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Stimulated graciloplasty for faecal incontinence

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG159

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0994 (full guidance)
- N0995 (information for the public).

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Contents

About this information	4
About the procedure	5
How well the procedure works	6
Risks and possible problems with the procedure	7
What has NICE decided?	8
What the decision means for you	9
Further information	10

About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called stimulated graciloplasty for faecal incontinence. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether stimulated graciloplasty is safe enough and works well enough for it to be used routinely for the treatment of faecal incontinence.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of stimulated graciloplasty for faecal incontinence and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About the procedure

The procedure NICE has looked at, which is called stimulated graciloplasty, is for faecal incontinence that hasn't improved with other treatments. It's an alternative to a colostomy operation, which involves joining the bowel to the abdomen to make an artificial exit for the bowel contents.

Normally, if someone feels they have to empty their bowels, they can 'hold on' until they reach a toilet. One of the ways the body does this is by closing the exit from the anus using a ring of muscle called the anal sphincter. One of the reasons a person might develop faecal incontinence is if the anal sphincter becomes weak or damaged.

Stimulated graciloplasty involves making a new anal sphincter from muscle taken from the thigh. Electrodes are put into the new sphincter and are connected to a small unit called a pulse generator, which is implanted in the abdomen. The pulse generator produces an electrical current that goes to the new sphincter and gradually changes the way the muscle works to make it behave more like the natural sphincter muscle.

The procedure can be performed in one or two stages. If it's done in two stages, the electrodes are put in place a few weeks after the new sphincter is put in place.

How well the procedure works

What the studies said

A thorough review of the published studies found that faecal incontinence greatly improved or stopped in 42% to 85% of people after they'd had the procedure (42% is the same as saying 42 people out of every 100 who had the procedure). One study compared people who'd had the procedure with people who hadn't had surgery. It found that after 2 years, the incontinence had improved in the people who'd had the surgery, but not in the ones who hadn't. Another study that followed what happened in people who'd had stimulated graciloplasty 5 years beforehand found that the procedure was successful in 144 out of the 200 people who'd had it.

A study that looked at 'quality of life' found that it improved more in people who had the procedure than it did in people who didn't have surgery. Another study that followed what happened in 129 people who had stimulated graciloplasty also found that peoples' quality of life was better after the procedure.

What the experts said

The experts thought that a newer procedure called sacral nerve stimulation was being used more often than stimulated graciloplasty.

Risks and possible problems with the procedure

What the studies said

In the studies, the most common problem that affected people who had stimulated graciloplasty was infection at the place where the procedure was carried out. Looking at the results from 403 people in a number of studies, just over one-quarter (28%) had an infection. In two studies that each followed what happened in around 120 people who had stimulated graciloplasty, about 15% of people had a serious infection that meant they needed to go back into hospital or have more surgery.

In another study that checked on people 3½ years after the procedure, nearly half the people (48%) had had to go back into hospital because of electrical or technical problems with the pulse generator. In another study, 3 out of 123 people (2%) developed a deep vein thrombosis (deep blood clot) and 1 patient died 3 weeks after surgery from a blood clot on the lungs.

Some people had problems emptying their bowels after they'd had the new sphincter put in. In one study, 33 out of 48 people (69%) had this type of problem or serious pain that meant they had to go back into hospital for further checks. In another study, 32 out of 200 people (16%) had problems emptying their bowels after the procedure.

What the experts said

The experts said that problems after the procedure were mainly linked to the pulse generator. In particular, this seemed to be a common place for infections (straight after the procedure and also infections that happened some time later).

What has NICE decided?

NICE has considered the evidence on stimulated graciloplasty. It has recommended that when doctors use this procedure for people with faecal incontinence, they should be sure that:

- it's only used for people who have tried non-surgical treatments without success or for whom non-surgical treatments aren't an option for medical reasons
- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

Stimulated graciloplasty should be carried out in specialist units by doctors who have had specific training and are experienced in assessing and treating people with faecal incontinence.

What the decision means for you

Your doctor may have offered you stimulated graciloplasty for faecal incontinence. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS, but it should be an option for you only if you've tried other non-surgical treatments and these haven't worked, or they aren't suitable for you for medical reasons. You should understand the benefits and risks of stimulated graciloplasty for faecal incontinence before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

If you have stimulated graciloplasty for faecal incontinence, the doctors who carry it out should have experience and training in assessing and treating people with faecal incontinence, and the surgery should be performed in a specialist unit.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on stimulated graciloplasty for faecal incontinence that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance on sacral nerve stimulation for faecal incontinence. You can get information on this from the NICE website at www.nice.org.uk/IPG099, or you can phone the NHS Response Line on 0870 1555 455 and ask for the information for the public, quoting reference number N0747.

If you have access to the internet, you can find more information on faecal incontinence on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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