NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of non-surgical reduction of myocardial septum

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 more specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name
Non-surgical reduction of myocardial septum

Specialty society
British Cardiovascular Intervention Society

Indication(s)
Hypertrophic obstructive cardiomyopathy.

People with hypertrophic obstructive cardiomyopathy (HOCM) have abnormally thickened heart muscle. Thickening is usually most severe in the wall (septum) between the right and left ventricles and may cause obstruction to the flow of blood out of the left ventricle. The severity of obstruction is described in terms of pressure gradient (gradient across left ventricular outflow tract), the higher the gradient, the greater the obstruction.

The cause of HOCM is unknown though in many people it appears to be inherited.

HOCM may cause chest pain, breathlessness, palpitations and fainting spells. People with HOCM have an increased risk of sudden death from heart attacks or abnormal heart rhythms.

The estimated prevalence of abnormalities typical of HOCM on echocardiogram is about 1 in 500.[1]

Summary of procedure
Most people with HOCM are treated with medication. More invasive treatments may be considered in people who still get symptoms despite drug treatment.

The standard surgical treatment is ventricular septal myotomy-myectomy. This is an open surgical technique that requires cardiopulmonary bypass. A small amount of muscle is removed from the septum to reduce its thickness and reduce obstruction.

Non-surgical ablation of the septum does not require open chest surgery or cardiopulmonary bypass. It involves inserting a catheter into the femoral artery and passing it up into the heart under X ray control. Alcohol is injected into an artery supplying blood to the septum. This destroys a part of the septal muscle which then becomes thinner.

Non-surgical ablation of the septum is potentially a less risky procedure with a shorter recovery time. However, it may increase the risk of dangerous abnormal heart rhythms. Some patients may require a pacemaker after the procedure.

Literature review

Appraisal criteria

We included studies of septal ablation for HOCM examining clinical outcomes.

List of studies found

We found no systematic reviews or randomised controlled trials.

We found three non-randomised controlled studies.[2-4]

We found 13 case series including at least 40 people. The two largest are described in the table.[5,6]

Summary of key efficacy and safety findings (1)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability and validity issues
Nagueh [2] Non-randomised study 2 centres in USA Published 2001 82 people • 41 surgery, mean age 49, severe breathlessness 78% • 41 non-surgical ablation, mean age 49, severe breathlessness 90% Follow up 12 months	Mean reduction in gradient across left ventricular outflow tract (LVOT): • Surgery: 41 mmHg • Non-surgical ablation: 42 mmHg 'not significant' Fainting spells: • Surgery: 17% • Non-surgical ablation: 5% Severe breathlessness (New York Heart Classification III or IV): • Surgery: 2% • Non-surgical ablation: none Average exercise duration: • Surgery: 480 seconds • Non-surgical ablation: 417 seconds	Mild aortic regurgitation: • Surgery: 27% • Non-surgical ablation: 7% Required permanent pacemaker: • Surgery: 41% (1 patient 2% for complete heart block) • Non-surgical ablation: 44% (9 patients 22% for complete heart block) Death: • Surgery: None • Non-surgery: 1 person	Allocation to treatment according to treatment centre Surgical and non-surgical groups similar age, symptoms and use of medication before treatment Outcome data evaluated blind to treatment group Outcomes appropriate Length of follow up appropriate
Qin[3] Non-randomised study USA 1997 to 1999 51 people • 26 surgery, mean age 48 (range 39-85); mean LVOT gradient 62 mmHg • 25 non-surgical ablation, mean age 63 (range 30-70); mean resting LVOT gradient 64 mmHg Exclusion criteria for non-surgical ablation: • valve disease • severe ischaemic heart disease Follow up 3 months	Mean LVOT gradient: • Surgery: 11 mmHg • Non-surgical ablation: 24 mm Hg Mean hospital stay: • Surgery: 8 days • Non-surgical ablation: 6 days	Required permanent pacemaker: • Surgery: 8% • Non-surgical ablation: 24% Deaths: none	Method of allocation to surgery or non-surgical ablation not described Non-surgical ablation patients had more concomitant medical conditions than surgical patients Outcomes appropriate Length of follow up short

Summary of key efficacy and safety findings (2)

