Precise evaluation of bilateral pulmonary artery banding for initial palliation in high-risk hypoplastic left heart syndrome

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Objectives: In patients with high-risk hypoplastic left heart syndrome (HLHS), the Norwood operation (NW) in the neonatal period still results in high mortality compared with other cardiac surgery. Bilateral pulmonary artery banding (bPAB), a very effective initial procedure for HLHS, for which the specific evaluation is as yet unsatisfactory, was performed, and we report our findings in the present study.

Methods: We have performed bPAB since 2006. A total of 17 patients with HLHS or a variant underwent bPAB before the NW. Echocardiography was performed between bPAB and the NW, and the flow acceleration just after bPAB and before NW was evaluated. Before the NW, a catheter examination was also performed.

Results: bPAB was performed at 6.6 ± 0.6 days of age, and the NW at 130 ± 88 days. The patients' mean body weight (BW) was 2.5 ± 0.4 kg at bPAB and 4.0 ± 1.1 kg at the NW. The length of the tape for bPAB was 9.9 ± 0.6 mm in the right pulmonary artery (RPA) and 9.4 ± 0.6 mm in the left (LPA) because the RPA was usually wider than the LPA. The tape width was 2 mm in all cases. The catheter examination was performed at 95 ± 85 days after bPAB. The arterial oxygen saturation (SaO₂) was $71\% \pm 8.6\%$. Multivariate regression analysis revealed that SaO₂ was estimated well using 4 factors: the banding size of the RPA, BW at bPAB, BW at NW, and BW in the period between bPAB and catheter examination ($R^2 = 0.79$). Echocardiography just after bPAB showed that the blood flow at the bPAB had accelerated to 3.0 ± 0.8 m/s in the RPA and 3.3 ± 0.8 m/s in the LPA ($P = .004$). The estimated pressure gradient was 39.2 ± 17.6 mm Hg in the RPA and 46.1 ± 23.0 mm Hg in the LPA ($P = .006$). The blood flow at bPAB was accelerated to 3.7 ± 0.7 m/s in the RPA and 4.0 ± 0.6 m/s in the LPA before NW ($P = .013$). The estimated pressure gradient was 62.6 ± 27.6 mm Hg in the RPA and 56.1 ± 19.6 mm Hg in the LPA before NW ($P = .014$). The catheter examination revealed mean wedge pressures of 18.0 ± 7.2 mm Hg for the RPA and 16.2 ± 4.3 mm Hg for the LPA. The operative mortality rate was 0%. One patient required a repeat operation to adjust the bPAB, and prolonged pleural effusion was observed in 1 case.

Conclusions: The postoperative SaO₂ after bPAB correlated closely with the banding size and BW at bPAB, NW and during the period after bPAB. Because the mean PA pressure before NW was low enough for single ventricular circulation, the bPAB in this study was an effective option for high-risk patients undergoing HLHS or a variant. We believe the bPAB sizes used were suitable and were determined as follows: BW plus 7 mm for the LPA and BW plus 7.5 mm for the RPA. (J Thorac Cardiovasc Surg 2010;140:1084-91)

Hypoplastic left heart syndrome (HLHS) is still a challenge for cardiac surgeons.¹⁻³ Norwood performed his first palliation procedure, the Norwood operation (NW), in 1981, and it has been a standard procedure for first-step palliation since then.⁴ This was a great breakthrough that opened the way for treatment of high-risk children

with HLHS.⁵ Because the postoperative management and medical machinery surrounding surgery have greatly improved, its mortality has recently been decreasing.⁶⁻⁹ In a high-risk neonate with HLHS, however, the mortality is still high. According to the published data, a low birth weight, prematurity, preoperative shock, renal failure, a small ascending aorta, restrictive atrial communication, extracardiac abnormalities, and chromosomal abnormalities are risk factors for mortality after the NW operations.^{3,10-14}

Bilateral pulmonary artery (PA) banding (bPAB) has recently attracted attention, because it is less invasive than surgery requiring cardiopulmonary bypass support.¹³⁻¹⁷ In particular, in a neonate with high-risk HLHS, bPAB can be an initial approach preceding the NW, which can then be performed relatively safely. We have performed bPAB in 17 patients in the high-risk HLHS group, followed by the NW since 2006. We evaluated our outcomes in the present study.

