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LETTER

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

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Dear editor

We read with interest the recent study by Bilir et al[1] evaluating fluoroscopy-guided transforaminal epidural steroid injections (TFESIs) for lumbar radicular pain secondary to lumbar disc herniation. Several methodological and analytical issues may have affected the interpretation of the reported treatment effects.

First, the interpretation of treatment efficacy is not supported by the study design. The authors conclude that TFESI is effective based on reductions in pain and disability; however, the study employed a single-arm observational design without a comparator. Such a design does not allow causal inference, as observed improvements may reflect the natural course of lumbar radicular pain, regression to the mean, placebo effects, or concurrent conservative treatments.[2] Although the lack of a control group was acknowledged, the conclusions in the Discussion and Abstract directly attribute clinical improvement to TFESI, exceeding the level of evidence provided.[3]

Second, the analytical strategy introduces selection bias that may overestimate treatment success. Among 252 enrolled patients, only 221 completing three-month follow-up were included in the final analysis, while patients undergoing surgery and those lost to follow-up were excluded. Such attrition is unlikely to be random and more plausibly reflects treatment failure. Excluding these patients removes non-responders from analysis and inflates the reported responder rate.[4] No intention-to-treat or sensitivity analyses were performed, limiting robustness.

Third, the handling of repeated interventions further complicates the interpretation of treatment efficacy. The authors reported that ten patients received a second TFESI and that their post-treatment outcomes were incorporated into the primary efficacy analysis. However, repeated injection constitutes an additional intervention rather than continuation of the initial treatment. Combining patients who responded after repeated injections with those responding after a single procedure inevitably inflates the apparent effectiveness of a single TFESI. Separate analyses according to the number of injections, or sensitivity analyses excluding repeat procedures, would have provided a more transparent assessment of treatment efficacy.

Fourth, important sources of residual confounding were insufficiently addressed. Most patients had received pharmacological treatment before intervention, over half had previously undergone physical therapy, and the authors acknowledged that medication use after TFESI was not strictly controlled. However, no information was provided regarding the continuation of analgesics, rehabilitation, or other conservative treatments during follow-up. Consequently, the observed improvements cannot be confidently attributed to TFESI alone. Moreover, the statistical analyses relied exclusively on within-group comparisons without adjustment for baseline characteristics or concurrent treatments. Considering the observational nature of the study, multivariable regression or mixed-effects modelling would have provided a more appropriate analytical framework to reduce residual confounding.[5]

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Finally, the study missed an important opportunity to investigate treatment heterogeneity. Approximately one-third of patients failed to achieve the predefined threshold for clinically meaningful pain improvement, while nearly half failed to reach the functional success criterion. These findings indicate substantial heterogeneity in clinical response to TFESI. Given the relatively large cohort, analyses exploring predictors of treatment response, including symptom duration, neurological deficits, imaging characteristics, or baseline disability, would have substantially enhanced the clinical relevance of the study and improved patient selection in routine practice.

Collectively, these issues suggest that the observed outcomes should be interpreted as uncontrolled post-treatment improvements rather than evidence of TFESI efficacy.

Disclosure

The authors declare no conflicts of interest in this communication.

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