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A Novel Adjustable Pulmonary Artery Banding System for Hypoplastic Left Heart Syndrome

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Purpose. We describe the first case in which a neonate with hypoplastic left heart syndrome was initially managed using a mini adjustable banding system.

Description. Through a mid-sternotomy, a 5-day-old neonate underwent bilateral pulmonary artery banding using this new system, combined with placement of a main pulmonary artery to the innominate artery shunt.

Evaluation. The patient had an uneventful postoperative course. Three percutaneous adjustments of the banding system were necessary to keep the arterial oxygen saturation in the 75% to 85% range. On day 48 of life, she was submitted to stent placement (6 mm) within the atrial septum to treat a restrictive atrial septal defect. Afterward, seven additional percutaneous adjustments of the banding system were necessary. The Norwood operation and the bidirectional Glenn shunt were carried out on the day 106 of life. The bands were removed with no pulmonary artery distortion.

Conclusions. The clinical use of this innovative pulmonary artery banding system was feasible, safe, and effective. This allowed for customization of the pulmonary blood flow according to the underlying clinical needs, resulting in a more precise balance between the pulmonary and systemic circulations.

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An alternative approach for palliation of the hypoplastic left heart in the neonatal period has been to stent the arterial duct in combination with branch pulmonary artery banding (PAB) [1–3]. However, fine adjustment of the pulmonary blood flow has proved to be a particularly difficult aspect of the procedure [4]. Generally the bands are surgically adjusted, based on arterial oxygen saturation monitoring (range, 75% to 85%). However, to avoid hypoxemia as the infant rapidly grows up, the balance between the pulmonary and systemic blood flows should be adjusted, which is impossible with the fixed bands.

Technology

To deal with these problems, we devised a mini-banding device named the ABS (Silimed Inc, Rio de Janeiro, Brazil) that allows for fine percutaneous adjustments of the pulmonary blood flow in the postoperative period. This innovative percutaneously adjustable mini-PAB system (patent pending) permits a fine control of the pulmonary blood flow by accurately increasing or decreasing the pulmonary artery (PA) cross-sectional diameter. Therefore, it is adjusted according to the underlying clinical conditions of the patient.

Technique

In this article we report the first clinical application of this new PAB system in a newborn with hypoplastic left heart syndrome who underwent successful initial palliation. Neoaoartc reconstruction along with bi-directional cavopulmonary connection was successfully performed at 3.5 months of life.

Our prototype is all silicone covered, a miniaturized and improved device developed from previous experimental studies that resulted in a more delicate banding system for neonatal use (Fig 1) [5, 6]. It consists of three parts: (1) a banding ring, (2) connecting tubing, and (3) an inflation reservoir. The banding ring is a C-shaped hydraulic cuff with a 5-mm width and a rigid outer layer, reinforced with a polyester mesh, which keeps it from deforming centrifugally. The cuff compresses the lumen of the PA when expanded, according to the volume injected percutaneously into the inflation reservoir subcutaneously implanted. The banding ring is potentially...
able to increase 500% in volume size, promoting a wide range of reversible constriction of the banded PA (from 1 mm to 6 mm internal diameter range). The connecting tubing (70 mm × 2 mm) hermetically connects the banding ring to the inflation reservoir.

Clinical Experience

The patient was a full-term female newborn, weighing 2.76 kg, with a prenatal diagnosis of hypoplastic left heart syndrome. Postnatal echocardiogram confirmed the intracardiac findings of the aortic and mitral valves, which were atretic and stenotic, respectively, and the diameter of the ascending aorta, which was 2.5 mm. There was an unrestrictive atrial septal defect measuring 6 mm. The patient was started on prostaglandin infusion and systemic saturation was 90% to 95% on room air with spontaneous breathing. Perinatal management with the new adjustable PAB system had been planned beforehand in a tertiary care center. After extensive discussions with the parents during gestation, including explanation of the benefits and risks of the procedure and the possibility of heart transplantation, the new banding device was used on a compassionate basis after obtaining approval from the local ethics committee and written informed consent from the parents.

