JECT. 2008;40:65–67
The Journal of The American Society of Extra-Corporeal Technology

Use of a New Implantable Adjustable Pulmonary Artery Banding Device: A Report of Two Patients

Matthew C. Davis, LCCP, ECCP

Department of Cardiothoracic Anesthesia, Rigshospitalet, Copenhagen, Denmark

Abstract: Pulmonary artery banding (PAB) is a method for reducing pulmonary artery blood flow and pressure by tying a surgical band around the main pulmonary artery (MPA). Originally, the procedure was primarily performed to palliate intracardiac left to right shunts for ventricular septal defects (VSDs). Currently, the use of PAB has expanded to allow it to be used in ventricular training, prior to total corrective surgery. At the Rigshospitalet, Copenhagen, Denmark we have been trying a new device. The Flo-Watch PAB implant (EndoArt, Lausanne, Switzerland) is only currently available within certain European countries. The device is a mechanical PAB that allows noninvasive adjustment of the band post implantation, in an outpatient clinic. This has multiple advantages, not only in terms of convenience for the patient, and the reduced risk of multiple surgical interventions, but also from a financial standpoint to the health system. We would like to present our findings and comment on the use of the device in this report. **Keywords:** pulmonary artery, banding, palliation, mechanical device. *JECT. 2008;40:65–67*

Pulmonary artery banding (PAB) is a method for reducing pulmonary artery blood flow and pressure by tying a surgical band around the main pulmonary artery (MPA); this method was first described in 1952 (1).

Originally, the procedure was primarily performed to palliate intracardiac left to right shunts for ventricular septal defects (VSDs).

Currently, two main indications for PAB stand out: flow/pressure limitation in stage 1 single ventricle palliation and training of the left ventricle (LV) in a congenitally corrected transposition of the great arteries (CCTGAs) and previously arterial switch–operated d-transposition of the great arteries (D-TGA) patients in preparation for arterial switch/double switch procedures (2).

Adjusting the band in the operating room can be guided by a variety of measurements: pulmonary artery pressure (PAP), ventricular pressure, and arterial and venous saturations. However, once the band is fixed, further adjustments always need re-operation if the hemodynamics are unsatisfactory.

In fact, patients undergoing surgery in group 2 nearly always require repetitive reoperations to properly train the LV.

A new implantable device designed to allow fine degrees of adjustment to the band postoperatively has become available within certain countries in Europe. These adjustments can be made transcutaneously using only radio signals in much the same way one adjusts the settings of an implanted pacemaker. We used this device in two patients and report our experience.

Address correspondence to: M. Davis, LCCP, ECCP, Chief Perfusionist, Department 3043, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen, Denmark. E-mail: RH18246@rh.dk
The senior author has stated that authors have reported no material, financial or other relationship with any healthcare-related business or other entity whose products or services are discussed in this paper.

DESCRIPTION

The FloWatch-PAB implant (EndoArt, Lausanne, Switzerland) is a remotely adjustable device for restricting blood flow within the PA. It consists of four main components.

The case of the device contains the aerial, the electronics, and the micromotor, which drives the piston. The piston has a total stroke length of 3 mm for tightening and loosening the banding around the MPA.

A silicone membrane (0.25 mm thick) protects the piston and electronic components from bodily fluids while allowing for movement of the piston during adjustment. The membrane material was designed to avoid the formation of fibrous tissue, giving a soft non-abrasive surface to face the MPA. A counter piece was designed to be placed around the back of the MPA against which the piston operates (Figure 1).

The entire device measures 26 mm × 18 mm × 17 mm; the manufacturer recommends that the device only be used in patients weighing between 2.5 and 6 kg and whose MPA external diameter is between 10 and 20 mm. Currently, this is the only size of device available.

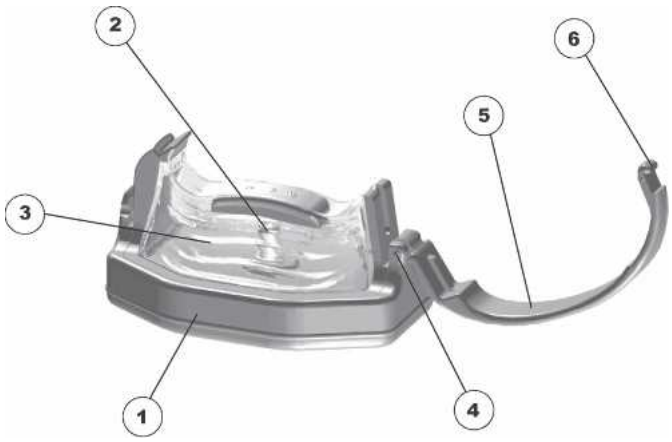

Figure 1. 1, casing; 2, piston; 3, silicone membrane; 4, hinge; 5, counter piece/clip; 6, locking clip.

When in position, the device has an orifice that varies between 72 and 38 mm^2; these values correspond with a conventional PAB with a diameter of between 9.6 and 6.9 mm (Figure 2). At the time of writing, this device is only commercially available within Europe for clinical use, and is CE marked.

METHODS

We thus far have implanted two devices, the details of the patients were as follows.

Patient 1: Diagnosis: Congenitally Corrected Transposition of Great Arteries, Multiple Ventricular Septal Defects, Congenital A-V block, Tricuspid valve Insufficiency
Weight: 5.9 kg
Sex: Male
Age at time of implant: 5 months
Date of Implant: August 2005

Patient 2: Diagnosis: Dextrocardia, Double Inlet Left Ventricle, Transposition of the Great Arteries, Non restrictive Ventricular Septal Defect
Weight: 2.975 kg
Sex: Male
Age at time of implant: 49 days
Date of Implant: July 2006

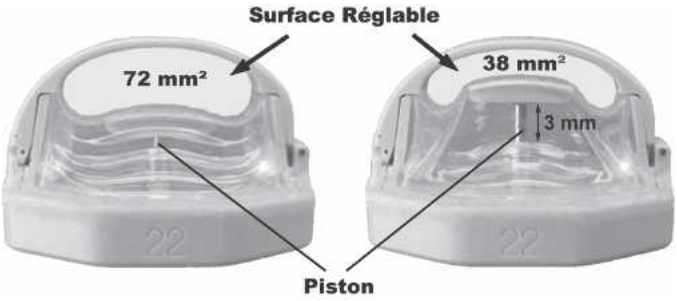

Figure 2. PAB device in both fully open and fully occlusive positions.

Both procedures were done through a median sternotomy for ease of access because of the size of the patient and the complex anatomy. However, a thoracotomy approach may be used in more straightforward situations.

The MPA was visualized and dissected free as per a normal PAB operation; the clip was passed around the back of the MPA through a passage as with a conventional banding.

A suture was placed into a hole in the clip and tied in a loop; this allows for a secure tie once the device is in position. The pericardium and the chest were closed in standard fashion.

Once all the disposable drapes had been removed and the patients were settled and comfortable on the operating table, the device was programmed; this involved using the FloWatch Control Unit. This is a passive telemetry system operating at 27 MHz. The external antenna of the control unit is shown in Figure 3; this allows for optimal communication between the two devices. The initial position of the piston is 5% closed from fully open. While monitoring pressure and saturation, the device can be adjusted in 1% steps of constriction. As a safety measure, each PAB implant is identified with a unique microchip card that must be inserted into the control unit before any adjustments can be made.

There are certain contraindications to the use of this device, as recommended by the manufacturers: patients <2.5 kg, because of the physical dimensions of the device; children with an external diameter of the pulmonary trunk that is not between 10 and 20 mm; children requiring magnetic resonance imaging while the device is implanted; children who already have a device sensitive to radiofrequency emissions, such as an implantable pacemaker or implantable defibrillator.

Once the units have confirmed that they have estab-

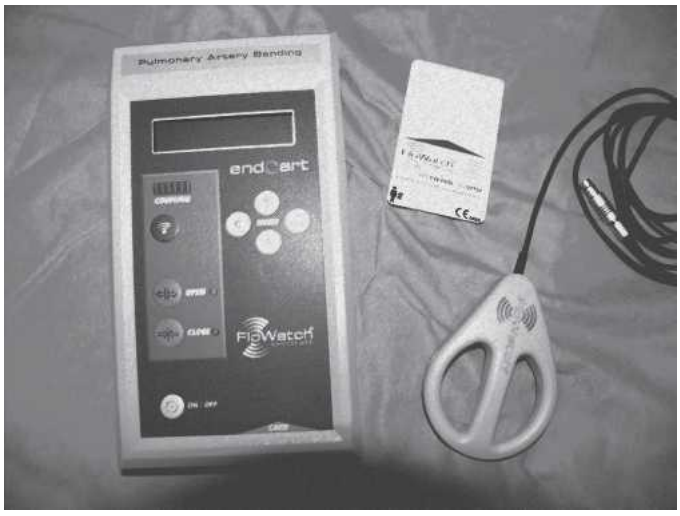

Figure 3. FloWatch device showing control box, memory chip, and adjustment transceiver.

lished communication, adjustments can made to position the piston in 1% increments, allowing a very fine degree of control of the restriction of the MPA.

