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A COMPARATIVE STUDY OF INTRATHECAL 0.5% BUPIVACAINE WITH NORMAL SALINE AND 0.5% BUPIVACAINE WITH FENTANYL IN CESAREAN SECTION FOR POSTOPERATIVE ANALGESIA

Mani Kumari Karuturi[1], Manju Sravani Marni[1], Sri Jyotsna Anaparthy[2], Vijaya Lakshmi Gattu[3]

[1]*Assistant Professor, Department of Anesthesia, GSL Medical College & General Hospital, Rajahmundry, India.*
[2]*Assistant Professor, Department of Obstetrics & Gynecology, GSL Medical College & General Hospital, Rajahmundry, India.*
[3]*Professor, Department of Anesthesia, GSL Medical College & General Hospital, Rajahmundry, India.*

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Corresponding Author:
Dr. Manju Sravani Marni,
Assistant Professor, Anesthesia, GSL Medical College & General Hospital, Rajahmundry, India.
Email: manjusravanim@gmail.com

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ABSTRACT

Background: The subarachnoid block was the dominant form of neuraxial anesthesia in the 20th century. The ensuing anesthesia is predictable, occurs rapidly, and is associated with profound muscle relaxation. The addition of opiates like the lipophilic opioid fentanyl to local anesthetics varies many of its clinical effects after intrathecal administration.

Materials and Methods: The study was designed to compare the efficacy of intrathecal fentanyl along with bupivacaine and bupivacaine alone and their effect on prolonging the duration of postoperative analgesia in lower segment cesarean section without any adverse effects on the fetus, determined clinically by apgar scoring. Patients were randomly divided into two groups i.e., group FB and group B consisting of 25 patients each. GROUP Patients in group FB were given 8.5mg of Bupivacaine plus 25µg (0.5ml) of Fentanyl. GROUP B- Received 8.5mg of Bupivacaine plus 0.5ml of normal saline to adjust the final volume to 2.2ml. The demographic and pre-anesthetic hemodynamic data were comparable in both groups.

Results: In our study, all patients in the two groups were comparable concerning age, height, weight, gestational age, and ASA status. In both the groups, the mean onset of sensory block occurred between 2 minutes and 3 minutes in most of the patients (76%) and the maximum level of sensory blockade at T4 is achieved in 5 to 7 minutes. This observation shows that the addition of fentanyl to Bupivacaine does not influence Bupivacaine's sensory block. In this study, we also did not observe respiratory depression. In our research shivering was not seen in the Fentanyl group but 12% of patients in the Bupivacaine group had shivering. In the Bupivacaine group, two patients had hypotension and one patient had bradycardia. Other complications with intrathecal Fentanyl in group FB were bradycardia (12%) and nausea (12%) but none of the patients had vomiting, and two patients had hypotension. In our study, the mean duration of 2 segment regression time in Group FB was 100 minutes, and in Group B was 94.8 minutes. There was no difference in the duration of 2 segment regression in both the groups.

Conclusion: In conclusion, Fentanyl 25µg does not enhance the onset and duration of sensory block produced by 8.5mg of hyperbaric intrathecal Bupivacaine. Fentanyl, however, prolongs postoperative analgesia and lowers the incidence of shivering. The incidence of pruritus is high, but it is usually mild. Fentanyl 25µg along with 8.5 mg Bupivacaine is very much safer than other opioids like morphine which has more postoperative complications like intense, intermittent respiratory depression.

Keywords: Bupivacaine, Cesarean Deliveries, Fentanyl, Postoperative analgesia, Spinal Anesthesia.

INTRODUCTION

The subarachnoid block is the regional anesthesia obtained by blocking the spinal nerves in the subarachnoid space. The anesthetic agents deposited in the subarachnoid space act on the spinal nerve roots. The subarachnoid block was the dominant form of neuraxial anesthesia in the 20th century. The ensuing anesthesia is predictable, occurs rapidly, and is associated with profound muscle relaxation. Subarachnoid block produces intense sensory & motor blockade as well as sympathetic blockade. The technique benefits surgery involving the lower extremities, pelvis, perineum, and lower abdomen. The addition of opiates like the lipophilic opioid fentanyl to local anesthetics varies many of its clinical effects after intrathecal administration. In the intraoperative period, it enhances surgical anesthesia and prolongs the duration of anesthesia in the postoperative period.

