

# Post-operative Epidural Analgesia with Ropivacaine and Tramadol in Lower Abdominal Surgery

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## ABSTRACT

**Background:** Post-operative pain is a major concern for patients undergoing surgery. The fear of pain keeps on preying on their minds leading to various stress related dysfunctions. The present study was designed to compare the efficacy and safety of two combinations of Ropivacaine & Tramadol in preventing post-operative pain in patients undergoing lower abdominal surgery.

**Patients and Methods:** 60 ASA I and II patients undergoing lower abdominal surgery were randomly assigned to two groups of thirty patients each, receiving either 50mg Tramadol with 0.2% Ropivacaine (Group A) or 100mg Tramadol with 0.2% Ropivacaine (Group B) epidurally. Total volume injected was 10ml in each case. Epidural top-ups were given every 8 hourly for post-operative analgesia till 48 hrs after surgery. VAS was used to assess analgesia.

**Results:** Demographic data and baseline parameters were comparable in both the groups. Better analgesia, as seen by lower VAS scores, was observed in Group B. Side-effects were similar in both the groups.

**Conclusion:** 100mg Tramadol as an adjuvant to Ropivacaine 0.2% provides better analgesia as compared to 50mg Tramadol, without significant side-effects.

**Key Words:** Ropivacaine, Tramadol, VAS, Post-operative Analgesia.

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## INTRODUCTION

Pain is not a straightforward sensory “perception” but an “experience”<sup>1</sup>. It disrupts the normal physiological and psychological homeostasis, manifesting clinically as organ dysfunction and altered human behaviour. Failure to relieve pain is morally and ethically unacceptable and adequate pain relief could be considered a basic human right<sup>2,3</sup>.

It is widely believed that pain is an inevitable consequence of surgery. In fact, the fear of postoperative pain preys on the patients’ mind more than the consequences of surgery. Therefore the treatment of pain after surgery becomes central to the care of the postoperative patient. Epidural analgesia with local anaesthetics gives good pain relief and the addition of various adjuvants has made it even more popular<sup>4,5</sup>.

## AIM

The present study was designed to compare the efficacy and safety of two combinations of Ropivacaine & Tramadol in preventing post-operative pain in patients undergoing lower abdominal surgery.

## PATIENTS AND METHODS

After requisite approval from the Institutional Ethics Committee, the current study was undertaken as a prospective, double blind random study & 60 patients of either sex between the ages of 18 and 80 years were included. Only patients categorized as ASA physical status I or II scheduled to undergo surgery on the lower abdomen were included. Post-operative analgesia was provided by intermittent epidural administration of 10 ml of the study drug. Written informed consent was taken from all the patients and the procedure was explained to them in detail. The visual analog scale (VAS) and the method of rating pain were explained to them prior to surgery.

Patients having any history of drug or alcohol abuse; any hepatic, renal, circulatory or respiratory abnormality; any history of drug allergy; chronic headache, backache or any neurological deficit, bleeding diathesis or abnormal coagulation profile, pregnant females and caesarean sections were not included in the study.

All the patients were kept fasting after midnight prior to surgery & were premedicated with 5mg of diazepam orally on the night before surgery and 5mg orally 3 hours before surgery. Patients were randomly divided into two groups of thirty patients each:

1. Group A – Patients in this group received 8ml Ropivacaine, 0.2% + 50 mg of Tramadol (in 2 ml).

2. Group B – Patients in this group received 8 ml Ropivacaine, 0.2% + 100 mg of Tramadol (in 2 ml).

Both the groups were matched for age, sex and weight of the patients; and the type and duration of surgery. Epidural 'top-up' was provided postoperatively just after conclusion of surgery before shifting the patient out of the recovery room. Subsequent 'top-ups' were provided every 8 hours for the next 48 hours. Analgesia and sedation scores were recorded at 1, 2, 3, 6, 12, 18, 24, 36 and 48

hours after the end of surgery. VAS scores were recorded at rest, on movement (touching the side of bed opposite the side of surgery) and while coughing. Vital parameters and any complications or side effects were also recorded at the same time. The epidural catheter was removed 48 hours after the end of surgery.

