Surgery following primary right ventricular outflow tract stenting for Fallot’s Tetralogy and variants: rehabilitation of small pulmonary arteries†

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Abstract

OBJECTIVES: Primary surgical repair of Tetralogy of Fallot (ToF) in small infants with small pulmonary arteries (PAs) or complex anatomies can be hazardous. We assessed the effect of right ventricular outflow tract (RVOT) stenting on subsequent surgical intervention with attention to growth of the PAs.

METHODS: Primary RVOT stenting was performed in 32 symptomatic patients with ToF physiology. Twenty patients had surgical intervention, with 15 undergoing complete repair to date. Median age at stenting was 61 (range 8-406) days, and median weight, 3.9 (range 1.8-12.2) kg.

RESULTS: Stenting improved saturations from 72 ± 8 to 92 ± 2% (P < 0.001). Four patients required early surgical palliation for persistent desaturation (within 4 weeks). Twenty patients went on to have surgical intervention at a median time of 220 days after stenting. There was no operative mortality after complete repair. Removing the stent lengthened the procedure time and 86% required transannular patch (TAP; bypass time 109 ± 42 min, cross clamp 68 ± 29 min). Median intensive therapy unit stay was 2 days. There was 1 late death at 3 months due to chronic lung disease. The median left PA Z-score increased from a preinterventional value of +0.11 (~4.12 to +1.97). The median right PA Z-score increased from ~2.02 (~1.77 to ~4.68) to ~0.65 (~0.29 to ~2.04) over the preinterventional and presurgical time intervals. Growth was greatest in the right PA.

CONCLUSIONS: Primary RVOT stenting facilitates staged palliation for ToF in small infants and complex anatomies. Improved PA blood flow generated by the stent leads to growth of the branch PAs and may improve the substrate for subsequent surgical repair. Surgery is safe; however, the majority will require a TAP.

Keywords: Right ventricular outflow tract • Tetralogy of Fallot • Stenting

INTRODUCTION

Single-staged repair of Tetralogy of Fallot (ToF) has become the preferred management strategy for the majority of cases, particularly in elective situations. However, there remains an important sub-group of higher-risk patients in whom staged repair (an initial palliative procedure followed by definitive elective repair) may still be indicated. These patients can be divided into: (i) neonates/small infants with small pulmonary arteries (PAs) and (ii) complex anatomical variants (such as Fallot/atrioventricular septal defect [AVSD] or major non-cardiac conditions) where single-stage repair may carry high risk or there may be benefit from planned delay.

The ideal management of these high-risk groups remains debatable, particularly when they present in an urgent or emergency situation with cyanosis and spells [1-3]. If a staged approach is preferred, then an arterial shunt is also not without risk, particularly in neonates [4-7]—which has led to increasing interest in the use of the right ventricular outflow tract (RVOT) stent as an alternative palliative strategy to secure pulmonary blood flow in these cyanotic patients [8-10].

RVOT stenting has many potential benefits in terms of stabilizing the clinical condition, improving PA flow and allowing for elective repair in the future. However, the presence of the stent may make subsequent repair more complex and commit to transannular incision. This study sought to review our experience with the use of RVOT stents in ToF (and variants), with particular focus on the outcome of subsequent surgery and defining the risks and benefits associated with the stenting procedure.

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MATERIALS AND METHODS

In our institution, we began using the RVOT stent in 2005 as an alternative to the Blalock-Taussig (BT) shunt. In this retrospective study, all patients with ToF (and variants) who received palliation with an RVOT stent were included from 2005 to the end of the study in September 2011. During this period, 32 patients underwent primary RVOT stenting. There were two indications for stent implantation:

(i) Cyanotic infants with small PAs or low birth-weight neonates with or without spells. Patients under 4 kg in weight or with branch PAs Z-score of < −2 were considered (n = 19).

(ii) Complex anatomy or comorbidity that increased the risk and complexity of complete surgical repair, e.g. AVSD/Fallot, anomalous left anterior descending artery (LAD), unroofed coronary sinus or chronic lung disease (n = 13).

