NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects

Adjustable pulmonary artery banding is used in some young children born with heart problems. In this procedure an adjustable metal band is clipped around the blood vessel that carries blood from the heart to the lungs to restrict blood flow and reduce pulmonary artery blood pressure. The aim is to reduce the risk of heart failure caused by high blood pressure in the lungs. The tightness of the band can be adjusted at any time using a remote control (for example, as the child grows), without the need for further surgery to adjust the band.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in February 2014.

Procedure name

- Telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects

Specialist societies

- British Congenital Cardiac Association
- Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS).

Description

Indications and current treatment

Congenital heart defects with a left-to-right shunt and excessive pulmonary blood flow can result in pulmonary hypertension and congestive heart failure in the neonatal period. The usual treatment is surgical correction of any defect when the infant is big enough. The most common defects needing this type of treatment include functionally univentricular hearts, transposition of the great arteries and atrioventricular or multiple septal defects. The symptoms include fatigue, dyspnoea, tachypnoea and failure to thrive if the lungs are not protected. Infants may develop a condition of irreversible pulmonary hypertension because of hypertrophy of the pulmonary arterioles.

Pulmonary artery banding (PAB) is a palliative procedure that is used as part of staged treatment before definitive surgical correction of congenital heart defects. The aim of PAB is to reduce the diameter of the main pulmonary artery, decreasing blood flow and reducing pulmonary artery pressure. Improvement of systemic pressure, cardiac output and ventricular function can also be expected in patients with a large left-to-right shunt. Risks of the procedure include lowering of systemic oxygen saturation, ventricular hypertrophy, subaortic obstruction, and pulmonary branch and valve distortion. The conventional technique of PAB involves surgical placement of a (not telemetrically adjustable) band around the main pulmonary artery. Different techniques using a variety of materials (such as strips of polytetrafluoroethylene, polydioxanone or nylon) and sutures are used. In non-adjustable PAB methods, reoperation is often needed to adjust the tightness of the band.

What the procedure involves

Telemetric adjustable pulmonary artery banding is mainly used in infants with multiple or single ventricular septal defects and those needing left ventricular retraining for congenitally corrected transposition of the great arteries.

The procedure is done under general anaesthesia, either through a median sternotomy or lateral thoracotomy depending on the child’s anatomy and nature of their disease. The pericardium is opened over the great vessels and, with minimal dissection, a tunnel is created between the ascending aorta and the main pulmonary artery. The adjustable pulmonary artery band (which contains a micro-motor) is fastened around the main pulmonary artery. The band is sutured to the pulmonary artery to prevent it from migrating. Coupling between the band and an external remote control unit (powered by an external antenna) is tested and the incision is closed.

Immediately after surgery, the infant is treated in a neonatal intensive care unit and the band is adjusted wirelessly by the control unit, according to the child’s

haemodynamic status, to control pulmonary artery flow. Echocardiography is used to gauge the adjustment needed. Later adjustments to the band can be done in an outpatient setting, without the need for further surgery. The band is removed at the same time as cardiac surgery for definitive repair of any heart defect.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to adjustable pulmonary artery banding for reducing pulmonary hypertension in infants with congenital heart defects. Searches were conducted of the following databases, covering the period from their commencement to 24-2-2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Infants with congenital heart defects.
Intervention/test	Telemetric adjustable pulmonary artery banding for pulmonary hypertension.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 64 patients from 4 non-randomised comparative observational studies[1-4]; 1 prospective, 1 retrospective and 1 with a retrospective-prospective comparison; 2 observational studies[5,8] and 2 case reports[6,7].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects

Study 1 Corno AF (2007)

Details

Study type	**Prospective non-randomised comparative (observational) study**
Country	United Kingdom
Recruitment period	2003-6
Study population and number	Consecutive infants n=**40 (TA-PAB 20 vs con-PAB 20) infants**
Age and sex	Mean age: Telemetric adjustable PAB 2.6±1.3 months, Conventional PAB 1.8±1.5 months, Sex: not reported
Patient selection criteria	Not reported Mean weight: TA-PAB 4.1±0.8 kg; Con-PAB 3.7±0.7 kg Operation indications: biventricular repair in 65% (13/20) infants, univentricular repair in 25% (5/20) infants, and left ventricular retraining in 10% (2/20) infants in TA-PAB group and 80% (16/20), 10% (2/20) and 10% (2/20) infants respectively in the con-PAB group. The only significant difference between the 2 groups was the length of pre-operative mechanical ventilation, which was higher in the TA-PAB group (17.5±19.0 days vs 3.3±4.3 days; p<0.005).
Technique	In all infants PAB performed through a median sternotomy. Con-PAB with a 4 mm Teflon band measured with the Trusler rule, tightness adjusted intraoperatively according to the measured distal pulmonary artery pressure and systemic oxygen saturation. TA-PAB with a Flowatch device and required adjustments to the band were done telemetrically in the TA-PAB group and by re-operation in the con-PAB group.
Follow-up	Until debanding during intra-cardiac repair or end of study **TA-PAB: mean 13.4±10.4 months, range 1-38 months** **Con-PAB: mean 10.8±9.6 months, range 1-33 months**
Conflict of interest/source of funding	First author reports a consulting fee from EndoArt.

Analysis

Study design issues: small sample size. Patients could not be randomly selected because of limited availability of the device. Clinicians were not blinded to type of device/intervention used. This is a specialised procedure for relatively rare conditions and so this is not unexpected. There were no significant differences between the 2 groups in terms of age, weight or condition and clinical protocols. Patients were allotted to groups based on the limited availability of the TA-PAB device and the likelihood of having difficult post-operative management, eg: prolonged mechanical ventilation or preparation for a univentricular type of repair.

Other issues: comparative data on costs were not extracted from the study because it is not in IP remit.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **40 (20 vs 20)**

Postoperative outcomes

	TA-PAB (n=20)	**Con-PAB (n=20)**	**p value**
Duration of postoperative mechanical ventilation (days)	3.0±3.1	10.4±11.2	p<.01
length of stay in ICU (days)	5.3±4.6	20.3±19.9	p<.005
length of hospital stay (days)	15.4±6.4	45.6±41.6	p<0.005

A mean of 3.3±1.3 telemetric adjustments were done per infant to narrow the TA-PAB and 0.7±1.0 to release it.

Debanding during intra-cardiac repair

During follow-up, 19 patients underwent intra-cardiac repair and pulmonary artery debanding (7 in TA-PAB group and 12 in con-PAB group). None of them died.

Infants waiting for cardiac repair

At the end of study, 12 in TA-PAB group and 3 in con-PAB were waiting for intra-cardiac repair.

Safety

	TA-PAB % (n=20)	**Con-PAB % (n=20)**	**p value**
Deaths			
Early	0	15 (3/20) (at 1, 15, 20 days postoperatively) 1-cardiac arrest during tracheal suctioning 1-inexorable heart failure 1-multiorgain failure	NS
Late	10 (2/20) (at 2 and 3 months postoperatively) 1 due to respiratory infection and 1 neurological damage	12 (2/17) (1 due to sepsis and 1 heart failure)	NS
PA reoperations	0	35 (7/20)	p<0.005
Reconstruction of PAB during intra-cardiac repair after debanding	0	83 (10/12)* needed surgical enlargement of pulmonary artery, with a patch of pericardium to relieve residual stenosis after band removal	p<.0005

*infants who underwent intra-cardiac repair after pulmonary artery debanding.

