

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of radiofrequency valvotomy in pulmonary atresia

Introduction

This overview has been prepared to assist members of 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. Updated by NICE in April 2004.

Procedure name

Radiofrequency valvotomy in pulmonary atresia

Specialty society

British Paediatric Cardiac Association

Description

Radiofrequency valvotomy is used to treat pulmonary atresia, a congenital malformation of the pulmonary valve in which the valve orifice fails to develop. The valve is completely closed thereby obstructing the outflow of blood from the heart to the lungs. Babies with this type of cyanotic congenital heart disease survive only for the first few days of life while the normal fetal shunts between left and right circulations remain patent. Without an operation in that period to open the pulmonary valve or to make a shunt between the aorta and the pulmonary arteries, the condition is fatal.

The standard treatment for pulmonary atresia is open heart surgery which includes the Fontan procedure (the surgical creation of a right ventricular bypass by directly connecting either the right atrium or the superior or inferior vena cava and the pulmonary artery) and the Blalock-Taussig shunt (a palliative procedure where a shunt is created to allow blood to pass from the aorta to the pulmonary artery by dividing the left subclavian artery and connecting it to the left pulmonary artery). Further open heart surgery may include open surgical valvotomy.

Radiofrequency valvotomy is a minimally invasive cardiac catheterisation procedure which involves creating an opening in the blocked pulmonary valve followed by dilation using balloon angioplasty. It avoids open surgery but some children will later need a permanent shunt procedure.

Benefits

Based on the literature, we found limited evidence that laser or radiofrequency valvotomy of pulmonary atresia restores pulmonary blood flow, and that some children may avoid the need for open surgery in the long term. We found no studies that reliably compared laser or radiofrequency valvotomy with other techniques.

Risks

Based on the literature, we found limited evidence that laser or radiofrequency valvotomy may cause perforation of the pulmonary artery and death. However, open surgery also carries a high risk of death.

The Specialist Advisors considered the main risks of the procedure to be death, perforation of the heart, cardiac tamponade, cardiac or pulmonary artery perforation/rupture, arrhythmias, infection and multi-organ failure.

Literature review**Appraisal criteria**

We included studies examining clinical outcomes of laser or radiofrequency valvotomy in babies with pulmonary atresia.

List of studies found

We found no randomised controlled trials.

We found one historical controlled study, which is described in the table.¹

We found 13 case series. The four largest are described in the table.²⁻⁵

The annex gives references to case series with 10 or fewer participants.

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>Alwi, 2000¹ Historical controlled study Malaysia n=33 babies with pulmonary atresia with intact ventricular septum, mild to moderate right ventricle hypoplasia and patent infundibulum (81% newborn):</p> <ul style="list-style-type: none"> • 19 had radiofrequency (RF) valvotomy and balloon dilatation • 14 had surgical valvotomy and Blalock-Taussig shunt <p>Mean follow up 18 months for valvotomy group and 51 months for surgery group.</p>	<p>'Procedural success':</p> <ul style="list-style-type: none"> • RF valvotomy: 19/21 <p>Median length of hospital stay:</p> <ul style="list-style-type: none"> • RF valvotomy: 9 days • surgery: 20 days <p>p=0.009</p> <p>Median length of ventilation:</p> <ul style="list-style-type: none"> • RF valvotomy: 0 days • surgery: 5 days <p>p=0.0002</p>	<p>Deaths:</p> <ul style="list-style-type: none"> • RF valvotomy: 3 babies • surgery: 4 babies <p>Further procedures:</p> <ul style="list-style-type: none"> • RF valvotomy: 2 repeat balloon dilatation, 1 right ventricular outflow tract reconstruction, 2 transcatheter closure of inter-atrial communication, 2 partial biventricular repair. • surgery: 10 required a 2nd right ventricle decompression (8 balloon dilatation, 2 right ventricular outflow tract reconstruction) 	<p>Historical controls, but groups similar on age, sex, weight, and cardiac features.</p> <p>Small study</p> <p>Follow up short for some babies</p>
<p>Humpl, 2003² Case series Canada n=30 babies with pulmonary atresia with intact ventricular septum, median age 2 days (range 0 days to 22 months), treated with radiofrequency valvotomy and balloon dilation of the pulmonary valve. Mean follow-up: 28 months (range 1 to 87 months)</p>	<p>Successful perforation of the pulmonary valve: 27/30</p> <p>Biventricular circulation: 16/30</p>	<p>Postoperative deaths: 3 babies Late deaths: 2 babies (including one 2 years after surgery of noncardiac cause)</p> <p>Loss of arterial pulse: 4 babies Rhythm disturbances: 7 babies Perforation of pulmonary artery: 1 baby</p>	<p>Uncontrolled case series</p> <p>Small study</p> <p>3.3% (1/30) lost to follow-up</p>
<p>Hausdorf, 1993² Case series Germany n=18 people with pulmonary atresia, age range 4 days to 19 years, treated with radiofrequency valvotomy Follow up duration not specified</p>	<p>Procedural success: 14/18</p>	<p>Perforation of right ventricular outflow tract: 3 babies</p> <p>Perforation of pulmonary artery: 2 babies</p>	<p>Published in German</p> <p>Data extracted from abstract only</p> <p>Uncontrolled case series</p> <p>Small study</p>
<p>Cheung, 2002³ Case series Hong Kong n=15 children with pulmonary atresia with intact ventricular septum who had laser valvotomy, median age 5 days (range 1 to 750) Median follow up 3 years</p>	<p>Procedural success: 14/15</p> <p>Required subsequent procedures: 6/12 survivors had shunt insertion; 9 required 2nd balloon dilatation</p>	<p>Deaths within 6 weeks: 3 babies</p>	<p>Uncontrolled case series</p> <p>Small study</p>

