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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

## Horizon Scanning Technology Prioritising Summary

# FloWatch-PAB<sup>®</sup>: an implantable device for pulmonary artery banding

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Australian  
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# PRIORITISING SUMMARY

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**REGISTER ID**

**S000088**

**NAME OF TECHNOLOGY**

**FLOWATCH™**

**PURPOSE AND TARGET GROUP**

**PULMONARY ARTERY BANDING TO PALLIATE  
CONGENITAL HEART DEFECTS IN INFANTS AND  
CHILDREN**

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |             |           |
|---|-------------|-----------|
| <input type="checkbox"/> Yes            | ARTG number | <b>NA</b> |
| <input checked="" type="checkbox"/> No  |             |           |
| <input type="checkbox"/> Not applicable |             |           |

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
England	✓		
France	✓		
Germany	✓		
Greece	✓		
Switzerland	✓		

## IMPACT SUMMARY

FloWatch™ is a new implantable device designed to treat infants and children with congenital heart defects, where pulmonary artery banding is indicated, as an alternative to traditional methods of banding. This technology is currently yet to emerge in Australia.

## **BACKGROUND**

Congenital heart defects are abnormalities of the heart or central blood vessels that are present at birth (Australian Institute of Health and Welfare 2008a). These abnormalities can be of the heart, heart valves, arteries or a combination of cardiac structures (Australian Institute of Health and Welfare 2008a). The most common defects which affect the cardiovascular system are:

- Transposition of the great vessels, or TGA, which is characterised by transposition of the primary arteries (aorta and pulmonary artery) of the heart. That is, the aorta rises from the morphological right ventricle and the pulmonary artery rises from the morphological left ventricle. There are two anatomic classifications of TGA; they are dextro-TGA (d-TGA) where the aorta is anterior to the right of the pulmonary artery and levo-TGA (l-TGA) where the aorta is anterior to the left of the pulmonary artery (Charpie 2007).
- Tetralogy of Fallot, describes four specific defects (National Heart, Lung and Blood Institute 2007).
  1. Ventricular septal defect (VSD), or a hole in the wall that separates the left and right side (ventricle) of the heart (septum). Atrioventricular septal defects are characterised by a lack of separation between the left ventricle and the right atrium (Espinola-Zavaleta et al 2008),
  2. Pulmonary stenosis, or the narrowing of the valve and passageway that blood flows from the right ventricle to the pulmonary arteries,
  3. Right ventricular hypertrophy, which results from pulmonary stenosis as the right ventricle wall must work harder to move blood through the narrowed pulmonary valve, resulting in thickening of the cardiac muscle (hypertrophy), and
  4. Overriding aorta, where the aorta is attached between the left and right ventricles, directly over the VSD, instead of to the left ventricle as in a healthy heart. Resulting in deoxygenated blood flowing into the aorta instead of the pulmonary artery.
  5. Hypoplastic left heart syndrome, which results from an underdeveloped left ventricle, associated with aortic and/or mitral valve absence or blockage. This results in reduced flow of oxygenated blood from the lungs back into the heart to be supplied to the rest of the body (Abeywardana & Sullivan 2008).
  6. Coarctation of the aorta, this is an obstruction in the descending aorta, almost always at the insertion of the connecting blood vessel between the aorta and pulmonary artery in a foetus (ductus arteriosus). Coarctation of the aorta causes reduced blood flow to the body and increased blood pressure above the point of obstruction; this may result in hypertrophy (Abeywardana & Sullivan 2008).

Pulmonary artery banding (PAB) was first used in patients in 1952 for the palliation of congenital heart disease (Locker et al 2008). PAB is commonly used in a subset of patients where primary complete repair of their cardiac anomalies is not possible. This predominately includes patients in infancy and early childhood generally due to the sensitivity of their age and body weight to the current repair techniques available (Corno 2005). Many of these patients undergo complete repair with debanding and reconstruction of the pulmonary artery at a later time when surgical intervention is appropriate (Locker et al 2008). Traditionally, PAB involves the placement of a band around the main pulmonary artery which is tightened as required in accordance with the pulmonary artery pressure distal and proximal to the band (Locker et al 2008). The objective of the band is to achieve a distal pulmonary artery pressure at one third to one half of systemic blood pressure (Locker et al 2008). Due to the dynamic nature of the cardiac variables which influence blood flow and pressure (for example, heart rate), particularly in the first few hours or days following surgery, it is difficult to apply banding at an appropriate degree of occlusion to predict long-term treatment effectiveness. As a result, invasive reoperation to adjust band width is often required; this may also increase the cost of intensive care hospitalisation.

