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Comparison of Efficacy of Epidurally Administered Butorphanol and Tramadol in Providing Post Operative Pain Relief in Lower Abdominal, Pelvic and Lower Limb Surgeries

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Abstract

Context: Till date many attempts have been made to find out a particular drug of choice so that the patient can be pain free after the surgery. *Aims:* To evaluate the efficacy and safety of epidural butorphanol (1 mg) in comparison with epidural tramadol (50 mg) for post- operative pain relief. *Settings and design:* The hospital based comparative study was performed at S.V.S Medical Hospital, Mahabubnagar. *Methods:* In the post-operative period, when patient first complained of pain, they received either epidural tramadol 50 mg (Group-T) or butorphanol 1 mg (Group-B) diluted in 10 ml of normal saline. The parameters monitored were onset, duration and quality of analgesia, cardio respiratory effects, pulse rate, blood pressure, respiratory rate, level of consciousness (sedation scores), side effects like nausea, vomiting, pruritus, respiratory depression, urinary retention. *Statistical analysis:* Chi square test and student's t test were used. *Results:* The mean time of onset of analgesia in two groups was statistically insignificant ($p > 0.05$). Duration of analgesia in butorphanol group was significantly lesser. Significantly more patients in Butorphanol group expressed satisfaction for analgesia compared to Tramadol group. In both groups, majority of patients expressed their analgesia as good to excellent. When compared to Tramadol group, butorphanol group had statistically significant fall in pulse rate and respiratory rate without much alteration in blood pressure. In Tramadol group, 16% of patients had nausea and 10% of patients had vomiting while only 2% of Butorphanol group had nausea and vomiting which was statistically insignificant. *Conclusion:* Epidural Butorphanol provides a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol.

Keywords: evaluation; efficacy; safety; epidural; butorphanol; tramadol.

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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. Because of pain, these 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. Due to this, they may experience feelings of helplessness, fear, anxiety, low mode and loss of self-control [1].

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We as an anesthesiologist, always feel that our patient should undergo a pain free surgery.

Till date many attempts have been made to find out a particular drug of choice so that the patient can be pain free after the surgery. In line with this, many drugs were tried epidurally and studies were published. Drugs like morphine when used epidurally have variety of side effects [2].

Action of tramadol is that it acts as an agonist of opioid. It also blocks the reuptake of monoamines. It has been shown to be a good analgesic around the time of surgery. It does not lead to depression of the respiratory system. But it has been shown that it can cause a variety of side effects. Hence other drugs should be considered [3].

In this direction butorphanol is promising. It is more effective as compared to morphine. It helps in the relief of the pain after the surgery. It has lesser side effects as compared to tramadol. But has been found out to be more sedative and this action is considered to be required after the surgery to make patient feel free of pain [4].

Present study was carried out to evaluate the efficacy and safety of epidural butorphanol (1 mg) in comparison with epidural tramadol (50 mg) for post- operative pain relief.

Material and Methods

The study was performed at S.V.S Medical Hospital, Mahabubnagar during the period of October 2015 to October 2017 after the approval from the hospital ethics committee. Written and informed consent were obtained from each patient who participated in the study.

Study Design: Randomized control trial.

Study Subjects: Total of hundred patients with fifty in each group.

Study Sample: One group of 50 patients were given inj. Butorphanol 1 mg epidurally (Group B) and another group of 50 patients were inj. Tramadol 50 mg epidurally (Group T).

Pre-anesthetic Evaluation was done prior to surgery.

Inclusion Criteria:

1. ASA I and II grade patients.
2. Patients aged between 21 and 60 years.
3. Patients scheduled for lower abdominal, pelvic and lower limb surgeries.

Exclusion Criteria

1. All patients above ASA grade III.
2. Patients physically dependant on opioids.
3. Patients below 20 years and above 60 years of age.
4. All known contraindications to epidural anesthesia like.
5. Patients with raised intracranial pressure.
6. Coagulation defects or hemophiliacs and patients on anticoagulants.
7. Local inflammation or infection.

Basic lab investigations were carried out for all patients in both the groups. They were trained on how to tell about the pain.

Pre-medication was done with Tab. Diazepam 10 mg orally

The patients were given anesthesia as per the standard operating protocol.

No relief from pain was given score of zero. Litter relief from pain was given score of one. Some relief from pain was given score of two. A lot of relief from pain was given score of three and a score of four was considered when the relief from pain was complete.

Onset, duration and quality of analgesia, level of consciousness, cardio-respiratory effects and side effects were recorded.

Statistical analysis

For comparison of mean values in the two groups, student's t test was used and if it was found that the p value was less than 0.05, it was taken as significant.

Results

The minimum age of the patient was 21 years and the maximum age was 60 years. The mean age of the patient in Group-T was 39.3 ± 9.3 and in Group-B 41.8 ± 10.3. Both the groups had similar distribution of the age. (Table 1).

In Group-T, 20 (40%) were males and 30 (60%) were females. In Group-B, 19 (38%) were males and 31 (62%) were females. (Table 2).