Abbreviations used: Con-PAB, conventional pulmonary artery banding; ICU, intensive care unit; NS, not significant; TA-PAB, telemetric adjustable pulmonary artery banding.

Study 2 Dhannapuneni RR (2011)

Details

Study type	**Retrospective non-randomised comparative (observational) study**
Country	United Kingdom
Recruitment period	2000-9
Study population and number	Infants less than 1 year of age with complete atrioventricular septal defects (cAVSDs) n=**20 (TA-PAB 7 vs con-PAB 13) infants**
Age and sex	Mean age: TA-PAB 111±40 days; Con- PAB 74±56 days, Sex: not reported
Patient selection criteria	Infants with unsuitable intra-cardiac anatomy (unbalanced ventricles, associated lesions, or both in 10 infants) and/or poor clinical condition (continuous chest infections with positive cultures, contraindicating cardiopulmonary bypass in 10 infants, with 8/10 requiring preoperative mechanical ventilation) were allocated to each group based on surgical preference and the intervention received. Children older than 1 year with cAVSDs with late presentation and severe pulmonary hypertension were excluded. Mean weight: TA-PAB 4.3±1.2kg; Con-PAB 3.3±1.1kg Pre-operative mechanical ventilation was needed by 5 infants in the TA-PAB group and 3 in the con-PAB group ($p<0.05$). Down syndrome present in 6 infants in the TA-PAB group and 5 in the con-PAB group.
Technique	In all infants PAB performed through a median sternotomy. Con-PAB with a 4 mm Teflon band, adjusted intraoperatively. TA-PAB with a Flowatch device, postoperative adjustments to the band were done telemetrically in the ICU guided by Doppler echocardiographic analysis and by re-operation in the con-PAB group.
Follow-up	Not reported
Conflict of interest/source of funding	One of the authors reports consulting fees from the manufacturer.

Analysis

Study design issues: this study involved a small number of patients because of the specialised nature of the procedure and condition.

Other issues: The authors attributed the high mortality rate to differences in surgical technique between the 2 groups, because there were no significant differences in age or weight between the 2 groups. The authors also suggested that the improved outcomes observed with the TA-PAB device were a result of the ability to carry out repeated, graduated tightening of the PAB, facilitating a more controlled reduction in arterial flow and pressure. There is also a reduced need to delay sternal closure for PAB adjustment when using TA-PAB.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **20 (7 vs 13)**

Postoperative outcomes

	TA-PAB (n=7)	**Con-PAB (n=13)**	**p value**
Duration of postoperative mechanical ventilation (mean days)	3±2	21±17	p<0.05
Length of stay in ICU (mean days)	7±6	22±18	p<0.05
Length of hospital stay (mean days)	29±25	54±12	p<0.05
Delayed sternal closure % (n)	0	46 (6/13)	p<0.05

Degree of atrioventricular valve regurgitation

Left atrioventricular valve regurgitation increased) in 2 infants (mild-to-moderate in 1 and moderate-to-severe in 1) in the con-PAB and decreased in 2 infants (severe-to-moderate) in the TA-PAB group, and remained unchanged in all other infants in both groups.

Number of required TA-PAB adjustments

A total of 44 telemetric adjustments (41 to tighten and 3 to release) were needed in 7 patients in the TA-PAB group.

Debanding during intra-cardiac repair

Of 10 survivors, 6 (5 in the TA-PAB group and 1 in the con- PAB group) underwent pulmonary artery de-banding and repair after a median interval of 125 days (range 34-871 days);

Infants waiting for cardiac repair

4 of the10 survivors were awaiting repair at the time of publication.

Safety

	TA-PAB % (n=7)	**Con-PAB % (n=13)**	**p value**
Hospital deaths	0	77 (10/13)*	<0.001

*due to cardiorespiratory failure in 4, multi-organ failure in 2 and aspiration pneumonia in 1, 2 died after transfer back to referral hospital, 1 cause of death unknown.

Abbreviations used: Con-PAB, conventional pulmonary artery banding; cAVSDs, complete atrioventricular septal defects (cAVSDs); ICU, intensive care unit; NS, not significant; TA-PAB, telemetric adjustable pulmonary artery banding.

Study 3 Serkasi N (2012)

Details

Study type	**Prospective and retrospective non-randomised comparative (observational) study**
Country	Switzerland
Recruitment period	Before and in 2003
Study population and number	Consecutive infants with simple transposition of the great arteries (TGA) and an involuted left ventricle n=**10 (TA-PAB 4 vs con-PAB 6) infants**
Age and sex	Mean age: Telemetric adjustable PAB 11.7±11.1 months Conventional PAB 6.4±7.6 months, Sex: not reported
Patient selection criteria	Patients in whom echocardiogram showed a decrease in left ventricular posterior wall thickness and a pancaked appearance of the left ventricle consistent with low pressure in the left ventricle, in some cases, left ventricular pressure was less than half of right ventricular pressure (confirmed on cardiac catheterization). Mean weight: TA-PAB 5.8±2.4 kg (since 2003); Con-PAB 5.0±2.3 kg (before 2003)
Technique	Retraining of the left ventricle in late diagnosed transposition of the great arteries (TGA) either with a TA-PAB or with a con-PAB. In all PAB was performed through a median sternotomy. Con-PAB was with a polytetrafluoroethylene (PTFE) band, adjusted intraoperatively to achieve the pulmonary gradient and oxygen saturation. TA-PAB with a Flowatch device (only 5% closed) and required adjustments to the band were done telemetrically guided by Doppler echocardiographic analysis in the TA-PAB group and by re-operation in the con-PAB group. Arterial switch procedure was performed in both groups when 2/3 of right ventricular wall thickness and left ventricular pressure was greater than 2/3 of right ventricular pressure. Mean time between banding and arterial switch procedure was 4.2 months in both groups.
Follow-up	**19.8±17.7 months (mean).**
Conflict of interest/source of funding	None reported

Analysis

Study design issues: Small numbers of patients were included in the study; this was because of the specialised nature of the procedure and condition. The authors state that they had an agreement to operate on patients from countries where cardiac surgery was not available, hence the late referral of their TGA. Long-term follow-up was not possible because most patients returned to their country of origin.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **10 (4 vs 6)**

PAB procedural outcomes

	TA-PAB (n=4)	**Con-PAB (n=6)**
Mean surgical time	61 min	203
Associated procedures during PAB	0	8 procedures (, Arterial Septal Defect enlargement, BT shunts and patient ductus arteriosus ligation) in 5 infants

All patients showed increased left ventricular wall thickness with no difference between groups (p=0.07).

Number of adjustments to PAB from banding to arterial switch surgery:

The TA-PAB was gradually closed between 5 and 8 times per patient, and 1 patient required 3 reopenings during the left ventricle retraining period.

Outcomes after banding and arterial switch surgery

	TA-PAB (n=4)	**Con-PAB (n=6)**	**p value**
Arterial switch surgery % (n)	100	83 (5/6)	NR
initial mean gradient after banding	25.5±4.43	49.2±21.4	NR
mean pulmonary gradient before arterial switch (mmHg)	63.5 ±9.8	68.4±7.86	NS

The mean pulmonary gradient decreased more quickly after debanding in the TA-PAB group than in the con- PAB group because the artery expanded immediately after removal of the TA-PAB.

Survival

Survival was 100% in the TA-PAB group ad 66% for the con-PAB group.

