Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/rdhvc638

# INTRATHECAL LOW DOSE BUPIVACAINE WITH FENTANYL VERSUS CONVENTIONAL DOSE OF BUPIVACAINE FOR CAESAREAN SECTION AND INFRAUMBILICAL SURGERIES: A RANDOMIZED CONTROLLED TRIAL

**Falak Deeba[1*], Mohd Khalik[2], Bhawna Singh[3]**

[1*]3rd year Post Graduate, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, UP India
[2]Professor, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, UP India
[3]Associate Professor, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, UP India

***Corresponding Author: Dr. Falak Deeba**
*****Post Graduate, Department of Anaesthesiology, Rohilkhand Medical College & Hospital, Bareilly, UP India, email id – falakdeeba31@gmail.com

**Abstract:**
**Background:** Spinal anaesthesia was described over 100 years ago. Since then neuroaxial administration has become advanced exponentially and now a days includes a huge variety of medication that provides not only anaesthesia including analgesia as well, spinal anaesthesia is most common method of regional blocked in caesarean section as well as in infraumbilical surgeries.
**Objective:** To compare the hemodynamic stability and post-operative analgesia including sensory and motor-blockade of Intrathecal low dose of Bupivacaine along with Fentanyl with usual dose of intrathecal Bupivacaine in caesarean section and infraumbilical surgeries.
**Methods:** This is randomized controlled trial was conducted in patients posted for elective & emergency surgeries using low dose of bupivacaine with an adjuvant Fentanyl versus conventional dose of Bupivacaine in caesarean section and infraumbilical surgeries. Following approval by the Board of Thesis/Research committee, Department of Anesthesia & Ethical committee, Rohilkhand Medical College & Hospital Bareilly, 58 patients was randomly divided in two groups in 1:1 allocation ratio, each comprising 29 patients.
**Result:** the onset and duration of sensory and motor blocks, postoperative pain, and adverse effects like nausea, vomiting, and shivering. We found that there were no significant differences in age, gender, or weight found between the two groups. while comparing sensory and motor Blockade, Group 1 (low dose Bupivacaine + Fentanyl) exhibited earlier onset of both sensory and motor blockades. The mean onset time of sensory blockade in Group 1 was 4.13±1.15 minutes, significantly faster than Group 2 (7.25±0.81 minutes, $p<0.001$). Similarly, Group 1 experienced a quicker onset of motor blockade (5.58±0.86 minutes) compared to Group 2 (9.54±1.62 minutes, $p<0.001$). In our study when duration of sensory and motor blockade were assessed sensory blockade lasted longer in Group 1 (188.32±18.56 minutes) than in Group 2 (159.86±14.12 minutes, $p<0.001$), whereas motor blockade duration was longer in Group 2 (176.06±8.76 minutes) than in Group 1 (152.06±14.04 minutes, $p<0.001$).

**Conclusion:** The low-dose Bupivacaine with Fentanyl combination ensures better hemodynamic stability than the conventional Bupivacaine alone dose. Therefore, using this combination for spinal anesthesia is a more favorable option for cesarean sections and infraumbilical surgeries.

**Keywords:** Intrathecal, low dose Bupivacaine with Fentanyl, conventional dose of Bupivacaine, caesarean section, infraumbilical surgeries

**INTRODUCTION:** The choice of anaesthesia for lower segment caesarean section is determined by multiple factors, including the indication for operative delivery, its urgency patient and obstetrician performances and skill of anaesthetist[1].

The onset of action of bupivacaine is between 4 and 6 minutes, and maximum anaesthesia is obtained between 15 to 20 minutes. The duration of anaesthesia varies according to the block, the average duration of peridural block is about 3.5 to 5 hrs and for nerve blocks, it is about 5 to 6 hours.

The onset and action of the drug is intermediate. The bupivacaine can be detected in the blood within 5 minutes of infiltration or following epidural or intercostal blocks. The pKa of bupivacaine is 8.1 which determines the onset and action of the drug. The plasma levels are related to the total dose administered, peak levels of 0.14 to 1.18 μg/mL were found within 5 minutes and upto 2 hours after administration of anaesthesia, and they gradually decline to 0.1 to 0.34μg ml by four hours. The tissue blood partition coefficient of bupivacaine 1:28, and has a clearance of 0.47 L/min. The elimination half-life of bupivacaine is 3.5 hours in adults and 8.1 to 14 hours in neonates[2].

In subarachnoid block, the onset and action of the drug is about 3 to 4 minutes, and complete anesthesia occurs in 5 minutes and lasts for 3.5 to 4 hours. The motor blockade is definitely inferior to tetracaine[2].

Fentanyl when given i.v. has an onset of action in 7 to 8 minutes and action lasts for 30 to 60 minutes, while intramuscularly, it has onset within 4 to 6 minutes and lasts for 1 to 2 hours. 75% of fentanyl undergoes first pass uptake by lungs. It has a rapid distribution half-life of 1-2 minutes and second distribution phase of 10-30 minutes. The short duration of action of fentanyl is associated with decrease in the concentration of the drug due to its rapid redistribution to inactive sites such as fat and skeletal muscles. Fentanyl is 86% is protein bound, High volume of distribution of 3 to 6 L/Kg. Context sensitivity half time is 260 minutes after a 4 hour infusion[2].

Fentanyl undergoes high hepatic extraction with extraction ratio of 8-1 and is metabolized by N-dealkylation and hydroxylation to Norfentanyl and Despropionylfentanyl, which are excreted in the urine and bile. Metabolites have minimal activity. Elimination half-life is prolonged which is about 185-219 minutes[2].

Post operative pain is common problem during orthopaedic surgeries of lower limb under spinal anaesthesia, using only local anaesthesia is associated with relative limited duration of action, & thus early analgesic intervention is needed during postoperative period. So, number of adjuvents prolongs the effect of spinal anesthesia[3].

Spinal anesthesia with bupivacaine provides a dense neural block in cesarean delivery. Addition of low dose hyperbaric bupivacaine with Fentanyl may reduce the incidence of these complications. Aim of this study was to compare hemodynamic parameters, nausea & vomiting with low dose intrathecal bupivacaine with fentanyl versus conventional dose of bupivacaine in patient posted for elective cesarean section and infraumbilical surgeries.

Limited studies has been done with this combination of low dose Bupivacaine with Fentanyl (opioid) versus conventional dose of Bupivacaine, adding intra-thecally for caesarean section and infraumbilical surgeries which enhances quality of surgical analgesia. Therefore, present study was conducted, to compare the hemodynamic stability and post-operative analgesia including sensory and motor-blockade of Intrathecal low dose of Bupivacaine along with Fentanyl with usual dose of intrathecal Bupivacaine in caesarean section and infraumbilical surgeries.

**Material and Methods:** This is randomized controlled trial was conducted in patients posted for elective & emergency surgeries using low dose of bupivacaine with an adjuvant Fentanyl versus conventional dose of Bupivacaine in caesarean section and infraumbilical surgeries. Following approval by the Board of Thesis/Research committee, Department of Anesthesia & Ethical committee, Rohilkhand Medical College & Hospital Bareilly, 58 patients was randomly divided in two groups in 1:1 allocation ratio, each comprising 29 patients. Consent and approval of patient for participation in study was taken. Duration of study was 1 August 2023 to 31 July 2024

**Sample size:** In our study a total of 58 patients was included which were statistically

calculated by using the software Power and and sample size programme. The sample size calculated in each group was 29[4].

***Inclusion Criteria: Patients fulfilling the following:***

- Undergoing lower segment of caesarean section and infraumbilical surgeries.
- American society of Anaesthesiology (ASA)[5] grade I, II undergoing caesarean section andinfraumbilical surgeries.
- From age group of (18-60 yr) for infraumbilical surgeries.
- Female patient of age group 18-45 years (reproductive age group) for caesarean section.

***Exclusion Criteria:***

- Patient refusal for spinal anaesthesia.
- American society of Anaesthesiology (ASA) grade III, IV, V.
- Allergic to local anaesthesia.
- Patient with spine deformity, local site infection.
- With bleeding or coagulation disorders.

**METHODOLOGY:**

The methodology of the study adheres to the ethical principles for medical research involving human subjects as outlined in the Declaration of Helsinki.

**Group 1-** Low dose Bupivacaine (7.5mg) + Fentanyl (25mcg)

**Group 2-** Conventional dose of Bupivacaine (12.5 mg)

One day before the procedure, a thorough pre-anaesthetic examination was performed, and informed & written consent for research participation was obtained. Patients were randomly allocated to Groups 1 and Group 2. Group 1 received Low dose Bupivacaine (7.5mg) with Fentanyl (25 mcg). Group 2 was given a conventional dose of 0.5% of Bupivacaine combined (12.5mg), while The anaesthetists, who were not involved in the observation, prepared the drugs. Patients were informed about the procedure for spinal anaesthesia. They were kept nil per oral for 6 hours, and Tablet Ranitidine 150 mg and tablet Alprazolam 0.25 mg were administered orally the night before surgery.

After arriving in operating room, routine monitoring (non-invasive blood pressure, electrocardiography, and pulse oximetry) was applied. A 20-gauge peripheral i.v. cannula was introduced and fixed, and preloading with Ringer's Lactate solution (15 mL/kg) was started. Antiemetic prophylaxis was administered using Injection Ondansetron (0.08 mg/kg, 4 mg) and Injection Ranitidine (1 mg/kg, 50 mg).

Patients were placed in a sitting posture under aseptic precautions. After disinfecting the skin and infiltrating with 2% lignocaine, lumbar puncture was done at the L3-L4 interspace using a 26-gauge Quincke needle. After obtaining a clear flow of CSF, Group 1 received a low dose (7.5 mg) of 0.5% of Bupivacaine combined with Fentanyl

(25mcg) while Group 2 received an intrathecal dose of conventional (12.5mg) Bupivacaine. The

medication was administered intrathecally in each groups.

After the completing the spinal injection, the patient was immediately made to lie supine.
The patient was evaluated for hemodynamic stability every 5 minutes for the first 30 minutes, then every 15 minutes for the next 30 minutes, and then every hour for up to 6 hours. After spinal anaesthesia, the patient received an intravenous injection of Midazolam 1 mg.
The patient's heart rate, systolic and the diastolic blood pressure, mean arterial pressure (MAP), and arterial oxygen saturation were monitored throughout the procedure: every 5 minutes for the first 30 minutes, every 15 minutes for the next 30 minutes, and then every hour for up to 6 hours until the procedure was completed.
The level of the sensory blockade was assessed in a caudal to cephalad direction, with the loss of pinprick sensation being the indicator.
The following parameters were noted:
onset time of sensory blockade (i.e., the time from intrathecal injection of the drug to complete loss of the sensation to pinprick at the T10 level).

The motor block was assesed using modified bromage scale.[53]:
The following parameters will be noted:

- Time to onset of the motor blockade by Modified Bromage Score (time from the intrathecal injectionto achievement of Bromage 2).
- Time taken to achieve complete motor block by Modified Bromage Score (time from the intrathecal injectionto achievement of Bromage 3).
- Duration of the motor blockade was noted (time from Bromage 3 to Bromage 2).

Readiness for the surgery was defined as the loss of pin prick sensation ≥ T10 withmodified Bromage ≥2.
During surgery, evaluation of the motor blockade was suspended until the end of the procedure. If the patient complained of the pain, an intravenous injection of Diclofenac 75 mg was administered. If additional sedation was needed, Midazolam 1 mg i.v. was given. Total dose of each medication was recorded. If the patient continued to feel pain, general anaesthesia was provided, and the case was excluded from the study. Any complications, side effects, and adverse effects up to 24 hours postoperatively were noted.

***Assessment of Analgesia***

Visual analogue scale score, shivering was assessed hourly till 6 hours of post- operative period and at 12, 18, 24 hours post-operatively. 24 hour Post operative nausea vomiting (PONV)[4] score was also be assessed.Rescue analgesia will be given when Visual analogue scale (Fig.9) (VAS)[6] > 4 and the time for first the rescue analgesia were noted. Analgesia was given as Inj. Paracetamol 1 gram i.v. Total requirement of analgesic in first 24 hours was also be noted. Post-operative shivering were managed with use of warm blankets and forced air warming system.

1. Pain score ‘0’ to ‘3’ - Mild pain,
2. Pain score ‘3’ to ‘7’ – Moderate pain,
3. Pain score > ‘7’ - Severe pain

**TABLE 1: W.A. Crossley and R.P. Mahajan[7] Shivering Score:**

| Grade | Description |
|---|---|
| 0 | No shivering. |
| 1 | No visible muscle activity but 1 or more of piloerection, peripheral vasoconstriction or peripheral cyanosis (other cause excluded) |
| 2 | Muscular activity in only one muscle group. |
| 3 | Moderate muscular activity in more than 1 muscle group, but not generalised shaking. |

| | |
|---|---|
| 4 | Violent muscular activity that involves the entire body. |

**Results:** The mean age in Group 1 was 40.55 ± 14.64 years and that of Group 2 was 36.93 ± 12.86 years. No statistically significant differences were seen in terms of age between Group 1 and Group 2.

In our study, Group 1 consisted of 17 males and 12 females, in Group B consisted of 14 males and 15 females. There were no statistically significant differences seen in t h e gender of patients between Group 1 and Group 2.

The mean weight (in kg) in Group 1 was 60.07 ± 6.22 kg and that of Group 2 was 56.98

± 10.04 kg. There were no statistically significant differences seen in terms of mean weight (in kg) between Group 1 & Group 2.

The mean onset time of the sensory blockade in Group 1 was 4.13 ± 1.15 and that of Group 2 was 7.25 ± 0.81 These findings indicate that the onset time of sensory blockade was early in Group 1 compared to Group 2. There were statistically significant differences seen in terms of t h e mean onset time of sensory blockade between Group 1 & Group 2 (p-value <0.001).

The mean onset of motor blockade in Group 1 was 5.58 ± 0.86 and that of Group 2 was 9.54 ± 1.62. These findings indicate that the onset time of motor blockade was early in Group 1 compared to Group 2. There were statistically significant differences seen in terms of t h e mean onset time of motor blockade between Group 1 & Group 2 (p- value <0.001).

The duration of sensory blockade in Group 1 was found as 188.32 ± 18.56 minutes, compared to in Group 2 it was 159.86 ± 14.12 minutes. This indicates that the duration of the sensory blockade was prolonged in Group 1 compared to Group 2. There was a statistically significant difference in the duration of the sensory blockade between Group 1 & Group 2 (p-value <0.001).

The duration of the motor blockade in Group 1 was 152.06 ± 14.04 minutes, whereas in the Group 2 was 176.06 ± 8.76 minutes. This indicates that the duration of the motor blockade was prolonged in Group 2 compared to Group 1. There was a statistically significant difference in duration of the motor blockade between Group 1 & Group 2 (p-value <0.001).

