# Compression stockings in addition to low-molecular-weight heparin to prevent venous thromboembolism in surgical inpatients requiring pharmacoprophylaxis: the GAPS non-inferiority RCT

Joseph Shalhoub,<sup>1</sup> Rebecca Lawton,<sup>1</sup>
Jemma Hudson,<sup>2</sup> Christopher Baker,<sup>3</sup>
Andrew Bradbury,<sup>4</sup> Karen Dhillon,<sup>3</sup>
Tamara Everington,<sup>5</sup> Manjit S Gohel,<sup>1,6</sup>
Zaed Hamady,<sup>7</sup> Beverly J Hunt,<sup>8</sup> Gerard Stansby,<sup>9</sup>
David Warwick,<sup>10</sup> John Norrie<sup>11</sup> and Alun H Davies<sup>1\*</sup>
on behalf of the GAPS trial investigators

**Declared competing interests of authors:** Alun H Davies reports other grants from the National Institute for Health Research (NIHR), the Stroke Association (London, UK), The Graham-Dixon Charitable Trust, Sir Halley Stewart Trust, the J P Moulton Charitable Foundation, Laboratoires URGO SA (Chenõve, France) and Actegy Health Ltd (Bracknell, UK) during the conduct of the study, none of which is related to the submitted work. Manjit S Gohel reports personal fees and Advisory Board speaker fees from Medtronic plc (Dublin, Ireland) and from Cook Medical (Bloomington, IN, USA), and grants from Laboratoires URGO SA outside the submitted work. John Norrie reports

<sup>&</sup>lt;sup>1</sup>Department of Surgery and Cancer, Imperial College London, London, UK

<sup>&</sup>lt;sup>2</sup>Health Services Research Unit, University of Aberdeen, Aberdeen, UK

<sup>&</sup>lt;sup>3</sup>Department of Surgery and Cancer, Imperial College Healthcare NHS Trust, London, UK

<sup>&</sup>lt;sup>4</sup>College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

<sup>&</sup>lt;sup>5</sup>Department of Haematology, Hampshire Hospitals NHS Foundation Trust, Basingstoke, UK

<sup>&</sup>lt;sup>6</sup>Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

<sup>&</sup>lt;sup>7</sup>Southampton HPB Unit, University Hospital Southampton NHS Foundation Trust, Southampton, UK

<sup>&</sup>lt;sup>8</sup>Department of Thrombosis and Haemostasis, Guy's & St Thomas' NHS Foundation Trust, London, UK

<sup>&</sup>lt;sup>9</sup>Northern Vascular Unit, Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

<sup>&</sup>lt;sup>10</sup>Department of Trauma and Orthopaedic Surgery, University Hospital Southampton NHS Foundation Trust, Southampton, UK

<sup>&</sup>lt;sup>11</sup>Usher Institute of Population Health Sciences and Informatics, University of Edinburgh, Edinburgh, UK

<sup>\*</sup>Corresponding author a.h.davies@imperial.ac.uk

membership of the following NIHR boards: Commissioning Priority Review Decision-making Committee (2015); Health Technology Assessment (HTA) Commissioning Board (2010–16); HTA Commissioning Sub-board (expression of interest) (2014); HTA Funding Boards Policy Group (2016–19); HTA General Board (2016–19); HTA post-board funding teleconference (2016–19); NIHR Clinical Trials Unit Standing Advisory Committee (2018 to present); NIHR HTA and Efficacy and Mechanism Evaluation Editorial Board (2014–19); and the Pre-exposure Prophylaxis Impact Review Panel (2017). Andrew Bradbury and Joseph Shalhoub report grants from NIHR during the conduct of the study.

Published December 2020

DOI: 10.3310/hta24690

# **Plain English summary**

### The GAPS RCT

Health Technology Assessment 2020; Vol. 24: No. 69

DOI: 10.3310/hta24690

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

# **Plain English summary**

### Why did we conduct this research?

People undergoing operations are at risk of developing blood clots in their legs, which is known as a deep-vein thrombosis. Blood clots occur for several reasons, such as not being able to move around after an operation, changes in the blood or damage to the veins in which blood travels.

To decrease the risk of getting deep-vein thrombosis, patients having operations are given tight elastic socks to wear called graduated compression stockings. They are also given blood thinning medicine to prevent clotting.

There is little evidence that wearing elastic socks in hospital will reduce the risk of blood clots if blood thinners are also given. Many patients say that the socks can hurt or cause bruising and can be difficult to put on.

The graduated compression as an adjunct to thromboprophylaxis in surgery (GAPS) trial investigated whether or not patients having an operation would benefit from wearing elastic socks as well as getting blood thinners, or if blood thinners on their own prevented blood clots.

### What did we do?

A total of 1905 patients who were having operations at seven hospitals in England agreed to take part. They were randomly assigned to different treatments by a computer program. Half of the patients were given elastic socks plus blood thinners, and the other half were given the blood thinners alone.

### What did we find?

There was no significant difference in the number of people who had a blood clot in either study group. This could mean that blood thinners are as good at stopping blood clots as blood thinners and elastic socks for patients having operations.

### What could be carried out next?

The NHS spends around £63M per year across England on elastic stockings. This research indicates that patients might not get extra benefit from wearing them if they have taken blood thinners.

## **Health Technology Assessment**

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and 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 14/140/61. The contractual start date was in December 2015. The draft report began editorial review in December 2019 and was accepted for publication in July 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. This report has been published following a shortened production process and, therefore, did not undergo the usual number of proof stages and opportunities for correction. 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 Shalhoub *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).

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

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 Professor of Digital Health Care, 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 Senior Scientific Adviser (Evidence Use), Wessex Institute, University of Southampton, 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 Emeritus 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