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Title: Duct stenting versus modified Blalock Taussig shunt in neonates with duct-dependent pulmonary blood flow. Associations with clinical outcomes in a multicenter national study. Bentham. Duct stent or Blalock shunt for infant palliation?

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Abstract

Background: Infants born with cardiac abnormalities causing dependence on the arterial duct for pulmonary blood flow are often palliated with a shunt usually between the subclavian artery and either pulmonary artery. A so-called modified Blalock Taussig shunt (MBTS), allows progress through early life in order to reach an age and weight at which repair or further more stable palliation can be safely achieved. MBTSs continue to present concern for post-procedure instability and early mortality such that other alternatives continue to be explored. Duct stenting is emerging as one such alternative with potential for greater early stability and improved survival.

Methods: To compare post-procedure outcomes and survival to next stage palliative or reparative surgery between patients undergoing modified Blalock Taussig Shunt (MBTS) and arterial duct stenting (DS) in infants with duct-dependent pulmonary blood flow. All patients undergoing cardiac surgery and congenital interventions in the UK are prospectively recruited to an externally validated national outcome audit. From this audit, participating UK centers identified infants less than 30 days of age undergoing either a BTS or a DS for cardiac conditions with duct-dependent pulmonary blood flow between January 2012 and end December 2015. 171 patients underwent a MBTS and 83 patients an attempt at DS. Primary and secondary outcomes of survival and need for extra-corporal support (ECMO) were analyzed using multivariable logistic regression. Longer term mortality pre-repair and re-intervention were analyzed using Cox proportional hazards regression. All multivariable analyses accommodated a propensity score to balance patient characteristics between the groups.

Results: There was an early (to discharge) survival advantage for infants pre-next stage surgery in the DS group (OR=4.24, 95% CI 1.37 to 13.14, p=0.012). There was also a difference in the need for ECMO support post-procedure in favor of the DS group (OR=0.22, 95% CI 0.05 to 1.05, p=0.058). Longer term survival outcomes showed a reduced risk of death pre-repair in the DS group (HR=0.25, 95% CI 0.07 to 0.85, p=0.026), but a slightly increased risk of re-intervention (HR=1.50, 95% CI 0.85 to 2.64, p=0.165).

Conclusions. Duct stenting is a viable alternative to surgical placement of a modified Blalock-Taussig shunt with evidence for greater post-procedure stability and improved patient survival to destination surgical treatment.

Clinical perspective

What is new?

- Ductal stenting is a technically challenging procedure and whether it can obviate the need for a Blalock Taussig shunt (MBTS) needs to be established.
- Stenting the arterial duct is preferable over a MBTS in terms of survival to next stage surgery, early post procedure hemodynamic stability and shorter intensive care and hospital stay.
- There is a high failure rate both early, with inability to stent the duct, and late, with greater need for re-intervention on the stented duct, compared with a MBTS.

What are the clinical implications?

- Stenting the arterial duct remains an important and preferred option for palliation of neonates with dependence on the arterial duct for pulmonary blood flow.
- This needs to be in the context of a well orchestrated follow up program given the high likelihood of need to re-intervene on the stented duct to provide similar length of palliation to a MBTS.

Introduction

Babies born with complex cardiac abnormalities are not infrequently dependent on the arterial duct for pulmonary blood flow following birth. Patency of the arterial duct can be temporarily maintained with intravenous prostaglandins whilst preparations are made for surgical palliation with a shunt. The Blalock Taussig Thomas shunt has provided palliation for congenital heart disease since the initial description in 1944[1]. Other than the adoption of a Gore-Tex conduit to provide a predictably-sized connection between the subclavian and pulmonary artery, the technical aspects of the procedure have remained largely unchanged over 70 years[2]. Whilst procedural mortality has significantly declined over time, it is still measurable and has driven consideration of alternative approaches[3]. This mortality largely results from early hemodynamic instability associated with diastolic run-off through the shunt and coronary artery steal. The competing alternative, first described in 1992, is a transcatheter approach to stent the arterial duct and secure pulmonary blood flow[4]. Given the precarious conditions we seek to palliate, it is perhaps unsurprising that stenting the arterial duct is also associated with significant morbidity and mortality[5]. Consequently neither procedure has emerged as superior, with preference tending to center around the chosen practice of individual programs. In the last few years there has been an increase in the number of arterial duct stent procedures performed as well as an acceptance that the difficult experiences of the early procedures have resulted in some standardization of equipment and approach[6-9]. It is timely and appropriate to seek to compare the two procedures given that appreciable early mortality continues to be reported for both[5, 10].

