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ORIGINAL ARTICLE

Stent or Shunt, What Could be Better for Children with Duct Dependent Pulmonary Circulation?

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Abstract

Background: **Systemic to pulmonary shunt (Shunt) is offered for children with duct dependent pulmonary circulation to augment pulmonary flow. Recently patent ductus arteriosus (PDA) stent (Stent) is widely used as an alternative method. We aimed to compare post intervention outcomes in children underwent either procedure.**

Methods: **Infants under 3 months who had an initial palliation by Shunt or Stent were retrospectively reviewed between 2008 and 2016, then followed till the second intervention or 1 year whichever earlier.**

Results: **187 patients (110 Shunt and 77 Stent) were included. Initial weight and pulmonary artery (PA) branches size were similar between the groups. Shunt patients had more shock preoperatively and required more emergency intervention. Stent group showed less ICU stay 4 (1–8) vs 13 (7–23) days, $p < 0.0001$ and less positive pressure ventilation days 1 (0–2) vs 5.5 (3–11), $p < 0.0001$. However, Stent group had more symptomatic arterial and deep venous thromboses. In Stent patients the branch PAs growth was better and more homogeneous. At follow-up, no difference between groups regarding cumulative readmission days to hospital, hemoglobin levels and the weight percentile for age. Mortality was not different with a tendency to be higher in the Shunt group (13%) compared to the Stent group (5%), p 0.1.**

Conclusions: **The implantation of PDA stent in patients with duct dependent pulmonary circulation results in a smoother ICU course and a shorter hospital stay, with higher risk of vascular injury. Shunt and Stent procedures have a good outcome for PA growth, somatic growth and survival.**

Keywords: Patent ductus arteriosus, Stent, Shunt, Pulmonary artery growth

1. Introduction

Surgery is the standard intervention in congenital heart diseases (CHD) with arterial duct dependent pulmonary circulation, known classically as Blalock-Taussig-Thomas shunt [1]. In 1988 Mullins et al. used expandable stents in dogs' pulmonary arteries (PAs) [2]. 3 years later, stents were used in human with CHD [3]. In 1992, Gibbs and his colleagues reported two cases of patent ductus arteriosus (PDA) stent implantation in CHD with duct dependent pulmonary circulation [4]. Both systemic to pulmonary shunt (Shunt) and PDA stent (Stent) are not complications free. We aimed to compare both procedures in the immediate course in the ICU for the hemodynamics, ventilation, infection and the length of stay. Furthermore, we followed those patients for the cumulative readmission days to hospital, PAs growth as well as the homogeneity of this growth and patient's growth.

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2. Methods

Retrospectively we reviewed all infants under 3 months of age who were admitted to pediatric cardiac ICU after Stent or Shunt for initial palliation to maintain pulmonary blood flow. Patients who had an intervention to either PA branches at the first intervention or during follow-up were excluded. The study was approved by the Institutional Review Board (IRB). Patient consent was waived by IRB being a retrospective study.

All Shunt patients underwent median sternotomy with creation of the Shunt by Gortex® material [5]. Stent was mostly implanted through an arterial femoral access and rarely from a venous access to PA or aorta. Stents were performed under general anesthesia in the catheterization laboratory utilizing 4–7 French sized sheaths. Stents were 3.5–7 mm in diameter with a variable length to cover the entire arterial duct [6]. [Table 1]. Occasionally prostaglandin E1 was stopped 6 hours prior to ductus stenting if PDA was large to minimize the risk of stent migration [7].

Both groups were compared for demographics, shock required emergent intervention (needed intervention within 6 hours from admission), size of PA branches (z score), the presence of pulmonary forward flow, track of repair to be on the single ventricle (SVR) or biventricular future repair (BiVR). SVR was considered when the patient is planned for future cavo-pulmonary isolation (Fontan operation). We compared the immediate ICU outcomes as well: inotropic score (IS) [8], positive pressure ventilation (PPV) days and the duration of the ICU and hospital stay.

Complications were recorded including hospital acquired infection, necrotizing enterocolitis (NEC) and the need for cardio-pulmonary resuscitation (CPR). Arterial or venous thromboses were confirmed by Doppler study after clinical suspicion (i.e. decreased limb perfusion, absence of pulsation or congestion).

All patients were followed till the second intervention or for one-year whichever earlier. Cardiac readmission to calculate the cumulative hospital days through the follow up period was documented.

