Adaptable Pulmonary Artery Band for Late Arterial Switch Procedure in Transposition of the Great Arteries

Nicole Sekarski, MD, Michel Hurni, MD, Ludwig K. von Segesser, MD, Erik J. Meijboom, MD, and Stefano Di Bernardo, MD

Department of Pediatric Cardiology and Department of Cardiovascular Surgery, University Hospital, Lausanne, Switzerland

Background. **In late-diagnosed transposition of the great arteries (TGA), the left ventricle (LV) involutes as it pumps against low resistance and needs retraining by applying a pulmonary artery band (PAB) in preparation for an arterial switch operation. We report our experience with a telemetrically adaptable band compared with classic banding.**

Methods. **Ten patients underwent retraining of the LV, 4 patients with an adaptable band and progressive weekly tightening of the band (group 1) and 6 patients with a traditional band (group 2).**

Results. **Mean weight and age at pulmonary band placement was 5.8 ± 2.36 kg and 11.7 ± 11.1 months for group 1 and 5.0 ± 2.3 kg and 6.4 ± 7.6 months for group 2. Time between palliation and switch procedure was 4.2 months in both groups. Group 1 showed an initial mean pulmonary gradient of 25.5 ± 4.43 mm Hg with a 5% closure of the device. The mean gradient increased with progressive closure to 63.5 ± 9.8 mm Hg at the time of the arterial switch operation. There were no reinterventions or deaths in this group. In group 2, the mean pulmonary gradient increased with growth from 49 ± 21.4 mm Hg to 68.4 ± 7.86 mm Hg at the time of the switch procedure. However, 4 of these patients required reoperations during retraining: 2 needed 1 reoperation and 2 needed 2 reoperations. Two patients died—1 after banding and 1 after the switch operation.**

Conclusions. **Retraining of the LV by the adaptable device allows precise control of the tightening, avoids repetitive operations, and diminishes morbidity.**

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Current standard surgical management for transposition of the great arteries (TGA) with intact ventricular septum is the arterial switch operation [1–3]. This operation should be performed in the first few weeks of life before a physiologic drop in pulmonary resistance results in involution of the left ventricle (LV) [4, 5]. In the case of late diagnosis or if there is delay in the timing of the operation for other reasons, 2 options remain: either an atrial switch procedure (Senning or Mustard operation) at a later time or a late arterial switch procedure with left ventricular retraining. Left ventricular preparation is achieved through pulmonary artery band (PAB) placement with or without addition of an aortopulmonary shunt to increase left ventricular pressure and mass [6–8]. Traditionally a PAB consisted of a polytetrafluoroethylene band placed surgically around the main pulmonary artery (PA) and tightened to achieve a decrease in PA pressure. Currently a new type of band that is telemetrically regulated, the FloWatch-PAB (Leman Medical Technologies, Plan-les-Ouates, Switzerland), has been developed and can be used instead [9, 10].

At our institution we have agreements with nongovernmental organizations to operate on patients with congenital heart disease from countries where cardiac operations are unavailable, making late TGA 1 of the more frequently seen diagnoses. For patients with late-presenting TGA, we have opted for an arterial switch operation with left ventricular retraining, as the literature supports less long-term morbidity with an arterial switch operation than with an atrial switch operation [1]. We report here our experience with retraining of the LV in late-diagnosed TGA with the adaptable PAB and compare it with our results with the classic band technique.

Patients and Methods

The study was approved and patient consent was waived by our institutional ethics committee.

The FloWatch-PAB is a telemetrically adaptable device consisting of a micromotor that moves a piston covered by a silicone membrane up and down, thus squeezing or unsqueezing the PA. The device is clipped around the PA by a hinge piece (Fig 1A). The micromotor is activated by impulses received through an external antenna placed on the child's chest. A memory card inserted into the control unit stores the data of each device (Fig 1B). The detailed functioning of the device has been described in previous publications [9, 10]. The device is designed for infants weighing between 3 and 10 kg. Since the availability of the adaptable band (FloWatch-PAB) in 2003, 4 consecu-

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Address correspondence to Dr Sekarski, Department of Pediatric Cardiology, University Hospital, Rue du Bugnon 11, CH-1011 Lausanne, Switzerland; e-mail: nicole.sekarski@chuv.ch.

