NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg505

## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 1 Recommendations

1.1 The evidence on the efficacy of telemetric adjustable pulmonary artery banding shows that the procedure can provide adjustable reduction of pulmonary artery flow in infants with congenital heart defects, but there are uncertainties about which infants will derive benefit from the procedure. The evidence on safety is limited in quantity. Therefore the procedure should only be used with special arrangements for consent, audit or research and clinical governance.

1.2 Clinicians wishing to undertake telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects should take the following actions.

- Inform the clinical governance leads in their NHS trusts.
- Ensure that parents and carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Enter details about all infants undergoing telemetric adjustable pulmonary artery banding for pulmonary hypertension associated with congenital heart defects onto the UK Central Cardiac Audit Database and review clinical outcomes locally.

1.3 Patient selection for telemetric adjustable pulmonary artery banding for pulmonary hypertension in infants with congenital heart defects should

only be done in paediatric cardiac centres, by a multidisciplinary team experienced in managing infants and children with congenital heart defects.

1.4 Further research should focus on the extended use of telemetric adjustable pulmonary artery banding for ventricular retraining and for its use pending the resolution of ventricular septal defects. Data collection may provide useful information. NICE may review the procedure on publication of further evidence.

# 2 Indications and current treatments

2.1 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. Infants may develop a condition of irreversible pulmonary hypertension because of hypertrophy of the pulmonary arterioles.

2.2 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.

# 3 The procedure

3.1 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.

3.2 The procedure is done with the infant under general anaesthesia, either through a median sternotomy or lateral thoracotomy depending on the child's anatomy and the 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.

3.3 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 defects.

# 4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 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 plus or minus [±]

-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 days 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).

4.2 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).

4.3 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.

4.4 In a non-randomised comparative study of 20 infants with complete atrioventricular septal defects (7 treated with TA-PAB and 13 with con-PAB), 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).

4.5 In the non-randomised comparative study of 20 infants, left atrioventricular valve regurgitation decreased in 2 infants (from severe to moderate) 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.

4.6 A non-randomised comparative study of 10 infants 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, 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, 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 the switch procedure was not statistically significant between the 2 groups. The authors state that 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 in the TA-PAB group and 14.5±10.34 mmHg in the con-PAB group, p value not given).

4.7 The specialist advisers listed additional key efficacy outcomes as control of hypertension in children with high pulmonary blood flow, retraining of a low pressure ventricle and survival to corrective surgery.

# 5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 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 infants died within 30 days in the TA-PAB group and that 15% (3/20) of infants 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, 1 attributed to respiratory infection and 1 to neurological damage (2 and 3 months after surgery respectively), and 2 (12%, 2/17) deaths in the con-PAB group, 1 caused by sepsis and 1 by heart failure.

5.2 In a case report of a 6-month-old infant (weighing 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.

5.3 Reoperation 8 days after TA-PAB for drainage of a pericardial effusion was reported in 1 infant in a case series of 17 infants treated with TA-PAB for multiple VSDs. Reoperation to remove the TA-PAB because of haemodynamic compromise related to the bulk of the device was needed in 1 infant in the TA-PAB group in a non-randomised comparative study of 19 infants who had PAB (11 with TA-PAB and 8 with con-PAB).

5.4 Patch augmentation of the pulmonary artery at the time of corrective surgery was needed in 5 infants (4 in the TA-PAB group and 1 in the con-PAB group) in the non-randomised comparative study of 19 infants. The course of recovery was similar in both groups.

5.5 Persistent sepsis after TA-PAB developed in 3 infants in a case series of 8 infants. This was successfully treated with antibiotics in all 3 infants, without the need for surgical re-intervention or removal of the band.

5.6 The specialist advisers listed additional adverse events as: device migration; device removal because of haemodynamic instability; the device losing coupling so it could not be telemetrically adjusted; failure of the band control unit; inability of the band to dilate; pulmonary valve regurgitation; and cardiac compression.

# 6 Committee comments

6.1 The Committee noted that conditions needing pulmonary artery banding are rare and large randomised studies would therefore be impractical. This consideration underpinned the recommendation for data collection as a way of providing information for review of the procedure.

6.2 The Committee noted that the UK Central Cardiac Audit Database collects data on pulmonary artery banding but does not currently distinguish between the different kinds of pulmonary artery banding. It was advised that steps could be taken to enable data on telemetric adjustable banding to be recorded with the type of banding identified.

# 7 Further information

7.1 For related NICE guidance, see the NICE website.

## Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.