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Original Article

Anaesthesia Section

Incidence of Intraoperative Hypotension and Bradycardia in Spinal Anaesthesia with 0.5% Bupivacaine alone and 0.5% Bupivacaine with Fentanyl for Abdominal Hysterectomy: A Cross-sectional Study

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ABSTRACT

Introduction: Bupivacaine hydrochloride, when used for spinal anaesthesia, is associated with varying degree of hypotension and bradycardia. Intrathecal opioids provides haemodynamic stability and improves quality of perioperative analgesia.

Aim: To compare the incidence of intraoperative hypotension, bradycardia and its side-effects when using 0.5% hyperbaric bupivacaine alone and with 25 µg fentanyl added to it for subarachnoid block for abdominal hysterectomy.

Materials and Methods: This cross-sectional study was conducted at Government Medical College, Thrissur, Kerala, India from June 2019 to May 2020 on 96 American Society of Anaesthesiologists Physical Status (ASA-PS) I and II patients posted for total abdominal hysterectomy under lumbar subarachnoid block. They were divided into Group A and B, carrying 48 patients in each group. Group A received 3.3 mL of 0.5% hyperbaric bupivacaine alone. Group B received 3.3 mL of 0.5% hyperbaric bupivacaine and 25 µg fentanyl. Haemodynamic characteristics, analgesic properties and side-effects were compared between Group A and Group B. Data were entered in Microsoft Excel Software, and analysed using Statistical Package for the Social Sciences (SPSS) software version 16.0 and p-value <0.05 was considered as statistically significant.

Results: The incidence of hypotension in group A was 41.7% and in group B was 39.6%. Incidence of analgesia was significantly higher in group B (group A - 181.2±4.9, group B - 220.9±13.9). In group A, no one had nausea and vomiting. In group B, 8.3% experienced nausea and vomiting and none in both groups experienced pruritus.

Conclusion: There was no difference in the development of hypotension and bradycardia when fentanyl was added to bupivacaine for spinal anaesthesia and had the advantage of increased duration of postoperative analgesia.

Keywords: Intrathecal opioids, Haemodynamic stability, Postoperative analgesia, Rescue analgesia

INTRODUCTION

Spinal anaesthesia produces intense motor, sensory and sympathetic block. Excellent anaesthesia and analgesia produced by motor and sensory block makes spinal anaesthesia the choice of anaesthesia for surgeries below the level of umbilicus. Level of spinal blockade depends on the dose, concentration, volume and baricity of local anaesthetic administered [1,2]. Surgeries of obstetrics and gynaecology, pelvic, perineal, urological and lower limb surgeries are usually done under spinal anaesthesia. Spinal anaesthesia is simple to perform, economical and produces complete muscle relaxation and has the advantage of avoiding unnecessary airway interventions as in general anaesthesia. However, the adverse effect of spinal anaesthesia is the occurrence of hypotension and bradycardia.

Some degree of hypotension is always associated with spinal anaesthesia. Another disadvantage is that duration of anaesthesia and analgesia depends on the duration of action of local anaesthetic used [3]. Spinal anaesthesia is preferred when the expected duration of surgery is 1-2 hours. Additives, like opioids can be used with local anaesthetics for subarachnoid block to prolong the duration of anaesthesia [4]. Hypotension and bradycardia if not detected and treated promptly can lead to intraoperative cardiac arrest or even death [5].

Bupivacaine hydrochloride is the most common local anaesthetic used for subarachnoid block. It is a long acting amide group local anaesthetic and can be used for surgeries taking one to two hours duration. Onset of action and duration of action of local anaesthetics depend on the pKa (ionisation constant) and protein binding characteristics [6]. Bupivacaine has a pKa of 8.16 and 96% protein bound makes its onset of action slower with a long duration of action [7].

