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CLINICAL & BASIC RESEARCH

Blalock-Taussig Shunt versus Ductal Stenting as Palliation for Duct-Dependent Pulmonary Circulation

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abstract: ***Objectives:*** There is limited data published from outside North America and Europe comparing the outcomes of a modified Blalock-Taussig shunt (MBTS) and ductal stenting as the first palliative procedure for infants with duct-dependent pulmonary circulation. This study reports the National Heart Center's, in Muscat, Oman, experience in comparing the outcomes of these 2 interventions. ***Methods:*** This retrospective study included all infants with duct-dependent pulmonary circulation who received either a MBTS or ductal stenting from 2016–2019. The primary outcomes were death or re-interventions. Secondary outcomes included death, subsequent re-interventions, survival to subsequent surgical intervention, survival to hospital discharge, post-procedural mechanical ventilation and duration of intensive care unit stay. ***Results:*** A total of 71 patients were included in the study, 33 (46%) of whom received ductal stenting. The prevalence of the primary outcome (death or re-intervention) in the patent ductus arteriosus (PDA) stent group was 54.5% versus 31.6% in the MBTS group but this was not statistically significant (P = 0.06). There was no difference between the 2 groups in terms of time to next surgical intervention (P = 0.233). The PDA stent group had shorter post-procedural, mechanical ventilation and intensive care unit stay durations (P <0.05). Syndromic patients were at higher risk of mortality compared to non-syndromic patients. ***Conclusion:*** MBTS and ductal stenting are both acceptable modalities as a palliative intervention for infants with duct-dependant pulmonary circulation. Syndromic patients are at higher risk of mortality. This can be considered an important factor for patient selection.

Keywords: Blalock-Taussig Procedure; Patent Ductus Arteriosus; Pulmonary Atresia; Oman.

Advances in Knowledge

- *When comparing the modified Blalock-Taussig shunt (MBTS) versus patent ductus arteriosus (PDA) stenting as the first palliative procedure for infants with duct-dependent pulmonary circulation, death or re-intervention occurred more in the PDA stent group than in the MBTS group but was not statistically significant.*
- *There was a greater need for post-procedural mechanical ventilation and the duration thereof was higher in the MBTS shunt group than the PDA stent group.*
- *The duration of intensive care unit stay was shorter in the PDA stent group. Yet, there was no difference in survival to hospital discharge or time to next surgical intervention between the two groups.*
- *Syndromic patients are at an increased risk of mortality.*

Application to Patient Care

- *This manuscript contributes to the world data of the outcome of the palliative procedures for infants with duct-dependent pulmonary circulation.*
- *This manuscript may help in considering the factors that may influence the outcome of MBTS and PDA.*

The management of congenital heart diseases with duct-dependent pulmonary circulation requires early palliative interventions in the neonatal period. Modified Blalock-Taussig shunt (MBTS) is the most common procedure used to maintain pulmonary flow but with a recognisable risk of mortality and morbidity. Despite the advances in surgical techniques, mortality and morbidity after MBTS placement remains high at 7.2% and 13.1%, respectively.[1] As an alternative, patent ductus arteriosus (PDA) stent placement was introduced to maintain duct patency using a percutaneous approach with potential advantages such as avoiding surgical intervention and reducing procedure-related risks.[2] A study by the Congenital Catheterization Research Collaborative (CCRC) in 2008 showed no difference in primary outcomes (death and unplanned reintervention due to cyanosis); however, differences in secondary outcomes favoured ductal stenting.[3]

Limited studies on the early and midterm outcomes of ductal stenting have been published from

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Table 1: List of anatomical diagnoses (N = 71)

Diagnosis	n (%)			*P* value
	Total	PDA stent (n = 33)	MBTS (n = 38)	
Pulmonary atresia with ventricular septal defect	22 (31)	13	9	0.23
Tetralogy of Fallot with pulmonary stenosis	10 (14)	1	9	
D-transposition of great vessels with pulmonary atresia/stenosis and VSD	4 (6)	2	2	
L-transposition of great vessels with pulmonary atresia/stenosis and VSD	3 (4)	1	2	
Pulmonary atresia with intact ventricular septum	10 (14)	5	5	
Tricuspid atresia with pulmonary stenosis or atresia	16 (23)	8	8	
Atrioventricular septal defect with pulmonary stenosis and atresia	6 (8)	3	3	

PDA = patent ductus arteriosus; MBTS = modified Blalock-Taussig shunt; VSD = ventricular septal defect.

outside Europe and North America. This study aimed to compare the outcome of MBTS and PDA stenting in early palliation of infants with duct-dependant pulmonary circulation.

