BEST PRACTICE ADVOCACY CENTRE NEW ZEALAND

SCOPE

1 Guideline title

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

2 Guideline Contextualisation

This is a contextualisation of 'Urinary incontinence in women' (NICE clinical guideline 171, published in 2006, partially updated in September 2013). The guideline contextualisation process is described in detail on the BPACnz website (see section 6, 'Further information'). The NICE guideline development process is described in detail on the NICE website (see section 6, 'Further information'). The scope of NICE clinical guideline 171 is available here.

A Guideline Review and Contextualisation Group has been convened with recognised experts and clinical leaders in New Zealand (see section 5). This group will be responsible for reviewing the NICE guideline and recommending to the Clinical Advisory Group any changes deemed necessary for the New Zealand context. The evidence base for the guideline being contextualised will not be reviewed and/or updated.

The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

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 (OAB) 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. It is more common in women than men. A New Zealand study[1] used 'any incontinence' as a definition, but also recorded the frequency of urinary incontinence. The overall prevalence of urinary incontinence for this study was 34%, with a slightly higher prevalence in Māori, 47%, and European, 31%, than Pacific Island women, 29%.There is a linear increase in the incidence of incontinence in women with advancing age. For Pacific women the prevalence increased from 16% in the age-group 18 to 29 to 30% in those aged 50+. For Māori the figures were 20% and 62% and for European 13% and 56%.

c) Recent overseas 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. Within New Zealand, a study revealed 37% of women with urinary incontinence had incontinence once or more daily. About 50% of urinary incontinence treatment will be unsuccessful or the condition will recur. The literature on progression and remission is scarce. Annual incidence rates 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 OAB ranges from 4 to 6% and the annual remission rate ranges from 2 to 3%

d) Urinary incontinence is particularly prevalent amongst Māori and Pacific women. There is a need to provide better care and access to services for populations who have poorer general health and reduced access to health services within New Zealand.

3.2 Current practice

General

a) Lifestyle interventions such as bladder training and modification of fluids are used throughout the treatment pathway. They are an important part of strategies to manage the symptoms of urinary incontinence. They are used as part of ongoing management alongside treatment and are to control long-term symptoms if treatment fails.

Management of overactive bladder

b) Overactive bladder is managed primarily by lifestyle interventions, in particular retraining, followed by antimuscarinic drug therapy if retraining is not helpful. Several antimuscarinics are used to treat OAB symptoms. A 2006 NICE guideline on urinary incontinence (CG40) recommends offering immediate release oxybutynin (subsidised by PHARMAC in New Zealand) as the first pharmacological treatment. Since the publication of that guideline new drug therapies and new preparations of existing drugs have been made available in the United Kingdom. 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 type A into the bladder muscle.

c) Neuromodulation for OAB is becoming more popular in the United Kingdom, so it is important to evaluate how effective and acceptable it is as a treatment option. Neuromodulation is not currently part of the continence services specification in New Zealand. Neuromodulation includes sacral neuromodulation, percutaneous (posterior) tibial nerve stimulation (PTNS) and transcutaneous electrical nerve stimulation (TENS). Sacral neuromodulation (SNM) involves threading stimulating wire electrodes through the gap in the sacral spine and placing a battery stimulator under the skin in the buttock. TENS involves using surface electrodes positioned over a particular nerve (sacral or tibial). PTNS involves inserting a stimulating needle electrode near to the posterior tibial

nerve close to the ankle. This would be repeated on regular outpatient visits.

d) Botulinum toxin type A injection into the wall of the bladder is used widely for women with OAB caused by detrusor overactivity in whom antimuscarinic drugs have failed or have not been tolerated. The effect of therapy lasts for 3 to 10 months. After treatment with botulinum toxin type A, 10% of women will have to self-catheterise, so it is not an acceptable treatment option for all women. No botulinum toxin type A option is currently subsidised by PHARMAC in New Zealand, although an option is listed on the Hospital Pharmaceutical schedule. Some botulinum toxin type A preparations, and botulinum toxin B are not currently recommended for treatment of OAB.

e) Surgery is also an option for treatment of OAB if conservative management is unsuccessful. The most common surgical option for OAB is the clam cystoplasty, in which a segment of bowel is attached to the bladder. This may not cure OAB symptoms (such as frequency, urgency or urge incontinence), and possible complications include recurrent infections and tumour development in the bowel segment. Long term surveillance is needed. Within New Zealand some populations have reduced access to surgical options for OAB due to geographical and economic factors.

Management of stress incontinence

f) Stress incontinence is primarily treated by lifestyle options such as weight loss and pelvic floor muscle training. Duloxetine was recommended in a 2006 NICE guideline on urinary incontinence (CG40) 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. The Guideline Review and Contextualisation Group notes that duloxetine is not currently subsided by PHARMAC in New Zealand.

g) 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 newer 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. The Guideline Review and Contextualisation Group notes that PHARMAC will be taking over the funding of devices in New Zealand, which may impact the options available for use throughout DHBs.

Mixed urinary incontinence

h) 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

This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline review and contextualisation group will consider.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

Groups that will be covered

a) Women in New Zealand 18 years and older with urinary incontinence (OAB, stress or mixed urinary incontinence). The GRCG will consider contextualising recommendations specific for Māori and Pacific women, where appropriate.

