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# Intrathecal Fentanyl as an Adjuvant to Hyperbaric Bupivacaine in Lower Abdominal Surgeries: A Placebo Controlled Randomised Study

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**Abstract**

*Aim:* The aim of our study was to evaluate the efficacy of intrathecal fentanyl as an adjuvant to bupivacaine on the block characteristics, hemodynamic stability and side effects in patients undergoing lower abdominal surgeries. *Methods:* Sixty patients aged between 18-60 yrs, belonging to ASA I and II posted for elective lower abdominal surgeries under spinal anaesthesiawere recruited for the study. Patients were randomly divided into two groups of thirty each. One group received 2.5 ml of 0.5% Inj. bupivacaine with 0.5 ml of fentanyl (Group FB) and the other group received 2.5 ml of 0.5% Inj. bupivacaine with 0.5 ml of normal saline (Group B). Patients were monitored for onset, duration and quality of sensory and motor block, duration of analgesia, highest dermatomal level, hemodynamic parameters and side effects. *Results:* Onset of sensory block, motor block, time to reach highest dermatomal level duration of motor block was comparable between the groups. Duration of sensory block and two segment regression was prolonged in group FB compared to Group B which was statistically significant ($p < 0.001$). Hemodynamic stability was maintained throughout intra and post-operative period in Group FB compared to Group B. Incidence of pruritis was higher in Group FB compared to Group B which was statistically significant ( $p< 0.001$). *Conclusion:* Fentanyl as an adjuvant to bupivacaine provided sufficient post-operative analgesia with hemodynamic stability.

**Keywords:** Fentanyl; Bupivacaine; Intrathecal; Postoperative analgesia.

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## Introduction

Subarachnoid block introduced by Karl August Bier is one of the oldest forms of regional blocks and is still a very commonly used procedure in our country. Subarachnoid block gives a clear advantage which is difficult to duplicate with general anaesthesia for surgical procedures below the level of the umbilicus. Over and above, one of the most useful effects of central neuraxial blockade is postoperative analgesia.

Local anaesthetics used in day to day practice are usually amides like bupivacaine, lignocaine, ropivacaine, levobupivacaine etc. Though bupivacaine has become the mainstay of spinal anaesthesia it has certain disadvantages like late onset of action and prolonged motor blockade which makes it an unsuitable agent for ambulatory

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anaesthesia [1,2,3]. The discovery of opioid receptors in the spinal cord [4] led to the use of opioids as additives along with the local anaesthetics.

Opioids are being used widely in the world with the advantage of prolonging analgesia, thus providing maximum benefit with low cost and easy techniques. Of the opioids, morphine, pethidine, fentanyl, buprenorphine etc are used. Lipophilic opioids like fentanyl and sufentanilare increasingly being administered intrathecallyas adjuncts to local anaesthetics to overcome the disadvantages of conventional doses of bupivacaine.

In our present study we evaluated the efficacy of intrathecal fentanyl as an adjuvant to 0.5% bupivacaine on sensory and motor block characteristics, hemodynamic stability and side effects due to its intrathecal administration.

## Methods

Sixty American Society of Anaesthesiologists physical status I & II, patients of either gender and aged between 18-60 yrs scheduled for lower abdominal surgeries were included for the study. Ethical committee approval was obtained from Institutional Ethical committee, and written informed consent was taken from the patients. Patients with American society of anaesthesiologists physical status III and IV, with history of major cardiac, renal, hepatic, respiratory or neurological disorders and those with spine deformity, psychiatric illness, altered coagulation profile and active infection were excluded from the study.

All patients were evaluated thoroughly on the previous day of surgery and were allowed to fast overnight.Tab. Diazepam 10 mg and Tab. Ranitidine 150mg were prescribed on the night before surgery. On the day of surgery 18 G intravenous cannula was secured in non dominant hand; patients wereco-loaded with ringer lactate intravenous fluid at a rate of 15 ml/kg body weight. Standard monitoring was accomplished using electrocardiogram, non-invasive blood pressure and pulse oximetry.

