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Title **Outcomes of Electrically Stimulated Gracilis Neosphincter Surgery**

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Aim

To test the hypotheses:

1. That electrically stimulated gracilis neosphincter surgery (ESGNS) leads to a better quality of life (QoL) than continued medical management of anal incontinence, or the formation of a permanent stoma.
2. That the long-term costs of patient care following ESGNS are less than the costs of alternative management options, or are justifiable in terms of improved patient quality of life.

Conclusions and results

At 3 years after surgery, this third-party evaluation observed that nearly three fourths of all patients had a functioning neosphincter and nearly two thirds had a satisfactory continence outcome. However, half of those with satisfactory continence had ongoing bowel evacuatory difficulties, and many experienced continuing leg and groin pain.

Bowel-related QoL and continence, measured between 1 and 3 years after surgery improved significantly and in excess of 20% when compared with preoperative status in nearly two thirds of patients. These improvements in quality of life and symptoms were maintained in the smaller cohort of patients who reached 4 and 5 years of followup, although by then the success rate had fallen somewhat. Generic measures of QoL demonstrated small improvements at 2 years of followup and moderate and significant improvements at 3 years. Patients in the comparison arm of the study experienced no significant changes in symptoms, QoL, anxiety, or depression over a 2-year followup period. Addition of cross-sectional data from patients who underwent ESGNS at 3 other UK centers confirmed that findings for the patient-based and clinical outcome measures were consistent across all centers, although surgical techniques differed. Length of hospital stays and hospital costs were substantially greater at RLH than at any of 3 other centers, which may be explained by differences in surgical techniques and differences in case-mix.

Costs modeled over 25 years of followup suggested that for patients with prior fecal incontinence the decision to refer to ESGNS at RLH resulted in a cost-effectiveness ratio of about 40 000 British pounds (GBP) per quality adjusted life year (QALY) gained. Using inpatient care costs based on the 3 other UK centers, this value reduced to around GBP 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 GBP 15 000 per QALY gained, reducing to GBP 5000 per QALY gained when inpatient costs were based on the 3 other UK ESGNS centers. Cost-effectiveness ratios of around GBP 30 000 per QALY gained or less are generally regarded to be reasonably attractive in the UK NHS context.

Recommendations

One view of ESGNS is that negative outcomes and costs outweigh the improved continence achieved in two thirds of patients. An alternative view is that ESGNS deserves consideration as an option for patients who face a permanent stoma or must continue to live with a debilitating, socially disabling disorder. In any case, ESGNS should not be performed outside of experienced, multidisciplinary, specialist centers able to give life-long followup.

Methods

See Executive Summary link above.

Further research/reviews required

1. Independent study of long-term patient-based outcomes of sacral nerve stimulation.
2. Audit of centers performing artificial bowel sphincter (ABS) operations within the UK.
3. Further study of the effects of different surgical techniques on ESGNS outcomes.
4. Research into the reasons and possible treatment for disordered evacuation and groin and leg pain following ESGNS.

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