Outcomes of electrically stimulated gracilis neosphincter surgery

T Tillin,* M Chambers and R Feldman

Unit for Costs and Outcomes Evaluation, Barts and The London, Queen Mary’s School of Medicine and Dentistry, London, UK

* Corresponding author

Executive summary

Health Technology Assessment 2005; Vol. 9: No. 28
Electrically stimulated gracilis neosphincter surgery (ESGNS) is a complex surgical procedure designed to improve bowel function for people living with faecal incontinence refractory to conventional medical or surgical treatments.

Objectives
The objectives of the study were to test two hypotheses:

1. That ESGNS leads to a better quality of life (QoL) than either continued medical management of refractory anal incontinence or the formation of a permanent stoma.
2. That the long-term costs of ESGNS are less than the costs of alternative management options or are justifiable in terms of improved patient QoL.

Method

Part 1 (prospective case-comparison study)
Outcomes were determined by comparing measurement on recruitment to the London study with measurement at regular intervals following surgery (for cases) or recruitment to the study (for the comparison groups). The main outcomes described are:

1. clinical success or failure of surgery
2. QoL, bowel- and surgery-related symptoms, anxiety, depression and patients’ opinions of surgical outcomes
3. the comparative costs to the NHS of caring for patients who undergo ESGNS or the conventional alternative treatments.

Part 2 (cross-sectional study)
Postal questionnaires and case-note review were used to determine outcomes, as listed above, for patients who had previously undergone ESGNS at Hull, Newcastle and Edinburgh.

Results

Clinical and patient-based outcomes
Based on the findings of this study, a realistic expectation might be that 3 years postoperation, nearly three-quarters of all patients will still have a functioning neosphincter.
Approximately two-thirds will have a satisfactory continence outcome at 3 years of follow-up, although half of them will have ongoing evacuatory difficulties. Bowel-related QoL and continence, when measured between 1 and 3 years postoperation, improve significantly (in excess of 20%) when compared with preoperative status for nearly two-thirds of all the patients who undergo the surgery. The findings indicate that these improvements in QoL and symptoms are maintained in the smaller cohort of patients who have reached 4 and 5 years of follow-up, even though the clinical success rate has fallen somewhat at this length of follow-up. ESGNS was unsuccessful in two-thirds of the small group of patients whose disorders were caused by congenital anomalies.

Addition of cross-sectional data from the three northern centre ESGNS patients confirmed the findings recorded for the RLH patients in the postoperative period. Similar, but not identical, surgical techniques were used in the four centres.

Comparison group patients experienced no significant changes in symptoms, QoL, anxiety or depression over a 2-year follow-up period.

**Costs of ESGNS**

The mean cost of patient care at RLH during and before the intervention itself was £23,253, 91% of which was for inpatient ward use, theatre use and devices. The estimated cost per patient year was higher for patients with prior stomas than for patients without prior stomas. Costs of patient care for those with stomas who did not undergo ESGNS were estimated at £2125 per patient year and for those who remained with severe faecal incontinence costs were estimated at £442 per patient year.

In the northern centres, the estimated mean cost of the intervention per patient was lower at £11,731. This value is lower than that for RLH, reflecting differences in techniques for performing ESGNS requiring fewer repeat admissions and operations.

Calculating costs for 25 years of follow-up with prior faecal incontinence, it was estimated that the decision to refer to ESGNS at RLH resulted in a cost-effectiveness ratio of around £15,000 per QALY gained, reducing to £5000 per QALY gained when inpatient costs were based on the three northern ESGNS centres.

For patients with prior stoma, referral to ESGNS at RLH resulted in a cost-effectiveness ratio of around £30,000 per QALY gained or less are generally regarded as being reasonably attractive in the UK NHS context.

### Conclusions

#### Limitations

Evaluating a surgical intervention without a randomised controlled trial is difficult enough, but in addition this evaluation faced other limitations in the fulfilment of its objectives, principally relating to insufficient numbers of patients. A separate limitation became evident during the study, when it was observed that outcomes of surgery were unstable for several years in some patients, suggesting that a longer than planned follow-up was important. To deal partially with these difficulties, the study period was extended and limited data from patients from the northern areas were collected. A third limitation, associated with the time period, involved dealing with changes in the management of incontinence and the growing expertise of teams in selecting patients and in performing the surgical procedure. Further limitations apply to the economic analyses, where caution is needed in interpreting cost-effectiveness ratios owing to the small numbers of patients and very small changes observed in the EQ-5D measure on which the QALY calculations are based.

Although these methodological limitations are significant and the conclusions must be interpreted with caution, we believe that, without the option of a randomised controlled trial, we have come as close as is possible to providing robust evidence concerning the outcomes of the procedure.

#### Implications for healthcare

One view is that this treatment has limited long-term benefit. It may also lead to pain and difficulty with evacuation. Improved continence is of measurable benefit in some patients, but is achieved at considerable cost and the procedure has not achieved the desired outcome in sufficient numbers to justify its continuation.

An alternative view is that there is a place for ESGNS, but it is at the extreme end of the treatment spectrum for refractory faecal...
incontinence. It is a complex operation associated with a high incidence of morbidity and a high incidence of failure in the long term (15–30% at 3 years and 30–50% at 5 years after surgery). However, as an option for patients who have considered other conventional treatments and are facing the formation of a permanent stoma or continuing to live with a debilitating, socially disabling disorder, the procedure deserves consideration. It may be the only alternative for patients intolerant of a stoma. Previous studies have indicated a high level of long-term serious complications associated with stomas. Patients should be given a realistic picture of the possible outcomes of ESGNS.

