

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon angioplasty with or without stenting for coarctation or recoarctation of aorta

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 April 2003 (updated by NICE in May 2004).

Procedure name

Balloon angioplasty with or without stenting for coarctation or recoarctation of aorta (paediatric)

Specialty society

British Paediatric Cardiac Association

Description

Aortic coarctation is a congenital narrowing of part of the aorta, most commonly the aortic arch, usually close to the origin of the left subclavian artery.

Balloon angioplasty of aortic coarctation is a minimally invasive procedure that involves inserting a catheter into a large blood vessel, usually in the groin and passing it up to the area of narrowing under X-ray control. A balloon is then inflated within the narrow area. A stent (a small tube) may be placed within the narrowing to keep it dilated. Balloon angioplasty and stenting may be carried out as a first treatment (in 'native' coarctation) or if previous surgical or angioplastic treatment fails and coarctation recurs ('recoarctation').

Standard treatment for native and recurrent coarctation involves open chest surgery. The type of surgery used depends on the anatomy of the lesion and experience of the surgeon. Types of surgery that may be used include resection of the coarctation site and end-to-end anastomosis repair, patch aortoplasty, left subclavian flap angioplasty and bypass graft repair.

Efficacy

Based on the literature that was found, balloon angioplasty for native or recurrent coarctation reduces the pressure gradient across the coarctation, suggesting that stenting reduces the degree of narrowing of the aorta. One small randomised controlled trial was found suggesting that balloon angioplasty had similar efficacy to surgery. The literature found on stenting for coarctation was much weaker, but it suggests that stenting also reduces the pressure gradient across the coarctation.

According to the Specialist Advisors, balloon angioplasty is now established practice. The benefits of stenting are that it is less invasive than surgery with short hospital stay, and has a reduced risk of spinal cord injury.

Safety

Based on the literature found, the risks of balloon angioplasty include death (about 1%), tears in the aorta, bleeding, thrombosis, stroke and aneurysm.

According to the Specialist Advisors, possible adverse effects include failure to cure stenosis (about 20%), aneurysm formation (about 5%), vascular injury (less than 5%), aortic rupture (less than 1%), stroke (less than 1%), death (less than 1%), hypotension and femoral artery injury.

Based on the literature we found, the additional risks of stent placement include stent embolisation.

Literature review

Appraisal criteria

Studies describing balloon dilatation or stenting for native or recurrent aortic coarctation were included.

List of studies found

One randomised controlled trial was found comparing balloon angioplasty with surgery in native coarctation (described in the table).¹

Four non-randomised controlled studies were found comparing balloon angioplasty with surgery, and one comparing balloon angioplasty with stenting in native coarctation (described in the table²).

Eighteen case series of balloon angioplasty in native coarctation or recoarctation including 50 or more people were found. The table gives details of the two largest.^{3,4}

Five case series of stenting for coarctation including 10 or more people were found. The table give details of the largest.⁵

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

Summary of key efficacy and safety findings (1)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
Shaddy, 1993¹ Randomised controlled trial USA n=36 with native coarctation, age range 3 to 10 years: 20 received balloon angioplasty 16 received surgery Exclusions: - previous surgery - connective tissue disorder - Turner's or Noonan's syndrome - bacterial endocarditis, - coarcted segment > 1 cm Follow up 1 year	Reduction in peak systolic pressure gradient: - Angioplasty: 44 to 6 mmHg (86%) - Surgery: 48 to 7 mmHg (86%) Hospital stay: - Angioplasty: 18/20 discharged next day; 2 stayed 1 more day - Surgery: minimum stay 3 days, mean stay 4.5 days	Aneurysm: - Angioplasty: 4 people - Surgery: none 'Diminished pulse' (in the leg through which angioplasty was performed): - Angioplasty: 2 people - Surgery: none Bleeding: - Angioplasty: 1 person - Surgery: 2 people Restenosis: - Angioplasty: 5 people - Surgery: 1 person Hypertension - Angioplasty: 1 person - Surgery: none	Randomisation method not described Treatment groups similar at baseline Small study; power limited Outcome assessment not blinded Primary outcome measure not clear Follow up 21/36
Zabal, 2002² Historical controlled study Mexico n=54 adults: 32 received balloon angioplasty alone, 1995 to 1997 22 received stent (either primary approach or because residual gradient >20mmHg after balloon), 1997 to 1999 Follow up: balloon angioplasty: 60 months, stent: 22 months	Reduction in peak systolic gradient: - Balloon angioplasty: 83% - Stent: 96% p<0.001 Immediate success (residual gradient < or = 20mm Hg) : - Balloon angioplasty: 29/32 - Stent: all Recoarctation: - Balloon angioplasty: 3 people - Stent: none	Paradoxical hypertension or post-coarctectomy syndrome: none Local bleeding requiring blood transfusion: 1 person Aneurysm at coarctation site: 2 people (in balloon angioplasty group)	Allocation not random Treatment groups similar at baseline Primary outcome measures not clear Follow up different length for two groups

