HAUTE AUTORITÉ DE SANTÉ

MEDICAL DEVICES ASSESSMENT DEPARTMENT

Assessment of spinal cord stimulation

Summary of the health technology assessment report

March 2014

The full report supporting this assessment can be downloaded from
www.has-sante.fr

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Contents

Project management team

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Senior managers:

Medical Devices Assessment Department:
- Catherine DENIS, head of department;
- Hubert GALMICHE, deputy head of department.

Public Documentation and Information Department:
- Frédérique PAGÈS, head of department.

Composition of the working group

- Dr Myriam CADENNE, rheumatologist, BORDEAUX (33);
- Dr Luc CHADAN, neurosurgeon, DRACY LE FORT (71);
- Dr Alexis FAURE, neurosurgeon, CHOLET (49);
- Prof. Jean-Louis GUILMOT, vascular specialist, TOURS (37);
- Prof. André MULLER, anaesthetist, resuscitation and pain management specialist, STRASBOURG (67);
- Dr Bruno RIOULT, anaesthetist, resuscitation and pain management specialist, NANTES (44);
- Dr Denis SINARDET, neurosurgeon, CLERMONT FERRAND (63);
- Prof. Eric VIEL, anaesthetist, resuscitation and pain management specialist, NIMES (30);

The opinion of the working group presented in this report was validated by each of its members.

Members of the working group were appointed on the basis of suggestions from the relevant associations or learned societies (French College of Anaesthetists and Resuscitation Specialists, French College of Vascular Surgery, French College of Rheumatologists, College of Neurosurgery, French College of Vascular Pathology, French-language Society of Vascular Surgery, French Society for the Study and Treatment of Pain, French Society of Neurology, French Society of Vascular Medicine), following a call for contributions and direct consultation with healthcare professionals. In accordance with Decree No. 2004-1139 of 26 October 2004 (Articles R. 161-84 to R. 161-86 of the Social Security Code), all the members of the group completed a public declaration of interest, the object of which was to inform HAS of any conflicts of interest that some of the members of the group might have with a manufacturer. The public declarations of interest of the candidates for the working group were analysed in accordance with the “Guide to declarations of interest and the management of conflicts of interest” of July 2013.

Healthcare professionals questioned

Three neurosurgeons with particular expertise in the area of spinal cord stimulation were identified but could not participate in the working group because of the existence of conflicts of interest. For this reason they were questioned individually. The healthcare professionals involved in these interviews were:

- Dr Jacques BENEZECH, MONTPELLIER (34);
- Prof. Serge BLOND, LILLE (59);
- Dr Denys FONTAINE, NICE (06).

The experts were each sent a questionnaire, to which they responded individually. The aim was to obtain their reasoned view on the matters addressed without seeking to reach a consensus.

Summary

Background

Implanted pulse generators for spinal cord stimulation are used in refractory chronic pain. Since 2002, the National Committee for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) has assessed 3 categories of neurostimulators:

- Non-rechargeable neurostimulator with a maximum of 8 electrode leads (referred to below as a nonspecific neurostimulator).
- Non-rechargeable neurostimulator with high-capacity cell and a maximum of 16 electrode leads (referred to below as a specific neurostimulator).
- Rechargeable neurostimulator with a battery and a maximum of 16 electrode leads.

Until now, nonspecific neurostimulators were indicated for refractory chronic pain of neuropathic or ischaemic origin (peripheral arterial disease) regardless of the topography. Specific neurostimulators were indicated only for bilateral pain and rechargeable neurostimulators were reserved for patients requiring a high level of stimulation. These reimbursed indications may overlap and the aim of the assessment was to clarify the indications for each category, the technical environment, the preoperative examination and the form of monitoring.

Objectives - working method

The principal objectives of the re-assessment of spinal cord stimulators were to determine the level of evidence of the studies available and to define the criteria for assessing efficacy and safety with a view to specifying their indications in the context of those already being reimbursed. The project also aimed to specify the role of these devices in the therapeutic strategy and to estimate the target population in each indication. The conditions of realisation and the technical environment were also specified.

