Economic evaluation of sacral nerve stimulation for faecal incontinence

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 estimated the cost-effectiveness of sacral nerve stimulation (SNS) in faecal incontinence, compared with ongoing conservative therapy. SNS was beneficial, and although higher than the NICE threshold, it can be considered an efficient use of NHS resources. The authors' conclusions should be treated with caution given the quality of the evidence.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The aim was to estimate the cost-effectiveness of sacral nerve stimulation (SNS) in treating adults with faecal incontinence, compared with ongoing conservative, nonsurgical therapy.

Interventions
Conservative treatment consisted primarily of drugs such as loperamide or codeine phosphate, the use of absorbent pads or anal plugs, and behavioural therapies including biofeedback, anal sphincter exercises and dietary advice. SNS was one of the current surgical options and a first-line surgical treatment in those with intact anal sphincter muscles. SNS modulates the extrinsic nerve supply to the pelvic floor, distal bowel and anal sphincter complex using a two-stage procedure with a trial of temporary stimulation, followed by, in those patients with a greater than 50 per cent reduction in the total number of incontinence episodes, the implantation of a permanent neurostimulator and lead.

Location/setting
UK/hospital and outpatient.

Methods
Analytical approach:
A cohort analysis using a decision tree was performed. The time horizon appears to have been seven years. The authors stated that the study had a societal perspective, but they also present in the paper a basic model which considered only the health service perspective. Baseline pre-stimulation data were assumed to be equivalent to the continued use of conservative treatment and were used as the comparator.

Effectiveness data:
SNS information came from prospectively collected data from 70 patients who had undergone SNS at a single institution between 1996 and 2006 (case series design), and who had failed to benefit from previous conservative treatments. The median follow-up was 24 months. The incremental effectiveness was calculated as the reduction in faecal incontinence from baseline. The main clinical outcomes included incontinence severity using bowel habit diaries, and complications.

Monetary benefit and utility valuations:
The utility values were derived from the SF-36 scores during the clinical cohort study. The clinical SF-36 score was converted into a SF-6D score. The questionnaire was administered to SNS patients at baseline, repeated after temporary screening, and repeated again after implantation of the permanent neurostimulator.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs) and the discount rate was 3.5%.
Cost data:
The authors estimated direct medical, direct non-medical and indirect (productivity) costs. Direct medical costs included consultations, peripheral nerve evaluations, SNS, lead migration, implantation, repositioning of implant, and infection, in the corresponding setting (outpatient or inpatient). For conservative management, patients were assumed to be taking regular constipating medications and attending one annual outpatient follow-up appointment. Direct non-medical costs included incontinence pads and travel costs. Indirect non-medical costs were work absenteeism, lost productivity, and help from paid or unpaid workers. Direct medical costs were obtained from the national tariff for gastroenterology 2005 to 2006 and the Health Resource Group codes. The cost of pads and travel were retail prices and the average hourly wages were based on UK 2005 annual survey of hours and earnings. Work absentee rates due to faecal incontinence were taken from a Swedish study. All costs were reported in UK pounds sterling (£) for 2005 to 2006 and the discount rate was 3.5%.

Analysis of uncertainty:
Selected one-way and scenario sensitivity analyses were performed and an overall “confidence interval” for the cost-effectiveness ratio was constructed using the upper and lower effectiveness ranges.

Results
In the basic model (which excluded indirect non-medical costs) the conservative strategy gained 4.25 QALYs and cost £2,529, while SNS gained 4.54 QALYs and cost £9,795. This implies an incremental cost-effectiveness ratio (ICER) of £25,070 per QALY gained for SNS.

The ICERs were £3,329 for a patient-year of full continence, and £1,543 for a patient-year of improved continence.

Using the effectiveness ranges, the highest possible ICER was £30,783 and the lowest was £6,028.

When indirect non-medical costs were included, the ICER was reduced to £12,959.

The findings were robust to the other analyses reported except for device battery life (assumed in the base-case to be seven years). A battery life of five years increased the ICER to £35,389.

Authors' conclusions
Although the ICER (excluding indirect non-medical costs) is greater than the National Institute for Health and Clinical Excellence threshold of £20,000, SNS can still be considered cost-effective. A further prospective study is planned by the authors to improve the accuracy and reliability of the cost data.

CRD commentary
Interventions:
SNS was adequately described, although the specific device used was not stated. Conservative treatment was assumed to consist of only medication and follow-up, but most of the patients in this sample had previously used biofeedback techniques. The reader should judge whether or not these interventions are similar in their own setting.

Effectiveness/benefits:
The effectiveness and benefits were calculated from a case series study, with the assumption that conservative management produced the baseline values, and in accordance with the SNS strategy. Bias in deriving the effectiveness parameters of SNS is a significant limitation of this design. Also, the authors acknowledged that SF-36 was not designed to measure QALYs, but SF-6D was a reasonable instrument. The authors attempted to explain some counterintuitive QALY results, but the explanation was difficult to follow and these results could be attributed to chance in the small sample population.

Costs:
The costs relevant to the study perspective were included. A limitation acknowledged by the authors was that the costs were not collected from patients, and the assumptions made may bias the results, but this was countered by various sensitivity analyses. It is not clear which device was included and its cost and it is unclear whether the Swedish work absenteeism due to faecal incontinence data is generalisable to the UK or not. The cost data used in the analysis were
adequately reported.

Analysis and results:
Several analyses and their results were presented, using different perspectives and outcomes measures, which helps gauge the cost-effectiveness in different ways. An incremental cost-effectiveness analysis was performed. Uncertainty could have been more fully evaluated through a probabilistic sensitivity analysis.

Concluding remarks:
The authors’ conclusions should be treated with caution given the quality of the evidence.

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