

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transurethral laser ablation for recurrent non-muscle-invasive bladder cancer

Non-muscle-invasive bladder cancer is present only in the lining of the bladder. It has not grown into the deeper muscle layer. In this procedure, a tube with a camera (cystoscope) is inserted into the bladder through the tube that carries urine out of the body from the bladder (urethra). A laser within the cystoscope is then used to destroy the cancer cells.

The National Institute for Health and Care Excellence (NICE) is looking at transurethral laser ablation for recurrent non-muscle-invasive bladder cancer. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

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

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our

interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations 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: 18 April 2019

Target date for publication of guidance: July 2019

1 Draft recommendations

- 1.1 The evidence on the safety of transurethral laser ablation for recurrent non-muscle-invasive bladder cancer shows that there are no major safety concerns. However, current evidence on its efficacy is limited in quality and quantity. Therefore, this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to do transurethral laser ablation for recurrent non-muscle-invasive bladder cancer should:
- Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information to support [shared decision making](#). In addition, the use of NICE's [information for the public](#) is recommended.

- Audit and review clinical outcomes of all patients having transurethral laser ablation for recurrent non-muscle-invasive bladder cancer. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

- 1.3 Patient selection should be done by a specialist bladder cancer multidisciplinary team.
- 1.4 NICE encourages further research and prospective data collection into transurethral laser ablation for recurrent non-muscle-invasive bladder cancer. Studies should investigate patient selection, types of laser used, tumour recurrence and long-term follow up.

2 The condition, current treatments and procedure

The condition

- 2.1 The most common form of bladder cancer is transitional cell carcinoma. Non-muscle-invasive transitional cell carcinoma is classified as stage Ta when it is confined to the uroepithelium and stage T1 when it has spread into the connective tissue layer between the urothelium and the muscle wall. Non-muscle-invasive transitional cell carcinomas usually appear as small growths from the bladder lining. They can be graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Carcinoma in situ consists of aggressive cancer cells that spread within the surface lining of the bladder and appear flat. It is more likely to recur after removal.

Current treatments

- 2.2 NICE's guideline on [bladder cancer](#) describes its diagnosis and management. Surgical interventions for non-muscle-invasive transitional cell carcinoma include transurethral resection, in which

malignant tissue is removed with an electrocautery device during cystoscopy. Bacillus Calmette-Guérin (BCG) vaccine or chemotherapy drugs may be put directly into the bladder, either as treatments in themselves or as adjuvant therapy after transurethral resection. Cystectomy may also be necessary in some patients.

The procedure

- 2.3 This procedure is most often used for very small, recurrent bladder tumours. It is usually done as day surgery using local anaesthesia. A flexible cystoscope is passed through the urethra into the bladder. The tumours are then ablated using a laser fibre contained in the cystoscope.
- 2.4 If there is a lot of bleeding after the procedure, a urinary catheter may be inserted to allow bladder irrigation.
- 2.5 The aim is to destroy the tumour with less morbidity than is seen with conventional treatments. The suggested benefits over cystodiathermy include less bleeding and reduced pain.

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 9 sources, which was discussed by the committee. The evidence included 6 case series, 2 non-randomised comparative studies and 1 case report, 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: patient-reported outcome measures, tumour ablation, reduction in tumour recurrence rates and survival.

- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: bleeding, pain and bladder perforation.

Committee comments

- 3.4 The committee was informed that this procedure is used in 2 distinct groups of patients: those with small superficial tumours in whom the intention is to completely ablate the tumour; and for symptom control in those with more advanced disease who are unfit for, or unwilling to have, surgery.
- 3.5 The technology used in this procedure is evolving.
- 3.6 A chemical may be instilled into the bladder to aid with tumour detection, using a blue light.

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Chairman, interventional procedures advisory committee

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