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Comparative study of duration of analgesia with epidural bupivacaine & bupivacaine with tramadol in lower limb and lower abdominal surgeries

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Abstract

The administration of local anaesthetic opioid mixtures neuraxially (particularly epidurally) is excellent for post-operative pain following abdominal, pelvic or orthopaedic procedures on lower extremities. The rational for this relatively new technique in post-operative pain management is a better quality of analgesia that can be achieved by systemically administered analgesics, a lower incidence of side-effects, improved surgical outcome and high levels of patient satisfaction. Therefore, this study was taken up to evaluate the efficacy of epidural opioids in the management of post-operative pain.

A total of 80 patients group A 40& group B 40 ,of age 20-70yrs and ASAI &II, were selected for the study who were admitted for lower abdominal and lower limb surgeries . Group A was given epidural bupivacaine 0.5% & group B was given epidural bupivacaine 0.5% with tramadol 50mg. The onset & duration of analgesia, effects on the hemodynamics and side effects were evaluated and compared between two groups. Pain was evaluated on VAS scale and end point of study was when rescue analgesic was given on demand.

In this study, we used 1 ml (50 mg) tramadol with 0.5% bupivacaine (15-20 ml) through epidural route in patients for short surgical procedures in lower extremity & lower abdomen, it was found that mean duration of analgesia was significantly longer than the patients who received 15-20 ml 0.5% bupivacaine only through the same route.

Keywords: neuraxial, epidural, tramadol, bupivacaine

Introduction

The World Health Organisation has defined pain as “an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage”.

Pain

An unpleasant sensation that can range from mild, localized discomfort to agony. Pain has both physical and emotional components.

The administration of local anaesthetic opioid mixtures neuraxially (particularly epidurally) is excellent for post-operative pain following abdominal, pelvic or orthopaedic procedures on lower extremities. Patient often have better preservation of pulmonary function and are able to ambulate early Epidural administration of opioids in combination with local anaesthetic agents in low dose offers new dimensions in the management of post-operative pain. The rational for this relatively new technique in post-operative pain management is a better quality of analgesia that can be achieved by systemically administered analgesics, a lower incidence of side-effects, improved surgical outcome and high levels of patient satisfaction.

Therefore, this study was taken up to evaluate the efficacy of epidural opioids in the management of post-operative pain.

Aims and Objective

To evaluate the duration and quality of analgesia with a single epidural injection of 0.5% Bupivacaine versus 0.5% bupivacaine and 50 mg Tramadol for surgeries that can be done under lumbar epidural anaesthesia i.e. lower abdominal and lower limb surgeries.

To evaluate safety, tolerance and side effects for the combination of tramadol and bupivacaine.

Materials and Methods

Materials

Patients

Selection Criteria

Informed voluntary consent was taken from all patients for the study prior to surgery during pre-anaesthetic check up.

All patients belong to ASA grade 1 or 2 with no or minimal disease.

The patients included were those of either sex whose age between 20-70 yrs and weight 40-65 kgs.

All patients were those undergoing elective lower abdominal and lower limb surgeries which could be performed under lumbar epidural anaesthesia.

Exclusion Criteria

Patients on anticoagulant therapy, bleeding disorders, evidence of cardiac, respiratory, hepatic, metabolic, hematological diseases, known allergy to anaesthetic agent, pregnant patients. etc.

Plan

A total of 80 patients were enrolled in this study who were admitted in different surgical disciplines of Patna Medical College and Hospital for lower abdominal and lower limb surgeries. All patients were screened out through pre-anaesthetic check up including relevant history, general and systemic examination and routine investigations.
All 80 patients were randomly allocated into two groups by picking lots on the day of surgery.
Group A - 40 patients receiving 0.5% bupivacaine.
Group B - 40 patients receiving 0.5% bupivacaine and 50 mg of Tramadol.

Drugs and Equipments

Drugs Bupivacaine 0.5%, Injection ephedrine, Injection Atropine, 1 V crystalloids (Normal Saline and Ringer's Lactate), IV colloids (Hemaccel, Hexastarch), Injection Tramadol

Equipments Epidural Kit - Epidural Tuohy needle (18 G) and catheter, Loss of resistance syringe, NIBP by sphygmanometer, SPO2, HR by pulse oximeter.

Methods

All patients were kept nill per orally after light dinner and were given tablet ranitidine 150 mg orally with dinner. Pulse, BP and body weight was noted on reaching OT. All patients were premedicated with I. M. atropine (0.6 mg) injection, metoclopramide (0.2 mg/kg) thirty minutes before the probable time for the anaesthetic procedure. Patient were monitored for these 30 minutes for changes in heart rate and B.P.
After securing on I.V. access using an 18 G I.V. cannula, ringer's lactate (1 bottle) was used in all patients for preloading. All patients were connected to the monitors to monitor heart rate, NIBP, continuous ECG monitoring and SPO_2. All patients were administered epidural anaesthesia in the sitting position. All patients were blinded i.e. they never know which drugs they receive. After thoroughly cleaning the area interspinous space chosen between L2-3 or L3-4 and local infiltration of 0.5% bupivacaine was done using fine syringe. After waiting for 2 minutes epidural needle 18G introduced. Epidural space was identified using loss of resistance technique with loss of resistance syringe supplied with the kit. After completion of the procedure the patients were returned back to supine position with head end elevated to 15 degrees. While performing the procedure pulse, BP, ECG, SPO_2, was monitored closely. Any side effects was observed. Any signs of toxicity of drug (Bupivacaine) eg. bradycardia, convulsions were closely monitored. No other analgesic or opioid was given during surgery and end point of the study was when patient complains of pain and rescue analgesic in the form of pentazocine required.

Results

Table1: Mean and standard deviation (SD) of age and their test of significance.

Age (years)	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
	38.63 ± 8.86	38.70 ± 7.45	>0.05

When the age of the patients in the two groups were compared using the Student's test, the p value was > 0.05. So, there was no statistically significant differences in age of the patients between the two groups.

Table 2: Mean and standard deviation (SD) of weight and their test of significance.

Weight (kg)	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
	55.85 ± 6.52	56.35 ± 6.42	>0.05

When the weight of the patients in the two groups were compared using the Student's test, the p value was > 0.05. So, there was no statistically significant differences in weight of the patients between the two groups.

Table 3:Distribution of patients by Sex.

Sex	Group A	Group B	Percentage
	Male 24	Male 27	40
	Female 16	Female 13	32

Table 4: Onset of Analgesia

Onset	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
	19.33 ± 2.28	19.45 ± 1.66	>0.05

Comparison of onset of analgesia in the two groups using students t test shows no statistically significant difference as the p value is > 0.05.

Table 5: Comparison of Level of Analgesia

Group A		Group B		Significance
Level of Analgesia	No. of patients	Level of Analgesia	No. of patients	
T5	8	T5	7	>0.05
T6	22	T6	23	
T7	10	T7	10	

Applying a Chi-square test no statistically significant difference in the level of analgesia was found between the two groups as the p value was greater than 0.05.

Table 6:Mean and standard deviation of heart rate at different points of time and their p-values.

Point of time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
0 min.	80.40 ± 7.25	82.90 ± 8.10	>0.05
10 min.	79.55 ± 7.10	81.60 ± 7.31	>0.05
20 min.	73.05 ± 5.40	70.90 ± 6.78	>0.05
30 min.	69.35 ± 6.13	68.25 ± 3.86	>0.05
1 hr.	70.00 ± 3.92	75.75 ± 4.41	>0.05
2 hrs.	72.45 ± 5.76	71.75 ± 5.01	>0.05
3 hrs.	76.35 ± 8.73	73.95 ± 6.32	>0.05
4 hrs.	74.30 ± 5.09	74.40 ± 5.19	>0.05
5 hrs.	79.50 ± 5.72	81.25 ± 5.02	>0.05
6 hrs.	75.25 ± 6.44	76.02 ± 4.49	>0.05

The heart rate were compared at 0min, 10min, 20min, 30min, 60min, 120min, 180min, 240min, 300min and 360min by applying students t-test. No statistically significant difference was found between the two groups.

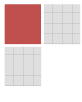
Table 7: Mean and standard deviation of Systolic Blood Pressure at different point of time in each group and their p-value.

Point of Time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
0 min.	127.90 ± 6.39	127.95 ± 6.33	>0.05
10 min.	126.58 ± 6.49	126.90 ± 6.75	>0.05
20 min.	114.40 ± 10.27	115.05 ± 9.82	>0.05
30 min.	113.80 ± 10.99	113.85 ± 10.76	>0.05
1 hr.	112.90 ± 8.29	108.40 ± 5.75	>0.05
2 hrs.	118.55 ± 7.70	118.55 ± 7.70	>0.05
3 hrs.	129.45 ± 5.96	127.70 ± 6.28	>0.05
4 hrs.	125.85 ± 6.44	124.50 ± 6.51	>0.05
5 hrs.	127.85 ± 5.95	127.65 ± 5.00	>0.05
6 hrs.	120.85 ± 3.50	120.50 ± 3.84	>0.05

The systolic blood pressure were compared at 0min, 10min, 20min, 30min, 60min, 120min, 180min, 240min, 300min and 360min by applying students t-test. No statistically significant difference was found between the two groups.

Table 8: Mean and standard deviation of Diastolic Blood Pressure at different point of time in each group and their p-value.

Point of Time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
0 min.	79.40 ± 5.82	79.40 ± 5.82	>0.05
10 min.	76.90 ± 6.55	76.90 ± 6.55	>0.05
20 min.	70.75 ± 9.34	70.55 ± 9.42	>0.05
30 min.	71.70 ± 9.23	71.50 ± 9.40	>0.05
1 hr.	72.90 ± 7.66	71.68 ± 5.69	>0.05
2 hrs.	74.65 ± 6.92	74.40 ± 7.03	>0.05
3 hrs.	80.25 ± 6.61	79.25 ± 5.87	>0.05
4 hrs.	77.05 ± 6.23	77.05 ± 6.23	>0.05
5 hrs.	78.90 ± 5.40	80.05 ± 4.55	>0.05
6 hrs.	74.90 ± 5.16	74.90 ± 5.16	>0.05



The diastolic blood pressure were compared at 0min, 10min, 20min, 30min, 60min, 120min, 180min, 240min, 300min and 360min by applying students t-test. No statistically significant difference was found between the two groups.

Table 9: Mean and standard deviation of Respiratory Rate at different point of time in each group and their p-value.

Point of Time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
0 min.	16.55 ± 1.01	16.95 ± 2.26	>0.05
10 min.	16.10 ± 1.01	16.20 ± 1.86	>0.05
20 min.	16.65 ± 1.23	16.35 ± 2.12	>0.05
30 min.	16.95 ± 2.17	17.10 ± 1.92	>0.05
1 hr.	17.10 ± 1.92	16.55 ± 2.26	>0.05
2 hrs.	17.35 ± 1.99	17.95 ± 2.37	>0.05
3 hrs.	17.90 ± 2.17	17.65 ± 2.02	>0.05
4 hrs.	17.65 ± 2.16	17.65 ± 2.16	>0.05
5 hrs.	18.95 ± 1.66	18.25 ± 2.72	>0.05
6 hrs.	19.90 ± 1.50	19.70 ± 2.74	>0.05

The respiratory rate were compared at 0min, 10min, 20min, 30min, 60min, 120min, 180min, 240min, 300min and 360min by applying students t-test. No statistically significant difference was found between the two groups.

Table 10: Mean and standard deviation of SpO_2 at different point of time in each group and their p-value.

