NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

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

Rhinosinusitis is when the air-filled cavities of the face (the sinuses) become infected and inflamed. It can cause facial pain and tenderness, a blocked or runny nose, fever and headache. In this procedure, a stent (short tube) or spacer is inserted through the nose using an endoscope (a thin tube with a camera on the end) and placed in the drainage system of a sinus. The stent or spacer holds the drainage system open, and slowly releases corticosteroid medication into the sinus. The aim is to reduce inflammation. After several weeks the stent or spacer dissolves.

The National Institute for Health and Care Excellence (NICE) is examining corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis and will publish guidance on its safety and efficacy to the NHS. NICE's Interventional Procedures Advisory Committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The Advisory Committee has made provisional recommendations about corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis.

This document summarises the procedure and sets out the provisional recommendations made by the Advisory Committee. It has been prepared for public consultation. The Advisory Committee particularly welcomes:

- comments on the provisional recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The Advisory Committee will meet again to consider the original evidence and its provisional recommendations in the light of the comments received during consultation.
- The Advisory Committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the Interventional Procedures Programme process guide, which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 18 December 2015

Target date for publication of guidance: 23 March 2016

1 Provisional 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 NICE's 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 6.2).

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 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 several weeks.

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% (16/85) and 34% (29/85) of sinuses respectively at day 30, ($p=0.002$). In the RCT of 43 patients, there were polypoid mucosal changes in 18% (7/38) of

sinuses treated by a corticosteroid-eluting stent and in 37% (14/38) of sinuses treated by a control stent (p=0.039) at day 60. 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% (9/90) of sinuses and frank polyposis in 2% (2/90) of sinuses.

4.4 In the RCT of 105 patients, there were significant adhesions in 5% (5/104) of sinuses treated by a corticosteroid-eluting bioabsorbable stent and in 13% (13/104) 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% (2/38) of sinuses treated by a corticosteroid-eluting bioabsorbable stent and in 21% (8/38) of sinuses treated by a control stent (p=0.031) at day 60. In the case series of 50 patients treated by corticosteroid-eluting bioabsorbable stent insertion during endoscopic sinus surgery, there were significant adhesions in 1% (1/90) 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% (32/96) of sinuses treated by a corticosteroid-releasing bioabsorbable stent and in 47% (45/96) 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 Food and Drug Administration (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 For related NICE guidance, see the NICE website.

6.2 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion). This tool will be available when the guidance is published.

Bruce Campbell
Chairman, Interventional Procedures Advisory Committee
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