In case of inadequate analgesia or patient complaints of pain before the expiry of eight hours, rescue analgesic was provided to the patients in the form of Inj Diclofenac Sodium, 1.5mg/kg body weight. At the end of 48 hours, the patients were evaluated for the quality of analgesia, sedation, amnesia and the side effects. Rescue analgesic requirement for each group was calculated and compared at the end of the study. Data was analyzed applying the Chi-square test & Fischer Exact test. A 'p' value < 0.05 was taken as significant.

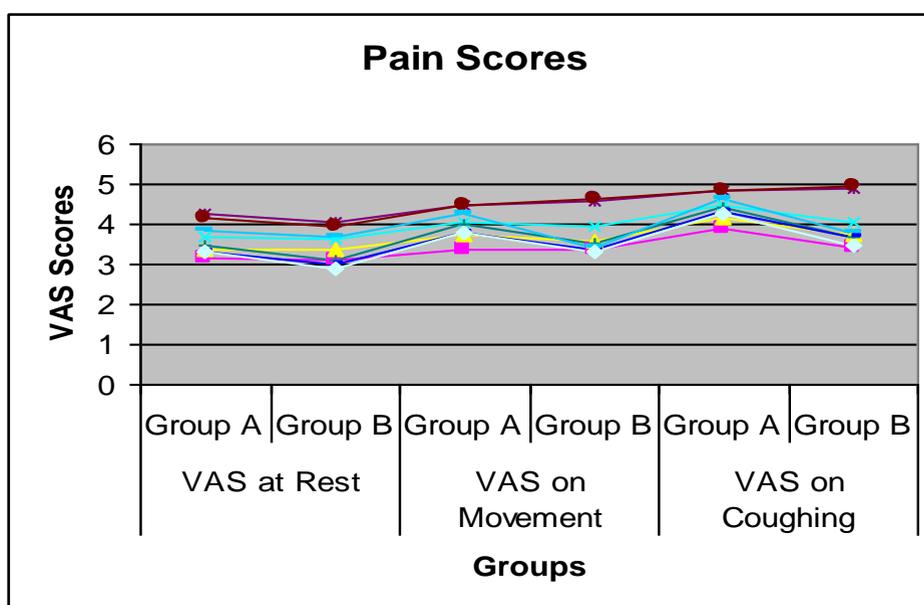
## RESULTS

**Demographic Data:** Demographic data and baseline parameters were comparable in both the groups (Table 1).

**Table 1: Demographic Profile.**

Parameter	Group A			Group B		
	Male	Female	Group mean $\pm$ S.D.	Male	Female	Group mean $\pm$ S.D.
Age (in years)	49.1	44.4	46.1 $\pm$ 13.03	47.5	45.5	46.1 $\pm$ 11.19
Weight (in kgs)	64.8	53.0	57.3 $\pm$ 12.11	63.5	59.2	60.5 $\pm$ 7.74
Duration of Surgery (in mins)	108.6	92.2	98.2 $\pm$ 32.16	113.7	90.8	97.7 $\pm$ 26.53

**Pain Scores:** VAS scores recorded at Rest, on Movement & on Coughing (Fig 1) in both the groups were comparable and the differences were not significant ( $p > 0.05$ ).



**Fig 1: Pain (VAS) Scores.**

**Sedation Scores:** The mean sedation scores (Fig 2) revealed higher sedation & amnesia levels in Group B, although, no intervention was required.