Patients whose disorders are caused by anorectal agenesis (congenital anomalies) pose awkward surgical challenges. The outcomes for this group were poor; two-thirds of procedures failed during the study period.

The study has indicated the value of centres of excellence that can, when needed, perform this procedure with the support of a multidisciplinary and experienced team. Funding for centres treating faecal incontinence needs to include all the elements of treatment for refractory faecal incontinence, including the most conservative. ESGNS should not be performed outside such centres owing to the rarity and complexity of the procedure and the need for specialist support before, during and after surgery. Lifelong specialist follow-up is required.

**Recommendations for research**

1. Since the start of this study, less invasive procedures such as sacral nerve stimulation (SNS) have developed and these may benefit some patients who might previously have undergone ESGNS. We recommend an independent study of long-term patient-based outcomes of SNS. All four existing UK ESGNS centres are ideally placed to conduct such an assessment.

2. Audit of centres performing artificial bowel sphincter operations within the UK. (The Acticon Neosphincter artificial bowel sphincter consists of an inflatable cuff of silicone elastomer placed around the anal canal and connected to a pressure-regulating balloon in the iliac fossa via a control pump placed in the labium or scrotum. Although this is less invasive than ESGNS, it is still a major procedure and is associated with a high level of complications, morbidity and explantation.) We advise that such centres should provide details of the number of procedures performed, immediate and long-term outcomes and provision for follow-up, prior to a possible National Institute for Health and Clinical Excellence (NICE) interventional procedures review. There is no good-quality evidence regarding safety and efficacy of this procedure; if it is still being performed in the UK, it should also undergo a long-term patient-based outcomes study.

3. Further study of the effects on outcomes of ESGNS of different surgical techniques is warranted, in particular with regard to the formation of a covering stoma in those patients who do not already have a stoma. Interim stoma formation is associated with increased numbers and lengths of hospital stays and it is not clear from our data that the outcomes are better as a result of this additional procedure.

4. In view of the frequency of disordered evacuation and groin and leg pain following ESGNS, research into the reasons and possible treatment for these distressing symptoms is needed.

The above recommendations may be problematic in their implementation. Waiting for available data means that any study is not prospective, not independently organised, is small and does not present either patient perspectives or the long-term outcomes. Funding bodies will have to decide whether to fund future studies such as this one – we believe that they should.

**Publication**

How to obtain copies of this and other HTA Programme reports.

An electronic version of this publication, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (http://www.hta.ac.uk). A fully searchable CD-ROM is also available (see below).

Printed copies of HTA monographs cost £20 each (post and packing free in the UK) to both public and private sector purchasers from our Despatch Agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per monograph and for the rest of the world £3 per monograph.

You can order HTA monographs from our Despatch Agents:

– fax (with credit card or official purchase order)
– post (with credit card or official purchase order or cheque)
– phone during office hours (credit card only).

Additionally the HTA website allows you either to pay securely by credit card or to print out your order and then post or fax it.

Contact details are as follows:

HTA Despatch Email: orders@hta.ac.uk

c/o Direct Mail Works Ltd Tel: 02392 492 000
4 Oakwood Business Centre Fax: 02392 478 555
Downley, HAVANT PO9 2NP, UK Fax from outside the UK: +44 2392 478 555

NHS libraries can subscribe free of charge. Public libraries can subscribe at a very reduced cost of £100 for each volume (normally comprising 30–40 titles). The commercial subscription rate is £300 per volume. Please see our website for details. Subscriptions can only be purchased for the current or forthcoming volume.

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in pounds sterling, made payable to Direct Mail Works Ltd and drawn on a bank with a UK address.

Paying by credit card
The following cards are accepted by phone, fax, post or via the website ordering pages: Delta, Eurocard, Mastercard, Solo, Switch and Visa. We advise against sending credit card details in a plain email.

Paying by official purchase order
You can post or fax these, but they must be from public bodies (i.e. NHS or universities) within the UK. We cannot at present accept purchase orders from commercial companies or from outside the UK.

How do I get a copy of HTA on CD?

Please use the form on the HTA website (www.hta.ac.uk/htacd.htm). Or contact Direct Mail Works (see contact details above) by email, post, fax or phone. HTA on CD is currently free of charge worldwide.

The website also provides information about the HTA Programme and lists the membership of the various committees.
The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts. Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

The research reported in this monograph was commissioned by the HTA Programme as project number 99/12/01. The contractual start date was in October 2000. The draft report began editorial review in September 2003 and was accepted for publication in January 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. 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 referees 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.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

Editor-in-Chief: Professor Tom Walley
Series Editors: Dr Peter Davidson, Dr Chris Hyde, Dr Ruairidh Milne, Dr Rob Riemsma and Dr Ken Stein
Managing Editors: Sally Bailey and Sarah Llewellyn Lloyd

© Queen’s Printer and Controller of HMSO 2005

This monograph may be freely reproduced for the purposes of private research and study and 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 NCCHTA, Mailpoint 728, Boldrewood, University of Southampton, Southampton, SO16 7PX, UK.

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.