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RESPONSE TO LETTER

Methodological Concerns Regarding the Interpretation of Transforaminal Epidural Steroid Injection Efficacy for Lumbar Radicular Pain [Response to Letter]

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Dear editor

We sincerely thank the authors for their thoughtful comments regarding our study evaluating fluoroscopy-guided transforaminal epidural steroid injection (TFESI) for lumbar radiculopathy due to lumbar disc herniation. We appreciate the opportunity to clarify several methodological aspects of our work.

First, we agree that our retrospective single-arm cohort design does not permit definitive causal inference regarding treatment efficacy. The primary objective of our study was to evaluate clinical outcomes following TFESI in routine clinical practice rather than to establish efficacy through comparison with the natural history of lumbar radiculopathy or alternative treatments. As acknowledged in the Discussion, spontaneous recovery, placebo effects, and concomitant conservative therapies may have contributed to the observed improvements. Therefore, our findings should be interpreted within the methodological limitations of an uncontrolled observational study while recognizing that they provide valuable real-world evidence regarding outcomes following TFESI.[1]

Second, regarding patient attrition, 221 of the 252 enrolled patients completed the scheduled three-month follow-up and were therefore included in the final outcome analysis. Patients who subsequently underwent surgery or who were unavailable for follow-up could not provide the required outcome measures. We acknowledge that exclusion of these patients may introduce attrition bias, as discussed in the manuscript. However, because this was a retrospective observational study rather than a randomized trial, intention-to-treat analysis was not feasible.[2] While our study provides valuable real-world data, we recognize that future prospective studies incorporating predefined handling of missing data and sensitivity analyses would further strengthen the evidence.

Third, the authors raise an important point concerning repeat TFESI procedures. In our clinical practice, a second injection is considered part of the same treatment strategy rather than a separate therapeutic modality.[3] The small number of patients requiring a second injection (10 of 221; 4.5%) reflects routine clinical decision-making for incomplete early response. Given this limited proportion, we believe its influence on the overall results is minimal. Nevertheless, we agree that separate analyses according to the number of injections could provide additional information and should be considered in future prospective investigations.

We agree that residual confounding is an inherent limitation of observational studies. Information regarding post-procedural medication use and rehabilitation was not systematically available because of the retrospective design. Accordingly, we deliberately limited our analyses to descriptive within-patient changes over time rather than attempting multivariable adjustment using incompletely captured covariates. We acknowledge that prospective studies with standardized follow-up and mixed-effects or multivariable regression analyses would provide a more robust assessment of treatment effects and better account for potential confounding.[4]

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Finally, we agree that identification of predictors of treatment response represents an important area for future research. Although our cohort size was relatively large, the present study was not specifically designed or statistically powered to develop predictive models. Development of reliable prognostic models generally requires prespecified analyses, adequate events per predictor, and preferably external validation before clinical application.[5] Future prospective studies with predefined prognostic analyses incorporating clinical and radiological variables will undoubtedly improve patient selection and optimize individualized treatment strategies.

In conclusion, we appreciate the constructive comments and agree that our findings should be interpreted within the context of an observational retrospective cohort study. Nevertheless, we believe that our results provide valuable real-world evidence demonstrating meaningful improvements in pain and disability following TFESI among patients with lumbar radiculopathy who had failed conservative treatment, while also highlighting areas requiring confirmation in future controlled prospective studies.

Disclosure

The author declares no conflicts of interest in this communication.

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