**TABLE-2. COMPAIRISON OF MEAN HEART RATE AT VARIOUS TIME INTERVAL IN BETWEEN GROUP 1 & GROUP 2.**

| | **Group 1** | **Group 2** | |
|---|---|---|---|
| Heart Rate | Mean ± SD | Mean ± SD | P-Value |
| Pre-operative | 85.72 ± 10.53 | 82.14 ± 7.54 | 0.142# |
| After Induction | 83.72 ± 10.74 | 80.21 ± 9.29 | 0.188# |
| 5min | 81.17 ± 9.6 | 77.38 ± 8.82 | 0.123# |
| 10min | 80.83 ± 11.06 | 77.21 ± 6.69 | 0.137# |
| 15min | 81.72 ± 10.4 | 77.93 ± 6.77 | 0.105# |
| 20min | 80.76 ± 10.19 | 78.28 ± 5.26 | 0.249# |
| 25min | 79.12 ± 8.55 | 76.07 ± 4.82 | 0.101# |
| 30min | 76.62 ± 7.98 | 77.40 ± 8.84 | 0.733# |
| 45min | 75.72 ± 6.18 | 77.24 ± 6.64 | 0.385# |
| 1hr | 76.07 ± 5.52 | 77.93 ± 6.77 | 0.256# |
| 2hr | 76.48 ± 4.59 | 76.28 ± 5.26 | 0.874# |
| 3hr | 76.62 ± 3.38 | 76.09 ± 4.84 | 0.615# |
| 4hr | 76.97 ± 4.16 | 77.98 ± 6.78 | 0.516# |
| 5hr | 76.55 ± 4.56 | 76.28 ± 5.26 | 0.832# |
| 6hr | 76.41 ± 4.42 | 76.02 ± 4.84 | 0.777# |

#statisitically not significant.

There was no significant difference in the mean Heart rate of patients between Group 1 & Group 2 at various time intervals.

The mean SBP of the patient in our study in Group 2 was decreased from after induction to 6 hours post-operatively and was stable in patients of Group 1 and there was a significant difference in mean SBP of patients in between Group 1 & Group 2 at different time intervals, except at preoperative, at 3 hours, at 4 hours, at 5 hours, and at 6 hours. There was a statistically significant difference in the mean SBP between Group 1 & Group 2.

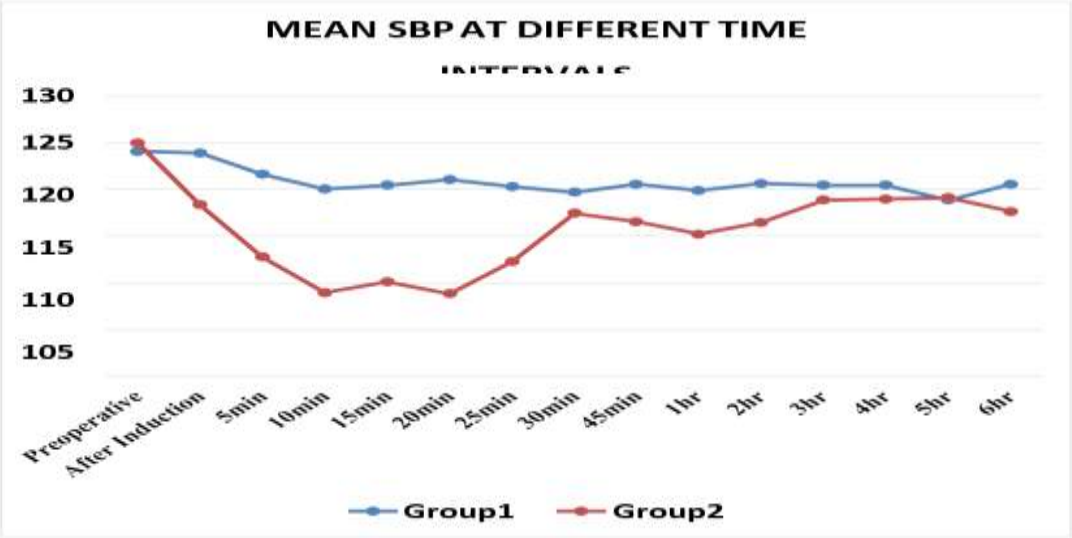


**FIGURE-1. MEAN SBP AT DIFFERENT TIME INTERVAL IN BETWEEN GROUP 1 & GROUP 2.**

The mean DBP of the patient in our study in Group 2 was decreased from after induction to 6 hours post-operatively and was stable in patients of Group 1 and there was a significant difference in mean DBP of patients in between Group 1 and Group 2 at different time intervals, except at preoperative, at 3 hours, at 4 hours, at 5 hours, and at 6 hours.

