NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery for chronic rhinosinusitis

Chronic rhinosinusitis is when air-filled cavities in the face (sinuses) are infected and inflamed for a long time. Symptoms include facial pain and tenderness, a blocked or runny nose, fever and headache. When medical treatment has not worked, it may be treated by endoscopic sinus surgery. A thin tube with a camera on the end (endoscope) is inserted through the nostrils to open up the affected sinuses. In this procedure, a short tube (stent) or spacer (implant) is placed into the sinus at the end of the surgery. This holds the sinus open, then slowly releases corticosteroid medication to reduce inflammation. The stent or spacer is bioabsorbable (it dissolves over time). The aim is to allow the sinuses to heal better so they stay open for longer after the surgery.

This is a review of NICE's interventional procedures guidance on corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

Issue date: August 2024

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 26 September 2024

Target date for publication of guidance: February 2025

1 Draft recommendations

1.1 Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery for chronic rhinosinusitis can be used in the NHS while more evidence is generated. It can only be used with special arrangements for clinical governance, consent, and audit or research.

1.2 Clinicians wanting to do corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery for chronic rhinosinusitis should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

Evidence generation

1.4 Evidence generation, in the form of randomised controlled trials or registry data, is needed on:

- patient selection
- patient-reported outcomes
- longer-term outcomes.

Why the committee made these recommendations

There is not enough long-term evidence on this procedure. Also, there is not enough good-quality evidence on long-term benefits and improvements that matter to patients (patient-reported outcomes). It is unclear who would benefit most from the procedure. There are no major safety concerns. So, it can be used with special arrangements.

The condition

1.5 The paranasal sinuses are air-filled cavities, located in the bony structures of the face. Small openings (ostia) connect the sinuses with the nasal space. Rhinosinusitis occurs when the mucosal lining of the paranasal sinuses becomes inflamed and infected. Typical symptoms include fever, pain and tenderness over the infected area, together with a blocked or runny nose. Acute rhinosinusitis frequently resolves spontaneously with little or no treatment, but in some cases it becomes chronic.

Current treatments

1.6 The symptoms of chronic rhinosinusitis are usually managed with a combination of analgesics, antibiotics, topical corticosteroids and nasal irrigation. If these interventions fail, surgical procedures may be needed to enhance drainage from the sinuses and allow topical medical therapy to reach the sinus mucosa. But adhesions and scarring may develop after surgery, compromising drainage. Scarring occurs less frequently if the mucosa remains intact. Foam

dressings, nasal packing and middle meatal spacers are sometimes used after surgery to try and maintain sinus patency.

The procedure

1.7 Inserting a corticosteroid-releasing bioabsorbable stent or spacer during surgery for chronic rhinosinusitis aims to deliver topical corticosteroids directly to the sinus mucosa after surgery and to maintain patency of the newly created drainage system. It is usually done with the patient under general anaesthesia, during functional endoscopic sinus surgery. At the end of the surgery, the corticosteroid-eluting stent or spacer is inserted into the relevant ostium under endoscopic guidance. The stent or spacer dissolves over time.

2 Committee considerations

The evidence

2.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 11 sources, which was discussed by the committee. The evidence included 2 systematic reviews, 1 retrospective cohort study, 4 randomised controlled trials, 1 prospective cohort before-after study, 2 case reports and a report from the Food and Drug Administration Manufacturer and User Facility Device Experience registry. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

2.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life; symptomatic improvement; endoscopic improvement of oedema, polyposis and

adhesions; long-term maintenance of sinus patency on clinical examination; and the need for postoperative intervention.

2.3 The professional experts and the committee considered the key safety outcomes to be: infection, and stent migration or expulsion.

2.4 A submission was received from a patient organisation.

Committee comments

2.5 The committee noted that chronic rhinosinusitis can be a disabling condition. There may be some people who would particularly benefit from this procedure but more evidence is needed to identify how they should be selected.

2.6 There is more than 1 device available for this procedure.

2.7 The committee was informed that the type of endoscopic sinus surgery that is done is key to the success of the procedure.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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