NICE National Institute for Health and Care Excellence

NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg799

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.

1 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 evidence generation and research is needed

1.3 More research and evidence generation, 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

- medicine
- intravesical therapy
- intradetrusor botulinum toxin injection
- neuromodulation
- sacral nerve stimulation
- cystoscopy plus hydrodistension.

2.5 For overactive bladder, current treatment options are:

- physical therapies, such as pelvic floor muscle training
- medicine
- 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 generates an 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 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.

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

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.