PAs growth was reviewed before intervention and at last follow-up. Ipsilateral PA branch was defined as the branch on the same side of the Stent or Shunt and the contralateral branch was defined as the branch on the other side. The ipsi:contralateral ratio was determined to observe the homogeneity of either sides PA branches growth (this ratio was not taken into consideration for patients with central Shunt), the more the ratio is closer to 1 the more the homogeneity of the PA branches [9]. Due to the lack of angiographic data from catheterization before Shunt, echocardiographic images have been utilized to calculate the Nakata index for quantification of PAs size [7,10]. Body surface area was calculated using Mosteller formula [11].

Abbreviation

BiVR	Bi-Ventricular Repair
CHD	Congenital Heart Disease
IQR	Interquartile Range
IRB	Institutional Review Board
IS	Inotropic Score
LPA	Left Pulmonary Artery
NEC	Necrotizing Enterocolitis
PA	Pulmonary Artery
PDA	Patent Ductus Arteriosus
PPV	Positive Pressure Ventilation
RPA	Right Pulmonary Artery
Shunt	Systemic to pulmonary Shunt
Stent	patent ductus arteriosus Stent
SVR	Single Ventricle Repair

Table 1. Groups preoperative demographics.

Variables	Shunt (n = 110)	Stent (n = 77)	*P* value
Gender			
Female	48 (44%)	46 (60%)	
Male	62 (56%)	31 (40%)	0.7
Weight (kg)	3.4 ± 0.8	3.2 ± 0.6	0.5
Age (months)	1.2 (0.7–2.3)	0.6 (0.3–1)	*<0.0001**
Size (mm)	3.5 ± 0.6	4.3 ± 0.4	*<0.0001**
Emergency intervention	30 (36%)	1 (1.5%)	*<0.0001**
Pre-operative shock	8 (10%)	1 (1%)	*0.04 **
RPA z	−1.4 (−2.9 to 0.2)	−1.3 (−2 to −0.1)	0.7
LPA z	−1.3 (−3 to 0.2)	−1.3 (−2.8 to 0)	0.9
Nakata index	163 ± 91	146 ± 48	0.2
Pulmonary forward flow	41 (49%)	30 (43%)	0.5
Single ventricle repair track	63 (78%)	35 (52%)	*0.0013**

LPA: left pulmonary artery, RPA: right pulmonary artery, z: z score.

Body weight centiles and hemoglobin (Hb) levels (as a secondary indicator for the chronic hypoxia) were reviewed before procedure and at last follow-up. The increment of body weight centiles was calculated from the difference between initial and last weight percentile for age. The increment of Hb levels was calculated from the difference between initial and last Hb levels.

Mortality was reviewed in the early stage (less than 28 days from the procedure) and late mortality till one year after the procedure.

Data were expressed as numbers and percentages for categorical variables and as mean ± SD for continuous variables. Data that did not fit a normal distribution were expressed as medians and interquartile range (IQR). Continuous variables were compared using paired Student *t*-test or Mann-Whitney test for the nonparametric variables whenever needed, and categorical variables were compared using chi-square test or Fisher exact test whichever appropriate. Further sub-analyses were done checking the influence of SVR and/or emergent intervention on the outcome variables. A *p* value of less than or equal to 0.05 was considered statistically significant. We used SPSS statistics software Version 21 (IBM, Armonk, NY) for the analyses.

3. Results

We collected 187 patients over 9 years, 110 Shunt and 77 Stent. Shunt group were older 1.2 (0.7–2.3) months in comparison to Stent group 0.6 (0.3–1) months, $p < 0.0001$ but they have comparable weight 3.4 ± 0.8 vs 3.2 ± 0.6 kg, p 0.5. Four patients were excluded from follow up, 3 of them were from the Shunt group (2 had PA branches stenting and 1 had PA plasty). The fourth patient was from Stent group required Shunt and PA plasty due to desaturation. Shock that required emergent intervention was mainly in Shunt group. More patients of single ventricle repair track were subjected to Shunt. [Table 1].

Weight and PA branches size (indicated by Nakata index and z score) for both groups were comparable at the time of the procedure. [Tables 1 and 3].

Inotropic score (IS) 24 hours after intervention was higher in Shunt group vs Stent group 7.3 ± 7.2 and 1.1 ± 4.1 respectively, $p < 0.0001$. Shunt group had more positive pressure ventilation (PPV), ICU and hospital days. Sepsis occurred more in the Shunt group with 30 patients (27%) vs 5 patients (6%) in the Stent group (p 0.0003). [Table 2].

