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Comparative Study of Postoperative Analgesia with Epidural Bupivacaine Versus Epidural Bupivacaine and Tramadol

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Abstract

Background: Pain is constant and predominant complaint of individual following, most surgical intervention. Epidural narcotics have been in large number of studies for treatment of postoperative epidural n arcotic like morphine has adverse effects like respiratory depression, drug dependence and cannot be used in elderly. Hence this clinical study of epidural bupivacaine and epidural bupivacaine plus tramadol is undertaken to evaluate the feasibility has ef fective analgesia for postoperative pain relief. *Objectives:* To compare epidural bupivacaine and epidural bupivacaine plus tramadol for postoperative analgesia focusing on onset of analgesia, duration of analgesia, cardiorespiratory effects like pulse rate, blood pressure and respiratory rate, sedation. *Methods:* 100 patients belonging to ASA physical status I & II scheduled for abdominal, pelvic, lower limb surgeries, were randomly selected for study are divided into two groups of 50 patients each. Group B patient received 10 ml of 0.125% bupivacaine epidurally. Group B+T patient received 10ml of 0.125% bupivacaine+ 50 mg tramadol epidurally during their postoperative period, when they complain pain for the first time onset and duration of analgesia, haemodynamic parameters and adverse effects if any were studied. *Results:* There was no significant difference be tween two groups in mean time of onset of analgesia, 14.40±0.85 minutes with group B and 14.62±0.69 minutes with group B+T (p-value 0.14), total duration of analgesia in group B was 231.6±9.1 minutes and in group B+T was 350.60±15.9 minutes which was significant (p-value <0.05). Quality of postoperative analgesia, haemodynamic parameters and side effects were comparable between both groups. *Conclusion:* Epidural bupivacaine (10ml of 0.125%) plus 50 mg tramadol combination not only provides an adequate, rapid, excellent postoperative analgesia, but also has significant longer duration of analgesia compared to bupivacaine alone.

Keywords: Bupivacaine; Tramadol; Epidural; Postoperative Analgesia.

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Introduction

Pain has been a major concern of humankind since our beginning and it has been the object of ubiquitous efforts to understand and to control it. Today, as then, proper management of pain remains one of the most important and most pressing issues of society in general, the scientific community and the health care professionals in particular.

Pain is a consistent and predominent complaint of most individuals following most surgical interventions. Because of pain, these disadvantaged patients are often unable to breathe adequately and cough effectively. They may not be able to move enough even to carry out their own daily needs.

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Due to this, they may experience feelings of helplessness, fear, anxiety, low mode and loss of self control. The anesthesiologists, the health care providers have, the first and foremost, a moral and ethical obligation to help all patients manage their pain adequately, which may lead to better outcomes for both the patient and the health care system.

Various modalities have been tried to relieve the post-operative pain. Epidural analgesia with various drugs have been tried. Epidural narcotics have been tried in large number of studies for the treatment of post-operative pain. Epidural narcotics like morphine have adverse effects like, respiratory depression, drug dependence, pruritis and cannot be used in the elderly.

Tramadol, an opioid agonist and monoamine reuptake blocker has been shown to be a peri-operative analgesic without respiratory depression. It's analgesic potency is 1/5th to 1/10th as morphine. But it also has side affects like nausea, vomiting, urinary retention and hypotension.

Management of post operative pain is one of the most challenging and gratifying domains of anaesthesia. Use of epidural blockade has increased steadily in popularity for the management of moderate to severe pain following surgery. Anaesthetic drugs like lignocaine, bupivacaine along with analgesic additives like opioids and tramadol has been tried to reduce the post operative pain.

Bupivacaine is a local anesthetic drug belonging to amino amide group. It is the most commonly used local anesthetic in epidural anesthesia in post operative pain management. However sequel of sympathetic blockade like hypotension, urinary retention and loss of perineal sensation can occur with epidural bupivacaine. Bupivacaine is the currently available local anaesthetics with long duration of action and its maximum analgesic effect is upto 6-12 hours [1,2].

In recent years use of epidural narcotics has become wide spread. However the side effects like nausea, vomiting, and respiratory depression have lead to search for drugs with least side effects. Low dose offers new dimensions in the management of post-operative pain in Epidural administration of opioids in combination with local anaesthetic agents [3].

