
The cost-effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome

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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

The aim was to assess the cost-effectiveness of spinal cord stimulation compared with conventional medical management or reoperation, for patients with failed back surgery syndrome. The authors concluded that spinal cord stimulation was a cost-effective addition to conventional medical management and alternative to reoperation, for these patients. The methods and the reporting of the study were good. The results appear to be reliable, but this depends on an assumption that the clinical data were robust and comprehensive.

Type of economic evaluation

Cost-effectiveness analysis, cost-utility analysis

Study objective

The aim was to assess the cost-effectiveness of spinal cord stimulation, compared with conventional medical management or reoperation, for patients with failed back surgery syndrome (FBSS).

Interventions

Spinal cord stimulation was compared with conventional medical management, and then separately compared with reoperation, to alleviate the recurrent and persistent pain associated with FBSS. Medical management was available as an additional treatment, in each case, to reflect the usual care. Spinal cord stimulation was delivered by non-rechargeable implanted pulse generators (IPGs); rechargeable generators were considered in a sensitivity analysis. Patients who received stimulation entered a trial period, after which those who achieved optimal pain relief had a permanent IPG inserted, while the remaining patients received medical management or reoperation.

Location/setting

UK/secondary care.

Methods

Analytical approach:

The study used a two-stage model, consisting of a decision tree, followed by a Markov state-transition model, to estimate the clinical and economic outcomes for each FBSS treatment strategy. The responses to therapy in the first six months were captured in the decision tree, and the Markov model was then used to simulate the costs and outcomes, over 15 years. The perspective was not explicitly reported.

Effectiveness data:

The effectiveness evidence came from two randomised controlled trials (RCTs). The Prospective Randomised Controlled Multicentre Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS) trial compared stimulation with medical management (Kumar, et al. 2007, see 'Other Publications of Related Interest' below for bibliographic details), while a trial published by North, et al. (2005, see 'Other Publications of Related Interest' below for bibliographic details) compared stimulation with reoperation. The main clinical parameters were the achievement of a 50% reduction in pain from baseline and the complication rates. The model used the six-month complication rate from the PROCESS trial for stimulation and management, while no complications were assumed for reoperation.

Monetary benefit and utility valuations:

The utility estimates were from the PROCESS trial and were collected using the European Quality of life (EQ-5D)

questionnaire.

Measure of benefit:

The measure of benefit was the number of quality-adjusted life-years (QALYs), which were discounted at an annual rate of 3.5%.

Cost data:

The direct costs included those of screening for spinal cord stimulation, the IPD implantation and complications, and additional pain medication, non-drug pain therapy, and reoperation. These costs were from UK Hospital Episode Statistics, the NHS National Tariff, and published data. The resource use data was from the PROCESS trial. All costs were in 2008 UK pounds sterling (£) and were discounted at an annual rate of 3.5%.

Analysis of uncertainty:

Univariate analyses and a probabilistic sensitivity analysis were performed on the key model parameters to assess the impact of their uncertainty on the results. Cost-effectiveness acceptability curves were presented.

Results

Over the 15-year time horizon, the total cost was estimated to be £89,013 for spinal cord stimulation, compared with £81,986 for conventional medical management; an incremental cost of £7,027. The total cost was £88,970 for stimulation, compared with £82,713 for reoperation; an incremental cost of £6,257.

The total QALYs were 5.31 for stimulation, compared with 4.06 for management; an incremental QALY gain of 1.25. They were 5.13 for stimulation, compared with 4.15 for reoperation; an incremental QALY gain of 0.98.

The incremental cost per QALY gained for stimulation relative to management was £5,624 and relative to reoperation it was £6,392.

The cost-effectiveness acceptability curve, for stimulation compared with management, suggested that the likelihood that stimulation was cost-effective, at a willingness-to-pay of £30,000 per QALY, was 98%. The curve, for stimulation compared with reoperation, suggested that the likelihood of it being cost-effective was 93%.

The results were most sensitive to fluctuations in the cost of additional pain therapy, the working lifespan of the IPG, the cost of management, and the probability of pain relief with stimulation.

Authors' conclusions

The authors concluded that spinal cord stimulation was a cost-effective addition to conventional medical management and alternative to reoperation for patients with failed back surgery syndrome.

CRD commentary

Interventions:

Spinal cord stimulation was well described and was compared with two alternatives that were usual practices in the study setting. It is likely that these comparators will be generalisable to other settings. What is not clear is whether the two comparators should have been assessed in one analysis, rather than two separate analyses.

Effectiveness/benefits:

The effectiveness data were from two RCTs, but limited information was presented. Their design implies good methods, but it is not possible to fully assess them from the reported details. The trials reflected the comparisons modelled, but it was not clear if they were of two distinct populations or if they included samples from the same population. The modelled population was described, but the two trial populations were not. The measure of benefit was QALYs, which were derived from the PROCESS trial participants, using the EQ-5D. The authors provided a justification for the use of the utilities from the PROCESS trial for the comparison between stimulation and reoperation, but the lack of population details makes it difficult to ascertain if these utilities were reasonable for the modelled population, for both comparisons. It was not clear if these two trials comprised all of the available evidence or were selected by the authors. There was no discussion of the need for a systematic review to identify the effectiveness

inputs, and the validity of the conclusions depends on the validity of the model inputs.

Costs:

The authors did not explicitly state the perspective, but they included those costs relevant to a health care payer perspective. The cost estimates were well presented and were relevant to the population and setting. The resource use was from the PROCESS trial, but the details of how it was collected and what was included were not reported. The unit cost estimates were provided and were fully referenced. The price year and discount rate were reported.

Analysis and results:

The analytic approach was well reported. The model structure was reported in full, with diagrams of the decision tree and the subsequent state-transition model. The results were reported clearly and sensitivity analyses that were appropriate for the type of analysis were performed. The reporting was sufficient and the base-case estimates of the effectiveness and costs were given. A number of assumptions were made to facilitate the modelling, and most of these were tested in threshold analyses. The authors discussed the limitations of their study.

Concluding remarks:

The methods and the reporting of the study were good. The results appear to be reliable, but this depends on an assumption that the clinical data were robust and comprehensive.

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Bibliographic details

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http://journals.lww.com/clinicalpain/Abstract/2010/07000/The_Cost_effectiveness_of_Spinal_Cord_Stimulation.2.aspx

Other publications of related interest

Kumar, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007; 132: 179-188.

North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery* 2005; 56: 98-106.

Indexing Status

Subject indexing assigned by NLM

MeSH

Back Injuries /surgery /therapy; Cost-Benefit Analysis /methods; Electric Stimulation Therapy /methods; Great Britain; Health Expenditures; Humans; Models, Statistical; Neurosurgical Procedures /adverse effects; Pain Measurement; Probability; Quality of Life; Retrospective Studies; Sensitivity and Specificity; Treatment Failure

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