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EDITORIAL

A Call for Reckoning and Reform in Interventional Pain Medicine and Neuromodulation Research

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Introduction

The field of interventional pain medicine, and neuromodulation, in particular, has recently come under scrutiny from voices outside the specialty. Analyses such as those by Hara et al[1] and Wang et al[2] have challenged the scientific legitimacy and value proposition of these interventions, prompting heated rebuttals from within the community.[3,4] While some of these criticisms were themselves limited by methodological flaws and a lack of contextual nuance, the pain community's impulse to defend should not supersede the opportunity for introspection. In truth, these critiques should serve as a wake-up call. If anything, they reflect how our field is increasingly being seen from the outside: as one driven more by industry than evidence, and by expedience rather than inquiry. Rather than merely disputing these claims, we should examine how we may have allowed elements of truth to arise within them. This editorial highlights the most pressing deficiencies in interventional pain medicine today. These are not abstract problems; they are real, pervasive, and correctable Our goal is to advance the field by highlighting the deficiencies and gaps that are stalling our evolution into a truly evidence-based, patient-centered, and ethically grounded discipline.

Industry's Narrative, Not Ours

A defining feature of our field is the overwhelming influence of industry in both the production and dissemination of scientific knowledge. Many pivotal trials are industry-funded, which in itself is not inherently problematic given the lack of alternative funding mechanisms.[5,6] However, the unintended consequences of this dependence should not be ignored: companies frequently dictate study designs that are most likely to produce favorable results, selectively report outcomes, and suppress less favorable data.[7] This dynamic is exacerbated by the fact that many interventional pain therapies, especially implantable devices, are expensive and their adoption hinges on perceived superiority over conventional care.

Of importance, selective outcome reporting is of particular concern. For example, a study on 60-day temporary peripheral nerve stimulation for chronic low back pain reported favorable responder rates post-intervention.[8,9] A closer examination of the published figures reveals that only the data from the responder subgroup were displayed, masking the broader variability of outcomes of the entire cohort. Similarly, the pivotal trial comparing multifidus muscle stimulation to placebo failed to meet its primary endpoint, which was comparison of responder rates at 120 days. Irrespective, marketing materials have focused on modest improvements in secondary outcomes, effectively reframing the narrative.[10] Compounding this issue are non-CME industry-sponsored workshops and dinners at which data are presented in a curated fashion from the lens of industry, omitting nuance, methodological limitations, and potential risks.[11] While these practices are not technically illegal, they may contribute to a distorted understanding of effectiveness and safety among both clinicians and patients.

This selective narrative may not only confuse patients, but also can mislead clinicians. It creates an illusion of consistent benefit while minimizing or altogether ignoring the risks. It fosters a perception that we, as physicians, are fully in control

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when offering these therapies, armed with data that appear robust and reproducible. However, in reality, industry is the entity scripting the narrative. Consequently, when these interventions are deployed in the real world, the outcomes infrequently match those reported in industry-sponsored RCTs.[12,13] Even more troubling is the growing body of long-term, post-market surveillance studies that reveal higher-than-expected complication rates and significantly attenuated efficacy over time.[14–17]

Catchy Branding Does Not Equate to Scientifically-Based Labeling

In an effort to make therapies more marketable, the interventional pain field has embraced terminology that often obfuscates more than it clarifies. Phrases such as "targeted drug delivery" and "restorative neurostimulation" lend an aura of precision and scientific elegance but frequently fail to reflect the underlying biology. Intrathecal drug delivery, for instance, is widely referred to as "targeted drug delivery",[18] yet the pharmacokinetic profile of drugs administered intrathecally often results in widespread central nervous system distribution as well as distribution into the periphery. Lipophilic agents such as fentanyl readily cross into systemic circulation, while hydrophilic agents such as morphine, though slower to redistribute, spread extensively within the cerebrospinal fluid and are associated with side effects including pruritus, urinary retention, and sedation.[19] If the term "targeted" is meant to imply anatomical or functional specificity, then one could argue that a peripheral nerve block with a continuous catheter is more targeted than intrathecal drug delivery.

