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Patient Controlled Epidural Analgesia (PCEA) with or without Background Infusion using Fentanyl and Bupivacaine for Major Upper Abdominal Surgery

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Abstract

Background:
Pain thresholds vary in individuals. Need for analgesia thereby differs in individuals.

Methods
The aim was to compare, patient controlled epidural analgesia (PCEA) with demand bolus (Group A) versus demand bolus and continuous infusion (Group B) in terms of analgesic efficacy and side effects after major abdominal surgery. The primary outcome of the study was VAS score at rest and on coughing, number of demand and successful delivery of analgesia. The secondary outcomes evaluated were total fentanyl and bupivacaine doses, frequency of rescue analgesia, sedation scores and side effects.

No drug was given through epidural catheter passed preoperatively. Postoperatively, when VAS > 3, Patient Controlled Analgesia (PCA) pump was programmed to deliver on demand, 3.5 ml containing 10 mcg of Fentanyl and 2 mg of Bupivacaine in Group A with a lockout interval of 15 minutes. In Group B, continuous infusion of same solution at 3.5 ml/hr was also given. Patient was asked to rate the analgesia. Rescue analgesia was given with IV Tramadol 2mg/kg when VAS > 3 at rest despite three consecutive demands.

Results
74 patients were studied. Number of demands, VAS scores was significantly less in group B. Requirement of rescue analgesia was more in group A. Amount of bupivacaine and fentanyl needed and incidence of nausea and vomiting were more in the group B. No incidence of over sedation, hypotension and respiratory depression was noted.

Conclusion
PCEA with continuous infusion plus demand bolus gave better quality of analgesia and had better acceptability, without any significant side effects.

Keywords
PCA; Fentanyl; Bupivacaine; Infusion; Bolus; Epidural

Brief Summary Statement
Pain thresholds vary in individuals. Need for analgesia thereby differs in them. Pain relief is an essential component of postoperative management. Patient controlled analgesia (PCA) is one of the methods employed for the same.

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Introduction

Effective pain relief allows patient to maintain the respiratory function, while early mobilization leads to quick recovery and shorter hospital length of stay [1]. Pain threshold and thereby analgesia needs varies in individuals. Hence this randomized study was planned using patient controlled epidural analgesia with bolus of bupivacaine and fentanyl (Group A) and with bolus and continuous infusion of bupivacaine and fentanyl (Group B) to compare the effectiveness on post operative pain and safety after major upper abdominal surgery.

Methods

The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all subjects. Our aims & objective was to compare, patient controlled epidural analgesia (PCEA) with demand bolus (Group A) versus demand bolus and continuous infusion (Group B) in terms of analgesic efficacy and side effects after major upper abdominal surgery. The primary outcome of the study was VAS score at rest and on coughing, number of demand and successful delivery of analgesia. The secondary outcomes evaluated were total fentanyl and bupivacaine doses, frequency of rescue analgesia, sedation scores and side effects. The study was open labeled prospective and randomized. Sample size was calculated taking a change in at least 15 % change in VAS scores as per study done by Komatsu [2]. The sample size was calculated to 37 in each group. The primary outcome of the study was visual analogue scale at rest and on coughing, number of demand and successful delivery of PCA. The secondary outcomes evaluated were total fentanyl and bupivacaine doses, frequency of rescue analgesia, sedation scores and side effects if any

After ethics committee approval and a valid informed written consent, ASA grade I–III adults undergoing elective upper abdominal surgery and aged 18–60 years were randomized and included in the study groups. The patients were explained about the use of patient controlled analgesia pump and visual analogue scale (VAS) score. Preoperatively epidural catheter was inserted. Intraoperatively standard general anaesthesia with endotracheal tube intubation was given.

No drug was given through epidural catheter passed preoperatively. Postoperatively, when patient had VAS > 3, on demand patient had to press the button of PCA pump. Patient Controlled Analgesia (PCA) pump was programmed to deliver on demand, 3.5 ml containing 10 mcg of fentanyl and 2 mg of bupivacaine in Group A with a lockout interval of 15 minutes. However, if the demand was in lock out interval, the drug was not delivered.