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Abbreviations and Acronyms

BCPS	= bidirectional cavopulmonary shunt/ bidirectional Glenn operation
bPAB	= bilateral pulmonary artery banding
BTS	= Blalock-Taussig shunt
BW	= body weight
HLHS	= hypoplastic left heart syndrome
LPA	= left pulmonary artery
NW	= Norwood operation
PA	= pulmonary artery
PDA	= patent ductus arteriosus
RPA	= right pulmonary artery
TEE	= transesophageal echocardiography

METHODS

The Scientific Committee of our hospital approved the present study. We performed 17 cases of bPAB from January 2006 to October 2009 and evaluated the data retrospectively.

Patient Characteristics

The patient characteristics, including the diagnoses and risk factors, are listed in Table 1.

bPAB Operation

The bPAB operation was performed with the oxygen saturation (SaO₂) maintained at about 80%. The tape for bPAB was made of Gore-Tex tubing. The tube was cut longitudinally to create a strip 2 mm wide for all cases. The length of the strip needed for the left PA (LPA) was determined by measuring its central portion to 7 mm and adding the patient's BW, expressed as 1 mm for each 1 kg (e.g., for a 3-kg infant, the length of this central portion was 7 mm plus 3 mm for a length of 10 mm). This was marked

off with a marker suture at each end. If the baby's weight was not an exact number of kilograms, it was rounded to the nearest 0.5 mm (0.5 kg), with a fraction of 0.25 kg and 0.75 kg rounded down and up, respectively; thus, 3.3 kg was rounded to 3.5 kg (converted to 3.5 mm) and 3.25 kg was rounded to 3.0 kg (converted to 3.0 mm). Thus, the lengths of the marked-off central portions differed from each other by amounts divisible by 0.5 mm. During bPAB, the fraction of inspiratory oxygen was kept at 21%, as was the room air. Intraoperative transesophageal echocardiography was performed to detect any flow reduction in the pulmonary vein and, if possible, flow acceleration at the bPAB site.

If the SaO₂ was more than 85% and flow acceleration was less than 2 m/s, the PA band was tightened by intervals of 0.5 mm, alternating, from right to left. In contrast, if the SaO₂ became less than 75%, the PA band was loosened in reverse order. The ideal goal of flow acceleration is greater than 3 m/s during the operation; however, it often remains within the range of 2 to 3 m/s, which is acceptable.

Aristotle Score

The comprehensive Aristotle score was estimated assuming that the patients underwent the NW in the neonatal period. The actual comprehensive Aristotle score was calculated after they had undergone the NW in infancy after bPAB.

Examination

Echocardiography was performed arbitrarily, and cardiac catheterizations were done before the NW.

Statistical Analysis

The data are presented as numbers and percentages or as the mean $\pm$ standard deviation. All statistical tests were 2-sided. Statistical calculations were performed using the StatView software package, version 5.0 (SAS Institute, Inc, Cary, NC).

RESULTS

Demographics

Of the 17 patients, 10 (56%) had aortic atresia, and 9 of the infants with aortic atresia (53%) had a small ascending

TABLE 1. Profile of patients with hypoplastic left heart syndrome

Diagnosis	Aortic valve	Mitral valve	AAo (mm)	Gestational age (wk)	Birth weight (g)	Other risk factors
HLHS	AA	MA	1.7	37	2664	
HLHS	AA	MS	1.8	41	2120	
HLHS	AA	MA	1.5	40	2200	Jacobsen syndrome
HLHS	AA	MA	2	36	2454	Biliary atresia
HLHS	AS	MA	7	39	3342	bPAB in previous hospital
Hypo LV, CoA	AS	MS	6.3	38	2450	Cleft lip and palate, bPAB in previous hospital
HLHS	AA	MA	1.3	39	2462	Jacobsen syndrome, cor triatriatum, DIC
Hypo LV, CoA	AS	MS	7.2	37	2368	Esophageal atresia, omphalocele
HLHS	AS	MS	5.2	38	2812	Ductal shock
HLHS	AA	MA	1.6	38	2633	
HLHS	AS	MS	4.3	38	2530	Restrictive PFO
HLHS	AA	MA	2.2	40	3301	Restrictive PFO
HLHS	AS	MS	3.8	40	2232	DIC
HLHS	AS	MS	4.7	37	2587	Sotos syndrome, renal failure
HLHS	AA	MS	5	39	2769	Jacobsen syndrome
TA(2C), CoA	AS	—	5.9	39	2785	High-flow shock
HLHS	AA	MS	1.3	38	2643	

