NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endovascular closure of persistent ductus arteriosus

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committe (IPAC) in making recommendations about 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 originally prepared by Bazian Ltd in March 2003. Updated by NICE in March 2004.

Procedure name

Endovascular closure of persistent ductus arteriosus

Specialty society

British Paediatric Cardiac Association

Indications

Persistence of the ductus arteriosus

The ductus arteriosus is a normal vessel in the foetus that connects the pulmonary artery and the aorta. It allows the foetal blood flow to bypass the lungs, which are not used in utero. At or shortly after birth, this vessel should close, completing the separation between the right and left sides of the heart.

Sometimes, the ductus arteriosus fails to close on its own and this is called a persistent (or patent) ductus arteriosus (PDA). Blood can therefore pass from the aorta into the pulmonary artery exposing the lungs to increased blood flow. If the PDA is small, there may be no obvious symptoms but a large PDA may cause symptoms such as poor weight gain and breathlessness. Without medical treatment, blood vessels in the lung may eventually become diseased by the extra pressure of the increased blood flow. This in turn puts strain on the heart and can lead to heart failure. Persistent ductus arteriosus is also associated with an increased risk of endocarditis, a life-threatening infection of the lining that covers the heart chambers, valves, and main arteries.

Current treatment and alternatives

Open surgery is the conventional treatment. Access to the heart is gained via an incision in the chest and a stitch and or clip is placed around both ends of the ductus arteriosus, which is then cut in half if there is enough length (ligation and division).

What the procedure involves

The endovascular procedure involves passing a catheter through a vein or artery, into the heart. Pressure measurements and angiograms may be performed to assess the size and shape of the ductus.The catheter is then used to introduce an occlusion device into the ductus under X ray guidance. The choice of device largely depends on the size of the PDA. Coils are only suitable for closing small to moderate sized PDAs. Other occlusion devices are used to close larger PDAs.

Small residual shunts after the procedure often resolve as endothelial tissue grows over and around the device.

Efficacy

Three non-randomised controlled studies reported efficacy data. In two of these, immediate occlusion was reported in 68% (71/105) and 77% (23/30) of patients treated with endovascular closure and in 89% (8/9) and 96% (140/146) of patients treated with open surgery. The third study reported that 94% (93/99) patients treated with endovascular closure had a successful outcome immediately after the procedure, compared with 99% (109/110) of patients treated with open surgery.

The four case series studies, with a total of 2035 patients, reported rates of immediate complete occlusion between 44% (90/205) and 98% (214/218). In all studies, occlusion rates after a period of follow-up were higher than immediately after the procedure. One case series of 1258 patients reported an occlusion rate of 96% at a two year follow-up compared with an immediate occlusion rate of 59%.

The Specialist Advisors stated that a small proportion of patients will have a residual shunt.

Safety

The most commonly reported complications were haemolysis and inadvertent embolisation of the device. Rates of haemolysis varied from 0.3% (1/316) to 8.8% (3/34) and rates of embolisation varied from 0.6% (2/316) to 7% (7/105). A study of 316 patients reported one death as a result of the procedure.

The Specialist Advisors considered that inadvertent device embolisation, haemolysis, death and vascular injury were potential adverse events.

Literature review

Appraisal criteria

We included studies examining any clinical outcomes in people receiving the Amplatzer device or coil embolisation for persistent or patent ductus arteriosus.

List of studies found

We found no systematic reviews or randomised controlled trials.

We found ten studies comparing endovascular occlusion with surgery. Six of these examined coil embolisation compared with surgery. The table summarises the three largest.[1-3] Two comparison studies examined case series of people receiving endovascular occlusion with the Rashkind device, which is not covered by this overview. References to these are given in

the annex. For the other two studies, the device used was not clear from the abstract. Both were small.

Four large case series examined coil embolisation for occlusion of patent ductus arteriosus. The largest is described in the table.[4] Three case series including over 200 people examined the Amplatzer device.[5,6,7] These studies are described in the table.

