

Outcomes of systemic to pulmonary artery shunts in patients weighing less than 3 kg: Analysis of shunt type, size, and surgical approach

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Objective: To evaluate outcomes of systemic to pulmonary artery shunts (SPS) in patients weighing less than 3 kg with regard to shunt type, shunt size, and surgical approach.

Methods: Patients weighing less than 3 kg who underwent modified Blalock-Taussig or central shunts with polytetrafluoroethylene grafts at our institution from January 1, 2000, to May 31, 2011, were reviewed. Patients who had undergone other major concomitant procedures were excluded from the analysis. Primary outcomes included mortality (discharge mortality and mortality before next planned palliative procedure or definitive repair), cardiac arrest and/or extracorporeal membrane oxygenation (ECMO), and shunt reintervention.

Results: In this cohort of 80 patients, discharge survival was 96% (77/80). Postoperative cardiac arrest or ECMO occurred in 6/80 (7.5%), and shunt reintervention was required in 14/80 (17%). On univariate analysis, shunt reintervention was more common in patients with 3-mm shunts (11/30, 37%) compared with 3.5-mm (2/36, 6%) or 4-mm shunts (1/14, 7%) ($P < .003$). There were no statistically significant associations between shunt type, shunt size, or surgical approach and cardiac arrest/ECMO or mortality. Multiple logistic regression demonstrated that a shunt size of 3 mm ($P = .019$) and extracardiac anomaly ($P = .047$) were associated with shunt reintervention, whereas no variable was associated with cardiac arrest/ECMO or mortality.

Conclusions: In this high-risk group of neonates weighing less than 3 kg at the time of SPS, survival to discharge and the next planned surgical procedure was high. Outcomes were good with the 3.5- and 4-mm shunts; however, shunt reintervention was common with 3-mm shunts. (*J Thorac Cardiovasc Surg* 2014;147:672-7)

The neonatal systemic to pulmonary artery shunt (SPS) procedure continues to be associated with appreciable mortality. According to a recent harvest report of the STS Congenital Heart Surgery Database (1/2013 report), mortality for a neonatal modified Blalock-Taussig shunt was 7.1%.¹ Among the many factors accounting for this, small patient size has consistently been reported as a risk factor for worse outcomes.²⁻⁶ Given the limited size options of commercially available shunts, it can be challenging in a small neonate to create a durable shunt that provides an

appropriate amount of pulmonary blood flow. In addition to shunt size, other variables that could potentially modify outcomes include shunt type (central shunt [CS], modified Blalock-Taussig shunt [MBTS]) and surgical approach. These surgically controllable factors and any potential relationships with outcomes in a high-risk group of neonates weighing less than 3 kg at the time of SPS were evaluated in this study.

METHODS

Patients and Data Collection

Patient information was obtained retrospectively from the medical records of all patients weighing less than 3 kg who underwent either a CS or an MBTS with a polytetrafluoroethylene (Gore-Tex; W.L. Gore and Associates, Inc, Newark, Del) graft at our institution between January 1, 2000, and May 31, 2011. Patients who had undergone other major concomitant surgery (Norwood, Starnes procedure, unifocalization of collaterals, and so forth) were excluded from the analysis; patch enlargement of the central pulmonary arteries was not an exclusion criterion. Patients who had undergone autologous CS (eg, Melbourne shunt) due to the absence of accurate information about shunt size were also excluded. Patient information was deidentified, and study data were collected and managed using REDCap electronic data capture tools hosted at the Children's Hospital of Wisconsin. The Institutional Review Board at the Children's Hospital of Wisconsin authorized the collection of data from existing medical records under a waiver of the Health Insurance Portability and Accountability Act (HIPAA) for this retrospective study.