Authors, location, date, patients	Key efficacy findings	Key safety findings	Key reliability and validity issues
Firoozi[4] Non-randomised study UK 1990 to 2000 44 people • 24 surgery, mean age 38; mean LVOT gradient 83 mmHg; mean follow up 46 months • 20 non-surgical ablation; mean age 49; mean LVOT gradient 91 mmHg; mean follow up 28 months	Mean LVOT gradient: • Surgery: 15 mmHg • Non-surgical ablation: 22 mmHg Severe breathlessness (New York Heart Classification III or IV): • Surgery: 2 people • Non-surgical ablation: 2 people Fainting spells: • Surgery: 2 people • Non-surgical ablation: 1 person	Deaths: • Surgery: 1 person • Non-surgical ablation: 1 person Required permanent pacemaker: • Surgery: 4% • Non-surgical ablation: 15%	Allocation to surgery or non-surgical ablation based on 'patient choice and physician guidance'; younger people encouraged to have surgery Outcomes appropriate Follow up appropriate length but long for the surgical group
Faber[5] Case series Germany 1996 to 1999 159 people, mean age 53, mean LVOT gradient 77 mm Hg Follow up 3 months	Symptom improvement: 94% Mean LVOT gradient 12 mmHg Gradient reduction >50%: 88%	Deaths: 3%	Uncontrolled case series Short follow up
Lakkis[6] Case series USA 1996 to1999 106 people, age not provided, mean LVOT gradient 76 mmHg Follow up up to 2 years	'Successful' procedure: 90% 'Immediate symptom improvement' in 100% of the successful procedures Mean LVOT gradient 7 mmHg at 1 year	2 wire-induced dissections: 2 people Procedure related deaths: 2 people; one from dissection, one heart attack at 10 days Required permanent pacemaker: 13% Repeat procedure: 6 people	Uncontrolled case series May include same patients as in Nagueh[2]

Validity and generalisability of the studies
All the studies were carried out in settings applicable to the UK.

We found three non-randomised studies.[2-4] This study design is susceptible to confounding. Follow up in one study was very short.[3] None of the studies provide long term follow up data.

The one large case series provided little information on adverse effects and complications of non-surgical ablation.[5]

Bazian comments
The studies we found provide limited information about long term safety of non-surgical ablation compared with surgery, particularly in relation to sudden death and disability.

Specialist advisor's opinion / advisors' opinions
Specialist advice was sought from the British Cardiovascular Intervention Society

Issues for consideration by IPAC
None other than those discussed above.

References

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2. Nagueh, S. F., Ommen, S. R., Lakkis, N. M., Killip, D., Zoghbi, W. A., Schaff, H. V., Danielson, G. K., Quinones, M. A., Tajik, A. J., and Spencer, W. H. Comparison of ethanol septal reduction therapy with surgical myectomy for the treatment of hypertrophic obstructive cardiomyopathy. Journal of the American College of Cardiology 2001; 38: 1701-1706
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Annex: References to studies not described in the table

Reference	Number of study participants
Seggewiss, H., Faber, L., Ziemssen, P., and Gleichmann, U. [One-year follow-up after echocardiographically-guided percutaneous septal ablation in hypertrophic obstructive cardiomyopathy]. [German] Deutsche Medizinische Wochenschrift 2001; 126: 424-430.	100 (may include same patients as in Faber[5])
Faber, L., Seggewiss, H., and Gleichmann, U. Percutaneous transluminal septal myocardial ablation in hypertrophic obstructive cardiomyopathy: results with respect to intraprocedural myocardial contrast echocardiography. Circulation 1998; 98: 2415-2421	91 (may include same patients as in Faber[5])
Zhang, W., Li, Z., Zhang, M., Yuan, L., Guan, R., Hou, A., Jin, Y., and Deng, Z. Complications of percutaneous transluminal septal myocardial ablation in hypertrophic obstructive cardiomyopathy. Chinese Medical Journal 2002; 115: 1283-1286	72
Seggewiss, H., Faber, L., and Gleichmann, U. Percutaneous transluminal septal ablation in hypertrophic obstructive cardiomyopathy. Thoracic & Cardiovascular Surgeon 1999; 47: 94-100	66 (may include same patients as in Faber[5])
Lakkis, N. M., Nagueh, S. F., Dunn, J. K., Killip, D., and Spencer, W. H., III. Nonsurgical septal reduction therapy for hypertrophic obstructive cardiomyopathy: one-year follow-up. Journal of the American College of Cardiology 2000; 36: 852-855	50 (may include same patients as in Nagueh[5])
Nielsen, C. D., Killip, D., and Spencer, W. H., III. Nonsurgical septal reduction therapy for hypertrophic obstructive cardiomyopathy in South Carolina: the MUSC experience (1999 through 2001). Journal - South Carolina Medical Association 2002; 98: 62-65	50
Gietzen, F. H., Leuner, C. J., Raute-Kreinsen, U., Dellmann, A., Hegselmann, J., Strunk-Mueller, C., and Kuhn, H. J. Acute and long-term results after transcoronary ablation of septal hypertrophy (TASH). Catheter interventional treatment for hypertrophic obstructive cardiomyopathy. European Heart Journal 1999; 20: 1342-1354	50
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