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Abbreviations and Acronyms

ASD = atrial septal defect
BT = Blalock-Taussig
CPB = cardiopulmonary bypass
LV = left ventricle
PA = pulmonary artery
PAB = pulmonary artery band
PDA = patent ductus arteriosus
RV = right ventricle

tive patients with simple TGA underwent its implantation at our institution (group 1). Their mean age at implantation was 11.66 ± 11.1 months with a mean weight of 5.8 ± 2.36 kg and a mean body surface area of 0.31 ± 0.08 m^2. Before 2003, 6 consecutive patients with simple TGA and an involuted LV underwent classic PAB placement (group 2). Their mean age at PAB was 6.3 ± 7.6 months with a mean weight of 5.0 ± 2.3 kg and a mean body surface area of 0.28 ± 0.09 m^2. Patients from both groups had an initial echocardiogram before band placement, which showed a decrease in left ventricular posterior wall thickness and a pancaked appearance of the LV consistent with low pressure in the LV. In some cases, a cardiac catheterization was performed, confirming that left ventricular pressure was less than half of right ventricular pressure. In both groups, the PAB was placed through a median sternotomy. In group 1, the adjustable band was placed around the PA and was not tightened (5% closure) in the operating room. None of these patients needed additional procedures during or after band placement and therefore none of these patients required cardiopulmonary bypass (CPB). The band was tightened thereafter by 10% on an ambulatory weekly basis with concomitant echocardiographic measurement of the pulmonary Doppler gradient, the left ventricular posterior wall thickness, and left ventricular function. Oxygen saturations were measured during tightening, with a lowest accepted saturation of 70%. If the saturation decreased to less than 70% or if left ventricular function diminished during tightening, the band was reopened to its previous value and was retightened a week later. After all band adaptations, the patient was observed for an hour before being discharged. The aim of band tightening was to progressively achieve a left ventricular pressure greater than two thirds of the systemic pressure.

In group 2, the band was tightened in the operating room to achieve a pulmonary gradient between 40 and 70 mm Hg with oxygen saturations between 75% and 85%. If additional procedures were required to improve oxygenation, such as surgical enlargement of the atrial septal

A

B

Fig 1. (A) FloWatch-PAB is an adaptable pulmonary artery band consisting of a micromotor able to move a piston covered by a silicone membrane up and down. The device is clipped around the pulmonary artery by a hinge piece. The image on the left shows the FloWatch completely opened with the piston in its original position; the image on the right shows the FloWatch closed by the movement of the piston upwards which squeezes the pulmonary artery. (B) External antenna is placed on the child's chest with its control unit. This allows signals to be sent to the micromotor, enabling it to move the piston in either direction. Data of each device are stored on a microchip memory card inserted in the control unit.

defect (ASD) and Blalock-Taussig (BT) shunt, they were done during the same operation.

The arterial switch operation was performed in both groups when the left ventricular posterior wall thickness was greater than two thirds of the right ventricular anterior wall thickness and left ventricular pressure was greater than two thirds of right ventricular pressure. Cardiac catheterization was performed in all patients before the arterial switch procedure to measure right ventricular and left ventricular pressures.

Statistics were performed with STATA 11.0 (State Corp LP, College Station, TX). Descriptive variables were expressed as mean and standard deviations. All echocardiographic measurements except gradients were normalized for body surface area. Comparisons within the groups were done with a paired *t* test. Comparison between the 2 groups was done with the 2-sample Wilcoxon rank sum (Mann-Whitney) test. Freedom from reoperation between palliation and arterial switch operation was analyzed by the Kaplan-Meier survival estimate method and compared with the log-rank Wilcoxon test. A *p* value less than 0.05 was considered significant.

Results

Initial Evaluation Before Band Placement

Initial evaluation was done by echocardiography. Mean left ventricular wall thickness before banding was 12.2 ± 3.7 mm/m^2 for a mean right ventricular wall thickness of 20.9 ± 10.3 mm/m^2 in group 1 and a mean left ventricular wall thickness of 14.4 ± 8.8 mm/m^2 for a right ventricular wall thickness of 16.1 ± 4.2 mm/m^2 in group 2. Mean right ventricular and left ventricular diastolic diameters were 60.9 ± 23.3 mm/m^2 and 75 ± 8.3 mm/m^2, respectively, for group 1 and 57.2 ± 16.8 mm/m^2 and 78.4 ± 36.7 mm/m^2, respectively, for group 2. There were no statistically significant differences between the 2 groups as to right and left ventricular wall thickness or diameter measured by echocardiography before band placement.

