Early Clinical Results of the Telemetric Adjustable Pulmonary Artery Banding FloWatch-PAB

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Background—Adjustment of pulmonary artery banding (PAB) may be a challenging procedure in complex congenital heart defects. Whatever the technique used, subsequent re-operations are frequently needed to control the pulmonary blood flow or pressures.

Objective—To report the efficacy of a new telemetric adjustable PAB (FloWatch-PAB) operated with the help of an external control unit that transmits to the implant energy and commands to further narrow or release the pulmonary artery using radiofrequency waves.

Methods and Results—In a multicenter, prospective, nonrandomized, single-arm clinical investigation, 13 children (median age, 4.5 months; range, 6 days to 11 years; median weight, 4.2 kg; range, 3.1 to 27kg) underwent implantation of the FloWatch-PAB through median sternotomy in 8 and left thoracotomy in 5. The diagnosis was multiple ventricular septal (VSD) defects with complex anatomy in 3, single ventricle without pulmonary stenosis in 2, VSD with elevated pulmonary vascular resistance (PVR) in 2, atrio-ventricular canal (AVC) with elevated pulmonary vascular resistance in 1, AVC with diminutive right ventricle in 1, complex transposition of the great arteries in 3, and pulmonary atresia with complex pulmonary arteries anatomy in 1. All patients had normosystemic systolic pulmonary artery pressure. Additional procedures were performed in 7: atrial septectomy in 2, double aortic arch division in 1, patent ductus arteriosus ligation in 2, and coarctation repair in 2. There were no early or late deaths or device-related complications in a mean follow-up of 24 weeks (range, 18 to 42 weeks). A mean of 5.8 telemetric regulations per patient using the FloWatch-PAB were required to adjust the tightening of the PAB to the clinical needs (narrowing 74%, releasing 26%). At last follow-up, systolic pulmonary artery pressure was within normal range in all patients but 1. Systemic oxygen saturation demonstrated optimal regulation of the pulmonary blood flow in all according to each specific defect. Four patients were successfully corrected (VSD closure, AVSD repair, and 2 arterial switches with VSD closure). The device was easily removed and the pulmonary artery re-expanded spontaneously.

Conclusion—This new device is safe and allows optimal adjustment of PAB in complex heart defects. In children requiring PAB, the use of this technology can obviate the need for early re-operations and appears to be a valuable option in the panel of surgical alternatives for selected infants. (Circulation. 2004;110[suppl II]:II-158–II-163.)

Key Words: congenital heart defects ■ pulmonary artery banding ■ adjustable device
The concept of adjustable PAB using inflatable balloons has already been developed in previous experimental and clinical studies. In this study, we used the same concept of progressive inflation of a silicone membrane in an implantable, telemetrically controlled, battery-free device (FloWatch-PAB; EndoArt S.A.; Figure 1), allowing for repeated adjustment of the percentage of occlusion through a remote control. Experimental studies in the minipigs gave encouraging results. Feasibility and safety of the FloWatch-PAB implantation in children have been reported previously. We report here the clinical outcome of a series of 13 infants and children who underwent a FloWatch-PAB implantation as an alternative to standard banding in a variety of congenital heart defects.

Methods

Patients

Patients characteristics are summarized in Table 1. The Institutional Ethical Committees of each hospital has been obtained. Informed consent was obtained from the parents of all children enrolled in the study. Indications for the device implantation were based on the judgment of the clinicians involved, because the inclusion criteria were the same as for standard PAB.

Median age was 4.5 months (range, 6 days to 31 months); median weight was 4.2 kg (range, 3.2 to 27 kg). All patients had normosystolic systolic pulmonary artery pressure with elevated pulmonary vascular resistance measured during right heart catheterization (PVR) in 3 and there was low PVR in the remaining 10 patients. Indications for the implantation of the FloWatch-PAB were elevated pulmonary vascular resistance in 3 patients (patients 1, 2, and 11) who had a large ventricular septal defect and a complete atrioventricular septal defect, respectively. Patients 1 and 2 were referred late because they originated from developing countries with no pediatric cardiology facilities. The ratio of pulmonary vascular resistance/systemic vascular resistance was 0.6 (patient 1) and 0.5 (patient 2), and the ratio of pulmonary blood flow/systemic blood flow was 1.5 in patient 1 and 1 in patient 2. Inhalation of oxygen and nitric oxide demonstrated a decrease in pulmonary vascular resistance in both, but it was considered unsafe to perform the complete repair without probative testing of the evolution of the pulmonary vascular resis-

### Table 1. Characteristics of the Patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Diagnosis</th>
<th>Age (mo)</th>
<th>Weight (kg)</th>
<th>Surgical Access</th>
<th>Additional Procedures</th>
<th>Final Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>VSD–elevated PVR</td>
<td>31</td>
<td>11.6</td>
<td>S</td>
<td></td>
<td>VSD closure</td>
</tr>
<tr>
<td>2</td>
<td>AVSD–elevated PVR</td>
<td>18</td>
<td>7.1</td>
<td>S</td>
<td></td>
<td>AVSD repair</td>
</tr>
<tr>
<td>3</td>
<td>Multiple VSD–double aortic arch</td>
<td>4.5</td>
<td>6.4</td>
<td>T</td>
<td>Division of double aortic arch</td>
<td>—</td>
</tr>
<tr>
<td>4</td>
<td>Multiple VSD–PDA</td>
<td>2</td>
<td>4.2</td>
<td>S</td>
<td>PDA ligation</td>
<td>—</td>
</tr>
<tr>
<td>5</td>
<td>Multiple VSD–PDA</td>
<td>6.5</td>
<td>6.8</td>
<td>T</td>
<td>PDA ligation</td>
<td>—</td>
</tr>
<tr>
<td>6</td>
<td>Right isomerism, single ventricle, TAPVR</td>
<td>7.5</td>
<td>6.1</td>
<td>S</td>
<td>Atrial septectomy, PDA ligation</td>
<td>—</td>
</tr>
<tr>
<td>7</td>
<td>Hypoplastic left heart, VSD</td>
<td>1.5</td>
<td>3.5</td>
<td>S</td>
<td></td>
<td>Atrial septectomy</td>
</tr>
<tr>
<td>8</td>
<td>AVSD–diminutive RV</td>
<td>1</td>
<td>3.5</td>
<td>T</td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>9</td>
<td>TGA–VSD</td>
<td>0.3</td>
<td>3.5</td>
<td>S</td>
<td></td>
<td>Arterial switch + VSD closure</td>
</tr>
<tr>
<td>10</td>
<td>PA–VSD, LPA from aorta, right MAPCAs</td>
<td>131</td>
<td>27</td>
<td></td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>11</td>
<td>VSD–elevated PVR</td>
<td>5.5</td>
<td>3.2</td>
<td>S</td>
<td></td>
<td>—</td>
</tr>
<tr>
<td>12</td>
<td>DORV–Multiple VSD–Coa-diminutive RV</td>
<td>0.2</td>
<td>3.5</td>
<td>T</td>
<td>Coa repair</td>
<td>—</td>
</tr>
<tr>
<td>13</td>
<td>TGA–VSD–Coa-complex coronary anatomy</td>
<td>0.2</td>
<td>3.3</td>
<td>T</td>
<td></td>
<td>Arterial switch + VSD closure</td>
</tr>
</tbody>
</table>

VSD indicates ventricular septal defect; PVR, pulmonary vascular resistance; S, sternotomy; AVSD, atrioventricular septal defect; T, thoracotomy; PDA, patent ductus arteriosus; TAPVR, total anomalous pulmonary venous return; RV, right ventricle; TGA, transposition of the great arteries; PA-VSD, pulmonary atresia ventricular septal defect; LPA, left pulmonary artery; MAPCAs, major aorto-pulmonary collateral arteries; Coa, coarctation.
tance after banding. Patient 11 had elevated PVR associated with bronchopulmonary dysplasia. In 3 patients with multiple ventricular septal defects (patients 3, 4, 5), pulmonary artery banding was proposed because primary repair was not possible. In 3 patients, the banding was required because a total cavopulmonary connection was considered in 2 (patients 6 and 7), and a likely 1.5 ventricle repair was considered in the remaining patient (patient 8). The parents of patient 9 initially refused cardiopulmonary bypass. In patient 10, the device was implanted on a major aorto-pulmonary collateral artery without stenosis at its origin. In the remaining patients (patients 12 and 13) who had transposed great vessels, the device was implanted because the anatomy and the associated coarctation of the aorta appeared to complex for a primary repair during the neonatal period.

**Surgical Procedure**

The implantation of the FloWatch-PAB was performed through a median sternotomy in 8 and through a left thoracotomy in 5. Additional procedures were performed in 7 (Table 1). No technical difficulties were encountered during implantation. All functional tests in the operating room were successfully completed. The coupling criteria (Figure 2) were checked in the operating room.

**Results**

There was no early or late death during follow-up. Median intensive care unit stay was 1 day (range, 1 to 12 days). No re-operations or complications that were device-related were noticed during a mean follow-up of 13 months (range, 4 to 12 months). Echographic and radiographic examinations showed no evidence of migration or rotation of the device in all patients (Figure 3).

**FloWatch-PAB Regulations**

A mean of 5.8 regulations per patient (range 1 to 14) was required to adjust the tightening of the banding to the clinical needs. Table 2 gives a summary of the number of FloWatch-PAB regulations performed. Early regulations include tightening or release of the PAB during hospital stay. Late regulations were performed after hospital discharge. Indications for regulations were based on estimation of the Doppler gradient across the PAB and on systemic oxygen saturation. Pressure gradient was considered adequate at last regulation when the maximum Doppler velocity across the PAB was >4 m/second. Systemic oxygen saturation was considered adequate when >80% in patients with parallel circulation and complete mixing, and when >70% in patients with transposition. In 74% of the cases, the regulation was required to increase the degree of pulmonary artery constriction. It is notable that only 4 of 13 patients required only increased tightening (Table 2). In the remaining 9, release of the banding was necessary at least once: during emergency in 3 cases (postoperative severe cyanosis in 2 [patients 8 and 9] and during the control catheterization procedure in patient 1) in a programmed fashion in the 2 patients with a single-ventricle physiology to delay the time of the cavopulmonary connection and to optimize the pulmonary blood flow, and during follow-up in the remaining 4. These 9 of 13 patients needed a bi-directional adjustment of their banding during the follow-up.

**Hemodynamic Condition at Last follow-up**

All patients were doing well at last follow-up. Patient 1 underwent uneventful closure of his ventricular septal defect 3 months after FloWatch-PAB implantation. Preoperative catheterization showed a normal pulmonary artery pressure (mean pulmonary artery pressure 16 mm Hg), and the ratio of the pulmonary vascular resistance/systemic vascular resistance was estimated to be <0.2. The explanted device was still functioning. Echocardiography 4 months after surgery showed a normal pulmonary artery trunk and systolic pulmonary artery pressure was 38 mm Hg. Patient 2 also underwent catheterization. Mean pulmonary artery pressure was 30 mm Hg, decreasing at 20 mm Hg with nitric oxide inhalation, and the ratio of PVR/SVR was 0.25. She underwent a successful complete repair 9 months after implantation. Patient 9 had to undergo the arterial switch operation with VSD closure 6 days after FloWatch-PAB implantation because echocardiography showed a pulmonary valve regurgitation caused by proximal implantation of the device. Patient 13 underwent a successful arterial switch operation.
TABLE 2. Regulation of the FloWatch-PAB and Hemodynamic Condition at Last Follow-up