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Abbreviations and Acronyms

CPB	= cardiopulmonary bypass
CS	= central shunt
ECMO	= extracorporeal membrane oxygenation
HIPAA	= Health Insurance Portability and Accountability Act
MBTS	= modified Blalock-Taussig shunt
SPS	= systemic to pulmonary artery shunt

Patients were characterized according to diagnostic group, shunt type (CS or MBTS), shunt size (3 mm, 3.5 mm, or 4 mm), and surgical approach (thoracotomy or sternotomy). Diagnostic groups included pulmonary atresia with ventricular septal defect, pulmonary atresia with intact ventricular septum, anomalies with anticipated biventricular repair, and anomalies with anticipated univentricular palliation. These groups were selected according to the methods used by Petrucci and colleagues⁵ and the finding that pulmonary atresia with intact ventricular septum was a risk factor for mortality. Patient characteristics included diagnostic group, gestational age, gender, weight at surgery, extracardiac/genetic anomalies, as well as other factors with potential association with outcomes. Operative variables included cardiopulmonary bypass time, aortic crossclamp time, approach via thoracotomy or sternotomy, type of shunt, and size of shunt (Table 1).

Technique

All CS were created via a median sternotomy approach according to the method reported by Gates and colleagues.⁷ Surgeon discretion determined the use of thoracotomy versus sternotomy for MBTS, which was created using standard techniques based on the method of de Leval and colleagues,⁸ with the exception that the distal innominate artery was used for the proximal anastomosis of the MBTS placed through a sternotomy. The patient's anatomy and clinical condition determined the use of cardiopulmonary bypass (CPB). For off-pump cases, heparin was administered after completion of the proximal anastomosis. Protamine was administered only to patients who had been weaned from CPB. Postoperatively, heparin was administered as a continuous infusion at 10-20 units/kg/h with conversion to aspirin once enteral tolerance was achieved.

Outcomes

Primary outcomes measures included mortality, defined as death occurring any time after the shunt procedure and before the next planned palliation or definitive repair; postoperative cardiac arrest or extracorporeal membrane oxygenation (ECMO); and shunt reintervention. Shunt reintervention was defined as surgical or catheter-based intervention to address inappropriate shunt flow (thrombus, anastomotic stenosis, undersizing, oversizing).

Statistical Analysis

Descriptive characteristics of the sample were summarized by median and interquartile range. A nonparametric Wilcoxon-Mann-Whitney test or Kruskal-Wallis test was used to compare continuous variables. The χ^2 test or Fisher exact test was used to examine the associations in categorical variables. Stepwise logistic regression was used to determine the important covariates for various outcomes. Kaplan-Meier survival analysis was used to assess death or intervention-free survival, with Wilcoxon log-rank comparisons among the 3 shunt size groups. A competing risk analysis was performed.⁹ Patients were grouped into 4 different categories: survived without any reintervention; unplanned shunt reintervention; death before any reintervention; and transition to definitive palliation or repair.

Cumulative incidence functions among the shunt size groups for each event were compared using the Gary test. All statistical tests were 2-tailed. All analyses were done in SAS 9.2 (SAS Institute, Inc, Cary, NC).

RESULTS

Preoperative and Operative Characteristics

The cohort included 80 patients with a median age and weight at the time of SPS of 7 days (range, 1-79 days) and 2.6 kg (range, 1.4-2.9 kg). Table 1 provides a comparison of preoperative and operative characteristics according to shunt type. Only 12 patients received a CS, and a higher percentage of CS were 3 mm (9/12, 75%) compared with 21/68 (31%) of MBTS ($P = .021$). As expected, all CS were placed via a median sternotomy; whereas 25 of 68 (37%) MBTS were placed via thoracotomy. Also, use of CPB was more common in the CS group (4/12, 33% for CS vs 4/68, 6% for MBTS; $P = .015$). Other characteristics were similar for both shunt type groups.

Table 2 provides a comparison of preoperative and operative characteristics for the 3 shunt size groups. More patients with 3-mm shunts demonstrated preoperative shock or acidosis ($P = .010$); prematurity ($P < .0001$); extracardiac anomalies ($P = .046$); and a higher proportion of CS ($P = .022$). Table 3 compares preoperative and operative characteristics according to surgical approach. A higher percentage of patients undergoing sternotomy received a 3-mm shunt (28/55, 51%) compared with those undergoing thoracotomy (2/25; 8%) ($P < .001$). The 2 groups were otherwise similar.

