

Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis

1 Guidance

- 1.1 Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 This procedure should only be carried out by surgeons with experience of complex sinus surgery, and specific training in both the procedure and the use of fluoroscopy.
- 1.3 Publication of long-term outcomes will be helpful in guiding the future use of this technique. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 The paranasal sinuses are small, air-filled cavities, located within the bony structures of the face, which communicate with the nasal space via small openings (ostia). Sinusitis occurs as a result of inflammation of the mucosal lining of the paranasal sinuses. Typical symptoms include fever, pain and tenderness over the infected area, together with a blocked or runny nose. Acute sinusitis frequently resolves spontaneously with little or no treatment. Chronic sinusitis is less common, and symptoms can persist for weeks or months.
- 2.1.2 The symptoms of chronic sinusitis are normally managed with decongestants, analgesics, antibiotics, topical steroids or nasal/sinus irrigation. If these interventions fail, surgical procedures to enhance drainage of secretions from the sinuses may be required. However, surgical procedures may be ineffective in the

long term because of the development of adhesions and scarring around the ostium of the sinus. Scarring occurs less frequently if the mucosa is preserved.

2.2 Outline of the procedure

- 2.2.1 Balloon catheter dilation of paranasal sinus ostia aims to restore normal sinus drainage and function without damaging the mucosa of the sinus. With the patient under general anaesthetic, a catheter and flexible guidewire are inserted through the nostril using endoscopy and fluoroscopy to identify the target sinus. A balloon catheter is positioned across the blocked ostium. Inflation of the balloon catheter to a pressure of between 2 and 8 atmospheres aims to restructure and widen the ostium by creating microfractures in the surrounding bone. The inflamed sinus may also be irrigated (sinus lavage). The catheter and guidewire are then removed.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview, available at www.nice.org.uk/IP670overview

2.3 Efficacy

- 2.3.1 In a case series of 115 patients, balloon catheter dilation was attempted in 358 sinuses and cannulation of the sinus ostia was achieved in 97% (347/358). The ostium was patent in 68% (232/341) of sinuses at 1-week follow-up and in 81% (247/304) of sinuses at 24-week follow-up.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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- 2.3.2 In a case series of 1036 patients (3276 sinuses), revision surgery for mucosal alteration or opacified sinuses was required in 2% (25/1036) of patients at a mean follow-up of 40 weeks. In another case series of 115 patients, revision surgery was required in 3% (3/109) at a mean follow-up of 24 weeks; in this series the indications for revision surgery were not described.
- 2.3.3 In the study of 1036 patients, 95% reported an improvement in sinusitis symptoms and 73% were completely free of symptoms at a mean follow-up of 40 weeks (absolute numbers not reported). In the study of 115 patients, sinusitis symptoms were measured by the Sino-Nasal Outcome Test (SNOT) 20, a scale on which symptoms are rated from 0 (least severe) to 5 (most severe). Symptoms lessened significantly from a mean SNOT 20 score of 2.14 at baseline to 1.27 at both 1-week and 24-week follow-up ($p < 0.0001$) in a subgroup of 44 patients who had balloon catheter dilation. Patient satisfaction surveys in this subgroup showed that 80% (35/44) of patients experienced an 'improvement in symptoms' at 24-week follow-up. A non-randomised controlled trial of 70 patients showed significantly greater improvements in the 35 patients treated by balloon catheter dilation than in the 35 control patients treated by functional endoscopic sinus surgery (0.78 and 1.29 points, SNOT 20 scale; $p = 0.006$).
- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include demonstrable patency of sinus ostia and improved SNOT 20 scores, standard sino-nasal symptom scores and quality of life.
- 2.4 Safety**
- 2.4.1 In the case series of 115 patients, bacterial sinusitis occurred in 8% (9/109) of patients following the procedure (exact time of exacerbation unknown), but resolved with antibiotic treatment. In this case series, the balloon ruptured in 2% (7/358) of sinuses, and a problem occurred with the catheter tip in 1% (4/358).
- 2.4.2 In the non-randomised controlled trial of 70 patients, 23% (8/35) of patients in the balloon catheter dilation group had turbinate lateralisation/scarring, compared with 9% of patients in the functional endoscopic sinus surgery group (not significant).
- 2.4.3 In the case series of 18 patients, the mean fluoroscopy time per sinus was 0.81 minutes, with an average radiation dose of 730 millirem per patient. In the case series of 115 patients, the mean fluoroscopy time was 9.3 minutes per patient.
- 2.4.4 The Specialist Advisers considered adverse events to be intracranial injury, cerebrospinal fluid leak, scarring of the mucosa, orbital damage and bleeding. Additional theoretical adverse events noted were balloon misplacement and damage to the dura.
- 2.5 Other comments**
- 2.5.1 The Committee noted that the procedure is not used in ethmoid sinuses. Some of the evidence seen by the Committee was on hybrid procedures including concurrent conventional ethmoidectomy.
- 2.5.2 The Committee noted that both patient selection and the selection of specific sinus(es) for treatment can be difficult. The Committee also noted that the evidence presented relates to patients with chronic sinusitis that was refractory to medical treatment.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See www.nice.org.uk/IPG273publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1692 for this guidance or N1693 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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