Pulmonary Artery Band Placement and Associated Procedures

In group 1, the adaptable band was placed around the main PA without CPB, with a mean surgical time of 61 minutes (15–100 minutes). No additional procedures were necessary at band placement and no complications caused by device injury were noted.

In group 2, 5 of the 6 patients underwent CPB for PAB placement because 8 associated procedures had to be performed during the surgical procedure to improve oxygenation: ASD creation in 5 patients, BT shunt in 3 patients, and patent ductus arteriosus (PDA) ligation in 1 patient. Three of these patients needed a combination of ASD enlargement and BT shunt or PDA ligation. CPB time ranged from 17 to 70 minutes depending on the associated procedure. Total surgical time in this group was 203 minutes (130–420 minutes).

Left Ventricular Retraining Period (From Band Placement to Arterial Switch Operation)

No patient in group 1 required reoperation between band placement and arterial switch operation. Retraining was achieved by progressive closure of the device. The FloWatch-PAB was closed between 5 and 8 times per patient. In 3 patients, no reopening had to be performed, and 1 patient underwent 3 reopenings during the retraining period. No technical difficulties were encountered on closure or opening of the device in any patient.

Four patients in group 2 needed reoperation between palliation and arterial switch operation, mostly to adjust the tightening of the band or to improve oxygenation. Two patients needed 2 reoperations. One patient needed

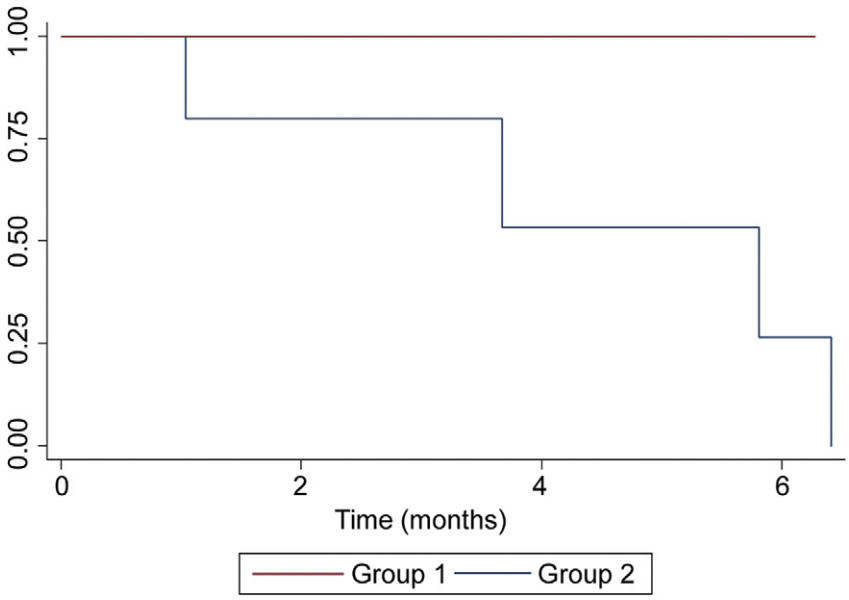

Fig 2. Kaplan-Meier freedom from reoperation between band placement and arterial switch operation.

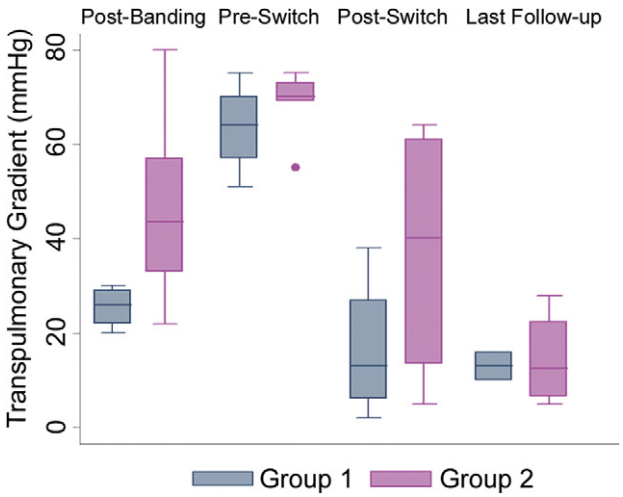

Fig 3. Evolution of pulmonary gradient 24 hours after banding, before the switch procedure, after the switch procedure, and at last follow-up for group 1 and group 2.

a partial shunt closure 3 weeks after the initial operation and then underwent a coarctation repair because with increasing flow through his aorta, a previously mild isthmic gradient became significant. One patient had a reopening of the band in the first 24 hours and then needed rebanding 1 month later. One patient needed rebanding 2 weeks after the initial band placement, and 1 patient needed shunt placement within 24 hours of band placement. Mean time between band placement and first reoperation was 8.75 ± 9.84 days and mean time between band placement and second reoperation was 54 ± 26.86 days. Figure 2 shows the freedom from reoperation in the 2 groups during the LV retraining period.