FloWatch™ is a wireless, battery free, implantable device which allows the repeated progressive occlusion and reopening of the device through remote control, which removes the need for invasive reoperation to adjust the band as required by conventional PAB techniques (Corno 2005). The FloWatch™ apparatus consists of an implant and external control unit with an antenna. The main mechanisms of the device itself include an antenna, which supplies the electronics with energy and commands from the external control unit in regards to banding modification, a piston, which adjusts the degree of banding (the piston has a stroke of 3 mm for tightening and loosening) and a micro-motor which activates the piston (Corno 2005). The device is surgically implanted around the main pulmonary artery, with dimensions of 26 mm (length) x 18.4 mm (width) x 17 mm (height) (Corno 2005).

#### **CLINICAL NEED AND BURDEN OF DISEASE**

Congenital heart defects are one of the largest contributors to death in infants, less than one year of age (Australian Institute of Health and Welfare 2008b). In 2002, congenital heart defects accounted for 224 deaths (125 males and 99 females) or 0.17% of all deaths in Australia (Australian Institute of Health and Welfare 2008b).

In 2001–2002, there were 4,960 hospitalisations where the principal diagnosis was congenital heart disease, which accounts for 0.08% of all hospitalisation in that year and 14.6% of all hospitalisations for congenital malformations (Australian Institute of Health and Welfare 2008b). In the same year, there were a reported 889 procedures performed for closure of a atrial septal defect, 466 for closure of patent ductus arteriosus and 387 for closure of a ventricular septal defect (Australian Institute of Health and Welfare 2008b).

#### **DIFFUSION**

The FloWatch™ device has not been approved by the Therapeutic Goods Administration or the US Food and Drug Administration; however it has received the “EC mark” and is

commercially available throughout Europe. Multicentre clinical trials have recently been carried out in Europe. This technology has not developed an evidence base elsewhere in the world, particularly in Australia where usage of FloWatch™ for PAB appears to be yet to emerge.

### **COMPARATORS**

Although primary complete repair is often the treatment of choice for patients with congenital heart defects, it is not always recommended in certain patient subgroups, particularly infants and children. Therefore, the main comparator of FloWatch™, or remotely adjustable pulmonary artery banding, is conventional PAB techniques.

### **SAFETY AND EFFECTIVENESS ISSUES**

There were three studies identified as suitable for inclusion in this summary, one level III study (Corno et al 2007) and two level IV studies (Bonnet et al 2004; Corno et al 2003). These studies looked at the effectiveness of FloWatch™ for PAB in infants and young children and in the case of Corno et al (2007) compared the outcomes of this device with conventional PAB techniques.

In the prospective, nonrandomised comparative study conducted by Corno et al (2007), 40 consecutive infants underwent either conventional PAB or PAB using the FloWatch™ device. There were three indications for PAB in the patient population, these included, preparation for a biventricular type of repair for single or multiple ventricular or atriventricular septal defects associated with hypoplasia, interrupted aortic arch or the clinical conditions of the patient (16 and 13 patients from the conventional and FloWatch™ PAB groups were treated for this indication, respectively). The other indications were, preparation for a univentricular type of repair in functionally univentricular hearts with pulmonary hypertension (2 and 5 patients from the conventional and FloWatch™ groups were treated for this indication, respectively) and the need for left ventricular retraining surgery in patients with late referral TGA (2 patients in each group were treated for this indication). The allocation of patients into treatment groups was determined by the availability of the device itself and, in general, was reserved for infants more likely to suffer difficulties in their postoperative course. The preoperative characteristics seen to predispose infants with a difficult follow-up period were the necessity for prolonged mechanical ventilation or univentricular repair, or both. As a result, patients were well matched at baseline, with the exception of the mean duration of mechanical ventilation, which was significantly higher in the FloWatch™ PAB group ( $17.5 \pm 19.0$  days [range, 0–60 days]) compared with the conventional PAB group ( $3.3 \pm 4.3$  days [range, 0–15 days];  $P < 0.005$ ). The mean duration of follow-up was not significantly different between the groups at  $10.8 \pm 9.6$  months (range, 1–33 months) in the conventional PAB group and  $13.4 \pm 10.4$  months (range, 1–38 months) in the FloWatch™ PAB group.

