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COMPARATIVE STUDY OF POSTOPERATIVE ANALGESIA WITH EPIDURAL TRAMADOL OR BUTORPHANOL IN LOWER ABDOMINAL SURGERIES

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ABSTRACT

Introduction: Post-operative analgesia in patients undergoing lower abdominal surgery is very essential for immediate postoperative pain relief which can be provided by oral or parenteral medication, epidural analgesia, local blocks etc. The combined spinal–epidural technique (CSE) has become increasingly popular in recent years. The study was designed to evaluate the efficacy of epidural butorphanol and tramadol for postoperative pain relief. After the surgical procedure and regression of spinal analgesia, the epidural catheter can be used to provide postoperative pain relief. **Materials and Methods:** After permission from hospital ethics committee, study was conducted on 60 patients undergoing lower abdominal surgeries. Combined spinal epidural anesthesia was planned in all these 60 patients using two segment technique.18 G epidural catheter was placed in L2-L3 space and spinal anesthesia was given at L3-L4 space using 26 G Quincke's needle and 0.5% bupivacaine 3ml. Sensory, motor block and hemodynamic parameters were monitored intraoperatively. Postoperatively along with hemodynamic parameters visual analogue score (VAS) was observed and at VAS > 4, study drug (either butorphanol 1mg or tramadol 50mg) was given through epidural catheter. Onset of analgesia, quality of analgesia, duration of analgesia, cardio-respiratory parameters and any side effects were monitored and documented. **Statistical Analysis:** Data analysis was done using the SPSS (Statistical Package for the Social Science) Version 17 for window. **Discussion:** Mean onset of analgesia in Butorphanol group (10.03 ± 1.85 min) was significantly faster than Tramadol group (12.17 ± 2.19 min) [Z = 4.07, p<0.0001]. Mean duration of analgesia was significantly more in Tramadol group (6.27 ± 0.53 hrs) than with Butorphanol group (3.40 ± 0.42 hrs) [Z=23.06, p<0.0001]. Quality of Analgesia and sedation score was better with Butorphanol group than Tramadol group. **Conclusion:** Epidural butorphanol provides a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol.

KEYWORDS: Butorphanol, Tramadol, Postoperative analgesia, Epidural analgesia.

INTRODUCTION

In major abdominal surgeries, a postoperative analgesia becomes the most important aspect of anesthesia. Such surgeries can cause severe abdominal pain, atelectasis of lungs, retention of secretions and more time in ambulation. This may lead to more incidence of postoperative morbidity and delayed recovery.[1] Effective pain control is vital for early mobilization and postoperative discharge.[2] Regional anesthesia and analgesia are considered to be the safest and cost-effective method of relieving the postoperative pain. The combined spinal–epidural technique (CSE) has become increasingly popular in recent times. It combines the advantages of both spinal and epidural technique by initially providing an intense sensory and motor block of for operative procedure. After the surgical procedure and regression of spinal analgesia, the epidural catheter can be used to provide postoperative pain relief.[3]

Epidural analgesia provides good pain relief in the perioperative period. The epidural analgesic technique for major abdominal surgeries provide effective pain relief with lesser side effects and hence higher levels of patient satisfaction and an improved outcome.[4]

Opioids given orally undergo extensive first pass metabolism and intramuscular doses are absorbed unpredictably. Epidural analgesia avoids these problems and excellent results have been obtained after using opioids via epidural route for control of postoperative pain, however, disadvantage could be its various side effects.[5,6]

Butorphanol, a synthetic morphine derivative is a mixed agonist and antagonist non-narcotic opioid analgesic whereas tramadol is a synthetic 4-phenyl-piperdine analogue of codeine, which inhibits serotonin reuptake and norepinephrine reuptake, enhancing inhibitory effects on pain transmission in the spinal cord.[7] These drugs are most commonly used and easily available, hence the present study was undertaken with the to compare the efficacy between epidural butorphanol and

epidural tramadol for postoperative analgesia in lower abdominal surgeries.

MATERIALS AND METHODS

A randomized controlled (trial) study was carried out in Government Medical College, Jammu, during the period: April 2018 to September 2018 (6 months) on 60 patients undergoing lower abdominal surgeries in, general surgery, urology and gynecology. Ethical approval was duly obtained from Institutional Ethical Committee. All patients were informed about anesthesia technique and research study and their written informed consent was taken.

