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Cochrane Corner: Spinal cord stimulation for chronic back pain

Despite numerous randomized controlled trials, the effectiveness of spinal cord stimulation for chronic back pain is controversial. A recent systematic review from the Cochrane Collaboration classifies the evidence.

Evidence report.

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The case: A construction worker with chronic pain after trauma

Marco Steiner, a 55-year-old construction worker, had a serious fall on a building site three years ago, resulting in a fracture of the fifth lumbar vertebra. As a result, Mr. Steiner had to be operated on promptly. Despite intensive rehabilitation, he continued to experience chronic back pain with pain radiating into the leg. Considerable pain-related restrictions remained. Treatment with stronger analgesics, including morphine derivatives and tricyclic antidepressants failed to sufficiently alleviate the pain. Conservative measures such as acupuncture and transcutaneous electrical nerve stimulation (TENS) were also not effective. After two attempts at returning to work, it was clear that Mr. Steiner would not be able to return to the construction site and he was subsequently assessed as unfit for work.

In an effort to intensify the treatment, the pain therapist submitted an application to the accident insurance company requesting the coverage of costs for epidural spinal cord stimulation (SCS). The insurance physician planned an evaluation of the evidence on the effectiveness of spinal cord stimulation using evidence-based guidelines, systematic reviews and, if these were lacking, primary studies. In addition to pain reduction, the search also included studies evaluating patient-relevant outcomes such as functionality, quality of life, maintenance of social activities, and the ability to maintain or regain work (1).

Background

Chronic pain in the lumbar spine - with or without a previous accident, with or without previous lumbar spinal surgery, and with or without radiation into the leg - can be neuropathic in nature. The etiology often remains unclear. Despite a broad spectrum of analgesic (non-opioids and opioids) and adjuvant medication (antidepressants, antiepileptics, cannabinoids, muscle relaxants, etc.), non-pharmacological measures (cognitive behavioral therapy, hypnosis, acupuncture, TENS) or various physiotherapy methods, this pain is difficult to treat. Around 30% of affected patients are inadequately treated.

In SCS, electrodes stimulate the spinal cord in the epidural space at the level of the suspected source of pain. Electrical impulses trigger sympatholytic and other neuromodulatory effects. The number and type of electrodes, as well as the type of stimulation parameters, varies between devices. Spinal cord stimulators are often recommended if patients find the pain unbearable or otherwise have multiple restrictions despite conservative therapy.
The extent to which pain improves with spinal cord stimulation has not been convincingly proven despite numerous randomized studies. Conducting such studies in a methodologically robust manner is not impossible, but it is challenging. This could be one of the main reasons why a robust comparison of the effectiveness of spinal cord stimulation versus placebo (sham stimulation) or intensive medical treatment has not been carried out for some time.

The evidence

In this situation, a group of scientists examined the available scientific evidence with a Cochrane Review (2). The review analyzed 13 randomized controlled trials with 699 participants and compared the treatment of low back pain with spinal cord stimulation versus placebo treatment or no treatment. The observation period was between 3 and 12 months. In order for pain studies to deliver reliable results, certain methods must be built into the design, e.g., blinding of doctors and patients as well as the specialists who assess the treatment outcome. These methods are intended to protect against the suggestive effect of expectations of pain relief. In addition, compliance with further methodological standards is assessed, e.g., consideration of all patients in the results or the use of appropriate statistical methods in cross-over studies. The appropriate use of such methods establishes the trustworthiness of the results.

After testing, the researchers came to the conclusion that spinal cord stimulation for the treatment of lumbar spine pain was no more effective than a placebo and would probably result in little to no pain relief for patients and no improvement in their functionality or quality of life (3). Based on the methods used to protect against spurious conclusions, the authors assessed the reliability of the results as moderate (on a four-point scale: high - moderate - low - very low). This assessment suggests that the result is close to the true treatment effect.

The comparison of spinal cord stimulation plus conservative (non-invasive) treatment versus conservative treatment alone yielded similar results: here too, spinal cord stimulation resulted in little or no clinically relevant improvement in back pain, pain radiating into the leg, functionality, or health-related quality of life. The methods used in the studies' designs to protect against false conclusions were so inadequate that the reliability of the results was rated as low to very low.

The studies provided insufficient information regarding risks, side effects, and possible harm to patients.

Conclusion and resolution of the case

The current review does not support the use of spinal cord stimulation to treat people with chronic back pain outside of clinical trials. The current evidence suggests that spinal cord stimulation is unlikely to have lasting clinical benefits that justify the costs and risks of this intervention.

In view of the available evidence, the insurance physician is not convinced about the efficacy of SCS compared to placebo or in combination with other conservative treatment in patients with chronic back pain with a suspected neuropathic component. They decide against recommending the assumption of costs. On the other hand, they recommend trying conservative treatment, e.g., by measuring blood levels of essential drugs such as pregabalin and, if necessary, intensifying it with a trial of controlled conservative therapy and regular documentation using a pain diary. Whether a treatment attempt with spinal cord stimulation should be carried out after an unsuccessful course of optimized conservative therapy of a sufficient duration must be decided together with the patient as part of a detailed and well-informed consultation.

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