Original research article

Comparative Study of Epidural Butorphanol andTramadol for Postoperative Analgesia in Orthopedic Lower Limb Surgeries

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ABSTRACT

Background and objectives: Epidural analgesia is a safe technique for post-operative pain relief and equivalentto traditional analgesic methods. Epidural narcotics have been extensively used for post- operative analgesia. In a quest to find a better and safer alternative to older drugs like morphine this study was undertaken to compare the safety and efficacy of postoperative analgesia with epidural butorphanol and epidural tramadol in patients undergoing orthopaedic lowerlimb surgeries.

Methods: A total of 100 patients of either sex, belonging to 20-60 yrs of age, ASA grade I and II admitted for orthopedic lower limb surgeries in the department of Anesthesiology, DMCH Darbhanga. were selected randomly for the study. Combined spinal-epidural was administered to all the patients. Postoperatively when patient complained of pain (Visual Analog Scale > 4), either butorphanol 1mg or tramadol 50mg diluted to 10ml was given epidurally and allthe parameters were recorded.

Conclusion: Epidural butorphanol (1mg) is a safe and efficacious drug for post-operative analgesia. Epidural butorphanol provides a rapid, excellent but shorter duration of analgesia whencompared to epidural tramadol. It has mild sedation which is advantageous in the postoperative period.

Keywords: Epidural butorphanol; epidural tramadol; visual analog scale; visualresponse score.

Introduction

Effective pain control is essential for optimal care of surgical patients; especially in patients undergoing orthopedic surgeries as these patients suffer from considerable pain in the postoperative period. Acute postoperative pain is a complex physiologic reaction to tissue injury, visceral distension or disease. Its manifestation of autonomic, psychological and behavioral responses results in unpleasant, unwanted sensory and emotional experience. Despite advances in knowledge of patho-physiology of pain, pharmacology of analgesics and development of effective techniques for post- operative pain control, many patients continue to experience considerable discomfort.[1, 2] Epidural analgesia is a safe technique for post-operative pain relief andequivalent to traditional analgesic methods. Epidural narcotics have been extensively used for post-operative analgesia. However, disadvantage with use of traditional drugslike morphine is that many side effects such as nausea, vomiting, pruritis,

urinary retention, drug dependence and delayed respiratory depression have been reported.[3] They can not be used in elderly patients. With discovery of newer opioids like butorphanol, tramadol and fentanyl, a new era in pain relief has commenced. Butorphanol, a synthetic morphian derivativeis a mixed agonist and antagonist non-narcotic opioid analgesic where as tramadol is asynthetic 4-phenyl-piperdine analog of codeine with a dual mechanism of action. The advantage with these newer drugs is that their potency is comparable to that of morphine, produce lesser respiratory depression, easily available, larger margin of safety and lesser incidence of nausea, vomiting, urinary retention, pruritis compared to morphine.[4, 5]

Objectives

To assess and compare the safety and efficacy of postoperative analgesia with epidural butorphanol and epidural tramadol in patients undergoing orthopaediclower limb surgeries.
To compare the degree and duration of analgesia, cardio respiratory effectsand side effects between epidural butorphanol and epidural tramadol.

Material and Method

A total of 100 patients of either sex, belonging to 20-60 yrs of age, ASA grade I and II admitted for orthopedic lower limb surgeries in the department of Anesthesiology, Darbhanga Medical College and hospital Darbhanga, Laheriasarai. were selected randomly for the study. Combined spinal-epidural was administered to all the patients. Postoperatively when patient complained of pain (Visual Analog Scale > 4), either butorphanol 1mg or tramadol 50mg diluted to 10ml was given epidurally and allthe parameters were recorded. The hospital statistics has shown that about 95 cases of various orthopedic lower limb surgeries were performed every year. The mean weight of 66.27 kg with SD of 6.82 at allowable error $\square 2^{12}$, the calculated sample size n is 46.
Hence a total number of 50 patients in each group with inclusion and exclusion criteria were selected for study, during a period of 18 months (time bound study). Patientswill be allocated randomly to each group by lottery method.

Inclusion criteria

*****Patients undergoing orthopaedic lower limb surgeries in the age group of 20- 60 years of both sexes will be included with ASA grade I and grade II.

Exclusion criteria

*Patients with ASA grade III, IV and V
*Those with known hypersensitivity to local anaesthetics.
*Patients, physically dependent on opioids.
*Patients with local infection / inflammation
During preoperative visit patient's detailed history, general physical examination and systemic examination was carried out. Basic demographic characterslike age, sex and weight were recorded. During the pre anaesthetic check up, linear visual analogue score LVASwas explained to all patients using a 10 centimeter scale. Written informed consent was taken from the patient. All the patients were preloaded with 10 ml / kg infusion of Ringer Lactate solution. All patients were administered combined spinal epidural anaesthesia using 2 segment technique after recording baseline pulse, BP and respiratory rate. An 18G epidural catheter was introduced in L3-L4 space and subarachnoid block was given in L4-L5 space using 2.5 ml of 0.5% heavy bupivacaine. Level of sensory block and haemodynamic parameters were monitored intraoperatively. All surgeries were performed under spinal anaesthesia. No narcotics were administered through out intra operative period.

In the post-operative period, at Visual Analogue Score (VAS) of > 4, patients were administered 1 mg of butorphanol diluted to 10 ml with normal saline,in one group(group B) and 50 mg of tramadol diluted to 10 ml with normal saline, in another group(group T) through epidural catheter. Both the drugs used in the study forepidural injection are preservative free. Assessment of pain relief was done every 5 min for first 30 min and later every 30 min using five point verbal response score.

Table 1:

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

Patients were observed for 24 hours postoperatively and parameters likepulse, BP, respiratory rate and duration of analgesia (the time when patient asked for rescue analgesia) were recorded as given in the proforma. After giving first dose of epidural opioid (butorphanol/tramadol) following variables were assessed at ½ hour, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours and 24 hours in respect to,

- Onset of analgesia.
- Duration of analgesia.
- Quality of analgesia.
- Level of consciousness.

Results

Hundred adult patients in ASA grade I and II of either sex, agedbetween 20-60 years posted for various orthopedic lower limb surgeries were selected for the study. The study was undertaken to evaluate the efficacy and safety of epiduralbutorphanol 1mg diluted to 10 ml of normal saline in comparison with epiduraltramadol 50mg diluted to 10 ml of normal saline given for post-operative pain relief.

The minimum age of the patient was 20 yrs and the maximum was 60 yrs. Themean age of the patient in group T was 44.8±13.1 and in group-B 46.2±11.9. Age incidences between two groups were comparable.

Table 2: Age Distribution

Age group (yrs)	Group-T (Tramadol) n=50	Group-B (Butorphanol) n=50
20-30	9	6
31-40	13	12
41-50	9	9
51-60	19	23
Total	50	50
Mean	44.8	46.2
SD (±)	13.1	11.9

Table 3: Sex Incidence

Sex	Group-T (Tramadol) n=50	Group-B (Butorphanol) n=50
Male	35(70%)	41(81%)

Female	15(30%)	9(18%)
Total	50	50

The duration of action of analgesia in group-T was 369.8±25.6 (SD)min and in group-B was 215.2±26.0 (SD) min. The statistical analysis by 'Z' test showed that the difference between the duration of action of analgesia in group-T andgroup-B is Z=29.94 (p<0.01) The Quality of Analgesia (VRS) in group-T was 3.22±0.54 (SD)min and in group-B was 3.62±0.49 (SD) min. The statistical analysis by 'Z' test showed that the difference between the Quality of Analgesia (VRS) in group-B and group-T is Z=1.74 (p<0.01).

Table 4: Onset, Duration and Quality of Analgesia (VRS)

Variable	Group-T (Mean±SD)	Group-B (Mean±SD)	Statistical test	Significance
Onset of Analgesia(in min)	13.28±2.04	11.20±1.02	Z=5.25	P<0.01
Duration of Analgesia(in min)	369.8±25.6	215.2±26.0	Z=29.94	P<0.01
Quality of Analgesia(VRS)	3.22±0.54	3.62±0.49	Z=1.74	P<0.01

In group-T, (34) 68% of patients had pain scores of 3 when compared to group-B 19 (38%) of patients had pain score of 3. 14(28%) of patients in group-T hadpain scores of 4 when compared to 31 (62%) of patients in group-B had pain score of 4.

Cardiovascular and Respiratory Effects :

In group-T, before giving tramadol, pulse rate ranged between 70-90/min(81.32±4.7), systolic BP 106-130 mm of Hg (118.4±6.5), diastolic BP 70- 90mm of Hg(80.44±6.2) and respiratory between 13-17(14.7±1.0) bpm. After giving tramadol, pulse rate ranged between 64-92/min (78.42±5.9), systolic BP 102-130 mm of Hg (115.77±5.9), diastolic BP 64-90 mm of Hg (78.21±5.7) and respiratory between 12-18(14.20±0.9) bpm. In group-B, before giving butorphanol, pulse rate ranged between 66- 90/min (78.36±6.4), systolic BP 106-130 mm of Hg (117.8±7.1), diastolic BP 64-86 mm of Hg (77.2±6.7) and respiratory between 14-17(15.0±1.0) bpm. After giving butorphanol, pulse rate ranged between 64-92/min (75.98±6.9), systolic BP 100-130 mm of Hg (115.1±6.8), diastolic BP 62 -90 mm of Hg (75.1±6.7) and respiratorybetween 12-18(14.9±1.0) bpm.

Table 5: Sedation Score

	After ½ hr			After 1hr			After 2hr			After 4hr		
Sedation Score	0	S	1	**0**	**S**	**1**	**0**	**S**	**1**	**0**	**S**	**1**
Group-T	18	32	--	03	47	--	12	38	--	41	09	--
Group-B	15	35	--	03	38	09	13	33	04	31	19	--
Chi-Square test(X^2)	0.407			9.953			4.392			4.96		
Test of Significance	p>0.05			(p<0.01)			p>0.05			p>0.05		

Where as in group-B, after half an hour of giving drug 35(70%), after 1 hr about 38(76%) and after 2 hrs 33(66%) of the patients were sleeping normally.9(18%) of the patients after 1hr and 4(8%) of the patients after 2 hrs in group-B had sedation score of 1. Sedation score was higher and was maximum at 1 hr with group- B, which was statistically significant (Chi-square test

$X^2 = 9.95$, $p<0.01$) In group-T, 9(18%) of the patients had nausea, 5(10%) had vomiting and none of the patients had sedation; compared to which in group-B, 3(6%) of thepatients had nausea, 1(2%) had vomiting and 8(16%) of the patients had sedation. None of the patients in either group had respiratory depression or any other sideeffects in this study. Urinary retention could not be commented as few of the patients had indwelling urinary catheter.

Discussion

Acute post-operative pain is a complex physiologic reaction to tissue injury. Pain is unpleasant sensory emotional experience associated with actual or potential tissue damage. There are two components of pain; physiological and pathological.Post operative pain is due to direct trauma to the tissue caused by surgery but may be aggravated by associated reflex muscle spasm or visceral distension. Pain being a subjective experience, it is difficult to convey or assess theseverity. However in clinical practice two basic approaches in forms of subjective assessment by patients and objective assessment of parameters altered in presence of pain like cardiovascular changes and respiratory changes in response to pain are studied to judge the severity of pain. Management of post operative pain still posses lot of challenge to anaesthetists, in spite of advances in anaesthesia and analgesia. Presence of painindicates presence of some disease or damage in the body. Cutting, tearing, stretchingand burning of tissues during surgery produces intraoperative and post operative pain. Pain is maximum with orthopedic surgery. If this surgical pain is nottreated adequately, it may lead to derangement in various body functions. So treating pain is necessary to reduce the post operative morbidity and mortality. Combined spinal-epidural (CSE) anesthesia is commonly used in orthopedic surgery. It combines both the rapid onset of the spinal analgesia and the flexibility of the epiduralcatheter. Opioids are powerful, centrally acting agents which have peripheral effects also, so opioids have been administered for many years to allay anxiety and to reduce pain associated with surgery. Opioids exert this therapeutic effect by mimicking the action of endogenous opioid peptide at opioid receptors. In recent times role of epidural and subarachnoid opioids for the post-operative pain promotes a new platform in this field as they have wider margin of safety and acceptability. Tramadol is a well known, time tested drug in the field of anaesthesia. It is a synthetic piperdine analog of codeine. Tramadol is1/5-1/10th as potent as morphine and analgesic doses of Tramadol may produce less respiratory depression because of its non-opioid receptor mediated actions. The analgesic potency of Butorphanol has been found to be greater than morphine andpethidine. Butorphanol unlike morphine, exhibits a ceiling effect on respiratory depression. In our study, a total of 100 patients belonging to age group 20-60 yrs were, divided randomly into two groups(n=50). There were no differences between two groups with regard to demographic profile. Mean age in group-T (receiving epidural tramadol) was 44.8±13.1 and in group-B (receiving epidural butorphanol)was 46.2±11.9. Sex ratio was also comparable. Onset of action of tramadol in a study conducted by Pinky and others[6] who used 100mg of epidural tramadol is 12±3.53 min which is comparable to our studies. Where as onset of analgesia was about 21±3.5 with use of 50 mg tramadol in another study conducted by Baraka et al.[7] A study by Mok showed that onset of action with 4 mg butorphanol was 15min and 6.9±3.6 in another study by Catherine O in 1989 when, 2mg butorphanol wasmixed with 0.25% bupivacaine.[8] Quality of analgesia was assessed at the time when rescue analgesia was given to the patient. Patient was asked to give global assessment of overall effectiveness of the analgesic treatment. 28% of patients in group-T and 62% of patients in group-B graded their pain relief as excellent, where as 68% of patients in group-T and 38% of patients in group-B 19% graded their pain relief as good. In both the groups majority of the patients expressed their analgesia as good toexcellent. Quality of Analgesia (VRS) in group-T was 3.22±0.54 and in group-B was 3.62±0.49. The difference

in both the groups by 'Z' test was Z=1.74, p<0.01 which is statistically significant. In a study by Palacios[9], they have shown that adequacy of analgesia were indistinguishable between epidural morphine and epidural butorphanol. In another study by Yaddanapudi and others[10], overall pain relief with epidural morphine and epidural tramadol was similar in both the groups. Palacios et al[9]. found that no patients in their study group receiving epidural butorphanol developed clinically important change in haemodynamic parameters while study by Rathie Pinky et al[6]. showed that, even tramadol does not have significant alterations in these parameters. In our study, even though there is mild fall in pulse rate and diastolic BP with butorphanol group, the cardiovascular and respiratory parameters were stable in both groups. The fall may be due to adequate analgesia resulting in less sympathetic discharge and comfortable sleeping. In our study majority of the side effects were nausea, vomiting and sedation. Mild sedation is desirable in the post-operative period, which is seen with the butorphanol group (16%). In tramadol group about 9(18%) patients had nausea, 5(10%) had vomiting, where as about 3(6%) had nausea, 1(2%) had vomiting in the butorphanol group. None of the patients in both groups had pruritis, hypotension and respiratory depression. Incidence of nausea and vomiting was less with butorphanol group which is consistent with other studies by Delilkan[11], Mok[8] and others.

Conclusion

*Epidural butorphanol provides a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol, Epidural butorphanol had lesser side effects like nausea and vomiting but has sedation in milder degree which is an additional advantage in the post-operative period, Quality of analgesia in terms of patient satisfaction is also better with epidural butorphanol.

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