Sub-analysis comparing SVR vs BiVR patients was done. Both SVR and BiVR had similar PPV days 3 (1–8) vs 4 (0–8) p 0.9, ICU days 8 (4–18) vs 8 (3–18) p 0.9 and hospital days 23 (13–41) vs 22 (13–35) p 0.64.

Furthermore, we sub-analyzed the emergency vs elective cases. Patients required emergency intervention had more PPV days 6 (3–9) vs 2 (0–7) p 0.04 and more ICU days 11 (7–18) vs 7 (2–18) p 0.004 but they have similar hospital days 24 (16–54) vs 21 (12–35) p 0.3.

Arterial injury was more frequent in Stent group with 13 patients (17%) vs 5 patients (5%) in the Shunt group (p 0.005). There was no correlation between body weight and evidence of arterial injury. Weight was 3.14 ± 0.7 in those with arterial injury and 3.2 ± 0.6 in those without arterial injury, p 0.6.

Patients were followed for 7.5 (3–12) months and 6.2 (3.3–10.4) months in Shunt and Stent groups,

Table 2. Immediate outcome variables comparison.

Variables	Shunt (n = 110)	Stent (n = 77)	*P* value
Inotropic score (12hrs)	7.9 ± 7.6	0.6 ± 1.8	*<0.0001**
Inotropic score (24hrs)	7.3 ± 7.2	1.1 ± 4.1	*<0.0001**
PPV days	5.5 (3–11)	1 (0–2)	*<0.0001**
ICU stay days	13 (7–23)	4 (1–8)	*<0.0001**
Hospital stay days	27 (18–52)	14 (8–26)	*<0.0001**
Oxygen saturation on admission	80.9 ± 10.7	87.3 ± 7.0	*0.0001**
Oxygen saturation on discharge	83.3 ± 13.9	86 ± 10.2	0.19
Intervention site thrombosis:			
Arterial	5 (5%)	13 (17%)	*0.005**
Venous	3 (3%)	7 (9%)	0.057
Hospital acquired infections:			
Sepsis	30 (27%)	5 (6%)	*0.0003**
CAUTI	6 (5%)	4 (5%)	0.9
NEC	3 (3%)	1 (1%)	0.5
CPR	12 (11%)	5 (6%)	0.3

Hrs: hours, PPV: Positive Pressure Ventilation; CAUTI: Catheter Associated Urinary Tract Infection, NEC: Necrotizing enterocolitis. CPR: Cardio-pulmonary resuscitation.

Table 3. Comparison of follow-up outcome variables.

Variables	Shunt (n = 110)	Stent (n = 77)	*P* value
Follow-up duration	7.5 (3–12)	6.2 (3.3–10.4)	0.27
Nakata index (mm^2/m^2)			
Initial	163 ± 91	146 ± 48	0.2
Follow-up	162 ± 110	194 ± 97	0.09
Ipsi:contralateral ratio:			
Initial	1 ± 0.2	1 ± 0.5	0.8
Follow-up	1.2 ± 0.4	1 ± 0.2	*0.01*[a]
Readmissions hospital days	0 (0–9)	3 (0–14)	0.12
Increment of Hb (g/l)[b]	22.6 ± 67	43 ± 93	0.2
Increment of weight percentile[c]	3.6 ± 2.2	3.1 ± 1.6	0.2
Mortality			
≤28 days	9 (8%)	2 (2.6%)	
29 days-12 months	5 (5%)	2 (2.6%)	0.1
Total	14 (13%)	4 (5%)	

Hb: hemoglobin.
[a] Significant *p* value.
[b] Calculated as: last Hb - Initial Hb.
[c] Calculated as: Last weight percentile for age - Initial weight percentile.

respectively, *p* 0.27. PA branches showed a tendency of a better growth at follow-up in the Stent group with Nakata 194 ± 97 vs 162 ± 110 in the Shunt group, *p* 0.09. [Fig. 1]. However, ipsi:contralateral PA branch ratio was similar before either procedure, but more homogeneous growth was observed in patients after Stent procedure. [Table 3, Fig. 2]. Five patients from Shunt group required stenting the Shunt during follow up without PA branches intervention and still considered in the Shunt group.

Accumulative readmission hospital days during follow-up were similar between the groups. Changes in the hemoglobin levels and in the weight percentile for age from the procedure date till the last follow-up were not statistically different between groups [Table 3].

Early mortality within 28 days from the procedure was 9 (8%) in Shunt group and 2 (2.6%) in the Stent group, *p* 0.1. Survival at one year was 87% and 95% for the Shunt and Stent group, respectively, *p* 0.1. [Table 3, Fig. 3].

4. Discussion

Different approaches were introduced to improve outcome in patients with CHD presenting with

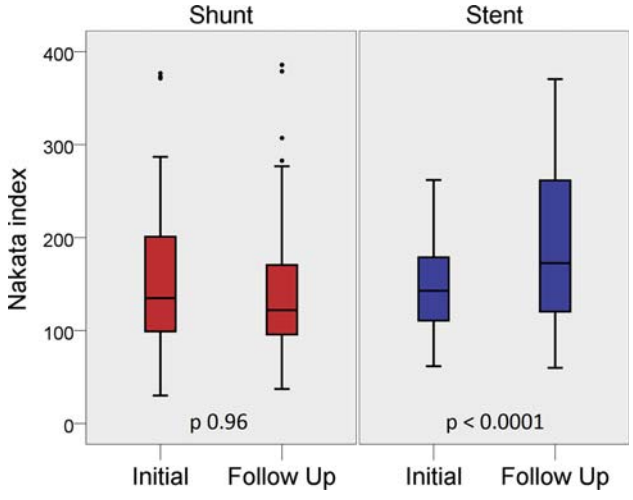

Fig. 1. Comparing the progression of Nakata index for pulmonary arteries at initial diagnosis and last follow-up for Shunt and Stent groups. Nakata index was maintained in Shunt group through follow-up period indicating acceptable growth. In Stent patients was higher over follow-up period indicating better growth.

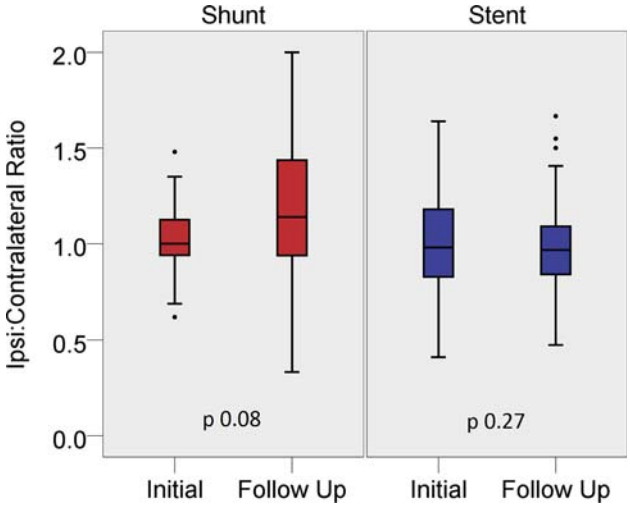

Fig. 2. Comparing the ratio between intervention side and the other side (ipsi:contralateral ratio) at initial diagnosis and at last follow-up for Shunt and Stent groups, indicating similar homogeneity of the branch pulmonary arteries growth.

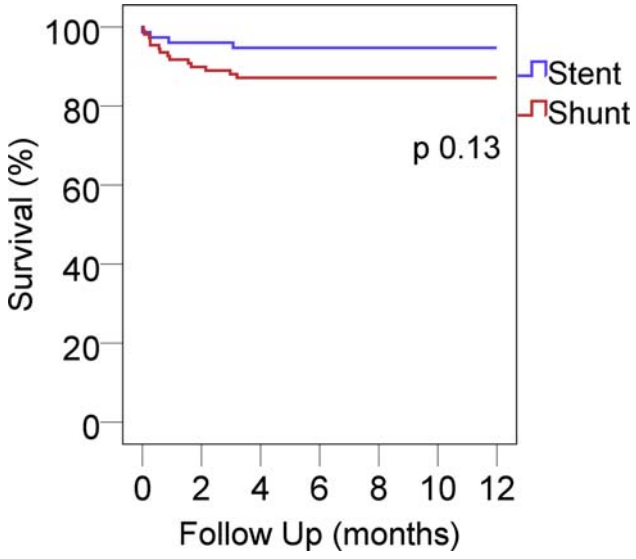

Fig. 3. Kaplan Mayer survival rate for Shunt and Stent groups, with a trend toward more mortality in the Shunt group.

ductal-dependent pulmonary blood flow to enhance a homogeneous growth of both PA branches [5,9,12]. A multi-institutional review of more than 1200 neonates who had Shunt showed no difference in their outcome if surgery was done off vs on pump or if they ligated the PDA or if it was left opened [13].

