Do the Age of Patients with Tetralogy of Fallot at the Time of Surgery and the Applied Surgical Technique Influence the Reoperation Rate?

A Single-Center Experience

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Abstract

Background and Purpose: Primary repair of tetralogy of Fallot (TOF) has been favored in many centers for years now and results and advantages of this management seem to verify this procedure. The authors wanted to know, if the age at the time of surgery and the surgical techniques had an influence on the long-term results.

Patients and Methods: Between 1992 and 2003, 124 patients underwent complete repair of TOF at the University Hospital Münster, Germany. Patients were subdivided into two groups based on their age (< 1 year and > 1 year of age). Patients in whom a transannular patch (TAP) was used were compared with those without (NTAP), or in whom a conduit was used.

Results: Overall mortality was 8%, with an average age of death of 9.53 years (range 0.06–19.77 years). The patients' age at the time of surgery affected their survival as only two cases of death were reported among the group of children < 1 year of age (3.2%) whereas eight patients were older (12.9%; p = 0.0483). Six patients died within the first 30 days post surgery. Reoperation had to be performed in 21 cases, 13 (61.9%) of these patients were < 1 year of age at the time of surgery, eight were older (38.1%). A TAP, NTAP or conduit treatment did not show significant differences in long-term survival or freedom from reoperation.

Conclusion: Early repair of TOF within the 1st year of life can be recommended, because mortality is lower than in patients treated at a higher age. There seems no significant difference in the reintervention rate between patients treated within the 1st year of life or later.

Key Words:
Tetralogy of Fallot · Infancy · Surgical repair · Transannular patch

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Beeinflussen das Alter von Patienten mit Fallot-Tetralogie zum Zeitpunkt der Operation und die Art des chirurgischen Eingriffs die Reoperationsrate? Erfahrungen eines Herzzentrums

Zusammenfassung

Hintergrund und Ziel: Die primäre Korrektur der Fallot-Tetralogie (TOF) wird in vielen Zentren favorisiert, und die Ergebnisse und Vorteile scheinen dieses Vorgehen zu rechtfertigen. In der vorliegenden Studie sollte untersucht werden, inwieweit das Alter der Patienten zum Zeitpunkt der Operation und die chirurgische Technik einen Einfluss auf die langfristigen Ergebnisse haben.

Patienten und Methodik: Zwischen 1992 und 2003 wurden 124 Patienten mit TOF an der Universitätsklinik Münster korrektiv operiert. Die Patienten wurden, basierend auf dem Alter zum Zeitpunkt der Operation, in zwei Gruppen unterteilt (< 1 Jahr oder > 1 Jahr). Patienten, bei denen zur Korrektur ein transanulärer Patch (TAP) verwendet wurde, wurden mit Patienten verglichen, die keinen TAP erhielten (NTAP) oder bei denen ein Conduit vom rechten Ventrikel zur Pulmonalarterie implantiert wurde.

Ergebnisse: Die Gesamtmortalität betrug 8% mit einem durchschnittlichen Alter von 9,53 Jahren (0,06–19,77 Jahre). Das Alter zum Zeitpunkt der Operation beeinflusste das Überleben, da nur zwei Todesfälle in der Gruppe der Patienten < 1 Jahr auftraten (3,2%), während acht Patienten der älteren Gruppe verstarben (12,9%; p = 0,0483). Sechs Patienten verstarben in den ersten 30 postoperativen Tagen. Eine Reoperation musste in 21 Fällen durchgeführt werden, 13 (61,9%) dieser Patienten waren zum Zeitpunkt der Operation < 1 Jahr, acht waren älter (38,1%). Die Art der Operation (TAP, NTAP oder Conduit) hatte keinen signifikanten Einfluss auf das Überleben oder die Reoperationsrate.

Schlussfolgerung: Eine frühe Korrekturoperation der TOF kann empfohlen werden, da die Mortalität niedriger ist als bei später operierten Patienten. Es scheint keine Unterschiede bezüglich der Reinterventionsrate zwischen Patienten, die innerhalb des 1. Lebensjahrs oder später therapiert wurden, zu geben.

