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Efficacy and Safety of Tramadol Versus Buprenorphine as Post-operative Analgesia: A Comparative Study

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Abstract:
Background*: Pain was not just a sensory phenomenon, but a combination of cognitive, sensory, and affective factors, as per Breecher.Tramadol is a weak opioid agonist which acts by interacting with opioid receptors named mu, alpha and delta. Buprenorphine is a semisynthetic opioid with both agonist and antagonist properties. It is highly lipid soluble and had a greater affinity for opioid receptors. In view of less literature on the comparison of tramadol with buprenorphine as postoperative analgesics, the current study was undertaken.*
Objective: *To compare the efficacy and safety of tramadol with buprenorphine in patients scheduled for lower abdominal surgeries.*
Materials and Methods*: This study was done at a tertiary care teaching hospital in the Department of Anaesthesiology at NRI Institute of Medical Sciences, Chinakakani, Andhra Pradesh., India from July 2022 to December 2022. 100 patients scheduled for lower abdominal surgeries under spinal anaesthesia were included.They were divided into groups B and T. Each group contained 50 patients.Age, gender, ASA grade, postoperative pain by visual analogue scale (VAS), number of doses of rescue analgesia needed, and side effects were assessed and compared between two groups.*
Results*: There is no significant difference in the mean age, gender, ASA grade between the two groups. There a was significant difference in the mean VAS score. It was significantly less in Buprenorphine group patients at 12 and 24 hours after surgery. Rescue analgesia requirement was significantly less for buprenorphine group. Adverse effects were more for tramadol.*
Conclusion:*We recommend using Injection Buprenorphine as postoperative analgesia compared to Injection Tramadol for postoperative pain relief after lower abdominal surgeries.*
The study is self-sponsored. There were no conflicts of interest.
Key Words: *Tramadol,Buprenorphine, Efficacy, Safety, Postoperativeanalgesia*

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I. Introduction

Though postoperative pain is self-limiting and decreases with time, its relief is justified on humanitarian grounds, which helps to improve physiological function after surgery. Breecher reported that pain was not just a sensory phenomenon, but a combination of cognitive, sensory, and affective factors.[1] Patient's pain was perceived to be more severe in the hospital due to anxiety and fear ofsurgery or illness[2]. Postoperative pain is an unpleasant sensory, emotional and mental experience, that is precipitated by surgical trauma and is linked with various autonomic, endocrine–metabolic, physiological and behavioral responses[3]. Commonly, non-steroidal anti-inflammatory drugs (NSAIDs) were given to provide an effective postoperative analgesia but these drugs have many drawbacks[4]. Tramadol is a weak opioid agonist which acts by interacting with opioid receptors named mu, alpha and delta[5]. It produces less sedation and respiratory depression compared to other opioids, but the quality of analgesia is excellent. Buprenorphine is a semisynthetic opioidwith both agonist and antagonist properties. It is highly lipid soluble and had greater affinity for opioid receptors. Hence the incidence of adverse effects and addiction were minimal.[6] In view of less literature on comparison of tramadol with buprenorphine as postoperative analgesics, especially in Indian settings, the current study was undertaken.
Objective: To compare efficacy and safety of tramadol with buprenorphine in patients scheduled for lower abdominal surgeries.

II. Material And Methods

This randomized,single-blinded study was done at a tertiary care centre in IndiafromJuly 2022 to December 2022

Study Design: Randomized, single blinded study

Study Location: This study was done at a tertiary care teaching hospital in the Department of Anaesthesia at NRIInstitute of Medical Sciences, Andhra Pradesh, India.

Study Duration: July 2022 to December 2022

Sample size: 100 subjects

Sampling procedure: Convenience sampling

Sample size calculation: As per the previous study done by Mwakaet al.[7]55.3% of patients will have postoperative pain after 24 hours of surgery.Considering this prevalence, with 95% confidence level and 10% error, minimum sample size was calculated 95 in the study. We included 100 adults considering 5% of incomplete data.

