Gastrostomy versus nasogastric tube feeding for chemoradiation patients with head and neck cancer: the TUBE pilot RCT

Vinidh Paleri, 1,2,3* Joanne Patterson, 4 Nikki Rousseau, 4 Eoin Moloney, 4 Dawn Craig, 4 Dimitrios Tzelis, 4 Nina Wilkinson, 5 Jeremy Franks, 4 Ann Marie Hynes, 6 Ben Heaven, 4 David Hamilton, 4 Teresa Guerrero-Urbano, 7 Rachael Donnelly, 7 Stewart Barclay, 8 Tim Rapley 4 and Deborah Stocken 5,9

Declared competing interests of authors: Vinidh Paleri is a member of the National Institute for Health Research (NIHR) Health Technology Assessment programme Interventional Procedures Panel, and has received travel expenses to disseminate the trial results, as well as expenses from DP Medical Systems (Chessington, UK) and Merck & Co., Inc. (Kenilworth, NJ, USA); the expenses paid by Merck & Co., Inc., include fees to speak at a meeting. Nikki Rousseau and Tim Rapley report grants from NIHR during the conduct of the study.

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published April 2018 DOI: 10.3310/hta22160

¹Head and Neck Unit, The Royal Marsden Hospital, London, UK

²Division of Clinical Studies, Institute of Cancer Research, London, UK

³Northern Institute for Cancer Research, Newcastle University, Newcastle upon Tyne, UK

⁴Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK

⁵Biostatistics Research group, Institute of Health and Society, Newcastle University, Newcastle upon Tyne, UK

⁶Newcastle Clinical Trials Unit, Newcastle University, Newcastle upon Tyne, UK

⁷Department of Radiation Oncology, Guy's and St Thomas' NHS Foundation Trust, London, UK

⁸Department of Restorative Dentistry, The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

⁹Leeds Institute of Clinical Trials Research, University of Leeds, Leeds, UK

^{*}Corresponding author vinidh.paleri@rmh.nhs.uk

Plain English summary

Gastrostomy versus nasogastric tube feeding: the TUBE pilot RCT

Health Technology Assessment 2018; Vol. 22: No. 16

DOI: 10.3310/hta22160

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

Plain English summary

ead and neck cancer is frequently treated with a combination of drug and radiation therapies (chemoradiotherapy). Almost all patients need help with nutrition during and after chemoradiotherapy. This help may be given in one of two ways: (1) the person carries on taking food by mouth for as long as possible and then a tube is inserted through the nose into the stomach (nasogastric tube) to supplement intake by mouth as needed; or (2) a tube is placed directly into the stomach through the abdomen (gastrostomy) before chemoradiotherapy. Our study explored the feasibility of a randomised controlled trial to compare these two options.

Our study recruited 23% of people who were eligible. However, most people (88%) stayed in the study and provided the data that would be needed in a full study. Interviews revealed several important issues. Some people were not happy that the treatment they received was based on a random allocation, some already had a strong preference for one type of tube and there were concerns about the study interrupting the treatment. Health professionals did not always communicate equipoise (the idea that it is not currently known which treatment is best for patients) consistently. Centres in which health-care professionals worked as a team to demonstrate equipoise recruited a higher proportion of patients. Preliminary economic work showed that gastrostomy placement is costlier than as-needed nasogastric tube insertion.

In summary, our study has taught us more about encouraging people to be part of a study of tube-feeding options for people being treated for head and neck cancer.

HTA/HTA TAR

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the 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

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 12/35/32. The contractual start date was in January 2014. The draft report began editorial review in July 2016 and was accepted for publication in July 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 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 2018. This work was produced by Paleri 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).

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 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 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 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 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