Details of the patients and indications for intervention are summarized in Table 1. All patients were discussed at the multidisciplinary cardiac conference, and the decision to palliate or undertake single-stage repair was taken according to the criteria outlined above. The characteristics and complexity of the anatomy and associated non-cardiac lesions were assessed on an individual patient basis and are summarized in Tables 1 and 2.

Table 1: Patient characteristics (Group a): patients of low weight and/or small branch PAs

| (n = 19) | 
| Mean age | 33 ± 25 days |
| Median age | 23 days |
| Age range | 7–80 days |
| Mean weight | 3.2 ± 0.9 kg |
| Median weight | 3.2 kg |
| Weight range | 1.7–4.4 kg |
| Branch PA size | 3.2 ± 0.6 mm |
| Branch PA Z-score | −1.5 ± 0.8 |

Table 2: Patient characteristics (Group b): patients with complex anatomical variants and comorbidities

| (n = 13) | 
| ToF/AVSD | 3.7 kg | 2 months | Down’s syndrome |
| ToF/AVSD/multiple VSD | 8.0 kg | 8 months | Down’s syndrome |
| ToF/DORV/multiple VSD/borderline LV | 7.9 kg | 12 months | Isomerism |
| ToF | 3.9 kg | 10 months | Down’s syndrome, short gut syndrome, TPN, chronic lung disease |
| ToF | 12.2 kg | 14 months | Alstrom syndrome, recent pulmonary TB |
| ToF/unroofed CS/BiSVC | 4.4 kg | 8 months | Previous infected BT shunt (explanted) |
| ToF/AVSD | 3.1 kg | 2 months | Down’s syndrome |
| ToF/MAPCAs | 5.6 kg | 3 months | Laryngeal web, tracheostomy |
| ToF | 4.6 kg | 2 months | Isomerism |
| ToF/AVSD/BiSVC/TAPVC | 5.9 kg | 4 months | CHARGE, bilateral complete cleft, chronic lung disease |
| ToF/DORV | 7.0 kg | 8 months | CHARGE, premature, chronic lung disease |
| ToF | 4.5 kg | 5 months | VACTRL, Fanconi syndrome, oesophageal atresia |
| ToF | 2.4 kg | 1 month | |

AVSD: atrio-ventricular septal defect; BT: Blalock-Taussig; DORV: double outlet right ventricle; LV: left ventricle; CS: coronary sinus; BiSVC: bilateral superior vena cava; TAPVC: total anomalous pulmonary venous connection; TB: tuberculosis; TPN: total parenteral nutrition.

Stent implantation

Stents were implanted using bi-plane angiography via femoral venous route. The implantation technique involved crossing the RVOT with a telescopic configuration of catheters with the aid of a guide wire, securely placing a coronary wire, preferentially, into the distal right PA (RPA) and deploying the stent through the guide catheter.

The most commonly used fluoroscopic planes for positioning and stent deployment were a right anterior oblique projection with cranial angulation and a left anterior oblique projection also with cranial angulation.

In this cohort of patients, the stent types used consisted of the Liberté Premounted Coronary Stent (Liberté stent; Boston Scientific, Natick, MA, USA) and the Jostent peripheral stent graft (Jomed International AB, Helsingborg, Sweden). In all but 3 patients, the stent crossed the pulmonary annulus. Stent dimensions were 4–5 mm diameter and 12–16 mm length. Four patients required deployment of a second stent during the same procedure to address an area of uncovered infundibulum on post-deployment angiography (3 distal and 1 proximal). The median duration of surgery from the first stent placement was 218 (range 0–758) days.

All patients undergoing RVOT stenting were commenced on aspirin therapy.

Measurement of pulmonary arteries

Left PA (LPA) and RPA growth were assessed retrospectively in the 20 operated patients on echocardiographic images obtained prior to all interventional procedures and surgical interventions. Echocardiography was used because detailed and complete studies were available on all patients at all time points. Angiography was not routinely performed in all cases at the time of surgery and so could not be used for uniform analysis across the series.

The most frequently used views for analysis comprised of the parasternal, suprasternal and sub-costal right anterio-oblique type views. Measurements were taken in systole just distal to the
main pulmonary artery bifurcation of the PAs. Measurements were repeated on multiple frames, and only values that were reproducible to within ≤0.10 mm were accepted for analysis.

