Multisociety Response to BMJ Publications on Interventional Spine Procedures for Chronic Back and Neck Pain

We commend the efforts of Wang et al., Busse et al., and Ballantyne to address the complex issue of chronic spine pain through their systematic review/network meta-analysis (NMA), clinical guideline, and editorial, respectively [1-3]. Their works have stimulated important dialogue about the role of interventional procedures in managing chronic spine pain and have called appropriate attention to the need for high-quality randomized controlled trials to allow progressive improvement in clinical care for patients with spine pain. We disagree that interventional pain medicine does not consider patient preferences for treatment and refer to two recently published guidelines that emphasize the importance of informed consent and patient values in choosing treatment [4,5]. Furthermore, based on extensive clinical experience and a review of the evidence, we, the undersigned societies comprising physicians who prescribe or perform interventional spine procedures, have serious concerns about the methodology and conclusions drawn in these publications and their potential impact on patient care.

Heterogeneity

The analysis aggregates diverse patient populations, diagnoses, spinal regions, and interventional procedures. According to the Cochrane Handbook, "A valid network meta-analysis relies on the assumption that the different sets of studies included in the analysis are similar, on average, in all important factors that may affect the relative effects" [6]. Grouping the studies in this way allowed pooling of data at the expense of interpretable conclusions. For example, clinicians familiar with the conditions, procedures, spinal structures, and populations will identify concerning forest plots such as eFig 2, where novel and non-standard radiofrequency techniques for the cervical spine and sacrum are considered alongside historical and modern radiofrequency techniques for the lumbar spine. Another jarring aggregation of studies occurs in eFig 6 and eFig 8, where several non-ablative intra-articular pulsed radiofrequency treatments of varying structures (lumbar facet joints and sacroiliac joints) are presented as "joint radiofrequency" alongside several studies of medial branch or lateral branch nerve radiofrequency neurotomy.

It seems necessary to point out that these procedures are not similar and that intra-articular pulsed radiofrequency treatments are uncommonly performed procedures not covered in the United States. A serious clinician would not use evidence about non-ablative sacroiliac joint intra-articular pulsed radiofrequency treatment to inform a medial branch radiofrequency neurotomy treatment in the cervical spine. Nor should serious clinician scientists or policymakers accept aggregating such diverse techniques when considering the evidence.

The authors of the systematic review/NMA are certainly aware that these sources of clinical heterogeneity commonly lead to differences in point estimate and confidence interval, resulting in a broadening of the estimated pooled effect. We note that appropriate selection of

studies to pool would have resulted in too few studies to effectively conduct a meta-analysis, as indicated by the authors.

The guideline conclusions similarly aggregate the same disparate groups of patients, conditions, spinal regions, and procedures. Conflating these groups in analysis is convenient but misguided; in guideline development, it is misleading and irresponsible.

Another fatal flaw of the proposed guidelines is that they use studies of non-standard and noncovered techniques and selection criteria to draw conclusions about the use and coverage of commonly used and well-accepted techniques. We frankly cannot understand why this would be acceptable in any field of medicine, and we reject the position taken by these authors that the guidelines reflect a reasonable interpretation of the meta-analysis.

The disappointing truth is that there are not enough high-quality RCTs in interventional spine care to perform a well-powered meta-analysis, so we rely on carefully reasoned and balanced systematic reviews that incorporate the breadth of the available literature [7-16]. We are certain that the authors will support our call for increased research funding on interventional spine care to provide clarity and improve clinical decision-making. We hope to partner with the authors to pursue the best possible care for patients with spine pain as we pursue informative research in this field, which we recognize is needed.

Omission and inaccuracy of extraction

Unfortunately, the systematic review/NMA omitted the strongest RCT addressing the efficacy and effectiveness of lumbar transforaminal epidural steroid injections [17]. This omission is particularly concerning given the importance of this study in demonstrating the significant benefits for patients with lumbar radicular pain.

