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Spinal-Cord Stimulators - Even Worse Than Opioids?

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A new patient presents to your clinic with a seven-year history of low back pain, two failed spinal surgeries and chronic use of opioids. She asks if she should consider your therapy or get a surgically implanted spinal-cord stimulator.

She tells you her medical doctor and a representative for the spinal-cord stimulator company both suggested she get a stimulator. Her medical doctor said she has run out of options, especially since he will not write more prescriptions for opioids because of the government crackdown. If she does not get a stimulator, he said, she will be faced with a lifetime of pain.

How do you answer the patient's questions? What does the current research demonstrate? As medical practitioners move to more judicious use of opioids, what will they use instead for patients with serious chronic pain? Unfortunately, your patient might be considering a therapy that has serious problems of its own.

A Disturbing Trend – Without Any Research to Support Its Value

Spinal-cord stimulator surgical implants have increased dramatically in the past decade. An analysis showed that total inflation-adjusted expenditures increased from $292 million in 2009 to $1.142 billion in 2018; a 291 percent increase from 2009 to 2018.[1]

An international research team published a scientific review in the prestigious journal *Pain*[2] that examined all the published randomized clinical trials comparing spinal-cord stimulators with placebo. *They found no quality studies.* All of the studies had serious research failures and were industry sponsored. This medical research team concluded that there was no valid evidence suggesting spinal-cord stimulators are effective.

In a double-blind, randomized study of patients with chronic back pain, patients experienced similar results from spinal-cord stimulation as they did from placebo stimulation.[3] Spinal-cord stimulation was not significantly better than placebo.

Despite the evidence that spinal-cord stimulators are bad for patients, insurance companies frequently pay for them. In fact, some insurance companies do not even require prior authorization. Perhaps we can use the research findings of ineffectiveness and high rates of harms at the negotiation table to improve our insurance reimbursements. Insurance companies are paying over $50,000 ($57,896 under Blue Cross Blue Shield) per case for spinal-cord stimulation implants. Meanwhile, they are de-incentivizing the use of evidence-based preventive therapeutic rehabilitation that can prevent chronic pain by paying chiropractors $17.86 for 15 minutes of care. The more we stand together, the more effective our associations will be.

Also Doesn't Decrease Opioid Use

A research team from Johns Hopkins School of Medicine and Penn State College of Medicine

published a scientific study in *JAMA* about the association between spinal-cord stimulation and long-term opioid therapy.[4] They demonstrated that spinal-cord stimulation did not reduce the use of opioids compared to patients without spinal-cord stimulation.

Additionally, in opioid-naive patients, spinal-cord stimulation was associated with no decreased likelihood of patients subsequently receiving long-term opioid therapy. These findings showed that under real-life conditions, spinal-cord stimulation failed to reduce opioid use.

Complications Are Common – And Some Can Even Be Deadly

A research team from Cleveland Clinic investigated the harms caused by spinal-cord-stimulation surgery.[5] Most of the cases they examined were complex regional pain syndrome and failed back surgery syndrome. This team discovered that hardware-related complications were common (38%) and included lead migration (22.6%), lead connection failure (9.5%), and lead breakage (6%). Revision surgery was required in all of those failures.

Additionally, 12% of patients reported a new source of pain at the hardware site, which is the exact opposite of what this device is supposed to accomplish.

Over a four-year period, the U.S. Food and Drug Administration received a total of 107,728 medical device reports related to implanted spinal-cord stimulators, including 497 cases associated with patient deaths, 77,937 reports of patient injuries and 29,294 case reports of device malfunction.

Better Options: Evidence-Based, Effective Alternatives to Implement

What evidence-based therapies do we have that are safe and effective for patients with chronic pain? For chronic low back pain, we use five interventions in our clinics that are evidence-based and demonstrate

safety and effectiveness: spinal manipulation, acupuncture, spinal rehab, massage and neuroscience pain education.

The American College of Physicians orchestrated a systematic review of all available non-pharmacological therapies for patients with chronic low back pain. The study was published in the *Annals of Internal Medicine*.[6] This medical research team demonstrated that spinal manipulation, spinal rehab, massage and acupuncture were first-line choices. Based on quality clinical trials, these therapies were recommended as safe and effective.

A randomized clinical trial investigated the effects of neuroscience pain education in patients with chronic low back pain.[7] Sixty-six percent of participants randomized to neuroscience pain education were pain-free or nearly pain-free at post-treatment (reporting a pain intensity score of 0 or 1 out of 10), compared with 20% of participants in a saline injection group and 10% of participants randomized to usual medical care. An international medical research team agreed with these findings in a systematic review and meta-analysis.[8]

Practical Takeaway

Based on the scientific research, your patient should avoid spinal-cord-stimulation surgery because this intervention lacks quality data of effectiveness and poses a high likelihood of serious adverse events. Instead, she should begin a treatment plan of care that includes spinal manipulation, acupuncture, spinal rehab, massage and neuroscience pain education.

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