Inclusion criteria

All patients undergoing lower abdominal surgeries.
Patients with physical status ASA I or ASA II
Age between 20 to 60 years

Exclusion criteria

All patients with physical status ASA III or higher.
Patients with coagulation defects, severe haemorrhage or shock
Patients with local inflammation / infection or drug allergy
Non-consenting patients

The ASA PSCS[8] is a system is to assess and communicate a patient's pre-anesthesia medical co-morbidities, which could be helpful in predicting perioperative risks. The final assignment of Physical Status classification is made on the day of anesthesia care by the anesthesiologist after evaluating the patient. (Table 1)

Patient's detailed history, age, sex and weight were recorded, and basic investigations like random blood sugar, Prothrombin time, blood urea, serum creatinine, Chest X-ray and ECG were carried out. Patients were also taught to assess the intensity of pain using visual analogue scale (VAS): 0-3 - Mild Pain; 4-7 - Moderate Pain and >7 - Severe Pain.

All the patients received tablet alprazolam 0.5 mg orally on the previous night of surgery and kept on fasting for 8 hrs before surgery. All patients were administered combined spinal epidural anesthesia using 2 segment technique. Subarachnoid anesthesia was given in L3-L4 space using 26G Quincke's needle and 3ml of 0.5% heavy bupivacaine.

In the post-operative period, at Visual Analogue Score (VAS) of ≥ 4, patients were administered 50 mg of tramadol diluted to 10 ml with normal saline, in group-1 and 1 mg of butorphanol diluted to 10 ml with normal saline, in group-2. Pulse rate, blood pressure (SBP and DBP), respiratory rate and sedation score were recorded at baseline, 30 min, 1 hr., 2 hr., 4 hr. and 8 hr.

Specific clinical benchmarks and parameters were studied: Onset of analgesia, duration of analgesia (time gap between the epidural injection of drug and rescue analgesia), level of consciousness, quality of analgesia via verbal response score (VRS)[9] (Table 2), Cardio-respiratory parameters and side effects like nausea, vomiting, pruritis, hypotension, etc.

Data was analyzed using the SPSS Version 11 software. The 't-test' was used to find significant differences in data/parameters. $P<0.05$ was considered as statistically significant.

Table 1: ASA (Grades): Definitions and Examples (among adults).

ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (<3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, shock, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis

Table 2: Assessment of pain relief: five point verbal response score.

Score	Subjective Relief in Pain	
0	No pain relief	0% pain relief
1	Little pain relief	Appox. 25% pain relief
2	Some pain relief	Appox. 50% pain relief
3	Good pain relief	Appox. 75% pain relief
4	Complete pain relief	100% pain relief

RESULTS

Demographic parameters were comparable in both the groups. The average age of patients was: 40.67 ± 8.79 years and average weight was: 61.21 ± 5.90 Kg. Males were predominant at 55%. (Table 3)

Table 3: Demographic Parameters of two groups.

Parameters	Group 1 (n=30) Mean ± SD	Group 2 (n=30) Mean ± SD	Total (n=60) Mean ± SD
Age (Years)	40.22 ± 8.46	40.94 ± 9.19	40.67 ± 8.79
Weight (Kg)	61.83 ± 5.94	60.91 ± 5.85	61.21 ± 5.90
Gender:			
Males	16 (53.3 %)	17 (56.7 %)	33 (55 %)
Females	14 (46.7 %)	13 (43.3 %)	27 (45 %)

In 14 (46.7 %) of patients, onset of analgesia was within 10 minutes, in Group 2, while it was only among 6 (20 %) patients in Group 1. Mean onset of analgesia in Group 2 was significantly faster when compared to Group 1. (p<0.001) (Table 4)

Table 4: Onset of analgesia.

Onset of analgesia (minutes)	Group 1	Group 2
0-3	0	0
4-6	1	2
7-9	5	12
10-12	9	14
13-15	15	2
Mean Time (minutes)	12.17 ± 2.38	9.46 ± 2.05

Quality of Analgesia with Group 1 was better than Group 2, as complete pain relief was there in 60 % of Group 2 patients while it was in only 33.3% patients in Group 1. (Table 5)

Table 5: Quality of analgesia in study groups (Verbal Response Score).

VRS score	Quality of Analgesia	Group 1 (n=30)	Group 2 (n=30)	P Value
0	No pain relief	0	0	-
1	Little pain relief	0	0	-
2	Some pain relief	4 (13.3 %)	1 (3.3 %)	0.243
3	Good pain relief	16 (53.3 %)	11 (36.7 %)	0.663
4	Complete pain relief	10 (33.3 %)	18 (60 %)	0.003*

*p-value <0.05 = statistically significant

Better sedation was seen with butorphanol group at different time intervals as compared to tramadol. At 60 min mean sedation score with butorphanol (1.91 ± 0.97) was significantly higher than when compared to tramadol (1.30 ± 0.84). (Table 6)

Table 6: Sedation score in study groups.

Sedation Score	Group 1 (n=30) Mean ± SD	Group 2 (n=30) Mean ± SD	p-value
Baseline	0	0	--
30 Minutes	1.29 ± 0.85	1.41 ± 0.89	0.232
60 Minutes	1.30 ± 0.84	1.91 ± 0.97	0.044*
120 Minutes	1.38 ± 0.88	1.76 ± 0.96	0.147
4 Hours	0.78 ± 0.65	0.96 ± 0.73	0.549
8 Hours	0	0	--

*p-value <0.05 = statistically significant

Mean duration of analgesia (hrs) was 5.97 ± 0.60 hours in Group 1 and in Group 2 mean duration of analgesia (hrs) was 3.91 ± 0.44 hours. This mean duration of analgesia (hrs) was analyzed quantitatively within groups. The p value was statistically highly significant. (Table 7)

Table 7: Duration of analgesia in study groups.

	Group 1 (n=30) Mean ± SD	Group 2 (n=30) Mean ± SD	p-value
Duration of Analgesia (Hours)	5.97 ± 0.60	3.91 ± 0.44	0.00045*

*p<0.05 = statistically significant, p<0.001 = highly significant

Tramadol group had more nausea and vomiting as compared to butorphanol, but none of the patients in both groups had pruritis, cardio- respiratory depression and no patients showing any signs of clinical desaturation or hypoxia.

DISCUSSION

Pain is best defined as "an uncomfortable feeling that tells you something may be wrong." Because of pain, post-operative patients are unable to breathe adequately and cough effectively. Hence Effective pain control is vital for early mobilization and postoperative discharge.[1] The prime function of anesthesiologist is to relieve pain. Postoperative analgesia decreases tachycardia, tachypnea and oxygen consumption which is useful in patients with ischemic heart disease, anemia and cardiac failure. Postoperative analgesia also minimizes the stress response to surgery and helps in wound healing and also helps in better postoperative ventilation of patient.[10]

Opioids administered in epidural space, by an anesthesiologist, for pain relief/ control, can enter the cerebrospinal fluid (CSF) by penetrating the Dura, can remain in epidural fat and can leave epidural space as a result of uptake by radicular arteries and epidural venous plexus. Hydrophilic opioids such as morphine tend to stay in the CSF and then migrate rostrally, whereas lipophilic opioids such as fentanyl diffuse into the lipid rich areas in spinal cord and exhibit little CSF migration.[11] Studies have shown that Tramadol in doses of 100 mg and above has side effects like nausea, vomiting, hypotension etc. Butorphanol is more potent than morphine and pethidine and has been employed in postoperative pain relief.[12]

Pokharel *et al*.[13] have also used VAS/VRS scale to assess the quality of analgesia and have inferred that quality of analgesia is better with butorphanol. Quality of analgesia has been proven to be better with butorphanol group in several studies and a statistically significant difference was seen between the two groups more so within 2 hours of administration of the drug ($P < 0.05$). We had a comparable results with Ramsay sedation scale. However, there have been comparable results. Mild sedation may be beneficial to patients in the immediate postoperative period.

In the study by Bhagwat et al.[14], VAS/VRS at 1 h with 1 mg butorphanol was found significantly higer than that of 50 mg tramadol . In our study, complete pain relief was significantly higher at 60 % of Group 2 patients while it was in only 33.3% patients in Group 1.

