

Electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg638

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.

This guidance replaces IPG277.

1 Recommendations

- 1.1 Current evidence on electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer shows there are no major safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.
- 1.2 Further research should include randomised controlled trials compared with standard care, which should report details of patient selection.

2 The condition, current treatments and procedure

The condition

- 2.1 The most common form of bladder cancer is transitional cell carcinoma (TCC). Non-muscle-invasive TCC is classified as stage Ta when the tumour is confined to the urothelium with no spread into the wall of the bladder or beyond, and stage T1 when there is spread into the

connective tissue layer between the urothelium and the muscle wall. It is graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Another type of non-muscle-invasive cancer is carcinoma in situ, in which aggressive cancer cells spread within the surface lining of the bladder.

Current treatments

- 2.2 Conventional treatment for non-muscle-invasive cancer is transurethral resection of bladder tumour (TURBT), in which malignant tissue is removed with an electrocautery device during cystoscopy. Intravesical chemotherapy with Bacillus Calmette-Guérin (BCG) vaccine or other chemotherapeutic drugs may also be used. The drug is instilled directly into the bladder, either alone or as adjuvant therapy after TURBT. The aim is to reduce the risk of cancer recurrence. Intravesical microwave hyperthermia may also be used, in combination with intravesical chemotherapy. Cystectomy may be needed in some patients.

The procedure

- 2.3 Electrically stimulated intravesical chemotherapy (also known as electromotive drug administration) can be used as neoadjuvant treatment before TURBT, or as adjuvant treatment after TURBT. The procedure involves the use of a device to create an electric field across the bladder wall, with the aim of stimulating directional ionic and solute movement of the intravesical fluid. This increases absorption of the drug into the bladder lining.
- 2.4 The procedure is usually done using local anaesthesia. With the patient in a supine position, electrode pads are placed on the skin of the lower abdomen and a catheter (with an intravesical electrode) is inserted into the bladder through the urethra. When the catheter and electrodes are in place the chemotherapeutic drug solution (usually mitomycin C in saline or distilled water) is instilled into the bladder through the catheter. The cutaneous and intravesical electrodes are connected to a generator that creates a current of up to 25 milliamps. Treatment sessions last about 30 minutes and are repeated, often weekly, for 4 to 8 weeks or longer for

adjuvant treatment. After the procedure, the bladder is drained and the catheter is removed.

3 Committee considerations

The evidence

- 3.1 To inform the committee, 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 systematic review, 2 non-randomised controlled trials and 3 case series and is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: time to disease progression, progression-free survival and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: infection and bleeding.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that the procedure may have a role when treatment with Bacillus Calmette-Guérin (BCG) vaccine is contraindicated or has been unsuccessful, and in patients who are unable to have a cystectomy.
- 3.6 The committee noted that the authors of the Cochrane review described the studies for this procedure as being poorly reported.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).