

Real-time ultrasound elastography in the diagnosis of newly identified thyroid nodules in adults: the ElaTION RCT

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Published August 2024
DOI: 10.3310/PLEQ4874

Scientific summary

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Health Technology Assessment 2024; Vol. 28: No. 46
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Scientific summary

Background

Strain elastography (STE) which is commonly used with concurrent real-time imaging known as real-time elastography (RTE) and shear wave elastography (SWE) are new diagnostic techniques that have been reported to be useful in the diagnosis of nodules in several organs. There is conflicting evidence regarding its benefit over ultrasound-guided fine-needle aspiration cytology (US-FNAC) alone in thyroid nodules.

Objectives

The primary objective was to determine if strain/shear wave ultrasound elastography (USE) in conjunction with FNAC will reduce the number of patients with thyroid nodules who have a non-diagnostic first FNAC result as compared to conventional ultrasound (US)-only guided FNAC.

Design

ElaTION was a pragmatic, multicentre randomised controlled trial.

Setting

Eighteen centres with a radiology department across England.

Participants

Adults with thyroid nodules who had not undergone previous FNAC with single or multiple nodules undergoing investigation.

Interventions

Ultrasound shear/strain wave elastography-US guided FNAC (intervention arm) – strain or shear wave elastography (USE)-guided FNAC. US-only guided FNAC (control arm) – routine US-only guided FNAC (the current standard recommended by the British Thyroid Association guidelines).

Main outcome measures

Primary outcome

The proportion of patients who have a non-diagnostic cytology (Thy 1) result following the first FNAC.

Secondary outcomes

The number of FNACs required to obtain a definitive diagnosis; time from first FNAC to a definitive diagnosis; the false-positive rate of nodules; the number of patients who have a non-diagnostic cytology result following any FNAC; the proportion of patients undergoing thyroidectomy; accuracy of US alone

(overall); accuracy of first FNAC; accuracy of USE or US without FNAC compared to accuracy of USE or US with FNAC; and patient reported anxiety, pain and quality of life [by the Hospital Anxiety and Depression Scale (HADS), Visual Analogue Pain Scale (VAPS) and EuroQol (EQ)-5D questionnaire at baseline, 3, 6 and 12 months post randomisation].

Results

A total of 982 participants were randomised: 493 were randomised to USE-US guided FNAC and 489 were randomised to US-only guided FNAC. There was no evidence of a difference between USE and US in non-diagnostic (Thy 1) rate following the first FNAC [19% vs. 16% respectively; risk difference (RD): 0.030; 95% confidence interval (CI), -0.007 to 0.066; $p = 0.11$], the number of FNACs needed [odds ratio (OR): 1.10; 95% CI, 0.82 to 1.49; $p = 0.53$] or in the time to reach a definitive diagnosis [hazard ratio (HR): 0.94; 95% CI, 0.81 to 1.10; $p = 0.45$]. There was a small, non-significant reduction in the number of thyroid operations undertaken when USE was used (37% vs. 40% respectively; RD: -0.02; 95% CI, -0.06 to 0.009; $p = 0.15$), but no difference in the number of operations yielding benign histology - 23% versus 24% respectively, $p = 0.70$ (i.e. no increase in identification of malignant cases) - or in the number of serious adverse events (2% vs. 1%). There was no difference in anxiety and depression, pain or quality of life between the two arms.

Limitations

The study was not powered to detect differences in malignancy.

Conclusions

Ultrasound shear/strain wave elastography does not appear to have additional benefit over US-FNAC in the diagnosis of thyroid nodules.

Study registration

This study is registered as ISRCTN (ISRCTN18261857).

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 12/19/04) and is published in full in *Health Technology Assessment*; Vol. 28, No. 46. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

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This article

The research reported in this issue of the journal was funded by the HTA programme as award number 12/19/04. The contractual start date was in April 2014. The draft manuscript began editorial review in October 2022 and was accepted for publication in April 2023. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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