Tramadol, a synthetic opioid of amino cyclo hexanol group with analgesic properties has a low preferential action at mu opioid receptor. Tramadol, a synthetic 4-phenyl-piperidine analog of codeine, is a racemic mixture of two enantiomers, with synergistic anti-nociceptive interaction [4].

Equi analgesic dose of tramadol has much less effect on respiratory centre and thus has a high therapeutic action. Tramadol is equal in potency to pethidine. Epidural tramadol can provide effective post operative analgesia.

Hence this clinical study of epidural bupivacaine in comparison with epidural bupivacaine and tramadol is under taken to evaluate their feasibility as effective analgesics for post-operative pain relief.

The aim of present study is to determine the Effectiveness of Bupivacaine and Bupivacaine with Tramadol in post operative pain management.

Objectives

Comparison of epidural bupivacaine and epidural bupivacaine with tramadol for postoperative analgesia in relation with Onset of analgesia, Duration of analgesia, Cardio respiratory effects like pulse rate, blood pressure and respiratory rate and Sedation.

Methodology

The present study was conducted on patients undergoing surgery in Bapuji Hospital, Chigateri General Hospital and Women and Children Hospital attached to J.J.M. Medical College, Davangere.

Methods for Collection of Data

100 patients undergoing gynecological, lower abdominal, lower limb and urological surgeries would be randomly selected. Informed consent would be taken. Result values recorded using a preset proforma.

Inclusion Criteria

- ASA class I and II
- Aged between 20 to 60 years
- SBP 100-139- mmgHg
- DBP 60-89 mmgHg

Exclusion Criteria

- All patients above ASA-III grade
- All known contraindications to epidural anaesthesia like

① Patients with raised intracranial pressure

② Coagulation defects or haemophiliacs and patients on anticoagulants.

③ Uncooperative or apprehensive patients

④ Severe haemorrhage or shock

⑤ Local inflammation / infection

- In patients where epidural anaesthesia had to be converted to general anaesthesia.
- Patients who are pregnant and lactating mothers.

Anaesthesia Technique

The present study conducted on patients two groups of 50 each randomly

a. Group B - Patient receiving epidural 10 ml of bupivacaine (0.125%).

b. Group B+T - Patient receiving epidural 10 ml of bupivacaine (0.125%) and tramadol (50 mg).

After aseptic preparation of skin and local infiltration, an epidural puncture would be made by loss of resistance technique to air at L3/L4 or L2/L3 with Tuohy needle. Epidural catheter passed through the needle. Needle removed and catheter secured. 3cc of 2% xylocaine with adrenaline would be given as test dose. Intra operative anaesthesia achieved by sole epidural anaesthesia technique. The study begins in the post operative ward, when patient complained of pain, clinically correlating with visual analogue score (VAS) of 3, the test drug would be given epidurally by a randomized single blinded manner and onset of analgesia, duration of analgesia, vital parameters and sedation are noted.

Investigations like: Blood : Haemoglobin, TC, DC, BT, CT, RBS, Blood urea, Serum creatinine, HbsAg, HIV Chest X-ray, ECG Urine: Albumin, sugar and microscopy.

Observations made

a. Onset of analgesia

b. Duration of analgesia:

Duration of analgesia was calculated from the time of giving the drug to VAS score > 3.

c. Degree / quality of analgesia:

Quality of analgesia was assessed by Verbal response score.

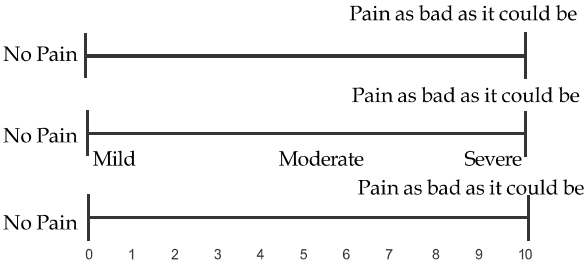

Fig. 1: Visual analogue score

Five point verbal response score (VRS)

Score	Subjective	
0	No pain relief	0%
1	Little (poor) pain relief	25% pain relief
2	Some (fair) pain relief	50% pain relief
3	A lot of (good) pain relief	75% pain relief
4	Complete pain relief	100% pain relief

d. Cardio-respiratory effects:

Cardiorespiratory effects were assessed by monitoring PR, SBP, DBP, and RR at 0, 1, 3, 5, 10, 20, 30, 45 and 60 minutes.

e. Side effects (if any) were noted

All the observations and particulars of each patient were recorded in a proforma.

