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Original Research Article

A Study to Compare the Analgesic Effects of two Different Doses of Fentanyl as an Adjuvant to 0.5% Hyperbaric Bupivacaine in Lower Segment Caesarean Surgeries under Spinal Anaesthesia

Ankita Jain[1], Leelawati Siyag[2], Rajendra Prasad[3], Manish khandelwal[4], Nidhi Khandelwal[5]

[1]Consultant, Anaesthesiology, SPS hospital, Sirsa
[2]Assistant Professor, Anaesthesiology, Govt. Medical College, Sri Ganganagar
[3]Assistant Professor, Anaesthesiology, Govt. Medical College, Sri Ganganagar
[4]Professor, Anaesthesiology, RUHS College of Medical Sciences, Jaipur
[5]Senior lecturer, Biochemistry, Rajasthan Dental College, Jaipur

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Corresponding Author: Manish Khandelwal
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Abstract:

Background: Postoperative pain is a well-known morbidity and is the most distressing complication of surgery. Effective management of postoperative pain relievers suffering and leads to earlier mobilization; reduced cost of care and increased patient satisfaction. The present clinical study includes the study of intrathecal administration of Bupivacaine(10mg) with different doses of Fentanyl 10ug and 15ug in respect to time of onset of sensory and motor blockade up to maximal possible level, duration of sensory and motor blockade, time to 1st dose of required analgesic, cardiovascular effects and any side effects due to varying doses of Fentanyl.

Material and Methods: The study was confined to hundred patients including parturients of 20-40 years of age and undergoing LSCS. The patients were divided in the two groups - Group A and Group B. Patients of group A received 10mg Bupivacaine and 10ug of Fentanyl & group B received 10mg Bupivacaine and 15ug of Fentanyl. A standard technique of subarachnoid blockade was used.

Result: The demographic variables like age, sex, weight and ASA physical state were similar in both groups. The mean onset of sensory and motor block was non-significant ($p > 0.05$) in both groups. The mean time to two segment regression in Group A was 128.44 ± 6 (min) and in Group B was 163.98 ± 17.22 (min). The p- value was < 0.001 between the groups (statistically highly significant). The mean duration of motor block in Group A was 109.0 ± 6.25 min and in Group B was 143.90 ± 16.71 min. The p- value was < 0.001 between the groups (statistically highly significant).

Conclusion: Our study shows a dose-dependent prolongation of duration of sensory and motor blockade and time to 1st dose of rescue analgesic by intrathecal fentanyl in dose range of 10 - 15ug with hyperbaric bupivacaine. The duration of effective and postoperative analgesia was significantly more with increased dose of fentanyl.

Keywords: Postoperative Pain, Bupivacaine, Fentanyl.

Introduction

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." [1]

Post-operative pain is a major source of fear and anxiety. Pain is frequently the result of nociception; an activity in the nervous system that results from the stimulation of nociceptors. [2] Severe postoperative pain is a well-known morbidity and is the most distressing complication of surgery. Effective management of postoperative pain relievers suffering and leads to earlier mobilization; fewer pulmonary and cardiac complications; a reduced risk of deep vein thrombosis; faster recovery with less likelihood of the development of neuropathic pain; reduced cost of care and increased patient satisfaction. [3]

Post operative pain management remains a challenge despite recent advances of new opioid and non-opioid analgesics, novel methods of drug delivery (systemic, regional and local) and more widespread use of pain reducing minimally invasive surgical techniques [4,5].

Intravenous opioids are commonly used for moderate to severe postoperative pain. [6] Neuraxial and peripheral techniques can provide superior analgesia compared to systemic drugs. Spinal anaesthesia is the anaesthesia of choice and is the

gold standard for lower abdominal and lower limb surgeries. [7]

It can also be administered safely in many patients with systemic diseases where general anaesthesia and endotracheal intubation can be hazardous like sensitive airway diseases, hepatic and renal diseases, endocrine disorders, old age and cardiac patients etc. [8]

Bupivacaine, an amide type of local anaesthetic, has high potency, slow onset and long duration of action is commonly employed for spinal anesthesia. [9] Intrathecal opioids are synergistic with local anaesthetics and intensify the sensory block without increasing the sympathetic block while achieving satisfactory quality of spinal anaesthesia at a much lower dose of local anaesthetic.

