International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 24s, 2025
https://theaspd.com/index.php

Efficacy of Nalbuphine, Tramadol and Pethidine for Control of Shivering in Post Subarachnoid Block in Lower Limb and Lower Abdominal Surgeries - A Comparative Study

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ABSTRACT

Introduction: *Spinal anesthesia is one of the most commonly used anesthetic techniques for lower abdominal and lower limb surgeries. Post-spinal shivering is a frequent complication, which can adversely affect patient comfort and recovery, as well as increase metabolic demand and oxygen consumption.*

Objective: *To assess and compare the clinical efficacy of intravenous nalbuphine, tramadol, and pethidine in the management of post-spinal anesthesia shivering.*

Materials and Methods: *A comparative observational study was conducted on 210 patients undergoing elective lower limb and lower abdominal surgeries under subarachnoid block. Patients were randomized into three groups: Group T (Tramadol 0.5 mg/kg IV), Group P (Pethidine 0.5 mg/kg IV), and Group N (Nalbuphine 0.05 mg/kg IV). The time of onset and cessation of shivering, recurrence, and adverse effects were recorded. Data was entered in Microsoft Excel and analyzed using SPSS version 22.*

Results: *The mean age of patients in Group T, Group P, and Group N was 41.7, 41.9, and 44.6 years, respectively. ASA I and ASA II patients comprised 52.2% and 47.3% of the study population, with groups being comparable in terms of age, gender distribution, ASA grading, and BMI.*

The mean time to cessation of shivering was shortest with Pethidine (3.1 ± 0.4 min), followed by Tramadol (5.01 ± 0.4 min) and Nalbuphine (5.2 ± 0.48 min), which was statistically significant ($p < 0.05$). Shivering recurrence was most common in the Pethidine group (24.6%), compared to Tramadol (14.4%) and Nalbuphine (15.9%). Adverse effects varied across groups: 46.3% of patients in the Tramadol group experienced nausea or vomiting, while none in the Nalbuphine group had vomiting. Respiratory depression was observed in 13% of patients in the Pethidine group. Sedation scores were significantly higher with Nalbuphine, where 86.9% of patients exhibited Ramsay sedation score 3, compared to lower sedation scores with Tramadol and Pethidine.

Conclusion: *All three drugs—Nalbuphine, Tramadol, and Pethidine—were effective in treating post-spinal anesthesia shivering. However, Pethidine had the fastest onset of action but showed higher recurrence and respiratory depression. Tramadol was associated with more gastrointestinal side effects, while Nalbuphine provided better sedation with minimal adverse effects. Choice of agent should be tailored to individual patient needs and clinical context.*

Keywords: *Spinal anesthesia, Shivering, Pethidine, Nalbuphine, Tramadol*

1. INTRODUCTION

Spinal anesthesia is the most widely used procedure for surgeries as it is inexpensive and simple to perform [1]. It is conventionally used as a frequent, safe, and approved anesthetic procedure [1,2] subarachnoid block technique is simple to perform and the onset of anesthesia is rapid, allowing the surgical incision to be made sooner and provides good sensory block, motor block with better analgesia that can be extended to postoperative period.

One of the common complications encountered after subarachnoid block is shivering. Shivering is a reflex activity of the skeletal muscles that occurs in response to cold, especially during spinal anesthesia, to regulate body temperature. The occurrence of shivering in patients receiving anesthesia varies between 40% and 50%, presenting difficulties beyond patient discomfort, such as metabolic and cardiovascular

repercussions. (Madem et al.) Perioperative hypothermia is the chief cause of post-spinal anesthesia shivering, which occurs due to anesthetic-induced inhibition of thermo-genesis causing cutaneous vasodilation (triggered by pain) and decreased threshold for stimulation of vasoconstriction. This leads to the dissemination of body heat from the core from the torso (beneath the level of the block) to the periphery with subsequent rapid hypothermia during anesthesia.

Post spinal shivering may further deteriorate the patient's condition after surgery like post-op pain may aggravate due to incision stretching. It can lead to rise in intracranial and intraocular pressure. The oxygen demand of the body tissues also increases by 500% in addition to raised cardiac output and amount of air breathed per minute for the maintenance of aerobic metabolism. Further deleterious effects can result in patients who already have a low cardiac reserve or who have an impaired breathing. Shivering causes difficulty in monitoring of the patients due to artefacts in pulse oximetry, ECG, and blood pressure (nazeen et al).

Diversified approaches are available for the control of post-spinal anesthesia shivering, including non-pharmacological and pharmacological methods. Non-pharmacological approaches utilizing equipment to maintain body temperature are efficient but costly, and they lack feasibility; they include blankets, plastic sheets, surgical drapes, space blankets, and insulators, etc. The pharmacological methods include drugs like ketamine, tramadol, meperidine, pethidine, nefopam, and clonidine. Unfortunately, there is no gold standard treatment for shivering because the use of all available medications is associated with multiple negative side effects.

Tramadol is a synthetic opioid which has been frequently recommended and used to control shivering after spinal anaesthesia. The anti-shivering property of tramadol is mediated by the inhibition of the reuptake of serotonin, norepinephrine, and dopamine as well as its ability to facilitate 5-HT release [8-10]. Though it has opioid-like characteristics, it lacks significant naloxone reversibility. Nevertheless, it has numerous undesirable effects, most commonly nausea, vomiting, and dizziness.

Nalbuphine is a semisynthetic, mixed agonist-antagonist opioid that contains both antagonist and agonist characteristics. In the central nervous system, nalbuphine has a higher affinity for opioid receptors. In the hypothalamus, nalbuphine inhibits shivering. Because of the large density of alpha-2 adrenoreceptors in the hypothalamus, nalbuphine reduces the temperature regulation threshold for vasoconstriction and shivering. It has a minimal respiratory depressant effect and a low potential for abuse compared to other centrally acting opioids. [1,11-12]

Pethidine, an opioid derivative, is frequently recommended for the treatment of post-neuraxial anesthesia shivering. Pethidine is a combined μ- and κ-receptor agonist. Although its mechanism of anti-shivering effect has yet to be fully elucidated, probably acts directly on the thermoregulatory center, and through not only receptor activation but also it causes excessive sedation, respiratory depression, and postoperative nausea and vomiting, which may be stimulated with previously administered opioids or anesthetics

This study was undertaken to compare the efficacy as well as the hemodynamics and adverse effects of nalbuphine, tramadol and pethidine when used for the control of post-spinal anesthesia shivering.

2. METHODOLOGY

Study design: Comparative Study

210 patients of both sexes aged between 18-55 years with ASA 1 and 2 physical statuses posted for lower limb orthopedic and lower abdominal surgeries in AH and RC were divided into 3 groups.

Group 'N' received Nalbuphine 0.05 mg/kg.

Group 'T' received Tramadol 0.5 mg/kg,

Group 'P' received Pethidine 0.5 mg/kg

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. Independent sample t-test was used to assess statistical significance.

Chi-square was performed between categorical variables to find out the association.

P value < 0.05 was considered statistically significant. Data was analysed by using SPSS software, V.22. (1) [Statistical package for Social Sciences. Version 22] SPSS I. IBM SPSS Statistics Version 22 Statistical Software: Core System Users' Guide. SPSS Inc. 2014

3. RESULTS

Demographic profile

Table 1: Comparison of Mean age of Participants in each group.

	Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		P value
Age (In years)	Mean	SD	Mean	SD	Mean	SD	0.105
	41.7	10.8	41.9	12	44.6	10.3	

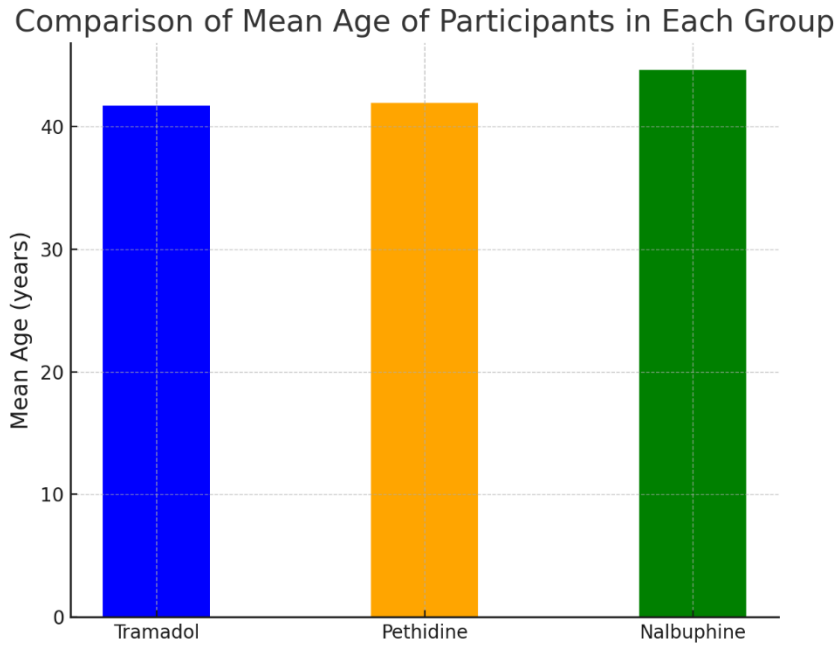


Figure 1: Comparison of Mean age of Participants in each group

Observation:
The mean age of patients in the Tramadol, Pethidine, and Nalbuphine groups was 41.7 ± 10.8 years, 41.9 ± 12 years, and 44.6 ± 10.3 years, respectively. Statistical analysis using ANOVA revealed a p-value of 0.105, indicating that the differences in mean age among the three groups were not statistically significant. This suggests that the study groups were well matched with respect to age, thereby minimizing potential bias and ensuring the comparability of outcomes across treatment arms.

Table 2: Comparison of Gender of Participants in each Group.

Gender		Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		Total		P value
		Count	%	Count	%	Count	%	Count	%	0.72
	Female	30	42	26	36.2	25	36.2	81	38.2	
	Male	40	58	44	63.8	45	63.8	129	61.8	
	Total	70	100	70	100	70	100	210	100	

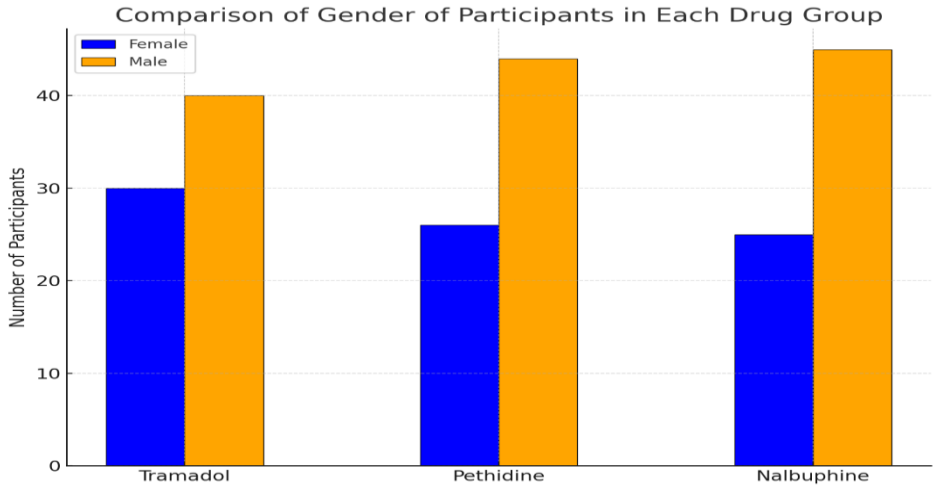


Figure 2: Comparison of Gender of Participants in each Group.

Observation:

In this study involving 210 participants, the overall gender distribution comprised 38.2% females (n = 81) and 61.8% males (n = 129).The distribution of gender across the three intervention groups was as follows:Tramadol group: 42% females (n = 30), 58% males (n = 40),Pethidine group: 36.2% females (n = 26), 63.8% males (n = 44),Nalbuphine group: 36.2% females (n = 25), 63.8% males (n = 45).The statistical analysis yielded a p-value of 0.72, indicating no significant difference in gender distribution between the groups.This suggests that the study groups were well matched in terms of gender, helping to ensure comparability and reduce potential gender-related bias in assessing drug efficacy and safety.

Table 3: Comparison of ASA of Patients in each Group.

		NALBUPHINE		PETHIDINE		TRAMADOL		Total		P-Value
		Count	%	Count	%	Count	%	Count	%	
ASA	I	40	56.3%	35	48.6%	35	50.7%	110	51.9%	.635
	II	30	43.7%	35	51.4%	35	49.3%	100	48.1%	
Total		70	100.0%	70	100.0%	70	100.0%	210	100.0%	

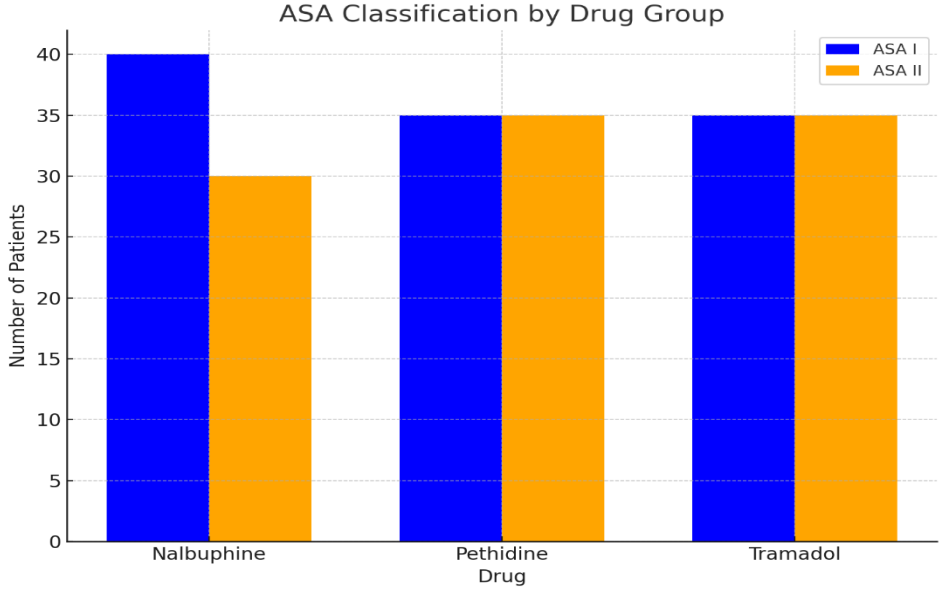


Figure 3: Comparison of ASA of Patients in each Group.

Observation:
The American Society of Anesthesiologists (ASA) physical status classification was assessed among all 210 participants, with the distribution across the three drug groups as follows:Nalbuphine group: 40 patients (56.3%) were ASA I and 30 patients (43.7%) were ASA II,Pethidine group: 35 patients each in ASA I (48.6%) and ASA II (51.4%),Tramadol group: 35 patients in ASA I (50.7%) and 35 in ASA II (49.3%).Overall, 51.9% of patients were classified as ASA I, while 48.1% were ASA II.Statistical analysis yielded a p-value of 0.635, indicating no significant difference in ASA status among the three groups.This demonstrates that the study groups were comparable in terms of preoperative physical status, minimizing potential bias from underlying health conditions in evaluating the efficacy and safety of the study drugs.

Table 4: Comparison of Mean BMI of Participants in each Group.

BMI ($kg/m^{2)}$	Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		P value
	Mean	SD	Mean	SD	Mean	SD	0.2
	23.6	4.10	24.2	5.61	23.1	2.36	

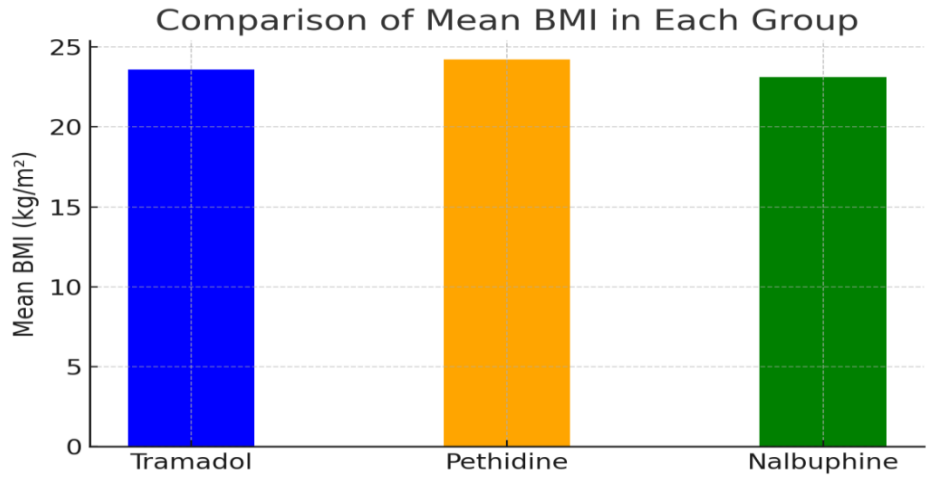


Figure 4: Comparison of Mean BMI of Participants in each Group.
Observation:
The mean Body Mass Index (BMI) among participants in the three treatment groups was as follows:Tramadol group: 23.6 ± 4.10 kg/m², Pethidine group: 24.2 ± 5.61 kg/m², Nalbuphine group: 23.1 ± 2.36 kg/m².The overall analysis revealed a p-value of 0.200, indicating that the difference in BMI across the three groups was not statistically significant.This suggests that all three groups were comparable in terms of body habitus, and BMI was unlikely to act as a confounding factor in evaluating the therapeutic response or side effect profile of the study drugs.

Table 5: Comparison of surgical procedure in different groups.

SURGERY	**Drugs Used**			**Total**
	NALBUPHINE	**PETHIDINE**	**TRAMADOL**	
ORCHIDECTOMY	0	0	1	1
ACHILLES TENDON REPAIR	0	0	1	1
APPENDICECTOMY	1	3	12	16
BELOW KNEE AMPUTATION	1	0	0	1
CRIF	5	0	1	6
CYSTECTOMY	1	0	2	3
FASCIOTOMY	2	5	2	9
FISSURECTOMY	0	2	0	2

FISTULA IN ANO	2	6	0	8
HEMIARTHROPLAST	1	0	0	1
HEMORRHOIDECTOMY	8	11	2	21
HERNIOPLASTY	23	16	18	57
HYDROCOELE	3	0	0	3
IMPLANT REMOVAL	3	1	0	4
INCISION AND DRAINAGE	1	6	2	9
K WIRING	0	0	8	8
ORIF	3	0	11	14
PILONIDAL SINUS	1	3	0	4
SPLIT SKIN GRAFT	3	4	0	7
TAH	0	0	3	3
VARICOCELE	2	0	0	2
VARICOSE VEIN	10	5	7	22
WOUND DEBRIDEMENT	0	8	0	8
TOTAL	**70**	**70**	**70**	**210**

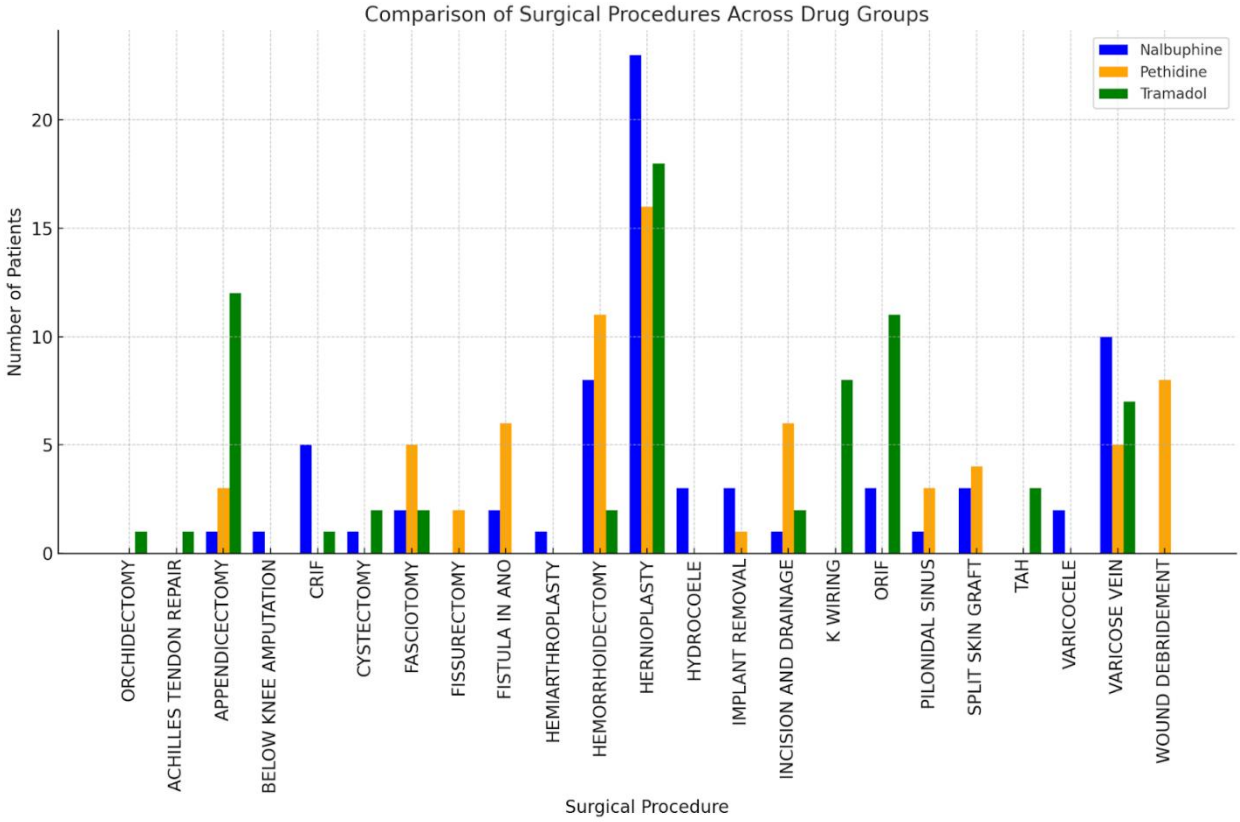


Figure 5: Comparison of surgical procedure in different groups.

Observations:

The comparison of surgical procedures across the three drug groups (Nalbuphine, Pethidine, and Tramadol) reveals that hernioplasty was the most commonly performed surgery overall, with a total of 57 cases distributed among all three groups. Hemorrhoidectomy and appendicectomy were the next most frequent procedures, with 21 and 16 cases respectively. Certain surgeries like K-wiring and ORIF were predominantly observed in the Tramadol group, suggesting a higher utilization of Tramadol in orthopedic interventions. On the other hand, procedures like fistula in ano and incision and drainage were more common in the Pethidine group, whereas the Nalbuphine group showed greater representation in hernioplasty and hemorrhoidectomy. Rare procedures such as orchidectomy, Achilles tendon repair, and below-knee amputation were minimally represented, indicating their limited occurrence in the study population. Overall, the distribution of surgeries appears relatively balanced, though slight variations may reflect either procedural trends or random allocation within the study design

Table 6: Comparison of Duration of SAB (min) among Participants in each Group.

Duration of SAB (min)	Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		P value
	Mean	SD	Mean	SD	Mean	SD	0.97
	145	22.0	145	21.8	144	21.8	

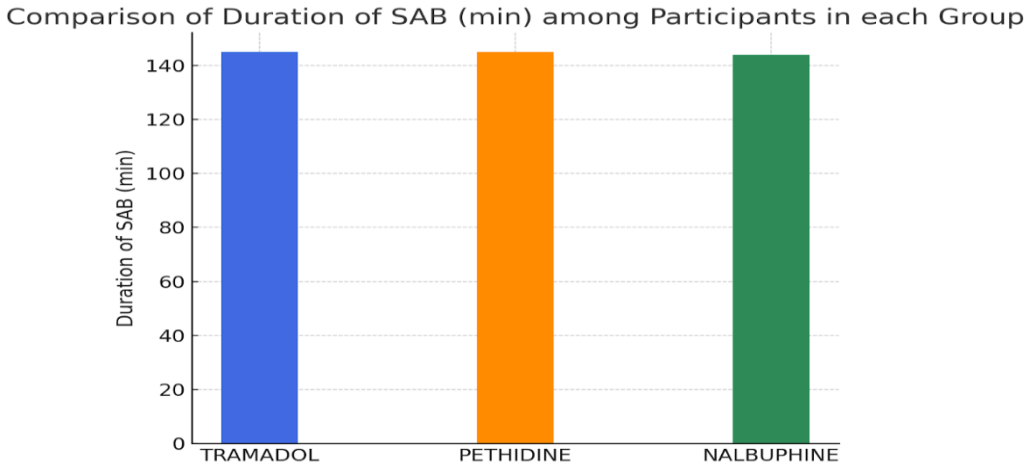


Figure 6: Comparison of Duration of SAB (min) among Participants in each Group.

Observation:

The mean duration of subarachnoid block (SAB) was compared among the three groups:Tramadol group: 145 ± 22.0 minutes,Pethidine group: 145 ± 21.8 minutes, Nalbuphine group: 144 ± 21.8 minutes.The p-value was 0.97, indicating no statistically significant difference in the duration of SAB between the groups.This shows that the effect of the spinal anesthetic was consistent across all study participants, minimizing its potential influence as a confounding variable on the assessment of shivering control.

Table 7: Comparison of Duration of Surgery (min)among Participants in each Group.

Duration of Surgery (min)	Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		P value
	Mean	SD	Mean	SD	Mean	SD	0.99
	99.4	11.71	99.3	11.71	99.3	11.7	

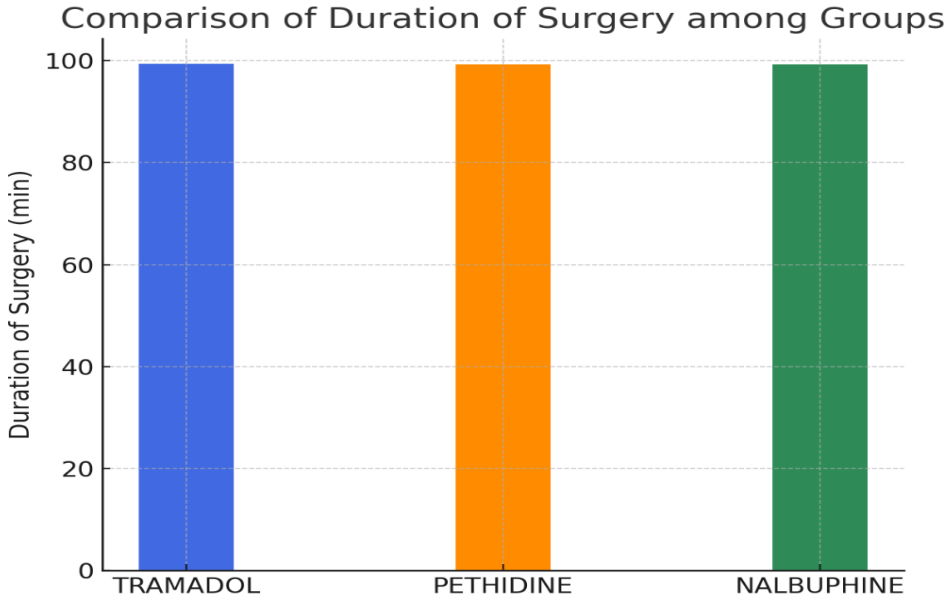


Figure 7: Comparison of Duration of Surgery (min)among Participants in each Group.

Observation:
The mean duration of surgery was compared among the three treatment groups: Tramadol group: Mean = 99.4 minutes, SD = 11.71, Pethidine group: Mean = 99.3 minutes, SD = 11.71, Nalbuphine group: Mean = 99.3 minutes, SD = 11.70. The p-value of 0.99 indicates that there was no statistically significant difference in the duration of surgery among the three groups. This confirms that the surgical time was well balanced across the groups, ensuring that any differences in treatment outcomes were not influenced by variations in surgical duration.

Table 8: Comparison TSAI AND CHU Grading in different group

TSAI AND CHU Grading		Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		Total		Pvalue
		Count	%	Count	%	Count	%	Count	%	
	2	44	65.2	38	55.1	43	60.8	125	59.9	0.47
	3	26	34.8	32	44.9	27	39.2	85	40.1	

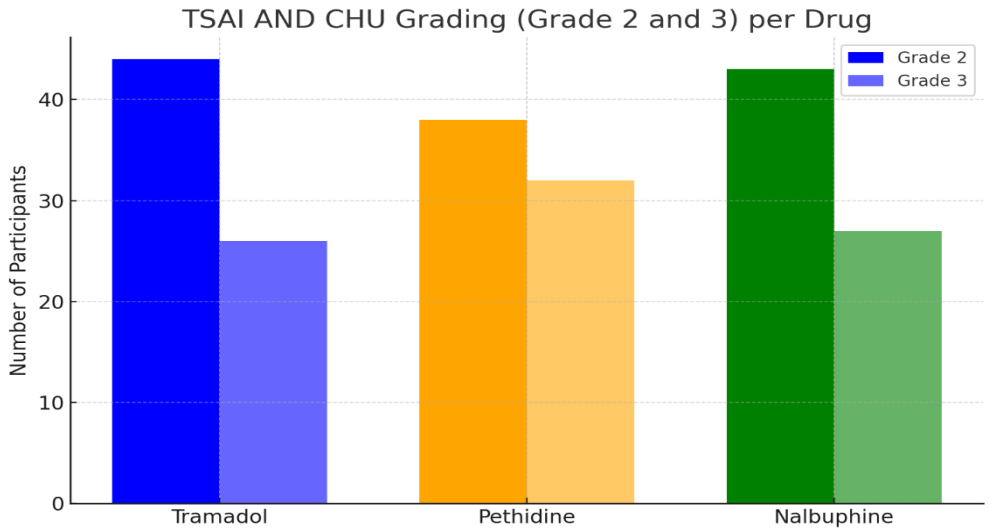


Figure 8: Comparison of TSAI AND CHU Grading in different group

Observation:
The intensity of shivering was evaluated using the Tsai and Chu grading system, and the distribution across the three treatment groups was as follows: Tramadol group: Grade 2 – 44 patients (65.2%) and Grade 3 – 26 patients (34.8%),Pethidine group: Grade 2 – 38 patients (55.1%) and Grade 3 – 32 patients (44.9%),Nalbuphine group: Grade 2 – 43 patients (60.8%) and Grade 3 – 27 patients (39.2%) Out of the total 210 patients, 125 patients (59.9%) experienced Grade 2 shivering, while 85 patients (40.1%) experienced more intense Grade 3 shivering. The p-value was 0.47, indicating that there was no statistically significant difference in the severity of shivering across the three groups prior to treatment. This demonstrates that all three groups were well-matched at baseline with regard to the severity of shivering, which adds strength to the comparative analysis of drug efficacy.

Table 9: Comparison of Duration of onset of shivering (in mins) among Participants in each Group.

Onset of shivering (in mins)	Group TRAMADOL		Group PETHIDINE		Group NALBUPHINE		P value
	Mean	SD	Mean	SD	Mean	SD	0.99
	41.3	7.6	41.3	7.6	41.3	7.6	

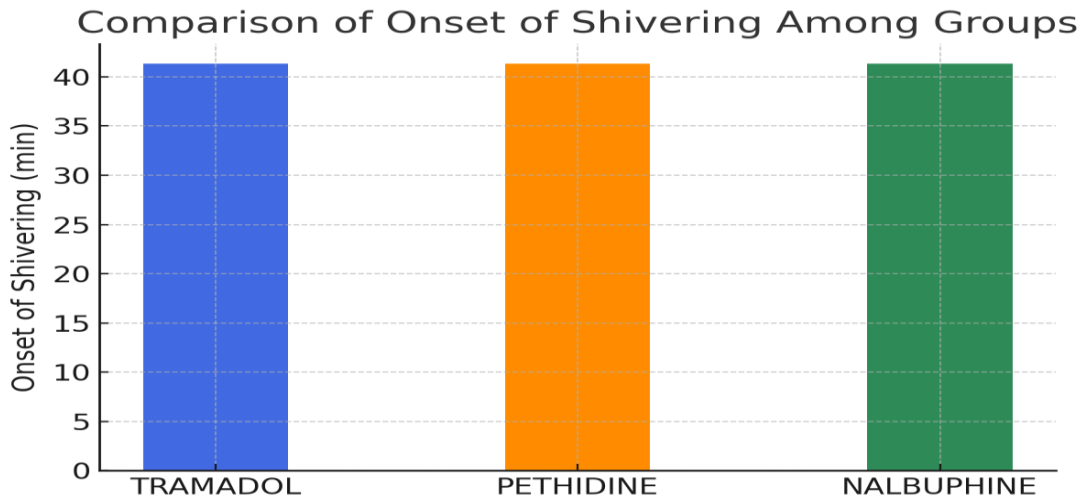


Figure 9: Comparison of Duration of onset of shivering (in mins) among Participants in each Group.

Observation:

The mean time of onset of shivering was measured across all three groups: Tramadol group: Mean = 41.3 minutes, SD = 7.6, Pethidine group: Mean = 41.3 minutes, SD = 7.6, Nalbuphine group: Mean = 41.3 minutes, SD = 7.6. The p-value of 0.99 indicates that there was no statistically significant difference in the onset of shivering among the three groups. This observation confirms that shivering began at a similar postoperative time point for all patients, providing a uniform baseline for assessing the efficacy of the three drugs in controlling shivering.

Table 10: Comparison of Duration of Disappearance of shivering (in mins) among Participants in each Group.