Patients were randomly allocated into 2 groups by computer generated number and study drugs were prepared by one of our OT technician in colour coded syringes. Group FB (test group, n=30) received 2.5mlof 0.5% Bupivacaine heavy and 25 μg freshly drawn fentanyl citrate (0.5 ml) and Group B(control group, n=30) received 2.5 ml of 0.5% Bupivacaine heavy with0.5ml saline. Anaesthesiologists who administered the drug and patients were blinded for the study.

Subarachnoid block was performed under aseptic precautions with patients in lateral decubitus position using 25G Quincke-Babcock spinal needle at $L_2$-$L_3$ or $L_3$-$L_4$ interspace. The study solution was injected over 20-30 seconds after confirming free flow of CSF. After the intrathecal injection the patients were immediately made to lie in supine position.

Sensory level was assessed by pin prick sensation every minute till adequate sensory level was achieved and thereafter every 5 minutes for the first hour and 20 minutes till 2 segment regression. Onset of sensory block, duration of analgesia, two segment regression, time taken to reach highest dermatomal level and the highest dermatome reached were noted. Motor block was assessed by modified Bromage scale ( I - free movement of legs and feet; II - just able to flex knees with free movement of feet; III - unable to flex knees but with free movement of feet; and IV - unable to move legs and feet). Onset of motor block (Bromage II), duration of motor block (regression to Bromage I) were noted.

Intravenous boluses of 6 mg mephenteramine and additional I.V. fluids were given to treat hypotension, which was defined as a systolic blood pressure <20% of preoperative value or <90 mm Hg, atropine 0.6 mg to treat bradycardia (40/min) or 30% of baseline and $O_2$ via face mask if pulse-oximetry reading decreased below 92%. If respiratory rate decreased to <8/min, patients were gently aroused by tapping.

Presence of side effects like pruritus, nausea, vomiting, respiratory depression and were noted intraoperatively and postoperatively. Results were tabulated and analysed.

Statistical analysis done using software SPSS version 11.5. Continuous variables were summarized as mean and standard deviation. Student unpaired 't' test was applied to onset of sensory and motor block time to highest sensory level, time for 2 segment regression, time for effective analgesia, time to motor activity. Chi-square test was applied to highest sensory level, pruritus and nausea. p value <0.05 is considered as significant (S), <0.01 is considered as highly significant (HS) and <0.001 is considered as very highly significant (VHS)

**Table 1:** Demographic data

| | Group FB | Group B | p Value |
|---|---|---|---|
| Age in years | 38.26±13.05 | 38.76±11.65 | 0.876 |
| Male/Female | 18/12 | 19/11 | 0.791 |
| ASA I/II | 16/14 | 17/13 | 0.795 |

Data expressed as Mean ± Standard deviation.

**Table 2:** Sensory and Motor block characteristics

| | Group FB | Group B | P value |
|---|---|---|---|
| Onset of sensory block (min) | 3.7±1.2 mins | 4.0±1.1 | 0.371 |
| Onset of motor block (min) | 4.5±1.2 | 4.8±0.9 | 0.277 |
| Median maximum sensory level | T4/T6/T8= 14/12/5 | T4/T6/T8= 10/14/6 | 0.637 |
| Time to reach highest sensory level (min) | 12.9±2.8 | 13.08±2.2 | 0.789 |
| Time for two segment regression(min) | 84.3±16.33 | 63.3±10.72 | <0.0001*** |
| Time for rescue analgesia (min) | 180.0±22.2 | 153.0±13.42 | <0.0001*** |
| Time for complete motor recovery (min) | 148.66±20.465 | 142.6±18.06 | 0.228 |

Data expressed as Mean ± Standard Deviation

**Table 3:** Side effects

| | Group FB | Group B | P value |
|---|---|---|---|
| Pruritis | 10 (33.33%) | 0 | 0.0006* |
| Hypotension | 9 (30.00%) | 12 (40.00%) | 0.427 |
| Bradycardia | 2 (6.66%) | 4 (13.33%) | 0.393 |
| Hypoxia | 0 | 0 | 0 |
| PONV | 5 (16.66%) | 8 (26.66%) | 0.351 |

## Results

All the sixty patients enrolled, successfully completed the study. Two groups were comparable with regards to age, gender and ASA grading. (Table 1).

