Peer reviewed article

Pulmonary artery banding

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Summary

Pulmonary artery banding is a palliative surgical procedure used to treat functionally univentricular hearts, multiple ventricular septal defects and complete atrioventricular septal defects. Pulmonary artery banding has recently gained in interest for left ventricular retraining and hypoplastic left heart malformations.

The indication for pulmonary artery banding is limited by several factors: difficulty of determining optimal band tightness, influence of perioperative variables with mutual interference, age-related variability of the ventricular adaptive response, difficulty of securing sufficiently tight banding in older children, repeated surgical procedures needed to adjust the band perimeter, long periods under intensive respiratory and/or pharmacological support, and the frequent need for reconstruction of the pulmonary artery at intracardiac repair.

The need for adjustable banding has now been met by the clinical availability of telemetrically controlled adjustable pulmonary artery banding (FloWatch™, EndoArt, Lausanne, Switzerland), which has been successfully tested in clinical practice after favourable evaluation in animal experiments.

This new wireless, battery free, implantable device (FloWatch™), allows repeated progressive occlusion and reopening of the device by remote control, at the desired percentage occlusion, without the need for reoperation to adjust the band.

The introduction of FloWatch™ has brought substantial changes in the management of patients with increased pulmonary artery blood flow and pressure, a reduction in the mortality and morbidity associated with conventional banding, and significant shortening of intensive care unit and hospital stay.

New therapeutic strategies could well extend the applicability of this device in patients with congenital heart defects.

Key words: atrio-ventricular septal defects; congenital heart defects; left-to-right shunts; pediatric cardiac surgery; pulmonary artery banding; pulmonary hypertension; transposition of the great arteries; univentricular hearts; ventricular septal defects

Pulmonary artery banding was introduced in 1952 as a palliative procedure for patients with congenital heart defects characterised by increased pulmonary blood flow and pressures, in a period when the surgical repair of congenital heart defects was not yet available [1].

In the following years the introduction of cross-circulation operations by Lillehei [2] and the use of the heart and lung machine by Gibbon [3] made feasible the repair of the simplest intra-cardiac defects.

Due to the multiple deleterious effects of the early heart and lung machines, combined with the absence of anaesthesia and intensive care appropriate for small children, the repair of most of the congenital intra-cardiac defects became a standard approach only a few decades later. Pulmonary artery banding remained the preferred palliation to delay the definitive repair to an age and body weight suitable for the available techniques. The increased application of this palliative approach to more complex defects with increased pulmonary blood flow and pressure prompted the establishment of rules to obtain the best outcome, like the "Trusler's rule", determining the length of the band in relation to the underlying defect and the body weight of the patient [4].

In the subsequent decades the development of peri-operative management of children with congenital heart defects, including refinement of surgical techniques and cardiopulmonary bypass [5], made possible surgical repair even in infancy of most intra-cardiac defects [6, 7].

Nowadays pulmonary artery banding is still used as a palliative surgical procedure for congenital heart defects. Recent clinical reports considered pulmonary artery banding not only for classical indications like functionally univentricular hearts [8–11], but also for more controversial situations like multiple ventricular septal defects [12]

No financial support declared.

and complete atrio-ventricular septal defects [13, 14].

Furthermore, increasing interest for pulmonary artery banding has been recently dictated by the need for left ventricular retraining in transposition of the great arteries with late referral [15] and in congenitally corrected transposition of the great arteries (= double discordance) [16–18].

Finally, new indications for pulmonary artery banding have been considered in hypoplastic left heart malformations, either as a rescue procedure in critical neonates or as an elective preparation for the subsequent surgical stage, either Norwood procedure or heart transplant [19–22].

Indication for pulmonary artery banding is still currently limited by several factors:

a the difficulty in determining the optimal tightness of the band. Since both turbulent and viscous losses are highly dependent on the radius of the vessel, even minor changes in the diameter of the pulmonary artery have large impact on blood flow and pressure gradient across the band site

b the influence of several peri-operative variables with mutual interference, related to general anaesthesia with positive pressure ventilation and chest opening, particularly with thoracotomy [23]. Substantial changes of heart rate and contractility, values of arterial PO_2 and PCO_2, acid-base status, haematocrit, and balance between systemic and pulmonary vascular resistance, occur for all these variables with mutual interference, particularly within the first few hours or days after the operation [24]. As a consequence it is very difficult to predict the effectiveness of a pulmonary artery banding, with the band applied in an almost instantaneous fashion, and only some of the above parameters (systemic and pulmonary artery pressure, systemic oxygen saturation, expired CO_2) followed few minutes after the band fixation, before chest closure [24]

c the age-related variability of the ventricular adaptive response. This is evident particularly in children with "functionally" univentricular hearts [25] or transposition of the great arteries requiring retraining of a low pressure left ventricle in view of late arterial switch operation [26], and where simultaneous associated surgical procedures are required, like aortic coarctectomy, aortic arch reconstruction, atrial septectomy, cavo-pulmonary connection

d the difficulties to sufficiently tighten the banding in older children with pulmonary hypertension. In these circumstances the single stage surgical repair is accompanied by mortality and morbidity higher than the two-stage approach, where repair follows a period with decreased pulmonary artery pressure accomplished with pulmonary artery banding. The clinical situation due to the presence of severely elevated pulmonary artery resistance does not allow immediately achieving the desired low level of distal pulmonary artery pressures, and therefore a progressive tightening of the band over a period of time is needed

e the flow adjustment in children with congenital heart defects with very high pulmonary blood flow, with or without cyanosis. In these patients the pulmonary artery banding is frequently successful in controlling the distal pulmonary artery pressures, but overflow might persist, accompanied by a very poor clinical tolerance because of congestive heart failure

f the repeated surgical procedures frequently required to adjust the band perimeter. This occurs not only in the immediate post-operative period, but also weeks or months after surgery, including children outgrowing bands, which tighten too rapidly, when complete repair is not yet indicated

g the long periods with intensive respiratory and/or pharmacological interventions to control the pulmonary blood flow. Substantial mortality and morbidity are dependent upon the long stay in Intensive Care Unit and in hospital, particularly when prolonged controlled or assisted mechanical ventilation is required because of excessive total pulmonary blood flow [26]

h the frequent need for a reconstruction of the pulmonary artery at the moment of de-banding with intra-cardiac repair. With conventional banding the reconstruction of the pulmonary artery, narrowed and distorted by extensive fibrosis of the arterial wall around the band, is the rule at the moment of the conventional de-banding for surgical repair, with extension of the operative duration and risk. Not infrequently the pulmonary artery reconstruction is accompanied by the need of further surgical and/or interventional treatments because of residual or recurrent pressure gradient as a consequence of the previous pulmonary artery banding [27–30].

To overcome these difficulties, due to the fact that a fixed band does not fulfil the continuously variable clinical requirements, several attempts have been made to develop adjustable pulmonary artery banding, allowing for external regulation during the hours or days following the surgical procedure [31–46].

A MedLine search conducted in 2002 for "adjustable pulmonary artery banding" revealed 16 different techniques or devices reported in the literature within a 10 year period, from 1992 to 2001, after evaluation in experimental or clinical studies. The reported techniques included externally adjustable banding obtained with a ligature around the pulmonary artery controlled with a rubber tourniquet with the end left in the subcutaneous tissue for access in case of needed adjustment; banding realised with a series of surgical absorbable sutures with different time frames, to be dilated by percutaneous ballon dilatation in case of

needed relief of banding; banding with totally absorbable material for the tape; banding realised with modified devices similar to the ones used for subcutaneous administration of medications. However, none of them resulted in a reliable device allowing a precise, long-term, non-invasive, adjustment of pulmonary blood flow and pressures in both directions, with repeated narrowing and releasing of the pulmonary artery.