Outcomes

Hospital survival for the cohort was 96% (77/80). Of the 77 survivors, 91% (70/77) survived to definitive repair or next planned palliation, and 4 patients died after repair or next planned palliation. Causes of death included multiple organ dysfunction syndrome (5 patients); unspecified (4 patients); sepsis (2 patients); meningitis (1 patient); cardiopulmonary failure (1 patient, unknown if overcirculation); and shunt thrombosis (1 patient). Excluding mortality occurring after the next planned procedure, on univariate analysis there were no statistically significant associations between mortality and diagnostic group, shunt type, shunt size, or surgical approach (Table 4). Postoperative cardiac arrest or use of ECMO occurred in 6/80 (7.5%) without association with diagnostic group, shunt type, shunt size, or surgical approach (Table 4).

Shunt reintervention occurred in 14/80 (17%); most were done surgically. Five patients received a larger shunt; 5 received a same-size shunt (some in addition to existing shunt); and 1 received a smaller shunt (coarctation of pulmonary artery excluding flow from left MBTS to right lung; second smaller shunt placed to right pulmonary artery leaving previous shunt open). Shunt-related factors leading to shunt reintervention included thrombus in 6 patients;

TABLE 1. Patient characteristics versus shunt type

	CS (N = 12), n (% of column)	MBTS (N = 68), n (% of column)	P value
PA-VSD	2 (17)	12 (18)	.745
PA-IVS	3 (25)	16 (24)	
BVR	4 (33)	30 (44)	
UVP	3 (25)	10 (15)	
Preoperative mechanical ventilation	5 (42)	25 (37)	.746
Preoperative shock/acidosis	6 (50)	24 (35)	.332
Surgical delay because of infection	1 (8)	5 (7)	.999
Preoperative ECMO	0	0	.999
Weight at surgery			
≥2 kg to 3 kg	11 (92)	63 (93)	.999
<2 kg	1 (8)	5 (7)	
Use of CPB	4 (33)	4 (6)	.015
Genetic anomaly	2 (17)	15 (22)	.999
Gestational age			
≥37 wk	4 (33)	37 (54)	.22
<37 wk	8 (67)	31 (46)	
Extracardiac anomalies	3 (25)	19 (28)	.999
Shunt size			
3 mm	9 (75)	21 (31)	.022
3.5 mm	2 (17)	34 (50)	
4 mm	1 (8)	13 (19)	
Surgical approach			
Thoracotomy	0	25 (37)	.014
Sternotomy	12 (100)	43 (63)	

CS, Central shunt; MBTS, modified Blalock-Taussig shunt; PA-VSD, pulmonary atresia with ventricular septal defect; PA-IVS, pulmonary atresia with intact ventricular septum; BVR, anticipated biventricular repair; UVP, anticipated univentricular palliation; ECMO, extracorporeal membrane oxygenation; CPB, cardiopulmonary bypass.

potentially technical factors in 3 patients; and other factors in 5 patients (inadequate flow, small pulmonary artery, and/or coarctation of the pulmonary artery). Shunt reintervention was significantly associated with 3-mm shunts: 11/30 (37%) 3-mm shunts compared with 2/36 (6%) 3.5-mm shunts and 1/14 (7%) 4-mm shunts ($P < .003$).

Logistic Regression

The relationship between surgically controllable factors and outcomes was further assessed using logistic regression analysis to account for differences in patient and operative variables demonstrated in Tables 1-3. There were no significant associations between diagnostic group, shunt type, shunt size, or surgical approach with ECMO/cardiac arrest or mortality. However, shunt size and extracardiac anomaly were significantly associated with shunt reintervention ($P = .019$ for shunt size, $P = .047$ for extracardiac anomaly).

