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Comparative Study Between Two Different Doses of Local Anesthetic with Adjuvant i.e., Opioids Such as Hyperbaric Bupivacaine with Fentanyl in Subarachnoid Block in Case of Emergency Lower Uterine Cesarean Section

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ABSTRACT

Various adjuvants have been used with local anesthetics in spinal anesthesia to avoid intraoperative visceral and somatic pain and to provide prolonged postoperative analgesia. The new highly selective drug is now being used as a neuraxial adjuvant. The aim of this study was to evaluate the onset and duration of sensory and motor block, hemodynamic effect, postoperative analgesia and adverse effects of fentanyl given intrathecally with hyperbaric bupivacaine. This study was done to compare the block characteristics, relative efficacy and adverse effect of two comparative doses of hyperbaric intrathecal bupivacaine with fixed dose fentanyl in emergency lower uterine caesarean section. This Randomized Controlled, Single-Blinded and Prospective, observational cohort study was done to compare the effects of lower and comparatively higher doses of hyperbaric intrathecal injection of bupivacaine with fentanyl in 100 consenting pregnant mother of ASA II who underwent emergency lower uterine caesarian section during December 2014 till November 2015. The recommended level of regional anaesthesia for LUCS is T4. It was observed that the mean time for duration of sensory block was 115.8±1.53 for Group A and 153.7±2.752 for Group B. On intergroup comparison, there was significant difference in duration of sensory block between two groups ($p<0.05$). This study concludes that using 10 mg of hyperbaric bupivacaine with 25 mcg of fentanyl in pregnant mothers for subarachnoid block in emergency LUCS has a better perioperative outcome because there is a longer duration of analgesia, a shorter time for onset of sensory and motor block, a longer duration of sensory and motor block, a longer duration of anaesthesia and no significant changes in hemodynamic status due to subarachnoid block.

INTRODUCTION

Spinal anaesthesia (subarachnoid anaesthesia SAB) was first introduced by August Karl Gustav Bier, a German surgeon who used 3 mL of 0.5% of cocaine intrathecally on six patients for lower extremity surgery in 1898[1]. Thereafter, fears of neurologic deficits and complications caused anaesthesiologists to use less of spinal anaesthesia. The development of novel intravenous anaesthetic agents and neuromuscular blockers coincided with the decreased use of spinal anaesthesia. Subarachnoid anaesthesia is most commonly used regional anaesthesia technique today. Cocaine was the first spinal anaesthetic used and procaine and tetracaine soon followed. Spinal anaesthesia performed with lidocaine, bupivacaine, tetracaine, mepivacaine and ropivacaine have been successful[2]. Among them bupivacaine is one of the most widely used local anaesthetics for spinal anaesthesia and provides adequate anaesthesia and analgesia for intermediate to long duration surgeries. Certain factors are important which governs spread of an intrathecal injection of bupivacaine. These are density and basicity of the anesthetic solution injected, position of the patient, dose, volume and temperature1 of the local anesthetic drug that is injected, anatomic configuration of the spinal column, site of injection, the direction of the needle during injection, volume of CSF, density of CSF, patient's age, height. It has also been observed that level of sensory block is higher in cases of isobaric and hypobaric drugs as compared to hyperbaric agents. Spinal anaesthesia has been widely used for caesarean section has been found to be efficacious and safe. In pregnant mothers, due to gravid uterus there is increase in intra abdominal pressure, so there is increased chance of aspiration pneumonitis if balanced general anaesthesia is given[1]. So subarachnoid block is safer in lower uterine caesarean section for pregnant mothers. It is very efficient, requires fewer medication dosages, causes less new-born depression, keeps the mother awake and reduces the risk of aspiration pneumonitis. However, it causes a set period of anesthesia, postdural puncture headache, hypotension and decreased control over block height. Bupivacaine was also the first local anaesthetic that produced adequate pain relief, without a major effect on motor fibers and Fentanyl [l] is one of the most extensively used opioids as adjuvant with local anaesthetic agent for this purpose and has been found to be safe and effective both in terms of neonatal and maternal outcome in caesarean section.

Aims of this study were done to compare the block characteristics, relative efficacy and adverse effect of two comparative doses of hyperbaric intrathecal bupivacaine with fixed dose fentanyl in emergency lower uterine caesarean section.

MATERIALS AND METHODS

Study area: Obstetrics Operation Theatres in Murshidabad Medical College and Hospital.

Study population: Total 100 pregnant mothers pertaining ASA2 posted for emergency lower uterine cesarean section.

Type of study: Randomized Controlled, Single-Blinded and Prospective study.

Study period: One Year and three months. (One year for data collection and 3 months for Data Analysis, Review and Report writing.).