All branch PA measurements were Z-scored against the body surface area as calculated using body weight by the Boyd Equation and charted in the British National Paediatric Formulary. Z-score calculations were performed on vessel measurements prior to each intervention with the primary focus on preinterventional and presurgical right and left PA Z-scores. Z-scores were calculated using the regression equations outlined by Pettersen et al. [11].

**Statistical methods**

Data have been examined using the statistical software package ‘R’ (version 2.4, R Foundation, Vienna, Austria). Continuous variables are expressed as mean (standard deviation) or median (range), and comparative univariable analyses have been made using the Wilcoxon test for PA measurements and unpaired t-test for a comparison of bypass data between groups. Binomial or ordinal data are expressed as percentages, and comparative univariable analyses have been made using two-sided Fisher’s exact test. A probability value, \( P < 0.05 \), was taken to represent a statistically significant difference between groups.

**RESULTS**

The outcomes for the 32 patients are shown in Fig. 1. Stenting was successfully achieved in 31 of the 32 patients. In the remaining case, the outflow tract was perforated in the catheter lab and the patient required emergency surgery. The case was of a 3.7-kg infant with ToF/AVSD, who underwent a limiting RVOT patch with good result and complete repair 1 year later. Three further patients required early (within 4 weeks) surgical reintervention for recurrent desaturation and/or spelling. Two of these procedures were BT shunts with one early mortality from sudden cardiac arrest 2 days postoperatively. The third patient underwent complete repair: this 1-year old child had been stented due to having recently completed treatment for tuberculosis, but had well-developed PAs.

Of the 27 patients with successful sustained palliation, 15 have gone on to have definitive repair (discussed below) and the remaining 12 remain on-track for planned repair in the future.

**Stenting of the RVOT**

Stents were successfully deployed in 31 of the 32 patients (1 patient required emergency surgery, below), and there were no other cases during the time of this study in whom the procedure had to be abandoned or was not achievable (Fig. 2). There were 19 patients in Group (a), classified as being small in size ± small PAs. The median age at stent placement was 23 (range 8–87) days, and median weight, 3.2 (range 1.75–4.4) kg. There were 10 neonates, of whom 6 had a weight <3.0 kg. Every patient was either under 3 kg in weight or had a branch PA size Z-score of ≤−2. The 13 patients in Group (b) with complex anatomy (Table 1) presented at a wider age range with stent placement performed at a median of 135 (range 36–406) days and median weight 5.6 (range 3.1–12.2) kg.

For the whole group of patients, RVOT stenting increased oxygen saturations by a mean of 20% after the RVOT stent implantation, from a mean of 72 ± 8 to 92 ± 2% post-stent implantation (\( P < 0.001 \)).

During the study period, 4 patients received a second stent for recurrence of cyanosis. All were in Group (b), for which it was agreed that further palliation was indicated. The second stents were placed at a median of 139 (range 41–194) days after the initial stent. All patients have subsequently gone on to have complete repair.

Figure 1: Outcome for the entire cohort of 32 patients with ToF (and variants) undergoing RVOT stenting.
Pulmonary artery growth

Within the entire group of patients who have undergone complete surgical repair, the median LPA Z-score increased from a preinterventional value of −1.27 (−0.19 to −2.87) to a presurgical value of +0.11 (−4.12 to +1.97) as shown in Fig. 3.

The median RPA Z-score increased from −2.02 (−1.77 to −4.68) to −0.65 (−0.29 to −2.04) over the preinterventional and presurgical time intervals (Fig. 3).

Surgical intervention

All the patients underwent standard cardiopulmonary bypass techniques with aorto-bicaval cannulation and moderate hypothermia. Thirteen of the 15 (86%) repaired patients required a transannular patch (TAP) utilizing a monocusp aortic homograft patch. Complete stent removal was possible in only 7 patients. The usual finding was fibrous growth in the muscle bars around the stent (Fig. 4). In 9 patients, a small part of the stent was left in situ to avoid damage to the surrounding tissue and the margin of the VSD. The remnant of the residual stent did not appear to make placement of the VSD sutures difficult, and there were no instances of residual VSD. One patient required an right ventricle-pulmonary artery (RV-PA) conduit for anomalous LAD and, in this patient, the stent was left in situ.

The average bypass time was 109 ± 42 min (median 95 min) and cross-clamp time 68 ± 29 min (median 67 min). The median intensive therapy unit (ITU) stay was 2 days.

We compared the bypass times, cross-clamp times and the use of TAP in the last 90 consecutive patients (2008–11) who had ToF repair (not palliated with an RVOT stent) in our hospital. Sixty-four of the 90 (71%) patients had TAP, and the mean bypass and cross-clamp times were 63 ± 22 and 88 ± 36 min, respectively. This was not significantly different from the TAP rate in the stented patients (Fisher’s exact test, P = 0.12). Although the cross-clamp times and total bypass times in the stented group

Figure 2: Angiograms from the same patient undergoing RVOT stenting. (A) as a cyanotic neonate and (B) 3 months later.

Figure 3: PA growth (Z-scores) at the time of RVOT stenting and prior to surgery. Box and Whisker plot showing the inter-quartile range and median (solid line) for the Z-scored branch PA sizes. L: left PA; R: right PA. ‘Stent’ is the size of the PA at the time of RVOT stenting. ‘Surg’ is the size of the pulmonary artery at the time of surgical repair. ‘Growth’ represents the change in the PA Z-score between stenting and surgery.
Complications following complex Fallot
previously had BT shunt endocarditis. She underwent emergency unroofed coronary sinus and bilateral superior vena cava for RVOT obstruction.

Muscle bars proximal to the stent that were creating persistent symptoms were in good position, but there were further infundibular differences did not reach statistical significance ($P = 0.2$ and 0.3, respectively).

Complications following RVOT stenting

As discussed above, 1 patient suffered cardiac perforation needing emergency surgical intervention. A further 3 patients had recurrent symptoms early after RVOT stenting and underwent surgical reintervention as outlined above. One of these patients died after BT shunt. In all 3 cases, the stents were found to be in good position, but there were further infundibular muscle bars proximal to the stent that were creating persistent RVOT obstruction.

There was one episode of stent endocarditis in a patient with unroofed coronary sinus and bilateral superior vena cava who previously had BT shunt endocarditis. She underwent emergency correction of complex Fallot's tetralogy, left-sided bidirectional Glenn (1¼ type repair), RV-PA conduit (16-mm Contegra), excision of infected RVOT stents and closure of coronary sinus ASD. She made a complete recovery with no evidence of further infection.

Four patients required a second RVOT stenting procedure. All were in Group (b) and were performed at a median of 139 days after the initial stent with no complications (see Section 3.1 above). There were no instances of stent fractures.

Complications following surgery

No patient suffered from postoperative tachycardia or heart block. There was no 30-day mortality following complete repair in the 15 patients. There was 1 late mortality 3 months after surgery due to chronic lung disease. This 10-month old patient had Down's syndrome and short-gut syndrome on TPN following neonatal necrotizing enterocolitis and had been an inpatient since birth with chronic respiratory problems.

Among the five surgical palliations, there was 1 early mortality following a BT shunt and left PA plasty on bypass in the context of poor growth of the LPA after initial RVOT stenting 3 days after surgery. He had sudden cardiac arrest and went on to have extra corporeal life support and subsequently developed multiorgan dysfunction. One patient with ToF/DORV had initially undergone RVOT stenting due to concerns over the size of the left ventricle. At follow-up, these concerns were confirmed and the patient underwent bidirectional Glenn shunt, with the RVOT stent left in situ, which will probably go down the single-ventricle pathway.

DISCUSSION

Despite constant improvements in outcomes for ToF, most series recognize a small group of patients who remain at high risk even in the current era. These patients fall into two groups: the cyanotic neonate/small infant with small PAs and patients with complex anatomical variants or significant comorbidities. There is an argument for palliation within these high-risk groups to allow for elective repair in the future [4–7, 12].

There is increasing enthusiasm for single-stage repair, even in symptomatic neonates—but in most cases, the outcomes are strikingly different from those achieved in older age groups. The recent Southern Thoracic Society (STS) series analysed over 3000 ToF repairs (2002–07) and showed a 7.3% mortality compared with 1.5% in older infants [13]. The study concluded that the best results for repair were achieved if performed at 3–12 months of age. There are few large studies of neonatal repair in the literature, and although outcomes are improving, they are associated with longer ITU stay, increased need for circulatory arrest, a high TAP rate and a high surgical reintervention rate of 25–30% at 5 years [1–3].

