Tidsskriftet Tidsskrift for Den norske legeforening

The imaginary effect of epidural spinal cord stimulation

OPINIONS

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Epidural spinal cord stimulation is an expensive therapy for selected patients with chronic pain conditions. Public funding for such treatment should be reassessed.

The treatment has been used for more than 40 years in Norway and its use is increasing internationally (1). However, this does not necessarily imply that it is effective.

The most methodologically robust studies cast considerable doubt on the efficacy of this treatment. Two Cochrane meta-analyses (2, 3), two placebo-controlled trials (4, 5), a study with long-term follow- up (6), and a systematic literature review (1) provide no evidence for any effect beyond placebo. In randomised, industry-independent clinical trials, the placebo response is equal to what is reported as a treatment effect in meta-analyses of observational studies (7).

Observational studies advocating treatment effect lack placebo control or relevant control groups, and often have short follow-up times, financial ties to manufacturers, and weaknesses that prevent from drawing causal conclusions on effect (8). Pharmacoepidemiological studies show that spinal cord stimulation is not associated with a reduction in the use of opioids, healthcare services or new interventions for chronic pain (9, 10). The high rates of complications and reoperations give reason for concern with regard to patient safety. A high proportion of patients with an implanted spinal cord stimulator choose to have the system removed later, which is not unexpected given that the placebo effect generally diminishes over time (11).

> ***«Observational studies making the argument for treatment effect often have short follow-up times, links to manufacturers, and weaknesses that prevent from drawing causal conclusions on effect»***

In a recent article in the Journal of the Norwegian Medical Association, it was stated that patients treated with spinal cord stimulation report a high degree of satisfaction (12). However, satisfaction with treatment is not necessarily associated with treatment effect (13). Patient satisfaction after spinal cord stimulation is not validated as an outcome measure and most likely incorporates a large placebo effect. It is to be expected that patients who are closely followed up and receive highly specialised treatment report that they are satisfied. The strong placebo effect means that the positive experiences of both therapists and patients cannot be used as proof of the efficacy of the treatment.

There are numerous manufacturers, stimulator program settings, and treatment indications for spinal cord stimulation. Irrespective of the type of stimulation that is applied, and what indication there is for treatment, the treatment effects are insufficiently documented. Spinal cord stimulators have regulatory approvals from the US Food and Drug Administration (FDA). However, it is not necessary to document treatment effect for surgical implants to obtain approval for clinical use. In the period 2008–17, the US Food and Drug Administration received more than 80 000 reports of complications associated with spinal cord stimulators (14). Among more than 4 000 implants monitored by the FDA, spinal cord stimulators receive the third highest number of complaints.

Following a Norwegian trial that showed that spinal cord stimulation was no better than placebo for chronic radicular pain after lumbar spine surgery (5), a debate arose in Australia about whether the treatment should be covered by public health insurance (15). Doubts concerning treatment effect and high complication rates have resulted in the Australian health authorities now withdrawing approval for new implants of spinal cord stimulators (16), but strong corporate forces are highly critical of research that casts doubt on the treatment effect (17, 18).

> ***«Doubts concerning treatment effect and high complication rates have resulted in the Australian health authorities now withdrawing approval for new implants of spinal cord stimulators»***

Spinal cord stimulation is one of many examples of treatments that have no proven efficacy, but are nevertheless in widespread use. Campaigns such as Choosing Wisely aim to reduce unnecessary treatments that at worst are harmful to the patient. However, improving clinical practice takes a long time. It is conceivable that stronger measures are needed, and public funding of evidentially ineffective and insufficiently documented treatments should be reassessed. Research in recent years has cast major doubt on the effect, and in our opinion, spinal cord stimulation should only be offered in well-planned, placebo controlled clinical trials that are independent of manufacturers.

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Publisert: 14 November 2024. Tidsskr Nor Legeforen. DOI: 10.4045/tidsskr.24.0483
Received 10.9.2024, first revision submitted 6.10.2024, accepted 31.10.2024.