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ORIGINAL ARTICLE

Interventions After Norwood Procedure: Comparison of Sano and Modified Blalock–Taussig Shunt

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Abstract Improved results have evolved from the modified Norwood procedure (NP). This study compares the incidence of interventions after NP with the Sano ($n = 37$) and modified Blalock–Taussig (BT $n = 70$) shunt. Incidence, location, interval of interventions, and weight were retrospectively analysed for 107 neonates undergoing NP during the period from October 2002 to December 2009. Forty-six (43.0 %) patients underwent interventions, mostly for dilatation of the aortic arch ([DAA] $n = 26$ [24.3 %]; Sano $n = 10$, BT $n = 16$, $p = 0.6$), dilatation of the shunt ([DS] $n = 15$ [14.0 %]; Sano $n = 11$, BT $n = 4$; $p = 0.002$), or closure of aortopulmonary collaterals ([APC] $n = 15$ [14.0 %]; Sano $n = 3$, BT $n = 12$; $p = 0.08$). Mean interval after NP and body weight at DAA, DS, and APC were 72.4 ± 18.9, 108.5 ± 15.8, and 110.7 ± 17.8 days and 4.5 ± 1.3, 4.9 ± 1.9, 5.3 ± 1.2 kg, respectively. The interventions were not associated with mortality but with a greater rate of complications (9 of 46 [21.4 %]) compared with the rate after diagnostic catheterization (0 of 45, $p = 0.03$). Complications included closure of the femoral or subclavian artery ($n = 5$), cerebral embolic or bleeding events ($n = 4$), cardiopulmonary resuscitation ($n = 3$), and temporary heart block ($n = 2$). Actuarial survival was similar from the postoperative month 8 onward at 78.6 ± 4.9 % (95 % confidence interval [CI] 67.0–86.5 %) for Sano and 78.4 ± 6.8 % (95 % CI 61.4–88.6 %) for BT ($p = 0.95$). Interventions after NP were common irrespective of shunt type. However, a significantly greater rate of shunt interventions was noted in the Sano group. In particular, interventions addressing the aortic arch and the shunt were related with a significant rate of complications.

Keywords Congenital heart disease · Norwood operation · Intervention · Sano · RV–PA shunt

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Introduction

Since the Norwood procedure (NP) [12] surgery has successfully palliated neonates with hypoplastic left heart syndrome, numerous variations have been implemented to improve midterm outcome. The latest modification of NP was introduced by Sano et al. [20], who revitalized the concept of a right-ventricular–to–pulmonary artery (RV–PA) conduit, originally proposed by William Norwood. They switched the origin of the shunt supplying the pulmonary blood flow from the subclavian artery to the right-ventricular outflow tract. The Sano shunt was reported to provide a more stable postoperative hemodynamic situation. No diastolic pulmonary runoff results in greater postoperative diastolic pressures and may contribute to a better outcome [9, 17]. However, improved hospital survival did not translate into superior midterm survival [13, 16], most likely due to various events causing interstage and later attrition of patients.

There are several case reports in regard to interstage catheter interventions [3, 11]. The goal of this study is to systematically compare incidence, location, interval of intervention, and weight at the time of interventions after NP with either Sano or modified BT shunt.

Methods

Patients and Surgical Management

The 109 neonates included in the study underwent NP for hypoplastic left heart syndrome from October 2002 to December 2009. Two patients successfully underwent biventricular repair and were removed from further analysis. Of the remaining 107 consecutive patients, 37 received a Sano shunt, and 70 received a BT shunt in a concomitant fashion according to surgeon's preference. The age at the time of surgery ranged from 1 to 27 days (mean 7.8 ± 0.4), and the weight was 3.2 ± 0.1 kg (range 1.7–4.4). Preoperative risk of the Sano and BT groups was estimated by Aristotle comprehensive score [6]. Patient characteristics are listed in Table 1.

The standardized surgical technique and postoperative management after NP, introduced in October 2002, has been described as follows [14]: A continuous antegrade cerebral perfusion is installed using a BT shunt. During aortic arch reconstruction, the coarctation ridge is excised, followed by reconnection of the descending aorta and anterior homograft patch augmentation of the entire arch and ascending aorta. The Sano shunt is inserted curving around the right side of the augmented aorta [19]. Study patients were assigned to the surgeon on call, who chose the type of shunt according to his preference. The shunt diameter in Sano shunt group was generally 5 mm. In the BT shunt group, the shunt diameter was chosen in accordance to patient body weight, with diameter of 3.5 mm used in neonates weighing <4.0 kg and a diameter ≥4.0 mm in heavier patients. Postoperative management included monitoring of pulmonary-to-systemic blood flow ratio aiming at 1.5 [15]. Echocardiogram before discharge ensured adequate right-ventricular function, less-than-moderate tricuspid valve incompetence and no significant gradient across the aortic arch. Patients were discharged with peripheral oxygen saturations of approximately 75–85 %, constant weight gain of at least 50 g/week, and usually on anticongestive medication consisting of diuretics and a ß-blocking agent (carvedilol or metoprolol). The standardized home monitoring protocol was applied [4].

Table 1 Patient characteristics at NP[a]

Characteristics	Sano	BT shunt	p
NP (n)	37	70	
Weight (kg)	3.2 ± 0.1	3.2 ± 0.1	1.0
Aristotle comprehensive score	18.7 ± 0.4	18.9 ± 0.3	0.8
HLHS (no. of patients)	33	53	0.1
Aortic clamp time (min)	38.2 ± 3.7	37.2 ± 2.9	0.8
Length of hospital stay (d)	28.1 ± 3.2	30.4 ± 2.7	0.6

HLHS typical hypoplastic left heart anatomy

[a] Values display the total number of patients or mean values ± SEM in each shunt group

Indication and Management of Interventions

Patients were followed-up by monthly routine visit in the outpatient clinic or more intensively if desaturation or failure to thrive was recognized during home monitoring by the parents. The indications of interventions were defined as follows:

1. Dilatation of the aortic arch (DAA): DAA was performed when recoarctation of the aortic arch was seen on transthoracic echocardiogram or cardiac catheter as a sudden reduction of diameter from the aortic arch to the descending aorta >30 % [8].
2. Dilatation of the shunt (DS): DS was performed when stenosis or kinking was verified on echocardiography and oxygen saturation was ≤70 % at rest. Stent implantation ensued if stenosis or kinking could not be alleviated or in case the result of dilatation was not sustainable.
3. Closure of the systemic-to-pulmonary collaterals (APC): APC was performed when collaterals were accessible and contrast fluids could be passed and visualized in the pulmonary veins. APC was performed as a concomitant procedure with routine catheterization before second stage surgery or during DAA.
4. Shunt banding (SB): SB was performed when there was pulmonary overcirculation despite medical vasodilation therapy as determined by means of a Titan clip or wrapping and tightening of a GORE-TEX strip (GORE-TEX, ELKTON, MD 21921, USA) around the shunt.

All interventions were performed by way of a retrograde approach through the femoral artery, except for interventions on the Sano shunt and the interatrial septum, in which case the femoral vein was used for access. After intervention, pressure gradients und oxygen saturation were routinely measured to monitor achieved results. At the end of the procedure, 200 to 400 IU/kg/d heparin were perfused for 24 h to maintain a partial thromboplastin time of 60–90 s. In case of stent or coil implantation, acetyl salicylic acid perfusion (2–5 mg/kg/d) was commenced and maintained until Glenn surgery.

Data Collection and Statistical Analysis

Preoperative and postoperative data were collected retrospectively. Informed consent was obtained from the patients' parents for data collection and statistical analysis for study purposes in accordance to national laws. Preoperative risk was assessed by the Aristotle complexity score [6]. The survey ended in December 2009. From then on, the implantation of a Sano shunt was limited to patients with a proximal vessel that proved inadequate for a BT shunt, such as an interrupted aortic arch or an aberrant subclavian artery (*Arteria lusoria*). The follow-up data collection was complete. For statistical comparison between the two shunt groups, subsequent interventions in the same location were counted only once per patient and location. All analyses were conducted using the statistical software package SPSS 20.0 (IBM, SPSS Statistics, Ehningen, Germany). Data were summarized as mean ± SEM. Chi-square test or Fisher's exact test was used for nonparametric data analysis as appropriate. Independent Student *t* test was used to compare means of parametric variables for significant differences between groups. Levene's test was employed to test for equality of variances. A difference was considered significant at $p < 0.05$.

Results

Incidence and Location

Forty-six of 107 (43.0 %) neonates required interventions between the NP and Glenn operations. The most common intervention was dilatation for recurrent aortic arch obstruction (DAA $n = 26$ [24.3 %]), stenosis of the system-to-pulmonary shunt (DS $n = 15$ [14.0 %]), or for closure of aortopulmonary collaterals (APC $n = 15$ [14.0 %]). SB was required in 4 patients. Interval and weight for commonest interventions are listed in Table 2.

Interventions occurred at any time interval and body weight between the NP and Glenn operations. Age and weight at Glenn surgery were not significantly different (5.3 ± 0.3 vs. 5.5 ± 0.2 months [$p = 0.7$] and 6.1 ± 0.2 vs. 5.9 ± 0.2 kg [$p = 0.4$]) for Sano and BT shunt, respectively. The mean interval and weight, respectively, after NP was shortest for SB (8.3 ± 6.7 days and 2.6 ± 0.4 kg) followed by DS (75.4 ± 18.3 days and 4.5 ± 1.3 kg), recurrent arch obstruction (104.9 ± 16.2 days and 4.9 ± 1.8 kg), and coil occlusion of the aortopulmonary collaterals (110.7 ± 17.8 days and 5.3 ± 1.2 kg). In three patients (one Sano and two BT), the proximal left or right pulmonary artery was dilated. One patient with BT required a Rashkind atrioseptostomy for recurrent interatrial obstruction.

Table 2 Interval and weight for the most common interventions

Interval and weight	Sano	BT shunt	*p*
NP (*n*)	37	70	
Shunt band (*n*)	2	2	1.0
Interval (d)	0	16.5 ± 15.5	0.5
Weight (kg)	2.4 ± 0.2	2.8 ± 0.8	0.7
Shunt dilatation (*n*)	11	4	0.002
Interval (d)	67.8 ± 18.9	100.0 ± 16.4	0.4
Weight (kg)	4.3 ± 0.5	6.2 ± 0.3	0.004
Aortic arch dilatation (*n*)	10	16	0.6
Interval (d)	115.7 ± 20.9	103.9 ± 11.8	0.6
Weight (kg)	5.2 ± 0.3	4.7 ± 0.2	0.2
APC closure (*n*)	2	13	0.08
Interval (d)	124.5 ± 3.5	123.6 ± 19.4	1.0
Weight (kg)	6.8 ± 0.8	5.1 ± 0.3	0.05

[a] Values display the total number of patients or mean values ± SEM in each shunt group

Shunt Banding

A total of four patients (3.7 %) required SB to overcome pulmonary overcirculation despite efforts to decrease afterload by infusion of milrinone and phentolamine. All four cases had an Aristotle comprehensive score ≥20 or more (4 of 4 = 100 %) (high-risk patients) compared with 12 patients among the remaining 42 (28.6 %) who underwent interventions ($p = 0.006$). Two Sano and one BT shunt patients were banded at the time of surgery or on the first postoperative day. Two of these had the banding removed during chest closure 2 and 4 days after NP, respectively, and one 40 days after NP with progression of cyanosis. The fourth patient with a BT shunt required banding 32 days after NP during emergency chest opening and resuscitation with extracorporeal membrane oxygenation. The banding in this patient was not removed until Glenn surgery. There was a tendency toward a lower weight at the time of NP in neonates requiring banding compared with the other patients (2.7 0.5 kg vs. 3.2 ± 0.1 kg, $p = 0.05$). At the time of intervention itself, patient weight was significantly different between patients who needed banding and those who underwent intervention for other reasons (2.6 ± 0.3 kg vs. 5.0 ± 0.2 kg, respectively; $p < 0.001$).

Dilatation and Stenting of the Shunt

Fifteen patients with cyanosis (14 %) underwent dilatation, including stent implantation ($n = 13$), to eliminate kinking or stenosis. The interval between NP and DS was significantly shorter than the interval for arch dilatation and APC (DS 76.4 ± 14.7 vs. DAA 114.1 ± 9.1 days; $p = 0.04$). Weight was not significantly different between the two intervention groups. Typical sites of Sano shunt stenoses are shown in Fig. 1a, b.

The rate of Sano shunt intervention was significantly greater (Sano 11 of 37 [29.7 %] vs. BT 4 of 70 [5.7 %], $p = 0.002$). Mean weight at shunt intervention was significantly lower for Sano (Sano 4.3 ± 0.5 kg vs. BT 6.2 ± 0.3 kg, $p = 0.004$). In addition, the time interval to shunt intervention was shorter, but this difference did not reach significance (Sano 68 ± 18.9 vs. BT 100 ± 16.3 days, $p = 0.4$). One Sano shunt had to be stented to overcome severe cyanosis due to compression between the sternum and the enlarged ventricle shortly after chest closure.

Dilatation and Stenting of Recurrent Arch Obstruction

With 26 interventions (24.3 %), DAA was the most common intervention after NP. DAA became apparent later than shunt interventions after a mean of 109 ± 15.8 days. Interval and weight were not significantly different from APC interventions. The rate of aortic arch interventions was similar in both shunt groups (Sano 10 of 27 [27.0 %] vs. BT 16 of 70 [22.9 %], $p = 0.6$). Neither interval nor weight differed significantly at the time of intervention.

Coiling of Aortopulmonary Collaterals

In 15 patients, coils were placed to close large aortopulmonary collaterals before Glenn surgery. The associated time interval until intervention was significantly longer than that for the shunt-related interventions, but weight was not different. Coil occlusions were more prevalent in the BT group, although a significance level was not reached (Sano 5.4 % vs. BT 18.6 %, $p = 0.08$). A tendency toward greater weight at APC intervention was observed in the Sano group (6.8 ± 0.8 vs. BT 5.1 ± 0.3 kg, $p = 0.05$).

Single and Combined Interventions

Of all interventions, 78.2 % (36 of 46) involved only 1 site (DAA $n = 16$, DS $n = 11$, APC $n = 9$). The remaining interventions were a combination of DS and DAA in 4 and a combination of DAA and APC in 6 patients. There was no combination of DS and APC.

Complications

In 9 patients, 14 complications comprised closure of the femoral or subclavian artery or vein ($n = 5$ [10.9 %]), cerebral embolic or bleeding events ($n = 4$ [8.7 %]), cardiopulmonary resuscitation ($n = 3$ [6.5 %]), and temporary heart block ($n = 2$ [4.3 %]). During stent implantation into a narrow proximal Sano shunt, the stent slipped into the right-ventricular cavity and had to be removed during an emergency surgery.

Complications were significantly more prevalent with these "therapeutic" interventions compared with the complication rates for diagnostic cardiac catheters before Glenn operations (9 of 46 [19.6 %] vs. 0/45 [0 %], $p = 0.03$). Shunt-type interventions presented with significantly greater complication rates than non-shunt catheterizations (4 of 15 [26.7 %] and 5 of 76 [6.6 %], respectively, $p = 0.04$). A greater occurrence of complications also characterized interventions on the aortic arch (7 of 26 [26.9 %] vs. non–aortic arch catheterizations 2 of 65 [3.1 %], $p = 0.002$). In contrast, APC was not associated with more complications