A component of the drive towards single-stage repair has been on-going concerns with outcomes of the BT shunt in neonates that remains an unpredictable circulation to manage and in whom operative mortality is also significant—the STS have also published current outcomes from the BT shunt in over 1200 cases between 2002 and 2009 with an early mortality of 7.3% [14]. Even excluding univentricular circulations, the mortality was 5.1% among ToF. Results in the UK registry were almost identical to the STS series—results showing low procedure-related mortality, primary RVOT stenting seems a safe alternative to systemic-to-pulmonary shunting to achieve improved pulmonary blood flow while avoiding low diastolic pressures [8–10]. There has also been evidence of PA growth following stenting, which may create a more suitable substrate for subsequent repair. However, the impact of the stent on subsequent surgical repair has not previously been described.
This study has provided further evidence of true PA growth subsequent to stent placement. This is particularly valuable in the smaller patients who present with severe cyanosis, may have very small branch PAs and not be attractive candidates for primary repair. Small PAs have been repeatedly shown to be a risk factor for early death in ToF repair [12, 16]. We chose a Z-score of $-c.2$ as a guide to defining the ‘small’ PA for the purpose of this study, but any patient under 4 kg was also considered for RVOT stent palliation over repair. These results suggest that the stent can successfully palliate these patients such that elective repair can be performed in the low-risk age group—and with better-sized PAs.

The disadvantages of RVOT stenting that we perceived in our experience are:

(i) More patients may be committed to TAP (though not statistically significant in our study). We cannot say whether this is the case from this study, but it is important to comment that most neonatal fallots that present with severe cyanosis are those with more severe RVOT obstruction and small outflow tracts that would predispose them to requiring TAP using any strategy. (In the Toronto series, the pulmonary annulus Z-score was $-6.7$ [8]) The rates of TAP in this study were very similar to those reported in series of neonatal repair [1–3, 12].

(ii) Complete removal of the stent is not possible in all cases contrary to other reports [17, 18]. Often, remnants of the stent are embedded into the myocardium and close to the VSD margins. It is still unknown whether these retained stents will be a focus for future ventricular arrhythmias or infections. The small retained portions of the stent did not prevent satisfactory anatomical repair in this experience, but will need close surveillance in the future.

Complications following RVOT stenting need special attention. The technique requires experienced interventionists and can be technically difficult in small infants. Tamponade, stent migration, arrhythmias, stent fracture, stent endocarditis, coronary artery compression and death have all been described [9, 19–21] but are rare, as we found in our experience with only one episode of tamponade and no failed deployment. It is believed that the high forces from the hypertrophied muscle can lead to stent fractures and subsequent restenosis, but we have not encountered this to date. The relatively short period for which the stents are required may reduce this risk [19–21].

The limitations of this study are self-evident in that this is an observational retrospective study. Although there were clear indications for the use of the RVOT stent, we recognize that the final decision was a subjective decision taken by consensus, in assessing individual patient risk factors. A prospective and randomized study between RVOT stent and primary repair would be necessary to evaluate this further. The measurements of PA size were undertaken by a non-blinded observer, which could have biased results, although they were based on repeated measurements.

In conclusion, primary RVOT stenting is a valuable mode of staged palliation in ToF in small neonates and children with complex anatomy and significant morbidities. Stenting allows for genuine growth of small PAs and creates a better substrate for subsequent surgical repair. Surgery following RVOT stenting is safe, with few complications, but a high incidence of TAP. Although the great majority of children with ToF can successfully undergo single-stage repair, there remains this small but higher-risk sub-group who may benefit from a staged approach, avoiding the risks of the BT shunt.

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REFERENCES

APPENDIX. CONFERENCE DISCUSSION

Dr A. Bogers (Rotterdam, Netherlands): Indeed, small children with complex anatomy or important comorbidities may need preparative treatment before corrective or further palliative treatment may be applied, and in this regard, RVOT stenting may be a useful approach in selected cases with obstructed RVOT. I agree that RVOT stenting has been shown to be feasible. It should, however, be applied on appropriate indication, and it should not be used when surgery is not yet indicated at all.