Summary of key efficacy and safety findings (2)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
McCrindle, 1996³ Prospective case series USA and Canada n=907 with aortic coarctation who received balloon angioplasty: 422 native, median age 4 years 548 recurrent, median age 3 years	Reduction in systolic pressure gradient: - native: 74% - recurrent: 70%	Deaths: 7 people Transmural aortic tear: 4 people Intimal tear: 31 people Neurological event: 6 people Thrombosis: 4 people Surgery required: 9 people Transfusion: 65 people	Large case series Part of a large registry – ascertainment likely to be complete Detailed outcome data
Munayer Calderon, 2002⁴ Retrospective case series Mexico n=333 with coarctation who received balloon dilatation (mean age 10 years, range 14 days to 62 years), 13 had received previous surgery) 272 patients followed for 24 months	Immediate success: 94% Gradient reduced from 51 to 14 mmHg	Deaths: 4 people Stroke: 5 people Vascular perforation: 2 people Thrombosis of entry site: 19 people Aneurysm: 15 people Reopening of ductus arteriosus: 4 people Hypertension: 3 people Blood transfusion: 28 people Balloon rupture: 5 people	Large case series Data collected retrospectively Detailed outcome data
Ledesma, 2001⁵ Case series Mexico and USA n=54 with native or recurrent coarctation received stents (mean age 22 years, range 8 to 49 years); 4 had had previous balloon dilatation; 1 had received surgery 11 patients followed up 22 months later	Technical success (stent placement and no major complications): 98% Clinical success (pressure gradient <20mmHg and no major complications): 96% Mean pressure gradient decreased from 50 to 5 mmHg	Required operation: 2 people Aneurysm: 2 people Hypertension: 2 people Restenosis: 2 people Bradycardia: 1 person Stent embolisation: 1 person Deaths: none	Uncontrolled case series Follow up short for most people

Validity and generalisability of the studies

One small randomised controlled trial of limited quality comparing balloon angioplasty with surgery in native coarctation was found.¹ One small historical controlled study was found comparing balloon angioplasty with stenting in native coarctation, which provides limited evidence of efficacy or safety of either procedure.²

Two large case series of balloon angioplasty in native or recurrent coarctation were found.^{3,4} The first of these collected data prospectively,³ so is more reliable than the second.⁴

No large case series of stent placement in coarctation were found. One case series including 54 people was found, in which follow up was short.⁵

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.

These procedures are now established practice. These procedures should only be performed in a tertiary paediatric cardiology unit with involvement of a lead interventional paediatric cardiologist with surgical back up in the unit and an appropriately trained operator.

References

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4. Munayer, Calderon J., Zabal, Cerdeira C., Ledesma, Velazco M., Aldana, Perez T., Ramirez, Reyes H., Lazaro Castillo, J. L., Attie, F., Alva, Espinoza C., Buendia, Hernandez A., Jimenez, Zepeda D., Martinez Rios, M. A., Jimenez, Arteaga S., Luis Miranda, R. S., Calderon, Colmenero J., Martinez, Sanchez A., Maza, Juarez G., Gomez, F. D., Ortegon, Cardenas J., Garcia Montes, J. A., Quintero, L. R., Campos, Gomez A., and Sanchez, Soberanes A. Balloon angioplasty in aortic coarctation: a multicentric study in Mexico. *Archivos de Cardiologia de Mexico* 2002; 72: 20-28.
5. Ledesma, M., Alva, C., Gomez, F. D., Sanchez-Soberanis, A., Diaz, E., Benitez-Perez, C., Herrera-Franco, R., Arguero, R., and Feldman, T. Results of stenting for aortic coarctation. *Am J Cardiol* 2001; 88: 460-462.