Point of Time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
0 min.	98.08 ± 1.58	98.08 ± 1.58	>0.05
10 min.	98.20 ± 1.34	98.20 ± 1.34	>0.05
20 min.	97.83 ± 1.34	97.83 ± 1.34	>0.05
30 min.	96.83 ± 1.17	96.83 ± 1.17	>0.05
1 hr.	96.53 ± 1.36	96.53 ± 1.36	>0.05
2 hrs.	96.38 ± 1.25	96.38 ± 1.25	>0.05
3 hrs.	96.65 ± 1.21	96.65 ± 1.21	>0.05
4 hrs.	96.70 ± 1.30	96.70 ± 1.30	>0.05
5 hrs.	96.65 ± 1.21	96.38 ± 1.21	>0.05
6 hrs.	96.25 ± 1.37	96.25 ± 1.37	>0.05

The SPO2 pressure were compared at 0min, 10min, 20min, 30min, 60min, 120min, 180min, 240min, 300min and 360min by applying students t-test. No statistically significant difference was found between the two groups.

Table 11: Mean and standard deviation of VAS score at different point of time in each group and their p-value.

Point of Time	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
1 hr.	0.33 ± 0.47	NA	NA
2 hrs	0.52 ± 0.82	0.15 ± 0.36	<0.01
2.5 hrs	2.38 ± 0.94	2.18 ± 0.81	<0.001
3 hrs	5.44 ± 0.97	2.08 ± 0.80	<0.001
3.5 hrs	NA	2.30 ± 0.61	NA
4 hrs	NA	2.75 ± 0.67	NA
4.5 hrs	NA	3.23 ± 0.87	NA
5 hrs	NA	4.86 ± 1.03	NA
6 hrs	NA	NA	NA

The VAS score were monitored at 1hr, 2hrs, 2.5hrs, 3hrs, 3.5hrs, 4hrs, 4.5hrs, 5hrs and 6hrs. They were compared at every point of time and was found statistically significant by student t-test ($p<0.05$) at around 2hrs, 2.5hrs and 3hrs of monitoring when the mean VAS scores were 0.52 ± 0.82 & 0.15 ± 0.36 and 2.38 ± 0.94 & 2.18 ± 0.81 and 5.44 ± 0.97 & 2.08 ± 0.80 for group A & group B respectively.

Table 12: Comparison of Duration of Analgesia

Group	Group A Mean ± (SD)	Group B Mean ± (SD)	p-value
A	180.00 ± 15.19	300.88 ± 22.07	<0.001

The mean duration of analgesia was 180 ± 15.19 minutes in group A patients and 300.88 ± 22.07 minutes in group B patients. The duration of analgesia is significantly longer in group B patient than in group A patients. The p value obtained by students t test was less than 0.05.

Table 13: Comparison of Side Effects in Two Groups.

Side Effects	Group A	Group B
Respiratory rate < 10/min.	0	0
Pruritus	0	0
Vomiting	0	0
Urinary retention	0	1 (2.5%)
Nausea	0	4 (10%)
Somnolence	0	5 (12.5%)

Somnolence was the most common side effect occurring in 12.5% in group B but noticed in patients of group A. Nausea occurred in 10% patients of group B. Urinary retention occurred in 2.5% patients of group B. Respiratory depression, vomiting or pruritus was not observed in any of the patients of either group.

Discussion

In this study the mean duration of analgesia in Group A patients was found to be 180.00 ± 15.19 mins, whereas in Group B patients it was 300.88 ± 22.07 mins.

Baraka & Colleagues reported effective analgesia of 24 hrs with epidural morphine & tramadol [1].

Dellikan et al have reported it to be 9.36 hrs by using tramadol 100mg epidurally [2].

Rud & Fisher et al and Siddik et al found that duration of pain relief after 100 mg tramadol epidurally to be 4.5 ± 3.1 hrs [3,4].