Competing Risk Analysis

In an analysis evaluating shunt size and competing risks of survival without any reintervention; death before any

reintervention; transition to next planned palliation or definitive repair; and transition to an unplanned shunt reintervention, the only statistically significant finding was a much higher risk of transition to an unplanned shunt reintervention with 3-mm shunts ($P = .002$); Figure 1 shows the cumulative incidence curve.

DISCUSSION

Small patient size has been recognized as a significant risk factor for worse outcomes after a neonatal SPS procedure.²⁻⁶ Other than completing a technically excellent SPS procedure, variables amenable to control by the surgeon with potential to influence outcomes include shunt type and size and operative approach. Therefore, the present study was undertaken to assess whether or not these variables were associated with important outcome measures in this high-risk group of patients.

The main finding of our study is that 3-mm shunts were associated with a substantially higher rate of shunt reintervention. This is consistent with published results. Wells and colleagues¹⁰ conducted a histopathologic analysis of 155 explanted MBTS and reported smaller shunt size (<4 mm) to be a risk factor for significant stenosis. Also, O'Connor and colleagues¹¹ reported smaller shunt size as a significant risk factor for reintervention in MBTS. Other investigators, however, have not found shunt size to be associated with inferior outcomes for either MBTS or CS.^{3,6,12} Our data offer no reconciliation of these differences. Although it is our impression that 3-mm shunts are associated with an increased risk of reintervention, the potential importance of other factors, such as underlying anatomy and physiology, size of the source arterial inflow, size of the branch pulmonary arteries, ductal patency, degree of anticoagulation, and technical factors related to different methods of shunt placement, must be recognized.

Of the 14 reinterventions in our cohort, 11 occurred with 3-mm shunts; 5 of these involved upsizing the shunt. In contrast, of the 3 reinterventions for 3.5- and 4-mm shunts, only 1 involved placing a smaller shunt (this was a smaller second shunt with the previous shunt left open). It is perhaps surprising that to the extent congestive heart failure existed in patients with larger shunts, it did not manifest in the outcomes evaluated in our study. Also, shunt size remained insignificant in an analysis (data not shown) in which mortality was redefined to include death occurring after the next planned procedure (in the event larger shunts unfavorably predisposed patients for their next surgery). Although this is not conclusive, it suggests that the lower durability of 3-mm shunts may offset any advantage related to more restricted pulmonary blood flow. This should not necessarily be inferred for CS or for patients weighing less than 2 kg, as these groups were underrepresented in our cohort, and only 1 of 6 patients weighing less than 2 kg received a shunt larger than 3 mm. Although no relationship between

TABLE 2. Patient characteristics versus shunt size

	3 mm (N = 30), n (% of column)	3.5 mm (N = 36), n (% of column)	4 mm (N = 14), n (% of column)	P value
PA-VSD	4 (13)	3 (8)	7 (50)	.069
PA-IVS	7 (23)	11 (31)	1 (7)	
BVR	13 (43)	16 (44)	5 (36)	
UVP	6 (20)	6 (17)	1 (7)	
Preoperative mechanical ventilation	12 (40)	13 (36)	5 (36)	.938
Preoperative shock/acidosis	16 (53)	13 (36)	1 (7)	.01
Surgical delay because of infection	4 (13)	2 (6)	0	.324
Preoperative ECMO	0	0	0	.999
Weight at surgery				
≥2 kg to 3 kg	25 (83)	35 (97)	14 (100)	.062
<2 kg	5 (17)	1 (3)	0	
Use of CPB	6 (20)	2 (6)	0	.096
Genetic anomaly	6 (20)	7 (19)	4 (29)	.769
Gestational age				
≥37 wk	7 (23)	21 (58)	13 (93)	<.0001
<37 wk	23 (77)	15 (42)	1 (7)	
Extracardiac anomaly	12 (40)	5 (14)	5 (36)	.046
Shunt type				
CS	9 (30)	2 (6)	1 (7)	.022
MBTS	21 (70)	34 (94)	13 (93)	
Surgical approach				
Thoracotomy	2 (7)	15 (42)	8 (57)	<.001
Sternotomy	28 (93)	21 (58)	6 (43)	