Methods

This retrospective cohort single center study included all newborns who had either PDA stenting or MBTS as the first palliation from January 2016 to December 2019 at the National Heart Center's, in Muscat, Oman. Patient allocation was based on the first procedure performed and the decision of choosing the type the palliative intervention was based on the treating primary paediatric cardiologist. The patients were evaluated after receiving the palliative intervention and were followed-up for a period of 3 years. The primary outcomes were death or re-intervention and the secondary outcomes were death, re-interventions, survival to subsequent surgical intervention, survival to hospital discharge, duration of post-procedural mechanical ventilation and duration of intensive care unit (ICU) stay. Prematurity was defined as gestational age at birth <37 weeks. The presence or absence of a syndrome and/or abnormal karyotype was recorded. All procedures were performed under general anaesthesia and mechanical ventilation. MBTS and PDA stenting were performed as described in previous literature.[4,5] After both procedures, heparin infusion was continued for at least 48 hours before transitioning to acetylsalicylic acid 5 mg/kg/dose.

The Statistical Package for the Social Sciences (SPSS), Version 21 (IBM Corp., Armonk, New York, USA) was used for analysis. Median, inter-quartile, 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. Associations were tested using Fisher's exact test and a Chi-squared test to compare the MBTS and PDA stent groups, as well as the dead and alive cases. Survival analysis using Kaplan-Meier methods was applied and significant difference was tested by Log Rank (Mantel-Cox) and Breslow (Generalized Wilcoxon). Test values were considered significant if $P < 0.05$.

The study has been approved the institution's ethical committee.

Results

A total of 71 patients were included in the study; 33 patients were included in the PDA stent group and 38 patients were in the MBTS group. Pulmonary atresia with ventricular septal defect (PA/VSD) was the most common diagnosis encountered (31%), followed by tricuspid atresia with pulmonary atresia or stenosis (23%) [Table 1]. A single ventricle pathway was adopted for 19 patients in the PDA stent group and 15 patients in the MBTS group ($P = 0.157$). There were 4 syndromic patients in the PDA stent group (Glodenhar syndrome, Down syndrome, DiGeorge Syndrome and Trisomy 13) compared to 5 patients in the MBTS group (1 patient with multiple congenital anomalies without identifiable pathogenic mutations, 2 patients with Down syndrome, Dandy Walker malformation and 1 patient with VACTERL association). The baseline characteristics of the patients were similar in both groups including gender, weight, prematurity, syndrome, presence of pulmonary artery confluence, side of the aortic arch and preoperative mechanical ventilation. However, the age at the time of the first procedure was higher in the MBTS group than the PDA stent group (30 versus 4 days; $P < 0.001$). Antegrade pulmonary blood flow was higher in the MBTS group than the PDA stent group (19 versus 4; $P = 0.001$) [Table 2].

Table 2: Baseline patient characteristics for each treatment strategy

Characteristic	n (%)		*P* value
	PDA stent (n = 33)	MBTS (n = 38)	
Gender female	18 (55)	21 (55)	0.95
Median weight (25, 75 IQ)	3.20 (2.70, 3.55)	3.2 (2.68, 4.10)	0.422
Weight minimum/ maximum	2.1/6.5	1.8/8.9	
Prematurity	6	15	0.69
Syndrome	4	5	0.90
Single ventricle	19	15	0.157
Confluent pulmonary arteries	31	37	0.59
Right aortic arch	5	6	0.94
Presence of antegrade pulmonary blood flow	4	19	0.001
Preoperative mechanical ventilation	11	15	0.81
Median age at time of first procedure in days (25, 75 IQ)	4 (1.0, 14.50)	30 (6.0, 120.75)	<0.001
Median			
Min /Max			
Minimum/maximum age at time of first procedure in days	0.0/56.00	3.0/578.0	

PDA = patent ductus arteriosus; MBTS = modified Blalock-Taussig shunt; IQ = interquartile range.