FU and colleagues (1991) reported 12 hrs. of analgesia with tramadol 50 mg & 11.5 hrs with 75 mg tramadol with low VAS scores [5].

Rajib Bhattacharya and Bhashkar Dutt carried out a prospective, randomized and controlled study involving 90 patients of ASA physical status I and II coming for elective lower limb orthopaedic surgeries carried under spinal anaesthesia 2.5 ml bupivacaine and epidural bupivacaine with tramadol. The duration of analgesia was 206.8 ± 97.5 min and 399.3 ± 152.1 min respectively [6].

Choudhary AH. compared caudal 0.5 ml/kg bupivacaine 0.25% plus ketamine and bupuvacaine 0.25% plus tramadol and showed significant long duration of analgesia without increase in adverse effects when compared with bupivacaine alone [7].

The data derived from this study were closely related to the above mentioned studies and were found to be statistically significant ($p<0.001$) when compared between the two groups (Group A & Group B). (Table XII).

VAS SCORE

Visual Analogue Scale (VAS) score was applied to assess pain following surgery in the patients of both the groups and they were monitored in the Post Anaesthetic Care Unit (PACU) for VAS score at an one hour intervals for four hours, starting at the second hour from the time of epidural injection i.e. for six hours from the administration of the epidural injection. Rescue analgesic was given to each patient when the VAS score was greater than or equal to 4, and on demand when the VAS scores were noted accordingly. As the VAS score was a subjective mode of measurement, the scores varied widely according to the pain threshold of individual patients in each group.

It was found that the patient of Group A received rescue analgesic at around the two and half hour and the third hour of observation where the mean VAS score was noted as 2.38 ± 0.94 & 5.44 ± 0.97 respectively. But in the patients of Group B, no rescue analgesic was needed at around the two and half hour or third hour of observation where the mean VAS score was found as 2.18 ± 0.81 and 2.08 ± 0.80 respectively. These observations at the two and half hour and third hour of monitoring were found to be statically significant, ($p<0.001$). The Group B patients received rescue analgesics at the fifth hour of monitoring when the mean VAS score were recorded as 4.86 ± 1.03. The VAS score of the patients at the fourth, fifth and sixth hours of monitoring could not be statistically compared with the Group A patients, as the latter group had already received rescue analgesic earlier (Table XI). It was found that due to differences in individual pain threshold, the VAS score varied widely with the administration of rescue analgesics on demand.

Anis Aribogan and Colleagues found lower VAS score in the group receiving bupivacaine with tramadol epidurally ($p<0.05$) similar to our study [8].

Lin WQ et al. obtained similar result too [9].

Haemodynamic Status

In this study, no statistically significant difference was observed regarding heart rate and blood pressure between the two groups which were monitored at 10, 20, 30, 60, 120, 180, 240, 300 & 360 mins intervals till six hours since the time of epidural injection. These findings corroborated to the study of Baraka and Colleagues [1] (Table VI, VII & VIII).

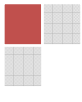
Side Effects

Early or late respiratory depression in a major concern with epidurally administered opioids. Dellikan et al concluded that 100 mg epidural tramadol gives better analgesia than 10 ml 0.25% bupivacaine. They showed respiratory depression not significant with epidural tramadol [2].

In this study all the patients were observed for six hours from the time of epidural injection and none of them were found to have respiratory depression. (Table XIII).

In this study, only 4 patients (10%) of Group B complained of nausea. Only one patient (2.5%) of Group B developed urinary retention (Table XIII). Baraka and Colleagues reported nausea and vomiting in 20% of patient with tramadol epidurally which was closely related to this study [1].

In the study somnolence was noticed in 5 (12.5%) patients from Group B (Table XIII). Vickers and Colleagues reported sedation potential of tramadol to be 1.1% [10].



In this study no patient from either group was reported to have vomiting or pruritus. Baraka & Colleagues found itching in 10% of tramadol treated patient [1].