PA-VSD, Pulmonary atresia with ventricular septal defect; PA-IVS, pulmonary atresia with intact ventricular septum; BVR, anticipated biventricular repair; UVP, anticipated univentricular palliation; ECMO, extracorporeal membrane oxygenation; CPB, cardiopulmonary bypass; CS, central shunt; MBTS, modified Blalock-Taussig shunt.

reintervention and mortality was found (data not shown), ineffective rescue therapy would further heighten concern regarding 3-mm MBTS.

Our discharge survival of 96% compares favorably with the range of 85%-94% reported by others for cohorts not restricted to small patients.^{4-6,11-18} Recently, Petrucci and colleagues⁵ reported on a multiinstitutional series from the STS Congenital Heart Surgery Database of more than 1200 patients; 592 patients weighed between 1.5 and 3.0 kg at the time of SPS. Discharge survival was 84.4% in patients weighing 2-2.5 kg and 89% in all patients weighing less than 3 kg. Another report by Erez and colleagues¹⁹ evaluated outcomes using saphenous vein homografts as shunts in patients weighing less than 3 kg. In that series of 32 patients, hospital survival was approximately 94%, but overall survival was approximately 80%. Neither of these 2 studies offered a comparison between shunt size and type (CS or MBTS) or surgical approach. Our cohort's postdischarge survival to next planned palliation or definitive repair was somewhat higher than what has been reported by others in cohorts not restricted to small patients.^{11,14-16,20} For our

TABLE 3. Patient characteristics versus surgical approach

	Thoracotomy (N = 25), n (% of column)	Sternotomy (N = 55), n (% of column)	P value
Preoperative mechanical ventilation	8 (32)	22 (40)	.493
Preoperative shock/acidosis	6 (24)	24 (44)	.093
Surgical delay because of infection	0	6 (11)	.169
Preoperative ECMO	0	0	
Weight at surgery			
≥2 kg to 3 kg	24 (96)	50 (91)	.66
<2 kg	1 (4)	5 (9)	
Genetic anomaly	7 (28)	10 (18)	.32
Gestational age			
≥37 wk	15 (60)	26 (47)	.291
<37 wk	10 (40)	29 (53)	
Extracardiac anomalies	5 (20)	17 (31)	.311
Shunt size			
3 mm	2 (8)	28 (51)	<.001
3.5 mm	15 (60)	21 (38)	
4 mm	8 (32)	6 (11)	

ECMO, Extracorporeal membrane oxygenation.

cohort, it is not known if shunt-related deaths were truly uncommon or if proximate cause of death was simply not discernable from the available documentation.

TABLE 4. Outcomes versus shunt type, size, surgical approach, and diagnostic group

	Discharge or late death, n (% of row)	Cardiac arrest or ECMO, n (% of row)	Shunt reintervention, n (% of row)
Shunt type (n)			
CS (12)	3 (25)	2 (17)	2 (17)
MBTS (68)	7 (10)	4 (6)	12 (18)
P value	.168	.22	.999
Shunt size (n)			
3 mm (30)	2 (7)	4 (13)	11 (37)
3.5 mm (36)	7 (19)	2 (6)	2 (6)
4 mm (14)	1 (7)	0	1 (7)
P value	.263	.324	.003
Surgical approach (n)			
Thoracotomy (25)	5 (20)	0	5 (20)
Sternotomy (55)	5 (9)	6 (11)	9 (16)
P value	.272	.169	.755
Diagnostic groups (n)			
PA-VSD (14)	3 (21)	1 (7)	3 (21)
PA-IVS (19)	2 (11)	0	1 (5)
BVR (34)	3 (9)	3 (9)	5 (15)
UVP (13)	2 (15)	2 (15)	5 (38)
P value	.655	.354	.097

P values based on univariate analysis. See text for results of logistic regression. ECMO, Extracorporeal membrane oxygenation; CS, central shunt; MBTS, modified Blalock-Taussig shunt; PA-VSD, pulmonary atresia with ventricular septal defect; PA-IVS, pulmonary atresia with intact ventricular septum; BVR, anticipated biventricular repair; UVP, anticipated univentricular palliation.