The annex provides references to the studies not described in the table.

Summary of key efficacy and safety findings (1)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Hwang, 2000[1] Historical controlled study Location not clear n=163 infants • 153 received coil embolisation • 10 received surgical ligation Follow up 1.5 years	Coil: • immediate occlusion: 68% (71/105) • additional coil closure for residual shunt at 1.5 years: 8% (6/105) Surgery: • immediate occlusion: 89% (8/9) • additional coil closure for residual shunt at 1.5 years: 11% (1/9)	Coil: • Embolisation requiring endovascular retrieval: 7% (7/105) • haemolysis: 1% (1/105) Surgery: no complications	69% (105/153) patients with complete follow-up – losses to follow-up not described Method of patient allocation not described
LeBlanc, 2000[2] Historical controlled study Location not clear n=261 children • 30 received coil embolisation, median age 31 months • 231 received surgical ligation, median age 13 months	Coil: • residual duct after initial procedure: 23% (7/30) • second procedure to close residual duct: 13% (4/30) Surgery: • residual duct: 4% (6/146) • reoperation: 0.9% (2/231)	Coil: • thrombosis: 3.3% (1/30) • femoral vein exploration for removal of catheter remnant: 3.3% (1/30) • haemolysis: 3.3% (1/30 Surgery: • intraoperative death: 0.4% (1/231) • pneumothorax requiring drainage: 0.4% (1/231) • wound infection: 1.7% (4/231) • vocal cord paralysis: 1.3% (3/231) • left pulmonary artery stenosis: 0.4% (1/231)	Method of patient allocation not described Completeness of follow-up not described
Klestov, 2002[3] Comparison of case series Location not clear, probably Russia n=209 • 99 received coils or Saveliev-Prokubovsky occluders • 110 received open surgery Follow up 'immediate'	'Success': • Coil or occluder: 94% (93/99) • Surgery: 99% (109/110)	Coil or occluder: none described Surgery: • Incomplete expanding of lung: 0.9% (1/110) • Pleural exudate: 0.9% (1/110) • Chylothorax: 0.9% (1/110)	Published in Russian Data extracted from abstract Data on ascertainment, allocation and follow up not available

Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Magee, 2001[4] Prospective case series Several European and Middle Eastern centres n=1258 people who had coil embolisation, median age 4 years (range 0.1 to 52 years), median weight 29kg Follow up: up to 36 months	Immediate occlusion: 59% Occlusion at 1 year: 95% Occlusion at 2 years: 96%	Embolisation during procedure: 3.2% (40/1258) Late embolisation: 0.6% (8/1258) Haemolysis: 0.9% (11/1258)	Uncontrolled case series Completeness of follow up not described Completeness of ascertainment not clear
Faella, 2001[5] Case series Location not clear n=316 people who received the Amplatzer device, median age 2 years Follow up 6 months	Immediate occlusion: 56% (177/316) Occlusion after 24 hours: 76% (235/308) Occlusion at 6 months: 94.6% (109/114) Occlusion at 1 year: 100% (38/38)	Device embolisation: 0.6% (2/316) Death: 0.3% (1/316) (after device embolised) Haemolysis: 0.3% (1/316) Significant blood loss: 0.6% (2/316) Transient asystole: 0.3% (1/316) Device misplacement: 0.3% (1/316)	
Bilkis, 2001[6] Case series Malaysia n=209 people who received the Amplatzer device, median age 1.9 years 109/209 were symptomatic, with heart failure or failure to thrive Exclusions: • weight <3.5kg Follow up 1 year	Successful placement: 98% (205/209) Immediate occlusion: 44% Occlusion at 1 month: 97%	Significant blood loss: 1% (2/209) Aortic narrowing: 0.5% (1/209) Embolisation: 1.4% (3/209)	Uncontrolled case series Detailed outcome data Follow up to 6 months 93%, to one year 43%