Opioids are one of the major group of drugs used intrathecally and epidurally as additives along with local anaesthetics. Intrathecally administered opioids acts on the opioid receptors present in the spinal cord, brain, and activation of peripheral and central receptors after systemic absorption. Lipid solubility is the most important characteristic of opioids that determines the potency of a particular drug. Fentanyl is a highly lipid soluble opioid and has a rapid onset and short duration of action. A study by Ebrie AM et al., compared the effect of fentanyl added to low dose and conventional dose of bupivacaine and found that duration of analgesia was prolonged after adding fentanyl to bupivacaine and incidence of hypotension was less when low-dose bupivacaine is used [8].

The present study aimed to compare the incidence of hypotension, bradycardia, development of side-effects and duration of analgesia between two groups receiving bupivacaine alone and bupivacaine in combination with fentanyl.

MATERIALS AND METHODS

This cross-sectional study was conducted in Government Medical College, Thrissur, Kerala, India, from June 2019 to May 2020.

The study was undertaken after obtaining approval from the Institutional Ethical Committee (IEC) [Order No: B6-8772/2016/MCTCR(10) dated 15/11/2018].

Inclusion criteria: Total 96 patients belonging to American Society of Anaesthesiologists Physical Status (ASA-PS) class I and II, aged between 40-60 years undergoing total abdominal hysterectomy under spinal anaesthesia were the study group.

Exclusion criteria: Patient refusal, patients on drugs like beta blockers, antiarrhythmic, antianginal, bleeding disorders or on anticoagulants, space occupying lesions of brain, spine deformity, stenotic valvular lesions were excluded from the study.

Sample size calculation: The sample size was calculated based on the study by Unal D et al., [9]. α=0.05, β=0.1, σ1=13.1, μ_1=95.5, μ_2=87.5, σ2=10.1 ratio(r)=1, Sample size was calculated by using the equation, $n=(Z1-\alpha/2 + Z1-\beta)^2 (\sigma12 +\sigma22/r) / (\mu_1-\mu_2)^2$ and included 48 patients in each group.

Study Procedure

Informed written consent was taken from all patients after explaining the procedure. Preanaesthetic check-up was done. Routine investigations like complete haemogram, renal function tests, liver function tests, prothrombin time, international normalised ratio, Chest X-ray, Electrocardiography (ECG), were advised and verified. Preoperatively all selected patients were explained about the spinal anaesthesia. All patients were given T. alprazolam 0.5 mg, T. ranitidine 150 mg and T. metoclopramide 10 mg, on the previous night and in the morning of surgery.

On the day of surgery, patients were taken to the operation theatre and 18G intravenous cannula was secured and preloaded with ringer lactate solution 10 mL/kg body weight. ECG, Pulse Oxymeter and non invasive Blood Pressure (BP) cuff were attached and baseline Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP) were recorded. Patients were premedicated with Inj. Midazolam 0.02 mg/kg i.v. and Inj. Ondansetron 0.08 mg/kg IV. In the lateral decubitus position and under strict aseptic precautions local infiltration with 2 mL of 2% lignocaine was given and lumbar puncture was performed at L3-L4 interspace through a mid-line approach using a 23-gauge Quincke Babcock spinal needle. Group A patients received 3.3 mL of 0.5% hyperbaric bupivacaine and Group B received 3.3 mL of 0.5% hyperbaric bupivacaine with 25 µg fentanyl.

After intrathecal injection patients were made supine and Oxygen (4 L/min) administered via simple face mask. Vitals were monitored and recorded every three minutes for the first 15 minutes, then every five minutes till 30 minutes and then every 10 minutes till 60 minutes and 120 minutes and throughout the surgery period. Duration of effective analgesia was measured as the time from intrathecal drug administration to the time when patient demands for rescue analgesia postoperatively. Incidence of intraoperative hypotension and bradycardia were recorded in each group. Decrease in SBP >25% from baseline or a fall below 90 mmHg was considered as hypotension and treated with i.v. mephentermine 6 mg and i.v. fluids as required. HR <50 beats per minute was taken as bradycardia and planned to treat with i.v. atropine 0.6 mg if bradycardia occurs. Incidence of adverse effects, like nausea, vomiting, pruritus also was recorded.

