# Is routine rapid-staged bilateral pulmonary artery banding before stage 1 Norwood a viable strategy?

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**Objective:** We adopted a policy of rapid-staged bilateral pulmonary artery banding (bPAB) before the Norwood (NW) procedure for all patients with hypoplastic left heart syndrome. We hypothesized that this strategy might mitigate some of the traditional risk factors and that postponing a major bypass procedure beyond the newborn period could have both short- and long-term benefits. The purpose of the present study was to evaluate the efficacy of this strategy with respect to the short-term outcomes.

**Methods:** From 2008 to 2010, 14 patients underwent bPAB and maintenance of ductal patency with prostaglandin $E_1$ infusion before stage 1 NW. For reference, we also reviewed the data from patients who had undergone the primary NW procedure in the 2 years immediately before the study period.

**Results:** The bPAB was performed at a median age of 6 days (range, 2-39), gestational age of 38.5 weeks (range, 36-41), and weight of 2.75 kg (range, 2.3-3.6). The subsequent NW was performed at a gestational age of 43.5 weeks (range, 41-51) and weight of 3.2 kg (range, 2.2-4.9). When the NW procedure was eventually performed on the pBAB group, the maximum blood lactate levels within the first 24 hours after the NW were lower than those in the earlier primary NW group ($2.8 \pm 0.9$ vs $10.1 \pm 6.5$ mmol/dL, $P = .0002$) and the urine output in the first 24 hours after the NW was greater in the pPAB group ($4.1 \pm 2.1$ vs $2.2 \pm 1.5$ mL/kg/h; $P = .0051$).

**Conclusions:** These data suggest that rapid-staged bPAB before NW can reduce the challenge of postoperative management in the early postoperative period after the NW procedure and have potential to improve the outcomes. (J Thorac Cardiovasc Surg 2014;148:1519-25)

Hypoplastic left heart syndrome (HLHS) is still a challenge for cardiac surgeons and multidisciplinary care teams.[1-3] Norwood performed his first palliation procedure, the Norwood (NW) operation, in 1981, and it has been a standard procedure for first-stage palliation since then.[4] This was a great breakthrough that opened the way for treatment of high-risk children with HLHS.[5] Since its introduction, the NW procedure has led to progressively better outcomes for patients with HLHS.[5,6] In particular, with the continued improvements in perioperative management and refinements in the surgical technique, several centers have reported 30-day survival rates of >75%, and an increasing number of families have elected to continue with a pregnancy after an antenatal diagnosis of HLHS.[3,7-9] Bilateral pulmonary artery banding (bPAB) and stenting of the ductus arteriosus for the management of HLHS has been more recently developed as an alternative strategy that involves a less technically demanding initial procedure. It has recently attracted attention for the initial treatment of high-risk neonates with HLHS, because it is less invasive than surgery requiring cardiopulmonary bypass support.[10-14] The encouraging results from these reports influenced us to adopt rapid-staged bPAB followed shortly by NW stage 1 in all neonates with HLHS. Our hypothesis was that such an approach would result in less-challenging postoperative management after the NW procedure and could potentially be associated with other advantages related to the postponement of a complex reconstructive procedure requiring cardiopulmonary bypass until after the early newborn period. In the present study, we sought to assess the feasibility of a rapid 2-stage approach to palliation using the initial placement of bPABs followed shortly by NW stage 1 and to assess the effect of this strategy on the early post-NW course and management.

## METHODS
### Study Design
We conducted a single-center, retrospective review of the medical records of 14 consecutive patients (5 boys and 9 girls) with HLHS. These patients had undergone rapid-staged bPAB followed shortly by NW stage 1 reconstruction at Mt. Fuji Shizuoka Children's Hospital (Shizuoka, Japan) from 2008 to 2010. We also analyzed the data from a group of 18

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**Abbreviations and Acronyms**
BDG = bidirectional Glenn cavopulmonary shunt
bPAB = bilateral pulmonary artery banding/band
ECMO = extracorporeal membrane oxygenation
HLHS = hypoplastic left heart syndrome
NW = Norwood
PA = pulmonary artery
pNW = primary NW procedure
TR = tricuspid valve regurgitation

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consecutive patients (8 boys and 10 girls) who had undergone a primary NW procedure (pNW) in accordance with the standard management strategy of the cardiovascular program in the 2 years immediately before the study period. The institutional review board of the hospital approved the present study, and individual consent for the present study was waived.

The patients with HLHS or its variants who had undergone bPAB as a salvage procedure (n = 2, weight < 1.5 kg, fetal hydrops) or the combined NW stage I+II after bPAB (n = 1) were excluded from the present study. In accordance with our institutional policy, the Fontan candidates underwent cardiac catheterization before bidirectional Glenn cavopulmonary shunt (BDG) and the Fontan operation, and we performed an early Fontan operation.[15,16]

The medical records, operative records, and echocardiographic data for all the patients were reviewed. The anatomic diagnosis was determined from a review of the echocardiographic and operative findings. The follow-up status was determined by a review of the medical records and interviews with the referring cardiologists. The follow-up data were complete for all the patients.

## Patients

From January 2008 to December 2010, 14 patients with HLHS and related variants underwent rapid-staged bPAB at Mt. Fuji Shizuoka Children's Hospital (bPAB group). The 18 consecutive patients who had undergone the pNW before institution of the rapid-stage protocol were similar in weight at birth, anatomy, and crossclamp times at the NW procedure (Tables 1 and 2). For patients in the rapid-stage protocol, the timing of the NW procedure was selected by the attending cardiologist and surgeon, with approval of the family of the patient.

The risk factors initially present among the patients in the pNW group and the rapid-staged protocol group included intact or highly restrictive atrial septum in 8 of 32 patients (4 in each group) and severe tricuspid valve regurgitation (TR) in 4 of the 32 patients (2 in each group). The Aristotle scores were similar in both groups (17.5 ± 2.0 vs 17.8 ± 2.8; $P = .80$; Table 1). All 32 patients had functionally univentricular hearts.

## Operative Procedure

**Bilateral pulmonary artery banding.** We performed bPAB in the operating room. Through a median sternotomy, bilateral bPABs were placed around the left and right branch pulmonary arteries (PAs) using a 0.4-mm-thick polytetrafluoroethylene sheet (Gore-Tex; W.L. Gore & Associates, Flagstaff, Ariz) divided longitudinally and wrapped around the branch PAs. The right PA band was positioned laterally to the ascending aorta. Confirmation of the bPAB was done using epicardial echocardiography in the operating room. Patent ductal arteriosus was maintained by prostaglandin $E_1$ ($PGE_1$) infusion before the stage 1 NW procedure. We aggressively pursued decompression of the left atrium with septostomy at the bPAB procedure, using the briefest possible period of cardiopulmonary bypass (n = 4), if needed. Septostomy was performed under temporary fibrillation without interruption of coronary perfusion.

Delayed sternal closure was performed routinely for the patients who underwent septostomy, total anomalous pulmonary vein drainage repair (n = 1), or tricuspid valve repair (n = 1) at bPAB. Close monitoring (echocardiograms 3 times per week) was used.

**Rapid 2-stage NW operation and PA debanding during surgical palliation.** In the bPAB group, we performed the NW stage I operation (rapid 2-stage NW operation) 3 to 4 weeks after bPAB. As soon as cardiopulmonary bypass was established, the PA bands were removed, and the heart continued to eject. Periadventitial scar tissue was carefully excised (Figure 1, *A* and *B*). Temporary occlusion of the branch PAs peripheral to the sites of previous banding helped to expand the proximal branches and enabled us to determine that fixed stenosis due to scarring or fibrosis was not present (Figure 1, *C*). The branch PAs were assessed using both visual inspection and calibrated vascular dilators.

The NW procedures were performed using standard surgical techniques, regional cerebral perfusion, modified Blalock-Taussig shunts (17 of 32 [53.1%]: 11 of 14 in the bPAB group and 6 of 18 in the pNW group) or right ventricle–pulmonary artery (RV–PA) conduits (15 of 32 [56.9%]: 3 of 14 in the bPAB group and 12 of 18 in the pNW group). Standard neoaortic arch reconstruction was undertaken using autologous pericardium treated with glutaraldehyde. Delayed sternal closure was performed routinely. We used modified ultrafiltration in all cases. After modified ultrafiltration, we controlled the pulmonary blood flow using hemostatic clips on the RV–PA conduit or Blalock-Taussig shunt, as needed. Generally, we aimed for a systemic oxygen saturation of approximately 80% with a fraction of inspired oxygen of 1.0 in the operating room. We have introduced the strategy of pulmonary blood flow control using clips since the end of the 1990s.[17] All NW procedures in both groups were performed by a single surgeon. Postoperative management was according to same standardized protocols during the study period.

## Statistical Analysis

The data are presented as the mean ± standard deviation, as indicated. Differences between the 2 groups (Table 1) were evaluated using Fisher's exact test, the Mann-Whitney rank sum test, or Student *t* test, as appropriate. The survival rate was estimated using the Kaplan-Meier method, and differences in these rates between the groups were assessed using the log-rank test. All analyses were conducted with Prism software, version 5.0.0 (GraphPad Software, Inc, San Diego, Calif).

## RESULTS
### Patients

bPAB was performed at a median age of 6 days (range, 2-15) and median weight of 2.8 kg (range, 2.3-3.4). The bPAB and pNW groups had a median age of 35 days (range, 21-91) and 4.5 days (range, 0-43; $P < .0001$) and median weight of 3.2 kg (range, 2.2-4.9) and 2.7 kg (range, 1.4-4.9), respectively ($P = .025$) at the NW operation. The major cardiac defects were HLHS in 23 patients (71.9%, 23 of 32; 11 in the bPAB group and 12 in the pNW group) and variant HLHS in 9 (28.1%, 9 of 32; 3 in the bPAB group and 6 in the pNW group). The median age at the subsequent BDG was 5.7 months (range, 4.4-9.8) for 13 patients in the bPAB group and 6.2 months (range, 4.0-10.7) for 15 patients in the pNW group ($P = .56$). The median age at the Fontan operation was 1.6 years (range, 0.9-2.5) for the 13 patients in the bPAB group and 1.7 years (range, 1.0-3.1) for the 15 patients in the pNW group ($P = .22$). Of the 14 patients in the bPAB group, 2 (14.3%) had greater