Summary and Conclusion

Epidural administration of local anaesthetic with opioids can provide very good analgesia during and after surgical procedures of lower extremity.

In this study 80 patients of age group between 20 and 70 years were selected and were randomly allocated in two equal groups Group A (n=40) and Group B (n=40). Group A received 0.5% bupivacaine (15-20 ml) with 0.9% saline (1 ml) through epidural route whereas Group B patients received 0.5% bupivacaine (15-20 ml) with tramadol (50 mg) epidurally.

These patients were monitored in the PACU maintaining double blind protocol for 6 hours from the time to beginning of the epidural injection.

The two groups (Group A and Group B) were compared for duration analgesia using Visual Analogue Scale (VAS) score for pain for 6 hours which was explained to each patient previously during the preanaesthetic checkup. It was found that the mean duration of analgesia in Group B patients, who received 50 mg tramadol along with 0.5% bupivacaine (15-20 ml) epidurally was longer than the patients in Group A who received 0.5% bupivacaine and 1 ml of 0.9% saline in the same route.

This findings was found to be statistically significant ($p<0.05$).

All the patients of both the groups were monitored for blood pressure, heart rate, respiratory rate in the PACU and recorded in different intervals which were compared statistically. No significant difference was found between the two groups.

During the study, 4 patients (10%) complained of nausea, 1 patient (2.5%) developed urinary retention and somnolence was found in 5 (2.5%) patients of group B.

None of the patients from each group was found to have respiratory rate les s than 10 breaths per minute and no patient from any group was found to have vomiting or pruritus.

In conclusion, in the study using 1 ml (50 mg) tramadol with 0.5% bupivacaine (15-20 ml) through epidural route in patients for short surgical procedures in lower extremity & lower abdomen it was found that mean duration of analgesia was significantly longer than the patients who received 15-20 ml 0.5% bupivacaine only through the same route. It was also found that there was no significant difference regarding the mean onset of analgesia between the two groups.

A few patients who received tramadol with 0.5% bupivacaine were found to have nausea (10%), urinary retention (2.5%) and somnolence was found in 12.5% patients in PACU postoperatively which were not significant.

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References

[1]. Baraka A, Jabbour S, Ghabash M, Nader A, khoury G, Sibai A. Comparison of epidural tramadol & epidural morphine for post operative analgesia. Can J Anesth 1995; 40;308-13.

[2]. Dellikan AE, Vijayan R-Epidural tramadol for post operative to pain relief. Anaesthesia. 1993; 48(4):328-31.

[3]. Rud U Fisher MV et al. post operative analgesia with tramadol. Anaesthesia 1995; 43(5) : 316-21

[4]. Siddik – Sayyid S, Aouad Maroun M et al. Epidural tramadol for post-operative pain relief Can J Anaesth 1999; 46(8):731-5.

[5]. FU YP, Chan KH, Lee TK, Chang JC, Daiy YP, Lee TY Epidural tramadol for post operative pain relief. Ma Jin Xeu Za. Zhi 1991;29:648-52.

[6]. Bhattacharya Rajib, Dutta Bhaskar : Post operative analgesia with LA and opioid combination. Indian Journal of Anaesthesia 2007; 51(5):409-414

[7]. Choudhary AH, Dharmani P, Prakash N comparison of caudal epidural, bupivacaine with bupivacaine plus tramadol & bupivacaine plus ketamine for post operative analgesia in Children Anaesth. Intensive Care 2008 Mar. ; 36(2):174-9.

[8]. Anis Airbogan and Colleagues : comparison of tramadol with or without bupivacaine after major urologic studies. Uro Int 2003; 71:168-75.

[9]. Lin WQ, Zing WA et al comparison of post-operative analgesia with tramadol, morphine versus their combination undergoing abdominal cancer surgery. Ai Zheng 2002; 21(7) 794-6.

[10]. Vickers MD, Parvinic D comparison of tramadol with morphine for abdominal Surg. Eur J Anesth 1995; 12:268-7.