NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon angioplasty with or without stenting for pulmonary artery or right ventricular outflow tract obstruction

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.

Procedure name

Balloon angioplasty with or without stenting for pulmonary artery or right ventricular outflow tract obstruction

Date prepared

This overview was prepared by Bazian Ltd in April 2003

Specialty society

British Paediatric Cardiac Association

Description

The right ventricular outflow tract includes the pulmonary valve and the regions above and below it. Narrowing (stenosis) of this region may involve the area below the valve (subvalvar), the valve itself (valvar) or the area above the valve (supravalvar). Balloon angioplasty of valvar right ventricular outflow tract narrowing (pulmonary valve stenosis) is covered in a separate overview.

Congenital subvalvar and supravalvar right ventricular outflow tract stenosis usually occurs with other cardiac defects such as ventricular septal defect or tetralogy of Fallot. Postoperative right ventricular outflow tract obstruction may occur after surgery to create a conduit between the right ventricle and pulmonary artery in children with congenital anomalies.

Narrowing may also occur beyond the right ventricular outflow tract, in one of the pulmonary arteries, or in their branches. This may also be congenital or occur following surgery for congenital defects.

Balloon dilatation is a minimally invasive transvenous procedure to dilate the obstruction during cardiac catheterisation. Stenting involves the insertion of a small tube within the narrow region following balloon angioplasty. Traditionally, treatment of right ventricular outflow tract or pulmonary artery obstruction involves open chest surgery.

Efficacy
Balloon angioplasty and stent placement of pulmonary arterial branches:

- Based on the literature, balloon angioplasty and stent placement of pulmonary arterial branches improves pressure gradients and stenosis diameter.
- According to the Specialist Advisors, balloon angioplasty and stent placement of pulmonary arterial branches is efficacious.

Stent placement in right ventricular outflow obstruction:
- Based on the literature, stent placement in right ventricular outflow obstruction improves pressure gradients and stenosis diameter. Information is, however, very limited.
- According to the Specialist Advisors, stent placement in right ventricular outflow obstruction may be efficacious in selected cases.

Safety
Balloon angioplasty and stent placement of pulmonary arterial branches:
- Based on the literature, adverse effects of balloon angioplasty and stent placement of pulmonary arterial branches include death, pulmonary artery dissection, perforation, aneurysm or thrombosis, stent migration or fracture, complete heart block and retroperitoneal haemorrhage.
- The Specialist Advisors listed potential complications as rupture of pulmonary artery, death and embolisation.

Stent placement in right ventricular outflow obstruction:
- Based on the literature, adverse effects of stent placement in right ventricular outflow obstruction include stent migration and covering of the pulmonary artery origins. Information is, however, very limited.
- According to the Specialist Advisors, potential adverse effects include cardiac or pulmonary artery rupture and arrhythmias.

Literature review

Appraisal criteria
Studies of balloon dilatation or stenting for right ventricular outflow tract stenosis, pulmonary artery stenosis or peripheral pulmonary stenosis were included.

List of studies found
No systematic reviews or controlled trials.

Nineteen case series were found including 20 or more people. Of the five largest,[1-5] four considered pulmonary artery or branch pulmonary artery balloon angioplasty or stenting,[1-3,5] and one considered pulmonary artery and right ventricular outflow tract balloon angioplasty or stenting.[4] The table describes these studies.[1-5] Because these studies provided limited data on right ventricular outflow tract angioplasty or stenting, the table gives details of two further, smaller studies focusing on this procedure.[6,7]

The Appendix gives the references to other studies identified.

Summary of key efficacy and safety findings (1)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Formigari,1998[1] Case series Italy n=150 children with pulmonary artery stenosis: • 120 received balloon angioplasty (162 procedures) (mean age 42 months, range 1 to 156 months) • 60 received stents (79 stents) (mean age 6 years, range 2 to14 years) • 30 received both Mean follow up: balloon angioplasty: 56 months; stents: 30 months	Technical success (defined as >50% increase in predilation diameter, >50% decrease in pressure gradient or >20% decrease in right ventricular to aortic peak pressure ratio): • Balloon angioplasty: 60% • Stent: 97% Mean diameter of stenosis: • Balloon angioplasty: increase from 3 to 5 mm • Stent: increase from 4 to 13 mm Mean pressure gradient: • Balloon angioplasty: decreased from 51 to 28 mmHg • Stent: decreased from 53 to 13 mmHg	Procedural complications: • Balloon angioplasty: 3% 5/162 (7% in paper*) (1 femoral vein thrombosis, 3 pulmonary artery major dissections, 1 transient pulmonary oedema) • Stent: 1% 1/79 (2% in paper*) (1 pleural perforation with haemopericardium) Late restenosis: • Balloon angioplasty: 25% • Stent: 2% Further procedures required: • Balloon angioplasty: 30 people • Stent: 1 person	Uncontrolled case series Not clear whether native or postoperative stenosis Completeness of ascertainment not clear Follow up fairly short Outcomes appropriate *Note: the complication rate percentages have been miscalculated in this study
Shaffer, 1998[2] Case series USA n=151 adults and children with pulmonary artery stenosis received stents: • 136 postoperative • 15 native [49 people also included in the study who had venous stents] Mean follow up 19 months	Immediate systolic pressure gradient averages: • postoperative: 46 to 13 mmHg • native: 71 to 15 mmHg Average systolic pressure gradient at follow up catheterisation: • postoperative: 13 mmHg (75 people) • native: 21 mmHg (7 people)	Of all people who had stents (including the 49 who had venous stents) • Procedural deaths: 2 people • Stent migration: 4 people • Stent thrombosis: 3 people • Systemic embolisation or thrombosis: none • Retroperitoneal haemorrhage: 3 people • Haemoptysis: 4 people • Aneurysm: 1 person	Uncontrolled case series Completeness of ascertainment not clear Follow up short Detailed information on complications Outcomes appropriate
Hosking, 1992[3] Case series Canada n=74 with pulmonary artery stenosis who received balloon angioplasty (mean age 7 years) • 67 postoperative • 7 native Mean follow up 38 months	Technical success (defined as >50% increase in predilation diameter, >20% increase in flow to dilated lung or >20% decrease in right ventricular to aortic peak pressure ratio): 53%	• Restenosis: 17% • Perforation: 1 person • Aneurysm: 5 people	Uncontrolled case series Completeness of ascertainment not clear Follow up fairly short Outcomes appropriate

