The HubBLe Trial: haemorrhoidal artery ligation (HAL) versus rubber band ligation (RBL) for symptomatic second- and third-degree haemorrhoids: a multicentre randomised controlled trial and health-economic evaluation

Steven Brown,1 Jim Tiernan,2 Katie Biggs,3* Daniel Hind,3 Neil Shephard,3 Mike Bradburn,3 Allan Wailoo,3 Abualbisher Alshreef,3 Lizzie Swaby,3 Angus Watson,4 Simon Radley,5 Oliver Jones,6 Paul Skaife,7 Anil Agarwal,8 Pasquale Giordano,9 Marc Lamah,10 Mark Cartmell,11 Justin Davies,12 Omar Faiz,13 Karen Nugent,14 Andrew Clarke,15 Angus MacDonald,16 Phillip Conaghan,17 Paul Ziprin18 and Rohit Makhija19

1Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK
2Leeds Teaching Hospitals NHS Trust, Leeds, UK
3School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK
4NHS Highland, Inverness, UK
5University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK
6Oxford University Hospitals NHS Trust, Oxford, UK
7Aintree University Hospital NHS Foundation Trust, Liverpool, UK
8North Tees and Hartlepool NHS Foundation Trust, Stockton-on-Tees, UK
9Barts Health NHS Trust, London, UK
10Brighton and Sussex University Hospitals NHS Trust, Brighton, UK
11Northern Devon Healthcare NHS Trust, Devon, UK
12Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
13North West London Hospitals NHS Trust, London, UK
14University Hospital Southampton NHS Foundation Trust, Southampton, UK
15Poole Hospital NHS Foundation Trust, Poole, UK
16NHS Lanarkshire, Airdrie, UK
17Royal Berkshire NHS Foundation Trust, Reading, UK
18Imperial College Healthcare NHS Trust, London, UK
19Peterborough and Stamford Hospitals NHS Foundation Trust, Peterborough, UK

*Corresponding author
Declared competing interests of authors: Pasquale Giordano reports personal fees, from THD UK, outside the submitted work, and Paul Skaife is a member of the National Institute for Health Research Health Technology Assessment Elective and Emergency Specialist Care (EESC) panel.
Plain English summary

Background

There are many treatments for piles (haemorrhoids). In less-severe cases, one treatment is rubber band ligation (RBL), which involves placing a small band around the base of the pile to cut off the blood supply. RBL is a relatively painless outpatient treatment with minimal complications but recurrence is common. Haemorrhoidal artery ligation (HAL) uses a device to locate the arteries feeding the piles, which are then stitched. This procedure takes longer and is more painful but may reduce recurrence. We compared these two procedures to see which was best.

Results

One year after surgery, 49% of the patients had a recurrence of symptoms after RBL compared with 30% of patients undergoing HAL. About one-third of RBL patients, whose symptoms persisted, underwent a further surgical procedure, many having repeated RBL. If patients having further RBL are considered as having a ‘course’ of therapy then there was minimal difference between the treatments. Most patients initially felt better after surgery, but symptoms returned within the year. Symptom scores, quality of life, continence and complications were similar after both procedures. Those undergoing HAL tended to have more pain but the discomfort was not severe in the majority of patients and resolved by 1–3 weeks after the operation. HAL is much more expensive.

Conclusion

Haemorrhoidal artery ligation reduced recurrence compared with RBL, but these RBL recurrences can often be treated successfully by simple re-banding. A course of RBL, therefore, has similar recurrence rates to HAL. HAL is also more painful in the short term, waiting time is longer and it is more expensive.
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](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 10/57/46. The contractual start date was in June 2012. The draft report began editorial review in March 2016 and was accepted for publication in July 2016. 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 2016. This work was produced by Brown *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](http://www.journalslibrary.nihr.ac.uk)), produced by Prepress Projects Ltd, Perth, Scotland ([www.prepress-projects.co.uk](http://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 Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andree Le May  Chair of NIHR Journals Library Editorial Group (EME, 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

Professor Aileen Clarke  Professor of Public Health and Health Services Research, Warwick Medical School, University of Warwick, UK

Dr Tessa Crilly  Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin  Senior Scientific Advisor, Wessex Institute, UK

Ms Tara Lamont  Scientific Advisor, NETSCC, UK

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

Professor Geoffrey Meads  Professor of Health Sciences Research, Health and Wellbeing Research Group, 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:  nihredit@southampton.ac.uk