

A COMPARATIVE STUDY BETWEEN EPIDURAL BUPRENORPHINE vs TRAMADOL FOR POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL SURGERIES.

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ABSTRACT:

Introduction: Patients who receive epidural opioids have fewer respiratory issues and can be deployed sooner in the postoperative phase than those who get standard, intermittent IV/IM dosing. The present study was done to compare the postoperative analgesia between tramadol and Buprenorphine through an epidural technique in patients undergoing lower abdominal surgeries, along with their onset, duration of analgesia, and side effects.

Materials and Methods: This study was a prospective comparative randomized study. Our study comprised 60 patients who came in for elective lower abdomen surgery and were randomly divided into two groups of 50 individuals each. Group T received 50 mg of Inj. Tramadol hydrochloride and Group B received 100 micrograms of Inj. Buprenorphine hydrochloride through epidural route (epidural catheterization done). Both groups of patients were monitored for 24 hours after surgery. In the postoperative phase, the VAS (VISUAL ANALOG SCORE) score for pain severity, onset and duration of analgesia, and side effects was monitored.

Results: The onset of analgesia in Group T was quicker, but the duration of analgesia was shorter than in Group B. Group T had a mean onset of analgesia of 9.65 ± 4.25 minutes, whereas Group B had a mean onset of 14.85 ± 4.75 minutes. The mean duration of postoperative analgesia in Group T was 345.12 ± 78.65 minutes, while it was 595.45 ± 88.42 minutes in Group B, with a P-value of 0.02 which was significant. Throughout the study, all of the patients were hemodynamically stable, and no severe side effects such as respiratory depression were detected. However, Group B had a higher incidence of nausea, vomiting, and pruritus than Group T.

Conclusion: At the end of the study, It was observed that epidural Buprenorphine gives a substantially longer and higher quality of analgesia than epidural Tramadol. Nausea, vomiting, and pruritus were the most common adverse effects associated with injectable buprenorphine, which may be alleviated by antiemetics and antihistaminics, respectively.

Key Word: Buprenorphine, epidural, postoperative analgesia, tramadol. VAS-visual analog score of pain

Introduction:

Because postoperative pain has a wide range of physiological and psychological impacts, pain treatment is crucial for early mobility and postoperative discharge. [1]

Tramadol is a synthetic derivative of codeine that has a moderate affinity for mu opioid receptors but a weak affinity for kappa and delta opioid receptors. It has a 5 to 10 times lower analgesic potency than morphine. In addition to its mu opioid agonist effect, tramadol enhances the function of the spinal descending inhibitory pathways by blocking norepinephrine and 5-hydroxytryptamine (Serotonin) neuronal reuptake and presynaptic stimulation of 5-hydroxytryptamine release. In volunteers, naloxone was shown to prevent only around 30% of tramadol's effect. [2]

Buprenorphine hydrochloride is a semisynthetic opioid that is extremely lipophilic and comparable to morphine. It's a long-acting analgesic with narcotic agonist and antagonist properties. Buprenorphine has a 50-fold higher affinity for mu receptors than morphine, and its delayed dissociation from these receptors accounts for its long duration of action and resistance to naloxone antagonism. [3]

The purpose of this study was to compare the efficacy of epidurally administered buprenorphine to that of tramadol in the management of postoperative pain in patients who underwent lower abdominal surgeries, as well as the onset and duration of analgesia and side effects of the two drugs.

Materials and Methods:

The present clinical study was conducted during the period of March 2020 to December 2021. This study was a prospective comparative randomized study carried out in the Department of Anaesthesiology, Panimalar medical college hospital and research institute, Chennai. After ethical committee approval, a total of 60 patients undergoing elective lower abdominal surgeries were included in the study

Inclusion Criteria:

- Patients posted for various elective lower abdominal surgeries.
- Age group 18 - 60 years of both sex.
- Patients in ASA grade I and II.

Exclusion Criteria :

- Patients in ASA grade III and IV.
- All contraindications for epidural anaesthesia.
- Uncooperative patients/patient refusal.
- Severe haemorrhage or shock.
- Coagulation defects or on anticoagulant therapy.

