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Outcome of Management of Tetralogy of Fallot in a Cardiac Center of a Tertiary Care Hospital in Bangladesh

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Abstract **Original Research Article**

Background: Congenital heart diseases (CHD) represent one of the major groups of birth defects and make up approximately 1% of human malformations. Incidence of congenital heart disease is 8-10/1000 live births. The incidence is higher in premature infants. In Bangladesh incidence of congenital heart diseases was found up to 25/1000 live birth in a one year study conducted in CMH Dhaka. Congenital cyanotic heart disease accounts for less than 25% of total congenital cardiac defects. In TOF the lungs are under-perfused as blood shunts from right to left bypassing the lungs. TOF constitutes 5-7% of congenital heart disease**.** It is the commonest congenital cyanotic heart disease in Bangladesh. ***Objective:*** The aim of this study was to assess outcome of management of Tetralogy of Fallot in a cardiac center of a tertiary care hospital in Bangladesh. ***Methodology:*** It was a retrospective observational study and was conducted in the department of Pediatric Cardiology of Combined Military Hospital (CMH), Dhaka, Bangladesh from January 2015 to December 2016. We included 50 patients with TOF taking treatment from our department. All the patients were divided into three groups according to treatment type. Medical management group, palliative surgery group and total intra cardiac repair group and their outcome were assessed. ***Results:*** In our study we found 6 (12%) patients were in medical management group, 8 (16%) were in palliative surgery group and 36 (72%) were in total intra cardiac repair group. Among them 33 (66%) were male and 17 (34%) were female. Majority patients 30 (60%) were in less than 3 years of age. In medical management group all the patients had oxygen saturation <80%, 4 (66.68%) patients reduced frequency of hyper-cyanotic spell, 1 (16.67%) patient had cerebral abscess. In palliative surgery group 6 (75%) patients had >90% oxygen saturation, 2 (25%) had <90% oxygen saturation, tet spell reduced in all the cases. After total intra cardiac repair no patient had oxygen saturation <90%, no patient had tet spell, no residual large VSD, 5 (13.89%) patients had small residual VSD, 1 (2.78%) patient had residual moderate VSD with PS and PHT and 34 (94.44%) patients had RBBB and 2 (5.56%) patients had failure to thrive. ***Conclusion:*** Study reflects that medical management while waiting for surgery reduces the frequency of hyper-cyanotic spell. Palliative surgery increases the oxygen saturation, reduces the hyper-cyanotic spell and increases the growth of the patient. After total surgical repair there was complete cure of the patient and also increased the growth and development.

Keywords: Tetralogy of Fallot, Palliative surgery, Intra Cardiac Repair, Definitive surgery.

INTRODUCTION

Congenital heart diseases (CHD) represent one of the major groups of birth defects and make up approximately 1% of human malformations. Incidence of congenital heart disease is 8-10/1000 live births. The incidence is higher in premature infants [1]. In Bangladesh incidence of congenital heart diseases was found up to 25/1000 live birth in a one year study conducted in CMH Dhaka [2]. Congenital cyanotic heart disease accounts for less than 25% of total

congenital cardiac defects [3]. In TOF the lungs are under-perfused as blood shunts from right to left bypassing the lungs [4]. The symptoms are cyanosis, dyspnea, feeding difficulty, not gaining weight and hyper-cyanotic spell. Syncope and chest pain may occur [5]. TOF constitutes 5-7% of congenital heart disease [6]. It is the commonest congenital cyanotic heart disease in Bangladesh also [7, 8]. There is very limited study on outcome of treatment of TOF in Bangladesh. This study will serve as a future reference for study in this field. TOF is actually a combination of four different defects which includes right ventricular outflow tract obstruction, mal aligned VSD, overriding of aorta on ventricular septum, and right ventricular hypertrophy [9]. Several abnormalities may occur in association with TOF including right aortic arch (25%), atrial septal defect (10%), coronary arterial anomalies (10%) and Pulmonary atresia (18%) [10]. The common presentation of infants are cyanosis and hypercyanotic spells [11]. Older infants and children may assume a squatting position during playtime or long walks which increases their oxygenation and prevent hypercyanotic spell [12]. Complications of TOF include cerebral thrombosis (most often in children younger than 02 years of age), brain abscess, bacterial endocarditis, growth failure, and rarely heart failure (inacyanotic TOF) [14]. Treatment of tetralogy of fallot depends on the severity of the right ventricular outflow tract obstruction, size of pulmonary artery and age of presentation. Treatment outcome depends on age and type of intervention. There is very limited study on the outcome of cyanotic congenital heart disease including Tetralogy of Fallot in Bangladesh. This study aimed to determine the outcome of tetralogy of fallot in a cardiac center of a tertiary care hospital in Bangladesh.

