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Insertion of biological slings for stress urinary incontinence in women

1 Guidance

1.1 Current evidence on the safety and short-term efficacy of the insertion of biological slings for stress urinary incontinence in women is adequate to support the use of this procedure provided that normal arrangements are in place for consent and clinical governance.

1.2 Data on the long-term efficacy of the insertion of biological slings for stress urinary incontinence in women are limited to autologous slings. Clinicians should therefore audit patients in the longer term. Publication of further audit data and research will be helpful in determining the usefulness of different types of sling for this procedure.

1.3 Clinicians should ensure that patients understand that slings made of cadaveric or animal tissue may be implanted, and that the use of such slings is acceptable to the patient.

2 The procedure

2.1 Indications

2.1.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or movements such as coughing, sneezing and laughing. It is usually caused by weak or damaged muscles and connective tissues of the pelvic floor, or by weakness of the urethral sphincter itself. It is estimated that 10–52% of adult women have some form of stress incontinence.

2.1.2 Typically, first-line treatment is conservative and includes lifestyle changes such as weight loss, pelvic floor muscle training, electrical stimulation and biofeedback. If the condition does not improve, surgical alternatives in women may include colposuspension, the use of tension-free vaginal tape, transobturator foramen procedures or traditional suburethral slings.

2.2 Outline of the procedure

2.2.1 Biological slings may be made from the patient's own fascial tissue (autograft), from human donor tissue (allograft) or from animal tissue (xenograft). Allografts are solvent dehydrated or freeze dried, and may be gamma irradiated. Autologous fascial slings are the most established option.

2.2.2 Suburethral sling procedures involve making an incision in the lower abdomen and one in the anterior vaginal wall. An instrument is tunnelled between the incisions to introduce the sling and position it around the bladder neck where it forms a supportive hammock. There are three main methods of positioning the sling, depending on its length. A full-length sling passes through the retropubic space, underneath the urethra to the other side, and is fixed by sutures to the anterior abdominal wall. Shorter slings are attached by suspending sutures at each end of the sling to the anterior abdominal wall. Alternatively, bone screws may be used to secure the sutures into the pubic bones. Once the sling is in position, a cystoscopy may be performed to check that there has been no bladder perforation.

2.3 Efficacy

2.3.1 Two non-randomised controlled trials compared allograft slings with autograft slings. These reported similar improved rates of continence: 71% (45/63) and 74% (77/104) for the allograft groups; and 77% (55/71) and 73% (22/30) for the autograft groups. One of these studies reported that 89% (93/104) of women with allograft slings and 90% (27/30) of women with autograft slings were satisfied and would undergo the procedure again. In another study comparing long-term outcomes, subjective stress continence was reported by 92% (24/26) of

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This guidance is written in the following context

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

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This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

patients with allograft slings at 42 months, and 91% (19/21) of patients with autograph slings at 35 months. A case series of 198 women with autograft slings reported an overall success rate of 72% (142/197) after a median follow-up of 6 years. Another case series reported that 85% (75/88) of patients who were followed up for longer than 5 years were continent.

2.3.2 One randomised controlled trial reported that 82% (56/68) of women had improved rate of continence with a xenograft sling, compared with 88% (53/60) of women who had had a vaginal tape procedure (not statistically significant). The patient satisfaction rates were similar for the two groups. In a second randomised study of 139 patients, published in abstract form, 12.5% patients (6/48) with a xenograft sling required reoperation within 12 months for delayed failure. There were no reports of failure in the vaginal tape or autograft group at 12 months. For more details, refer to the sources of evidence.

2.3.3 The Specialist Advisors stated that there are concerns about the long-term efficacy of this procedure.

2.4 Safety

2.4.1 The two most commonly reported complications were urge incontinence and urinary retention. Urge incontinence affected between 3% (5/152) and 50% (5/10) of women. One study reported that 94% (232/247) of women had transient urinary retention (for longer than 1 day postoperatively; mean duration of catheterisation was 8.4 days), and prolonged urinary retention was reported in 2% (1/63) to 10% (3/30) of women. Two studies reported severe or persistent pain in 1% (1/74) and 4% (5/134) of women, respectively. Other complications included infection, pelvic haematoma, haemorrhage and urethral stenosis.

2.4.2 The Specialist Advisors noted that potential adverse effects include urethral obstruction and retention, bladder perforation, haemorrhage, infection and urgency. There is also an additional potential risk of infection associated with the use of cadaveric tissue.

2.5 Other comments

2.5.1 It was noted that a variety of types of biological slings are available, including allogenic, xenogenic or autogenic grafts; and that outcomes may vary according to the type of graft used. It was also noted that a variety of methods are used for the implantation of slings.

2.5.2 It was noted that this procedure is different from the tension-free vaginal tape insertion procedure (which is subject to NICE guidance – see below).

3 Further information

3.1 NICE has issued guidance on tension-free vaginal tape insertion (www.nice.org.uk/TA056), insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women (www.nice.org.uk/IPG133) and intramural urethral bulking agents for stress urinary incontinence in women (www.nice.org.uk/IPG138).

Andrew Dillon
Chief Executive
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Information for the public

NICE 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 from www.nice.org.uk/IPG154publicinfo

Sources of evidence

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

'Interventional procedures overview of biological slings for stress urinary incontinence', April 2005.

Available from www.nice.org.uk/ip264overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0967. *Information for the public* can be obtained by quoting reference number N0968.

The distribution list for this guidance is available at www.nice.org.uk/IPG154distributionlist

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