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ORIGINAL ARTICLE

A COMPARATIVE STUDY OF HEAMODYNAMIC PARAMETERS IN LSCS WITH INTRATHECAL FENTANYL-BUPIVACAINE COMBINATION AND BUPIVACAINE ALONE

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ABSTRACT: BACKGROUND: Caesarean section is considered as a major abdominal surgery, which requires profound blockade of spinal segments. Spinal anaesthesia is the most elegant approach providing profound anaesthesia and excellent operative conditions. Hypotension, the most clinically significant effect of spinal anaesthesia can occur rapidly and have a significant impact on neonatal outcome. There has been interest in using analgesic additives to local anaesthetics to decrease the dose of local anaesthetics and reduce in incidence of hypotension without compromising intra-operative analgesia, enabling faster motor recovery and providing efficient post-operative analgesia. This study was conducted to compare the incidence of hypotension between intrathecal fentanyl-bupivacaine combinations with bupivacaine alone in patients undergoing elective LSCS. **INTRODUCTION:** In Caesarean section, the surgery is major and profound blockade of many spinal segments is required. Strong visceral stimulation is present, sudden cardiovascular changes is compounded by posture and fetal wellbeing may be influenced by several physiologic variables and drugs. Spinal anaesthesia is perhaps the most efficient and elegant approach to this challenge. With a small needle and little amount of drug, profound anaesthesia and excellent operating conditions can be readily provided for this major intrabdominal surgery. Spinal hypotension, the most clinically significant aspect of spinal anaesthesia can occur rapidly and may have a significant impact on the neonatal outcome. Recently, there has been an interest in using analgesic additives to subarachnoid local anaesthetic dose so as to reduce the incidence and degree of hypotension but at the same time without compromising intraoperative analgesia and also to enable faster recovery and providing efficient post-operative analgesia. Opioids were the first clinically used selective spinal analgesics after the discovery of opioids receptors in the spinal cord. Lipophilic opioids (fentanyl and sufentanil) are increasingly being administered intrathecally as adjuvant to local anaesthetics.[1] They have been shown to enhance the quality of local anaesthetic induced subarachnoid block and to provide postoperative analgesia and also, they reduce the hypotension due to subarachnoid block by reducing the dose of local anaesthetics and decrease the ephedrine requirements to combat hypotension. In our study, we compared the efficacy of intrathecal 25mcg fentanyl and 7.5 mg of hyperbaric bupivacaine 0.5% with that of 10 mg hyperbaric bupivacaine 0.5% alone regarding the incidence of hypotension and ephedrine requirements in lower segment caesarean section during surgery and early post-operative period. **OBJECTIVES:** To evaluate the efficacy of the combination of intrathecal fentanyl 25mcg and 7.5 mg of 0.5% hyperbaric bupivacaine in comparison with 10 mg of 0.5% hyperbaric bupivacaine used alone for lower segment caesarean section with respect to; Incidence of hypotension, Ephedrine

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requirements to combat hypotension, Side effects and complications that may arise with the use of intrathecal fentanyl.

KEYWORDS: Hypotension, MAP, LSCS, Opiod analgesics.

INTRODUCTION: MATERIALS AND METHODS: This study was conducted between august 2015 and September 2015 at ACSR Govt. Medical College, Nellore after getting approval from the ethics committee.

A total of 50 patient who underwent elective caesarean section were taken up for the study.

Inclusion Criteria:

1. Patients belonging to ASA grade I and II posted for elective caesarean surgery.
2. Patients between the age group 20-37 years.
3. Patients weighing between 40 to 65 kgs.
4. Patients belonging to ASA Grade – I and II.

Exclusion Criteria:

1. Patient refusal.
2. Patient having systemic cardiovascular, respiratory, hepatic, renal or central nervous system disorders.
3. Patients with haemorrhagic disorders or patients who are on anticoagulant therapy.
4. Disease and deformities of spinal cord or vertebral column.

The Selection of Patients was carried out randomly: An initial preoperative counseling and reassurance to again confidence of the patient was done. Informed consent was obtained and procedure was explained.

Inj. Ranitidine 50mg. was given intravenously as premedication 45 minutes before surgery and patients were randomized into 2 groups of 25 each.

Group A: Patients received 2.0 ml of 0.5% hyperbaric bupivacaine (10mg).

Group B: Patients received 1.5 ml of 0.5% bupivacaine (7.5mg) with 0.5 ml fentanyl (25 mcg).

The final volume of the injected soluted is 2.0 ml in both groups.

