Cost-effectiveness analysis of sacral neuromodulation (SNM) with Interstim for fecal incontinence patients in Spain

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 study assessed the cost-effectiveness of sacral neuromodulation (SNM) therapy with Interstim versus usual care in patients with faecal incontinence. A budget impact analysis was also carried out. The analysis demonstrated the cost-effectiveness of adding SNM to the current management of faecal incontinence, with a minor impact on the total costs to the National Health Service. The quality of the study methodology was good in terms of the sources used and presentation of the results. Overall, the authors’ conclusions are valid and robust.

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

Study objective
The primary objective of the study was to examine the cost-effectiveness of sacral neuromodulation (SNM) therapy with Interstim versus current management in two populations of patients with faecal incontinence (FI). The two populations were those with intact anal sphincter (IAS), and those with structurally deficient anal sphincter (SDAS) after sphincteroplasty. A budget impact analysis was also undertaken to estimate the economic impact of adding SNM therapy to current management in Spain.

Interventions
Two strategies for the management of FI were under examination. Under the first scenario, patients were treated using current management without SNM. Under the second scenario, SNM was offered as first-line therapy to IAS patients not responding to conservative treatment, and as a second-line therapy in SDAS patients not responding to sphincteroplasty.

Location/setting
Spain/hospital.

Methods
Analytical approach:
A Markov model was developed in order to assess the clinical and economic impact of the two strategies under examination. The time horizon of the analysis was 5 years. The authors stated that the analysis was carried out from the perspective of the Spanish National Health Service.

Effectiveness data:
The clinical estimates used in the decision model for surgical options (artificial anal sphincter, sphincteroplasty) were derived from a published clinical review, which included different study designs, some of which were of low-level such as case-series. Data on the effectiveness of SNM were taken from a systematic review commissioned by the National Institute for Clinical Excellence (NICE) in the UK. However, few details of these sources, which appear to have been identified selectively, were given. Assumptions about the long-term effectiveness of the different strategies were made.

Monetary benefit and utility valuations:
Utility valuations were based on a published study on patients with FI, the main characteristics of which were not reported, although utility values were presented.
Measure of benefit:
The summary benefit measures were the quality-adjusted life-years (QALYs) and symptom-free years (SFYs). Both measures were estimated using the decision model. An annual discount rate of 3% was applied.

Cost data:
The health services included in the analysis were grouped under two main categories: costs of disease and costs of the procedures under examination. A breakdown of the cost items was not given. The resource use data were estimated by means of expert opinion. The costs were taken from a Spanish Health Costs Database. Future costs were discounted at an annual rate of 3%. The price year was not reported. The costs were in euros (EUR).

Analysis of uncertainty:
A probabilistic sensitivity analysis was performed by means of a Monte Carlo simulation for a cohort of 1,000 hypothetical patients. Cost-effectiveness acceptability curves were generated. The probabilistic distributions assigned to model inputs were reported.

Results
In the population of patients with muscular lesion (SDAS patients), the expected costs were EUR 5,363 without SNM and EUR 6,688 with SNM. The expected SFYs and QALYs were 3.012 and 3.99, respectively, without SNM and 3.326 and 4.05 with SNM.

In the population of patients without muscular lesion (IAS patients), the expected costs were EUR 9,192 without SNM and EUR 10,247 with SNM. The expected SFYs and QALYs were 1.64 and 3.73, respectively, without SNM and 1.98 and 3.79 with SNM.

The incremental analysis showed that the incremental cost per SFY gained with SNM over no SNM was EUR 4,217 in SDAS patients and EUR 3,074 in IAS patients. The incremental cost per QALY gained with SNM over no SNM was EUR 22,195 in SDAS patients and EUR 16,181 in IAS patients.

The sensitivity analysis indicated that, at a threshold of EUR 35,000 per QALY, the probability of the introduction of SNM being cost-effective was 98% for SDAS patients and 81% for IAS patients.

The budget impact analysis, which assumed a prevalence rate of 1.4%, indicated that the estimated net impact of the introduction of SNM to the current management of FI in Spain was negligible, representing an increment ranging from 0.07 to 0.1% of total disease costs for these patients.

Authors' conclusions
The authors concluded that the introduction of Interstim into the management of FI in both IAS and SDAS patients was a cost-effective strategy, with a relatively acceptable additional cost to the Spanish National Health Service. The authors stated that the current findings should be corroborated in prospective studies.

CRD commentary
Interventions:
The authors described in an exhaustive fashion all the possible strategies available for the management of FI. The pros and cons of each approach were discussed. The inclusion (or exclusion) of SNM appears to have been valid in the selection of the comparators. These approaches are also likely to be valid in other settings.

Effectiveness/benefits:
The primary clinical data were identified from selected sources which the authors identified directly. The authors did not mention the details of a potential review of the literature. Instead, the two sources were published reviews of clinical evidence. One of them was commissioned by NICE, the methodological criteria of which should have ensured the validity of the clinical estimates. The clinical evidence of the second source was also based on case series and observational studies, which was acknowledged to be a limitation of the study. In general, the authors noted some problems relating to the use of data from heterogeneous sources, the validity of which was unclear given to the methodological weaknesses.
Costs:
The categories of costs included in the analysis were consistent with the authors’ stated perspective. However, the costs were presented as macro-categories and were not broken down into single items, and the price year was not stated. These missing data may limit the possibility of replicating the analysis in other settings and time periods. The sources of the economic data were reported and reflected the Spanish health care setting. The probabilistic distributions given to the cost estimates were reported and followed typical recommendations made in probabilistic studies. The assumptions made in the budget impact analysis were explicitly reported. The authors discussed the difficulties in identifying appropriate cost categories for FI. Nevertheless, it was pointed out that conservative assumptions were made, resulting in a potential underestimation of the cost of disease, which could further favour the intervention strategies.

Analysis and results:
A synthesis of the costs and benefits was appropriately performed, and the results of both the base-case and the sensitivity analysis were presented clearly. The issue of uncertainty was appropriately addressed by means of conventional probabilistic analysis, which is usually considered to be the best approach to dealing with uncertain model inputs. Despite the uncertainty surrounding the estimation of some clinical and economic data, the sensitivity analysis confirmed the robustness of the final results. The structure and assumptions of the decision model were explicitly reported.

Concluding remarks:
The quality of the study methodology was good, with satisfactory reporting of both sources and results. The authors’ conclusions appear valid and were enforced by the probabilistic sensitivity analysis.

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