New ideas

A new implantable device for telemetric control of pulmonary blood flow

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Abstract

The main problem encountered in pulmonary artery banding is the difficulty in determining the optimal perimeter of the band, and sometime repeated surgical operations are required to adjust the band perimeter in order to control the pulmonary blood flow. To overcome these difficulties EndoArt S.A. (Lausanne, Switzerland) developed an externally adjustable, telemetrically controlled device for pulmonary artery banding (FloWatch e), which is wireless, battery free, easy to implant and use, and we here report on the technical characteristics of the device. The preliminary acute experimental studies demonstrated the feasibility of the implant and the good functioning of the device.

Keywords: Congenital heart defects; Congenital heart surgery; Palliative procedure; Pulmonary artery banding; Pulmonary hypertension

1. Introduction

The main problem encountered in pulmonary artery banding is the difficulty in determining the optimal perimeter of the band. Both turbulent and viscous losses are highly dependent on the radius of the vessel; therefore a minor change in diameter has a large impact on blood flow and pressure gradient across the band site.

Moreover, the effects of the banding on pulmonary artery pressure and flow are influenced by several variables, including general anaesthesia with positive pressure ventilation, chest opening (particularly with thoracotomy), heart rate and contractility, arterial PO2 and PCO2, acid-base status, hematocrit, systemic and pulmonary resistance. Substantial changes occur to all these variables with mutual interference, particularly within the first few hours or days after the operation [1]. It is therefore very difficult to predict the effectiveness of a pulmonary artery banding, with the band applied in an almost instantaneous fashion, and some parameters (systemic and pulmonary artery pressure, systemic oxygen saturation, expired CO2) followed only few minutes before the chest closure [1].

Furthermore, an additional problem is given by the variability of the ventricular adaptive response, particularly in ‘functionally’ univentricular hearts [2], in transposition of the great arteries where a left ventricular training is required in view of arterial switch operation [3], and where simultaneous associated surgical procedures are required, like aortic coarctectomy, atrial septectomy, systemic-to-pulmonary artery shunt.

Because of all the above reasons, it may happen that repeated surgical operations are required to adjust the band perimeter, or a long period with intensive respiratory and pharmacological interventions is needed to control the pulmonary blood flow [3].

To overcome these difficulties, several attempts have been made to find an adjustable pulmonary artery banding, allowing for external regulation during the hours or days following the surgical procedure [4–9]. A MedLine research for ‘adjustable pulmonary artery banding’ revealed 16 different techniques reported within the last 10 years, the majority of which, however, did not allow for a precise, long-term, non-invasive, adjustable pulmonary artery banding.

We report on the technical characteristics of a telemetrically controlled device (FloWatch e), developed by EndoArt S.A. (Lausanne, Switzerland) for an externally adjustable pulmonary artery banding [10], as well as the preliminary experimental application.

2. Materials and methods

The FloWatch e system comprises the implant and an external control unit with an antenna. The device is placed with a surgical procedure around the pulmonary artery, in a
fashion similar to the conventional pulmonary artery banding. Fig. 1 shows the implant in its clipped and unclipped position. With the device in clipped position, the dimensions are: $26 \text{ (length)} \times 18 \text{ (width)} \times 18 \text{ mm (height)}$. 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 (i.e. reopening after several weeks of compression). The adjustable area in fully open position correspond 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. Accordingly with the Trusler’s rule, theoretically the device should be suitable for pulmonary artery banding in neonates and infants from 3 to 10 kg of body weight. The adjustment is done via an external control unit. The control unit delivers to the implanted device, via the antenna, the energy as well as the commands to drive the micro-engine. The device does not contain any battery. The telemetric system is designed such that the implant sends back to the control unit information about its functioning, which allows for a good control of the regulation by the treating doctor.

A feasibility test has been performed with an acute experimental study on two mini-pigs, in order to evaluate: (a) the applicability of the device around the pulmonary artery; (b) the possibility of progressively narrowing and releasing the pulmonary artery with telemetric control; and (c) the functioning of the device with closed chest.

After induction of general anaesthesia, tracheal intubation and mechanical ventilation, through a left lateral thoracotomy the pericardium has been longitudinally opened with an anterolateral incision, and a short segment of the main pulmonary artery has been dissected free. A pressure catheter has been inserted into the right ventricle and another one into the distal pulmonary artery for simultaneous pressure monitoring.

3. Results

The area of the FloWatch™ can be adjusted very precisely within the range of 72 (fully open) and 38 mm² (fully closed), as shown in Fig. 2, with a linear relation between the % of piston excursion and the adjustable area. The obtained regression line is the following: \[ \text{area} = 72 - 0.3405 \times \% \text{of piston excursion} \] \((r^2 = 0.99)\). The area is reduced by 0.34 mm² per each 1% of piston excursion.

The acute experimental study confirmed the easy application of the device around the main pulmonary artery. The invasive pressure monitoring showed the appearance of a pressure gradient between the right ventricle and the distal pulmonary artery, with progressive increasing of the pressure gradient in correspondence with the progressive occlusion of the device. The progressive re-opening of the device has been immediately followed by the reduction of the pressure gradient. After pericardial and chest closure, the progressive occlusion and re-opening of the device has been once again followed by changes of the pressure gradient accordingly.

4. Discussion

The well known clinical need for an externally adjustable pulmonary artery banding has been confirmed by the several attempts to develop such a technique reported in the literature [4–9]. The MedLine research confirmed the persistent unavailability of a reliable device, capable of both narrowing and releasing the pulmonary artery with external control.

With our research we developed a telemetric controlled device (FloWatch™) for adjustable pulmonary artery banding, wireless, battery free, easy to implant and to use. The preliminary acute experimental studies demonstrated the feasibility of the implant and the good functioning of the device. Of course long-term experimental studies will be required to test the tolerance of the device and its long term functioning.

Fig. 1. FloWatch™ in clipped and unclipped position.

Fig. 2. Graphic representation of the linear correlation \((r^2 = 0.99)\) between the % of piston excursion and the adjustable area.
References


Appendix A. ICVTS on-line discussion

Author: Dr. Khaled Samir, Thoracic and Cardiovascular Dept., La Timone Children’s Hospital, 264 rue St Pierre, Marseilles, France

Date: 09-Aug-2002 15:09

Message: Pulmonary artery banding (BAP) introduced by Mutler in 1951 for lung protection against pulmonary over circulation during embryonic lung development. The advent of modern pulmonary artery banding procedures in the ICU. The main indications are premature or too small infants with hemodynamic dysfunction. But still we have less common but more dangerous complications like band migration, RPA compression, coronary artery compression, pulmonary artery dysplasia, aneurysm or erosion, PI and subaortic stenosis in single ventricles. Albus or Trusler’s formula are only useful guidelines (not always possibly applicable). The authors represent an excellent promising idea for postoperative telemetric adjustment despite the very limited number of trials in animals and the lack of postoperative data concerning the hemodynamic effects of the device. We think that it is a promising idea that with further studies and also trials to reduce the device size be applicable in neonates and to diminish its possible effects on the pulmonary artery and the surrounding structures; the desired goal can be achieved of having a simple remotely controlled adjustable device that can at the same time avoid the other complications of BAP.

Response

Author: Dr. Antonio Corno, CHUV, Cardiovascular Surgery, 46 rue du Bugnon, Lausanne, CH-1011, Switzerland

Date: 13-Aug-2002

Message: We decided to test the device for remote control of pulmonary blood flow exactly because of some of the problems you listed, namely the post-operative situation with pulmonary artery banding insufficient or too tight. With regard to your comments, this manuscript was prepared just to propose a “new idea” and to inform the scientific community, since we are still convinced about the desperate need to solve the clinical problems with the conventional pulmonary artery banding. As a matter of fact the device underwent an extensive, long-term study in mini-pigs, and all the hemodynamic results up to 6 months as well as the histology showing preservation of the surrounding structures will be presented at the upcoming meeting of the European Association for Cardio-Thoracic Surgery in Montecarlo. The experimental results, as for your question, largely supported the potential clinical advantages of the application of this device, and a multi-center clinical trial has been started recently.

