Original Article

Ultrasound versus fluoroscopy-guided caudal epidural steroid injection for the treatment of chronic low back pain with radiculopathy: A randomised, controlled clinical trial

Address for correspondence:
Prof. Dipasri Bhattacharya, B26/10, Abhyudoy Housing, EKTP, Kolkata - 700 107, West Bengal, India.
E-mail: dipasribhattacharya123@gmail.com

Arindam Kumar Hazra, Dipasri Bhattacharya, Sayantan Mukherjee, Santanu Ghosh[1], Manasij Mitra[2], Mohanchandra Mandal[1]

Department of Anaesthesiology and Critical Care, R. G. Kar Medical College and Hospital, Kolkata, [1]Department of Anaesthesiology, North Bengal Medical College, Darjeeling, West Bengal, [2]Department of Anaesthesiology, MGM Medical College, Kishanganj, Bihar, India

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ABSTRACT

Background and Aims: Caudal epidural steroid administration is an effective treatment for chronic low back pain (LBP). Fluoroscopy guidance is the gold standard for pain procedures. Ultrasound guidance is recently being used in pain clinic procedures. We compared the fluoroscopy guidance and ultrasound guidance for caudal epidural steroid injection with respect to the time needed for correct placement of the needle and clinical effectiveness in patients with chronic LBP. **Methods:** Fifty patients with chronic LBP with radiculopathy, not responding to conventional medical management, were randomly allocated to receive injection depot methyl prednisolone (40 mg) through caudal route either using ultrasound guidance (Group U, $n = 25$) or fluoroscopy guidance (Group F, $n = 25$). Pre-procedural visual analogue scale (VAS) score and Oswestry Disability Index (ODI) were noted. During the procedure, the time needed for correct placement of needle was observed. Adverse events, if any, were also noted. All patients were followed up for next 2 months to evaluate Visual Analogue Scale (VAS) score and ODI at the 2nd week and again at the end of 1st and 2nd month. **Results**: The needle-placement time was less using ultrasound guidance as compared to fluoroscopy guidance (119 ± 7.66 vs. 222.28 ± 29.65 s, respectively, $P < 0.001$). Significant reduction in VAS score and ODI (clinical improvement) was noted in the follow-up time points and comparable between the groups at all time points. **Conclusion:** Ultrasound guidance can be a safe alternative tool for achieving faster needle placement in caudal epidural space. Clinical effectiveness (reduction of VAS and ODI scores) remains comparable between both the techniques.

Key words: Disability evaluation, epidural steroids, fluoroscopy, low back pain, radiculopathy, ultrasonography

INTRODUCTION

Low back pain (LBP) is termed as 'chronic' after 3 months where pathological and/or anatomical instability is still present. Common causes of LBP are degenerative disc disorder, herniated disc, spinal stenosis and compression fracture of the lumbar spine. Degenerative disc disease is one of the most common causes of LBP.[1] Prevalence of LBP in Indian population ranges from 6.2% to 92% with an increase of prevalence with age and more prevalence in the age group of 30–55 years.[2] The high prevalence of LBP is such that the World Health Organisation declared the first decade of the third millennium as the 'decade

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of campaign against musculoskeletal disorders— the silent epidemic'.[2]

Traditional conservative medical treatments include trials of oral medication, exercise therapies, manual therapies, back school and lifestyle modifications. Lumbar epidural steroid injections, first advocated in 1952 by Robecchi and Capra, have also become a widely utilised conservative therapeutic modality.[3] Transforaminal approach is technically more difficult than caudal epidural. In clinical scenarios when repeated injections are required at intervals, caudal epidural approach gained popularity.[3] Subsequently, fluoroscopy-guided caudal epidurals gained popularity and was being practised and studied extensively.[4,5] It was seen to be associated with minor complications later on. Moreover, exposure to radiation is a serious concern. The contrast agent used to determine proper drug deposition is also blamed for several side effects such as nausea, vomiting, scattered hives to extensive urticaria, bronchospastic reaction, hypotension, tachycardia and anaphylactic reaction.[6]

Today, improved understanding of ultrasonography (USG) imparts better visualisation of anatomical structures in real time without the hazards of radiation and iodinated contrast agent. There are limited studies regarding caudal epidural block under ultrasound guidance.[4,7-9] Hence, we conducted this study to compare both of these techniques in terms of promptness of the procedure and clinical effectiveness.

METHODS

Approval from Institute's Ethics Committee was obtained. Patients aged between 30 and 60 years with chronic LBP with unilateral or bilateral radiculopathy of more than 3 months duration, not responding to conventional therapy, attending our pain clinic were investigated (haemoglobin, fasting blood sugar, serum urea and creatinine and magnetic resonance imaging [MRI] of lumbosacral spine). Patients with MRI findings of disc protrusion and disc bulge at various levels of lumbar spine and impingement of exiting and traversing nerve roots were included in the study. Patients with the rapidly progressing neurological deficit, cauda equina syndrome, motor weakness, previous spine surgery, use of steroid, local site infection, history of allergy to steroids and iodinated contrast agents, patients with multiple co-morbidities (hypertension, diabetes mellitus, ischaemic heart disease, etc.,) were excluded from the study. Informed written consent was obtained from all patients. All the patients who were on tablet pregabalin, tablet amitryptiline and tablet paracetamol-tramadol combination pre-operatively, continued to receive the same.

The patients were randomly allocated to receive injection depot methylprednisolone acetate (40 mg) through caudal route either using ultrasound guidance (Group U, $n = 25$) or fluoroscopy guidance (Group F, $n = 25$). Randomisation was done using 'coin flip' method. A coin was flipped for every two consecutive patients; the first patient was allocated to Group U on getting 'head' or to Group F on getting 'tail'. The next of this set was allocated to the other group.[10]

Pre-procedural visual analogue scale (VAS) scores and Oswestry Disability Index (ODI) values were noted and standard fasting guideline was followed for all the patients. In the operating room, after establishing intravenous access, attaching monitors and keeping all resuscitative measures ready, patients were kept in prone position with pelvis supported by a pillow.

In Group U, after skin disinfection and application of a sterile transducer sheath and gel, the following structures were identified using linear array transducer: The 2 sacral cornu, the apex of the sacral hiatus and the sacrococcygeal ligament that stretches across the sacral hiatus and separates the subcutaneous tissue layer from the epidural space underneath. After local anaesthesia with 2 ml preservative-free lignocaine (1%) [pre-formulated 2% solution was diluted with normal saline to make it 1%], the sacral hiatus was visualised longitudinally and an 18-gauge epidural needle (Tuohy) was inserted and advanced under sonographic guidance through the sacrococcygeal ligament into the epidural space of the sacral canal. Slow injection of about 2 ml of air was used as a final check of correct needle placement in which the air in the epidural space will appear as hypoechoic zone as judged by real-time sonography.

In Group F, after proper antiseptic dressing and draping, sacral hiatus was identified and local infiltration was done with 2 ml preservative-free lignocaine (1%). An 18-gauge epidural needle (Tuohy) was advanced at an angle of 45° to the skin until a 'give-way' sensation was felt and position of the needle was confirmed by lateral and anteroposterior fluoroscopic images. Then 5 ml of iohexol solution was injected through it to

confirm the position. A properly placed needle would produce a classical 'inverted fern tree' appearance in anteroposterior view after dye injection or a 'filling defect'. The needle was introduced up to S_3 level for proper spread of the drug.

Time taken from completion of draping to correct placement of needle was noted in the both groups. Then injection depot methylprednisolone (40 mg) diluted in 10 ml of normal saline was injected through the needle in all patients. The needle was pulled out and sterile dressing was applied.

The present study compared the two groups regarding the promptness of the procedure (time taken for correct placement of epidural needle), clinical effectiveness (pain relief, i.e., reduction of VAS score, and functional improvement, i.e., reduction of ODI) and safety (occurrence of adverse events).

Patients were monitored for 4 h and subsequently discharged with the advice to attend our pain clinic next week. In the pain clinic, they were followed up for 2 months. VAS scores and ODI values were noted at the 2nd week and again at the end of 1st and 2nd month.

The level of disability owing to LBP was evaluated by interrogating patients following the 'Oswestry LBP disability questionnaire'.[11] It is a scoring system having ten parameters for evaluation. Each parameter is evaluated on a six-point scale (0–5). During pre-procedural evaluation of every patient, the ODI score was determined (baseline ODI) and again this ODI score was evaluated after the procedure, at 2nd week and at the end of 1st and 2nd month. The point in each section that best describes the patient's problem was noted and the sum of these scores from 10 sections constituted the 'point-total'. This 'point-total' divided by '50' and multiplied by '100' = per cent disability (ODI score). For example, if on interrogation a point-total of 18 is achieved, then the functional disability will be $18/50 \times 100 = 36\%$ and ODI score is noted as 36.

The estimated effect size was presumed to be 10%, assuming faster needle placement under USG guidance. With alpha value at 0.05 and power of study at 80%, the sample size of 25 for each group was obtained. All data were entered into Excel sheet and analysed using Statistical Package for Social Sciences version 20 [IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.]. Continuous data were expressed as mean ± standard deviation and were analysed using independent samples *t*-test except for intragroup analysis which was analysed using paired *t*-test. Categorical data were expressed as number of patients (*n*) and analysed using Chi-square test. $P < 0.05$ was considered significant.

RESULTS

The study spanned from January 2015 to June 2015. The demographic profile and baseline VAS score and ODI were comparable in both groups [Table 1]. The needle placement time was found to be less in Group U compared to Group F (119 ± 7.66 vs. 222.28 ± 29.65 s, respectively, $P = 0.0001$). Characteristic 'filling defect' was observed in the epidurogram in 8 out of 25 patients receiving an epidural injection under fluoroscopy guidance. No adverse incident was observed in any group. Significant improvement in VAS score and ODI was observed at 2nd week, at the end of 1st and 2nd month after intervention in both the groups when compared with the baseline [Table 2]. However, the both the VAS scores and ODI values were comparable between the groups at all those time points [Table 2]. There was no drop out in this study.

DISCUSSION

This study finds that correct placement of caudal epidural needle is faster under USG-guidance as compared to fluoroscopy-guidance. However, fluoroscopy-guidance offered certain advantages because the contour of the epidural space can be seen in the epidurogram. In fluoroscopy group, a 'filling defect' in epidurogram was noted in eight patients who subsequently received further intervention with injection hyaluronidase for adhesiolysis at a later date,

Table 1: Demographic data

Parameters	Group U (*n*=25)	Group F (*n*=25)	*P*
Age (years)	44.48±6.48 (1.296)	41.88±8.05 (1.610)	0.215
Height (cm)	160.80±5.88 (1.776)	158.76±6.31 (1.261)	0.243
Weight (kg)	64.12±8.57 (1.713)	59.80±8.03 (1.605)	0.072
Duration of pain (months)	13.04±5.98 (1.195)	13.72±6.59 (1.318)	0.704
VAS score	8.68±0.63 (0.125)	8.76±0.52 (0.105)	0.627
ODI	63.52±6.86 (1.372)	62.48±5.14 (1.028)	0.547
Sex (female: male)*	14:11	16:9	0.773

*Data were analysed using unpaired *t*-test except marked continuous; Data expressed as mean±SD (SE). VAS – Visual analogue scale; ODI – Oswestry Disability Index; SE – Standard error

Table 2: Comparison between baseline and post-procedural visual analogue scale scores and Oswestry Disability Index values

Parameters	Group U (*n*=25)	Group F (*n*=25)	Intragroup (Group U) significance (two-tailed)	Intragroup (Group F) significance (two-tailed)	Intergroup significance (two-tailed)
VAS at baseline	8.68±0.63	8.76±0.52			0.627
VAS at 2nd week	7.40±1.00	7.44±0.82	0.000*	0.000*	0.878
VAS at 1st month	3.92±0.81	3.84±0.62	0.000†	0.000†	0.698
VAS at 2nd month	3.00±0.71	2.84±0.62	0.000‡	0.000‡	0.401
ODI at baseline	63.52±6.86	62.48±5.14			0.547
ODI at 2nd week	60.72±6.80	59.28±4.24	0.000*	0.000*	0.374
ODI at 1st month	34.56±4.78	33.20±3.65	0.000†	0.000†	0.264
ODI at 2nd month	32.16±4.08	30.88±4.00	0.000‡	0.000‡	0.268

*Baseline versus 2 weeks; †Baseline versus 1st month; ‡Baseline versus 2nd month; Data expressed as mean±SD

4 weeks after the first intervention. Under ultrasound guidance, the drug spread was confirmed by increased hypoechogenicity and there was no way to understand the contour of epidural space. Moreover, the needle tip at S_3 could be visualised properly under fluoroscopy while under ultrasound-guidance it was not possible. With the help of real-time USG, only the piercing of sacrococcygeal membrane was confirmed. For the pain physician, the specific pattern of epidurogram as seen vivid during fluoroscopy might be more helpful than USG, and accordingly further management can be planned. Significant decrease in post-procedural VAS score and ODI values in both the groups in the current study translates into comparable efficacy irrespective of the guidance mode. Current evidence regarding the fluoroscopy guidance[4,5,12,13] and ultrasound-guidance[4,7-9] also support this finding.

Epidural steroid is commonly used for the treatment of LBP with reported good results.[12,13] The patients who have disc bulge at multiple levels commonly benefit with this modality. Caudal epidural injection is considered as semi-invasive procedure and allows sufficient proximal spread of medication with 10 ml volume.[14]

Maximal beneficial effect of epidural long-acting steroid is usually experienced after few weeks of injection. However, individual variation of receptor response to methylprednisolone might occur.[15] Injection of normal saline with steroid in epidural space distends and decompresses the epidural space. Normal saline is helpful for adhesinolysis.[16,17]

The ODI, the assessment of which is based on feedback received using Oswestry LBP Disability Questionnaire,[11,16] is an extremely important tool to assess one's ability to manage in everyday life. It remains the 'gold standard' of functional outcome tools in persons with LBP. Disability evaluators and researchers often use ODI scoring to measure a person's permanent functional disability. In this study, patients presenting with 'severe disability' or 'crippled', ultimately entered into the status of 'moderate disability' in both the groups. This indicates the success of epidural steroid injection using either of the guidance modes.

