Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of LAser, Surgery and foam Sclerotherapy (CLASS) randomised controlled trial

Julie Brittenden, 1* Seonaidh C Cotton, 2 Andrew Elders, 2 Emma Tassie, 3 Graham Scotland, 2, 3 Craig R Ramsay, 2 John Norrie, 2 Jennifer Burr, 4 Jill Francis, 5 Samantha Wileman, 2 Bruce Campbell, 6 Paul Bachoo, 1 Ian Chetter, 7 Michael Gough, 8 Jonothan Earnshaw, 9 Tim Lees, 10 Julian Scott, 8 Sara A Baker, 11 Graeme MacLennan, 2 Maria Prior, 2 Denise Bolsover 2 and Marion K Campbell 2

Declared competing interests of authors: Bruce Campbell, Paul Bachoo, Ian Chetter, Michael Gough, Jonothan Earnshaw, Tim Lees, Julian Scott and Sara A Baker declare that they receive direct payments in private practice for undertaking treatment of varicose veins using one or more of the treatments examined in the CLASS trial.

Published April 2015 DOI: 10.3310/hta19270

¹Division of Applied Medicine, University of Aberdeen, Aberdeen, UK

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

³Health Economics Research Unit, University of Aberdeen, Aberdeen, UK

⁴School of Medicine, University of St Andrews, St Andrews, UK

⁵School of Health Sciences, City University London, London, UK

⁶Department of Vascular Surgery, Royal Devon and Exeter Hospital (Wonford), Exeter, UK

⁷Department of Vascular Surgery, Hull Royal Infirmary, Hull, UK

⁸Vascular Surgery, St James University Hospital, Leeds, UK

⁹Vascular Surgery, Gloucestershire Royal Hospital, Gloucester, UK

¹⁰Vascular Surgery, Freeman Hospital, Newcastle upon Tyne, UK

¹¹Vascular Surgical Unit, Royal Bournemouth Hospital, Bournemouth, UK

^{*}Corresponding author

Plain English summary

Results from the CLASS randomised controlled trial

Health Technology Assessment 2015; Vol. 19: No. 27

DOI: 10.3310/hta19270

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

Plain English summary

M any people undergo treatment for varicose veins, which are visible tortuous veins. Different types of treatment are available. These are surgery (that is, removing the vein by stripping it out), laser (using the heat energy of the laser to close the vein) or injection of a foam to make the walls of the vein stick together.

We compared these three treatments in terms of how well they worked from a participant and clinician perspective and their relative cost-effectiveness. Seven hundred and ninety-eight people with varicose veins requiring treatment were allocated at random to one of these three treatments. Outcomes were assessed at 6 weeks and 6 months. We found that all three treatments reduced the symptoms associated with varicose veins and improved quality of life (QoL). Foam allowed people to return to their normal activities quickly, but had fewer benefits in terms of patient-reported QoL and more complications.

Foam was also less likely to close the leaky vein, thus increasing the chance of more treatment being needed in the future. Overall, the main finding is that consideration of both success at 6 months and estimated 5-year costs and benefits suggests that laser should be considered as the preferred treatment for patients who are suitable for all three treatment options. We are following the study participants to 5 years, as long-term results are important to determine the longer-term costs and consequences (in terms of recurrent varicose veins) of these three treatments.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 5.116

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

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

Editorial contact: nihredit@southampton.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

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 06/45/02. The contractual start date was in June 2008. The draft report began editorial review in September 2013 and was accepted for publication in June 2014. 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 2015. This work was produced by Brittenden *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).

Editor-in-Chief of *Health Technology Assessment* and NIHR Journals Library

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the HTA 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 Peter Davidson Director of NETSCC, HTA, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Professor Elaine McColl Director, Newcastle Clinical Trials Unit, Institute of Health and Society, Newcastle University, UK

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

Professor Geoffrey Meads Professor of Health Sciences Research, Faculty of Education, University of Winchester, 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 Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, 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