

Comment: "Prospective case control evaluation of epidural midazolam for improving pain and ambulation after microdiscectomy"

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Madam, I read with interest the article published in the June 2012 issue of JPMA by Shamim MS et al.¹ I have a few important concerns regarding this article.

Firstly, the authors mention the design of their study as prospective case control. As an epidemiologist, I disagree with labeling this study in this category. It appears that all patients with microdiscectomy were included in the study. A prospective case-control study is where participants are selected on the basis of presence or absence of outcome with their exposure information prospectively collected. It is an observational study design where there is no treatment intervention. In this study, it seems that there was an intervention by the investigators with the treatment being either midazolam or saline and the outcome early ambulation and post-operative pain control. It would best be labeled as a non-randomized intervention study among patients undergoing microdiscectomy.

The second point I would like to raise is that the data presented seem a bit incomplete, particularly in terms of statistical indicators. It seems the 95% confidence intervals of the ORs have not been presented, rather the columns simply say '95'. This is quite important given the small sample size of the study and to determine how precise the confidence intervals are that will, in turn, indicate the power or efficiency of the study.

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Thirdly, although the authors indicate that the groups were comparable with respect to some of the characteristics mentioned like gender, age, duration of symptoms, operative time and hospital stay. However, it is important to understand that the p-value tests are severely underpowered in this study because of small sample size and there may actually be differences in these characteristics between the two groups. The patients may differ according to other characteristics as well such as severity of index disease and presence of co-morbidities. These differences may introduce confounding given the fact that the study was not a randomized trial. This would necessitate control for confounding in the analysis because unadjusted results may be biased and not valid with limited clinical implications. Given the small number of outcome events and exposure, it might have been reasonable to use a propensity score approach to control at least for the few four or five most important confounders. Given the prospective nature of the study, confounder information could have been easily collected.

In summary, the authors fail to mention any of these epidemiologic limitations of their study in discussion. It would have also been more reasonable to have the patients randomized at the start of the study to achieve baseline exchangeability between the two groups in the characteristics. Otherwise, control of confounding becomes necessary.

References

1. Shamim MS, Enam SA, Tahir MZ, Khan M. Prospective case control evaluation of epidural midazolam for improving pain and ambulation after microdiscectomy. J Pak Med Assoc 2012; 62: 561-5.