

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

Patient Evidence Submission by BackCare

BackCare (registered as the National Back Pain Association, charity no. 256751) is an independent national charity that helps people manage and prevent back pain by providing information, promoting self help, encouraging debate and funding research into better back care.

The charity represents people with back pain, a broad range of health professionals treating back pain, researchers and employers.

Activities include:

- operation of a telephone helpline 0845 1302704;
- sponsorship of research into the causes, management and prevention of back pain;
- publication of a quarterly magazine covering topical issues on back pain and back care;
- provision of information through standard reference works, factsheets, booklets, audiotapes, videos and a website www.backcare.org.uk

This submission is made on the basis of:

- BackCare staff and Trustee knowledge of the issues around chronic pain;
- BackCare's experience of representing people living with long-term back pain – its members, helpline volunteers, callers to the helpline, email enquirers;
- Conversations with people who have experience of the technology – either as those who have been given a spinal cord stimulator, who were tried out for fitting but were deemed unsuitable or are waiting for a spinal cord stimulator.

A. What is like to have chronic back pain?

People with chronic low back pain suffer many consequences, including:

- pain that doesn't go away affects every waking moment – it dominates one's thinking and colours one's approach to everything else;
- pain curtails one's activities, it reduces the range of things one can do;
- pain leads to increased dependence on others;
- pain brings fear and anxiety – for the future, if it never gets better; for the increasing loss of work, domestic and leisure activities;
- fatigue and depression often accompany pain;
- loss of the activities that give meaning to life and consequent loss of self-esteem;
- many of the pharmaceutical treatments for pain cause side-effects including sedation and

confusion which further curtails people's ability to function normally.

It is difficult to overestimate the impact that back pain has on society and the individual.

The scale is enormous -

- Almost half the adult population of the UK (49%) report low back pain lasting for at least 24 hours at some point in the year. ⁽¹⁾
- Over 2.5 million people have chronic back pain which is with them every single day. ⁽²⁾
- Nearly 5 million working days were lost as a result of back pain in 2003-04. This means that on any one day 1% of the working population are on sickness leave due to a back problem. ⁽³⁾

Back pain, in particular persistent back pain, can have a significant impact on people's lives. It frequently reduces their quality of life and adversely affects their family and social relationships. ⁽⁴⁾ Many of those affected by back pain face a future of long-term disability and pain, resulting in depression, loss of employment and social isolation

The National Health Service spends per year more than £1 billion on back pain related costs, this includes:

- £512 million on hospital costs for back pain patients.
- £141 million on GP consultations for back pain.
- £150.6 million on physiotherapy treatments for back pain. ⁽⁵⁾

The total cost of back pain corresponds to between 1% and 2% of gross national product (GDP). ⁽⁶⁾

References

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- 2) The Prevalence of Back Pain in Great Britain 1998 Department of Health
- 3) Back Health at Work. HSE 2005
- 4) Pain in Europe; A 2003 report. <http://www.paineurope.com>
- 5) Maniadakis A, Gray A. The economic burden of back pain in the UK. Pain 2000;84:95-103
- 6) Norlund AI & Waddell G. Cost of back pain in some OECD countries. In: Nachemson AL, Jonsson E (eds). Neck and back pain: The scientific evidence of causes, diagnosis and treatment. Philadelphia: Lippencott, Williams & Wilkins, 2000.

B. What are the outcomes that matter most to patients?

This treatment is currently only offered to people who have tried and failed to find relief from their pain using other methods. They are thus likely to have been living with severe, unremitting pain for a long time (often more than ten years). The outcome that matters most is therefore a *significant reduction in pain*. From this, many other positive outcomes will follow (increased ability to do everyday activities, reduced dependence on pain-killers and resultant reduction in side-effects, improved quality of life).

It is very important for people with severe chronic pain to have access to this treatment, currently a

treatment of last resort, since it offers hope of relief; the worst thing for people is to be told that there is nothing more that can be done for one's pain. The impact of chronic pain on the small number of people who cannot find relief through other means is such that this treatment should be available to them.

C. What difference does the technology make?

This treatment, involving as it does a rigorous and lengthy assessment, several hours on the operating table, part of the time under sedation, part under general anaesthetic, 6-8 months before outcome is properly known, risks of rejection, infection, etc, is not a treatment that anyone would undergo lightly.

When it is successful however, it may offer advantages over other treatments for chronic pain:

- patient control over the operation of the device – being able to increase/decrease the stimulation in response to levels of pain experienced. This is very important – it is comparable to the advantages of post-operative patient-controlled pain relief (where patients have a button to press to regulate administration of morphine after surgery). The control that a patient has over the amount of pain relief delivered can reduce anxiety and fear, which in turn has an impact on pain experienced
- fewer side-effects, particularly sedation, than opioids
- lower risks once the device is successfully implanted and accepted by the body than other drugs like NSAIDs

Most importantly, the treatment may be the only hope for a small but significant number of people for a reduction in pain and consequent improvement in their quality of life. When the treatment is successful it can transform people's lives.

D. Using the technology

The procedure is a very demanding one for the patient. This description is based on the experiences of one patient.

After the usual checks, the patient has to undergo a gruelling period of an hour or more on the operating table with sedation-only while the anaesthetist pinpoints the source of pain to decide where the device is to be implanted. Then the device is implanted under general anaesthetic. There are likely to be three incisions and the pain from the incision for the stimulator can be severe for the first few days. Antibiotics will be given to combat risk of infection.

The patient has to avoid bending, twisting, lifting and raising arms above shoulder-height for a period of about two months after surgery to allow the implants to bed in.

There is a risk that the body will reject the device and one cannot properly assess the outcome in terms of pain relief for six to eight months after implantation. However, people report that the device takes the sharpness off the edge of the pain even in the early weeks.

Some people have reported increased weakness in the first few months after the procedure which can be alarming. This can also worsen symptoms of depression that many people living with chronic pain can experience.

Once fitted, people report that the device is fairly easy to manage: to switch on and off, increase or decrease the level of the electrical impulses, etc.

The support of a trained technician who spends time with the patient and family members or carers in first few days and at regular intervals as levels are adjusted, in order to explain how to use the device, and to find optimum settings, is very important. This support needs to be available for a few months as the patient gradually adapts to using the device.

Patients need access to alternative treatment or support for occasions when batteries fail or the device is faulty, which can happen. If the device suddenly stops working for some reason, the sudden return of severe pain can be very distressing and difficult to manage without prior planning.

Conclusion

BackCare would support the approval of approval by NICE of Spinal Cord Stimulation for chronic pain of neuropathic or ischaemic origin.

BackCare would be happy to provide further information on any of the points raised above if this would be helpful.


On behalf of BackCare
20/11/07