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Original Article

Comparative Study between Buprenorphine and Butorphanol when Administered Epidurally in Abdominal and Lower Limb Surgeries

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Abstract

Introduction: It was a randomized controlled study to compare the effects of Buprenorphine and Butorphanol in the lower limb surgeries when administered epidural route in terms of analgesia and side effects.

Materials and Methods: The study was conducted on 60 randomly selected patients based on inclusion and exclusion criteria in AC Subba Reddy Govt Medical College, Nellore during the period of 1 year, that is, June 2021 to June 2022.

Results: In our study, we compared Buprenorphine and Butorphanol's safety and efficacy when given epidurally for postoperative pain relief on 60 patients undergoing elective lower limb and abdominal surgeries. We found that both drugs as safe and effective postoperative analgesics. There is no significant difference between the drugs with respect to the onset of analgesia. Epidural buprenorphine significantly reduced pain with a longer duration of action and was a better alternative to butorphanol for post-operative pain relief. It was found to be safe due to less incidence of side effects like sedation and vomiting compared to butorphanol. We did not find any case of hypotension or respiratory depression in both groups. No other complications were seen.

Conclusion: We conclude that epidural buprenorphine was a better alternative to epidural butorphanol for providing post-operative pain relief.

Key words: Buprenorphine, Butorphanol, Epidural

INTRODUCTION

Pain is always a subjective, personal, and unpleasant experience. Pain is the predominant complaint of most individuals following surgical intervention. Patients are often unable to breath adequately and cough effectively due to pain. They may not able to mobilize enough to do their daily activities. Due to this, they may experience feelings of helplessness, fear, anxiety, and depression. Effective pain relief is necessary for early mobilization and postoperative discharge. Being anesthesiologist, we should have a concern to help patients to relieve their pain adequately, which can lead to better outcomes for both the patient and the health care system.

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Various techniques have been developed to relieve the post-operative pain. Epidural opioids were used in large number of studies for the relief of post-operative pain. They provide better analgesia for early mobilization which reduces the risk of thromboembolic events and respiratory complications.

Aims and Objectives

The objecyives are as follows:

1. To compare the efficacy of epidurally administered Buprenoirphine and Butorphanol tartrate in providing post-operative pain relief in abdominal and lower limb surgeries.
2. To compare the duration, quality of analgesia, cardiorespiratory effects, and side effects between Buprenorphine and Butorphanol tartrate.

Inclusion Criteria

The following criteria were included in the study:

- Patients of either sex
- Age between 18 and 65 years
- Patients with ASA Grades 1 and 2

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- Patients undergoing elective surgeries of abdomen and lower limb.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients who did not provide consent
- Patients with ASA Grades 3 and 4
- Patients with clotting disorders
- Patients with known allergies to opioids
- Patients with sepsis - local and systemic
- Patients with spinal deformities like kyphoscoliosis
- Patients who underwent previous spinal surgeries or injuries in lumbar region
- Patients who were physically and psychologically dependent on opioids.

MATERIALS AND METHODS

The current study was conducted at Siddhartha Medical College on 60 patients undergoing lower limb and abdominal surgeries after getting permission from the institutional ethics committee.

Sample Size, Study Type, Duration

The study was conducted on 60 randomly selected patients based on inclusion and exclusion criteria.

Sample size: Approximately 12% of patients underwent undergo lower limb or lower abdominal surgeries who received buprenorphine or butorphanol at our institution for post-operative analgesia, epidurally. Hence, the prevalence as estimated by us is 10% Around 500 lower limb or lower abdominal surgeries happened under at SMC during the study duration.

$$N = z^2pq/e^2$$

N - Population size
Z - confidence level of 95%-standard value of 1.96
p - Expected prevalence or proportion: p=0.1 (since prevalence is 10%)
e - Allowable error-7%
Basing on this formula, the sample size came as 62.

Two patients did not provide consent to participate in this study, so we included 60 patients in the current study. The current study is a prospective, randomized, double blinded, comparative study, and conducted for 18 months from December 2019 to June 2021.

Methodology

Preoperative preparation

The patient's age, body weight, and ASA grades were recorded. Informed consent was taken from all the participants. ECG, pulse oximetry, and blood pressure (BP) monitoring were done continuously. All the patients were divided in to two groups: Group BT, those who received Butorphanol 1 ml in 1 mg, and Group BP, those who received Buprenorphine 1 ml in 0.3 mg. These injections were given over 10–15 s. Drugs were diluted to 10 ml with NS and injected through an epidural catheter. Patients are observed in the recovery room. Observations are recorded by the investigator visual analog pain scales that are assessed every hour till the 6th h, then the 2nd h till the 12th h subsequently every 6th h till 48 h after surgery.

Preoperative investigations

- Hb%
- Blood grouping and typing
- Bleeding time, clotting time
- RBS, S. Creatinine
- 12 lead ECG and CXR PA view

Procedure

An intravenous line was established using an a18 G IV cannula and preloading with 500ml of Ringer's Lactate solution was done with the patient in the left lateral decubitus position. Under aseptic precaution, L3-L4 intervertebral space was identified with the highest point of the iliac crest as the anatomical landmark. After local infiltration, an epidural puncture was made by the loss of resistance technique to air at L3/L4 space with a Tuohy needle. An epidural catheter passed through the needle. Needle removed and catheter secured 3cc. of 2% xylocaine with adrenaline given as test dose.

Statistical analysis

Categorical values were given percentages. Differences between buprenorphine's duration and butorphanol's duration, onset, and effects on BP, respiratory rate (RR), and pulse rate (PR), visual analog score (VAS) were compared with the student's unpaired T-test. $P < 0.05$ was considered statistically significant.

Ethical considerations

The permission from the institutional ethical committee attached to Siddhartha Medical College was taken before conducting the study. Every patient explained the whole process and advantages of the study. After he/she accepts, an informed consent form is given in the local language or patient understandable language, and the person was asked to sign it or put a thumb impression. The procedure for assessing study parameters has minimal interference. The patients were told that their information is kept confidential. Patients were informed that their participation is purely voluntary.

RESULTS

Statistical analysis was done using statistical software named Statistical Package for the Social Sciences version 21.0.0

(SPSS Inc., Chicago, Illinois, USA). All categorical variables (qualitative data) are expressed in percentages. 60 patients were evaluated in this study. They belonged to two groups. 30 members belonged to Buprenorphine group and 30 patients belonged to Butorphanol group.

Demographic Variables

Age of patients

The age of patients involved in this study ranged from 30 to 60 years. Most common age of patients found to be 30–40 years. The average age of all patients was 39.63 years [Table 1].

Gender

More patients are females in this study.

Onset of analgesia

There is no significant difference in the onset of analgesia produced by Buprenorphine or Butorphanol. Student *t*-test was applied to compare between these two groups $P < 0.05$ so there is significant difference [Table 3].

Duration of analgesia

The mean duration of analgesia for all 60 patients was 7.61 h. The mean duration in BT group was 6.03 ± 0.99 h or around 360 min. In BP group was 9.2 ± 0.76 h or around 560 min.

Rescue drug

It was given for 12 patients. It was not required for 48 patients.

About 33% patients required rescue drug in BT group indicating that butorphanol may be less efficacious compared to buprenorphine, as only 10% required rescue drug in buprenorphine group. The rescue drug used in the current study was IV Diclofenac.

Side effects

61.6% patients had no side effects. Sedation and vomiting were seen in remaining patients [Table 5].

More patients suffered from sedation in BT group and there is significant difference with respect to sedation between both groups, as evident from the *P* value. More patients suffered from vomiting's in BP group and there is significant difference with respect to vomiting between both groups, as evident from the *P* value [Table 7].

PR

PR was monitored at various intervals. It ranged from 70 to 90 bpm for most of the patients. No patient had extreme changes in PR.

There is no significant difference between both groups with respect to PR at various intervals between both groups [Table 8].

Table 1: Age of patients

Age	Number of patients (%)
30–40	41 (68.335)
41–50	14 (23.3)
51–60	5 (8.3)

Table 2: Gender of patients

Gender	Number of patients (%)
Male	12 (20)
Female	48 (80)

Table 3: Onset of analgesia in both groups

Onset of analgesia in minutes	Mean and SD	P value
BT group	11.63±1.72	0.36
BP group	12.06±1.94	

Difference	0.430
Standard error	0.473
95% CI	-0.5175 to 1.3775
t-statistic	0.908
DF	58
Significance level	P = 0.3674

SD: Standard deviation, CI: Confidence interval

Table 4: Duration of analgesia in both groups

Duration of analgesia in hours	Mean and SD	P value
BT group	6.03±0.99	< 0.0001
BP group	9.2±0.76	

ifference	3.170
Standard error	0.228
95% CI	2.7139 to 3.6261
t-statistic	13.912
DF	58
Significance level	P < 0.0001

