

Remote Control of Pulmonary Blood Flow

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Abstract: Pulmonary artery banding is a suitable approach for complex heart defects suitable to later bi-ventricular repair, functionally uni-ventricular hearts, and left ventricular retraining.

Despite the existence of a very large spectrum of congenital heart defects and clinical situations with potential indication for pulmonary artery banding, the availability of only the conventional surgical technique is still limiting the application of this approach.

A solution to the clinical need for an adjustable pulmonary artery banding has been found with a telemetrically controlled adjustable pulmonary artery banding, FloWatch® (EndoArt, Lausanne, Switzerland). This new implantable, wireless, battery free, device (FloWatch®), demonstrated the feasibility of repeated progressive occlusions and re-openings of the device at the wanted percentage of occlusion through a remote control, with long-term experimental evaluation in animals, followed by successful introduction in clinical practice in different institutions.

The availability of a reliable adjustable pulmonary artery banding, avoiding any re-operation and the need for pulmonary artery reconstruction at the moment of de-banding, has substantially modified the clinical management of infants with congenital heart defects with increased pulmonary artery blood flow and pressures. New therapeutic strategies can now be considered to expand the applicability of this device.

Key Words: Congenital heart defects, left-to-right shunts, pediatric cardiac surgery, pulmonary artery banding, pulmonary blood flow, pulmonary hypertension.

INTRODUCTION

In 1952, when the surgical repair of congenital heart defects was not yet available, pulmonary artery banding, consisting in the surgical application of a tape around the main pulmonary artery in order to create a fixed narrowing, had been proposed as a palliative procedure for children with congenital heart defects complicated by increased pulmonary blood flow and pressures [1].

After few years the introduction by Lillehei of operations with cross-circulation [2] and by Gibbon of the heart and lung machine [3] made feasible the intra-cardiac repair of the simplest heart malformations.

The repair of most of the congenital heart defects has been prevented from becoming a standard clinical practice for few decades, mostly because of the multiple deleterious effects of cardiopulmonary bypass with the early heart and lung machines, combined with the absence of techniques of general anesthesia and intensive care appropriate for small children. Palliation with pulmonary artery banding, most frequently in children with ventricular septal defects, remained the preferred surgical approach to delay the complete repair to an age and body weight suitable for the available equipments and techniques. The establishment and application 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] allowed the extension of this palliative approach to more

complex heart defects with increased pulmonary blood flow and pressure, like atrio-ventricular septal defects and functionally uni-ventricular hearts.

The improvement of the peri-operative management of patients with congenital heart defects, including refinement of surgical techniques, cardiopulmonary bypass designed for reduced body surface area [5] and better post-operative care, made the surgical repair of most of the intra-cardiac defects a clinical possibility with good outcomes even in small infants in the following decades [6,7].

Palliation with pulmonary artery banding is nowadays rarely considered as a suitable surgical approach for simple congenital heart defects like isolated ventricular septal defects. Recent clinical reports considered the pulmonary artery banding not only for classical indications, like ventricular septal defects associated with aortic arch interruption [8,9], functionally univentricular hearts [9-17], but also for more controversial situations, like multiple ventricular septal defects [9,18] and complete atrio-ventricular septal defects [9,16,17,19,20].

Progressively increasing interest in pulmonary artery banding has been recently dictated by the indication for left ventricular retraining in transposition of the great arteries with late referral [21] and in congenitally corrected transposition of the great arteries (= double discordance) [22-26].

Interestingly 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 towards a uni-ventricular type of repair or heart transplant [27-33].

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Despite the existence of a very large spectrum of congenital heart defects and clinical situations with potential indication for pulmonary artery banding, the availability of only the conventional surgical technique as the option to perform a pulmonary artery banding is still limiting the application of this approach because of several reasons:

1. To find a method to intra-operatively determine the optimal tightness of the band, suitable for not only the immediate clinical requirement but for the follow-up.

Turbulences and vortices are highly dependent on the radius of the vessel; as a consequence, even minor changes in the diameter of the pulmonary artery have large impact on blood flow and pressure gradient across the band site.

2. Multiple peri-operative variables with mutual interference, related to general anesthesia with positive pressure ventilation and chest opening, particularly with thoracotomy [34], have a substantial influence on the hemodynamic effects of the pulmonary artery banding.

Particularly within the first few hours or days after the operation continuous and substantial variations of heart rate and contractility, values of arterial PO₂ and PCO₂, acid-base status, hematocrit, and balance between systemic and pulmonary vascular resistance, occur to all these variables with mutual interference [35]. The effectiveness of a pulmonary artery banding is therefore very difficult to predict, with the band surgically implanted in an almost instantaneous fashion, and only some of the above parameters (systemic and pulmonary artery pressure, systemic oxygen saturation, expired CO₂) followed few minutes after the band fixation, before the chest closure [35].