Statistical Analysis

Descriptive statistics such as mean, SD and percentage was used to present the data. Comparison between two groups for quantitative data was done by using student 't test and for qualitative data was done by using chi-square test. A p-value less than 0.05 were considered as significant.

Results

The minimum age of the patient was 21 years and maximum age was 60 years. Age incidences between the two group were comparable.

In group B there were 2 males (4%) and 48 females (96%). In group B+T there were 4 males (8%) and 46 females (92%), sex distribution between the two groups were comparable.

Table 1: Time of onset of analgesia

Parameter	Bupivacaine		Bupivacaine + Tramadol		Mean Diff.	P- value
	Mean	SD	Mean	SD		
Onset of analgesia (min)	14.40	0.857	14.62	0.635	0.220	0.148 NS

Table 2: Duration of analgesia and Quality of analgesia

Parameter	Bupivacaine		Bupivacaine + Tramadol		Mean Diff.	P-value
	Mean	SD	Mean	SD		
Duration (min)	231.6	9.116	350.60	15.960	119.0	<0.001 Significant
Quality of analgesia	3.74	0.44	3.84	0.37	0.1	0.224 NS

Table 3: Pulse rate

Pulse rate (beats/min)	Bupivacaine		Bupivacaine + Tramadol		Mean diff.	p- value	Sig.
	Mean	SD	Mean	SD			
0 min	86.62	8.03	85.04	7.53	1.58	0.31	NS
1 min	86.32	8.103	84.92	7.62	1.40	0.37	NS
3 min	85.54	7.56	84.24	7.54	1.40	0.35	NS
5 min	85.16	7.41	84.0	7.59	1.16	0.43	NS
10 min	83.78	7.77	83.96	7.40	0.18	0.90	NS
15 min	83.66	8.17	83.46	7.49	0.20	0.89	NS
20 min	82.94	8.56	83.50	7.82	0.56	0.73	NS
30 min	82.64	8.13	82.96	7.21	0.32	0.83	NS
45 min	82.46	7.79	82.68	7.04	0.22	0.88	NS
60 min	81.62	6.84	82.72	7.23	1.1	0.43	NS

Table 4 : Systolic blood pressure (SBP)

SBP (mmHg)	Bupivacaine		Bupivacaine + Tramadol		Mean diff.	p- value	Sig.
	Mean	SD	Mean	SD			
0 min	123.2	5.55	120.32	6.53	2.88	0.001	S
1 min	123.04	5.49	119.84	6.33	3.20	0.02	S
3 min	120.80	5.64	118.00	5.99	2.80	0.008	S
5 min	119.64	5.85	116.48	6.17	3.16	0.01	S
10 min	118.24	5.68	115.20	5.88	3.04	0.01	S
15 min	117.05	5.88	113.40	6.03	3.64	<0.00	S
20 min	115.28	5.56	111.72	5.98	3.56	<0.00	S
30 min	114.12	5.53	110.32	5.90	3.80	<0.00	S
45 min	112.28	5.48	109.32	5.56	2.96	0.001	S
60 min	110.72	4.94	108.48	5.42	2.24	0.03	S

The mean time of onset of analgesia in group B was 14.40±0.857 minutes, in group B+T the mean time of onset was 14.62±0.635. The findings showed that the difference between the time of onset of analgesia in the two groups were statistically not significant (p=0.148) (Table 1).

The mean duration of analgesia in group B was 231.6±9.116 minutes and in group B+T was 350.60±15.960 minutes. The findings showed that time duration of analgesia in group B+T was statistically significant more compared to Group B (p<0.0001). In group B the mean of the quality of analgesia assessed by visual response score was 3.74 and in group B+T, mean score was 3.84. The findings showed that the quality of analgesia between the two groups were statistically insignificant (p=0.22) (Table 2).

The results revealed that the pulse rate between the two groups measured at 0, 1, 3,5, 10, 15, 20,30,45 and 60 minutes were statistically insignificant (p>0.05) (Table 3).

The result showed that the systolic blood pressure between the two groups measured at 0,1,3,5,10, 20,30,45 and 60 minutes were statistically significant (p<0.0001) (Table 4).

Statistical analysis by student s unpaired-t test showed that the diastolic blood pressure between the two groups measured at 0, 1, 3, 5, 10, 15, 20, 30, 45, and 60 minutes were statistically significant (Table 5).

Statistical analysis by student s unpaired-t test showed that the respiratory rate between the two groups measured at 0, 1, 3, 5, 10, 15, 20, 30, 45, and 60 minutes were statistically insignificant (Table 6).

In group B no side effects seen and in group B+T 4, patients had sedation. There is no significant difference of side effects between two groups (p=0.13) (Table 7).

Discussion

Management of post-operative pain still poses lot of challenge to anaesthetists paradoxically after all the efforts taken to make the intra-operative period pain free and stress free, the patient is left to fend themselves in the post-operative period.

"Pain free at rest" is a reasonable aim. Pain relief is necessary for both humanitarian and therapeutic reasons. Uncontrolled pain in the postoperative period can have detrimental physiological effects.

1. Pain can greatly impede the return of normal pulmonary function, inability to cough, bronchospasm–all leads to atelectasis and hypoxemia especially in upper abdominal and thoracic surgeries.
2. Pain promotes immobility and hence the development of deep vein thrombosis.
3. Alteration in the stress response to surgery, increased catecholamine release, increased oxygen demand and increased cardiac work.
4. Increased catabolic response to surgical trauma and impaired immune mechanisms and delayed wound healing.

Table 5: Diastolic blood pressure (DBP)

DBP (mmHg)	Bupivacaine		Bupivacaine + Tramadol		Mean diff.	p- value	Sig.
	Mean	SD	Mean	SD			
0 min	81.24	3.93	78.96	4.16	2.28	0.00	S
1 min	80.84	3.89	78.84	4.08	2.00	0.01	S
3 min	79.32	3.86	76.76	3.87	2.56	0.00	S
5 min	78.04	3.90	75.68	3.82	2.36	0.00	S
10 min	77.12	4.06	74.40	3.93	2.72	0.00	S
15 min	75.88	4.48	73.04	3.92	2.84	0.00	S
20 min	74.68	4.34	72.00	3.65	2.68	0.00	S
30 min	73.04	3.90	71.08	3.75	1.96	0.01	S
45 min	72.32	3.64	70.24	4.07	2.08	0.00	S
60 min	71.36	3.39	69.96	4.05	1.40	0.06	NS

* Student s unpaired „t test

Table 6: Respiratory rate (rr)

Respiratory rate (RR)	Bupivacaine		Bupivacaine + Tramadol		Mean diff.	p- value	Sig.
	Mean	SD	Mean	SD			
0 min	16.24	1.09	15.94	0.89	0.30	0.13	NS
1 min	16.16	1.06	15.74	0.94	0.40	0.05	NS
3 min	15.82	0.96	15.50	0.90	0.32	0.09	NS
5 min	15.62	1.04	15.42	1.03	0.20	0.33	NS
10 min	15.48	0.93	15.20	1.05	0.28	0.16	NS
15 min	15.18	0.87	14.96	1.02	0.22	0.25	NS
20 min	15.06	0.81	14.94	0.95	0.12	0.50	NS
30 min	15.08	0.77	14.80	0.94	0.28	0.11	NS
45 min	14.88	0.68	14.60	0.96	0.28	0.09	NS
60 min	14.72	0.75	14.36	0.94	0.36	0.03	S

* Student s unpaired t-test

Table 7: Side effects

Side effects	Bupivacaine		Bupivacaine + Tramadol		P-value
	No	%	No	%	
Nil	50	100	46	92	0.13
Sedation	0	0	4	8	

Hence, its relief undoubtedly decreases morbidity and mortality. In recent times, the role of epidural tramadol for the relief of postoperative pain promotes a new platform in this field. This is because of low preferential action at μ opioid receptor. Equation an analgesic dose of tramadol than much less effect on respiratory center and than has a high therapeutic action.

Bupivacaine is a long acting amide local anesthetic. It is 3-4 times more potent than lignocaine. It was synthesized by Ekenstam et al in 1957. Bupivacaine when used epidurally for postoperative analgesia causes good pain relief with mild hypotension and motor blockade as its chief side effects.

Here an attempt is made to assess the efficacy of Bupivacaine and Bupivacaine + Tramadol combination through epidural route in management of postoperative pain.

A total number of 100 patients, belonging to age group 20-60 have been taken. Out of which mean age of Group B (receiving epidural Bupivacaine was 41.9 years and in group Bupivacaine + Tramadol was 42.3 years. Hence, all of these groups were comparable as regards to age.

Patients undergoing lower abdominal, lower limb gynaecological and urological surgeries were selected, patients were randomly divided in 2 groups of 50 each; group B (Bupivacaine) and group B+T (Bupivacaine + Tramadol). All surgeries were done under epidural anaesthesia. In postoperative period as soon as patients complained of pain, patients in group B received 10 ml of 0.125% isobaric bupivacaine and group B+T received 10 ml of 0.125% isobaric Bupivacaine + 50 mg Tramadol epidurally.

Onset of Analgesia

In our study, the mean time of onset of analgesia in group B (Bupivacaine) was 14.40 minutes and in group B+T (Bupivacaine + Tramadol) was 14.62 minutes. The statistical analysis showed that, the difference in time of onset of analgesia in the 2 groups were statistically insignificant ($p>0.05$).

A study comparing combination of 50 mg Tramadol to 0.5% Bupivacaine and 50 mg fentanyl + 0.5% bupivacaine, by Duman A, et al. shown that there is no difference in the onset of analgesia in combination of 50 mg Tramadol to 0.5% Bupivacaine. These findings were similar to our study [5].

Duration of Analgesia

In our study the mean duration of analgesia in group B was 231.6 minutes and in group B+T was 350.6 minutes. The duration of analgesia when compared between the two groups was statistically significant ($p<0.001$).

In a study by Saleem Sabar et al. [6], 60 patients equally divided into 2 groups. Group I received 0.5% Bupivacaine 20ml epdiurally and group II received 0.5% Bupivacaine 20 ml and Inj. Tramadol 1.5mg/kg epidurally. The results were out of 60 patients the duration of postoperative analgesia in group I was 3.8±0.28 hours and in group II it was 7.60±0.31. Conclusion was that addition of tramadol 1.5 mg/kg to 0.5% Bupivacaine given epidurally produces prolonged postoperative analgesia as compared to Bupivacaine alone in patients undergoing lower abdominal surgeries. In the study by Singh et al the mean duration of analgesia in Group A patients was found to be 180.00±15.19 minutes, whereas in Group B patients it was 300.88±22.07 minutes [3].

Quality of Analgesia

Quality of analgesia was assessed at the time when rescue analgesia was given to the patient using verbal response score. In our study there was no significant difference in the quality of analgesia between in the two groups.

Saleem Sabar et al. [6], did a study comparing 0.5% bupivacaine and 0.5% Bupivacaine + 1.5 mg/kg Tramadol. Their study showed that both the group had effective analgesia and there was no difference in the quality of analgesia between the groups.

Cardio Respiratory Effects: Pulse Rate and Blood Pressure

In our study the two groups did not differ significantly in pulse rate and changes in these parameters were insignificant in these two groups and there was change in blood pressure, which was statistically significant between two groups in our study.

In a study by Saleem Sabar et al. [6], comparing 0.5% bupivacaine and 0.5% Bupivacaine + Tramadol showed that haemodynamic changes were similar and comparable between the two groups. The findings in above mentioned studies are comparable to our study.

Respiratory rate

In our study the two groups did not differ significantly in respiratory rate at any interval. The changes in the respiratory rate were insignificant between the two groups.

A study conducted by Saleem Sabar et al. [6], also showed that there were no significant changes in the respiratory rate between the two groups.

Side effects

In our study 4 patients in the Bupivacaine+ Tramadol group (B+T) had sedation. No patient in the Bupivacaine group had sedation. The side effects between the two groups were found to be insignificant.

A study conducted by Akrity et al. [7], also showed that the side effects were statistically insignificant between the two groups. In their study no patient in the Bupivacaine group had sedation. The findings in above mentioned studies are comparable to our study.

Conclusion

It was concluded that epidural Bupivacaine and epidural Bupivacaine + Tramadol combination provide an adequate, rapid and excellent postoperative analgesia.

The duration of analgesia was found to be longer when tramadol was added to Bupivacaine.

There were no significant differences in onset, quality of analgesia, respiratory effects when tramadol was added to Bupivacaine and there was significant fall in BP in both groups, which may be attributed by Bupivacaine. There was no significant increase in the incidence of side effects with the addition of Tramadol.

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