AAo, Ascending aorta; HLHS, hypoplastic left heart syndrome; AA, aortic atresia; MA, mitral atresia; Hypo LV, hypoplastic left ventricle; CoA, coarctation of aorta; MS, mitral stenosis; AS, aortic stenosis; TA, tricuspid atresia; bPAB, bilateral pulmonary artery banding; DIC, disseminated intravascular coagulation; PFO, patent foramen ovale.

aorta (≤ 2 mm) (Table 1). The birth weight in 7 patients (41%) was less than 2.5 kg. Chromosomal abnormalities were found in 4 patients. Of these 4, 3 were Jacobsen syndrome and 1 was Sotos syndrome. Major digestive tract disease was seen in 2 patients: esophageal atresia and biliary atresia. Two patients had symptoms of shock when they had arrived at our hospital.

bPAP Operation

bPAB was performed at 6.6 ± 0.6 days of age, and the NW at 130 ± 88 days. The BW was 2.5 ± 0.4 kg at bPAB and 4.0 ± 1.1 kg at the NW. The actual tape length for bPAB was 9.9 ± 0.6 mm in the right PA (RPA) and 9.4 ± 0.6 mm in the LPA, because the RPA was often wider than the LPA. The tape width was 2 mm in all cases. Of the 17 patients, 16 underwent the NW after bPAB; the remaining child had developed a substantial pleural effusion. This patient had had a very small patent foramen ovale at birth, and balloon atrial septotomy had not been effective. Cardiopulmonary bypass was therefore used for atrial septal defect enlargement when bPAB was performed. Only for this patient was cardiopulmonary bypass used.

Echocardiography

Echocardiography just after bPAB showed that the blood flow at bPAB had accelerated to 3.0 ± 0.8 m/s in the RPA

and 3.3 ± 0.8 m/s in the LPA ($P = .004$) (Figure 1). The estimated pressure gradient was 39.2 ± 17.6 mm Hg in the RPA and 46.1 ± 23.0 mm Hg in the LPA ($P = .006$). The blood flow at bPAB had accelerated to 3.7 ± 0.7 m/s in the RPA and 4.0 ± 0.6 m/s in the LPA before the NW ($P = .013$). The estimated pressure gradient was 62.6 ± 27.6 mm Hg in the RPA and 56.1 ± 19.6 mm Hg in the LPA before the NW ($P = .014$).

Catheter Examination

A catheter examinations were performed 95 ± 85 days after bPAB and just before the NW. The SaO_2 was $71\% \pm 8.6\%$. This examination revealed a mean wedge pressure of 18.0 ± 7.2 mm Hg for the RPA and 16.2 ± 4.3 mm Hg for the LPA (Table 2).

PA Band Size

Univariate regression analysis revealed that the approximate LPA band size could be determined from the BW at bPAB ($R^2 = 0.40$) (Figure 2). A linear approximation curve (Figure 2, thick line) was drawn on the LPA graph. The area between the 2 parallel thin lines, 1 mm apart, with the thick line parallel to, and equidistant from both, included most of the plotted points (15 of 17 points, 88%). The data shown

FIGURE 1. Accelerated blood flow velocity at bilateral pulmonary artery banding (bPAB) sites and estimated pressure gradients just after bPAB and before the Norwood operation (NW), both determined echocardiographically. LPA, left pulmonary artery; RPA, right pulmonary artery; PG, pressure gradient.