	NALBUPHINE		PETHIDINE		TRAMADOL		P-Value
DISAPPEARANCE OF SHIVERING (In minutes)	Mean	SD	Mean	SD	Mean	SD	<0.001
	5.487	0.4157	3.929	0.3640	5.015	0.4049	

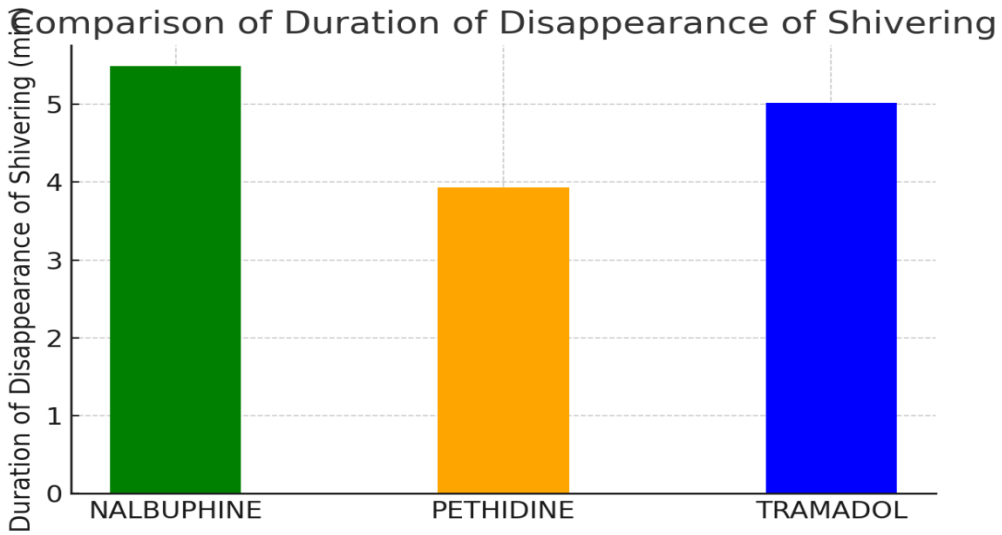


Figure 10: Comparison of Disappearance of shivering (in mins) among Participants in each Group.

Observation:

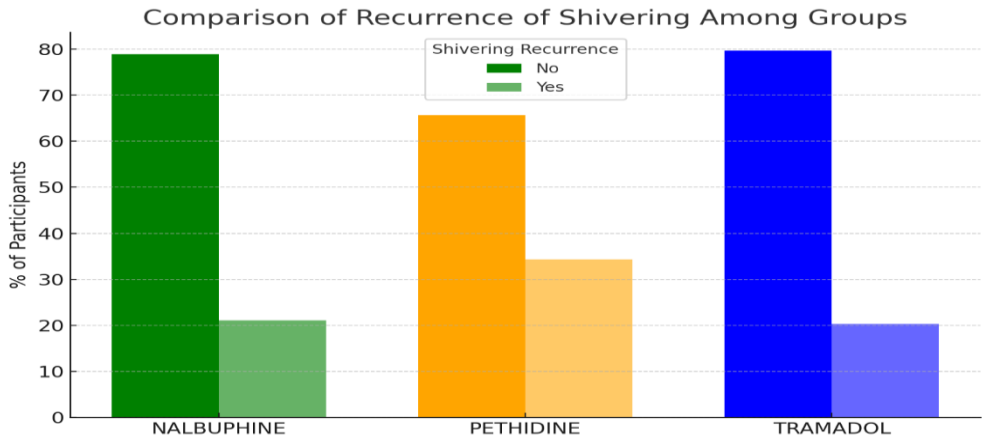
In the present study, the mean time for cessation of shivering following administration of the study drugs was significantly different across the three groups ($p < 0.001$). Among the three drugs: Pethidine demonstrated the fastest onset of action, with a mean shivering cessation time of 3.93 ± 0.36 minutes. Tramadol had a comparatively slower response, with a mean cessation time of 5.01 ± 0.40 minutes.Nalbuphine showed a similar profile to Tramadol, with a mean cessation time of 5.48 ± 0.42 minutes.The statistically significant difference suggests that Pethidine is superior in rapidly controlling shivering when compared to Tramadol and Nalbuphine. However, while the speed of action is a clinical

advantage, this must be balanced against other parameters such as side effects, sedation, and recurrence, which are critical for holistic evaluation.

Table 11: Comparison of recurrence of shivering among Participants in each Group.

RECURRENCE OF SHIVERING		DRUG GROUPS			Total
		NALBUPHINE	PETHIDINE	TRAMADOL	
NO	Count	56	46	55	157
	%	78.9%	65.7%	79.7%	74.8%
YES	Count	14	24	15	53
	%	21.1%	34.3%	20.3%	25.2%
Total	**Count**	**70**	**70**	**70**	**210**

Figure 11: Comparison of recurrence of shivering among Participants in each Group.



Observation:

The recurrence of shivering following treatment was assessed across the three drug groups: Nalbuphine group: Recurrence in 14 patients (21.1%) and No recurrence in 56 patients (78.9%),Pethidine group: Recurrence in 24 patients (34.3%) and No recurrence in 46 patients (65.7%),Tramadol group: Recurrence in 15 patients (20.3%) and No recurrence in 55 patients (79.7%).Out of 210 participants, 53 patients (25.2%) experienced recurrence, while 157 patients (74.8%) did not. Although recurrence was most frequently observed in the Pethidine group (34.3%), This indicates that while Pethidine showed quicker cessation of shivering, it was also associated with a higher recurrence rate, whereas Tramadol and Nalbuphine were more consistent in maintaining shivering control.

Table 12: Comparison of side effects following medication among Patients in each Group.

SIDE EFFECTS		Drug Groups			TTotal	P-Value
		NALBUPHINE	PETHIDINE	TRAMADOL		
DIZZINESS	Count	0	0	4	4	

	%	0.0%	0.0%	5.8%	1.9%	
HYPOTENSION	Count	6	6	0	12	<0.001
	%	8.5%	8.6%	0.0%	5.7%	
NAUSEA	Count	14	2	27	43	
	%	19.7%	2.9%	39.1%	20.5%	
RESPIRATORY DISTRESS	Count	0	10	0	10	
	%	0.0%	14.3%	0.0%	4.8%	
SEDATION	Count	48	39	0	87	
	%	67.6%	55.7%	0.0%	41.4%	
VOMITING	Count	3	13	27	43	
	%	4.2%	18.6%	39.1%	20.5%	
NIL	Count	0	0	12	12	
	%	0.0%	0.0%	15.9%	5.2%	
Total	**Count**	**70**	**70**	**70**	**210**	

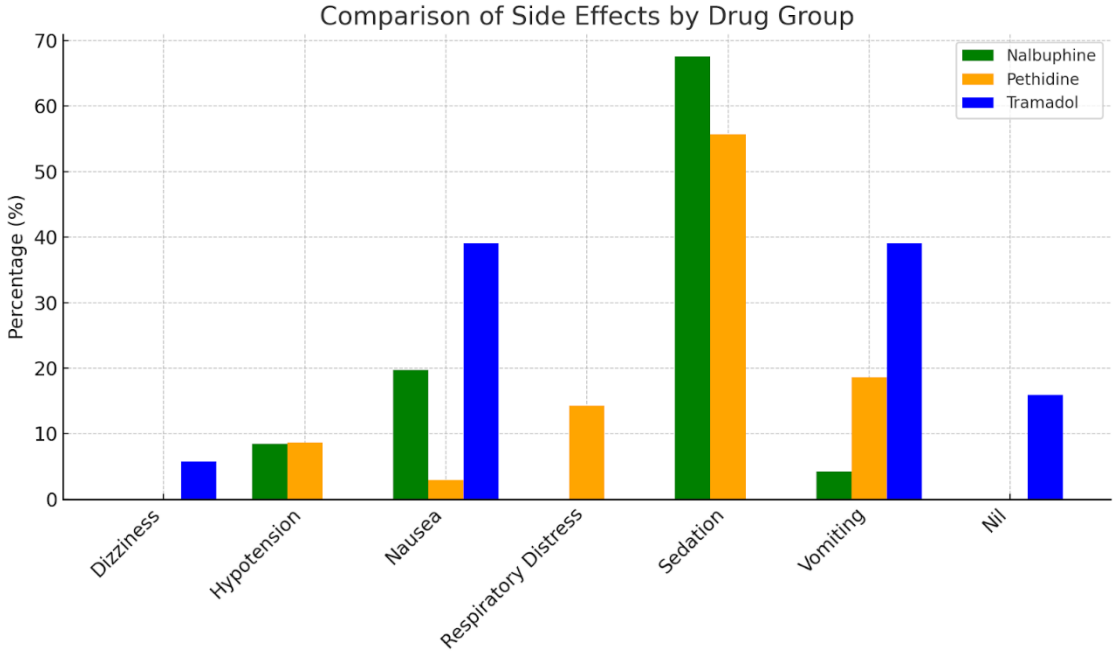


Figure 12: Comparison of side effects following medication among Patients in each Group.

