



Original Research Article

A comparative study of epidural nalbuphine versus tramadol as an adjuvant to bupivacaine for post operative analgesia in lower limb orthopaedic surgeries

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ABSTRACT

Background: Post operative pain management plays a vital role in ensuring optimal patient recovery and satisfaction, particularly in lower limb surgery where pain can significantly impede mobility and rehabilitation. Epidural anaesthesia provides targeted analgesia with lesser complications. tramadol and nalbuphine are two frequently used opioids for epidural analgesia to reduce postoperative pain. This study aims to compare the post-operative analgesic efficacy of epidural nalbuphine versus epidural tramadol as adjuvant with inj. bupivacaine 0.125% in lower limb orthopedics surgery.

Aims and Objective: This study aimed to compare the post-operative analgesic efficacy of epidural nalbuphine versus epidural tramadol as an adjuvant with inj. bupivacaine 0.125% in lower limb orthopaedic surgery. The primary objectives were the duration and quality of analgesia. Secondary objectives included an assessment of postoperative hemodynamic changes, sedation levels and associated side effects.

Materials and Methods: 60 patients of ASA I and II aged between 18-60 years were randomized into two groups with 30 patients each. Group N received epidural 0.125% bupivacaine (9ml) with 10 mg nalbuphine (1ml) total 10 ml. Group T received epidural 0.125% bupivacaine (9ml) with 50mg tramadol (1 ml) total 10 ml. The drugs were administered when patient complained of pain (i.e. VAS \geq 4).

Results: It was observed that both the groups were found to have similar demographics and hemodynamic parameters. Epidural nalbuphine had faster onset of analgesia (8.4 ± 0.69 mins v/s 10.7 ± 0.68 mins), longer duration of postoperative analgesia (11.2 ± 0.84 hours v/s 9.2 ± 1.42 hours) and better quality of analgesia as compared to tramadol as an epidural adjuvant.

Conclusion: Nalbuphine 10 mg when added as an adjuvant to 0.125% bupivacaine epidurally provided a faster onset, better quality and longer duration of postoperative pain relief as compared to Tramadol 50 mg.

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1. Introduction

Post-operative pain management plays a vital role in ensuring optimal patient recovery and satisfaction, particularly in lower limb surgery where pain can significantly impede mobility and rehabilitation.¹ Pain is an unpleasant sensory and emotional experience associated

with real or possible harm to tissues.² Eliminating pain provides significant comfort for the patient in distress.³ Effective post-operative pain management speeds up the recovery time. Epidural administration of opioids is among the various methods of postoperative analgesia.⁴

Neuraxial block inhibits nociceptive transmission from peripheral to central neuronal system thus providing analgesia, but the short half-life of local anesthetic acts as a limiting factor.⁵ Epidural anesthesia has gained popularity

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due to its ability to provide targeted and continuous pain relief with fewer systemic side effects.⁴ The advantages of epidural analgesia after surgery include better pain relief, enhanced bowel movement, reduced risk of heart problems, quicker recovery following joint surgery, enhanced lung function improved success rates for lower limb vascular procedures and support for early mobilization.^{6–8} Local anesthetics in addition with opioids increase the duration of analgesia reducing frequent supplementation of drugs and hence reduction in dosage and less frequency of systemic side effects.⁹

Tramadol and Nalbuphine are two opioids which are frequently given for epidural analgesia in the post-operative phase. Tramadol, a synthetic 4 phenyl-piperidine analog of codeine is a racemic mixture of two enantiomers; (+) enantiomer and (-) enantiomer. The (+) enantiomer has a moderate affinity towards the μ opioid receptor which inhibits serotonin uptake but a weak affinity for kappa and delta opioid receptors.⁶ The (-) enantiomer inhibits the synaptic release of norepinephrine thereby enhancing the function of spinal descending inhibitory pathways.^{6,10,11} It has a lesser risk of serious side effects like causing suppression of breathing in comparison to other opioids.^{1,3,12,13} Side effects like nausea and vomiting pose a matter of concern for postoperative patients.³

