



International Neuromodulation Society Statement on News Articles Concerning Spinal Cord Stimulation

A Message from the INS President

By now, I am quite certain that every neuromodulation practitioner has seen or heard about the recent spate of articles by the Associated Press. After a year long investigation, to my mind, these reporters found that:

- (1) Some patients were significantly helped by spinal cord stimulation
- (2) Some patients were not helped by spinal cord stimulation
- (3) Some patients reported worsening or injury following spinal cord stimulation
- (4) Some patients reported that their implanting physician did not fully disclose the risks, benefits and alternatives of spinal cord stimulation
- (5) Some physicians received consulting fees from the neuromodulation industry and were not fully disclosing these arrangements
- (6) The process behind FDA approval of neuromodulation technology is, to their mind, inadequate

As a group of health care providers dedicated to the well being of our patients, it is important to carefully consider these issues and determine how this investigation may help us to become better physicians. It is also important to put these issues in context and stand up when issues are not fairly presented.

First, while it is true that some patients are helped by spinal cord stimulation and some patients were not, it is critical to note that these numbers are not nearly equal. In carefully performed randomized controlled trials, spinal neurostimulation techniques provide 50% or more pain relief in over 80% of patients, with 70% of patients achieving 80% pain relief or more. Even using the rigid criteria of greater than 50% pain relief for success, over four times as many patients treated with spinal cord stimulation are successes rather than failures. And while any surgical procedure has its risks, the risks of spinal cord stimulation are quite low. The risk of any neurologic injury following surgical paddle lead implantation is 0.56%; thus 99.44% of patients avoid any type of neurologic injury including such issues as numbness or tingling.

The Associated Press articles, published worldwide, suggest that some patients reported that their physicians did not fully disclose the risk, benefits and alternatives of spinal cord stimulation prior to the procedure. In reality, this may or not be the case. Under the stress of a physician visit and signing informed consent, patients often forget the details of the conversation. That being said, the INS strongly supports the practice of full disclosure of the risks, benefits and alternatives to any neuromodulation procedure. Practitioners should be especially sensitive to this going forward.

The Associated Press further disclosed that some neuromodulation physicians consulted with industry, benefited financially from these consultations and may not have fully disclosed this to their patients. Transparency usually helps develop trust between the physicians and their patients and so such disclosure is advised. Part of my usual and customary discussion with patients includes that over my career I have consulted with most if not all neuromodulation businesses that make spinal cord stimulation products. I tell patients that I will implant whatever device I feel will best suit their needs and, that if they prefer, I will implant the device of any company that they choose. That being said, information concerning physician/industry collaboration and reimbursement is available to anyone who wants it, at least in the United States. Through the Sunshine Act, all payments made to physicians by industry are reported annually and appear on the United States sponsored website.

December 19, 2018

Finally, I take issue with the criticism of the Food and Drug Administration. The FDA serves a critical role in ensuring the safety and efficacy of medical devices in the United States and they have been dedicated to monitoring and improving their processes in real time. Their record in the field of neurostimulation and neuromodulation is virtually unassailable.

So how are we to react to such a flurry of critical articles? I would suggest by simply continuing to practice good medicine. Inform patients of our potential real or perceived conflicts of interest, fully inform them of the risks, benefits and alternatives of the procedures we perform, and continue to have our patients' best interest at heart.

Robert M. Levy, MD, PhD
INS President