Bupivacaine was synthesized in 1957 by Ekenstam and his colleagues and is marketed as Marcaine. The first reports of its use were made in 1963. Like other local anesthetics it is a weak base and so crosses the placenta, but the foetal-maternal ratio is very low: 0.3. The base is sparingly soluble but the hydrochloride is readily soluble in water. Bupivacaine is highly stable and can withstand repeated autoclaving. Bupivacaine is approximately 3-4 times more potent than lidocaine or mepivacaine and eight times more than procaine.

Bupivacaine is one of the longest-acting local anesthetics known (3-5 hrs). It has a high degree of lipid solubility. Bupivacaine shows differential blocking properties which allows effective analgesia with minimal motor blockade. The absorption of local anesthetic depends on the site of deposition, the dose administered and the type of drug used. Site of deposition – An increased vascularity at the site of injection enhances systemic absorption of local anesthetic.

The dose–plasma levels are related to the dose of local anesthetic in a linear fashion, independent of the site of administration. Agent factors - These also influence plasma levels. Bupivacaine has a pronounced intrinsic vasodilator property that helps to enhance vascular absorption. In general, the distribution of a local anesthetic agent shows an α phase which is the distribution to tissues of high vascular perfusion and accounts for the initial rapid disappearance. Next, the slower disappearance from blood is due to further transfer to poorly perfused tissues i.e. the ß phase and ultimately the metabolic and excretion (γ) phase. The pharmacokinetic behavior of Bupivacaine can be understood by reviewing the various half-lives for each of the above processes. Bupivacaine is presently marketed as a racemic mixture of stereoisomers. Its R-isomer has significantly more cardiovascular toxicity with no increase in local anesthetic potency and therefore accounts for the cardiovascular toxicity of Bupivacaine.

Bupivacaine toxicity is primarily manifested as derangement of the central nervous system and cardiovascular system, generally, significantly lower doses and blood levels of local anesthetic are required to produce central nervous system toxicity compared to those needed to disrupt the cardiovascular system. So mostly the toxic reactions involve the central nervous system.

Opioids placed in the epidural space may undergo uptake into epidural fat, systemic absorption, or diffusion across the dura into the cerebrospinal fluid.[26] Epidural administration of opioids produces considerable cerebrospinal fluid concentration of the drug.

Penetration of the dura is influenced by lipid solubility, but molecular weight may also be important. Fentanyl and Sufentanil are, respectively, approximately 800 and 1600 times as lipid-soluble as morphine. After epidural administration, cerebrospinal fluid concentration of Fentanyl peaks in about 20 minutes in contrast to 1 to 4 hours of morphine.

Fentanyl is a synthetic opioid that is related to the phenylpiperidines. Fentanyl was first synthesized in 1960, and as an analgesic, 75 to 125 times more potent than morphine. It is primarily a Mu receptor agonist. The greater lipid solubility of Fentanyl is responsible for its rapid onset and shorter duration of action compared with that of morphine, which facilitates its passage across the blood-brain barrier likewise, the shorter duration of action of a single dose of Fentanyl reflects its rapid redistribution to inactive tissue sites, such as fat and skeletal muscles.[41] Activation of μ - opioid receptors in the brain and spinal cord produces analgesia, sedation, sleep, suppression of cough, and obtundation of somatic autonomic and endocrine responses to noxious stimulation. High doses of opioid agonists produce unconsciousness and anesthesia. Opioids do not possess amnesia properties. Fentanyl modestly decreases the cerebral blood flow (CBF) and cerebral metabolic rate (CMR). Opioids may possess direct vasodilatory properties. This action may increase intracranial pressure in head trauma. Advantages include intense analgesia, no sympathetic blockade, no motor blockade, and prolonged pain relief.

MATERIALS AND METHODS

The study protocol was approved by the committee of G.S.L Medical College and General Hospital of NTR University of Health Sciences. A written, informed consent was obtained from all the patients.

Inclusion Criteria: ASA physical status I scheduled for elective lower segment cesarean section.

Exclusion Criteria: Patients with deformities of the spinal column, mental disturbance, and neurological disease were excluded from the study.

A clinical study was undertaken using spinal analgesia as an anesthetic technique, to study the clinical effects of intrathecally administered preservative-free Fentanyl along with hyperbaric Bupivacaine.

