Personal Statement to NICE re HTA and SCS

I am nominated as an expert on behalf of the Society of British Neurological Surgeons. Surgery to the nervous system for the treatment of chronic pain is a recognised area of neurosurgery. Techniques include direct procedures to relieve the cause of the pain such as microvascular decompression in trigeminal neuralgia; the creation of lesions in the pain pathways such as cordotomy or DREZ lesioning, and neuromodulation which includes intrathecal drug delivery and electrical stimulation of the nervous system. There are several targets for stimulation – from peripheral nerves through to the spinal cord, and then deep brain targets and the cerebral motor cortex. The most frequently used target is the dorsal aspect of the spinal cord as addressed in this appraisal.

My personal involvement in the practice of spinal cord stimulation dates back to 1990, thus I have 18 years of experience of the practice of spinal cord stimulation. This has been at the Walton Centre in Liverpool, where all of the above techniques are in use, and I personally have experience of all of the repertoire of techniques listed above. In addition the unit has several specialists in pain medicine, and an active pain management program. Thus my experience of spinal cord stimulation is of its delivery in a pluripotential multidisciplinary context. The majority of my personal experience is with the use of spinal cord stimulation for neuropathic pain or CRPS; I have very limited experience of its use in lower limb ischaemia, and even less of its use in angina. I do not consider myself in a position to make comment in these areas, though I have seen patients who have responded well in these categories.

I have contributed to the British Pain Society Guidelines on Spinal Cord Stimulation on behalf of the Society of British Neurological Surgeons, and publications in peer reviewed journals and chapters in textbooks on this subject. I have contributed to the assessment group preparing the report for this committee. I have at various times acted as advisor to manufacturers of devices in use for spinal cord stimulation. I am currently secretary to the Society of British Neurological Surgeons.

My personal observation is of many patients over the years, with refractory neuropathic pain deriving substantial benefit from spinal cord stimulation. I am of the belief from my own practice that it is a valid treatment for neuropathic pain and produces excellent responses in the majority of patients after suitable multidisciplinary assessment. Although definitions have changed over the years, and currently the syndrome CRPS is not technically regarded as a neuropathic pain, it is one of the indications that responds to spinal cord stimulation.

Although there is much evidence reporting good results from this technique, relatively little is in the preferred form - ie randomised controlled trial. The majority of evidence – in terms of case numbers is comprised by individual clinicians case series. The criticisms of this level of evidence are well known though taken together the reports comprise several thousand cases. This produces a number of problems. Since the evidence is not of the highest level, and the initial costs of the device high, there is a reluctance on the part of commissioners to agree funding for this treatment. Whilst I do subscribe to basing treatment on the best possible evidence I also feel uncomfortable to discount entirely lower levels of evidence. The therapy has been around for 41 years and in effect there are – taking into account the international practice – tens of thousands of devices

implanted over this period and the majority return for surgery to replace the IPG – odd behaviour if it doesn't work. An important question therefore is what levels of evidence are accepted, and what it is safe to ignore.
However the recently published randomised trials do present evidence of effectiveness, which is consistent with published case series and my own personal experience and that of colleagues. The current appraisal by NICE of SCS is therefore most timely. The challenge in this data for NICE is to balance the relative paucity of randomised controlled trial data against the substantial clinical experience as reported by case series, and personal statements from clinicians with significant experience of implantation.
There are also problems to address in respect of techniques in use, recent changes in technology, and incidence of complications. Each of these areas impacts on the cost effectiveness models –which see later.

Different techniques.

Currently some units practice without percutaneous trial; some units implant surgical leads after a trial, others convert a percutaneous system to a fully implanted system.

Newer technologies

Since the start of this appraisal process each of the manufacturers engaged in this area has developed new varieties of electrodes – in particular concentrating on multiple electrode arrays. In addition different methods for controlling the current – be this voltage controlled or current controlled, and with multiple independent anodes and cathodes, all of which affect the distribution of paraesthesiae. It is also claimed that this increased complexity allows consideration of wider indications, including axial low back pain. Currently we do not implant at the Walton for this indication, awaiting more evidence of efficacy in this area, though have observed occasional patients with leg pain from FBSS in association with low back pain to benefit in respect of the latter. Finally there is the issue of rechargeable devices which allow for longer battery life but as importantly the use of more energy consumptive stimulation parameters – using multiple electrodes. The use of multiple electrodes allowing more precise targeting may improve the effectiveness of stimulation by reducing unwanted paraesthesias. Owing to the recent nature of such developments they have not been subject to evidence based analysis, though anecdotal accounts suggest that improvements are obtained, and this matches my own impression. However this must be acknowledged as the lowest possible level of evidence. Inevitably the advances in technology come with increased costs from the manufacturers.

