Case Report

Telemetrically Adjustable Pulmonary Artery Banding: First Application in Greece

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We describe the first application in Greece of a telemetrically adjustable device for pulmonary artery banding (FloWatch®-PAB device) in a 2-month-old baby, weighing 3.6 kg, with congenital heart disease (complete atrioventricular septal defect with pulmonary hypertension). The surgical application of the device was easy, the postoperative course of the patient was smooth, and the telemetric regulation of the device was simple and effective. We believe that the FloWatch®-PAB device is suitable for most cases of pulmonary artery banding in congenital heart disease with pulmonary hypertension in infants and small children.

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For more than half a century, pulmonary artery banding (PAB) has been the common means for controlling excessive pulmonary blood flow in congenital heart diseases (CHD). Though technically a simple procedure, PAB poses acute changes in haemodynamics. The problems encountered in PAB are several:[1]

a) Difficulty in determining the optimal banding, since minor changes in the diameter of the main pulmonary artery (PA) may have a large impact on blood flow and pressure gradient across the PAB.
b) Influence of several perioperative variables with mutual interference related to general anaesthesia, positive pressure ventilation, chest opening (particularly with thoracotomy), etc.[2]
c) Difficulty in tightening the PAB sufficiently in children with pulmonary hypertension.
d) Frequent need for repeated operations to adjust the band perimeter, i.e. children outgrowing a banding that is becoming too tight.
e) Long periods of intensive respiratory and pharmacological interventions to control the pulmonary blood flow.
f) Frequent need for a reconstruction of the pulmonary artery at the time of debanding during total repair.

Several attempts have been made to overcome the above mentioned difficulties, and to invent an adjustable PAB that allows regulation during hours, days, or weeks after surgery. Five years ago, the FloWatch®-PAB device (EndoArt S.A., Lausanne, Switzerland) was used for adjustable PAB experimentally in mini-pigs, and soon thereafter in clinical practice.[3] The published positive early and long-term results of the use of the FloWatch®-PAB device in clinical practice,[1,4] as well as some personal experience of one of the authors from the use of this device at the Royal Liverpool Children's Hospital, prompted us to use it in our centre.

Case presentation

On 6 July 2007, a 40-day-old female infant, weighing 3.370 kg, was admitted to the Paediatric Department at "Aghia Sophia" Chil-

dren's Hospital because of vomiting and inadequate weight gain.

History

Born at 40 + 4 weeks of gestation with normal delivery, and weighing 3.8 kg, she was diagnosed to have Down's syndrome and congenital heart disease: atrioventricular septal defect with a large ventricular septal defect, mitral valve cleft with moderate mitral valve regurgitation, intact primum atrial septum, secundum atrial septal defect, and pulmonary hypertension. On her 9th day of life she was discharged from the maternity hospital on diuretics (furosemide, spironolactone) and digitalis (15γ bid), with body weight (BW) 3.380 kg, and saturation at room air: 95-98%.

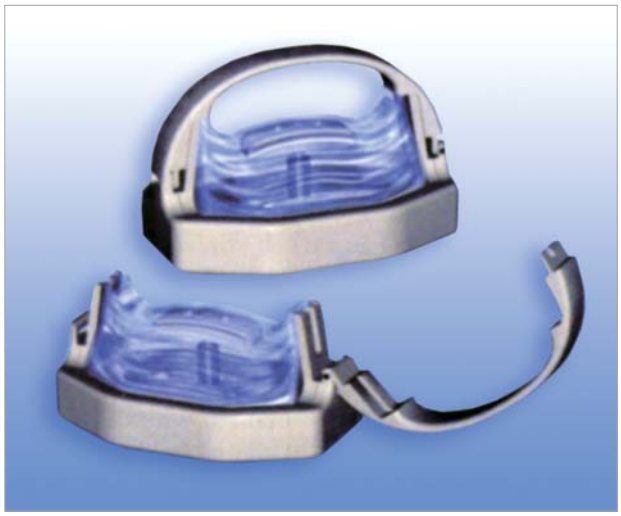

Figure 1. The FloWatch-PAB® device in open and closed position.

Presentation

The clinical examination at presentation had no striking finding apart from an active precordium and 3/6 systolic murmur on the left sternal border. The chest X-ray revealed "wet lungs". Laboratory test results were within normal limits. After 12 days of hospitalisation in the Paediatric Department, the child was transferred to the Cardiology Department for cardiac catheterisation and evaluation of her pulmonary hypertension. The catheterisation confirmed the echo diagnosis and revealed a pulmonary artery pressure (PAP) at 80% of systemic (PAP 50/25 mmHg vs. systemic blood pressure 60/30 mmHg).

A decision was made for palliative surgical treatment (pulmonary artery banding with a telemetrically adjustable device) because of severe pulmonary hypertension and the patient's failure to thrive.

