Clinical and cost effectiveness 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
The objective was to examine the cost-effectiveness of sacral nerve stimulation (SNS) for the treatment of faecal incontinence. The authors concluded that SNS was cost-effective from the perspective of a Spanish hospital. The study had some methodological limitations, which may have affected the validity of the authors' conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to examine the cost-effectiveness of sacral nerve stimulation (SNS) for the treatment of faecal incontinence.

Interventions
The intervention was the SNS protocol, the details of which were reported, and the comparator was the conventional protocol, but the key details of this were not reported.

Location/setting
Spain/hospital.

Methods
Analytical approach:
The clinical analysis was based on a single study and the cost-effectiveness analysis was based on a Markov model, with a five-year time horizon. The authors stated that the perspective of the hospital was adopted.

Effectiveness data:
The clinical analysis was based on a within-group comparison study, which included 47 patients, 44 of whom were women. The inclusion criteria were reported and all patients received SNS. The mean age was 58.2 years (SD 10.9) and the total length of follow-up was five years. Visits were scheduled at one, three, and six months, one year, and then once yearly. The key clinical endpoint was the reduction in incontinence episodes with SNS compared with baseline.

Monetary benefit and utility valuations:
Quality of life was assessed using two questionnaires: a generic Short Form (SF-36) health survey and a specific questionnaire for faecal incontinence; the Fecal Incontinence Quality of Life (FIQL) scale.

Measure of benefit:
Quality-adjusted life-years (QALYs) and incontinence-free life-years were the summary benefit measures.

Cost data:
The economic analysis included the cost of materials for provisional and permanent stimulation, hospital stay, and operating time. The unit costs and resource quantities were reported for some items. The sources of data were not explicitly reported, but the costs were derived from the authors' institution. They were in Euros (EUR) and the price year was not reported.

Analysis of uncertainty:
Not investigated.
Results
Compared with baseline, SNS provided improvements in all domains of the SF-36 and the FIQL scale at all time points. A significant mean percentage reduction in faecal incontinence episodes was observed during follow-up, reaching 89% at three years.

In the whole series of patients, the total costs amounted to EUR 371,434. A large part of these costs was associated with the permanent implantation of the device.

Over five years, there was an incremental gain of 0.34 incontinence-free life-years and an additional cost of EUR 1,054, resulting in an incremental cost per QALY gained with SNS over the old protocol (no SNS) of EUR 16,181, which was below the commonly accepted Spanish threshold for cost-effectiveness of EUR 30,000 per QALY.

Authors' conclusions
The authors concluded that SNS was cost-effective from the perspective of a Spanish hospital.

CRD commentary
Interventions:
The authors presented extensive information on the health technology for SNS, but the comparator was not clearly described. SNS was compared against the old protocol, which was probably no intervention, but no details of this protocol were given. Other interventions for faecal incontinence were not considered and the authors did not provide a justification for this.

Effectiveness/benefits:
The clinical analysis compared the SNS procedure with the preoperative status of the patients. Thus, a before-and-after study was undertaken in a single group of patients, who acted as their own controls. The clinical endpoints were appropriate for the scope of the clinical analysis and were well reported. No formal justification for the sample size was provided. The evidence came from a single institution and care should be taken when assessing the applicability of these results to other patient populations. Both disease-specific and generic benefit measures were used. QALYs are widely accepted and commonly used as they not only capture the impact of the interventions on quality of life and survival, but can also be directly compared with the benefits of other health care interventions. Preferences were directly elicited from patients included in the study, which was a valid method. No discount rate was applied even though a five-year time horizon was used.

Costs:
The categories of costs were consistent with the viewpoint of the hospital, but only the costs of the SNS procedure were considered. The economic analysis was only partially reported. Data on the unit costs and quantities of resources used, price year, and the sources of data were not reported, which limits the transparency of the analysis. No discount rate was applied even though a five-year time horizon was used.

Analysis and results:
The results of the clinical study were clearly presented, but less clear information on the benefits of the analysis and the Markov model were reported. Only incremental costs and benefits were reported and the expected costs and QALYs of the two strategies (SNS versus the old protocol) were not given. The issue of uncertainty was not investigated. The authors provided an extensive discussion of the clinical features of SNS. It was stated that few economic evaluations of treatments for faecal incontinence were available in the literature.

Concluding remarks:
The study had some methodological limitations, which may have affected the validity of the authors' conclusions.

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