Schlüsselwörter:
Fallot-Tetralogie · Säuglingsalter · Chirurgische Therapie · Transanulärer Patch

Introduction

Total corrective surgery for tetralogy of Fallot (TOF) was introduced more than 50 years ago [16], and it has been used as the primary therapy for more than 30 years [4, 6, 7]. Depending on the anatomy and the surgeon's experience, a modified Blalock-Taussig shunt with the use of a polytetrafluoroethylene (PTFE) graft might be used as an initial palliative treatment [2, 5, 18]. Primary repair of TOF has been favored in many centers, because the advantages of this technique include an early termination of cyanotic periods, less late postoperative ventricular arrhythmia, and a prevention of extending right ventricular hypertrophy due to the right ventricular outflow tract obstruction as well as palliative shunt procedures and subsequent secondary total corrections [9, 10, 12]. Nowadays, the diagnosis of TOF itself implies surgical treatment.

Complete repair of TOF consists of closure of the ventricular septal defect and treatment of right ventricular outflow tract obstruction. This can be achieved with a subvalvular patch after infundibulotomy, a transannular/transvalvular patch or a valved or nonvalved conduit from the right ventricle to the pulmonary arteries, depending on the anatomic details.

In the Heart Center of the University of Münster, Germany, TOF is regularly treated since the early 1990s. There were a few patients initially palliated based on the pulmonary artery anatomy (total number of patients palliated: 13; Blalock shunt n = 7, Waterson shunt n = 3, aortopulmonary shunt n = 2, aortopulmonary shunt + Waterson shunt n = 1; all patients received palliative treatment during their 1st year of life), but the majority underwent corrective surgery at different ages. Only one of the patients who underwent palliative procedures (aortopulmonary shunt) belonged to group 1 (see below). We elected to review our institutional experience over 12 years to determine if the age at the time of surgery and the surgical techniques affected the long-term results.

Patients and Methods

Data for this retrospective study was acquired from the cardiosurgical database of the University Hospital Münster (UKM), Germany, and a review of medical records. Included were patients who underwent surgical treatment for TOF, but all patients identified with nonconfluent pulmonary arteries, absent pulmonary valve syndrome, associated atrioventricular septal defect, or significant aortopulmonary collaterals were excluded, because surgical treatment is different in these entities. All patients underwent echocardiography preoperatively. Furthermore, cardiac catheterization was performed to clarify the pulmonary artery anatomy. The echocardiographic and catheterization reports as well as the surgical notes were reviewed.

Patients were divided into two groups according to their age at surgical repair (group 1 < 1 year, group 2 > 1 year). This was typically dependent on their age at referral to our institution. As many centers nowadays treat children with TOF within the first few months of life, we subdivided group 1 into children < 6 months and > 6 months of age. There was no difference found in this analysis and, therefore, the division was kept as described above.

Surgical technique consisted of patch closure of the ventricular septal defect, infundibulectomy or valvulotomy (as appropriate). Depending on the anatomy, either a right ventricular outflow tract plasty, a transannular patch (TAP) or the combination of both was performed. If a homograft was used, it was typically oversized by around 150% of the expected vessel diameter.

Operative management included hypothermia (average 30.52 °C), cardioplegia, and low-flow cardiopulmonary bypass.

Postoperative management was consistent for all patients over the whole study period.

Follow-up was defined as the time from surgery to the last available cardiologic examination including echocardiography.

Reoperation or reintervention was defined as an additional general procedure carried out after the initial treatment, like homograft exchange, interventional or surgical dilatation/augmentation of the right ventricular outflow tract or pulmonary valve, implantation of a valved conduit from the right ventricle to the pulmonary artery or additional patch augmentation of either the main or the branch pulmonary arteries. Indication for reintervention or reoperation was based on echocardiographic and catheterization data and included severe regurgitation from the pulmonary arteries to the right ventricle, and stenosis of the main or branch pulmonary arteries (or of a homograft, if used).

Mortality and the frequency of reoperation/reintervention were compared between all patients with an age at surgery of < 1 year (group 1) to those > 1 year (group 2). Early mortality was defined as death earlier than 30 postoperative days. Based on the surgical treatment the study population was split up in three groups: children treated with a TAP (44 patients, 35.5%), homo- or xenografts (conduit, 16 patients, 12.9%), and an infundibulectomy or valvulotomy (NTAP, 64 patients, 51.6%). The results of surgery with the use of a TAP were compared to those without (NTAP).