Sample size: If there is 15% difference between the effects of two groups with a power of 0.8 and alpha error of 0.05 and estimated standard deviation of 0.8 the sample size became 42. Assuming a dropout of 20%, we took 50 pregnant mothers in each group.

Sample design: A total of 100 pregnant mothers had been selected for the study. The patients had been randomized into two groups of 50 each.

- **Group A:** The patients had been administered with 8 mg of hyperbaric bupivacaine with 25 mcg of fentanyl
- **Group B:** The patients has received 10 mg hyperbaric bupivacaine with 25 mcg fentanyl. The selection into either of the groups had been done as per computer generated randomized table using concealed envelope technique

Inclusion criteria:

- Patients of ASA Physical status: II
- Patients planned for emergency lower uterine cesarean section in supine position
- Giving consent to present study

Exclusion criteria:

- ASA Physical Status III/IV
- Underweight, overweight, obese patient
- Presence of upper respiratory tract infection
- Patient with history of sleep apnea
- History of pulmonary disease
- History of motion sickness and severe nausea vomiting
- Pregnant mother associated with severe comorbidities such as pregnancy induced hypertention, eclampsia and heart disease
- Allergy to amide local anaesthetics
- Patient contraindication to spinal anaesthesia
- Inadequate block (i.e., sensory block <T8 segment)
- Patient refusal

Parameters to be studied:

- Onset of sensory block
- Duration of sensory block
- Onset of motor block
- Duration of motor block
- 2-segment regression time of sensory block
- Duration of analgesia
- Consumption of vasopressor (i.e., phenylephrine)
- Incidences of complications, if any
- Comparative cost analysis of the study drugs
- Frequency of hemodynamic instability interoperability-blood pressure, pulse rate
- Duration of anaesthesia
- Duration of Surgery
- Episode of any complications: Nausea, vomiting, intraoperative shivering

Study tools:

- Patients' informed consent form (in Bengali, Hindi and English)
- Scale for height
- Weighing machine for measuring weight of the patient
- Bed head ticket (BHT)
- Relevant investigations
- Study proforma
- Equipments for aseptic dressing and draping
- Spinal needle (25 G Quincke needle)
- Study drugs (8 mg and 10 mg of 0.5% hyperbaric bupivacaine , 25 mcg fentanyl)
- Drugs for premedication [inj. ranitidine(50 mg) i.v, injondansetron (0.1 mg/kg i.v.]
- Ringers Lactate infusion with infusion sets and i.e., cannula (18 G)
- Drugs for treating bradycardia (atropine 0.6 mg) and hypotension (phenylnephrine 25-50 mcg)
- Disposable syringes
- ECG
- Pulse
- NIBP
- Pin for prick test for sensory block test anesthesia machine
- Endotracheal tube
- Difficult intubation cart

Analysis of data: All recorded data were analyzed using standard statistical methods including standard diagrams and graphs and the findings discussed in details to draw appropriate conclusion in consultation with a statistician.

Continuous variables like age, weight, height, BMI, hemogram, FBS, PPBS, serum creatinine, pulse rate at different time points of time, SBP at different time points of time, DBP at different time points of time, duration of surgery, duration of anaesthesia, onset of sensory block, duration of sensory block, onset of motor block, duration of motor block, 2 segment regression time of sensory block and duration of analgesia are expressed as Mean±standard deviation and compared across the groups using One-way ANOVA test.

Categorical variables like type of operation, ASA, relax Score, incidence of hypotension, bradycardia, requirement of phenylnephrine 100 mcg and atropine 0.6 mg are expressed as number of patients and percentage and compared across the two groups using Pearson's Chi Square test for Independence of Attributes.

The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e., if any p-value is less than 0.05 it has been considered as significant.

RESULTS AND ANALYSIS

From Table 1, the ASA status of the patients among the two groups were comparable with no significant difference ($p>0.05$). From Table 2, the duration of surgery was comparable among the two groups with no significant difference ($p>0.05$). From Table 3, the duration of anaesthesia was comparable among the two groups with significant difference ($p<0.05$). From Fig. 1, it was observed that there was significant difference between two groups with regards to 2 segment regression time of sensory block ($p<0.05$). The mean value of 2 segments regression of sensory block for Group A was 141.2 ±1.448 min and for Group B was 163±2.365 min.

From Table 3, it was observed that on intergroup comparison there was significant difference between with regard to onset of motor block ($p = 0.0041$). The mean value of onset of motor block for Group A was 5.49±0.1502 min and for Group B was 3.09±0.1556 min. From Table 4, it was observed that on intergroup comparison there was significant difference between the two groups with regard to duration of motor block ($p<0.05$). The mean value of duration of motor block for Group A was 137.7±1.621 min and for Group B was 159.2±2.48 min. It can be seen that between two groups there was a significant difference in duration of analgesia ($p = 0.0051$).

