Laparoscopic supracervical hysterectomy compared with second-generation endometrial ablation for heavy menstrual bleeding: the HEALTH RCT

Kevin Cooper, 1* Suzanne Breeman, 2 Neil W Scott, 3 Graham Scotland, 2,4 Rodolfo Hernández, 4 T Justin Clark, 5 Jed Hawe, 6 Robert Hawthorn, 7 Kevin Phillips, 8 Samantha Wileman, 2 Kirsty McCormack, 2 John Norrie 9 and Siladitya Bhattacharya 1,10 on behalf of the HEALTH Study Group

¹NHS Grampian, Aberdeen Royal Infirmary, Aberdeen, UK

Declared competing interests of authors: T Justin Clark reports grants and personal fees from Hologic Inc. (Santa Clara, CA, USA), outside the submitted work, and membership of the Health Technology Assessment (HTA) Prioritisation Committee. John Norrie declares grants from the University of Aberdeen and the University of Edinburgh during the conduct of the study, and membership of the following National Institute for Health Research (NIHR) boards: HTA Commissioning Board (2010–16); NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2014–19); HTA Commissioning Sub-board (Expression of Interest) (2016–present); HTA Funding Boards Policy Group (2016–present); HTA General Board (2016–present); HTA Post-board Funding Teleconference (2016–present); the Pre-exposure Prophylaxis Impact Review Panel (2018); and the NIHR Clinical Trials Unit Standing Advisory Committee (2018–present). Siladitya Bhattacharya is the Editor-in-Chief of *HROpen* and an Editor for *Cochrane Gynaecology and Fertility*.

Published September 2019

DOI: 10.3310/hta23530

²Health Services Research Unit, University of Aberdeen, Aberdeen, UK

³Medical Statistics Team, University of Aberdeen, Aberdeen, UK

⁴Health Economics Research Unit, University of Aberdeen, Aberdeen, UK

⁵Birmingham Women's NHS Foundation Trust, Birmingham Women's Hospital, Birmingham, UK

⁶Countess of Chester Hospital NHS Foundation Trust, Chester, UK

⁷NHS Greater Glasgow and Clyde, Southern General Hospital, Glasgow, UK

⁸Hull and East Yorkshire Hospitals NHS Trust, Castle Hill Hospital, Cottingham, UK

⁹Usher Institute of Population Health Sciences & Informatics, University of Edinburgh, Edinburgh, UK

¹⁰Institute of Applied Health Sciences, University of Aberdeen, Aberdeen, UK

^{*}Corresponding author kevincooper@nhs.net

Plain English summary

The HEALTH RCT

Health Technology Assessment 2019; Vol. 23: No. 53

DOI: 10.3310/hta23530

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

Plain English summary

Almost 1.5 million women in England and Wales suffer from heavy periods. Initial treatment involves tablets or a medicated coil inserted within the womb. Sometimes these treatments do not work and many women need an operation, either endometrial ablation (EA) (removing the lining of the womb) or a full hysterectomy (complete removal of the womb). Previous studies have shown that a full hysterectomy is better at relieving symptoms, but the risk of complications during surgery is higher and patients take longer to recover fully.

A newer operation, laparoscopic (keyhole) supracervical hysterectomy, or 'LASH', removes only the part of the womb that causes periods and preserves the cervix or neck of the womb. Women who have LASH can expect fewer complications, earlier discharge from hospital and quicker recovery time.

In this study, we compared EA with LASH by asking women who had either procedure how they felt about it 1 year after their operation.

Regardless of which operation they had, most women were very satisfied and felt that their symptoms were better. However, the results were much better for those who had the LASH operation, although these women stayed in hospital for longer and took more time to recover. There was no difference in complications from either surgery, although nearly 1 in 20 women who had an EA returned within 1 year to have their wombs removed in a second operation.

Although LASH led to a greater improvement in symptoms and levels of satisfaction, it was more expensive in terms of costs incurred by both the health service and society. Given that some women who had an EA are likely to need a second operation in the future, LASH surgery may provide better value for money in the long term.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index

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. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the Health Technology Assessment journal

Reports 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 report

The research reported in this issue of the journal was funded by the HTA programme as project number 12/35/23. The contractual start date was in January 2014. The draft report began editorial review in October 2018 and was accepted for publication in February 2019. 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' report 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 report.

This report presents independent research funded by the National Institute for Health 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, NETSCC, 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, NETSCC, the HTA programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2019. This work was produced by Cooper et al. under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

NIHR Journals Library Editor-in-Chief

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

NIHR Journals Library Editors

Professor John Powell Chair of HTA and EME Editorial Board and Editor-in-Chief of HTA and EME journals. Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK, and Senior Clinical Researcher, Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals) and Editor-in-Chief of HS&DR, PGfAR, PHR journals

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont Director, NIHR Dissemination Centre, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Ken Stein Professor of Public Health, University of Exeter Medical School, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

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