Statistical Analysis

For statistical analysis we used the software SPSS version 12.0 (SPSS Inc., Chicago, IL, USA). Student's t-test or Fisher's exact test as well as Kaplan-Meier

survival analysis for evaluation of time-dependent events in reoperation and survival were applied, as appropriate. A $p < 0.05$ was considered to show statistical significance.

Results

Between January 14, 1992, and June 17, 2003, 124 patients underwent complete repair of TOF. There were 75 male (60.5%) and 49 female (39.5%) patients with an average age at operation of 4.06 years (range 0.04–33.04 years).

62 patients were < 1 year at the time of surgery (average age: 0.47 years, 37 male, 25 female; group 1) and the same number of patients were older (average age: 7.64 years, 38 male, 24 female; group 2). Demographic data are shown in Table 1.

Dependent on the anatomic findings, 44 patients had to be treated with a TAP, and 16 patients needed a homo- or xenograft reconstruction of the continuity between right ventricle and pulmonary arteries.

Overall mortality was 8% (six male and four female patients), with an average age at death of 9.53 years (range 0.06–19.77 years). Six patients died within the first 30 days post surgery (early mortality: three male, three female), the remaining four died later during follow-up (late mortality: three male, one female).

Within group 2, eight patients died (12.9%); among these there were all six cases of early mortality. Two cases of death were reported among group 1 (3.2%), both of them belonging to late mortality (see Table 1 and Figure 1). Low output during the first 4 days postoperatively was the cause of death in three patients of group 2. One patient of group 1 died 3.5 years postoperatively from left heart failure of unknown origin. The others died out of hospital and the cause of death was not specified in the notes of the UKM.

A significant difference (log rank $p = 0.0483$) could be seen in comparison of survival of group 1 and group 2.

Median follow-up was 4.68 years (range 0.06–11.53 years).

Reoperation had to be performed in 21 cases, 13 of these patients were < 1 year of age at the time of surgery (group 1: 61.9%), eight were older (group 2: 38.1%). The type of reoperation is shown in Table 2.

Patients of group 1 had to undergo reoperation at an earlier age (average of 1.94 years after initial surgery), whereas the interval until secondary surgery was longer in older children of group 2 (average of 2.71 years; see Figure 2). Despite the obvious differences in both groups log rank of 0.09 did not show significance.

Among the groups of NTAP and conduits three patients died (two patients of group 1, one patient of group 2 [4.9% NTAP, 18.8% conduit]). The group of children treated with a TAP showed four cases of death (9.1%), all of these were > 1 year of age at the time of surgery (group 2; see Figure 3). Significant differences on survival regarding the use of TAP could not be seen (log rank 0.1687).

As already mentioned above, reoperation had to be performed in 21 patients (16.0%; ten female, 47.6%, eleven male, 52.4%). There were ten cases of NTAP

Table 1. Demographic data, mortality rates after total repair of tetralogy of Fallot (TOF), and surgical technique applied during total repair of TOF. (N)TAP: (no) transannular patch.

Tabelle 1. Demographische Daten, Mortalitätsrate nach korrektiver Chirurgie der Fallot-Tetralogie (TOF) und angewandte chirurgische Technik. (N)TAP: (kein) transanulärer Patch.

	Overall	Group 1	Group 2
Patients (n)	124	62	62
Sex [n (%)]	Male: 75 (60.5) Female: 49 (39.5)	Male: 37 (59.7) Female: 25 (40.3)	Male: 38 (61.3) Female: 24 (38.7)
Age (years)	4.06 (0.04–33.04)	0.47 (0.04–0.99)	7.64 (1.02–33.04)
Weight (kg)	15.77 (3–77)	6.15 (3–11)	25.04 (7–77)
Overall mortality [n (%)]	10 (8)	2 (3.2)	8 (12.9)
Early mortality (n)	6	0	6
Late mortality (n)	4	2	2
NTAP [n (%)]	64 (51.6)	31 (50.0)	33 (53.2)
TAP [n (%)]	44 (35.5)	24 (38.7)	20 (32.3)
Conduit [n (%)]	16 (12.9)	7 (11.3)	9 (14.5)
Follow-up period (years)	4.68 (0.06–11.53)	4.21 (0.15–11.53)	5.12 (0.06–11.05)
Palliative operations (n)	13	1	12

