A pragmatic multicentre randomised controlled trial comparing stapled haemorrhoidopexy with traditional excisional surgery for haemorrhoidal disease: the eTHoS study

Angus JM Watson,1* Jonathan Cook,2 Jemma Hudson,3 Mary Kilonzo,4 Jessica Wood,3,5 Hanne Bruhn,3 Steven Brown,6 Brian Buckley,7 Finlay Curran,8 David Jayne,9 Malcolm Loudon,10 Ramesh Rajagopal,11 Alison McDonald3,5 and John Norrie3,5

1NHS Highland, Department of Surgery, Raigmore Hospital, Inverness, UK
2Oxford Clinical Trials Research Unit, University of Oxford, Oxford, UK
3Health Services Research Unit, University of Aberdeen, Aberdeen, UK
4Health Economics Research Unit, University of Aberdeen, Aberdeen, UK
5Centre for Healthcare Randomised Trials, Health Services Research Unit, University of Aberdeen, Aberdeen, UK
6Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK
7Department of Surgery, University of the Philippines Manila, Manila, the Philippines
8Central Manchester University Hospitals NHS Foundation Trust, Manchester, UK
9Leeds Teaching Hospitals NHS Trust, Leeds, UK
10NHS Highland, Department of Surgery, Belford Hospital, Fort William, UK
11Glan Clwyd Hospital, Betsi Cadwaladr University Health Board, North Wales, UK

*Corresponding author angus.watson@nhs.net

Declared competing interests of authors: Jonathan Cook reports membership of the Health Technology Assessment (HTA) Efficient Study Designs Board outside the submitted work; Malcolm Loudon states that between 2002 and 2004 his research fellowship was sponsored by Ethicon Inc. to carry out a randomised controlled trial evaluating rubber band ligation against stapled haemorrhoidopexy; he received no direct financial support. John Norrie reports membership of the National Institute for Health Research (NIHR) Journals Library Editorial Group; non-financial support from the HTA commissioning board; and is a member of the NIHR HTA Editorial Board.

Published November 2017
DOI: 10.3310/hta21700
Plain English summary

Haemorrhoids (or ‘piles’) are swellings of blood vessels inside the anus. Common symptoms include bleeding, pain, itch and swelling. Haemorrhoids are graded in severity based on symptoms and size, from grade I (small piles with mild symptoms) to grade IV (large piles and major symptoms).

Traditional surgery for haemorrhoids, called traditional haemorrhoidectomy (TH), involves removal of haemorrhoids and is generally used for larger piles. Newer surgical techniques have been created as a result of an increased understanding of haemorrhoids; the treatment stapled haemorrhoidopexy (SH) was conceived over 15 years ago. Its potential advantages include less pain and a quicker return to normal activities. In this study, we wanted to compare SH with TH.

Patients could take part in the study if they had grades II–IV piles and had not had surgery before.

In this study we randomly allocated patients to receive either SH or TH. During the course of the study we asked participants about their quality of life, symptoms, recurrence of their piles and if they received further treatment. We compared the results of the different operational procedures. Within the first 6 weeks after surgery, participants who had received SH had a better quality of life because they had less pain, but over 24 months, the TH group had better quality of life, fewer symptoms and fewer further procedures.
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

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

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.

For more information about the HTA programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hta

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/24/02. The contractual start date was in September 2016. The draft report began editorial review in October 2016 and was accepted for publication in April 2017. 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. 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.

© Queen’s Printer and Controller of HMSO 2017. This work was produced by Watson et al. under the terms of a commissioning contract issued by the Secretary of State for Health. 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).
Health Technology Assessment Editor-in-Chief

Professor Hywel Williams  Director, HTA Programme, UK and Foundation Professor and Co-Director of the Centre of Evidence-Based Dermatology, University of Nottingham, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley  Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein  Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

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

Dr Martin Ashton-Key  Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck  Chair in Public Sector Management and Subject Leader (Management Group), Queen's University Management School, Queen's University Belfast, UK

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson  Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, 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 John Powell  Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), 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 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 Jim Thornton  Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

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

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

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