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A Comparative Study Of Hemodynamic Changes And Side Effects Between Epidural Bupivacaine With Low Dose Butorphanol And Epidural Bupivacaine Alone In Patients Undergoing Elective Infra Umbilical Surgeries

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ABSTRACT

Background: Effective pain management is crucial and has been acknowledged as an anesthesiologist's top priority. The initial postoperative intake of oral nourishment, the decrease in perioperative stress reactions and organ dysfunction, the avoidance of weariness, better mobilization, and the earliest postoperative release all depend heavily on postoperative pain treatment**.**

Aim and Objective: The present research was aimed to study the Hemodynamic changes and side effects between epidural bupivacaine with low dose butorphanol and epidural bupivacaine alone in patients undergoing elective infra umbilical surgeries.

Methodology: The Department of Anaesthesiology at Santosh Medical College & Hospital in Ghaziabad, Uttar Pradesh, conducted this prospective, randomized clinical study between the years of 2018 and 2020 with approval from the Board of Studies and Ethical Committee. There were 60 ASA grade I/II patients in the overall sample.

Result: There were 23.3% females and 76.7% males in the study population. In the groups receiving bupivacaine alone, the mean age was 39.26 10.82 years, while in the groups receiving bupivacaine with butorphanol, it was 36.44 10.19 years. Nausea and Vomiting was found to be

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significantly more among Group Bupivacaine (33.3%) compared to Group Bupivacaine + Butorphanol (20.0%).

Conclusion: The study found that when compared to bupivacaine alone, bupivacaine plus low dose butorphanol offered greater anaesthetic characteristics and post operation analgesia.

Keywords: Bupivacaine, Butorphanol, Analgesia, Hemodynamic changes.

INTRODUCTION

The word pain is derived from the Greek term poine (penalty). Pain is an actual sensation as well as a sensory modality. According to the International Association for the Study of Pain, pain is a distressing sensory and emotional experience connected to real or potential tissue damage or expressed as such harm. Pain has been found to alter nearly every system's physiology, including the cardiovascular, respiratory, and metabolic profiles, in addition to psychological trauma, increasing morbidity. [1] The anesthesiologist's primary concern is therefore providing the best possible pain treatment.

The identification of opioid receptors has created new possibilities for the treatment of pain. Small amounts of opioids given in the subarachanoid or epidural regions provide potent analgesia by crossing the blood-brain barrier. This is a significant development in the treatment of pain. [2]

The most crucial component of anesthesia, particularly during big abdominal procedures, is postoperative analgesia. As a result, postoperative morbidity rates rise and recovery times lengthen. [3] According to the dose, concentration, or volume of local anesthetic, spinal, epidural, and caudal neuraxial blocks result in sympathetic block, sensory analgesia, and motor block.

The most appropriate and practical neuraxial approach in daily clinical practice is spinal anesthesia, which produces intense, consistent sensory analgesia with only a modest mass (i.e., volume) of medication and almost no systemic pharmacologic effect. [4] For major abdominal surgeries today, regional anesthesia is the method of anesthesia of choice [5]. Although spinal and epidural blockades are well-known regional anesthetic procedures, combined spinal-epidural approach has gained popularity in recent years. [6] Due to their inherent negative effects, parenteral opioids may not be able to produce the same level of analgesia as epidural analgesia. [7] Better pain scores have been obtained with the epidural administration of opioids as an addition to bupivacaine for postoperative pain treatment.

Bupivacaine was first synthesized by Ekenstam in 1956, but Telivuo and Widman introduced it into clinical use in 1963, making it one of the most often utilized drugs in epidural anesthesia. Because the molecule contains an asymmetric carbon atom, it is classified as a pipecoloxylidedes type of

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amide group of local anesthetic. By using the epidural route, butorphanol, a kappa agonist with a weak mu (μ) agonist/antagonist, relatively high lipid solubility, and fewer adverse effects, has been utilized successfully to produce long-term post-operative pain relief. [8,9] Strong analgesic activity is reported to exist without concern for respiratory depression.

More research has been done on the use of butorphanol in conjunction with local anesthetics during labor in pregnant women. [10] Studies evaluating the effectiveness of the aforementioned combination in infraumbilical procedures, which account for the bulk of hospital admissions and cause morbidity, are few and far between. Compared to opioids, butorphanol has been shown to have a low incidence of side effects. [11] In order to compare the effects of epidural, bupivacaine with low dose butorphanol, and bupivacaine alone in patients undergoing elective infra-umbilical operations, the current study was designed.

