

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

High-intensity focused ultrasound for symptomatic benign thyroid nodules

A thyroid nodule is a lump in the thyroid gland. Most are benign (not cancerous). This procedure uses heat generated by high-frequency sound waves to destroy tissue in the nodule. The aim is to make the nodule smaller, to relieve pressure symptoms and improve appearance.

The National Institute for Health and Care Excellence (NICE) is looking at high-intensity focused ultrasound for symptomatic benign thyroid nodules. 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: 22 November 2018

Target date for publication of guidance: February 2019

1 Draft recommendations

1.1 The evidence on the safety of high-intensity focused ultrasound for symptomatic benign thyroid nodules raises no major safety concerns. Current evidence on its efficacy is limited in quantity and quality. Therefore, this procedure should only be used with [special arrangements](#) for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do high-intensity focused ultrasound for symptomatic benign thyroid nodules should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear written information to support [shared](#)

[decision-making](#). In addition, the use of NICE's [information for the public](#) [URL to be added at publication] is recommended.

- Audit and review clinical outcomes of all patients having high-intensity focused ultrasound for symptomatic benign thyroid nodules. 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 Further research should report details of patient selection, nodule size and position, and whether the nodule is cystic.

2 The condition, current treatments and procedure

The condition

2.1 Thyroid nodules may be cystic, colloid, hyperplastic, adenomatous or cancerous. Most thyroid nodules are benign and are usually asymptomatic. There may be a single thyroid nodule (solitary nodule) or multiple thyroid nodules (multinodular goitre). Some thyroid nodules produce thyroxine or triiodothyronine and cause thyrotoxicosis. These are called hyper-functioning or toxic thyroid nodules.

Current treatments

2.2 Treatment of benign thyroid nodules may be needed if they cause symptoms or cosmetic problems. Conventional treatment includes levothyroxine to suppress thyroid-stimulating hormone (TSH)-stimulated growth of thyroid tissue or surgery. Other less invasive approaches than surgery include ethanol ablation, percutaneous laser ablation, radiofrequency ablation and microwave ablation.

The procedure

- 2.3 High-intensity focused ultrasound is a minimally invasive technique that aims to reduce symptoms and improve cosmetic appearance, while preserving thyroid function, and with fewer complications than surgery.
- 2.4 High-intensity focused ultrasound for symptomatic benign thyroid nodules is usually done using sedation and systemic analgesia, in an outpatient setting. The patient is placed in the supine position with moderate neck extension. The focused ultrasound device is positioned on the patient's neck to deliver the treatment and allow for simultaneous imaging of the treatment area. The technology uses high-energy sound waves that pass through the tissues, generating local heat and inducing coagulative necrosis, protein denaturation and cellular destruction. A strong acute inflammatory response follows. The treatment duration depends on the nodule size.

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 8 sources, which was discussed by the committee. The evidence included 1 systematic review, 4 comparative studies and 3 case series, and is presented in table 2 of the [interventional procedures overview \[add URL\]](#). 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: nodule volume reduction and improvement of nodule-related symptoms.

- 3.3 The specialist advisers and the committee considered the key safety outcomes to be: pain, damage to the recurrent laryngeal nerve and to other adjacent structures.

Committee comments

- 3.4 Patients should have appropriate assessment in a thyroid clinic to exclude malignancy.
- 3.5 The committee was informed that there was an upper limit to the size of nodules that have been treated with this procedure, but the software used for this procedure is continuously improving and bigger nodules can now be treated.
- 3.6 The committee noted that the procedure is not an effective treatment for hyper-functioning nodules causing thyrotoxicosis.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

October, 2018

ISBN: