NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Botulinum toxin type A injections into the urethral sphincter for idiopathic chronic non-obstructive urinary retention

Difficulty passing urine or being unable to completely empty the bladder (urinary retention) can happen if the muscle controlling release of urine from the bladder (urethral sphincter) does not relax. In some people, it can happen without any known cause (idiopathic) and with no physical obstruction to the urine flow (non-obstructive).

In this procedure, botulinum toxin type A is injected into the urethral sphincter. The aim is to relax it and allow urine to be passed more easily, without needing to use a catheter to empty the bladder. The effects are temporary, and the procedure may need to be repeated every few months.

NICE is looking at botulinum toxin type A injections into the urethral sphincter for idiopathic chronic non-obstructive urinary retention.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 19 January 2023

Target date for publication of guidance: May 2023

1 Draft recommendations

1.1 Evidence on the safety and efficacy of botulinum toxin type A injections into the urethral sphincter for idiopathic chronic non-obstructive urinary retention is inadequate in quality and quantity. So, this procedure should be used only in research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 Further research should ideally be in the form of randomised controlled trials. Details of patient selection, the procedure and long-term outcomes should be reported.

2 The condition, current treatments and procedure

The condition

2.1 Idiopathic non-obstructive urinary retention is the inability to completely empty the bladder when there is no physical obstruction (in the urethra or bladder neck) to normal urine flow. It can be caused by urethral sphincter dysfunction. This can be because of dysfunctional voiding, urethral sphincter hyperactivity or inadequate relaxation of the urethral sphincter (for example, Fowler's syndrome in younger women), or bladder functional problems (detrusor muscle underactivity, or detrusor hyperreflexia and inadequate contractility). But the specific underlying cause of the condition is unknown. Idiopathic non-obstructive urinary retention is often asymptomatic, but some people have lower abdominal discomfort and pain. Also, it can cause complications such as recurrent urinary tract infections and chronic kidney disease.

Current treatments

2.2 Current treatments for non-obstructive urinary retention include urotherapy (that is, education and rehabilitation for bladder and bowel management), an alpha-adrenoreceptor blocker medicine, urethral dilatation or clean intermittent catheterisation. When the condition is refractory to these treatments, it may be treated with sacral nerve stimulation or urinary diversion procedures.

The procedure

2.3 Botulinum toxin type A injection into the urethral sphincter for idiopathic chronic non-obstructive urinary retention is usually done under electromyography, or electrical stimulation and cystoscopy guidance. It is usually done with the person awake and lying in the lithotomy position. A local anaesthetic may be used. Botulinum toxin type A diluted with normal saline is injected directly into the external urethral sphincter using a syringe needle. A transperineal route is used in women and a transurethral route is used in men.

2.4 The dose and number of injections used, and the depth and the position of injections on the endoscopic ultrasound, vary and depend on the discretion of the clinician. After the treatment, an overnight catheter is inserted for drainage. People are discharged from hospital the next day and have oral antibiotics for a week. The aim of the procedure is to relax the sphincter muscle and restore voiding function. It may be repeated every few months.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from

6 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 5 case series. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: symptom relief, improvement in quality of life, a reduction in the need and frequency of self-catheterisation, improved bladder emptying and a reduction in the need for further procedures.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, stress urinary incontinence, bladder outlet obstruction and botulinum toxicity.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was informed that a multidisciplinary team should decide who the procedure is suitable for.

3.6 Women have the procedure more commonly than men.

3.7 The procedure is most likely to be useful in people with sphincter overactivity.

3.8 The randomised controlled trial evidence was from people with a mixed group of indications.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
December 2022

ISBN: