

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## 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.<sup>1</sup>

We found 11 case series. The table gives details of the four largest.<sup>2-5</sup>

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
<p>O'Connor, 1992<sup>1</sup> Historical controlled study USA</p> <p>n=40 children</p> <ul style="list-style-type: none"> <li>• 20 balloon valvuloplasty (mean age 4.3 years)</li> <li>• 20 open surgery (mean age 4.7 years)</li> </ul> <p>Exclusions:</p> <ul style="list-style-type: none"> <li>• dysplastic pulmonary valve</li> <li>• anulus hypoplasia</li> <li>• complex anomaly</li> </ul> <p>Mean follow up:</p> <ul style="list-style-type: none"> <li>• Valvuloplasty: 5.3 years</li> <li>• Surgery: 11.7 years</li> </ul>	<p>Residual pressure gradient across valve:</p> <ul style="list-style-type: none"> <li>• Valvuloplasty: 24 mmHg</li> <li>• Surgery: 16 mmHg</li> </ul>	<p>Pulmonary insufficiency:</p> <ul style="list-style-type: none"> <li>• Valvuloplasty: 9 mild</li> <li>• Surgery: 9 mild, 9 moderate</li> </ul> <p>p&lt;0.01</p> <p>Ventricular arrhythmias:</p> <ul style="list-style-type: none"> <li>• Valvuloplasty: 1 grade 1 ectopics</li> <li>• Surgery: 6 had complex ventricular arrhythmia</li> </ul> <p>p&lt;0.01</p>	<p>Historical controls but matched on age and peak pulmonary stenosis gradient</p> <p>Small study</p> <p>Ascertainment methods not clear</p> <p>Losses to follow up: 4 people who received valvuloplasty</p> <p>Follow up length different for valvuloplasty and surgery groups</p>
<p>Stanger, 1990<sup>2</sup> Case series, partly prospective USA, multicentre</p> <p>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</p> <p>Follow up immediate</p>	<p>Immediate results:</p> <p>Residual gradient &lt; 15 mmHg: 25%</p> <p>Gradient &gt; 30 mmHg: 8%</p> <p>Therapeutic failures: 2%</p> <p>Average gradient 16.5 mmHg</p>	<p>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</p>	<p>Uncontrolled case series</p> <p>Immediate results only presented</p>
<p>McCrinkle, 1994<sup>3</sup> Case series, partly prospective USA, multicentre</p> <p>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)</p> <p>Median follow up 33 months, range 1 month to 8.7 years</p>	<p>Immediate residual gradients &lt; 36 mmHg: 74%</p> <p>Residual gradient &gt;=36 mmHg or further treatment required: 23%</p>	<p>Pulmonary regurgitation at follow up:</p> <ul style="list-style-type: none"> <li>• Trivial: 22%</li> <li>• Mild: 45%</li> <li>• Moderate: 7%</li> </ul>	<p>Uncontrolled case series</p> <p>Only included people for whom follow up data available.</p> <p>Patients with a gradient of &gt;=36 mmHg were defined as having a suboptimal long term outcome.</p> <p>Includes the same people as in Stanger, 1990<sup>2</sup></p>

## Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
<p>Schmaltz, 1989<sup>4</sup></p> <p>Case series 20 centres in Germany</p> <p>n=273 children with isolated pulmonary stenosis, mean age 6 years, range 3 days to 18 years</p> <p>Mean follow up 11 months</p>	<p>Mean pressure gradient: 32 mmHg</p> <p>Gradient reduced by &gt;50%: 64%</p> <p>Further procedure required: 14 people</p>	<p>Influndibular reaction 12% 4% (11) patients had major complications</p> <p>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.</p>	<p>Uncontrolled case series</p> <p>Completeness of ascertainment not described</p> <p>Follow up data only available for 140 children (51%)</p>
<p>Echigo, 2001<sup>5</sup></p> <p>Retrospective case series 8 centres in Japan</p> <p>n=172 people, mean age 5.4 years</p> <p>Exclusions: Critical pulmonary stenosis</p> <p>Minimum follow up 6 years</p>	<p>Mean pressure gradient post-procedure: 28 mmHg</p> <p>Follow up mean pressure gradient: 16 mmHg</p> <p>Repeat valvuloplasty required: 15 people (9%) Surgery required: 5 people (3%)</p>	<p>'No major complications'</p> <p>Mild pulmonary regurgitation: 69%</p> <p>Moderate to severe pulmonary regurgitation: 6%</p>	<p>Uncontrolled case series</p> <p>Completeness of ascertainment and follow up not described</p>

### **Validity and generalisability of the studies**

We found one small historical controlled study.<sup>1</sup> 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.<sup>2-5</sup> The first of these provided detailed information about procedural complications.<sup>2</sup> The other three provided longer term follow up data on some, but not all included patients.<sup>3-5</sup> This could bias estimates of long term safety and efficacy. In the two smallest studies, the completeness of ascertainment was not clear.<sup>4,5</sup>

### **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

1. O'Connor, B. K., Beekman, R. H., Lindauer, A., and Rocchini, A. Intermediate-term outcome after pulmonary balloon valvuloplasty: comparison with a matched surgical control group. *Journal of the American College of Cardiology* 1992; 20: 169-173.
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3. McCrindle, B. W. Independent predictors of long-term results after balloon pulmonary valvuloplasty. *Circulation* 1994; 89: 1751-1759.
4. Schmaltz, A. A., Bein, G., Gravinghoff, L., Hagel, K., Hentrich, F., Hofstetter, R., Lindinger, A., Kallfeltz, H. C., Kramer, H. H., Mennicken, U., Mocellin, R., Pfefferkorn, J. R., Redel, D., Rupprath, G., Sandhage, K., Singer, H., Sebening, W., Ulmer, H., and Vogt, J. Balloon valvuloplasty of pulmonary stenosis in infants and children - Co-operative study of the German Society of Pediatric Cardiology. *European Heart Journal* 1989; 10: 967-971
5. Echigo, S. Balloon valvuloplasty for congenital heart disease: Immediate and long-term results of multi-institutional study. *Pediatrics International* 2001; 43: 542-547.

## Annex: References to smaller case series

Reference	Number of study participants
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Lazaro Castillo, J. L., Munayer, Calderon J., Aldana, Perez T., San Luis, Miranda R., Maza, Juarez G., Ramirez, Reyes H., Roberto, Quintero L., Arias, Monroy L., and Campos, Gomez A. Pulmonary valvuloplasty. Long term results at the Centro Medico la Raza [Spanish]. <i>Archivos del Instituto de Cardiologia de Mexico</i> 1999; 69: 338-343.	109
Buheitel, G., Bohm, B., Koch, A., Trusen, B., Hofner, G., and Singer, H. Balloon dilatation of the pulmonary valve. <i>Zeitschrift fur Kardiologie</i> 2001; 90: 503-509.	100
Hernaez Cobeno, M. A., Bermudez-Canete, R., Herraiz, I., Fernandez, Pineda L., Quero, Jimenez C., and Diaz, Garcia P. Balloon valvuloplasty for valvular pulmonary stenosis in 100 consecutive children: Medium-term follow-up. <i>Anales Espanoles de Pediatria</i> 1998; 49: 264-272.	100
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Fontes, V. F., Sousa, J. E., Esteves, C. A., Silva, M. V., Cano, M. N., and Maldonado, G. Pulmonary valvoplasty--experience of 100 cases. <i>International Journal of Cardiology</i> 1988; 21: 335-342.	100