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INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon dilatation for pulmonary valve stenosis

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 March 2003.

Procedure name
Balloon dilatation for pulmonary valve stenosis

Synonyms: Balloon valvuloplasty.

Specialty society
British Paediatric Cardiac Association

Description
Pulmonary valve stenosis.

Pulmonary valve stenosis is narrowing of the pulmonary valve in the heart. It is usually congenital. The outflow of blood from the right ventricle of the heart to the lungs is obstructed. Symptoms include shortness of breath, chest pains, fainting and, in some instances, sudden death.

Balloon dilatation is an alternative to open surgical valvotomy.

Efficacy
We found limited evidence from one small historical controlled study that pulmonary valvuloplasty reduces gradient across the pulmonary valve to a similar degree as open surgery. We found several large case series suggesting that pulmonary valvuloplasty leads to a reduction in gradient across the pulmonary valve.

Other potential benefits, based on conjecture, include avoiding the risks of cardiopulmonary bypass and surgical scars and shorter lengths of hospital stay.

Safety
We found evidence that pulmonary regurgitation and arrhythmias are common and that serious procedural complications such as cardiac perforation are relatively uncommon.

According to the specialist advisor, pulmonary regurgitation is common, but the long term effects of this are unknown. Arrhythmias are common. The death rate is < 1% (in older infants and children, but higher in neonates). Pulmonary artery tear occurs in < 1% of procedures. The risks are greatest in neonates.

Literature review

Appraisal criteria
We included studies examining balloon dilatation of the pulmonary valve.

List of studies found
We found no systematic reviews or randomised controlled trials.

We found one historical controlled study.[1]

We found 11 case series. The table gives details of the four largest.[2-5]

The annex gives references to the smaller case series.

Summary of key efficacy and safety findings (1)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
O'Connor, 1992[1] Historical controlled study USA n=40 children • 20 balloon valvuloplasty (mean age 4 .3 years) • 20 open surgery (mean age 4.7 years) Exclusions: • dysplastic pulmonary valve • anulus hypoplasia • complex anomaly Mean follow up: • Valvuloplasty: 5.3 years • Surgery: 11.7 years	Residual pressure gradient across valve: • Valvuloplasty: 24 mmHg • Surgery: 16 mmHg	Pulmonary insufficiency: • Valvuloplasty: 9 mild • Surgery: 9 mild, 9 moderate p<0.01 Ventricular arrhythmias: • Valvuloplasty: 1 grade 1 ectopics • Surgery: 6 had complex ventricular arrhythmia p<0.01	Historical controls but matched on age and peak pulmonary stenosis gradient Small study Ascertainment methods not clear Losses to follow up: 4 people who received valvuloplasty Follow up length different for valvuloplasty and surgery groups
Stanger, 1990[2] Case series, partly prospective USA , multicentre n=811 people received pulmonary balloon valvuloplasty (age range 1 day to 76 years) Cases identified through the Valvuloplasty and Angioplasty of Congenital Anomolies (VACA) Registry Follow up immediate	Immediate results: Residual gradient < 15 mmHg: 25% Gradient > 30 mmHg: 8% Therapeutic failures: 2% Average gradient 16.5 mmHg	Deaths: 2 people Cardiac perforation: 1 person Tricuspid regurgitation: 2 people Femoral vein thrombosis: 5 people Femoral vein tears: 2 people Respiratory arrest: 1 person Arrhythmias: 8 people Hypoxia: 3 people Bleeding from catheter site: 7 people Arterial thrombosis: 2 people	Uncontrolled case series Immediate results only presented
McCrindle, 1994 [3] Case series, partly prospective USA , multicentre Cases identified through (VACA) Registry n=533 children who received balloon pulmonary valvuloplasty who had follow up data (81% of those who received the procedure) Median follow up 33 months, range 1 month to 8.7 years	Immediate residual gradients < 36 mmHg: 74% Residual gradient >=36 mmHg or further treatment required: 23%	Pulmonary regurgitation at follow up: • Trivial: 22% • Mild: 45% • Moderate: 7%	Uncontrolled case series Only included people for whom follow up data available. Patients with a gradient of >=36 mmHg were defined as having a suboptimal long term outcome. Includes the same people as in Stanger, 1990[2]

Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Schmaltz, 1989[4] Case series 20 centres in Germany n=273 children with isolated pulmonary stenosis, mean age 6 years, range 3 days to 18 years Mean follow up 11 months	Mean pressure gradient: 32 mmHg Gradient reduced by >50%: 64% Further procedure required: 14 people	Influndibular reaction 12% 4% (11) patients had major complications 4 patients had bradycardia, arrhythmia 3 patients had hypotension 1 patient pulmonary incompetence 1 patient perforation myocardium (requiring surgical intervention) 1 patient wire breakage (requiring surgical intervention) 1 patient intima stripping 1 patient had vascular insufficiency cased by septicaemia leading to late death.	Uncontrolled case series Completeness of ascertainment not described Follow up data only available for 140 children (51%)
Echigo, 2001[5] Retrospective case series 8 centres in Japan n=172 people, mean age 5.4 years Exclusions: Critical pulmonary stenosis Minimum follow up 6 years	Mean pressure gradient post-procedure: 28 mmHg Follow up mean pressure gradient: 16 mmHg Repeat valvuloplasty required: 15 people (9%) Surgery required: 5 people (3%)	'No major complications' Mild pulmonary regurgitation: 69% Moderate to severe pulmonary regurgitation: 6%	Uncontrolled case series Completeness of ascertainment and follow up not described

Validity and generalisability of the studies
We found one small historical controlled study.[1] The groups were matched on two possible prognostic variables, age and gradient. However, the groups may have differed on other characteristics. Length of follow up was different in the two groups, and four people were lost to follow up in the valvuloplasty groups.

We found several large case series.[2-5] The first of these provided detailed information about procedural complications.[2] The other three provided longer term follow up data on some, but not all included patients.[3-5] This could bias estimates of long term safety and efficacy. In the two smallest studies, the completeness of ascertainment was not clear.[4,5]

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.

- Now established practice.
- Should only be carried out in a tertiary Paediatric Cardiology unit with involvement of a lead international paediatric cardiologist.
- Surgical back up should be available in the unit. Appropriate training of operators is required.

Issues for consideration by IPAC
Pulmonary balloon valvuloplasty may only be suitable for pulmonary stenosis not associated with dysplastic valves or more complex abnormalities.

References

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Annex: References to smaller case series

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