In the multicentre, prospective, nonrandomised, single-arm clinical investigation by Bonnet et al (2004), a total of 13 infants and children underwent implantation of FloWatch™ as an alternative to conventional banding for a variety of congenital heart defects. Indications for FloWatch™ were based on the clinicians' judgements, as the

inclusion criteria were the same as that of conventional PAB. Common indications included single or multiple ventricular or atrioventricular septal defects, elevated pulmonary vascular resistance and TGA. The median age of the patient population was 4.5 months (range, 6 days to 131 months) and the median weight was 4.2 kg (range, 3.2–27 kg). Mean follow-up length was 13 months (range, 4–12 months).

FloWatch™ PAB regulations describe the tightening or release of the banding, either during early (in hospital stay) or late (post-discharge from hospital) follow-up. Indications for regulation were based on the estimation of the Doppler gradient across the band (adequate when maximum Doppler velocity across the PAB was > 4m/second) and systemic oxygen saturation (adequate when > 80% in patients with parallel circulation and complete mixing, and when > 70% in patients with transposition) (Bonnet et al 2004).

In the prospective, multicenter trial by Corno et al (2003), six patients underwent PAB with FloWatch™. The mean age of the patient population was 10.6 months (range, 1–31 months) and mean body weight was 6.5 kg (range, 3.5–11 kg). Indications for treatment in the population included univentricular heart in two patients, complete atrioventricular septal defects in two patients, isolated ventricular septal defect in one patient and multiple ventricular septal defects and double aortic arch in one patient. All of the patients presented with systolic pulmonary artery pressure at systemic levels. Mean follow-up duration was 7 months (range, 6–9 months).

### **Safety**

There were no reported safety outcomes in the study by Corno et al (2007). This does not mean that no adverse events occurred. Death was measured as an effectiveness outcome in all three studies.

In the study by Bonnet et al (2004) there were no technical difficulties during implantation of the device. All functional tests carried out in the operating room, including the assessment of the coupling of the device with the external control unit, were completed successfully. At three months follow-up, two patients experienced difficult telemetric coupling between their implanted device and external antenna. The problem was resolved in one patient who underwent their final regulation under general anaesthetic but could not be resolved in the other patient. The second patient's device was unable to respond to the external unit due to growth of that patient during follow-up; however, at this time the patient was found to be suitable for debanding and complete repair which eliminated any future issues with coupling of the device.

Corno et al (2003) reported that there were no device related complications throughout the follow-up period. No other safety data was reported.

### **Effectiveness**

In the study by Corno et al (2007), the total number of deaths, as well as the number of early and late deaths, was not significantly different between patients receiving conventional PAB or FloWatch™ PAB. In the conventional PAB group, early (< 20

days) deaths were caused by cardiac arrest during tracheal suctioning, inexorable heart failure and multi-organ failure. There were no early deaths in the FloWatch™ group. Late (> 2 months) deaths, in the conventional PAB group, were caused by sepsis and heart failure and in the FloWatch™ PAB group, by respiratory infection and neurologic damage. PAB-related reoperation was required in 35% (7/20) of infants following conventional PAB, whereas, no reoperations were required in the FloWatch™ PAB group (P<0.005). Instead, in the FloWatch™ group there was a mean  $3.3 \pm 1.3$  (range, 1–5) telemetric adjustments per infant to narrow the band and a mean  $0.7 \pm 1.0$  (range, 0–3) telemetric adjustments per infant to widen it. During follow-up, 12 patients who underwent conventional PAB and 7 patients who underwent FloWatch™ PAB submitted to debanding and intracardiac repair, with no deaths were reported. Pulmonary artery reconstruction was required by 83% (10/12) of patients in the conventional PAB group, compared with none in the FloWatch™ group — these patients' arteries expanded to normal size following the removal of the device (P<0.0005). By the end of the observation period 3 and 12 conventional PAB and FloWatch™ PAB patients were awaiting surgical repair.

Mean postoperative mechanical ventilation duration was significantly greater in the conventional PAB group ( $10.4 \pm 11.2$  days [range, 1–51 days]) compared with the FloWatch™ PAB group ( $3.0 \pm 3.1$  days [range, 1–7 days]; P<0.01). Mean intensive care unit (ICU) stay and hospital stay were also significantly longer in the conventional PAB group compared to in FloWatch™ patients (P<0.005). Mean ICU stay was  $20.3 \pm 19.9$  days (range, 1–51 days) and  $5.3 \pm 4.6$  days (range, 1–20 days) in each group, respectively and mean hospital stay was  $45.6 \pm 41.6$  days (range, 5–182 days) and  $15.4 \pm 6.4$  days (range, 6–30 days) in each group, respectively (Corno et al 2007).