Methods

Study population and design

This was a UK multi-center cohort study of all patients less than 30 days of age with a diagnosis of duct dependent pulmonary blood flow undergoing as their first procedure either a modified Blalock Taussig shunt (MBTS) or an arterial duct stent (DS) over a four year period (1st January 2012 to 31st December 2015). One-year follow up continued to 31st December 2016. Groups were assigned on an intention to treat basis; duct instrumentation regardless of whether a duct stent was successfully achieved were assigned to the DS group. All UK centers contribute to a mandatory validated prospective audit of cardiac surgical and intervention outcomes (National Congenital Heart Disease Audit) and 9 UK centers searched their audit to identify all cases that met these inclusion criteria. Written informed consent is obtained for inclusion in this audit. The primary outcome was survival to next stage surgery (either further palliation or repair), while secondary outcomes were survival to 30 days, to discharge, to one year and need for post procedure extra-corporal membrane oxygenation (ECMO). Other measures of interest included early hospital morbidity (duration of intensive care stay, need for post-procedure ventilation and hospital stay), incidence of unintended interventions pre-next stage surgery; need for pulmonary artery plasty at next stage surgery or repair and pre-repair pulmonary artery dimensions. DS procedural success was defined as stable pulmonary blood flow without need for crossover to a MBTS.

Patient details

Baseline demographics were investigated to explore similarity of the two cohorts. Pulmonary artery imaging data prior to next stage surgery were captured when performed (angiography, computed tomography or magnetic resonance imaging). Pulmonary artery dimensions were only performed if a reliable calibration factor was present and measurements were made using digital calipers. The right (RPA) and left pulmonary artery (LPA) measurements were obtained between the shunt anastomosis or duct stent insertion and proximal to the upper lobe branch pulmonary artery. Given the relative frequency of stenotic lesions, the narrowest diameter was not necessarily recorded, but rather the length of pulmonary artery most representative of the overall vessel diameter. Multiple measurements were obtained in two views and the means recorded. Pulmonary artery diameter was corrected for body surface area at the time of the procedure and also by using the Nakata index[11] (π{(RPA radius^2, mm^2)+(LPA radius^2, mm^2)}/4[body surface area, m^2]).

Surgical and Intervention details

Modified Blalock Taussig Shunt

The Gore-Tex shunt (W.L. Gore and Assoc, Flagstaff, AZ) size was at the discretion of the surgeon but generally a 4mm shunt for patients over 3.5-4kg and 3.5mm shunt for weight <3.5kg. The surgical approach was at the discretion of the surgeon. The pulmonary artery end was sewn to the distal main/right or left pulmonary artery depending on anatomy with a running suture. The aortic end was sutured to either the subclavian artery or to the distal innominate artery with a similar technique.

Duct stent placement

Access varied depending on anatomy and operator preferences. The technique has become relatively standardized to 4 French access followed by instrumentation of the duct with an 0.014 inch coronary wire followed by placement of a coronary stent (mounted on a balloon between 3 and 5mm). Some operators used a 'buddy' wire to facilitate stent positioning removing this wire before deployment. In the majority of cases a 4Fr long sheath was used to provide stability and distal angiography during stent positioning. One or multiple stents were used to cover the length of the duct.

Statistical analysis

Stata version 14.2[12] was used for all statistical analyses. Baseline and univariable comparisons were performed using a Mann-Whitney comparison of non-paired samples (two-tailed) for continuous measures, and a chi-squared test or Fisher's exact test for categorical measures. Medians and interquartile ranges (IQR) are given for numeric variables, while numbers and percentages of patients are given for categorical variables. A statistical significance level of $p<0.05$ is assumed. The presented p-values were not adjusted for multiple comparisons.

