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Remote control of pulmonary blood flow: a dream comes true

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Summary

The indication for pulmonary artery banding is currently limited by several factors. Previous attempts have failed to produce adjustable pulmonary artery banding with reliable external regulation. An implantable, telemetrically controlled, battery-free device (FloWatch™) developed by EndoArt SA, a medical company established in Lausanne, Switzerland, for externally adjustable pulmonary artery banding was evaluated on mini-pigs and proved to be effective for up to 6 months. The first human implant was performed on a girl with complete atrioventricular septal defect with unbalanced ventricles, large patent ductus arteriosus and pulmonary hypertension. At one month of age she underwent closure of the patent ductus arteriosus and FloWatch™ implantation around the pulmonary artery through conventional left thoracotomy. The surgical procedure was rapid and uneventful. During the entire postoperative period bedside adjustments (narrowing or release of pulmonary artery banding with echocardiographic assessment) were repeatedly required to maintain an adequate pressure gradient. The early clinical results demonstrated the clinical benefits of unlimited external telemetric adjustments. The next step will be a multi-centre clinical trial to confirm the early results and adapt therapeutic strategies to this promising technology.

Key words: adjustable device; congenital heart defects; congenital heart surgery; palliation; pulmonary artery banding; pulmonary hypertension

The indication for pulmonary artery banding is currently limited by several factors:

a) the difficulty of determining the optimal band perimeter, since minor changes in diameter have a major impact on blood flow and pressure gradient across the band site;
b) the influence of several mutually interfering clinical variables, including general anaesthesia with positive pressure ventilation, chest opening (particularly by thoracotomy), heart rate and contractility, arterial PO_2 and PCO_2, acid-base status, haematocrit [1];
c) variability of ventricular adaptive response, particularly in "functionally" univentricular hearts [2], transposition of the great arteries requiring left ventricular retraining for arterial switch operation [3], and with associated procedures;
d) repeated surgery frequently required adjustment of the band or long periods of intensive respiratory/pharmacological intervention to control pulmonary blood flow [3].

Several attempts have failed to produce adjustable pulmonary artery banding with reliable external regulation: MedLine research revealed 16 different techniques over the last 10 years.

An implantable, telemetrically controlled, battery-free device (FloWatch™), developed by EndoArt SA, a medical company established in Lausanne, Switzerland, for externally adjustable pulmonary artery banding [4], was evaluated on mini-pigs and proved to be effective for up to 6 months [5].

The FloWatch™ system comprises implant and external control unit. The change in the adjustable area is obtained by a piston driven by an incorporated electrical micro-motor. The adjustment is done via the external control unit, delivering energy as well as commands to drive the micro-engine [4].

After completion of our experimental study [5], and with the approval of the Institutional Ethical Committee, the first human implant was performed in a girl with Down's syndrome, complete atrioventricular septal defect with unbalanced ventricles, large patent ductus arteriosus and pulmonary hypertension. At one month of age she underwent closure of the patent ductus arteriosus

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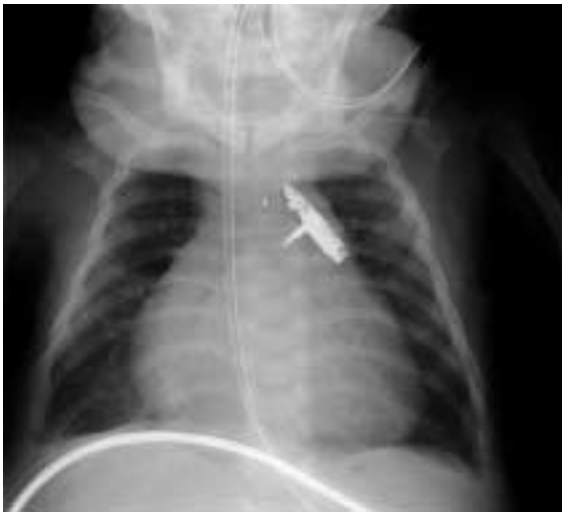

Figure 1

Postoperative chest X-ray showing the FloWatch™ implanted around the pulmonary artery.

and FloWatch™ implantation around the pulmonary artery through conventional left thoracotomy. The surgical procedure was rapid and uneventful. During the entire postoperative period (fig. 1) bedside adjustments (narrowing or release of pulmonary artery banding with echocardiographic assessment) were repeatedly required to maintain an adequate pressure gradient.

Several literature reports have confirmed the clinical need for externally adjustable pulmonary artery banding. Our experimental research [5] has tested a device (FloWatch™) for telemetrically adjustable pulmonary artery banding very easy to implant and use. The early clinical results have demonstrated the clinical benefits of unlimited external telemetric adjustments. The next step will be a multi-centre clinical trial to confirm the early results and adapt therapeutic strategies to this promising technology.

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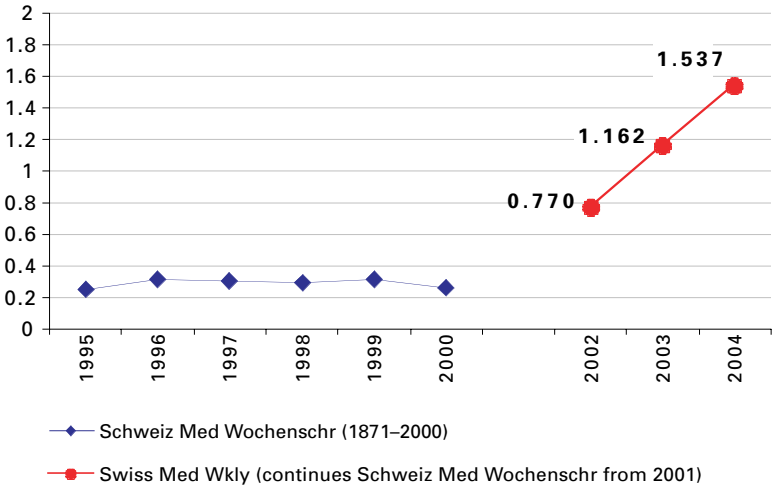

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