Nalbuphine, a derivative of 14 hydroxy morphine, is a synthetic opioid analgesic that has strong kappa agonist and weak μ receptor agonist and antagonist properties,¹⁴ acts as a good sedative due to its action on kappa receptor while its partial agonism at the μ receptor results in a ceiling effect on respiratory depression. It also potentiates action of local anaesthetic agents.⁸ Nalbuphine has a prolonged action due to its hydrophilic property. It has the ability to improve or maintain the μ opioid receptor-based analgesia while decreasing the μ opioid side effects.¹⁴ It is a potent analgesic with low side effect and dependency profile.¹⁵

A comparative evaluation of nalbuphine and tramadol is essential to optimize postoperative pain management and improve patient outcomes. This study aimed to address the knowledge gap by conducting a prospective, randomized trial to assess the analgesic efficacy of these two opioids in patients undergoing lower limb surgeries.⁷ The primary endpoints were the duration of analgesia and the quality of pain relief, measured using the Visual Analogue Scale (VAS). Secondary endpoints included an assessment of postoperative hemodynamic changes, sedation levels, and associated side effects.

2. Materials and Methods

After getting approval from the institutional ethics committee (SVIEC/MEDI/SRP/JULY/23/129) and written informed consent, this randomized double blinded, prospective study was done in a tertiary care hospital over a period of six months on 60 patients belonging to 18-60

years of age under American Society of Anesthesiologists (ASA) classification grade I and II who underwent elective lower limb orthopedic surgeries under spinal-epidural anaesthesia. The exclusion criteria included the patients who were not willing for surgery, ASA Grade III or more, pregnant or lactating women, with known allergy to the study drug, patients having any vertebral anomalies, who needed supplementation of general anaesthesia and having any contraindication to epidural anaesthesia (local site infection, coagulation disorder, raised intracranial pressure, hemodynamic instability, neurological disorders).

For the sample size calculation, a clinically significant decrease in 24-hour tramadol and nalbuphine consumption was considered to be a 25% absolute reduction. Based on pilot data, 28 patients per group were calculated to be required for an experimental design with equal group sizes, using alpha and beta errors of 0.05 and 0.2, respectively. To account for potential data loss, 30 patients per group were recruited for the study.

60 patients were randomly divided into 2 groups of 30 patients each based on computer-coded sealed envelopes. Group N received epidural 0.125% bupivacaine (9ml) along with 10 mg nalbuphine (1ml) to make a total volume of 10 ml. Group T received epidural 0.125% bupivacaine (9ml) and 50mg tramadol (1ml) to make a total volume of 10ml. The anesthesiologist who was not part of the research team gave the study medication.

One day before surgery, pre-anesthetic evaluation was done. The patients were educated regarding the visual analogue scale (VAS) for the evaluation of postsurgical pain.¹⁶ The patients were advised not to take solids 6 hours prior and clear fluids 4 hours prior to surgery. The procedure was explained and informed consent was documented.

Before surgery, an 18-gauge intravenous cannula was inserted and intravenous fluid was initiated. In operation theatre, all ASA standard monitors were connected to the patients and they were premeditated with Inj. Glycopyrrolate 0.004mg/kg i.v. and Inj. Ondansetron 0.1mg/kg i.v.

The anaesthetic management consisted of combined spinal epidural procedure. Local anaesthesia was given at L₂-L₃ intervertebral space with 2% lidocaine. 18-gauge Touhy epidural needle was inserted and epidural space was identified by hanging drop method; epidural catheter was inserted 5cm into the epidural space and was secured. 3ml of lignocaine 2% with adrenaline (1:200000) was injected through the epidural catheter as test dose. Sub-arachnoid block was performed at the L₃-L₄ interspace in sitting position using a 25-gauge Quincke's spinal needle. After confirming free flow of clear cerebrospinal fluid, inj. 0.5% bupivacaine was injected. The anesthesiologist who administered combined spinal epidural anaesthesia and the investigator who assessed its outcome were blinded to the drug used.

Following parameters were observed:

1. Onset of analgesia: Time interval from administration of the study drug (VAS = 4) till VAS score <4.
2. Duration of analgesia: Is the time interval between onset of analgesia (VAS < 4) till patient complaints of pain (VAS = 4).
3. Quality of analgesia: Was assessed during the duration of analgesia using VAS score, hourly till VAS = 4.
4. Vitals were noted at baseline (before epidural injection) and after epidural injection. It was assessed at 15 minutes, 30 minutes, 60 minutes and there after hourly till VAS = 4 till 10 hours postoperative.
5. Side effects: Any side effects like nausea, vomiting, pruritis, sedation was noted.
6. Ramsay Sedation Score: Was used as tool for assessing level of sedation (Table 1).

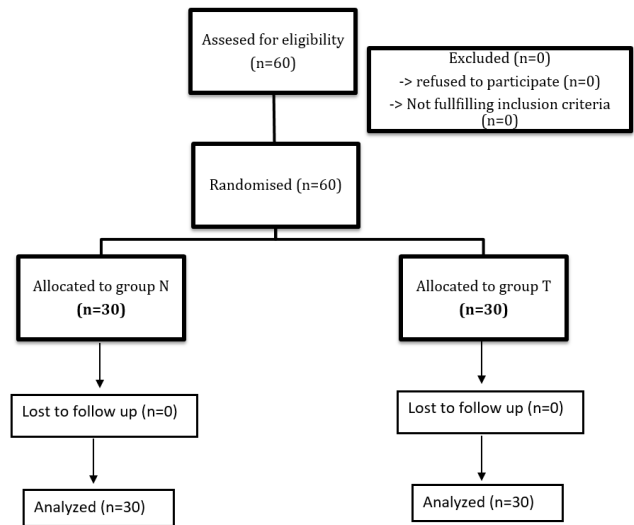


Diagram 1: Consort flow diagram

Table 1: Ramsay sedation score

Score	Response
1	Anxious or restless or both
2	Cooperative, oriented and tranquil
3	Responding to verbal commands
4	Brisk response to stimulus
5	Sluggish response to stimulus
6	No response to stimulus

The dataset recorded in the respective case report forms of the study participants were decoded and analyzed after the end of the study.

2.1. Statistical analysis

The sample size of 60 patients, with 30 patients in each group, was calculated using MedCalc 12.5 software. Data were collected in a tabulated format. Numerical variables were summarized as mean and standard deviation (SD), while categorical variables were expressed as frequency and percentage. For numerical variables, between-group comparisons were performed using tests such as the unpaired Student’s t-test and/or ANOVA, as appropriate. The chi-square test was applied for categorical variables. A p-value of less than 0.05 was considered statistically significant, while a p-value of less than 0.001 was deemed highly significant.

3. Result

60 patients were enrolled in the study and were randomly divided into two groups; group N (nalbuphine) and group T (tramadol) as shown in the consort flow Diagram 1.

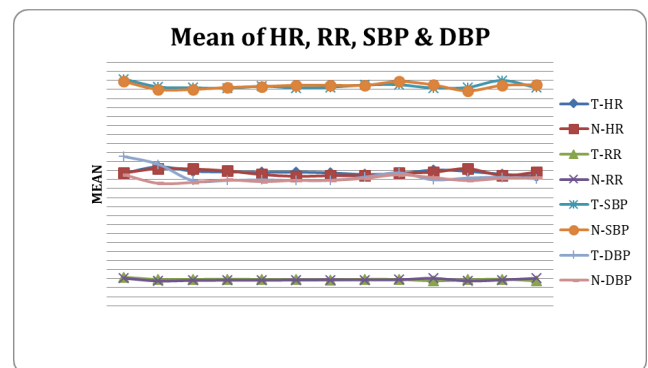
The groups were comparable with respect to age, weight, gender, ASA, type of surgery and total duration of surgery (Table 2).

Patients in Group N showed faster onset of analgesia as compared to Group T which was statistically significant

(8.4± 0.69 minutes, 10.7 ± 0.68 minutes respectively; p value<0.001). Group N also provided a significantly longer duration of analgesia in comparison to Group T (11.2 ± 0.84 hours, 9.2 ± 1.42 hours respectively; p value<0.000) (Table 3).

On comparing the postoperative pain scores using median inter-quartile range, it was found that pain scores (VAS scores) were significantly lower at 15 mins, 30 mins, 1-hour, 2 hour, 4 hours, 6 hours, 8 hours, 10 hours, 12 hours, 18 hours and 24 hours post administration of study drug in group N as compared to group T (Table 4).

No statistical differences were noted in the hemodynamic parameters between two groups (Graph 1).



Graph 1: Hemodynamic changes in the postoperative period. [HR: Heart rate; RR: Respiratory rate; SBP: Systolic blood pressure; DBP: Diastolic blood pressure, N: nalbuphine ; T: tramadol]

None of the patient in both study groups had Ramsay Sedation Score (RSS>=3) in our study.

Table 2: Comparison between the demographic parameters

Parameters	Group T Tramadol		Group N Nalbuphine		P value
	Mean ± SD	N(%)	Mean ± SD	N(%)	
Age (years)	49.47 ±11.68		44.2 ±16.1		0.1521
Weight (kg)	59.9 ±8.75		57.6 ±7.77		0.2861
Gender					
Male	16 (53%)		20 (67%)		0.4292
Female	14 (47%)		10 (33%)		
ASA					
I	9 (30%)		14 (47%)		0.2882
II	21 (70%)		16 (53%)		
Type of Surgery					
Tibia Fractures	8(27%)		9(30%)		>0.999
Femur Fractures	7(23%)		8(27%)		
Ankle and Foot fractures	3(10%)		3(10%)		
External Fixation	9(30%)		7(23%)		
Illizarov	3(10%)		3(10%)		
Total duration of surgery (in hours)	3.2 ±0.46		3.4±0.89		0.2787

Table 3: Mean onset of analgesia and duration of analgesia

	Group T Tramadol		Group N Nalbuphine		P value
	Mean	SD	Mean	SD	
Mean onset of analgesia (in minutes)	10.7	0.68	8.4	0.69	P <0.0001
Total Duration of analgesia (in hours)	9.2	1.42	11.2	0.84	

Table 4: Quality of analgesia and VAS score post study drug administration

Time	Tramadol		Nalbuphine		P Value
	Median (Q1-Q3)		Median (Q1-Q3)		
0 Mins (at study drug administration)	4 (4 - 5)		4 (4 - 5)		0.4840
15 Mins	2 (2 - 2)		1 (1 - 1)		P < 0.0001
30 Mins	2 (2 - 3)		1 (1 - 1)		P < 0.0001
60 Mins	3 (2 - 3)		1 (1 - 1.75)		P < 0.0001
2 Hrs	3 (3 - 3)		2 (1 - 2)		P < 0.0001
4 Hrs	3 (2 - 3)		2 (2 - 2)		P < 0.0001
6 Hrs	3 (3 - 3)		2 (2 - 3)		P < 0.0001
8 Hrs	3 (3 - 5)		3 (2 - 3)		P < 0.0001
10 Hrs	5 (3 - 6)		3 (3 - 4)		P < 0.0001
12 Hrs	3 (2.25 - 3)		5 (2.25 - 5)		P < 0.0001

Mins: Minutes; Hrs: Hours

There were no significant side effects noted in the study patients.

4. Discussion

Post-operative pain has harmful effects on multiple organ systems which can lead to cardiovascular stress, autonomic hyperactivity, increased metabolic rate, dysfunction of immune system, and delayed return of bowel function.^{14,17,18} Hence pain relief is of utmost importance for humanitarian and therapeutic reasons.⁹

Epidural opioids in combination with local anesthetics are being used effectively for postoperative pain relief which

provides superior analgesia as compared to intermittent parenteral opioid injection and have a wider margin of safety.⁹ The analgesic action of opioids is due to its action on spinal and supraspinal site. The opioid and adrenergic systems are closely linked in the spinal cord and stimulation of μ and α_2 receptors produces analgesia.¹⁹ The supraspinal action of opioids involves activation of noradrenergic and serotonergic pathways.²⁰ With small doses of opioids, the threshold doses of local anaesthetics greatly reduce the “C” fibers evoked nociceptive response compared to usage of the drug alone. The synergistic effect of opioids and local anaesthetics leads to reduction in the noxious

stimuli arriving at the dorsal horn neuron thereby reducing the excitability of the cells⁸ Due to markedly decreased μ receptor affinity of tramadol and the weak μ agonist and antagonist property of nalbuphine, both the drugs can be compared as adjuvants to epidural bupivacaine for postoperative analgesia.

Hence, as it is observed that opioids when used as epidural adjuvant to local anesthetics enhances the quality of analgesia, we chose to evaluate the efficacy of 10 mg nalbuphine (Group N) and 50 mg tramadol (Group T) as an epidural adjuvant to 9ml of 0.125% bupivacaine for postoperative analgesia in 60 patients.

A 10 mg dose of nalbuphine was selected as an adjuvant based on the study by Babu S et al. where 10 mg nalbuphine was compared to 2 mg butorphanol as an adjuvant to 0.2% ropivacaine.¹⁴ The study found that nalbuphine provided effective analgesia without significant side effects. Similarly, a study by Singh et al. compared two doses of epidural tramadol (2 mg/kg and 1 mg/kg) as an adjuvant to 0.2% ropivacaine for postoperative analgesia and observed a slightly higher incidence of nausea and vomiting in the group with 2 mg/kg of tramadol. Based on this, a 50 mg dose of epidural tramadol was chosen for the current study.

In this study, postoperative pain was assessed using the VAS, and Group N (nalbuphine) demonstrated a faster onset of analgesia, longer duration of analgesia, and better quality of analgesia compared to Group T (tramadol), with significantly lower VAS scores at all time intervals until rescue analgesia was administered. These findings are consistent with the study by Babu S et al. which compared 10 mg nalbuphine and 2 mg butorphanol as adjuvants to 0.2% ropivacaine via the thoracic epidural route for postoperative analgesia in emergency laparotomy patients.¹⁴ The results showed significantly lower VAS scores in the nalbuphine group during the first 6 hours postoperatively, as well as an earlier onset of action compared to butorphanol.

Similarly, in a study conducted by Chatrath et al., which assessed the postoperative analgesic effect of 10 mg nalbuphine (Group A) versus 100 mg tramadol (Group B) as epidural adjuvants to 8 ml of 0.25% bupivacaine in orthopedic surgeries, it was concluded that the quality of surgical analgesia was excellent in 100% of patients in Group A compared to 90% of patients in Group B. Additionally, the patient satisfaction score was significantly higher in Group A compared to Group B ($p < 0.05$).⁴

Dalal ST et al. compared the postsurgical analgesic efficacy of epidural nalbuphine 10 mg added to 9 ml of 0.2% ropivacaine versus 9 ml of 0.2% ropivacaine with 1 ml of normal saline in patients undergoing lower abdominal surgeries.⁸ The quality of analgesia, assessed using a patient-rated scale, was significantly higher in the nalbuphine-ropivacaine combination group (mean score: 3.53 ± 0.50) compared to the ropivacaine alone group (mean

score: 2.06 ± 0.63). In the nalbuphine group, 53.3% of patients reported excellent analgesia and 46.7% reported good analgesia, while in the ropivacaine group, 23.3% reported good, 60% reported fair, and 16.7% reported poor analgesia. The duration of analgesia was also significantly longer in the nalbuphine-ropivacaine group. Our study findings were consistent with this study.