A directed acyclic graph (DAG)[13] was constructed to assess covariate causal relationships. The DAG was assessed using the R package dagitty[14] and found to be consistent with the dataset. A propensity score[15, 16] was calculated using all confounding variables: age, weight, procedure (elective or emergency), antegrade pulmonary blood flow, single ventricle status and prematurity; i.e. those variables that potentially affect both the exposure (shunt type) and the outcome (survival, ECMO or re-intervention). The balancing property was satisfied within Stata, which uses a comparison of means approach. As the propensity score cannot accommodate the

effects of unmeasured variables, it is assumed that there are no missing variables with sizeable causal impacts. Although patients are clustered by UK center, a multilevel analysis would not be appropriate as random effects would not be robust with only nine upper level units, hence the propensity score calculation includes the fixed effects of the centers attended. Sensitivity analysis compared the effect of including competing exposures within the calculation of the propensity score (in some instances this can improve model precision). Single-level logistic regression analysis, including propensity score, was then performed for primary and secondary outcomes, and odds ratios (OR) are reported together with 95% confidence intervals (CI). A minimally sufficient adjustment set was identified from the DAG, and a multivariable analysis that explicitly adjusted for each confounder was compared to the model which used the propensity score. Survival analysis was performed on the longer-term survival outcomes of mortality pre-repair and re-intervention, using Cox proportional hazards regression whilst accommodating the propensity score in the same manner as for the logistic regression analyses. Hazard ratios (HR) and 95% CI's are reported.

Results

Baseline demographics

Over the study period 171 neonates underwent placement of a MBTS shunt across nine centers (median age 8 days (IQR 5-15) and weight 3.1kg (IQR 2.8-3.4); table 1, figures 1 & 2, supplementary table 1). 83 neonates underwent a transcatheter procedure to place a DS (median age 8 days (IQR 4-13) and weight 3.1kg (IQR 2.8-3.5). All baseline characteristics were similar between the two groups (table 1) with similar diagnostic categorization (supplementary table 2). In the MBTS group 90% underwent a right shunt with the predominant approach being through a median sternotomy (76%). 75.6% received a 3.5mm shunt (6.1% 3mm and 18.3% 4mm). DS was approached predominantly from a femoral approach (73.8%, 44 femoral artery, 26 femoral vein, 12 common carotid artery [hybrid cut down and repair], 1 axillary artery). The majority of stents placed were mounted on 3.5-4mm balloons (87.1%, 24 3.5mm, 37 4mm, 6 3mm and 2 4.5mm). Most cases required one or two stents (95.9%, one stent 50, two stents 20, three stents 2, and four in 1). Median procedure time was 90 minutes ($\pm$50.4 minutes), median fluoroscopy time 17.5 minutes ($\pm$14.2 minutes) and median total radiation dosage 152cGy/cm^2 ($\pm$340 cGy/cm^2). In the DS group there were 17% failed procedures (procedural success 82.9%) requiring conversion to a MBTS (n=13). Four were for failure to cross a tortuous duct and secure adequate wire position (though procedure attempted), in two the proximal duct was not covered, in one perforation of the right ventricle occurred and in one the duct was dissected. One stent resulted in inadequate perfusion of the LPA and there were four early stent failures (occlusion, inadequate pulmonary blood flow, in-stent stenosis).

Multivariable analysis of primary and secondary outcome measures

Table 2 shows the results of the multivariable analysis, accommodating propensity score, which was calculated using all confounding variables plus the fixed effects of the center attended. Patients in the DS group had an elevated odds of surviving pre-repair, compared to patients in the MBTS group (OR=4.24, 95% CI 1.37 to 13.14, p=0.012). Patients in the DS group had reduced odds of receiving post-procedure ECMO (OR=0.22, 95% CI 0.05 to 1.05, p=0.058), compared with patients in the MBTS group. The inclusion of competing exposures in calculating propensity scores did not substantially affect the results with no improvement in the precision of estimates of effect. Analysis of the minimally sufficient adjustment set identified by the DAG gave results consistent with the propensity score analysis.

Survival analysis of longer-term outcomes

Table 3 shows the results of the survival analysis on the two longer term survival outcomes of mortality pre-repair or next stage surgery and re-intervention whilst adjusting for the propensity score. Patients in the DS group experienced a reduced risk of death pre-repair, compared to patients in the MBTS group (HR=0.25, 95% CI 0.07 to 0.85, p=0.026). This supports the result seen for survival pre-repair in the multivariable analysis. Patients in the DS group had slightly increased odds of re-intervention compared with patients in the MBTS group (HR=1.50, 95% CI 0.85 to 2.64, p=0.165). The proportional hazards assumption was met for each outcome. As with the multivariable analysis, the inclusion of competing exposures in calculating the propensity score did not alter the findings. The analysis of re-intervention with the minimally sufficient adjustment set differed modestly from that using the propensity score (HR=1.96, 95%

CI 1.06 to 3.61, p=0.031). In the MBTS group the majority of interstage reintervention was the need for early shunt revision or change to another source of pulmonary blood flow (11 of 15 early interventions; right ventricle to pulmonary artery conduit or transannular patch) alongside later stenting of the shunt to provide a greater period of palliation (14 of 24 late interventions). In the DS group, apart from the early procedural failures that crossed over to the MBTS group interventions predominantly occurred late (23 of 30 including 14 procedures to re-stent or balloon the existing duct stent). Figures 3 and 4 show Kaplan-Meier curves comparing survival and reintervention in patients across the two groups pre-repair or next stage surgery.

