Bone-anchored cystourethropexy

Interventional procedures guidance
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nice.org.uk/guidance/ipg18

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. However, 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.

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.

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 Guidance

1.1 Current evidence of the safety and efficacy of bone-anchored cystourethropexy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake bone-anchored cystourethropexy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and

should provide them with clear written information. In particular patients should be informed that the long-term efficacy of the procedure appears to be poor. Use of the Institute's information for the public is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

2 The procedure

2.1 Indications

2.1.1 Bone-anchored cystourethropexy is used to treat stress incontinence in women. Stress incontinence refers to urine leakage that occurs when the pressure within the abdomen is raised during, for example, lifting, coughing or laughing. It is often a result of damage to the pelvic muscles during childbirth, which leads to the bladder 'dropping', so that the normal muscular mechanism that prevents the flow of urine into the urethra is disturbed.

2.1.2 Stress urinary incontinence is a common problem. Most women with stress incontinence are treated without surgery. Surgical options in women with stress incontinence include colposuspension and sling procedures. During 2000/01, about 10,000 operations on the outlet of the female bladder were carried out in England. These were largely performed through open abdominal operations or transvaginally.

2.2 Outline of the procedure

2.2.1 Bone-anchored cystourethropexy is a minimally invasive bladder-neck needle-suspension procedure. Bone anchors are screwed into the pubic bone through the vagina or by a small abdominal incision. Sutures are passed into the vaginal wall on either side of the bladder neck and pulled upwards to elevate the vaginal wall and the bladder neck. These sutures are then tied to the bone anchors.

2.3 Efficacy

2.3.1 In three studies of the In-tac® cystourethropexy bone-anchoring system, 1-year continence rates were between 80% (24/30) and 82% (50/61). In a more recent

case series of 28 women with a mean follow-up of 67.7 months, only six (21.4%) women remained continent at final follow-up. Four studies of the Vesica® cystourethropexy bone-anchoring system have followed up women for at least 1 year, with one study reporting on 5-year outcomes. This study reported that 95% (39/41) of women were continent at 6 months but only 15% (6/41) remained continent at 5 years. For more details refer to 'Sources of evidence'.

2.3.2 The Specialist Advisors considered that the long-term data for this procedure were poor.

2.4 Safety

2.4.1 The studies reported a number of complications including bone and urinary tract infection, urinary retention and dyspareunia. However, the incidence of these complications was low. The procedure may be undertaken percutaneously or transvaginally and these approaches may be associated with different complication rates. For more details refer to 'Sources of evidence'.

2.4.2 The Specialist Advisors reported that osteomyelitis is a potentially important complication.

2.5 Other comments

2.5.1 Evidence was presented to the Interventional Procedures Advisory Committee on the use of two devices for this procedure (In-tac, and Vesica,) as specified in the Safety and Efficacy Register of New Interventional Procedures (SERNIP). The Committee's decision was made on the basis of data from the use of these two devices.

Andrew Dillon
Chief Executive
November 2003

3 Further information

Sources of evidence

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

following documents.

'Interventional procedure overview of bone-anchored cystourethropexy (In-tac®)', December 2002.

'Interventional procedure overview of bone-anchored cystourethropexy (Vesica®)', December 2002.

Information for patients

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

4 Changes since publication

As part of NICE's work programme, the current guidance was considered for review but did not meet the review criteria as set out in the IP process guide. The guidance below therefore remains current.

31 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.