STATISTICAL ANALYSIS

The data obtained from both the groups (A and B) were recorded and entered in Microsoft Excel Software, and analysed using SPSS software version 16.0 and p-value <0.05 was considered as statistically significant. In both groups, the continuous variables age, height, weight and duration of surgery were summarised as mean and standard deviation. Categorical independent variable ASA category was summarised as proportions between both groups. Duration of analgesia, haemodynamic parameters (SBP, DBP, MAP and HR) at different time points were summarised as mean±Standard deviation and compared between the groups using unpaired t-test. Incidence of hypotension, bradycardia, nausea, vomiting or pruritus were summarised as proportions and Chi-square test or Fisher's exact test was done to find association with drugs given depending on the distribution.

RESULTS

Demographic characteristics like age, weight, height, duration of surgery and ASA physical status of both groups were comparable [Table/Fig-1].

Groups	Group A n=48	Group B n=48	p-value
Age (years)	48.8±4.9	50.3±6.3	0.19
Weight (kg)	61.6±6.65	62.7±8.0	0.46
Height (cm)	155.7±3.8	155.9±0.77	0.77
Duration of surgery (mins)	117.0±7.5	116.1±7	0.52
ASA I, n (%)	25 (52.1)	22 (45.8)	0.54
ASA II, n (%)	23 (47.9)	26 (54.2)	0.38

[Table/Fig-1]: Demographic data.

The SBP, DBP, MAP and HR was comparable between the groups at baseline [Table/Fig-2].

Variables	Group A n=48	Group B n=48	p-value
HR (bpm)	91.4±10.7	87.2±14.2	0.10
SBP (mmHg)	133.2±4.6	133.3±7.3	0.92
DBP (mmHg)	80.9±6.1	81.0±6.0	0.93
MAP (mmHg)	98.4±5.0	98.2±5.8	0.91

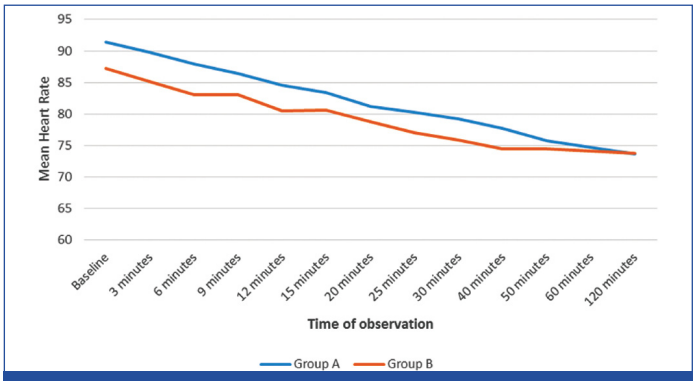
[Table/Fig-2]: Baseline Haemodynamics.
HR: Heart rate, SBP: Systolic blood pressure; DBP: Diastolic blood pressure; MAP: Mean arterial pressure; Group A (Bupivacaine), Group B (Bupivacaine+Fentanyl)

Hypotension and heart rate reduction from baseline was 41.7% and 16.2% in group A (bupivacaine) and in group B (bupivacaine+fentanyl) 39.6% and 11.6%, respectively. There was no statistical significance between groups [Table/Fig-3].

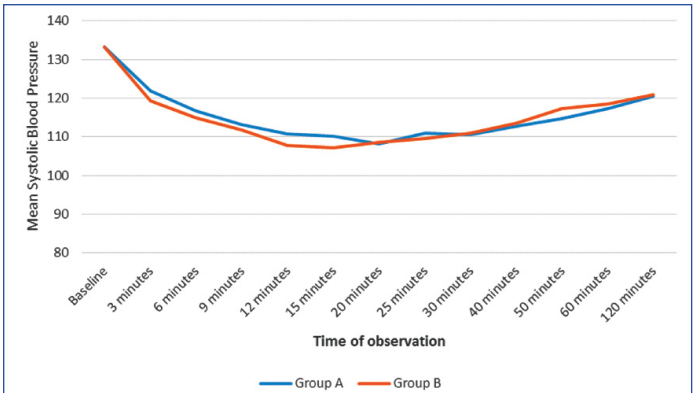
Groups	Hypotension	Decrease in heart rate
A (n=48)	20 (41.7%)	16.2%
B (n=48)	19 (39.6%)	11.6%
p-value	0.83	0.91

[Table/Fig-3]: Incidence of hypotension and decrease in heart rate.

