Surgical interventions for uterine prolapse and for vault prolapse: the two VUE RCTs

Christine Hemming,1* Lynda Constable,2 Beatriz Goulao,2 Mary Kilonzo,3 Dwayne Boyers,3 Andrew Elders,4 Kevin Cooper,1 Anthony Smith,5 Robert Freeman,6 Suzanne Breeman,2 Alison McDonald,2 Suzanne Hagen,4 Isobel Montgomery,7 John Norrie8 and Cathryn Glazener2

1Aberdeen Royal Infirmary, NHS Grampian, Aberdeen, UK
2Health Services Research Unit, University of Aberdeen, Aberdeen, UK
3Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
4Nursing, Midwifery and Allied Health Professionals Research Unit (NMAHP RU), Glasgow Caledonian University, Glasgow, UK
5St Mary’s Hospital, Central Manchester University Hospitals NHS Foundation Trust, Manchester, UK
6Derriford Hospital, Plymouth NHS Trust, Plymouth, UK
7Independent patient representative, c/o Health Services Research Unit, Aberdeen, UK
8Usher Institute of Population Health Sciences and Informatics, Edinburgh BioQuarter, University of Edinburgh, Edinburgh, UK

*Corresponding author christine.hemming@nhs.net

Declared competing interests of authors: Robert Freeman reports speaker fees [from Bard Medical (Covington, GA, USA), Astellas Pharma Inc. (Tokyo, Japan) and Pfizer Inc. (New York City, NY, USA)] and grants from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme. John Norrie reports membership of the following NIHR boards: the Cardiopulmonary Resuscitation Decision-making Committee, HTA Commissioning Board, HTA Commissioning Sub-Board (Expression of Interest), HTA Funding Boards Policy Group, HTA General Board and HTA Post-board Funding Teleconference; the NIHR Clinical Trials Unit Standing Advisory Committee; the NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board; and the Pre-exposure Prophylaxis Impact Review Panel.

Published March 2020
DOI: 10.3310/hta24130
Plain English summary

Surgical interventions for uterine prolapse and for vault prolapse
Health Technology Assessment 2020; Vol. 24: No. 13
DOI: 10.3310/hta24130

NIHR Journals Library www.journalslibrary.nihr.ac.uk
Plain English summary

About 1 in 10 women has pelvic organ prolapse (POP) surgery, and around three of these women require a further operation.

The aim of this study was to identify the most appropriate surgery for two different types of POP found in women: (1) when the uterus itself has come down – the Uterine trial – and (2) when a previous hysterectomy has resulted in the top of the vagina coming down – the Vault trial.

In the Uterine trial, preserving the uterus was compared with removing it vaginally. In the Vault trial, uplifting and supporting the vault prolapse using an abdominal approach was compared with a vaginal approach. Women were asked about their prolapse and other symptoms affecting their quality of life (QoL).

The majority of women reported that their prolapse symptoms and QoL improved after surgery. The women’s prolapse was also measured by clinical examination before and 12 months after their operation. All of these results were compared between the different procedures.

It was found that all the surgical procedures were successful within the 12-month review period. Abdominal surgery in the Vault trial as well as any that was required in the Uterine trial, was, however, slightly less cost-effective.

Serious complications and the need for further prolapse surgery were similar in all groups. A small number of women did require additional surgery for prolapse recurrence or for small mesh exposure when additional or prolapse procedures had involved mesh.

Women in both trials will be followed up for at least 6 years to determine longer-term costs and consequences.
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 11/129/183. The contractual start date was in November 2012. The draft report began editorial review in February 2018 and was accepted for publication in August 2018. 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 2020. This work was produced by Hemming 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 Andréée 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