Bilateral pulmonary arterial banding results in an increased need for subsequent pulmonary artery interventions

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Objective: Despite increasing use of bilateral branch pulmonary artery banding (bPAB), both as a temporary stabilizing treatment and as part of comprehensive hybrid management of hypoplastic left heart syndrome, little is known about the long-term outcomes of the pulmonary arteries (PAs) in banded patients.

Patients and Methods: We conducted a retrospective review of all patients with ductal-dependent systemic circulation (2001-2013) undergoing bPAB placement at a single institution (bPAB, n = 50); patients who underwent a stage I Norwood procedure (Norwood, n = 53) were used for comparison. The need for PA interventions (surgical arterioplasty, balloon angioplasty, and stent implantation) and PA growth were assessed.

Results: Bands were in place for a median of 76 days. PA growth and size were similar between groups, but bPAB patients required more interventions $(1.4 \pm 2.9 \text{ vs } 0.5 \pm 1.2, P = .01)$. In competing risks analysis, only 20% of bPAB patients were alive and free from intervention at 5 years after bPAB removal. Multivariable Cox proportional hazards regression of operative interventions within the bPAB group demonstrated the following risk factors: subsequent 2-ventricle repairs (hazard ratio [HR], 2.2; 95% confidence interval [CI], 0.7-6.7), smallest band diameter (HR per additional millimeter, 0.059; 95% CI, 0.004-0.849), and duration of band placement more than 90 days (HR, 3.5; 95% CI, 1.0-12.6). Hemodynamics and Fontan candidacy did not differ between groups.

Conclusions: Patients with bPAB require additional interventions at earlier time points than Norwood patients. Patients with smaller bands and longer duration of banding are at high risk. Despite stenoses requiring additional interventions, Fontan candidacy is maintained. (J Thorac Cardiovasc Surg 2014;147:706-12)

Bilateral branch pulmonary arterial banding (bPAB) is an attractive method for control of pulmonary blood flow in ductal-dependent lesions. It is performed both as part of a comprehensive strategy for hybrid palliation and to stabilize patients in the immediate postnatal period with pulmonary overcirculation and ductal-dependent blood flow.¹⁻⁴ Pulmonary arterial banding has important consequences on the vascular wall that may result in important longterm consequences to pulmonary arterial growth potential.¹⁻⁶ Patients with hypoplastic left heart syndrome undergoing a comprehensive stage 2 procedure have an increased need for pulmonary artery interventions.^{3,6} Whether this is a consequence of the stage 2 operation or attributable to the bPABs and whether particular patients might be at high risk for pulmonary arterial stenosis and growth impairment have not been investigated.

Copyright © 2014 by The American Association for Thoracic Surgery http://dx.doi.org/10.1016/j.jtcvs.2013.10.038 At our institution, bPAB has been used both as part of a comprehensive hybrid management strategy and for immediate stabilization in both single-ventricle and 2-ventricle patients with ductal-dependent lesions. We undertook a review of all patients undergoing bPAB placement to evaluate the impact of bPAB on the long-term outcomes of the pulmonary artery (PA), identify risk factors for poor outcomes, and suggest strategies to mitigate the negative impact of bPABs.

METHODS

Patient Population

We performed a retrospective review of all patients undergoing bPAB at a single institution (bPAB, n = 50). These patients were compared with a contemporaneous group of patients undergoing stage 1 Norwood palliation (Norwood, n = 54). Diagnoses and birth history are shown in Table 1. Overall median follow-up was 32.9 months (intraquartile range [IQR], 4.3-69.6). The Nemours Institutional Review Board approved the study.

Surgical and Interventional Procedure Performed

During this time period, patients underwent either bPAB or standard surgical palliation based on preoperative condition and physician preference. Technical details of patients undergoing bPAB have been reported previously.⁷ In summary, bPABs of polytetrafluoroethylene were placed without cardiopulmonary bypass and typically over a 2.5-mm probe. Band tightness was adjusted to maintain systemic oxygen saturation in the 80% to 85% range. In selected patients, bPABs were placed before either ductal stenting, stage 1 Norwood palliation, or definitive 2-ventricle repair to stabilize patients with excessive pulmonary artery blood

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Abbreviations and Acronyms	
BDG	= bidirectional Glenn
bPAB	$\mathbf{B} =$ branch pulmonary arterial banding
CI	= confidence interval
HR	= hazard ratio
IQR	= intraquartile range
OR	= odds ratio
PA	= pulmonary artery

flow and/or maldistribution of cardiac output. Modified stage 1 Norwood palliation was performed using deep hypothermic circulatory arrest; pulmonary blood flow was provided by either a right ventricle (RV)-pulmonary artery (PA) conduit or a modified Blalock-Taussig shunt.

Superior cavopulmonary connections were usually performed using a hemi-Fontan connection constructed of pulmonary homograft. Bidirectional Glenn (BDG) anastomoses were used at the surgeon's discretion.