Hospital and procedural morbidity

The DS group had a shorter length of stay, shorter intensive care stay and fewer ventilation days (see table 4).

Pre-next stage surgery variables

The DS group came to next stage palliative surgery or complete repair at a median age of 246 days (IQR 176-393 days) compared with the MBTS group at a median age of 254 days (IQR 172-356 days, p=0.954). Oxygen saturations and weight at this time point were similar across the two groups (see table 4) although hemoglobin level was higher in the MBTS group (15.6 g/dL (IQR 14.0-17.2) vs. 14.9 g/dL (IQR 12.8-16.4) in the DS group, p=0.027). Destination surgical procedures performed were similar (supplementary table 3) with more need for pulmonary artery reconstruction work in the DS group (52% [28 of 54] vs. 39% [47 of 122], p=0.14). Where imaging was performed (43 of 76 DS and 69 of 137 MBTS) there was no difference in the size of

the branch pulmonary arteries (DS median Nakata index 210mm/m^2 (IQR 166-313) vs. MBTS 209mm/m^2 (IQR 139-302); p=0.660).

Discussion

Even in the current era Blalock Taussig shunts are associated with 30-day mortality rates far in excess of many more technically complex neonatal operations[17]. Post-operative instability following MBTS, with associated morbidity and mortality has resulted in a drive towards early neonatal repair where technically possible, alongside alternative approaches to secure pulmonary blood flow where the possibility of repair does not exist[18, 19]. In the context of avoiding high risk shunting, ductal stenting has increased in prevalence over recent years as alternative palliation in this patient group. This study analyses and compares the outcomes of ductal stenting and surgical shunting in patients with duct-dependent pulmonary blood flow in a large, unselected, prospectively collected contemporary series. This study clearly demonstrates a survival advantage with ductal stenting through to destination surgical therapy (either repair or next stage palliation). As importantly, it also demonstrates greater stability post procedure with less need for post-operative ECMO.

Although published studies have suggested ductal stenting is an alternative to a surgical shunt, comparisons of outcomes have been limited to much smaller single center series and consequently further limited by the given institution's enthusiasm for a particular approach[5, 20]. Advantages and disadvantages of either approach have been difficult to demonstrate.

These results are partly tempered by procedural success (83% for duct stenting with 17% of the group requiring an early MBTS for procedural failure). Although equipment has improved substantially since the early descriptions of the technique, complex duct anatomy remains a

significant technical challenge[4]. In addition, re-intervention in the inter-stage period is also an important issue, with 39.8% of the DS group requiring additional procedures before next stage surgery as opposed to only 24.0% of the MBTS group. Re-intervention rates in this study are not significantly different from other published single center case series[20] and it seems likely that achieving the length of palliation required (median of 243 days for MBTS and 231 days for DS group) comes at the cost of further transcatheter treatments in a significant proportion of patients. With this approach good palliation can be achieved with post-duct stent infants generally coming to next-stage surgery at a similar age, weight, oxygen saturations, hemoglobin and pulmonary artery dimensions to infants post-MBTS.

In the absence of randomization the major limitation and criticism for discussion is whether the two groups really are similar. The two groups reflect national UK practice and are demonstrably well-matched at baseline and continue to remain so through the study (diagnosis, single ventricle status and next stage surgery performed). However, lack of randomization is a legitimate concern. Observational analyses of this nature fail fully to account for selection bias subtly and inadvertently introduced into the study, which cannot be controlled. A simple example of selection of unknown significance would be interventionists choosing cases with echocardiographic straighter ductal courses given the higher likelihood of successful stenting. The only way to account for these factors is to perform a randomized trial of similar magnitude and design to the single ventricle reconstruction trial which compared shunt types in the Norwood procedure[21]. It should also be noted that assumptions and caveats are inherent within statistical analyses, and that alternative analyses could have been performed on the

given data. The results presented in this paper are those that the authors believe to be the most appropriate for the available data. Effect sizes may be mitigated or attenuated should other approaches be utilized.