The working method used was based on a systematic review of the literature, analysis of the data provided by the manufacturers, and recourse to the expertise of healthcare professionals meeting in a multidisciplinary working group dedicated to the subject. The experts approached declared any potential conflict of interest at the start of and throughout the project. Also, three neurosurgeons with particular expertise in the area of spinal cord stimulation were identified but did not participate in the working group because of their conflicts of interest. For this reason they were questioned individually by responding to a pre-established questionnaire.

Analysis of data from the literature

A literature analysis identified 190 references, from which 2 health technology assessment reports and 3 clinical practice guidelines were selected.

The assessment considered the following criteria: pain, patient satisfaction, quality of life, the Oswestry disability index, the consumption of analgesics, the number of amputations and complications. Each article selected was analysed in accordance with the principles of critical reading of the literature using reading checklists drawn up beforehand and scoring grids.

The publications selected were of good methodological quality, but the quality of the studies included was considered poor to moderate (limited numbers of patients, identified biases, lack of blinding). The data from the literature identified dealt with failed back surgery syndrome,

chronic reflex sympathetic dystrophy and critical limb ischaemia. In the first two clinical situations, the results from the literature were in agreement and confirmed the importance of spinal cord stimulation in the treatment of chronic pain associated with these syndromes. With regard to critical limb ischaemia the clinical data did not allow any conclusions to be drawn about either the reduction in pain or the reduction in the number of amputations.

The indications and the methods of treatment were compared among different European countries (the United Kingdom, the Netherlands, Belgium, Germany and France). The indications for treatment vary from one country to another and reflect the low level of evidence available for spinal cord stimulation.

Finally, none of the clinical data allow the indications for spinal cord stimulators to be identified on the basis of their technical characteristics. Within Europe, several countries reserve rechargeable systems for patients with a high consumption of energy but none (except France) distinguishes the indications for nonspecific neurostimulators from those for specific neurostimulators.

Opinions of healthcare professionals

Healthcare professionals questioned

The experts questioned consider that:

- Spinal cord stimulators are important in the treatment of refractory pain of neuropathic origin associated with failed back surgery syndrome, chronic reflex sympathetic dystrophy or component radicular pain.
- Rechargeable systems should be reserved for patients initially implanted with a non-rechargeable system with a short life (30 months) because of high energy consumption.
- The indications for specific or nonspecific neurostimulators could not be distinguished.
- Carrying out an epidural stimulation test before final implantation is essential. Final implantation must be done only when there is a reduction in pain of at least 50% (determined by validated measurement scales) and complete coverage of the painful area.
- It is important to involve a multidisciplinary team or facilities specialising in the treatment of pain to suggest an alternative to spinal cord stimulation.
- Validation of the indication must be accompanied by a patient psychological assessment.
- Spinal cord stimulation does not prevent the use of drug treatments for pain.
- A follow-up examination must be carried out 3 months and 6 months after implantation and then annually.

However, each professional questioned suggested different durations and conditions for performing the epidural stimulation test before permanent implantation. Similarly, two of the three experts interviewed questioned whether a study of somatosensory evoked potentials should routinely be performed in order to examine the functional integrity of somatosensory pathways.

Healthcare professionals meeting in a working group

The working group emphasised that all the comparative clinical studies were conducted in cases where conventional treatments had failed. In the current state of knowledge, spinal cord stimulation must be considered where conventional drug treatment has failed. Clinical evidence exists only for failed back surgery syndrome and chronic reflex sympathetic dystrophy. However, the working group emphasised that failed back surgery syndrome includes numerous aetiologies for pain. Therefore, in view of the clinical evidence and their current practice, the working group suggested reserving spinal cord stimulation for:

- chronic pain of neuropathic origin, after the failure of therapeutic alternatives, secondary to:
  - chronic radicular pain syndrome persisting for at least one year after surgery;
  - chronic axial pain syndrome (of diabetic, post-herpetic, traumatic or surgical origin) persisting for at least one year;
  - complex regional pain syndrome types I and II persisting for at least 6 months.
- pain of ischaemic origin, after the failure of therapeutic alternatives, secondary to Buerger's disease.

In view of the literature and current practice, the working group emphasised that there was no reason to reserve specific spinal cord stimulators only for bilateral or extensive pain. With regard to rechargeable systems, the working group considered that there was no reason to change the allocation criteria in respect of current treatment conditions.

In addition the working group stated:
- Carrying out a pre-implantation assessment is essential, with assessment of the pain, a psychosocial assessment and a quality of life assessment. These assessments must be carried out within a specialist chronic pain facility with the involvement of a multidisciplinary team (at least a pain management specialist and a psychologist or a psychiatrist) and must be accompanied by a report attached to the patient's medical file.
- The pre-implantation assessment must be followed by a neurological assessment, possibly including a neurophysiological component to assess somatosensory evoked potentials.
- It is essential to conduct an epidural stimulation test before permanent implantation. It should last at least seven days at the patient's home. There should be at least a 50% reduction in pain (determined by validated measurement scales), a significant reduction in the consumption of analgesics and an improvement in patient quality of life for a system to be implanted permanently.
- An identification card, a log book and a booklet of guidelines must be given to the patient after permanent implantation.
- A follow-up examination must be carried out 3 months and 1 year after implantation and then annually.

Conclusions of CNEDiMTS

In view of the suggestions of the working group and of the healthcare professionals questioned, CNEDiMTS considers that spinal cord stimulation has a role in the treatment of chronic pain with the following characteristics:
- chronic pain of neuropathic origin, after the failure of therapeutic alternatives, secondary to:
  - radicular or axial pain syndrome of diabetic, post-herpetic, traumatic or surgical origin persisting for at least one year;
  - complex regional pain syndrome types I and II persisting for at least 6 months.
- chronic pain of ischaemic origin, after the failure of therapeutic alternatives, secondary to Buerger's disease.

CNEDiMTS does not include spinal cord stimulation in the treatment of pain of ischaemic origin secondary to peripheral arterial disease, given the lack of conclusive clinical data.

CNEDiMTS recommends reserving rechargeable neurostimulators for patients requiring a high level of stimulation as shown by:
- implant survival of less than 30 months after initial implantation of an implantable non-rechargeable neurostimulator;
- or a stimulation threshold with an amplitude greater than 3.5 V or 4.7 mA at the end of the test stimulation phase.

Considering the lack of conclusive clinical data comparing neurostimulators with one another, the unanimous and consensual view of the working group and reimbursement at European level, CNEDiMTS takes the view that specific neurostimulators are of no particular clinical importance compared with nonspecific neurostimulators. For this reason, there is no reason to distinguish between the indications for these two categories of medical devices. Nonspecific neurostimulators need not be reserved only for unilateral or localised pain.

CNEDiMTS recommends that a pre-implantation assessment and a neurological assessment be done, and it specifies the procedures for doing so. These assessments must be followed by a compulsory epidural stimulation test before permanent implantation. The test must be performed in the patient's home over a period of at least 7 days. CNEDiMTS recommends implanting only patients in whom a reduction in pain of at least 50% measured on a validated scale (identical to that used during the pre-implantation assessment) was observed during the test period.

With regard to patient information, CNEDiMTS specifies that the identification card given to the patient must show details of the type of MRI compatible with the complete system implanted (implantable pulse generator, leads and, if appropriate, extension). Similarly, patients must be informed of the risk of repeat surgery due to technical complications (lead fracture, lead migration, infection, loss of efficacy over time).

For any new device with technical characteristics of stimulation distinct from those of the systems currently in use or with different methods of implantation or for any system for which the manufacturer makes a special claim, CNEDiMTS requires a randomised, controlled, superiority or non-inferiority study intended to compare the new system with a spinal cord stimulator currently reimbursed in France, or any other reference treatment, to be provided. The patients must be randomised to one of two treatment groups following a period of test stimulation before permanent implantation. In order to receive a permanent implant and be randomised, the reduction in pain must be at least 50%. The primary efficacy endpoint must be the reduction in pain compared to baseline as observed after at least 6 months of use. In addition to the superiority measured by this endpoint, the clinical relevance of the analgesic effect observed must be systematically demonstrated. If the design selected is a non-inferiority study, the non-inferiority of the new device must be shown in relation to a comparator with an agreed, clinically acceptable and justified loss of efficacy on pain (limit of non-inferiority), but with demonstration of its superiority in another clinical endpoint (for example, reduction in the level of complications, greater longevity, etc.).

All HAS publications can be downloaded from
www.has-sante.fr