Editor’s Response: Group vs Categorical Data in Epidural Studies

Dear Editor,

In their letter, Nampiaparampil and Engel raise a number of concerns about the study of Pinto et al. [1], and their exchange provides us a valuable opportunity to discuss study design and interpretation. Some of their concerns can be questioned, but they do reflect the irritation felt by practitioners who find their procedures being assaulted, seemingly unfairly, by academics who do not practice in the field under review. The concern that studies differed in the doses used are not fair criticisms of a review, because in practice there is no uniformity of dose for epidural injections. Nor is it a fair criticism that studies may have been compromised because the injection was at the wrong level, for there is no evidence that epidural injections have to be that target-specific.

Of some relevance is the criticism that blind injections should not be lumped with fluoroscopically guided injections, for it has been shown that blind injections often miss the epidural space completely. In their letter of response, Pinto et al. retort that they did perform a subgroup analysis of fluoroscopically guided injections; but here the arguments get confused. The subgroup in question was not studies of fluoroscopically guided epidural injections but studies of transforaminal injections, which is a different procedure from interlaminar injections, either blind or fluoroscopically guided. The review in question repeats the same error as past reviews, of lumping all procedures as alike, when they are not, either with respect to technique or the associated evidence.

Nampiaparampil and Engel raised one, serious and valid criticism that I would like to rearticulate. They stated that the review of Pinto et al. [1], like previous reviews, drew their conclusions on the basis of group data, i.e., mean values (and standard deviations). This emerges as an important point and happens to underlie another concern of Nampiaparampil and Engel, namely that practitioners “recognize the clinical benefits of ESI.”

Group data do not reflect reality. Practitioners do not encounter “mean” patients or “mean” responses. Reality is measured by success or failure, and this is what practitioners encounter. The liability, however, is that practitioners are likely to remember their successes but forget their failures and, therefore, exaggerate the apparent success of their interventions. This is why documentation of success rates are the gold standard in both observational studies or randomized controlled trials.

In responding to this point, Pinto et al. use eminence-based medicine, rather than data. In an authoritative manner they write dismissively that “the only way a subgroup of patients would experience great benefit from ESI would be if another subgroup experienced great harm . . .”. The available data refute this dismissal.

Ghahreman et al. [2] showed and emphasized that group data camouflage outcomes. Upon analysis, their own group data showed no statistically significant change in pain scores after transforaminal injection of steroids; however, their categorical data were strongly significant.


References
The success rate of transforaminal injection of steroids outstripped that of any of the four control groups. When a treatment has a success rate of 54%, group data obscure its efficacy. In the case of Ghahreman et al. [2], the outcomes were distinctly bimodal, with nearly half of the patients retaining high pain scores, and half having scores at or near zero. No patient reported the mean score or median score, and there were no patients within half a standard deviation of the mean score.

Under such conditions, the mean score is representative of no patient and is not a reflection of the efficacy of the treatment. Under such conditions, the mean score is representative of no patient and is not a reflection of the efficacy of the treatment. Nor can these data legitimately be lumped with those of others to derive some artificial measure such as an effect-size and especially not so in order to discredit an intervention. A success rate of 54% may not be perfect, but it is not zero (as the group data imply), and it is that success that patients appreciate and which underlies the impression of clinicians that this treatment, transforaminal injection of steroids, works.

Repeatedly, Nampiaparampil and Engel refer to the difference in methods and conclusions of the disparate reviews of Pinto et al. [1] and MacVicar et al. [3], but they did not manage to explain the difference. The critical difference is that MacVicar et al. [3] sought categorical data on success rates, not group data as used by Pinto et al. [1]. In doing so, MacVicar et al. [3] found that the data from controlled trials were consonant with the data of observational studies: there were modest but consistent success rates of transforaminal injection of steroids, which significantly exceed that of sham treatment, and this success was unearthed by looking at subgroups within studies instead of being blinded by group data. Furthermore, the review found that success was contingent upon additional factors. Not all patients with radicular pain responded to treatment, but the success rate is greater in those patients with lesser grades of nerve-root compression, in whom it is about 75%, which is a more impressive figure than 54%.

To large extent, the correspondence between Nampiaparampil and Engel and Pinto et al. was along conventional lines but at crossed purposes, but what it has prompted is greater awareness of the differences between group data and categorical data, and the conflict between conclusions drawn from each. Future studies—and future reviews—would serve procedures more fairly and would be more consonant with the clinical impressions of practitioners, if they provided data on success rates rather than good outcomes camouflaged by group data.

NIKOLAI BOGDUK, MD, PhD
The University of Newcastle, Newcastle, New South Wales, Australia

References

Is Pain a Disease or a Symptom of Disease?

Dear Editor,

Lynn Webster and Gary Reisfield’s review and commentaries on the concurrent use of opioids and benzodiazepines [1] renew the question as to whether pain is a disease or a symptom of disease and the prescribing practices that are affected by such a distinction. Is the fourth vital sign a disease anymore than fever, pulse, and blood pressure alterations? We would not treat tachycardia as a disease but as a symptom of a system failure, and the treatment of an infection with an antipyretic would entirely miss the pathology. As a pain community, we recognize distinct pain categorizations: cancer pain, neuropathic pain, and musculoskeletal pain, which is the most common category in most pain practices. Is pain the disease we are treating or are we treating discs, stenosis, facet joints, affect, cognition, and neuropathology? It takes time and patience to treat chronic musculoskeletal pain encompassing the whole individual anatomically, socioeconomically, and psychologically. It is easiest to reach for a pharmacological solution and if pain is the disease, medication is a pragmatic solution. The philosophical approach to the treatment of chronic nonmalignant pain syndromes is influenced by its nomenclature.

LESLIE SCHOFERMAN, MD
San Francisco, CA, USA

Reference