The main strength of this study is that it brings to the fore a national comparison of these two approaches. Given the results presented here, one reasoned approach would be to offer duct stenting to all cases in need of secure pulmonary blood flow regardless of duct morphology. We have seen no evidence that crossover from the DS group to a MBTS results in a survival disadvantage in cases where there was failure to successfully stent the duct. These infants, however, are likely to benefit from close follow-up given the high likelihood of need for re-intervention before they reach an age or weight to proceed with next stage surgery. Cost comparison of these two approaches is beyond the scope of this study but is achievable in the data presented. Less need for ECMO, shorter intensive care stay with less need for ventilation and shorter overall hospital stay need to be balanced against greater need for reintervention in the duct stent group.

Is stenting the arterial duct superior to a Blalock shunt? In this study, the first to assess the two competing procedures side-by-side across multiple centers, there are still twice as many shunts performed as duct stents. In the 25 years since the procedure was first described, duct stenting cannot be regarded as a panacea of palliation but we have demonstrated that it can safely be considered as a preferred alternative. This paper does offer centers confidence that this

procedure has tangible advantages over an arterial shunt, particularly in relation to early post-procedure stability, but the quest for truly excellent palliation remains.

Conclusions

Stenting the arterial duct to secure pulmonary blood flow in infants with duct-dependent congenital heart disease appears to offer early survival advantage and improved early hemodynamic stability over a surgical arterial shunt. This is at the expense of procedural failure in a proportion of patients and increased likelihood of re-intervention in the inter-stage period.

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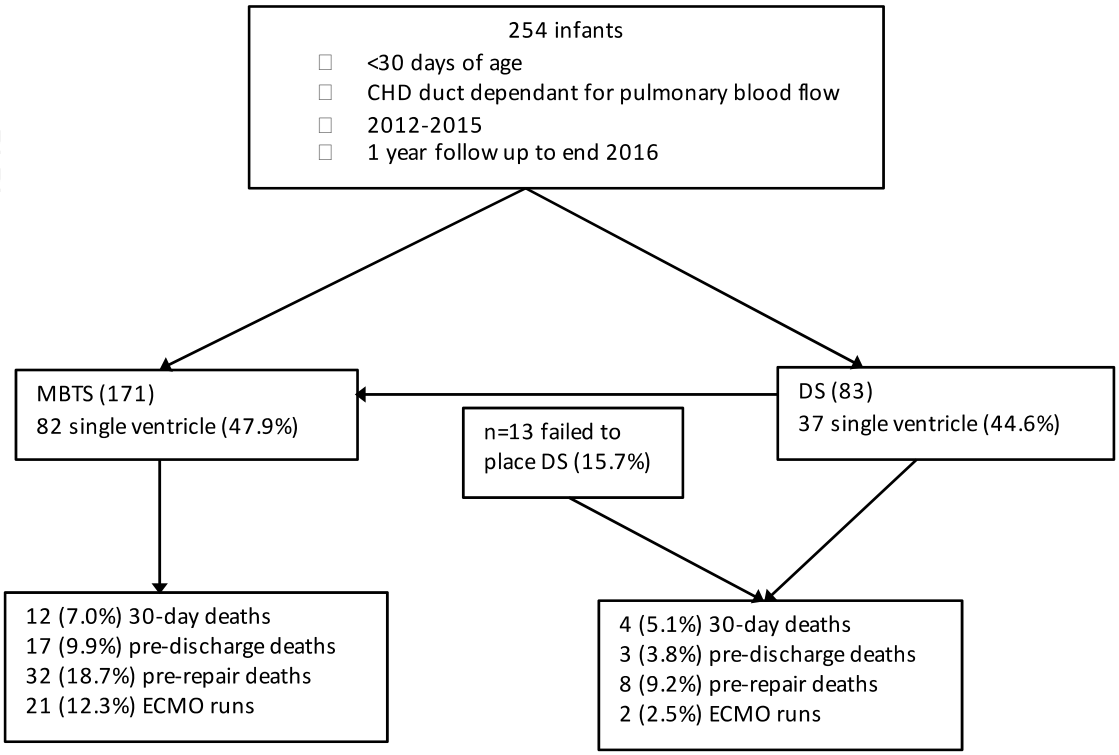

Figure 1. Study group subject selection, inclusion and exclusion criteria. MBTS, Modified Blalock-Taussig shunt; DS, duct stent; ECMO, extra-corporal membrane oxygenation; CHD, congenital heart disease.

