RESEARCH ARTICLE

A Comparative Study between Butorphanol and Fentanyl as an Analgesic in Patients Undergoing Abdominal Surgeries under General Anesthesia

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ABSTRACT

Background: Narcotic analgesics are frequently utilized during epidural anesthesia in addition to local anesthetics (LA). However, the parent drug, morphine, had a long latency and was poorly soluble in lipids when it was first used for epidural analgesia. Fentanyl and butorphanol have not been compared in any research as supplements for intraoperative epidural anesthesia. For lower abdominal surgery, the current study compared the effectiveness and safety of epidural fentanyl versus epidural butorphanol.

Materials and Methods: Patients undergoing abdominal surgery in the Department of Anesthesiology at a Tertiary Care Teaching institute in Tamil Nadu participated in a hospital-based randomized clinical study. All of the patients in the Department of Anesthesiology who had elective abdominal surgery were included in the 15-month research. The patients were split into two groups: Group A received an intravenous dose of 40 µg/kg butorphanol, whereas group B received an intravenous dose of 2 µg/kg fentanyl.

Results: There were 100 participants in all, with men making up the majority (57.0%) and having a M:F ratio of 1.3:1. The participants in the study were 46.9 ± 6.8 years old on average.

Conclusion: Butorphanol is found to be a better analgesic when compared to fentanyl, along with cardio-stability and fewer complications.

Keywords: Abdominal surgeries, Analgesics, General anesthesia.

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INTRODUCTION

In addition to local anesthetics (LA), narcotic analgesics are frequently utilized during epidural anesthesia. They shorten the length, enhance the block's quality, and hasten the onset of analgesia. Despite being used for epidural analgesia at first, the parent medication, morphine, had a long half-life and low lipid solubility.[1,2] Adverse side effects like pruritus, nausea, vomiting, urine retention, and respiratory depression have been linked to its use. There is still a hunt for a better molecule. Butorphanol is a lipid-soluble narcotic that functions as a mild agonist and antagonist on other receptors while also substantially inhibiting the K-receptor. It is an analgesic and hypnotic solid without slowing breathing. For labor analgesia and postoperative pain management, butorphanol has been widely utilized.[3,4] Fentanyl is a derivative of phenyl piperidine that is a strong receptor agonist that is highly soluble in lipids and has a brief half-life. The two opioids for post-operative epidural analgesia were compared in earlier research. There hasn't been enough research done on butorphanol and fentanyl added to intraoperative epidural anesthesia. In this study, epidural butorphanol was compared to epidural fentanyl for lower abdominal surgery in terms of efficacy and safety.[5,6] Given the present body of knowledge, it is crucial to find a more efficient agent to reduce pain during propofol induction during abdominal procedures and a more effective agent for hemodynamic stability and the requirement for rescue analgesia. There isn't much research on the topic in this part of the country.[7] In a tertiary care center, patients undergoing elective abdominal surgery under general anesthesia participated in this study to examine the hemodynamic responses and analgesic efficacy of intravenous fentanyl and butorphanol.

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MATERIALS AND METHODS

Anesthesiology patients who undertook abdominal surgery at a tertiary care teaching facility in Tamil Nadu were the subjects of a hospital-based randomized clinical trial. All patients who underwent elective abdominal surgery at the Department of Anesthesiology were included in the 15-month research. Two sets of individuals were created: Group A received intravenous butorphanol of 40 mg/kg, while group B received intravenous fentanyl 2 mg/kg. The study covered individuals aged between 20 and 60 with an "American Society of Anesthesiologists Physical Status" of I or II and underwent surgery for less than two hours. The study excluded patients who had clinically significant conditions related to the heart, lungs, liver, kidneys, neurologic, psychiatric, or metabolic systems, who were allergic to butorphanol or fentanyl, at risk for regurgitation, abusing alcohol or other drugs, or who were taking anticonvulsants, antipsychotics, or anti-hypertensives. The total sample size for this study was 100 patients who undertook abdominal surgery during the period of study, with a sample size of 50 patients in each group. A specified computer-generated random number allocation scheme was used to randomly assign patients in an equal number to each of the two study groups. We chose the members of each group by utilizing essential random sampling. An institutional ethical clearance was obtained before data collection, and all patients were allowed to give their informed permission in writing after being informed of the process. The medical histories of all participants were then gathered through an interview conducted with them during their first study visit. The study included participants who has been scheduled for abdominal procedures electives under general anesthesia and assessed as having an ASA I or II.

