NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Urinary incontinence in women: the management of urinary incontinence in women

1.1 Short title

Urinary incontinence in women

2 The remit

This is a partial update of 'Urinary incontinence', NICE clinical guideline 40 (2006), available from www.nice.org.uk/guidance/CG40. See section 4.3.1 for details of which sections will be updated. We will also carry out an editorial review of all recommendations to ensure that they comply with NICE's duties under equalities legislation.

This update is being undertaken as part of the guideline review cycle.

3 Clinical need for the guideline

3.1 Epidemiology

a) Urinary incontinence is the complaint of any involuntary urinary leakage. There are two main causes: overactive bladder, resulting in symptoms such as urgency, urge incontinence and/or urinary frequency; and weakness of the pelvic floor and urethral sphincter, resulting in stress incontinence. The main clinical feature of stress incontinence is the involuntary passage of urine when the intra-abdominal pressure is raised for example by coughing or sneezing.

b) There is large variation in the estimates of prevalence of urinary incontinence. This relates to differences of definition, method and population characteristics. A recent longitudinal study from one country in the UK estimated the prevalence for women as 34%.

c) Recent prospective studies on the incidence and natural history of the condition (progression, regression and resolution) suggest that urinary incontinence or urine loss occurring at least once in the past 12 months affects between 5 and 69% of women. Limited data on twins suggest a genetic component to urinary incontinence, especially stress incontinence. The literature on progression and remission is scarce. The annual incidence rates of urinary incontinence in women range from 2 to 11%, with the highest incidence occurring during pregnancy. Rates of complete remission range from 0 to 13%, with the highest remission rate after pregnancy. The annual incidence of overactive bladder ranges from 4 to 6% and the annual remission rate ranges from 2 to 3%.

3.2 Current practice

Management of overactive bladder

a) Overactive bladder is managed primarily by retraining, followed by antimuscarinic drug therapy if retraining is not helpful. Several antimuscarinics are used to treat overactive bladder symptoms. The current NICE guideline on urinary incontinence recommends offering oxybutynin as the first pharmacological treatment. Since the publication of that guideline new drug therapies have become available on the NHS. Pharmacological treatment options are not always successful or may produce unacceptable side effects, which has encouraged the development and use of other techniques such as neuromodulation or injection of botulinum toxin into the bladder muscle.

b) Neuromodulation for overactive bladder is becoming more popular across the NHS, so it is important to evaluate how effective and acceptable it is as a treatment option. Neuromodulation includes

sacral neuromodulation and percutaneous (posterior) tibial nerve stimulation (PTNS). Sacral neuromodulation involves threading stimulating wire electrodes through the gap in the sacral spine nd placing a battery stimulator under the skin in the buttock. PTNS involves inserting a stimulating needle electrode near to the posterior tibial nerve close to the ankle. This is repeated on regular outpatient visits.

c) Botulinum toxin injection into the wall of the bladder is used widely for women with OAB caused by detrusor overactivity in whom antimuscarinic drugs have failed. The effect of therapy lasts for 3 to 10 months. After treatment with botulinum toxin 10% of women will have to self-catheterise, so it is not an acceptable treatment option for all women. It is currently unlicensed for use in overactive bladder in the UK.

d) Surgery is also an option for treatment of overactive bladder if conservative management is unsuccessful. The most common surgical option for overactive bladder is the clam cystoplasty, in which a segment of bowel is attached to the bladder. Possible complications include failure, recurrent infections and tumour development in the bowel segment. Long term surveillance is needed.

Management of stress incontinence

e) Stress incontinence is primarily treated by lifestyle options such as weight loss and pelvic floor muscle training. Duloxetine was recommended in the original NICE guideline on urinary incontinence as an alternative to surgery for treatment of stress incontinence. However, it has a high incidence of side effects, which makes it an unpopular treatment.

f) If pharmacological and non-pharmacological treatments are not successful, surgical treatment can be considered. Surgical options include mid-urethral tapes, colposuspension, sling procedures and

para-urethral bulking agents. The use of mid-urethral tapes has grown over the past decade and procedures such as colposuspension and slings are now performed much less frequently. There are new procedures that may be as effective and may have a shorter recovery period. The evidence has focussed on the retropubic approach, but many variants (including the transobturator approach and single incision technique) have been introduced and it is not currently clear which of these approaches or techniques is most effective. Furthermore it is not clear whether the different tapes manufactured for each of these approaches are equally effective.

Mixed urinary incontinence

g) The original NICE guideline on urinary incontinence recommended that treatment for mixed incontinence should be determined by whether stress or urge incontinence was the dominant symptom.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Women 18 years and older with urinary incontinence (overactive bladder, stress or mixed urinary incontinence).

4.1.2 Groups that will not be covered

a) Women with incontinence in association with neurological disease (this is covered by a separate guideline, see section 5.2).

a) Children and young people younger than 18 years.

b) Men.

4.2 Healthcare setting

b) The guideline will cover all NHS funded settings in which NHS care is provided by primary, community, secondary and tertiary healthcare professionals.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform their decisions for individual patients.