Summary of key efficacy and safety findings (3)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Arora, 2003[7] Case series India n=218 people who received the Amplatzer device n=34 people who had coil embolisation Follow up 4-53 months for Amplatzer device	Amplatzer: • Immediate occlusion: 98% (214/218) • Occlusion at follow-up: 99% (216/218) Coil: • Immediate occlusion: 88% (30/34) • Occlusion at follow-up: 97% (33/34)	Amplatzer: • Embolisation: 0.5% (1/218) Coil • Haemolysis: 8.8% (3/34), 1 requiring additional coil	Uncontrolled case series Completeness of follow up not described Study also included 240 people who received the Rashkind device Selection of device dependent on age of patient, angiographic anatomy and size of PDA.

Validity and generalisability of the studies

The three studies comparing people who had surgery and people who had endovascular treatments for persistent ductus arteriosus were unreliable for assessing the effectiveness of endovascular treatments compared with surgery.[1-3]

We found a large case series of coil embolisation. It provides detailed information on complications and precise estimates of complication rates.[4] However, completeness of ascertainment and follow up were not described.

We found three fairly large case series of the Amplatzer device. We had the full text of two studies of the Amplatzer device.[5,7] These provided fairly detailed information on complications.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

For coil embolisation: Now established practice. Appropriate training of operator required. Good quality fluoroscopy and catheter lab need to be available.

For Amplatzer device: Now established practice. Appropriate training of operator required. High quality fluoroscopy, catheter lab facilities and surgical back up should be available.

References

1. Hwang, B., Lee, P. C., Weng, Z. C., Fu, Y. C., Hsing, H. P., Lu, J. H., Hsieh, W. H., Jan, S. L., and Meng, C. C. Comparison of the one-and-a-half-year results of closure of patent ductus arteriosus by transcatheter coils placement with surgical ligation. Angiology 2000; 51: 757-763.

2. Klestov, K. B., Kokov, L. S., Glagolev, S. V., Korostelev, A. N., and Perevalov, A. P. Roentgeno-endovascular occlusion and surgical correction of patent ductus arteriosus [Russian]. Khirurgiia 2002; 14-19.

3. LeBlanc, J. G., Russell, J. L., Sett, S. S., Potts, J. E., Human, D. G., and Culham, J. A. The evolution of ductus arteriosus treatment. International Surgery 2000; 85: 1-5.

4. Magee, A. G., Huggon, I. C., Seed, P. T., Qureshi, S. A., and Tynan, M. Transcatheter coil occlusion of the arterial duct: Results of the European registry. European Heart Journal 2001; 22: 1817-1821.

5. Faella, H. J. and Hijazi, Z. M. Closure of the patent ductus arteriosus with the amplatzer PDA device: immediate results of the international clinical trial. Catheterization & Cardiovascular Interventions 2000; 51: 50-54.

6. Bilkis, A. A., Alwi, M., Hasri, S., Haifa, A. L., Geetha, K., Rehman, M. A., and Hasanah, I. The Amplatzer duct occluder: experience in 209 patients. Journal of the American College of Cardiology 2001; 37: 258-261.

7. Arora, R., Sengupta, P. P., Ashish, K. T., Mehta, V., and Trehan, V. Device closure of patent ductus arteriosus. Journal of Interventional Cardiology 2003; 16: 385-391.

