NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES
PROGRAMME

Interventional procedure overview of balloon or blade atrial septostomy

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 one or more 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 or blade atrial septostomy including static balloon atrial septostomy

Synonym for balloon septostomy: Rashkind septostomy
Synonyms for blade septostomy: knife or Park septostomy

Specialty society
British Paediatric Cardiac Association

Indications
The main indication for this procedure is transposition of the great arteries; an uncommon congenital cardiac anomaly in which the aorta arises from the right ventricle and the pulmonary trunk arises from the left ventricle. This results in two separate circuits of blood flow, where highly-oxygenated blood keeps cycling through the lungs, while oxygen-depleted blood recycles around the body. As a result, the baby develops a blue colour (cyanosis) shortly after birth. The newborn can survive for a few days because the foramen ovale, a small hole in the foetal interatrial septum, allows some oxygenated blood to mix with the blood that is being circulated around the body. However, the foramen ovale normally closes within a few days after birth. Less commonly, septostomy is carried out in children with other cyanotic congenital abnormalities.

The aim of balloon or blade atrial septostomy is to enlarge the foramen ovale to allow some of the oxygenated blood to pass from the left ventricle into the aorta to circulate around the body. A catheter is passed through a large vein, into the right atrium and through the foramen ovale. Once in the left atrium, the operator expands a balloon at the end of the catheter and pulls it back into the right atrium, making the hole bigger. If the wall is too thick or the hole too small, the operator may use a blade at the end of the catheter to cut the wall. Static balloon atrial septostomy is a variation of balloon atrial septostomy, which is usually used to enlarge the hole made in the interatrial wall during blade septostomy.

Without a treatment to make a connection between the right and left atria, most babies would die very soon. The only babies likely to survive for even a few weeks without septostomy are those with a congenital ventricular septal defect. There is no reliable alternative to septostomy procedures in neonates. Definitive surgery is usually done several months after septostomy.

Benefits
We found limited evidence that balloon atrial septostomy improves oxygen saturation and survival. We found very limited evidence of the efficacy of blade atrial septostomy, and found no evidence on the efficacy of static balloon atrial septostomy.

Risks
We found evidence that up to 3% of children may die during or immediately after balloon or blade septostomy.

According to the specialist advisor, complications include transient arrhythmias (very common), necrotising enterocolitis (<1%), cardiac injury or tear (<1%) and death (1%).

Literature review

Appraisal criteria
We included studies examining the clinical outcomes of balloon or blade atrial septostomy in humans.

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

We found 19 case series including 50 or more people who had either standard balloon or blade atrial septostomy. Four of the studies included children who had blade atrial septostomy.

The seven largest studies are described in the table.[1-7]

We found no studies of static balloon atrial septostomy.

The annex provides references to smaller case series.

Summary of key efficacy and safety findings (1)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability and validity issues
Alekian, 1995[1] Case series Assumed to be Russia n=535 children with cyanotic congenital heart disease: • 500 received balloon atrial septostomy • 35 received knife atrial septostomy	'An immediate hemodynamic effect at the operation table was attained in 95% of patients'	None provided	Published in Russian; data extracted from abstract Large case series
Schmaltz, 1990[2] Case series Assumed to be Germany n=248 with cyanotic congenital heart disease received balloon atrioseptostomy	None provided	Minor complications: 26 (11%) Lethal complications: 3 (1%)	Published in German; data extracted from abstract Large case series
Beitzke, 1977[3] Case series Assumed to be Germany n=149 children with transposition of the great arteries received balloon atrial septostomy	Mean increase in arterial oxygen saturation: 21%	Required 2nd procedure: 11 children Procedural deaths: 3 children 'Early deaths': 13% 'Late deaths': 17%	Published in German; data extracted from abstract Large case series
Leanage, 1981[4] Retrospective case series UK n=144 children with transposition of the great arteries receiving balloon atrial septostomy, median age 4 days (range 1 day to 10 years) Exclusions: • imperforate valves • common atrioventricular orifice Follow up not described	Median systemic arterial oxygen saturation 48% before the procedure to 69% after the procedure Survival to 6 months: • 1970-1972: 55% • 1972-1975: 72% • 1976 onwards: 86% Required further procedure before definitive surgery: 22%	None described	Large case series Designed to examine factors influencing survival, not efficacy or safety

Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Powell, 1984[5] Case series UK n=124 infants with transposition of the great arteries received balloon septostomy, median age 5 days, range 1 to 131 days	Median systemic arterial oxygen saturation 60% before the procedure and 76% after Failure of procedure (second procedure or died): 60 (48%)	None described	Case series Designed to examine factors influencing survival, not efficacy or safety
Mani, 1994[6] Case series Assumed to be India n=108 children with transposition of the great arteries • 100 received balloon septostomy • 8 received blade septostomy	Average improvement in oxygen saturation: • balloon: 27% • blade: 24%	Procedure related deaths • balloon: 3 children • blade: none	Full text not available, data extracted from abstract Case series
Schmaltz, 1982[7] Case series Germany n=104 children with transposition of the great arteries received balloon septostomy Exclusions: • valve atresia • univentricular heart Follow up at least 8 months	Survival to one month: 80% 2nd procedure required: 18% 2 year survival: 48%	Procedure related deaths: 2 children Deaths between 1 month and date of corrective surgery: 25%	Case series

Validity and generalisability of the studies
We found case series only. Many were not published in English, so full quality assessment was not possible.This is likely to be due to lack of a reliable comparator treatment – most babies with transposition of the great arteries would die without septostomy. The case series were relatively large. Four of the studies were published more than 15 years ago.[3-5,7]

Specialist advisor's opinion / advisors' opinions
Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Societies or Royal College.

Balloon septostomy: Now established practice. Requires appropriate training of operators. High quality echocardiography and fluoroscopy equipment should be available.

Static balloon septostomy: Requires appropriate training of operator. High quality echocardiography, fluoroscopy and catheter lab facilities required. Should only be carried out in a tertiary paediatric cardiology centre with involvement of a lead interventional paediatric cardiologist. Surgical back up should be available in the unit.

Issues for consideration by IPAC
This overview does not examine efficacy or safety of balloon compared with blade atrial septostomy.

References

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2. Schmaltz, A. A. and Apitz, J. Interventional cardiology in children. [German] Klinische Padiatrie 1990;202:12-17

3. Beitzke, A., Sauer, U., Mocellin, R., Dohlemann, C., and Buhlmeyer, K. Transposition of the great arteries: natural history and indications for surgery after balloon-atrioseptostomy. [German] Zeitschrift fur Kardiologie 1977;66: 28-34

4. Leanage, R., Agnetti, A., Graham, G., Taylor, J., and Macartney, F. J. Factors influencing survival after balloon atrial septostomy for complete transposition of great arteries. British Heart Journal 1981;45: 559-572

5. Powell, T. G., Dewey, M., West, C. R., and Arnold, R. Fate of infants with transposition of the great arteries in relation to balloon atrial septostomy. British Heart Journal 1984;51: 371-376

6. Mani, S., Venkitachalam, C. G., Subramaniam, R., Balakrishnan, K. G., Titus, T., Tharakan, J. A., Ajithkumar, V. K., Bhat, A., and Pillai, V. R. Blade and balloon atrial septostomy for creation of an adequate interatrial communication. Indian Heart Journal 1994;46:161-164

7. Schmaltz, A. A., Knab, I., Seybold, Epting W., and Apitz, J. Prognosis of children with transposition of the great arteries, treated in a regional heart centre between 1967 and 1979. European Heart Journal 1982;3: 570-576

Annex: References to smaller case series

Reference	Number of participants
Knab, I., Schmaltz, A. A., Seybold-Epting, W., and Apitz, J. Transposition of the great arteries: results of treatment in the years 1967-1980. Monatsschrift fur Kinderheilkunde 1981;129:627-632	104 (balloon)
Mok, Q., Darvell, F., and Mattos, S. Survival after balloon atrial septostomy for complete transposition of great arteries. Archives of Disease in Childhood 1987;62:549-553	102 (balloon)
Champsaur, G., Bozio, A., Andre, M., Jocteur-Montrozier, D., Normand, J., and Michaud, P. Palliative treatment of transposition of the great vessels. Indications and results. [French] Chirurgie Pediatrique 1980;21:29-33	93 (balloon)
Guarnera, S., Contarini, M., Sciacca, P., Patane, L., Parisi, M. G., Pulvirenti, A., Marletta, M., D'Agata, G., and Distefano, G. Indications for percutaneous atrioseptostomy. Comparison of echocardiographic and fluoroscopic monitoring. [Italian] Pediatria Medica e Chirurgica 1997;19:253-256	91 (balloon)
Vitola, D., Guillermo-Cal, L., Zielinsky, P., Lucchese, F. A., Leboute, F. C., Feldman, C. J., and Rodrigues, R. Atrio-septostomy using a Rashkind catheter in complete transposition of the great arteries. Immediate and late results. [Spanish] Archivos del Instituto de Cardiologia de Mexico 1985;55:115-119	71 (balloon)
Chro, Gornicki, B., Gizycka, I., Szreter, T., Kubicka, K., Lisicka, D., Czarnowska, M., Wysocka, K., Kami, Urbanik, H., Werme, Wo, and Karcze. Rashkind's operation in treatment of complete transposition of the great vessels in the newborn and infants. Polish Medical Sciences & History Bulletin 1975;15:223-228	65 (balloon)
Ashfaq, M., Houston, A. B., Gnanapragasam, J. P., Lilley, S., and Murtagh, E. P. Balloon atrial septostomy under echocardiographic control: six years' experience and evaluation of the practicability of cannulation via the umbilical vein. British Heart Journal 1991;65:148-151	63 (balloon)
Gutgesell, H. P. and McNamara, D. G. Transposition of the great arteries. Results of treatment with early palliation and late intracardiac repair. Circulation 1975;51:32-38	62 (balloon)
Reddy, V., Sharma, S., and Cobanoglu, A. Atrial switch (Senning procedure) in the era of the arterial switch operation: current indications and results. European Journal of Cardiothoracic Surgery 1996;10:546-550	54 (balloon)
Chandrashekhar, Y. S., Khattri, H. N., and Bidwai, P. S. Balloon atrial septostomy in infants with transposition of the great arteries (d-TGA): PGIMER experience. Indian Heart Journal 1990;42:51-54	53 (balloon)
Park, S. C., Neches, W. H., Mullins, C. E., Girod, D. A., Olley, P. M., Falkowski, G., Garibjan, V. A., Mathews, R. A., Fricker, F. J., Beerman, L. B., Lenox, C. C., and Zuberbuhler, J. R. Blade atrial septostomy: collaborative study. Circulation 1982;66:258-266	52 (blade)
Khan, M. A. A., Bricker, J. T., Mullins, C. E., Yousef, S. A., Nihill, M. R., and Vargo, T. A. Blade atrial septostomy: Experience with the first 50 procedures. Catheterization & Cardiovascular Diagnosis 1991;23:257-262	50 (blade)