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)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
<th>Key efficacy findings</th>
<th>Key safety findings</th>
<th>Key reliability and validity issues</th>
</tr>
</thead>
</table>
| Naghieh²  
Non-randomised study  
2 centres in USA  
Published 2001 | 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 |
| Qin³  
Non-randomised study  
USA  
1997 to 1999 | 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 |

82 people  
• 41 surgery, mean age 49, severe breathlessness 78%  
• 41 non-surgical ablation, mean age 49, severe breathlessness 90%  
Follow up 12 months  

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
## Summary of key efficacy and safety findings (2)

<table>
<thead>
<tr>
<th>Authors, location, date, patients</th>
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<th>Key safety findings</th>
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</tr>
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</table>
| **Firoozi**<sup>4</sup>  
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**<sup>5</sup>  
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**<sup>6</sup>  
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<sup>2</sup> |
Validity and generalisability of the studies
All the studies were carried out in settings applicable to the UK.

We found three non-randomised studies. This study design is susceptible to confounding. Follow up in one study was very short. 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.

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


### Annex: References to studies not described in the table

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of study participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>100 (may include same patients as in Faber5)</td>
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<td>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</td>
<td>91 (may include same patients as in Faber5)</td>
</tr>
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<td>Seggewiss, H., Faber, L., and Gleichmann, U. Percutaneous transluminal septal ablation in hypertrophic obstructive cardiomyopathy. Thoracic &amp; Cardiovascular Surgeon 1999; 47: 94-100</td>
<td>66 (may include same patients as in Faber5)</td>
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<td>Faber, L., Seggewiss, H., Ziemssen, P., Schmidt, H. K., and Gleichmann, U. Percutaneous transluminal septal myocardial ablation in hypertrophic obstructive cardiomyopathy: Reduction of risk factors after 12 months. Journal fur Kardiologie 1999; 6: 351-358</td>
<td>50 (may include same patients as in Faber5)</td>
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