Outcomes of electrically stimulated gracilis neosphincter surgery

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Executive summary

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Executive summary

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.

Design

Part 1 was a longitudinal and prospective case-comparison study of patients at the Royal London Hospital (RLH). As a result of a recruitment shortfall, Part 2 was added; this was a cross-sectional and retrospective study of outcomes of ESGNS performed at three other UK centres.

Setting

Three NHS Hospital Surgery Departments in England (London, Hull and Newcastle) and one in Scotland (Edinburgh).

Participants

Cases were patients who underwent ESGNS at the participating hospitals during a 5-year period from 1997. Comparisons were made with two groups of people with similar bowel disorders who did not undergo ESGNS.

Intervention

ESGNS involves the transposition of the gracilis muscle from the inner thigh to form a neo-anal sphincter. The transposed muscle is then electrically stimulated via an electronic pulse generator (IPG) implanted beneath the skin of the abdomen. The IPG initiates and maintains conversion of the gracilis muscle from a fast-twitch fatiguable muscle to a slow-twitch non-fatiguable muscle, and results in the formation of a potentially continent neosphincter.

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.

Difficulties in evaluating response to bowel surgery using **generic** QoL measures can be minimised by using **bowel-specific** measures, but such measures, because they are symptom-specific, are difficult to use as a measure of an overall response. Both types of measure were used in this study.

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 about £40,000 per quality-adjusted life-year (QALY) gained. Using inpatient care costs based on the three northern ESGNS centres, this value reduced to around £30,000 per QALY gained. The choice of stoma for these patients resulted in a slightly higher cost than ESGNS.

For patients with prior stoma, referral 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.

Cost-effectiveness ratios 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

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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.

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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.

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