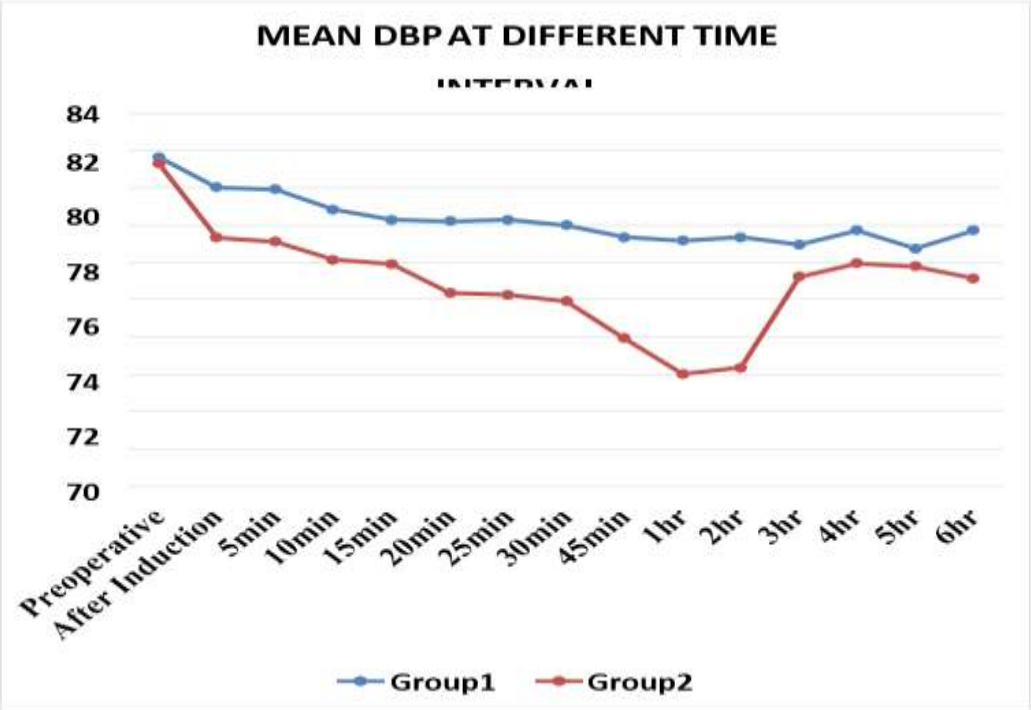

**FIGURE-2. MEAN DBP AT DIFFERENT TIME INTERVAL IN BETWEEN GROUP 1 AND GROUP 2.**

The mean MAP of the patient in our study, there was a significant difference in the mean MAP of patients between Group 1 & Group 2 at various time intervals, except at preoperative, at 3 hours, at 4 hours, at 5 hours, and 6 hours.