TABLE 2. Data of catheter examination performed just before Norwood operation

Catheter examination data	
LPA pressure (LPV wedge pressure)	15.9 ± 4.1 mm Hg
RPA pressure (RPV wedge pressure)	18.0 ± 7.2 mm Hg
PA index	186 ± 93 mm ² /m ²
Rp	2.2 ± 1.1 Wood-U
SaO ₂	71% ± 8.6%

LPA, Left pulmonary artery; *LPV*, left pulmonary vein; *RPA*, right pulmonary artery; *RPV*, right pulmonary vein; *Rp*, pulmonary vascular resistance; *SaO₂*, arterial oxygen saturation.

on this graph indicated that the LPA band size was adjusted to within 0.5 mm of the BW plus 7 mm.

Estimated SaO_2 at NW

Multivariate regression analysis revealed that the SaO₂ just before NW could be estimated precisely using 4 factors: the band size of the RPA (x_1), the BW at bPAB (x_2), the BW at the NW (x_3), and the interval between bPAB and the catheter examination (x_4). The correlation between the actual SaO₂ and the estimated SaO₂ was very high ($R^2 = 0.79$) (Figure 3).

The multiple regression equation was as follows:

$$\text{Estimated SaO}_2 = 4.8144 * x_1 + 8.5828 * x_2 + 0.8611 * x_3 - 0.0779 * x_4$$

Ductus Arteriosus Patency

To maintain a patent ductus arteriosus (PDA), stenting was performed in 4 patients; in 1, stent migration occurred. In the other 14 cases, lipoprostaglandin E₁ was continuously administered to maintain the PDA. No patient had any major complication related to lipoprostaglandin E₁ use.

Aristotle Comprehensive Score

The Aristotle score, estimated on the assumption that the NW was performed during the neonatal period, was a little

higher than the actual Aristotle score (23.2 ± 3.4 vs 22.1 ± 2.9 , $P = .08$).

bPAB Outcome

No patient died intraoperatively. One patient required a repeat operation to adjust the PA band. Prolonged pleural effusion was observed in 1 case.

Eight infants underwent the NW with a Blalock-Taussig shunt (BTS) or right ventricle-pulmonary artery shunt (four each). An additional 8 patients underwent the NW simultaneously with a bidirectional Glenn operation (also termed “bidirectional cavopulmonary shunt” [BCPS]). In 1 of the 8 NW with BCPS, a BTS had to be added because of LPA stenosis. At the last follow-up, 1 of the 11 survivors after BCPS placement had undergone the Fontan procedure, and the other 10 were awaiting it.

Survival Rate After Discharge

One patient died 4 days after the NW, and 1 died of heart failure in the hospital 103 days after the NW. The 30-day survival rate after NW was 93.8%. The discharge mortality and 90-day mortality rates were both 12.5%. All other children were able to return home; however, 4 died suddenly at home—1 of aspiration pneumonia and 3 of unknown causes (Figure 4).

DISCUSSION

In patients with high-risk HLHS, the NW in the neonatal period is still a challenging procedure that has high mortality.³ For this syndrome, a “hybrid operation” combining bPAB and PDA stenting has recently been developed.^{15,16,18} The difficulty of bPAB is that 2 PA bands must be placed. However, infants’ BWs vary greatly, from 2 to 3.5 kg or even more; thus, we do not believe the same PA band size would be suitable for all infants. Although the PA band of the main PA is adjusted using the BW according to the Trusler rule,¹⁹ no rule has been created to determine the size for bPAB. We treated 17 patients requiring bPAB, most of whom were able to undergo the NW. The exception

FIGURE 2. Results of univariate regression analysis between bilateral pulmonary artery banding (*bpAB*) size and body weight (*BW*). Linear approximation curve shown as *thick line*. Two *thin lines* border area extending 0.5 mm on either side of *thick line*.

