

Endovascular stent grafting and open surgical replacement for chronic thoracic aortic aneurysms: a systematic review and prospective cohort study

Linda Sharples,^{1*} Priya Sastry,² Carol Freeman,³
Joanne Gray,⁴ Andrew McCarthy,⁴ Yi-Da Chiu,^{3,5}
Colin Bicknell,⁶ Peter McMeekin,⁴
S Rao Vallabhaneni,⁷ Andrew Cook,^{8,9} Luke Vale¹⁰
and Stephen Large¹¹ on behalf of the ETTAA
Collaborative Group

¹Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK

²Department of Cardiac Surgery, John Radcliffe Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, UK

³Papworth Trials Unit Collaboration, Royal Papworth Hospital NHS Foundation Trust, Cambridge, UK

⁴Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, UK

⁵Medical Research Council (MRC) Biostatistics Unit, School of Clinical Medicine, University of Cambridge, Cambridge, UK

⁶Department of Surgery and Cancer, Faculty of Medicine, Imperial College London, London, UK

⁷Liverpool Vascular & Endovascular Service, Royal Liverpool University Hospital, Liverpool, UK

⁸Wessex Institute, University of Southampton, Southampton, UK

⁹Southampton Clinical Trials Unit, University of Southampton, Southampton, UK

¹⁰Health Economics Group, Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne, UK

¹¹Department of Cardiac Surgery, Royal Papworth Hospital NHS Foundation Trust, Cambridge, UK

*Corresponding author Linda.Sharples@lshtm.ac.uk

Declared competing interests of authors: S Rao Vallabhaneni reports unrestricted research grants from Cook Medical (Bloomington, IN, USA) and Terumo Aortic (UK) (Vascutek Ltd, Inchinnan, UK) during the conduct of the study. Colin Bicknell reports personal fees and non-financial support from Medtronic plc (Dublin, Ireland) and grants, personal fees and non-financial support from W. L. Gore & Associates, Inc. (Newark, DE, USA), all outside the submitted work. Luke Vale reports that he was a member of the NIHR Health Technology Assessment Clinical Trials and Evaluation Panel (2015–18).

Published January 2022

DOI: 10.3310/ABUT7744

Plain English summary

Chronic thoracic aortic aneurysms

Health Technology Assessment 2022; Vol. 26: No. 6

DOI: 10.3310/ABUT7744

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

Plain English summary

The aorta is the main artery that carries oxygen-rich blood from the heart to the body. An aneurysm is a swelling or bulging in a blood vessel, which usually occurs where the wall has become weak and has lost its elastic properties, which means that it does not return to its normal shape after the blood has passed through. A thoracic aortic aneurysm, or TAA for short, is an aneurysm in the section of the aorta in the chest (www.bhf.org.uk/informationsupport/conditions/thoracic-aortic-aneurysms).

The Effective Treatments for Thoracic Aortic Aneurysms (ETTAA) study aimed to investigate aneurysm growth rates, patient outcomes, quality of life and costs, including those from surgery. Surgical treatments include open heart surgery, in which the section of the aorta that contains the aneurysm is removed and replaced by a new aorta made from a synthetic material, and stent grafting, in which tubes are inserted into arteries to allow blood to flow freely, using less invasive 'keyhole' surgery. The existing research evidence was reviewed, but data comparing the effectiveness of these two approaches were sparse or of limited quality, and outdated.

Between 2014 and 2018, clinical experts were surveyed and 886 NHS patients with chronic thoracic aortic aneurysms (≥ 4 cm in diameter) were observed to monitor aneurysm growth and patient outcomes.

If patients were unfit or unwilling to have surgery, they had conservative management with medication and lifestyle changes. For small aneurysms, experts recommended watchful waiting, with regular monitoring, until the aneurysm grew to about 6 cm in diameter. Open surgery was preferred for larger arch aneurysms and for descending aneurysms in patients with genetic disorders. Otherwise, stent grafting was preferred.

The observational study recruited 321 women and 565 men with an average age of 71 years from 30 English hospitals. A total of 489 patients underwent watchful waiting and 112 received conservative management. Without surgery, death rates were higher for women and older patients, while the risk of dying doubled for each centimetre of aneurysm diameter at baseline. Of the remaining patients, 150 underwent stent grafting and 135 had open surgery. One-year overall survival was 83% after stent grafting and 79% after open surgery but the difference could be due to chance. The factors affecting survival after stent grafting or open surgery were aneurysm location, age, breathlessness and time waiting for a procedure.

Small aneurysms are low risk, so blood pressure management and smoking cessation are recommended. For larger aneurysms, it is important that surgery is not delayed, as a longer waiting time to surgery means that outcomes are poorer.

Only about half of patients who had surgery were considered suitable for both stent grafting and open surgery, which limited the ability to determine the best use of NHS resources. No comparative cost-effectiveness analysis was feasible. The main cost in a stent grafting procedure was the stent graft, and the main cost in an open surgery procedure was days in an intensive care unit.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.014

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 11/147/03. The contractual start date was in February 2014. The draft report began editorial review in October 2020 and was accepted for publication in July 2021. 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.

Copyright © 2022 Sharples *et al.* This work was produced by Sharples *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

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 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 (HSDR, PGfAR, PHR journals) and Editor-in-Chief of HSDR, 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 Consultant in Public Health, Delta Public Health Consulting Ltd, UK

Dr Peter Davidson Consultant Advisor, Wessex Institute, University of Southampton, UK

Ms Tara Lamont Senior Adviser, Wessex Institute, University of Southampton, UK

Dr Catriona McDaid Reader in Trials, 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 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, Child and Adolescent Mental Health, Palliative Care and Paediatrics Unit, Population Policy and Practice Programme, UCL Great Ormond Street Institute of Child Health, London, 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

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

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