NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of balloon valvuloplasty for aortic valve stenosis

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 March 2003.

Procedure name
Balloon valvuloplasty for aortic valve stenosis

Synonyms: balloon dilatation of the aortic valve

Specialty societies
British Paediatric Cardiology Association
British Cardiovascular Intervention Society

Indications
Aortic valve stenosis (narrowing), may be congenital, or may develop later in life as a result of rheumatic fever, calcification or scarring. The narrowing of the aortic valve causes the pressure in the left ventricle to increase. In order to continue to pump blood through this narrowed area, the left ventricle must pump harder causing thickening (hypertrophy) of the left ventricular muscles. Symptoms include angina, shortness of breath or fainting on exertion, and palpitations. This condition may eventually lead to heart failure.

Balloon aortic valvuloplasty involves inserting a catheter into a large blood vessel, and passing it into the narrowed valve under X-ray control. A balloon is then inflated to dilate the aortic valve orifice. This avoids the need for open chest surgery

The traditional treatment involves open chest surgery to perform a valvotomy, or to replace the valve.

Benefits
Limited research evidence was found that aortic balloon valvuloplasty is less efficacious than aortic valve replacement in older people, and more efficacious than open valvotomy in neonates.

According to the Specialist Advisors, the efficacy has been clearly demonstrated in the literature, although there is some doubt about safety and efficacy in neonates.

Risks

Limited evidence was found that, in neonates, balloon valvuloplasty of the aortic valve is more likely to lead to aortic regurgitation than open valvotomy. Limited evidence was found that in older people, death rates are higher with balloon valvuloplasty of the aortic valve than with aortic valve replacement. Evidence from case series suggests that serious complications are fairly common with balloon valvuloplasty of the aortic valve, especially in older people.

According to the Specialist Advisors, the potential risks of balloon valvuloplasty include: myocardial infarction, stroke, aortic valve disruption or regurgitation, myocardial rupture or perforation, mitral valve damage, arterial damage or occlusion, and arrhythmia. The safety is similar to that of conventional surgery.

Literature review

Appraisal criteria

Studies examining clinical outcomes of balloon dilatation of the aortic valve were included.

List of studies found

No systematic reviews or randomised controlled trials were found.

Four non-randomised controlled studies were found. The two largest are described in the table.[1,2]

Fourteen case series were found including 150 people or more. The three largest are described in the table.[3-5]

References to smaller studies given in the Appendix.

Summary of key efficacy and safety findings (1)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
McCrindle, 2001[1] Prospective non-randomised study USA and Canada, multicentre n=110 neonates with critical aortic stenosis (moderate to severe stenosis plus reduced left ventricular function or systemic perfusion dependent on right ventricular output through patent arterial duct): • 82 received balloon dilatation • 28 received open surgical valvotomy Exclusions: other cardiac anomalies Follow up: up to 5 years	Mean reduction in systolic gradient: • Balloon dilatation: 65% • Surgery: 41% p<0.001 Median residual gradient: • Balloon dilatation: 20 mmHg • Surgery: 36 mmHg p<0.001 Second procedure required during index admission: • Balloon dilatation: 13% • Surgery: 25% p=0.16	Aortic regurgitation: • Balloon dilatation: 18% • Surgery: 3% Immediate major complication: • Balloon dilatation: 4% • Surgery: 0% Death before hospital discharge: • Balloon dilatation: 11% • Surgery: 18% p=0.35 Survival at 5 years: • Balloon dilatation: 75% • Surgery: 58% p=0.1	Allocation not random Groups different in terms of baseline characteristics Includes only neonates with critical aortic stenosis Survival estimates in multiple regression analyses not adjusted all clinically relevant variables e.g. centre and year of procedure Follow up rates not provided
Bernard, 1992[2] Retrospective comparison of case series France n=69 people over 75 years old with severe aortic stenosis: • 46 received balloon dilatation • 23 received aortic valve replacement Method chosen by patient preference Mean follow up 22 months for balloon dilatation and 28 months for surgery	Mean gradient decrease: • Balloon dilatation: From 65 to 41 mmHg • Surgery: From 67 to 12 mmHg	Deaths within 5 days of procedure: • Balloon dilatation: 3 (6.5%) • Surgery: 2 (9%) Deaths to end of follow up period: • Balloon dilatation: 24 (52%) • Surgery: 3 (13%) Required further operation: • Balloon dilatation 16 (35%) • Surgery: none	Allocation not random Groups similar on age, functional class, aortic pressure gradient and left ventricular function Follow up lengths different for the two groups