Groups that will not be covered

a) Women with incontinence in association with neurological disease.

b) Children and young people younger than 18 years.

c) Men.

4.2 Healthcare setting

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

4.3 Clinical management

Key clinical issues that will be covered

Overactive bladder

Drugs

a) Comparative effectiveness of the following drugs (all subsidised by PHARMAC*):

- oxybutynin – immediate release tablets
- oxybutynin – oral liquid
- solifenacin succinate (on Special Authority if the patient has overactive bladder and a documented intolerance of, or is non-responsive to oxybutynin)
- tolterodine tartrate (on Special Authority if the patient has overactive bladder and a documented intolerance of, or is non-responsive to oxybutynin)
- tolterodine tartrate – extended release (on Special Authority if the patient has overactive bladder and a documented intolerance of, or is non-responsive to oxybutynin)

in

- all women with OAB
- women with OAB caused by detrusor overactivity only.

* The Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown agency that decides, on behalf of District Health Boards (DHBs), which medicines and related products are subsidised for use in the community and public hospitals.

The Guideline Review and Contextualisation Group noted the following drugs, listed in the 2013 NICE guideline, are not currently funded in New Zealand. Some unregistered medications can be prescribed under Sections 25 and 29 of the Medicines Act, and patients can pay for prescribed medications if not funded. At risk people (particularly Māori and Pacific island populations) will have less access to these options.

- trospium
- trospium – extended release
- darifenacin
- darifenacin – extended release
- fesoterodine – modified release
- propiverine
- propiverine – extended release

Neuromodulation

b) Sacral nerve stimulation compared with either no active treatment or placebo in:

- all women with overactive bladder
- women with OAB caused by detrusor overactivity only.

c) PTNS compared with either no active treatment or placebo in:

- all women with overactive bladder
- women with OAB caused by detrusor overactivity only.

d) TENS compared with no either no active treatment or placebo in:

- all women with overactive bladder
- women with OAB caused by detrusor overactivity only.

e) A comparison of TENS, sacral nerve stimulation and PTNS (if these treatments are found to be effective compared with no treatment or placebo) in:

- all women with overactive bladder
- women with OAB caused by detrusor overactivity only.

Botulinum toxin type A

f) Botulinum toxin type A compared with placebo in women with OAB caused by detrusor overactivity.

Comparison of all treatments above shown to be effective compared with no treatment or placebo

g) Comparative effectiveness of pharmacological treatment and neuromodulation in all women with overactive bladder.

h) Comparative effectiveness of pharmacological treatment, neuromodulation and botulinum toxin type A in women with OAB caused by detrusor overactivity only

Stress urinary incontinence

i) Comparative effectiveness of the following surgical approaches for mid-urethral procedures in women undergoing their primary surgical tape procedure:

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

Details of tape properties (colour, material, size, for example) were reported if these had been included in the individual studies.

j) Comparative effectiveness of the following interventions for women for whom the primary tape procedure had failed:

- conservative management, looking only at:

- lifestyle interventions, specifically weight loss, fluid management and smoking cessation
- physical therapy, specifically pelvic floor muscle training
- repeat tape procedure
- fascial sling
- colposuspension.

k) The following areas will also be addressed. These areas were included in the 2006 NICE guideline and were not updated in the 2013 NICE guideline (the existing recommendations remained):

- Diagnostic accuracy, identification of other conditions, prediction of outcome, outcome effectiveness, and reliability of all tests, investigations and observations across the urinary incontinence pathway
- Conservative management except in the contexts described in sections 4.3.1 a and i.
- Mulitchannel cystometry in preoperative assessment for stress incontinence
- Multichannel cystometry with imaging before surgical treatment to determine treatment outcomes if non imaging UDS is inconclusive.
- Surgical procedures other than single-incision sling, transobturator tape and tension-free vaginal tape for women with urinary incontinence.
- Management of mixed urinary incontinence

Clinical issues that will not be covered

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

b) Faecal incontinence with or without urinary incontinence.

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

4.4 Review questions

- What impact do PHARMAC and Medsafe have on the treatment of urinary incontinence in New Zealand?

- Are there factors specific to New Zealand which reduce access to services and care for management of urinary incontinence?

4.5 Economic aspects

Developers of the NICE guideline took into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence was conducted and analyses were carried out as appropriate. Further detail on the methods can be found in 'Developing NICE Guidelines: The Manual' (2014). (see 'Further information').

In considering economic aspects for New Zealand, the Guideline Review and Contextualisation Group note that PHARMAC funding is based on cost effectiveness. Work is underway in New Zealand on the funding of devices. Due to this governance, the guideline group recommendations will be subject to the decisions of PHARMAC where appropriate.

4.6 Status

Scope

This is the guideline scope.

References

1. Lara C, Nacey J. Ethnic differences between Maori, Pacific Island and European New Zealand women in prevalence and attitudes to urinary incontinence. NZ Med J 1994;107:374-376

Related guidance

Recommendations covered in other NICE guidance considered for incorporation in the guideline:

- 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

Guideline

The contextualisation of the guideline recommendations will begin in May 2015.

5 Guideline Review and Contextualisation Group

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6 Further information

Information on the Guideline Contextualisation process is available from the BPAC website: www.bpac.org.nz/guidelines

Information on the NICE guideline development process available from the NICE website and in 'Developing NICE Guidelines: The Manual' (2014).