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Transobturator foramen procedures for stress urinary incontinence

1 Guidance

1.1 Current evidence on the safety and short-term efficacy of transobturator foramen procedures for stress urinary incontinence appears adequate to support the use of these procedures provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Transobturator foramen procedures for stress incontinence should only be performed by clinicians with a particular expertise in the assessment and treatment of female urinary incontinence, following adequate mentoring.

1.3 Long-term results of the procedures are not available and clinicians are encouraged to collect data on rates of recurrence and other late complications.

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 in the pelvic floor, compromising urethral support, or by weakness of the urethral sphincter itself.

2.1.2 Typically, first-line treatment is conservative and includes pelvic floor muscle training, electrical stimulation and biofeedback. If the condition does not improve, surgical alternatives in women may include colposuspension, tension-free vaginal tape, traditional suburethral slings, and injectable agents. Of these four types of procedure, colposuspension and tension-free vaginal tape are currently the most common.

2.2 Outline of the procedure

2.2.1 These procedures use tape similar to the tension-free vaginal tape, but different techniques are used to insert it.

2.2.2 The tape may be inserted under spinal, general or local anaesthesia. A vaginal incision is made at the level of the mid-urethra. Two methods are in use for inserting the tape through the obturator foramina: passing the tape from the skin to the vaginal incision bilaterally (the outside-in technique), and passing it from the vaginal incision to the skin (the inside-out technique). The tape is positioned without tension beneath the mid-urethra, in order to maintain its correct position.

2.3 Efficacy

2.3.1 The majority of the evidence looked at the outside-in procedure. Two randomised controlled trials were reported, although one of the trials was still ongoing and information was only available from an unpublished conference abstract. Follow-up was 12 months in the other trial. In these two trials, 96% (46/48) and 90% (27/30) of patients treated with transobturator foramen procedures

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achieved continence, compared respectively with 93% (50/54) and 84% (26/31) of patients treated with tension-free vaginal tape. Neither of these results is statistically significant. For more details, refer to the Sources of evidence.

2.3.2 In three case series reports, the percentage of patients with complete resolution of incontinence ranged from 82% to 94%. The proportion of patients with some improvement in stress urinary incontinence symptoms ranged from 89% to 100%. For more details, refer to the Sources of evidence.

2.3.3 Efficacy data were not reported in the one case series that looked at the inside-out procedure. For more details, refer to the Sources of evidence.

2.3.4 The Specialist Advisors stated that there were uncertainties about the efficacy of the procedures because of the lack of long-term data.

2.4 Safety

2.4.1 The main complication reported for the outside-in procedure was urinary retention, affecting between 1% (1/94) and 16% (5/32) of patients. Other complications included haemorrhage in 2% of patients (2/94), urethral perforation in 1% (2/165), bladder perforation in less than 1% (1/165) and vaginal perforation in less than 1% (1/165). Vaginal erosion was reported in 4% (6/175) of patients and urethral erosion in less than 1% (1/175). One study reported that 20% (6/30) of patients had a urinary infection after the procedure. For more details, refer to the Sources of evidence.

2.4.2 In the case series that looked at the inside-out technique, the main complication reported was urinary retention, which affected 3% (3/107) of patients. Other complications were: severe pain lasting 1 week in 2% (2/107) of patients, vaginal erosion in 1% (1/107) and sepsis in 1% (1/107). For more details, refer to the Sources of evidence.

2.4.3 The Specialist Advisors considered damage to the obturator nerve to be theoretically possible. Other potential adverse effects were bleeding, infection, bladder perforation, urethral damage, vaginal or skin erosion, long-term voiding dysfunction and de novo detrusor over activity.

2.5 Other comments

2.5.1 It was noted that there may be a risk of urethral damage and some clinicians routinely perform cystoscopy.

3 Further information

3.1 The Institute's technology appraisal work programme issued guidance on the use of tension-free vaginal tape (GynecareTVT) for stress incontinence in February 2003 (www.nice.org.uk/TA056).

Andrew Dillon
Chief Executive
January 2005

Information for the public

NICE has produced information describing its guidance on these procedures for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedures 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/IPG107publicinfo

Sources of evidence

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

Interventional procedure overview of transobturator tape insertion for stress urinary incontinence, March 2004.

Available from: www.nice.org.uk/IP223overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0789. *Information for the public* can be obtained by quoting reference number N0790 for the English version and N0791 for a version in English and Welsh.

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