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Original Article

Anaesthesia Section

Efficacy of Bupivacaine with Morphine versus Bupivacaine with Dexamethasone for Ultrasound Guided Caudal Block in Patients undergoing Lumbar Discectomies: A Randomised Control Study

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ABSTRACT

Introduction: Patients scheduled for spinal surgeries often complain of severe pain postsurgery. Using an additive to the caudal local anaesthetic can provide better pain relief and facilitate early ambulation. Adding an opioid like morphine extends pain relief, while using a steroid like dexamethasone also contributes to prolonged pain relief.

Aim: To compare the combination of morphine with bupivacaine and the combination of dexamethasone with bupivacaine in order to assess which provides better pain relief postsurgery.

Materials and Methods: In this randomised controlled study, ninety patients in American Society of Anaesthesiologists (ASA) grade I and II categories, scheduled for single-level lumbar discectomies, were randomised into three groups. Patients in group A received an ultrasound-guided caudal injection of 25 mL of morphine (3 mg) and bupivacaine (0.25%). Patients in group B received 25 mL of dexamethasone (8 mg) and bupivacaine (0.25%). Lastly, patients in group C received 25 mL of bupivacaine (0.25%) pre-surgery. Postoperative pain was assessed periodically using Visual Analogue Scale (VAS) scores. The time to ambulation, need for rescue analgesics, and side effects were also studied. Data were collected and analysed using Statistical Package for Social Sciences (SPSS) software. Qualitative variables between the groups were compared using the Chi-square test of significance. A p-value of <0.05 was considered statistically significant.

Results: Age (p-value=0.997), sex (p-value=0.928), ASA grades (p-value=0.312), fentanyl consumption during surgery (p-value=0.224), and surgery duration were comparable across all groups (p-value=0.082). VAS static scores were significantly lower in the early postoperative period in group A (p-value=0.021) compared to group B (p-value=1.49) and group C (p-value=0.341). VAS dynamic scores were significantly lower in all groups (p-value <0.01); however, intergroup comparison showed that none of the scores were statistically significant (p-value >0.05 at all times). The time to ambulate was significantly shorter in group A (27.23±11.13 hours) compared to group B (32.87±13.55 hours) and group C (36.07±14.61 hours) (p-value=0.03). The need for rescue analgesics was recorded, with the time taken for rescue analgesics in group A being (8.23±4.56 hours), in group B (8.00±3.67 hours), and in group C (8.77±3.37 hours). The difference in time required was not statistically significant (p-value=0.73). Side effects, including nausea and vomiting, were recorded, with statistical significance observed (p-value=0.03).

Conclusion: Ultrasound-guided caudal block provides effective pain relief in lumbar surgeries. In our study, the addition of morphine to bupivacaine provided better pain relief than dexamethasone. However, side effects are not uncommon and should be considered when using such combinations.

Keywords: Early ambulation, Pain relief, Visual analog pain scale

INTRODUCTION

Patients scheduled for lumbar laminectomy surgical procedures often complain of severe pain in the postoperative period [1]. A questionnaire-based study reported the incidence of postoperative pain to be around 70% in the Indian subpopulation [2]. Various studies have demonstrated that persistent postoperative pain can interfere with daily activities, sleep, and the emotional wellbeing of patients. This can hinder early recovery and ambulation of patients in the postoperative period [2,3]. Persistent nerve root pain that occurs after surgery is mainly attributed to peridural fibrosis and arachnoiditis. The inflammation and compression involved in these surgical procedures trigger this nerve root pain, which then spreads to the paraspinal muscles. The prone position is considered the most favourable for the caudal block [4]. For surgical procedures involving the T10-S5 dermatome, a caudal block is effective in providing pain relief to some extent after surgery [5].