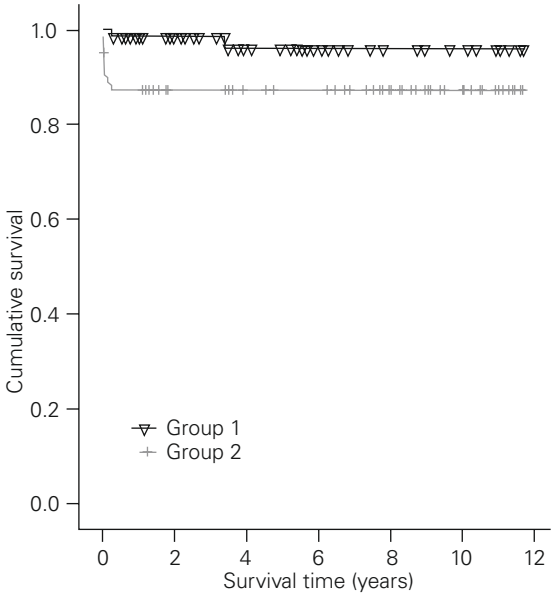

Figure 1. Kaplan-Meier graph showing overall survival rate after corrective surgery of TOF in children < 1 year (group 1) and > 1 year (group 2) at the time of surgery.

Abbildung 1. Kaplan-Meier-Kurve: Überleben nach korrektiver Chirurgie der TOF bei Patienten < 1 Jahr (Gruppe 1) und > 1 Jahr (Gruppe 2) zum Zeitpunkt der Operation

Table 2. Reoperations. PA: pulmonary artery; PV: pulmonary vein; RV: right ventricle; VSD: ventricular septal defect.

Tabelle 2. Reoperationen. PA: Pulmonalarterie; PV: Pulmonalvene; RV: rechter Ventrikel; VSD: Ventrikelseptumdefekt.

Type	Number
RV-PA conduit exchange	2
PA augmentation	3
Implantation of valved RV-PA conduit	8
Closure of residual VSD	5
Pacemaker implantation	2
PV commissurotomy	1

(15.6%), six of these belonging to group 1, the remaining four children were > 1 year of age (group 2). Seven cases of TAP (15.9%) were reoperated, three children of group 1 and four older children of group 2. 25.0% (four cases, all group 1) of the children treated with a conduit in the first line needed reoperation later (see Figure 4). There was no statistical significance when comparing the different kinds of surgical treatment (log rank 0.7197).

Surgical details (bypass time, X-clamp) are shown in Table 3.

Discussion

More than 50 years after Lillehei's first total repair of TOF in infants, there still are discussions about the best way to treat patients in their 1st year of life. Depending on the anatomy, most centers are performing early total repair of TOF nowadays [1, 8, 15]. Data of long-term survival and freedom from reintervention after early total repair of TOF is increasing but the outcome is still little indeterminate as long follow-up periods are limited in literature. Our report sums up a single-institution's experiences with early and late total repair of TOF as well as an influence of a TAP, NTAP or conduit surgical performance on survival and freedom from reoperation. All our patients were treated by the same surgeons and intensivists. Thus, both groups are easily comparable.

We can report an overall survival rate of 92% during a follow-up period of up to 11 years (Table 4). This is comparable to other reports of patients corrected at different ages in their lives [1, 11, 14, 17, 20].