Out of 100 patients, 18 underwent general surgery, 34 underwent gynecological surgery and 48 underwent orthopedic surgery. (Table 3).

It took 13.1 ± 2.6 min for patients in the group T for onset of the analgesia compared to 14.3 ± 3.7 minutes

for patients from group B and this was statistically insignificant ($p > 0.05$). (Table 4).

Duration of analgesia was more i.e. 6.2 min in group T patients compared to 35 min in group B patients and this difference was significant. (Table 5).

There was no one in no pain or little pain relief groups. Some relief was seen in one patient with tramadol compared to two with group B. a lot of pain relief was more in tramadol. But complete pain relief was more with group B. (Table 6).

In Group-T, before giving Tramadol, pulse rate ranged between 70 – 90 bpm (81.7 ± 5.0), Systolic BP ranged between 110–140 (119.1 ± 9.5), Diastolic BP ranged between 70–80 (80.2 ± 6.6) and respiratory rate ranged between 12–18 (14.1 ± 1.8) cpm. After giving Tramadol, The pulse rate ranged between 68–90 bpm (80.1 ± 5.4), systolic BP 100–140 mmHg (115.2 ± 10.1), diastolic BP 70–90 mmHg (29.7 ± 6.9) and respiratory rate ranged between 12 – 16 (13.4 ± 1.3) cpm. In group B, before giving Butorphanol, pulse rate ranged between 70–90 bpm (79.0 ± 7.1), Systolic BP 100–140 mmHg (117.4 ± 10.1), diastolic

Table 1: Distribution of study subjects as per age

Age (years)	Group T		Group B	
	Number	%	Number	%
< 25	3	6	5	10
26-35	15	30	11	22
36-45	22	44	14	28
46-55	6	12	16	32
56-60	4	8	4	8
Total	50	100	50	100

Table 2: Distribution of study subjects as per sex

Sex	Group T		Group B	
	Number	%	Number	%
Male	20	40	19	38
Female	30	60	31	62
Total	50	100	50	100

Table 3: Distribution of study subjects as per surgical procedure

Surgical procedure	Group T		Group B	
	Number	%	Number	%
General surgery	3	6	15	30
Gynecological surgery	22	44	12	24
Orthopedic surgery	25	50	23	46
Total	50	100	50	100

Table 4: Comparison of onset of analgesia in two groups

Groups	Onset of analgesia (min)			Significance	
	Range	Mean	SD	T value	p value
Group T	8-18	13.1	2.6	1.91	0.06
Group B	6-23	14.3	3.7		

Table 5: Comparison of duration of analgesia in two groups

Groups	Onset of analgesia (min)			Significance	
	Range	Mean	SD	T value	p value
Group T	5-8	6.2	0.5	30.8	< 0.001
Group B	3-4	3.5	0.4		

BP 70–90 mmHg (78.9 ± 6.3) and respiratory rate ranged between 12–18 (15.0 ± 1.3) cpm. After giving Butorphanol, the pulse rate ranged between 64–90 bpm (75.6 ± 6.7), systolic BP 100–140 mmHg (113.3 ± 9.4), diastolic BP 70–90 mmHg (78.2 ± 6.2) and respiratory rate ranged between 12–16 (13.1 ± 1.2) cpm. When compared to Group-T, Group-B had statistically significant fall in pulse rate and respiratory rate (Table 7).

In Group-T, 70% of patients were sleeping, 30% of patients were awake and none of the patient had sedation score of 1. In Group-B, 62% of patients were sleeping normal, 22% of patients were awake and 16% of patients had sedation score of 1. Statistical analysis by Chi-square test showed that, this difference in sedation score was significant ($p < 0.05$). (Table 8).

In Group-T, 16% of patients had nausea, 10% of patients had vomiting and none of the patients had sedation when compared to Group-B where 2% of patients had nausea, 2% of patients had vomiting and 16% of patients had sedation scores. The difference was statistically insignificant by Chi-square test ($p < 0.005$). (Table 9).

Table 6: Comparison of quality of Analgesia (VRS – Verbal Response Score) in two groups

Pain score	Quality of analgesia	Group T (N = 50)		Group B (N = 50)	
		Number	%	Number	%
0	No pain relief	0	0	0	0
1	Little (poor) pain relief	0	0	0	0
2	Some (fair) pain relief	1	2	2	4
3	A lot (good) of pain relief	23	46	17	34
4	Complete (excellent) pain relief	26	52	31	62

Table 7: Comparison of cardiovascular and Respiratory Effects in two groups

Variable	Groups	Before the drug	After the drug	Difference	Significance	
					T value	p value
Pulse rate	Group T	81.7 + 5.0	80.1 + 5.4	1.6 + 3.3	7.35	< 0.01
	Group B	117.4 + 10.1	113.3 + 9.4	4.1 + 5.1	5.61	< 0.01
Systolic blood pressure	Group T	119.1 + 9.5	115.2 + 10.1	3.9 + 6.2	4.42	< 0.01
	Group B	117.4 + 10.1	113.3 + 9.4	4.1 + 5.1	5.61	< 0.01
Diastolic blood pressure	Group T	80.2 + 6.6	79.7 + 6.9	6 + 2.9	1.36	0.18
	Group B	78.9 + 6.3	78.2 + 6.2	0.7 + 2.6	1.97	0.06
Respiratory rate	Group T	14.1 + 1.5	13.4 + 1.3	0.7 + 1.4	3.42	< 0.01
	Group B	15.0 + 1.3	13.1 + 1.2	13.1 + 1.2	11.05	< 0.01

Table 8: Comparison of sedation score (Level of Consciousness) in two groups

Score	Group T (N = 50)		Group B (N = 50)	
	Number	%	Number	%
0	15	30	11	22
S	35	70	31	62
1	0	0	8	16
Total	50	100	50	100

0 – Awake, S – Sleeping, 1 – Drowsy, but arousible

Table 9: Comparison of side effects in two groups

Side effects	Group T (N = 50)		Group B (N = 50)	
	Number	%	Number	%
Nausea	8	16	1	2
Vomiting	5	10	1	2
Sedation	0	0	8	16
Nil	37	74	40	80
Total	50	100	50	100

Discussion

Male to female ratio was almost same. Out of 100 patients, 18 belonged to general surgery, 34 patients underwent gynecological surgeries and 48 patients underwent orthopedic surgeries.

It took 13.1 ± 2.6 min for patients in the group T for onset of the analgesia compared to 14.3 ± 3.7 minutes for patients from group B and this was statistically insignificant ($p > 0.05$). Similar findings were given by Rathie P et al. [5], Swathi N et al. [6]

Duration of analgesia was more i.e. 6.2 min in group T patients compared to 35 min in group B patients and this difference was significant. Abboud et al. [7], Singh B et al. [8] reported similar findings.

There was no one in no pain or little pain relief groups. Some relief was seen in one patient with tramadol compared to two with group B. a lot of pain relief was more in tramadol. But complete pain relief was more with group B. Palacios Q et al. [9] observed similar reports. Singh B et al. [8] in their study found that Quality of analgesia by using VAS score was better in group 'Butorphanol' (0.53 ± 0.5) than group Tramadol (0.92 ± 0.70).

Comparing VAS scores, it was found that VAS score was not statistically significant between two groups before giving drugs. Significant reduction in VAS scores were also observed by Swathi N et al. [6], Palacios et al. [9]

In Group-T, before giving Tramadol, pulse rate ranged between 70 – 90 bpm (81.7 ± 5.0), Systolic BP ranged between 110–140 (119.1 ± 9.5), Diastolic BP ranged between 70–80 (80.2 ± 6.6) and respiratory rate ranged between 12–18 (14.1 ± 1.8) cpm. After giving Tramadol, The pulse rate ranged between 68–90 bpm (80.1 ± 5.4), systolic BP 100–140 mmHg (115.2 ± 10.1), diastolic BP 70–90 mmHg (29.7 ± 6.9) and respiratory rate ranged between 12 – 16 (13.4 ± 1.3) cpm. In group B, before giving Butorphanol, pulse rate ranged between 70–90 bpm (79.0 ± 7.1), Systolic BP 100–140 mmHg (117.4 ± 10.1), diastolic BP 70–90 mmHg (78.9 ± 6.3) and respiratory rate ranged between 12–18 (15.0 ± 1.3) cpm. After giving Butorphanol, the pulse rate ranged between 64–90 bpm (75.6 ± 6.7), systolic BP 100–140 mmHg (113.3 ± 9.4), diastolic BP 70–90 mmHg (78.2 ± 6.2) and respiratory rate ranged between 12–16 (13.1 ± 1.2) cpm. When compared to Group-T, Group-B had statistically significant fall in pulse rate and respiratory rate. Similar results were given by Palacious QT et al. [9], Rathie P et al. [5].

In the study, 8 (16%) patients of Group-B (Butorphanol) had sedation scores of 1 when compared to Group-T (Tramadol) where none had this score.

Gupta R et al. [10] proved that Butorphanol causes more sedation than Tramadol when given epidurally.

In Group-T, 16% of patients had nausea, 10% of patients had vomiting and none of the patients had sedation when compared to Group-B where 2% of patients had nausea, 2% of patients had vomiting and 16% of patients had sedation scores. The difference was statistically insignificant by Chi-square test ($p < 0.005$). Similar findings were given by Gupta R et al. [10], Delilkan AE et al. [11]

Gupta R et al. [10] conducted a study on "A comparison of epidural Butorphanol and Tramadol for postoperative analgesia using CSEA technique". The results of their study regarding duration of analgesia, sedation scores, and side effects are comparable to the present studies.

The results were comparable with the study done by Swathi N et al. [6] which also showed that onset of action was faster with Butorphanol.

Conclusion

Epidural Butorphanol provides a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol. Epidural Butorphanol has a lesser side effects like nausea, vomiting but has a mild degree of sedation, which is an added advantage in the post-operative pain. Both Epidural Tramadol (50 mg) and epidural Butorphanol (1 mg) have equal efficacy except duration of action, which is shorter for Butorphanol.

Key messages

Epidural Butorphanol can be used instead of epidural tramadol

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