3. The ventricular adaptive response is characterized by an evident age-related variability.

This aspect becomes very important particularly in children with “functionally” univentricular hearts [36] or transposition of the great arteries with late referral requiring retraining of a low pressure left ventricle in view of arterial switch operation [37], and where simultaneous associated surgical procedures are required, like aortic coarctectomy, aortic arch reconstruction, atrial septectomy, cavo-pulmonary connection.

Several experimental studies have been performed and recently reported on the various types of ventricular response to different types of pressure overload, with investigation on the effects at structural, ultra-structural, biochemical, functional and phenotypical levels [38-42].

4. In older children with late referral because of a congenital heart defect with severe pulmonary hypertension it is always difficult to perform in one surgical stage a banding sufficiently tightened to adequately reduce the distal pulmonary artery pressure.

In these patients, frequently referred with severe respiratory complications, the single stage surgical repair carries much higher mortality and morbidity than the two-stage approach, with a period with decreased pulmonary artery

pressure obtained with a pulmonary artery banding, followed by later intra-cardiac repair. The desired low level of distal pulmonary artery pressures cannot be obtained immediately because of the presence of severely elevated pulmonary artery resistance, and therefore a progressive tightening of the band over a period of time would be required.

5. There is a well known problem in effectively adjusting the total pulmonary blood flow in children with congenital heart defects with very high pre-operative pulmonary blood flow, with or without cyanosis.

In these patients the pulmonary artery banding frequently allows the control of the distal pulmonary artery pressures, but despite the reduction in blood pressure a substantial overflow might persist, accompanied by a very poor clinical tolerance because of congestive heart failure

6. Repeated surgical procedures, with chest re-opening, are frequently required to adjust the band perimeter to the clinical needs, not only in the immediate post-operative period, but sometimes weeks or months after surgery.
7. Not infrequently long periods with intensive respiratory and/or pharmacological interventions are required to control the pulmonary blood flow.

In these cases mortality and morbidity are increased in correlation with the duration of stay in Intensive Care Unit and in hospital, particularly when prolonged controlled or assisted mechanical ventilation is required to control an excessively increased pulmonary blood flow [37]

8. Surgical reconstruction with patch enlargement of the pulmonary artery at the moment of de-banding with intra-cardiac repair is frequently required, particularly if the band remained in place for a long period.

After conventional banding, narrowing and distortion occur because of extensive fibrosis of the pulmonary artery arterial wall in response to band. The need for pulmonary artery surgical reconstruction is the rule at the moment of the conventional de-banding associated with intra-cardiac repair, with increase of the duration and risk of the surgical procedure. Further surgical and/or interventional treatments, because of residual or recurrent pressure gradient in the correspondence of the previous pulmonary artery banding, are required despite reconstruction of the pulmonary artery [43-46].

Several experimental and clinical studies have been performed and reported trying to address the above concerns, due to the evidence that a fixed band doesn't fulfil the continuously variable clinical requirements; the aim of the studies was to design an adjustable pulmonary artery banding allowing for external regulation during the hours or days following the surgical procedure [17, 47-64].

Sixteen different techniques or devices have been reported in the literature within a 10 year period, from 1992 to 2001, after evaluation in experimental or clinical studies, as shown by a MedLine research conducted on 2002 for “adjustable pulmonary artery banding”.

The reported techniques included the following: a) externally adjustable banding obtained with a ligature placed around the pulmonary artery and controlled with a rubber tourniquet, with the end positioned in the subcutaneous tissue for ease of surgical access in case of required adjustment; b) banding induced narrowing the pulmonary artery with a consecutive series of surgical absorbable sutures with different time frames, to be relieved by repeated percutaneous balloon dilatations in case of wanted relief of banding; c) banding with totally absorbable material for the tape; d) banding induced with modified devices similar to the ones used for subcutaneous administration of medications; e) bilateral intra-luminal pulmonary artery banding, introduced through percutaneous interventional technique.

Unfortunately none of above proposals resulted in a reliable device for a precise, long-term, non-invasive, adjustment of pulmonary blood flow and pressures in both ways, allowing for repeated narrowing and releasing of the pulmonary artery over long periods of time after implantation.

The main problems remained: a) the reliability of the devices; b) the consistency and reproducibility of the adjustments; c) the need for invasive approaches in order to adjust the tightness of the band.

Furthermore the most frequently observed limit was that, some time, generally weeks or months, after the implantation, it was maybe possible to further narrow the pulmonary artery, but always impossible to release the narrowing, because none of the available devices was able to counteract the induced fibrosis of the wall of the pulmonary artery with re-expansion of the pulmonary artery itself.