Bupivacaine has become increasingly popular for spinal anesthesia using a hyperbaric solution. It may be used for any nerve block. Fentanyl is a tertiary amine, a phenylpiperidine derivative and synthetic opioid agonist with analgesic and anaesthetic properties. [10]

This study is designed to compare analgesic effects of different doses of fentanyl (10 ug vs 15 ug) as an adjuvant to 0.5% heavy bupivacaine for onset and duration of sensory and motor block, duration of analgesia, sedation and to evaluate the side effects, if any.

Material and Methods

The study was conducted in S.M.S. Medical College and Attached group of hospitals, Jaipur with Due permission from institution ethics committee (Ethics Committee No.236/MC/EC/2020) The required size is 50 in each group at 95% confidence interval and 80% power to verify the expected minimum difference of 17.3% of cases who had developed pain score≥3 in both groups in postoperative period.100 patients satisfying inclusion criteria were selected using simple random technique by sealed enveloped method.

The study was conducted in the following 2 groups of 50 patients each.

Group A: 50 Patients received injection fentanyl, 0.2 ml (10 mcg) and 0.3 ml normal saline with injection hyperbaric bupivacaine 0.5%, 2ml (10 mg) intrathecally, therefore total volume - 2.5 ml.

Group B: 50 Patients received injection fentanyl,0.3 ml (15 mcg) and 0.2 ml normal saline with injection hyperbaric bupivacaine 0.5%, 2 ml (10 mg) intrathecally, therefore total volume - 2.5 ml. Parturients of more than 37 weeks gestation aged 20-40 yrs, belonging to ASA class 1 or 2 were included in the study.

Patients refusing regional anaesthesia, contraindications to spinal anaesthesia**,** Body wt over 100 kg, shorter than 145 cm and taller than 175 cm were excluded. History of hypersensitive reactions to local anaesthetics, medical complications such as anemia, heart disease, severe hypovolemia, shock, septicemia, and sever hypertension, patients with neurological and psychiatric disorders were excluded from the study.

Procedure

After taking informed written consent and confirming overnight fasting, patient taken on the operation table, standard monitors applied and baseline vitals like BP, pulse rate, SPO_2, respiratory rate recorded. After IV canula insertion lactated Ringer's solution was administered as a bolus of 10 ml/kg before subarachnoid block to all patients.

Spinal anaesthesia was performed at L3-L4 interspace with the patient in left lateral position by using a 25 Gauge Quincke's needle under strict aseptic conditions. Free flow of cerebrospinal fluid verified before injection of the anaesthetic solution 2.5 ml volume, which was administered over 30 seconds. The direction of the needle aperture was cranial during the injection. All patients were immediately placed in a supine position with a 15 head down tilt immediately after spinal injection to achieve level of block at T5-T6. Vitals were checked every 5 minutes for first 30 minutes then every 10 minutes till surgery and then every 30 minutes for 4 hours postoperatively.

Hypotension was defined as a systolic arterial blood pressure (SABP) < 90 mm of Hg or a drop in SABP below 80% of baseline values, not responding to additional fluid of 300 ml, was treated by incremental doses of mephentermine 6 mg IV. Bradycardia was defined as fall in heart rate below 50 beats per minute and was treated with incremental doses of atropine 0.3 – 0.6 mg IV. Respiratory depression was defined as a respiratory rate less than 8 breaths per minute and/or oxygen saturation less than 90% in room air.

The onset of sensory block was defined as the time from the intrathecal injection of the study drug to the time taken to achieve T5-T6 level of sensory block. This was assessed every 2 minutes by cold gauze bilaterally in the midclavicular line. The highest level of the block and the time to achieve the same was also noted. Onset of motor block was defined as the time from intrathecal injection of the study drug to the time taken to achieve complete motor block (grade-3) by using Bromage scale. Duration of motor block was assessed by recording the time elapsed from the maximum to the lowest Bromage score (3-0).

Total duration of analgesia was taken from intrathecal drug administration to patient's first demand of rescue analgesia (On VAS 3). The pain was assessed by using visual analogue pain scale

(VAS) between 0 and 10 (0 = no pain, 10 = most severe pain). It was assessed at every 30 min.