Subjects & selection method: The study population was drawn from patients who were admitted at our tertiary care center scheduled for various lower abdominal surgeries. The study is randomized, as patients were divided into two groups by computer-generated randomization software.

The study is single blinded, as the investigator knows which drug the patient is getting- either buprenorphine or tramadol but the patient doesn't know what he is receiving.

Group B: 50 adults- received injection buprenorphine- 150mcg given by intravenous route twice daily

Group T: 50 adults- received injection tramadol-100 mg given by intravenous route twice daily

Inclusion criteria:

1. Patients aged 20 to 60 years, scheduled for various lower abdominal surgeries
2. Either sex
3. Patients of ASA physical status I and II
4. Patients who provided informed consent.

Exclusion criteria:

1. Patients with a history of allergy to study medications.
2. Pregnant and lactating women
3. Patients with spinal deformities
4. Patients using anticoagulants
5. Patients with local infection or inflammation
6. Patients with a history of opioid abuse
7. Patients who are in hemorrhagic shock

Methodology:

After getting informed consent from the patients, from 10 p.m. of day before surgery, all patients were kept nil by mouth. They were given Alprazolam 0.25mg along with cap. Omeprazole as pre medications.ust beforegivinganaesthesia, multiparameter monitor was connected to record blood pressure, pulse rate, respiratory rate, oxygen saturation and ECG continuously.Spinal anaesthesia was given under aseptic conditions at L3-L4 space. During surgery, no analgesics were given, and the patient was taken to the post-operative ward once the surgery was completed. Patients were given either buprenorphine or tramadol in the postoperative ward. Patients' pain was monitored every sixth hourly. Pain was assessed using 11-point VAS.

The following image shows VAS scoring:

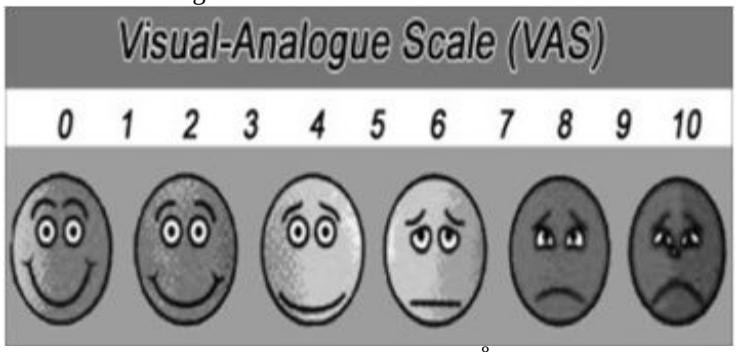


Image 1: VAS scoring[8]

Parameters assessed:

- Age
- Gender
- ASA grade
- VAS score at 6,12, 18 and 24 hours of surgery
- Rescue analgesia requirement
- Side effects

Statistical analysis

Data was analyzed using Epi info software version 7.2.5.Results were expressed as percentages and mean with standard deviation.Student's t test was used to compare numerical parameters between two groups. Chi square test was used to compare categorical variables. P value below 0.05 is considered significant.

III. Results

The current study included 100 adults scheduled for various lower abdominal surgeries.

Age:

There is no significant difference in the mean age of patients between two groups, as per students t test(p=0.112).

