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RESEARCH ARTICLE

A COMPARATIVE ANALYSIS OF 0.125% BUPIVACAINE AND 100MG TRAMADOL GIVEN VIA EPIDURAL ROUTE FOR POSTOPERATIVE PAIN CONTROL IN INFRAUMBILICAL SURGERIES

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ABSTRACT

Infraumbilical surgeries are associated with significant postoperative pain. The pain is usually of a long duration. Post operative pain treatment is very important for a variety of reasons as its proper treatment influences the quality standards of hospital care and associated comorbidities linked to an inadequate management thereof. This study was conducted to evaluate postoperative analgesic efficacy of four doses of epidurally administered Bupivacaine versus Tramadol in infraumbilical surgeries. Epidural Tramadol has better postoperative analgesic efficacy than epidural Bupivacaine. Nausea and vomiting was more in group T which was easily treatable with anti emetic. **Methods**: 40 adult cases ranging in age from 30 to 50 years with ASA Grade I & II, presenting for elective infraumbilical surgery. Cases were allocated by computer generated randomization into two groups containing 20 cases each. Cases in Group B received 10ml of 0.125% Bupivacaine and those in Group T received Tramadol 100mg in 10ml of normal saline,via the epidural route. **Results** – Cases in Group T receiving epidural Tramadol with antiemetic had significantly longer duration of analgesic effect. These cases also had significantly longer dosage intervals compared to Group B cases receiving Bupivacaine. Cardiovascular parameters were stable and similar between both groups[2]. **Conclusion**: Epidural Tramadol has better postoperative analgesic efficacy than epidural Bupivacaine. Nausea and vomiting was more in group T which was easily treatable with anti emetic.

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INTRODUCTION

Postoperative pain has many components,including hyperalgesia in the area of the incision, local ischaemia in the wound, central neuronal sensitisation and inflammatory response to surgery[1]. Treating post operative pain can provide subjective relief, blunt the autonomic and somatic responses[2].Postoperative pain management is still a challenging task for anaesthetist. Bupivacaine is the currently available local anaesthetics with long duration of action[3] and its maximum analgesic effect is upto 6-12 hours[4].Bupivacaine binds to the intracellular potion of voltage gated Na^+ channels and block Na influx in neuronal cells preventing depolarization. The unique feature of tramadol includes 1)binding with opioid receptors .inhibiting reuptake of serotonin and norepinephrine 2)it is metabolised to o-desmethyltramadol which is a more potent opioid.The primary aim of the study was to compare the pharmacological analgesic efficacy of four different doses of tramadol 100mg versus bupivacine 0.125%used separately in postoperative pain management of forty adult cases of infraumbilical surgery and identify which drug at which dose has maximum duration of epidural analgesia.

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Inclusion Criteria

a. Consent of the patients
b. ASA I or ASA II patients.
c. Age between 30 years to 50years.
d. Patients of either sex.
e. Patients scheduled for elective infraumbilical surgery.

Exclusion Criteria

a. Patients refusal.
b. Any contraindication to epidural anaesthesia –
   i. Infection at the site of injection
   ii. Coagulopathy and platelet count less than 100000/cmm
   iii. Neurological disorders and history of seizure
   iv. Heart diseases
   v. Haemodynamically compromised patients
   vi. Sepsis
   vii. Gross anatomical abnormality at the puncture site.
c. Known allergy to the aforementioned drugs.
d. Patients on chronic analgesic therapy or antiplatelet drugs and anticoagulants
e. Emergency surgery

MATERIAL AND METHODS

The present study was carried out in the Department of Anaesthesia, IGIMS, Patna. After obtaining ethical clearance

from the Institutional Ethics Committee and obtaining written consents from the participants, 40 adult cases ranging in age from 30 to 50 years with ASA Grade I & II requiring elective infraumbilical surgery under epidural anaesthesia were selected for this prospective, randomized, double-blind study. Cases were allocated by computer generated randomization into two groups containing 20 cases each. Cases in Group B received 10ml of 0.125% Bupivacaine and those in Group T received Tramadol 100mg in 10ml of normal saline,via the epidural route. All cases were briefed and examined one day before the study. The epidural technique was explained to them. They were told that in case of failure of epidural technique they would be automatically be from the study. All cases were directed to remain nil by mouth 8 hours before the surgery.They were premedicated with 5mg Diazepam orally on the night before surgery. Baseline blood pressure, pulse rate, and SpO_2 were recorded. Adequate preloading (500 ml) was done with 18-gauge intravenous cannula. Patients received injection glycopyrrolate (0.004 mg/kg) and injection ranitidine (1 mg/kg) intravenously as premedication. Thereafter, an epidural catheter was inserted at the lumbar level (L1–L2 or L2–L3). The space was checked by loss of resistance technique and confirmed by the meniscus sign. Epidural test dose was given with 3 ml 2% adrenalized lignocaine. The absence of tingling numbness in the lower limbs and tachycardia was confirmed after 5–7 cm of catheter was placed in the epidural space. After fixation of catheter, patients were made supine and free injection of saline through the catheter was checked. Patients were premedicated with injection fentanyl 2 ug/kg and injection midazolam 0.02 mg/kg. Patients were preoxygenated with 100% O_2 for 3 min. General anesthesia was given with injection propofol 2 mg/kg mixed with injection xylocard 20 mg intravenously. Suitable relaxant was given to facilitate tracheal intubation after confirming ventilation. Anesthesia was maintained with O_2, N_2O, and propofol or isoflurane. Muscle paralysis was maintained with injection atracurium besylate (0.5mg /kg) intravenously. Post surgery the cases were transferred to the postoperative ward for pain management and resuscitation. The cases were now randomly allocated to one of the study groups. The drugs under this study were randomly injected when analgesic effect was demanded by the subject. This was the first dose and the time was recorded. Patients were monitored for postoperative pain immediately after surgery when they had completely recovered and regained consciousness from general anesthesia, and subsequently 2 4, 8, 12 and 24 hours thereafter. Pain was quantified using the visual analog scale (VAS) along with pulse rate, blood pressure and breathing rate. The drug was repeated on demand by the cases and time of each additional dose was recorded. A maximum of four doses of each drug were permissible under this study and cases with severe persistent pain were given a rescue dose of 75mg intravenous. Pethidine and excluded from the study being considered a failure case. The time of administration of rescue dose was also noted. After 24 hours, the epidural catheter was removed and pain management was left at the discretion of the attending specialist.

Observation – 40 adult cases ranging in age from 30 to 50 years with ASA Grade 1&ASA 2, requiring elective Infraumbilical surgery under epidural anaesthesia were selected for this study. Cases were randomly allocated into two groups containing 20 cases each. Cases in Group B received Bupivacaine 0.125% and those in Group T received Tramadol 100mg.

Table 1. Age in years of each participant in each group

Case No.	Group B (Bupivacaine)	Group T (Tramadol)
01	29	30
02	28	45
03	41	57
04	54	47
05	52	37
06	38	58
07	39	28
08	51	60
09	59	46
10	37	51
11	48	54
12	54	29
13	28	41
14	42	35
15	55	24
16	29	36
17	36	39
18	24	29
19	43	51
20	40	40

Note: It was observed that the cases in both groups were comparable on the basis of mean age being 41.35 years and SD 10.51 (Group B) and mean age of 41.85 years and SD 10.97 (Group T)

Table 2A.Table showing dosage intervals in minutes in Group B

S. No.	$1^{st} – 2^{nd}$ Dose	$2^{nd} – 3^{rd}$ Dose	$3^{rd} – 4^{th}$ Dose	4^{th} – Rescue Dose
01	304	314	NIL	NIL
02	214	204	300	NIL
03	322	NIL	NIL	NIL
04	244	260	306	NIL
05	292	312	284	NIL
06	304	298	268	NIL
07	281	326	292	NIL
08	222	322	304	NIL
09	302	286	282	NIL
10	294	282	278	292
11	264	300	276	NIL
12	254	240	248	304
13	352	NIL	NIL	NIL
14	240	310	NIL	NIL
15	198	244	220	372
16	305	298	274	NIL
17	362	340	NIL	NIL
18	250	250	264	309
19	212	254	232	354
20	274	300	NIL	NIL

Table 2B.**Table showing dosage intervals in minutes in Group T**

S. No.	$1^{st} – 2^{nd}$ Dose	$2^{nd} – 3^{rd}$ Dose	$3^{rd} – 4^{th}$ Dose	4^{th} – Rescue Dose
01	480	420	NIL	NIL
02	508	NIL	NIL	NIL
03	398	364	NIL	NIL
04	384	402	350	NIL
05	528	NIL	NIL	NIL
06	374	396	NIL	NIL
07	338	354	362	NIL
08	290	340	354	384
09	464	480	NIL	NIL
10	388	368	370	NIL
11	362	396	380	NIL
12	269	300	312	380
13	474	448	NIL	NIL
14	310	248	300	NIL
15	396	382	NIL	NIL
16	382	364	340	NIL
17	394	358	330	NIL
18	390	424	NIL	NIL
19	502	NIL	NIL	NIL
20	400	410	NIL	NIL

Note: It was observed that mean interval between $1^{st} – 2^{nd}$ dose in Group B was 274.55 with SD 45.63 and in Group T was 401.65 with SD 72.15. Dose intervals between $2^{nd} – 3^{rd}$ dose in Group B was 285.67 with SD 36.21 and in Group T was 379.64 with SD 54.37. Dose intervals between $3^{rd} – 4^{th}$ dose in Group B was 273.42 with SD 25.71 and in Group T was 344.22 with SD 26.46. Between 4^{th} – rescue dose 6 cases and 2 cases were observed in Group B and Group T respectively.

Table 3. Table showing frequency of dose administration

No. of dose required	Group B (*n* =20)	Group T (*n* =20)
One	NIL	NIL
Two	2	3
Three	4	8
Four	8	7
Rescue	6	2

Note: Rescue dose was required in 6 cases in Group B and in only 2 cases in Group T

Table 4. Table showing comparison of mean dosing intervals

S. No.	Interval	Group B (minutes)	Group T (minutes)
1	$1^{st} – 2^{nd}$	274.55	401.65
2	$2^{nd} – 3^{rd}$	379.64	385.66
3	$3^{rd} – 4^{th}$	344.22	273.42
4	4^{th} - Rescue	382.00	326.00

Note: Higher dose intervals were observed in Group T

Table 6. Incidence of side effects

S. No.	Side effect	Group B (*n* =20)	Group T (*n* =20)
1	Nausea – Vomiting	4	12
2	Numbness in lower limbs	3	NIL
3	Shivering	2	NIL
4	Respiratory depression	NIL	NIL
5	Pruritus	NIL	NIL
6	Dizziness	4	3
7	Bowel pain	NIL	NIL
8	Generalized burning sensation	NIL	NIL
9	Inability to walk after 24 hour period	8	2

Note: Most common side effect of Nausea – Vomiting was observed in 12 cases in Group T

DISCUSSION

In our present study we found lower VAS pain scores and a longer duration of postoperative analgesia and a much significant decrease in the 24 h consumption of rescue anaesthesia in Group T. There was also earlier recovery of unassisted ambulation and home discharge[8]. No significant side effects were detected in any group. Although tramadol was initially considered to be a weak µ–opioid agonist, it appears to have multimodal mechanisms of action. It is now accepted that in addition to µ–opioid agonist effect, tramadol enhances the function of the spinal descending inhibitory pathway by inhibition of reuptake of both 5-hydroxytryptamine (5-HT) and norepinephrine, together with pre-synaptic stimulation of H-HT release[9,10]. The local anaesthetic action of tramadol remains unproven. 5-HT3 receptors are exposed on the peripheral and spinal terminals of the nociceptive primary afferent fibers as well as on the superficial lamina of the dorsal horn which indicates possible peripheral sites of action of tramadol[11,12]. Studies have shown a definitive local anaesthetic effect of tramadol in experiments on frog sciatic nerves revealing that the nerve conduction block of tramadol is 3-6 times weaker than that of lidocaine. Although lidocaine inhibits Na^+ channels, it is suggested that tramadol inhibits K^+ channels. Headache, nausea, vomiting, dizziness, somnolence are major side effects of IV tramadol when used for postoperative analgesia[13]. Such incidence seems to be directly related to peak serum concentration levels of tramadol. Activation of hypothalamo-pituitary-adrenal axis and rise of cortisol and epinephrine plasma levels associated with surgical trauma re very important postoperative stress responses. Caudal tramadol has more analgesic efficacy than bupivacaine[14]. In equipotent analgesic doses of tramadol to morphine is free of respiratory symptoms[15].

Conclusion

Our study concluded that both epidurally administered bupivacaine and tramadol are safe and effective postoperative analgesics. Postoperative consumption of analgesic was higher in the Bupivacaine group. Epidural tramadol 100mg in 10ml provides better and longer duration of anaesthesia with rapid onset and no incidence of complications.

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