Several adverse events such as accidental intravascular injection, haematoma, dural puncture, nerve trauma, etc., have been reported in the literature.[14] We did not confront any adverse event, and further observations involving a larger sample is warranted for a comment.

There are limitations in the present study. We did not conduct the study exclusively on either unilateral or bilateral radiculopathy. Some of the patients of the USG group might need subsequent adhesionolysis but they remained undetected as epidurogram could not be obtained in the same sitting. Another limitation is that the present reporting is based on 2-months' follow-up data which should preferably be of at least 6-months' duration. The usefulness of US guidance can be exploited in future studies on a larger sample size with adequate follow-up duration.

CONCLUSION

Ultrasound-guidance can be a safe, alternative tool for achieving faster needle placement in caudal epidural space. Clinical effectiveness remains comparable between the techniques. Specific advantages like vivid visualisation of needle-tip and patterns of epidurogram maintain the superiority of fluoroscopy.

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Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Iversen T, Solberg TK, Romner B, Wilsgaard T, Twisk J, Anke A, *et al.* Effect of caudal epidural steroid or saline injection in chronic lumbar radiculopathy: Multicentre, blinded, randomised controlled trial. BMJ 2011;343:d5278.
2. Bindra S, Sinha AG, Benjamin AI. Epidemiology of Low Back Pain in Indian Population: A Review. Available from: http://www.cibtech.org/jms.htm. [Last accessed on 2016 Jan 17].
3. Collighan N, Gupta S. Epidural steroids. Contin Educ Anaesth Crit Care Pain 2010;10:1-5.
4. Park Y, Lee JH, Park KD, Ahn JK, Park J, Jee H. Ultrasound-guided vs. fluoroscopy-guided caudal epidural steroid injection for the treatment of unilateral lower lumbar radicular pain: A prospective, randomized, single-blind clinical study. Am J Phys Med Rehabil 2013;92:575-86.
5. Murakibhavi VG, Khemka AG. Caudal epidural steroid injection: A randomized controlled trial. Evid Based Spine Care J 2011;2:19-26.
6. Andreucci M, Solomon R, Tasanarong A. Side effects of radiographic contrast media: Pathogenesis, risk factors, and prevention. Biomed Res Int 2014;2014:741018.
7. Chen CP, Tang SF, Hsu TC, Tsai WC, Liu HP, Chen MJ, *et al.* Ultrasound guidance in caudal epidural needle placement. Anesthesiology 2004;101:181-4.
8. Jee H, Lee JH, Kim J, Park KD, Lee WY, Park Y. Ultrasound-guided selective nerve root block versus fluoroscopy-guided transforaminal block for the treatment of radicular pain in the lower cervical spine: A randomized, blinded, controlled study. Skeletal Radiol 2013;42:69-78.
9. Klocke R, Jenkinson T, Glew D. Sonographically guided caudal epidural steroid injections. J Ultrasound Med 2003;22:1229-32.
10. Thall PF, Wathen JK. Practical Bayesian adaptive randomisation in clinical trials. Eur J Cancer 2007;43:859-66.
11. Fairbank JC, Pynsent PB. The Oswestry disability index. Spine (Phila Pa 1976) 2000;25:2940-52.
12. Southern D, Lutz GE, Cooper G, Barre L. Are fluoroscopic caudal epidural steroid injections effective for managing chronic low back pain? Pain Physician 2003;6:167-72.
13. Barre L, Lutz GE, Southern D, Cooper G. Fluoroscopically guided caudal epidural steroid injections for lumbar spinal stenosis: A restrospective evaluation of long term efficacy. Pain Physician 2004;7:187-93.
14. Goodman BS, Posecion LW, Mallempati S, Bayazitoglu M. Complications and pitfalls of lumbar interlaminar and transforaminal epidural injections. Curr Rev Musculoskelet Med 2008;1:212-22.
15. Manchikanti L. Role of neuraxial steroids in interventional pain management. Pain Physician 2002;5:182-99.
16. Pandit P, Bhattacharya D, Pandit S, Biswas M, Srivastav S, Maiti S, *et al*. Comparative study of C-arm guided caudal-epidural block with bupivacaine and steroid versus normal saline and steroid for relief of chronic low back pain-our experience in 100 cases. Indian J Pain 2012;26:162-8.
17. Lee F, Jamison DE, Hurley RW, Cohen SP. Epidural lysis of adhesions. Korean J Pain 2014;27:3-15.