The primary composite outcome (death or re-intervention) occurred more in the PDA stent group than in the MBTS group (54.5% versus 31.6%) but did not reach statistical significance (*P* = 0.06) [Figure 1]. Among secondary outcomes, death alone or re-interventions alone were higher in the PDA stent group than the MBTS group, but this was not statistically significant (27.3% versus 15.8%; *P* = 0.25; 33.3% versus 21.1%; *P* = 0.24) [Figures 2 and 3]. In the PDA stent group, 4 patients died during the initial procedure and 3 patients died during re-interventions due to procedure-related technical complications. In the PDA stent group, 2 patients had inter-stage mortality due to undefined causes and 11 patients required re-interventions which was due to in-stent restenosis. A total of 2 patients had LPA stenosis in addition to the in-stent restenosis. The re-interventions were performed to treat cyanosis in 3 patients and the rest of the patients the re-interventions were performed for re-dilatation of the stent or LPA dilatation.

The need for post-procedural mechanical ventilation and the duration thereof was higher in the MBTS shunt group than the PDA stent group (*P* <0.05). Furthermore, the duration of ICU stay was shorter in the PDA stent group (2 versus 6 days; *P* = 0.014). However, there was no difference in survival to hospital discharge between the two groups (*P* = 0.09). Moreover, there was no difference between the

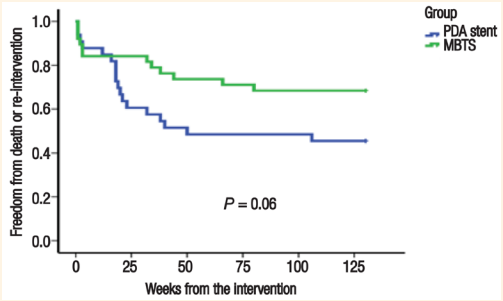

Figure 1: Kaplan-Meier curve of time to death or re-intervention (primary outcome) after receiving patent ductus arteriosus (PDA) stenting and modified Blalock-Taussig shunt (MBTS).

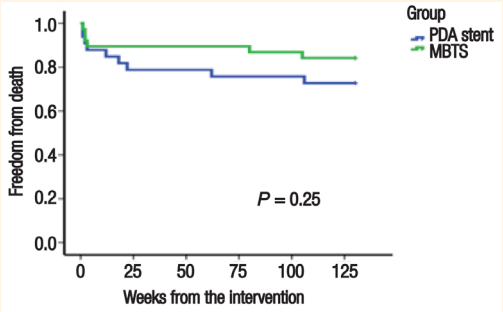

Figure 2: Kaplan-Meier curve of time-to-death after receiving patent ductus arteriosus (PDA) stenting and modified Blalock-Taussig shunt (MBTS).

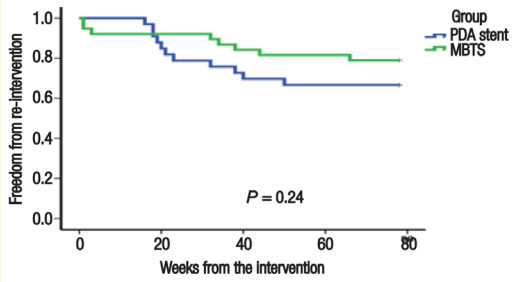

Figure 3: Kaplan-Meier curve of time to re-intervention after receiving patent ductus arteriosus (PDA) stenting and modified Blalock-Taussig shunt (MBTS).

2 groups in terms of time to next surgical intervention (*P* = 0.11) [Figure 4]. A comparison was made between the two groups after excluding cases with anti-grade flow and age >60 days at first procedure. No difference was found between the 2 groups in long-term mortality and re-intervention (*P* >0.05). Risk factor analysis showed that being a syndromic patient was the only risk factor associated with increased risk of mortality (*P* <0.05).

