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.

Health technology
The use of spinal cord stimulation (SCS) implantation for the treatment of failed back surgery syndrome (FBSS).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised adult patients with FBSS who had not undertaken surgery.

Setting
The setting was primary and secondary care. The economic study was carried out in the UK.

Dates to which data relate
The dates during which effectiveness and resource use data were gathered were not reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was conducted on the same sample of patients as that used in the effectiveness study.

Study sample
The use of power calculations was not reported. A sample of 20 adult patients was identified at the study hospital and was included in the study. There were 12 men with a mean age of 55.6 years (age range: 43 - 61) and 8 women with a mean age of 50.5 years (age range: 28 - 58). It was not stated whether any patients were excluded from the initial study sample or refused to participate.

Study design
This was a within-group comparison study that was presumably carried out in a single centre, the Mornington Clinic in Bradford, UK. The patients had not undergone any surgery for at least 2 years before the commencement of the study in order to ensure that they were in a steady state. The length of follow-up was 5 years. Only one patient was lost to
follow-up.

**Analysis of effectiveness**
The analysis of effectiveness was restricted to those patients for whom follow-up data were available. The health measures used were:

treatment outcomes and complications, and

measured parameters, such as back and leg pain (estimated using a visual analogue scale, VAS), physical functioning, work status and quality of life.

**Effectiveness results**
In terms of treatment outcomes and complications, 40% of the patients had no problems, 25% replaced the Itrel (internalised) with the Xtrel (externalised) generator, 10% had electrolyte resisting, 10% experienced receiver position adjustment, and 5% had the system removed (the patient who was lost to follow-up).

After implantation, back pain decreased from 8.5 to 6 on the VAS and leg pain decreased from 8 to 5.5. Physical functioning improved by 20%.

Three patients returned to work and quality of life improved in terms of sleep, mood and mobility.

After 5 years, back pain decreased from 6 to 3.2 on the VAS and leg pain decreased from 5.5 to 2.1.

Physical functioning improved by a mean of 30% (range: 10 - 100).

Four patients had remained at work but functioned more efficiently and with minimal time off work. Another 4 patients returned to work, 10 remained in the unemployment status they were in before the intervention, and one returned to work but retired after 2 years due to age.

Quality of life improved in terms of sleep, mood, and mobility.

**Clinical conclusions**
The effectiveness study showed that the implantation of SCS for the treatment of FBSS led to a general improvement in patient health in both the short and long term.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the study. In effect, a cost-consequences analysis was conducted.

**Direct costs**
Discounting was relevant since the costs were incurred over a 5-year timeframe, but it was not reported. The unit costs were provided but no information on resource use was reported. The health services considered in the study were equipment costs, hospital costs and operative costs. The cost/resource boundary of the study was unclear. Resource use was estimated using actual data derived from the same sample of patients as that used in the effectiveness study. The source of the cost data was not reported. The price year was not given.

**Statistical analysis of costs**
The costs were treated deterministically.
**Indirect Costs**
The indirect costs were not included.

**Currency**
UK pounds sterling (€).

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
In the pre-implant year, the mean cost of treatment was 1,954.18 (range: 354.26 - 5,296.51).

In the first year post-implantation, the mean costs of care were 1,250.16 (range: 477.12 - 2,831.50). However, when the costs of the capital outlay were added, the average costs were 9,129.66 (range: 8,053.86 - 11,442.50).

Over the 5 years, the extrapolated pre-implantation costs were 9,770.90.

Therefore, the author noted that cost-neutrality was achieved after 5 years. However, the author stressed that modifications in technique and management could lead to cost-neutrality after 3.4 years.

**Synthesis of costs and benefits**
The costs and benefits were not combined because a cost-consequences analysis was performed.

**Authors' conclusions**
The implantation of spinal cord stimulation (SCS) led to improvements in patient health and was cost-neutral in comparison with no intervention.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator was made to reflect patients in a steady state. There was no comparison with an alternative strategy for the treatment of FBSS. You should decide whether this represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The basis of the analysis of effectiveness was a within-group comparison study, which was appropriate for the study question as no external comparison group was required. Blinding was not conducted and presumably would not have been feasible due to the nature of the intervention. It was unclear whether the study sample was representative of the study population. Some selection and assessment bias could have been introduced due to the study design. The main limitation to the validity of the analysis was the fact that the author did not justify the size of the sample, which was very small. Indeed, power calculations were not performed and there was no evidence that the sample was appropriate. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.
Validity of estimate of costs
The author did not explicitly report the perspective of the study. It was therefore unclear whether all the relevant categories of costs were considered. Information on the unit costs was not provided separately from the quantities of resources used, as only the unit costs were reported. The price year was not given, which makes reflation exercises in other settings difficult. Discounting would have been relevant due to the long time horizon of the study, but it does not appear to have been conducted. The source of the cost data was not provided. The costs were treated deterministically and were specific to the study setting since no statistical tests were conducted.

Other issues
The author compared the findings with those from other study that reported comparable results. However, the issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not performed to ensure the transferability of the study conclusions. Therefore, the external validity of the analysis was low. The study referred to the general group of patients suffering from FBSS and this was reflected in the author's conclusions.

Implications of the study
The study results suggested that SCS could be a clinically effective and cost-neutral strategy for the treatment of patients with FBSS in their own setting. More cost-effective studies, with larger samples of patients, should be carried out to corroborate the findings of the current study.

Source of funding
None stated.

Bibliographic details

Other publications of related interest

Indexing Status
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