In the assessment room, vital parameters like pulse rate, blood pressure respiratory rate and baseline investigations like haemoglobin, urine analysis for albumin sugar, blood sugar, urea and creatinine and ECG were checked. Through examination of all the systems and airway assessment was done.

Visual Analog Scale (VAS) was explained to the patient. The patients were shown a 10 cm long scale marked 0-10 on a blank paper and told that '0' represented 'no pain' and 10 represented worst possible pain. Patients were advised nil per oral 6 hours before the procedure.

PROCEDURE: Patients were shifted to operating room in left lateral position. A wedge was kept under the right buttock to give a lateral tilt to the uterus. NIBP, pulse oxymeter and ECG were connected to the patient. Base line SBP, DBP, MAP, Pulse rate, Respiratory rate and oxygen

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saturation was recorded. Patients were canulated 18G iv cannula and preloaded with 20 ml per kg RL. Patient was placed in left lateral position. The L3-L4 inter space was identified and 25G Quincke spinal needle was introduced through midline approach. After confirming free flow of CSF the prepared solution was injected. The patients were made to lie supine immediately after injection and left lateral tilt was provided by wedge under right buttock. The following parameters were observed.

VITAL SIGNS AND SIDE EFFECTS: The SBP, DBP MAP, pulse rate, respiratory rate and oxygen saturation were recorded in every minute for the first 10 min and thereafter every 5 min until the immediate post-operative period.

Hypotension was defined as fall in SBP greater than 30% from base line or SBP < 90 mm Hg. This was managed with iv ephedrine in increments of 6mg. Bradycardia was defined as heart rate <60/ min and was planned to be managed with IV atropine 0.6mg. Respiratory depression was said to be present if RR <8/min and Spo2 <85%.

The occurrence of sedation was assessed using a bedside scale.

Sedation scale:

0 – None	Patient alert.
1 – Mild	Occasionally drowsy, easily aroused.
2 – Moderate	Frequently drowsy, easily aroused.
3 – Somnolent	Difficult to arouse.

QUALITY OF SURGICAL ANAESTHESIA:

Excellent – No pain.
Good – Minimal pain or discomfort –relieved by small dose of IV fentanyl.
Poor – if GA has to be administered.

INCIDENCE OF HYPOTENSION: In group A, 21 patients had hypotension whereas in group B, only 9 patients had hypotension. The incidence is 84% with group A against 36% in group B. This was tested to be statistically significant (P<0.001).

MEAN EPHEDRINE REEQUIREMENTS: The mean ephedrine required to counter hypotension was 6mg in group A whereas it was 3mg in group B.

SIDE EFFECTS:

- The incidence of pruritus was 32%. In group B where it was nil with group A.
- 3 patients complained of nausea in group A and one in group B.
- Urinary retention was seen in 3 patients in group B.
- Sedation of grade 1 was seen with 7 patients in group B.

ASSESSMENT OF THE FETUS: The APGAR scores at 1 min and 5 min after delivery of the baby were noted. Significant depression was managed with proper resuscitative measures and by inj. Naloxone 1 – 4 mcg/kg. All the babies showed 1min APGAR of 8 and above and 5 min APGAR of 9 and above in both the groups. The difference was statistically insignificant.

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RESULTS:

HAEMODYNAMIC PARAMETERS:

HR(Beats/min)	Group A	Group B
61 - 70	1	3
71 - 80	5	2
81 - 90	6	9
91 - 100	13	11

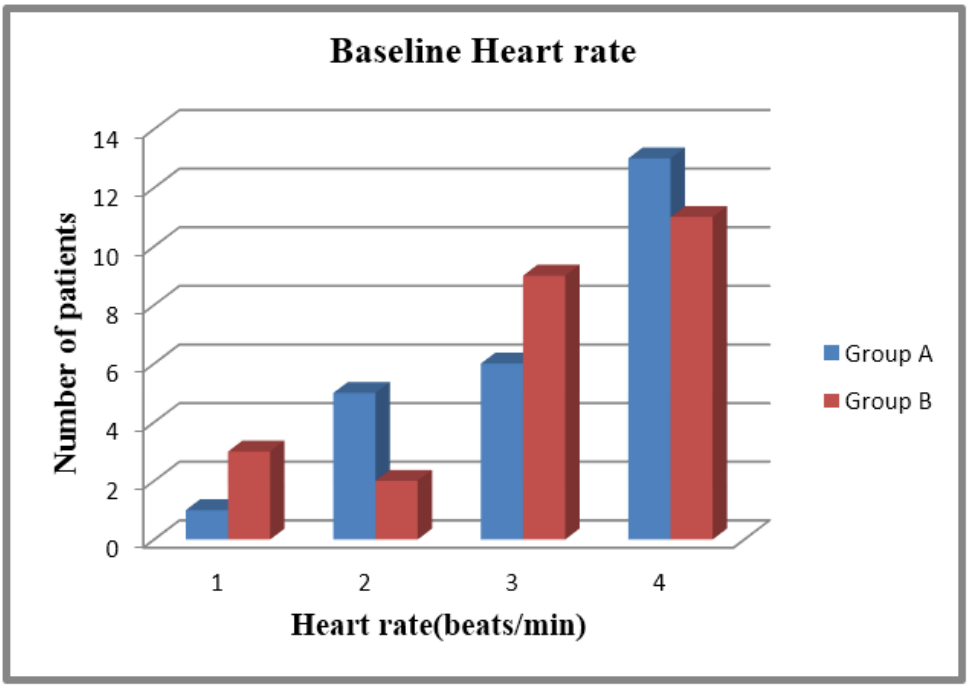
Table 1: Heart Rate (HR)