Discussion

This study found that patients who received MBTS had a lower rate of mortality or reintervention than

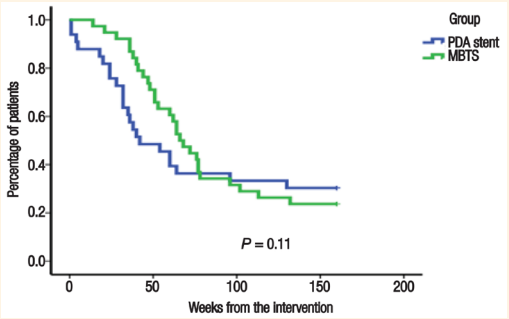

Figure 4: Kaplan-Meier curve of time before subsequent surgical intervention after receiving patent ductus arteriosus (PDA) stenting and modified Blalock-Taussig shunt (MBTS).

the PDA stent group, though it was not statistically significant. Patients who underwent PDA stenting had a shorter ICU stay, requiring mechanical ventilation less often and for a shorter time; however, that did not affect the survival rate to hospital discharge between the 2 groups. The re-intervention rate was higher in the PDA stent group compared to the MBTS group, but it was not statistically significant and it was not a risk factor for long-term mortality.

MBTS remains the most common palliative procedure performed on patients with duct-dependent pulmonary circulation. Despite advances in congenital heart surgery, morbidity and mortality after MBTS remain high. The operative mortality ranges from 3.7–14%.[1] Alsoufi *et al*. studied the outcome of MBTS as palliation for patients undergoing a single ventricle pathway. They found that the operative mortality was 15% and the interstage mortality was 10%. The rate of unplanned re-intervention was 14%; the overall 8-year survival rate was 68%.[6] PDA stenting was introduced in 1992 and has been used in multiple centres as an alternative procedure to maintain duct patency and thus minimise the risks and surgical stress associated with MBTS.[2] This technique offers uniform pulmonary artery growth and balanced pulmonary vascular development compared to MBTS.[3,7–9]

Few studies are available that compare the outcomes of PDA stenting with MBTS; they include 5 small single-centre studies and 2 multicentre studies.[10] Amoozgar *et al*. compared the short-term outcomes of neonates who underwent PDA stenting with those of patients who underwent MBTS, but the number of patients was small (18 patients with PDA stent, 20 with MBTS), and each procedure was performed at one of two different centres in Iran.[11] There was no difference in the mortality between the 2 groups (PDA stenting 20% versus MBTS 30%; P = 0.09). The PDA stent group was demonstrated to have a shorter mean length of hospital stay compared to the MBTS group. McMullan *et al*. evaluated the safety and the durability of PDA stenting as an alternative to MBTS from 2002 to 2011.[12] It was a retrospective single-centre study and they found no survival difference between the 2 groups. There was also no difference in time to second-stage palliation or definitive repair. There was no difference in the number of interval re-interventions to maintain adequate pulmonary blood flow and good oxygen saturation. Mallula *et al*. compared the outcomes of PDA stenting and MBTS specifically on patients with pulmonary atresia with an intact ventricular septum (PA/IVS).[13] There were 13 patients in the PDA stent group and 16 patients in the MBTS group. They found that the PDA stent group had a shorter duration of mechanical ventilation and shorter length of hospital stay. Acute complications and acute re-interventions were more common in the MBTS group and post-discharge complications were more common in the PDA stent group.

In 2020, Nasser *et al*. reported their short and midterm outcome of PDA stent compared MBTS in a single centre in Saudi Arabia.[7] A total of 43 patients were included in the study (PDA stenting: n = 33 and MBTS: n = 10); 42 patients were initially offered PDA stenting, but because of stenting failure or the need for re-interventions, 10 patients finished in the MBTS group. The PDA stent group had less need for mechanical ventilation and a shorter ICU stay compared to the MBTS group. Both groups achieved similar growth of pulmonary artery branches, but the patients in the PDA stent group reached the second stage of surgery with lower saturation.

The first multicentre study from the USA was published by Glatz *et al*. in 2018.[3] This retrospective review of patients from 4 centres enrolled in the CCRC had either PDA stenting or MBTS. There were 106 patients in the PDA stent group and 251 in the MBTS group. There were some differences in patient-level factors between the 2 groups; for example, the PDA stent group included more PA/IVS and the MBTS group had more pulmonary atresia with ventricular septal defect (PA/VSD). Moreover, there were more patients with 2-ventricle physiology and antegrade pulmonary blood flow in the PDA stent group. Although the unadjusted analysis favoured the PDA stent group for the primary outcomes of death or unplanned re-intervention for cyanosis, the adjusted study using propensity scoring showed no significant difference between the 2 groups regarding the primary outcomes or each component when considered separately. The MBTS group had a lower risk of re-interventions but the PDA stent group had less diuretic use, a shorter ICU stay and more symmetrical growth of the pulmonary arteries. Moreover, PDA stenting was associated with simpler feeding regimens and less

feeding-related admissions but with no difference in somatic growth than MBTS.[14] PDA stenting was also associated with lower healthcare costs in the first year of life.[15]