Extrapolation

The trials under consideration concern FBSS and CRPS. How far is it reasonable to extrapolate from this specific situations?

Environment for successful stimulation.

I firmly believe this should be in the context of a multidisciplinary unit, that should have available to it expertise in pain medicine, pain management techniques and requisite surgical expertise. There is evidence in other areas of neurosurgery that a larger caseload favours good outcomes, and that untis capable of delivering all possible treatment modalities for a condition produce better outcomes.
It is also important to have available dedicated facilities to follow-up this cohort of patients – we have a neuromodulation clinic and have published to the effect that hardware problems do occur but when they are attended to good results are restored to the patient. Another important role for the follow-up function is to perform validated

outcome measures as an audit of the effectiveness of the treatment, though it must be acknowldeged that the current financial climate militates against this; in our institute commissioners are asking that their limited budget be spent more on new patients to meet 18 week targets and that the relative numbers of follow-ups be reduced. There is no recognition in the tariff for a more rigorous assessment of outcome compared to a basic assessment. I believe it will also be important to establish for spinal cord stimulation a device registry similar to that in use for other technologies such as CSF shunts, cardiac valves, artifical joints – the list is not comprehensive. The council of the society of british neurological surgeons is keen to support a national device registry and I would encourage NICE to support such an initiative.

Reference has been made to complications of the procedure, and it is likely that these are under-reported, and also that although rare serious complications do occur. Anecdotally cases are known to me; incomplete paraplegia has happened in our practice and I have acted as medical expert in respect of another case at another institution.

Comparators

I would be concerned throughout the evidence as to the validity of comparators. In the case of neuropathic pain what constitutes best conventional medical management is not clearly defined; nor is the point at which a patient becomes refractory to treatment. In the same way that I have been concerned as to the under reporting of the complications of surgery for spinal cord stimulation I am similarly concerned as to the under-reporting of side effects from medications used for neuropathic pain. Such medication is in use in trigeminal neuralgia, and it is usual to be able to completely cease medical treatment after surgery; it is not until this point that the patient is able to appreciate the side effects of such medication, and in particular the cognitive side effects of such medication. This effect does not appear to be well examined in the literature. It does impact on the comparisons between different arms of a trial, and suggests that patients should be offered consideration of spinal cord stimulation at an earlier stage, especially if it can be predicted they will have a good outcome. Whilst it seems sensible to try non-invasive methods before spinal cord stimulation, it is not clear what represents failure of medication – considering both lack of efficacy and side effects; nor how many agents should be tried before failure of medical treatment be accepted. One presumes the patient should have a voice in this decision! Similarly the role of the cognitive (ie pain management techniques) needs to be defined.

Cost effectiveness

In the report a number of factors influence the ICER. Unsuprisingly amongst these are the basic cost of the device and its longevity. The basic cost of the device rises as more complex devices – in particular rechargeable devices are used. Although anecdotal experience (see above) is that these are better it will be important to establish this point. The longevity of the device should clearly be extended as long as possible, and this is not just confined to considerations of battery life, but also to reductions in hardware failures, and infection rates –again a registry will be important. Maybe it will be important to set a cost limit for an implanted device in this category. I think it should also be appreciated that the history of companies making devices of this type that with time the older simpler types of implant are progressively withdrawn, so that patients can end up with obsolescent unsupported devices, and this is more likely to happen if older devices are implanted as maybe motivated by cost considerations.

It is also admitted that the cost base is not derived in full from UK data; now that the PROCESS study is in the public domain it would seem sensible to include this data in the model, it being a significant study. I understand this study may have been industry sponsored (Medtronic), though the data has been independently collected and analysed.