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

Hisham Mehanna,^{1*} Jonathan J Deeks,² Kristien Boelaert,³ Gitta Madani,⁴ Paul Sidhu,⁵ Paul Nankivell,¹ Neil Sharma,⁶ Rebecca Woolley,² Judith Taylor,⁷ Tessa Fulton-Lieuw¹ and Andrew Palmer²

Published August 2024 DOI: 10.3310/PLEQ4874

Plain language summary

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

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

DOI: 10.3310/PLEQ4874

NIHR Journals Library www.journalslibrary.nihr.ac.uk

¹Institute of Head and Neck Studies and Education, University of Birmingham, Birmingham, UK

²Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK

³Institute of Applied Health Research, University of Birmingham, Birmingham, UK

⁴Imperial College Healthcare NHS Trust, London, UK

⁵King's College Hospital NHS Foundation Trust, London, UK

⁶Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, UK ⁷The Thyroid Trust, London, UK

^{*}Corresponding author h.mehanna@bham.ac.uk

Plain language summary

About half the population will have lumps in their thyroid if examined by an ultrasound scan but may not know they have one. About one in twenty people will feel a thyroid lump in their neck at some time in their life, with about one in twenty of those being malignant. Currently, the recommended way of getting a diagnosis of thyroid nodules is by using ultrasound to guide a needle to get cells from the lump, called ultrasound-guided fine-needle aspiration cytology. These cells are examined to determine the cause of the lump. If there are enough cells, Doctors can then make a diagnosis of whether the lump is benign or malignant. If not, patients will undergo another ultrasound-guided fine-needle aspiration cytology. One in five ultrasound-guided fine-needle aspiration cytologies are non-diagnostic with an overall false-positive rate of approximately 24%. This means one in five patients, with benign disease, may undergo unnecessary diagnostic operations. Thyroid surgery carries risks of complications, which could be avoided if we had better ways to diagnose which patients actually need an operation.

We conducted a randomised trial, ElaTION, to determine if a new technology called strain and shear wave elastography, commonly known as real-time elastography, would be better at helping the radiologist take a sufficient sample of cells and reduce the number of non-diagnostic results, reducing the number of fine-needle aspiration cytologies required to make a definitive diagnosis.

Nine hundred eighty-two patients were recruited between 2015 and 2018 and followed up until the end of the trial. Patients were randomised into two groups: 489 patients received the standard ultrasound-guided fine-needle aspiration cytology alone, and 493 patients received ultrasound-guided fine-needle aspiration cytology + shear wave elastography. Ultrasound shear/strain wave elastography did not reduce non-diagnostic cytology at first fine-needle aspiration cytology or improve the likelihood of determining whether the lump is benign or malignant.

The results of ElaTION do not support the use of shear wave elastography-fine-needle aspiration cytology in the diagnosis of thyroid nodules.

Health Technology Assessment

ISSN 2046-4924 (Online)

Impact factor: 3.6

A list of Journals Library editors can be found on the NIHR Journals Library website

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2022 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), EMBASE (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the Health Technology Assessment journal

Manuscripts are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

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.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the HTA programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Copyright © 2024 Mehanna et al. This work was produced by Mehanna et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: https://creativecommons.org/licenses/by/4.0/. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).