Similar to our study, Singh et al[15] in 2011 compared the efficacy of epidural butorphanol (1 mg) and tramadol (50 mg) and found that onset of action was faster with butorphanol than tramadol and also quality of analgesia was better with butorphanol while duration of analgesia was significantly longer with epidural tramadol.

Group 2 patients had side effects like nausea and vomiting which were less when compared to group 1, but not significant, however, Gupta et al.[4] in 2011 compared the efficacy of epidural butorphanol and tramadol and found that nausea and vomiting was found in tramadol group only.

None of the patients in both groups, in the present study, had pruritis, cardio- respiratory depression and no patients showing any signs of clinical desaturation or hypoxia. Rathie et al,[16] in their study group receiving epidural tramadol, have also found that no patients developed clinically important change in haemodynamic parameters and Malik et al,[17] in their study group receiving epidural butorphanol, have also shown similar results.

Therefore, both epidural butorphanol (1 mg) and epidural tramadol (50 mg) have good efficacy, but butorphanol has a better sedation score and a shorter duration of action.

CONCLUSION

Quality of analgesia in terms of patient satisfaction is better with epidural Butorphanol. Epidural Butorphanol provided a rapid, excellent but shorter duration of analgesia when compared to epidural tramadol.\

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REFERENCES

1. Ahmed A, Latif N, Khan R. Post-operative analgesia for major abdominal surgery and its effectiveness in a tertiary care hospital. J Anaesthesiol Clin Pharmacol, 2013; 29: 472–7.
2. Wu CL. Acute postoperative pain. In: Miller RD, editor. Anesthesia, 6th ed. Pennsylvania: Churchill Livingstone, 2005; 2764-5.
3. Cousins MJ, Mather Laurence E. Intrathecal and epidural administration of opioids. Anaesthesiology, 1984; 65: 276-310.
4. Gupta R, Kaur S, Singh S, Aujla KS. A comparison

of epidural butorphanol and tramadol for postoperative analgesia using CSEA technique. J Anaesthesiol Clin Pharmacol, 2011; 27: 35–8.
5. Nimmo SM. Benefit and outcome after epidural analgesia. Continuing Education in Anesthesia, Critical Care and Pain., 2004; 4: 44-7.
6. Morgan M. The rational use of intrathecal and extradural opioids. Br J Anaesth, 1989; 63: 165-88.
7. Vandam Leroy D. Drug therapy: Butorphanol. Eng J Med., 1980; 302: 381-84.
8. https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system; ASA Physical Status Classification System, October 15, 2014.
9. Delilkan A.E, Vijayan R. Epidural tramadol for postoperative pain relief. Journal of the Association of Anaesthetists of Great Britain, 1993; 48: 328-31.
10. Abbound TK, Moore M, Zhu J, Murakawa K, Minehart M, Longhitano M, et al. Epidural Butorphanol or morphine for the relief of post-caesarean section pain: ventilatory responses to carbon dioxide. AnaesthAnalg, 1987; 66: 887-93.
11. Jablonka DH, Davis PJ. Opioid in PediatricAnesthesia. AnaesthesiologyClin N Am., 2005; 23: 621-34.
12. Stoelting RK, editor. Pharmacology and Physiology in Anesthesia Practice. 3rd Ed, Philadelphia: Lippincott- Raven, 1999; 77-112.
13. Pokharel K, Rahman TR, Singh SN, Bhattarai B, Basnet N, Khaniya S. The efficacy and safety of low dose epidural butorphanol on postoperative analgesia following cesarean delivery. JNMA J Nepal Med Assoc, 2008; 47: 57–61.
14. Bhagwat S, Sanjay N. Postoperative analgesia: A comparative study of epidural butorphanol and epidural tramadol. J Adv Res Biol Sci., 2011; 3: 86–9.
15. Singh B, Nihlani S. Post-operative analgesia: A comparative study of Epidural Butorphanol and Epidural Tramadol. Journal of Advance Researches in Biological Sciences, 2011; 3: 86-9.
16. Rathie P, Verma RS, Jatav TS, Kabra A. Post-operative pain relief by epidural tramadol. Ind J Anaesth, 1998; 42: 26-31.
17. Malik P, Manchanda C, Malhotra N. Comparative Evaluation of Epidural Fentanyl and Butorphanol for Postoperative Analgesia. J AnaesthClinPharmacol, 2006; 22: 377-82.