NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transvaginal laser therapy for stress urinary incontinence

Stress urinary incontinence causes urine to leak when you exercise, cough, laugh or sneeze. In this procedure, a device containing a laser is inserted into the vagina (transvaginal). The laser heats the tissue of the vaginal wall, causing changes to its structure. It is thought that this could improve support to the bladder. The aim is to reduce the symptoms of stress urinary incontinence.

NICE is looking at transvaginal laser therapy for stress urinary incontinence.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the draft guidance for consultation.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.

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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 12 February 2021

Target date for publication of guidance: May 2021

1 Draft recommendations

1.1 Evidence on the long-term safety and efficacy of transvaginal laser therapy for stress urinary incontinence 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 CO_2 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 11 sources, which was discussed by the committee. The evidence included 2 randomised controlled trials, 1 non-randomised comparative study, 6 case series and 2 case reports. 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 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.

NICE interventional procedures consultation document, January 2021

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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