A solution to the clinical need for an adjustable pulmonary artery banding has been found with the clinical availability of a telemetrically controlled adjustable pulmonary artery banding, FloWatch® (EndoArt, Lausanne, Switzerland). The device underwent long-term experimental evaluation in animals [65], followed by the successful introduction

in clinical practice in different institutions after positive results obtained in 13 children enrolled in a multi-center clinical trial [66-69].

This new implantable, wireless, battery free, device (FloWatch®), demonstrated the feasibility of repeated progressive occlusions and re-openings of the device at the wanted percentage of occlusion through a remote control. The functioning is therefore as a real adjustable pulmonary artery banding, avoiding any re-operation or invasive procedure to adjust the band in both ways [66-69].

Technical Characteristics of the Device

The FloWatch® system comprises the implant (Fig. 1) and the external control unit with an antenna. The device is implanted around the main pulmonary artery, with a surgical technique similar to the conventional pulmonary artery banding. With the device in clipped position, the dimensions are: 26 mm (length) X 18 mm (width) X 18 mm (height). The modifications of the adjustable area are 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 cross-sectional area changes without reductions of the perimeter of the pulmonary artery; this is ideal for long-term purposes, when reopening of the device will be required after several weeks or months of pulmonary artery compression. The adjustable area in fully open position is corresponding 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], the device is theoretically suitable for pulmonary artery banding in patients from 3 to 10 kg of body weight. Telemetric adjustments of the degree of the pulmonary artery narrowing are obtained with an external control unit delivering to the implanted device, *via* the antenna, the energy as well as the commands to drive the micro-engine. The device therefore does not contain any battery. The telemetric system is designed such that

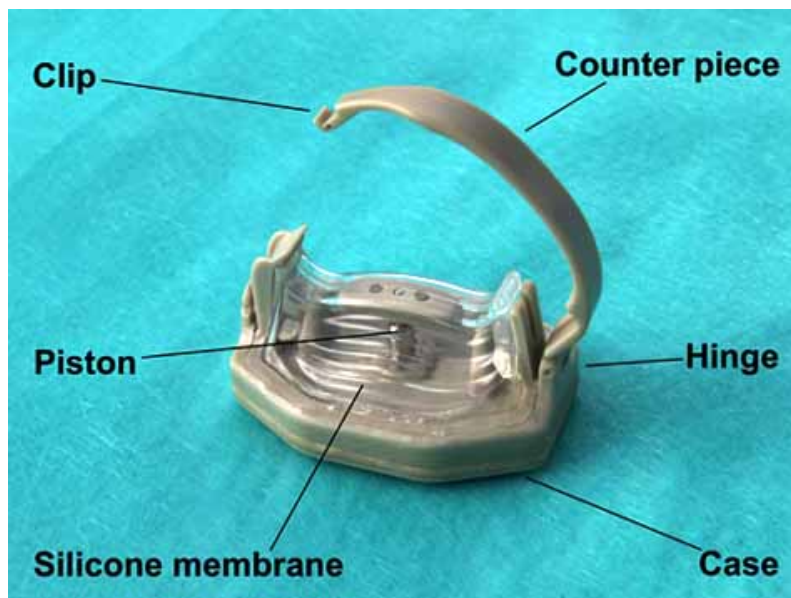


Fig. (1). Photograph of the device for telemetrically adjustable pulmonary artery banding (FloWatch®, EndoArt, Switzerland).

the implant sends back to the control unit information about its functioning and the obtained percentage of occlusion, allowing full control of the regulation by the treating physician.

The clinical introduction of FloWatch® as adjustable pulmonary artery banding has substantially modified the management of patients with increased pulmonary artery blood flow and pressure, with positive results already available in a total number of 86 patients across Europe, with good functioning of the device even longer than 2 years of follow-up after surgical implantation [70].

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, a 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 the wanted age and body weight, thanks to the possibility of releasing the tightness of the banding with the growth of the patient [6, 66-69].

In the presence of infants with functionally uni-ventricular hearts this device makes feasible the adequate and progressive titration of the pulmonary artery pressures distally to the narrowing, in order to reach the desired low values and later perform a staged cavo-pulmonary connections (Fig. 2) [7,9-17,67-69].



Fig. (2). Post-operative X-ray of a neonate with tricuspid atresia, ventricular septal defect and pulmonary hypertension, requiring pulmonary artery banding for preparation to univentricular type of repair. The FloWatch® is visible, as well as the metal clip used to close a patent ductus arteriosus.