In Group B, continuous infusion of same solution at 3.5 ml/hr was also given. Patient was asked to rate the analgesia. Rescue analgesia was given with IV tramadol 2mg/kg when VAS > 3 at rest despite three consecutive demands. Pain score, sedation score, frequency of rescue analgesia and side effects such as nausea, vomiting, pruritus, objective motor blockade, hypotension and respiratory depression along with heart rate, respiratory rate, blood pressure, oxygen saturation, were recorded every hourly for 24 hours. Hypotension was defined as a drop of systolic blood pressure of more than 20% of preoperative value or < 90 mmHg during the study period. Respiratory depression was defined as respiratory rate of < 10 per minute. Pain intensity was measured by using 0–10 cm Visual Analogue Scale (VAS) score wherein 0 cm was no pain and 10 cm was worst pain imaginable. At the end of study patient were asked to rate their pain control.

Statistical Analysis

The data was entered using MS-Excel-2007 and analyzed using SPSS-16 software. Descriptive analysis for numerical data consisted of mean with standard deviation (SD) and frequencies for categorical data were expressed in percentage. Un-paired t test was used for comparison of mean between two groups and Chi square test for comparison of proportions between two groups. A value of $P < 0.05$ was considered significant.

Results

In our study, patients were divided into 2 groups of 37 each with the help of a computer generated table (Table 1) of random numbers. They received patient controlled epidural analgesia using bupivacaine and fentanyl as demand bolus (Group A) or continuous infusion plus demand bolus (Group B) for post-operative pain relief after major abdominal surgery.

Demographic data was comparable with respect to age, gender, weight and ASA grading. As shown in table 2, although mean VAS at rest was more in first two hours in group A, it was statistically not significant. Later, mean VAS values were lower in group B and were statistically significant.

It was found that VAS on coughing was more in group A and was statistically significant at all intervals except at 13 hours. This is shown in table 3.

As seen in table 4, in group A, average demands over the entire study period, were 32.62 ± 7.98 and in Group B they were only 11.78 ± 8.72. This was statistically significant. In Group A total deliveries were 24.22 ± 7.37 and in Group B they were 7.37 ± 4.24. This difference was also statistically significant. Thus in group A, out of mean of 32 demands only mean of 24 were delivered as the rest demands were in the lock out interval. Similarly, in group B, out of mean 11 demands only 7 were delivered.

In Group A, total bupivacaine used was 47.68 ± 11.14 mg and fentanyl 233.8 ± 59.69 mcg. In Group B total bupivacaine used was 65.31 ± 10.28 mg and fentanyl used was 320 ± 43.90 mcg. This was statistically significant and is shown in table 5.

It was found that 25 out of 37 patients in group A required rescue analgesia whereas only 8 out of 37 patients in group B required rescue analgesia. This was statistically significant. Most of the patients were awake or drowsy and the sedation scores were lower in group A with statistical significance at 5, 7, 8, 9, 12, 13 and 18 hours.

Three patients had both nausea and vomiting out of 37 patients in group A. In group B nausea was seen in seven patients while vomiting in six patients. Two patients had pruritus in group B. No patient developed respiratory depression in the study. The incidence of side effects was not statistically significant.

17 out of 37 patients in group A were satisfied whereas 36 out of 37 patients in group B were satisfied with the pain relief. This was statistically significant.

In our study the heart rate, respiratory rate, oxygen saturation and Mean Arterial Pressure at all intervals were statistically not significant.

Variable	Group A (N=37)	Group B (N=37)	P value	Significance
Age (yrs)	44.4 + 14.7	42.4 + 12.7	0.528	Not significant
Weight (kg)	56.8 + 8.7	57.2 + 11.4	0.864	Not significant
Gender (Male: Female)	20:17	19:18	0.816	Not significant
ASA (I/II)	26/11	28/9	0.601	Not significant

