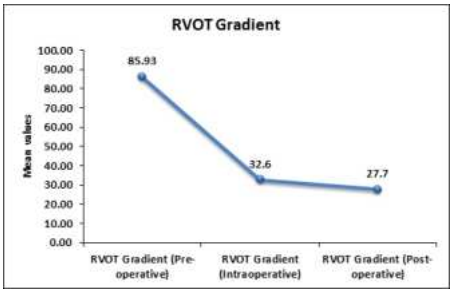


Figure 3:- Comparison of Pre-operative RVOT Gradient with Intraoperative and Post-operative RVOT Gradient.

DISCUSSION

The present study is one of the few Indian studies that assessed RVOT gradient in children undergoing ToF repair. [10, 11] It holds significance since RVOT gradients are an important objective measure determining the success of the surgery – thereby deciding the long term prognosis of the patients. Despite affluent guidelines,[1,2] the cut off of RVOT gradients remain obscure and moreover its values may fall in the immediate post-operative stage as found in the present study results.

We found that there was a significant reduction in the RVOT gradient from intraoperative levels of 32.6±2.3 mmHg to postoperative levels of 27.7±3.1 mmHg ($P<0.0001$). The post-operative values were found to be below 30 (standard cut off) – enforcing the fact to wait and allow for the fall in values after the surgery, rather than jumping into a reinstitution of CPB based on the intra-operative values.

Likewise, in Upadhyay V et al [2] study, post-bypass residual RVOT gradient was 11.33 ± 1.39 that decreased to 7.81 ± 1.29, 24h after extubating ($P < 0.05$). Similar decline in the RVOT gradient was also seen by Kaushal et al [6] as predischarge ECHO showed that RVOT gradients were significantly reduced (54±15.4 to 31.5±14.7 mm Hg, $p<0.005$). A significant reduction in gradients was observed at an average follow-up of 18.5±8.3 months (21±8.8 mm Hg, $p<0.05$) – showing the values may further fall in the follow up. Banday et al [1] found that after TOF repair, the Mean RVOT gradient in early postoperative ECHO was 28mmHg, which declined on follow up

ECHO to a mean of 16 mmHg.

The fall in the RVOT gradient can be due to the fact that – immediately postbypass, there is a hypercontractile state as a result of inotropes and hypovolemia, and this leads to systolic clamping of the RVOT, With passage of time, the hypercontractility decreases along with remodeling of RVOT; thereby, Decreasing the RVOT gradient. Denault et al [8] proposed that early decline in the RVOT gradient may be due to less requirement of inotropes in the postoperatively or reduced susceptibility of infundibular muscle to inotropes & Decreased myocardial edema.

Also response of inotropic agent in the infundibular tract is greater than the RV inflow tract, this can be a mechanism to protect the pulmonary vasculature from high pressure. Excessive excision at RVOT can result in injury of septal branch of left anterior descending artery, creating a new VSD, RV dysfunction and increasing CPB time. [9]

Limitations

Less sample size was one of the limitations of the study. Moreover, no long term follow-up of the patients was not done. The study was conducted at a single center, which limits its generalization. The gradients were measured intraoperatively and post-operative. Long-term follow-up was not done, which limits the study in assessing long-term effect of surgery on changes in RVOT. Long-term functional outcomes such as right ventricular function were not assessed.

Strengths Of The Study

There is lack of Indian studies that assessed the changes in Right ventricle outflow tract residual gradient after intracardiac repair for ToF. Thus, this study will add to the knowledge about RVOT changes in Indian patients with ToF undergoing intracardiac repair.

CONCLUSION

To conclude, there was a significant reduction in Right ventricle outflow tract gradients in the early postoperative period from Intraoperative value following intracardiac repair for ToF. So aim should be adequate resection of fixed obstruction, as dynamic gradient is can be left as it decreases significantly postoperatively.

Moreover, it can be suggested that when there is adequate resection of fixed RVOT, which can be confirmed by intraoperative TEE, if residual gradient is marginally high, it can be left as postoperative residual gradient decreases significantly after operation, which can be measured by postoperative ECHO. Continuous monitoring and advanced imaging technologies play crucial roles in achieving these goals.

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