Safety

Outcomes after banding

	TA-PAB % (n=4)	**Con-PAB % (n=6)**	**p value**
Early deaths	0	27 (2/6) (1 at 24 hrs after banding due to low cardiac output and 1 after the arterial switch surgery on day 7 for multi-organ failure)	NS
Late deaths	0	0	
PAB reoperations (to tighten or improve oxygenation during retraining)	0	66 (4/6) (*2 needed 1 reoperation:* rebanding after 2 weeks in 1, and a shunt placement within 24 hrs after banding in 1] and *2 needed 2 reoperations:* reopening within 24 hrs and rebanding after 1 month in 1 and partial shunt closure after 3 weeks of banding and then a coarctation repair in 1)	

No device-related complications were recorded on removal of TA-PAB.

Abbreviations used: Con-PAB, conventional pulmonary artery banding; hrs, hours; NS, not significant; PTFE, polytetrafluoroethylene; TA-PAB, telemetric adjustable pulmonary artery banding, TGA, transposition of the great arteries.

Study 4 D'Alfonso A (2010)

Details

Study type	**Retrospective non-randomised comparative (observational) study**
Country	Italy
Recruitment period	2005-8
Study population and number	Consecutive infants who underwent banding of the main pulmonary trunk with either TA-PAB or con-PAB n=**19 (TA-PAB 11 vs con-PAB 8) infants**
Age and sex	Mean age: TA-PAB 2.6 months Con- PAB 3.5 months Sex: TA-PAB: female36% (4/11); Con-PAB: 37% (3/8)
Patient selection criteria	Primary operation indications: Patients requiring left ventricular retraining for congenitally corrected transposition of great arteries (1 patient in the FloWatch group), palliation before biventricular repair (91%) (10/11) in the FloWatch group [3 multiple VSD, 5 single VSD, 2 AVSD] and 87% (7/8) in the conventional PAB group [6 single VSD, 1 truncus arteriosus], staged univentricular repair - double outlet right ventricle (DORV) (1 in the conventional PAB group). Mean weight: TA-PAB 3.1 kg; Con-PAB 4.1 kg
Technique	In all infants PAB was performed through a median sternotomy. Con-PAB was with a 4 mm Teflon band or a flattened GoreTEX PTFE tube graft, adjusted intraoperatively to achieve the pulmonary gradient and oxygen saturation. TA-PAB with a Flowatch device and required adjustments to the band were done telemetrically guided by Doppler echocardiographic analysis in the TA-PAB group and by re-operation in the con-PAB group. In 1 90-day-old patient with congenitally corrected transposition of the great arteries TA-PAB was used. For left ventricular retraining a different strategy was used.
Follow-up	**Mean 16±11 months for TA-PAB and 16±13 months for con-PAB**
Conflict of interest/source of funding	None

Analysis

Study design issues: Small numbers of patients were included in the study; this was because of the specialised nature of the procedure and condition. Interventions assigned based on surgeon's preference but not on prospective protocol.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **19 (11 vs 8)**

Outcomes after banding

	TA-PAB (n=11)	Con-PAB (n=8)	p value
Postoperative mechanical ventilation (mean±SD) hours	230±302	109±174	0.3
Stay in ICU(mean±SD) days	11.4±12.9	7.8±10.7	0.4
Stay in hospital (mean±SD) days	18 ±10	17±9	0.9

Number of adjustments to TA-PAB from banding

In the TA-PAB a mean of 3.1±1.7 regulations per patient were undertaken. Of the regulations, 85% (29/34) were adjustments to tighten the device in 8 patients, and 15% (5/34) were to loosen it in 3 patients.

Infants waiting for cardiac repair

At the end of follow-up, 2 patients in con-PAB group and 5 patients in TA-PAB group were awaiting intra-cardiac repair. For 2 patients in con-PAB group, banding was considered as definitive palliation and intra-cardiac repair was not planned.

Safety

	TA-PAB % (n=11)	Con-PAB % (n=8)	p value
In-hospital mortality	0	0	NA
late deaths	18.2 (2/11) 1 at 14 months after banding and 1 at 15 days after intra-cardiac repair for VSD	0	0.7
Perioperative complications	9.1 (1/11) cardiac arrest in ICU with subsequent neurological consequences	0	
PAB related reoperation	9.1 (1/11) removed same day for severe hemodynamic compromise attributed to bulk of the device causing right ventricular compression and con-PAB done	0	0.8
Subsequent debanding and intra-cardiac repair	50 (4/8)	36.4 (4/11)	0.7
Pulmonary artery reconstruction at intra-cardiac repair	25 (1/4) 1 had patch augmentation of PA at debanding	100 (4/4) all had patch augmentation of PA at debanding 1VSD closure	0.021

One of the authors stated that they had prior experience (anecdotal observations) with instances of TA-PAB removal for presumed compression of cardiovascular structures: left superior vena cava compression in 1 case and coronary artery compression in another.

Abbreviations used: AVSD, aterioventricular septal defect; Con-PAB, conventional pulmonary artery banding; DORV, double outlet right ventricle; ICU, intensive care unit; NS, not significant; PTFE, polytetrafluoroethylene; TA-PAB, telemetric adjustable pulmonary artery banding; VSD, ventricular septal defect.

Study 5 Corno AF (2013)

Details

Study type	**Multicentre prospective observational study**
Country	Saudi Arabia and UK
Recruitment period	2004-12
Study population and number	Consecutive infants with multiple ventricular septal defects (VSDs) n=**17 (3 premature, 14 infants)**
Age and sex	Mean age: 3.2 months (9 days-9 months) Sex: female 36% (4/17);
Patient selection criteria	Infants with the presence of multiple muscular apical VSDs (Swiss cheese type), with or without associated congenital heart defects, including the presence of other restrictive or unrestrictive VSD, either of peri-membranous or inlet type. Mean weight: 4.2 kg (3.1-6.1 kg) Associated anomalies: patent ductus arteriosus (12), aortic coarctation (2), hypoplastic aortic arch (2), and left isomerism (3) 29% (5/17) needed preoperative mechanical ventilation, with a mean duration of 64 days.
Technique	In all infants TA-PAB with a Flowatch device was performed through a median sternotomy, required adjustments to the band were done telemetrically guided by Doppler echocardiographic analysis. Associated patient ductus arteriosus was closed during PAB in 9 patients. Cardiopulmonary bypass was needed in 18% (3/17).
Follow-up	**Mean 48 months (range 7-98 months; to December 2012)**
Conflict of interest/source of funding	None

Analysis

Study design issues: Small numbers of patients were included in the study.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **17**

Outcomes after banding

	TA-PAB (n=17)
Postoperative mechanical ventilation (mean±SD) days	2.4
Stay in ICU (mean±SD) days	5.6
Stay in hospital (mean±SD) days	16.8

Number of adjustments to TA-PAB from banding

A mean of 4.8 times per patient (2-9) were undertaken to tighten the band and a mean of 1.1 times per patient (0-3) to release the band with the patient's growth. In the late follow-up, adjustments were needed to loosen the band due to patient growth, with or without concomitant reduction of the multiple muscular VSDs.

Closure of multiple muscular VSDs

Including the patients with the PAB still in place, the multiple muscular VSDs had spontaneously closed in 88.2% (15/17) of patients over time and no surgical closure was necessary.