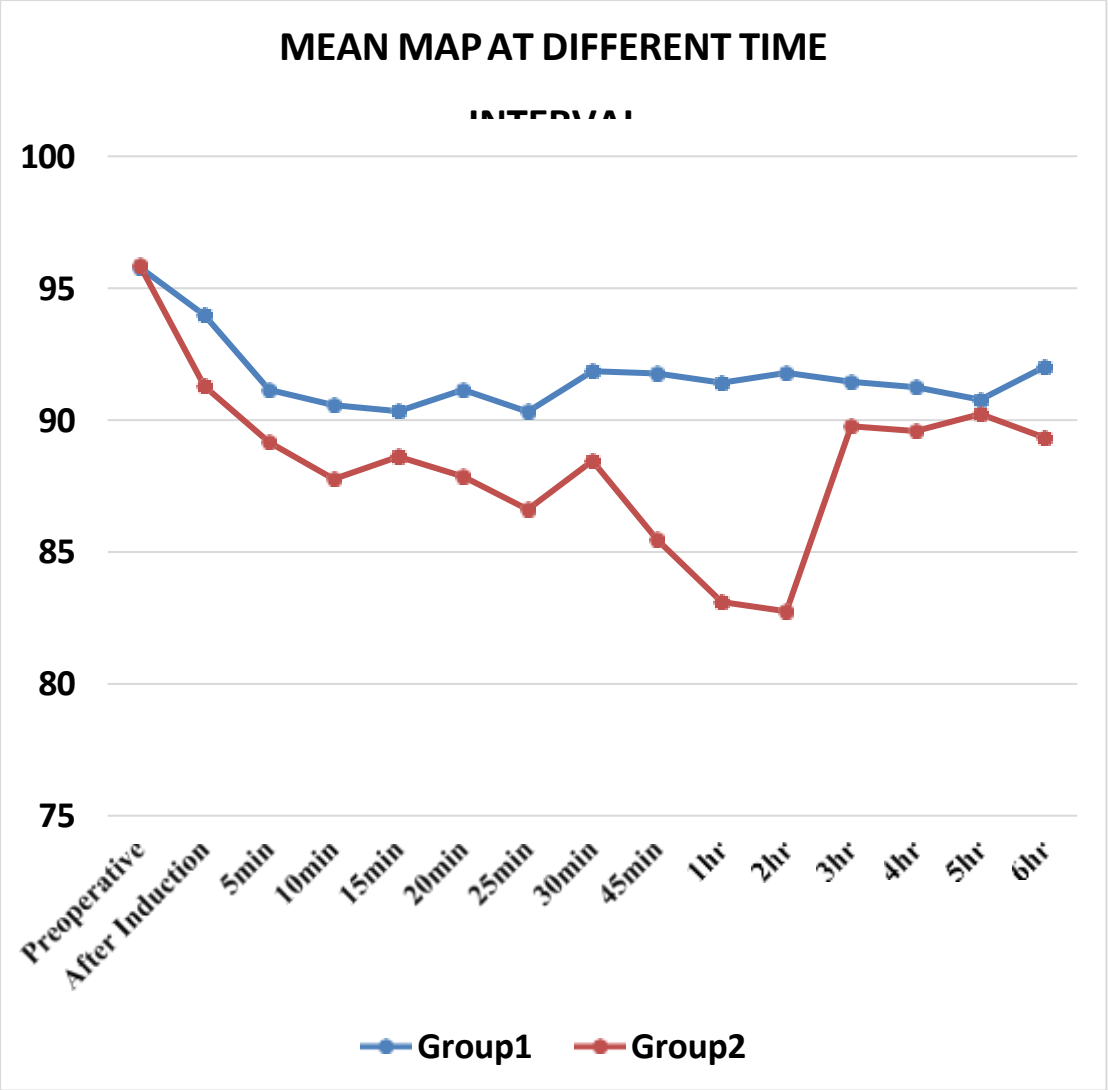


**FIGURE-3. MEAN MAP AT DIFFERENT TIME INTERVAL IN BETWEEN GROUP1AND GROUP 2.**

The mean SPO2 of the patient in our study, there was no significant difference in mean SPO2 of patients between Group 1 & Group 2 at the different time intervals.

