

Transvaginal laser therapy for stress urinary incontinence

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg696

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 The evidence on transvaginal laser therapy for stress urinary incontinence does not show any short-term safety concerns. Evidence on long-term safety and efficacy is inadequate in quality and quantity. 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 report long-term safety and efficacy outcomes, the type of laser and energy used, treatment protocols, and patient selection including age, menopausal status and severity of stress urinary incontinence.
- 1.3 NICE encourages further research into transvaginal laser therapy for stress urinary incontinence and may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

- 2.1 Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements, such as coughing, sneezing and laughing. In women, it is most commonly associated with previous pregnancy, with or without recognised obstetric trauma. Previous urogynaecological surgery may also result in stress urinary incontinence.

Current treatments

- 2.2 [NICE's guideline on urinary incontinence and pelvic organ prolapse](#) makes recommendations for the management of urinary incontinence in women, accompanied by a [patient decision aid to promote shared decision making](#). Conventional treatment is conservative and includes lifestyle changes, such as weight loss and pelvic floor muscle training. Surgical options are only offered if conservative measures do not help.

The procedure

- 2.3 Transvaginal laser therapy for stress urinary incontinence is done as an outpatient procedure and can be done without anaesthetic. A laser-probe device is inserted into the vagina to apply laser energy to the vaginal wall. The laser causes a controlled thermal injury, which is claimed to promote tissue remodelling and the production of new collagen. Treatment typically consists of 3 sessions at 4 to 6 weeks apart. The aim is to improve the support to the bladder and reduce the symptoms of stress urinary incontinence.
- 2.4 There are different types of lasers used for this procedure, including carbon dioxide (CO₂) and erbium-doped yttrium aluminium garnet (Er:YAG) lasers. The type of laser and the energy level used have different tissue penetration and can cause different types of thermal injury.

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 14 sources, which was discussed by the committee. The evidence included 1 systematic review, 2 randomised controlled trials (1 of which is also included in the systematic review), 1 non-randomised comparative

study, 6 case series (4 of which are also included in the systematic review) and 3 case reports. In addition, there are data from a survey of 535 sites with 113,174 patients. The evidence 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 professional experts and the committee considered the key efficacy outcomes to be: subjective and objective measures of stress urinary incontinence, and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: vaginal discharge, ulceration, scarring, de novo urge incontinence, and fistula.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that continuation of pelvic floor exercises is important in the management of stress urinary incontinence.
- 3.6 The committee was informed that this procedure has been done in a large number of patients and it was disappointed with the level of published evidence on the procedure's long-term efficacy.

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Endorsing organisation

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