Observation:

This study observed a wide range of side effects across the three medication groups, with significant differences noted ($p < 0.001$), indicating a statistically significant association between the type of drug administered and the incidence of adverse effects. Sedation was most commonly seen in the Nalbuphine group (67.6%), followed closely by the Pethidine group (55.7%). No sedation was reported in the Tramadol group, indicating a clear sedative profile for Nalbuphine and Pethidine. Nausea and vomiting were significantly more prevalent in the Tramadol group (39.1% each), followed by vomiting in the Pethidine group (18.6%). Nalbuphine was associated with less vomiting (4.2%) but showed nausea in 19.7% of cases. Respiratory distress was observed exclusively in the Pethidine group (14.3%), underlining a potential respiratory depressant effect of this opioid. Hypotension occurred equally in both Nalbuphine (8.5%) and Pethidine (8.6%) groups but was absent in the Tramadol group, suggesting a more stable hemodynamic profile with Tramadol. Dizziness was only reported in the Tramadol group (5.8%), while it was completely absent in the other two groups. Interestingly, 15.9% of patients in the Tramadol group

reported no side effects at all, while no such reports were noted in the Nalbuphine or Pethidine groups. These findings suggest that while Pethidine is effective and acts faster, it is associated with higher risk of respiratory distress and vomiting. Tramadol, although slower in action, had fewer serious side effects but caused more nausea and vomiting. Nalbuphine provided a balanced profile with moderate side effects, primarily sedation and nausea.

Table 13: Comparison of RAMSAY sedation score in different group

RAMSAY SEDATION SCORE		DRUG GROUPS			TTotal
		NALBUPHINE	PETHIDINE	TRAMADOL	
1	Count	0	0	55	55
	%	0.0%	0.0%	78.3%	25.7%
2	Count	26	5	14	45
	%	36.6%	7.1%	20.3%	21.4%
3	Count	52	27	1	80
	%	74.3%	39.4%	1.4%	38.6%
4	Count	17	13	0	30
	%	23.9%	18.6%	0.0%	14.3%
Total	**Count**	**70**	**70**	**70**	**210**

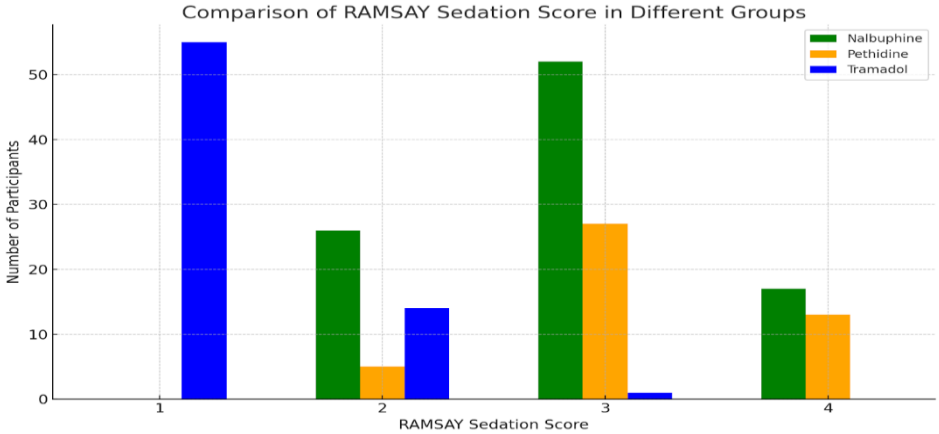


Figure 13: Comparison of RAMSAY sedation score in different group.

Observation:

The distribution of Ramsay Sedation Scores across the three drug groups reveals significant variation in sedative effects induced by Nalbuphine, Pethidine, and Tramadol. Tramadol group exhibited the least sedative effect, with a striking 78.3% of patients scoring 1, indicating they remained alert, anxious, or restless, and no patients scored above 2, confirming its minimal sedative properties. Nalbuphine group demonstrated the highest level of sedation, with 36.6% scoring 2 (cooperative, oriented, tranquil),74.3% scoring 3 (responds only to commands), and 23.9% scoring 4 (brisk response to a loud stimulus), suggesting a strong sedative profile. A large proportion reached moderate to deep sedation. Pethidine group also displayed a notable sedative effect: 39.4% scored 3, and 18.6% scored 4, though less than Nalbuphine in both intensity and frequency of deep sedation. These findings suggest: Nalbuphine offers robust sedation, suitable in clinical situations where moderate to deep sedation is beneficial. Pethidine provides moderate sedation, while Tramadol maintains patient alertness, which may be preferred when sedation is not desired. This distribution of sedation scores reflects the pharmacodynamic differences between the agents and supports individualized patient care based on required sedation levels.

Table 14: comparison of mean heart rate among different groups at different time intervals after giving the antishivering drug.

TIME INTERVAL	NALBUPHINE		PETHIDINE		TRAMADOL		P-Value
	Mean	SD	Mean	SD	Mean	SD	
0	81.48	5.570	78.93	5.347	81.19	5.832	0.333
2	90.83	6.787	84.27	5.574	87.35	6.317	<0.001
4	81.48	5.570	84.27	5.574	78.54	5.756	<0.001
6	80.21	4.748	84.13	6.986	84.49	5.671	0.005
8	79.00	5.337	84.27	5.574	81.19	5.832	<0.001
10	81.48	5.570	84.27	5.574	78.54	5.756	<0.001
20	81.48	5.570	78.93	5.347	76.22	5.549	<0.001
30	81.48	5.570	78.93	5.347	76.22	5.549	<0.001

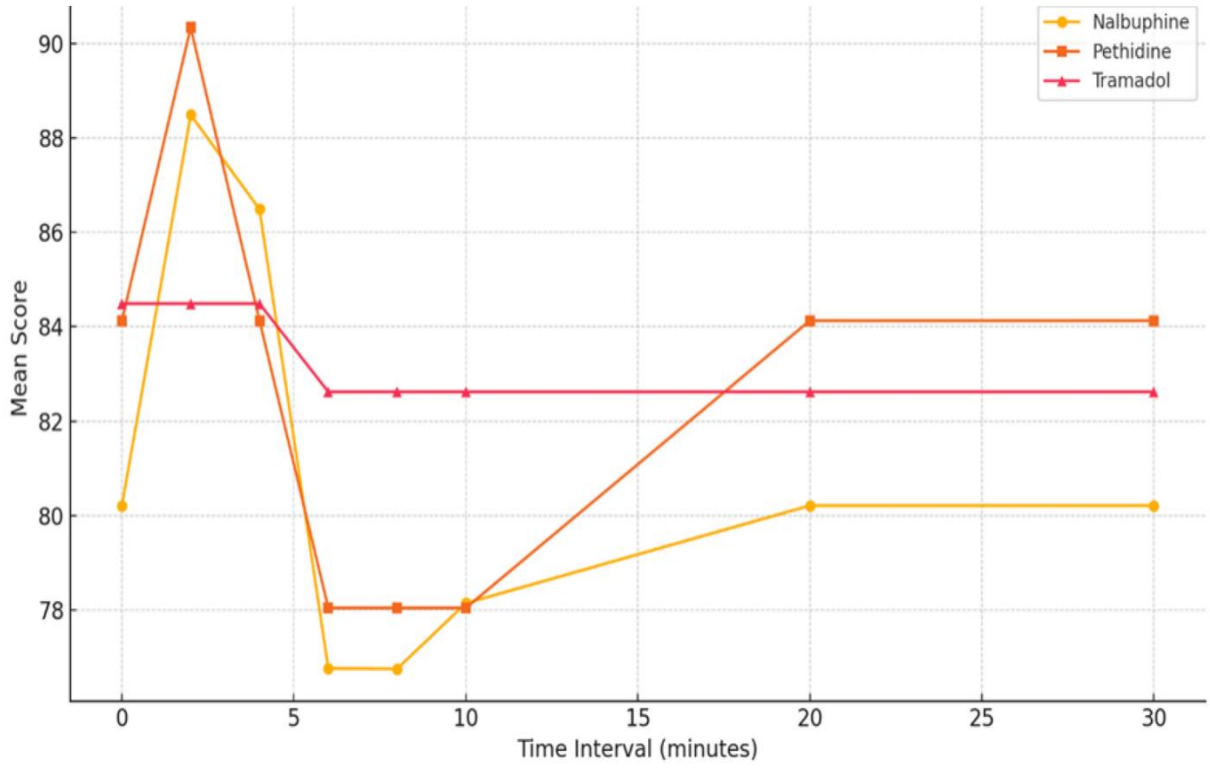


Figure 14: comparison of mean heart rate among different groups at different time interval after giving the antishivering drug.

Observation:
The mean heart rate among participants varied across the three drug groups (Nalbuphine, Pethidine, and Tramadol) at different time intervals following administration of the antishivering drug. At baseline (0 minutes), heart rates were comparable with no statistically significant difference (p=0.333). However, from 2 minutes onwards, significant variations were noted. At 2 minutes, the heart rate peaked in all groups, most notably with Nalbuphine (90.83 bpm), followed by Tramadol (87.35 bpm) and Pethidine (84.27 bpm), showing a highly significant difference (p<0.001). From 4 to 30 minutes, Tramadol consistently showed a gradual decrease in heart rate, while Pethidine tended to maintain a higher mean heart rate throughout. Nalbuphine maintained more stable heart rates across the time intervals with less fluctuation. Statistically significant differences (p<0.001 or p=0.005) were seen at almost all post-drug time intervals except the baseline, indicating that the antishivering agents influenced heart rate dynamics differently over time.

Table 15: comparison of mean MAP among different groups at different time interval after giving the antishivering drug

TIME INTERVAL	NALBUPHINE		PETHIDINE		TRAMADOL		P-Value
	Mean	SD	Mean	SD	Mean	SD	
0	80.21	4.748	84.13	6.986	84.49	5.671	0.005
2	88.49	6.033	90.34	7.625	84.49	5.671	0.001
4	86.49	7.061	84.13	6.986	84.49	.671	0.003
6	76.76	5.266	78.04	6.599	82.62	5.552	0.003
8	76.75	5.266	78.04	6.599	82.62	5.552	0.003
10	78.14	5.018	78.04	6.599	82.62	5.552	0.003
20	80.21	4.748	84.13	6.986	82.62	5.552	0.005
30	80.21	4.748	84.13	6.986	82.62	5.552	0.005

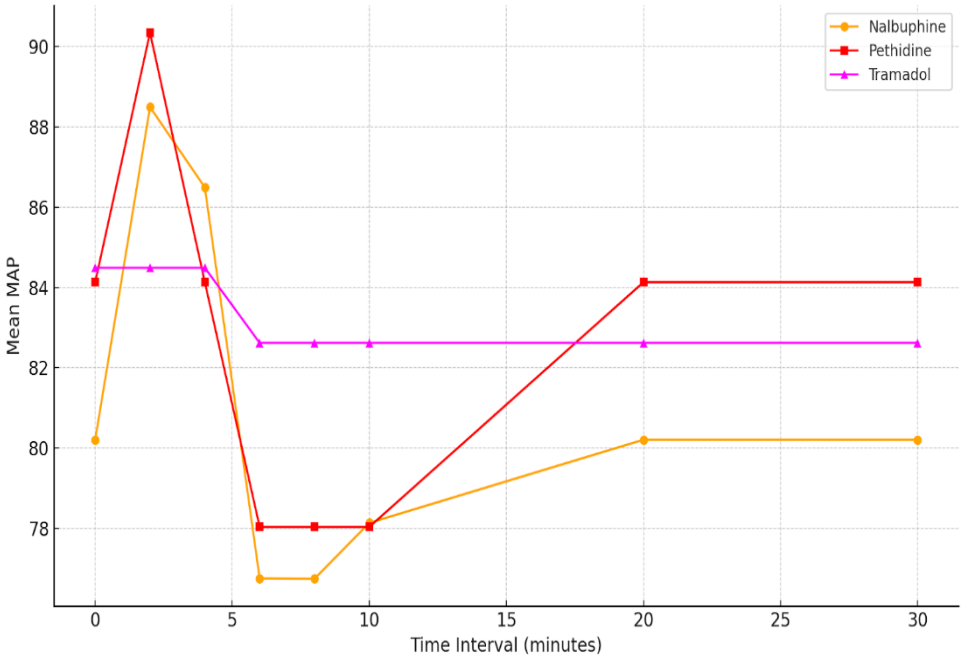


Figure 15: comparison of mean MAP among different groups at different time interval.

Observation:
The mean arterial pressure (MAP) showed notable fluctuations among the three drug groups at various time intervals after administration of the anti-shivering medication. At baseline (0 minutes), the MAP was significantly lower in the Nalbuphine group (80.21 mmHg) compared to Pethidine (84.13 mmHg) and Tramadol (84.49 mmHg), with a statistically significant difference (p=0.005). At 2 minutes, all groups exhibited a rise in MAP, with Pethidine showing the highest increase (90.34 mmHg), followed by Nalbuphine (88.49 mmHg), while Tramadol remained constant at baseline levels. From 4 minutes onward, MAP in the Tramadol group remained consistently higher than in the Nalbuphine and Pethidine groups. Interestingly, Nalbuphine and Pethidine both showed a dip in MAP at 6 and 8 minutes, while Tramadol maintained elevated values. By 10 minutes, the MAP for Nalbuphine slightly rebounded, while Pethidine plateaued and Tramadol continued at a higher level. At 20 and 30 minutes, MAP values in all groups began to stabilize, but the significant differences persisted (p=0.005), indicating persistent hemodynamic variation post-drug administration.

DISCUSSION

Subarachnoid block (SAB) is the preferred anesthetic technique for lower abdominal and lower limb surgeries due to its ease of administration and rapid onset. However, shivering is a frequent and discomforting complication of SAB, with a multifactorial origin that includes core hypothermia, vasodilation, heat redistribution, pain, and the systemic release of pyrogens. SAB disrupts normal thermoregulation primarily by inhibiting tonic vasoconstriction and affecting central thermoregulatory pathways (Sessler DI et al., 1991) [22].

While non-pharmacological measures such as warming systems and warm IV fluids are useful, their application can be limited by cost or feasibility in resource-constrained settings (Singh P et al., 2022) [21]. Pharmacological agents like Pethidine, Tramadol, and Nalbuphine remain the most practical and widely employed interventions.

This study aimed to compare the efficacy of IV Tramadol (0.5 mg/kg), Pethidine (0.5 mg/kg), and Nalbuphine (0.05 mg/kg) in managing post-spinal anesthesia shivering (PSAS) among 210 patients undergoing elective lower abdominal and lower limb surgeries.

Demographics and baseline characteristics

The patients across the three groups (T, P, N) were comparable with respect to demographic variables. The mean age was 42.5 ± 11.07 years, aligning with findings from Badle et al. (2022) [14] and Nirala et al. (2020) [6]. In contrast, younger populations were studied in Latif et al. (2020) [13], Yaakup et al. (2021) [1], and Chowdhury et al. (2019) [21], where the mean age was around 26–30 years, primarily reflecting cesarean cohorts. Our inclusion of both genders and broader surgical procedures contributes to the generalizability of findings.

ASA status and BMI were also evenly distributed across groups, with the majority being ASA I (52.2%) and mean BMI ranging from 23.1 to 24.2 kg/m². This was lower than values reported in Yaakup et al. [1], but consistent with Nirala et al. [6].

Duration of surgery and SAB

The mean duration of SAB was 145 mins ± 22, 145 mins± 21.8 & 144 mins ± 21.8 respectively in Group T, Group P & Group N. Mean duration of surgery was 99.4± 11.71, 99.3± 11.71, 99.3± 11.71 respectively in Group T, Group P & Group N. The duration was comparable in the groups. The mean duration of anaesthesia was much lower in studies by Siddique et al [18] (tramadol=122.96± 29.2 mins., Musaf AA et al [71] (Tramadol=48.2 ± 8.02, pethidine= 47.8± 7.39), Chowdhary et al [21]] (Nalbuphine = 58.2 ± 0.81, Pethidine=57±0.82).

Shivering in patients

Severity of shivering

In the present study, the Tsai and Chu grading system was used to assess the severity of post-subarachnoid block (PSAB) shivering. Among all participants, 59.9% of patients had grade 2 shivering, while 40.1% exhibited grade 3 shivering, indicating moderate to severe intensity.When stratified by treatment group:Grade 2 shivering was observed in 65.2% of patients in Group T (Tramadol), 55.1% in Group P (Pethidine), and 60.8% in Group N (Nalbuphine).Grade 3 shivering was seen in 34.8% in Group T, 44.9% in Group P, and 39.2% in Group N.These intergroup differences in severity grading were not statistically significant ($p > 0.05$), suggesting that the initial intensity of shivering before intervention was comparable across all three treatment groups. Similar findings were reported by Latif et al. [12], who observed comparable severity grading between nalbuphine and tramadol in their study using a modified

Tsai and Chu scale. Likewise, Destaw et al. [16] reported that the majority of patients presented with grade 2 and grade 3 shivering prior to intervention, without significant differences across study arms. Montal et al. [19] also supported the observation of comparable severity in their comparative study on anti-shivering agents. Conversely, Tudimilla S. et al. [17], using the Wrench's shivering scale, found a statistically significant difference in severity reduction between tramadol and nalbuphine, favoring nalbuphine for quicker reduction of higher-grade shivering.Interestingly, Badle et al. [14] reported no incidence of shivering when tramadol was administered intrathecally, suggesting its potential as a preventive agent when administered via spinal route, though this finding diverges from the intravenous approach used in the current study.Overall, while the severity of shivering at presentation was predominantly moderate (grade 2), all three drugs were administered after comparable baseline severity, ensuring that the differences observed in treatment efficacy and outcomes were not influenced by initial severity levels.