Patients were allowed to receive rescue analgesics on VAS score of 3 or more. Intravenous Diclofenac 3mg/kg was given as rescue analgesic. This time from intrathecal injection to first administration of rescue analgesic (total duration of analgesia) was noted. This was the end point of our study. Patient was monitored for 12 hours for any adverse effects. The incidence of adverse effects such as nausea, vomiting, shivering, respiratory depression, and hypotension were recorded. End point of study was noted as motor and sensory block recovered completely.

Statistical Analysis: Statistical analysis was performed with the SPSS, version 23.0 for Windows statistical software package (SPSS Inc., Chicago, USA). Categorical data i.e. duration of surgery and the incidence of adverse events are presented as numbers (percentage) and analyzed with Chi-Square test. Groups are compared for demographic data (age, weight), duration of surgery, time for two segment regressions, VAS score, total duration of sensory and motor block and duration of analgesia by analysis of variance (ANOVA) and pair-wise analysis by paired t-test. Probability was considered to be significant if less than 0.05. Data is represented as mean and standard deviation. ($p< 0.05$ = significant, $p < 0.001$ = highly significant.)

Observation and Results

Demographic Variables

Table 1

Demographic Variables	Group A Mean ± SD	Group B Mean ± SD	Result (p value)
Age	23.70±1.73	24.42±2.14	0.067 (NS)
Weight (Kg)	65.60±2.20	65.60±2.71	0.159

S = Significant; NS = Non Significant

The demographic variables like age, sex, weight and ASA physical state were similiar in both groups.

The mean onset of sensory block for Group A was 82.68 ± 13.86 (sec) and for Group B was 79.58 ± 11.42 (sec) The mean onset of motor block for Group A was 209.70 ± 30.94 (sec) and for Group B was 204.20 ± 28.29 (sec) and the difference was found to be non-significant ($p > 0.05$).

Table 2: Mean time to two segment regression and Duration of Motor block

	Group A		Group B		Result
	Mean	SD	Mean	SD	(p value)
Duration of Sensory Block(minutes)	128.44	6.00	163.98	17.22	p<0.001 (S)
Duration of Motor Block(minutes)	109.00	6.25	143.90	16.71	p<0.001 (S)

S = Significant; NS = non-significant

Table 2 shows the mean duration of sensory block in the groups. The mean time to two segment regression in Group A was 128.44 ± 6 (min) and in Group B was 163.98 ± 17.22 (min). The p- value was < 0.001 between the groups (statistically highly significant).

The mean duration of motor block in Group A was 109.0 ± 6.25 min and in Group B was 143.90 ± 16.71 min. The p- value was < 0.001 between the groups (statistically highly significant).

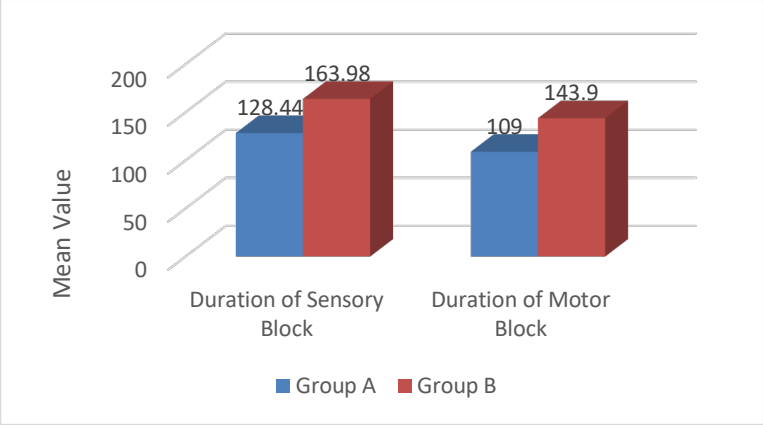

Figure 1: Mean time to two segment regression and Duration of Motor Block

The mean duration of analgesia in Group A was 170.28 ± 11.26 (min) and in Group B was 273.90 ± 29.12 (min) that was found to be statistically highly significant between the groups(p<0.001).

