Surgical strategies for faecal incontinence: a decision analysis between dynamic graciloplasty, artificial bowel sphincter and end stoma

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the cost-effectiveness of three surgical approaches for faecal incontinence, which were artificial bowel sphincter (ABS), dynamic graciloplasty, and permanent end stoma (ES). ES was the most cost-effective strategy, over five years, from the payer’s perspective, but, over 10 years, ABS became the preferred strategy. The methodology appears to have been robust, but the data sources could have been more extensively reported. The authors’ conclusions might have been different had incremental rather than average cost-effectiveness ratios been calculated.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the comparative cost-effectiveness of three surgical approaches for faecal incontinence (FI), which were artificial bowel sphincter (ABS), dynamic graciloplasty (DG), and permanent end stoma (ES). These procedures were performed on a typical 40-year-old patient, who was unsuccessfully treated with sacral nerve stimulation (SNS) or sphincteroplasty.

Interventions
The three surgical procedures were ABS, DG, and ES. These strategies were also implicitly compared with a strategy of no intervention.

Location/setting
UK/hospital.

Methods
Analytical approach:
This economic evaluation was based on a decision model analysis, using a Markov model, with a base-case five-year time horizon. The authors stated that the perspective was that of the health service payer, which was the UK National Health Service (NHS).

Effectiveness data:
A literature review was undertaken to identify the relevant sources of data, in the MEDLINE database, over the period from 1990 to 2007. Published criteria were applied to appraise the quality of the studies, to select the relevant sources for the clinical data. A weighted mean was calculated for each variable taking into account the number of patients. Data were extracted from 58 studies and two systematic reviews. These published studies were supplemented by expert opinion from four specialist colorectal surgeons, who provided the ranges of values for each input. The primary model input was the rate of success with each of the procedures.

Monetary benefit and utility valuations:
The utility values were derived from published studies that used the Short Form (SF-36) questionnaire, plus experts’ opinions.

Measure of benefit:
Quality-adjusted life-years (QALYs) were used as the summary benefit measure.
Cost data:
The economic analysis considered the costs of each surgical procedure and further follow-up. A breakdown of cost items was not provided. The costs were mainly derived from NHS reference prices for 2004 to 2005 and were in UK pounds sterling (£). These estimates were supplemented by data collected by the Royal London Hospital, and the manufacturer of the ABS device.

Analysis of uncertainty:
Deterministic one-way and two-way sensitivity analyses were undertaken on all the model inputs, using ranges of values derived from published studies or from the panel of experts. Longer time horizons were considered, and subgroup analyses were also performed considering only obstetric patients. A comprehensive probabilistic analysis was undertaken by assigning probability distributions to all the model inputs. A 6% annual discount rate was also analysed.

Results
Over five years, the average costs were £16,280.00 with ES, £25,034.73 with DG, and £23,568.53 with ABS and the QALYs were 3.450 with ES, 4.001 with DG, and 4.375 with ABS. The incremental cost per QALY gained, compared with no intervention, was £4,718.84 with ES, £6,257.12 with DG, and £5,387.09 with ABS.

Better cost-utility ratios were achieved over a 10-year horizon, with ABS being the preferred strategy with greater benefits at lower costs compared with the other procedures. The results of the sensitivity analysis showed that the base-case findings were robust, within plausible ranges of values. The probabilistic sensitivity analysis showed that all three strategies had a cost-utility ratio below the threshold of £30,000 per QALY.

Authors' conclusions
The authors concluded that ES was the most cost-effective strategy, over five years, from the perspective of the NHS, but, over ten years, ABS became the preferred strategy. They highlighted the need for long-term studies evaluating how long functional continence lasts after the ABS and DG procedures.

CRD commentary
Interventions:
The authors justified their selection of the comparators, which were the available procedures for patients unsuccessfully managed with SNS or sphincteroplasty. These surgical approaches might not be available in all settings, given the high expertise required for some of them.

Effectiveness/benefits:
The approach used to identify the relevant sources for data was appropriate given that a systematic search was carried out. The method used to pool the clinical estimates was valid. The authors acknowledged the limitation that most of the data came from case series, with small sample sizes, because randomised controlled trials were unacceptable in this area. Also, expert opinions were required. Extensive sensitivity analyses were carried out to address the issue of uncertainty underlying the clinical inputs. QALYs are an appropriate benefit measure, given the impact of the disease on quality of life, even though none of the procedures was considered to have an effect on mortality, which was assumed to have been the same as for the general population. A validated instrument was used to elicit patient preferences for health conditions.

Costs:
The analysis of costs was consistent with the perspective. The costs were presented as macro-categories and were not broken down into individual items. This reduces the transparency of the economic analysis. Other details of the study such as the sources of data, price year, and use of probability distributions were reported. Discounting, which was relevant, given that follow-up costs were considered, appears to have been applied only in the sensitivity analysis.

Analysis and results:
An average, rather than an incremental, approach appears to have been used to synthesise the costs and benefits of the alternative strategies. A direct comparison of the three procedures in terms of their incremental benefits and costs was not performed; instead each strategy was compared with no intervention. An incremental approach would have shown the dominance of ABS over 10 years compared with DG, and that the incremental cost per QALY for ABS compared
with ES was relatively low. The issue of uncertainty appears to have been satisfactorily addressed, by means of both
deterministic and probabilistic sensitivity analyses, and the alternative scenarios and main findings were clearly
presented. The model structure and assumptions were clearly presented. The authors noted that the main limitation of
their analysis was the scarcity of published studies, which required the use of experts’ opinions.

Concluding remarks:
On the whole, the methodology appears to have been robust, although more extensive reporting of the clinical and
economic sources would have been useful. The authors’ conclusions might have been different if incremental rather
than average cost-effectiveness ratios had been calculated.

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