

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## INTERVENTIONAL PROCEDURES PROGRAMME

### Interventional procedure overview of balloon angioplasty for systemic to pulmonary arterial shunts

#### **Introduction**

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by Specialist Advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

#### **Date prepared**

This overview was prepared by Bazian Ltd in April 2003.

#### **Procedure name**

Balloon angioplasty for systemic to pulmonary arterial shunts

#### **Specialty societies**

*British Society of Interventional Radiologists*

*British Paediatric Cardiac Association*

#### **Description**

Systemic to pulmonary shunts are surgically-created connections between the aorta and a pulmonary artery in children with cyanotic congenital heart disease such as tetralogy of Fallot or tricuspid atresia. They increase the blood supply to the lungs and the arterial oxygen saturation. The procedure is palliative, aiming to improve symptoms. In some children, definitive surgery may be possible later. The most common type of systemic to pulmonary shunt is known as the Blalock-Taussig shunt.

Systemic to pulmonary shunts may become blocked or narrowed (stenosed) because of scarring or thrombosis. Balloon angioplasty of shunts is a palliative procedure carried out to relieve the blockage or narrowing. The procedure involves inserting a catheter into a large blood vessel (usually in the groin), passing it up in to the chest under X-ray surveillance and inflating a balloon in the narrowed area. This may avoid a repeat surgical systemic to pulmonary shunt procedure.

**Efficacy**

According to the literature, balloon angioplasty of systemic to pulmonary shunt improves arterial oxygen saturation. There are no studies comparing the benefits of balloon angioplasty with repeat open surgical shunt creation.

According to the Specialist Advisors, the procedure is efficacious.

**Safety**

The literature on risks of the procedure is very limited.

According to the Specialist Advisors, risks tear of vessel or shunt, death, complete shunt occlusion, rupture, thrombosis, haemorrhage, embolic stroke, and pulmonary embolism.

**Literature review****Appraisal criteria**

Studies examining balloon angioplasty procedures for systemic to pulmonary arterial shunts were included.

**List of studies found**

No systematic reviews, randomised controlled trials or non-randomised controlled studies were found.

Thirteen case series including two or more people were found. The five largest are described in the table.

References to smaller studies are given in the Appendix.

## Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Key reliability and validity issues
<p>Wang, 2001<sup>1</sup> Case series Taiwan</p> <p>n=46 (age range 1 month to 7.4 years)</p> <p>Follow up 12 months</p>	<p>Successful angioplasty (defined as &gt;20% increase in oxygen saturation): 42 people</p> <p>Mean oxygen saturation in the aorta increased from 74 to 81%</p>	<p>8 people required early additional procedure</p> <p>At follow up, 29 people had repeat imaging; 26 had open heart surgery, of whom 2 died</p>	<p>Uncontrolled case series</p> <p>Excluded 21 people referred for definitive repair</p> <p>10 people had additional balloon angioplasty to pulmonary artery</p>
<p>Saltik, 2000<sup>2</sup> Case series Turkey</p> <p>n=8 (7 children, age range 1 to 11 years) and 1 adult (aged 38)</p> <p>Follow up 3 to 37 months</p>	<p>Increase in mean arterial oxygen saturation from 66% to 78% (p&lt;0.05)</p> <p>At follow up, condition of all patients improved</p>	<p>Pulmonary hypertension: 1 person</p> <p>1 person could not be weaned off ventilator, died of pneumonia</p>	<p>Uncontrolled case series</p> <p>Very small study</p>
<p>Alcibar, 1994<sup>3</sup> Case series Location not clear, assumed to be Spain n=6</p>	<p>Mean oxygen saturation increased from 63% to 82% (p&lt;0.05)</p>	<p>None provided</p>	<p>Uncontrolled case series</p> <p>Very small study</p> <p>Data extracted from abstract</p>
<p>Rao, 1990<sup>4</sup> Case series USA</p> <p>n=6 (age range 6 to 60 months)</p> <p>Mean follow up 6 months</p>	<p>Technical 'success': 5/6</p> <p>Mean oxygen saturation increased from 71% to 81%</p>	<p>'No complications'</p>	<p>Uncontrolled case series</p> <p>Very small study</p>
<p>Marx, 1988<sup>5</sup> Case series USA</p> <p>n=6 (mean age 12 months)</p> <p>Mean follow up 4 months</p>	<p>Mean oxygen saturation increased from 72% to 77%:</p> <p>Technical success: 5/6</p>	<p>3 complications:</p> <ul style="list-style-type: none"> <li>• 1 thrombosed femoral artery</li> <li>• 1 balloon rupture</li> <li>• 1 severe arterial vasospasm</li> </ul>	<p>Uncontrolled case series</p> <p>Very small study</p>

