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CLINICAL & BASIC RESEARCH

Pulmonary Annulus Growth Pattern in Patients with Tetralogy of Fallot Prior to Surgical Repair

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abstract: ***Objectives:*** The size of the pulmonary valve annulus often determines the feasibility of pulmonary valve preservation at the time of intracardiac repair of Tetralogy of Fallot. Currently, there is limited available data regarding the growth pattern and the determining factors that contribute towards pulmonary valve annulus growth. ***Methods:*** This retrospective study included patients who underwent surgical repair of Tetralogy of Fallot with or without prior palliation. These patients had an echocardiogram at the time of initial diagnosis and a second echocardiogram prior to intracardiac repair. The sizes of the pulmonary annulus, the right and left pulmonary arteries with z-scores were recorded. Patients with improvement in the pulmonary annulus z-scores between the 2 echocardiographic examinations were allocated in Group I (n = 46) and Group II (n = 68) were those with no improvement. ***Results:*** A total of 114 patients were included in the study. The right and left pulmonary arteries size and z scores improved significantly between the 2 echocardiograms. Although the median size of the pulmonary annulus increased between the 2 echocardiograms (6 and 7.9 mm; $P<0.001$), there was no significant change in the z-score (-2.2, -2.34; $P = 0.185$). Multivariate logistic regression analysis showed that gender, blood group, presence of collaterals, and palliation with Blalock-Taussig shunt had no impact on the improvement in pulmonary annulus z-score. ***Conclusion:*** In Tetralogy of Fallot, the pulmonary valve annulus z-score may not change significantly prior to the intracardiac repair. Although in certain subgroups there may be an improvement, there was no specific factor that could be identified and had an influence on this improvement.

Keywords: Tetralogy of Fallot; Pulmonary Valve; Pulmonary Artery; Modified Blalock-Taussig Shunt; Oman.

Advances in Knowledge

- *This study highlights the pattern of growth of pulmonary valve and arteries pattern of growth prior surgical repair.*
- *This study explores the factors that may influence the growth of the pulmonary valve annulus.*

Application to Patient Care

- *The knowledge of the pulmonary valve annulus growth pattern may influence the timing of the surgical repair.*
- *To explore and study genetic or haemodynamic factors that may have an impact on this size and the growth of the pulmonary valve annulus.*

Tetralogy of fallot (TOF) is a common cyanotic congenital heart disease accounting for approximately 10% of all cardiac malformations. It consists of 4 main anatomical features: ventricular septal defect (VSD), right ventricular hypertrophy, overriding aorta and right ventricular outflow tract obstruction (RVOTO). The pulmonary valve is often bicuspid and with different degrees of annular hypoplasia. There is also a variation in the degree and the location of the obstruction in the RVOT and that will affect the clinical presentation.[1,2] Furthermore, the preoperative size pulmonary valve annulus often predicts the likelihood of saving the PV or the use of a trans-annular patch (TAP) during the surgical repair.[3–7] TAP results in free pulmonary insufficiency which in turn leads to right ventricular dysfunction, arrhythmia, and poor functional status that will eventually often necessitate reoperation for pulmonary valve (PV) replacement.[8,9]

Limited studies are available on the natural growth of the PV annulus in TOF prior to surgical repair. In this study, we reviewed the echocardiographic data of patients with TOF and examined the growth pattern of the pulmonary valve annulus and pulmonary artery branches before the corrective intracardiac repair.

Methods

This retrospective cohort study included all patients with TOF who underwent surgical repair in our institution from January 2016 to December 2019. All patients who had at least two echocardiographic examinations more than three months apart before

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Table 1: Baseline characteristics for improved pulmonary valve z-score group and the no improvement group (N = 114)

Characteristic	n (%)	
	Group I* (n = 46)	Group II* (n = 68)
Gender		
Male	27 (59)	42 (62)
Female	19 (41)	26 (38)
Collaterals		
Yes	6 (13)	9 (13)
No	40 (87)	59 (87)
Syndrome		
Yes	8 (17)	10 (15)
No	38 (83)	58 (85)
Preoperative intervention		
Yes	12 (26)	12 (18)
No	34 (74)	56 (82)
BT shunt		
Yes	10 (22)	11 (16)
No	36 (78)	57 (84)
Cyanotic spells		
Yes	14 (30)	21 (31)
No	32 (70)	47 (69)
Blood group		
A+	10 (22)	17 (25)
A-	1 (2)	0
B+	7 (15)	8 (12)
B-	1 (2)	0
AB+	1 (2)	0
O+	23 (50)	41 (60)
O-	3 (7)	2 (3)

**Group I = improved pulmonary valve (PV) z-score; Group II = no improvement PV z-score.*

surgical repair were included. The following groups of patients were excluded: TOF with pulmonary atresia, TOF with absent pulmonary valve, TOF with atrioventricular septal defect and TOF patients who only had one echocardiography prior to surgical repair or if they had two echocardiography which was less than three months apart. The size and z-score of the PV annulus, right pulmonary artery, and left pulmonary artery were recorded. The z-score was calculated using The Boston Children's Hospital z-score. Baseline characteristics were obtained for all patients including gender, blood group, associated syndromes, presence of non-cardiac anomalies, collaterals, side of the aortic arch, presence of cyanotic spells prior to surgery and pre-operative palliative procedures. The surgical approach (valve-sparing versus TAP) used in the intracardiac repair was also recorded. The patients were further divided into two groups to study the factors that influence the improvement of z-score. Group I includes patients with improvement in the pulmonary annulus z-scores (difference of z-score between the second and first echocardiogram >0) between the 2 echocardiographic and Group II were those with no improvement (difference of z-score between the second and first echocardiogram ≤0).

STATA BE/17.0 was used for analysis. Median, maximum and minimum values were used for the descriptive analysis of the continuous variables, and frequencies and percentages for descriptive analysis of the categorical data. For analytical analysis, a Mann-Whitney test was used to test differences between the two groups' continuous variables; a Chi-squared test was used to assess the differences between the two groups for the categorical variables. Multivariable linear regression were used to identify risk factors that may be associated with improvement in pulmonary valve annulus z-score (ΔPVA-Z). Moreover, Cox hazard regression was used to study the effect of preoperative palliation with BT shunt on PV annulus improvement after adjusting for gender, presence of collateral, and blood group.

Statistical differences were considered as significant if the *P* value was less than 0.05. Test values were considered significant if <0.05.

This study has been approved the ethical committee of the National Heart Center, The Royal Hospital (SRC#104/2019).

Results

A total of 114 patients were included in the study out of 173 patients operated in the centre from 2016 to 2019; 61% of the patients were male and 15% of them had non-cardiac anomalies such as anorectal malformation, tracheoesophageal fistula, cleft lip and palate. Approximately a third (31%) of the patients had a history of cyanotic spells prior to the intracardiac repair and 21% underwent palliative procedures (24 patients) such as modified Blalock-Taussig shunt (MBTS; 21 patients), RVOT stent (one patient), PDA stent (one patient) or pulmonary valvuloplasty (one patient). Most of the patients had blood group O+ (52%) followed by blood group A+ (22%). The majority of patients underwent TOF repair with TAP (63%)

Table 2: Echocardiographic data of all patients included in the study (N = 114)

Variable	First echocardiography (min-max)	Second echocardiography (min-max)	Median difference (min-max)	*P* value
PV in mm	6 (4–15)	7.9 (4–18)	1 (-4.5–10)	0.001
PV z-score	-2.22 (-1.58– -2.64)	-2.34 (-1.35–-2.88)	-0.19 (0.53–-0.83)	0.185
RPA in mm	5 (2-13)	6.7(3-14)	1.5 (-2–8.5)	0.001
RPA z-score	-1.15 (-0.28–-1.82)	-0.63 (0.17–-1.48)	0.59 (1.53–-0.69)	0.001
LPA in mm	4.7(2–12)	6.5(3–13)	1.8 (-3–6.1)	0.001
LPA z-score	-1.22 (-0.17–-1.85)	-0.42 (0.46–-1.33)	0.32 (1.70–-0.33)	0.001

Table 3: Comparison of the change in pulmonary valve annulus z-score in TOF patients with BT shunt versus patients with no BT shunts

Variable	First echocardiography (min-max)	Second echocardiography (min-max)	Median difference (min-max)
PV z-score (no palliation) n = 93	-2.05 (-3.64–2.43)	-2.33 (-3.99–1.34)	-0.28 (-0.35–-1.09)
PV z-score (BT shunt) n = 21	-3.43 (-0.47–-5.79)	-3.13 (0.75–-6.23)	0.3 (1.22–-0.44)

TOF = tetralogy of fallot; BT = Blalock-Taussig; PV = pulmonary valve.
P = 0.07.

Table 4: The effect of BT shunt on the improvement of PV annulus z-score in TOF patients

	BT shunt		Total	Fisher's exact Test
	Yes	No		
Improved z-score	10	36	46	
No improvement in z-score	11	57	68	*P* = 0.642
Total	21	93	114	

BT = Blalock-Taussig; PV = pulmonary valve; TOF = tetralogy of fallot.

Table 5: Multivariable linear regression to measure the association between mean difference of PV-annulus and preop palliation after adjusting for gender, MAPCASb and blood group

Mean difference in PV annulus z-score	Coefficient ± SE	t	P>t	95% CI
Gender*	-0.25 ± 0.25	-0.98	0.329	-0.74 – 0.25
MAPCAs†	-0.21 ± 0.36	-0.57	0.567	-0.92 – 0.51
Pre-op palliation (BT shunt)‡	-0.40 ± 0.29	-1.37	0.175	-0.98 – 0.18
Blood group§				
A+	0.83 ± 1.31	0.63	0.529	-1.78 – 3.45
B+	0.31 ± 0.40	0.78	0.440	-0.49 – 1.12
O+	-0.10 ± 0.31	-0.33	0.740	-0.71 – 0.51
O-	0.06 ± 0.64	0.09	0.931	-1.20 – 1.32
_cons	0.47 ± 0.46	1.00	0.319	-0.46 – 1.39

PV= pulmonary valve; SE = standard error; CI = confidence interval.
**Female versus male. †Absence vs presence of collaterals. ‡Not received vs received palliative procedure (BT shunt). §Baseline.*

compared to 37% who had a valve-sparing approach. Most of the patients who underwent MBTS eventually had TOF repair with TAP (87%). The median length of the hospital stay was 8 days (range: 7–12 days) and the surgical mortality was only for one patient.

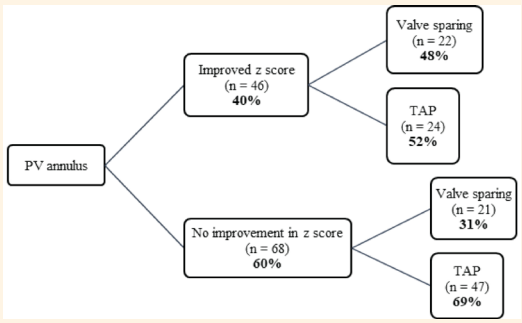

Figure 1: Outline of the distribution of patients according to the improvement in the PV z-score and the surgical approach.
PV = pulmonary valve; TAP = repair with transannular patch.

The median age of the patients at the initial echocardiogram assessment was one month (range: 1 day–4 months). The median duration of the interval period from the initial echocardiogram to preoperative echocardiogram was 9 months (range: 7–14 months).

The patients were divided into two groups: Group I (n = 46) includes patients with improvement in the pulmonary annulus z scores (>0) between the 2 echocardiographic assessments and Group II (n = 68) were those with no improvement (z-score ≤0). Table 1 summarises the baseline characteristics of the patients in each group. Approximately half (48%) of the patients in Group I underwent valve sparing surgery compared to 31% in Group II (P = 0.162) [Figure 1].

The median right pulmonary artery diameter and z-score increased significantly from the initial to the second echocardiogram (diameter: 5 to 6.7 mm, z-score: −1.15 to −0.63; P = 0.001) [Table 2]. A similar observation was noted on the left pulmonary artery diameter (4.7–6.5 mm) and z-score (−1.22– −0.42), and it was statistically significant (P = 0.001). The median pulmonary valve annulus diameter increased significantly with time from 6–7.9 mm (P = 0.001). However, the median z-score did not change significantly (z-score: −2.22– −2.34; P = 0.185).

A total of 21 patients included in the study underwent BT shunt prior complete repair. Tables 3 and 4 summarise the change in PVA z-score of the patients with BT shunt and without BT shunt. Overall, the number of patients with BT who had improvement in PVA z-score was 10 compared to 11 patients with no improvement (P = 0.65). The patients who received BT shunt had improvement in the PVA z-score compared to the patients with no palliation who had a decrease in the PVA z-score with time; however, it was not statistically significant (P = 0.07). Multivariable linear regression was done to identify the factors that influence the improvement of the PV annulus z-score [Table 5]. Gender, blood group, presence of collaterals and palliative procedures (MBT shunt) were the variables included in the analysis and it was found that none of them were contributing to the improvement of PV annulus z-score (P >0.05). Finally, Cox hazard regression showed that after controlling for gender, presence or absence of collaterals and blood group, the risk for no improvement in PV-annulus growth was 1.33 times higher among those who did not receive BT shunt compared to those who were palliated with BT shunt [Supplementary Table 1]; however, the evidence was not statistically significant.