Table 1: Demographic Data

VAS	Group A	Group B	Intergroup	Significance Intergroup
	Mean ± SD	Mean ± SD	p value	Significance
Immediate Postoperative	1.19 ±1.02	0.97 ± 1.01	0.364	Not significant
1 hr	4.43 ± 1.48	3.95 ± 1.29	0.136	Not significant
2 hr	4.03 ±1.50	3.76 ± 1.09	0.378	Not significant
3 hr	3.81 ± 1.50	3.03 ± 1.32	0.020	Significant
4 hr	3.41 ± 1.51	2.62 ± 1.27	0.019	Significant
5 hr	2.86 ± 1.33	2.05 ± 1.22	0.008	Significant
6 hr	2.92 ± 140	1.70 ± 1.22	< 0.001	Significant
7 hr	2.86 ± 1.33	1.51 ± 1.07	< 0.001	Significant
8 hr	2.57 ± 1.34	1.24 ± 1.14	< 0.001	Significant
9 hr	2.57 ± 1.62	1.16 ± 1.09	< 0.001	Significant
10 hr	2.57 ± 1.44	1.22 ± 1.05	< 0.001	Significant
11 hr	2.38 ± 1.34	1.30 ± 1.05	< 0.001	Significant
12 hr	2.16 ± 1.36	1.22 ± 0.94	< 0.001	Significant
13 hr	2.35 ± 1.31	1.08 ± 1.03	< 0.001	Significant
14 hr	2.38 ± 1.25	0.95 ± 0.94	< 0.001	Significant
15 hr	2.49 ± 1.62	0.89 ± 0.80	< 0.001	Significant
16 hr	2.35 ± 1.33	2.35 ± 0.84	< 0.001	Significant
17 hr	2.49 ± 1.32	0.97 ± 0.98	< 0.001	Significant
18 hr	2.11 ± 1.30	0.76 ± 0.92	< 0.001	Significant
19 hr	2.00 ± 0.57	0.57 ± 0.80	< 0.001	Significant
20 hr	2.27 ± 1.53	0.46 ± 0.65	< 0.001	Significant
21 hr	1.95 ± 1.43	0.65 ± 0.88	< 0.001	Significant
22 hr	2.00 ± 1.37	0.51 ± 0.83	< 0.001	Significant
23 hr	1.76 ±1.48	0.41 ± 0.59	< 0.001	Significant
24 hr	1.78 ± 1.29	1.78 ± 0.31	< 0.001	Significant

Table 2: VAS at rest

Cough	Group A	Group B	Intergroup	Significance Intergroup
	Mean ± SD	Mean± SD	p value	Significance
Immediate Postoperative	2.08 ± 1.14	1.14 ± 1.31	0.160	Not significant
1 hr	5.51 ± 1.50	5.05 ± 0.99	0.126	Not significant
2 hr	5.08 ± 1.51	4.76 ± 1.09	0.294	Not significant
3 hr	4.84 ± 1.44	4.03 ± 1.25	0.012	Significant
4 hr	4.41 ± 1.49	3.62 ± 1.27	0.018	Significant
5 hr	3.89 ± 1.35	3.16 ± 1.48	0.030	Significant
6 hr	3.89 ± 1.41	2.65 ± 1.39	< 0.001	Significant
7 hr	3.84 ± 1.45	2.41 ± 1.18	< 0.001	Significant
8 hr	3.51 ± 1.30	2.08 ± 1.36	< 0.001	Significant
9 hr	3.46 ± 1.62	2.11 ± 1.35	< 0.001	Significant
10 hr	3.46 ± 1.53	2.08 ± 1.34	< 0.001	Significant
11 hr	3.19 ± 1.30	2.11 ± 1.10	< 0.001	Significant
12 hr	3.19 ± 1.39	2.08 ± 1.16	< 0.001	Significant
13 hr	3.22 ± 1.47	3.89 ± 1.15	0.725	Not significant
14 hr	3.32 ± 1.33	1.76 ± 1.11	< 0.001	Significant
15 hr	3.49 ± 1.64	1.68 ± 0.97	< 0.001	Significant
16 hr	3.35 ± 1.37	1.76 ± 1.21	< 0.001	Significant
17 hr	3.54 ± 1.28	1.81 ± 1.12	< 0.001	Significant
18 hr	3.14 ± 1.27	1.43 ± 1.11	< 0.001	Significant
19 hr	3.03 ± 1.28	1.43 ± 0.92	< 0.001	Significant
20 hr	3.19 ± 1.66	1.27 ± 0.69	< 0.001	Significant
21 hr	2.84 ± 1.51	1.49 ± 1.14	< 0.001	Significant

