

High-intensity focused ultrasound for symptomatic benign thyroid nodules

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg643

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 the safety of high-intensity focused ultrasound for symptomatic benign thyroid nodules raises no major safety concerns, however the 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. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 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 on high-intensity focused ultrasound for symptomatic benign thyroid nodules 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 has developed an audit tool (which is for use at local discretion).
- 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 hyperfunctioning 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 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](#). 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.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 Patients should have assessment in a thyroid clinic to exclude malignancy.
- 3.6 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.
- 3.7 The committee noted that there is little evidence for using the procedure in treating thyrotoxicosis caused by hyperfunctioning nodules.

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Endorsing organisation

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