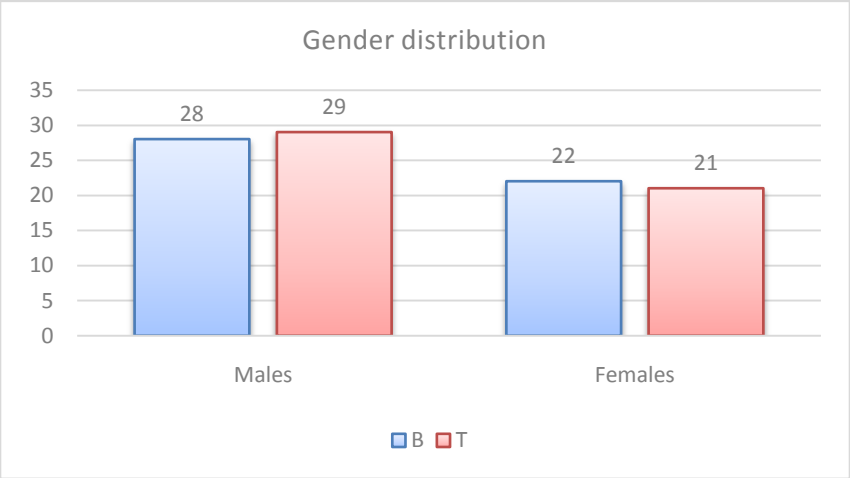
Table no 1: Mean age of patients in both groups

Group	Mean age	P value
B	45.3 ±4.1 years	
T	46.8±5.2 years	0.112

Gender:

Most of the patients were females. There is no significant difference in gender between two groups (0.83), as per chi square analysis.

Graph 1 shows gender distribution of patients in both groups



ASA grade:

Most of the patients belonged to ASA grade I. There is no significant difference in the ASA grade between two groups, as per chi square analysis(p=0.67).

Table 2 shows ASA Grade of patients in both groups

Groups	ASA Grade I(percentage)	ASA Grade II	P value
A	64%	36%	
B	66%	34%	0.67

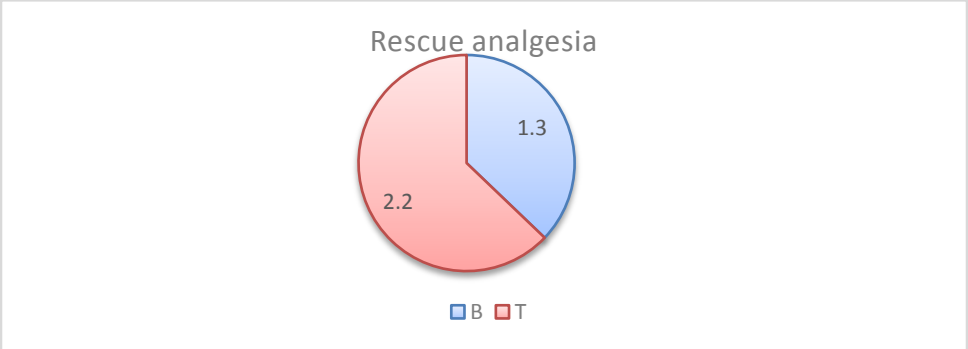
VAS score:
There is significant difference in VAS score at 12 and 24 hours of surgery between both groups. It was less in buprenorphine group. There is no significant difference in VAS score at baseline and at 6 hours after surgery.

Table 3 shows VAS scores from baseline to 24 hours

Mean VAS score	Group B	Group T	P value
Baseline	4.2±0.8	4.3±1.1	0.60
6 hours	3.5±1.2	3.6±1.8	0.74
12 hours	1.8±0.09	2.3±0.9	0.0002
24 hours	0.9±0.01	2.0±0.8	0.0001