Safety

	TA-PAB % (n=17)
Early deaths	0
Late deaths	0
PAB-related reoperation (8th postoperative day)	(1/17) Drainage of a pericardial effusion through a sub-xiphoid approach in 1 infant.
PAB-related reoperation (mean 29 months)	59 (10/17) * 7 PAB removal with closure of a remaining unrestrictive VSD in 6 (peri-membranous in 3 patients, mid-muscular in 2 and inlet in 1) and Damus-Kaye-Stansel, bi-directional Glenn and atrial septectomy in 1. 3 only PAB removal without need for cardiopulmonary bypass.
Pulmonary artery reconstruction at intra-cardiac repair	1/10 Patch enlargement of main pulmonary artery because of residual velocity of 3.2 m/s through PA on ECG Doppler.

*All multiple multiple VSDs had closed in all 10 patients.

In 5/7 of remaining patients with PAB still in situ, all muscular VSDs had already closed. The only 2 patients with persistent multiple muscular VSDs are the 2 patients with the shortest follow-up (7 and 25 months).

Abbreviations used: Con-PAB, conventional pulmonary artery banding; ECG, echocardiography; ICU, intensive care unit; NS, not significant; TA-PAB, telemetric adjustable pulmonary artery banding; VSD, ventricular septal defect. (VSD).

Study 6, 7 Venugopal PS (2010), Michel-Behnke I (2005)

Details

Study type	**Case report**
Country	UK
Recruitment period	2004-12
Study population and number	1) Infants underwent closure of an inlet muscular ventricular septal defect (VSD) and were found to have hemodynamically significant residual VSD and ventilator dependent. n=**2**
Age and sex	1) Age: 6 months, Sex: female 2) not reported
Patient selection criteria	1) Weight: 6 kg 2) not reported
Technique	TA-PAB with a Flowatch device was performed through a median sternotomy
Follow-up	**7 weeks**
Conflict of interest/source of funding	None

Analysis

Study design issues: none

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **2**	**Device-related complications** **Erosion of the device and pseudoaneurysm formation after implantation of the TA-PAB** <u>Case 1</u> On third postoperative day, resternotomy was performed for cardiac tamponade. No surgical cause for the tamponade was identified. Subsequently the child made an uneventful recovery and was discharged ion 12th postoperative day. 6 weeks later the band was remotely readjusted, increasing the Doppler velocity across the band from 3 m/s t0 3.7 m/s and the constriction from 50% to 60%. A week after this, her PA pressure was found to be suprasystemtic, and she was found to have a pseuodaneurysm on the PA. Investigations (CT, ECG analysis and skiagram revealed a large pseuodanureysm of the PA, with the device floating freely in the psudoanuresym cavity. There was also a significant residual VSD. She was taken for surgical intervention and intraoperatively the device was seen to have completely eroded through the main PA and was lying free inside the pseudoaneurysm cavity with the blood contained in this thin walled cavity. The residual VSD was closed transatrially with a polytetrafluoroethylene patch, and the pseudoanuerysm cavity was resected, and the PA was reconstructed by an end-to-end anastomosis. The patient postoperative recovery was uneventful; patient discharged to local hospital on 12th postoperative day. <u>Case 2</u> Pseudoaneurysm formation 7 weeks after insertion of TA-PAB.
Abbreviations used: ECG, echocardiography; NS, not significant; PA, pulmonary artery; TA-PAB, telemetric adjustable pulmonary artery banding; VSD, ventricular septal defect.	

Study 8 Kouerinis IA (2010)

Details

Study type	**Case series**
Country	Greece
Recruitment period	2007-8
Study population and number	Congenital heart disease: ASD+VSD in 1, AV canal type C in 1 and VSD/PH in 1. n=**3** (of 8 patients)
Age and sex	Age: 74 days, 282 days, 197 days Sex: all female
Patient selection criteria	not reported
Technique	Emergency TA-PAB with a Flowatch device was performed through a median sternotomy in 1 and planned TA-PAB in 2 patients.
Follow-up	**16 months**
Conflict of interest/source of funding	None

Analysis

Study design issues: Criteria for sepsis made in accordance with the guidelines published by the Centre for Disease Control and Prevention.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **3**	**Sepsis after implantation of TA-PAB** Preoperative signs of infection: • controlled respiratory infection in 1 • fever of unknown origin in 1 • recent history of respiratory infection in 1. All had antibiotic prophylaxis and postoperative blood culture was positive in 2. Isolated organisms: Enterococcus faecalis, Pseudomonas aeruginosa in blood in 1 Enterococcus faecalis in blood and peri-cardiac fluid in 1. Re-exploration of the mediastinum for signs of infection performed in 1 patient despite lack of evidence from transthoracic ECG of debris or the accumulation of fluid around the device. During surgery no macroscopic signs of infection were observed and the device was functioning well and free of debris. Multiple samples for culture from operative field and the device and sheath proved negative and the patient continued treatment with antibiotics. Signs of sepsis showed complete remission 27 days after treatment with antibiotics and patient was discharged in good health. The other 2 patients were treated successfully with intensive medical therapy alone without surgical intervention or removal of the device. Debanding and closure of the defect was done after 16 months in the first patient and the other 2 had PAB for 14 and 12 months.
Abbreviations used: ASD, atrial septal defect; ECG, echocardiography; NS, not significant; PH, pulmonary hypertension; TA-PAB, telemetric adjustable pulmonary artery banding; VSD, ventricular septal defect;	

Efficacy

Duration of postoperative mechanical ventilation and length of stay in intensive care unit and hospital

In a non-randomised comparative study of 40 infants who had pulmonary artery banding (20 with telemetric adjustable pulmonary artery banding [TA-PAB] and 20 with conventional pulmonary artery banding [con-PAB]), postoperative mechanical ventilation time was significantly shorter after TA-PAB than con-PAB (3.0±3.1 days versus 10.4±11.2 days, $p<0.01$), as was length of stay in the intensive care unit (5.3±4.6 versus 20.3±19.9 days, $p<0.005$) and in hospital (15.4±6.4 days versus 45.6±41.6 days, $p<0.005$)[1].

In a non-randomised comparative study of 20 infants with complete atrioventricular septal defects (7 treated with TA-PAB and 13 with con-PAB), the mean duration of mechanical ventilation, intensive care unit stay and hospital stay were each significantly shorter in the TA-PAB group than in the con-PAB group (3±2 days versus 21±17 days; 7±6 days versus 22±18 days; 29±25 days versus 5±12 days respectively [$p<0.05$])[2].

A non-randomised comparative study of 19 infants who had PAB (11 with TA-PAB and 8 with con-PAB) reported no differences between groups with respect to postoperative ventilation time (230±302 hours versus 109±174 hours, $p=0.3$), or length of stay in the intensive care unit (11.2±12.9 days versus 7.8±10.7 days, $p=0.4$) or in hospital (18±10 days versus 17±9 days, $p=0.9$).

Mean surgical time and associated procedures

A non-randomised comparative study of 10 patients with late-referral transposition of the great arteries (4 treated with TA-PAB and 6 with con-PAB) reported that mean surgical time was 61 minutes in the TA-PAB group and 203 minutes in the con-PAB group. No associated procedures were required at the time of banding in the TA-PAB group whereas 8 procedures to improve oxygenation (involving cardiopulmonary bypass were needed in 5 patients in the con-PAB group[3].

Frequency of telemetric band adjustments (to narrow or release the device)

In a case series of 17 infants with multiple muscular apical ventricular septal defects, all infants had percutaneous adjustments of the TA-PAB, with a mean of 4.8 adjustments per patient (range from 2 to 9 times) to tighten the band and a mean of 1.1 adjustments per patient (range from 0 to 3 times) to loosen the band with the patient's growth. All adjustments were guided by doppler echocardiography[5].