The stage I operation was carried out on the fifth day of life. Through a median sternotomy, the patient underwent bilateral PAB with the new percutaneously adjustable system (Fig 2), associated with a reversed modified Blalock-Taussig shunt (6 mm) between the main PA and the proximal innominate artery, without cardiopulmonary bypass. The strategy of stenting the arterial duct was not applied in this case due to the absence of an obstructive aortic arch lesion or coarctation. Once the adjustable banding ring was placed around the PAs and the inflation reservoirs were left in the infraclavicular subcutaneous tissue, the degree of constriction of the banding rings was adjusted after sternal closure (Fig 3). Each band was inflated with 0.30 mL saline solution to decrease arterial oxygen saturation to the 75% to 85% range while breathing under a 30% inspired oxygen fraction. Prostaglandin infusion was discontinued after the procedure.

The patient had an uneventful postoperative course with no need for inotropic medications or bicarbonate. Nitroprusside was used to control systemic hypertension. She was weaned from mechanical ventilation on postoperative day 6. She was discharged home 21 days after the operation. Three percutaneous adjustments of the banding system were necessary during the hospital stay to achieve the desired arterial oxygen saturation.

The infant was followed closely with serial echocardiographic assessment every week, which showed progressively decreasing presence of any atrial septal defect. There was no obstruction within the aortic arch, and the main PA to the innominate artery shunt was widely patent. There was good qualitative right ventricular function and minimal tricuspid valve regurgitation. Therefore, on day 48 of life, a 6 × 19 mm, pre-mounted Palmaz Genesis stent (Cordis Co, Miami, FL) was implanted across the atrial septal defect with clear hemodynamic and arterial oxygen saturation improvement, despite remaining in an
blood cultures and in the central venous catheter. She had Monas aeruginosa. The infectious agent was also found in a subcutaneous tissue abscess caused by flucloxacillin. However, on postoperative day 11, she was reoperated on to drain a subcutaneous tissue abscess caused by a 3-mm orifice that caused restrictive blood flow through the atrial septal defect. The initial postoperative period was uneventful with adequate systemic cardiac output and angiography showed low PA pressure and vascular resistance and no PA stenoses, which may have a deleterious impact for subsequent cavopulmonary operations. Fortunately, the scar tissue surrounding the banding devices was minimal in our patient and did not result in any of these complications.

The anatomy of the pulmonary arteries was well preserved with no distortions. The stent was removed from the interatrial septum and a complete atrial septectomy had been noted on repeat echocardiograms before surgery. Direct anastomosis of the main PA to the transverse aortic arch with no prosthetic materials was performed along with a bi-directional cavopulmonary connection. The anatomy of the pulmonary arteries was well preserved with no distortions. The stent was removed from the interatrial septum and a complete atrial septectomy was carried out. Upon removal, inspection of the stent displayed significant intrastent neoproliferation, leaving an off-center position. After that, seven additional percutaneous adjustments (removal of saline from the reservoir) of the banding system were necessary, so that in the last adjustment performed on day 91 of life, only 0.12 mL saline was left in each band to maintain the arterial oxygen saturation in the recommended range (Fig 4).

The patient was electively submitted to the “comprehensive” stage II surgical palliation on day 106 of life. Progressive obstruction within the interatrial stent had been noted on repeat echocardiograms before surgery. Direct anastomosis of the main PA to the transverse aortic arch with no prosthetic materials was performed along with a bi-directional cavopulmonary connection. The anatomy of the pulmonary arteries was well preserved with no distortions. The stent was removed from the interatrial septum and a complete atrial septectomy was carried out. Upon removal, inspection of the stent displayed significant intrastent neoproliferation, leaving a 3-mm orifice that caused restrictive blood flow through the atrial septal defect. The initial postoperative period was uneventful with adequate systemic cardiac output and oxygen saturation under inhaled nitric oxide for the first 2 postoperative days, with no respiratory problems. However, on postoperative day 11, she was reoperated on to drain a subcutaneous tissue abscess caused by Pseudomonas aeruginosa. The infectious agent was also found in blood cultures and in the central venous catheter. She remained on antibiotic therapy for 3 weeks with good clinical response. After that, she had oropharyngeal candidiasis with esophageal involvement that responded readily to fluconazole. Oral feeding was progressively re-established and she was discharged home on postoperative day 50. At present, she is 21 months old and has just submitted to a fenestrated modified Fontan operation with a lateral tunnel. Preoperative catheterization and angiography showed low PA pressure and vascular resistance and no PA stenoses. She is doing well with an arterial oxygen saturation in the low 90s.

