Original Article

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Comparative Study of Epidural Butorphanol & Epidural Fentanyl for the Relief of Post Operative Pain in Lower Abdominal & Lower Limb Surgery

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Abstract

Background and Aim: Post operative pain relief is an essential part of responsibility for an anaesthesiologist. Epidural opioids acting through the spinal cord receptors improve the quality and duration of analgesia. The present study compared the efficacy and safety profile of epidurally administered butorphenol and fentanyl. *Methods*: In this double blinded study, 60 patients undergoing lower abdominal and lower limb surgery were randomly divided into two groups by computer generated random number. In all patients, epidural space is located at L2-L3 space using 18G Tuohy needle with loss of resistance technique.20G catheter passed through needle till about 2-3cm of catheter was in space. Test dose was injected. After 5 min, induction was done with spinal anaesthesia with inj. Bupivacaine heavy 0.5% 3cc at same lumber space in sitting position. Group A patients received epidural Butorphenol 1mg diluted in 10ml Ns as first dose post op when VAS>5 and top up dose 0.5 mg diluted in 10ml NS when VAS>5. Group B patients received epidural fentanyl 100microgram diluted in 10ml NS as first dose post op when VAS>5 and top up dose fentanyl 50microgram diluted in 10ml NS when VAS>5.Vital parameter, onset, duration, quality of analgesia, side effects, VAS score, sedation score were observed. The data was collected and tabulation formed and statistical analysis of continuous data was done by unpaired student "t" test and chi-square test was applied for discrete data. Results were considered statistically significant with p value <0.05 and highly significant with p value <0.001. *Results*: Demographic profiles of patients were comparable in both the groups. Onset of analgesia was earlier in fentanyl group than butorphenol group. Butorphenol provides longer duration of analgesia compared to fentanyl group. Quality of analgesia was better with butorphanol than fentanyl. *Conclusion*: Butorphanol and fentanyl both drugs are safe to provide analgesia via epidural route in post operative period without significant side effects. Fentanyl is having earlier onset with short duration of analgesia while butorphanol provide analgesia for longer duration with delayed onset.

Keywords: Butorphenol; Fentanyl; Lower Abdominal and Lower Limb Surgeries; Lumber Epidural Anaesthesia; Post Operative Pain Relief.

Introduction

Acute pain produces an increase in sympathetic tone that manifests as an increase in heart rate, blood pressure, and cardiac output, systemic and coronary vascular resistances [1,2]. Epidural opioid techniques has been found to provide better pain relief than systemic opioids, decreased incidence of postoperative complications and decreased side effects of systemic opioids. Epidural catheter placed in a location congruent to the incision dermatome has been shown to provide superior analgesia. Maintenance of epidural anaesthesia for 48 to 72 hours postoperatively has salutary effect [3]. Butorphanol tartarate is an agonist on *k* receptor and either antagonist or partially agonist on μ receptor. It is considered safer than pure agonist opioids because of its ceiling effect on respiratory depression, lower addiction potential, lesser nausea, vomiting,

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pruritus and urinary retention [4,5] and also produces sedation, which is desired in postoperative period. Fentanyl, an opiate μ receptor agonist has analgesic potency greater than morphine. Respiratory depressant effect of fentanyl is less pronounced and of shorter duration of action as compared to morphine and pethidine. Postoperative analgesia not only improves quality of life of the patient but also results in fast recovery and hence reduces the medical costs. Hence, this clinical study of comparative evaluation of epidural butorphanol with epidural fentanyl is undertaken to evaluate their feasibility as effective analgesics for postoperative pain relief.