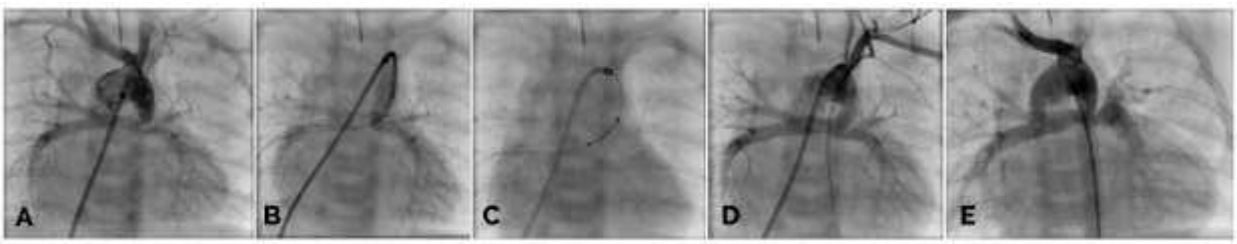

Figure 2. Aortograms demonstrating duct stent placement from a femoral vein approach in a patient with pulmonary atresia ventricular septal defect. (a) Aortogram through a four French long sheath positioned in the ascending aorta demonstrates the pulmonary artery anatomy and the insertion of the duct with restriction into the main pulmonary artery. Note the moderate left pulmonary artery narrowing which is also seen in images d and e. **(b)** two coronary wires (one working wire and one 'buddy' wire are positioned in the RPA through an internal mammary catheter in the proximal duct. **(c)** the 'buddy' wire was removed and a coronary stent has been positioned and deployed. The balloon is then removed before a repeat angiogram demonstrates good perfusion of both the right and left pulmonary vascular beds **(d)**. **(e)** Pre-repair angiogram through a pigtail catheter in the transverse arch at six months of age demonstrates acceptable growth of both pulmonary arteries. The duct stent has remained widely patent.

	MBTS	DS	Comparison
	n (%)	**n (%)**	**P-value**
Patients	171 (67.3)	83 (32.7)	-
	Median (IQR)	**Median (IQR)**	**P-value**
Age (days)	8 (5-15)	8 (4-13)	0.240
Weight (kg)	3.1 (2.8-3.4)	3.1 (2.8-3.5)	0.550
	n (%)	**n (%)**	**P-value**
Procedure			
Elective	100 (58.5)	47 (56.6)	
Emergency	59 (34.5)	35 (42.2)	0.100
Missing data	12 (7.0)	1 (1.2)	
Aortic arch			
Left	117 (68.4)	54 (65.1)	
Right	27 (15.8)	15 (18.1)	0.856
Missing data	27 (15.8)	14 (16.9)	
Antegrade PBF			
Yes	66 (38.6)	34 (41.0)	
No	76 (44.4)	34 (41.0)	0.871
Missing data	29 (17.0)	15 (18.1)	
Single ventricle future			
Yes	82 (48.0)	37 (44.6)	
No – biventricular	74 (43.3)	44 (53.0)	0.098
Missing data	15 (8.8)	2 (2.4)	
Prematurity			
Yes	10 (5.8)	5 (6.0)	
No	149 (87.1)	77 (92.8)	0.136*
Missing data	12 (7.0)	1 (1.2)	
Syndromic			
Yes	11 (6.4)	8 (9.6)	
No	141 (82.5)	70 (84.3)	0.313
Missing data	19 (11.1)	5 (6.0)	
Pre-procedure infection			
Yes	13 (7.6)	1 (1.2)	
No	146 (85.4)	74 (89.2)	0.094
Missing data	12 (7.0)	8 (9.6)	

Table 1. Patient demographics prior to DS or MBTS demonstrating no statistically significant differences between the two groups at baseline. Median and interquartile range (IQR) or n (%). P values obtained using chi-squared test, Fisher's exact test (indicated by *) or Mann-Whitney comparison of non-paired samples (two-tailed). Antegrade PBF: antegrade but inadequate pulmonary blood flow from either ventricle to the lungs.

	OR (95% CI)	P-value
Primary outcome		
Survival – pre-repair	4.24 (1.37-13.14)	0.012
Secondary outcomes		
Survival – 30 day	2.22 (0.44-11.16)	0.332
Survival – pre-discharge	6.09 (0.75-49.33)	0.091
Survival – 1 year	2.04 (0.80-5.22)	0.136
ECMO	0.22 (0.05-1.05)	0.058

Table 2. Multivariable analyses of primary and secondary outcomes. OR – odds ratio of effect of DS compared with MBTS, 95% CI – confidence interval.