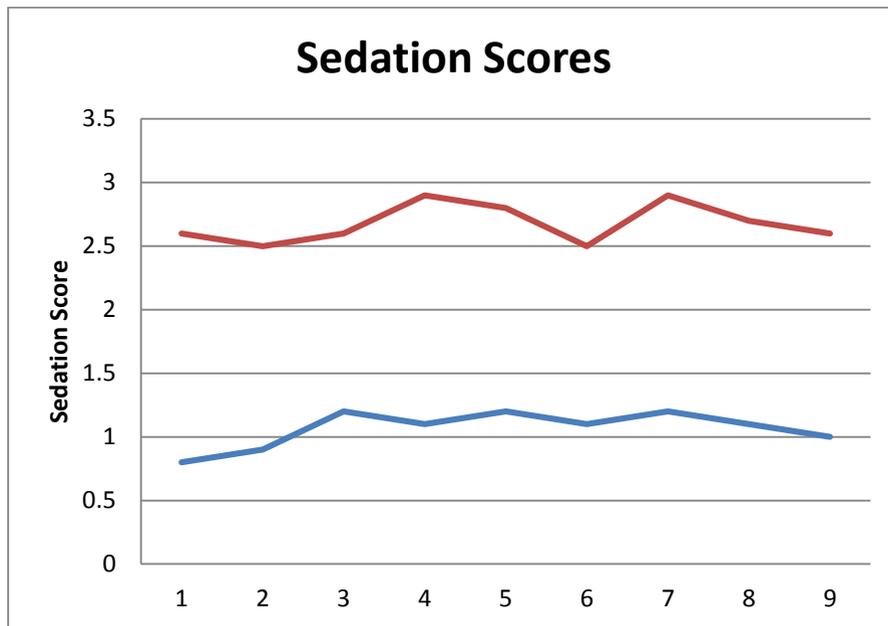


Fig 2: Sedation Scores.

**Vital Parameters:**

**Pulse Rate:** The mean pulse rates in the two groups were comparable (Fig 3) and the differences were not significant ( $p > 0.05$ ).

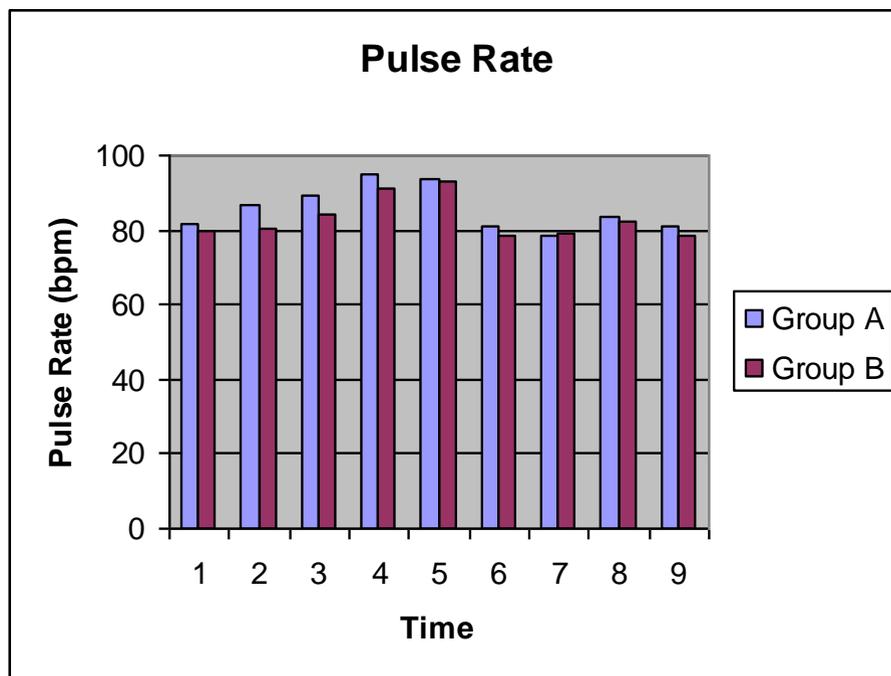


Fig 3: Pulse Rate.

**Mean Arterial Pressure:** Group A had a higher mean arterial pressure as compared to Group B (Fig 4) & the difference was statistically significant ( $p = 0.017792$ ,  $F = 4.22$ ). However, no intervention was required in either group.