The FloWatch®-PAB device

The FloWatch®-PAB (Figure 1) is an implantable, telemetrically controlled, battery-free device that allows repeated progressive closing and reopening of the device through a remote control to the required percentage of occlusion. The change in the adjustable area is achieved by a piston driven by an incorporated electric micromotor. The concave form of the adjustable area allows for changes of the area during compression, but the perimeter of the PA remains unchanged. This specific feature of the device design allows for long term use, i.e. reopening after several weeks or months of PA compression. The adjustable area in the completely open position corresponds to a PAB with a 30 mm PA perimeter, and in the completely closed position to a PAB with a 23 mm PA perimeter. The adjustment is achieved through an external control unit, which delivers the energy and commands via an antenna to drive the micro-engine. The size of the device is 26 × 18 × 18 mm.

Surgery

On 2 August 2007, surgery was performed (BW 3.6 kg). The approach was the usual one for conventional PAB. Through a median sternotomy, the thymus was subtotally excised for optimal exposure. The pericardium was opened over the great vessels with an inverted "T" incision. With minimal dissection, a tunnel was created between the ascending aorta and main PA, and with the aid of a 5.0 Prolene suture guiding the arm of the device around the back of the main PA, the Flo Watch®-PAB was put in place and clipped (Figure 2). Care was taken that the device should not compress surrounding structures, such as coronary arteries, PA branches, or bronchi. For that purpose, a polytetrafluorethylene membrane (Goretex®) was used to cover the pericardial opening over the great vessels. For safety reasons, the coupling between the control unit and the device was tested before chest closure and the device was closed to 30%. No change in blood pressure or saturation was noticed. The sternotomy was closed in the usual fashion.

The baby was extubated within two hours post surgery. On postoperative day (POD) 1, the device was closed to 40% under echocardiographic monitor-

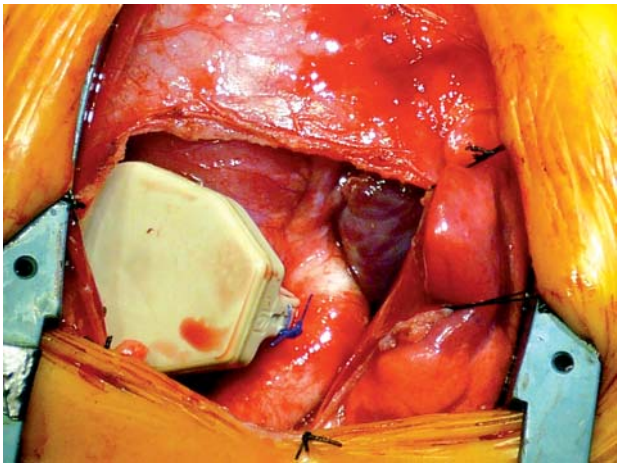

Figure 2. The FloWatch-PAB® device in place (the head of the patient is towards the top of the picture).

ing (Figure 3). The peak systolic pressure gradient across the PAB increased from 34.8 mmHg to 45 mmHg, and the mean pressure gradient from 17 mmHg to 21 mmHg. Saturation remained in the mid 90s on room air. On POD 2, a spike of temperature (39˚C), together with upper right lobe haziness on the chest X-ray and a C-reactive protein level of 152 iu, prompted removal of the central venous catheter, a blood culture (negative), as well as a change in the antibiotic protocol (meropenem + tazobactam / piperacillin in place of teicoplanin + netilmicin, for 10 days). The fever was not repeated, and infection indexes came down within two days. The postoperative course was otherwise uneventful. On POD 3, the child was transferred to the ward. She stayed there for 14 days, and an effort was made, successfully, to wean her from the nasogastric tube to full oral feeding. During her hospitalisation, the device was closed twice, reaching 70%. At this point the echocardiographic findings were: peak systolic pressure gradient across the PAB 51 mmHg, mean pressure gradient 25 mmHg, and transventricular mean pressure gradient across the ventricular septal defect 10 mmHg (almost equal pressures in both ventricles). Saturation was around 90% on room air; there was no pericardial fluid accumulation. The child was discharged on diuretics (furosemide 2 mg bid; spironolactone 2 mg bid), with a BW at 4.2 kg (Figure 4).

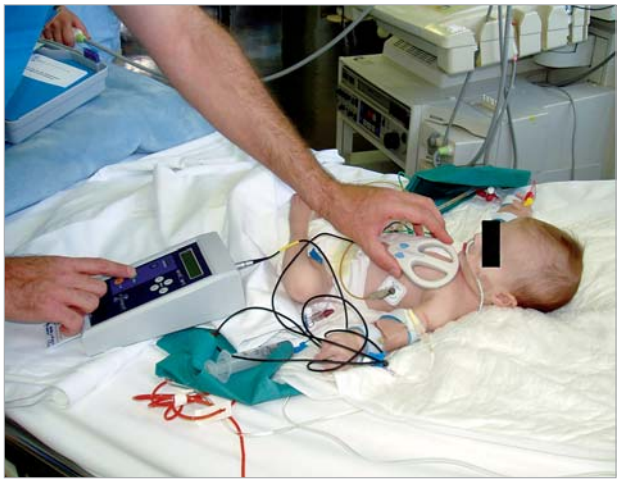

Figure 3. Regulation of the FloWatch-PAB® device at bedside under echocardiographic monitoring.