Objective of the study

The main objective of the study was to find the outcome of medical, palliative and surgical management of tetralogy of fallot.

METHODOLOGY & MATERIALS

This was a retrospective observational study and was conducted in Pediatric cardiology department of Combined military hospital (CMH), Dhaka, Bangladesh**.** In our study we included 50 patients with TOF taking treatment from the department. All the patients were divided into three groups according to treatment type- medical management group, palliative surgery group and total intra-cardiac repair group.

These are the following criteria to be eligible for the enrollment as our study participants: a) Patients aged upto 18 years old; b) Patients with tetralogy of fallot ; c) Patients admitted in the Pediatric Cardiology department; d) Patients who needed palliative & definitive surgery; e) Patients gave consent to participate were included in the study And a) Patients of cyanotic congenital heart disease other than TOF; b) Patients unwilling to participate in the study were excluded from our study.

Statistical Analysis

Data were collected from patients registry, interview and examinations of the admitted and OPD patients. The patients were managed either medically or by palliative surgery (systemic to pulmonary shunt) or total intracardiac repair both in this hospital and abroad (for surgical correction). All data were recorded systematically in preformed data collection sheet. Statistical analysis was performed by using SPSS 21 (Statistical Package for Social Sciences) for windows version 10.

RESULTS

Table 1: Distribution of patients by study group, (N=50)

Group	Number	(%)
Medical management group	6	12
Palliative surgery group	8	16
Definitive surgery group i) By transannular patch & RVOT patch (n=26) ii) Transatrial approach(n=5) iii) With conduit (n=3)	36	72

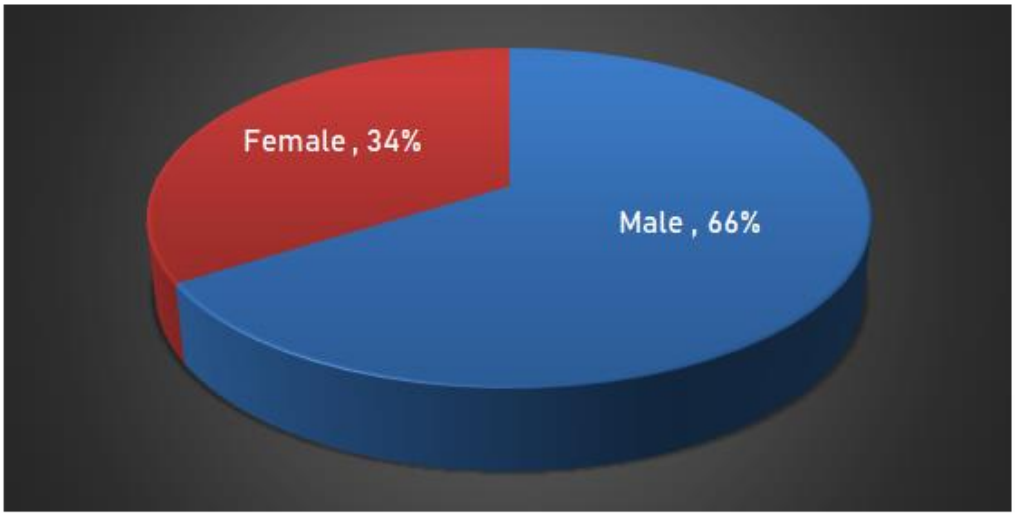

Figure 1: Distribution of study subjects as per Gender, (N=50)