	HR (95% CI)	P-value
Mortality pre-repair	0.25 (0.07-0.85)	0.026
Reintervention	1.50 (0.85-2.64)	0.165

Table 3. Survival analyses of longer term outcomes. HR – hazard ratio of effect of DS compared with MBTS, 95% CI – confidence interval.

	MBTS	DS	Comparison
	n (%)	**n (%)**	**P-value**
Post MBTS/DS intubation			
Yes	145 (84.8)	37 (44.6)	
No	23 (13.5)	45 (54.2)	<0.001*
Missing	3 (1.8)	1 (1.2)	
Re-intervention pre-repair			
Yes	41 (24.0)	33 (39.8)	
No	126 (73.7)	49 (59.0)	0.026*
Missing	4 (2.3)	1 (1.2)	
PA plasty			
Yes	47 (27.5)	28 (33.7)	
No	75 (43.9)	26 (31.3)	0.160
Missing	49 (28.7)	29 (34.9)	
	Median (IQR)	**Median (IQR)**	**P-value**
LOS hospital (days)	21 (14-31)	14 (7-22)	<0.001
LOS ICU (days)	7 (4-15)	2 (0-6)	<0.001
LOS on ventilation (days)	4 (2-8)	1 (0-4)	<0.001
O_2 Sats post-palliation (%)	85 (80-88)	87 (82-91)	0.002
O_2 Sats pre-repair (%)	77 (73-81)	80 (74-84)	0.214
Weight pre-repair (kg)	7.2 (5.9-8.7)	7.0 (6.0-8.7)	0.867
Hb (g/dL)	15.6 (14.0-17.2)	14.9 (12.8-16.4)	0.027
Time to repair (days)	243 (160-351)	231 (141-380)	0.559
Age at repair (days)	254 (172-356)	246 (176-393)	0.954
LPA (mm)	6.6 (5.0-8.3)	6.1 (5.1-7.1)	0.465
RPA (mm)	6.9 (5.5-9.0)	7.0 (6.0-8.6)	0.505
Nakata index (mm^2/m^2)	208.9 (139.2-301.5)	210.2 (165.7-313.3)	0.660

Table 4. Other measures of interest following DS or MBTS procedures. Median and interquartile range (IQR) or n (%). P values obtained using chi-squared test, Fisher's exact test (indicated by *) or Mann-Whitney comparison of non-paired samples (two-tailed). PA, pulmonary artery; LOS, length of stay; ICU, intensive care unit; LPA, left pulmonary artery; RPA, right pulmonary artery.

