Comment on Technology Assessment Report for NICE

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Personal Statement

SCS is a technology established over the past 40 years with a still incompletely understood mode of action in modulating the perception of pain of neuropathic or ischaemic origin.

Neuropathic pain has a high prevalence (estimated at 400,000 persons in UK). Only a tiny fraction are currently assessed for possible SCS implantation. Although there has been a welcome increase in the number of pain specialists in the UK, not all pain centres will have the personnel or access to facilities to provide a SCS service. A multi-disciplinary team is required for the assessment, treatment and maintenance of patients undergoing SCS.

Some pain centres will have a surgeon, almost always a neurosurgeon, as the device implanter. Other centres will have a pain physician or anaesthetist implanter. The specialty of the doctor doesn't matter as long as they have training to deal with any complication arising from the implantation of the device. The multi-disciplinary team should continue to follow-up the patient in a dedicated clinic and audit their work.

The cost of hardware is high and this has been a significant factor in tempering enthusiasm for the use of SCS. It is usually suggested as a "last resort" rather than as an early treatment. The uncertainty of a long-term good response to stimulation coupled with an up to 35% complication/revision rate for hardware failure are also factors for consideration.

Despite attempts to identify suitable patients pre-implantation, either by clinical screening alone, or in combination with a trial of percutaneous stimulation; there are still a significant percentage of patients who fail to benefit from the procedure. Even for those in whom there is an initial response, over the course of months and years there can be a loss of efficacy for as yet unknown reasons.

New electrode configurations can help with the spread of the stimulation but have not been yet been fully assessed. The current clinical trials in the above report have used the previous generation of pulse generators and electrodes and the costs may change due to the claimed improvement in battery technology allowing a longer device life.

Problems can arise as the the hardware design does not allow a free range of movement, particularly in the cervical region, with electrode displacement and wire breakage/disconnection. A cervical epidural electrode is more likely to be displaced by movement and these patients may require revision after a fall or sudden twist of the spine.

Cyclical fatigue can also occur particularly where there are sharp changes in direction of the electrode cable. Manufacturers are starting to address this problem with revised electrode cable fixation systems.

A SCS precludes MRI scanning with a body coil, although head-only MRI can be done after suitable precaution. The patients underlying pain problem must not require ongoing body MRI investigations for diagnosis. There are similar safety issues with surgical diathermy where only bipolar diathermy is accepted as safe.

The power source is finite and although there are rechargeable systems coming onto the market, their current price does not make them an automatic choice for replacement over single-use systems. For patients with high treating current demands RF systems are available with an external power supply. These are bulky and restrict the site of the receiving aerial to the belt-line of the lower abdomen to maintain good contact between the transmitter and receiver. Stimulation can be lost due to movement. Long-term there can be problems from the development of skin hypersensitivity to the attachment adhesive.

Despite these caveats SCS can work effectively for some patients with spinal neuropathic pain and CRPS type 1. The data presented by ScHARR have highlighted the few studies which are well designed and adequately powered to demonstrate potential efficacy.

There being only one study of CRPS Type 1 of suitable design is disappointing. These patients are often severely disabled by pain and dysfunction. Alternative treatments pursued by patients have included amputation of the limb; the physical and psychological effects of which are great. More good quality data need to be collected for this indication.