8. Annex: References to studies not described in the table

Reference	Number of participants	Type of device
Non-randomised comparison studies		
Singh, T. P., Marrow, W. R., Walters, H. L., Vitale, N. A., and Hakimi, M. Coil occlusion versus conventional surgical closure of patent ductus arteriosus American Journal of Cardiology 1997; 79: 1283-1285.	46	Coils
Hawkins, J. A., Minich, L. L., Tani, L. Y., Sturtevant, J. E., Orsmond, G. S., McGough, E. C., Davis, J. T., Guyton, R. A., Miller, D. C., Pennington, D. G., Jonas, R. A., and Griepp, R. B. Cost and efficacy of surgical ligation versus transcatheter coil occlusion of patent ductus arteriosus. Journal of Thoracic & Cardiovascular Surgery 1996; 112: 1634-1639.	40	Coils
Human, D. G., McIntyre, L., Gniewek, A., and Hanna, B. D. Technology assessment of nonsurgical closure of patent ductus arteriosus: an evaluation of the clinical effectiveness and costs of a new medical device. Pediatrics 1995; 96: 703-706.	40	Not clear, probably coils
Vieu, T., Beaurain, S., Angel, C., Leriche, H., Petit, J., Conso, J. F., Planche, C., and Losay, J. Percutaneous closure of patent ductus arteriosus: results and costs compared to surgical closure [French]. Archives des Maladies du Coeur et des Vaisseaux 1995; 88: 1431-1435.	40	Not clear
Prieto, L. R., DeCamillo, D. M., Konrad, D. J., Scalet-Longworth, L., and Latson, L. A. Comparison of cost and clinical outcome between transcatheter coil occlusion and surgical closure of isolated patent ductus arteriosus. Pediatrics 1998; 101: 1020-1024.	36	Coils
Case series		
Samion, H., Alwi, M., Latif, H. A., Kandavel, G., Lim, K. M., and Zambahari, R. Long-term outcome comparison between Rashkind Umbrella and Gianturco coils occlusion in native patent ductus arteriosus. Asia Pacific Heart Journal 1999; 8: 102-105.	522	Rashkind (244) and coils (278)
Zhang, Z., Qian, M., Wang, H., and Li, Y. Transcatheter closure in 354 pediatric cases of patent ductus arteriosus using five different devices. Chinese Medical Journal 2001; 114: 456-458.	354	Several different types
Hofbeck, M., Bartolomaeus, G., Buheitel, G., Esser, R., Gravinghoff, L., Hoffmann, W., Kienast, W., Michel-Behnke, I., Scharabrine, E. G., Schranz, D., Schmaltz, A. A., Shakhov, B. E., Singer, H., and Lindinger, A. Safety and efficacy of interventional occlusion of patent ductus arteriosus with detachable coils: a multicentre experience. European Journal of Pediatrics 2000; 159: 331-337.	317	Coils
Galal, M. O., Bulbul, Z., Kakadekar, A., Fatani, A. E., de Moor, M., el Oufi, S., Solymar, L., al Fadley, F., and Fawzy, M. E. Comparison between the safety profile and clinical results of the Cook detachable and Gianturco coils for transcatheter closure of patent ductus arteriosus in 272 patients. Journal of Interventional Cardiology 2001; 14: 169-177.	272	Coils
Alwi, M., Kang, L. M., Samion, H., Latiff, H. A., Kandavel, G., and Zambahari, R. Transcatheter occlusion of native persistent ductus arteriosus using conventional Gianturco coils. American Journal of Cardiology 1997; 79: 1430-1432.	211	Coils
Studies of Rashkind occluders		
Non-randomised controlled studies		
Gray, D. T., Fyler, D. C., Walker, A. M., Weinstein, M. C., and Chalmers, T. C. Clinical outcomes and costs of transcatheter as compared with surgical closure of patent ductus arteriosus. The Patient Ductus Arteriosus Closure Comparative Study Group. New England Journal of Medicine 1993; 329: 1517-1523.	631	Rashkind
Galal, O., Nehgme, R., al Fadley, F., de Moor, M., Abbag, F. I., al Oufi, S. H., Williams, E., Fawzy, M. E., and Al Halees, Z. The role of surgical ligation of patent ductus arteriosus in the era of the Rashkind device. Annals of Thoracic Surgery 1997; 63: 434-437.	354	Rashkind
Case series		
Report of the European Registry. Transcatheter occlusion of persistent arterial duct. Lancet 1992; 340: 1062-1066.	686	Rashkind