In patients where left ventricular retraining is required because of late referral in the presence of transposition of the great arteries [21] and in congenitally corrected transposition of the great arteries (= double discordance) [22-26], the FloWatch® is the only technique allowing to modulate the

distal pulmonary artery pressure in a fashion suitable with the continuously variable clinical needs of these conditions, generally requiring repeated adjustments and prolonged stay in intensive care unit [21].

The clinical experience with this device confirmed in all the above situations a substantial reduction of mortality and morbidity associated with the conventional surgical banding, in addition to a significant reduction of intensive care unit and hospital stay [67-69].

A prospective study on two homogeneous groups of 20 infants each, without differences regarding age, body weight, and indication, compared the conventional banding versus the FloWatch®, showing a reduction of early mortality (from 3/20 to 0/20). Duration of post-operative mechanical ventilation, stay in ICU and stay in hospital were significantly longer after conventional banding than after FloWatch®, respectively 10.4±11.2 versus 3.0±3.1 days ($P<0.01$), 20.3±19.9 versus 5.3±4.6 days ($P<0.005$) and 45.6±41.6 versus 15.4±6.4 days ($P<0.005$). Re-operation was required in 7/20 (=35%) infants after conventional banding to adjust the band versus no re-operations (0/20=0%) after FloWatch® ($P<0.005$), with 3.3±1.3 telemetric adjustments/infant to narrow and 0.5±0.6 to release the PAB (unpublished data).

Also in other clinical situations the extended application of this device can completely modify the currently available management, like in patients with late referral with severe pulmonary hypertension in the presence of congenital heart defects with intra-cardiac left-to-right shunt. The surgical indication for complete intra-cardiac repair is generally not accepted in these patients because of a very elevated risk of peri-operative mortality. In these cases the FloWatch® allows a progressive reduction of the distal pulmonary artery pressure, with the possibility of adaptation of both the cardiac and respiratory functions with good clinical tolerance; after a period of few months with decreased pulmonary vascular pressures and resistance, the same patients can undergo surgical repair with a much better outcome [67-69].

Finally, there is another important advantage of FloWatch®: following the implantation of this device for telemetrically adjustable pulmonary artery banding, at the moment of subsequent intra-cardiac repair and de-banding, consisting in FloWatch® un-clipping and removal, surgical reconstruction of the pulmonary artery is not required anymore [70,71].

While the conventional banding produces a narrowing of the main pulmonary artery with the internal shape corresponding to a circular cross sectional area, due to the shape of FloWatch® the internal shape of the pulmonary artery becomes banana-shape, and it is this particular shape that provides its favorable properties [71]. The FloWatch® allows for the same reduction of the cross sectional pulmonary artery area than the conventional circular banding, but with a significantly larger perimeter, thanks to the banana-shape of the circumference. Therefore the perimeter of the pulmonary artery remains constant for the entire range of regulation of the banding. These observations have been validated by a recent study with Computational Fluid Dynamics [71].

After conventional circular banding, the substantial reduction of the perimeter of the pulmonary arterial wall is

accompanied by anatomical and histological changes with increased thickness, dense fibrosis and loss of elasticity. At the moment of removal of the conventional band, the wall of the pulmonary artery remains fixed in the same position, and it is impossible to obtain an increase of the cross sectional area without changing its diameter. Therefore a surgical incision/resection with subsequent reconstruction is mandatory, sometime with residual or recurrent pressure gradient [43-46].

Since the banding with FloWatch® obtains the same reduction of cross sectional area of the conventional circular banding, and therefore the same pressure gradient, without any reduction of the perimeter of the pulmonary artery, the wall of the artery can maintain intact its anatomical properties, without any reduction of elasticity. Therefore the simple device removal at the time of intra-cardiac repair is enough to obtain spontaneous and complete expansion of the wall of the pulmonary artery up to a circular cross sectional area with the same perimeter of the previously banded pulmonary artery, with maintenance of its elasticity and pliability [71].

The positive personal clinical experience collected in 24 children, none of them requiring pulmonary artery reconstruction at the time of FloWatch® removal, has been successfully repeated by all colleagues cardiac surgeons in other hospitals, where in no circumstances the device removal has been accompanied by the need for pulmonary artery reconstruction in a total of 32 cases [70, 71].

The potential limits are due to the fact that, so far, the device is available only in one size, unsuitable in small premature neonates because of the space occupation, and also 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 orders from the external antenna to the device itself.

In summary, the clinical management of infants with congenital heart defects with increased pulmonary artery blood flow and pressures has been completely modified by the clinical introduction of this adjustable pulmonary artery banding with FloWatch®. New therapeutic strategies can now be considered to expand the applicability of this device in patients with congenital heart defects.

Conflict of Interest

I have no disclosure to declare, including ownership/partnership relations, consulting fees and honoraria, research support, salary support, institutional benefits (Antonio F. Corno).

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