Clinical and cost-effectiveness analysis of an open label, single-centre, randomised trial of spinal cord stimulation (SCS) versus percutaneous myocardial laser revascularisation (PMR) in patients with refractory angina pectoris: the SPiRiT trial

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 evaluate the clinical outcomes and cost-effectiveness of spinal cord stimulation (SCS) versus percutaneous myocardial laser revascularisation (PMR) in patients with refractory angina pectoris. The authors concluded that SCS was less cost-effective than PMR in the UK. Overall, the study methodology was presented clearly and valid sources of data were used. The results are likely to be robust, but the small sample size should be considered as a limitation.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to evaluate the clinical outcomes and cost-effectiveness of spinal cord stimulation (SCS) versus percutaneous myocardial laser revascularisation (PMR) in patients with refractory angina pectoris.

Interventions
SCS was compared with PMR.

Location/setting
UK/hospital.

Methods
Analytical approach:
This economic analysis was based on a single clinical study, with a time horizon of 24-months. The authors stated that a National Health Service (NHS) perspective was adopted.

Effectiveness data:
The clinical data were derived from a randomised controlled trial (RCT) that enrolled 68 patients (34 in each group) over the period from December 2000 to December 2003. Patients were followed up at three, 12 and 24 months. The two groups were comparable at baseline in terms of their demographic characteristics and severity of illness. The details of the RCT were presented elsewhere (McNab, et al. 2006, see 'Other Publications of Related Interest' below for bibliographic details). The primary outcome for the clinical trial was exercise treadmill time. Secondary outcomes included angina, morbidity or mortality, and quality of life, measured by the disease specific Seattle Angina Questionnaire and the Short Form (SF-36) questionnaire.

Monetary benefit and utility valuations:
The utility valuations were derived from the sample of patients enrolled in the RCT, using the self-reported European Quality of life (EQ-5D) questionnaire administered at baseline, and three, 12 and 24 months. The utility data between 12 and 24 months were discounted at an annual rate of 3.5%.

Measure of benefit:
The health benefit measure was quality-adjusted life-years (QALYs).
Cost data:
The costs were those for procedures, cardiac-related medications, and cardiac or non-cardiac-related in-patient or out-patient admissions up to 24 months post procedure. The cost data on procedures were obtained from a NHS Trust, whilst the data on medication costs were from the British National Formulary. All costs were in 2005 to 2006 UK pounds sterling (£). Those costs incurred between 12 and 24 months were discounted at an annual rate of 3.5%.

Analysis of uncertainty:
The uncertainty surrounding the incremental cost-effectiveness estimates was demonstrated by means of a cost-effectiveness acceptability curve (CEAC). A one-way sensitivity analysis was also performed by varying some key model inputs.

Results
There was little difference in the exercise tolerance tests, between the SCS and the PMR groups (difference: 0.05, 95% confidence interval, CI: -2.08 to 2.18, p=0.96). There was no significant difference in Canadian Cardiovascular Society classification or quality of life outcomes between the groups.

The overall costs of SCS were £17,736 (95% CI: £16,398 to £19,202) and PMR were £12,215 (95% CI: £9,603 to £15,448), with a difference of £5,520 (95% CI: £1,966 to £8,613, p<0.01).

The QALYs for SCS were 1.19 (95% CI: 1.040 to 1.319) and for PMR were 1.07 (95% CI: 0.960 to 1.178), with a difference of 0.12 (95% CI: -0.04 to 0.30).

The incremental cost-effectiveness ratio of SCS over PMR was £46,000 per QALY.

The CEAC showed that the probability of SCS being cost-effective (under £30,000 per QALY) compared with PMR over a two year period was approximately 30%.

Authors' conclusions
The authors concluded that SCS was less cost-effective when compared with PMR in the UK.

CRD commentary
Interventions:
The two comparators were well reported and were both in use, within the authors’ setting, at the time.

Effectiveness/benefits:
The use of a RCT was appropriate and should have ensured the validity of the clinical analysis. Full details of the RCT were not presented in this paper. To fully assess its validity the reader should refer to the clinical paper (McNab, et al. 2006). The results from the clinical study, which were used to inform this economic analysis, were reported in full and appropriate statistical analyses were conducted to test their significance.

Costs:
The reporting of the cost analysis was transparent and all the costs relevant to the perspective appear to have been considered. The authors did not provide a breakdown of the cost items. The resource use reflected the real consumption of services in the sample of patients enrolled in the clinical analysis. Statistical analyses were performed to assess the significance of the cost differences. Other details of the analysis, such as the price year and sources of costs, were reported. Since the time horizon was longer than one year, discounting was appropriately conducted.

Analysis and results:
A synthesis of the costs and benefits was conducted and the incremental cost-effectiveness ratio was clearly presented. The issue of uncertainty was satisfactorily addressed in the sensitivity analysis. The results were clearly presented along with a CEAC which will aid decision-makers. The authors highlighted that the small sample size was a limitation to their study.

Concluding remarks:
Overall, the study methodology was presented clearly and valid sources of data were used. The results are likely to be robust, but the small sample size was a limitation.

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