NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transvaginal laser therapy for urogenital atrophy

Urogenital atrophy is thinning, drying and inflammation of the tissues around the vaginal area. It most often happens after the menopause and can cause itching, burning and painful sexual intercourse. 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 that are thought to increase the strength and elasticity of the vagina. The aim is to improve the symptoms of urogenital atrophy.

NICE is looking at transvaginal laser therapy for urogenital atrophy.

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This document contains the draft guidance for consultation.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 The draft guidance may change after this consultation.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- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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 urogenital atrophy 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 be randomised controlled trials and report details of patient selection, treatment protocols, and long-term safety and efficacy outcomes.

1.3 NICE encourages further research into transvaginal laser therapy for urogenital atrophy and may update the guidance on publication of further evidence.

2 The condition, current treatments and procedure

The condition

2.1 Urogenital atrophy most often happens during or after the menopause. Lack of the hormone oestrogen leads to thinning of the tissues around the vaginal area and reduction in the number of mucus-producing glands. The most common symptoms affect the vulva and vagina including dryness, pain on sexual intercourse, itching and vaginal discharge. There is increased vulnerability to inflammation, trauma and infection. Urogenital atrophy can also result in urinary symptoms, such as urgency to urinate and urinary tract infections.

Current treatments

2.2 NICE's guideline on diagnosis and management of menopause describes the management of menopausal symptoms. The main treatments for urogenital atrophy are vaginal oestrogen, and non-hormonal lubricants and moisturisers.

The procedure

2.3 Transvaginal laser therapy for urogenital atrophy 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 controlled thermal injury, which is claimed to make the tissue remodel, improve tissue elasticity and stimulate the production of new collagen. Treatment typically consists of 3 sessions at 4 to 6 weeks apart. The aim is to reduce the symptoms of urogenital atrophy.

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 systematic reviews, 4 randomised controlled trials, 1 non-randomised comparative study and 4 case series. 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: improvement in symptoms of dryness or atrophy, dyspareunia, itching or burning, measures of vaginal health and sexual functioning, and patient satisfaction.

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 was informed that the procedure may have a role for patients who are unable to use topical oestrogen.

3.6 The committee was informed that patients may need repeated courses of treatment at regular intervals.

NICE interventional procedures consultation document, January 2021

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Chair, interventional procedures advisory committee
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