Appendix: References to studies not described in the table

Reference	Number of participants
BALLOON ANGIOPLASTY OF NATIVE COARCTATION	
Controlled studies	
Shim D, Lloyd TR, Moorehead CP, Bove EL, Mosca RS, Beekman RH 3 rd . Comparison of hospital charges for balloon angioplasty and surgical repair in children with native coarctation of the aorta. <i>Am J Cardiol</i> 1997;79:1143-1146.	45
Rao PS, Chopra PS, Kosciuk R, Smith PA, Wilson AD. Surgical versus balloon therapy for aortic coarctation in infants < or = 3 months old. <i>J Am Coll Cardiol</i> 1994;23:1479-1483.	29
Choy M, Rocchini AP, Beekman RH, Rosenthal A, Dick M, Crowley D, Behrendt D, Snider AR. Paradoxical hypertension after repair of coarctation of the aorta in children:balloon angioplasty versus surgical repair. <i>Circulation</i> 1987;75:1186-1191.	15
Case series	
Ino T, Nishimoto K, Kato H, Momma K, Ishizawa A, Kamiya T, Koike K. Balloon angioplasty for aortic coarctation:Report of a questionnaire survey by the Japanese Pediatric Interventional Cardiology Committee. <i>Japanese Circulation Journal</i> 1997;61:375-383.	208
Tynan M, Finley JP, Fontes V, Hess J, Kan J. Balloon angioplasty for the treatment of native coarctation:Results of Valvuloplasty and Angioplasty of Congenital Anomalies Registry. <i>Am J Cardiol</i> 1990;65:790-792.	140
Lababidi Z. Percutaneous balloon coarctation angioplasty: long-term results. <i>J Intervent Cardiol</i> 1992;5:57-62.	110
Saba SE, Nimri M, Shamaileh Q, Al Hakim F, Krayyem M, Abu-Ata I, Saket A, Harbi N, Hiari A, Turi ZG, David SW, Goussous Y. Balloon coarctation angioplasty: follow-up of 103 patients. <i>J Invas Cardiol</i> 2000;12:402-406.	103
Fletcher SE, Nihill MR, Grifka RG, O'Laughlin MP, Mullins CE. Balloon angioplasty of native coarctation of the aorta: midterm follow-up and prognostic factors. <i>J Am Coll Cardiol</i> 1995;25:730-734.	102
Galal MO, Schmaltz AA, Joufan M, Benson L, Samatou L, Halees Z. Balloon dilation of native aortic coarctation in infancy. <i>Zeitschrift fur Kardiologie</i> 2003; 92: 735–741.	80
Ledesma Velasco M, Ramirez Reyes H, Aldana Perez T, Acosta Valdez JL, Munayer Calderon J, Carpio Hernandez JC, Verdin Vazquez R. Percutaneous transluminal angioplasty in aortic coarctation in adolescents and adults. Mid-term results [Spanish]. <i>Archiv Institut Cardiologia Mexico</i> 1992;62:339-343.	76
Ovaert C, McCrindle BW, Nykanen D, MacDonald C, Freedom RM, Benson L. Balloon angioplasty of native coarctation: clinical outcomes and predictors of success. <i>J Am Coll Cardiol</i> 2000;35:988-996.	69
Rao PS, Galal O, Smith PA, Wilson AD. Five- to nine-year follow-up results of balloon angioplasty of native aortic coarctation in infants and children. <i>J Am Coll Cardiol</i> 1996;27:462-470.	67
Mendelsohn AM, Lloyd TR, Crowley DC, Sandhu SK, Kocis KC, Beekman RH III. Late follow-up of balloon angioplasty in children with a native coarctation of the aorta. <i>Am J Cardiol</i> 1994;74:696-700.	59

BALLOON ANGIOPLASTY OF RECOARCTATION	
Case series	
Dodge-Khatami A, Backer CL, Mavroudis C. Risk factors for recoarctation and results of reoperation: A 40-year review. J Cardiac Surg 2000;15:369-377.	271
Hellenbrand WE, Allen HD, Golinko RJ, Hagler DJ, Lutin W, Kan J. Balloon angioplasty for aortic recoarctation:Results of Valvuloplasty and Angioplasty of Congenital Anomalies Registry. Am J Cardiol 1990;65:793-797.	200
Yetman AT, Nykanen D, McCrindle BW, Sunnegardh J, Adatia I, Freedom RM, Benson L. Balloon angioplasty of recurrent coarctation:a 12-year review. J Am Coll Cardiol 1997;30:811-816.	90
Walhout RJ, Lekkerkerker JC, Ernst SM, Hutter PA, Plokker TH, Meijboom EJ. Angioplasty for coarctation in different aged patients. Am Heart J 2002;144:180-186.	85
Mann C, Goebel G, Eicken A, Genz T, Sebening W, Kaemmerer H, Hammerer I, Hess. Balloon dilation for aortic recoarctation:morphology at the site of dilation and long-term efficacy. Cardiology in the Young 2001;11:30-35	71
Beitzke A, Stein JI, Haidvogel M, Pilhatsch A, Suppan C, Hammerer I, Fink C, Fritz M, Schlemmer M, Wimmer M, Marx M. Balloon dilation angioplasty for postoperative and native coarctation Zeitschrift fur Kardiologie 1994;83:939-945.	52

STENTS	
Case series	
Zabal C. Therapeutic catheterization in adults with congenital cardiopathy [Spanish]. Archivos de Cardiologia de Mexico 2002;72 Suppl 1:S233-S236.	54
Harrison DA, McLaughlin PR, Lazzam C, Connelly M, Benson LN. Endovascular stents in the management of coarctation of the aorta in the adolescent and adult:one year follow up. Heart 2001;85:561-566	27
Cheatham JP. Stenting of coarctation of the aorta. Catheteriz Cardiovasc Interventions 2001;54:112-125	21
Magee AG, Brzezinska-Rajszyk G, Qureshi SA, Rosenthal E, Zubrzycka M, Ksiazek J, Tynan M. Stent implantation for aortic coarctation and recoarctation. Heart 1999;82:600-606.	17