The same critique applies to "restorative neurostimulation" a phrase frequently used to describe multifidus muscle stimulation. Although the term may imply regeneration or structural repair of the multifidus muscle, there is currently no compelling evidence to support such an effect. In fact, while baseline magnetic resonance imaging was obtained in patients enrolled in the pivotal randomized controlled trial,[10] no follow-up imaging has been reported to assess for structural restoration of the multifidus. Given that the current device labeling includes MRI conditionality, such imaging-based follow-up studies would be not only feasible but crucial to substantiate claims of true restoration. At present, the therapy yields modest improvements in functional outcomes, benefits that are not unique to this device and have been similarly observed across other neuromodulation modalities.[20] By diluting scientific language for marketing purposes, we risk misleading both clinicians and patients and, in doing so, undermine the scientific integrity and credibility of our field.

Hiding Conflicts of Interest Undermines Scientific Integrity

It is no secret that much of the research in interventional pain medicine is funded by device manufacturers. The ethical concern does not lie in the presence of conflicts of interest (COIs), but in the failure to disclose them transparently. Unfortunately, a growing body of evidence suggests that COIs are frequently underreported or outright omitted.[21] Authors who hold stock options, serve as paid consultants, or have other financial ties to the companies sponsoring their research too often do not disclose these affiliations, even when such information is publicly available in registries (eg, Open Payments registry). The implications are profound. Readers rely on COI disclosures to critically assess the validity of study findings. Incomplete or misleading disclosures can erode trust in the specific publication and in the field at large. Transparency is not optional. It is a professional obligation and a prerequisite for scientific integrity. As discussed in a recent editorial, journals as well as institutions and academic societies, must enforce more stringent policies to ensure that disclosure standards are upheld.[22]

Quality and Reporting of Literature Remain Poor and Inaccurate

Several recent evaluations of the neuromodulation literature have exposed fundamental weaknesses in study design and reporting. Systematic reviews and meta-analyses, when appraised using tools such as A Measurement Tool to Assess Systematic Reviews version 2 (AMSTAR-2), frequently fall short of basic methodological rigor.[23] Scoping reviews often lack adherence to the Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for Scoping Reviews (PRISMA-ScR) reporting standards.[24] Perhaps most troubling are clinical guidelines that fail to meet established quality benchmarks such as the Reporting Items for practice Guidelines in HealThcare (RIGHT) and the Appraisal of Guidelines for Research and Evaluation (AGREE) checklists, despite issuing strong recommendations.[25] As an exemplar, a recent guideline on dorsal root ganglion stimulation (DRG-S) assigned a Grade A recommendation for its use in both complex regional pain syndrome types I and II.[26] This endorsement was given despite well-documented risks of lead migration, fracture, explantation, and therapy failure associated with DRG-S.[15,27] Guidelines are meant to

synthesize the best available evidence and help clinicians navigate uncertainty. When they are underpinned by weak data and insufficient reporting, they do the opposite and confer false certainty and mislead decision-making.

Equipoise is a Rarity in Research

The principle of clinical equipoise, genuine uncertainty regarding the superiority of one intervention over another, is a cornerstone of research.[28] Yet, in interventional pain trials, true equipoise is often absent. Many neuromodulation studies compare their intervention to conventional medical management, even when patients have already failed such treatment prior to enrollment in the trial. This essentially guarantees a favorable result for the intervention arm, as the control group remains stagnant while the experimental group receives a new therapy. Even more concerning is that many studies lack blinding, increasing the risk of placebo and nocebo effects that further bias outcomes. Rarely do we see neuromodulation trials comparing two active interventions, such as spinal cord stimulation (SCS) versus radiofrequency ablation or SCS versus peripheral nerve stimulation. Similarly, while neuromodulation manufacturers proclaim the superiority of their devices over the competitors, suggestion of head-to-head comparative studies are hardly embraced by these companies. Such comparisons would allow us to meaningfully explore which therapies are best suited to specific patient populations, but they are avoided because they carry a greater risk of null or negative findings. As long as study objectives and designs are crafted to protect commercial interests rather than scientific discovery, true equipoise will remain elusive.

