Epidural steroids for low backache: is this a valid trial?

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Dear Editor,

The authors of the original article “A randomized clinical trial of three different steroid agents for treatment of low backache through the caudal route” published in *MJAFI* in January 2011 (*MJAFI* 2011;67:25–33) must be complimented for drawing the attention of the Armed Forces Medical community to another available modality of treatment for treating low backache (LBA), a disease of epidemic proportions in our community with its effective management remaining an imposing challenge. However, there are quite a few areas of concern in this original work. Low backache is not a discrete entity and the diagnosis of the exact cause can be extremely difficult. This trial has included an extremely heterogeneous population rather than a specific disease or age or gender group (homogenous population).

The eligibility criteria for inclusion in the study itself were faulty as the age of 20–70 years is extremely heterogeneous as well as the body mass index (BMI) ranging between 18 Kg/m² and 30 Kg/m². There was a significant male predominance across all the groups (more than 90% in each group) not comparable to the patient population in clinical practice, which has equally comparable gender distribution.

Some of the other significant factors which may affect the outcome of a caudal epidural steroid and not been recorded by the authors in this study include employment status at the time of presentation, nature of employment (heavy work/desk work/poor posture required at work), smoking, large number of previous interventions for LBA, etc.

The treatment protocol was quite lax as patients continued with physical therapy in the form of exercise programmes in addition to epidural steroids. Exercise programmes combined with early return to normal activity were shown to be the most beneficial in chronic LBA.¹ Though exercise regimens were introduced in a large proportion of cases initially, a large proportion of cases did not continue with the physiotherapy/exercise regimens, especially the groups which had most significant relief. The reasons for this variation as well as justification for continuing with this significant confounding factor have not been brought out by the authors.

It is not clear as to who administered the caudal epidural injections—the authors themselves, other anaesthesiologists, anaesthesia residents under supervision or anaesthesia residents without supervision? The variability in the people administering the injections is a confounding factor itself because of different levels of experience and learning curve involved. Though the authors have mentioned that the anaesthesiologists making the assessment were different from the ones giving the injections, the identity of same is neither specified nor acknowledged. Was it one of the authors, an anaesthesia resident or yet another anaesthesiologist?

The accuracy of the drug delivery in the technique followed by authors cannot be determined. The authors have themselves acknowledged that the drug injection is ideally done under fluoroscopic guidance and the authors have themselves given the evidence to support this.^{2,3} As per the Institute for Clinical Systems Improvement Healthcare Guidelines, epidural steroid injections (ESI) should be performed under fluoroscopy with contrast for best results.⁴ There is hardly any Level I/II evidence to support the blind delivery method of steroid injection utilising “swoosh” test which the authors have used in this study comparing it with fluoroscopic guidance. The accuracy of drug delivery will be determined by the “specificity” of the technique rather than the “sensitivity”. Moreover, the original “swoosh” test avoids injection of air and the area auscultated during injection of local anaesthetic is lower lumbar spine whereas the authors injected air and auscultated in thoracolumbar spine.⁵ These variations also challenge the validity of the technique used by authors.

In conclusion, there is insufficient evidence to support the routine use of ESI therapy in subacute and chronic low back pain.⁶ Epidural injections may have a useful adjunct role in specific clinical situations. Side effects are relatively minor, and a tendency exists towards an outcome favouring injection therapy. The evidence for and against ESI should be clearly explained to allow patients to make an informed choice regarding their treatment.

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