Summary of key efficacy and safety findings (2)

Study details	Key efficacy findings	Key safety findings	Key reliability, generalisability and validity issues
NHLBI Balloon Valvuloplasty Registry, 1991[3] Case series Multicentre, USA and Canada n=674 people receiving aortic balloon valvuloplasty; 83% > 70 years old, none < 18 years; 80% considered inappropriate for valve replacement due to age or other disease Follow up 5 weeks	Procedure completed: 97% Mean aortic valve gradient reduced from 55 mmHg to 29 mmHg 86% of survivors (69% of original group) had symptomatic improvement 75% survivors had at least 1 functional class improvement	At least 1 significant complication • < 24 hours: 167 (25%) • before discharge: 211 (31%) Deaths: • During procedure: 17 (3%) • Before discharge: additional 52 (8%) • By 30 days: additional 23 (3%)	Uncontrolled case series Short follow up All adults, most elderly
McCrindle,1996[4] Case series Multicentre, Canada, USA, South America n=630 children receiving aortic balloon valvuloplasty; mean age 7 years (range 1 day to 18 years) Follow up only to hospital discharge	Mean pressure gradient reduced from 69 to 28 mmHg Mean reduction in pressure gradient: 60%	Procedure could not be completed in 4% Procedure related deaths: 2% Residual gradient >60mmHg or left ventricular: aortic pressure ratio >1.6 or major morbidity (transection of artery, severe regurgitation, pericardial tamponade, perforation of left ventricle or aorta, avulsion of aortic valve, stroke): 11%	Uncontrolled case series Follow up only to hospital discharge All participants were children
McKay, 1991[5] Case series Multicentre, USA and France n=492 people receiving aortic balloon valvuloplasty at increased surgical risk because of age of other disease; mean age 79 years (range 22 to 95 years) Exclusions: • severe aortic regurgitation • nonvalvular aortic stenosis • bacterial endocarditis Follow up only to hospital discharge	Mean aortic valve gradient improved from 60 to 30 mmHg Success (achievement of at least 25% increase in aortic valve area +/or at least 50% decrease in mean aortic valve gradient, plus patient did not die or require surgery within 7 days): 87%	Moderate or severe increase in aortic regurgitation: 2% Complication of procedure: 20% Death within 24 hours of procedure: 5% Death within 7 days: additional 3%	Uncontrolled case series Follow up only to hospital discharge All adults, most elderly

Validity and generalisability of the studies
Both the non-randomised controlled studies were fairly small. One examined neonates with critical aortic stenosis[1] and the other older people.[2]

The two case series examining older people included mainly people considered unfit for surgery due to age or concomitant pathology.[3,5] In both these studies, follow up was short.

In the case series including children, follow up was very short.[4]

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.

Generally used as procedure of first choice in children and adolescents but risks higher in neonates and surgery generally preferred in adults.

References

1. McCrindle BW, Blackstone EH, Williams WG, Sittiwangkul R, et al. Are outcomes of surgical versus transcatheter balloon valvotomy equivalent in neonatal critical aortic stenosis? *Circulation* 2001; 104: I152-8.

2. Bernard Y, Etievent J, Mourand JL, Anguenot T, et al. Long-term results of percutaneous aortic valvuloplasty compared with aortic valve replacement in patients more than 75 years old. *J Am Coll Cardiol* 1992; 20: 796-801.

3. NHLBI Balloon Valvuloplasty Registry. Percutaneous balloon aortic valvuloplasty. Acute and 30-day follow-up results in 674 patients from the NHLBI Balloon Valvuloplasty Registry. *Circulation* 1991; 84: 2383-97.