Onset of Shivering

In the present study, the mean duration of onset of shivering was 41.3 ± 7.6 minutes after administration of subarachnoid block across all three groups (Tramadol, Pethidine, and Nalbuphine). This observation is comparable to findings in previous literature. For instance, Nirala et al. [5] reported the onset of shivering at 39.4 ± 5.3 minutes for tramadol and 40.1 ± 4.9 minutes for nalbuphine. Similarly, Musaf AA et al. [20] observed the onset of shivering at 42.5 ± 6.7 minutes in their tramadol and pethidine groups. Destaw et al. [16] also documented shivering onset occurring approximately 40.2 ± 6.1 minutes post spinal anesthesia. These values are consistent with our study and reflect the expected timeframe for thermoregulatory changes after subarachnoid block, further supporting the reliability of our findings.

Onset of disappearance of shivering

This study observed a significant difference in the onset of disappearance of shivering following intravenous administration of the study drugs. The mean time to onset of shivering relief was shortest in the pethidine group (3.9 ± 0.36 minutes), followed by tramadol (5.01 ± 0.40 minutes) and nalbuphine (5.4 ± 0.41 minutes). The difference among the three groups was statistically significant ($p < 0.05$), indicating that pethidine produced the fastest anti-shivering response, followed by tramadol and nalbuphine. These findings are consistent with previous studies.

Wahdan et al. [1] reported a mean onset time of 2.8 ± 0.6 minutes for intravenous pethidine, significantly faster than other agents tested.Similarly, Shukla et al. [2] found that pethidine achieved shivering control within 3.2 ± 1.1 minutes, reinforcing its rapid action through μ- and κ-opioid receptor agonism.Nirala et al. [3] observed that nalbuphine had an onset time of 3.84 ± 1.2 minutes, which was faster than tramadol (4.84 ± 1.2 minutes) in their comparison, mirroring our result trends though with slightly shorter intervals.In contrast,

Madem et al. [4] found no significant difference in onset times between tramadol and nalbuphine, suggesting comparable efficacy when administered in equal doses.Further, Sun et al. [23] compared nalbuphine and dexmedetomidine, reporting an onset of 3.5 ± 2.7 minutes for nalbuphine and 4.7 ± 3 minutes for dexmedetomidine, also confirming nalbuphine's rapid efficacy.The variability in findings across studies may be attributed to differences in patient population, surgical type, ambient temperature, or dosing regimens. Nonetheless, the overall evidence supports the superior onset speed of pethidine for anti-shivering, with tramadol and nalbuphine also showing reliable, though slower, onset profiles.

Recurrence of shivering

Recurrence of shivering was highest in the pethidine group (34.3.%), followed by nalbuphine (21.1%) and tramadol (20.3%). Although this difference was not statistically significant, it suggests that pethidine may be associated with a higher tendency for recurrence compared to the other two agents. Similar trends have been reported in previous studies. Yaakup et al. [1] observed a higher recurrence rate with pethidine (14.3%) compared to tramadol (4.8%), indicating a more sustained anti-shivering effect with tramadol.

Mushtaq et al. [2] also found recurrence to be more frequent in the pethidine group (11.6%) than in the tramadol group (3.3%), supporting the current study's findings. Bhar et al. [3] noted that higher doses of nalbuphine significantly reduced shivering recurrence, indicating a possible.

Side effects of drugs

In this study, a significant difference in the incidence of side effects was observed among the three drug groups—nalbuphine, pethidine, and tramadol ($p < 0.001$). Each drug exhibited a distinct side-effect profile, which has important implications for clinical practice.

Sedation was most prominent in the nalbuphine group (67.6%), followed by pethidine (55.7%), with no sedation reported in the tramadol group. These findings align with those of Sharma et al. [15], who found

significantly higher sedation scores in patients receiving pethidine compared to tramadol. Similarly, Siddique et al. [18] and Musaf AA et al. [20] also observed enhanced sedative effects with nalbuphine due to its κ-opioid receptor agonism. The high sedation profile of nalbuphine may be useful intraoperatively but requires careful monitoring postoperatively.

Nausea and Vomiting: Tramadol was associated with the highest incidence of both nausea (39.1%) and vomiting (39.1%), followed by pethidine with vomiting (18.6%) and nausea (2.9%), and nalbuphine, which showed modest nausea (19.7%) and minimal vomiting (4.2%).These results are consistent with the findings of Yaakup et al. [1], who reported a significantly higher rate of nausea/vomiting in the pethidine group (48%) compared to tramadol (23.8%). Sajedi et al. [10] further reported that higher doses of tramadol were associated with a greater risk of nausea and vomiting, while lower doses reduced this incidence but increased recurrence. Musaf AA et al. [20] and Sharma et al. [15] also observed a higher incidence of nausea and vomiting in tramadol users. Interestingly, nalbuphine showed a lower emetogenic profile, making it potentially more favorable for patients prone to gastrointestinal side effects.

Respiratory Distress was reported only in the pethidine group (14.3%), consistent with its known μ-opioid agonist activity, which can cause dose-dependent respiratory depression. None of the patients in the nalbuphine or tramadol groups experienced respiratory distress. This mirrors findings by Montal et al. [9], who emphasized the respiratory safety of nalbuphine due to its ceiling effect on respiratory depression, a known benefit over pure μ-agonists like pethidine.

Dizziness was observed only in the tramadol group (5.8%), which may be attributed to its action on serotonin and norepinephrine reuptake inhibition, causing mild central nervous system side effects. Yaakup et al. [1] also noted dizziness in 9.5% of tramadol users, while none was reported with pethidine.

Hypotension Both nalbuphine (8.5%) and pethidine (8.6%) showed a modest incidence of hypotension, with no cases in the tramadol group. While hypotension may result from spinal anesthesia, its exacerbation by opioids—particularly via histamine release with pethidine—has been documented. This trend aligns with findings from Tudimilla et al. [17], who also reported mild hemodynamic changes with both pethidine and nalbuphine but not tramadol.

No Side Effects Notably, 15.9% of patients in the tramadol group experienced no side effects, suggesting a better overall tolerance despite its emetogenic nature. No patients in the nalbuphine or pethidine groups were free of side effects.

LIMITATIONS

This study has several limitations. Being a single-center study, the findings may not be generalizable across all clinical settings or diverse patient populations. Although efforts were made to standardize external variables, slight differences in ambient temperature and warming measures might have influenced thermoregulation and the severity of shivering. The grading of shivering, while based on the standardized Tsai and Chu scale, remains partially subjective and susceptible to observer interpretation. Additionally, the study focused solely on immediate postoperative outcomes, without assessing long-term effects or delayed side effects. The use of a fixed single-dose regimen for each drug may not accurately reflect optimal titration or individualized dosing as practiced in real-world clinical scenarios.

CONCLUSION

This study demonstrates that all three drugs—Tramadol, Pethidine, and Nalbuphine—are effective in treating post-spinal anesthesia shivering (PSAS), with varying profiles in terms of onset, efficacy, recurrence, and adverse effects. Pethidine had the fastest onset of anti-shivering effect, making it a potent first-line option for rapid control. However, its higher recurrence rate and increased incidence of respiratory depression make it less favourable in patients with compromised respiratory reserve. Tramadol showed a favourable recurrence profile and lack of sedation or hypotension, but was associated with a significantly higher incidence of nausea and vomiting, limiting its tolerability in certain patients. Nalbuphine was comparable in efficacy to tramadol and pethidine, with the lowest rates of nausea/vomiting and no respiratory depression, but its high sedation rate necessitates caution in postoperative monitoring. Ultimately, drug selection should be individualized based on patient characteristics, surgical setting, and risk factors for side effects. Nalbuphine may be ideal in patients requiring sedation and lower GI side effects; tramadol in those where respiratory safety and hemodynamic stability are priorities; and pethidine in settings requiring the fastest response despite its side effect burden.

Conflict of interest: The authors declare no conflict of interest whatsoever.

Ethical statement: Before starting the study, ethical clearance was taken from the institutional ethical committee.

Consent for publication: Informed consent was taken from the patient and patient's relatives to enroll in the study.

Funding: No financial support or funding was provided for the conduct of this study.

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