Premedication, an injection of glycopyrrolate 0.004 mg/kg, and an ondansetron 4 mg intravenously were administered as per the standard procedure. In the operating room, systolic blood pressure, diastolic blood pressure, baseline heart rate, and mean arterial pressure were noted using all standard monitors, such as pulse oximetry, NIBP, and electrocardiography. A large-bore peripheral IV catheter was fastened on the hand's dorsum. Before moving the patients, the anesthesia machine was examined, and all of the airway supplies, including a laryngoscope of the suitable size, an endotracheal tube of the proper size, an oropharyngeal airway, and suction equipment, were kept on hand. Additionally, medications for emergency resuscitation, such as vasopressors, were kept on hand.

Vital signs were recorded in the preoperative holding area. Both groups' patients underwent a 3-minute pre-oxygenation with 100% oxygen. Following the administration of either injection of butorphanol 40 mg/kg or injection of fentanyl (2 g/kg) intravenously, induction of anesthesia was initiated using an injection of propofol (2 mg/kg) intravenously. Vecuronium injection (0.1 mg/kg) was given intravenously to relax the muscles, with a top-up dose of 0.02 mg/kg given as needed. After three minutes, the patient was intubated using direct laryngoscopy with a Macintosh curved blade size 3/4. Throughout the surgical procedure, vital signs such as pulse rate, blood pressure, ETCO2, and oxygen saturation were checked every 15 minutes for the first 60 minutes and every 30 minutes for the final 120 minutes. As required, N_2O: O_2, 0.8 to 1% isoflurane, and further doses of vecuronium were used to maintain anesthesia. Vital signs were monitored for one minute following propofol administration, one- and five minutes following intubation, and then every 15 minutes throughout the procedure until the patient was stable in the recovery room. This happened when the patient was extubated as needed and spontaneous and regular breathing was established, as well as the complete reversal of the N-M blockage with the injections of neostigmine and glycopyrrolate. The time between the last dose of vecuronium and extubation was recorded.

Additionally, a six-point scale was used to rate the patient's reaction to agitation: 1 indicates nervousness, agitation, or apprehension; 2 indicates focus cooperation, and Indicators 3 and 4 indicate that the patient is tired but responsive to orders, whereas Indicators 5 and 6 indicate that the patient is asleep but responds slowly to auditory or tactile stimuli. We graded the extubation response on a five-point scale based on the patient's comfort and responsiveness. No cough, smooth extubation, minor cough (one or two times), moderate cough (three to four times), severe cough (five to ten times), and severe cough (more than ten times) or laryngospasm or breath holding are all indicated by the numbers 1 through 5.

After extubation, the patients had a 4-point nausea and vomiting scale evaluation (0 for no nausea, 1 for mild nausea, 2 for severe nausea requiring antiemetics, and 3 for vomiting with retching). During the first 90 minutes of recovery, patients' activity, breathing, and alertness were assessed every 15 minutes. After that, patients were checked for sedation every hour until a Ramsay score of 3 was reached and were checked for pain and the need for analgesics every hour. Rescue analgesia was administered with inj. Paracetamol 1-g intravenously at a visual analogue score of 4. In addition to postoperative pain, patients were checked every 15 minutes for other symptoms such as postoperative nausea and vomiting (PONV), shivering, drowsiness, and respiratory depression (respiratory rate of 8 breaths/minute) or hypoxemia (SpO_2 92%). From when the patient arrived in the recovery room until they needed rescue analgesia, postoperative analgesia was assessed using a visual analog scale (VAS) at intervals of fifteen minutes. After moving to the recovery room following surgery, all patients received oxygen (4 L/min) through a Hudson facemask.