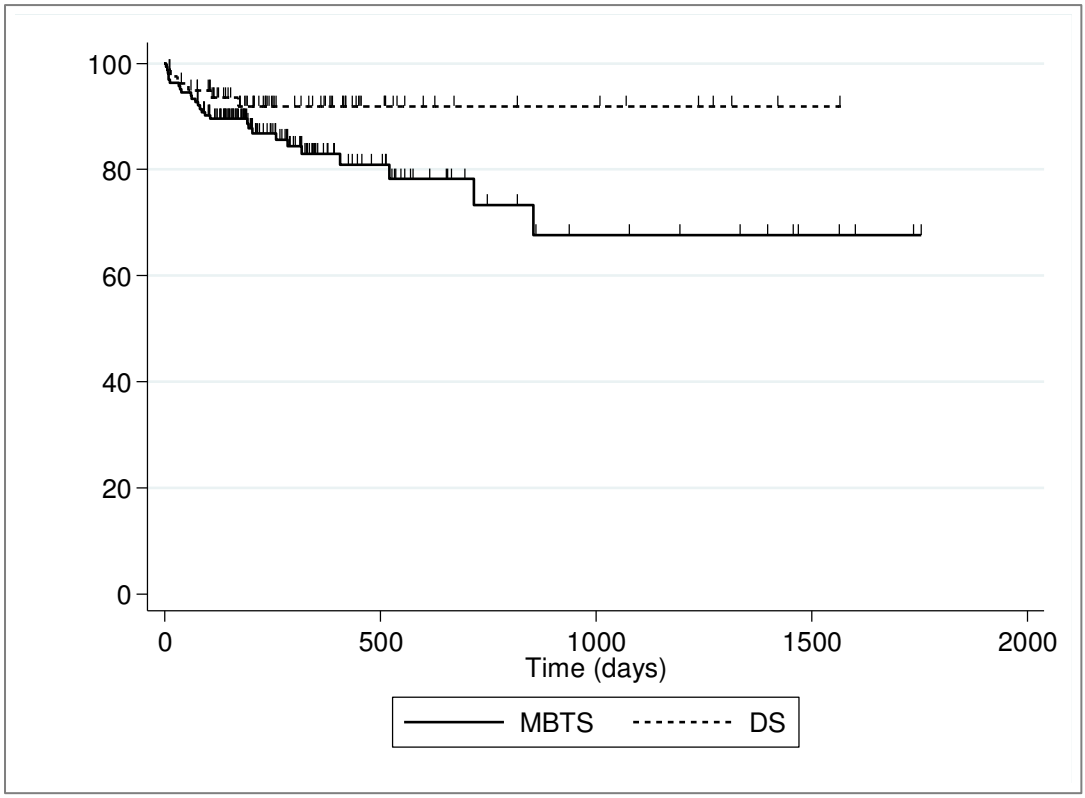

Figure 3. Kaplan-Meier curve comparing survival in patients with a modified Blalock-Taussig shunt to a duct stent to maintain adequate pulmonary blood flow to repair.

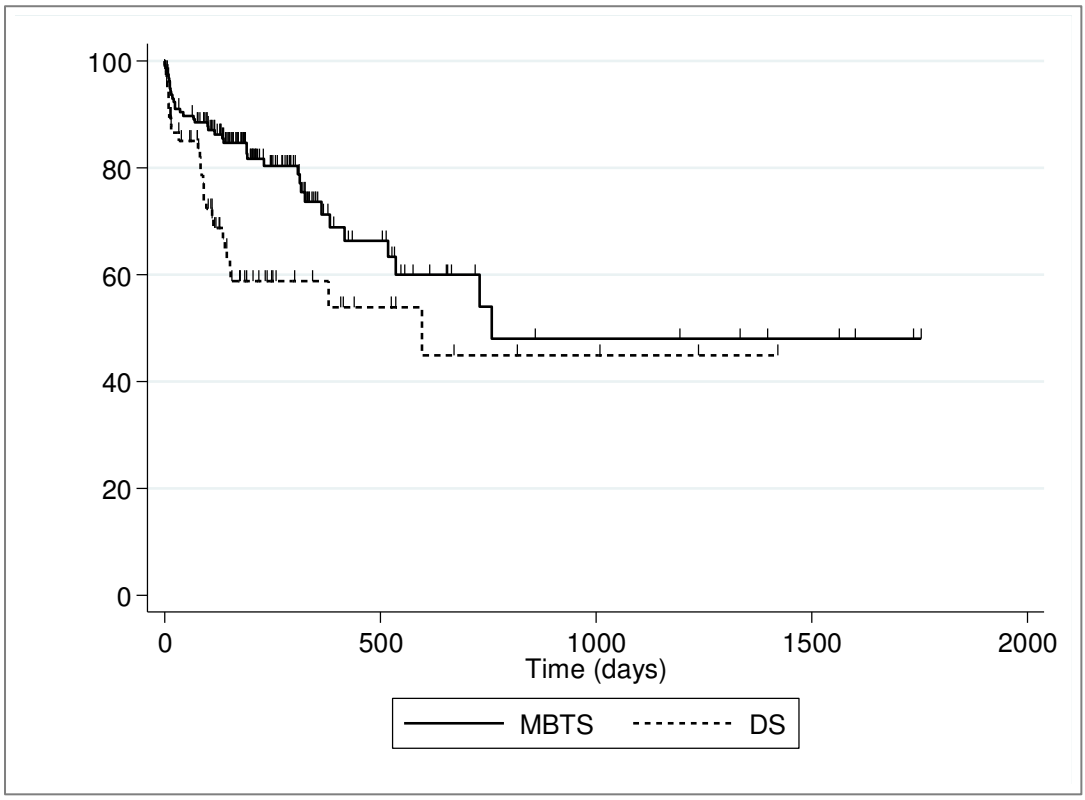

Figure 4. Kaplan-Meier curve comparing freedom from re-intervention in patients with a modified Blalock-Taussig shunt to a duct stent to maintain adequate pulmonary blood flow before further palliative surgery or repair.

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