Follow up

On the latest follow-up at 6 months after surgery, the echocardiogram showed peak systolic pressure gradient across the PAB 76 mmHg, mean pressure gradient 45 mmHg, transventricular mean pressure gradient 10 mmHg; saturation was 90%. The device remained at 70% closure. The BW was 5.2 kg.

Discussion

The technical problems encountered in PAB were noted in the introduction to this report. It is therefore very difficult to predict the effectiveness of a conventional PAB. This can lead to either surgical reoperation for adjustment of the PAB, or prolonged respiratory and pharmacological support in the intensive care unit

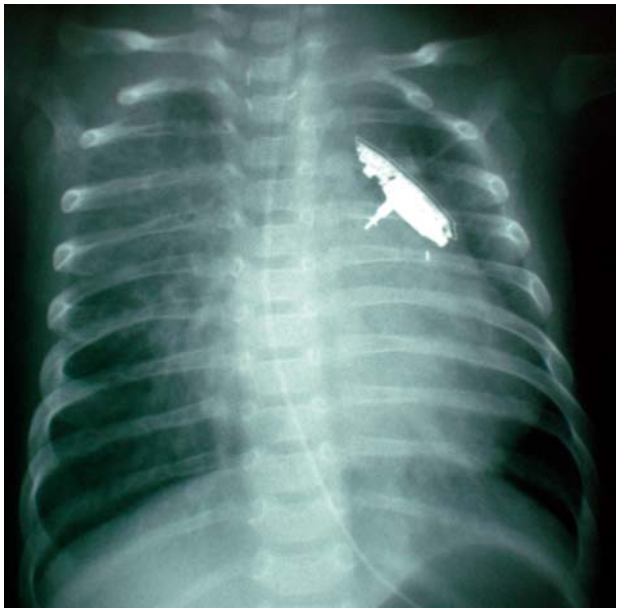

Figure 4. Chest X-ray with the FloWatch-PAB® device implanted.

(ICU) to control pulmonary blood flow; it is also the cause of considerable mortality (up to 15%[7]) following this "simple" procedure. The need for an adjustable PAB has been confirmed by the extensive experimental and clinical research in different institutions, which has resulted in 16 different techniques for an "adjustable banding" in the last 35 years.[1] However, none of these techniques or devices are reliable and capable of a precise, long-term, non-invasive adjustment of pulmonary blood flow.

The concept of the FloWatch®-PAB device is to allow PAB through a fast-track surgical procedure with the effective possibility of telemetric control of the pulmonary blood flow in a bidirectional way, i.e. decreasing and increasing the diameter of the PA, even a long time after implantation. Another advantage of this device is the maintenance of normal morphology and histology of the PA wall in conjunction with the narrowing, allowing for full distension of the PA after removal of the device, without stenosis, and therefore without PA reconstruction.[1,6] The reason is that the FloWatch®-PAB device reduces the diameter of PA by imparting a "banana" shape to the vessel, but not to the perimeter of the PA. The removal of the device at the time of the total repair is very easy using the special tool provided, which unclips the device.

The limitations of the FloWatch®-PAB technology are: 1) Its use is recommended in children with BW between 2.8 to 6 kg; in smaller children it cannot be accommodated within the chest; in bigger children, there may be problems in coupling between the device and the external antenna of the control unit, if the distance is more than 4 cm. 2) The cost can vary from 5 to 10,000 Euros per device, plus an annual fee of 2,800 euros for the control unit.

In a prospective comparative study at the Royal Liverpool Children's Hospital "Alder Hey", the patients with the FloWatch®-PAB device, compared to the patients with conventional PAB, had lower early mortality (zero vs. 15%), a shorter mean duration of mechanical ventilation, a shorter mean ICU stay and mean hospital stay, no redo PAB, and a lower cost of hospitalisation.[7]

In conclusion, the FloWatch®-PAB device represents an almost ideal means for PAB, because:

1. It is adjustable in both ways (tightening and loosening).
2. It can be regulated reliably and repeatedly by remote control for a long time after surgery (up to 3 years).
3. It is associated with practically no mortality, and reduced morbidity (no banding-related reoperations; reduced ICU/hospital stay).
4. It requires no reconstruction of the PA after debanding.
5. It can easily be incorporated in new therapeutic strategies (e.g. training of the left ventricle in transposition of great arteries).

Overall, this promising technology can largely replace conventional pulmonary artery banding.

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