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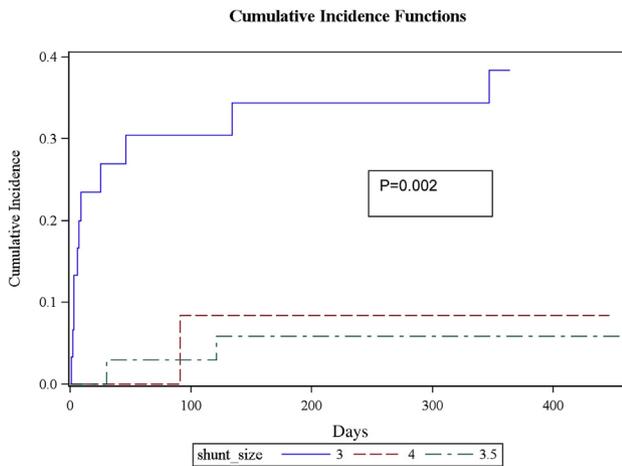


FIGURE 1. Cumulative incidence of unplanned shunt reintervention according to shunt size.

Significant relationships between outcomes and diagnostic group, shunt type, and surgical approach were not found in our study.^{2,4,5,12,17,21-25} Previous reports have demonstrated inconsistent findings regarding these issues. Factors that may in part account for our findings include the weight restriction of the cohort and the exclusion of patients undergoing other major concomitant procedures. We presently prefer the median sternotomy approach, as it offers much greater versatility in determining proximal and distal shunt sites; permits placement of the distal anastomosis more centrally, which may favor more uniform development of the branch pulmonary arteries; does not require collapse of 1 lung in a small, clinically unstable baby; and readily permits use of CPB as needed to ensure patient stability. We have not encountered major issues with sternal reentry for subsequent planned surgeries.

Probably the main advantage of the CS is the avoidance of branch pulmonary artery distortion and perhaps more uniform distribution of blood flow. Also, particularly for a small neonate, the shorter length of a CS permits a certain degree of increased flow, which may be beneficial depending on the specific circumstance. However, based on other features of shunts (such as technical ease of creation, provision of an appropriate amount of pulmonary blood flow, risk of occlusion, ease of takedown, and so forth), it can be difficult to predict superiority of one shunt type over the other for a small neonate.

An intuitively appealing explanation of our findings is that neonates weighing less than 3 kg who require SPS present with patient characteristics that are likely strong determinants of outcome, regardless of the nonpatient, surgically controllable factors. Nevertheless, our results suggest that a 3-mm diameter shunt may not be optimal for an isolated MBTS in these patients.

Limitations

Our study is subject to the limitations and biases inherent to a retrospective single-institutional study of a small cohort. The group of patients receiving 3-mm shunts seemed to have higher risk features and showed a statistically nonsignificant, but nonetheless more common use of CPB for the shunt procedure. Despite using logistic regression to account for these and other patient variables, a confounding effect cannot be completely ruled out. One controllable factor that we did not analyze was anticoagulation, which could potentially be more important with smaller shunts. Although patients received heparin and aspirin, the degree of anticoagulation or antiplatelet effect was not routinely assessed. Another limitation is the small number of patients with CS, which limits the strength of inference that may be made regarding these patients. Because of the exclusion criteria in this study, our findings do not necessarily apply to patients undergoing concomitant major surgery. In addition, CS created from native pulmonary arterial tissue were not assessed and no comment can be made on the comparative advantages or disadvantages of this approach.

CONCLUSIONS

In this high-risk group of neonates weighing less than 3 kg at the time of SPS procedures, discharge survival was high. Outcomes were good with 3.5- and 4-mm shunts; however, shunt reintervention was common with 3-mm shunts.

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