A visual analog scale (VAS) constituting of 100mm line with 0=no pain, and 10=severe possible pain was explained to all patients in their preoperative checkup.

Detailed history and a complete preoperative examination were made to exclude patients with any systemic disorders especially neurological disease and bleeding diathesis.

All patients were subjected to routine investigations such as urine analysis, complete blood picture, blood sugar, blood urea, and blood grouping, and Rh typing was obtained.

Patients were randomly divided into two groups i.e., group FB and group B consisting of 25 patients each.

GROUP FB- Patients in group FB were given 8.5mg of Bupivacaine plus 25µg (0.5ml) of Fentanyl.

GROUP B- Received 8.5mg of Bupivacaine plus 0.5 ml of normal saline to adjust the final volume to 2.2 ml.

The demographic and pre-anesthetic hemodynamic data were comparable in both groups.

Preparation of the operating room: Boyles's anesthesia machine was checked. Appropriate-sized endotracheal tubes, working laryngoscope with medium and large size blades, stylet, and working suction apparatus were kept ready before the procedure. Emergency drug trays consisting of atropine, adrenaline, mephenteramine, ephedrine, and dopamine were kept ready.

Procedure: Premedication, especially with analgesics was avoided as this might influence and modify the hemodynamic changes produced. Preoperatively, the heart rate and blood pressure of the patient were recorded and an intravenous line was established with a large bore intravenous cannula in a large peripheral vein. Pre-loading with intravenous fluids with a dose of 15ml/kg of crystalloid solution (ringer lactate) infused over 20-30 minutes.

Monitoring: Intraoperatively heart rate, blood pressure, respiration, and oxygen saturation levels of the patients were monitored at frequent intervals. Sterility was given vital importance since infection introduced from outside is a dangerous avoidable complication.

After thorough scrubbing, a sterile gown and gloves are worn. The necessary equipment, which includes towels, cotton swabs, swab holding forceps, skin cleaning solutions and syringes that were sterile packed were used. The patient's back was cleaned widely using surgical spirit and draped with sterile towels. The operating table was adjusted to a horizontal position. The patient was placed in the lateral decubitus position with the shoulders and anterior superior iliac spine in a straight line. With the back parallel to the edge of the operating table nearest to the anaesthesiologist, with thighs flexed on the abdomen and neck flexed. Lumbar puncture was done using a midline approach at L3-L4 space using a 23 gauge disposable Quickie needle which tends to split the dural fibers rather than cut them when introduced with the bevel parallel to dural fibers. This was done to decrease the incidence of postspinal headaches due to cerebrospinal fluid leak. After lumbar puncture was performed and subarachnoid space entered a free flow of cerebrospinal fluid was obtained and the drug, either 8.5mg Bupivacaine and 25µg Fentanyl or 8.5mg Bupivacaine with 0.5ml normal saline was instilled and the time recorded. Then the patient was immediately turned into a supine position for the rest of the study. Then crystalloids (ringer lactate) were infused 8ml/kg for over 30 minutes. Later fluids were administered on the basis of changes in arterial pressure. All the patients received 100 percent oxygen via face mask till the baby was delivered.

The following parameters were recorded

1. For the first 45 minutes during and after the spinal injection systolic, diastolic arterial pressures, heart rate, SpO2, and respiratory rate were recorded every 5 minutes.
2. Level of sensory block, defined as loss of sharp sensation to pinprick, was recorded bilaterally at the midclavicular line every 30 seconds until sensory analgesia was established at T10 level, then every one minute until maximum level had stabilized for 3 consecutive tests, testing was conducted every 15 minutes until 2 segmental regression occurred.
3. Duration of 2 segment regression.
4. Duration of Post-Operative analgesia was measured as the time between the administration of local anesthetic and opioid intrathecally and the first request for supplemental analgesia. 100mm visual analog scale was made use of. A score of 40 on the scale was taken as the end point of analgesia provided by the intrathecal administration of local anesthetic and opioids.
5. Any complications were noted – A decrease in systolic arterial pressure of more than 30 percent or more below preoperative levels as well as a decrease in heart rate of more than 20 percent were considered significant and treated with 3mg ephedrine and 0.6mg atropine sulfate respectively. A respiratory rate of less than 10 per minute and SpO2 of less than 90 percent were considered respiratory depression and were noted.

Patients were followed throughout their hospital stay and complications were recorded.

Statistical Analysis

MS EXCEL 2010 and SPSS version 21 were used for the statistical analysis. Means, Standard Deviations, and percentages were used for interpreting the results. For the comparison of means, a student t-test was used and for categorical data, a chi-square test was used. A 'P' value of less than 0.05 was considered statistically significant.

RESULTS

This study of the clinical effects of intrathecally administered Fentanyl (preservative-free) along with hyperbaric Bupivacaine was conducted in ASA-I patients undergoing elective lower-segment cesarean section. There were 25 patients in each group. Preloading is done with intravenous fluids with a dose of 15 ml/kg of crystalloid solution (ringer lactate) infused over 20-30 minutes. 25 patients in the control group received 8.5 mg of Bupivacaine and 0.5 ml of normal saline intrathecally. 25 patients in the study group received 8.5 mg of Bupivacaine and 25 µg of Fentanyl intrathecally.

The time of onset of analgesia, level of analgesia, adverse effects, treatment given, 2-segment regression time, and the duration of analgesia were recorded. Pulse rate, blood pressure, peripheral arterial oxygen saturation, and respiratory rate were recorded every 5 minutes. Duration of postoperative analgesia was measured as the time between the administration of local anesthetic and opioid intrathecally and the first request for supplemental analgesia. 100mm visual analog scale was made use of. A score of 40 on the scale was taken as the end point of analgesia provided by the intrathecal administration of local anesthetic and opioids. Time was noted, indicating the post-operative analgesia duration, and supplemental analgesic by injection form was administered.

As summarised in Table 1 demographic and preoperative hemodynamics and respiratory rate were comparable in the 2 groups.

Table 1: Demographic and pre-operative hemodynamic data

Patient Characteristics	Study Group (Group FB) n=25	Control Group (Group B) n=25
Age (years)	23 ± 3.65	23.5 ± 3.61
Weight (Kg)	62.6 ± 7.43	60.9 ± 5.58
Pulse rate (/min)	86 ± 7.32	87 ± 8.60
Systolic Blood pressure (mm Hg)	121.5 ± 9.17	118 ± 10.9
Diastolic Blood Pressure (mm Hg)	79.2 ± 7.6	78 ± 8.16
Respiratory Rate (/min)	17.5 ± 2.08	16.9 ± 2.14

The mean age is 23 years in group FB and 23.5 years in group B. The mean weight is 62.6kg in group FB and 60.9kg in group B. The mean pulse is 86 per minute in group FB and 87 in group B. The mean systolic blood pressure is 121mmHg in group FB and 118mmHg in group B. The mean diastolic blood pressure is 79mmHg in group FB and 78mmHg in group B. The mean respiratory rate is 17 per minute in group FB and 16.9 in group B.

Table 2: Onset of sensory blockade

Time	(Group FB) n=25	(Group B) n=25
1 min	0	0
1 min 30 sec	2	1
2 min	7	9
2 min 30 sec	6	5
3 min	6	5
3 min 30 sec	3	1
4 min	1	2
4 min 30 sec	0	0
5 min	0	2

FB group mean onset of analgesia 2 min 32 sec.

B group mean onset of analgesia 2 min 61 sec.

P value-0.258

This shows that there is not much difference in the onset of analgesia between FB and B Groups. The values are statistically not significant. P>0.05.

Table 3: Highest level of sensory block

Level	(Group FB) n=25	(Group B) n=25
T_6	7(28)	7(28)
T_5	4(16)	5(20)
T_4	14(56)	13(52)

Values shown in brackets are percentages.

The above table shows that majority of the patients in both the groups had a highest sensory levels of T4.

Table 4: Time to reach highest sensory level

Time	(Group FB) n=25	(Group B) n=25
4 min	2	1
4 min 30 sec	0	0
5 min	5	3
5 min 30 sec	0	2
6 min	7	9
6 min 30 sec	2	4
7 min	5	4
7 min 30 sec	1	0
8 min	1	1
8 min 30 sec	0	0
9 min	2	1

The values are shown in mean and standard deviation.
Group FB - 5.99 ± 1.35 Minutes
Group B - 5.94 ± 1.05 Minutes
P value-0.880
There is no significant difference between the time to reach the highest sensory level in both groups (P > 0.05).