Material and Method

Following institutional approval by the ethical committee at our Institute, written informed consent from the participant were obtained which consisted of 60 randomly selected adult patients of age 18-60 years, of either sex, belonging to class ASA I & II, weight 50-70 kg, which were admitted for elective lower abdominal and lower limb (mainly orthopedics) surgical procedures under regional anaesthesia. Patients having pre-existing uncontrolled systemic disorder or coagulation abnormality were excluded from our study. This was a randomised double blind prospective study. All patients were divided by computer generated random number into two study groups A and B each consist of 30 patients. During the pre operative visit, thorough examination done and procedure explained to the patients. On the day of surgery, IV access was secured with 18G cannula and injection RL infusion was commenced, and premedications given to the patients. Epidural space was located in sitting position, at L2-L3 interspace 18 G disposable Tuohy needle with loss of resistance (LOR) technique with normal saline was inserted. Then 20G PORTEX epidural catheter was passed through the epidural needle till about 2-3 cm of the catheter was in the space. Test dose was injected through the catheter and observed for any accidental intravascular or intrathecal injection. After 5 min, induction was done with spinal anaesthesia with inj.bupivacaine 0.5% 3 cc at same lumbar space in sitting position. Surgery was undergone. Post operatively, Group A received epidural Butorphanol 1 mg diluted to 10 ml normal saline as first dose postoperatively when VAS >5 and top up dose of epidural butorphanol 0.5 mg diluted to 10 ml normal saline when VAS>5. Group B received epidural Fentanyl 100 microgram diluted to 10 ml normal saline as first dose postoperatively when VAS>5 and top up dose of epidural fentanyl 50 microgram diluted to 10 ml normal saline when VAS>5. Vital parameters were recorded on multipara monitor. Post operative data collection was in the form of VAS score, sedation score and assessments of side effects were done clinically and Quality of analgesia was assessed by grading system. The data was collected and tabulation formed and statistical analysis of continuous data was done by unpaired student "t" test and chi-square test was applied for discrete data. Results were considered statistically significant with p value <0.05 and highly significant with p value <0.001.

Observation and Results

No statistically significant difference between the groups was observed with respect to age, gender, weight or ASA grading. Percentage of different surgeries in both the groups was also equal. Mean Base line (Pre induction) pulse rate, systolic BP, diastolic BP and mean arterial BP were recorded in both groups and compared. Statistically there was no difference between the two groups in respect to above vital parameters. The mean onset time of action of Group A was 6.4 ± 1.3 min and Group B was 4.33 ± 0.82 min. The difference between two was very much significant. In Group A, mean duration of first dose of analgesia was 375±49.9 min as compared to 228±29 min in Group B. The mean duration for first analgesia was higher in Group A than Group B which was highly statistically significant. The requirement of the first supplementation of dose was significantly delayed in group A. The mean duration analgesia of second dose of epidural analgesic was 516±99 min in group A, as compared to 364±77.3 min in Group B. There was a statistically significant prolongation of duration for second analgesia in Group A than Group B. In Group A, 18 (60%) patients required only one epidural analgesic and 12 (40%) out of 30 patients required two top up doses of analgesics in 24 hours post-operatively. In Group B, 20 (66.67%) patients had two supplementations of epidural analgesia and 10 (33.33%) patients had three supplementations in 24 hours. In Group A, no patient required more than two doses of analgesic. The mean number of analgesic doses required was 1.40 ± 0.49 in Group A compared to 2.30 ± 0.53 in group B. Total number of analgesic consumption for 24 hours post-operatively was less (42) in Group A as compared to 68 in Group B which was statistically highly significant. The mean quality score of analgesia was 3.13 ± 0.51 in Group A and 2.73 ± 0.58 in Group B. The quality of analgesia was

better in Group A than Group B; this result was statistically highly significant. Sedation was observed only in Group A (butorphanol) and significantly large number of patients (24 out of 30) had noticeable sedation while no patients in Group B had documentable sedation. In Group A, 80% patients had grade 1 or grade 2 sedation score at first hour of post operative period, as compared to none of the patient in Group B which was statistically highly significant.

Discussion

Epidurally given opioids acting on spinal cord receptors provide distinct advantage over its systemic administration for better quality of analgesia, lower sedation scores, preservation of physiological function and improved outcome. Ruchi gupta et al [6] and Premila Malik et al [7] administered butorphanol 2 mg epidurally whereas Naulty MD et al [8] administered 1, 2, 4 or 6 mg butorphanol via epidural route. Rutter DV et al [9] administered 100 μg fentanyl epidurally whereas Naulty JS et al [10] administered 12.5,25,50,70 or 100 μg of fentanyl epidurally and Lomessy et al [11] and Negre I et al [12] used 200 μg for post operative analgesia. We have chosen 1 mg butorphanol as first dose and 0.5 mg as top up doses whenever VAS>5 in Group A whereas 100 μg fentanyl as first dose and 50 μg as top up doses whenever VAS>5 in Group B in our study as provide adequate analgesia with fewer side effects. Bijur PE et al [13] has described VAS score as the simple effective way to measure the intensity of pain. In our study we observed VAS score to decide the time to give the dose of the analgesic post operatively and also to compare the onset, duration and quality of analgesia between both the study groups. We decided to give the dose of the analgesic when VAS>5 as it correlates with the moderate to severe intensity of pain which is associated with haemodynamic changes and patients' discomfort. In most of the literature reviewed before designing this study, the first dose of analgesia was administered on demand of the patient and VAS score was more than 4 or 5. In our study, the first dose of analgesic was administered after the effect of spinal anaesthesia regressed and patient complained of pain with VAS>5. VAS score and sedation score were observed at 0, 1hr, 2hr, 4hr, 6hr, 8hr, 12hr, 24 hrs postoperatively after administration of the study drug as it correlates with the pharmacokinetic properties of the selected study drugs.

