NICE National Institute for Health and Care Excellence

NICE guidance

Bone-anchored cystourethropexy

HealthTech guidance
Published: 26 November 2003

www.nice.org.uk/guidance/htg6

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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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.

Contents

This guidance replaces IPG18.

1 Recommendations

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 NICE'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 to 2001, 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 3 studies of the In-tac cystourethropexy bone-anchoring system, 1-year continence rates were between 80% (24 of 30) and 82% (50 of 61). In a more recent case series of 28 women with a mean follow-up of 67.7 months, only 6 (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 1 study reporting on 5-year outcomes. This study reported that 95% (39 of 41) of women were continent at 6 months but only 15% (6 of 41) remained continent at 5 years. For more details, refer to the overviews for this guidance.

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 the overviews for this guidance.

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 committee on the use of 2 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 2 devices.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overviews for the In-tac and Vesica cystourethropexy bone-anchoring systems.

Information for patients

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

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 18 has been migrated to HealthTech guidance 6. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8281-3

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.