<table>
<thead>
<tr>
<th>Patient</th>
<th>N of Regulations</th>
<th>Tightening of the Band</th>
<th>Releasing of the Band</th>
<th>Final Stroke of the Banding (%)</th>
<th>Follow-up (mo)</th>
<th>Max Doppler Gradient at Last Follow-up (mm Hg)</th>
<th>Transcutaneous Oxygen Saturation at Last Follow-up (%)</th>
<th>Estimated or Measured Pulmonary Artery Pressure (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6</td>
<td>Early 1 Late 1</td>
<td>Early 2 Late 2</td>
<td>45</td>
<td>6.7</td>
<td>80</td>
<td>98</td>
<td>24/10 mean 16*</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>Early 0 Late 0</td>
<td>Early 0 Late 0</td>
<td>55</td>
<td>12</td>
<td>65</td>
<td>97</td>
<td>40/18 mean 30*</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Early 0 Late 0</td>
<td>Early 0 Late 0</td>
<td>70</td>
<td>9.5</td>
<td>73</td>
<td>98</td>
<td>Systolic pressure 35†</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>Early 1 Late 0</td>
<td>Early 0 Late 0</td>
<td>0</td>
<td>7</td>
<td>55</td>
<td>97</td>
<td>Systolic pressure 30</td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>Early 1 Late 0</td>
<td>Early 0 Late 0</td>
<td>25</td>
<td>8.5</td>
<td>65</td>
<td>85</td>
<td>37/12 mean 25*</td>
</tr>
<tr>
<td>6</td>
<td>4</td>
<td>Early 1 Late 1</td>
<td>Early 1 Late 1</td>
<td>30</td>
<td>8</td>
<td>60</td>
<td>82</td>
<td>Systolic pressure 25</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>Early 3 Late 1</td>
<td>Early 0 Late 1</td>
<td>60</td>
<td>8</td>
<td>55</td>
<td>87</td>
<td>Systolic pressure 28</td>
</tr>
<tr>
<td>8</td>
<td>14</td>
<td>Early 7 Late 3</td>
<td>Early 2 Late 2</td>
<td>40</td>
<td>4</td>
<td>44</td>
<td>82</td>
<td>Systolic pressure 21</td>
</tr>
<tr>
<td>9</td>
<td>10</td>
<td>Early 5 Late 1</td>
<td>Early 4 Late 0</td>
<td>75</td>
<td>11</td>
<td>74</td>
<td>93</td>
<td>Systolic pressure 25</td>
</tr>
<tr>
<td>10</td>
<td>5</td>
<td>Early 4 Late 0</td>
<td>Early 1 Late 0</td>
<td>60</td>
<td>7</td>
<td>-</td>
<td>82</td>
<td>—†</td>
</tr>
<tr>
<td>11</td>
<td>10</td>
<td>Early 3 Late 4</td>
<td>Early 1 Late 2</td>
<td>45</td>
<td>7</td>
<td>20</td>
<td>77</td>
<td>Systolic pressure 52</td>
</tr>
<tr>
<td>12</td>
<td>4</td>
<td>Early 3 Late 0</td>
<td>Early 0 Late 0</td>
<td>40</td>
<td>7</td>
<td>72</td>
<td>72</td>
<td>16/8 mean 12*</td>
</tr>
<tr>
<td>13</td>
<td>5</td>
<td>Early 5 Late 0</td>
<td>Early 0 Late 0</td>
<td>85</td>
<td>7</td>
<td>43</td>
<td>80</td>
<td>35/7 mean 17*</td>
</tr>
</tbody>
</table>

*Measured pressures during catheterization.
†Estimated systolic pulmonary artery pressure by using Doppler velocity through the pulmonary artery banding.
‡No measure available.

and VSD closure at age 5 months. The pulmonary artery re-expand completely after removal of the device in all patients. Estimated systolic pulmonary artery pressure was within normal range in all remaining patients (mean, 23±5 mm Hg). In patient 10, the exact pulmonary artery pressure in the collateral artery is not available.

Technical Limitations Encountered

In 2 patients (patients 2 and 8), the controls at 3 months revealed that the telemetric coupling between the implant and the external antenna was difficult. This problem was solved in patient 8 in whom the last regulation had to be performed under general anesthesia but could not be solved in patient 2. In this patient, the coupling criteria were not fulfilled because of the growth of the patient during follow-up. At that time, she was suitable for complete repair and no further regulation of the banding was required.

Discussion

The main problem encountered in PAB implantation is the difficulty for the surgeon to determine the optimal perimeter of the band during the surgical procedure. Various mathematical formulae have been proposed to adapt the diameter of the band to the child weight and/or to the underlying heart defect. The use of these measures has proven to be useful as a starting point for banding but does not allow immediate postoperative adjustment or midterm regulations. Achieving an appropriate tightness of the band can be explained by Poiseuille’s law that predicts that blood flow is related to the fourth power of the radius of the vessel; therefore, a minor change in the diameter of the banding has a large impact on flow and pressure gradient across the band site. Further, the diameter is not the only factor influencing the flow. Mechanical ventilation, chest opening, heart rate, acid base status, viscosity, pulmonary and systemic vascular resistances, etc, play an important role. Different devices have been developed to bypass these difficulties during the postoperative period. Most of the reported devices have been used in experimental studies and only a few bi-directional chronic adjustable bands have been developed for human use.

Our study shows that our device helped to overcome these problems during the postoperative days. There was no need to adjust the band during operation and the first regulation to tighten it was performed in the intensive care unit under echocardiographic control in a patient in stable condition. Median intensive care unit stay was very short and only 1 patient with single ventricle physiology required angiotensin-converting enzyme (ACE) inhibitors at hospital discharge for tricuspid valve regurgitation. For the 4 patients who required only tightening of the banding, a standard PAB would have been certainly adequate. However, patient 2 had increase pulmonary vascular resistances and tolerance of an acute banding was not predictable. Patient 5 had a peculiar double outlet right ventricle and we were concerned about a major increase of the cyanosis after banding. In the remaining 2 patients, we speculated that spontaneous closure of the ventricular septal defects will not occur rapidly and, consequently, we intended to release the band when it became too tightened during the child growth. We did not have to do it during the follow-up in these 2 patients but we may take advantage of this possibility to delay the complete repair if a right-to-left shunt appears when the patient is still not suitable for surgery.

A bi-directional chronic adjustable banding is also a seductive approach for patients with single-ventricle physiology. Maintaining suitability for a subsequent cavopulmonary shunt requires an early banding of the pulmonary artery when there is no pulmonary stenosis. In our 2 patients, we were able to improve hypoxemia and to delay the date of the...
second palliative procedure by releasing the banding after a few months. Both will probably undergo a bi-directional cavopulmonary shunt in a few months and subsequent releases of the band could delay the date of the total cavopulmonary connection by maintaining additional blood flow to the pulmonary artery. In patients with transposed great vessels, optimal regulation of the pulmonary blood flow is often difficult to perform with a conventional banding and additional aorto-pulmonary shunts might be required. In 2 of our 3 cases, implantation of the FloWatch-PAB was performed because the complete repair was considered at high risk during the neonatal period and the postoperative course was uneventful. Progressive tightening of the banding may be necessary to retrain the subpulmonary ventricle after atrial repair of transposition of the great arteries or in congenitally corrected transposition of the great arteries. Sequential bandings are often necessary to prepare the subpulmonary ventricle to support the systemic circulation because of the reduced capacity of the myocardium to respond to chronic pressure overload in older patients. Reconditioning of the left ventricle might be easier with a soft progressive tightening made possible by telemetric adjustments of the band. It could also be proposed in neonates with congenitally corrected transposition of the great arteries and tricuspid valve regurgitation. In this situation, restoring a flat ventricular septum geometry that reduces tricuspid regurgitation may be an alternative to combined neonatal arterial and atrial switch operation. Finally, preparation of the left ventricle for anatomical correction in patients with simple transposition of the great arteries referred too late is also a challenge because it requires both increasing in left ventricle afterload and adequate mixing. The most frequently chosen approach was to associate a loose PAB with a systemic-pulmonary shunt. Nonsurgical left ventricular preparation has also been successfully performed in this condition. Bi-directional adjustable banding could be useful for achieving optimal preparation.

Limitations of the FloWatch-PAB

While promising in various indications, we encountered difficulties with the telemetry in 2 patients. In these patients, the coupling criteria described in Figure 2 was no more fulfilled. It was not easy, however, to translate this limitation to either age or weight. In fact, the 2 patients in whom the telemetric control failed were not the oldest or the heaviest of the study. Both the anatomy of the chest and its changes with growth may modify the position of the center of the implant base from its initial position. For this reason, as the maximum distance between antenna and implant is 4 cm, we recommend to implant the FloWatch-PAB in patients between 3 and 10 kg. A larger implant with a deported subcutaneous antenna is undergoing development. This will solve the problem of the coupling criteria and make the device available for older patients. The second complication was pulmonary regurgitation in our patient 9, who had transposition of the great arteries and ventricular septal defect. The FloWatch-PAB regulations were successful in this patient and we obtained an optimal gradient with mild hypoxemia. But, after 5 days, the pulmonary valve became insufficient because of the proximal position of the device and we had to perform the anatomical correction to preserve the function of the future aortic valve. There was no neo-aortic valve regurgitation after the operation. Finally, the length of banding may lead to underestimating the pulmonary artery pressure, because simplified Bernoulli’s equation might overestimate the Doppler gradient through this wide banding. Notwithstanding this limitation, there was a correlation between the percentage of stroke and the Doppler gradient in all patients (not shown). The wide interindividual variability can be linked to the type of defect, the level of pulmonary vascular resistance, and the different consequences on pulmonary blood flow of the pulmonary artery constriction. Catheterization is mandatory in dubious cases because it will be with standard management.

Conclusion

Our study does not prove the clinical efficacy of the FloWatch-PAB compared with standard approaches. However, we believe that this is a promising technology that may facilitate postoperative care and avoid early re-operations in complex congenital heart defects. When larger sizes will be available and the telemetric control improved, the most interesting indication will probably be left ventricular training in older patients with transposition-intact ventricular septum or double discordance.

References

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FloWatch-PAB

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