Research has shown that a single caudal epidural injection given atleast 20 minutes before the surgery is a simple, safe, and highly effective method for providing postoperative pain relief. Local anaesthetics administered into the epidural space adhere to the nerve root within approximately 20 minutes and are said to provide pain relief for atleast the first 24 hours after surgery [6]. With the advent of ultrasound, regional anaesthesia has become a safe and reliable technique. The use of ultrasound ensures the accurate deposition of the drug in the caudal space after identifying the correct anatomy [7,8]. Ultrasound-guided caudal epidural steroid injection has been shown to be more beneficial compared to fluoroscopically guided interventions [9].

The addition of an adjuvant to a local anaesthetic helps prolong the effects of the block. Dexamethasone, when used as an additive in a caudal block, provides pain relief for approximately 24 hours with minimal side effects [10,11]. Dexamethasone is used due to its anti-inflammatory properties and its ability to block the effect of

nociceptor C fibers, which leads to decreased pain conduction. Morphine, as an opioid, has also been utilised as a single injection in the caudal epidural space to provide postoperative pain relief in lumbar discectomies. It acts by binding to pre- and postsynaptic mu-opioid receptors in the substantia gelatinosa of the dorsal horn of the spinal cord. Due to its action on primary afferent neurons, morphine decreases the conductance of action potentials through voltage-gated calcium channels. Consequently, there is a reduced calcium influx and decreased neurotransmitter release. This leads to diminished signalling in the dorsal horn, resulting in the decreased transmission of pain signals [12].

Various pain relief modalities have been studied in this regard, but there remains insufficient data on the incidence of postoperative pain following lumbar surgeries. Gaps exist in pain management knowledge among practitioners as well as patients. Additionally, there are research gaps concerning the treatment of chronic lumbar pain in surgical patients. With the intention of addressing these gaps, we decided to conduct this study to manage pain in postsurgical patients, particularly those who have undergone lumbar surgeries [13]. Through this study, we planned to test our hypothesis that the addition of an adjuvant to a local anaesthetic would provide a superior quality of pain relief while simultaneously reducing the dosage of the drug deposited in the caudal space using ultrasound. Since we were testing different combinations of drugs, this trial was designed as a high-quality study. The primary objective was to evaluate the efficacy of effective ultrasound-guided caudal blockade in patients receiving either of the drugs by assessing postoperative pain scores (the VAS scores) [6]. Our secondary objective was to determine which combination of drugs was better for providing pain relief.

MATERIALS AND METHODS

This triple-blinded randomised controlled study was conducted at a Himalayan institute of medical sciences in Dehradun, a tertiary care teaching hospital, over the span of approximately one year for patients enrolled from September 2019 to February 2021. Approval for the study was obtained from the Institutional Ethics Committee, bearing number (SRHU/HIMS/ETHICS/2022/217). Prior to commencing the study, written informed consent was obtained from all patients before surgery.

Sample size calculation: With an alpha error set at 0.05 and the power of the study at 80%, the sample size was estimated to be around 30 in each group, using the formula for equivalence in N Master software. However, anticipating possible dropouts and for more reasonable calculations, we included 35 patients in each group.

$n=Z^2_{\alpha/2}PQ/l^2$

n=required sample size

Z=1.96 at 0.05 level of significance

P=65% pain score reduction [14]

Q=1-P

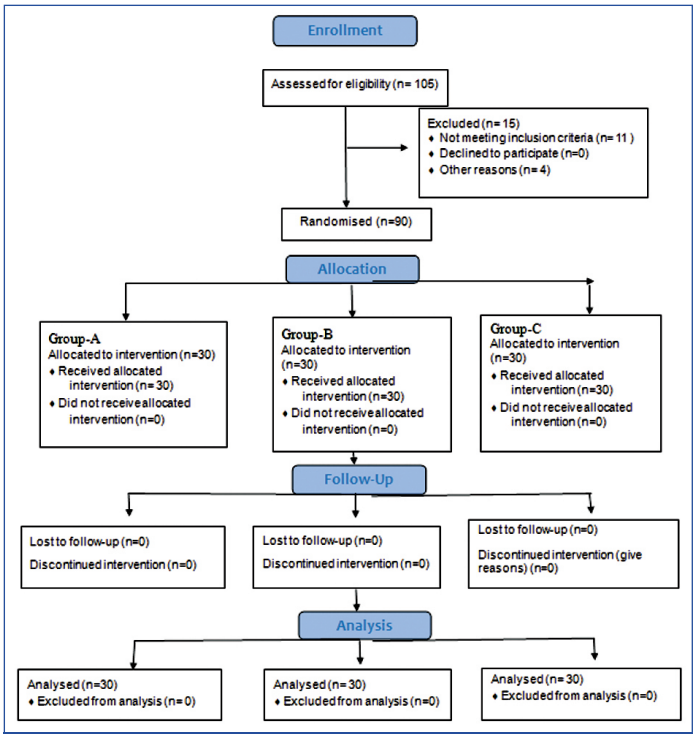
l=20% relative precision

Inclusion criteria: Patients classified as ASA (American Society of Anaesthesiologists) Grade I and II, aged 20 to 60 years, of either sex, scheduled for elective surgical procedures (single-level lumbar discectomy) under general anaesthesia. Ninety patients were included in the study.

Exclusion criteria: Patients with diabetes mellitus, severe hepatic, cardiac, or renal disorders, significant neurological disorders, coagulation abnormalities, airway abnormalities, altered caudal anatomy as determined by ultrasound, and known allergies to any of the drugs were excluded from the study. A total of fifteen patients were excluded.

The patients were randomly divided into three groups using the fishbowl method for randomisation [Table/Fig-1]. Depending on which group the patients belonged to, they received the following medications:

- Group A: Patients received 25 mL of 0.25% Bupivacaine and 3 mg of Morphine.
- Group B: Patients received 25 mL of 0.25% Bupivacaine and 8 mg of Dexamethasone.
- Group C: Patients received 25 mL of 0.25% Bupivacaine.



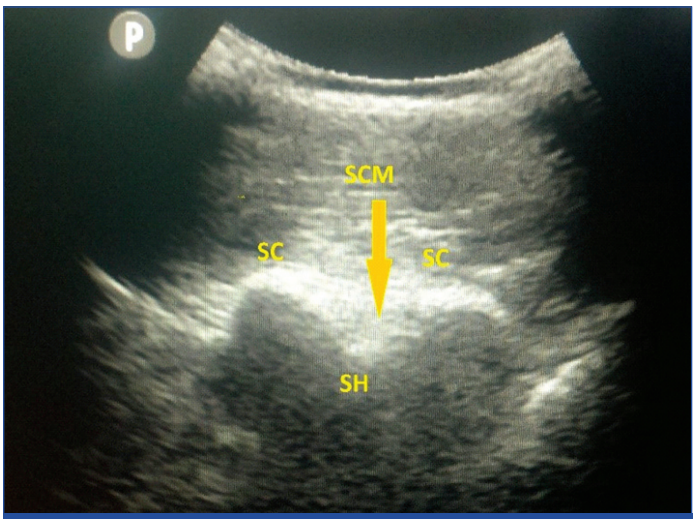
[Table/Fig-1]: The consolidated standards of reporting trials (Consort) flow diagram depicting the study patients.

The calculation of drugs and dosages used was based on previous studies and other literature [15-17]. Age, sex, intraoperative haemodynamic parameters, total blood loss, fentanyl consumption during surgery, and surgery duration were noted. The VAS static and dynamic scores were recorded postoperatively in all the groups, along with the time required for ambulation, the need for rescue analgesics, and any side effects.

To reduce bias and ensure fair data collection, this study was conducted as a triple-blind trial. The groups were numbered and placed in a bowl, which was opened by the attending anaesthesiologist just before transferring the patient to the operating theatre. The drugs were prepared in identical syringes and labelled. The preparation of the drugs was done by the anaesthetist participating in the study, while the block was administered by an anaesthetist who did not participate in the study and did not follow-up with the patients postoperatively. The anaesthesiologist who prepared and administered the drug was not involved in data collection. The patients were unaware of the drugs administered to them in the caudal block. A blinded investigator, unrelated to the intraoperative care of the patient, collected the data during the postoperative period.

