NHS

National Institute for Clinical Excellence

Artificial anal sphincter implantation

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

June 2004

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National Institute for Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Website: www.nice.org.uk

ISBN: 1-84257-661-5

Published by the National Institute for Clinical Excellence
June 2004
Typeset by Icon Design, Eton
Print on Demand

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called artificial anal sphincter implantation. 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 artificial anal sphincter implantation is safe enough and works well enough for it to be used routinely for the treatment of severe faecal incontinence.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of artificial anal sphincter implantation 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 artificial anal sphincter implantation

Faecal incontinence is the medical term for what happens when a person passes faeces (stools) without the normal amount of control. It can happen as a result of problems with the anal sphincter, which is the ring of muscle that keeps the anus closed. Such problems may be due to sphincter damage, spinal injury or other neurological disorders.

Artificial anal sphincter implantation involves placing a circular cuff under the skin around the anus. The cuff is filled with fluid and sits tightly around the anus, keeping it closed. A tube runs under the skin from the cuff to a control pump. In a man, the pump is in his scrotum (the area of the testicles). In a woman, it's put into the area near to her vagina. A special balloon is placed into the patient's abdomen, and this is connected to the control pump by tubing that runs under the skin.

When the person is in the toilet, they can activate the pump, which takes the fluid out of the cuff and sends it up to the balloon. The cuff opens up and the person can pass faeces. Once finished, the fluid slowly returns to the cuff, which tightens up again.

How well it works

What the studies said

There were no good-quality studies that compared what happened in patients who had an artificial anal sphincter with what happened in similar patients who didn't have the artificial sphincter.
In the studies that were found, some patients needed to have the artificial sphincter taken out.
In one study, 10 out of 53 patients needed to have the sphincter removed (19% of patients).
In another study, 7 out of 17 patients had to have it taken out (41% of patients). In the remaining patients, having the sphincter improved their incontinence, though the way this was measured was different in the different studies. In studies that looked at the pressure in the anus, the pressure was higher after the artificial sphincter had been implanted (which is what would be expected if the artificial sphincter was working).

What the experts said

The experts thought that having to remove the sphincter was likely to be the main problem.

Risks and possible problems

What the studies said

The biggest study NICE found, which looked at what happened in 115 patients, showed that most patients had problems with the artificial sphincter (99 out of 115 patients had a problem). The most common ones are listed below, together with the numbers of patients who had the problem (out of the group of 115):

- infection (38 patients)
- pain (37 patients)
- erosion of the device, usually the cuff (24 patients)
- faeces becoming wedged behind the sphincter (21 patients)
- faecal incontinence (21 patients)
- constipation (20 patients)
- injury during the procedure (15 patients)
- problems with the openings made for the cuff, pump, balloon or tubing (11 patients)
- difficulty passing faeces (10 patients)
- the site of the cuff, pump, balloon or tubing opening up again (10 patients).

What the experts said

The experts thought that the main problems would be infection, device erosion and problems passing faeces

What has NICE decided?

NICE has decided that, if a doctor wants to carry out artificial anal sphincter implantation, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place. NICE may look at the operation again if new information becomes available.

NICE has also recommended that the procedure should be carried out only in units that specialise in treating patients with faecal incontinence.

Other comments from NICE

The procedure may be useful in the treatment of patients if sacral nerve stimulation is unsuitable (this is a way of treating incontinence by sending an electrical message to the nerves that control the muscles involved).

Also, as with all procedures, it's important that patients understand what is involved and what could go wrong. Problems are quite common following this procedure, and patients may need to have more operations as a result.

What the decision means for you

Your doctor may have offered you artificial anal sphincter implantation at a specialist unit. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of artificial anal sphincter implantation which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these benefits and risks may be described above.

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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on artificial anal sphincter implantation is on the NICE website (www.nice.org.uk/IPG066guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0597. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on incontinence, a good starting point would be NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

Date: June 2004

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MidCity Place
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N0598 1P POD June 04

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Artificial anal sphincter implantation

1 Guidance

1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having artificial anal sphincter implantation.

1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence.

2 The procedure

2.1 Indications

2.1.1 The causes of faecal incontinence are diverse. Existing treatment options include medical therapy, biofeedback techniques and surgery in selected patients. Surgical treatments include sphincter repair, sacral nerve stimulation, encirclement procedures and muscle transposition (for example, dynamic graciloplasty). Some patients may require a colostomy if other treatments fail.

2.2 Outline of the procedure

2.2.1 Implantation of an artificial anal sphincter is used to treat severe faecal incontinence. In this procedure, a fluid-filled cuff is implanted around the anal canal. Tubing from the cuff is channelled under the skin of the perineum and connected to a control pump placed subcutaneously in the scrotum or labia. The control pump is connected by tubing to a pressure-regulating balloon implanted in the abdominal wall. The cuff simulates the natural function of the sphincter muscle; when the fluid is displaced from the cuff to the balloon via the patient-controlled pump, defaecation can take place. Once defaecation is complete, the fluid is slowly returned to the cuff and continence is again achieved. For more details, refer to the Sources of evidence (see overleaf).

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2.3 Efficacy

2.3.1 No controlled studies were identified. Some of the studies identified were small and some had high losses to follow-up. Among the studies identified, removal of the artificial sphincter system was required in 19% (10/53) to 41% (7/17) of patients. In patients who had not undergone explantation, all the studies showed improvement in continence. However, different measures of continence were used in the studies. The studies that reported manometric results showed increased mean anal pressures after implantation. For more details, refer to the Sources of evidence (see right).

2.3.2 The Specialist Advisors considered the main efficacy concern to be the frequent need to remove the implanted artificial sphincter.

2.4 Safety

2.4.1 The largest study identified reported that device-related complications occurred in 86% (99/115) of patients. The most common adverse events reported in this study were: infection 33% (38/115); pain 32% (37/115); erosion 21% (24/115); faecal impaction 18% (21/115); faecal incontinence 18% (21/115); constipation 17% (20/115); surgical injury 13% (15/115); wound problems 10% (11/115); difficult evacuation 9% (10/115); and wound dehiscence 9% (10/115). For more details, refer to the Sources of evidence

2.4.2 The Specialist Advisors considered the main safety concerns to be infection, erosion and evacuation difficulties.

2.5 Other comments

2.5.1 The procedure may have a place in the treatment of patients who are unsuitable for sacral nerve stimulation.

2.5.2 There is a significant rate of complications, such as infection, cuff erosion, wound dehiscence and haematoma, and patients may require revisional surgery or removal of the device. Fully informed consent is therefore particularly important.

Andrew Dillon
Chief Executive
June 2004

Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from www.nice.org.uk/IPG066publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

Interventional procedure overview of artificial anal sphincter implantation, November 2002

Available from: www.nice.org.uk/ip128overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0597. *Information for the Public* can be obtained by quoting reference number N0598 for the English version and N0599 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL www.nice.org.uk/IPG066distributionlist

Published by the National Institute for Clinical Excellence, June 2004 ISBN: 1-84257-660-7

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MidCity Place, 71 High Holborn, London WC1V 6NA, website: www.nice.org.uk

N0597 1P 20k June 04 (ASA)