The Next Generation is Vulnerable

Education is another domain in which the field is failing. Pain fellows and other trainees often lack structured research training, leaving them ill-equipped to critically appraise the literature or understand study methodology.[29] As a result, a substantial portion of their exposure to clinical research comes from industry-sponsored presentations and promotional materials. Without foundational education in study design, bias recognition, and statistical inference, these future leaders of our field are vulnerable to misinformation and manipulation. If we fail to build an academic infrastructure that prioritizes critical thinking and evidence literacy, we risk perpetuating a cycle in which clinical decisions are based on marketing, not medicine. Formal curricula in research methods, ethics, and interpretation should be required components of every pain fellowship program.[30]

Rarer Pain Conditions Remain De-Prioritized

Market-driven research inevitably favors common and prevalent conditions that promise high returns on investment. Consequently, low back pain receives an outsized share of attention due to its high prevalence[31] while less prevalent yet equally debilitating conditions such as painful chemotherapy-induced peripheral neuropathy (CIPN)[32] and post-stroke pain,[33] remain underexplored. The disparity is not due to a lack of clinical need, but rather to a lack of commercial viability.

Encouragingly, some high-impact research in these rarer domains is being driven by public agencies such as the National Institutes of Health (NIH). For example, neuromodulation technologies are being investigated for restoration of ambulation subsequent to spinal cord injury, representing a transformative application of this therapy outside of traditional pain indications.[34] However, these efforts remain exceptions. To fulfill our promise as a specialty, we must look beyond market forces and invest in areas in which patient need, not profit potential, dictates our priorities.

Technologically Sophisticated, Yet Scientifically Immature

Despite decades of development, neuromodulation research continues to lag behind other fields in its scientific maturity. Pivotal trials often ask simplistic questions, such as "Does intervention X reduce pain compared to conventional medical management?" Meanwhile, disciplines such as oncology, cardiology, and neurology are using adaptive trial designs, incorporating biomarkers, and focusing on hard outcomes such as survival, hospitalization, or functional restoration. Our field needs to evolve to ask more sophisticated questions. Can trialing predict long-term outcomes or does it delay access to care and lead to unnecessary costs? What are the differential effects of neuromodulation across pain etiologies? Can early intervention reduce mortality or mitigate opioid dependence? Is it possible to implement neuromodulation in chronic pain pathways similar to standardized perioperative enhanced recovery after surgery (ERAS) protocols? Can

biomarkers predict response to neuromodulation? Until we begin addressing these higher-order questions, we will remain a technically advanced field with primitive research goals.

Diversity and Inclusion Remain an Afterthought

Finally, the issue of diversity, both among clinicians and patients, remains grossly under-addressed. The interventional pain workforce is predominantly male and, in certain settings, lacks racial and ethnic diversity.[35] This homogeneity contributes to blind spots in care delivery and may influence referral patterns, patient trust, and therapeutic access. Meanwhile, studies have consistently demonstrated that racial and ethnic minority patients are less likely to receive adequate pain management and less likely to be offered advanced therapies.[36] If our research does not include diverse populations, its conclusions are not generalizable. If our workforce does not reflect the patients we serve, our care will never be truly equitable Diversity must become a central consideration in research design, trainee recruitment, and leadership development across the field.

Conclusion

Interventional pain medicine stands at a crossroads. We can either continue down a path shaped by industry interests, opaque science, and marketing-driven decision-making; or, we can course-correct. The problems we face are not insurmountable, but they require collective acknowledgment and coordinated reform.

We can reclaim the narrative of our field by embracing independent, transparent, and rigorous science. We should commit to better education, greater inclusivity, and more sophisticated inquiry. And, above all, we must be willing to confront uncomfortable truths because that is imperative if our field is to grow into the one our patients deserve.

Disclosure

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