

Executive Summary

Background

Chronic pain, a disease in its own right, is a major healthcare problem affecting an estimated 7 million adults across England and Wales. The disease has a devastating impact on the daily lives of patients and carers; quality of life (QoL) associated with chronic pain is substantially lower than other debilitating conditions such as congestive heart failure. Current management of chronic pain remains sub-optimal, with many patients failing to achieve clinically meaningful reduction in pain severity.

Spinal cord stimulation (SCS) is used to successfully treat patients with intractable pain syndromes who remain refractory to all other medical treatment options available. The current lack of adequate provision of SCS can result in many patients suffering pain unnecessarily.

There are three types of SCS devices: implantable pulse generators (IPG), (non-rechargeable and rechargeable) and radio-frequency (RF) coupled devices. The choice of SCS device depends primarily on an individual patient's medical condition. Good clinical practice and a multidisciplinary management context are also important factors.

Guidelines

According to national and international evidence-based clinical guidelines, patients most likely to respond to SCS include those with neuropathic pain conditions, such as failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS), as well as those with refractory angina (RA) and critical limb ischaemia (CLI). For these conditions, SCS should be considered early in the patient's management when simple first line therapies have failed; SCS should not be considered a treatment of last resort by commissioners.

Clinical effectiveness

In patients with FBSS, significantly more patients receiving SCS in addition to conventional medical management (CMM) achieve a clinically meaningful reduction in pain compared to patients receiving CMM alone or re-operation. Pain relief is accompanied by a significant improvement in the quality of life (QoL) and function of patients.

In patients with CRPS, SCS in addition to physical therapy provides significantly better pain relief than physical therapy alone, accompanied by a significant improvement in the QoL of patients.

Recent randomised controlled trials (RCTs) and systematic reviews demonstrate the clear clinical benefits of SCS in improving pain relief, in addition to circulatory endpoints, in patients with CLI. In patients with RA, SCS demonstrates a reduction in the frequency and severity of angina episodes.

Evidence from RCTs and long-term observational studies indicate that SCS is a minimally invasive, reversible procedure with a good safety profile.

Cost effectiveness

SCS is a cost-effective intervention for patients with FBSS and CRPS and represents efficient use of limited NHS resources; as the primary indications for which SCS is currently used in England and Wales, FBSS and CRPS were the focus of the economic evaluation.

Under very conservative base case assumptions, it was estimated that, in patients with FBSS, SCS+CMM vs CMM alone results in a cost per quality adjusted life year (QALY) of £9,155. Compared to re-operation, SCS+CMM produces a cost per QALY of £7,954.

In patients with CRPS, SCS is also a cost-effective intervention; base case results produce a cost per QALY of £18,881 when SCS+CMM is used in place of CMM alone (physical therapy alone).

Sensitivity analysis demonstrates that SCS remains cost-effective when key clinical and cost parameters are substantially varied; at any device cost between £7,000 and £15,000, the ICER was below £30,000 as long as average device longevity was ≥ 3 years for FBSS patients and ≥ 5 years for CRPS patients. Based on a hypothetical threshold of £30,000 per QALY, the probability of SCS being cost effective reaches $>95\%$ and $>60\%$ in FBSS and CRPS patients, respectively.

Wider NHS implications

Across England and Wales, conservative projections estimate that the total number of patients receiving SCS for chronic pain conditions will rise from current levels of 718 patients to 1,725 five years post-implementation.

The projected annual budget impact of treating FBSS patients with SCS+CMM, in place of CMM alone, ranges from £7.5 million to £10.6 million at year 5. Treating the same patients with SCS+CMM, in place of re-operation, results in a projected impact range of £6.6 million to £9.4 million at year 5. The projected annual budget impact of treating CRPS patients with SCS+CMM, in place of CMM alone (physical therapy alone), ranges from £3.2 million to £4.5 million at year 5. For the additional cost associated with increased uptake of SCS, the quality of life (QoL) of patients experiencing chronic pain will be substantially improved, as demonstrated by the economic evaluation.

The British Pain Society (BPS) have highlighted that provision of chronic pain services in the UK is under- and variably- resourced with clinics providing a variety of treatments and with only half of reported pain clinics being able to offer Pain Management Programmes. Increased uptake of SCS for the treatment of chronic pain will require commensurate funding in multidisciplinary, pain management services.