Both the groups were comparable with respect to onset of sensory and motor block. The highest dermatomal level reached and the time taken were comparable in both the groups. (12.9±2.8 vrs 13.08±2.2, p= 0.789).

The time taken for two segment regression was prolonged in Group FB when compared to Group B and the difference was found to be very highly significant (84.3±16.33 vrs 63.3±10.72, p < 0.0001). The time for rescue analgesia and duration of motor block were prolonged in Group FB when compared to Group B which was found to be statistically significant (Table 2).

Both the groups were monitored for side effects both intra and post-operatively. Hypotension was seen more in Group B when compared to Group F which was found to be statistically significant. (13.33% vrs 40.0%, p= 0.02). Six patients in Group FB had pruritis but none of them in Group B. This was found to be statistically significant.

Bradycardia, hypoxia and post operative nausea and vomiting were comparable in both the groups.

## Discussion

Subarachnoid block is one of the most popular techniques in our country, which unfortunately has the disadvantages of sympathetic and motor block, resulting in hypotension, bradycardia and immobility [4]. It has been a dream to produce sensory block without its accompanied complications and a major step in this path is the use of intrathecal opioids, [5] but they are not adequate anaesthetics for surgery. So local anaesthetics combined with opioids are the appropriate choice.

Studies using morphine by Semenikhin et al. [6] in 1990 concluded that addition of morphine considerably increased the quality of analgesia produced, but the incidence of late respiratory depression is more with morphine. Fentanyl, a phenyl piperidine derivative [11] and a synthetic opioid, is 100 times more potent then morphine and being more lipophilic, has fewer tendencies to cause late respiratory depression and hence, is more suitable especially in our country which has few monitoring facilities and a greater demand on them.So we decided to use fentanyl as an adjuvant to hyperbaric bupivacaine in our study.

Hunt et al. [7] showed the 6.25 µg fentanyl was capable of producing same analgesia as higher doses, with minimum side effects, after comparing 0, 6.25, 12.5, 37.5 and 50 µg doses (made to 1 ml with normal saline), with bupivacaine 0.75% in 28 parturients for caesarean section. As the dose of fentanyl increases to 0.5 to 0.75 µg/kg post operative pain relief lasts longer, but respiratory changes occur and incidence of adverse effects also increases. Hence, in our study we chose 25 µg fentanyl for non obstetric surgeries.

Hunt et al. [7] and Singh et al. [8] found onset of sensory block and motor block was not affected which was similar to our study. Though onset of sensory and motor block was hastened in our study, the difference was not significant. The time and the highest sensory level achieved were comparable in both the groups which was similar to the studies done in the past. Studies done by Singh et al. [9] and Bruce et al. [10] have shown prolongation of two segment regression which was similar to our present study findings. These findings were contradicted by the findings done by Kararmaz et al. [11].

Duration of sensory blockade was prolonged but no effect on motor block was seen in our study. This is consistent with the studies done by Belzarena et al. [12]. This could be explained by the

synergistic interaction between spinal opioids and local anaesthetics. That synergism is characterized by enhanced somatic analgesia without effect on the degree or level of the local anaesthetic-induced sympathetic or motor blockade.

Almost all the previous studies like those of Kararmaz et al. [11], Varrassi et al. [13] and Kuusniemi et al. [14] and Srivastava et al. [15] found an increased incidence of pruritus while in our study the incidence of pruritus was 33.3% (p=0.002) in test group which coincides with above studies. Hypotension was less in Group FB compared to Group B but the difference was found to be statistically non-significant. Similarly bradycardia was seen in two patients in Group FB while four in Group B which required treatment. There was no significant difference between the groups with respect to hypoxia, shivering, post-operative nausea and vomiting. Some studies like those of Singh et al. [9] and Olofsson et al. [16] found no statistically significant differences in perioperative hypotension, bradycardia, desaturation, pruritus, shivering, nausea and vomiting between test and control groups. In study of Kararmaz et al. [11] the incidence of hypotension and shivering was significant between control and test groups.

## Conclusion

Addition of fentanyl to hyperbaric bupivacaine increased the duration of analgesia maintaining hemodynamic stability when compared to placebo. Pruritis was the most common side effect observed during the study which is attributed to intrathecal fentanyl.

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