Since 1992 when Gibbs and his colleagues introduced the ductal stenting as an alternative method to maintain pulmonary blood flow [4], the technique of deploying stents in the PDA has been advanced further and improved the clinical outcome in those patients over the following years [6,14,15].

In our study, we observed that the Shunt group had a more complicated post-operative course: Shunt patients had ten times higher IS score at 12 and 24 hours post procedure, triple PPV hours and double ICU and hospital days. Complications such as necrotizing enterocolitis and cardiac arrest that required CPR were found more frequently in the Shunt group though this was not statistically significant. More emergent intervention and SVR were noticed in Shunt patients but both factors did not increase hospital days when sub-analyzed separately. SVR did not influence the ICU course while emergency intervention increased PPV and ICU days. Sepsis was observed 4 times more in Shunt subjects which could be explained by the critical pre-Shunt presentation and longer staying days.

Stent patients, on the other hand, had more vascular injury especially arterial, which is a major morbidity that occurred in our population (17%). Due to this observation, we used to send small babies (less than 2.5 kg) for Shunt procedure. Hopefully smaller and smoother sheaths will be introduced in the market to minimize this complication. We elected to highlight this finding objectively, which was similarly described by other researchers recently with comparable rate to our result for arterial injury [16]. Our data did not show correlation between weight and arterial injury, that may be due to the small number of cases with arterial injury and the selection bias for children underwent Stent. We think that utilizing ultrasound for the vascular access along with smaller sheaths may indeed minimize such complications in the near future [17]. Moreover, a carotid artery cut-down is being utilized in small patients with an excellent outcome and less vascular complications [18]. Boucek et al. reviewed six studies comparing Shunt with Stent outcomes and described similar results, though vascular injury was not highlighted [19].

Further follow-up for near a year time showed us a tendency for better growth of PA branches in the Stent group, as indicated by the Nakata index, however, the Shunt group had also a fairly acceptable growth. Furthermore, there was a statistical difference in the ipsi:contralateral ratio for either PA branches but we do not think that this finding has a significant clinical impact on the outcome on those patients, as reported and seen in other papers as well [Table 3] [7,19–21], although some authors have highlighted a distortion of PA branches growth [9,22,23].

Mortality tended to be more in the Shunt group (13%) compared to (5%) in Stent group, p 0.1; similarly, other researchers have reported mortality for Shunt (10–36%) and Stent (7–18%) [Table 2] [24,25].

Our study is a retrospective study with high possibility of selection bias as many emergency cases underwent Shunt for initial palliation, which may complicate the comparison. Many subclinical cases of vascular injury are expected in this context, which requires a prospective study to indicate the significance and to follow the corresponding limb growth in a longitudinal fashion. We have used echocardiographic images to calculate the Nakata index for quantification of PAs size as catheterization data was not available for us before Shunt. However, some of the missing comparable catheterization data would be obtainable in a prospective observation.

5. Conclusions

The implantation of PDA stent in patients with duct dependent pulmonary circulation results in a smoother ICU course and a shorter hospital stay,

with higher risk of vascular injury. Shunt and Stent procedures have a good outcome for PA growth, somatic growth and survival.

Conflict of interest

No conflict of interest among the co-authors.

Funding statement

No external funding to disclose, the study is unfunded.

Consent

Patient consent was waived by IRB being a retrospective study.

Author contribution

Conception and design of Study: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Omar Tamimi. Literature review: Ghassan A. Shaath, Ahmed Alomrani, Omar Tamimi. Acquisition of data: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Fahad Alhabshan, Mansour B. Almutairi. Analysis and interpretation of data: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Mohammed Fararjeh, Mohammad Allugmani, Fahad Alhabshan, Mansour B. Almutairi. Research investigation and analysis: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Mohammed Fararjeh, Mohammad Allugmani, Fahad Alhabshan, Mansour B. Almutairi, Ahmed Alomrani, Omar Tamimi. Data collection: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Mohammed Fararjeh, Mohammad Allugmani. Drafting of manuscript: Ghassan A. Shaath. Revising and editing the manuscript critically for important intellectual contents: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Ahmed Alomrani. Data preparation and presentation: Ghassan A. Shaath, Abdulraouf MZ. Jijeh, Mohammed Fararjeh, Mohammad Allugmani, Ahmed Alomrani. Supervision of the research: Ghassan A. Shaath, Omar Tamimi. Research coordination and management: Ghassan A. Shaath, Abdulraouf MZ. Jijeh.

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