Onset of analgesia was early in Group B as compared to group A. Fentanyl is having high lipid solubility and high protein binding capacity with more affinity for the opioid receptor which is responsible for early onset of action as compared to butorphanol. This result was similar to studies of Naulty JS et al [10], Rutter DV et al [9], Mok et al [14], Lippmann et al [15]. Longer duration of analgesia in Group A in comparison with Group B. This result was similar to studies of Abboud et al [16], Mok et al [14], Ruchi Gupta et al [6], Palacios et al [17], Quisqueya T et al [18], Premila Malik et al [7], Rutter DV et al [9]. Quality of analgesia was assessed at the time at which top up dose of analgesia was given to the patient. In majority (93.33%) cases of group A pain relief was satisfactory (grade 3 and grade 4). In two patients, they did complain of fair pain relief when asked, this pain was managed with repeated top up dose of butorphanol by epidural route. In group B, 20 (66.67%) patients had satisfactory pain relief (grade 3 and grade 4). In 10 patients, they did complain of fair pain relief when asked which was relieved by repeated top up dose of fentanyl administered by epidural route. None of the patients from both the study groups had no pain relief (grade 0) or poor pain relief (grade 1). In butorphanol group, 18 (60%) patients require only one injection of top up dose of butorphanol epidurally as compared to none in fentanyl group. 12 (40%) patients of butorphanol group required two top up doses as compared to twenty (66.67%) patients of fentanyl group. In fentanyl group 10 (33.33) patients required three top up dose of fentanyl as compared to none of the patient in butorphanol group. Total mean number of analgesic consumption in 24 hours in butorphanol group was 1.40±0.49 as compared to 2.33±0.47 in fentanyl group which was statistically highly significant ($p< 0.0001$). Naulty JS et al also found that if a longer duration of action required than repeated injections are needed.Butorphanol provided fairly better quality of analgesia than fentanyl which was statistically significant. This result was similar to study of Quisqueya T et al [18]. Statistically there was no difference between the two groups in respect to vital parameters. These results were supported by the studies done by Gough et al [19], Premila Malik et al [7].

In group A, majority of the patients had mild sedation (grade 1- patient awake but calm) which was required in the early post operative period. This result was similar to study of Naulty MD et al [8], Abboud et al [16], Catherine OH et al [20] and Ackerman et al [21], Ruchi Gupta et al [6], Naulty JS et al [10]. Pruritus was observed in 10% of group B patients. Ackerman et al [21], Naulty MD et al [8],

Palacios et al [17], Hwang KB et al [22], Premila Malik et al [7], Szabova A et al [23] studies reported side effect like pruritus in patients receiving epidural fentanyl. Nausea or vomiting was reported in 6.66 % of cases in Group A and 10% of cases in Group B which was not significant statistically. Opioid stimulates the chemoreceptor trigger zone in area postrema of the medulla which causes nausea and vomiting. These were compared to Abboud et al [16], Naulty JS et al [10] studies' results. No patients had respiratory depression or urinary retension in either of the groups. These results were compared to Naulty MD et al [8], Lippmann M et al [15], Catherine OH et al [20], Naulty JS et al [10] studies' results.

To conclude, both butorphanol and fentanyl are effective and safe drugs for postoperative epidural analgesia with minor side effects. The duration of analgesia is longer with epidural butorphanol but is associated with sedation. Epidural fentanyl is associated with increased incidence of nausea and pruritus.

Conclusion

Butorphanol and fentanyl both drugs are safe to provide analgesia via epidural route in post operative period without significant side effects. Fentanyl is having earlier onset with short duration of analgesia while butorphanol provide analgesia for longer duration with delayed onset. Quality of analgesia was better with butorphanol than fentanyl.

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