The only significant risk factor in our study was age at the time of surgery regarding survival (log rank p = 0.0483). Early mortality in children of group 1 (early mortality: 0%) compares favorably with recent studies that show a range from 0% to 5% [8]. Within group 2, eight patients died (12.9%); among these there were all six cases of early mortality (75% of deaths in this group). Five of these total repair procedures were done between 1992 and 1996, so that an improvement of survival can be seen in the more recent era most presumably on the basis of better surgical skills and

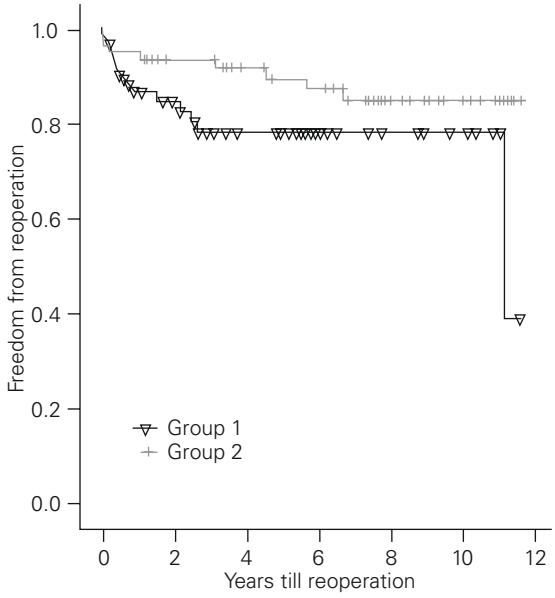

Figure 2. Kaplan-Meier graph showing time of freedom from reoperation after corrective surgery of TOF in children < 1 year (group 1) and > 1 year (group 2) at the time of surgery.

Abbildung 2. Kaplan-Meier-Kurve: Freiheit von Reinterventionen nach korrektiver Chirurgie der TOF bei Patienten < 1 Jahr (Gruppe 1) und > 1 Jahr (Gruppe 2) zum Zeitpunkt der Operation.

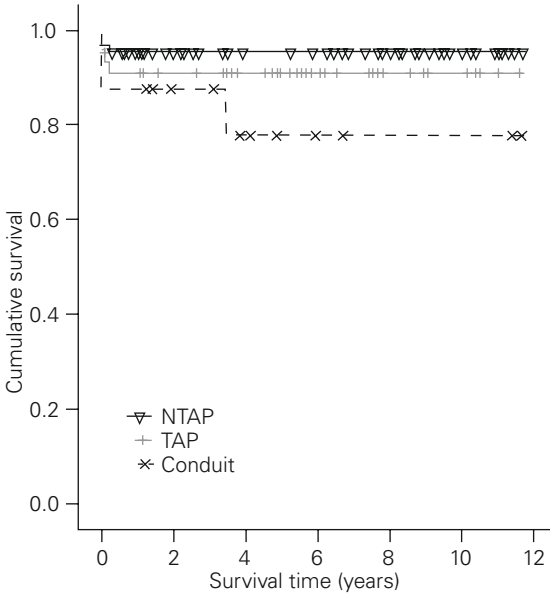

Figure 3. Kaplan-Meier graph showing overall survival rate after corrective surgery of TOF with and without the use of TAP and conduits.

Abbildung 3. Kaplan-Meier-Kurve: Überleben der Patienten nach korrektiver Chirurgie der TOF mit und ohne TAP oder mit Conduit.

	Overall	Group 1	Group 2	Overall mortality	Early mortality	Late mortality
Surgical procedure (min)	200.28 (100–815)	192.71 (100–445)	208.54 (113–815)	319.60 (135–815)	403.50 (181–815)	193.75 (135–256)
Cardiopulmonary bypass (min)	115.56 (40–743)	112.82 (44–284)	120.25 (40–743)	202.50 (73–743)	286.67 (86–743)	101.33 (73–125)
Aortic X-clamp (min)	61.34 (19–226)	57.77 (19–136)	64.90 (22–226)	104.33 (48–226)	115.17 (48–135)	85.33 (48–226)

Table 3. Surgical data (mean, ranges).

Tabelle 3. Chirurgische Daten (Mittelwert, Bereiche).

increased institutional experience. This thesis would correspond with a study done by Knott-Craig et al. [14] who were able to show that overall mortality was significantly higher before 1990. Other explanations for the higher early mortality can possibly be seen in Table 3. The duration of surgical intervention, cardiopulmonary bypass and aortic cross-clamp was significantly longer in patients who died early postoperatively compared to all patients and compared to all deaths. All patients who died were clinically symptomatic prior to surgery. These symptoms varied from discrete cyanosis to severe hypoxic spells with central cyanosis. Recently, Kolcz & Pizarro [15] assumed that early repair of TOF in asymptomatic neonates is safe and that those patients were not exposed to additional risk because of the strategy utilized.