Table 3: VAS on Coughing

	Group A	Group B
	Mean ± SD	Mean ± SD
Dvemand	32.62 ± 7.98	11.78 ± 8.72
Delivery	24.22 ± 7.39	7.73 ± 4.24
P Value	< 0.001	< 0.001
Significance	Significant	Significant

Table 4: Demand and Deliveries

	Group A	Group B
	Mean ± SD	Mean ± SD
Bupivacaine (mg)	47.68 ± 11.14	65.31 ± 10.28
Fentanyl (mcg)	233.8 ± 59.69	320.8 ± 43.90
P value	< 0.001	< 0.001
Significance	Significant	Significant

Table 5: Amount of bupivacaine and fentanyl

Discussion

Inadequate analgesia is often the fear amongst patients. The nature of pain itself is subjective. Patient's response to analgesics is also variable and the efficacies of post-operative pain relief methods are neither uniform nor sufficient in all patients.

PCA can be used either intravenously or epidural [3]. Advantages of PCA over conventional pain management are that the therapy is individualized to the patient. Patients are the best to assess their pain and they can get medication as and when required by pressing a button of PCA pump. Thus it reduces overdose and also reduces nursing aid. Our objectives of this study were to find out the analgesic efficacy, number of demand and successful delivery of analgesia, total fentanyl and bupivacaine dosage, frequency of rescue analgesia, sedation scores and side effects if any in.

In our study haemodynamic parameters were comparable in both the groups.

In the study done by Komatsu et al. [4], patient controlled epidural analgesia was compared with or without background infusion using bupivacaine and fentanyl in gastrectomy. They found that infusion plus bolus group provided better pain relief both at rest and during coughing for early thoracotomy pain and was associated with fewer side effects as compared to only bolus group. The numbers of demands were lower; the average hourly fentanyl and bupivacaine doses were more in continuous infusion plus demand bolus than in demand bolus group. There was greater incidence of pruritus in the bolus plus infusion group.

In our study we found that VAS score at rest were higher in first three hours. Later the scores were lower and statistically significant in group B as compared to group A. VAS on coughing was higher in first two hours in both the groups. Later the difference in VAS was statistically significance between the groups except at the interval of 13 hours. This implies that there was better pain relief in group B.

In our study, 25 out of 37 in group A and 8 out of 37 in group B needed rescue analgesia. In the study done by Behera et al. [5] comparing epidural and intravenous routes of PCA, the number of patients needing rescue analgesia was significantly less in PCEA group as compared to IV PCA group. Post-operative pain score at rest were comparable.

Komatsu et al. [2] assessed the analgesic efficacy and side effects of a supplemental night-time infusion in patient-controlled epidural analgesia (PCEA) after gastrectomy. In their randomized, double-blind study, the number of requests were significantly lower in the PCEA plus night-time infusion group than in the PCEA alone group during the postoperative nights. VAS pain scores on coughing were significantly lower in the PCEA plus infusion group than in the PCEA alone group during the night following postoperative day 1. They concluded that, a night-time infusion in PCEA following gastrectomy decreases the incidence of postoperative pain and reduces the degree of the pain associated with coughing during the night. Mann et al. [6] compared the effectiveness on postoperative pain and safety of PCEA and intravenous PCA after major abdominal surgery. They found pain relief was better at rest and after coughing in the PCEA group during the 5 postoperative days.

We found that in Group A though the demands were 32 and deliveries were only 24 as they were made in the lockout interval. In Group B, 7 of 11 demands were delivered. This data was statistically significant. This may be due to the background continuous infusion. Komatsu et al. [4] found that demands and deliveries were more in PCEA bolus group as compared to bolus plus infusion group.

In the study by Bremerich et al. [7] for managing labor pain, periods of VAS scores > 40 mm during all stages of labor were significantly more frequent in parturients receiving demand only PCEA as compared to parturients receiving PCEA plus continuous background infusion. They concluded that PCEA plus continuous background infusion was more effective than demand only PCEA in treating labor pain without increasing consumption of anesthetic solution.

A double blind study with or without background infusion using sufentanil was done by Vercauteren et al. [8], to evaluate the usefulness of a concurrent infusion in PCEA in patients scheduled for elective cesarean section under a combined spinal-epidural technique They concluded that a background infusion in PCEA with sufentanil offered major advantages in terms of analgesia than without background infusion. Ferrante et al. [9] conducted a double-blind, placebo-controlled study to compare the efficacy of demand-dose patient-controlled epidural analgesia (PCEA) with continuous epidural infusion (CEI) for management of pain during labor and delivery. They found that analgesia in both groups was comparable. A significant dose-sparing effect was associated with the use of demand dose PCEA as compared with standard CEI for analgesia during labor and delivery.

In our study, in group A, though demands and deliveries were more, total amount of bupivacaine and fentanyl was less as compared to group B. Komatsu et al. [2] found that total amount of bupivacaine and fentanyl was less as compared to continuous plus bolus group B and better pain relief was achieved in group B than group A.

Bernard et al. [10] did a comparative study of patient-controlled epidural analgesia during labor. They found that patient-controlled epidural analgesia that allowed a parturient to receive an increased analgesic dose improved satisfaction.

Michael et al. [9] compared the efficacy of demand-dose patient-controlled epidural analgesia (PCEA) with continuous epidural infusion for treatment of pain during labor and delivery. In their study, there was a significant reduction in total bupivacaine consumption associated with the use of PCEA. The hourly bupivacaine and fentanyl consumption during the stages of labor was also reduced. A significant dose-sparing effect was associated with the use of demand-dose PCEA as compared with standard CEI for analgesia during delivery.

In the similar study done by Komatsu et al. [4], PCEA plus infusion group required less rescue analgesia than only PCEA group.

In the study done by Behera et al. [5] the number of patients with analgesic failure was significantly less in PCEA group as compared to IV PCA group.

Bernard et al. [10] found that the need for rescue analgesia was comparable. In our study there was no difficulty in arousing any patients. Komatsu et al. [2] found that the incidence of sedation did not differ between the PCEA and infusion group and there were no incidence of respiratory depression.

In the study conducted by Cooper et al. [11] all the patients were arousable, the findings of which were similar to our study. In study done by Behera et al. [5], patients in IVPCA group were significantly more sedated than those in PCEA group.

Epidural administration of opioids are associated with side effects like delayed respiratory depression, nausea, vomiting, pruritus, urinary retention whereas epidural administration of local anaesthetics is associated with side effects like postural hypotension due to sympathetic blockade. No patient had respiratory depression. Though the incidence of nausea and vomiting was more in group B compared to group A, the difference was not statistically significant.

Komatsu et al. [2] found that side effects were less in bolus PCEA group A than bolus plus infusion group. In the study conducted by Cooper et al. [12] patients in bolus and infusion group had less nausea and vomiting due to decreased dose of fentanyl.

Teng et al. [12] concluded that patients receiving epidural fentanyl-bupivacaine PCA experienced better overall pain relief, while morphine PCA, either epidural or intravenously, caused more side effects. In our study, no patient developed hypotension. Similar findings were noted in studies done by Komatsu et al. [4] In the study conducted by Saito et al. [13] 18% patients developed significant hypotension in morphine bupivacaine group as compared to fentanyl bupivacaine group.

In the study conducted by Mann et al. [6] five episodes of postoperative hypotension occurred in the PCEA group versus none in the PCA group. The patients were treated by simple fluid loading.

Opioids are known to cause a delayed respiratory depression. However no respiratory depression was noted in any patient. This was similar to findings by Komatsu et al. [4]. In the study by Badner et al. [14], two patients required naloxone for respiratory depression.

Conclusion

A background infusion using PCEA with a solution containing bupivacaine and fentanyl gave a better quality of analgesia, decreased the incidence of postoperative pain and had better acceptability, without any significant side effects, for reasonably understanding patients.

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