In the non-randomised comparative study of 19 infants, in the TA-PAB group (n=11) a mean of 3.1±1.7 regulations per patient were undertaken. Eighty-five

per cent (29/34) of the regulations were adjustments to tighten the device and 15% (5/34) were to loosen it[4].

Delayed sternal closure

In the non-randomised comparative study of 20 patients, sternal closure was not delayed in any of the 7 infants in the TA-PAB group, compared with delayed closure in 46% (6/13) of infants in the con-PAB group ($p<0.05$)[2].

Valve regurgitation

In the non-randomised comparative study of 20 patients, left atrioventricular valve regurgitation decreased (from severe to moderate) in 2 infants in the TA-PAB group (n=7) and increased in 2 infants (from mild to moderate in 1 and moderate to severe in 1) in the con-PAB group (n=13), and remained unchanged in all other infants in both groups[2].

Haemodynamic control (transpulmonary gradient)

A non-randomised comparative study of 10 patients with late-referral transposition of the great arteries who underwent retraining of the left ventricle, 4 with TA-PAB and 6 with con-PAB, reported that the mean pulmonary gradient across the banding increased in the TA-PAB group (n=4), with progressive closure from 25.50±4.43 mmHg at the time of placement to 63.50±9.80 mmHg at the time of an arterial switch procedure (4 months after banding). In the con-PAB group (n=6), the mean pulmonary gradient increased with growth from 49.20±21.40 mmHg at the time of placement to 68.40±7.86 mmHg at the time of the arterial switch procedure (4 months after banding). The difference in gradient at the time of switch procedure was not statistically significant between the 2 groups. The authors state the difference between the groups at baseline was due to the TA-PAB not being tightened in the operating room. The pulmonary gradient at final follow-up (19.78±17.7 months) was similar in both groups (13±3.4 mmHg for TA-PAB group and 14.5±10.34 mmHg in the con-PAB group, p value not given). [4].

Safety

Early and late deaths

A non-randomised comparative study of 40 infants (20 with telemetric adjustable pulmonary artery banding [TA-PAB] and 20 with conventional pulmonary artery banding [con-PAB]) reported that no patients died within 30 days in the TA-PAB group (n=20) and that 15% (3/20) died at 1, 15 and 20 days after surgery in the con-PAB group. These 3 deaths were caused by cardiac arrest during tracheal suctioning, inexorable heart failure and multi-organ failure. There were 2 (10%, 2/20) deaths after 30 days in the TA-PAB group, which were attributed to respiratory infection and neurological damage (2 and 3 months after surgery

respectively), and 2 (12%, 2/17) in the con-PAB group, which were caused by sepsis and heart failure[1].

No deaths were reported in the TA-PAB group (n=7) compared with 77% (10/13) deaths in the con-PAB group (p<0.001) in the non-randomised study of 20 infants. These were due to cardiorespiratory failure in 4, multi-organ failure in 2, aspiration pneumonia in 1, unknown cause in 1 and after transfer back to referral hospital in 2[2].

No deaths occurred in the TA-PAB group (n=4) compared with 27% (2/6) deaths in the con-PAB group (1 after banding due to low cardiac output and 1 after arterial switch surgery on day 7 for multi-organ failure) in the non-randomised comparative study of 10 infants. No late deaths occurred in either group[3].

No early or late deaths during a mean follow-up of 48 months occurred in the case series of 17 infants with multiple ventricular septal defects treated with TA-PAB[5].

PAB related reoperations (to tighten, loosen or remove the band or device)

No reoperations to adjust the band were required in the TA-PAB group whereas reoperation was required in 35% (7/20) of infants after con-PAB (p<0.005) in the non-randomised comparative study of 40 patients[1].

Reoperation 8 days after TA-PAB was needed for drainage of a pericardial effusion through a sub-xiphoid approach in 1 infant in the case series of 17 patients treated with TA-PAB for multiple ventricular septal defects (VSDs)[5].

Reoperation to remove the TA-PAB because of hemodynamic compromise related to the bulk of the device was needed in 1 patient in the TA-PAB group (n=11) in the non-randomised comparative study of 19 patients[4].

Pulmonary artery reconstruction and intracardiac repair

Nineteen patients underwent intra-cardiac repair and pulmonary artery debanding (7 in the TA-PAB group and 12 in the con-PAB group) in the non-randomised comparative study of 40 patients. Reconstruction of the pulmonary artery (patch enlargement to relieve stenosis) was not needed for any patients in the TA-PAB group but was required for 83% (10/12) of patients in the con-PAB group (p<0.0005)[1].

Pulmonary artery patch enlargement because of residual velocity of 3.2 m/s through it was needed in 1 of the 10 patients who underwent reoperation for removal of the TA-PAB in the case series of 17 patients[5].

Patch augmentation of the pulmonary artery at the time of corrective surgery was needed in 5 patients (4 in the TA-PAB group and 1 in the con-PAB group) in the

non-randomised comparative study of 19 patients. The course of recovery was similar in both groups [4].

Erosion of device and psuedoaneursym formation

In a case report of a 6-month-old infant weighting 6 kg) who had a closure of an inlet muscular ventricular septal defect (VSD), complete erosion by the band causing a large pseudoaneurysm of the main pulmonary artery (with the device floating freely inside the pseudoaneurysm cavity and a significant residual ventricular septal defect) was reported 9 weeks after TA-PAB. The residual VSD was closed transatrially with a polytetrafluoroethylene patch, the pseudoaneurysm cavity was resected and the pulmonary artery was reconstructed by an end-to-end anastomosis. Recovery was uneventful and the patient was discharged to a local hospital 12 days after surgery. Before this, the patient also had cardiac tamponade 3 days after TA-PAB and made an uneventful recovery[6].

Pseudoaneurysm formation 7 weeks after insertion of TA-PAB was reported in a case report of 1 patient[7].

Persistent sepsis

Persistent sepsis after TA-PAB developed in 3 patients in a case series of 8 patients. There was good control of infection in all 3 patients; there was complete remission of sepsis by intensive treatment with antibiotics without the need for surgical re-intervention or removal of the band [8].

Validity and generalisability of the studies

- Lack of high-quality evidence and long-term data.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Transcatheter endovascular closure of perimembranous ventricular septal defect. NICE interventional procedure guidance 336 (2010). Replaces NICE

interventional procedure guidance172. Available from http://guidance.nice.org.uk/IPG336

- Hybrid procedure for interim management of hypoplastic left heart syndrome in neonates. NICE interventional procedure guidance 246 (2007). Available from http://guidance.nice.org.uk/IPG246
- Endovascular closure of atrial septal defect. NICE interventional procedure guidance 96 (2004). Available from http://guidance.nice.org.uk/IPG96

Clinical guidelines

- Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures. NICE clinical guideline 64 (2008). Available from http://guidance.nice.org.uk/CG64

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or royal college. The advice received is their individual opinion and does not represent the view of the society.

Mr David R Anderson, Mr Andrew Parry, Prof Robert Tulloh, British Congenital Cardiac Association (BCCA); Mr David Barron, Mr Prem Venugopal, Society for Cardiothoracic Surgery in Great Britain and Ireland (SCTS).

