The cost-effectiveness of spinal cord stimulation for complex regional pain syndrome
Kemler MA, Raphael JH, Bentley A, Taylor RS

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 adding spinal cord stimulation (SCS), using non-rechargeable implanted pulse generators (IPGs), to the conventional medical management for patients with complex regional pain syndrome type I. The authors concluded that non-rechargeable SCS was cost-effective as an addition to medical management. Rechargeable IPGs should be considered when the non-rechargeable IPG life was likely to be short. The study was based on valid and robust methods that ensure the validity of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of adding spinal cord stimulation (SCS), using non-rechargeable implanted pulse generators (IPGs), to the conventional management for patients with complex regional pain syndrome type I. It was an update of an economic evaluation carried out in 2008 by the National Institute for Health and Clinical Excellence (NICE) in the UK.

Interventions
SCS was added to the usual medical management and compared with the medical management alone. Both non-rechargeable and rechargeable IPGs were considered and compared.

Location/setting
UK/hospital and secondary care.

Methods
Analytical approach:
The analysis was based on a two-stage decision-analytic model, with a six-month decision tree followed by a Markov model up to a 15-year time horizon. The authors stated that the analysis was carried out from the perspective of the UK National Health Service (NHS).

Effectiveness data:
The clinical data came from a selection of relevant studies. The treatment effect for SCS with medical management, over five years, came from a published randomised controlled trial (RCT), which also provided the data on the long-term complications with SCS (Kemler, et al. 2000, see ‘Other Publications of Related Interest’ below for bibliographic details). The key input was the achievement of at least a 50% reduction in pain on the visual analogue scale (VAS) and these data came directly from the RCT. Other data for the long-term transition probabilities came from observational studies identified by a systematic review.

Monetary benefit and utility valuations:
Most of the utility values were derived from responses to the European Quality of life (EQ-5D) questionnaire, and these were collected during the RCT.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and they were discounted at an annual rate of 3.5%.
Cost data:
The economic analysis included the costs of SCS using an IPG (including implantation, removal, and related complications), and drug and non-drug treatments for pain. The resource use data were from the Prospective, Randomized, Controlled, Multicenter Study in Patients with FBSS (PROCESS) trial, an international trial of patients with failed back surgery syndrome. The unit costs were based on official NHS tariffs and data from the device manufacturer. All costs were in UK pounds sterling (£) and were discounted at a rate of 3.5% per annum. The price year was 2008.

Analysis of uncertainty:
A probabilistic sensitivity analysis, based on a Monte Carlo simulation, was undertaken by varying the success rate, resource use, complication rate, and SCS failure rate. Cost-effectiveness acceptability curves were generated. One-way sensitivity analyses were also carried out for all the inputs to the model. The assumption on the battery life of the rechargeable IPGs was also investigated.

Results
The total costs per patient were £86,770 with SCS and £79,775 with medical management only. The QALYs were 4.84 with SCS and 2.88 without it. The incremental cost per QALY gained with SCS over no SCS was £3,562.

The deterministic sensitivity analysis suggested that cost-effectiveness of SCS improved: when the cost of additional drugs for pain in SCS patients decreased; when the time before a replacement IPG was needed increased; when the cost of medical management drugs increased; and when the annual probability of no pain relief with SCS decreased. In all simulations the SCS option remained cost-effective.

In the probabilistic analysis, the probability that SCS was cost-effective at a willingness-to-pay threshold of £20,000 per QALY was 74% and at £30,000 it was 87%.

Compared with non-rechargeable, rechargeable IPGs lasting nine years were cost-effective at a threshold of £20,000 per QALY, when the expected longevity of the non-rechargeable IPG was less than four years.

Authors' conclusions
The authors concluded that non-rechargeable IPG SCS was cost-effective as an addition to conventional medical management. Rechargeable IPGs should be considered when the non-rechargeable IPG life was likely to be short.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear, but more details of the medical management would have been useful.

Effectiveness/benefits:
The bulk of the evidence was from a RCT, which is generally considered to be a valid source of clinical data due to its methodological strengths and rigorous design. The trial was published elsewhere and limited information on its characteristics and patient population was given. This RCT was also used to derive the utility values for the patient population, using a validated instrument. The long-term data were appropriately from a long-term UK observational study. QALYs were a valid benefit measure, because this pain syndrome has a big impact on quality of life. QALYs also allow cross-disease comparisons to be made.

Costs:
The cost categories and their sources were consistent with the perspective of the NHS. The data on resource use were from a multinational RCT with a slightly different patient population to that analysed in this study. This RCT was chosen because of its very detailed analysis of resource use compared with other sources. The unit costs came from standard UK sources and the costs were presented as total categories and were not broken down into individual items. Reflation exercises in other time periods should be possible as the price year was reported.

Analysis and results:
The results were clearly reported and an incremental analysis was performed to synthesise the costs and benefits. Conventional discounting was applied to both the costs and benefits. The decision model was clearly described. The uncertainty was satisfactorily investigated, using valid methods. The authors noted that their results were more favourable to SCS than the previous NICE findings, and this was due to higher QALY gains. They stated that their findings were based on patient-level data that allowed a better identification of the clinical outcomes from conventional management.

Concluding remarks:
The study was based on valid and robust methods that ensure the validity of the authors' conclusions.

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