

NICE interventional procedures consultation document, September 2024

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Electrically stimulated intravesical therapy for interstitial cystitis or overactive bladder in adults

Interstitial cystitis (also known as bladder pain syndrome) is a chronic inflammatory condition of the bladder. Symptoms include pelvic pain, a strong urge to urinate, frequent urination and excessive urination at night. Overactive bladder also causes a strong urge to urinate, usually with frequent urination and excessive urination at night, with or without involuntary urination. In this procedure, a solution containing medicine, or a mixture of medicines, is put into the bladder (intravesical) using a thin tube (catheter) inserted through the urethra (the tube that carries urine from the bladder out of the body). A generator connected to the catheter by a wire is used to deliver a small electrical current (electrically stimulated) to the end of the catheter in the bladder. The aim of this procedure is to increase the amount of medicine that is absorbed, so the medicines work better than in procedures without electrical current.

NICE is looking at electrically stimulated intravesical therapy for interstitial cystitis or overactive bladder.

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This document contains the [draft guidance for consultation](#).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.

NICE interventional procedures consultation document, September 2024

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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 26 September 2024

Target date for publication of guidance: February 2025

NICE interventional procedures consultation document, September 2024

1 Draft recommendations

- 1.1 [More research is needed](#) on electrically stimulated intravesical therapy to manage the symptoms of interstitial cystitis or overactive bladder in adults before it can be used in the NHS.
- 1.2 This procedure should only be done as part of a formal research study and a research ethics committee needs to have approved its use.

What research is needed

- 1.3 More research, ideally in the form of adequately powered randomised controlled trials with an appropriate comparator, is needed on:
- patient selection
 - the medicines used
 - the duration and number of treatments
 - effect on quality of life
 - duration of symptom relief
 - adverse events, including potential long-term complications.

Why the committee made these recommendations

There are no major safety concerns for this procedure. But there is very limited evidence of its efficacy. The evidence comes from studies that include small numbers of people. Also, the studies each use different medicines and vary in the number of repeat procedures people had. This makes the evidence uncertain. This procedure has the potential to address an unmet need for treatments for interstitial cystitis and overactive bladder, which can be debilitating conditions. Overall, there is not enough good quality evidence on the efficacy of this procedure. So, it should only be used in research.

2 The condition, current treatments and procedure

The condition

- 2.1 Interstitial cystitis, also known as bladder pain syndrome, is a chronic inflammatory condition of the bladder. The main symptoms are pelvic pain, urinary urgency, urinary frequency and nocturia. Symptoms can last for several months or years. It is diagnosed by exclusion and is challenging to treat.
- 2.2 Overactive bladder is defined as urinary urgency, usually with urinary frequency and nocturia, with or without urinary incontinence. In some people, it is accompanied by uncontrolled contractions of the detrusor muscle during bladder filling, called detrusor overactivity. It is diagnosed based on symptoms and is challenging to treat.

Current treatments

- 2.3 Current treatments for both conditions aim to reduce symptoms.
- 2.4 For interstitial cystitis, current treatment options are:
- lifestyle changes, such as dietary changes and stopping smoking
 - medication
 - intravesical therapy
 - intradetrusor botulinum toxin injection
 - neuromodulation
 - sacral nerve stimulation
 - cystoscopy plus hydrodistension.
- 2.5 For overactive bladder, current treatment options are:

NICE interventional procedures consultation document, September 2024

- physical therapies, such as pelvic floor muscle training
- medication
- intravesical therapy
- intradetrusor botulinum toxin injection
- sacral nerve stimulation.

The procedure

- 2.6 The procedure is done using topical local anaesthesia with the person lying in a supine position. An electrode catheter is inserted into the person's bladder through the urethra. The bladder is flushed and drained. A medicine solution is then instilled into the bladder. Electrode pads are placed on the person's skin. The cutaneous and intravesical electrodes are then connected to a generator, which releases electrical current, transmitted to the intravesical electrode. After the procedure, the bladder is drained, and the catheter is removed.
- 2.7 There are different medicine solutions that can be instilled for the procedure.
- 2.8 The procedure aims to increase the amount of the medicine absorbed compared with procedures without electrical stimulation.

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 5 sources on interstitial cystitis, and 4 sources on overactive bladder, which was discussed by the committee. The evidence on interstitial cystitis included 1 randomised prospective study, 2 cohort studies, 1 single-arm trial and 1 case report. The evidence

NICE interventional procedures consultation document, September 2024

on overactive bladder included 4 prospective cohort studies. 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 committee considered the key efficacy outcomes to be patient reported outcomes, quality of life and an extended period of symptomatic relief.

3.3 Patient commentary was sought but none was received.

Committee comments

3.4 The committee noted that the evidence for this procedure was mixed and included different medicines and variations in electric current, duration of procedure and the number of procedures per person.

3.6 The committee was informed that the procedure needs to be repeated multiple times, and this may be needed frequently.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

August 2024

ISBN: