ORIGINAL RESEARCH PAPER

Anaesthesiology

COMPARISON OF TWO LOW DOSE REGIMENS OF SUBARACHNOID BLOCK ANESTHESIA FOR LOWER SEGMENT CAESARIAN SECTION

KEY WORDS: Sympathetic Blockade, Low Dose Spinal Anesthesia, Intrathecal Fentanyl

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ABSTRACT

Hypotension and bradycardia due to sympathetic blockade are two commonest complications of spinal anesthesia leading to maternal and neonatal morbidity and mortality. Aortocaval compression due to gravid uterus also contributes to the development of hypotension. Preloading with crystalloids at 10ml/kg weight is done to prevent hypotension. Wedge under right buttock to provide 25 degrees sideways tilt is used to prevent the aortocaval compression by gravid uterus. Low dose bupivacaine heavy with intrathecal fentanyl is recommended as strategy to prevent spinal anesthesia induced hypotension and related complications. The present study was done in our tertiary care centre to compare the effects of fixed dose of Fentanyl 20mcg (0.4ml) administered along with two low doses 1.6 ml(8mg) and 1.8 ml(9mg) of 0.5% hyperbaric bupivacaine (heavy) and assess the adequacy of surgical anaesthesia for caesarean section and hemodynamic changes intra operatively. There was faster onset of sensory blockade, better haemodynamic stability and prolonged postoperative analgesia in patients administered with1.6ml of 0.5% Bupivacaine heavy (8mg) & 20mcg Fentanyl (Gp I) compared with patients administered with 1.8ml of 0.5% Bupivacaine heavy (9 mg) & 20mcg Fentanyl (Gp II). Perioperative analgesia was excellent in both the groups. No patient who developed bradycardia or hypotension in Gp I and only 2 patients in Gp II developed hypotension. Post-operative analgesia was for a longer period in Group II as compared to Gp I.

INTRODUCTION

Providing safe and effective anesthesia for Lower Segment Cesarean Section (LSCS) delivery requires detailed understanding of the physiological changes associated with pregnancy. These changes are a result of alteration in the maternal hormone balance, a biochemical shift related to larger metabolic demands of the fetus and placenta, and mechanical forces from the gravid uterus.[1, 2].Although each organ system is affected by pregnancy, the changes to the cardiovascular, respiratory and gastrointestinal systems have anesthetic implications. Subarachnoid Block (SAB) is the preferred anesthesia technique in LSCS for its better safety profile and other benefits like early materno-neonatal bonding .It avoids the complications of general anesthesia like aspiration pneumonia and PONV.

Hyperbaric bupivacaine 0.5% is the most commonly used drug for spinal anesthesia[3] Single shot SAB has limited duration of action. It is well known that the dose of the drug influences the duration of sensory blockade, motor blockade and degree of hypotension[4]. Adjuvants like Opioids (Morphine, Fentanyl, Sufentanyl) and Non opioids such as alpha-2 adrenergic agonists (Clonidine, Dexmedetomidine), anticholinesterases (Neostigmine), Midazolam, Steroids and Ketamine can be added to LA, to improve the quality of intra operative anesthesia and to prolong the duration of postoperative analgesia. Each adjuvant drug has its limitations and side effects, and the need for an alternative methods and drugs always exist.[5-9] Ideal adjuvant that can be used with bupivacaine for stable intraoperative hemodynamic conditions and prolonging the post-operative analgesia with minimal side effects are being investigated.

Fentanyl, a lipophilic opioid, has rapid onset of action after intrathecal administration, and does not migrate to 4th ventricle in sufficient concentrations to cause delayed respiratory depression. After intrathecal administration, Fentanyl diffuses into epidural space and subsequently into the plasma, suggesting that it acts not only through spinal opioid receptors but also systemically. 20mcg of Fentanyl added to low dose Bupivacaine Heavy intrathecally acts synergistically improving the quality of intraoperative analgesia and providing post operative analgesia as well[10].

Conventional SAB for caesarian section is done by using 2ml 0f 0.5% Hyperbaric Bupivacaine(10mg) or more of 0.5% Hyperbaric Bupivacaine which is associated with bradycardia and hypotension as a result of sympathetic blockade. The present study was done in our tertiary care centre to compare the effect of fixed dose of Fentanyl 20mcg (0.4ml) administered along with low dose 1.6 ml(8mg) – Gp I and 1.8 ml(9mg) of 0.5% hyperbaric Bupivacaine (heavy)-GP II and assess the adequacy of surgical anaethesia for caesarean section and hemodynamic changes intra operatively.

AIM

To compare the perioperative analgesia and hemodynamic changes after Subarachnoid Block (SAB) of two low dose combination of 0.5% Hyperbaric Bupivacaine along with fixed dose of Fentanyl in patients undergoing lower segment caesarean section.

OBJECTIVES

Primary:

1. To compare the time for onset of sensory and motor blockade after giving two different doses of 0.5% Hyperbaric Bupivacaine and fixed dose of 20 mcg Fentanyl intrathecally.
2. Hemodynamic (NIBP & Heart rate) changes compared to baseline prior to block.
3. Time to first dose of rescue analgesia after surgery or duration of post-operative analgesia.

Secondary:

1. Analgesia at the time of skin incision using pain score
2. Apgar Score of newborn

MATERIAL AND METHODS

A tertiary hospital based double blind, randomised, controlled trial study was undertaken to compare the analgesia and hemodynamic changes after intrathecal administration of two different low dose combinations of 0.5% Hyperbaric Bupivacaine along with fixed dose of 20 mcg Fentanyl in parturients undergoing lower segment caesarean section. 60 patients were allocated into following groups:

- **Group I:** 30 patients received 1.6ml (8mg) of 0.5% Bupivacaine heavy & 20mcg Fentanyl
- **Group II:** 30 patents received 1.8ml (9mg) of 0.5% Bupivacaine heavy & 20mcg Fentanyl

Study design: A tertiary hospital based double blind, randomised, controlled study
Study Duration: 2 year (2017-18)
Study area: The study was done at our tertiary care hospital in western India.
Study population: Parturients posted for elective caesarean section at Tertiary Care Hospital in western India who fulfilled the inclusion criteria.
Sample size: 60 patients
Minimum sample size calculated was 7 in each group and 30 patients in each group was taken making a total of 60 patients.

Inclusion criteria
1. Parturients belonging to ASA class I and II with singleton pregnancy with term gestation posted for caesarean section and who had no contraindication for spinal anaesthesia.

Exclusion criteria
1. Patients with co-morbid conditions like anemia, diabetes mellitus, asthma, hypertension, cardiac diseases and other systemic problems
2. Patients with PIH, eclampsia, multiple gestation, placenta previa,
3. Emergency LSCS.
4. Patient with BMI >30 kg/m^2..
5. Patient refusal.

METHODOLOGY

Approval from the Institutional Ethics Committee was obtained. As per the proforma demographic and anthropometric data including age, height & weight were obtained. History of drug allergy, and drug intake were noted. Patients with known allergy to any of the study drugs were excluded from the study. Vital parameters like heart rate, blood pressure were recorded. Pre-anaesthetic check-up was done to exclude co- existing medical conditions and complications of pregnancy and to assess the airway and spine. Routine investigations like hemoglobin, bleeding time, clotting time, blood grouping and typing, urine examination were done. Written & informed consent were taken prior to procedure. The procedure of spinal anaesthesia with hyperbaric Bupivacaine and Fentanyl was explained to the patients during their pre anaesthetic visit and prior to doing the procedure.

In the preoperative room intravenous line were obtained with 18 gauge IV cannula and preloading done with Ringer lactate 10ml/kg over 15-20 min. The parturient was brought into the operation theatre lying in the left lateral position to avoid aortocaval compression and placed on the operating table in supine position with 25 degrees tilt towards left by placing a wedge under the right hip. The sphygmomanometer cuff was tied to the upper arm and baseline line blood pressure was recorded. Pulse Oximeter was connected and saturation was noted. Before the commencement of anaesthesia, patients were instructed on the method of sensory and motor assessments all safety measures were taken for cardiovascular and pulmonary resuscitation.

TECHNIQUE

Double blinding was done by preparation of drug by a person other than observer after randomly picking a chit from total of 60 chits containing 30 of each group on chit with drug dose written. Drug is prepared and given by another anesthesia resident. Volume of prepared drug was equalized using normal saline to ensure double blinding.

Under aseptic precautions using a 25G Quincke needle spinal subarachnoid block was administered in L2-3/3-4 space with patient in sitting position. Group-I: received 1.6ml (8mg) of 0.5% Hyperbaric Bupivacaine & 20mcg Fentanyl Group-II: received 1.8ml (9mg) of 0.5% Hyperbaric Bupivacaine & 20mcg Fentanyl. After injection of the drug and the patient is placed in supine position and. 100% oxygen via face mask (at a rate of 4 l/min) was administered.

Cardiac parameters like, heart rate and NIBP were recorded immediately after subarachnoid block, NIBP and Heart rate were recorded at every 2 minute interval for first 10 minute followed by 5 minutes there after till 10 minute after surgery. Hypotension is defined as systolic blood pressure <90mm of Hg and was treated with intravenous boluses of Normal Saline and intravenous phenylephrine.

Dermatomal sensory block was assessed by temperature sensation at the mid clavicular line on both sides with cold swab every 2 min, till 10 min or until the block reaches T6 dermatome. Surgical incision was allowed when the sensory level is ≥ T6 dermatome and motor blockade is adequate. Degree of motor block in the lower limbs was assessed subjectively by asking the patient to move the lower limbs, and was noted as follows according to the Bromage scale.

Bromage Scale
Grade Criteria & Degree of block
0. Free movement of legs and feet Nil (0%)
1. Just able to flex knees with free movement of feet Partial (33%)
2. Unable to flex knees, but with free movement of feet almost complete (66%)
3. Unable to move legs or feet Complete (100%).

Delivery time of the baby was noted and 10 units of synthetic oxytocin was added to i.v drip. Assessment of newborn was done using Apgar score at 1 min and 5 mins. The birth weight was noted. Side effects such as hypotension, bradycardia, nausea, vomiting, shivering and pruritus or itching were recorded during and after surgery.

Time required for sensory recovery to T10 and motor recovery to B0 and onset of post operative pain after subarachnoid block were recorded after surgery.

OBSERVATIONS AND RESULTS

Table 1: Distribution of patients according to Age

Age (years)	Group I		Group II		p Value
	N	%	N	%	
18-20 years	3	10%	4	13.3%	0.645
21-30 years	25	83.3%	23	76.7%	
>30 years	2	6.7%	3	10%	
Total	30	100%	30	100%	
Mean ± SD	24.97 ± 3.66		25.03 ± 4.19		

Table 2: Distribution of patients according to BMI

BMI (kg/m^2)	Group I		Group II		p Value
	N	%	N	%	
Normal (18.5-24.9)	21	70%	23	76.6%	0.476
Overweight (25-29.9)	5	16.7%	5	16.7%	
Obese (≥30)	4	13.3%	2	6.7%	
Total	30	100%	30	100%	
Mean ± SD	24.81 ± 3.63		24.03 ± 2.43		

Table 3: Distribution of patients according to ASA Grading

ASA Grading	Group I		Group II		p Value
	N	%	N	%	
I	22	73.3%	21	70%	0.358
II	8	26.7%	9	30%	
Total	30	100%	30	100%	

Table 4: Comparison of Duration of Surgery between groups

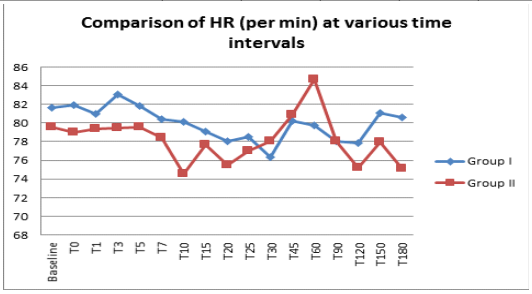
	Group I		Group II		p Value
	Mean	SD	Mean	SD	
Duration of Surgery (mins)	50.77	6.69	51.37	6.25	0.685

Table 5: Comparison of Sensory and Motor Blockade characteristics between groups

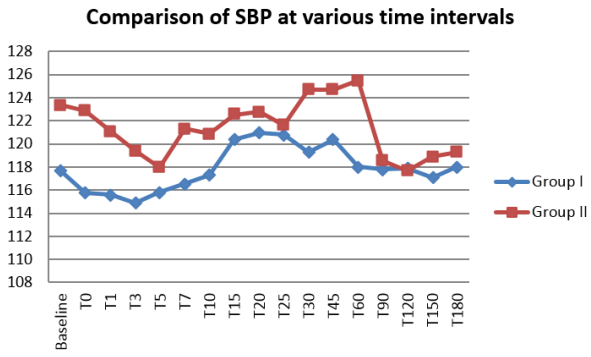
Characteristics	Group I		Group II		p value
	Mean	SD	Mean	SD	
Time of onset of sensory analgesia (secs)	141.97	11.04	137.97	12.63	0.184
Time of onset of motor block (secs)	284.53	20.92	276.33	13.89	0.242
Total duration of motor block (mins)	129.63	17.98	131.93	15.07	0.526

Table 6: Comparison of Duration of Analgesia between groups

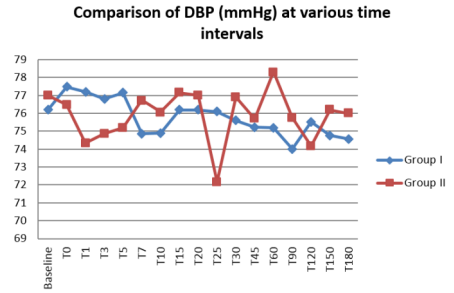
	Group I		Group II		p Value
	Mean	SD	Mean	SD	
Duration of Analgesia (mins)	210.83	22.52	281.17	21.61	0.002



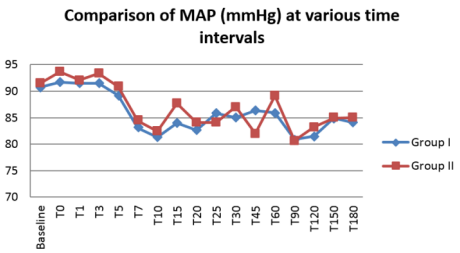
Graph 7: Comparison of HR (per min) at various time intervals



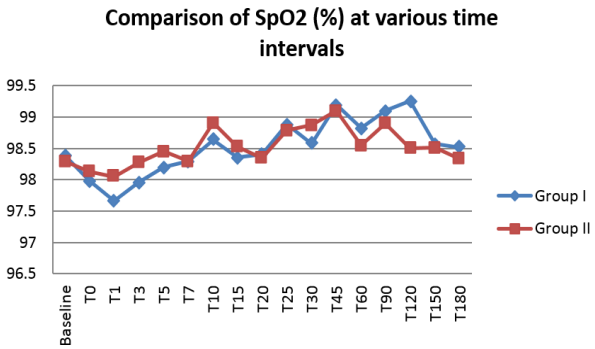
Graph:8 Comparison of SBP at various time intervals



Graph:9 Comparison of DBP (mmHg) at various time intervals



Graph:10 Comparison of MAP (mmHg) at various time intervals



Graph:11 Comparison of SpO2 (%) at various time intervals

Table 12: Comparison of Duration of post-operative analgesia between groups

Characteristics	Group I		Group II		p value
	Mean	SD	Mean	SD	
Duration of post operative analgesia (mins)	265.83	19.29	425.97	13.07	0.001

Table 13: Comparison of Post-operative VAS Score between groups

	Group I		Group II		p value
	Mean	SD	Mean	SD	
Post-operative VAS score	6.50	0.73	4.37	0.67	0.001

Table 14: Comparison of APGAR Score between groups

	Group I		Group II		p Value
	Mean	SD	Mean	SD	
APGAR Score	8.40	0.33	8.51	0.74	0.548

Table 15: Comparison of Side Effects between groups

Side Effects	Group I		Group II		p Value
	N	%	N	%	
Drowsiness	4	8%	6	12%	0.325
Nausea/Vomiting	3	6%	3	6%	
Hypotension	0	-	2	4%	

