Cost-effectiveness of sacral neuromodulation compared to botulinum neurotoxin A or continued medical management in refractory overactive bladder


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 assessed the cost-effectiveness of sacral neuromodulation, compared with botulinum neurotoxin A or continued best medical treatment, for patients with refractory overactive bladder not due to any other disease. The authors concluded that sacral neuromodulation was cost-effective for these patients. The methods were valid and transparent. Some key assumptions were based on expert opinion, but several areas of uncertainty were satisfactorily investigated and the authors’ conclusions appear to be robust.

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

Study objective
This study assessed the cost-effectiveness of sacral neuromodulation, compared with botulinum neurotoxin A (BTX-A) or continued best medical care, in patients with refractory overactive bladder not due to any other disease. A budget impact analysis was carried out.

Interventions
The three interventions were best medical care, which consisted of continued drug and pad use, sacral neuromodulation, with testing and then a permanent implant, and BTX-A injections of 100 units of Botox. Patients had failed one best medical treatment, before starting the study.

Location/setting
Spain/secondary care and hospital.

Methods
Analytical approach:
The analysis was based on a Markov model, with a 10-year time horizon. The authors stated that it was carried out from the perspective of the Spanish National Health Service.

Effectiveness data:
A literature review was performed in electronic databases to identify data for the treatment success or failure, which were the primary inputs for the model. The treatment effect for sacral neuromodulation was from published clinical trials, with up to five years of follow-up. The data for BTX-A were from a one-cycle injection trial, with nine months of follow-up. For refractory best medical care patients who continued on best medical care, only six months of data were available. All data were supplemented or validated by a panel of Spanish experts.

Monetary benefit and utility valuations:
The utility values were from two published sources, one of which was a synthesis of utilities collected from the Basque general population.

Measure of benefit:
Quality-adjusted life-years (QALYs) and the number of incontinence episodes were the summary benefit measures. A 3% annual discount rate was applied.
Cost data:
The economic analysis included the costs of procedures, drugs, follow-up, treatment of adverse events, and management of failure. The patterns of resource use were from the literature and the panel of Spanish experts who validated the effectiveness data. The unit costs were from Spanish official databases, except for that of sacral neuromodulation (including the device, implantation, and battery replacement), which was from the manufacturer. All costs were in Euros (EUR) and were discounted at an annual rate of 3%. The price year was 2008.

Analysis of uncertainty:
A Monte Carlo simulation (1,000 iterations) was carried out to assess the uncertainty, using set probability distributions for the model inputs. Estimates that based on expert opinion were varied by 15% to 200% of the initial estimate. Two deterministic sensitivity analyses were carried out. One examined the effect of variation in the treatment parameters, using data from a study of a 200 unit dose of BTX-A, and the other examined the effect of variation in the disutility values for the treatment outcomes.

Results
At five years, the total costs per patient were EUR 19,156 with sacral neuromodulation, EUR 18,235 with BTX-A, and EUR 15,932 with best medical care. The QALYs were 3.69 with sacral neuromodulation, 3.45 with BTX-A, and 2.75 with best medical care. The incontinence episodes were 9,561 with sacral neuromodulation, 9,790 with BTX-A, and 16,529 with best medical care.

The incremental cost per QALY gained with sacral neuromodulation was EUR 3,775 over BTX-A and EUR 3,412 over best medical care. Per incontinence episode avoided, it was EUR 4.02 over BTX-A and EUR 0.46 over best medical care.

After seven years, the incremental cost per QALY gained with sacral neuromodulation was EUR 9,830 over BTX-A and EUR 3,433 over best medical care. Per incontinence episode avoided, it was EUR 8.29 over BTX-A and EUR 0.47 over best medical care. After 10 years, sacral neuromodulation was dominant, as it was less expensive and more effective than each comparator, for each benefit measure.

At a threshold of EUR 30,000 per QALY, sacral neuromodulation was cost-effective in 99.7% of simulations compared with BTX-A, and 99.9% of simulations compared with best medical care. The cost-effectiveness of sacral neuromodulation held in both the deterministic sensitivity analyses.

The budget impact analysis, for the population of 31,000 eligible patients, showed that the net impact of increasing the rate of sacral neuromodulation treatment by 11.4% was small, in the Spanish National Health Service.

Authors' conclusions
The authors concluded that sacral neuromodulation was cost-effective for the treatment of patients with refractory idiopathic overactive bladder.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear and the commonly used, minimally invasive, interventions for refractory idiopathic overactive bladder were considered. The authors acknowledged that BTX-A was not licensed in Europe at the time of the study, but it was regularly used in Spain.

Effectiveness/benefits:
A valid approach was used to identify the relevant sources of evidence. Clinical trials are generally considered to be valid sources, due to the strengths of their design, but no head-to-head trials were found, which could have introduced bias. Only short-term data were available for two treatments and assumptions had to be made. The authors acknowledged that heterogeneity between the published clinical trials, and the need for assumptions to extrapolate the data beyond five years, were limitations of the clinical analysis. Both benefit measures were appropriate for capturing the impact of the disease on a patient's health. QALYs allow cross-diseases comparisons to be made. The assessment of health-related quality of life was based on Spanish data and some published estimates adapted to Spain.
Costs:
The categories of costs and their sources appear to have been appropriate for the perspective of the public payer. The unit costs were not presented for individual items, but some key details of the cost categories and resource quantities were reported. Expert opinion was required for some economic inputs, especially the treatment patterns and long-term resource use. The price year and discounting were reported. The impact of variations in the individual costs was not explicitly assessed in the deterministic sensitivity analyses.

Analysis and results:
The results were extensively presented for various time horizons. An incremental approach was used to synthesise the costs and benefits of the three interventions. The uncertainty was satisfactorily investigated, using both deterministic and probabilistic approaches, and the findings were clearly reported and discussed. The authors stated that the decision model reflected international guidelines for overactive bladder management. They also stated that this was the first study to compare sacral neuromodulation and BTX-A over a long-term horizon. The analysis appears to have been specific to the Spanish setting and the authors did not discuss the transferability of their results.

Concluding remarks:
The methods were valid and transparent. Some key assumptions were based on expert opinion, but several areas of uncertainty were satisfactorily investigated and the authors’ conclusions appear to be robust.

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