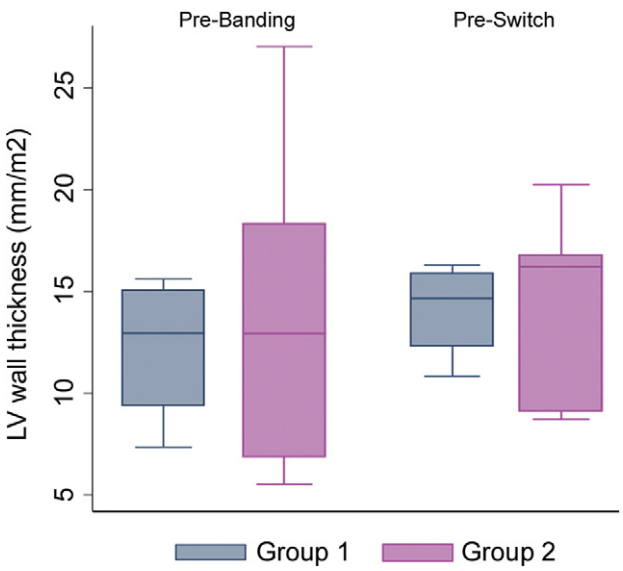

Fig 4. Increase in left ventricular (LV) posterior wall diameter from before banding to before the switch operation (normalized for body surface area).

Table 1. Right and Left Ventricular Pressures at Catheterization Before Switch Procedure (mm Hg)

	Patient	RVPs	RVPd	LVPs	LVPd
Group 1	1	75	10	65	7
	2	79	4	110	5
	3	76	7	70	5
	4	79	14	74	12
Mean (SD)		**77 (2)**	**8 (4)**	**80 (21)**	**7 (3)**
Group 2	1[a]				
	2	101	17	89	15
	3	76	6	83	10
	4	74	11	59	10
	5	72	12	83	11
	6	80	14	80	14
Mean (SD)		**81 (12)**	**12 (4)**	**79 (12)**	**12 (2)**

[a] Patient died 24 hours after banding.

LVPd = left ventricular diastolic pressure; LVPs = left ventricular systolic pressure; RVPd = right ventricular diastolic pressure; RVPs = right ventricular systolic pressure.

Outcome After Palliation

There was no death in group 1 after palliation. One patient in group 2 died 24 hours after palliation of low cardiac output. The initial mean gradient after banding measured within the first 24 hours after band placement was 25.5 ± 4.43 mm Hg in group 1 and increased to 63.5 ± 9.8 mm Hg before the switch procedure. In group 2, the initial band gradient after banding was 49.2 ± 21.4 mm Hg and 68.4 ± 7.86 mm Hg before the switch procedure (Fig 3). The initial gradient across the PAB was lower in group 1 than in group 2. The difference is explained by the fact that in group 1, the band was not tightened in the operating room. The gradient before the switch operation was not significantly different in the 2 groups. All patients showed an increase in left ventricular posterior wall thickness between band placement and the arterial switch procedure; however it was not statistically significant ($p = 0.07$) (Fig 4).

Switch Operation

Between the PAB placement and arterial switch operation, a mean time of 144 ± 41.5 days elapsed in group 1 and a mean time of 109 ± 73.62 days elapsed in group 2. Mean age at switch operation was 16.48 ± 14.77 months in group 1 and 11.04 ± 9.51 months in group 2. Mean weights and body surface area were 7.72 ± 1.8 kg and 0.36 ± 0.06 mm/m^2 for group 1 and 7.06 ± 3.43 kg and 0.33 ± 0.1 mm/m^2 for group 2. No significant differences between the 2 groups were noted. Echocardiographic measurements, pulmonary gradients, and hemodynamic measurements such as right ventricular and left ventricular systolic and diastolic pressures (Table 1) before the arterial switch operation were similar in the 2 groups. All patients in group 1 and 5 patients in group 2 underwent the arterial switch procedure. No complications were

encountered on removal of the FloWatch-PAB. No patient in either group needed pulmonary trunk plasty during the intervention, and 1 patient in group 2 had a right pulmonary arterioplasty at the site of the BT shunt.

Outcome After Arterial Switch

There were no deaths in group 1. One patient in group 2 died on postoperative day 7 while receiving extracorporeal membrane oxygenation for multiorgan failure. Pulmonary artery gradient 24 hours after the switch operation was lower in group 1 than in group 2 because with the FloWatch-PAB, the PA reexpands as soon as it is taken off the artery. However the pulmonary gradient in group 2 decreased to similar levels at last follow-up (14.5 ± 10.34 mm Hg in group 2 and 13 ± 3.4 mm Hg in group 1) (Fig 3). Mean follow-up time for all patients was 19.78 ± 17.7 months. Thus survival for the 2-stage switch operation at time of follow-up was 100% for group 1 and 66.6 % for group 2. There were no late deaths in either group of patients.

Comment

The arterial switch operation has changed the management of TGA. It not only allows an instant correction instead of palliation but also provides a long-lasting future with a normal quality of life based on a normal functioning systemic LV. Unfortunately there are 2 groups that do not qualify: those who present late and the large group of older patients who have undergone an atrial switch procedure. Both have a LV that will not sustain systemic pressure after an arterial switch procedure. Retraining of the LV with PAB placement is the only possibility described in this situation [6–8]. Our study demonstrates that a gradual closure with the FloWatch-PAB offers the possibility of optimal tightening of the band because it can be adjusted as needed and allows the LV to progressively adapt to an increased pressure load. It thus also obviates the necessity of additional procedures that often require CPB, such as ASD enlargement and BT shunts, as well as the need for second or third operations to optimize band tightening, as became necessary in most of our patients with conventional bands. In 1 case of conventional banding, the LV did not tolerate the acute pressure load at all, and this patient died 1 day postoperatively. In the FloWatch-PAB group no death occurred; immediately postoperatively the FloWatch-PAB was minimally closed (5%), allowing the patient to recover from the operation. Thereafter the gradual closing of the device allowed the LV to adapt slowly to the increasing pressure load and in case of left ventricular failure, the band could be loosened immediately. An additional advantage was that, unlike in the traditional PAB, no residual gradient over the new PA was noted after the arterial switch operation, and reconstruction of the PA was not necessary. Hemodynamic measurements were completely comparable in both types of banding; patients from both groups reached the same LV adaptation and were able to undergo a switch procedure, but the adaptable band allowed for a more progressive adjustment, with the advantage that no associated procedure or redo operation was warranted in these patients.

A major category of patients who might in the future benefit from an adaptable PAB are patients with a failing systemic right ventricle, in particular patients with TGA after an atrial switch procedure (Senning or Mustard procedure) and patients with congenital corrected transposition. This retraining technique was advocated by Mee and colleagues in the late 1980s [11]. They included 39 patients with a median age of 10 years [12]. Ten patients responded unfavorably to LV reconditioning, but 29 patients underwent a 2-stage switch procedure; there were 5 early deaths and 18 long-term survivors, all of whom were asymptomatic with good or mildly decreased left ventricular function. They concluded that this technique is an alternative to cardiac transplantation. Another study by Winlaw and colleagues in Birmingham [13] included 41 patients with systemic right ventricles; the intention was to retrain the LV in preparation for an anatomic correction. Only 33 patients underwent PAB placement. Sixteen patients were able to have an anatomic repair after PAB placement, 8 patients had a PAB but did not achieve anatomic repair, 5 patients died, 2 patients underwent cardiac transplantation, and 2 patients had other procedures performed. It should be noted that 13 patients had to undergo rebanding before anatomic correction, 1 patient had to have the band loosened, and all patients who had a successful anatomic conversion were younger than 16 years of age. The conclusion was that it was possible to retrain the LV, especially in younger patients, but that it was difficult to achieve an optimal tightening of the PAB and that maybe other types of band should be designed.

Although our study was performed in small children, we strongly believe that this technique could be used for all patients with failing right ventricles. In view of the increasing group of adults with failing systemic right ventricle after Mustard or Senning operations and the persistent shortage of donors for cardiac transplantation, it seems desirable to pursue the further adaptation of this device for the adult population.

Limitations

Limitations of this study are mostly due to the small number of patients, which could be the reason for the absence of statistical difference in the groups. Also there is a lack of long-term follow-up because the majority of these patients returned to the country of origin and thus were lost to our follow-up.

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