NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Self-expanding implant insertion into the intersphincteric space for faecal incontinence

Faecal incontinence can happen when 2 rings of muscle (sphincters) around the anus cannot control the passing of faeces. Faeces can leak out or pass suddenly, without control. In this procedure small implants (usually 6 or 10) are inserted next to each other, through small cuts, into tissue between the 2 sphincters (the intersphincteric space). The implants expand and press together, forming a ring that creates an artificial sphincter. The aim is to give the person more control over passing faeces.

NICE is looking at self-expanding implant insertion into the intersphincteric space for faecal incontinence.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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: July 2020

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 31 July 2020

Target date for publication of guidance: January 2021

1 Draft recommendations

1.1 Evidence on the safety and efficacy of self-expanding implant insertion into the intersphincteric space for faecal incontinence is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research.

1.2 Further research should be in the form of randomised controlled trials and registry-based research to capture long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Faecal incontinence is an inability to control bowel movements, resulting in the involuntary passage of faeces. The process of defaecation and its control is complex. Causes of incontinence include problems in the colon and rectum (including constipation and diarrhoea), problems with the sphincter muscles (such as damage caused by childbirth or surgery), or nerve damage (such as multiple sclerosis, stroke or spina bifida). Faecal incontinence

can also be caused by loss of higher-level cerebral control in conditions such as dementia or severe learning disability.

2.2 NICE's guidance on faecal incontinence in adults states that there is no consensus on methods of classifying the symptoms and causes of faecal incontinence. It is most commonly classified according to symptom, character of the leakage, patient group or presumed primary underlying cause. For many people faecal incontinence is the result of a complex interplay of contributing factors, some of which may be relatively simple to reverse. Therefore, a detailed initial assessment and structured approach to management is needed, starting with addressing reversible factors and, only if this fails to restore continence, progressing to specialised management.

Current treatments

2.3 Initial management of faecal incontinence includes interventions related to diet, bowel habit, toilet access and medication. Specialised management options depend on the underlying cause and include pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation. The main surgical treatment is anal sphincter repair. Sacral nerve stimulation may be offered to people for whom sphincter surgery is not appropriate. If a trial of sacral nerve stimulation is unsuccessful, a neosphincter may be considered (stimulated graciloplasty or an artificial anal sphincter).

The procedure

2.4 Self-expanding implant insertion into the intersphincteric space for faecal incontinence is done using local or general anaesthesia, with ultrasound guidance. About 6 to 10 small (2 mm) incisions are made in the perianal skin, equidistant to each other, about 2 cm from the anal margin. An introducer is inserted into each incision in

turn, pushed through a short subcutaneous tunnel and into the intersphincteric space. The implant is deployed in the desired position within the intersphincteric space. This is repeated around the entire circumference of the internal anal sphincter. The incisions are sutured with resorbable material. Patients are advised to avoid any heavy physical activity for a few days after surgery. One type of implant is a solid polyacrylonitrile cylinder (non-biological) that becomes thicker, shorter and softer over 1 to 2 days after implantation. The implants expand and press together, forming a ring that creates an artificial sphincter. The aim is to give the person more control over their ability to control defaecation.

3 Committee considerations

The evidence

3.1 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 8 sources, which was discussed by the committee. The evidence included 7 case series and 1 case report. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduced incontinence in the short and long term, improved quality of life and reduced need for later invasive procedures.

3.3 The professional experts and the committee considered the key safety outcomes to be: infection, bleeding, pain, and device extrusion or migration.

Committee comments

3.4 The committee noted that there is more than 1 size of device that can be used for the procedure.

3.5 The committee noted that there is a registry for this procedure.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

March 2020

ISBN: