Comparing the Efficacy of Caudal with Intravenous Dexamethasone in the Management of Pain Following Lumbosacral Spine Surgeries: A Randomized Double Blinded Controlled Study

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Abstract

Background: The challenge in providing analgesia for spine surgeries is to provide extended postoperative pain relief and simultaneously allow early neurological assessment and mobilization. Our study aimed to evaluate the analgesic efficacy of intravenous versus caudal dexamethasone in lumbosacral spine surgeries. Materials and Methods: In this prospective double-blind study, a total of 96 patients undergoing lumbosacral spine surgery were randomized into three groups to receive 25 ml of preemptive caudal epidural injection of either injection ropivacaine 0.2% (Group A, n = 32), a 25 ml of injection ropivacaine 0.2%, and intravenous injection dexamethasone 8 mg (Group B, n = 32) or 25 ml mixture of injection ropivacaine 0.2% with injection dexamethasone 8 mg (Group C, n = 32) under general anesthesia. Visual analog scale (VAS), heart rate, blood pressures, blood sugar levels, and time to rescue analgesia were recorded at regular intervals for the first 24 h. Time to discharge was noted. Analysis of variance has been used to find the significance of study parameters between the groups of patients. Statistical software, namely, SAS 9.2 and SPSS 15.0, have been used for the analysis of the data. Results: The mean VAS was significantly lower in the Group C for up to 24 h following the caudal block. No significant hemodynamic changes were noted in any of the groups. The intravenous dexamethasone group showed higher blood glucose levels at 24 h but was not clinically relevant. Conclusion: These results suggest that injection dexamethasone is a safe adjunct to caudal ropivacaine in lumbosacral spine surgeries.

Keywords: Analgesia, caudal, dexamethasone, intravenous, postoperative pain, ropivacaine, spine surgeries, steroids

INTRODUCTION

Postoperative pain following spine surgeries not only contributes to significant morbidity but also hampers early mobilization. The conventional parenteral regimen has been the mainstay of analgesic therapy in the postoperative management of spine surgeries.[1] Probable causes precluding the use of regional techniques could be the site of surgery, apprehension of the surgeon, and need of general anesthesia for the surgery per se.[2] The fact that regional analgesia causes lower pain scores, reduces narcotic requirement, and postoperative nausea and vomiting (PONV) is undisputed. Postoperative pain following lumbosacral spine surgeries can be alleviated by caudal analgesia using local anesthetics; duration of analgesia can further be prolonged by adding adjuvants to local anesthetics.[3] Preventive analgesia, which encompasses multimodal preoperative and postoperative analgesic therapies, should be part of our anesthetic strategy.[4]

Evidence by a systematic review of the efficacy of epidural steroids in patients undergoing lumbar spine surgeries shows decreased pain in the short-term and shortens the length of stay with no adverse events.[5] Dexamethasone is a highly potent, long-acting glucocorticoid with little mineralocorticoid effect. Used in the perioperative setting, it may prevent...
PONV, improve analgesia, and decrease opioid consumption, significantly decrease the incidence and severity of sore throat and hoarseness after general anesthesia and antagonize the inflammatory reaction. A meta-analysis by Waldron et al., on perioperative single-dose intravenous dexamethasone, was associated with small but statistically significant reductions in postoperative pain, postoperative opioid consumption, need for rescue analgesia, postanesthesia care unit stays, and a longer time to first analgesic dose and no increased risk of infection or delayed wound healing. Thomas and Beevi et al. conducted a randomized double-blind study on 94 patients undergoing laparoscopic cholecystectomy and found that preoperative epidural administration of 5 mg of dexamethasone with or without bupivacaine reduced postoperative pain and morphine consumption.

There is a need for studies of dexamethasone in which pain is the primary outcome as most of the evidence comes from studies without validated outcomes and that selectively report positive results. More research is required before establishing perioperative single dose of caudal steroids versus intravenous dexamethasone as an effective adjunct to surgery for reducing pain in the long term. Both caudal and systemic route have shown favorable results, though both were not compared; hence, this study aims to find the efficiency of two routes of dexamethasone administration.

**Materials and Methods**

A randomized double-blind prospective study was conducted on 96 patients undergoing lumbosacral spine surgeries (caudal to T12 spine) aged between 18 and 70 years who belonged to the American Society of Anesthesiologists (ASA) Grades 1 and 2 under general anesthesia from December 2015 to May 2016.

After the Institutional Ethical Committee clearance, informed consent was taken from all the 96 patients and were randomly allocated into three groups (Group A, Group B, and Group C) of 32 each using computer-generated random numbers. Patients with diabetes, coagulopathy, peptic ulcer disease or anomalies of sacrum, and the patients on steroid medications within the past 6 months were excluded from the study. In the operation theater, all essential monitors, electrocardiogram, pulse oximeter, noninvasive blood pressure monitoring, were connected and basal parametric readings were recorded. General anesthesia was induced using standard technique using injection fentanyl 2 μg/kg, injection propofol 2 mg/kg and tracheal intubation facilitated using injection vecuronium 0.1 mg/kg. Anesthesia was maintained with oxygen, air, and isoflurane. Once the endotracheal tube was secured, the patient was turned prone on padded bolsters and the caudal block was performed by senior anesthetist using 20-gauge needle under aseptic precautions and confirmed by loss of resistance technique.

- Group A received 2 ml of intravenous normal saline and 25 ml of 0.2% ropivacaine caudal
- Group B received 8 mg (2 ml) of dexamethasone intravenously and 25 ml of 0.2% ropivacaine caudal
- Group C received 2 ml of intravenous normal saline and 25 ml of 0.2% ropivacaine added with 8 mg dexamethasone caudal.

The demographic data including age, weight, ASA status, type and duration of surgery and hemodynamic parameters such as heart rate (HR), systolic, diastolic, and mean blood pressure were noted at baseline, after induction, after caudal block, 15 min and 30 min intraoperatively; then HR and mean blood pressure immediate postoperatively, 30 min, 1 h, 2 h, 4 h, 8 h, 12 h, and 24 h postoperatively were recorded. Intravenous paracetamol 1 g infusion was given 8th hourly for first 24 h.

Glucometric random blood sugar was recorded at baseline, 4 h, 8 h, 12 h, and 24 h from the caudal block.

A senior registrar in the Anesthesia Department, blinded to the study, assessed pain using visual analog scale (VAS) which was made familiar to patients preoperatively. This assessment was done immediately after surgery when the patient had completely recovered and regained consciousness from general anesthesia (0 h) and subsequently at 1 h, 2 h, 4 h, 8 h, 12 h, and 24 h thereafter. The time at which a patient first demanded supplemental analgesic medication injection tramadol 1 mg/kg was given as rescue analgesia or if VAS >4 and time from the caudal block was noted.

Then, total length of hospital stay was recorded. Any other adverse event was noted and was managed accordingly.

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented as mean ± standard deviation (minimum–maximum) and results on categorical measurements are presented in number (%). The significance is assessed at 5% level of significance. Analysis of variance has been used to find the significance of study parameters between the groups of patients; Chi-square/Fisher’s exact test has been used to find the significance of study parameters on a categorical scale between the groups. The statistical software, namely, SAS 9.2 (SAS Institute, Cary, NC, USA) and Statistical Package for Social Sciences (SPSS version 15.0 IBM Corp, Armonk, NY), were used for the analysis of the data, and Microsoft Word and Excel have been used to generate graphs, tables, etc.

**Results**

This study was conducted on 96 patients who underwent lumbosacral spine surgeries. The demographic data were comparable in all three groups as shown in Table 1.

| Table 1: Characteristics and distribution of patients | Group A | Group B | Group C |
|----------------|---------|---------|---------|
| Number          | 32      | 32      | 32      |
| Age (range)     | 21-60   | 29-70   | 21-70   |
| Male/female     | 21/11   | 19/13   | 21/11   |
| With/without instrumentation | 3/29    | 6/26    | 6/26    |
The mean HR, systolic, diastolic, and mean blood pressure changes were comparable between all three groups as shown in Figure 1a-d.

Glucometric random blood sugar (GRBS) was significantly ($P < 0.005$) higher in Group B compared to Groups A and C at 24 h as shown in Table 2.

VAS scores were significantly lower in Groups B and C at 8 h, 12 h, and 24 h compared to Group A. VAS scores between three groups were comparable until 4 h [Table 3].

Time for supplementary analgesia was comparable between all the three groups [Table 4].

There was no difference in days to discharge in all three groups [Table 5].

No adverse effects were seen in any of the three groups.

**DISCUSSION**

Our study revealed that 8 mg of caudal dexamethasone prolongs the analgesic duration of the ropivacaine block in patients undergoing lumbosacral spine surgeries.

A positive surgical outcome for spine surgeries depends on postoperative neurological examination and timely intervention when required, early ambulation and discharge.[5]

Epidural analgesia is known to reduce intravenous analgesic requirement and increase patient satisfaction.[6] Sekar *et al.* conducted a comparative study on 82 patients and concluded that patients receiving preemptive caudal single shot 20 ml of bupivacaine and tramadol had lower VAS scores compared to the control group which received normal saline for lumbosacral spine surgeries.[9]

Parenteral dexamethasone has been explored as an effective adjunct in pain control perioperatively after discectomy.[1]

![Figure 1: Comparison of (a) Heart rate, (b) Systolic Blood Pressure (SBP), (c) Diastolic Blood Pressure (DBP) (d) Mean Arterial Pressure (MAP) distribution of the three groups studied](image)

**Table 2: Comparison of GRBS distribution of three groups’ patients studied**

| GRBS   | Group A       | Group B       | Group C       | P      |
|--------|---------------|---------------|---------------|--------|
| PI     | 113.13±19.37  | 110.13±17.23  | 111.50±21.19  | 0.825  |
| 4 h    | 106.44±23.47  | 104.28±12.95  | 110.81±19.42  | 0.382  |
| 8 h    | 102.66±17.54  | 106.50±16.68  | 110.78±21.52  | 0.226  |
| 12 h   | 100.91±17.04  | 104.28±21.05  | 107.78±18.49  | 0.352  |
| 24 h   | 101.88±18.12  | 149.50±32.19  | 102.69±18.69  | <0.001**|

GRBS=Glucometric random blood sugar, PI=Pre induction

**Table 3: Comparison of visual analog scale distribution of three groups’ patients studied**

| VAS score | Group A       | Group B       | Group C       | P      |
|-----------|---------------|---------------|---------------|--------|
| IO        | 0.38±0.79     | 0.16±0.37     | 0.25±0.62     | 0.395  |
| 30 min    | 0.84±1.22     | 0.39±0.72     | 0.75±1.11     | 0.191  |
| 1 h        | 1.50±1.78     | 1.10±1.11     | 1.44±1.61     | 0.533  |
| 2 h        | 2.22±1.62     | 2.61±2.08     | 2.06±2.02     | 0.504  |
| 4 h        | 3.34±2.29     | 3.84±2.41     | 3.00±2.13     | 0.345  |
| 8 h        | 3.91±1.17     | 3.19±1.33     | 2.59±1.01     | <0.001**|
| 12 h       | 4.69±1.33     | 3.41±0.79     | 2.88±1.04     | <0.001**|
| 24 h       | 5.28±1.22     | 4.50±0.95     | 3.35±1.12     | <0.001**|

VAS= Visual analog scale, IO=Immediate postoperative
Even a single-dose intravenous steroid has been reported to improve postoperative analgesia.\cite{11} King suggested that 10 mg of intravenous dexamethasone reduced analgesic requirement following lumbar discectomies.\cite{11} Corticosteroids have been used as an adjunct to spine surgery, the rationale being a reduction of the inflammatory reaction and formation of scar tissue formation, hence preventing peridural fibrosis and late recurrence of pain.\cite{10} The probable mechanism behind this could be the inhibition of cyclooxygenase-2 and reducing prostaglandin synthesis by inhibiting phospholipase A2 through annexins.\cite{7,12-14} While few studies suggested a direct effect of glucocorticoids on the nerve conduction, others reported that perineural vasoconstriction caused by dexamethasone led to the concomitant slower absorption of the administered local anesthetics.\cite{13}

Evidence by a systematic review conducted by Ranguis et al. to assess the efficacy of epidural steroids in patients undergoing lumbar spine surgeries showed decreased pain in the short term and shortens the length of stay with no adverse events.\cite{5} Jo et al. investigated ninety patients and concluded that the administration of 5 mg of dexamethasone epidurally, before or after surgery, could reduce the pain and analgesic requirement after radical subtotal gastrectomy.\cite{14}

Bahrari et al. found that intraoperative application of adcortyl and bupivacaine in combination applied to the nerve root before closure is safe and effective in the management of postoperative pain in primary single level unilateral lumbar discectomy.\cite{17}

While there is enough evidence to recommend the use of dexamethasone intravenously and through the epidural route as co-analgesics, we intended to compare both these routes to look for any added advantage of using one route over the other in terms of analgesic efficacy and adverse effect profile.

With respect to hemodynamic, there were no significant changes noted in the HR or blood pressures. VAS scores in Group C were significantly lower compared to the other two groups at 8 h, 12 h, and 24 h; however, statistical significance was noted between Group A and Group C.

Time to mobilization was not one of the end parameters recorded since the protocol of the Neurosurgical Department was to mobilize postsurgical patients at 6 h. There was no delay in the mobilization of patients of all the study groups. Time for rescue analgesia was similar in all three groups. There was no delay or difference in the time to discharge in any of the patients. Patients were followed up at 8 days when they presented for suture removal and no delayed wound healing or surgical site infection was noted. This was concurrent with the findings of Hefni AF et al. who used different doses of epidural dexamethasone for postoperative analgesia in patients undergoing abdominal hysterectomy and showed that epidural dexamethasone in a dose of 8 mg was more effective than lower doses with no side effects of dexamethasone usage such as delayed wound healing and wound infection.\cite{19} Further strengthened by Coloma et al. who showed that a single intravenous dose dexamethasone (4 mg) reduced the time to home readiness without increasing the incidence of postoperative wound infections in a high-risk outpatient population undergoing anorectal surgery.\cite{19}

Patients of Group B receiving intravenous dexamethasone showed higher blood glucose levels at 24 h (149.50 ± 32.19 mg/kg) compared to the other two groups and this was statistically significant. Waldron et al. did a systematic search in MEDLINE, EMBASE, CINAHL, and Cochrane register for randomized, controlled studies that compared dexamethasone versus placebo or an aminetic in adult patients undergoing general anesthesia and found that hyperglycemic period after dexamethasone extended to the first 24 h postoperatively and said that it was unclear whether the hyperglycemia had any clinical implication.\cite{6} There were no other adverse events in any of the patients.

**Limitations**

Long-term follow-up could be considered to study the role of dexamethasone in prevention of late development of pain due to fibrosis.

**Conclusion**

Our study demonstrates that caudal epidural dexamethasone in a dose of 8 mg provides excellent postoperative analgesia when added to injection ropivacaine (0.2%) in lumbosacral spine surgeries without altering blood sugar levels or wound healing.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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**Table 4: Time for supplementary analgesia distribution of three groups’ patients studied**

| Time for supplementary analgesia | Group A        | Group B       | Group C       | P       |
|---------------------------------|----------------|---------------|---------------|---------|
| Mean±SD (min)                   | 401.19±59.26   | 420.00±52.67  | 427.00±59.28  | 0.629   |
| SD=Standard deviation           |                |               |               |         |

**Table 5: Time for discharge distribution of three groups’ patients studied**

| Time of discharge | Group A     | Group B      | Group C      | P       |
|-------------------|-------------|--------------|--------------|---------|
| Mean±SD (days)    | 2.88±1.60   | 3.00±1.37    | 2.98±1.42    | 0.868   |
| SD=Standard deviation |           |             |             |         |
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