SD: Standard deviation, CI: Confidence interval

Table 5: Rescue drug in both groups

Rescue drug	BT group	BP group
Given	9	3
Not given	21	27
Total *n*=60		

Table 6: Side effects among patients

Side effects	Number of patients (%)
Nil	46 (76.6)
Sedation	8 (13.3)
Vomiting	6 (10)

Table 7: Side effects in both groups-comparison

Side effects	BT Group	BP Group	*P*
Nil	22	24	
Sedation	7	1	0.028
Vomiting	1	5	0.017

Table 8: Pulse rate in both groups

Pulse rate	Mean±SD		*P*
	BT group	BP group	
Baseline	79.80± 6.88	79.5±6.75	0.89
30 min	78.37± 6.9	78.13±6.7	0.9
1 h	77.23± 5.87	76.13±6.55	0.81
2 h	78.4± 7.1	76.13±7.2	0.64
6 h	76.5± 6.23	77.12±6.8	0.21
12 h	77.1± 6.12	77.2±6.42	0.28

SD: Standard deviation

RR

RR was monitored at various intervals. It ranged from 11 to 18/min in most of the patients. No patient had extreme changes in RR in this study.

There is no significant difference between both groups with respect to RR at various intervals between both groups [Table 9].

VAS

It was monitored at various intervals. It ranged from 0 to 4 in most of the patients. No patient had extreme pain in this study. There is no significant difference in VAS score at 6 and 12 h between both groups. It was more in BT group less in BP group [Table 10].

Systolic blood pressure (SBP)

SBP was monitored at various intervals throughout the study. SBP ranged from 110 to 140 mm of hg for most of the patients.

There is no significant difference between both groups with respect to SBP at various intervals between both groups [Table 11].

Diastolic blood pressure (DBP)

DBP was monitored at various intervals throughout the study. DBP ranged from 70 to 90 mm of hg for most of the patients.

Table 9: RR in both groups

RR	Mean±SD		*P*
	Mean and SD in BT group	Mean and SD in BP group	
Baseline	14.2±4.1	14.93±2.96	0.67
30 min	15.8±3.54	15.43±3.29	0.222
1 h	15.57±4.39	16.07±5.19	0.189
2 h	16.03±2.65	16.33±2.23	0.23
6 h	14.5±3.2	15.1±3.92	0.12
12 h	15.1±4.0	15.1±2.9	0.98

RR: Respiratory rate, SD: Standard deviation

Table 10: VAS

VAS	Mean±SD		*P*
	BT group	BP group	
Baseline	4.27±0.96	4.23±1	0.82
6 h	2.9±0.9	1.8±0.57	0.056
12 h	1.3±2.0	1.1±0.53	0.08

VAS: Visual analogue score, SD: Standard deviation

Table 11: SBP

SBP	Mean±SD		*P*
	BT group	BP group	
Baseline	131.100±5.7974	128.500±4.1084	0.129
30 min	122.000±4.3072	120.367±4.5900	0.025
1 h	119.033±9.2680	118.200±12.7723	0.052
2 h	105.433±9.5545	108.400±8.2821	0.391
6 h	98.900±11.5739	98.333±10.3934	0.609
12 h	102.633±8.8454	99.200±11.0933	0.343

SBP: Systolic blood pressure, SD: Standard deviation

There is no significant difference between both groups with respect to DBP at various intervals between both groups [Tables 2, 4, 6 and 12].

DISCUSSION

In the present study, 60 patients undergoing lower limb and abdominal surgeries were evaluated. 30 members belonged to Buprenorphine group and 30 patients belonged to Butorphanol group. The most common age of patients found to be 30–40 years. The average age of all patients was 39.63 years. About 80% are females in the current study. There is no significant difference in the onset of analgesia produced by Buprenorphine or Butorphanol.

The mean duration of analgesia for all 60 patients was 7.61 h. The mean duration of analgesia was more in Buprenorphine group, indicating that Buprenorphine acts for long duration compared to Butorphanol. Rescue medication was given for 12 patients. It was not required for 48 patients. More patients in Butorphanol group required

Table 12: DBP in both groups

DBP	Mean±SD		*P*
	BT group	BP group	
Baseline	84.633±4.4989	84.822±3.7700	0.653
30 min	75.769±5.9055	74.800±7.2369	0.833
1 h	73.333±4.4515	70.967±9.4010	0.246
2 h	75.267±5.0986	72.733±7.5060	0.301
6 h	74.667±5.1013	75.267±5.0986	0.859
12 h	76.333±4.7874	76.000±7.7992	0.762

DBP: Diastolic blood pressure, SD: Standard deviation

rescue medication, indicating that Buprenorphine's efficacy is more than Butorphanol.

More patients suffered from sedation in BT group and there is significant difference with respect to sedation and vomiting between both groups. This indicates that Buprenorphine is safe compared to butorphanol. PR ranged from 70 to 90 bpm for most of the patients. No patient had extreme changes in PR. There is no significant difference between both groups with respect to PR at various intervals between both groups. RR ranged from 11 to 18/min in most of the patients. No patient had extreme changes in RR in this study. There is no significant difference between both groups with respect to RR at various intervals between both groups. VAS ranged from 0 to 4 in most of the patients. No patient had extreme pain in this study. There is significant difference in VAS score at 6 and 12 h between both groups. It was more in BT group. This indicates that pain relief can be best achieved by Buprenorphine compared to Butorphanol. SBP ranged from 110 to 140 mm of hg for most of the patients. There is no significant difference between both groups with respect to SBP at various intervals between both groups.

DBP ranged from 70 to 90 mm of hg for most of the patients. There is no significant difference between both groups with respect to DBP at various intervals between both groups. This indicates that hemodynamic stability can be maintained by both the drugs used in this study.

Comparison with Dona's Study[1]

Dona's study was done in 2016 to compare the safety and efficacy of epidural buprenorphine and butorphanol for PO analgesia. It concluded that epidural buprenorphine significantly reduced pain and increased the quality of analgesia with a longer duration of action and was a better alternative to butorphanol for postoperative pain relief. We are of same opinion, and we conclude the same.

Comparison with Gayatri's Study[2]

Gayatri's study was done during 2020 to compare the safety and efficacy of postoperative analgesia with epidural Buprenorphine with Butorphanol. 60 patients who belonged to the ASA physical status class I and II, aged between 30 and 50 years, scheduled for elective laparoscopic surgeries were included, similar to our study. Patients were randomized into 2 groups giving Buprenorphine diluted to 10 ml with NS and Butorphanol Tartrate diluted to 10 ml with NS through the epidural catheter, similar to our study.

Results were recorded by a blind observer anesthesiologist. To evaluate sedation, the Ramsay sedation score was used. In our study, sedation incidence was only 13% cases and we didn't assess RSS. Student's *t*-test and Mann–Whitney's tests were used for analysis. In our study, percentages and student's *t*-test were used. Results showed that there was significant difference in the duration of analgesia between the two groups. It was more in buprenorphine group, similar to our study. In Gayatri's study, respiratory depression was not seen in both the study groups, similar to our study.

Nausea, vomiting, and headache were more in the Buprenorphine group in Gayatri's study, in contrast in our study vomiting was more common in Buprenorphine group. Pruritus was found to be more with Butorphanol, but in our study, pruritus was not seen.

Comparison with Bhoopal Naik's Study[3]

This study was done in 2018 to compare PO analgesics-buprenorphine and butorphanol in combination with bupivacaine Duration of analgesia was more in buprenorphine group in both the studies.

Comparison with Neerja Bharti, Pramila Chari's Study[4]

This study was done to assess the effectiveness of epidural butorphanol with and without bupivacaine for PO analgesic effect after abdominal hysterectomy. Neerja's study[1] concluded that the addition of 2 mg of Butorphanol to 0.125% of epidural bupivacaine produced quick onset and longer duration of analgesia compared to butorphanol alone.

Comparison with Endoh, Matsuda study[5]

Endoh's study[5] compared the efficacy of epidurally given 0.2 mg of Buprenorphine after CSE and general with epidural anesthesia. In our study, comparison was done between epidural buprenorphine and butorphanol. Endoh's study found that the duration of pain relief with epidural buprenorphine was almost alike in both groups. It is about 11 h duration. In our study, Buprenorphine provided analgesia for around 9 h duration. The time period until postoperative first walk and the number of pain relief medication were also similar in both groups. In our study, rescue medication was used more for butorphanol

group compared to Buprenorphine group. Endoh's study concluded that the onset of pain relief was quicker in CSE group, due to flux of buprenorphine through a dural hole after epidural administration. In our study, we did not compare drugs; effect through various modes of anesthesia administration. We assessed only epidurally given medications.

Comparison with Chada Poorvi's Study[6]

This study was done on 60 patients undergoing abdominal surgery under GA. Patients were divided into two groups, 30 each. Our study analyzed 60 patients undergoing both lower limb and abdominal surgeries and they were also divided to two groups and given Buprenorphine and Butorphanol.

In Chada's study,[6] one group received fentanyl and another group received Buprenorphine as transdermal patch 12 h before the surgery. VAS score was lower in fentanyl group compared to Buprenorphine group at various intervals but there is no significant difference. In our study, VAS scores are less for Buprenorphine group compared to butorphanol group and there are significant statistical differences. Rescue analgesia was required for 16.7% in Buprenorphine group and 10% in fentanyl group. In our study, rescue analgesia was needed for 3% patients in Buprenorphine group. In chada' study, 1 patient had intractable nausea and vomiting with Buprenorphine patch. In our study, vomiting's were seen in 5 patients in Buprenorphine group.

Benefits and Strengths of the Present Study

- Knowing better post-operative analgesia agent helps improve patient care, satisfaction, and outcomes
- Studies with fewer subjects (60) like the present study were quick to conduct – a short duration of time is needed
- Easy to review patients' case record forms at any time
- Research question was addressed in a relatively short span of time
- Perfect vigilance of all parameters was done using the multiparameter
- Monitor on all 60 patients for 2 years of study duration, which helped avoid patient discomfort with no intervention.

The Economic Benefit to the Participants

- Physical examination, systemic examination, vitals were analyzed free of cost for all the subjects involved in the study
- A part of travel expenses for patients has been reimbursed
- All investigations were done to 60 patients free of cost
- Lower limb and abdominal surgeries were done free of cost
- Medications such as buprenorphine and butorphanol were provided freely to all study participants.

Recommendations for Future Studies

1. Data on patients below 20 years and above 60 years of age is required.
2. Multi-canter studies including various tertiary care hospitals and certain specialized clinics could be done as more patient populations from different backgrounds could be involved.
3. Research on other drugs like fentanyl could be done.
4. Meta-analysis of existing research could be done.
5. Studies could be done comparing epidurally given drugs with CSE, and general anesthesia.
6. Studies comparing different doses of buprenorphine and butorphanol could be done.
7. Studies can be done on pregnant women undergoing caesarean section.
8. Systematic reviews can be done on post-operative analgesics which carry more scientific validity than original research articles.
9. Pharmaco-economic studies comparing various drugs can be done.

CONCLUSION

We found that both drugs as safe and effective post-operative analgesics.

There is no significant difference between both the drugs with respect to the onset of analgesia. Epidural buprenorphine significantly reduced pain with a longer duration of action and was a better alternative to butorphanol for post-operative pain relief. It was found to be safe due to less incidence of side effects such as sedation and vomiting compared to butorphanol.

We did not find any case of hypotension or respiratory depression in both the groups. No other complications were seen. We conclude that epidural buprenorphine was a better alternative to epidural butorphanol for providing post-operative pain relief. The study is self-sponsored.

REFERENCES

1. Jose DE, Ganapathi P, Sharma NG, Shankaranarayana P, Aiyappa DS, Nazim M. Postoperative pain relief with epidural buprenorphine versus epidural butorphanol in laparoscopic hysterectomies: A comparative study. Anesth Essays Res 2016;10:82-7.
2. Gayatri P, Lakhsmi BS. Comparing the efficacy of epidural buprenorphine versus epidural butorphanol in postoperative pain relief in laparoscopic surgeries: A randomized double blinded controlled study. Int J Sci Res 2020;9:1274-6.
3. Naik VB, Reddy P, Reddy BC, Chaitanya K, Reddy N, Rajesh VS. Post-

operative epidural analgesia: A comparative study between bupivacaine with buprenorphine and bupivacaine with butorphanol for lower limb orthopedic surgeries. Indian J Anesth Analg 2018;5:719-23.
4. Bharti N, Chari P. Epidural butorphanol-bupivacaine analgesia for postoperative pain relief after abdominal hysterectomy. J Clin Anesth 2009;21:19-22.
5. Endoh M, Matsuda A. Epidural administration of buprenorphine after combined spinal epidural anesthesia. Masui 1996;45:1396-9.
6. Poorvi C, Kalpana V, Khayyam. Comparison of efficacy of transdermal fentanyl patch with buprenorphine patch post-operative pain relief in abdominal surgeries. Int J Sci Res 2021;10:9-11.

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