NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES
PROGRAMME

Interventional procedure overview of laser/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.

Procedure name
Laser/radiofrequency valvotomy in pulmonary atresia

Specialty society
British Paediatric Cardiac Association

Description
Laser or radiofrequency valvotomy is used to treat pulmonary atresia, a congenital malformation of the pulmonary valve. The valve orifice is obstructed, and all blood leaves the heart through the aortic valve. Babies with this condition survive the first few days of life because of the normal fetal shunts between left and right circulations. Without an operation in the first few days of life to open the pulmonary valve or to make a permanent shunt between the aorta and the pulmonary arteries, these babies will die.

Laser or radiofrequency valvotomy is a minimally invasive cardiac catheterisation procedure involving burning a hole in the blocked pulmonary valve. It avoids open surgery. It is often followed by balloon angioplasty. Some children will later have a permanent shunt procedure. Traditional treatments for pulmonary atresia include open surgical valvotomy and the Fontan 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.

According to the specialist advisor, the risks are: death (<20%), arrhythmias (frequent during the procedure), perforation of the heart (10%), cardiac tamponade (<10%), infection (unpredictable) and multiorgan failure (<5%).

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 12 case series. The three largest are described in the table.[2-4]

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
Alwi, 2000[1] 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): • 19 had radiofrequency (RF) valvotomy and balloon dilatation • 14 had surgical valvotomy and Blalock-Taussig shunt Mean follow up 18 months for valvotomy group and 51 months for surgery group.	'Procedural success': • RF valvotomy: 19/21 Median length of hospital stay: • RF valvotomy: 9 days • surgery: 20 days p=0.009 Median length of ventilation: • RF valvotomy: 0 days • surgery: 5 days p=0.0002	Deaths: • RF valvotomy: 3 babies • surgery: 4 babies Further procedures: • 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)	Historical controls, but groups similar on age, sex, weight, and cardiac features. Small study Follow up short for some babies
Hausdorf, 1993[2] 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	Procedural success: 14/18	Perforation of right ventricular outflow tract: 3 babies Perforation of pulmonary artery: 2 babies	Published in German Data extracted from abstract only Uncontrolled case series Small study
Cheung, 2002[3] 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	Procedural success: 14/15 Required subsequent procedures: 6/12 survivors had shunt insertion; 9 required 2nd balloon dilatation	Deaths within 6 weeks: 3 babies	Uncontrolled case series Small study
Ovaert, 1998[4] Case series UK n=12 children with pulmonary atresia with intact ventricular septum, median age 9 days (range 1 to 74) • 6 had laser valvotomy alone • 5 had radiofrequency valvotomy alone • 1 had both Follow up 8 to 68 months	Successful perforation of the pulmonary valve: 9 children	Procedural deaths: 2 children Deaths at 33 days: 4 children Unsuccessful procedure leading to surgery: 1 child Perforation of pulmonary artery: 4 children	Uncontrolled case series Small study

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 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

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2. Hausdorf, G., Schneider, M., Schirmer, K. R., Uhlemann, F., Will, J. C., Loebe, M., Hetzer, R., and Lange, P. E. Transcatheter radiofrequency perforation of pulmonary atresia. Zeitschrift fur Kardiologie 1993; 82: 123-130.

3. Cheung, Y. F., Leung, M. P., and Chau, A. K. Usefulness of laser-assisted valvotomy with balloon valvoplasty for pulmonary valve atresia with intact ventricular septum. Am J Cardiol 2002; 90: 438-442.

4. 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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Giusti, S., Spadoni, I., De Simone, L., and Carminati, M. Radiofrequency perforation in pulmonary valve atresia and intact ventricular septum. [Italian] Giornale Italiano di Cardiologia 1996; 26: 391-397.	4
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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. Arquivos Brasileiros de Cardiologia 2001; 77: 471-486.	3
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