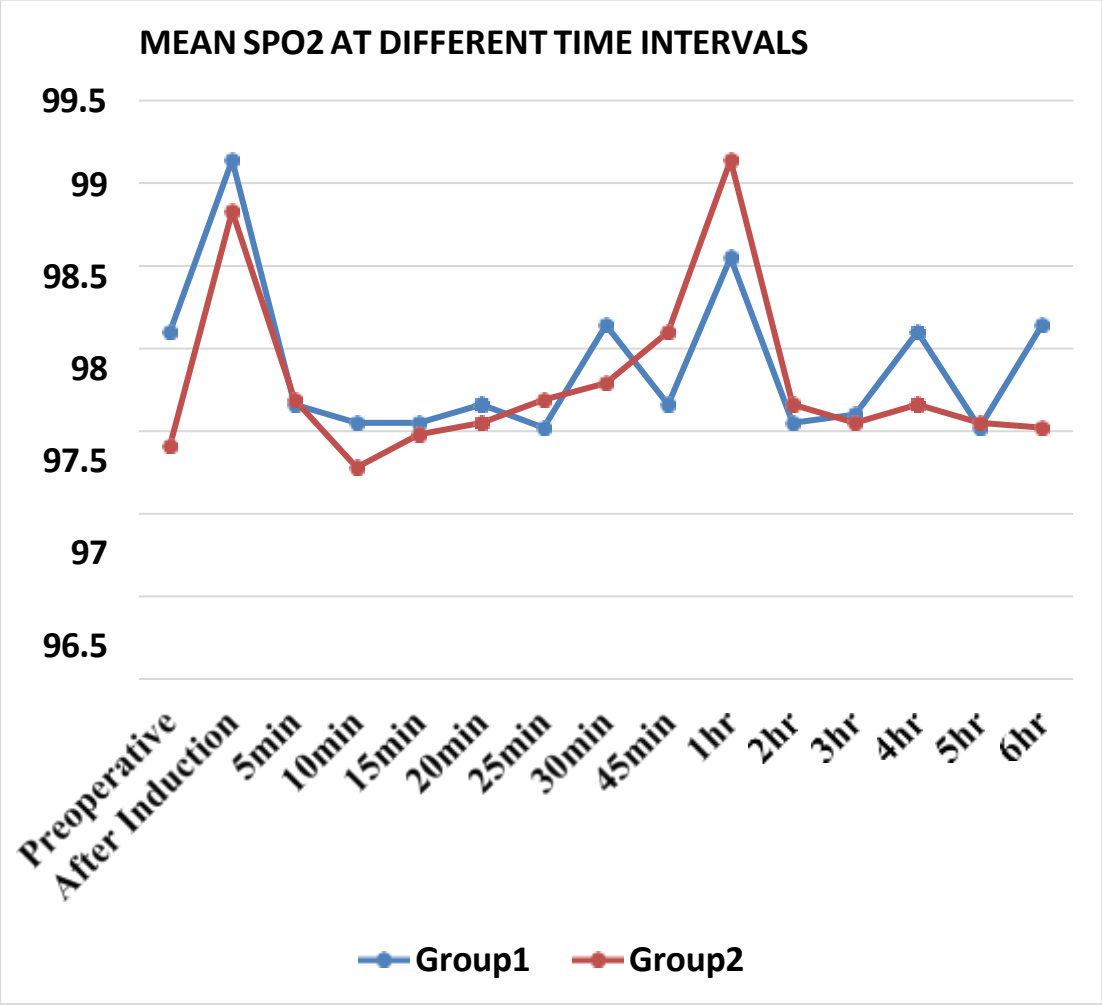


**FIGURE-4. MEAN SPO2 AT DIFFERENT TIME INTERVAL IN BETWEEN GROUP 1 AND GROUP 2.**

**TABLE-3. COMPAIRISON OF MEAN VAS SCORE AT DIFFERENT TIME INTERVAL IN BETWEEN GROUP 1 AND GROUP 2.**

| | **Group 1** | **Group 2** | |
|---|---|---|---|
| **VAS Score** | Mean ± SD | Mean ± SD | P-Value |
| 1hr | 3.76 ± 0.91 | 4.45 ± 1.02 | 0.009* |
| 2hr | 2.48 ± 0.74 | 3.41 ± 1.02 | 0.000* |
| 3hr | 1.52 ± 0.78 | 2.24 ± 0.91 | 0.002* |
| 4hr | 0.76 ± 0.79 | 1.24 ± 0.91 | 0.035* |
| 5hr | 0.25 ± 0.63 | 0.69 ± 0.66 | 0.012* |
| 6hr | 0.13 ± 0.19 | 0.58 ± 0.64 | 0.000* |

*statistically significant.

In our study, the mean VAS score was higher in the Group 2 patients versus Group 1 patients at various time intervals and, there was a significant difference in mean VAS score of patients between Group 1 & Group 2 at various time of intervals.

**TABLE-4. POST-OPERATIVE ADVERSE EFFECTS IN GROUP 1 AND GROUP 2**

| | **Group 1** | | **Group 2** | | |
|---|---|---|---|---|---|
| **Adverse Effects** | Frequency | % | Frequency | % | P-Value |
| Nausea | 10 | 34.5 | 16 | 55.2 | 0.113# |

| | | | | | |
|---|---|---|---|---|---|
| Vomiting | 9 | 31.0 | 13 | 44.8 | 0.279# |
| Post-op Shivering | 10 | 34.5 | 17 | 58.6 | 0.065# |

*statistically significant.

In our study out of 29 patients in Group 1, 34.5% had nausea,31.0% had vomited and 34.5% had post-operative shivering and out of 29 patients in Group 2, 55.2% had nausea, 44.8% had vomited and 58.6% had post operating shivering, and out of 29 patients. The Adverse Effects are more in patients in Group 2 after postoperatively in contrast to Group 1 patients but there was no significant difference in adverse effects after post-operatively in patients of Group 1 & Group 2.

**Discussion:**

In our study we found that, the Heart rate increases in all three groups at 5min, 15min and 1hr with p value (<0.05), which was statistically-significant and then start to decrease after 12 minutes with (P > 0.05) which was statistically insignificant.

In our study we found that, the mean SBP of patients in Group 1 was decreased from after induction to 6 hours post-operatively and was stable in patients of Group 2 and there was a significant difference in mean SBP of patients in between Group1 and Group 2 at various time intervals, except at Preoperative, at 3 hours, at 4 hours, at 5 hours, and at 6 hours, which was statistically-significant. These values were also found similar, with a p-value less than 0.05.

In our study we found that, the mean DBP of patients in the Group 2 was decreased from after Induction to 6 hours post-operatively and was stable in patients of Group 1, and there was a significant difference in mean DBP of patients in between Group 1 & Group 2 at different time intervals, except at preoperative, at 3 hours, at 4 hours, at 5 hours, and at 6 hours, which was statistically-significant. These values were also found similar, with a p-value less than 0.05.

In our study we observed that, there was no relevant difference in the mean SPO2 of patients between Group 1 and Group 2 at various time intervals, which was statistically not significant. These values were also found similar, with a p-value greater than 0.05.

In our study we found that, the Mean Arterial Pressure declined more in Group 2, but the decline was more in the Group 2 as compared to the Group 1, which was statistically-significant after induction of spinal anaesthesia with (P <0.05).

***Halvadia et al[8]*** Conducted a study in 2013 and found that subarachnoid block with 2cc bupivacaine 0.5% and 25µg fentanyl is a safer and better option, both in terms of maintaining hemodynamic stability and lower incidence of complications without compromising the surgical conditions, for geriatric patients undergoing lower limb surgeries, results of this study concluded that systolic B.P. decreased in both groups, maximum fall occurred at 15 to 20 min in both groups decrease were more severe in group A compared to group B,(P<0.O5). [Group A - 15mg of 0.5% bupivacaine & Group B - 10mg of 0.5% bupivacaine and 25mcg fentanyl], heart rates were better maintained in group B than in group A. thus group B showed better hemodynamic stability. These above observation were consistent with our study results.

**ONSET TIME OF SENSORY BLOCKADE**

In our study we found that, the mean onset time of the sensory blockade in Group 1 was 4.13 ± 1.15 and that of Group 2 was 7.25 ± 0.81. These findings indicate that the onset time of the sensory blockade was early in Group 1 compared to Group 2, there was a significant statistical differenceis seen in the mean onset time of the sensory blockade between Group1 and Group 2 (p < 0.001).