Additionally, the authors inaccurately extracted data from the strongest RCT supporting cervical medial branch radiofrequency neurotomy [18]. Supplementary meta-analysis materials incorrectly depicted this RCT's diagnostic block threshold as "unclear" despite a detailed explanation of the diagnostic block paradigm in the study's Methods section. Because mean visual analog scale (VAS) data were not reported, the study is not included in the forest plot. This omission is disappointing because of the high proportion of complete relief of pain reported in the study using an accepted and technically sound radiofrequency technique. However, the exclusion was appropriate per the systematic review's methodology. We were unable to review all extracted data against the studies and recognize the titanic effort required to review all of the included studies, but we note the discrepancy and wonder whether there may have been other errors in extraction.

Technical fidelity

Our societies strongly advocate that every study of interventional procedures should require documentation of technical accuracy. This documentation may include, for example,

verification of needle placement via imaging and contrast injection where indicated to ensure the intended target is reached. Published guidelines demonstrate the technical expectations for these procedures [19,20]. Deviation from these technical standards is unfortunately common among published studies and widespread among the studies reviewed for this systematic review/NMA. We encourage the development of novel techniques when there is an advantage for safety or efficacy and abandonment of the disfavored approaches. Unfortunately, this systematic review/NMA was not designed to assess whether the studies used accepted, anatomically accurate, and safe technique.

Additionally, the publications fail to acknowledge that different technical approaches (i.e., interlaminar vs. transforaminal vs. caudal for epidural steroid injections and parallel vs. non-parallel electrode placement for radiofrequency neurotomy) and factors (e.g., lesion size, number, and temperature for radiofrequency neurotomy) yield different results [21-23].

Compassion and multi-modal care

Interventional procedures are not a panacea and are not appropriate for all patients with spine pain. They are one part of a multimodal treatment strategy that may also include physical therapy, cognitive behavioral therapy, and other treatments. In appropriately selected patients, interventional spine procedures can offer substantial relief, improve function, allow for return to work, and may delay or obviate the need for more invasive surgical interventions or longterm reliance on opioids. Thus, they remain an essential treatment option for patients.

Our Recommendations

- **1. Balanced Authorship:** Future systematic reviews, meta-analyses, and guideline development should involve balanced panels with methodological experts and clinicians experienced in performing interventional procedures who bring clinical context to the efforts.
- 2. Enhanced Study Design: Future systematic reviews and meta-analyses should:
 - Ensure appropriate grouping of studies by patient population, spinal region, diagnosis, and procedure type.
 - Ensure the intervention meets current technical standards.
- **3.** Broader Evidence Inclusion when RCT data are lacking: Clinical guideline development must recognize the limitations of the supporting systematic review and incorporate well-designed prospective studies when RCT data are lacking.
- **4. Policy Implications:** Policies regarding the coverage and access to interventional pain procedures must consider the nuanced evidence that supports their use. Denial of these procedures based on inaccurate interpretations of limited data will drive patients toward more invasive, more expensive, and riskier treatments and remove options known to be safe and effective.
- **5. BMJ Clinical Practice Guideline Retraction:** Given the methodological issues discussed above and concerns regarding policy implications, we urge BMJ to retract the guideline publication.

Conclusion

We acknowledge that interventional spine procedures are not universally effective and that careful patient selection is essential. We agree with Wang et al., Busse et al., and Ballantyne that patients suffering from chronic spine pain deserve to be properly informed and receive personalized care where they choose their path to safe and effective pain relief. When provided a choice of treatment options and informed consent, we remain confident that many patients will continue to choose interventional spine procedures performed by highly skilled and caring physicians because, when performed with technical precision and integrated into a broader, individualized treatment plan, these procedures can offer significant benefits. We also stress the importance of selecting, analyzing, and aggregating appropriate studies when developing clinical guidelines. We call upon researchers, clinicians, and policymakers to recognize the complexity of chronic spine pain and to support expanded research and ongoing access to interventional procedures underpinned by rigorous clinical standards.

Sincerely,

[Insert society names]

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