The main problems remained the reliability of the devices, the reproducibility of the adjustments, and the need for invasive approaches in order to adjust the tightness of the band. Furthermore the most frequently observed limitation was that weeks or months after implantation it was maybe possible to further narrow the pulmonary artery, but impossible to release the narrowing because none of the devices was able to counteract the induced fibrosis of the wall with re-expansion of the pulmonary artery.

The need for adjustable pulmonary artery banding has been solved with the clinical availability of a telemetrically controlled adjustable pulmonary artery banding, FloWatch™ (EndoArt, Lausanne, Switzerland), successfully tested in the clinical practice in different institutions [47–50] after positive experimental evaluation in animals [51].

This new wireless, battery free, implantable device (FloWatch™), allows for repeated progressive occlusion and reopening of the device through a remote control, at the wanted percentage of occlusion, therefore functioning as a real adjustable pulmonary artery banding, without requiring reoperation to adjust the band.

Technical characteristics of the device

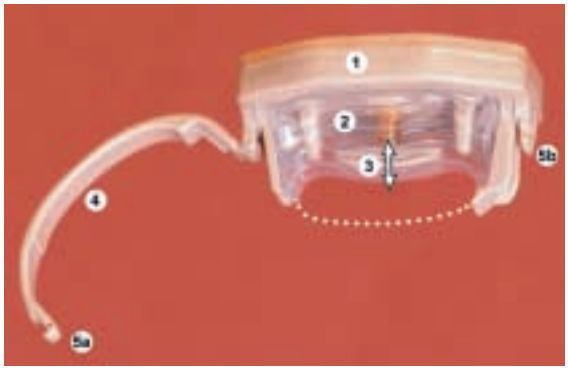
The FloWatch™ system comprises the implant and the external control unit with an antenna (figure 1). The device is surgically placed around the main pulmonary artery, in a fashion similar to conventional pulmonary artery banding. With the device in clipped position, the dimensions are: 26 mm (length) × 18 mm (width) × 18 mm (height). The change in the adjustable area is obtained by means of a piston driven by an incorporated electrical micro-motor. The concave form of the adjustable area has been chosen so that during compression the area changes but the perimeter of the pulmonary artery remains unchanged, which is optimal for long-term use (ie, reopening after several weeks of pulmonary artery compression). The adjustable area in fully open position corresponds to a pulmonary artery banding with a perimeter of 30 mm, and with fully closed position to a pulmonary artery banding with a perimeter of 23 mm. According to the Trusler's rule [4], theoretically the device is suitable for pulmonary artery banding in patients from 3 to 10 kg body weight. Adjustment occurs via an external control unit, which transmits energy and commands to drive the micro-engine of the implanted device via antenna. Therefore the device does not have a battery. The telemetric system is designed so that the implant sends information about its functioning back to the control unit, which allows control of the settings by the treating doctor.

The introduction of this adjustable pulmonary artery banding has substantially modified the management of patients with increased pulmonary artery blood flow and pressure, even though larger numbers of patients and longer follow-up are needed to confirm our observations.

For conventional indications, like Swiss-cheese multiple ventricular septal defects or complete atrio-ventricular septal defects with unbalanced ventricles, the FloWatch™ allows a fast track operation, very reliable management of the pulmonary artery blood flow and pressures in the post-operative period, and the possibility of delaying the intra-cardiac repair much later than with the conventional banding, at a suitable age and