- One specialist adviser performs this procedure regularly. Four advisers have not performed this procedure but 2 have operated to remove devices eroded into the pulmonary artery or at subsequent planned surgery.
- Two specialist advisers considered this as an established practice and no longer new. Two others considered it novel and of uncertain safety and efficacy. One stated that implantation is according to standard techniques with advice on subsequent telemetric signaling to the device. Three advisers said that it has been around for several years and is performed in small numbers by a few centres worldwide. Thus, they found it difficult to say that it is fully established, but nor is it experimental or of uncertain safety. They thought it

has limited indications and the technology behind the device is both innovative and worthy of support.

- Conventional/standard pulmonary artery banding using a nylon or Gore-Tex collar/tape is the comparator for this procedure.
- The specialist advisers stated that fewer than 10% of specialists are engaged in this area of work. Three said that only 1 centre in the UK regularly uses the technique. There is anecdotal evidence of its use in other paediatric cardiac centres.
- Efficacy outcomes include adequate gradient across the pulmonary artery, effective control of hypertension in infants with high pulmonary blood flow, effective retraining of a low pressure ventricle, ability to adjust after chest closure, re-intervention rates within 30 days, need for pulmonary artery plasty after device removal, and survival to corrective surgery. One adviser stated that the procedure might not be suitable for children weighing less than 2.5 kg because of the size of the device. Another said that there are concerns as to whether the technique is better than the standard ones. One adviser stated that there is insufficient data to make informed decisions. Successful transmission of the controlling signals through the body wall may not be possible in larger patients and the procedure may be difficult in small children when there is a large left-to-right shunt.
- One adviser stated that efficacy depends on the indication. If the technique is used to control heart failure, then efficacy is measured by successfully bringing the child to corrected circulation after subsequent corrective surgery. In the interim, the band should prevent the child from developing heart failure, without becoming so tight that it causes unwanted myocardial hypertrophy. If the device is used to train the heart for a subsequent ‘double-switch’ procedure (congenitally corrected transposition of great arteries [ccTGA]), then efficacy is based on successfully increasing myocardial strength without undue myocardial fibrosis and pathological hypertrophy. This will depend on the age of the child, other associated heart conditions and myocardial blood supply –

hence the impact of the adjustable band versus a standard band is very difficult to prove.

- Theoretical adverse events listed include the following:
  - The device may impinge on neighbouring cardiac structures, particularly the aorta, coronary arteries and branch pulmonary arteries, because it is bulky and may distort the pulmonary trunk and root, jeopardising the function of the valve.
  - Communication with an external controller may not be possible because of its orientation or positioning.
  - The device may fail because it is unable to transmit signals in larger patients.
- Anecdotal adverse events listed include erosion into the artery and pseudoaneurysm formation of the pulmonary artery after the insertion of the device.
- Adverse events reported in the literature include mortality, device migration, device removal (because of haemodynamic instability, reoperation or infection), the device losing coupling so it cannot be telemetrically adjusted, failure of the band control unit, inability of the band to dilate, pulmonary valve regurgitation, pulmonary artery distortion, cardiac compression, pseudoaneurysm formation of the pulmonary artery after device insertion, and transection with pseudoaneurysm formation of the pulmonary trunk after device placement.
- The procedure would be done by a surgeon trained in congenital cardiac surgery and subsequent adjustment supervised by paediatric cardiologists. The specialist advisers stated that minimal training is required for cardiac surgeons who routinely perform conventional pulmonary artery banding because the manufacturer provides additional training when setting up the device. Cardiologists would need training to alter the device settings in outpatient clinics.
- The National Institute for Cardiovascular Outcomes Research (NICOR) lists all pulmonary artery banding procedures but cannot differentiate between fixed

and adjustable bands. About 230 procedures are done in the UK of which 128 are isolated banding procedures (based on NICOR report for 2012/13). One adviser stated that less than 20% of patients are likely to need this technique.

- The procedure is likely to be carried out in fewer than 10 specialist centres in the UK. One adviser stated that it is a niche device used for a select subgroup of children as a palliation procedure and the cost of the device will be a factor if it is used more widely. One adviser stated that its value for targeted retraining of the left ventricle in ccTGA is innovative and superior to any other standard technique. Its value in controlling heart failure in babies with multiple or difficult ventricular septal defects (VSDs) is much less convincing, and standard fixed banding is probably as good.
- One adviser stated that the potential impact on the NHS is moderate while 4 stated that it is minor.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- No ongoing trials were found.
- There has been considerable variation in case mix between different centres.
- There might be some overlap of patients in the UK studies.
- The device is designed for infants weighing between 3 and 6 kg. However, in 1 study (conference abstract) the device had been used in infants weighing up to 10 kg.
- Bands adjusted via invasive or minimally invasive surgical methods, including catheter balloon adjustment or transcutaneous adjustment have not been considered in this guidance. Therefore the title of the guidance should be amended as follows: 'Telemetric adjustable pulmonary artery banding for reducing pulmonary hypertension in infants with congenital heart defects'.

- A briefing pack on the telemetric adjustable pulmonary artery band was produced in 2012 by the NHS Technology Adoption Centre.

References

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4. D'Alfonso A, Quarti A, Colaneri M et al. (July 2010) Pulmonary artery banding: when is the use of a telemetrically adjustable device indicated? World Journal for Pediatric & Congenital Heart Surgery 1 (2): 232-239.
5. Corno A, Kandakure P, Dhannapuneni R et al. (2013) Multiple ventricular septal defects: a new strategy Frontiers in Paediatrics 1(16):1-6.
6. Venugopal PS, Hayes N, Simpson J and Anderson, D(2010). Transection with pseudoaneurysm formation of the pulmonary trunk after placement of an adjustable pulmonary artery banding device (FloWatch-PAB) in a patient with residual muscular ventricular septal defect. Journal of Thoracic & Cardiovascular Surgery 139 (5) e103-e104.
7. Michel-Behnke I, Akintuerk H, Valeske K et al (2005). Pseudoaneurysm of the pulmonary trunk after placement of an adjustable pulmonary artery banding device (FloWatch-PAB) in a patient with muscular ventricular septal defect. J Thorac Cardiovasc Surg.130:894-5
8. Kouerinis IA, Papassotiriou I, and Kalavrouziotis G (2010). Implantation of the FloWatch device and sepsis: remove or wait? Thoracic & Cardiovascular Surgeon 58 (6) 361-363.

Appendix A: Additional papers on adjustable pulmonary artery banding for reducing pulmonary hypertension in infants with congenital heart defects.

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Angeli E, Napoleone CP, Turci, S et al. (2012) Pulmonary artery banding. *Multi-media manual of cardio-thoracic surgery* 2012(10.1093)			Review and methodological paper referring to the subject of pulmonary artery banding.
Bonnet D., Corno A.F., et al. (2004). 'Early clinical results of the telemetric adjustable pulmonary artery banding FloWatch-PAB. Circulation', *J Am Heart Assoc*,110(Suppl II), II158–II163.	n=13 Prospective case series Multiple ventricular septal (VSD) defects with complex anatomy in 3, single ventricle without pulmonary stenosis in 2, VSD with elevated pulmonary vascular resistance (PVR) in 2, atrio-ventricular canal (AVC) with elevated pulmonary vascular resistance in 1, AVC with diminutive right ventricle in 1, complex transposition of the great arteries in 3, and pulmonary atresia with complex pulmonary arteries anatomy in 1.	There were no early or late deaths or device-related complications in a mean follow-up of 24 weeks (range, 18 to 42 weeks). A mean of 5.8 telemetric regulations per patient using the FloWatch-PAB were required to adjust the tightening of the PAB to the clinical needs (narrowing 74%, releasing 26%). At last follow-up, systolic pulmonary artery pressure was within normal range in all patients but 1. Systemic oxygen saturation demonstrated optimal regulation of the pulmonary blood flow in all according to each specific defect. Four patients were successfully corrected (VSD closure, AVSD repair, and 2 arterial switches with VSD closure). The device was easily removed and the pulmonary artery re-expanded spontaneously.	Larger studies included in table 2 This is a previous publication of Corno 2013 included in table 2.
Corno AF, Prosi M, Fridez P et al. (2006) The non-circular shape of FloWatch-PAB prevents the need for pulmonary artery reconstruction after banding. Computational fluid dynamics and clinical correlations. *European Journal of Cardio-Thoracic Surgery* 29(1):93-99	n=7 case series	A proof-of-concept study assessing the distortion to the pulmonary artery created by the Flowatch PAB by geometrical analysis and fluid dynamics. The study found that there was little or no residual gradient in the pulmonary artery after the band was removed and that none of the patients required reconstruction. Mean PA internal diameter at banding was 13.3 ±4.5 mm. After a mean interval of 5.9 ±3.7 months, all children underwent intra-cardiac repair and simple FloWatch1-PAB removal without PA reconstruction. Mean PA internal diameter with FloWatch1-PAB removal increased from 3.0 ±0.8 to	Larger studies included in table 2 Geometrical analysis

		12.4 ±4.5 mm (normal mean internal diameter for the age = 9.9±1.6). No residual pressure gradient was recorded in correspondence of the site of the previous FloWatch1-PAB implantation in 6/7 patients, 10 mmHg peak and 5 mmHg mean gradient in 1/7.	
Corno AF, Fridezb P, von Segesser LK (2002) A new implantable device for telemetric control of pulmonary blood flow. Interactive Cardiovascular and Thoracic Surgery 1, 46–49		We here report on the technical characteristics of the device, an externally adjustable, telemetrically controlled device for pulmonary artery banding (FloWatche), which is wireless, battery free, easy to implant and use. The preliminary acute experimental studies demonstrated the feasibility of the implant and the good functioning of the device.	Report on the technical characteristics.
Corno AF, Sekarski N, von Segesser LK (2002) Remote control of pulmonary blood flow: a dream comes true SWISS MED WKLY 2 0 0 2; 1 3 2: 4 2 3 – 4 2 4.	Case report n=1 The first human implant performed on a girl with complete atrioventricular septal defect with unbalanced ventricles, large patent ductus arteriosus and pulmonary hypertension. Telemetric adjustable PAB	At 1 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.	Larger studies included in table 2
Corno A (2005) Pulmonary artery banding. *Swiss Medical Weekly* 135:515-519			Review
Corno A.F., Bonnet D., et al. (2003). 'Remote control of pulmonary blood flow: initial clinical experience', *J Thorac Cardiovasc Surg*, 126(6), 1775–1780.	n=6 Case series FloWatch-R-PAB device univentricular heart (2 patients), complete atrioventricular septal defect (2 patients), ventricular septal defect (1 patient), and multiple ventricular septal defects with double aortic arch (1 patient).	No early or late deaths, reoperations, or device-related complications. A mean of 5 regulations per patient (range 2-14) were required to adjust the tightening of the pulmonary artery banding, 50% (15/30) within the first postoperative week, 20% (6/30) during the second week, and 30% (9/30) within 8 months after surgery. In 70% (21/30) of the cases, the regulation was required to further narrow the	Larger studies included in table 2.

	mean follow-up of= 7 months	pulmonary artery, and in 30% (9/30) of the cases, the regulation was required to release the pulmonary artery.	
Corno AF (2007). Remote Control of Pulmonary Blood Flow. *Current Cardiology Reviews. 3,* 75-80 75.			Review
Davis, MC (2008). Use of a new implantable adjustable pulmonary artery banding device: a report of 2 patients. Journal of Extra-Corporeal Technology 40 (1) 65-67.	n=2 (1 congenitally corrected transposition of the great arteries, multiple VSDs and 1 dectrocardia, double inlet left ventricle and TOGA and non-restrictive VSD) case report	Adjustments were made to the banding in both cases as needed. It was removed at the time of total corrective surgery without complications in both cases	Larger studies included in table 2
Kalavrouziotis, Karanasios, Konstandopoulou, Paphitis (2008). Telemetrically Adjustable Pulmonary Artery Banding: First Application in Greece	n=1 case report (FloWatch-PAB device) in a 2-month-old baby, 3.6 kg, with congenital heart disease (complete atrioventricular septal defect with pulmonary hypertension)	The surgical application of the device was easy, the postoperative course of the patient was smooth, and the telemetric regulation of the device was simple and effective.	Larger studies included in table 2.
Shauq A, Lim J, Narayanan A et al (2011). Incidence of pulmonary artery complications after flo watch pulmonary artery banding. Cardiology in the Young.Conference: 45th Annual Meeting of the Association for European Paediatric Cardiology, AEPC with Joint Sessions with the Japanese Society of Pediatric Cardiology and Cardiac Surgery Granada Spain. Conference Start: 20110518 Confer (var.pagings) S95-S96.2011.	Describes experience with Flo Watch PA banding with regard to pulmonary complications in a large single-centre population. A retrospective analysis of all the patients, at our centre, who underwent FloWatch PA banding to control the pulmonary blood flow for initial single ventricle or bi-ventricle palliation	56 patients needed Flo Watch PA band between December 2003 and June 2010. 14/56 (25%) had single ventricle morphology and 42/56 (75%) biventricular morphology. Mean age at the time of PA band was 141 (range 7-1486) days and the mean weight 4.7 (range 2.6-15.9) kg. There were 7 deaths in our series, 6 were late deaths and were not associated with PA band. There was 1 early death. 27/56 (48%) had their band removed for next stage surgery and 29/56 (52%) still had the band in place. 18/27 (66%) did not have any PA distortion and did not need any patch enlargement. However, 9/27 (33%) had PA distortion and needed patch enlargement. In 2/27 (7%) the Flo Watch was found to have eroded through the MPA at the time of its	Conference abstract Some overlap with the datasets in more recent papers. Device has been also used on much older and heavier patients than currently indicated for. They also included the inventor (Corno) as an author by mistake and an erratum was put out- he also said he disagreed with their findings.

		removal. Conclusion: Though telemetric Flo Watch PA banding does have undoubted advantages in terms of adjustability of pulmonary flow without reoperation, there is a significant incidence of pulmonary artery distortion requiring patch reconstruction.	
Talwar, S., Kumar, M. V., Choudhary, S. K., and Airan, B. Conventional versus adjustable pulmonary artery banding: Which is preferable? Interactive Cardiovascular and Thoracic Surgery.18 (6) (pp 838-841), 2014.Date of Publication: June 2014. (6) 838-841.2014.	Studies compared conventional PAB with adjustable PAB. Four studies qualified (one prospective and three retrospective) and analysed data in human patients, while 3 were experimental studies in animals.	The results of 7 studies conclude that adjustable PAB provides superior early outcomes; reduces early mortality, need for inotropes and need for reintervention; and provides equivalent or superior band gradients when compared to conventional PAB. The use of the adjustable PAB was found to result in significant haemodynamic improvement by progressively reducing the pulmonary artery pressures and left-to-right shunt. The adjustable PAB was found to improve early survival and also made delayed repair feasible in a better clinical state, with reduced mortality and morbidity.	Review

