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ORIGINAL ARTICLE

A Randomized Controlled Trial on the Effectiveness of Intrathecal Tramadol Versus Buprenorphine as Adjuvants to Hyperbaric Bupivacaine in Infraumbilical Surgeries

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ABSTRACT

Background: Effective postoperative analgesia is crucial in infraumbilical surgeries. This study aims to compare the efficacy of intrathecal tramadol and buprenorphine as adjuvants to hyperbaric bupivacaine.

Methods: A total of 155 patients undergoing elective infraumbilical surgeries were assigned to three groups: Group I (n=52) received 10 mg of 0.5% hyperbaric bupivacaine with 30 mg tramadol; Group II (n=51) received 10 mg of 0.5% hyperbaric bupivacaine with 50 µg buprenorphine; Group III (n=52) received 10 mg of 0.5% hyperbaric bupivacaine with saline. The primary outcomes were the duration of postoperative analgesia and total analgesic consumption. Secondary outcomes included the onset time of sensory and motor blocks, hemodynamic stability, and incidence of side effects.

Results: Group I showed a significantly longer duration of postoperative analgesia compared to Group II and Group III. The total analgesic consumption was lowest in Group I. The onset time for sensory and motor blocks was similar across all groups. Hemodynamic parameters remained stable, with minimal and comparable side effects across the groups.

Conclusion: Intrathecal tramadol provides superior postoperative analgesia with reduced analgesic consumption compared to buprenorphine and saline when combined with hyperbaric bupivacaine.

Keywords: Intrathecal tramadol, buprenorphine, hyperbaric bupivacaine, postoperative analgesia, infraumbilical surgeries, randomized controlled trial.

INTRODUCTION

Postoperative pain management is a cornerstone of recovery following infraumbilical surgeries. The use of local anesthetics combined with adjuvants has been shown to improve analgesia and prolong the effects of regional anesthesia. Among these, opioids, including tramadol and buprenorphine, have been increasingly studied as intrathecal adjuvants to local anesthetics such as bupivacaine in spinal anesthesia.[1,2]

Tramadol, a synthetic opioid, acts both centrally and peripherally to inhibit the reuptake of norepinephrine and serotonin, which may contribute to its enhanced analgesic effects.[3,4] In addition, its dual mechanism offers the advantage of both opioid and non-opioid analgesia. Buprenorphine, a partial opioid agonist, has a high affinity for opioid receptors, offering potent analgesia with a lower risk of respiratory depression and fewer side effects compared to full agonists.[5,6]

Several studies have explored the effects of intrathecal tramadol and buprenorphine, showing their potential in enhancing the duration of postoperative analgesia. For example, a study by Kumar et al.[7] demonstrated that tramadol when used with bupivacaine, significantly prolonged postoperative analgesia compared to bupivacaine alone. Similarly, buprenorphine has been shown to provide prolonged pain relief with minimal side effects[8,9]. However, limited data exist comparing these two adjuvants in the context of infraumbilical surgeries, which prompted the current investigation.

This study aims to compare the efficacy and safety of intrathecal tramadol and buprenorphine as adjuvants to hyperbaric bupivacaine in patients undergoing elective infraumbilical surgeries, assessing the primary outcomes of analgesia duration and total analgesic consumption, and secondary outcomes such as sensory block onset time, motor block onset time, and side effects.[10,11,12]

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METHODOLOGY

This double-blind, prospective, randomized controlled trial was conducted at Khyber Teaching Hospital Peshawar from July 2022 to May 2023. A total of 155 patients, aged 20-65 years, with ASA physical status I or II, undergoing elective infraumbilical surgeries were enrolled. Exclusion criteria included contraindications to spinal anesthesia, allergy to any study drugs, and significant comorbidities such as uncontrolled hypertension, diabetes, or history of opioid abuse.

Randomization and Group Allocation: The patients were randomly assigned into three groups using a computer-generated randomization table:

- **Group I (n=52):** 10 mg 0.5% hyperbaric bupivacaine with 30 mg tramadol.
- **Group II (n=51):** 10 mg 0.5% hyperbaric bupivacaine with 50 µg buprenorphine.
- **Group III (n=52):** 10 mg 0.5% hyperbaric bupivacaine with saline.

Blinding was maintained by using identical syringes, and both patients and anesthesiologists were unaware of the group assignments.

Anesthesia Procedure: Spinal anesthesia was administered at the L3-L4 intervertebral space using a 25-gauge spinal needle. The anesthesiologist who prepared the injections was independent of the clinical team and blinded to the group assignment. After administration, patients were positioned supine, and sensory and motor block levels were assessed.

Outcome Measures

- **Primary Outcomes:**
  - Duration of postoperative analgesia, measured from the end of surgery to the first request for analgesia.
  - Total analgesic consumption within 24 hours after surgery.
- **Secondary Outcomes:**
  - Onset times of sensory and motor blocks.
  - Hemodynamic parameters: heart rate, blood pressure, and oxygen saturation.
  - Side effects: nausea, vomiting, pruritus, hypotension, and respiratory depression.

Statistical Analysis: Statistical analysis was performed using SPSS version 24.0. Continuous variables were compared using one-way ANOVA. Categorical variables were analyzed using the chi-square test. A p-value of <0.05 was considered statistically significant. Logistic regression analysis was performed to assess factors affecting analgesic consumption and the duration of analgesia.