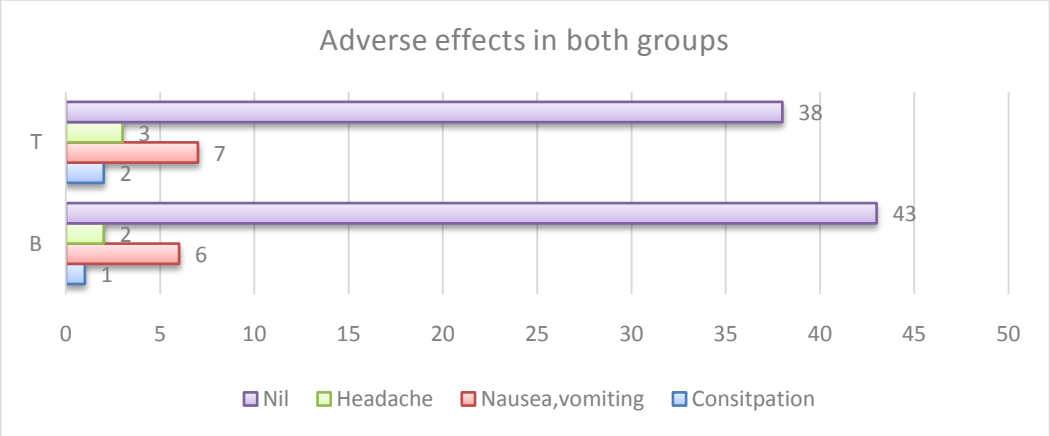
Rescue analgesia requirement:
Rescue analgesia used was Inj. Paracetamol (1 gm). It was given by intravenous route. Mean number of paracetamoldoses used in B group was 1.3±0.09 and mean number of doses used in T group was 2.2±1.2. Rescue analgesia requirement is significantly more for tramadol group patients compared to buprenorphine patients(p=0.001).

Graph 2 shows rescue analgesia requirement in both groups



Adverse effects:
Adverse effects were more for tramadol compared to buprenorphine.Overall, no adverse effects were seen in 87 patients. Most common adverse effects seen were nausea and vomiting.

Graph 3 shows adverse effects among both groups of patients



IV. Discussion

Tramadol is one of the commonly used analgesics during post-operative period.[9]It has good bioavailability and has been used for providing effective post-operative analgesia.[10-11]But it shows high incidence of postoperative nausea and vomiting. It should be used cautiously among patients with renal failure due to more risk of accumulation.[12]Buprenorphine is a centrally acting potent opioid analgesic, that has been used in clinically for30 years.[13]In this study tramadol was compared with buprenorphine.In our study, 100 patientswere included. There is no significant difference in the mean age, gender, ASA grade between these groups. Hence the comparison is justifiable. The postoperative pain score was assessed using VAS score. VAS score was significantly less in

buprenorphine group compared to tramadol group of patients at 12 and 24 hours after surgery.The rescue analgesia requirement was significantly less in the buprenorphine group. Adverse effects were seen more commonly for tramadol in our study.
Some studies have shown that multiple dosing can reduce medication compliance and fail to provide complete round-the-clock analgesia. So, we used twice daily injections of both drugs in our study.

In the study of **Desai et al**.[16] authors compared pain scores for seven days after surgery. Rescue analgesic requirement was significantly less in buprenorphine group compared to tramadol group. 100% of patients of tramadol group required rescue analgesia and 68% of patients needed rescue analgesia in the buprenorphine group. Rescue analgesia need was more in tramadol group compared to buprenorphine group, similar to our study. Incidence of vomiting was less in buprenorphine group compared to tramadol group, similar to our study.

Lee H et al.[17]did a randomized multicenter study. Pain was assessed using numeric rating scale. Patients received either buprenorphine or tramadol. Quality of life and satisfaction scores, compliance to medications and side effects were also compared between two groups apart from pain reduction score. There is a significant reduction in mean pain score in both groups along with improved quality of life. Buprenorphinegroup showed better compliance to medications. Adverse effects were comparable between groups.

Alon E at al.[18]compared analgesic effects and side effects of 50 mg tramadol with 0.3 mg of buprenorphine. He conducted a double-blind, randomized study to know safety and efficacy of these two drugs. Results showed that buprenorphineproduced more potent and long-lasting analgesic effect compared to tramadol, similar to our study. There were no significant side effects in both groups.

Limitations of our study:

1. Small sample size
2. We didn't assess quality of life and patient satisfaction scores
3. We didn't measure the duration of analgesia.

V. Conclusion

We recommend using Injection Buprenorphine as postoperative analgesic compared to Injection Tramadol for postoperative pain relief after lower abdominal surgeries.
The study is self-sponsored. There were no conflicts of interest.

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