Baseline heart rate of two groups of patients.
The range was 66-100 in Group A and 66-92 in Group B.

MAP (mm Hg)	Group A	Group B
71-80	3	2
81-90	13	6
91-100	7	13
>100	2	4

Table 2: Mean Arterial Pressure

Baseline Mean Arterial Pressure in two groups of patients.
The range was 76 -113 mmHg in group A and 73 -103 mm Hg in group B.



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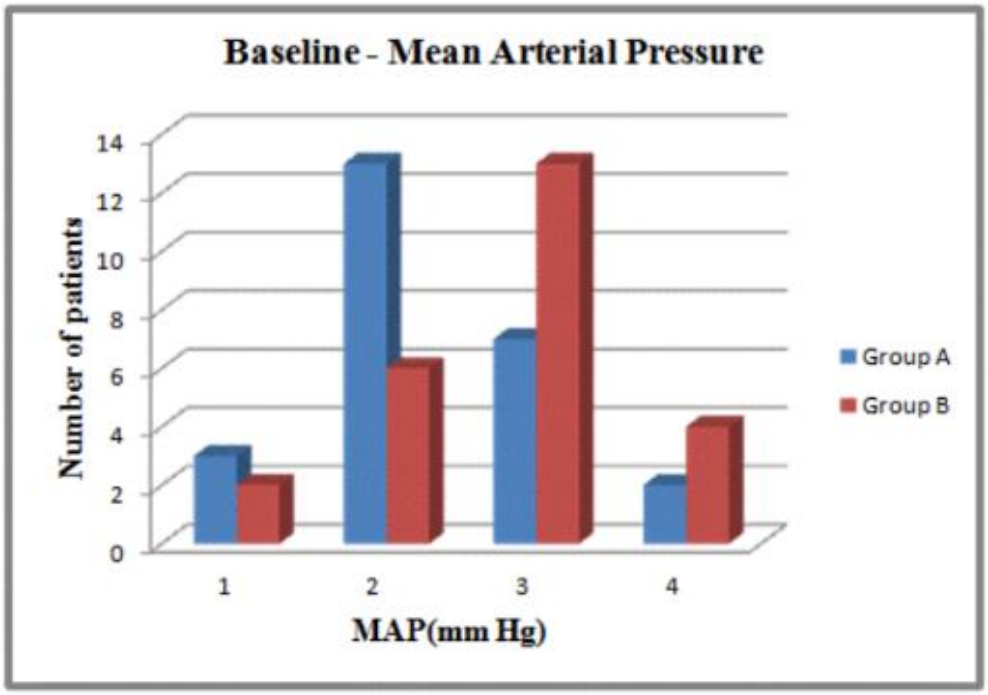

In group A, the lowest MAP was 72.48 mmHg at 10minutes, and the highest was 91.16 mmHg at 0 minutes. In group B, the lowest was 83.06.mmHg at5 minutes, and the highest was 93.06 mmHg at base line

Period	Group A		Group B		p value	Significant
	Mean	S.D.	Mean	S.D.		
Baseline	91.6	7.8	93.06	7.7	0.394	No
5 minutes	76.5	9.2	83.06	11.61	0.032	Yes
10 minutes	72.4	10.7	83.76	14.3	0.002	Yes
15minutes	83.1	7.0	83.84	11.66	0.8002	No
20 minutes	81.5	10.5	93.72	7.6	0.0001	Yes
25minutes	87.3	7.3	93.11	8.2	0.012	Yes
30 minutes	81.0	9.5	93.07	7.2	0.0001	Yes
45 minutes	82.6	11.123	92.68	8.8	0.01	Yes
60 minutes	84.6	7.0	95.18	9.9	0.0001	Yes
90 minutes	82.3	10.0	94.25	8.1	0.0001	Yes
120 minutes	84.8	7.7	95.03	7.6	0.0001	Yes

Table 3: Statistical comparison of MAP (mmHg) in the two groups

The differences are highly significant except at baseline and at 15 minutes.