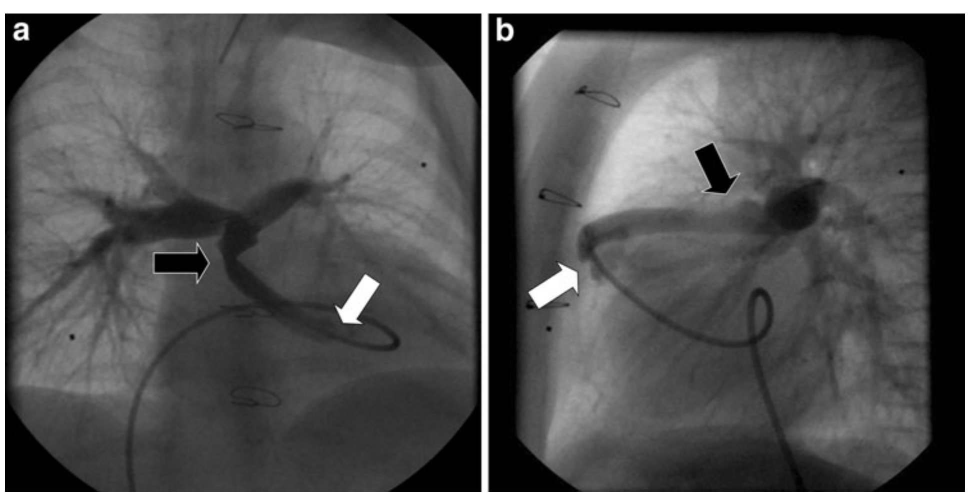

Fig. 1 Typical stenoses with the Sano shunt. Angiography shows typical locations of Sano shunt obstructions before stenting (*white arrow* indicates stenosis at offspring from right ventricle; *black arrow* indicates insertion into the pulmonary artery trunk). **a** Anterior-posterior view. **b** Lateral view

compared with non-APC catheterizations (2 of 15 [13.3 %] and 7 of 76 [9.2 %], respectively, $p = 0.6$).

Hospital, Interstage Mortality, and Midterm-Survival

There were 13 hospital deaths (Sano 4 of 37 [10.8 %] vs. BT 9 of 70 [12.9 %], $p = 1.0$) and 7 interstage deaths (Sano $n = 2$ and BT $n = 5$ [$p = 1.0$]). Interstage deaths were not related with interventional procedures. Median follow-up interval of the entire cohort was 3.5 years. Actuarial survival was similar from the postoperative month 8 onward at 78.6 ± 4.9 % (95 % CI 67.0–86.5 %) for Sano and 78.4 ± 6.8 % (95 % CI 61.4–88.6 %) for BT ($p = 0.95$).

Discussion

Interventions between NP stage one and bidirectional Glenn procedure are common. They frequently address recurrent stenosis of previous surgically reconstructed sites, such as the aortic arch, the system-to-pulmonary shunt, or the right or left pulmonary artery, more seldom the pulmonary arteries and the interatrial septum.

The earliest interventions in our survey were of the SB-type at surgery or during the first postoperative day. SB was performed to control pulmonary artery blood flow in three patients (two Sano and one BT) who had a low weight (2.0–2.5 kg). All three were high-risk cases at NP according to their Aristotle comprehensive score [22]. We generally prefer clipping or banding a larger shunt to using a smaller-diameter shunt. Indeed, in conditions of cyanosis, the clip or band can easily detached by means of balloon dilatation. As others did previously, we removed the banding with chest closure [10] unless significant pulmonary overcirculation was detected by oximetric evaluation.

The lower oxygen saturation detected by home monitoring was often associated with obvious shunt stenosis on echocardiogram, which is an indication for DS and stenting. Shunt interventions were significantly more prevalent for the Sano shunt in our cohort. Outgrowth was not the cause of lower saturation with the Sano shunt procedure because the mean weight at time of intervention was significantly lower compared with the BT shunt group.

The high propensity for stenosis or kinking stems from the substernal course of the right-sided Sano shunt. Its distal end is attached behind the reconstructed ascending aorta, whereas its proximal origin is adherent to the surface of the right ventricle. Natural growth or dilatation of the right ventricle may cause stretching or "pancaking" of the shunt. This can occur very early after NP despite optimal initial shunt function. Sano et al. place the RV–PA shunt [20] on the left-side of the reconstructed ascending aorta, which may shorten the substernal pathway and thus interventions to the shunt may be less frequently seen. However, stenoses of the central pulmonary arteries recognized with this course lead to a change to the right course at other centers [19]. Others have used a ring-enforced polytetrafluoroethylene conduit, which may relieve substernal compression but could not prevent emergency interstage interventions [21]. In comparison, the pathway of the BT shunt is straight, i.e., not influenced by ventricular function or dimension. Therefore, BT shunt–type interventions aiming to enhance the pulmonary blood flow were rarely seen in our hands.