- Local inflammation.
- History of opioid abuse.
- Allergy to any of the drugs used in the study

All the patients were explained about the study and the anesthetic technique. A valid, written and informed consent was obtained for the same. From 10 p.m. the day before surgery, all patients were kept nil by mouth and premedicated with a tab. Alprazolam 0.25mg at 10 p.m. the night before surgery and tab.Ranitidine 150mg with sips of water at 7 a.m. the day of operation A basic randomization procedure was used to divide sixty patients into two groups using computer-generated random numbers. The treatment assignment was put in random order in 60 sealed envelopes. When a patient was brought into the research, one envelope from the predefined pack of envelopes was opened in serial sequence. Just prior to the commencement of operation, the envelope was unsealed. The patients, as well as the investigators who were documenting the results, had no idea which medicine was being given to which patient. To reduce prejudice, a double-blinding procedure was used. The patients were placed into two groups: Group T received Tramadol (n=30), and Group B received Buprenorphine (n=30).

Procedure: After obtaining informed written consent from the patients, the procedure was explained to them. Prior to administering anaesthesia, the following measurements were taken: pulse rate and rhythm; blood pressure; and respiration rate. Vital signs were taken when the patient was transferred to the operating room. It was decided to start an intravenous infusion. A combined spinal epidural treatment was conducted on each patient under strict aseptic conditions. An 18G tuohys needle was inserted into the L2-L3 interspinous area while the patients were held in a left or right lateral posture. The catheter was put into the epidural space after the loss of resistance approach was used to identify it. A test dose of 2ml of 2% xylocaine+adrenaline (1:2,00,000) was administered to rule out intrathecal and intravascular epidural catheter implantation. A 25G spinal needle with 15mg of inj was used to produce a subarachnoid block in the L3-L4 region. Bupivacaine is a hefty 0.5 percent bupivacaine. During the intra-operative phase, no analgesics were given, and the patient was transferred to the post-operative ward once the procedure was completed. .

In the postoperative period in the recovery room patients were observed for vital signs and asked about pain. When the effect of epidural analgesia wore off and pain appeared, a single dose of tramadol 1 to 2 mg/kg diluted with 10cc of normal saline or distilled water was injected in the epidural space of 30 patients of T group at random, and a single dose of buprenorphine 2-3ug/kg diluted with 10ml of normal saline or distilled water was injected in the epidural space of the remaining 30 patients of B group. The patients were not given systemic analgesics until they complained of chronic discomfort.

For the first 24 hours after surgery, all patients were monitored and observed hourly. The level of discomfort and pain alleviation after injection of the medication in the epidural area were measured using the Visual Analogue Scale (VAS) (0–no pain to 10–worst imagined agony) in all patients. The onset and duration of analgesia were also recorded. From the initial dosage for the first 12 hours, pulse rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, respiration rate, and VAS score were recorded hourly for the following 12 hours. If there were any side effects, these were also reported.

STATISTICAL ANALYSIS:

SPSS 16 software was used to analyze the data. Data were analyzed, compiled, and presented as mean, standard deviation (SD), percentages, and t-test. The P-value < 0.05 was considered significant.

Result:

Table 1 shows the age wise distribution and weight wise distribution was similar in both the groups

Table 1: Comparison of demographic parameter

Demographic parameters	Group T (N=30)	Group B (N=30)
Age	35.52±7.94	34.26±6.84
Weight	54.82±5.75	57.48±5.58

Table 2 shows that the mean duration of Analgesia was longest in the Buprenorphine group compared to the Tramadol group, which was statistically significant.

Table 2: Mean Duration of analgesia in Minutes

Group	Mean ± SD	P-value
Group T (Tramadol)	345.12±78.65 Minutes	0.03*
Group B (Buprenorphine)	595.45±88.42 Minutes	

* Significant

Table 3 shows that the onset of Analgesia was short in the Tramadol group compared to the Buprenorphine group, which was statistically significant.