In both of our patients, initial settings were established very quickly; the patients where transferred to the intensive care unit, the MPA pressure was reviewed along with the systemic hemodynamics and SaO_2 4 hours after transfer, and further adjustments were made to the banding as needed. Although adjustable devices for PAB have been described previously (3), to the author's knowledge, none of these have become commercially available.

Patient 1 had initial settings in the operating room as follows: the banding device was 50% occlusive producing a gradient of 34 mmHg across the band and 100% saturation.

The band was adjusted remotely every ~1 month postoperatively as listed: August 2005, 60% occlusive, 30 mmHg gradient, 100% saturation; September 2005, 65% occlusive, 35 mmHg gradient, 100% saturation; November 2005, 75% occlusive, 30 mmHg gradient, 100% saturation; December 2005, 75% occlusive, 35 mmHg gradient, patient's weight was 8.1 kg.

The banding device was not adjusted again and was removed at the time of the patient's total corrective surgery in January 2007, without complications.

Patient 2 had initial settings in the operating room as follows: the banding device was 85% occlusive producing a gradient of 52 mmHg across the band, with a saturation of 83%. The device was adjusted in the intensive care unit later the same day; the occlusion was set to 100%, with a gradient of 53 mmHg and a saturation of 90%.

Because of the fact that the device was as restrictive as mechanically possible, no further adjustments were made.

The device was again removed at the time of the patient's corrective operation in August 2006, without complications.

CONCLUSIONS

The FloWatch pulmonary artery banding device is a very exciting device presenting enormous possibilities for patients who require some form of ventricular training. However, there are limitations, as we have learned from our experience; there is most definitely a size limitation in patient selection and patient's pulmonary artery size, to ensure that the device can function as designed. We saw no complications either with the telemetry system reported in an earlier series of patients (4) or the use of the band causing any erosion or other damage to the pulmonary artery (5).

Despite this and the high cost (10,000 Euro; 13,500 USD), we feel that this is outweighed by the fact that the device can be adjusted remotely as an outpatient procedure. This not only reduces trauma to the patient and families in terms of repeat surgery and anesthesia but also in terms of cost of both operating theater time and intensive care time.

Overall, with careful patient selection, this device has enormous potential for a select group of patients.

ACKNOWLEDGMENTS

The author thanks the following people for help and advice in writing this article: Morten Helvind, MD, Chief Pediatric Cardiac Surgeon, Rigshospital, Henrik Orbaek, MD, Pediatric Cardiac Surgeon, Rigshospital, and Peter Bo Hansen, MD, Pediatric Cardiac Anesthetist, Rigshospital. EndoArt (Lausanne, Switzerland) supplied pictures and technical details.

REFERENCES

1. Muller WH, Dammann JF Jr. The treatment of certain congenital malformations of the heart by the creation of pulmonic stenosis to reduce pulmonary hypertension and excessive pulmonary blood flow. Surg Gynecol Obstet. 1952;95:213–9.
2. Turley K, Tucker WY, Ebert PA. The changing role of palliative procedures in the treatment of infants with congenital heart disease. J Thorac Cardiovasc Surg. 1980;79:194–210.
3. Fishman NH, Roe BB. An adjustable pulmonary artery band. Arch Surg. 1971;102:143.
4. Bonnet D, Corno AF, Sidi D, et al. Early clinical results of the telemetric adjustable pulmonary artery banding FloWatch-PAB. Circulation. 2004;110:II-158–63.
5. Michael-Behnke I, Akintuerk H, Valeske K, Thule J, Mueller M, Schranz D. Pseudoaneurysm of the pulmonary trunk after the placement of an adjustable pulmonary artery banding device (FloWatch-PAB) in a patient with muscular ventricular septal defect. J Thorac Cardiovasc Surg. 2005;130:894–5.