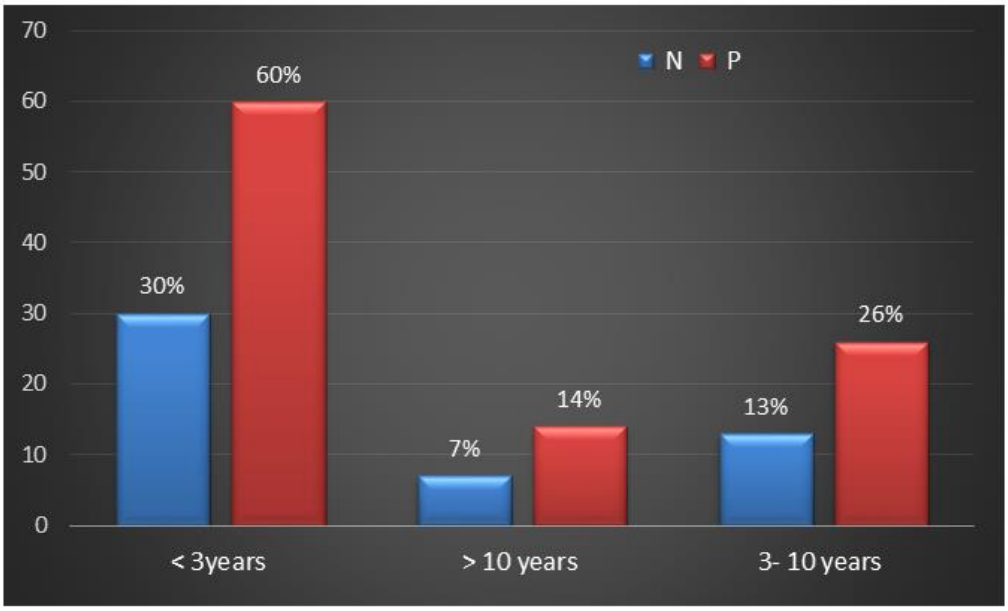

Figure 2: Age distribution of our study participants, (N=50)

Table 2: **Distribution of study subjects by association of TOF**

Anomaly	**Number**	**(%)**
Rt Aortic arch	10	20
ASD II	7	14
Additional VSD	3	6
Pulmonary atresia	4	8
AV Canal defect	3	6
Absent LPA	2	4
Absent RPA	1	2
Disconnected RPA	1	2
Peripheral origin/ stenosis of RPA/ LPA	3	6
Major coronary Crossing RVOT	3	6
Single LCA	2	4
Single RCA	1	2
MAPCA/ PDA	4	8

Table 3: Distribution of patients by age of surgical treatment, (N=44)

Age	Type of surgery		Number	(%)
	Palliative shunt	Total repair		
< 6month	8	2	10	22.73
6 – 12 months		20	20	45.45
>1year		14	14	31.82

Table 4: Overall and study group wise Mortality Rate

Group	Number of Death	(%)
Medical management group	0	0
Palliative surgery group	1	2
Definitive surgery group i)By transannular patch & RVOT patch (n=2) ii)Transatrial approach (n=0) iii)With conduit (n=0)	2	4
Total Death	3	6

Table 5: Distribution of our study subjects by the outcome of medical treatment, (N=6)

Outcome	Number	(%)
Cyanosis (SPO2 <80%)	6	100
Reduced frequency of Tet spell	4	66.67
Polycythemia	6	100
Cerebral abscess	1	16.67
Stroke	0	0
Growth retardation	6	100
Other thromboembolic manifestation	0	0

Table 6: Distribution of study subjects by the outcome palliative surgery, (N=8)

Outcome	Number	(%)
Oxygen Saturation >90%	7	87.5
Oxygen Saturation <90%	1	12.5
Reduced frequency of Tet spell	8	100
Shunt thrombosis	0	0
Shunt stenosis	0	0
Distal PA hypoplasia/ stenosis	0	0
Infective endocarditis	1	12.5
Growth retardation	1	12.5

Table 7: Distribution of patients by the outcome of definitive Surgery (N=36)

Outcome	Number	(%)
Oxygen saturation >90%	36	100
Oxygen saturation <90%	0	0
Tet spell	0	0
Growth retardation	2	5.56
Residual Large VSD	0	0
Residual small VSD	5	13.89
Residual moderate PS	1	2.78
Residual mild PS	5	13.89
Residual moderate VSD, mild PS and PHT	1	2.78
LPA/RPA origin stenosis	2	5.56
Severe TR	2	5.56
Dilated RVOT with PR	4	11.08
RBBB	34	94.44

A total 06 (12%) patients were in medical management group, 8 (16%) were in palliative surgery group and 36 (72%) were in total intra cardiac repair group (Table 1). Among all patients majority patients 33 (66%) were male and 17 (34%) were female (Figure 1). Among all patients, 30 (60%) patients were in less than 3 years of age, 13 (26%) were 3- 10 years and 7 (14%) were more than 10 years of age. Maximum

patients 32 (64%) were diagnosed at less than 06 months of age, 5 (10%) during neonatal period and 13 (26%) during more than 06 months of age (Figure 2).

Following were the association with TOF, Rt aortic arch 10 (20%), ASD II 7 (14%) , additional muscular VSD 3 (6%), pulmonary atresia 4 (8%), AV Canal defect 3 (6%), absent LPA 2 (4%), absent RPA 1 (2%), disconnected RPA 1 (2%), peripheral origin/ stenosis of LPA/ RPA 3 (6%), major coronary crossing RVOT 3 (6%), single LCA 2 (4%), single RCA 1 (2%) and MAPCA / PDA 4 (8%) (Table 2).

Most of the patients 20 (45.45%) undergone total surgery within 1 year of age, 14 (31.82%) after 1 year of age and all the palliative surgery were done within 6 months of age (Table 3).

There were no deaths occurred in medical management group, only 1 patient died after palliative surgery and 2 patients died after definitive surgery (Table 4).

In medical management group all the patient had oxygen saturation <80%, 4 (66.68%) patient reduced frequency of hypercyanotic spell, 1 (16.67%) patient had cerebral abscess, all patient had polycythemia and no patient had stroke or other thromboembolic manifestations. 4 (66.67%) patients had failure to thrive (Table 5).

In palliative surgery group 6 (75%) patient had >90% oxygen saturation, 2 (25%) had <90% oxygen saturation, tet spell reduced in all the case after palliative surgery. 1 (2%) patient had infective endocarditis. No patient had stent thrombosis/ stenosis or distal pulmonary artery hypoplasia and 1 (12.5%) had failure to thrive (Table 6).

After total intra cardiac repair no patient had oxygen saturation <90%, no patient had tet spell, no residual large VSD, 5 (13.89%) patient had small residual VSD, 1 (2.78%) patient had residual moderate VSD with PS and PHT, 1 (2.78%) had residual moderate PS, 5 (13.89%) had residual mild PS, 2 (5.56%) had LPA/RPA origin stenosis, 2 (5.56%) had severe TR, 4 (11.08%) had dilated RVOT and PR and 34 (94.44%) patient had RBBB and 2 (5.56%) patient had failure to thrive (Table 7).

DISCUSSION

Treatment of TOF depends on the age of presentation, severity of right ventricular out flow tract obstruction and size of the pulmonary artery. Neonates with marked right ventricular outflow tract obstruction require IV administration of prostaglandin E1 for maintaining patency of ductus arteriosus [15]. Infant with less severe obstruction treated with oral propranolol to prevent cyanotic spell [16]. Infant with severe cyanosis at one month need surgical intervention. Infant who has less severe cyanosis primary intervention can be done at 4-6 months of age [17]. Another option is palliative systemic to pulmonary shunt (e.g. Blalock- Taussing shunt, Pott's shunt or central shunt) followed by total correction in case of infants who have small pulmonary artery [6]. The complications of treatment of TOF can be immediate or long term effect. Immediate complications include right ventricular failure, transient heart block, residual VSD and myocardial infarction [18]. Long term effects are pulmonary valvular insufficiency, residual pulmonary stenosis, RBBB, ventricular arrhythmia, complete heart block and sudden death. Complications of BT shunt include chylothorax, diaphragmatic paralysis, horner syndrome and thrombosis of BT shunt [19]. After successful total correction patients are generally asymptomatic and are able to lead unrestricted lives. The surgical risk of total correction in major centers are <5% [20]. Repair of simple or complex TOF with pulmonary atresia can also be achieved with low mortality. Surgical outcome of TOF with absent pulmonary valve is better in older children [21]. Beta adrenergic blockade with propranolol has little to offer in the management of older patients with Fallot's tetralogy; it may have some value in treating young infants and children, especially those with hypoxic spells [22]. Long-term Treatment with Propranolol showed an increased tolerance to work. No cyanotic spells or hypoxic attacks appeared during treatment [23]. Preoperative use of propranolol may decrease the incidence of JET after full surgical repair of TOF [24]. Infants with symptoms and severe cyanosis in the 1st month of life usually have marked obstruction of the right ventricular outflow tract. Two options are available in these infants. The first is corrective open heart surgery performed in early infancy and even in the newborn period in critically ill infants. Tamesberger MI *et al*., found that there was no 30-day mortality; late mortality was 2% after a median follow-up time of 4.7 years. Early primary repair of tetralogy of Fallot can be performed safely and effectively in infants younger than 4 months of age and even in neonates younger than 28 days with duct-dependent pulmonary circulation or severe hypoxemia [25]. Jeong Ryul Lee *et al*., in their study showed excellent right ventricular function in most patients [26]. Children undergoing TOF repair had excellent short-term outcome with the current protective strategy aiming to spare valvular function, and conserving myocardial function [27]. Fernando Ribeiro de *et al*., in their study showed that the actuarial probability of survival at 12 years, including operative mortality was 97% [28]. Georg Nollert *et al*., showed that actuarial survival rates of 10, 20, 30 and 36 years were 97%, 94%, 89% and 85%, respectively [29]. Shuenn-Nan Chin *et al*., showed that although patients with TOF repaired within first 6 months of life had prolonged postoperative recovery and an increased chance of transannular patch usage, outcomes were comparable to those patients with TOF repaired later