**Validity and generalisability of the studies**

Only case series were found. These provide limited evidence of efficacy and safety of the balloon angioplasty of systemic to pulmonary shunts compared with repeat surgical shunt creation. One of the case series was reasonably large.<sup>1</sup>

**Specialist advisor's opinion / advisors' opinions**

Training required in complex interventional procedures. Catheterisation laboratory, anaesthesia and cardiac surgery backup required.

UK Central Cardiac Audit Database (UKCCAD) database is registering these procedures.

## References

1. Wang JK, Wu MH, Chang CI, Chiu IS, et al. Balloon angioplasty for obstructed modified systemic-pulmonary artery shunts and pulmonary artery stenoses. *Journal of the American College of Cardiology* 2001; 37: 940-7.
2. Saltik IL, lu AG, Oztunc F, and lu A. Balloon dilatation angioplasty of stenosed systemic-pulmonary artery shunts. *Turkish Journal of Pediatrics* 2000; 42: 43-7.
3. Alcibar J, Cabrera A, Onate A, Galdeano JM, et al. Angioplasty of the stenotic Blalock-Taussig [Spanish]. *Revista Espanola de Cardiologia* 1994; 47: 819-23.
4. Rao PS, Levy JM, and Chopra PS. Balloon angioplasty of stenosed Blalock-Taussig anastomosis: Role of balloon-on-a-wire in dilating occluded shunts. *American Heart Journal* 1990; 120: 1173-8.
5. Marx GR, Allen HD, Ovitt TW, and Hanson W. Balloon dilation angioplasty of Blalock-Taussig shunts. *American Journal of Cardiology* 1988; 62: 824-7.

## Appendix: References to studies not described in the table

Reference	Number of participants
Sivakumar K, Anil SR, Ravichandra M, Natarajan, KU, et al. Emergency transcatheter balloon recanalization of acutely thrombosed modified Blalock-Taussig shunts. <i>Indian Heart Journal</i> 2001; 53: 743-8	5
Marks LA, Mehta AV, and Marangi D. Percutaneous transluminal balloon angioplasty of stenotic standard Blalock-Taussig shunts: effect on choice of initial palliation in cyanotic congenital heart disease. <i>J Am Coll Cardiol</i> 1991; 18: 546-51	5
Vincent RN, Porter AG, Tam VK, and Kanter KR. Diagnosis and catheter treatment of innominate artery stenosis following stage I Norwood procedure. <i>Catheterization &amp; Cardiovascular Interventions</i> 2000; 49: 415-8	4
Ino T, Kishiro M, Okubo M, Akimoto K, et al. Dilatation mechanism of balloon angioplasty in children: assessment by angiography and intravascular ultrasound. <i>Cardiovascular &amp; Interventional Radiology</i> 1998; 21: 102-8	3
Ino T, Okubo M, Akimoto K, Nishimoto K, et al. Mechanism of balloon angioplasty in children with arterial stenosis assessed by intravascular ultrasound and angiography. <i>American Heart Journal</i> 1995; 129: 132-8	3
Qureshi SA, Martin RP, Dickinson DF, and Hunter S. Balloon dilatation of stenosed Blalock-Taussig shunts. <i>British Heart Journal</i> 1989; 61: 432-4	3
Peuster M, Fink C, Bertram H, Paul T, and Hausdorf G. Transcatheter recanalization and subsequent stent implantation for the treatment of early postoperative thrombosis of modified blalock-taussig shunts in two children. <i>Catheterization &amp; Cardiovascular Diagnosis</i> 1998; 45: 405-8.	2
Ormiston JA, Neutze JM, Calder AL, and Hak NS. Percutaneous balloon angioplasty for early postoperative modified Blalock-Taussig shunt failure. <i>Catheterization &amp; Cardiovascular Diagnosis</i> 1993; 29: 31-34	2