FIGURE 3. Results of multivariate regression analysis indicating oxygen saturation (SaO₂) just before the Norwood operation (NW). Four factors were used: banding size of right pulmonary artery (RPA), body weight (BW) at bilateral pulmonary artery banding (bPAB), BW at the Norwood operation (NW), and interval between bPAB and catheter examination. Between actual SaO₂ and estimated SaO₂ was significant ($R^2 = 0.79$).

was 1 infant who had developed a massive pleural effusion. Thus, of our 17 patients, bPAB must have been performed appropriately for single ventricular circulation—otherwise, some of them would probably have stopped the treatment. The PA in these 17 patients must have been well protected by bPAB. An analysis of the bPAB data revealed that the LPA had been adjusted to about the BW plus 7 mm (Figure 2). Our findings have indicated that the RPA band should have been 0.5 mm larger than the LPA. This was not an accurate expression of size but a reasonably close estimate. In the operating room, the PA bands should be readjusted to stabilize the SaO₂. Intraoperative transesophageal echocardiography can help in the adjustment of the banding size by showing the blood flow pattern of the pulmonary

vein. Since our analysis of these data, we have performed bPAB in accordance with our standards. Not only have we found no need to readjust the bPAB size, but also the patients have been very stable after bPAB.

In our hospital, PDA stent placement was performed in some cases, but PDA stents sometimes appeared to be almost rupturing the PDA or were contraindicated because of a stenotic aortic arch. Therefore, in patients with HLHS, PDA stent placement is not always possible. In the case of aortic atresia with a small transverse aortic arch, a PDA stent can obstruct the backflow of blood from the PDA into the ascending aorta and then into the coronary arteries; thus PDA stent placement is risky. However, we have not experienced such a case. We have recently used lipoprostaglandin E₁ administration to maintain ductus arteriosus patency instead of PDA stent placement. However, the patients treated with lipoprostaglandin E₁ cannot go home until the subsequent surgery has been completed; thus, the cost of this approach might be great compared with that of PDA stent placement. Patients receiving lipoprostaglandin E₁ had no major complications in our study. Despite the cost of the drug and hospitalization, the high degree of safety and effectiveness of lipoprostaglandin E₁ treatment make it worthy of serious consideration as an alternative to a PDA stent. Using the formula for the estimated SaO₂, we can estimate the hospital stay before the second-stage operation because we will know the size of the PA band and BW at bPAB, assuming that the BW and SaO₂ at the NW are acceptable.

Once the PA blood flow has been controlled appropriately by bPAB in patients with a nonstenotic PDA, the NW can be delayed until infancy, because it is much safer in infants than in neonates. The estimated Aristotle score of the NW in the neonatal period is also higher than the actual score in infancy, and the operative mortality of the NW after bPAB has been satisfactory. If the children treated in the present study had undergone the NW in the neonatal period, the mortality would have been very high.²⁰

The major problem of bPAB is postoperative PA stenosis. Debanding might result in re-expansion of the PA, but this

FIGURE 4. Flow chart of patients from bilateral pulmonary artery banding (bPAB) to last medical checkup, showing number of patients at each stage.

does not always happen. If the PA is slightly stenosed, we will not perform PA-plasty because the PA is too small for a successful procedure to be performed. In 1 case, BCPS placement was performed, but LPA stenosis remained. In that case, a BTS was placed in the LPA. However, in the present study, no PA-plasty was performed.

After bPAB, the volume overload had decreased. If the NW with a BTS or a right ventricular-PA shunt is performed after bPAB, the volume overload will increase again. It could lead to deterioration of cardiac function; thus, care is essential. In cases in which volume overload does occur, the NW with a BCPS is a good option; however, sufficient PA growth, including a low PA pressure, low pulmonary vascular resistance, and high PA index, is necessary. bPAB often causes PA stenosis, although not always severe; thus, a disadvantage might exist in BCPS placement with the NW. In patients with small PAs, we had to place a BTS, instead of a BCPS, because a PA can be expected to grow much more after placement of a BTS than after a BCPS. Regarding the Fontan procedure, at last follow-up, we had not had enough cases and thus cannot comment. Only 1 patient had undergone the complete Fontan procedure. This patient had undergone the NW with BCPS placement after bPAB.