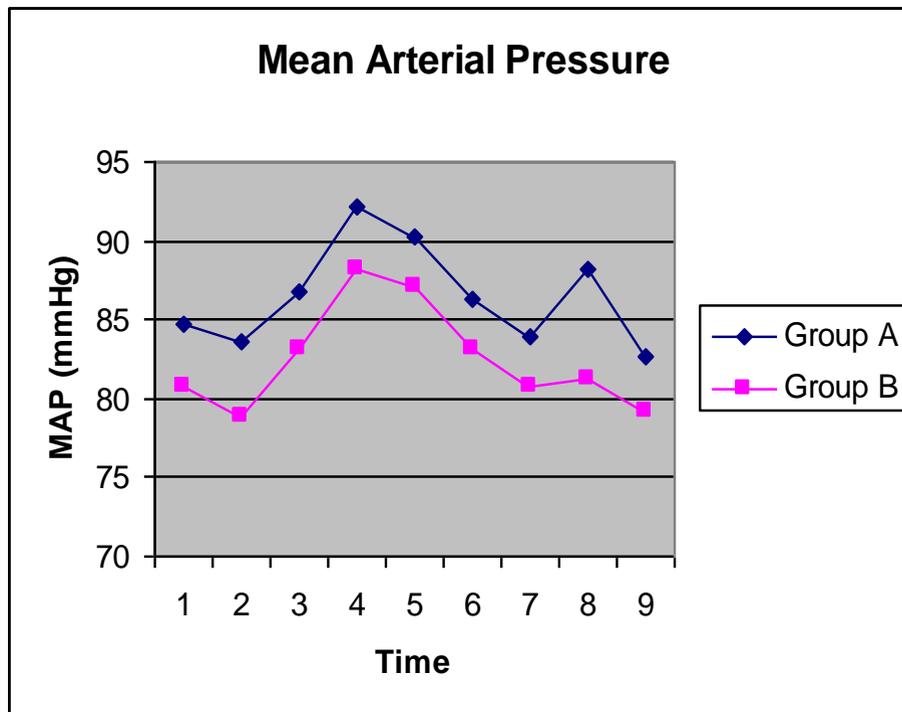


Fig 4: Mean Arterial Pressure.

**Oxygen Saturation (SpO<sub>2</sub>%):** SpO<sub>2</sub> measurements (Fig 5) in the two groups were comparable and the differences were not significant (p>0.05).

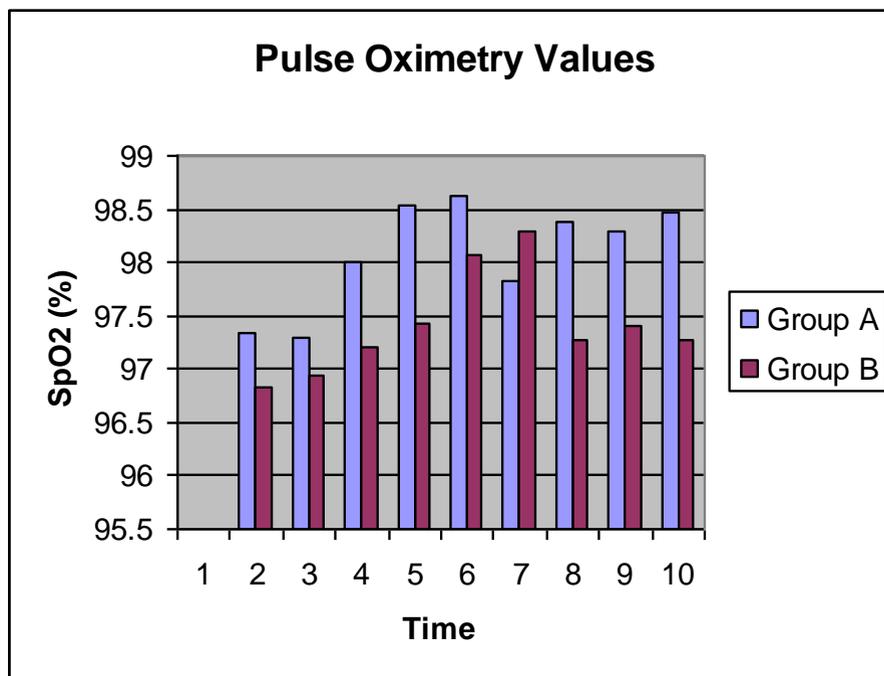


Fig 5: Oxygen Saturation (SpO<sub>2</sub>)

**Side Effects Noted:** Side effect profile (Fig 6) in the two groups was comparable and did not reveal any significant differences (p > 0.05). Urinary retention was not considered as almost all of our patients were catheterized in the postoperative period.