Uma G et al. conducted a randomized study similar to ours, comparing the analgesic effect of epidural nalbuphine versus tramadol in lower limb orthopedic surgeries. Eighty patients were randomly divided into two groups: one group received 0.125% bupivacaine with nalbuphine (2 mg/ml) infused at 6 ml/hr, while the other group received 0.125% bupivacaine with tramadol (2 mg/ml) infused at the same rate. The study concluded that epidural nalbuphine provided superior analgesia compared to tramadol.³

In the study by P. Sateesh Kumar et al.,¹⁵ 60 patients scheduled for lower abdominal surgeries under epidural anesthesia were randomly divided into two groups. One group received epidural 0.5% bupivacaine (19 ml) with normal saline (1 ml), while the other received epidural 0.5% bupivacaine (19 ml) with nalbuphine 0.2 mg/kg (1 ml). The results demonstrated that the addition of nalbuphine to bupivacaine significantly prolonged the duration of analgesia compared to the placebo group.

Similarly, Biswajit Sutradhar et al.²¹ compared the quality of analgesia provided by adding 10 mg nalbuphine versus 50 mg tramadol as epidural adjuvants to 8 ml of 0.2% ropivacaine in 90 patients undergoing elective abdominal hysterectomy. The findings showed that the nalbuphine group had a longer duration of analgesia and superior quality compared to the tramadol group.

Further studies have assessed the efficacy of nalbuphine as a potent intravenous analgesic and as an adjuvant to regional anesthesia and subarachnoid block, comparing it with tramadol. These studies consistently concluded that nalbuphine provided superior and longer-lasting analgesia compared to tramadol.^{21–27}

In our study the hemodynamic parameters like heart rate, respiratory rate, systolic and diastolic blood pressures were comparable between the groups. Similar findings were seen in the study done by Babu S et al. in which the hemodynamic parameters were comparable and there were no incidence of hypotension, bradycardia or respiratory depression throughout the study period.¹⁴ Likewise, in the study by Dalal ST et al. mean systolic blood pressure and mean respiratory rate did not show any significant difference between the groups.⁸

Ramsay's sedation score was used to analyze sedation in our study and it was observed that there was no deep sedation [RSS > 2] reported in either group. Our findings are consistent with the findings observed by Dalal ST et al. and Babu S et al. where no incidence of deep sedation was noted [8, 14] In contrast to our study results, Chatrath et

al. showed that epidural tramadol with bupivacaine showed higher incidence of sedation due to its direct agonist effect on μ receptors which mediates sedation when compared to epidural nalbuphine as nalbuphine is antagonist at μ receptors and has a ceiling effect on sedation.⁴

In our study none of the patients had nausea and vomiting. This is in contrast to the study by Biswajit Sutradhar et al. where 22.2% patients had nausea and 35.5% patients had vomiting in tramadol group while none of the patients in nalbuphine group had nausea and vomiting.²⁸ This might be due to the μ receptor mediated direct stimulation of chemoreceptor trigger zone and its partial agonist action at dopaminergic receptors.⁴

The observations of our study add strength and evidence to the studies by Babu et al., Dalal et al. and Chatrath et al. which showed nalbuphine when added as an epidural adjuvant to local anesthetic provided better analgesic efficacy in the immediate postoperative period with minimal side effects.^{4,8,14} Hence Nalbuphine is a viable alternative epidural adjunct to local anesthetics for providing effective post-operative analgesia.

5. Limitations

The limitations of our study include a relatively small sample size, which may impact the generalizability of the findings. Additionally, postoperative analgesia was only monitored for the first 24 hours, limiting our ability to assess the full analgesic efficacy over a 48-hour period. The study also did not account for delayed side effects or include a placebo group for comparison, which could have offered a more comprehensive evaluation of the intervention's effectiveness. Furthermore, the subjectivity inherent in Visual Analog Scale (VAS) pain assessments, combined with potential variations in anesthetic sensitivity across different ethnic groups and the single-center design of the study, further restrict the applicability and reliability of the results.

6. Conclusion

The addition of nalbuphine to epidural bupivacaine results in faster onset and longer duration of analgesia with fewer side effects compared to tramadol. Consequently, nalbuphine is a superior epidural adjuvant for postoperative analgesia in patients undergoing lower limb orthopedic surgeries

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Nil.

8. Conflict of Interest

There are no conflicts of interest.

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