Discussion

This study found that the growth of PV annulus in patients with TOF does not match the somatic growth before the corrective surgical repair. In the majority of the patients, the PV annulus z-score doesn't change significantly with time which is different from the right and left pulmonary artery z-scores that increase with the growth of the patients. Certain patients had an improvement in the PV annulus z-score, however, there was no specific factor that could be identified and contribute to this improvement.

The surgical repair of TOF has advanced over the last few decades with a low risk of mortality and excellent short-term and long-term survival.[10] A recent study from the Pediatric Cardiac Care Consortium on a total of 3,283 patients showed that the survival was 98.6% and 94.5% at 1 and 25 years after repair, respectively. The in-hospital mortality in the same registry was 4.1% and occurred mainly on patients with prior shunts, repair in the earlier era (1982–2000), genetic syndromes and weight <2.5 kg. It was also found that staged repair and repair with TAP was associated with lower short-term survival but had no impact on the long-term operative outcome.[11] Loomba *et al.* conducted a meta-analysis comparing surgical repair of TOF in the neonatal or non-neonatal period.[12] Increased mortality, longer intensive care unit stay and increased rate of TAP were found in the neonatal repair group. However, no significant difference was found in regards to the need for reoperation and cardiac catheterisation during follow-up. Kirklin *et al.* retrospectively studied 814 TOF patients and found that the mortality rate was higher in TAP compared to the valve-sparing approach (4% versus 1.4%) and recommended preservation of the annulus where possible to reserve the TAP for patients with RV/LV >0.65 after the repair.[13] Several studies highlight the advantages of preserving the pulmonary valve in TOF repair.[3,14,15] Padalino *et al.* performed a multicentre retrospective study on late outcomes of

TOF repair.[14] They found that cyanotic spells occurred in 18% of the patients (compared to 31% found in the current study) and patients who had palliative BT shunt was 15% (compared to 21% in the current study population). The surgical mortality was 3% and the reoperation rate was 11.7%. Moreover, they found that perseveration of the PV was achieved in 35% of the patients and showed that it was a significant protective factor against postoperative complications. Similarly, the majority of patients in the current study underwent TOF repair with TAP (63%) compared to 37% who had a valve-sparing approach. Hoashi *et al.* demonstrated that the preservation of the pulmonary valve in TOF repair has an excellent long-term outcome with a survival rate of 98.6%% and 95.8% freedom from reoperation at 20 years.[16] Notably, the freedom from moderate or greater pulmonary valve regurgitation at 20 years was only 35.7%. It has been shown in that study that having a preoperative PV annulus z-score of less -2 was associated with developing moderate or greater pulmonary valve regurgitation.

TOF is often diagnosed now early *in utero* using a fetal echocardiogram during the mid-gestation period. Previous studies showed that the diameter of the main pulmonary artery, size of the branch pulmonary arteries, and the direction of flow in ductus arteriosus during fetal life can predict the severity of clinical presentation of TOF after birth.[17,18] Friedman *et al.* found that a low mid-gestation PV annulus z-score can predict low growth of PV annulus during late gestation and postnatally before surgical repair.[19] They also showed that mid-gestation PV annulus z-score <3.5 is associated with a high risk of cyanotic spells and a high likelihood of TAP. The limited growth of the PV annulus during fetal life could be based on the theory that blood flow promotes cardiovascular growth.[20] Ebishima *et al.* described the fetal echocardiographic features in TOF and found that the branch pulmonary arteries have almost normal growth during the mid-gestation time contrary to what is seen in the main pulmonary artery and PV annulus.[21] It was postulated that the normal growth of branch pulmonary arteries reflects the normal growth of lung mass due to flow coming from ductus arteriosus. In our study, the pattern of growth of the branch pulmonary arteries and the PV annulus was similar to what have described in the fetal studies. The growth of the right and left pulmonary arteries were matching the somatic growth, evidence by the improvement of the z scores over time. In most of the patients, the source of the blood flow in the branch pulmonary arteries is from the antegrade flow with few patients having other sources of blood flow such as MBTS, PDA stent or collaterals. It is not clear why the pulmonary annulus z-score doesn't improve with time and the theory of limited blood flow doesn't explain completely this phenomenon. It is known that individuals with the A blood group are at decreased risk of congenital heart disease.[22] In the current study, we included the blood group was included in the analysis to evaluate its association with PV annulus growth and that may have a link with degree of severity of RVOT obstruction in TOF. However, this study did not find any significant contribution of blood group to the improvement of the PV annulus. Further studies are needed using sophisticated imaging modalities such as MRI studies to determine the amount of the flow across the pulmonary valve and its association with other factors that control the growth of the RVOT and pulmonary arteries in TOF.