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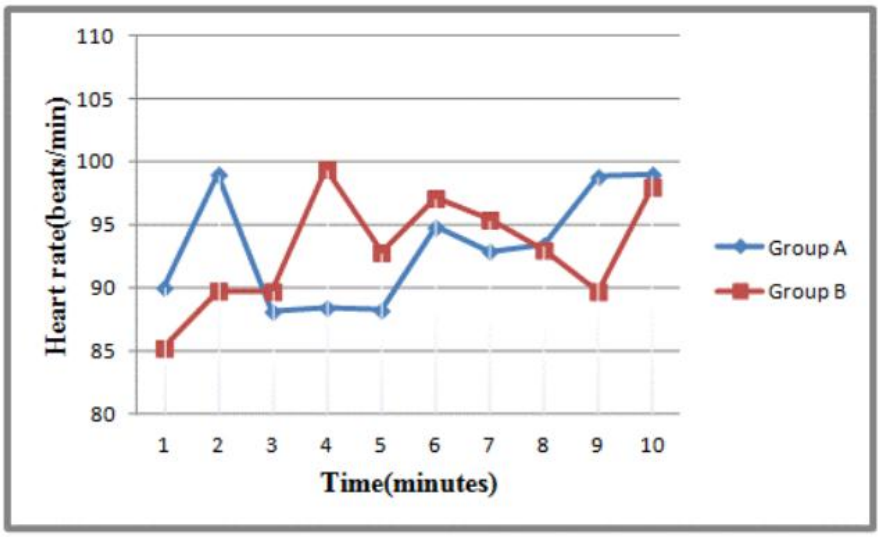
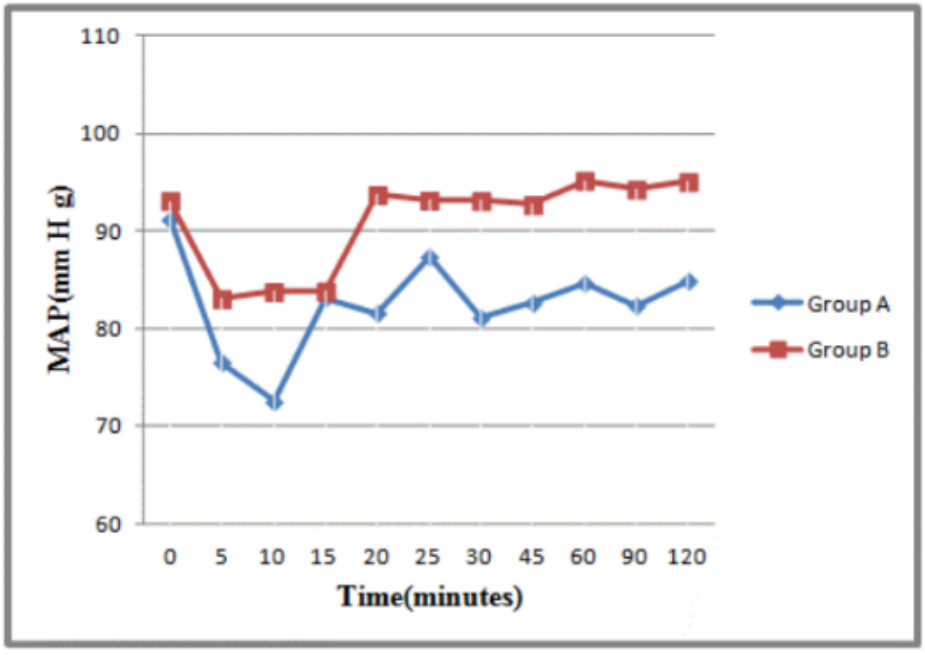


Graph-1: Comparison of Heart Rate between two groups at various time intervals



Graph-2: Comparison of Mean arterial pressure between two groups at various time intervals

DISCUSSION: Synergistic blockade of Aδ and C afferents by fentanyl allowed sub- therapeutic dose of bupivacaine to maintain surgical anaesthesia during regression of spinal anaesthesia in our study.

Our results are consistent with experimental studies done by Tejwani GA et al. and Akerman B et al who have shown that the combination of opioids and local anaesthetics are synergistic for somatic analgesia and that intrathecal opioids markedly enhanced analgesia from sub therapeutic dose of intrathecal local anaesthetics.

