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LETTER TO THE EDITOR

Response to: "Single-Center Retrospective Analysis of Device-Related Complications Related to Dorsal Root Ganglion Stimulation for Pain Relief in 31 Patients"

To the Editor,

We read with interest the recent single-center retrospective study on dorsal root ganglion stimulation (DRG-S) complications by Hines et al. (1). Detailing procedure-related complications is a vital component of therapy evolution and investigating potential underlying mechanisms of complications can improve the value of a therapy for patients and practitioners alike. The primary issue with this report is that the data are presented as if this is the first report to accurately provide insight into device-related complications of DRG-S, when in fact multiple larger studies on the topic have previously been published and may be more representative of the DRG-S population. We have some questions and comments regarding the presented complication rates, many of which surpass those previously described in the literature. We hope this can provide further insight into the interpretation and discussion of the results.

FRACTURE RATES

The authors reported that their rate of lead fracture was 8.5% ($n = 7/81$ leads), which is second in the literature only to the 23% reported by Horan et al. ($n = 13/56$ leads, discussed in citation #13 in the article).

We wonder whether the authors can explain how their leads were implanted. We recently conducted a large ($n = 249$ patients, $n = 756$ leads), multicenter, retrospective study with long-term follow-up on the effect of DRG-S lead anchoring on migration and fracture rates. Compared to unanchored leads, migration rates were reduced from 8.4% per lead to 1.4% and lead fracture rates from 3.1% per lead to 1.9% when leads are anchored in a deep fascial plane (2).

In addition, the authors only note two migrations, both occurring in the recovery room post-operatively. Given the cohort's very high fracture rate and two post-operative migrations, we wonder whether the leads were not anchored in this study. The presented rates are discordant with prior rates, and it would seem unlikely no lead migration occurred after the immediate postoperative period.

TECHNIQUE USED

The authors do acknowledge in the final sentences of the discussion, that migration and fracture rates could be improved by cutting down to deep fascia and placement of anchors. However, there is no detail provided to gain insight into this hypothesis. Lack of incisional depth at the Tuohy needle puncture site can cause the lead to become entrapped in the superficial fascial plane, leading to fracture, which is something we described in our recent multicenter report. If the authors had provided specifics on the depth of incision, if anchoring was performed, and whether the manufacturer provided anchor was used or a suture anchor, this may have clarified some of these risk factors. To clarify, it should be noted that DRG-S lead anchoring is indeed recommended by the device manufacturer (https://manuals.sjm.com/~/media/manuals/product-manual-pdfs/).

LACK OF PAIN RELIEF

The authors detail the highest rate of device explantation in the literature of 19.4% at 12 months and 25.8% at 17 months ($n = 8/31$ implants). Five out of 31 patients (16.1%) were explanted due to lack of pain relief. Can the authors explain their workup for patients who were explanted for lack of pain relief? If these cases were truly explanted for lack of pain relief, did the patients lose efficacy over time, or did they never have good pain relief? The authors did not include a report that may be a relevant comparator: Levy et al. demonstrated less habituation with DRG-S when compared to spinal cord stimulation (SCS) (69.3% average pain relief vs. 57.9%) (3) at one year, contrasting this study's results.

In patients with loss of efficacy, were images reviewed for lead migration or to diagnose where a lead fracture occurred? Undiagnosed migration could explain the high rate of explantation secondary to lack of pain relief, as opposed to simply poor patient selection.

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INFECTION RATE

Another point for clarifications is that the reported infection rate leading to explantation (6%) was significantly higher than previous reported rates in studies performed in the United States (e.g., up to 1.08% in 500 patients (4)). If the authors encountered most of their infections during the trial phase, we hypothesize that this may be due to the European practice of using staged trials of up to 30 days, vs. the American practice of trials lasting less than a week. This is noteworthy as Hines et al. used staged trials in 7 out of 31 patients. Contrary to the infection rate reported by Hines et al., a recent systematic review on infections with DRG-S found an average trial infection rate of 1.03% (5).

The authors reference Liem et al. (ref #7 in the article), one of the first DRG-S publications in 2013, who reported infection in 7 out of 32 cases (three explanted and four infections likely treated successfully with antibiotics). This European study included staged trials of up to 30 days. We wonder whether the authors can clarify if the encountered infections were encountered in the extended staged trials?

MAUDE DATABASE

Additionally, the Food & Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database is repeatedly cited for its reported high rates of DRG-S hardware failure. Device manufacturers must submit reports to the MAUDE database when they become aware of suspected device-associated deaths, serious injuries, and malfunctions. Because the MAUDE database does not contain the denominator of total devices implanted and because reporting may not be complete, the FDA specifically states that this type of data "cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices" (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).

SALVAGE CASES

Nearly a quarter of the implants reported by Hines et al. were salvage cases ($n = 7/31$). We wonder whether the authors can provide more data on the demographic and clinical characteristics of these patients? Patients who previously failed SCS likely represent a challenging patient population and it would thus seem difficult to extrapolate findings from this group to all DRG-S patients, without providing further details on the patients.

In conclusion, we applaud Hines et al. for demonstrating their complication rates when utilizing DRG-S. However, the lack of data on the presented patients and the limited interrogation into their own poor outcomes makes this paper read more as a departmental morbidity and mortality conference than an intellectual endeavor. DRG-S is a distinct form of neuromodulation with benefits that differ significantly from those obtained with SCS and is worthy of a more introspective evaluation of complications. Minimizing complications is of paramount importance to maximize the therapeutic value of DRG-S for patients. It was not long ago that SCS was faced with many of the same challenges. It is up to us neuromodulators to thoroughly investigate root causes rather than throw our hands up in despair, simply blaming the integrity of the system. Readers would be advised to also consider the findings from larger and more rigorous cohorts.

Authorship Statement

None.

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