

Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis

Interventional procedures guidance
Published: 23 March 2016

www.nice.org.uk/guidance/ipg551

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment

or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

1 Recommendations

- 1.1 Current evidence on the safety of corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis raises no major safety concerns. The evidence on efficacy is limited; there is some evidence of improving sinus patency in the short term, but there is inadequate evidence on patient-reported outcomes and quality of life. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to insert a corticosteroid-eluting bioabsorbable stent or spacer during endoscopic sinus surgery to treat chronic rhinosinusitis should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of the [information for the public](#) is recommended.
 - Audit and review clinical outcomes of all patients having a corticosteroid-eluting stent or spacer inserted during endoscopic sinus surgery to treat chronic rhinosinusitis (see [section 6.1](#)).
- 1.3 NICE encourages further research on corticosteroid-eluting bioabsorbable stent

or spacer insertion during endoscopic sinus surgery and, specifically, controlled studies designed for between-patient (rather than within-patient) comparisons. Outcomes should include symptom scores, quality of life and the need for retreatment in the long term. All complications should be reported. NICE may update this guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 The paranasal sinuses are air-filled cavities located within the bony structures of the face. They are connected to the nasal space via small openings (ostia). 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 it can become chronic.
- 2.2 The symptoms of chronic rhinosinusitis are usually managed with analgesics, antibiotics, topical corticosteroids or nasal irrigation. If these interventions fail, surgical procedures may be needed to enhance drainage from the sinuses. However, 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 to maintain sinus patency.

3 The procedure

- 3.1 Inserting a corticosteroid-eluting bioabsorbable stent or spacer for paranasal sinus disease aims to deliver topical corticosteroid 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, which may include balloon sinuplasty. At the end of the surgery, the corticosteroid-eluting stent is inserted into the relevant ostium under endoscopic guidance. The stent dissolves over a variable period of time.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery, the mean normalised sino-nasal outcome test (SNOT)-22 scores (scale 0 to 5, higher scores indicate worse symptoms) reduced from 2.8 at baseline to 1.0 at 6-month follow-up ($p < 0.0001$). The mean Rhinosinusitis Disability Index (scale 0 to 120, higher scores indicate worse symptoms) reduced from 48.5 at baseline to 18.2 at 6-month follow-up ($p < 0.0001$).
- 4.2 In a randomised controlled trial (RCT) of 43 patients treated by a corticosteroid-eluting bioabsorbable stent inserted in the ethmoid sinus on 1 side and a non-corticosteroid-eluting bioabsorbable stent inserted in the contralateral side, there was a statistically significant reduction in sinus inflammation, assessed at endoscopy, at days 21 to 45, but not at day 60, in the corticosteroid-eluting stent group compared with the control stent group. The scores (measured on a 100 mm visual analogue scale) were 29.6 at day 7 and 12.0 at day 60 in the treatment group; and 29.4 and 17.5 respectively in the control group ($p = 0.09$, between group comparison at day 60).
- 4.3 In an RCT of 105 patients treated by a corticosteroid-releasing bioabsorbable stent inserted in the ethmoid sinus on 1 side and a non-corticosteroid-releasing bioabsorbable stent inserted in the contralateral side, frank polyposis (judged by a blinded panel using endoscopy videos) was present in 19% (16 of 85) and 34% (29 of 85) of sinuses respectively at day 30, ($p = 0.002$). In the RCT of 43 patients, there were polypoid mucosal changes in 18% (7 of 38) of sinuses treated by a corticosteroid-eluting stent and in 37% (14 of 38) of sinuses treated by a control stent at day 60 ($p = 0.039$). In the case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery, there was polypoid tissue formation at day 30 in 10% (9 of 90) of sinuses and frank polyposis in 2% (2 of 90) of sinuses.
- 4.4 In the RCT of 105 patients, there were significant adhesions in 5% (5 of 104) of

sinuses treated by a corticosteroid-eluting bioabsorbable stent and in 13% (13 of 104) of sinuses treated by a non-corticosteroid releasing bioabsorbable stent at day 30 ($p=0.039$). In the RCT of 43 patients, there were significant adhesions in 5% (2 of 38) of sinuses treated by a corticosteroid-eluting bioabsorbable stent and in 21% (8 of 38) of sinuses treated by a control stent at day 60 ($p=0.031$). In the case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery, there were significant adhesions in 1% (1 of 90) of sinuses.

- 4.5 In the case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery, 1 patient needed surgical revision within 6 months. In the RCT of 105 patients, there was a need (as judged by a blinded panel using endoscopy videos) for postoperative intervention (either surgery to separate an adhesion or oral corticosteroids to resolve recurrent inflammation) in 33% (32 of 96) of sinuses treated by a corticosteroid-releasing bioabsorbable stent and in 47% (45 of 96) of sinuses treated by a non-corticosteroid-releasing bioabsorbable stent at day 30 ($p=0.028$).
- 4.6 The specialist advisers listed the following key efficacy outcomes: symptomatic improvement; endoscopic improvement of oedema, polyposis and adhesions; long-term maintenance of sinus patency on clinical examination; the need for postoperative intervention; and the need for oral corticosteroids.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Crusting, granulation and scarring of the middle turbinate 1 week after the procedure was reported in 1 patient in a randomised controlled trial (RCT) of 105 patients treated by a corticosteroid-releasing bioabsorbable stent in 1 side and a non-corticosteroid-releasing bioabsorbable stent in the other. The patient was treated by nasal irrigation, debridement and prednisone taper, and the condition resolved without sequelae.

- 5.2 Headache with sensation of sinus pressure and irritation was reported in 1 patient in a case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery. This was determined to be primarily due to the functional endoscopic sinus surgery, but was considered to be exacerbated by presence of crusting sticking to the stent. The condition resolved without sequelae after stent removal.
- 5.3 Infection at 2-week follow-up was reported in 1 patient in the RCT of 105 patients treated by a corticosteroid-releasing bioabsorbable stent in 1 side and a non-corticosteroid-releasing bioabsorbable stent in the other. The patient was treated with a prednisone taper and antibiotics. The infection resolved without sequelae.
- 5.4 Peri-orbital cellulitis was reported in 1 patient on the FDA manufacturer and user facility device experience (MAUDE) database. The patient had insulin-dependent diabetes and had been treated by revision functional endoscopic sinus surgery, including bilateral ethmoidectomies, maxillary antrostomies and frontal sinusotomies. Corticosteroid-releasing bioabsorbable stents had been placed in the right and left ethmoid sinuses. A haemostatic agent had also been used. Three weeks after surgery, the patient experienced symptoms of rhinosinusitis and developed peri-orbital cellulitis on the right side. Post-surgical debridement was done and the patient was treated with antibiotics.
- 5.5 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers reported the stent falling out as an anecdotal adverse event. They considered that the following were theoretical adverse events: damage to adjacent vital structures, including the cribriform plate (causing cerebrospinal fluid leak) or the orbital lamina (causing eye problems); foreign body reaction to stent components; biofilm formation on the stent; migration of the stent to another anatomical location, with possible aspiration or swallowing; fungal infection secondary to high local corticosteroid concentrations; systemic absorption of corticosteroids leading to idiosyncratic complications.

6 Further information

- 6.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an [audit tool](#) (which is for use at local discretion).

Information for patients

NICE has produced information on this procedure for patients and carers ([information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-1768-6

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).