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Low Mortality Due to Long Interval Period between Bilateral Pulmonary Artery Banding and Norwood Operation

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Abstract

Objectives: We reviewed our experience of Bilateral Pulmonary Artery Banding (BPAB) in neonate and assessed the predictors of postoperative mortality.

Methods: From May 2007 to December 2017, a total of 21 consecutive patients who underwent staged surgical treatment using BPAB strategy for univentricular repair of the complex congenital heart disease in neonate. We reviewed patients' clinical perioperative data, such as surgical outcomes, body weight gain, and the Interval Period (IP) between BPAB and Norwood operation. We performed BPAB operation at mean 6.8 ± 4.7 days after birth. The mean weight was 2.8 ± 0.4 kg at the time of BPAB.

Results: All patient underwent the Norwood operation included Glenn operation (n=6) or atrioventricular valve repair (n=2). Eighteen patients reached the total cavopulmonary connection. There were three early death and accounting for a hospital mortality of 14.3%. Mortality was strongly associated with the interval period between BPAB and second-stage operation, mortality was high (25%) with the IP<90 days, and low (7.7%) with the IP between BPAB and Norwood operation >90 days (p<0.03).

Conclusions: Long interval period between BPAB and Norwood operation seem to be associated with better surgical results.

Keywords: Long interval; BPAB; Norwood

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Abbreviations

AA: Aortic Valve Atresia; AS: Aortic Valve Stenosis; BDG: Bidirectional Glenn; BTs: Blalock-Taussig shunt; BW: Body Weight; cAVSD: Complete Atrioventricular Septal Defect; CoA: Coarctation Of Aorta; DORV: Double Outlet Right Ventricle; HLHS: Hypoplactic Left Heart Syndrome; IAA: Interrupted Aortic Arch; ICR: Intracardiac Repair; LVOTS: Left Ventricular Outlet Tract Stenosis; MA: Mitral Valve Atresia; MPAB: Main Pulmonary Artery Banding; MS: Mitral Valve Stenosis; PA: Pulmonary Artery; PAPVR: Partial Anomalous Pulmonary Venous Return; PLSVC: Persistent Left Superior Vena Cava; PS: Pulmonary Stenosis; RV: Right Ventricle; SV: Single Ventricle; TCPC: Total Cavo-Pulmonary Connection; TR: Tricuspid Valve Regurgitation; TrV: TruncalVelve; VCC: Ventricular Coronary Connection; VSD: Ventricular Septal Defect

Introduction

Although the outcome of cardiac surgery has dramatically improved in the last decades, published reports have suggested that gestational age and low body weight are risk factors for poor outcome of cardiac operations with cardiopulmonary bypass for many congenital heart diseases [1,2]. Some reports showed the advantages of Bilateral Pulmonary Artery Banding (BPAB) which has been performed as a first palliation for the treatment of severe complex congenital heart disease, such as a hypoplastic left heart syndrome, arch anomaly with Ventricular Septal Defect (VSD) or Transposition of the Great Arteries (TGA), in addition to truncus arteriosus. BPAB is a relatively minimally invasive procedure, and used as the initial palliative operation for Hypoplastic Left Heart Syndrome (HLHS) or related anomalies, and for other duct-dependent anomalies in poor preoperative condition [3,4]. The optimal timing of the second-stage operation following bilateral PA banding is still controversial. Generally speaking, higher body weight reduces the risks associated with Norwood operation as second palliation using cardiopulmonary bypass. However,

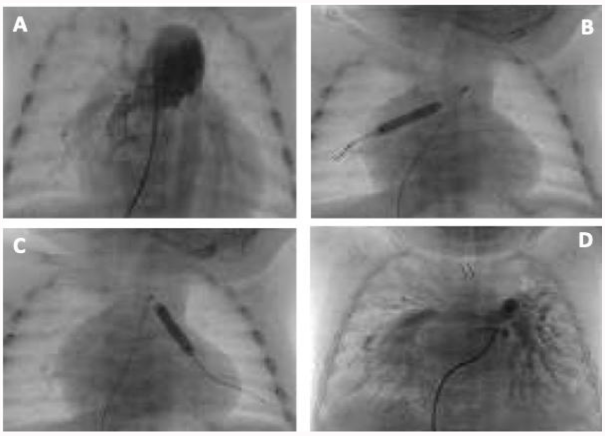

Figure 1: (FABPAB using Pulmonary Balloon Dilatation (PABD). A) Aortagram showing severe stenosis at the banding site, PA index is 140 mm^2/m^2. B) PABD at the site of banding using 3 mm in diameter. C) Aortagram showing PA index is 260 due to increased pulmonary blood flow after PABD. D) Pulmonary angiography after second operation (Norwood operation with RV-PA).