Overall recovery was measured using the Steward scoring method, which gives a score of 0 to 1 or 2 points to each of the three characteristics: consciousness, airway, and mobility. The score was determined at the 15, 30, 60, and 90-minute marks—the available scores at any given time range from 0 to 6. For the recovery room to be discharged, six points are needed. Patients were also asked to rate the effectiveness of pain reduction using the VAS, grading it as excellent, good, fair, or wrong. Additionally, any adverse drug reactions or side

effects were identified, documented, and examined. Age in years, gender, the length of intubation in seconds, the length of surgery in minutes, and the type of intervention are among the study's variables. Hemodynamic measures include heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial pressure. The study's outcome variables include mean variations in systolic and diastolic blood pressure, heart rate, oxygen saturation, emergence agitation score, steward scoring system recovery, rescue analgesic requirement (amount), Ramsay score for sedation and postoperative pain using VAS score.

Statistical Analysis

Using SPSS V21 for IBM for Windows, data was examined. Age and the length of the intubation were two continuous variables that were provided as mean (SD). The categorical variables are displayed as frequency and percentages. The baseline attributes were contrasted using the chi-square and independent samples t-test. A recurring action The correlation of the heart rate and blood pressure among the groups over time was examined using an ANOVA. The associations between various times were evaluated using Bonferroni's post hoc analysis. To analyze the relationship between the two groups' varying intubation durations, an independent samples t-test was performed. A recurring action The association between surgical recovery, sedation score, and VAS score over time was also determined using an ANOVA. A p-value of less than 0.05 was considered as significant statistically.

RESULTS

One hundred individuals, with a male-to-female ratio of 1.3:1, comprised most of the study (57.0%). The average age was 46.9 plus 6.8. The average BMI of the study subjects was 24.0 ± 2.0 kg/m^2, ranging from 20.1 to 28.5 kg/m^2. Patients in groups A and B had mean BMIs of 24.2 ± 1.9 and 23.8 ± 2.1 kg/m^2. Group B has considerably greater systolic blood pressure than group A, with a *p-value* of less than 0.001. When compared to patients who received butorphanol, the patients who received intravenous fentanyl had somewhat greater heart rates. (F = 139.8, Effect size = 0.588, p 0.001) The test for a change in mean heart rate over time was highly significant statistically. A significant variation in mean heart rate was noted in the majority of times. When compared to individuals who received IV butorphanol, people who received IV fentanyl had slightly greater systolic blood pressure. Table The variations in mean systolic blood pressure among the two groups was significant statistically (p <0.001) and had an effect size of 0.838. Additionally, the test for a difference in the mean systolic blood pressure over time was significant statistically. (F = 222.5; Effect size = 0.690; p <0.001) (Table 1). The results of the posthoc analysis revealed that mean systolic blood pressure varied significantly throughout most periods. During direct laryngoscopy, the diastolic blood pressure was noticeably greater in the individuals who received intravenous fentanyl than in the people who received intravenous butorphanol. It was determined that the variations in mean diastolic blood pressure among the two groups over time, which was 0.251 in size, was significant statistically (p = 0.024). Significantly statistically, the test for a change in mean diastolic blood pressure over time was similarly very significant (F = 293.5; Effect size = 0.750; p-0.001). According to the findings of the posthoc analysis, most of the time, a significant difference in mean diastolic blood pressure was seen. Patients who received intravenous fentanyl had slightly greater mean arterial pressure than those who received intravenous butorphanol. Between the two groups, the mean arterial pressure changed with time was 0.462 and was significant statistically (p-0.001). High statistical significance was also found in the test for a change in mean arterial pressure over time (F = 433.5; Effect size 0.816; p -0.001). According to the post hoc analysis results, there was typically a significant difference in mean arterial pressure. In comparison to group B, group A required more time to reach spontaneous breathing (27.4 *vs.* 24.6 minutes, p = 0.012), eye-opening to verbal response (36.3 *vs.* 34.2 minutes, p = 0.013), and extubation (32.1 *vs.* 29.4 minutes, p = 0.026). The respiratory rate and the severity of the nausea were the same in all groups at the time of extubation. In 20% of patients in the butorphanol group were composed and cooperative; 56% were sleepy but still responded to commands; 16% were sleeping but still replied swiftly; and 8% answered slowly and somnolently. 8% of the patients in the fentanyl group were composed, oriented, and cooperative; fourteen percent of them were worn out and reacted to commands; 6% of them were uneasy and restless. The emergence agitation score has a *p-value* of 0.034, less than 0.05, and is therefore significant statistically. In the butorphanol

Table 1: Comparison of hemodynamic characteristics at baseline between the groups (N=100)

	Type of intervention		*p-value*
	Group A mean (SD)	*Group B mean (Soit0-D)*	
Heart rate (per minute)	82.9 (7.9)	84.2 (4.5)	0.308
Systolic blood pressure (mmHg)	132.7 (6.9)	140.7 (4.9)	<0.001
Diastolic blood pressure (mmHg)	84.8 (6.1)	85.5 (3.6)	0.461

Table 2: Postoperative recovery characteristics between the two groups (N = 100)

	Group A mean (SD)	*Group B mean (SD)*	*Value*
Time for spontaneous breathing (mins)	26.5 (13.7)	23.7 (13.0)	0.011
Time to eye-openingin response to verbal response (mins)	36.0 (14.5)	33.4 (13.9)	0.012
Time to extubation(mins)	31.0 (13.5)	28.7 (12.7)	0.025
The respiratory rate at extubation	16 (3)	16 (3)	0.373
Grade of nausea at extubation	0	0	0.685

Table 3: Postoperative pain (VAS score) between the two groups (N = 100)

Duration (mins)	*Type of intervention*		*p-value*
	Group A mean (SD)	*Group B mean (SD)*	
Immediate	0.5 (0.7)	1.9 (1.4)	<0.001
15	1.5 (1.2)	2.9 (1.5)	<0.001
30	3.0 (0.8)	4.2 (0.8)	<0.001
60	3.5 (0.8)	4.5 (0.9)	<0.001
120	3.6 (0.9)	4.8 (0.8)	<0.001

Table 4: Postoperative sedation score (Ramsay score) between the two groups (N = 100)

Postoperative sedation (Ramsay score)	*Type of intervention*		*p-value*
	Group A mean (SD)	*Group B mean (SD)*	
Immediate	3.8 (0.5)	2.2 (0.4)	<0.001
15	3.2 (0.3)	2.2 (0.4)	<0.001
30	3.0 (0.3)	1.9 (0.3)	<0.001
60	2.2 (0.4)	1.9 (0.3)	>0.05

Table 5: Postoperative complications between the two groups (N = 100)

Postoperative complications	*Type of intervention*	
	Group An (%)	*Group Bn (%)*
Nausea	3 (6.0)	2 (4.0)
Vomiting	2 (4.0)	0
Respiratory depression	1 (2.0)	0

group, 16% of patients experienced moderate cough, 72% extubated smoothly with minimum cough, and 12% had no cough at all. During extubation, 76% of the fentanyl group had a moderate cough, while 18% had a minor one. In 6% of patients, the cough was quite bad. Extubation quality score statistical analysis reveals a *p-value* of 0.048, which is significant statistically. Up until two hours after surgery, the patients who got butorphanol had much less postoperative pain than those who received fentanyl, as determined by the VAS score. (p <0.001). The VAS scores across the two groups did not significantly differ after two hours. One hour after surgery, none of the patients in the butorphanol group needed rescue analgesia. Five individuals in the butorphanol group needed rescue analgesia at two hours postoperatively (VAS = 5). Four patients required rescue analgesia at 15 minutes, 11 patients at 30 minutes, 20 patients at an hour, and 24 patients at two hours in the fentanyl group. It is important to highlight that there was no discernible difference in the amount of analgesia required between the two groups. When compared to individuals who received intravenous butorphanol, those who received intravenous fentanyl had significantly greater pain scores and more frequent needs for rescue analgesia. The sedation scores significantly differed, with patients in the butorphanol group scoring higher up to 30 minutes after surgery. However, after 30 minutes, there was no discernible difference in the sedation scores between the two groups. Like this, patients in the butorphanol group took noticeably longer to recover. Patients who received intravenous butorphanol favorably compared to those who received intravenous fentanyl in terms of postoperative sedation. Vomiting and nausea were among the surgical problems that affected three patients receiving butorphanol and two patients receiving fentanyl. One patient in the butorphanol group had respiratory depression, but not even single patient in the fentanyl group did.

DISCUSSION

Pain reduction is a crucial component of balanced anesthesia. Therefore, picking a hemodynamically stable medicine that delivers adequate analgesia cheaply and with fewer side effects is crucial.[8,9] To examine the hemodynamic stability and analgesic effectiveness of intravenous butorphanol and fentanyl in a tertiary care setting, this study was conducted on adults who underwent elective abdominal surgery. Our investigation demonstrated that the patients' sociodemographic traits were equivalent across the groups. Additionally, it was discovered that the time spent intubating both groups was equivalent.[10,11] Similar findings were reported in studies by Verma RK *et al.* and Kaur J *et al*., where it was stated that no significant differences were observed between the butorphanol and fentanyl groups in terms of the length of intubation and operation.[5,6] In terms of the hemodynamic response, both the drugs were hemodynamically stable for heart rate, systolic, and diastolic blood pressure, and there was a significant change in the hemodynamic response over time (Table 2). However, it was shown that there was a significant statistical difference in hemodynamic stability between the patients in the butorphanol group and those in the fentanyl group. The group that received butorphanol had a far better sympathetic response during intubation than the group that received fentanyl (Table 3). The study by Rao MH *et al.* stated that the hemodynamic response was better in the butorphanol group till 45 minutes, which is consistent with our study results.[12] The butorphanol group also showed improved resistance to the autonomic stimulation towards surgical incision and tracheal intubation, according to Ahire SS *et al.*[13] Up until two hours after surgery, patients who got butorphanol experienced considerably less postoperative pain than those who received fentanyl (p 0.001), as judged by the VAS score. The VAS scores across the two groups did not significantly differ after two hours. In the fentanyl group, more patients needed rescue analgesia (Table 4). Since butorphanol's analgesic impact may only be a partial agonist activity, the ability to produce analgesia is linked to both receptors.[14,15] The early occurrence of discomfort in Fentanyl users is explained by the drug's rapid redistribution. However, butorphanol is a mild μ-receptor antagonist and a partial agonist of the κ-receptor. Simultaneously, fentanyl functions primarily as a μ receptor agonist. Thus, as a κ-agonist action, butorphanol is linked to more sedation than fentanyl. Similarly, our study findings also showed a significant difference in the sedation score, with a higher score for the patients in the butorphanol group until 30 minutes postoperatively. However, beyond 30

minutes, the two groups did not have significant differences in the sedation score. Similarly, the recovery time was longer significantly in the patients of butorphanol group. A Verma RK *et al.* study showed that the butorphanol group's emergence time and post-operative sedation were longer.[5] In a study by Sojitra BH *et al.* it was demonstrated that butorphanol prolonged the recovery time, which is also the case in a study by Patel H *et al.*, where the butorphanol group's recovery time was longer.[16,17] Within 30 minutes of extubation, participants in the fentanyl group in Gautam P *et al.*'s trial required rescue analgesia.[18] Notably, no patient in the group of butorphanol experienced a desaturation episode (SpO_2 95%) in the first 30 minutes following surgery, which may be related to the butorphanol's kappa agonist effect.[19,20]

Vomiting and nausea were postoperative problems that were seen by three and two subjects respectively in the group of butorphanol. With the fentanyl, two patients complained of nausea. One patient in the butorphanol group had respiratory depression, but not a single patient in the fentanyl group did. In the Ahire SS *et al.* trial, problems were observed in 11 patients who were given butorphanol and ten individuals who were given fentanyl.[13] According to Gautam P *et al.*, no discernible difference was observed among the two groups postoperatively and intraoperatively problems. Additionally, none of the groups had any instances of respiratory depression.[18] According to Arora V *et al.*, patients in the butorphanol group exhibited noticeably less postoperative shivering.[19] Shivering was more prevalent in the butorphanol group (16.7 *vs.* 13.3%) than in the fentanyl group, according to Kapoor K *et al.* Additionally, there were more cases of nausea and vomiting in the butorphanol group (23.3 *vs.* 20%). (Table 5).[21] However, neither group of participants in our study had any shivering patients.

The sample size was too small to have sufficient power to remark on the statistical significance of our investigation, which is one of the study's limitations. It is, therefore, wise to contrast our findings with the clinical relevance. However, because a representative sample was chosen, our study's findings might apply to a context like that.

CONCLUSION

When compared to fentanyl, butorphanol is reported to be a better analgesic, as well as having better cardio-stability and fewer side effects. It is advised to conduct additional multicentric research to strengthen the validity of our study's findings.

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