Comment

We believe that this is the first report to demonstrate the feasibility, safety, and efficacy of the use of the new percutaneously adjustable PAB system for stage I palliation for hypoplastic left heart syndrome in a neonate.

The idea of adjustable banding devices composed of a hydraulic cuff and a self-sealing button was first proposed by Jacobson and McAllister [7] in 1957. Since then, several other devices with similar concepts have been proposed by Bishop and Cole [8], Edmunds and colleagues [9], Park and colleagues [10], and Solis and colleagues [11]. Prior to applying this new technique in humans, we had extensively evaluated the feasibility of different banding devices, as well as safety in young goats for more than 1 decade, by assessing the acute right ventricular hypertrophy [5, 6, 12, 13]. The cumulative knowledge of our experimental work was crucial to test our system in a clinical setting, making implantation technically straightforward.

Our new banding system is a biocompatible device, which can be easily placed at operation with no technical difficulties. It proved to be a very efficient, simple, and precise method to percutaneously regulate the pulmonary blood flow with time, resulting in a balanced pulmonary and systemic circulation and adequate saturations as the patient rapidly grew up and gained weight. However, the calibration of the banding cuffs was sometimes difficult to achieve due to the extreme complexity of the continuously changing relationship between systemic and pulmonary vascular resistance, with the dependency on several inter-related variables such as the values of the arterial pO2, pCO2, pH, hemoglobin, cardiac output, level of sedation, use of peripheral or pulmonary vasodilators, or both, and so forth. Nevertheless, fine and reversible adjustments could be performed as many times as needed, both in acute and ambulatory settings, avoiding further surgical interventions. The use of this innovative banding system seemed to result in a more predictable postoperative course, and in a more stable patient, which is highly desirable for the comprehensive phase II operation.

A concern with any PAB technique or device, including ours, is the possibility of causing vessel distortions or stenoses, which may have a deleterious impact for subsequent cavopulmonary operations. Fortunately, the scar tissue surrounding the banding devices was minimal in our patient and did not result in any of these complica-
tions. Whether this is related to the material of the banding rings (silicone) is speculative. This issue remains to be clarified with ongoing experience. Corno and colleagues [14] have demonstrated that the noncircular shape induced to the wall of the PA by the FloWatch-PAB system (EndoArt, Lausanne, Switzerland) promotes the same pressure gradient as conventional circular PAB, but with significantly smaller reduction of the PA perimeter. In addition, PA reconstruction at the moment of definitive intracardiac repair could be avoided, suggesting that it may prevent the formation of fibrosis of the PA wall in correspondence of the band. However, the possibility of using the ingenious FloWatch-PAB system was not considered in a neonate with hypoplastic left heart syndrome due to space limitation in the branch PAs.

The main problem that has emerged in this case was the postoperative infection in the subcutaneous tissue, probably related to the presence of the subcutaneous reservoirs and repeated percutaneous access to titrate the narrowing of the device in the cyanotic neonate. Although this was a minor complication that was easily managed with antibiotic therapy and mechanical drainage of the subcutaneous abscess, it is of paramount importance to keep judicious sterile techniques to manipulate the required equipment to inflate or deflate the reservoirs.

Regarding other potential indications of the adjustable PA banding, it may be applicable to the very sick and small infants with large left-to-right shunting and torrential pulmonary blood flow. Initial palliation could be achieved using the adjustable PA banding, deferring total repair at an older age. Multiple muscular ventricular septal defects with a “Swiss cheese” septum, single or multiple ventricular septal defects with coarctation of the aorta or interrupted aortic arch, and single ventricle type of defects with increased pulmonary blood flow are among the lesions in which the use of the adjustable PA banding may allow time for growth of the patient before complete repair. Other possible indications of the adjustable PA banding system include patients with complete and congenitally corrected transposition of the great arteries, who are considered for a late arterial switch procedure and need “training” of the left ventricle.

In conclusion, the use of our innovative PAB system allowed for a fine control of the pulmonary blood flow in a neonate with hypoplastic left heart syndrome undergoing phase I palliation. This customization of the pulmonary blood flow according to the underlying clinical needs of an infant with rapid somatic growth seemed to result in a more precise balance between the pulmonary and systemic circulations during the inter-stage period.

Disclosures and Freedom of Investigation

The mini banding “ABS” device was donated to the study by Silimed Inc, Rio de Janeiro, Brazil. The authors declare having full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

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