Sacral neuromodulation for the treatment of fecal incontinence: analysis of cost-effectiveness
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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 sacral nerve modulation (SNM) for the treatment of faecal incontinence, from the perspective of the Italian National Health Service. The authors concluded that SNM was efficient and provided good value for money, with a modest budget impact. The cost-effectiveness framework was conventional, which should ensure the validity of the authors’ conclusions.

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

Study objective
This study examined the cost-effectiveness of sacral nerve modulation (SNM) for the treatment of faecal incontinence in patients with an intact anal sphincter and in those with a structurally deficient anal sphincter. A budget impact analysis was carried out.

Interventions
After conservative therapy had failed, for patients with an intact anal sphincter, SNM was assumed to be the first-line therapy, while for those with a structurally deficient anal sphincter it was assumed to be the second-line treatment, after sphincteroplasty. Dynamic graciloplasty or an artificial anal sphincter could be chosen if SNM failed and colostomy was the final treatment. The same pathway without SNM was the comparator.

Location/setting
Italy/hospital.

Methods
Analytical approach:
The analysis was based on a published decision model that included a Markov sub-model at the end of each treatment. A five-year time horizon was considered. The authors stated that the perspective of the Italian National Health Service (NHS) was adopted.

Effectiveness data:
The clinical evidence was derived from selected relevant studies. The key input for the model was the rate of success with SNM, which was defined as the number of patients not seeking further treatment because they considered that their reduction in incontinence was satisfactory. These data were from a published review of the literature commissioned by the UK National Institute for Health and Clinical Excellence (NICE) and from a study of the first 100 permanent SNM implants in a Dutch centre. The efficacy of other surgical options was from another review of published studies. Statistical tests were performed on the heterogeneity between these sources. Additional data were based on expert opinion.

Monetary benefit and utility valuations:
The utility values were from a published study.

Measure of benefit:
Quality-adjusted life-years (QALYs) and symptom-free years were the benefit measures and they were discounted at an
annual rate of 3%.

Cost data:
The economic analysis included the costs of sphincteroplasty, dynamic graciloplasty, artificial sphincter, colostomy, SNM, follow-up (out-patient visit, anal ultrasound, anorectal manometry, and laboratory tests), and disposables or devices (diapers for patients with faecal incontinence and bags for colostomised patients). The costs were from the Italian NHS procedure reimbursement list for hospital and ambulatory services. The patterns of resource consumption were based on expert opinion and published reports. All costs were in Euros (EUR) and a 3% annual discount rate was applied to the long-term costs.

Analysis of uncertainty:
A probabilistic sensitivity analysis, based on Monte Carlo simulation, was carried out using beta distributions for the frequencies and log-normal distributions for the costs. A multivariate sensitivity analysis was performed on the costs of an artificial sphincter, the SNM test, and a permanent SNM implant. The alternative costs were based on real-life estimates.

Results
In patients with a structurally deficient anal sphincter, SNM cost an additional EUR 2,417 and led to a gain of 0.45 symptom-free years or 0.085 QALYs, resulting in an incremental cost per symptom-free year gained of EUR 5,374 or an incremental cost per QALY gained of EUR 28,285 over no SNM. At a threshold of EUR 40,000 per QALY, the probability of SNM being cost-effective was 99%. When alternative cost estimates were used, the incremental cost per QALY fell to EUR 24,000.

In patients with an intact anal sphincter, SNM cost an additional EUR 4,878 and led to a gain of 0.66 symptom-free years or 0.13 QALYs, resulting in an incremental cost per symptom-free year gained of EUR 7,346 or an incremental cost per QALY gained of EUR 38,662 over no SNM. At the threshold of EUR 40,000 per QALY, the probability of SNM being cost-effective was 53%. When alternative cost estimates were used, the incremental cost per QALY fell to EUR 29,251.

The budget impact of SNM was modest, with an increase of approximately 0.5% of the total health care cost of treating faecal incontinence over five years.

Authors’ conclusions
The authors concluded that SNM was efficient and provided good value for money, with a modest budget impact.

CRD commentary
Interventions:
The selection of the comparators was appropriate and the authors described two possible pathways that did or did not include SNM, either as a first- or second-line option.

Effectiveness/benefits:
A selective approach was used to identify the relevant sources of data and limited information on these sources was given, but the selection of a NICE review should ensure the validity and rigour of the clinical inputs. The authors stated that the other review of clinical studies had high heterogeneity, which was investigated using appropriate tools, but none of the included studies was a clinical trial and none was a direct comparison. The authors attempted to overcome these limitations in the published literature by conducting an extensive sensitivity analysis. A disease-specific and a more generalisable benefit measure were used. QALYs were an appropriate measure because the disease has a dramatic impact on a patient’s quality of life. No details were given on the instruments used to elicit the preferences for health conditions for the utility valuations.

Costs:
The cost categories and their sources appear to have been appropriate for the perspective of the Italian NHS. The sources for the resource use and unit costs were typical for the Italian context. A breakdown of cost items was not given as the costs were estimated using diagnosis-related groups, which provide costs as category totals. This method is often
used when costs are calculated using reimbursement data, but it has the disadvantage of limiting the transparency of the evaluation. Alternative real-life cost estimates were considered, but their sources were not described. Reflation exercises will be difficult because the price year was not explicitly reported. The impact of variations in the cost estimates was considered in the sensitivity analyses.

Analysis and results:
The results were clearly and extensively presented, with both total and incremental costs and benefits. The incremental analysis was appropriate for synthesising the projected outcomes of the two strategies. A clear description of the decision model was provided. Conventional discounting was applied to both the costs and benefits. The uncertainty was investigated using two approaches, which were appropriate, and the findings were clearly presented. The authors acknowledged some limitations of their analysis, which mainly related to the poor quality of some published studies. They stated that a longer time horizon would have included the need for battery replacement for patients receiving SNM, but there was a lack of good long-term studies.

Concluding remarks:
The cost-effectiveness framework was conventional, which should ensure the validity of the authors’ conclusions.

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