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Comparative Efficacy of Nalbuphine Hydrochloride vs. Tramadol Hydrochloride for Post-Operative Analgesia in Orthopaedic Surgeries: A Double-Blind Randomized Control Study

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ABSTRACT

Background: Effective postoperative analgesia is crucial for early mobilization and recovery in orthopaedic surgeries. This study compares the efficacy and safety of Nalbuphine Hydrochloride and Tramadol Hydrochloride for postoperative pain management in patients undergoing orthopaedic procedures.

Methods: A double-blind, randomized controlled trial was conducted involving 100 patients who underwent various orthopaedic surgeries. Patients were randomly assigned to receive either Nalbuphine Hydrochloride or Tramadol Hydrochloride postoperatively. The primary outcomes measured were pain intensity using the Visual Analogue Scale (VAS) at specific time intervals and adverse effects. Secondary outcomes included hemodynamic stability and the need for additional analgesic doses.

Results: Patients receiving Nalbuphine reported significantly lower VAS scores at 30 minutes (1.80 ± 0.50) and 540 minutes (2.00 ± 0.29) post-operation compared to those receiving Tramadol (2.21 ± 0.41 and 2.38 ± 0.58, respectively; $p<0.01$). Nalbuphine also demonstrated fewer adverse effects such as nausea and vomiting. Hemodynamic parameters were stable and comparable between the two groups.

Conclusion: Nalbuphine Hydrochloride provides superior analgesia with fewer adverse effects compared to Tramadol Hydrochloride in the postoperative management of orthopaedic patients, making it a potentially preferable option for pain control in this population.

Keywords: *Nalbuphine, Tramadol, Orthopaedic Surgery, Postoperative Pain, Analgesia, Randomized Control Trial.*

1. INTRODUCTION

Effective postoperative pain management is crucial in orthopaedic surgeries to facilitate early mobilization and enhance recovery, reducing the risk of complications such as thromboembolism and persistent post-surgical pain. Two commonly used analgesics in the postoperative setting are Nalbuphine Hydrochloride and Tramadol Hydrochloride. Both drugs offer distinct mechanisms of action and pharmacokinetic profiles, warranting a comparative analysis to guide clinical practice.[1,2]

Nalbuphine, a synthetic opioid, acts as a kappa receptor agonist and a mu receptor antagonist. This dual action provides effective analgesia without the typical mu agonist side effects, such as significant respiratory depression and gastrointestinal disturbance, making it a potentially safer option in sensitive patient populations. Several studies have highlighted Nalbuphine's efficacy in various surgical settings, showing its ability to provide adequate pain relief while maintaining a favorable safety profile.[3]

On the other hand, Tramadol Hydrochloride is a centrally acting analgesic with a unique action, combining mu-opioid receptor agonism with inhibition of serotonin and norepinephrine reuptake. This multimodal mechanism not only provides

analgesia but can also enhance mood, which may be beneficial in the postoperative period. However, the use of Tramadol is often limited by its side effects, which can include nausea, dizziness, and, notably, the risk of seizures at higher doses.[4]

The comparative study of Nalbuphine and Tramadol in orthopaedic surgeries is driven by the need to optimize postoperative pain management protocols. Effective analgesia is paramount in orthopaedic patients to allow early ambulation and discharge, critical components of modern fast-track surgery protocols. Moreover, understanding the differential impact of these analgesics on opioid-related adverse effects, patient satisfaction, and overall recovery quality is essential.[5]

The prevalence of chronic pain after orthopaedic surgeries remains a significant challenge, with inadequate acute pain management being a key contributing factor. By comparing Nalbuphine and Tramadol, this study aims to elucidate which analgesic provides more effective pain control with fewer complications in the immediate postoperative period. This could significantly influence clinical decision-making, leaning towards more personalized and effective pain management strategies.

2. MATERIALS AND METHODS

Study Design: This double-blind randomized control study compared intravenous nalbuphine hydrochloride with tramadol hydrochloride for postoperative analgesia following lower limb orthopedic surgeries. The research was conducted at Shadan Hospital, Shadan Institute of Medical Sciences, Hyderabad, from October 2017 to August 2019. Ethical committee approval and written informed consent from all participants were secured prior to the study commencement.

Participants: A total of 100 patients, aged 20-60 years, of any sex, and classified as American Society of Anesthesiologists (ASA) grade I-II, were enrolled. These patients were scheduled for elective lower limb orthopedic procedures under spinal anesthesia. They were randomly allocated into two groups (n=50 each): Group A received nalbuphine hydrochloride, and Group B received tramadol hydrochloride.

Inclusion Criteria:

- Age between 20-60 years.
- Both sexes.
- ASA grade I-II.
- Scheduled for elective lower limb orthopedic surgery under spinal anesthesia.

Exclusion Criteria:

- ASA grade III or higher.
- History of drug tolerance, dependence, or allergy to the study drugs.
- Current use of oral anticoagulants, neuroleptic agents, or monoamine oxidase inhibitors.
- Medical history of epilepsy, increased intracranial tension, motion sickness, or opioid use in the last month.
- Diminished mental competence, sensory impairments, pregnancy, lactation, or substance abuse.

Anesthetic Procedure: Preoperative evaluations, including routine investigations and a pre-anesthetic check-up, were performed. Patients received 0.25 mg of oral Alprazolam the night before surgery. Spinal anesthesia was administered using 3.5 cc of 0.5% bupivacaine heavy. Post-surgery, patients were monitored in the post-anesthesia care unit where the study drugs were administered at the first complaint of pain.

Drug Administration:

- Group A (Nalbuphine): 0.1 mg/kg IV in 10 ml normal saline.
- Group B (Tramadol): 1 mg/kg IV in 10 ml normal saline.
- Drugs were administered every 6 hours, with half the dosage repeated for breakthrough pain.

Pain Assessment: Pain intensity was measured using a numeric visual analogue scale (VAS) and a verbal category scale (VCS) at predetermined intervals (immediately after drug administration, at 30 min, 3 hrs, and 6 hrs post-dose).

Sedation and Adverse Effects Monitoring: Sedation was assessed using the Wilson sedation score. Adverse effects and the need for rescue analgesia were carefully recorded. Vital parameters (blood pressure, heart rate, respiratory rate, and SpO2) were monitored hourly for the first 24 hours postoperatively.

Statistical Analysis: Data were analyzed using SPSS version 17.0. Continuous variables such as age, weight, and VAS scores were compared using Student's t-test, while categorical data such as sex distribution, VCS scores, and sedation scores were analyzed using the Pearson chi-square test. A p-value of less than 0.05 was considered statistically significant.

3. RESULTS

The comparative analysis of the postoperative analgesic efficacy and safety profiles of Tramadol and Nalbuphine in orthopaedic surgeries yielded the following results:

Demographic and Baseline Characteristics (Table 1): The study involved 100 patients, equally divided into two groups. The mean age of patients was 39.26 ± 14.04 years in the Tramadol group and 43.36 ± 13.68 years in the Nalbuphine group, with no statistically significant difference (t=1.47, p=0.14). Weight was comparable between the groups (Tramadol: 55.44 ± 11.36 kg, Nalbuphine: 55.22 ± 8.51 kg; t=-0.109, p=0.90). Gender distribution also showed no significant difference (Male/Female - Tramadol: 27/23, Nalbuphine: 21/29; t=1.44, p=0.11).

Analgesic Efficacy and Onset of Action (Table 2): The Nalbuphine group demonstrated significantly lower mean Visual Analogue Scale (VAS) scores at 30 minutes (1.80 ± 0.50) compared to the Tramadol group (2.21 ± 0.41; t=3.10, p=0.003). This trend continued at 540 minutes post-operation, with the Nalbuphine group showing better pain control (2.00 ± 0.29) versus the Tramadol group (2.38 ± 0.58; t=2.90, p=0.006).

Hemodynamic Stability Post-Operation (Table 3): There was no significant difference in systolic blood pressure (SBP) between the two groups at 1 hour (Tramadol: 116.8 ± 4.83 mmHg, Nalbuphine: 120.1 ± 7.50 mmHg; t=1.85, p=0.070) and at 24 hours (Tramadol: 116.2 ± 4.67 mmHg, Nalbuphine: 119.5 ± 7.16 mmHg; t=1.90, p=0.065).

Adverse Effects and Additional Dosage Requirement (Table 4): Nalbuphine showed a lower incidence of nausea (4 patients) and vomiting (2 patients) compared to Tramadol (16 and 8 patients, respectively). The requirement for additional analgesic dosages was similar between the two groups (Tramadol: 21 patients, Nalbuphine: 20 patients).

TABLE 1: PATIENT DEMOGRAPHICS AND BASELINE CHARACTERISTICS

Parameter	Tramadol Group (n=50)	Nalbuphine Group (n=50)	t-Value	P-Value
Age (years)	39.26 ± 14.04	43.36 ± 13.68	1.47	0.14
Weight (kg)	55.44 ± 11.36	55.22 ± 8.51	-0.109	0.90
Sex (Male/Female)	27/23	21/29	1.44	0.11

TABLE 2: ANALGESIC EFFICACY AND ONSET OF ACTION

Time (minutes)	Mean VAS Score - Tramadol	Mean VAS Score - Nalbuphine	t-Value	P-Value
30	2.21 ± 0.41	1.80 ± 0.50	3.10	0.003
540	2.38 ± 0.58	2.00 ± 0.29	2.90	0.006

TABLE 3: HEMODYNAMIC STABILITY POST-OPERATION

Time (hours)	SBP - Tramadol (mmHg)	SBP - Nalbuphine (mmHg)	t-Value	P-Value
1	116.8 ± 4.83	120.1 ± 7.50	1.85	0.070
24	116.2 ± 4.67	119.5 ± 7.16	1.90	0.065

TABLE 4: ADVERSE EFFECTS AND ADDITIONAL DOSAGE REQUIREMENT

Adverse Effect	Tramadol Group (n=50)	Nalbuphine Group (n=50)
Nausea	16 patients	4 patients
Vomiting	8 patients	2 patients
Additional Dosage	21 patients	20 patients

4. DISCUSSION

The results of this study align with the growing body of evidence supporting the use of Nalbuphine as an effective and safe analgesic in the postoperative setting, particularly in orthopaedic surgeries. The significantly lower VAS scores observed in the Nalbuphine group at both 30 and 540 minutes post-operation underline its superior analgesic properties when compared to Tramadol. These findings are crucial, as effective pain management is known to correlate with reduced postoperative

complications and faster recovery times.[6,7]

Nalbuphine's advantage in reducing pain scores may be attributed to its unique pharmacologic profile, acting as a kappa opioid receptor agonist and a partial mu opioid receptor antagonist. This mechanism provides effective analgesia without the ceiling effect on respiratory depression seen with pure mu agonists, which is particularly advantageous in a clinical setting where respiratory function may be compromised postoperatively.[8]

The lower incidence of nausea and vomiting in patients treated with Nalbuphine is consistent with its reported side effect profile and supports its use, especially in patients who are particularly prone to these complications. Such side effects are not only distressing for patients but can also delay recovery and discharge, increase the need for additional medications, and thereby, potentially, the cost of care.[9,10]

Despite these advantages, the hemodynamic parameters measured in this study showed no significant differences between the two drugs, indicating that both maintain a profile of cardiovascular stability postoperatively. This is an important consideration, particularly in orthopaedic patients who may be at risk for cardiovascular complications.[11]

The requirement for additional analgesic dosages being nearly equivalent between the two groups suggests that while Nalbuphine provides superior initial pain relief, the overall analgesic requirement during the later postoperative period evens out. This could indicate the need for a tailored analgesic plan post-surgery to maintain optimal pain control throughout the recovery phase.

Comparatively, Tramadol's multimodal mechanism of action, while effective in some patients, may present a risk of seizures and other central nervous system side effects, which limits its use in certain populations. The findings of this study advocate for a more selective approach to analgesic choice, considering both the efficacy and side effect profiles.[12]

Future research should aim to expand on these findings by including a larger cohort and different types of orthopaedic surgeries to generalize the results. Additionally, longer follow-up periods could elucidate the effects of Nalbuphine and Tramadol on long-term recovery and functional outcomes, which are crucial for patient quality of life post-surgery.

Overall, this study provides significant evidence that Nalbuphine is a superior analgesic compared to Tramadol in the context of orthopaedic surgeries, offering better pain control with fewer adverse effects. This supports its inclusion as a key component of postoperative analgesia protocols in orthopaedic settings, potentially improving patient outcomes and satisfaction.

5. CONCLUSION

The findings from this double-blind randomized control study demonstrate that Nalbuphine Hydrochloride offers superior postoperative analgesia with fewer adverse effects compared to Tramadol Hydrochloride in patients undergoing orthopaedic surgeries. Nalbuphine's effectiveness in significantly lowering pain scores at critical postoperative intervals and its favorable side effect profile, particularly in reducing nausea and vomiting, suggests its potential as a more suitable analgesic for managing post-surgical pain in orthopaedic patients. These results encourage the adoption of Nalbuphine in clinical pain management protocols to enhance patient comfort, safety, and overall recovery outcomes, making it a valuable addition to postoperative care strategies in orthopaedic settings.

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