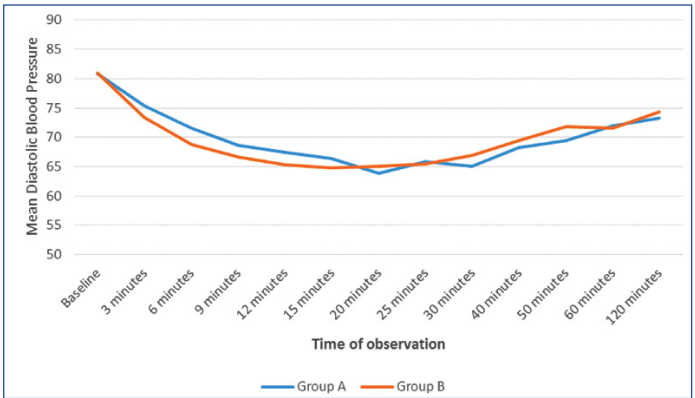
The HR <50/minutes was considered as bradycardia. Both the groups showed a decreasing trend throughout the study period without statistically significant fall in heart rate [Table/Fig-4]. Fall in SBP was similar in both groups group A (bupivacaine), group B (bupivacaine+fentanyl) [Table/Fig-5]. Decrease in DBP was comparable between groups [Table/Fig-6].



[Table/Fig-4]: Line chart showing mean heart rate at different time points.

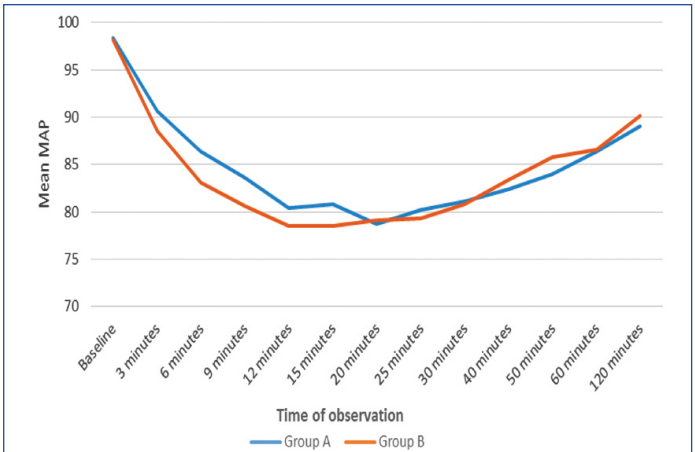


[Table/Fig-5]: Mean systolic blood pressure at different time points.



[Table/Fig-6]: Mean diastolic blood pressure at different time points.

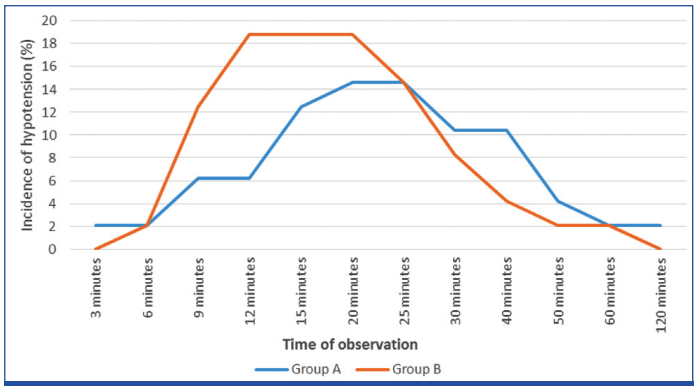
Decrease in MAP was similar in both groups [Table/Fig-7]. Incidence of hypotension was comparable in both groups at different time points of observation during the surgery. The incidence of hypotension was comparable between groups and it was not statistically significant. Hypotension is fall in SBP>25% from baseline. In present study maximum fall in SBP was at 12 minutes [Table/Fig-8a,b]. The duration of analgesia was significantly higher in group B (bupivacaine+fentanyl) [Table/Fig-9]. Incidence of nausea and vomiting was similar with Fisher's exact p-value 0.12. None in both groups experienced pruritus.



[Table/Fig-7]: Mean arterial pressure (mean) at different time point of both group.

Time	Group A (n=48)	Group B (n=48)	p-value
3 minutes	1 (2.1)	0 (0)	1.0
6 minutes	1 (2.1)	1 (2.1)	1.0
9 minutes	3 (6.2)	6 (12.5)	0.49
12 minutes	3 (6.2)	9 (18.8)	0.12
15 minutes	6 (12.5)	9 (18.8)	0.40
20 minutes	7 (14.6)	9 (18.8)	0.58
25 minutes	7 (14.6)	7 (14.6)	1.0
30 minutes	5 (10.4)	4 (8.3)	0.73
40 minutes	5 (10.4)	2 (4.2)	0.44
50 minutes	2 (4.2)	1 (2.1)	1.0
60 minutes	1 (2.1)	1 (2.1)	1.0
120 minutes	1 (2.1)	0 (0)	1.0

[Table/Fig-8a]: Incidence of hypotension. Group A (bupivacaine), group B (bupivacaine+fentanyl) Values in mean±SD, p-value <0.05 is considered as significant



[Table/Fig-8b]: Overall incidence of hypotension. Group A (bupivacaine), group B (bupivacaine+fentanyl).

Groups	Duration of analgesia (mean±SD)	p-value
Group A n=48	181.2±4.9	<0.001
Group B n=48	220.9±13.9	

[Table/Fig-9]: Duration of analgesia in groups.

DISCUSSION

Bupivacaine hydrochloride is the most common local anaesthetic used for spinal anaesthesia. It is a long-acting amide local anaesthetic with high protein binding and high pKa. Onset of action of bupivacaine is slow compared to other local anaesthetics because of its high pKa. Duration of action is also longer as its protein binding is high. Spinal anaesthesia with bupivacaine can be given for surgeries taking 1-2 hours duration. Opioids when used with local anaesthetics express a synergistic action. Fentanyl is a lipophilic opioid with rapid onset of action. Addition of fentanyl to bupivacaine improves the quality of anaesthesia, provides haemodynamic stability and increases duration of postoperative analgesia. Reason for hypotension in spinal anaesthesia are blockade involving T_1 to T_4 sympathetic fibres, decreased adrenal medullary secretion causing reduction in catecholamine circulation and venous and arteriolar dilation leading to reduction in preload and after load. Bradycardia results from blockage of sympathetic fibres involving preganglionic cardiac accelerator fibres from T_1 to T_5. Another reason is activation of stretch receptors in the right atrium in response to decreased venous return. The present study aimed to compare the haemodynamic characters, postoperative analgesia and side-effects when fentanyl is given along with bupivacaine heavy for abdominal hysterectomy.

In the present study group A received 3.3 mL of 0.5% hyperbaric bupivacaine alone and group B received 3.3 mL of 0.5% hyperbaric bupivacaine with 25 µg fentanyl. There was a decrease in SBP, DBP, MAP, and HR in both the groups. But the fall in BP and HR were not statistically significant. Same dose of bupivacaine in both groups may be the reason for comparable haemodynamic characteristics.