The patients were induced according to institutional protocol after ensuring adequate fasting status. Induction was performed with injection fentanyl (2 micrograms/kg), injection propofol (2 mg/kg body weight), and injection vecuronium (0.1 mg/kg). They were then intubated with an appropriately sized endotracheal tube, and post-intubation, they were positioned prone for surgery. Following sterile aseptic precautions, the caudal block was performed using a 22-gauge Quincke needle under ultrasound guidance after establishing anatomical landmarks. The sacral cornua were identified using transverse probe placement, and the sacrococcygeal ligament was located between the sacral cornua (Frog's Eye Sign)

[Table/Fig-2]. The probe was then rotated through 90 degrees, and the drug was deposited in the caudal space after ensuring the piercing of the sacrococcygeal membrane and confirming negative backflow of air or cerebrospinal fluid. Following the caudal block with the aforementioned drugs, the surgical procedure commenced approximately 30 minutes after administration of the block.



[Table/Fig-2]: Frog's eye sign under transverse probe placement for caudal block.
SC: Sacral cornua; SCM: Sacro-coccygeal membrane; SH: Sacral hiatus

Once the surgery began, the intraoperative haemodynamic parameters, total intraoperative opioid consumption, duration of the surgery, and intraoperative blood loss were recorded. Intravenous fentanyl was administered at a dose of one microgram/kg if the surgical duration exceeded one hour (60 minutes). One gram of intravenous paracetamol was routinely given to all patients intraoperatively. After the surgery, the patients were reversed and extubated, and after ensuring complete return of consciousness, they were transferred to the postoperative recovery room. An antiemetic (ondansetron 4 mg) was routinely given to all patients as part of our protocol before extubation. Postoperative pain scores were assessed using the VAS, and the need for rescue analgesics was noted. The VAS scores ranged from 0 to 10, with 0 indicating no pain and 10 representing maximum pain. Prior to the surgery, the patients had been acquainted with the Visual Analogue Scale.

The VAS pain scores were noted at 2, 4, 6, 8, 10, 12, 16, 20, and 24-hour intervals postsurgery, which was termed as VAS static. VAS dynamic scores (recorded after any form of movement) were recorded at 6, 8, 10, 12, 16, 20, and 24 hours after surgery. The time required to ambulate was also noted and compared between the groups. Postoperatively, injection paracetamol was prescribed to all patients three times a day. In addition to this, a rescue analgesic was administered for a VAS score greater than 5 or on patient demand and was recorded across the various groups (intravenous Diclofenac 75 mg). If the pain persisted even after the rescue analgesic, an opioid was given (Tramadol 100 mg in 100 mL Normal Saline over 10 minutes). Any side effects (vomiting, nausea, pruritus, constipation) were recorded for up to 24 hours after the surgery.

STATISTICAL ANALYSIS

The data was aggregated and entered into MS Excel 2010. For statistical analysis of the results, Statistical Package for Social Sciences (SPSS) version 22.0 was used. Post-hoc analysis was conducted within the group to study postoperative pain scores. Analysis of Variance (ANOVA) and repeated measures ANOVA were employed to tabulate the results between different study groups. Qualitative variables among the groups were compared using the Chi-square test of significance. If p-value >0.05, the hypothesis was deemed statistically insignificant; if p-value <0.05, the hypothesis/results were considered statistically significant; and if p-value <0.01, the hypothesis was assumed to be highly significant.

RESULTS

In this randomised controlled study, 105 patients were assessed for eligibility, and 15 patients did not meet the inclusion criteria. Consequently, 90 patients received interventions according to group allocation. None were lost to follow-up, and all were analysed.

Age, sex, ASA grades, fentanyl consumption during surgery, intraoperative blood loss, and surgery duration were comparable across all groups [Table/Fig-3]. Intraoperative vital signs recorded were also comparable among the groups. No significant or adverse intraoperative events were noted in any of the three groups.

		Group-A (n=30)	Group-B (n=30)	Group-C (n=30)	p-value
Age		48.81±9.71	48.60±10.95	48.67±9.81	0.997
Sex	Male	23 (76.6%)	22 (73.3%)	21 (70%)	0.928
	Female	7 (23.3%)	8 (26.7%)	9 (30%)	
ASA grade	I	23 (74.2%)	22 (73.3%)	21 (70%)	0.312
	II	8 (25.8%)	8 (26.7%)	9 (30%)	
Duration of surgery (minutes)		118.06±41.88	97.67±29.26	109.63±33.27	0.082
Total blood loss (mL)		143.87±121.37	90.17±56.48	131.17±101.09	0.086
Total intra-op Fentanyl consumption (micrograms)		126.77±30.23	137.00±24.58	126.50±24.53	0.224
Mean systolic blood pressure (mm Hg)		110±60.24	120±46.23	124±40.33	0.342
Mean diastolic blood pressure (mm Hg)		76±38.22	70±28.54	62±30.76	0.446

[Table/Fig-3]: Comparison of baseline parameters in all the groups.
n=Number of patients enrolled in each group; p<0.05 – Significant. None of the p value here is significant

The pain scores were recorded as VAS static and VAS dynamic (when the patient began to move, turn, or ambulate). The VAS scoring was performed at intervals of 2, 4, 6, 8, 10, 12, 16, 20, and 24 hours in all three groups. In group A, the VAS static scores were significantly lower at 2, 4, 6, and 8 hours postoperatively (p-value <0.05). However, in groups B and C, although the VAS static scores were initially low, this difference was not noted to be significant [Table/Fig-4]. When comparing the overall VAS static scores across the three groups, the differences were found to be statistically insignificant [Table/Fig-5].

The VAS dynamic scores were also compared across all the groups. In group A, the scores were significantly lower in the early hours (p-value <0.001). Similarly, in groups B and C, the VAS dynamic scores were significantly low during the early hours (p-value <0.001) [Table/Fig-6]. However, when comparing the scores overall, they were not statistically significant (p-value >0.05) at any time [Table/Fig-7].

The need for and timing of rescue analgesics was studied in all the groups, but the differences were not found to be statistically significant. The time to ambulate postoperatively was recorded in all three groups. In group A, the mean time for ambulation was 27.23±11.13 hours; in group B, it was 32.87±13.55 hours; and in group C, it was 36.07±14.61 hours. This difference between the groups was significant (p-value=0.03) [Table/Fig-8].

Zero patients in group A (0.0%) required opioids postsurgery, while six patients in group B (20%) and eight patients in group C (26.6%) required opioids. This difference was statistically significant (p-value=0.004). The occurrence of unwanted side effects was also recorded in all three groups. In group A, five patients experienced nausea and vomiting, four patients had nausea, vomiting, and constipation, and two patients reported pruritus (36.6%). In group B, three patients (10%) reported nausea and vomiting. In group C, four patients (13.3%) experienced nausea and vomiting. This difference was statistically significant (p-value=0.03) [Table/Fig-8].

Group	VAS scores (Mean±SD)									p-value
	2 hours	4 hours	6 hours	8 hours	10 hours	12 hours	16 hours	20 hours	24 hours	
A	1.26±2.20	1.90±2.63	1.13±1.60	1.61±1.85	1.90±1.72	1.74±1.75	2.03±1.79	2.19±1.27	1.94±1.81	0.021
B	1.53±1.75	2.77±2.28	1.67±2.13	1.30±1.36	2.10±2.19	2.17±1.85	1.77±1.50	1.90±1.39	1.87±1.00	1.49
C	1.53±2.08	1.77±2.17	1.60±1.95	1.33±1.39	2.17±1.84	1.97±1.88	1.90±1.32	1.87±1.35	1.93±0.94	0.341

[Table/Fig-4]: VAS scores in individual groups at different intervals postsurgery.
(p<0.05 in Group-A-Significant)

	Group-A	Group-B	Group-C	
	Mean±SD	Mean±SD	Mean±SD	p-value
2	1.26±2.20	1.53±1.75	1.53±2.08	0.828
4	1.90±2.63	2.77±2.28	1.77±2.17	0.215
6	1.13±1.60	1.67±2.13	1.60±1.95	0.489
8	1.61±1.85	1.30±1.36	1.33±1.39	0.691
10	1.90±1.72	2.10±2.19	2.17±1.84	0.851
12	1.74±1.75	2.17±1.85	1.97±1.88	0.664
16	2.03±1.79	1.77±1.50	1.33±1.08	0.184
20	2.19±1.27	1.90±1.39	1.87±1.35	0.580
24	1.94±1.81	1.87±1.00	1.93±0.94	0.959

[Table/Fig-5]: Comparison of VAS scores static intergroup at different time intervals postoperatively. None of the scores here were significant (p>0.05).

Group	VAS score (Mean±SD)							p-value
	6 hours	8 hours	10 hours	12 hours	16 hours	20 hours	24 hours	
A	1.03±0.547	1.55±0.92	1.97±1.42	1.84±0.96	1.48±0.67	1.61±0.615	1.90±0.79	<0.001
B	1.80±1.73	1.67±1.12	2.43±1.97	1.43±1.19	1.47±0.73	1.70±0.75	2.00±1.017	<0.001
C	1.67±1.76	1.73±1.20	2.17±1.84	1.70±1.20	1.90±1.32	1.93±0.78	2.07±1.015	<0.001

[Table/Fig-6]: VAS dynamic scores in the groups at different intervals postsurgery.
The scores were individually significant in all the groups (p=0.000)

	Group-A	Group-B	Group-C	
	Mean±SD	Mean±SD	Mean±SD	p-value
6	1.03±0.547	1.80±1.73	1.67±1.76	0.094
8	1.55±0.92	1.67±1.12	1.73±1.20	0.798
10	1.97±1.42	2.43±1.97	2.07±1.61	0.529
12	1.84±0.96	1.43±1.19	1.70±1.20	0.367
16	1.48±0.67	1.47±0.73	1.90±1.32	0.142
20	1.61±0.615	1.70±0.75	1.93±0.78	0.206
24	1.90±0.79	2.00±1.017	2.07±1.015	0.794

[Table/Fig-7]: VAS dynamic scores intergroup.
Comparison revealed none of the scores were significant (p>0.05)

	Group-A	Group-B	Group-C	p-value
Time noted to take the rescue analgesic (hours)	8.23±4.56	8.00±3.67	8.77±3.37	0.73
Time to ambulate (hours)	27.23±11.13	32.87±13.55	36.07±14.61	0.03
Requirement for opioid	0	6 (20%)	8 (26.6%)	0.004
Incidence of side-effects (pruritis, nausea, vomiting)	11 (36.6%)	3 (10%)	4 (13.3%)	0.03

[Table/Fig-8]: Comparison of various parameters.

For nausea and vomiting, an additional 4 mg of ondansetron was administered postoperatively if required. For constipation, surgical advice was sought.

DISCUSSION

In this study, different combinations of drugs were used to provide postoperative pain relief to patients following lumbar discectomies. We found that adding an adjuvant along with a local anaesthetic improves the quality of pain management. Additionally, we determined that the inclusion of morphine with bupivacaine in a caudal block significantly reduced postoperative VAS scores, particularly in the early hours after surgery, and facilitated early ambulation postoperatively.

Our results are consistent with a study conducted by Hussein EM et al., who compared the epidural use of morphine versus bupivacaine in patients undergoing lumbar laminectomies. They found that morphine provided effective postoperative analgesia with early ambulation and a lower incidence of side effects [12]. Kundra P et al., conducted a study with 60 patients to assess pain relief after lumbar laminectomy surgeries, comparing preoperative versus postoperative caudal morphine administration. Their recorded parameters, including VAS scores at eight hours, the time taken for the first dose of analgesia postoperatively, and total morphine consumption after surgery, showed lower values and were noted to be significant with the preoperative use of caudal morphine [18].