As for the Aristotle score, the variety of opinions is wide; however, it is the only method for evaluating the operative difficulty adjusted according to a patient's preoperative risk factors.²¹ In our study, the Aristotle comprehensive score was compared with the estimated comprehensive Aristotle score of the NW in the neonatal period; the latter was slightly greater than the score in infancy. This concurs with our opinion and is the reason we chose to perform bPAB before the NW. We know that the Aristotle score requires improvement; therefore, we intend to make a precise calculation of the degree of the risk of surgery. This will be helpful for surgeons to determine in advance the risk for a particular patient.

In our cases of bPAB, the operative mortality after the NW was quite low; however, death in the interim between hospital stays is not always low. In patients with aortic atresia (35%), a small ascending aorta is the only blood source for the coronary arteries; thus, it acts as a type of single coronary artery. The high risk of sudden death might be why relatively many patients died at home between hospitalizations. We have been unable to determine the exact reason for this high mortality, and we do not have any compelling evidence of a potential relationship between bPAB and the mortality between hospital stays. Additional investigation is required. It is clear, however, that perioperative bPAB is safe and minimizes the mortality of the NW in this high-risk group.

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Discussion

Dr Christopher A. Caldarone (Toronto, Ontario, Canada). Dr Kitahori, that was a very nice presentation.

Dr Kitahori has described a series of high-risk hypoplastic left heart syndrome (HLHS) patients treated with bilateral pulmonary artery (PA) banding (bPAB). He has tried to clarify the relationship between the geometry of the PA band and arterial oxygen saturation (SaO₂) at the second-stage procedure.

In a fully grown neonate, this might not be as important because numerous clinical reports have described the use of 3.5-mm diameter polytetrafluoroethylene shunts wrapped around the branch PAs. We have used this technique at the Hospital for Sick Children, and it seems to work well. We have typically evaluated the banding at the end of the procedure with angiography, but our approach has been very subjective. Dr Kitahori is to be applauded for trying to create some objective criteria for how to define these bands.

This is even more important in the small neonates in whom the degree of banding is very difficult to adjust precisely. Small changes in the circumference of a band will result in large changes in the internal diameter and, consequently, even greater changes in the resistance across the band.

We have competing interests in these small infants in that we want the bands tight enough to restrict pulmonary blood flow, prevent volume overload, and maintain adequate diastolic pressures, and, at the same time, we want the bands loose enough to allow adequate SaO₂ at banding and adequate SaO₂ to be able to persist to the time of the second-stage procedure, a difficult balancing act in these very small infants. For that reason, this is an important contribution because you are trying to define the relationship between the geometry at banding and the subsequent SaO₂.

As we discussed, I think the model would benefit if you could create a model that was derived solely from variables determined at bPAB. However, putting that aside, it would be a very valuable addition and perhaps something you could study in the future.

With regard to questions regarding the presented data, I have 3.

First, could you describe what clinical parameters are used when the bands were constructed in your series. Each band really must be assessed individually. Simply using the systemic SaO₂ would be inappropriate, because, as you know, you could have complete occlusion of 1 pulmonary artery and a very loose band on the other and have seemingly appropriate systemic SaO₂. Thus, each band really should be evaluated independently. How do you interrogate the bands and determine the appropriate tightness of the bands?

Dr Kitahori. Thank you, Dr Caldarone.

The infants' body weight varies so much, from 1.5 to 4 kg. This is a very large difference. We thought the PA band should be adjusted to the suitable size, because the PA band on the main PA trunk is adjusted according to Trusler's rule. Mainly, we have monitored the SaO₂ in the operating room. In addition, we usually use transesophageal echocardiography (TEE). TEE is also useful. Using TEE, we can see the pulmonary venous (PV) return well, and we can check the balance of the right and left PV return. Also, the bilateral PV return should be equivalent after bPAB. If the PV return of 1 side exceeds the other too much, the PA band should be readjusted to be tighter or the other looser. However, we do not yet have any clear criteria for the evaluation using TEE, such as the exact value of the flow velocity of the PA band. We just see the balance. Although our TEE probe is the smallest available, it is some-

times difficult to measure the blood flow velocity in the PA precisely, because the echoprobe direction does not always fit the blood flow direction. In such cases, we could over- or underestimate the flow velocity. Thus, evaluation using TEE is a future work for us—how to use TEE for the measurement of a precise evaluation of the PA band.