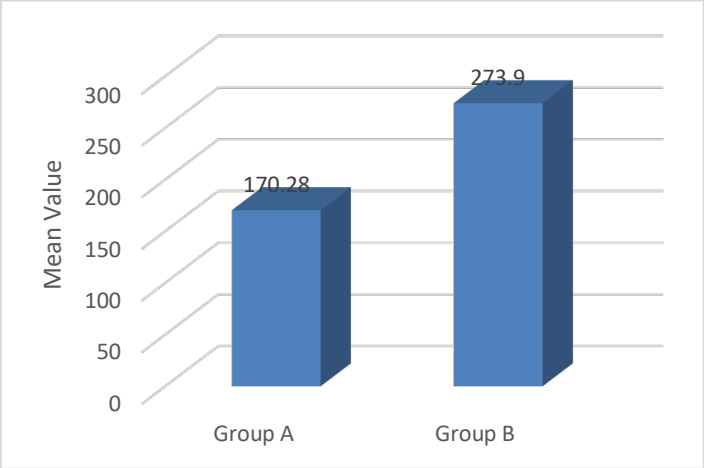

Figure 2: Mean duration of analgesia in each group.

Baseline clinical variable (HR, SBP, DBP, MAP, SpO2) were comparable between both groups (p value > 0.05).

Table 3: Comparison of post operative VAS Score among study groups (Mean ± SD)

	Group A		Group B		Result
	Mean	SD	Mean	SD	(p value)
30 min	0.00	0.00	0.00	0.00	-
60 min	0.00	0.00	0.00	0.00	-
90 min	0.00	0.00	0.00	0.00	-
120 min	0.10	0.42	0.00	0.00	-
150 min	0.82	0.85	0.22	0.46	p<0.001 (S)
180 min	2.54	0.61	1.30	0.68	p<0.001 (S)
210 min	3.60	0.67	1.98	0.77	p<0.001 (S)
240 min	3.13	0.68	3.12	0.75	0.958 (NS)
480 min	-	-	3.67	0.48	-

S = Significant; NS = Non-Significant

Table 3 shows comparison of mean VAS between the groups which is statistically significant at 4 and 5 hours (p <0.0001)

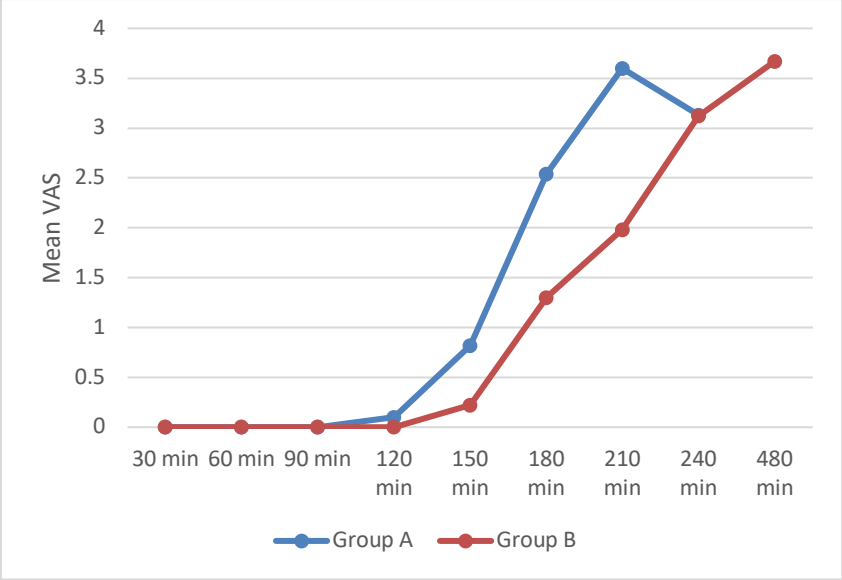

Figure 3: Comparison of mean VAS between the groups

comparison of APGAR score between two groups at 1 and 5 minutes. Difference is statistically non-significant between APGAR scores (p value- 0.905 and 0.302).

Discussion

Spinal anesthesia has many potential advantages over general anesthesia, especially for operations involving the lower abdomen, the perineum and the lower extremities. [3,6].