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Incidence of Hypotension: In our study, the incidence of hypotension was 84% in group A and 36% in group B. This was statistically significant and could be attributed to the lower dose of bupivacaine used in the group B. Our study confirmed the fact that the decrease in sympathetic efferent activity after spinal anesthesia with bupivacaine was dose related and that intrathecal fentanyl caused neither by itself nor in combination with bupivacaine, any further depression of efferent sympathetic activity.

This correlated with the study of Ben David et al.[1] who showed that a minidose of 4mg bupivacaine and 20µg fentanyl given intrathecally dramatically lowered the incidence of hypotension and nearly eliminated the need for vasopressors.

Another study by Ben David B et al.[2] confirms that 25µg fentanyl in combination with 5 mg isobaric bupivacaine caused less incidence of hypotension (31%) when compared to 10mg isobaric bupivacaine (94%) in spinal anesthesia for caesarean section.

In the study done by Grant GJ et al., it was confirmed that intrathecal administration of 25µg fentanyl did not produce clinically important maternal haemodynamic changes in non-laboring term parturients.

Kang FC et al.,[3] in their study on spinal anaesthesia for caesarean delivery revealed that the combination of small dose bupivacaine 5mg and fentanyl 25µg provided more stable hemodynamic status when compared to 8mg hyberbaric bupivacaine used alone.

Mean Ephedrine Requirements: The mean ephedrine requirements were 6mg with group A and 3 mg in group B. This is highly significant.

Ben David B et al.[2] confirms that the mean ephedrine requirements were 23.8mg with the combination of 5mg isobaric bupivacaine and 25µg fentanyl but it was 2.8mg with 10mg bupivacaine when used intrathecally for caesarean section.

Kangas Saarala et al.[4] has concluded that small doses of ephedrine given to correct maternal hypotension under spinal anaesthesia have only short lived effect on the fetal central nervous system.

Side Effects: Pruritus occurred in 8 patients in group B, its incidence being 32%.It was mild and occurred most commonly in the face.

Our study correlated with the view of Hamber EA and Viscomi CM that pruritus being a common complication with intrathecal fentanyl.

Kuusniemi KS et al.[5] reported pruritus as the most common adverse effect occurring in 22.5 % of the patients receiving intrathecal fentanyl with bupivacaine which correlated with our study.

In our study, 3 patients in group A complained of nausea intraoperatively. This could be attributed to the discomfort these patients felt intraoperatively for which supplementation of analgesia was given.

The occurrence of excellent surgical anaesthesia in patients receiving fentanyl could be the cause for absence of nausea in group B. This correlates with the study conducted by Manullang TR et al.[6] which concludes that intrathecal fentanyl as a part of spinal anesthetic for caesarean delivery was superior to intravenous ondansetron for preventing intraoperative nausea.

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Sedation of grade I was seen in 7 patients in group B. Patients were easily arousable and this could be attributed to the addition of fentanyl.

Urinary retention upto 6 hours was noticed in 3 patients in group B. It is thought to be caused by an increase in the urethral sphincter tone and a decrease in detrusor tone. 2 patients were managed conservatively and they passed urine. One patient required catheterisation.

A single dose of intrathecal fentanyl does not migrate to the medullary respiratory center in sufficient concentration to cause respiratory depression. Consistent with this observation, respiratory depression did not occur in our study Bradycardia did not occur in either of the groups in our study.

Assessment of the fetus: The APGAR scores at 1 minute and 5 minutes were comparable in both the groups and was statistically insignificant. This proves that intrathecal fentanyl 25µg as an adjuvant to hyperbaric bupivacaine does not adversely affect the neonatal outcome.

SUMMARY: This study was designed to compare the efficacy of the combination of 25mcg of fentanyl and 7.5mcg of hyperbaric bupavacaine 0.5% with that of 10mg of hyperbaric bupavacaine 0.5% alone intrathecally for lower segment caesarean section. The observation is:

1. The incidence of hypotention was significantly reduced by fentayl – bupavacaie combination.
2. The fentanyl – bupavacaine combination significantly reduced the ephedrine requirements to treat hypotention.
3. The incidence of side effects was limited to mild pruritus and grade-1 sedation in the fentanyl added group.
4. Intrathecal fentanyl has no effect on neonatal outcome.

CONCLUSION: This study confirms that the combination of intrathecal fentanyl 25mcg with 7.5mg hyperbaric bupavacaie 0.5% reduces the incidence of hypotension and ephedrine requirements and minimal side effects when compared to 10mg hyperbaric bupavacaie 0.5% alone in lower segment caesarean section without significant effects on the neonatal outcome.

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