Journal of Pain Research

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LETTER

Re: Strand N et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. J Pain Res. 2022 Aug 23;15:2483–2504 [Letter]

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Dear editor

We read with interest the recent publication by Strand et al regarding the use of Peripheral Nerve Stimulation (PNS) for the treatment of chronic pain.[1] This is a rapidly evolving area of pain medicine that is of great interest to physicians and patients alike.

However, several details relating to restorative neurostimulation for the treatment of chronic lower back pain (CLBP) need correction, and important clinical data supporting this therapy is missing from the article. ReActiv8 (Mainstay Medical) is a unique neurostimulator which acts in a rehabilitative manner by restoring neuromuscular control to the multifidus by stimulating a peripheral nerve, the medial branch of the L2 dorsal ramus. Technically considered and coded as PNS, this therapy was discussed in the manuscript, but inaccurately and incompletely.

When reviewing the medial branch PNS data for the treatment of CLBP, only 2 studies were cited.[2,3] Both of these case studies (Level 4 evidence) have significant limitations with negligible sample sizes (N = 15, 9) and follow-up to only 5 and 12 months. The authors failed to acknowledge the ReActiv8-B trial;[4] a Level 1, prospective, double-blind, sham-controlled RCT with a much larger sample size (204) and published long-term 36-month outcomes.[5]

The authors note that ReActiv8 is indicated for CLBP "associated with multifidus dysfunction on advanced imaging." The FDA indication for ReActiv8 is CLBP pain with multifidus dysfunction "as evidenced by imaging or physiological testing." This is a significant and relevant omission, since a positive Prone Instability Test was a critical inclusion criterion for the "B" Study, and diagnostic imaging of the multifidus was not.

The authors state the IPG is programmed to deliver "electrical stimulation with varying stimulation times and episodes per day." In fact, the prescribed therapy is the same for every patient: 30-minute stimulation sessions, twice daily. Finally, the authors indicate the ReActiv8 IPG "allows two to four-electrode leads." While potentially a typographical error, this mischaracterizes the IPG, which allows two leads, each of which have four contacts.

We believe that these corrections, and most importantly inclusion of the ReActiv8 data, would only add to the literature-supported validity of this PNS guideline publication.

Disclosure

Dr Robert D Heros reports personal fees from Abbott, personal fees from Boston Scientific, personal fees from Biotronik, personal fees, from Saluda Medical, from Ethos Laboratories, personal fees, from Mainstay Medical, outside the submitted work. Dr Christopher J Gilligan reports personal fees from Mainstay Medical, personal fees from Saluda,

Received: 28 September 2022
Accepted: 20 October 2022
Published: 21 December 2022

personal fees from Persica, personal fees from Iliad Lifesciences, outside the submitted work. Professor Krishnan V Chakravarthy reports grants and personal fees from Mainstay Medical, during the conduct of the study. The authors report no other conflicts of interest in this communication.

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https://doi.org/10.2147/JPR.S389970