DISCUSSION

.The mean age, BMI & ASA Grade of patients between both groups were comparable and statistically not significant as per Student t-test (p=0.645) & (p=0.476) & (p=0.358) respectively. The mean duration of surgery was comparable in Group I and Group II (50.77±6.69 mins vs. 51.37±6.25 mins) and statistically not significant as per Student t-test (p=0.685). The time of onset of sensory analgesia (141.97±11.04secs vs. 137.97±12.63secs; p=0.184), time of onset of motor block (284.53±20.92secs vs. 276.33±13.89secs; p=0.242) and total duration of motor block (129.63±17.98mins vs. 131.93±15.07mins; p=0.526) were comparable between Group I and Group II as per Student t-test. These are comparable to the studies of Sowmya N et al[10] Annavarapu VR et al[11], Shasikala TK et al[12] Prabha P et al[13] Venkata HG et al[14] Obara M et al[15] Bogra J et al[16], Choi DH et al[17].

Sowmya N et al[10] comparative study on intrathecal Fentanyl in different doses (10mcg,15mcg) with Hyperbaric Bupivacaine (10mg) for Caesarean Section observed mean HR, SBP and DBP was lower in group B than in Group A. This difference in mean values between two groups was statistically significant.

Annavarapu VR et al[11] study comparing the effect of Fentanyl 25mcg when mixed with 6mg, 7mg, 8mg and 9mg of 0.5% hyperbaric Bupivacaine in spinal anaesthesia for caesarean section observed level of sensory blockade and onset of motor blockade were almost similar in all pregnant women in all groups with average T4 [T3–T6] in all groups.

Bogra J et al[16] study reported that the onset of sensory block to T6 occured faster with increasing Bupivacaine doses in Bupivacaine only groups and Bupivacaine-Fentanyl combination groups.

Choi DH et al[17] study observed that when doses of Bupivacaine increased, the sensory recovery time was also prolonged and they also noticed that addition of Fentanyl further increased the sensory recovery time.

It was observed in our study that the duration of analgesia was significantly shorter in Group I compared to Group II (210.83±22.52 mins vs. 281.17±21.61 mins). The difference was statistically significant as per Student t-test (p=0.002). This is concordant to the studies of Kiran S et al[18].

Kiran S et al[18] study reported that increasing Bupivacaine dose increased the time for two segment sensory regression and also the duration of analgesia Annavarapu VR et al[11] study comparing the effect of Fentanyl 25mcg when mixed with 6mg,7mg,8mg and 9mg of 0.5% hyperbaric Bupivacaine in spinal anaesthesia for caesarean section observed no significant change in oxygen saturation and respiratory rate in any patient.

In our study, the mean duration of post-operative analgesia in Group I was significantly shorter as compared to Group II (265.83±19.29mins vs. 425.97±13.07mins respectively). There was significant difference between groups as per Student t-test (**p=0.001**).

It was observed in the present study that the post-operative VAS score was significantly higher in Group I compared to Group II (6.50±0.73 vs. 4.37±0.67) as per Student t-test (**p=0.001**).

It was observed in our study that the APGAR score was comparable in Group I and Group II (8.40±0.33 vs. 8.51±0.74) and statistically not significant as per Student t-test (p=0.548). This finding was consistent with the studies of Annavarapu VR et al[11].

In the present study, in Group I, 4 (8%) patients had drowsiness while 3 (6%) patients had nausea/vomiting. In Group II, 6 (12%) patients had drowsiness , 3 (6%) had nausea/vomiting and 2 (4%) patients had hypotension. The difference was statistically not significant as per Chi Square test (p=0.325). Similar observations were noted in the studies of Sowmya N et al[10] ,Kiran S et al[18].

Abate SM et al[19] systemic review and meta-analysis assessing the efficacy of low dose bupivacaine with intrathecal fentanyl on maternal and neonatal outcomes reported Incidence of hypotension was less likely in mothers who received low dose bupivacaine with Fentanyl as compared to those with conventional dose of bupivacaine alone. Low dose bupivacaine combined with intrathecal Fentanyl decreased incidence of hypotension.

CONCLUSION

There was faster onset of sensory, motor blockade, and prolonged postoperative analgesia in patients administered with Gp II compared with patients administered with Gp I. Post-operative analgesia was for a longer period in Group II as compared to Gp I. Better haemodynamic stability was observed in Gp I as compared to Gp II. No patient developed bradycardia or hypotension in Gp I while 2 patients in Gp II developed hypotension.

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