### Letter to the Editor



# Comments on Effect of High-Volume Injectate in Lumbar Transforaminal Epidural Steroid **Injections**

## TO THE EDITOR:

We read with great interest the recent work by Chun et al (1) in which they studied the effect of different injected volumes for a same dose of dexamethasone, for treatment of radicular pain and concluded that higher volumes are more effective.

However, there are a few points we would like to highlight. Firstly, the dose of lidocaine administered in the DL3 group was 10 mg versus 26 mg in the DL8 group i.e. almost 3 times. Almost in the same breath, the authors state that the difference in the lidocaine dose is so minimal that it is unlikely to be the main factor determining the effectiveness of TFESIs. According to their hypothesis, volume was the most important determinant for the effectiveness of lumbar TFESI, thus it would have been worthwhile if the total dose of lidocaine would have been similar in both the groups (maybe 10 mg) and the volume of injectate would have varied. Why the authors choose to maintain the concentration of lidocaine as 0.33% is still difficult to comprehend.

Secondly, the whole idea behind using smaller volumes in the transforaminal approach for epidural injections is that the space where the drug is delivered is small. If large volumes are given in such a space, the drug is bound to diffuse and spread to adjacent epidural spaces, rather than remain localized to the site of pathology. Thus, the whole purpose of the TF approach of epidural injections is defeated and one could opt for a simple alternative i.e. interlaminar approach.

Thirdly, it would be interesting to know how the authors decided on the injectate volume of "8 mL", for future studies.

Fourthly, post-procedure the patients were followed for a 1-month period at which time VAS and RMDQ were administered to them. The difference in RMDQ came out to be statistically insignificant between the 2 groups. It would have been a great idea if patients would have been assessed in the intervening

period of 1 month so that a lot of relevant information could have been gathered. A significant difference could have been noted, if the RMDQ were also administered at 1 or 2 weeks after the procedure. If the patient failed to visit the hospital, a telephone survey could have been of some help.

Fifth, out of 33 patients in each group, 30 of one group and 32 patients of the second group underwent statistical analysis. The intention-to-treat analysis has not been used in the study, which would have reduced the bias in this randomized trial (2).

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## In Response to Letter to Editor: Use of High Volume Injectate for Lumbar Epidural Steroid Injection via Transforaminal Approach Might Not Be Justifiable

We would like to thank Dr. Shikha Awal and coauthors for their interest in and comments on our study. We agree that the composition of the solution that has been used for epidural steroid injection is arguable. As we described in the article (1), we used a large volume, 8 mL of injectate, made of 0.33% lidocaine and dexamethasone 4 mg. Either lidocaine alone or lidocaine with steroid has shown significant evidence of efficacy, both in radiculopathy and spinal stenosis (2). In a study by Manchikanti et al (2), the composition of the injectate was highly variable; so it was difficult to evaluate the clinical effect of the 26 mg of lidocaine vs 10 mg of lidocaine. This study is necessary to find the key feature of the injectate that induces meaningful pain relief with TFESI (transforaminal epidural steroid injection).

We focused mainly on setting the proper volume for using low-dose dexamethasone with local anesthetic for TFESI. To summarize, first, we valued the potency of the low dose dexamethasone (3), second, the high volume administration may have an adhesiolysis effect (4,5), and third, we prefer the low concentration of lidocaine to avoid motor block and systemic toxicity; the low concentration of lidocaine had sufficient clinical effect (6).

We agree that a significant difference could have been noted if the Roland-Morris Disability Questionnaire (RMDQ) had been assessed at one or 2 weeks after the procedure. We assessed the RMDQ only at 4 weeks after the procedure in the study because we thought that the short-term relief of symptoms had limited clinical meaning.

Potential bias can be introduced by exclusions after randomization. The intention-to-treat analysis defined by the Consolidated Standards of Reporting Trials (CONSORT) strictly forbids the exclusion of any randomized individuals from the analysis although a complete case analysis is deemed reasonable in the presence of missing outcome data. However, in its updated 2010 statement, CONSORT no longer advocates the use of the term intention-to-treat analysis (7).

Despite several limitations of our study, including the small number of participants and a short 4-week period follow-up, we believe our results could provide the basis for further studies.

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