Table 5: Two segment regression time

Time	(Group FB) n=25	(Group B) n=25
2 segment regression	100 ± 8.78 min	94.8 ± 10.6 min

P value 0.064
The values are shown in mean and standard deviation.
P < 0.05 is significant
There was no significant difference between the two groups in two segment regression time.

Table 6: Duration of post-operative analgesia

Time	(Group FB) n=25	(Group B) n=25
2.00Hrs.	0	1
2.15 Hrs.	0	1
2.30 Hrs.	0	3
2.45Hrs.	0	3
3.00 Hrs.	0	9
3.15 Hrs.	2	5
3.30 Hrs.	6	0
3.45 Hrs.	5	0
4.00 Hrs.	5	3
4.15 Hrs.	2	0
4.30 Hrs.	5	0
4.45 Hrs.	0	0
5.00 Hrs.	0	0

P Value < 0.05 is significant.

In the Study Group i.e., Group FB duration of postoperative analgesia varies between 3.15 Hrs. to 4.30 Hrs. In the Control Group i.e., Group B the duration of postoperative analgesia is between 2.00 Hrs. to 4.00 Hrs.
Group FB mean duration 3.77±0.43
Group B mean duration 2.74±0.499
Postoperative analgesia lasted longer in the Group FB than in Group B. There is a significant difference of the duration of postoperative analgesia between the two groups

Table 7: Complications

Adverse Effects	(Group FB) n=25	(Group B) n=25
Nausea	3(12)	0
Vomiting	0	0
Pruritus	5(20)	0
Bradycardia	3(12)	1(4)
Hypotension	2(8)	2(8)
Shivering	0	3(12)
Respiratory depression	0	0

The values shown in brackets are percentages
Thirteen patients (52%) in Group FB developed complications of which pruritus (20%) is the most common adverse effect followed by nausea, bradycardia, and hypotension in Group FB. None of the patients had vomiting, shivering, and respiratory depression.
Only 6 patients (24%) had adverse effects in Group B out of which 3 patients (12%) had shivering, 2 patients (8%) had hypotension and 1 patient (4%) had bradycardia.

DISCUSSION

In recent years, neuraxial opioids have been increasingly used to augment the analgesia produced by local anesthetics. Subarachnoid morphine has been widely used for this purpose to provide effective postoperative analgesia. Fentanyl may be advantageous over morphine because of its rapid onset of action, superior intraoperative conditions, and lack of delayed respiratory depression.

This study suggests that the addition of 25µg of Fentanyl to 8.5mg of Bupivacaine does not affect the onset of analgesia to pinprick, the height of the sensory block achieved, and the time to reach the maximum level. Fentanyl does not prolong the Bupivacaine sensory block. However, there is a significant prolongation of postoperative analgesia with the addition of Fentanyl.

Wang et al found experimentally that there was a potential synergism between intrathecal Fentanyl and Bupivacaine.[1] Our results are consistent with the experimental effects of intrathecal opioids which shows that a combination of opioids and local anesthetics are synergistic for somatic analgesia.

Intrathecal opioids can markedly enhance analgesia from subtherapeutic doses of spinal Bupivacaine. Intrathecal opioids appear to produce analgesia by inhibition of synaptic transmission in nociceptive afferent pathways (Aδ and C fibers). Yet, they do not inhibit conduction in sympathetic pathways or somatosensory evoked potentials. Thus, synergistic blockade of Aδ and C afferents allowed subtherapeutic concentration of hyperbaric Bupivacaine to maintain surgical anesthesia during regression of spinal anesthesia.[1]

Thus our study results are consistent with an enhanced block of nociceptive afferents as a mechanism of improved analgesia with the addition of Fentanyl to spinal Bupivacaine.

In both the groups, the mean onset of sensory block occurred between 2 minutes and 3 minutes in most patients (76%) and the maximum level of sensory blockade at T4 is achieved in 5 to 7 minutes. This observation shows that the addition of fentanyl to Bupivacaine does not influence Bupivacaine's sensory block.