In the study by Bonnet et al (2004), there were no deaths or necessity for reoperation reported during the follow-up period. Median ICU stay was 1 day (range, 1–12 days). Echographic and radiographic examination showed that the device had not moved or rotated in any of the 13 patients. Regulation to increase pulmonary artery compression was required in 74% of cases. Only 30% (4/13) of patients only required band tightening, the remaining patients had subsequent loosening of the band at least once (with three cases of emergency release). A mean of 5.8 regulations (range, 1–14) per patient were required to adjust the PAB to suit the clinical needs of the patient.

All patients were doing well at the last follow-up. In all of the patients that underwent complete repair the pulmonary artery re-expanded completely after the removal of the FloWatch™ device. Estimated systolic pulmonary artery pressure was within normal range in all the remaining patients (Bonnet et al 2004).

Corno et al (2003) reported the implantation procedures in all six infants were easy and uneventful. The duration of the surgical procedure was less than 40 minutes in the two patients that underwent FloWatch™ PAB not in conjunction with another procedure. All of the patients were extubated within the first 24 postoperative hours. The median length of ICU stay was 1 day, with 4 patients staying 1 day, 1 patient staying 3 days and 1 Down

syndrome patient with major upper airway problems requiring endoscopic supraglottoplasty staying 29 days.

There were no deaths or reoperations reported in the follow-up period. After the first regulation (on the same day as the operation) a mean of 5 regulations (range, 2–14) were required per patient to adjust the FloWatch™ device. There were a total of 30 regulations among the patient population over the follow-up period, 50% (15/30) occurred in the first postoperative week, 20% (6/30) in the second postoperative week and 30% (9/30) between 3 weeks and 8 months postoperative. Narrowing of the PAB was required in 70% (21/30) of cases and widening in 30% (9/30), including 2 cases of emergency release due to arterial oxygen desaturation and bradycardia. During follow-up, only one patient underwent surgical repair (at 3 months postoperative); the procedure was successful, the device was uneventfully removed without the need for pulmonary artery reconstruction (Corno et al 2003).

### **COST IMPACT**

FloWatch™ is proposed to reduce the duration of ICU and hospital stay because the device can be adjusted noninvasively immediately following surgery, eradicating the need to reoperation.

One study looking at the cost effectiveness of FloWatch™ described the cost per unit as \$10,000 (currency not specified) (Corno et al 2007). Further cost calculation in the study found the average cost per patient for ICU stay to be \$60,900 in the conventional PAB group and \$15,900 in the FloWatch™ PAB group, and for hospital stay \$68,400 and \$23,100 per patient in each group, respectively. The average cost of reoperation to adjust the band width in the conventional PAB group was reported as \$2,275; therefore, the overall average cost per patient was \$92,575 less in FloWatch™ patients than in conventional PAB patients (Corno et al 2007).

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified from the retrieved material.

### **OTHER ISSUES**

No issues were identified from the retrieved material.

### **SUMMARY OF FINDINGS**

From the included evidence FloWatch™ appeared to exhibit superior effectiveness in regard to postoperative management. In particular, the use of the device eliminated the need for invasive reoperation to regulate band tightness, decreased the duration of time the patient spent in ICU and hospital (consequently minimising costs) and reduced the need for pulmonary artery reconstruction at debanding and complete repair.

However it is important to note the quality of these studies. In the nonrandomised comparative study, selection bias was present, as patients with longer preoperative mechanical ventilation requirement were more actively selected to undergo FloWatch™ PAB. The single-armed studies also provided lower quality evidence as the outcomes of

FloWatch™ were not evaluated against the comparator procedure. Therefore, high quality randomised controlled trials are required to further investigate the effectiveness of the use of FloWatch™ for pulmonary artery banding, with a particular emphasis on the safety of the device which is lacking in the current body of evidence.

#### **HEALTHPACT ACTION**

Based on the lack of high quality evidence and potential uptake of the technology it is recommended that this technology is monitored for 12 months.

#### **NUMBER OF STUDIES INCLUDED**

Total number of studies	3
Level III evidence studies	1
Level IV evidence studies	2

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#### **SEARCH CRITERIA TO BE USED**

FloWatch

Pulmonary artery banding

Congenital heart disease OR congenital heart defect\*