British Pain Society response to NICE Appraisal Consultation Document: Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

The Society wishes to comment upon some of the clinical and cost effectiveness interpretations and hence some of the preliminary recommendations of the Appraisal Committee. Since the distribution of SCHARR's assessment report, new evidence is available with regard to CRPS (1). We are not aware of any equality issues.

1. FBSS

We note the favourable clinical and cost effectiveness interpretations for FBSS and the recommendation of SCS as a treatment option, in the important contexts of multidisciplinary assessment and a successful trial.

2. CRPS

a. Clinical effectiveness

The assessment report determined that there was evidence, from good quality studies, for the clinical effectiveness of SCS in CRPS. This determination appears to have been disregarded by the Appraisal Committee on the basis of the Kemler study (1). The 5 year follow up data is reported not to be different on an intention to treat analysis. The validity of this analysis is very questionable because of significant crossover and non-implantation. A per treatment analysis, excluding those randomised to physical therapy who crossed over to SCS, shows a continued effect at 5 years. Compellingly, 19 of 20 patients reported they would undergo the treatment again for the same result.

b. Cost effectiveness

i) We would argue that the comparator group used in the SCHARR model is no longer appropriate. Patients with general neuropathic pain are likely to include cohorts with less severe pain than patients with CRPS. The severity of pain in patients with CRPS considered for SCS in the Kemler study (1) had a pre-treatment VAS higher than patients in the PROCESS study on FBSS (2). The original Association of Healthcare Industries (ABHI) analysis using FBSS utilities produced an acceptable cost-effectiveness profile. The Society understands that a further economic analysis by the ABHI, using the new utilities for CRPS provided by Kemler (1), is even more favourable.

ii) In all economic models CMM is assumed to have no complications or withdrawal rate. This is clearly not true so, in the absence of data to populate the models, leads to less favourable analyses for SCS.

3. Refractory Angina

a. Clinical effectiveness

There is some confusion with regard to terminology and definitions. However, the extant research clearly demonstrates the clinical effectiveness of SCS over no treatment and that SCS is as effective as other palliative interventions such as high-risk palliative CABG and PMR. In this context it is difficult not to

conclude that SCS should be a treatment option for patients with refractory angina who are not suitable for revascularisation.

b. Cost effectiveness
The cost effectiveness analysis is fundamentally flawed. According to NICE's own definition, refractory angina patients are not candidates for palliative revascularisation. It is therefore illogical and unfair to use cost effective comparisons with revascularisation procedures (bypass or percutaneous coronary intervention). The proper comparators for a cost effective analysis are alternatives to SCS, such as laser revascularisation, transplantation, enhanced external counter pulsation therapy and continued medical treatment.
A UK study, Murray et al (3), showed cost benefit due to decreased admission rates. Another UK study of the effectiveness of a comprehensive programme of rehabilitation, and SCS where appropriate, also demonstrated a reduction in unscheduled admissions (4). Neither study was suitable for the SCHARR model.

4. Critical Limb Ischaemia
a. Clinical effectiveness
The EPOS study (5) showed that a select group of patients with defined levels of tissue oxygenation had significantly better limb survival than unselected groups having SCS. We suggest that if pre-SCS tissue oxygenation meets EPOS entry criteria then a test for change in oxygenation with a trial of SCS should be offered. A significant improvement in oxygenation would trigger SCS implantation and greater limb survival.

5. Other peripheral neuropathic pain conditions
a. Clinical effectiveness
Apart from a small study in diabetic neuropathy all reported data comes from case studies. Nonetheless, the reports suggest that responses mirror that of FBSS and CRPS in carefully selected individuals

Further points for consideration by the Appraisal Committee

A. There are several small sub-groups of patients, particularly with critical limb ischaemia and peripheral neuropathic conditions, where the level of evidence is lower than randomized controlled trials. Nonetheless, evidence exists. We are very concerned that the ACD unaltered will result in commissioning bodies applying rigid criteria for very challenging clinical problems. Currently, cost-per-case commissioning panels assess individual requests for funding. We recommend that NICE recognises the limits of its advice on cost effectiveness and acknowledges the important role of specialist commissioning teams in assessing cost effectiveness in individual cases.

B. We agree that further research is required. Unfortunately, like many other surgical procedures, this is not always easy, and explains why data do not currently exist. We have proposed to several national bodies the establishment of a central register. Among other functions, this would enable the gathering of data to assess the utility of SCS in carefully selected cases. We remain convinced that SCS should be provided in specialist centres able to provide comprehensive multidisciplinary assessment and conventional medical management.

C. We have some concerns with regard to the specialist advisors selected by the Appraisal Committee; these concerns relate to their authority in the use of SCS in ischaemic conditions.
The contribution by Mr Paul Eldridge, of the Society of British Neurological Surgeons, contained in the Evaluation report is not acknowledged in the ACD.

D. Similarly, we have some concerns that ischaemic patient stakeholders have not been fully represented. Input from the British Heart Foundation is acknowledged in the ACD, but is absent in the Evaluation report.

References

1. Kemler MA et al. Effect of spinal cord stimulation for chronic complex regional pain syndrome Type I: five-year final follow-up of patients in a randomized controlled trial. Journal of Neurosurgery 2008; 108: 292-298.
2. Kumar, K et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain 2007; 132:179-188.
3. Murray et al. Spinal cord stimulation significantly reduces the need for acute hospital admission for chest pain in patients with refractory angina pectoris. Heart 1999; 82: 89-92.
4. Moore RKG et al. A brief cognitive-behavioral intervention reduces hospital admissions in refractory angina patients. Journal of Pain and Symptom Management 2007 Mar; 33: 310-316.
5. Amann, W. Spinal cord stimulation in the treatment of non-reconstructable stable critical leg ischaemia: results of the European Peripheral Vascular Disease Outcome Study (SCS-EPOS). European Journal of Vascular and Endovascular Surgery 2003; 26: 280-286.