MATERIALS AND METHODS

The Department of Anaesthesiology at Santosh Medical College & Hospital in Ghaziabad, Uttar Pradesh, conducted this prospective, randomized clinical study between the years of 2018 and 2020 with approval from the Board of Studies and Ethical Committee. Using G-power software, the study population was computed with a power of 80% and a significance level of 5%. There were 60 ASA grade I/II patients in the overall sample. One of the two groups, each with 30 patients, was given to the patients. Using sealed envelopes, the groups were randomly assigned.

Group I, (n = 30): The patients will receive 15ml of 0.5% bupivacaine hydrochloride plus 1.5 mg (3ml) butorphanol. (Total volume of drug-18ml)

Group II, (n = 30): The patients will receive 15ml of 0.5% bupivacaine hydrochloride plus 3ml normal saline. (Total volume of drug-18ml)

Patients with ASA grades 3 and 4 as well as a history of local anesthetic drug allergies, bleeding diathesis, spinal deformities, neurological disorders, infections in the lumbar region, and BMIs greater than 30 were excluded from the study. A thorough pre anaesthetic checkup was done for all the patients. Clinical examination of respiratory system, cardiovascular system and central nervous system with vertebral spine was done. Routine hematological, biochemical and radiological investigations appropriate for the surgery was done. The patients were explained in detail about the procedure of lumbar epidural block. All their queries and doubts were answered to get their confidence and support. Written informed consent was taken.

The statistical analysis was carried out using the statistical program SPSS version 21.0 after the data had been imported into Microsoft Excel. The chi-square test was used to compare frequency, while

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the student t-test was utilized to compare mean values between the two groups. When the p-value was less than 0.05, it was deemed significant.

RESULTS

This prospective randomized clinical study compared epidural bupivacaine with low dose butorphanol and epidural bupivacaine alone in patients undergoing elective infra umbilical surgeries. The patients were assigned to one of the two groups comprising of 30 patients each.

Table1: Demographic data distribution of study subject.

Demographic Distribution		Number (Percentage)
Gender	Male	30 (37.5)
	Female	50 (62.5)
Age (Mean±SD)	Group Bupivacaine	39.26±10.82
	Group Bupivacaine+Butorphanol	36.44±10.19
Weight (Mean±SD)	Group Bupivacaine	55.62±5.76
	Group Bupivacaine+Butorphanol	57.34±6.35

Table 1 shows that there were 62.5% women and 37.5% men in the study. Patients receiving bupivacaine had an average age of 39.26 years and a weight of 55.62 kilograms, whereas those receiving bupivacaine with butorphanol had an average age of 36.44 years and a weight of 57.34 kilograms.

Table2: Comparison of heart rate, mean Systolic blood pressure, mean Diastolic blood pressure, mean MAP, mean SpO2 (%) between Group Bupivacaine and Group Bupivacaine+Butorphanol at time intervals.

Comparison of mean Time		Mean±SD		p-value
		Group Bupivacaine	Group Bupivacaine+ Butorphanol	
Heart Rate	0minute	79.58±7.17	80.34±6.87	0.123
	30minutes	88.50±8.68	91.37±8.94	0.125
	60minutes	86.36±7.40	87.45±6.78	0.435
	120minutes	79.94±6.62	82.09±7.14	0.141
	240minutes	77.84±6.12	78.71±5.73	0.449
Systolic Blood Pressure	0 minute	120.92±6.52	121.58±6.45	0.743
	30 minutes	124.54±7.72	124.05±6.42	0.839
	60 minutes	121.24±7.54	120.87±6.77	0.901
	120 minutes	116.74±7.63	115.91±6.22	0.666
	240 minutes	114.42±7.28	113.37±5.95	0.549
Diastolic Blood	0minute	80.08±4.87	80.92±5.01	0.904

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Pressure	30minutes	76.64±7.11	77.05±5.74	0.705
	60minutes	73.72±6.74	74.73±5.39	0.401
	120minutes	68.94±7.62	69.81±6.49	0.521
	240minutes	66.82±7.23	67.35±6.43	0.661
MAP	0minute	93.69±5.30	94.47±5.39	0.824
	30minutes	92.38±7.08	92.85±5.40	0.666
	60minutes	89.20±6.32	89.97±5.07	0.481
	120minutes	84.70±7.13	85.55±5.62	0.490
	240minutes	82.48±7.05	83.13±5.53	0.578
SpO_2(%)	0minute	98.52±0.42	98.49±0.06	0.495
	30minutes	98.40±0.59	98.17±0.41	0.730
	60minutes	98.36±0.66	98.03±0.41	0.442
	120minutes	98.18±0.50	98.01±0.46	0.939
	240minutes	97.98±0.72	97.79±0.49	0.881

According to Table 2, there is No statistical difference in mean heart rate observed between Group Bupivacaine and Bupivacaine + Butorphanol all other time-intervals. Mean systolic blood pressure mean diastolic blood pressure observed between Group Bupivacaine and Bupivacaine+Butorphanol all other time-intervals differ insignificantly. No statistical difference in mean arterial pressure was observed between Group Bupivacaine and Bupivacaine+Butorphanol all other time-intervals. Mean SpO2 (%) observed between Group Bupivacaine and Bupivacaine+Butorphanol all also differs insignificantly in all other time-intervals.

Table 3: Comparison of distribution of side-effects between Bupivacaine and Bupivacaine + Butorphanol groups.

Incidence	**Number (Percentage)**		**Chi-square value**	**p-value**
	Group Bupivacaine	**Group Bupivacaine + Butorphanol**		
Nausea and Vomiting	10 (33.3%)	6 (20.0%)	3.934	0.047*
Hypotension	4 (8.0%)	5 (10.0%)	0.122	0.727
Bradycardia	3 (6.0%)	4 (8.0%)	0.154	0.695
Urinary retention	4 (8.0%)	8 (16.0%)	1.515	0.218

Nausea and Vomiting was found to be significantly more among Group Bupivacaine (33.3%) compared to Group Bupivacaine + Butorphanol (20.0%). Other side-effects such as Hypotension, Bradycardia and Urinary retention did not differ significantly between the 2 groups. Among Group Bupivacaine, Hypotension was reported among 4 (8.0%), Bradycardia among 3 (6.0%) and Urinary retention among 4 (8. %). Among Group Bupivacaine + Butorphanol, Hypotension was reported among 5 (10.0%), Bradycardia among 4 (8.0%) and Urinary retention among 8 (16.0%).

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DISCUSSION

In this study, Nausea and Vomiting was found to be significantly more among Group Bupivacaine. Other side-effects did not differ between the 2 groups. This was in accordance with findings of Abboudet al. [12] who found paucity of side effects with epidural butorphanol given after cesarean section and attributed this to high lipid solubility of butorphanol thus limiting its cephalic spread to the brainstem.

Gaikwad and Khot [13] found that of 30 patients in group II, 3 patients had Nausea and vomiting which was found to be significant statistically from group I i.e. butorphanol group where no patient had such problem. No patients on epidural Butorphanol had nausea or vomiting in study conducted By Hunt et al. [14] and Malik et al [9] showed that the incidence of nausea and vomiting was higher in Fentanyl group than butorphanol group.

In present study, no statistical difference in mean heart rate, systolic blood pressure diastolic blood pressure, MAP and SpO2 was observed between Group Bupivacaine and Bupivacaine+Butorphanol all other time-intervals. In a study by Gosavi et al., [15] the blood pressure remained stable throughout the intra-operative period in both the groups but demonstrated a significant rise in 3 hours after surgery in Bupivacaine group which was significant compared to group BB and BC.

Kapdi et al [16] found that heart rate, blood pressure and respiratory rate remained stable throughout the observatory period. 1 patient in group B had hypotension (Fall in systolic BP <20% of basal reading) and 2 patients in group B had respiratory depression (RR<10/min) which was not statistically significant ($p > 0.05$). Aswini A. et al [17] opined that there were no significant changes in pulse rate, BP and RR in either group throughout the post-operative period.

CONCLUSION

Butorphanol and bupivacaine combination also resulted in high ramsay sedation score though it showed no effect on Systolic and Diastolic blood pressures, Mean blood pressure and Spo2 uptil 240 mins of administration. Addition of butorphanol to bupivacaine in infra - umbilical surgeries are a remarkably safe and also documented to have less side effects such as nausea and vomiting. Therefore, bupivacaine with low dose butorphanol provided better anaesthetic properties and post operative analgesia when compared to bupivacaine alone.

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