Hemodynamics and Measurements of Pulmonary Arterial Size and Growth

Diagnostic catheterizations for all patients were reviewed. Branch PA size was reported as the smallest diameter within that branch before hilar branching. Sizes are reported both as raw data and indexed to patient body surface area. Growth was measured as the difference between the first and last measured size among patients with size measurements at least 6 months apart divided by the elapsed time. When calculating growth rates, interval interventions were ignored. Hemodynamic measurements were obtained from catheterization reports. Mean PA pressures are reported and are the lowest reported pressures within the main and branch PAs proximal to any significant stenoses with the branch PAs. Prestage 2 and pre-Fontan data were defined as the last catheterization containing the relevant measurement before performance of the respective surgery.

Operative and Catheter-Based Interventions

Operative interventions were defined as any surgical procedure involving an attempt to address branch PA stenosis: patch arterioplasty, excision and reconstruction of a pulmonary artery segment, rigid or balloon dilation, or placement of a stent via an open surgical procedure. Because the hemi-Fontan was performed routinely, this was not included as an operative intervention on the PAs (nor was placement of a BDG anastomosis). Catheter-based interventions were limited to either balloon angioplasty or stent placement in the PA. Interventions directed at other lesions (eg, recoarctation) were not included. Patients requiring more than 1 intervention on separate dates were considered to have undergone multiple interventions.

Statistical Analysis

Statistical analysis was conducted using SAS 9.2 for AIX (SAS Institute Inc, Cary, NC). Statistical tests used to identify predictors of outcomes included the χ^2 -test and the paired *t* test. Duration of bPAB placement was analyzed both as a continuous variable and stratified into 3 groups: 14 or less days, 14 to 90 days, and more than 90 days. Time-to-event outcomes were assessed with Kaplan-Meier survival estimates (log-rank rest for difference between strata, P < .05). Multivariate regression of binary outcomes was performed using logistic regression (backward selection, P < .2 to remain). Cox proportional hazards regression was used to identify risk-adjusted models for time-to-event analyses (backward selection, P < .2to remain). Competing risks analysis was performed using the cmprisk package of R for Windows.

RESULTS

Baseline demographics, birth history, and preoperative clinical condition for Norwood and bPAB patients are shown in Table 1. Median follow-up was longer among the Norwood patients (51.3 months [IQR, 16.2-82.5 months] vs bPAB:10.9 months [3.3-46.7 months], P = .01).

Median bPAB diameter was 2.5 mm for both right and left PA (range, 2.0-3.5 mm). Ductal stenting was performed during the same procedure as bPAB in 14 patients (28.0%), and an additional 17 patients (62.0%) had insertion of a ductal stent as a separate procedure. When performed as a separate procedure, the ductal stent was placed a median of 6.5 days (IQR, 4-11) after bPAB.

Adjustment of band diameter was necessary in 8 patients (16.0%) at a median of 6.5 days (IQR, 0-24 days) after band placement. Bands were in place for a median of 76 days (IQR, 18-103 days) before either removal or patient death. There was a trend toward higher in-hospital mortality among the bPAB patients (Norwood, 13.0%; bPAB, 26.0%; P = .09).

Superior cavopulmonary connections were created in 56 patients at a median of 5.4 months of age (IQR, 4.4-6.7 months). The Fontan procedure was performed in 34 patients at a median of 18.3 months (IQR, 14.7-23.5 months). Creation of a superior cavopulmonary anastomosis was more common among the Norwood patients (64.9% vs 42.0%; P = .02), and there was a trend toward a higher incidence of eventual Fontan palliation among Norwood patients (38.9% vs 26.0%; P = not significant [NS]). Two-ventricle repairs were performed in 17 patients at a median of 3.8 months of age (IQR, 2.1-5.8 months). A higher proportion of bPAB patients ultimately underwent a 2-ventricle repair (26.0% vs 7.4%; P = .01). Heart transplant was performed in 1 patient after a Norwood procedure and in 2 patients after bPAB.

Pulmonary Arterial Growth and Size

Right and left pulmonary arterial size (both raw and indexed to body surface area) did not differ significantly between groups at any defined time during follow-up (Table 2). Left pulmonary arterial growth was 1.3 ± 1.5 mm/y in Norwood patients and 0.6 ± 1.5 mm/y (P = .15). Indexed growth measurements in the left PA were 4.7 ± 4.3 mm/y/m² in the Norwood patients and 1.7 ± 10.9 mm/y/m² in the bPAB patients (P = .3). Right PA growth was also not different between groups, either nonindexed (Norwood: 1.7 ± 4.7 mm/y vs bPAB 3.7 ± 5.2 mm/y; P = .2) or indexed (Norwood 2.5 ± 1.5 mm/y/m² vs bPAB 3.3 ± 1.9 mm/y/m²; P = .3). Left and right PA size and band removal and subsequent PA growth did not differ between patients undergoing single- versus 2-ventricle repairs.

Obliteration of a branch PA occurred in 2 Norwood patients and 1 bPAB patient (P = NS). Obliteration of a

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