Table1: ASA status of the patients

ASA	Group A	Group B	p-value	Total
II	17 (34%)	12 (24%)	29	>0.05

Table 2: Duration of surgery and duration of anaesthesia (min)

	Group A	Group B	
	----------Mean±SD----------		p-value
Duration of surgery (min)	40.94±0.4467	42.20±0.9129	0.2180
Duration of anaesthesia (min)	118.90±0.3868	125.12±0.7627	0.0001

Table 3: Onset of motor block (min) and duration of motor block (min)

	Group A	Group B	
	----------Mean±SD----------		p-value
Onset of motor block (min)	5.49±0.1502	3.09±0.1556	0.0041
Duration of motor block (min)	137.70±1.621	159.20±2.48	0.0052

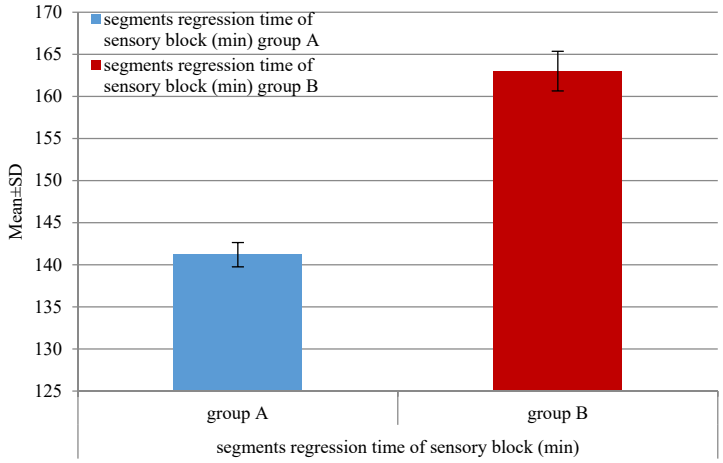

Fig. 1: Segments regression time of sensory block (min)

Table 4: Onset of sensory block (min), duration of sensory block (min) and segment regression time of sensory block

	Group A	Group B	
	----------Mean±SD----------		p-value
Onset of sensory block (min)	2.99±0.1083	1.8±0.1327	0.0031
Duration of sensory block (min)	115.80±1.53	153.7±2.752	0.0002
Segment regression time of sensory block	141.20±1.448	163.0±2.365	0.0063

From Table 4, it was observed that on intergroup comparison there was significant difference between the two groups with regard to onset of sensory block ($p<0.05$). The mean value of onset of sensory block for Group A was 2.99±0.1083 min and for Group B was 1.8±0.1327 min, It was observed that on intergroup comparison there was significant difference between the two groups with regard to duration of sensory block ($p<0.05$). The mean value of duration of sensory block for Group A was 115.8±1.53 min and for Group B was 153.7±2.752 min, It was observed that there was significant difference between two groups with regards to 2 segment regression time of sensory block ($p<0.05$). The mean value of 2 segments regression of sensory block for Group A was 141.2±1.448 min and for Group B was 163±2.365 min.

DISCUSSION

The demographic data with respect to age, body weight, height and BMI were comparable among the three groups with no significant difference. Hemodynamic variables like pulse rate was similar among the groups starting from baseline values till completion of operation these findings were similar to other studies by del-Rio-Vellosillo *et al*.[3] and Chari *et al*.[4]. On intergroup comparison, it was observed that there was difference between the two groups with regard to onset of sensory and motor block ($p<0.05$). In our study we found that Group B (1.8 mL hyperbaric bupivacaine) cases have significantly longer duration of both sensory and motor blockade. From our study it can be seen that there was significant difference of analgesic duration between the two different doses 0f bupivacaine ($p<0.05$). There was insignificant difference between the two different doses of bupivacaine regarding surgical relaxation score ($p>0.05$).

Hypotension among patients in the two groups were not comparable with significant differences throughout the procedure ($p<0.05$). Requirement of phenylephrine to manage hypotension in the two groups were not comparable ($p>0.05$). Incidence of bradycardia among patients in the two groups were comparable requirement of atropine to manage bradycardia were also similar ($p>0.05$).

Group A systolic BP in first 30 min is 1O4.1±1.499, whereas Group B finding is 99.5±1.51 which is statistically significant difference. Within next 60-90 min observation, Group A Statistic findings are 108.7±1.067 and 112.6±0.8897. On the other hand, Group B Statistic findings are 109.4±0.6269 and 112.4±0.6941. These findings are statistically insignificant($p>0.05$).

In case of perioperative pulse rate changes, in the first 30 min of anaesthesia there is significant changes of pulse rate in case of Group B compared to Group A (Group B 70.1±1.682 vs Group A 79.8±1.815, $p<0.05$). Within next 60-90 min observation, Group A, Statistic findings are 81.6±1.035and 83.84±1.09, On the other hand, Group B Statistic findings are 75.9±0.9088 and 82.4±0.951. These findings are statistically insignificant ($p>0.05$). This hemodynamic similarity was also observed by Chiari *et al*.[4] et al. A tendency of isobaric bupivacaine to cause more hypotension in the first 30 min was observed by Varun *et al*.[5]. Tuijl in their study with 75 µg intrathecal Clonidine noted that although mean arterial pressure (MAP) decreased but was not clinically important. Bhatia *et al*.[6] found in their study comparable changes of pulse rate between two groups of one is only with intrathecal hyperbaric bupivacaine and other is hyperbaric bupivacaine with

fentanyl, also found significant mean systolic blood pressure changes with insignificant diastolic and mean arterial blood pressure changes.

It was observed that the mean time for onset of sensory block was 2.99±0.1083 for group A and 1.8±0.1327 for Group B. On intergroup comparison, there was significant difference in onset of sensory block between two groups (p<0.05). This changes may be due to higher dose of hyperbaric bupivacaine and use of opioid adjuvant.

The recommended level of regional anaesthesia for LUCS is T4. It was observed that the mean time for duration of sensory block was 115.8±1.53 for Group A and 153.7±2.752 for Group B. On intergroup comparison, there was significant difference in duration of sensory block between two groups (p<0.05).The reason behind this result perhaps due to higher dose of bupivacaine. Mehta *et al*.[7] found in their study a comparable difference in total duration of sensory block between only and with fentanyl bupivacaine groups which was statistically insignificant.

The mean time for onset of motor block is 5.49±0.1502 for Group A and 3.09±0.1556 for Group B. On intergroup comparison, there was significant difference in onset of sensory block between two groups (p<0.05) may be due to increased dose of hyperbaric bupivacaine. It was observed that the mean time for duration of motor block was137.7±1.621 for Group A and 159.2±2.48 for Group B. On intergroup comparison, there was significant difference in duration of motor block between two groups (p<0.05). Mehta *et al*.[7] found similar result in their study. nIt was observed that the mean time for duration of 2 segment regression time of sensory block was 141.2±1.448 for Group A and 163±2.365 for Group B. On intergroup comparison, there was significant difference in duration of 2 segment regression time between two groups (p<0.05) due to higher dose.

From our study it can be seen that the mean duration of analgesia 146±1.513 for Group A and170.1±1.965 for Group B. On intergroup comparison, there was significant difference in duration of analgesia between two groups (p<0.05) may be as there is higher dose of bupivacaine in group B. Chavan *et al*.[8] mentioned that the mean duration of analgesia was prolonged in hyperbaric bupivacaine with fentanyl group compared to only bupivacaine group; their difference was statistically highly significant (p<0.01). Suresh found that group with intrathecal fentanyl with hyperbaric bupivacaine has highly statistically significant (p<0.001) mean duration of analgesia than group with dexmedetomidine with hyperbaric bupivacaine.

Rooke *et al*.[9] calculated surgical satisfaction in terms of “very good”, “good”, “moderate”, “bad” or “very bad”. In their study comparing hyperbaric bupivacaine and levobupivacaine, surgical satisfaction was more with bupivacaine. In this study the satisfaction rate of surgeons as “excellent” was significantly higher in bupivacaine and levobupivacaine group than in ropivacaine group (p<0.05).

Though the degree of hypotension within the first 30 minutes was significant, the overall degree of changes in BP throughout perioperative period was not significant. In Group A 44% of mothers faced hypotension mostly within 30 min of anaesthesia and in Group B 54% of pregnant mothers faced hypotesion mostly within 30 min of subarachnoid block. Ben-David *et al*.[10] observed that patients with plain bupivacaine were more likely to require treatment for hypotension than patients with bupivacine-fentanyl. This is because of less dose of bupivacaine used in latter. Mehta *et al*.[7] found that Incidence of hypotension and use of vasopressors was much higher in group receiving higher amount of hyperbaric bupivacaine and was found to be statistically significant. Our study also found a comparable difference but not statistically significant (p<0.05). The degree of intake of phenylephrine also not statistically significant between two groups.

CONCLUSION

It c an be concluded from this study that use of 10 mg of hyperbaric bupivacaine with 25 mcg of fentanyl in pregnant mothers for subarachnoid block in emergency LUCS has better perioperative outcome as there is prolonged duration of analgesia, due to lesser time for onset of sensory and motor block, prolonged duration of sensory and motor block, prolonged duration of anaesthesia and there is insignificant changes in hemodynamic status due to subarachnoid block.

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