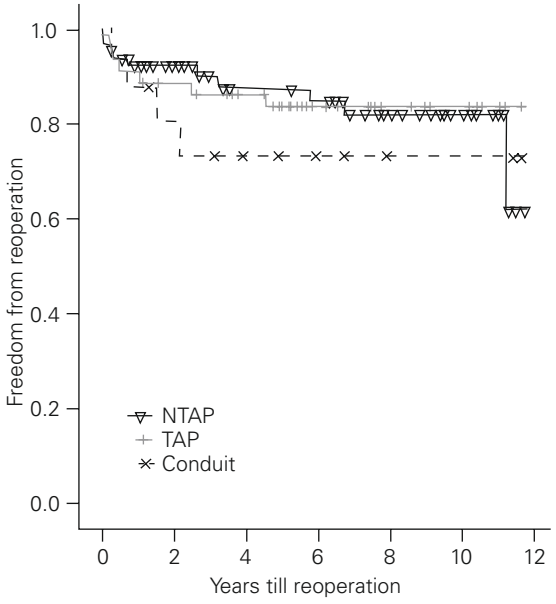

Figure 4. Kaplan-Meier graph showing time of freedom from reoperation after corrective surgery of TOF with and without the use of TAP and conduits.

Abbildung 4. Kaplan-Meier-Kurve: Freiheit von Reintervention nach korrektiver Chirurgie der TOF mit und ohne TAP oder mit Conduit.

Table 4. Number of patients during follow-up periods.

Tabelle 4. Anzahl der Patienten während der Nachuntersuchungszeit.

Number of patients during follow-up periods (years)	Beginning	Up to 3 years	Up to 6 years	> 6 years
Total	124	90	62	42
Group 1	62	42	21	14
Group 2	62	48	41	28

On the other hand, Van Arsdell et al. [19] found that age < 3 months at the time of total repair of TOF was associated with a prolonged hospital stay. Our results support these findings. The average hospital stay was 20.2 days, whereas children < 3 months of age had an average stay of 30.5 days.

Although children of group 1 had a better performance on survival after primary repair, they needed to be reoperated more frequently and showed a shorter average period of time (13 cases) before secondary surgery compared to group 2. The difference was not significant. Overall 16.9% of all our patients treated needed to undergo secondary surgery. In nine cases the need for reoperation was mostly based on right ventricular outflow tract obstruction which was either treated by augmenting the stenotic segment or a conduit was used for initial repair, whereas patients of group 2 just showed four cases of right ventricular outflow tract obstruction. A residual ventricular septal defect seemed to be another reason for reoperation in group 1. Five ventricular septal defect closing procedures were necessary, four of them were performed on children of group 1. Freedom from reoperation did not show a significant difference between the two groups, but struggling with reoperation of typical anatomic conditions of TOF was more common in group 1.

Treatment with or without a TAP did not make any significant difference in our study regarding the need for reoperation which compares very favorably with other studies [3, 13]. Patients treated with a con-

duit in first line had a much higher need for reoperation (25%) than those treated with or without a TAP. In one of the patients mentioned above, belonging to group 1, the conduit had to be replaced during reoperation.

Early repair of TOF is safe and has a good outcome. It prevents the children from hypoxic spells and increasing right ventricular outflow tract obstruction [9, 10, 12]. The need for reintervention is probably determined by the underlying anatomy. In cases of severe right ventricular outflow tract obstruction, a conduit might be needed, which has to be replaced due to growth. A TAP will cause pulmonary regurgitation, which will, dependent on degree and time, lead to right ventricular dilatation with the need for consecutive valve insertion, i.e., homograft implantation. Transvenous catheter approach to implant a pulmonary valve without open heart surgery was introduced by Khambadkone et al. [13] with favorable results, but is still only performed in very few centers, and is not routine by now.

Conclusion

Early repair of TOF within the 1st year of life can be recommended, because mortality is lower than in patients treated at a higher age. The reintervention rate for patients treated within or after the 1st year of life does not differ significantly.

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