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A Comparative Study of Post Operative Pain Management with Epidural Bupivacaine and Tramadol in Lower Abdominal Surgeries

[1]Dr.N.Syama Kumar, Asst. Professor, [2]Dr.K.Nagabhushanam, Asst. Professor

Abstract:
Introduction*: Pain is a consistent and predominant complaint of most individuals following most surgical interventions. Epidural analgesia with various drugs has been tried. Epidural opioids and local anesthetics have been tried in large number of studies in the treatment of post-operative pain. This clinical study is undertaken comparing epidural bupivacaine and epidural tramadol to evaluate their efficacy for post-operative analgesia and side effect profile.*
AIMS*: 1.To compare the efficacy of drug formulations viz. epidurally administered tramadol, bupivacaine for providing pain relief for lower abdominal, pelvic and lower limb surgeries being done under combined spinal epidural anaesthesia.*
2. To compare the deg ree and duration of analgesia, cardiorespiratory effects and Side-effects
Results*: The mean time of onset of analgesia in group T was6.24±0.29 min (mean±SD), and in group B was 14.72±0.31 min (mean±SD).unpaired test shows significant (p<0.0001).Duration of analgesia in group T was155.3±4.67minutess,and in group B was 121.2±3.26minutesThis difference was clinically significant (p<o.oo1).Quality of analgesia : In group T (tramadol) good22(44%)to excellent17(34%) pain relief is seen,in group B (bupivacaine) fair 27(54%) to good 20(40%) pain relief is seen.*
Conclusion*: Epidural tramadol, provides an adequate, rapid and excellent postoperative analgesia compared to epidural bupivacaine.The duration and quality of analgesia was found to be longer and superior with the epidural tramadol than with bupivacaine of these groups. This study found statistically significant difference in onset of analgesia among these groups.*
Keywords: *Bupivacaine, Tramadol, Epidural, Onset of Analgesia, Quality of analgesia, Duration of analgesia, Sideeffects.*

I. Introduction

Pain is a consistent and predominant complaint of most individuals following most surgical interventions. The anesthesiologists 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 relive the post-operative pain. Epidural analgesia with various drugs has been tried. Epidural narcotics have been tried in large number of studies in the treatment of post-operative pain. Epidural narcotics like morphine have adverse effects like respiratory depression, drug dependence, pruritus 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 -1/10th of morphine .But it also has side effects like nausea, vomiting, urinary retention and hypotension. Bupivacaine, a long acting amide local anaesthetic can be tried for epidural post-operative analgesia. Bupivacaine has a long duration of action of 180-300 minutes, it has also less incidence of nausea, vomiting and pruritus when compared with opioids. However it can cause motor blockade and hypotension.

Hence this clinical study is undertaken comparing epidural bupivacaine and epidural tramadol to evaluate their efficacy for post-operative analgesia and side effect profile.

II. Aims And Objectives

1. To compare the efficacy of drug formulations viz. epidurally administered tramadol and bupivacaine for providing pain relief for lower abdominal, pelvic and lower limb surgeries being done under combined spinal epidural anaesthesia.
2. To compare the degree and duration of analgesia, cardiorespiratory effects and side-effects between epidural tramadol, and bupivacaine. The drugs used were bupivacaine 0.125 %, and tramadol100 mg.

III. Materials And Methods

The present clinical study was conducted to evaluate the efficacy and safety of epidural tramadol 100 mg, bupivacane (0.125%) for comparison of their post-operative pain relief. The study was undertaken in the Government General Hospital ,Guntur attached to Guntur Medical College, Guntur.

One hundred patients undergoing various lower abdominal, pelvic and lower limbs surgeries were selected randomly. All the patients were ASA-1 and ASA-II and were aged between 18-75 years.

The following patients were excluded from the study:

1) All patients above ASA grade III.
2) Patients physically dependent on opioids.
3) Patients below 18 years and above 75 years of age.
4) All pregnant patients.
5) All known contra-indications of epidural anaesthesia like,

a) Patients with raised intracranial tension.
b) Coagulation defects and patients on anticoagulants.
c) Uncooperative or apprehensive patients.
d) Severe hemorrhage or shock.
e) Local infection/inflammation.

Patients were randomly divided into two groups of 50 each Group B received injection Bupivacaine 0.125% (10CC) epidurally, Group T received injection Tramadol 100 mg epidurally during their postoperative period when they complained of pain for the first time.

Patients were visited on the previous day of the surgery, Basic laboratory investigations were carried out routinely on all patients. The entire procedure was explained to the patients and were asked to notify after surgery when the patient experiences pain. Patients were also explained about visual analogue scale (VAS) and were taught how to express the degree of pain in the scale. Written informed consent was taken from the patient.

Technique:

Baseline bloodpressure, heart rate and respiratory rate were noted. With all aseptic precautions a skin wheal was raised at L2 -L3 interspace with 2 cc of 1% lidocaine. The epidural space was identified using a 16G or 18G Touhy needle with loss of resistance to normal saline & air technique. Then 18G catheter was passed through the epidural needle till about 2-3 cm of the catheter is in the space. Then the needle was withdrawn and the catheter was fixed to the back.3 ml of 2% lidocaine with adrenaline 1:2,00,0000 was injected through the catheter as a test dose and observed for any intravascular or intrathecal injection. After confirming correct placement of catheter, spinal anesthesia at $L_3 – L_4$ was given. Dose of the drug was according to the patient ,type of surgery and duration of surgery. The cases in which epidural blockade was inadequate with the need to supplement general anaesthesia were excluded from the study.

Pain Management:

When the patients complained of pain, they were shown VAS and were asked to express intensity of pain on the scale. When it reached > 5 mark on the scale, a single dose of Bupivacaine (0.125%) 10cc, Tramadol 100 mg (10 cc) was injected through the epidural catheter. Assessment of pain relief was done at every five minutes for first half an hour and later every ½ hour by using a 5 point verbal response 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

Observations Made:

a) Onset of analgesia
b) Duration of analgesia
c) Degree/quality of analgesia
d) Cardio-respiratory effects
e) Side effects (if any) were studied.

Statistical Analysis: Continuous data was analyzed by student's t-test and categorical data by Chi-square test. Any possible significance has been determined considering it statistically significant if it's P < 5 % level of significance.

The statistical analysis of data is done using -

- Student t test for parametric data.
- Chi-square test for non parametric data

IV. Observations And Results

Age Distribution:

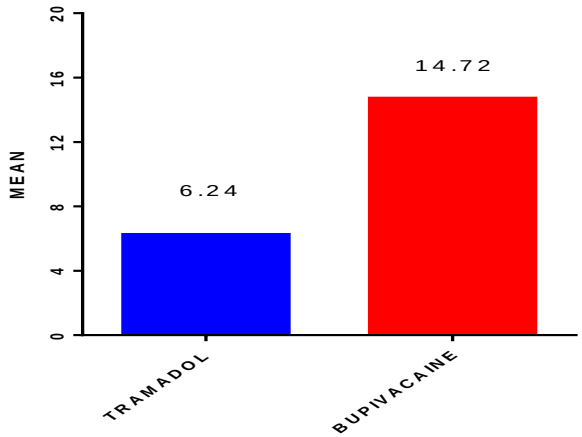
The minimum age of the patients was 18 years and maximum age was 75 years. Age incidences between the two groups were comparable. The mean age of Tramadol is 45.56 and mean age of Bupivacaine 44.58.Most of the patients in Tramadol group are in between 40 to 49 years (36%),in Bupivacaine group most of the patients in between 40 to 49 years(26%).

Sex Distribution:

In Group T there were 29 (58%) females&21(42%) males, in group B there were 26 (52%) females and 24 (48%) males.

Time Of Onset Of Analgesia;

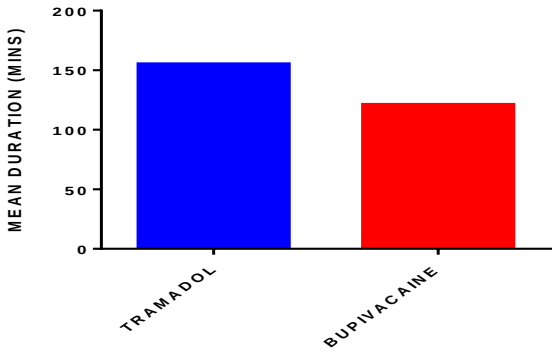
OOA(MINS)	TRAMADOL	BUPIVACAINE
MEAN	6.24±0.29	14.72±0.31
SD	2.07	2.25
RANGE	3-13	12-19



The mean time of onset of analgesia in Group T was 6.24±0.29 minutes, in group B was 14.72±0.31 minutes. The statistical analysis by Student's unpaired 't' test showed that the difference between the time of onset of analgesia in the 2 groups were statistically significant (p<0.0001) and t value is 19.63.

Duration Of Analgesia:

Duration(mins)	TRAMADOL	BUPIVACAINE
MEAN	155.3±4.67	121.2±3.26
SD	33.05	23.05
RANGE	90-210	75-190

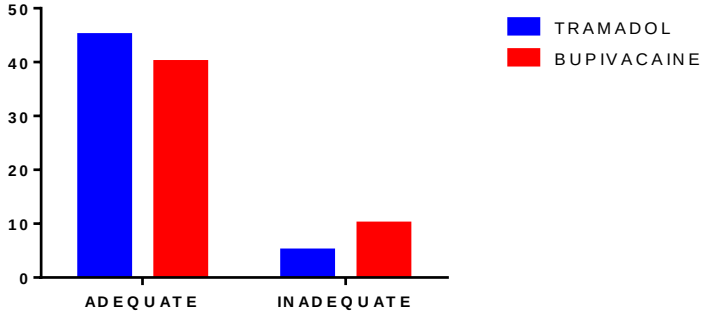


Duration of analgesia was observed in these 2 groups till patient asked for next dose of analgesic in post operative period, time was noted when patient asked for rescue analgesia. The mean duration of analgesia in Group T was 155.3±4.67 minutes in group B was121.2±3.26± minutes.

Statistical analysis by student's unpaired 't' test showed that time duration of analgesia in Group T was significantly more when compared to the Group B respectively.(t=5.988,p value<0.0001).

Quality Of Analgesia

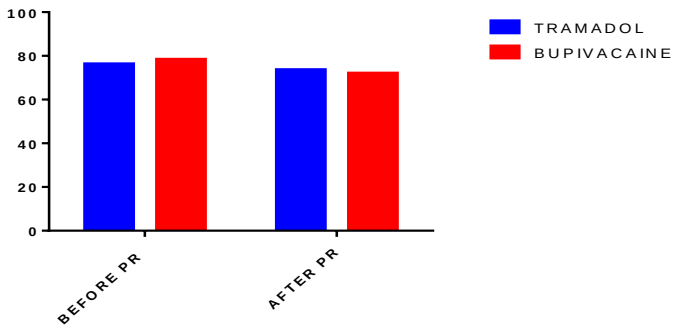
	QOA 1	QOA 2	QOA 3	QOA 4
TRAMADOL	0	11(22%)	22(44%)	17(34%)
BUPIVACAINE	1(2%)	27(54%)	20(40%)	2(4%)



In Group T had good 22(44%) to excellent 17(34%) pain relief and in group B fair 27(54%) to good 20(40%) pain relief.

Intra Group Comparison – Pulse Rate:

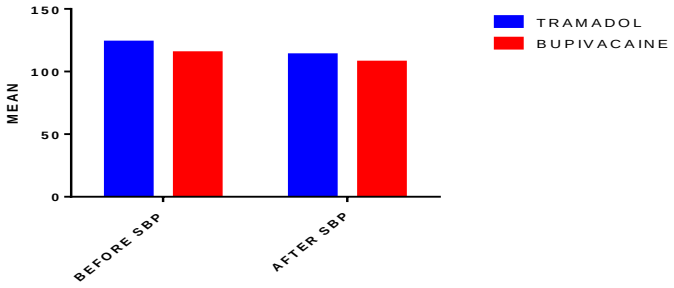
GROUPS	PR	Before	After	MD	P value
TRAMADOL	MEAN	76.30 ±0.78	73.65±0.74	2.65±1.08	0.0159 YES
	SD	5.54	5.27		
BUPIVACAINE	MEAN	78.36±1.37	72.08±1.03	6.28±1.71	0.0004 YES
	SD	9.70	7.31		



In bupivacaine group, significant decrease in pulse rate was observed in between15-90min. Also no incidence of bradycardia (pulse rate<60/min) was observed. In tramadol group fall in pulse rate is not as significant as bupivacaine group and the mean difference is 2.65±1.08.

Intra Group Comparison – Systolic Blood Pressure

GROUPS	SBP	BEFORE	AFTER	MD	SIGNIFICANCE
TRAMADOL	MEAN	123.6±1.26	113.4±1.03	10.16±1.63	P<0.0001 YES
	SD	8.947	7.344		
BUPIVACAINE	MEAN	115±0.92	107.5±0.66	7.52±1.13	P<0.0001 YES
	SD	6.518	4.706		



In Group T before giving tramadol systolic blood pressure was 123.6±1.26 mmHg. After giving tramadol systolic BP 113.4±1.03 was mmHg. In Group B before giving bupivacaine systolic blood pressure was 115±0.92mmHg. After giving bupivacaine systolic BP was 107.5±0.66. In both groups fall in systolic blood pressure is statistically significant.

Intra Group Comparision -Diastolic Blood Pressure

GROUPS	DBP	BEFORE	AFTER	MD	SIGNIFICANCE
TRAMADOL	MEAN	78.14±1.05	74.80±0.98	3.34±1.44	P<0.0228 YES
	SD	7.489	6.941		
BUPIVACAINE	MEAN	66.92±0.81	64.23±0.66	2.68±1.05	P<0.0123 YES
	SD	5.774	4.709		

In Group T before giving Tramadol diastolic blood pressure was78.14 ±1.05. After giving Tramadol diastolic blood pressure was 74.80±0.98 mmHg. In Group B before giving Bupivacaine diastolic blood pressure was 66.92±0.81 mmHg. After giving bupivacaine diastolic blood pressure was 64.23±0.66. In both groups fall in diastolic blood pressure is statistically insignificant.

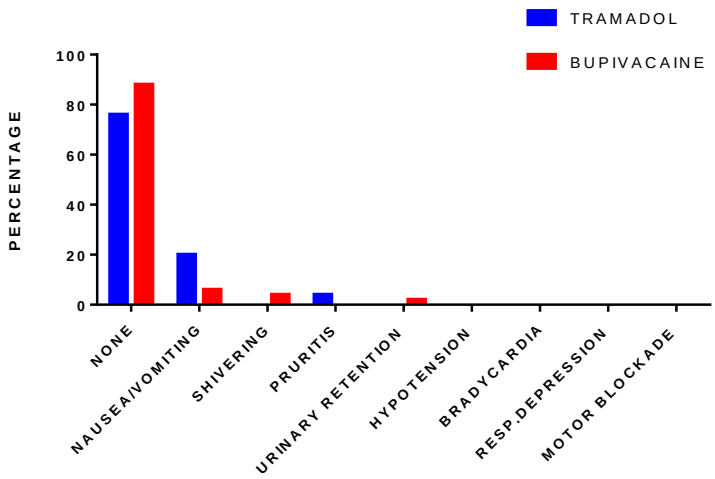
Intra Group Comparision –Respiratory Rate

GROUPS	RR	BEFORE	AFTER	MD	SIGNIFICANCE
TRAMADOL	MEAN	18.00±0.25	16.61±0.22	1.39±0.33	P<0.0001 YES
	SD	1.784	1.584		
BUPIVACAINE	MEAN	16.50±0.14	14.96±0.14	1.54±0.20	P<0.0001 YES
	SD	1.055	1.021		

In Group T before giving tramadol respiratory rate 18.00 ± 0.25cycles/min. After giving tramadol respiratory rate 16.61± 0.22 cycles/min. In Group B before giving Bupivacaine respiratory rate was 16.50±0.14 cycles/min. After giving bupivacaine respiratory rate was14.96±0.144.The fall in respiratory rate in both groups are statistically significant.

Side Effects

SIDE EFFECTS	TRAMADOL	BUPIVACAINE
Nausea&Vomiting	10	3
Shivering	0	2
Pruritus	2	0
Urinary retention	0	1
Hypotension	0	0
Bradycardia	0	0
Respiratory depression	0	0
NONE	38	44



In Group T 20% patients had nausea and vomiting 4% patient s had pruritus, and in Group B 6% had nausea and vomiting, 4% had shivering, 2% had urinary retention. No hypertension, bradycardia, respiratory depression, motor blockade was seen in both groups.

V. Discussion

A total number of 100 patients, belonging to age group 18-75 have been taken. Out of which mean age of Group T (receiving epidural tramadol) was 45.56 years and in Group B (receiving epidural bupivacaine) was 44.58 years. Hence these groups were comparable as regards to age.

Patients undergoing lower abdominal, pelvic and lower limb surgeries were selected, patients were randomly divided in 2 groups of 50 each; group T(tramadol),and Group B (bupivacine) groups. All surgeries were done under combined spinal epidural anaesthesia. In post operative period as soon as patients complained of pain, patients in group T received epidural tramadol 100mg diluted in 10ml of normal saline and Group B received bupivacine 0.125% (10ml).

In this study, the mean time of onset of analgesia in group T (tramadol) was 6.24±0.29minutes,and in group B (bupivacaine) was 14.72±0.31. The statistical
analysis by Student's unpaired 't' test showed that, the difference in time of onset of
analgesia in these 2 groups were statistically significant ($p < 0.0001$).

A study was conducted by Pinky Rathie, RS Verma, TS Jadav and Ajay Kabra1 to know the effectiveness and duration of post-operative analgesia with epidural tramadol. The group who received 100 mg of epidural tramadol in 10 ml of normal saline had onset of action 12.08 ± 3.53 minutes. Onset of analgesia in this study was comparable to above studies.

The duration of analgesia in group T ranged from 90 to210 minutes with a mean of 155.3±4.67, while in group B ranged from 75 to 120 with mean of 121.2±3.26. The duration of onset when compared between them was statistically significant ($p < 0.0001$). A study to compared epidural bupivacaine with epidural bupivacaine + tramadol combination by Choudhary AH, Dharmani P, Kumar N and Prakash A, too had shown duration of analgesia with bupivacaine as (mean ±SD) 6.5 ± 4.1 hours, while (combination) group B + T it was found to be (mean ±SD) 8.5 ±3.1 hours, which was statistically significant ($p < 0.05$).

A study conducted by S Prakash, R Tyagi, A Gogia and S Praksh3 for comparison of efficacy of caudally administered tramadol and combination of tramadol with bupivacaine has shown that combination of bupivacaine with tramadol provided a longer duration of post operative analgesia when compared to epidural tramadol.

Yassen Majid, Khairat Mohammad. Comparison of caudal Bupivacaine/ Bupivacaine – Tramadol / Tramadol combination for postoperative analgesia. Caudal Bupivacaine and Bupivacaine with Tramadol are equally effective in controlling postoperative pain however pain score is lesser with combination of Bupivacaine with Tramadol.[4]

Quality of analgesia was assessed at the time when rescue analgesia was given to the patient. Patient was asked to assess the analgesic effect with verbal response score. In group T (tramadol) good 22(44%) to excellent17(34%) pain relief is seen,in group B (bupivacaine) fair 27(54%) to good 20(40%) pain relief is seen. Delilkan AE, Vijayan R5 in their study noted that the quality of analgesia was significantly better with 100mg tramadol at 3, 12, 24 hours when compared to tramadol 50 mg as bupivacaine 0.25%. Hence the study is comparable to their study.

Study by Yaddanapudi LN, Wig J, Singh B and Tewari MK6 found that Summed Pain Intensity Difference (SPID) were comparable between tramadol group (50mg of epidural tramadol) and morphine group (3mg of epidural morphine) showing that, the overall pain relief was similar with both the groups.

In this study, the mean pulse rate (difference in pulse rate before and after the drug) was higher in bupivacaine than tramadol group but it was statistically significant. While the difference in systolic blood pressure in group T, mean difference 10.16±1.63, and in group B7.52±1.13 - all of which on comparison were found to be statistically significant ($p < 0.0001$).

Similarly diastolic blood pressure change was found to be significant on comparison of group T and group B .Changes in respiratory rate was found to be statistically significant when the two groups were compared. ($p<0.0001$).

The study of Delilkan AE, Vijayan MD5 noted transient drop in systolic blood pressure and other cardiovascular parameters remained stable.While study by Rathie, Pinky et al.1, showed that, even tramadol does not have significant alterations in these parameters. In this study there is a mild fall in the cardiovascular and respiratory parameters in both groups. The fall may be due to adequate analgesia resulting in less sympathetic discharge and comfortable sleeping.

In the study in group T 20% (10) patients were found to have nausea & vomiting as a side effect while 4% (2) were found to have pruritus as its side effect.In group B, 6% (3) of patients had nausea&vomiting,4%(2)had shivering and2%(1) had urinary retention.The difference of these was considered clinically significant. None of these patients in any group has clinically significant hypotension and respiratory depression.

The study of Delilkan AE, Vijayan MD5 noted more incidence of nausea and vomiting in group receiving epidural tramadol 100mg compared to epidural tramadol 50mg &0.25%bupivacaine. Overall frequencies of side effects were less in all the groups. Hence the study is comparable to the above results.

VI. Conclusion

It was concluded that epidural tramadol, provided an adequate, rapid and excellent postoperative analgesia compared to epidural bupivacaine.The duration and quality of analgesia was found to be longer and superior with the epidural tramadol than with bupivacaine of these groups. This study found statistically significant difference in onset of analgesia among these groups. The incidence of minor side effects were however higher with tramadol group compared to bupivacaine group.

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