These results are similar to those of our study, in which postoperative VAS scores were found to be periodically lower, particularly at six and eight hours after surgery. The addition of a local anaesthetic into the caudal space has already proven to be highly beneficial. Sekar C et al., studied 82 patients undergoing lumbosacral spine surgeries, where patients in the study group received an injection of 20 mL of bupivacaine with tramadol before surgery, while the control group received normal saline. In their study group, the VAS scores recorded were significantly lower at periodic time intervals [19]. Kumar S et al., used caudal ropivacaine in patients undergoing lumbar surgeries and found it to be a safe and simple approach that provides better postoperative pain relief and facilitates early mobilisation [20]. The use of caudal local anaesthetics has also proven effective in providing good pain relief in paediatric patients undergoing infraumbilical surgeries [21]. Cine HS et al., in their randomised control study of 120 patients undergoing lumbar disc herniation surgeries, found that using a local anaesthetic such as bupivacaine alone or in combination proved effective in reducing postoperative pain following lumbar discectomies [22]. Likewise, in our study, patients who received only bupivacaine also reported good pain relief. The recorded VAS dynamic scores were significantly low (p-value <0.001).

In our study, we also used dexamethasone as an additive in a specific group of patients. The pain scores, as indicated by the VAS dynamic scores, were significantly reduced postoperatively (p-value <0.001). Various studies and clinical reports have also been published regarding the safety of epidural steroids in treating chronic low back pain. A non particulate steroid like dexamethasone has proven to be highly beneficial with almost no side effects [23-25]. El Gendy H and Elsharnouby N found that adding dexamethasone to caudal bupivacaine provides a superior duration of analgesia in the postoperative period for geriatric patients undergoing hip replacement surgeries [10]. Similarly, Kalappa S et al., also found

that the addition of dexamethasone as an adjunct in caudal anaesthesia is highly effective in lumbosacral spine surgeries [26].

The intraoperative use of fentanyl was compared among different groups; however, the difference was not found to be clinically significant. Our results were similar to those of a study conducted by Kumar S et al., who studied lumbosacral spinal surgeries using the posterior approach along with the efficacy of a caudal injection of ropivacaine, concluding that this provides a good level of analgesia, particularly early in the postoperative period, while also reducing the need for intraoperative opioids [20].

In a study conducted by Saoud A et al., nausea and urinary retention were noted postoperatively in patients who received bupivacaine with morphine [27]. Meanwhile, Sridhar RB et al., reported no side effects in their study when examining the addition of dexamethasone to ropivacaine in caudal anaesthesia for paediatric patients undergoing infraumbilical surgeries [28]. In our study, 11 patients reported nausea, vomiting, and pruritus postoperatively in the group receiving the combination of morphine and bupivacaine (group A), while nausea and vomiting were reported by three patients in group B (dexamethasone and bupivacaine) and by four patients in group C (bupivacaine) postoperatively. Therefore, while the use of adjuvants has its benefits, some minor complications like nausea and vomiting may occur in certain patients, which can be managed with reassurance and medications.

The strength of our study lies in the use of ultrasound as a modality for providing pain relief to our patients. This ensures proper deposition of the drug in the anatomical space (caudal) while minimising the volume of the drug used. The addition of an adjuvant has resulted in superior pain control quality, as evidenced by our VAS static and dynamic scores.

Limitation(s)

We have only covered the postoperative period up to 24 hours after surgery. Prolonged studies should be conducted to evaluate pain relief in the long-term and assess pain that may arise due to secondary fibrosis postsurgery.

CONCLUSION(S)

We conclude that when administering a caudal block, the addition of an adjuvant to a local anaesthetic provides superior quality pain relief for patients undergoing lumbar discectomies. In our study, the addition of morphine as an adjunct proved to be a slightly better combination for providing pain relief and promoting early postoperative ambulation while reducing the need for other pain relief medications. Therefore, it is recommended to always choose an adjuvant to prolong the effect of the block, thereby providing improved pain relief for patients.

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