Figure 1

General View of the FloWatch-PAB implant: the four main functional parts are:
1) The case (body of the device)
2) The silicone membrane
3) The piston
4) The counter-piece
5) The clip (a) with the place for the attachment to the case (b)
The Case (1) contains an antenna, the electronics and an electric micro-motor. The antenna supplies the electronics energy and commands from the external control unit. It also transmits information on the working of the micro-motor to the external control unit. The electronics uses the energy received from the antenna as its own energy supply. It interprets the commands received from the external control unit, and it provides appropriate supplies to the micro-motor. It also retrieves information on the working of the micro-motor and relays them to the antenna. The micro-motor activates a piston (3) that adjusts the degree of banding of the pulmonary artery. The piston (3) has a stroke of 3 mm for tightening or loosening the banding. The silicone membrane (2) is flexible and extendible because of its shape and material. It protects the piston (3) and the inside of the case from body fluids while allowing the piston to perform its adjustment movements. Also, it has been designed to avoid the formation of fibrous tissues where they could block the adjustment mechanism. It presents a flexible and smooth contact surface to the pulmonary artery. This membrane is very fragile. The counter-piece (4) is designed to be placed around the pulmonary artery. One of its extremities is attached to the case by a hinge. The other is fixed to the clip part of the case (5b) during surgery by means of its clip (5a). It thus delimits the adjustable surface where the pulmonary artery is confined (dotted line). The measurements of the FloWatch-PAB implant when clipped are: 26 x 18.4 x 17 mm (length x width x height).



body weight, thanks to the possibility for reducing the tightness of the banding with the growth of the patient [6, 47–50].

In patients with functionally univentricular hearts with this device it is possible to accomplish adequate and progressive titration of the pulmonary artery pressures, in order to reach normal values and later perform a staged repair with cavopulmonary connections [7–11, 48–50].

When left ventricular retraining is required as in patients with transposition of the great arteries with late referral [15] and in congenitally corrected transposition of the great arteries (= double discordance) [16–18], the FloWatch™ is the only technique, which allows modulation of pulmonary blood flow in a way suitable with the continuously variable clinical needs of these clinical situations, generally requiring repeated adjustments and prolonged intensive care unit stay [15].

In all the above situations the device provided a substantial reduction of mortality and morbidity associated with the conventional banding, in addition to the significant reduction of intensive care unit and hospital stay [48–50].

The management of other clinical situations can be substantially improved by the extended application of this device, as in patients with severe pulmonary hypertension in the presence of congenital heart defects with intra-cardiac left-to-right shunt because of late referral. These patients are generally refused surgical treatment because of a very elevated risk of peri-operative mortality. In these cases the FloWatch™ allows reduction of distal pulmonary artery pressure, and after a period of a few months with decreased pulmonary vascular resistance the patients can undergo surgical repair with a much better outcome [48–50].

Potential limits so far are due to the size of the device, unsuitable in small premature infants because of the space it occupies, and in older patients where the distance between the skin and the pulmonary artery, site of the implantation of the device, is over 4 cm, the maximum distance suitable to transmit the energy and the instructions from the external antenna to the device itself.

In summary, the clinical introduction of an adjustable pulmonary artery banding with FloWatch™ has modified the management of patients with increased pulmonary artery blood flow and pressures, and new therapeutic strategies can be considered to extend the applicability of this device in patients with congenital heart defects.

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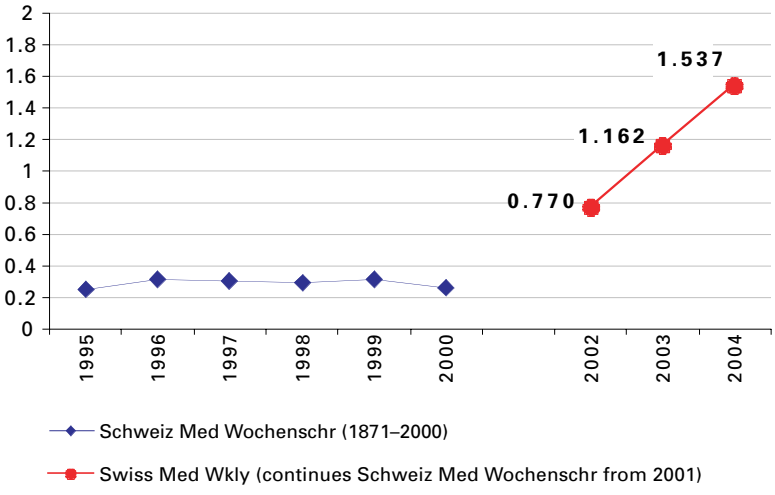

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