According to Hunt et al, the synergism between Fentanyl and Bupivacaine does not affect the onset of sensory block and the duration of motor block, but it facilitates effective postoperative analgesia.[2]

Shende D, Cooper GM, and Bowden studied the effect of adding 15µg Fentanyl to hyperbaric 0.5% Bupivacaine given intrathecally for elective cesarean section and concluded that onset times, neonatal outcomes were similar and duration of postoperative analgesia was prolonged in Fentanyl group.[3]

Roussel Jr. et al concluded that Fentanyl (25µg) does not enhance the onset and duration of sensory and motor block produced by 12 mg of intrathecal Bupivacaine. In their study, there was no significant difference between the 2 groups in two-segment regression time.[4]

Kan FC – T Sai YC. Chang PJ, and Chen TY studied the effects of adding 25µg Fentanyl to 5mg of hyperbaric Bupivacaine given intrathecally for cesarean section and disclosed that.[5]

I. Haemodynamic status was more stable in the Fentanyl group
II. The incidence of nausea and vomiting appeared to be not statistically significant between groups.
III. The incidence of pruritus was higher in the Fentanyl group.
IV. But the incidence of shivering was much lower in the Fentanyl group
V. The complete analgesia duration is longer in the Fentanyl group.
VI. There was no significant difference in the anesthetic and surgical status, 1 min and 5 min Apgar scores, and the time of regression of sensory level to T10.

In our study, the mean duration of the 2-segment regression time in Group FB was 100 minutes, and in Group B was 94.8 minutes. So there was no difference in the duration of 2 segment regression in both the groups. This finding is by Roussel Jr. et al.[4]

All the previous studies have shown that there is a significant increase in the duration of postoperative analgesia with the addition of Fentanyl to Bupivacaine. Our data shows that postoperative analgesia is better and longer lasting with the addition of Fentanyl 25µg to Bupivacaine. The mean duration of postoperative analgesia in Group FB was 3 Hrs. 58 Mins. and Group B was 3 Hrs. This is a very significant finding. This finding is per all other previous studies.

Kumar K et al, reported that pruritus would be frequently encountered after intrathecal opioid administration.[6] According to Hunt et al, 25 to 50µg Fentanyl in addition to intrathecal Bupivacaine increased the frequency of pruritus by 80%, which was statistically significant.[4] According to our results, the rate of pruritus is higher by 20% with intrathecal Bupivacaine and Fentanyl combination when compared to the control group. But it was well tolerated, none of the patients needed treatment.

The administration of intrathecal opioids carries the risk of respiratory depression. Fentanyl is much more lipid soluble than morphine and does not migrate intrathecally to the fourth ventricle to cause respiratory depression. Liu et al postulated that they did not observe any respiratory depression with the combination of intrathecal lidocaine and 20µg Fentanyl.[8] Hunt,[4] and Varassi et al,[7] did not report respiratory depression with intrathecal administration of Bupivacaine and 12.5 µg Fentanyl. In this study, we also did not observe respiratory depression. Our results are comparable with the results of Liu and Varassi et al.[7,8]

According to Chu et al., shivering subsided significantly with the combination of 12.5 µg Fentanyl and buprenorphine intrathecally.[8]

In our study shivering was not seen in the Fentanyl group but 12% of patients in the Bupivacaine group had shivering. In the Bupivacaine group, two patients had hypotension and one patient had bradycardia.

Other complications with intrathecal Fentanyl in group FB were bradycardia (12%) and nausea (12%) but none of the patients had vomiting, and two patients had hypotension.

CONCLUSION

Fifty ASA physical status I patients scheduled for elective lower segment cesarean section surgery were studied. Patients were randomly divided into two groups i.e., group FB and group B consisting of 25 patients each. Patients in group FB were given 8.5mg of hyperbaric Bupivacaine plus 25µg of Fentanyl (0.5ml) and group B received 8.5 mg of hyperbaric Bupivaine plus 0.5ml of normal saline to adjust the final volume to 2.2ml.

It was found that the addition of 25µg Fentanyl to 8.5mg of Bupivacaine does not affect the onset of analgesia to pinprick, the maximum level of analgesia, and the time to achieve the maximum level. Fentanyl does not prolong the Bupivacaine sensory block. However, there was a significant prolongation of postoperative analgesia with the addition of Fentanyl.

In conclusion, Fentanyl 25µg does not enhance the onset and duration of sensory block produced by 8.5mg of hyperbaric intrathecal Bupivacaine. Fentanyl, however, prolongs postoperative analgesia and lowers the incidence of shivering. The incidence of pruritus is high, but it is usually mild. Fentanyl 25µg along with 8.5 mg Bupivacaine is very much safer than other opioids like morphine which has more postoperative complications like intense, intermittent respiratory depression.

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