Table 3: Mean Time of onset of Analgesia in Minutes

Group	Mean± SD	P-value
Group T (Tramadol)	9.65±4.25 Minutes	0.02*
Group B (Buprenorphine)	14.85± 4.75 Minutes	

* Significant

Table 4 shows the mean VAS score was less than 1 in both the groups during the 24hrs after the first dose of epidural top-up

Table 4: Comparison of VAS score among the groups

	Group T (n=30)	Group B (n=30)
0 hr	1	1
1 hr	0	0
2 hr	0	0
3 hr	0	0

4 hr	0	0
5 hr	0.3	0
6 hr	0.34	0
7 hr	0.65	0
8 hr	0.2	0
9 hr	0	0
10 hr	0	0
11 hr	0.4	0
12 hr	0.25	0
18 hr	0.5	0
24 hr	0	0

Table 5 shows the comparison of side effects between the 2 groups. Pruritis was observed in 2 patients of the Buprenorphine group. No patient had Pruritis in the Tramadol group. Nausea and vomiting were seen in 3 patients in the Tramadol group and 5 patients in the Buprenorphine group. Headache, Hypotension, and Urinary retention were not observed in any group of patients.

Table 5: Comparison of side effects between the 2 groups

Side effects	Group T	Group B
Pruritis	0	2
Nausea and vomiting	3	5
Headache	0	0
Hypotension	0	0
Urinary retention	0	0

DISCUSSION:

The effectiveness of epidural tramadol vs epidural buprenorphine for postoperative pain management in patients following lower abdominal operations was examined in this study. In our study, the mean onset of analgesia with epidural tramadol was 9.65 ± 4.25 Minutes, whereas with epidural buprenorphine it was 14.85 ± 4.75 Minutes. We found that epidural tramadol has a rapid onset of analgesia when compared to epidural Buprenorphine. Rathie P et al found that epidural tramadol has a rapid onset of action and adequate analgesia.[4]

In our study, the mean duration of post-operative analgesia obtained with epidural tramadol was 345.12 ± 78.65 Minutes and with Buprenorphine was 595.45 ± 88.42 Minutes. Siddik-Sayyid et al concluded that epidural tramadol provided post-operative analgesia for a period of 4.5 ± 3.1 hours.[5] Rathie P et al (1998) found that the mean duration of post-operative analgesia with tramadol 100 mg was 10.26 ± 2.73 hours.[4] Delikan et al studied the analgesic effects of epidural tramadol and concluded that 100 mg of tramadol provided post-operative analgesia for 9.46 hours.[6]

With epidural Buprenorphine, Koshy T et al observed a longer duration of analgesia, 19.9 ± 8 hours.[7] Kumar D et al (1997) examined the effect of epidural Buprenorphine and ketamine.

With epidural Buprenorphine, the average duration of post-operative analgesia was 13.1 hours. [8] In 1998, Agarwal M et al compared post-operative pain relief with epidural morphine and epidural buprenorphine. They noticed that with buprenorphine, the average duration of analgesia was longer (31.24 hours). [9] Buprenorphine's extended duration of action can be explained by its high lipid solubility and affinity for opiate receptors.

Delikan AE et al in their study found a longer duration of postoperative pain relief and high incidence of nausea.[6] Rathie P et al in their study found that nausea and vomiting were common side effects.[4] In the present study, the incidence of nausea and vomiting were almost similar with both epidural tramadol and epidural buprenorphine. In the tramadol group, 3 out of 30 complained of nausea and vomiting. In the Buprenorphine group, 5 out of 30 complained of nausea and vomiting. Koshi T et al compared epidural morphine with epidural buprenorphine for postoperative analgesia and side effects. In their study, hypotension occurred in 1 case in the buprenorphine group. [7]

Churubasik S et al in 1996 studied the pain relief with peridural administration of opioids. They believed that epidural tramadol might be effective in clinical practise since it is cardiovascularly stable and has a minimal risk of central depressive effects, making it particularly useful in situations when patient care is not assured. [10]. In 1994, Koshi T et al studied postoperative analgesia and side effects of epidural morphine with epidural buprenorphine. With epidural buprenorphine, there was no risk of respiratory depression. [7] In their study, Y et al found that the morphine group had a higher rate of respiratory depression than the tramadol group. [11] There was no respiratory depression with either epidural tramadol or epidural buprenorphine in this study.

CONCLUSION: Based on the findings of this study, it is possible to infer that the two medications provided equivalent analgesia. Tramadol has the earliest onset of analgesia, but because it lasts less time, it must be administered more often than buprenorphine. Buprenorphine provides a longer duration of analgesia and so needed fewer doses than tramadol, however the start of analgesia was delayed with buprenorphine. The side effects that were identified were not concerning.

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