<p>Ovaert, 1998⁴ Case series UK</p> <p>n=12 children with pulmonary atresia with intact ventricular septum, median age 9 days (range 1 to 74)</p> <ul style="list-style-type: none"> • 6 had laser valvotomy alone • 5 had radiofrequency valvotomy alone • 1 had both <p>Follow up 8 to 68 months</p>	<p>Successful perforation of the pulmonary valve: 9 children</p>	<p>Procedural deaths: 2 children</p> <p>Deaths at 33 days: 4 children</p> <p>Unsuccessful procedure leading to surgery: 1 child</p> <p>Perforation of pulmonary artery: 4 children</p>	<p>Uncontrolled case series</p> <p>Small study</p>
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Validity and generalisability of the studies

We found one study comparing laser or radiofrequency valvotomy with open surgical valvotomy,¹ and some case series. All the studies are very small. These studies provide very limited evidence of efficacy of laser or radiofrequency valvotomy compared with open surgical procedures.

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.

- this procedure is no longer new and is performed regularly around the world
- the procedure is complex, training required
- there are concerns about the safety to operators of lasers
- there is a national register of congenital heart disease surgery

References

1. Alwi, M., Geetha, K., Bilkis, A. A., Lim, M. K., Hasri, S., Haifa, A. L., Sallehudin, A., and Zambahari, R. Pulmonary atresia with intact ventricular septum percutaneous radiofrequency-assisted valvotomy and balloon dilation versus surgical valvotomy and Blalock Taussig shunt. *J Am Coll Cardiol* 2000; 35: 468 – 476.
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5. Ovaert, C., Qureshi, S. A., Rosenthal, E., Baker, E. J., and Tynan, M. Growth of the right ventricle after successful transcatheter pulmonary valvotomy in neonates and infants with pulmonary atresia and intact ventricular septum. *J Thorac Cardiovasc Surgery* 1998; 115: 1055 – 1062.

Annex: References to studies not described in the table

Reference	Number of study participants
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Gournay, V., Piechaud, J. F., Delogu, A., Sidi, D., and Kachaner, J. Balloon valvotomy for critical stenosis or atresia of pulmonary valve in newborns. <i>Journal of the American College of Cardiology</i> 1995; 26: 1725-1731.	5
Giusti, S., Spadoni, I., De Simone, L., and Carminati, M. Radiofrequency perforation in pulmonary valve atresia and intact ventricular septum. [Italian] <i>Giornale Italiano di Cardiologia</i> 1996; 26: 391-397.	4
Park, I. S., Nakanishi, T., Nakazawa, M., Takanashi, Y., Imai, Y., and Momma, K. Radiofrequency pulmonary valvotomy using a new 2-French catheter. <i>Catheterization & Cardiovascular Diagnosis</i> 1998; 45: 37-42.	3
Pedra, C. A., de Sousa, L. N., Pedra, S. R., Ferreira, W. P., Braga, S. L., Esteves, C. A., Santana, M. V., Sousa, J. E., and Fontes, V. F. New percutaneous techniques for perforating the pulmonary valve in pulmonary atresia with intact ventricular septum. <i>Arquivos Brasileiros de Cardiologia</i> 2001; 77: 471-486.	3
Hofbeck, M., Wild, F., and Singer, H. Interventional treatment of pulmonary atresia with intact ventricular septum by radiofrequency perforation and balloon dilatation of the pulmonary valve. <i>Klinische Padiatrie</i> 1994; 206: 157-160.	2
Wright, S. B., Radtke, W. A., and Gillette, P. C. Percutaneous radiofrequency valvotomy using a standard 5Fr electrode catheter for pulmonary atresia in neonates. <i>American Journal of Cardiology</i> 1996; 77: 1370-1372	2