Bentham *et al.* performed a large multicentre study in 9 centres in the UK in 2018; 83 patients were included in the PDA stent group and 171 patients were in the MBTS group.[16] The adjusted analysis showed better survival to subsequent surgical intervention in the PDA stent group than the MBTS group. However, there was no difference between the 2 groups regarding 30-day survival, survival to discharge, survival at one year and the use of extracorporeal membrane oxygenation.

To the best of the authors' knowledge, the current study is the largest study outside Europe and North America. The groups were assigned on an intention-to-treat basis. The baseline characteristics were similar between the 2 groups except for antegrade flow and age at the time of the procedure. This study confirms previous findings on the advantage of PDA stenting by shortening the ICU stay, hospital stay and mechanical ventilation duration.[3] However, this did not affect the operative mortality and the overall survival of patients with MBTS. Patients with chromosomal and extracardiac malformations, heterotaxy and PA/IVS are challenging factors that affect overall outcomes of the palliative procedures.[1,6,17,18] The current study found that the presence of a syndrome was a risk factor that affected overall survival. Choosing the type of palliative procedure did not affect the overall outcome, although patient selection might be an important factor that influences overall survival. The presence of a syndrome does not affect whether PDA stenting or MBTS should be used as the initial palliation based on the current data. However, newborns with specific syndromes are known to require longer ICU and hospital stays. Therefore, PDA stenting might be preferred compared to MBTS as it offers shorter ICU and hospital stays.[19]

The re-intervention rate continues to be an important consideration after PDA stenting. The PDA stent stimulates intense neointimal proliferation, induces vascular smooth muscle proliferation and accelerates pre-existing branch pulmonary stenosis.[20,21] Therefore, multiple re-interventions are needed to keep the PDA stent patent and result in more additional manoeuvres for pulmonary artery reconstruction during the subsequent surgical procedure.[22] In addition, the re-intervention rate is more closely related to the morphology of the duct and is similar between univentricular and biventricular hearts.[23] The current study found that the re-intervention rate was 33%, similar to the previous finding reported in the literature. In our center, cardiac catheterisation post-PDA stenting is not done electively at defined intervals; it is usually performed when patients have worsening cyanosis or when there is a significant stenosis of the PDA stent observed by echocardiography. This may explain why there was no significant difference in re-interventions between PDA stent and MBTS groups. Notably, the rate of re-interventions in the PDA stent group increased 5 months after the procedure, which may be an important consideration in planning subsequent surgical procedures. This suggests that the re-intervention rate is related more to stent neointimal proliferation than to the implantation technique.

There are several limitations associated with this study. First, there was no randomization in allocating the patients in the two groups. Although the number of patients in this study is considered suitable for a single-centre study, it was not feasible to perform propensity matching to account for the few differences between the two groups. The outcome of PDA stenting in the study included our learning curve, and future studies are needed to account for the improvement in the techniques and patient selection. Classifying the re-interventions into elective or urgent interventions to treat cyanosis might be of better use to compare the current results with the previous studies. However, this was not possible because of the variability in decisions and justifications for re-interventions among the treating cardiologists. The overall re-intervention rate was 33% in the PDA stent group compared to 21% of the MBTS group; combining this with long term mortality (PDA group = 27%; MBTS group = 18%) explains the high rate of the primary outcome observed in this study.

Conclusion

The findings of this study support the assertion that MBTS remains essential in the management of patients with duct-dependent pulmonary circulation. PDA stenting is a good alternative procedure; it has several advantages, including shorter ICU and hospital stays and a reduced need for mechanical ventilation. Further studies, including prospective randomised studies, will help determine the factors essential for patient selection to improve the overall outcome.

AUTHORS' CONTRIBUTION

HK contributed to the project idea, data interpretation and manuscript writing. HH did the statistical data analysis. AB contributed to the data collection and interpretation. AA and SS also contributed to the data collection. KA contributed to the PDA stent data collection and interpretation. AF contributed to the

PDA data collection and interpretation. All authors approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interests.

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