Staged repair of TOF is preferred in many centres over primary repair in TOF patients with severe cyanotic spells and small hypoplastic pulmonary arteries who require intervention in the neonatal period or other non-cardiac causes that prevent primary repair. This is usually managed by the placement of systemic to pulmonary shunts in the form of MBTS or central shunts. Several studies highlight the potential role of MBTS in the growth improvement of the PV annulus and pulmonary arteries. Chong *et al.* have demonstrated that systemic pulmonary shunt enhanced outgrowth of the PV annulus in patients with TOF.[23] However, if the initial PV annulus is too small, then preservation of the annulus may not be achieved. Moreover, Nakashima *et al.* have shown that MBTS increased the pulmonary annular size and the left ventricular volume before complete repair, ensuing the preservation of the PV function.[24] They postulated that following MBTS, the left ventricular volume increases hence the pulmonary blood flow increase from the VSD and results in the growth of the PV annulus. Ross *et al.* studied patients with TOF palliated with MBTS and found significant inter-stage growth of the PV and branch pulmonary arteries.[25] MBTS allows for improvement in the z-score of the branch pulmonary arteries before surgical repair. There was an absolute growth of the PV annulus following MBTS but no improvement was seen in the z-score; however, it increases the chance of valve-sparing during the intracardiac repair. In the current study, a similar pattern of growth of the PV annulus and pulmonary artery branches was noted regardless of whether the patients received palliation or not. There was some improvement with time in the PV annulus z-score after placing MBTS; however, it was not statistically significant. The patients who received palliation with MBTS had a higher incidence of repair with TAP which is similar to the findings in previous studies.[26] This indicates that these subsets of patients

have significant obstruction of RVOT and small PV annulus with less chance of growth improvement that will allow for a valve-sparing approach.

There are several limitations associated with this study. First, this was a single-centre retrospective study with no randomisation to assess the effect of palliative procedures on the growth of the pulmonary artery branches and PV annulus. Second, the measurement of the PV annulus is challenging because it is a three dimensional (3D) structure and cannot be measured with accuracy using 2D imaging modalities. The use of multislice computed tomography with 3D reconstruction may facilitate the measurement of the size of the PV annulus and visualising the geometry and the shape of the right ventricular out flow tract. However, its routine use prior to surgical repair is not justified because it has no direct impact on the clinical management with unnecessary exposure to radiation. 3D echocardiogram might have a future role in defining the complex anatomy of the RVOT and the morphology of the PV that will aid in the surgical planning for TOF. The use of surgical hegar is another method of having an accurate measurement of the PV annulus, however it was not documented consistently in all the surgical reports. Third, the duration of between the first and second echocardiographic measurements may not be enough to have significant results in regards to the PV annulus growth. However, it was also not justifiable to delay the repair because of the risk of worsening cyanosis. Finally, there was no specific z-score that determines the operative strategy in regards to valve sparing or TAP. It was entirely dependent on the surgeon's preference and judgment.

Conclusion

Most of the patients with TOF had no growth improvement of the PV annulus that matched their somatic growth before surgical repair. In a certain subset of patients, there was some improvement in the PV annulus z-score that increased the chance of having a valve-sparing repair, however, there were no specific factors including MBTS that contributed to this improvement. Further studies may facilitate the identification of possible genetic, anatomical or haemodynamic factors that may help in improving the growth of PV annulus.

AUTHORS' CONTRIBUTION

HNK conceptualised the study. SK, AH and PK collected the data. PK validated the data. HNK analysed and interpreted the data. HH and TH performed the statistical analysis. HNK drafted the manuscript. All authors approved the final version of the manuscript.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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