We opted for DS and stenting to delay second-stage palliation until the age of 3–6 months. Indeed, unnoticed Sano shunt stenosis impacts interstage mortality, particularly when second-stage palliation is performed >120 days after NP [18]. These investigators recommend performing Glenn surgery ≤120 days after NP. In our cohort, however, this suggested timetable would lead to an increase in interstage mortality because median and mean time intervals to shunt intervention tallied only approximately 60 days. Moreover, although patients <3 months of age can undergo Glenn surgery, the early second stage is then characterized by longer periods of mechanical ventilation, pleural drainage, intensive care unit stay, and hospitalization [5].

DAA was the most frequently noted intervention in our cohort with no significant difference within the shunt groups. The incidence compares well with others groups, who alike us applied very low thresholds for arch dilatation to curtail afterload of the single ventricle [2, 7]. In this circumstance, we indicated balloon dilatation with a subsequent reduction in diameter from aortic arch to descending aorta >30 %. This sharp variation was measured by angiography as described by Lemler et al. [8]. Angiography is the favoured method because measurement of gradients with a system-to-pulmonary shunt remains unreliable, even in case the shunt offspring emerges from the ventricle.

APC was another common intervention performed during routine catheterization before the second stage or as a combined procedure with DAA. This intervention was rarely performed when the patient was <3 months of age (median age 125), with the median weight being 5.2 kg. The intervention rate tended to be lower, with no clear explanation, in the Sano shunt group. The management of APC before Fontan surgery remains controversial; no benefit is found in terms of postoperative hospital stay or late outcome [1]. To date, no data display superior parameters of outcome for APC management before second-stage palliation.

Our overall incidence of complications was approximately 20 %. No complication was registered with diagnostic catheters. There is still no systematic study on complications developing after interventional catheterization in infants. It is thus difficult to judge whether that rate of complication is acceptable. Most probably, a mismatch between the relatively large catheter sheath and the infant's small femoral vessels contributes to vessel occlusion after dilatation and stenting of the aortic arch or shunt. In addition, limited systemic flow in the single right ventricle may affect postprocedural vessel perfusion. Aortic arch and BT DS was usually performed retrograde through the femoral artery. The antegrade pathway through the femoral vein was chosen for Sano shunt interventions. This involves passing the tricuspid valve, which is certainly incompetent during the intervention. Hence forward, output can be decreased, accounting for rhythm disturbances and the need for resuscitation in some patients. No death case occurred during or after intervention at our center. Nonetheless, mortality can arise if a greater number of patients is considered.

Study Limitations

The major limitation to this study is its retrospective design, which covered a long period of time. Second, the small number of given interventions hampers statistical analysis. Although all patients were treated with the same standardized protocol, patient assignment to the Sano shunt group changed once we experienced a high incidence of shunt-related complications and interventions in 2008. As a result, only 1 of 26 patients was elected for a Sano shunt in 2009.

Conclusion

Recurrent stenoses requiring catheter interventions are common after NP. They may appear at any time until second-stage palliation. For that reason, close follow-up and home monitoring are essential to timely detect failure to grow, which is likely caused by a recurrent arch obstruction often seen in pulmonary overcirculation. Cyanosis may point toward shunt stenosis or kinking. Catheter interventions can successfully resolve stenoses and help avert early reoperation.

Significantly more interventions were undertaken with the Sano shunt. Institutions dealing with the Sano shunt must be aware of the possible complications. In those events, timely interventions by an experienced interventionalist are essential to avoid interstage mortality.

With a similar midterm outcome for both shunt types, the greater incidence of catheterization-related complications led to a preferential use of the modified BT shunt in our center. The use of the Sano shunt was restricted to the instance of an inadequately developed innominate artery or an aberrant subclavian artery.

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