Editorial Note: In the comment by Dr. Samir, on the first line there are two errors:

1) the name of the first Author who reported the Pulmonary Artery banding is “Mutler WH” and not “Mutler”  2) the year of the same report was 1952 and not 1951


On the 9th line of the same comment there is another error: “Albus or Trusler’s formula”.

Dr. Albus reported only later the formula for pulmonary artery banding published by Dr. Trusler 12 years before:


Author: Dr. Sukru Mercan, Cardiovascular Surgery, Baskent University Hospital, Baskent Universitesi Kalk-Dumar Cerr., Fevzi Cakmak cad. 10.sokak no.45 Bahcelievler, Ankara, Turkey

Date: 09-Aug-2002 16:12

Message: Although the device is a prototype, its size is huge for banding procedures during neonatal and infancy period. The main indications may be for left ventricular training for two-stage arterial switch operations in older age groups, since acute left ventricular failure is not uncommon even after a loose pulmonary artery banding in this group. By the help of this kind of device a second or even a third chance may be given to the left ventricle for retraining without applying detrimental emergency surgical debunking procedures in the ICU.

Response

Author: Dr. Antonio Corno CHUV, Cardiovascular Surgery, 46 rue du Bugnon, Lausanne, CH-1011, Switzerland

Date: 13-Aug-2002

Message: I fully agree with you about the potential advantage of our device for left ventricular (LV) re-training in view of arterial switch for transposition of the great arteries (TGA). At the recent meeting of the Association of European Pediatric Cardiologists I presented our experience with LV preparation for arterial switch in TGA after late referral (up to 25 months of age), and in fact we had to re-operated on 3/6 children in order to adjust the pulmonary artery banding.

On the other hand I respectfully disagree with you regarding your comment on the “huge size” of our device for banding procedures during neonatal and infancy period. In our experimental study on mini-pigs the device has been successfully implanted, with up to 6 months follow-up, on animals as small as 3.2 kg of body weight. In a multi-center clinical trial,
started after the end of the experimental study, the first patient who underwent implantation of this device was a neonate with 3.5 kg of body weight.

Author: Dr. Ali Dodge-Khatami, Cardiothoracic Surgery, Academic Medical Center University of Amsterdam, Amsterdam, Netherlands

Date: 10-Aug-2002 10:03

Message: The authors are to be congratulated in striving towards an implantable-adjustable device for regulating pulmonary blood flow, which is wireless and teleguidable, and hence minimally cumbersome to the patient. As they state, we are badly in need of such a device, which can potentially avoid repeat sternotomies or thoracotomies to adjust the band “a vue”, in the face of changing hemodynamics.

A question as to the design and materials used in the frame of the device, which has a straight and what looks like a rigid inferior edge: have the authors also implanted this through a sternotomy, as I wonder how the device will sit with regards to the sternum. Or are the materials soft enough to accommodate the surrounding tissues.

Response

Author: Dr. Antonio Corno, CHUV, Cardiovascular Surgery, 46 rue du Bugnon, Lausanne, CH-1011, Switzerland

Date: 13-Aug-2002

Message: Thank you very much for your interest and particularly for your positive comments. With regard to your questions, you are absolutely right that the material of the core of the FloWatch is fairly rigid: this characteristic is indispensable in order to sustain the elevated pressure of the proximal pulmonary artery without changes in shape and size.

With regard to the position of the device within the chest, due the orientation and morphology of the pulmonary artery, generally dilated in patients requiring pulmonary artery banding, the core of the device remains on the left side of the sternum, independently from the surgical approach through thoracotomy or median sternotomy. This observation has been confirmed after the submission of the present manuscript, where, after the completion of the long-term experimental studies, a multi-center clinical trial has been started with clinical implantation of the device either through thoracotomy as well as through median sternotomy, without any evidence of compression of the cardiac structures nor of the surrounding tissues.