Overactive bladder

Drugs

a) Immediate release oxybutynin compared with:

- darifenacin
- darifenacin – extended release
- fesoterodine – modified release
- oxybutynin – modified release
- oxybutynin – transdermal
- oxybutynin – topical gel
- propiverine
- propiverine – extended release
- solifenacin
- tolterodine
- tolterodine – extended release
- trospium
- trospium – extended release.

Neuromodulation

b) Sacral nerve stimulation compared with no active treatment.

c) Sacral nerve stimulation compared with no active treatment for overactive bladder caused by detrusor overactivity.

d) Percutaneous (posterior) tibial nerve stimulation (PTNS) compared with no active treatment.

e) PTNS compared with no active treatment for overactive bladder caused by detrusor overactivity.

f) Sacral nerve stimulation compared with PTNS.

g) Sacral nerve stimulation compared with PTNS for overactive bladder caused by detrusor overactivity.

h) Sacral nerve stimulation or PTNS compared with botulinum toxin A for overactive bladder caused by detrusor overactivity.

Botulinum toxin A

i) Botulinum toxin A compared with placebo for overactive bladder caused by detrusor overactivity.

Stress urinary incontinence

j) For women undergoing their primary surgical tape procedure, the comparative effectiveness of the following surgical approaches for mid-urethral procedures:

- retropubic bottom up
- retropubic top down
- transobturator inside out
- transobturator outside in
- single incision.

4.3.2 Clinical issues that will not be covered

a) Management and treatment of comorbidities, such as pelvic organ prolapse.

b) Incontinence caused by neurological disease.

c) Faecal incontinence with or without urinary incontinence.

d) Urinary incontinence in association with pregnancy (incontinence presenting in pregnancy, or surgery for incontinence before pregnancy).

e) The following areas addressed in the 2006 guideline will not be updated (the existing recommendations will remain as current guidance):

- Diagnostic accuracy, identification of other conditions, prediction of outcome, outcome effectiveness, and reliability of all tests, investigations and observations across the urinary incontinence pathway.
- Lifestyle interventions, physical therapies (other than neuromodulation), behavioural and complementary therapies, non-therapeutic interventions (products and aids) and preventive interventions.
- Mulitchannel cystometry in pre-operative assessment for stress incontinence.
- Multichannel cystometry with imaging before surgical treatment to determine treatment outcomes.
- Surgical procedures other than single incision sling, transobturator tape and tension free vaginal tape for women with urinary incontinence.
- Management of mixed urinary incontinence.

f) Other exclusions:

- Assessment and management of stress urinary incontinence following failed primary tape procedures.

4.4 Main outcomes

a) Continence status (zero episodes per day).

b) Adverse effects and tolerability, for example need for self-catheterisation, acquired urinary tract infection.

c) Psychological outcomes, such as anxiety and depression.

d) Patient satisfaction with treatment, for example Patient Global Improvement (PGI), Electronic Personal Assessment Questionnaire (e-PAQ).

e) Self reported rate of absolute symptom reduction, for example number of episodes of incontinence per day

f) Quality of life: generic validated scales for both physical and social functioning, for example Incontinence – QOL or the Kings Health Questionnaire.

g) Clinical measures, for example bladder function score, mean detrusor pressure, pressure flow functioning, mean cystometric capacity, post-void residual volume.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the consultation draft of the scope. The consultation dates are 6 June to 4 July 2010.

4.6.2 Timing

The development of the guideline recommendations will begin in November 2011.

5 Related NICE guidance

5.1 Published guidance

5.1.1 NICE guidance to be updated

Urinary incontinence. NICE clinical guideline 40 (2006). Available from www.nice.org.uk/guidance/CG40

5.1.2 NICE guidance to be incorporated

This guideline will incorporate the following NICE guidance:

- Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome. NICE interventional procedure guidance 362 (2010). Available from www.nice.org.uk/guidance/IPG362
- Insertion of biological slings for stress urinary incontinence. NICE interventional procedure guidance 154 (2006). Available from www.nice.org.uk/guidance/IPG154
- Sacral nerve stimulation for urge incontinence and urgency-frequency. NICE interventional procedure guidance 64 (2004). Available from www.nice.org.uk/guidance/IPG64

5.1.3 Other related NICE guidance

- Lower urinary tract symptoms. NICE clinical guideline 97 (2010). Available from www.nice.org.uk/guidance/CG97

- Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE interventional procedure guidance 262 (2008). Available from www.nice.org.uk/guidance/IPG262
- Faecal incontinence. NICE clinical guideline 49 (2007). Available from www.nice.org.uk/guidance/CG49
- Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence in women. NICE interventional procedure guidance 133 (2005). Available from www.nice.org.uk/guidance/IPG133
- Intramural urethral bulking procedures for stress urinary incontinence. NICE interventional procedure guidance 138 (2005). Available from www.nice.org.uk/guidance/IPG138

5.2 Guidance under development

- Incontinence in neurological disease. NICE clinical guideline. Publication expected October 2012.

6 Further information

Information on the guideline development process is provided in:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).