Summary of key efficacy and safety findings (2)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
O'Laughlin, 1993[4] Case series USA n=64 who received stents: • 58 with pulmonary artery stenosis (postoperative and native), median age 2 years • 6 with postoperative right ventricular outflow tract obstruction, median age 7 years [21 people who had venous stents also included in the study] Mean follow up 11 months	Mean stenosis of diameter: • Pulmonary artery stenosis: increased from 5 to 11mm • Right ventricular outflow tract obstruction: increased from 9 to 13mm Mean systolic gradient: • Pulmonary artery stenosis: decreased from 55 to 14 mmHg • Right ventricular outflow tract obstruction: increased from 41 to 21 mmHg	Of all people who had stents (including 21 people who had venous stents) Embolisation or malposition: 6 people • Deaths within 1 week: 2 people • Stent fracture: 2 people • Systemic emboli: none • Thrombosis at follow up: none • Redilatation within 24 months: 14 people	Uncontrolled case series Follow up short Outcomes appropriate
Gentles, 1993[5] Case series USA n=52 who received balloon dilatation of branch pulmonary artery (postoperative and native), age range 0.3 to 34.8 years, mean 7 years) Follow up in 7 people: 3 to 9 months after dilatation	Technical success (defined as > 50% increase in predilation diameter, or >20% decrease in right ventricular to aortic peak pressure ratio): 72% Mean diameter of stenosis: increased from 3.8 to 6.3 mm	• Procedural deaths: 1 person • Pulmonary artery perforation: 2 people • Hypotension: 3 people • Complete heart block: 1 person • Restenosis: 1 person at follow up	Uncontrolled case series Minority of patients followed up Follow up short
Ovaert, 1999[6] Case series Canada n=42 people who received stents of postoperative right ventricular outflow tract conduits Length of follow up: up to 6 years	Reduction in right ventricular systolic pressure: 71 to 48 mmHg Reduction in right ventricular outflow tract systolic gradient: 48 to 19 mmHg	• Immediate stent migration: 1 person • Stent covered origin of pulmonary artery orifices: 2 people • Immediate residual stenosis: 3 people • At follow up, surgical conduit replacement: 20 people	Uncontrolled case series Length of follow up not clear, but long in some participants Outcomes appropriate
Hosking, 1992[7] Case series Location not clear n=17 (mean age 7 years) received 24 stents: • 17 branch pulmonary artery • 5 right ventricular outflow tract conduits (postoperative) • 1 aortopulmonary collateral vessel Follow up 1 to 14 months	Optimal stent position: 22/24 stents Average reduction of gradient across pulmonary artery stenosis: 22 to 3 mmHg Average reduction in gradient across right ventricular outflow obstruction: 85 to 35 mmHg	• Stent slippage: 1 stent • Embolisation: none • Thrombosis: none	Uncontrolled case series Abstract only available at time of writing Data extracted from abstract

Validity and generalisability of the studies
All the studies were carried out in settings applicable to the UK.

All the studies found were case series.

Three studies examined balloon angioplasty of pulmonary arteries or their branches.[1,3,5] Four studies examined stenting of pulmonary arteries or their branches.[1,2,4,7] The studies included people with native and postoperative stenosis. Some of the studies examining balloon angioplasty or stenting of pulmonary arteries or their branches were reasonably large.[1,2] Follow up was short in most studies.

Three studies examined stenting of postoperative right ventricular outflow tract obstruction.[4,6,7] Two of these studies included a very small number of people with right ventricular outflow tract obstruction.[4,7]

None of the studies identified examined balloon angioplasty or stenting of native right ventricular outflow tract obstruction (balloon angioplasty of pulmonary valve stenosis is the subject of a separate overview).

Specialist advisor's opinion / advisors' opinions
Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Balloon angioplasty and stent placement of pulmonary arterial branches:
- most cases should receive stent
- surgical cover necessary
- very efficacious

Stent placement in right ventricular outflow tract obstruction:
- mostly for conduit stenosis
- many children have multiple defects
- often palliative
- remains subject of debate
- may have a role in highly selected cases
- surgical cover necessary

References

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Appendix: References to studies not described in the table

Reference	Number of participants
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