4. McCrindle BW. Independent predictors of immediate results of percutaneous balloon aortic valvotomy in children. Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) Registry Investigators. *Am J Cardiol 1996*; 77: 286-93.

5. McKay RG. The Mansfield Scientific Aortic Valvuloplasty Registry: overview of acute hemodynamic results and procedural complications. *J Am Coll Cardiol* 1991; 17: 485-91

Appendix: References to smaller studies

Reference	Number of participants
Non-randomised comparative studies	
Gatzoulis MA, Rigby ML, Shinebourne EA, and Redington AN. Contemporary results of balloon valvuloplasty and surgical valvotomy for congenital aortic stenosis. *Arch Dis Child*1995; 73: 66-9.	56 (children)
Hashimoto H, Tamura T, Ikari Y, Hara K, et al. Comparison of aortic valve replacement and percutaneous aortic balloon valvuloplasty for elderly patients with aortic stenosis. *Japanese Circulation Journal* 1996; 60: 142-8.	39 (older people)
Case series	
Isner JM. Acute catastrophic complications of balloon aortic valvuloplasty. The Mansfield Scientific Aortic Valvuloplasty Registry Investigators. *J Am Coll Cardiol* 1991; 17: 1436-44. Holmes DR, Jr. Nishimura RA, and Reeder GS. In-hospital mortality after balloon aortic valvuloplasty: frequency and associated factors. *J Am Coll Cardiol* 1991; 17: 189-92.	492 (older people)
Letac B, Cribier A, and Berland J. Percutaneous balloon valvuloplasty in acquired mitral and aortic stenosis in the adult. *Schweizerische Medizinische Wochenschrift* 1988; 118: 1673-80.	400 (adults)
Koning R, Cribier A, Asselin C, Mouton-Schleifer D, et al. Repeat balloon aortic valvuloplasty. *Catheteriz Cardiovasc Diag* 1992; 26: 249-54.	357 (adults)
Letac B, Cribier A, and Koning R. Treatment of acquired aortic stenosis in adults by percutaneous valvuloplasty with balloon catheterization. Experience of 245 cases. [French] *Archives des Maladies du Coeur et des Vaisseaux* 1989; 82: 17-25.	245 (adults)
Letac B, Cribier A, Koning R, and Bellefleur JP. Results of percutaneous transluminal valvuloplasty in 218 adults with valvular aortic stenosis. *Am J Cardiol* 1988; 62: 598-605.	218 adults (may be same patients as Letac 1989)
Kuntz RE, Tosteson AN, Berman AD, Goldman L, et al. Predictors of event-free survival after balloon aortic valvuloplasty. *New Engl J Med* 1991; 325: 17-23.	205 (older people)
Rocchini AP, Beekman RH, Ben Shachar G, Benson L, et al. Balloon aortic valvuloplasty: results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. Am J Cardiol 1990; 65: 784-9.	204 (children)
Otto CM, Mickel MC, Kennedy JW, Alderman EL, et al. Three-year outcome after balloon aortic valvuloplasty. Insights into prognosis of valvular aortic stenosis. *Circulation* 1994; 89: 642-50.	189 (adults)
Johnson RG, Dhillon JS, Thurer RL, Safian RD, et al. Aortic valve operation after percutaneous aortic balloon valvuloplasty. *Ann Thorac Surg* 1990; 49: 740-744.	179 (older people)
Davidson CJ, Harrison JK, Pieper KS, Harding M, et al. Determinants of one-year outcome from balloon aortic valvuloplasty. Am J Cardiol 1991; 68: 75-80.	170 (adults)
Safian RD, Berman AD, Diver DJ, McKay LL, et al. Balloon aortic valvuloplasty in 170 consecutive patients. *New Engl J Med* 1988; 319: 125-130.	170 (adults)
Lieberman EB, Bashore TM, Hermiller JB, Wilson JS, et al. Balloon aortic valvuloplasty in adults: failure of procedure to improve long-term survival. J Am Coll Cardiol 1995; 26: 1522-8.	165 (adults)