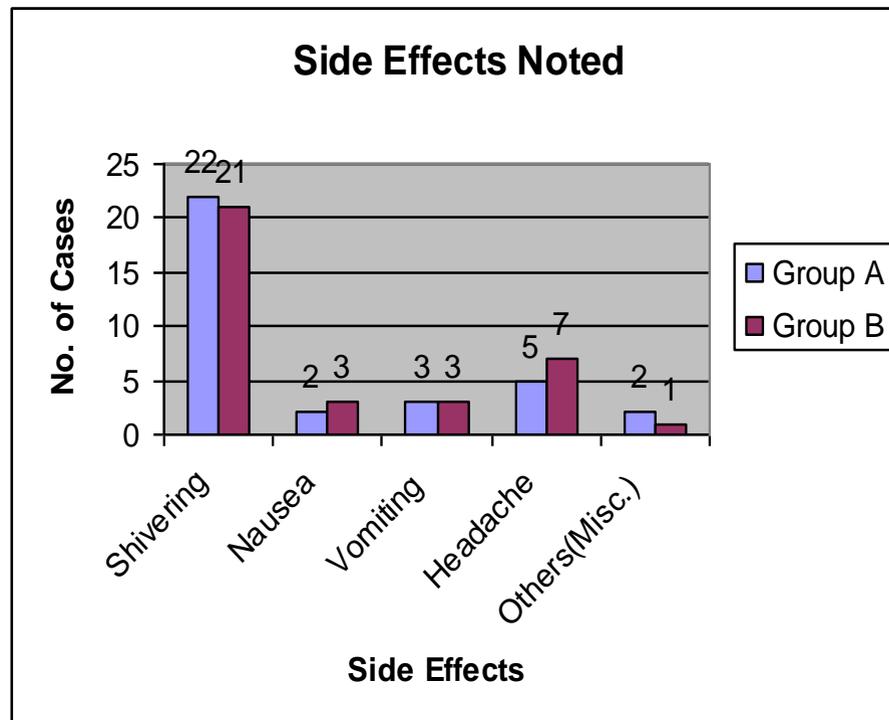


Fig 6: Side Effects Noted.

## DISCUSSION

Epidural analgesia is now accepted as the prime modality of pain relief following lower abdominal surgery. The quality of analgesia with an epidural has been described as equivalent to, or even better than that provided by opioids, of course, without the side-effects that accompany them<sup>5</sup>.

Long-acting local anesthetics like bupivacaine have been used as the mainstay, but motor block & significant cardio-toxicity have remained vital issues. Ropivacaine has recently been introduced into clinical practice in India with a better safety profile as its USP. Besides, Ropivacaine does not possess significant motor block, thus being the ideal candidate for epidural analgesia – providing pain relief without hindering early ambulation<sup>6</sup>. Opioids like Tramadol, added in low doses as adjuvant, increase the duration of analgesia thus subverting the need for repeated top-ups<sup>7,8,9</sup>.

In our study, we found good analgesia in both the groups, without any major side-effects, though Group B had lower VAS scores. Lower sedation scores in Group B were probably indicative of better analgesia and thus, deeper sleep. Vital parameters reflected the same pattern with lower Heart Rates, Blood Pressure & Pulse Oximetry values being recorded in Group B. Side effects noted were comparable in both the groups and did not require any therapeutic intervention. These findings are in agreement with those of Chhetty et al<sup>10</sup>, Berti et al<sup>11</sup> and Kirov et al<sup>12</sup> who found that Ropivacaine 0.2%

with low dose opioids like Tramadol provided good analgesia without significant side effects.

## CONCLUSION

Both the regimens provided effective analgesia with Group B recording consistently lower pain scores. Thus, we conclude that 100mg Tramadol as an adjuvant to Ropivacaine 0.2% provides better analgesia as compared to 50mg Tramadol, without significant side-effects.

## APPENDIX

### 1. Visual analog scale (VAS)

- 0= No pain,
- 1-3= Mild pain,
- 4-7 = Moderate pain,
- 8-10 = Severe pain.

### 2. Sedation score

- 0 = Fully awake,
- 1 = Slightly drowsy,
- 2 = Asleep but easily arousable,
- 3 = Fully asleep but arousable,
- 4 = Fully asleep and not arousable.

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