Good analgesic techniques minimize patient discomfort, facilitates early mobilization and discharge from hospital. Various drugs like opioids have been used in multimodal approaches to achieve adequate postoperative analgesia. Intrathecal opioids cause segmental analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. They prolong the duration of analgesia without affecting motor or autonomic nervous function.

Fentanyl is a highly selective μ receptor agonist, which is mainly responsible for its analgesic properties. With above background present study was conducted to compare anaesthetic effects of intrathecal hyperbaric bupivacaine with two different doses of fentanyl (10microgm and 15 microgm) in LSCS.

Perioperative hemodynamic variables, duration of postoperative analgesia and any adverse effects were observed in both the groups at different time interval. Demographic variables including Age, weight and ASA distribution were similar in both groups. The baseline Pulse, B.P. were statistically insignificant. In the present study the difference in the time of onset of sensory blockade in the group A & B was not significant, showing that decreasing the dose of fentanyl from 15ug to 10ug causes no effect on onset of sensory analgesia.

Results of our study coincides with the study of M Ali et al [11]. They found that there was no statically significant difference in mean time for onset of sensory block in patients of both groups. The onset of motor block was earlier in group B as compared to group A, which was statistically significant (p value < 0.001).

The duration of sensory block as calculated by the time to two segment regression in our study which was longer in group A compared to group B. The differences among the groups were found to be statistically highly significant (p<0.001). M Ali et al [11] concluded that the meantime duration of sensory block was longer in Fentanyl 15 microgm group compared to (128.4 ± 6 min) in Fentanyl 10 microgm group which was significant with P value < 0.001. Chu CC [12] also found that the duration of senorsy analgesia was clinically and statistically significantly more in fentanyl group compared to bupivacaine groups. Rajbhandari D.et al [10], also found that the duration of sensory block was more in fentanyl 20 microgm group compared to fentanyl 10 microgm group respectively.

Thus, our result correlates with the above-mentioned study in terms of onset time of motor block and duration of sensory block. The mechanism responsible for this increased duration of sensory block in fentanyl added groups might be the synergistic inhibitory action of local anaesthetic bupivacaine and opioid fentanyl on conduction of impulse through A- gamma and C - fibre.

With regard to duration of motor block was longer in group B compared to group A. The differences among the groups were found to be statistically highly significant (p < 0.001) which were similar with the studies done by M Ali et al [11] and Chu CC [12] Addition of fentanyl (opioid) to hyperbaric

bupivacaine prolongs the duration of sensory as well as motor block.

The mean duration of analgesia was 170.28 ± 11.26 minutes in group A and in group B was 273.90 ± 29.12 minutes. P value was <0.001, so difference was significant between the groups.

First dose of rescue analgesia between the groups was longer in group B compared to group A. The differences among the groups were found to be statistically highly significant (p<0.001). Chu CC et al [12] found that the duration of first rescue of analgesia was significantly delayed in fentanyl 12.5 & 15 ug (BC60 group). Jain K et al also found that time for first dose of rescue analgesic was delayed in fentanyl group 20ug with bupivacaine 12.5mg in comparison to bupivacaine alone 12.5mg which was statistically significant (P < 0.001).C M Palmer et al concluded that the duration of analgesia was significantly increased in fentanyl dose 25 microgm or more as compared to bupivacaine alone group with p value < 0.05. Our result correlates with the above-mentioned studies. In this study difference in VAS score was significant between two groups from 150-210 minutes. (p value<0.001) Mean VAS score was lower in group A as compared to group B.

In this study, there was no significant difference with respect to shivering, respiratory depression, nausea and vomiting in both groups.

No significant difference was found in APGAR score at 1 and 5 minutes after birth in neonates in both the groups.

Conclusion

Our study shows a dose-dependent prolongation of duration of sensory and motor blockade and time to 1st dose of rescue analgesic by intrathecal fentanyl in dose range of 10 - 15ug with hyperbaric bupivacaine. The duration of effective and postoperative analgesia was significantly more with increased dose of fentanyl. We conclude that, within the test dose range, 15ug is the preferred dose, in terms of effect versus side effects, for LSCS surgeries under spinal anaesthesia where the prolonged duration of post operative analgesia is desired.

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