Appendix B: Related NICE guidance for telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects

Guidance	Recommendations
Interventional procedures	**Transcatheter endovascular closure of perimembranous ventricular septal defect. NICE interventional procedure guidance 336 (2010)** This guidance replaces previous guidance on endovascular closure of perimembranous ventricular septal defect (interventional procedure guidance 172). 1.1 Current evidence on the safety and efficacy of transcatheter endovascular closure of perimembranous ventricular septal defect (VSD) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection is important, especially in children and in asymptomatic patients, and should be carried out by a multidisciplinary team including an interventional cardiologist and a cardiac surgeon with specific expertise in the management of congenital heart disease. 1.3 When carried out on children, this procedure should only be undertaken in specialist paediatric cardiology units. For patients of all ages, this procedure should only be undertaken by cardiologists trained in the technique, including the management of complications. There should be access to emergency cardiac surgery by a surgeon experienced in the treatment of congenital heart disease. 1.4 Clinicians should enter details about all patients undergoing transcatheter endovascular closure of perimembranous VSD onto the UK Central Cardiac Audit Database. 1.5 NICE encourages publication of further long-term follow-up data, specifically on the occurrence of heart block compared with open surgery. **Hybrid procedure for interim management of hypoplastic left heart syndrome in neonates. NICE interventional procedure guidance 246 (2007)** '*The hybrid procedure to which these recommendations apply consists of pulmonary artery banding, stenting of the ductus arteriosus and, if necessary, atrial septostomy.*' This guidance relates to the use of the 3 procedures in conjunction and not to pulmonary artery banding as a whole. It also applies only to hypoplastic left heart syndrome and not to other congenital conditions requiring pulmonary artery banding. 1.1 Current evidence on the safety and efficacy of the hybrid procedure for interim management of hypoplastic left heart syndrome (HLHS) in neonates does not cover sufficiently all the parts of the procedure (see italicised text above) when used in combination and synchronously. The procedure should therefore only be used with special arrangements for

	consent, audit or research, and clinical governance. 1.2 Clinicians wishing to undertake the hybrid procedure for interim management of HLHS in neonates should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that parents or carers understand the uncertainty about the procedure's safety and efficacy, and understand that the child will require further operations. They should provide parents or carers with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having the hybrid procedure for interim management of HLHS in neonates. 1.3 The procedure should only be undertaken in paediatric cardiology centres specialising in the treatment of HLHS. 1.4 Clinicians undertaking this procedure should enter all patients onto the Department of Health's UK Central Cardiac Audit Database. 1.5 Further publication about criteria for patient selection and on the particular combination of techniques used in the hybrid procedure would be useful. The Institute may review the procedure upon publication of further evidence. **Endovascular closure of atrial septal defect. NICE interventional procedure guidance 96 (2004)** 1.1 Current evidence on the safety and efficacy of endovascular closure of atrial septal defect appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance. 1.2 The procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications. 1.3 The Department of Health runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients onto this database.
Clinical guidelines	**Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures. NICE clinical guideline 64 (2008)** Adults and children with structural cardiac defects at risk of developing infective endocarditis 1.1.1 Healthcare professionals should regard people with the following cardiac conditions as being at risk of developing infective endocarditis: • acquired valvular heart disease with stenosis or regurgitation • valve replacement • structural congenital heart disease, including surgically corrected or palliated structural conditions, but excluding isolated atrial septal defect, fully repaired ventricular septal defect or fully repaired patent ductus arteriosus, and closure devices that are judged to be endothelialised • previous infective endocarditis • hypertrophic cardiomyopathy.

	Patient advice 1.1.2 Healthcare professionals should offer people at risk of infective endocarditis clear and consistent information about prevention, including: • the benefits and risks of antibiotic prophylaxis, and an explanation of why antibiotic prophylaxis is no longer routinely recommended • the importance of maintaining good oral health • symptoms that may indicate infective endocarditis and when to seek expert advice • the risks of undergoing invasive procedures, including non-medical procedures such as body piercing or tattooing. Prophylaxis against infective endocarditis 1.1.3 Antibiotic prophylaxis against infective endocarditis is not recommended: • for people undergoing dental procedures • for people undergoing non-dental procedures at the following site[1]: – upper and lower gastrointestinal tract – genitourinary tract; this includes urological, gynaecological and obstetric procedures, and childbirth – upper and lower respiratory tract; this includes ear, nose and throat procedures and bronchoscopy. 1.1.4 Chlorhexidine mouthwash should not be offered as prophylaxis against infective endocarditis to people at risk of infective endocarditis undergoing dental procedures. Infection 1.1.5 Any episodes of infection in people at risk of infective endocarditis should be investigated and treated promptly to reduce the risk of endocarditis developing. 1.1.6 If a person at risk of infective endocarditis is receiving antimicrobial therapy because they are undergoing a gastrointestinal or genitourinary procedure at a site where there is a suspected infection, the person should receive an antibiotic that covers organisms that cause infective endocarditis. [1]The evidence reviews for this guideline covered only procedures at the sites listed in this recommendation. Procedures at other sites are outside the scope of the guideline (see appendix 1 in the full guidance for details).

Appendix C: Literature search for adjustable pulmonary artery banding for reducing pulmonary hypertension in infants with congenital heart defects.

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	28/07/14	Issue 7 of 12, July 2014	2
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	28/07/14	Issue 7 of 12, July 2014	4
HTA database (Cochrane Library)	28/07/14	Issue 7 of 12, July 2014	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	28/07/14	Issue 7 of 12, July 2014	1
MEDLINE (Ovid)	28/07/14	1946 to July Week 3 2014	16
MEDLINE In-Process (Ovid)	28/07/14	July, 25 2014	40
EMBASE (Ovid)	28/07/14	1974 to 2014 Week 30	22
PubMed	28/07/14	-	0
JournalTOCS	28/07/14	-	0

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	Heart Defects, Congenital/
2	heart septal defects/ or exp heart septal defects, atrial/ or heart septal defects, ventricular/
3	(congenit* adj4 heart* adj4 (defect* or diseas* or abnormalit* or disorder*)).tw.
4	((heart or atrial* or ventricul* or atrioventricular or atrio-ventricular) adj4 septal* adj4 (defect* or diseas* or abnormalit* or disorder*)).tw.
5	"Transposition of Great Vessels"/
6	(transposition adj4 great adj4 (arter* or vessel*)).tw.
7	(discordant adj4 transposition).tw.
8	avsd.tw.
9	cctga.tw.
10	(discordant adj4 transposition).tw.
11	((atrioventricular or atrio-ventricular) adj4 canal* adj4 (defect* or diseas* or abnormalit* or disorder*)).tw.
12	AV canal.tw.
13	((univentricular or uni-ventricular) adj4 heart*).tw.
14	((hypoplastic or hypo-plastic) adj4 heart adj4 (syndrome* or malform*)).tw.
15	Hypertension, Pulmonary/
16	(pulmonary* adj4 hypertens*).tw.
17	or/1-16
18	(arter* adj4 (band or bands or banding)).tw.
19	17 and 18
20	FloWatch.tw.
21	(FW-PAB or FloWatch-PAB).tw.
22	or/19-21
23	animals/ not humans/
24	22 not 23
25	limit 24 to english language