

# Suburethral synthetic sling insertion for stress urinary incontinence in men

## 1 Guidance

- 1.1 Current evidence on the safety and efficacy of suburethral synthetic sling insertion for stress urinary incontinence in men appears adequate to support the use of this procedure, provided that normal arrangements are in place for clinical governance.
- 1.2 During consent, clinicians should clearly explain to patients that the procedure is not always successful, particularly in men with severe stress urinary incontinence or in those who have been previously treated with radiotherapy. Patients should also be made aware that the benefits of the procedure may decrease over time. Clinicians should provide patients with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from [www.nice.org.uk/IPG256publicinfo](http://www.nice.org.uk/IPG256publicinfo)).
- 1.3 This procedure should only be undertaken by units that specialise in the investigation and treatment of post-prostatectomy incontinence and that can offer alternative treatments, including insertion of artificial urinary sphincters.
- 1.4 Clinicians undertaking suburethral synthetic sling insertion for stress urinary incontinence in men should submit data on all patients to the British Association of Urological Surgeons registry (available from [www.baus.org.uk](http://www.baus.org.uk)).

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Stress urinary incontinence is characterised by the involuntary leakage of urine during movements such as coughing, sneezing or laughing. Previous prostatectomy is a common cause in men.

- 2.1.2 Conservative treatments include pelvic floor muscle training, electrical stimulation and biofeedback. More invasive options include injection of bulking agents into the urethra, insertion of a bulbar urethral sling, implantation of an artificial urinary sphincter and insertion of an extraurethral (non-circumferential) retropubic adjustable compression device.

### 2.2 Outline of the procedure

- 2.2.1 The purpose of a suburethral sling is to achieve bulbourethral support or compression. A number of devices are available for this procedure. The procedure is usually undertaken under general anaesthesia, but local anaesthesia can also be used. The sling is made of a synthetic mesh and is usually inserted via a perineal incision. Once the sling is in place, tension is applied to achieve the desired level of continence, while trying to avoid causing outflow obstruction. Tension can be adjusted intraoperatively using perfusion sphincterometry (the measurement of urethral resistance using fluid infusion into the bladder via the urethra under manometric control) and/or a cough test (if local anaesthesia is used). With certain devices, subsequent adjustment of the sling tension is possible, usually requiring a minor second procedure.

*Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, refer to the Sources of evidence.*

### 2.3 Efficacy

- 2.3.1 In four case series of between 48 and 62 men who were treated with suburethral synthetic sling insertion, between 34% and 73% were

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This guidance represents the view of the Institute, which 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.

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

reported to have achieved complete continence, requiring no pads. In a fifth case series, the success rate was reported to be 96% (26/27) using non-absorbable slings at a mean follow-up of 19 months and 8% (1/12) using absorbable slings at 29-month follow-up.

- 2.3.2 In a case series of 50 men, failure rates of 75% and 16% were reported in 8 and 42 men with and without previous radiotherapy treatment respectively (significance not reported). Conversely, a case series of 62 men reported no association between outcome and previous radiotherapy treatment ( $p = 1.00$ ).
- 2.3.3 In a case series of 48 men, quality of life (measured by the 'International consultation on incontinence questionnaire – short form tool' [21-point scale; a lower score reflects fewer symptoms]) improved from 19.2 (baseline) to 4 points at 7.5 months. In a second case series of 48 men, the median quality-of-life score (measured by the 'University of California, Los Angeles prostate cancer index' [500-point scale]) improved from 63 (baseline) to 343 points at 48 months (significance not stated in either study).
- 2.3.4 The Specialist Advisers considered key efficacy outcomes to include objective reduction in incontinence, patient satisfaction and quality of life, duration of effect and residual volume.

## 2.4 Safety

- 2.4.1 In five case series of between 38 and 62 men, urethral erosion requiring removal of the sling was reported in between 0% and 6%. In three of the studies, infection was reported in 6% (3/50), 5% (3/62) and 4% (2/48) of men (timing of infection not stated).
- 2.4.2 In the case series of 62 men, worsened incontinence was reported in 2% (1/62) and urinary retention requiring repeat surgery was reported in 3% (2/62) of men. In the case series of 50 men, acute urinary retention occurred in 12% (6/50) of men, resolving with catheterisation within 3 days.
- 2.4.3 No osseous complications were reported in two case series where bone anchorage was used. The rate of re-intervention for sling tension adjustment was reported as 8% (4/48) in one case series. In another case series, a repeat procedure to adjust tension (a minor procedure under local anaesthesia) was required in 86% (44/51) of patients at 1- to 4-month follow-up.

## Ordering information

For printed copies of this guidance or the 'Understanding NICE guidance', contact NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk)) and quote reference number N1499 for this guidance or N1500 for the 'Understanding NICE guidance'.

The distribution list for this guidance is available at [www.nice.org.uk/IPG256distributionlist](http://www.nice.org.uk/IPG256distributionlist)

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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- 2.4.4 Postoperative pain or dysuria following suburethral sling insertion was reported in 21% (10/48) of men in one case series and in 'most' men in three case series of 48 (time of occurrence not specified), 50 and 38 (resolving within 3 to 4 months) men. In two case series of 50 and 62 men, persistent pain (lasting longer than 3 months) was reported in 12% (6/50) and 8% (5/62) of men.

- 2.4.5 The Specialist Advisers reported anecdotal adverse events including infection, urinary retention, pain and erosion in the medium or long term. Additional theoretical adverse events suggested by the Advisers included rectal fistula, urinary retention, osteitis and direct injury to the urethra, bladder or blood vessels.

## 2.5 Other comments

- 2.5.1 The Committee did not see any evidence comparing suburethral synthetic sling insertion with other procedures so was unable to comment on the place of the procedure in the management of this condition.

## 3 Further information

- 3.1 The Institute has published interventional procedures guidance on insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in men ([www.nice.org.uk/IPG224](http://www.nice.org.uk/IPG224)).

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## Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). 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/IPG256publicinfo](http://www.nice.org.uk/IPG256publicinfo)

## Sources of evidence

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

'Interventional procedure overview of suburethral synthetic sling insertion for stress urinary incontinence in men', September 2007.

Available from: [www.nice.org.uk/ip656overview](http://www.nice.org.uk/ip656overview)