systemic oxygen saturation level may go down overtime according to patients' body weight gain. In order to overcome those dilemma, we perform bilateral PA banding combined with subsequent planned percutaneous pulmonary artery balloon dilation at banding sites, which would make minimally invasive adjustment of the pulmonary artery blood flow. We call this strategy "Flow-Adjustable Bilateral Pulmonary Artery Banding" (FABPAB). This may reduce the risks associated with the second-stage operation, and also help to maintain the systemic oxygen saturation level. In present study, we reviewed our experience of BPAB and FABPAB for the complex congenital heart disease in low body weight neonate and young infant and assessed the predictors of postoperative mortality.

Patients and Methods

At our institution, we perform BPAB in the first week of life as a less invasive first-stage palliation to avoid CPB and hypothermic circulatory arrest in the neonatal period. During a period of ten years, from May 2007 to December 2017, a total of 21 consecutive patients who underwent staged surgical treatment using BPAB strategy for univentricular repair of the complex congenital heart disease in low body weight neonate included 13 FABPAB procedures were analyzed.

The following preoperative and intraoperative variables were analyzed as risk factors for early mortality: weight and age at operation, sex, gestational age, prenatal diagnosis, mechanical ventilation, and type of surgery (correction or palliation). Reviewing hospital records to evaluate and efficacy of FABAPB retrospectively collected Preoperative and perioperative data. We performed BPAB operation at mean 6.8 ± 4.7 days after birth. The mean weight was 2.8 ± 0.4 kg at the time of BPAB. Six patients (28.6%) weighed 2,500 g or less. Balloon dilation was performed after mean interval of 54.9 ± 12.8 days from BPAB operation, at 3.5 ± 0.4 kg of body weight.

BPAB technique

Preoperatively, we prepared banding tapes, which consisted of 0.1 mm expanded polytetrafluoroethylene sheets. Each patch was doubled and trimmed to a width of 2 mm. Bilateral pulmonary artery banding was performed in the operating room under general anesthesia. After a standard median sternotomy and minimal mobilization of branches of the pulmonary artery, the right and left pulmonary arteries were individually encircled with the banding tapes. Then, the banding tapes were adjusted to the appropriate tightness by placing Weck Hemoclips (Teleflex Inc., Wayne, PA, USA) horizontally in order to achieve a partial pressure of oxygen in arterial blood of around 40 mm to 50 mm Hg at 40% to 50% of the fraction of inspired oxygen during surgery. The bilateral banding tapes were adjusted using a Weck Hemoclips and the final circumferences of the right and left PA bands were fixed at 10 mm, respectively. The clip was selected as the same size as the width of the banding tape. It was intended that both blades of the clips would fit into each other [5].

FABPAB using pulmonary artery balloon dilatation (PABD) technique

In such patients, it is very important to walt for a gain in body weight facilitated by PABD to reduce the risks of the second-stage operation. However, BPAB, in which constrictive tapes encircle both pulmonary arteries, frequently entails post-debanding residual pulmonary artery stenosis, resulting from pulmonary arterial intimal proliferation. Representative images from cardiac angiography during balloon dilatation are presented in Figure 1. At approximately 1 to 2 months after bilateral pulmonary artery banding, cardiac catheterization revealed severe stenosis at the bilateral PA banding (Figure 1A). We performed percutaneous pulmonary artery balloon dilatation to increase the pulmonary flow, using balloon catheters of 3-mm diameter at each bilateral PA band (Figure 1B,1C). For balloon dilatation, we first used a Judkins right-type catheter and guide-wire to insert the catheter into the bilateral peripheral pulmonary artery. Then, balloon dilatation was performed using high-pressure, non- compliant balloon catheters at each bilateral pulmonary artery banding site to increase pulmonary blood flow without exerting unnecessary artery tension on adjacent tissues. After the procedure, the clip had moved slightly and was opened (Figure 1D). The pulmonary artery was dilated by approximately 50% in diameter, and oxygen saturation was elevated by approximately 10% and reached around 75% to 85%.

Standard techniques of cardio-pulmonary bypass were used. Pump flow was adjusted to maintain a blood pressure not above 30 mmHg and a left atrial blood pressure not above 5 mmHg, monitored continuously. Intermittent crystalloid cold cardioplegia (St Thomas II) was administered antegradely into the aortic root or coronary ostia. During cardiopulmonary bypass, blood gas analysis was achieved using alpha-stat method. Modified ultrafiltration was carried out at CPB end in each patient. Deep hypothermic circulatory arrest had to be applied in no cases.

Statistical analysis

Data are expressed as mean ± Standard Deviation (SD). Comparisons of means between 2 groups were performed with the independent samples t test, and comparisons of dichotomous variables between 2 groups were performed with χ^2 analysis. Statistical analysis was performed with SPSS for Windows (SPSS Inc, Chicago, Ill). A p value of less than 0.05 was considered statistically significant. This study was approved in accordance with the ethics committee at the Gunma children's medical center.

Results

The main patients' characteristics are shown in Table-1 in BPAB, and Table-2 in FABPAB. Detailed these cases, according to weight, main procedure, outcomes and circumstances of death. All patient underwent the Norwood operation included Glenn operation (n=6)

Table 1: Biventricular repair (BPAB).

Diagnosis	Age at BPAB (d)	BW at BPAB (kg)	Age at 2nd-Ope. (d)	BW at 2nd-Ope. (kg)	2nd-stage Operation method	+ BTs due to PS	Outcome
IAA (type B), VSD	16	3.8	41	3.8	Arch repair + VSD cl.		po ICR
IAA (type B), VSD	4	2.7	52	3.6	Arch repair + VSD cl.		po ICR
CoA, VSD, PLSVC	10	2.9	60	3.9	Arch repair + VSD cl.		po ICR
CoA, VSD	6	2.7	72	4.5	Arch repair + VSD cl.		po ICR
cAVSD, hypo arch, CoA 21-trisomy	28	2.8	74	3.2	Arch repair + MPAB		po ICR
cAVSD, hypo arch, CoA 21-trisomy	17	2.2	111	4.2	Arch repair + MPAB		po ICR cAVSD repair
IAA(type A), severe AS	4	2.8	119	4.5	Norwood		Rastelli
DORV, Hypo RV, LVOTS	10	2.9	126	4.9	Norwood	+ BTs	Rastelli
cAVSD, hypo arch, CoA 21-trisomy	10	2.8	131	4.7	Arch repair + MPAB		po ICR cAVSD repair
Persistent truncus arteriosus TrV regurgitation	3	3	196	4.5	Rastelli, TrV repair RV-PA Conduit(14mm)		Rastelli

Table 2: Biventricular repair (FABPAB).

Diagnosis	Age at BPAB (d)	BW at BPAB (kg)	Age at 2nd-Ope (d)	BW at 2nd-Ope. (kg)	2nd-stage Operation method	+ BTs due to PS	Outcome
IAA (type A), VSD, mild AS	11	2.8	76	3.5	Arch repair + VSD cl.		po ICR
IAA (type B), VSD, AS	8	2.5	81	3.44	Norwood		Rastelli
DORV, CoA, VSD	9	2.8	104	4.3	Arterial switch Operation + Arch repair with swing back + VSD cl.		po ICR
CoA, VSD	19	2.6	105	3.5	CoA repair + VSD cl.		po ICR
IAA (type B), severe AS	4	2.4	122	4.9	Norwood		Rastelli
IAA (type B), hypoplastic arch	12	2.7	126	4.9	Norwood		Rastelli
Persistent truncus arteriosus	9	2.7	124	6.1	Rastelli, TrV repair RV-PA Conduit (12mm)		Rastelli
DORV, IAA(type B), VSD	14	3	131	4.1	Arterial switch Operation + Arch repair with swing back +VSD cl.		po ICR
Persistent truncus arteriosus	2	2.5	243	6.5	Rastelli, TrV repair RV-PA Conduit (14mm)		Rastelli
Persistent truncus arteriosus	5	2.9	280	8.2	Rastelli, TrV repair RV-PA Conduit (18mm)		Rastelli
Persistent truncus arteriosus	8	3.1	385	8	Rastelli, TrV repair RV-PA Conduit (16mm) PAPVR repair		Rastelli

or atrioventricular valve repair (n=2) in second-stage operation at a mean age of 117.1 ± 48.4 days, and 4.7 ± 1.0 kg. Eighteen patients reached the Total Cavo-Pulmonary Connection (TCPC) for univentricular repair as a definitive repair.

There were three early death and accounting for a hospital mortality of 14.3%. There was one late death. Death was a consequence of cardiogenic shock (n=2) after Norwood operation with atrioventricular valve operation, and intractable pulmonary hypertension (n=1). As shown in Figure 2, variables associated with higher early mortality were. Mortality was strongly associated with the interval period between BPAB and second-stage operation, mortality was high (2/8; 25%) with the interval period between BPAB and 2nd stage operation <90 days, and low (1/13; 7.7%) with an interval period between BPAB and 2nd stage operation >90 days ($p<0.03$). In particular, mortality strongly correlated with univentricular repair concomitant to atrioventricular valve operation with an early plus late mortality of 66.7% (2/3).

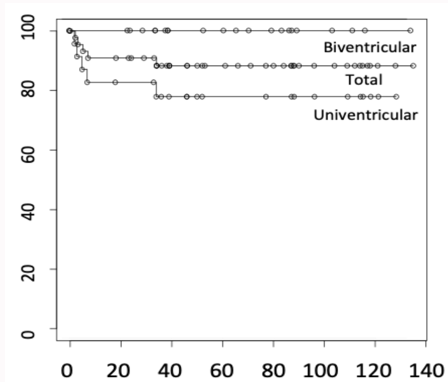

Figure 2: Kapla-Meier Survival Curve (Uni *vs.* Bi). Kaplan-Meier actuarial survival curves for Interval Period (IP) between bilateral Pulmonary artery banding and 2nd stage operation indicate highly significant differences in survival rate. (5 year 95% for IP>90 days group *vs.* 87.5% for IP<90 days group, p=0.02).

Discussion

Although the outcome of surgical correction of cardiac lesions has dramatically improved in the last decade, the risk of open-heart surgery in the neonatal period remains substantial with an operative mortality in the order of 10%. In previous reports, risk factors for early mortality after open-heart surgery in patients weighing less than 2,500 g were perioperative metabolic acidosis, univentricular palliation, duration of cardiopulmonary bypass, prolonged circulatory arrest, and postoperative low cardiac output. Additionally, a few postoperative complications such as requirement for ECMO, sepsis, and un-planned re-intervention were strong indicators of mortality [6]. This is due to higher complexity of lesions

Table 3: Univentricular repair (BPAB).

Diagnosis	Age at BPAB (d)	BW at BPAB (kg)	Age at 2nd-Ope (d)	BW at 2nd-Ope. (kg)	2nd-stage Operation method	+ BTs due to PS	Outcome
Shone's complex, MS, AS, CoA	10	3	55	3.2	Norwood	-	TCPC
SV, hypoplastic arch, heterotaxy	4	2.4	60	4.8	Norwood	*Hepati Vein Azygos conduit	TCPC
HLHS (MS/AS)	8	2.5	76	4.2	Norwood	-	TCPC
HLHS (MS/AS)	9	2.8	94	4.8	Norwood	+ IPAS	TCPC
HLHS (MS/AS)	17	3.6	95	5	Norwood	+ IPAS	unilateral TCPC
HLHS (MS/AA), VCC	5	2.3	101	4.6	Norwood	+ BTs	TCPC
HLHS (MS/AA), restrictive PFO	5	2.8	103	4.7	Norwood		TCPC
SV, hypoplastic arch	2	2.9	152	5.9	Norwood + BDG » Norwood SVC Reconstruction	+ BTs	TCPC

Table 4: Univentricular repair (FABPAB).

