NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance

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www.nice.org.uk/guidance/htg685

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG766.

1 Recommendations

1.1 For people with idiopathic chronic non-obstructive urinary retention caused by external urethral sphincter dysfunction (also known as Fowler's syndrome in younger women and people with female anatomy, primary disorder of urethral sphincter relaxation or high-tone non-relaxing urethral sphincter), botulinum toxin type A injections into the urethral sphincter should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wanting to do botulinum toxin type A injections into the urethral sphincter for idiopathic chronic non-obstructive urinary retention because of external urethral sphincter dysfunction should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people and their families understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team.

1.5 The procedure should only be done in a specialist centre by clinicians with expertise in managing the condition.

1.6 For people with idiopathic chronic non-obstructive urinary retention from all other causes, botulinum toxin type A injections into the urethral sphincter should be used only in research. Find out what only in research means on the NICE guidance page.

1.7 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.

Why the committee made these recommendations

External urethral sphincter dysfunction is rare, and evidence from observational studies suggests that the procedure may improve symptoms. But there are uncertainties about how well it works and how safe it is in the long term. So, it should only be used with special arrangements for external urethral dysfunction.

Evidence on the safety and efficacy of botulinum toxin type A injections into the urethral sphincter for idiopathic chronic non-obstructive urinary retention from all other causes is inadequate in quality and quantity. So, it should only be used in research when there are other causes.

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 and people with female anatomy), 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 as an outpatient procedure with the person awake and lying in the lithotomy position. A local anaesthetic is used

on either side of the external meatus. Botulinum toxin type A diluted with normal saline is injected directly into the external urethral sphincter using a syringe needle. A transperineal route (guided by electromyography) is used in women and a transurethral route (using electrical stimulation and cystoscopy guidance) 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. People 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 8 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial and 7 case series. It is presented in the summary of key evidence section in the 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 Four commentaries from patients who had experience of this procedure were received as part of public consultation, which were discussed by the committee.

Committee comments

3.5 Idiopathic chronic non-obstructive urinary retention is not included in the therapeutic indications for botulinum toxin type A.

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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 766 has been migrated to HealthTech guidance 685. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.