The HR decreased from the baseline with onset of sympathetic blockade and it showed a decreasing trend throughout the procedure. The mean HR showed no significant decrease between the groups. In a study conducted by Bogra J et al., in parturients planned for caesarean section, bradycardia was

found in 10-15% cases in each group and the overall incidence of bradycardia was 7% [10]. In the present study no incidence of bradycardia occurred at any point of time, but a decrease in HR from the baseline was noted in both study groups during the period of blockade. Decrease in HR was 16.2% in group A (bupivacaine) and 11.66% in group B (bupivacaine+ fentanyl). Heart rate never went below the cut-off value of 50 in either group. In study by Bogra J et al., parturients posted for caesarean section and pregnancy induced physiological changes might be the reason for bradycardia.

The maximum fall in SBP was at 12 minutes from the onset of sympathetic blockade, which was different from the study conducted by Bogra J et al., in which maximum fall in SBP was noticed after 25 minutes in all groups. On comparing the haemodynamic stability of bupivacaine and bupivacaine+fentanyl, they found that the latter was more stable. They also found that the intraoperative hypotension increased with increasing doses of bupivacaine, however along with fentanyl it increased more. This was different from present study in which bupivacaine+fentanyl group showed more haemodynamic stability.

Incidence of hypotension was similar in both groups and the findings were comparable with the study by Fernandez-Galinski D et al., [11]. They compared hyperbaric bupivacaine 12.5 mg with saline and the same dose of bupivacaine with 25 µg fentanyl for geriatric patients. The blood pressure response of both groups was similar. Duration of analgesia was significantly higher in group B (bupivacaine with fentanyl). This was in similarity with the study of Shim SM et al., in which duration of postoperative analgesia increased with addition of fentanyl to bupivacaine [12].

Study by Unal D et al., showed similar results when different doses of bupivacaine with 25 µg of fentanyl was used [9]. They studied the quality of block, haemodynamic stability, quality of anaesthesia, perioperative complication, and hospital release criteria. Time of request for first analgesia postoperatively was longer in group in which fentanyl was added. Ben-David B et al., studied 50 patients undergoing ambulatory surgical arthroscopy with diluted small dose of bupivacaine alone and 10 µg fentanyl added to bupivacaine and found that adding fentanyl increases the duration of sensory block with less intense motor block and early recovery to micturition or street fitness [13].

Wong CA et al., conducted a trial to determine the optimal dose of intrathecal fentanyl with 2.5 mg bupivacaine. They added 0,5,10,15,20,25 µg with 2.5 mg bupivacaine for labour analgesia and found that duration of analgesia was more with higher dose of fentanyl. There was no difference in the incidence of nausea and vomiting or in foetal heart rate tracing changes between groups [14]. Shende D et al., compared two groups of patients, 0.3 mL of 0.9% saline added to 2.5 mL of 0.5% bupivacaine in Group I, and 0.3 mL of fentanyl (15 µg) to 2.5 mL of 0.5% hyperbaric bupivacaine in group 2. They found that adding 15 µg fentanyl to hyperbaric bupivacaine markedly improved intraoperative anaesthesia for caesarean section [15].

Observations of the present study results were similar to those by Gauchan S et al., in which duration of sensory block was prolonged when fentanyl was added to intrathecal bupivacaine and duration of effective postoperative analgesia also prolonged in fentanyl group [16]. Martyr JW et al., [17] and Singh H et al., [18] in their study observed similar results.

When comparing side-effects between groups, in group A (bupivacaine) none experienced nausea, vomiting, and pruritus. But in Group B (bupivacaine+fentanyl), 8.3% experienced nausea and vomiting but no one had pruritus but it was statistically not significant. Lipid soluble opioids in minimum dose may not stimulate pruritus [19]. Nausea and vomiting in group B may be attributed to intrathecal fentanyl [20].

Limitation(s)

The volume in each group was different and height of the participants was not taken as criteria for comparison. These parameters can affect ascend of the drugs and haemodynamic characteristics.

CONCLUSION(S)

There was no difference in the incidence of intraoperative hypotension or bradycardia between groups and there is an added advantage of increasing the duration of postoperative analgesia by adding fentanyl to bupivacaine. Combination of bupivacaine and fentanyl was found to be superior to bupivacaine alone group as the quality of anaesthesia was better.

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