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)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
<th>Key efficacy findings</th>
<th>Key safety findings</th>
<th>Key reliability, generalisability and validity issues</th>
</tr>
</thead>
</table>
| **O’Connor, 1992**<sup>1</sup> Historical controlled study USA | Residual pressure gradient across valve:  
- Valvuloplasty: 24 mmHg  
- Surgery: 16 mmHg | Pulmonary insufficiency:  
- Valvuloplasty: 9 mild  
- Surgery: 9 mild, 9 moderate  
p<0.01 | Historical controls but matched on age and peak pulmonary stenosis gradient |
| 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 | Small study |
| **Stanger, 1990**<sup>2</sup> Case series, partly prospective USA, multicentre | 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 |
| n=811 people received pulmonary balloon valvuloplasty (age range 1 day to 76 years)  
Cases identified through the Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) Registry | Follow up immediate | Immediate results only presented |
| **McCrindle, 1994**<sup>3</sup> Case series, partly prospective USA, multicentre | 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 |
| 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 | 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<sup>2</sup> | |
Summary of key efficacy and safety findings (2)

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| Schmaltz, 1989<sup>4</sup>  
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 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<sup>5</sup>  
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


## Annex: References to smaller case series

<table>
<thead>
<tr>
<th>Reference</th>
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