[30]. Transatrial/transpulmonary repair avoids a ventriculotomy (in contrast to the transventricular approach) in order to preserve the structure and function of the right ventricle. This approach to repair TOF is associated with excellent surgical results [31]. Srikrishna Sirivella *et al*., in their showed that repair via ventriculotomy with transannular patch was the most common technique (63%) followed by infundibulotomy without transannular patch (20%) and transatrial/transpulmonary approach without ventriculotomy (15%). The operative and long-term mortality were 3.2% and 4.4%; 2% and 3.1%; 2% and 2.7% respectively. The overall operative and long-term mortality for repairs was 2.9% and 3.4%, with high 3.94% and 6.6% respectively for repairs with right ventricular pulmonary valve conduit. There was statistically significant correlation between the type of repair and mortality risk. Overall mortality for Tetralogy of Fallot repair was low. The repair by ventriculotomy with transannular patch was the most common technique and was associated with higher mortality. Repairs through infundibulotomy without transannular patch and repair without ventriculotomy were less common, but were associated with lower mortality [32]. The second option, more common in previous years, is a palliative systemic-to-pulmonary artery shunt (Blalock-Taussig shunt) performed to augment pulmonary artery blood flow. The rationale for this surgery, previously the only option for these patients, is to augment pulmonary blood flow to decrease the amount of hypoxia and improve linear growth, as well as augment growth of the branch pulmonary arteries. The modified Blalock-Taussig shunt is currently the most common aortopulmonary shunt procedure and consists of a Gore-Tex conduit anastomosed side to side from the subclavian artery to the homo lateral branch of the pulmonary artery. Sometimes the shunt is brought directly from the ascending aorta to the main pulmonary artery; in this case, it is called a central shunt. Gladman G *et al*., in their study showed Shunt stenosis was common and correlated with younger age at palliation. Shunt occlusion resulted in one death. Excluding noncardiac causes of death, overall survival was 90% in the palliated group versus 97% in the nonpalliated group [33]. Susumu Ishikawa et al showed the preoperative pulmonary artery index (PAI) was 129±42 in all patients and there were no significant differences between patients under or over a year old. Postoperative angiography was performed 32±13 months after the surgery. Room air arterial O2 pressure increased significantly from 29±5 mmHg to 42±5 mmHg just after an initial palliative shunt operation [34]. Dorobantu DM et al.,_showed that usage of SPS in Tetralogy of Fallot (ToF) has significantly decreased in the last decade. This study indicated that more severely ill patients benefit from shunting, but with an increase in mortality [35]. Hyungtae Kim *et al*., in their study showed that there was a high overall mortality rate in staged repair for the patients with TOF/PA with PDA. Majority of deaths occurred before the definitive repair was performed. Therefore, primary repair or early second stage definitive repair should be considered to enhance the survival rate for patients with TOF/PA with PDA [36]. Analysis of 72 cases of TOF who had undergone cardiac catheterization done by Fatema *et al*., showed about 8% death in palliative surgery group [37]. After successful total correction, patients are generally asymptomatic and are able to lead unrestricted lives. Uncommon immediate postoperative problems include right ventricular failure, transient heart block, residual VSD with left-to-right shunting and myocardial infarction from interruption of an aberrant coronary artery. Postoperative heart failure (particularly in patients with a large transannular outflow patch) may require anti congestive therapy. The long-term effects of isolated, surgically induced pulmonary valvular insufficiency are still being defined as more patients with repaired tetralogy of Fallot reach middle age, but insufficiency is generally well-tolerated through adolescence.

Limitations of the study

Our study was a single centre study. We took a small sample size due to limitation of time. The patients of three groups were not comparable in age and in number of patients and complication rate were higher due to small sample size and short duration of study. After evaluating once those patients we did not follow-up them for a long term and have not known other possible interference that may happen in the long term with these patients.

CONCLUSION AND RECOMMENDATIONS

In our study we found that medical management while waiting for surgery reduces the frequency of hepercyanotic spell. Palliative surgery increases the oxygen saturation, reduces the hypercyanotic spell and increases the growth of the patient. After total surgical repair there is complete cure of the patient and also increases the growth and development. In this study surgical complications and mortality rate is high.

So further study with a prospective and longitudinal study design including larger sample size needs to be done to identify more complications in the management of Tetralogy of Fallot.

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