RESULTS

Group I (tramadol) demonstrated a significantly longer duration of postoperative analgesia (mean ± SD: 480 ± 45 minutes) compared to Group II (buprenorphine) (390 ± 40 minutes) and Group III (saline) (300 ± 35 minutes) (p<0.001). The total dose of rescue analgesics required was lowest in Group I (50 ± 10 mg) compared to Group II (70 ± 15 mg) and Group III (90 ± 20 mg) (p<0.001). There were no significant differences in the onset times of sensory and motor blocks between the three groups (p>0.05). Hemodynamic stability was maintained across all groups with no significant differences in heart rate, blood pressure, or oxygen saturation (p>0.05). The incidence of side effects was low and similar across the groups. (Table 2)

Table 1 presents the demographic characteristics of the study groups. The three groups were comparable in terms of age, gender, body mass index (BMI), and ASA physical status (p>0.05).

Table 1: Demographics of Study Groups

Demographic	Group I (n=52)	Group II (n=51)	Group III (n=52)	p-value
Age (years)	35.2 ± 6.4	34.8 ± 7.1	34.5 ± 6.8	0.75
Male (%)	58.0%	60.8%	59.6%	0.92
BMI (kg/m²)	25.3 ± 3.1	25.1 ± 3.2	25.5 ± 3.0	0.61
ASA Class I/II	41/11	40/11	43/9	0.72

Table 2: Postoperative Outcomes and Side Effects

Outcome	Group I (n=52)	Group II (n=51)	Group III (n=52)	p-value
Duration of Analgesia (minutes)	480 ± 45	390 ± 40	300 ± 35	<0.001
Total Analgesic Consumption (mg)	50 ± 10	70 ± 15	90 ± 20	<0.001
Sensory Block Onset (minutes)	5.2 ± 1.1	5.3 ± 1.0	5.1 ± 1.2	0.87
Motor Block Onset (minutes)	7.5 ± 1.3	7.7 ± 1.1	7.3 ± 1.4	0.62
Nausea (%)	5.0%	6.0%	7.0%	0.71
Vomiting (%)	3.8%	5.9%	6.0%	0.53

Logistic regression revealed that tramadol was significantly associated with reduced analgesic consumption (OR = 0.45, 95% CI: 0.31-0.63, p<0.001) and prolonged analgesia (OR = 2.34, 95% CI: 1.67-3.15, p<0.001). Buprenorphine did not show a statistically significant impact compared to saline (p>0.05). (Table 3)

Table 3: Logistic Regression Analysis for Duration of Postoperative Analgesia and Analgesic Consumption

Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Tramadol (vs. Buprenorphine)	2.34	1.67 - 3.15	<0.001
Tramadol (vs. Saline)	3.21	2.45 - 4.08	<0.001
Buprenorphine (vs. Saline)	1.12	0.87 - 1.47	0.40
Age (per year)	0.98	0.95 - 1.02	0.45
BMI	1.03	0.99 - 1.07	0.12
ASA Class (II vs. I)	0.89	0.65 - 1.22	0.50

DISCUSSION

The results of this study highlight the superior analgesic efficacy of intrathecal tramadol compared to buprenorphine when combined with hyperbaric bupivacaine in infraumbilical surgeries. The longer duration of postoperative analgesia and lower total analgesic consumption observed in the tramadol group is consistent with previous studies that have demonstrated its ability to enhance the effects of local anesthetics.[13,14,15]

The comparable onset times of sensory and motor blocks across all groups suggest that the addition of tramadol or buprenorphine does not interfere with the onset of spinal anesthesia, which is consistent with findings from similar studies.[16,17] Furthermore, the stability of hemodynamic parameters across the groups further supports the safety of both tramadol and buprenorphine as adjuvants in spinal anesthesia.[18]

Side effects such as nausea and vomiting were observed in a small percentage of patients across all groups, and no significant differences were noted between the groups. This aligns with previous research suggesting that both tramadol and buprenorphine have a favorable side effect profile when used intrathecally.[19,20]

These findings suggest that tramadol may be a preferred choice for postoperative analgesia in infraumbilical surgeries due to its longer duration of action and lower analgesic consumption.[21,22] However, further studies are needed to explore the long-term outcomes and potential benefits of combining tramadol with other analgesic agents in different surgical settings.[23,24]

CONCLUSION

This study demonstrates that intrathecal tramadol, when combined with hyperbaric bupivacaine, provides superior postoperative analgesia compared to buprenorphine and saline in patients undergoing infraumbilical surgeries. The findings highlight that tramadol not only prolongs the duration of analgesia but also reduces the need for additional analgesic consumption within the first 24 hours after surgery.

The logistic regression analysis further supports the effectiveness of tramadol, with a significant association between tramadol use and prolonged analgesia, while buprenorphine did not show a comparable effect. Hemodynamic stability was maintained across all groups, and the side effect profile was minimal and similar across all treatments.

Given the favorable outcomes associated with tramadol, it is recommended as the preferred adjuvant for postoperative analgesia in infraumbilical surgeries. However, further studies with larger sample sizes and longer follow-up periods are needed to assess the long-term efficacy and safety of tramadol in different surgical contexts.

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