Diagnosis	Age at BPAB (d)	BW at BPAB (kg)	Age at 2nd-Ope (d)	BW at 2nd-Ope. (kg)	2nd-stage Operation method	BTs due to PS	Outcome
HLHS (MS/AA), severe TR	4	3.2	50	3.2	Norwood + Valve plasty	-	Death
HLHS (MA/AS)	6	2.7	60	3.1	Norwood	-	TCPC
unbalanced AVSD, CoA, severe cAVVR	5	2.5	75	3.54	Archrepair + MPAB + Valve replacement	-	Death
HLHS (MS/AA), VCC Left coronary atresia	3	2.6	87	3.83	Norwood	-	Death
SV, sub AS, hypo. Arch,	8	3.9	102	5.8	Norwood + Glenn	-	TCPC
HLHS (MS/AA), moderate TR	5	2.8	103	4.7	Norwood + Valve plasty	-	TCPC » Last death
SV, hypoplastic arch, CoA	7	2.7	123	4.3	Norwood + BDG + » SVC reconstruction	-	TCPC
SV, hypoplastic arch, CoA	7	2.7	128	5.9	Norwood	-	TCPC
HLHS (MS/AS), moderate TR	3	2.7	145	5	Norwood + BDG + Valve plasty	-	Death
HLHS (MS/AA)	6	2.5	149	4.2	Norwood	-	BDG
SV, hypoplastic arch, CoA	9	2.6	152	5.4	Norwood + Glenn	-	TCPC
SV, hypoplastic arch, CoA	2	3.4	157	5.3	Archrepair + MPAB	-	TCPC
SV, hypoplastic arch, CoA, Heterotaxy	2	3	160	5.4	Norwood + Glenn	-	TCPC
CoA, severe AS, large VSD	21	2.1	206	5.7	Norwood	-	TCPC
HLHS (MS/AA)	2	3.5	234	6.3	Norwood	-	TCPC

that dictate early intervention and to more marked deleterious effects of extracorporeal circulation in newborns. Cardiopulmonary bypass in patients with univentricular hearts was associated with high early mortality than in those with two ventricles. The outcome in these patients is determined by interplay of various factors including morphology of the single systemic ventricle, competence of the atrioventricular valves associated subaortic obstruction, degree and liability of pulmonary vascular resistance, and finally, the difficulty in balancing the pulmonary and the systemic flows. A recent Society of Thoracic Surgeons Congenital Heart Surgery Database review revealed 30% discharge mortality for the hybrid approach versus 16% for the traditional primary Norwood approach [7,8]. Thus, higher mortality should be expected in premature and low weight patients undergoing open-heart surgery.

This study has been particularly demonstrated for the Norwood operation, actually the univentricular palliative procedure. Our finding confirms this incremental risk factor with a 14.3% (3/21) mortality concerning Norwood operation. Noteworthy is the fact that 50% (2/4) of these univentricular cases had common atrioventricular valve surgery. After this experience, our current application of hybrid technique for neonatal complex heart disease without atrioventricular valve regurgitation in the form of pulmonary artery banding and prostaglandin infusion is feasible. Furthermore, cardiopulmonary bypass in the neonatal period carries a high risk of brain injury and leads to developmental deficit. Using FABPAB strategy, second-stage operation was delayed after neonatal period, gaining sufficient body weight and development of pulmonary artery. FABPAB is consistent and reliable strategy to improve outcome of complex cardiac lesions by avoiding bypass operation in neonatal period. Adequate body weight and pulmonary artery index at second stage operation may have additional positive impact. However, balloon dilation may worsen atrioventricular regurgitation, so the indication for the patient with severe atrioventricular regurgitation needs to be discussed. Further study is necessary to evaluate usefulness of this strategy. This series doesn't have long-term result so much. Long-term effects such as neurological outcome of these patients will be assessed when they reached adolescence. In conclusion, long interval period between BPAB and second-stage operation seem to be associated with better surgical results. In addition, present study reveals that our FABPAB strategy is a feasible and valid clinical option for the treatment of severe neonatal complex heart disease. Moreover, our strategy reduces the need for additional surgical interventions, including pulmonary angioplasties at the pulmonary artery banding sites.

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