Dr Caldarone. All right. Well, assuming that you have perfectly symmetric pulmonary artery bands, what is the appropriate SaO₂ at PA banding?

Dr Kitahori. We adjust the PA band with help of TEE. Our goal for SaO₂ is about 80% and 85% at maximum. In my opinion, the SaO₂ in the operating room should be in the slightly lower range, meaning 80%, because the SaO₂ usually gradually increases a little bit after surgery. As you said, we want to reduce the volume overload as much as possible, but we have to keep the SaO₂ at a good level. Thus, the SaO₂ must not be going to be quite low, which would result in a lethal level. Thus, I think 80% would be good.

Dr Caldarone. My third question. In the manuscript you reported that you administer prostaglandin to the infants from bPAB to the second-stage procedure and thus you do not require ductal stenting. This would eliminate the potential for duct-induced stenosis of the aortic isthmus and thereby a problem with retrograde flow in the aortic arch.

Two questions regarding that. First, did you have any complications associated with prolonged prostaglandin infusion? Second, at the second-stage procedure, did you see any stenosis or other anatomic abnormality in the isthmus?

Dr Kitahori. The reported side effects of prostaglandin have been apnea and thickening of the periosteum of the long bone. One patient had an apnea attack, but it was not so severe, and re-intubation was not needed. We have never observed thickening of the periosteum of the long bone to date. In our institute, prostaglandin E₁ administration is considered very safe and useful for maintaining the patent ductus arteriosus (PDA). The only problem has been the long hospital stay. Patients receiving prostaglandin cannot go home. At that point, a PDA stent might be superior. However, it has some problems, as you mentioned. The PDA stent can migrate and interfere with the blood flow of the transverse arch. It is dangerous because the blood supply to coronary artery is also interfered. In my opinion, the frequency of complications related to prostaglandin might be smaller than that of the PDA stent, so we chose prostaglandin.

Dr James S. Tweddell (Milwaukee, Wis). Can I just ask 1 follow-up question to Dr Caldarone. What is the fraction of inspiratory oxygen when you are doing the banding?

Dr Kitahori. Usually the fraction of inspiratory oxygen is set at 21%.

Dr Tweddell. 21%.

Dr Kitahori. That is room air.

Dr Tweddell. And normocapnia?

Dr Kitahori. Yes.

Dr Renato S. Assad (Sao Paulo, Brazil). I just would like to share with the Association some comments about this technique. We have used adjustable PA bands for high-risk patients with hypoplastic left heart syndrome, a simple method to percutaneously regulate the pulmonary blood flow over time. Regarding our protocol of adjusting the PA bands in the operating room, the precise degree of banding ring constriction is adjusted after sternal

closure. Because we do not have TEE for small neonates, we ask the anesthesiologist to keep the fraction of inspiratory oxygen in the 21% to 30% range to be able to achieve SaO₂ in the low 80s during banding adjustment. That is our straightforward protocol for PA banding adjustment, trying to administer the same amount of volume in both banding cuffs to achieve similar blood flow to both lungs. This system has allowed stable SaO₂ in the low 80s throughout the interstage 1-2.

Dr Kitahori. Thank you for your comments.

Dr Hideto Shimpo (*Tsu, Mie, Japan*). I congratulate Dr Kitahori on very interesting data. I have a couple of questions.

Are there any differences between the RPA groups and the LPA groups at the Fontan procedure?

Dr Kitahori. Sometimes we have seen LPA stenosis, but it has not been so severe. We did not need PA-plasty for LPA stenosis, but it can be a problem of this technique. The PA band can cause PA stenosis, especially at the PA banding site. However, we have not needed any PA-plasty so far and have just inserted a dilator into the LPA, which has been good enough.

Dr Shimpo. My second question: I think this technique is a very good option for complex disease, so have you applied this technique to other complex diseases, for example, truncus arteriosus and so on?

Dr Kitahori. I think bPAB is a good option for other diseases, but we have few such cases. So, I cannot comment on that, sorry.