Your manuscript could provide useful data in this regard, but the title of your manuscript is a little confusing and your analysis is blurring the information somewhat. I am sorry to say. You write that the entire cohort of RVOT stenting is beyond the scope of your manuscript. You mention, however, 32 patients, but describe only 20, of whom only 15 have clear-cut tetralogy of Fallot. And of the described patients, only a minority of them are below 3 kg, and only a minority are described as having important comorbidity. In addition, echocardiography is not the best reliable method to measure small vessels, and diameter increase will be not be linear. Of the 20 described patients, at least six are confronted with major adverse events after stent implantation.

Now, I am allowed only two questions. Question one: because it is not clear which patients had other treatment for RVOT obstruction in this era, and because it is not clear why exactly you selected the patients described, could you tell us about your selection process, and whether this included a formal heart team discussion?

And question two: do you agree that you should make a choice of doing a formal analysis of either all stents applied for RVOT obstruction, or of this application in tetralogy of Fallot, using in both an appropriate definition of adverse events and endpoints of analysis, in order to provide us with the best information from your data?

Dr Murala: I will answer your second question first. When we prepared this abstract almost eight months ago, we had 32 patients, but now we have about 48 patients. Now, there were 12 patients who were not operated on at that time. However, in the last eight months, seven of them have been operated and two of them had RV-PA conduits because of the coronary issues, and four of them had total repairs. So from the time of the abstract, yes, we have operated on seven more patients, so that leaves us with four of them who are still waiting for surgery. And the analysis of all the 48 patients is actually being done in comparison with our standard practice of B-T shunt and total correction. It is all under analysis, and the data should be out within the next year. It is being done by the cardiology group.

Now, the first question that you asked me was about the selection criteria; yes, I have included in this patients with tetralogy of Fallot physiology. So it includes DORV also and DORV/AVSD. So basically it is Fallot physiology type that we have considered.

Now, concerning the indications for stenting, we have two meetings every week with the cardiologists. It is called the Joint Cardiology/Cardiac Surgical Meeting. All the patient data of everyone who presented to the hospital are discussed, and we discuss whether they are good to go for a B-T shunt or an RVOT stent. There are variations in management. Even last week we operated on a five-day-old TOF child and performed a complete repair. So it is not a blanket rule, but we do look at the other comorbidities and the pulmonary arteries in deciding whether to do a B-T shunt or an RVOT stent. I did not include a slide of the comorbidities, but we do have significant comorbidities in this cohort of patients. Some of them are necrotizing enterocolitis, ileal atresias with colostomy patients, and tracheostomy. We also have patients who had RSV pneumonitis and other infections. So we have just different selection criteria, but it is all discussed in our joint meetings and we propose whatever is the best strategy for these children.

Dr O. Raisky (Paris, France): We have a very limited experience with RVOT stenting in Paris, but our impression is that with stenting, one does not get as good growth of the PAs as we can get with a transannular patch, or surgical RV-PA connection. The second thing is the circumferential extent of the fibrosis induced by the stent in the RVOT. We are concerned that this does not allow for as much growth as we would like. Could you comment on this?

Dr Murala: Well, of the 20 patients, the fact that in the 15 who had a complete repair, we did not have to do any pulmonary artery procedures shows that they have had adequate growth. So I am sure that this is not the final word, and we will hear more about RVOT stenting. This is an initial series experience about the surgical outcomes. We have not seen any of those 15 patients who had total corrections needing pulmonary artery procedures, so I think the pulmonary arteries are adequately grown.

Now, the second question about the RVOT stent itself, yes, there is a lot of fibrosis. In fact, it is difficult sometimes to completely take the stent out. In the limited literature, many of the previous authors have said that it is easy to take it out, but in our experience we have found that it is not easy to take the stents out completely. In fact, sometimes it is very close to the VSD margins. In one patient, it was very close to the aortic leaflet, and so we could not take it completely out. But compared to the RVOT patch, I cannot comment because we do not do that as a standard practice in our unit. This is not the final word in RVOT stenting or the management of neonates.