***Himabindu Gandam Venkata et al[9]*** Conducted a study in 2015 and found that with 25 µg fentanyl to 7.5 mg and hyperbaric bupivacaine (BF group) could significantly increase the rate of

onset of the sensory block than 10mg bupivacaine alone. The results of this study have shown that onset to peak of sensory block (loss of pin prick sensation) to T6 following intrathecal injection was faster in the group BF than group Bupivacaine alone. These above observation were consistent with our study results.

**ONSET TIME OF MOTOR BLOCKADE**

In our study we found that, the mean onset time of motor blockade in Group 1 was 5.58 ± 0.86 and that of Group 2 was 9.54 ± 1.62, as in [Table 11 & Figure 14]. These findings indicate that the onset time of motor blockade was early in Group 1 compared to Group 2. There were statistically significant differences seen in terms of the mean onset time of motor blockade between Group 1 and Group 2 (<0.001).

***Jayshree Prajapati et al[10]*** Conducted a study in 2015 and observed that onset time of motor blockade was delayed in group B while comparing to the Group-A, and the differences were statistically significant [Group-A: Inj. Bupivacaine 5 mg (0.5%) (1ml) + Inj. Fentanyl 25 µg (0.5 ml), Group-B: Inj. Bupivacaine 7.5 mg (0.5%) (1.5 ml)] .These above observation were consistent with our study results.

**DURATION OF SENSORY BLOCKADE**

In our study we found that, the duration of sensory blockade in Group 1 was found as

188.32 ± 18.56 minutes, whereas in Group 2 it was 159.86 ± 14.12 minutes. This indicates that the duration of the sensory block was longer in Group 1 compared to Group 2 as in [Table 12 & Figure 15].. There was a statistically significant difference in the duration of sensory block between Group 1 and Group 2 (p-value <0.001).

***Thaer Ali Hussein Al Akam et al[11]*** Conducted a study in 2020 and Observed that addition of fentanyl enhances duration of sensory blockade compared with the Bupivacaine group alone. Bupivacaine+fentanyl can be a safer alternative than conventional dose of bupivacaine. These above observation were consistent with our study results.

***Rama Rao VM et al[12]*** Conducted a study in 2021 and found that the intrathecal fentanyl 25mcg and 7.5 mg of hyperbaric Bupivacaine for spinal anesthesia in cesarean section reducing the incidence of side effects associated with it. By its synergistic effect with hyperbaric bupivacaine, it provides better excellent sensory blockade and postoperative analgesia, good hemodynamic stability, less incidence of complications like Nausea, vomiting, and shivering without compromising the safety of mother and fetus in comparison to intrathecal 10mg of 0.5% hyperbaric Bupivacaine alone. The total duration of sensory blockade and duration of effect of analgesia was longer in the B+F group with a P value of 0.001. These above observation were consistent with our study results.

***Jayshree Prajapati et al[10]*** Conducted a study in 2021 and observed that, The addition of fentanyl enhances the quality of block, increases duration of the sensory block and makes the blockade hemodynamically more stable than conventional dose of bupivacaine. These above observation were consistent with our study results.

***Basanta Ghimire et al[13]*** Conducted a study in 2021 and observed that addition of fentanyl 25 mcg prolongs the duration of sensory analgesia for lower limb surgeries. These above observation were consistent with our study results.

**DURATION OF MOTOR BLOCKADE**

In our study we found that, the duration of the motor block in Group 1 was 152.06 ± 14.04 minutes, whereas in Group 2 it was 176.06 ± 8.76 minutes. This indicates that the duration of motor blockade was longer in Group 2 compared to Group 1.

There was a statistically significant difference in the duration of the motor blockade between Group 1 and Group 2 (p-value <0.001).

***Thaer Ali Hussein Al Akam et al*[11]** Conducted a study in 2020 and found that Motor blockade last longer in group A than group B and none of patients required any supplementary anaesthetic interventions during surgery [group A (Bupivacaine- 15mg,3ml) & group B (Bupivacaine- 10mg, 2ml + 25 mcg [1ml] fentanyl)]. These above observation were consistent with our study results.

***Halvadia et al*[8]** Conducted a study in 2013 and found that group B had lesser duration of motor blockade without significantly compromising the duration of sensory block or the operative conditions, none of the patients required intraop anesthetic supplementation, [Group A - 15mg of 0.5% bupivacaine & Group B - 10mg of 0.5% bupivacaine and 25mcg fentanyl]. These above observation were consistent with our study results.

**POST OPERATIVE ANALGESIA**

In our study we found that, the mean VAS score was higher in Group 2 patients as compared to Group 1 patients at different time intervals and there was a significant difference in the mean VAS score of patients between Group 1 & Group 2 at various time intervals, which was statistically-significant, as in [Table 19 & Figure 22,23].

***Himabindu Gandam Venkata et al*[9]** Conducted a study in 2015 and found that combination of low dose 0.5% Bupivacaine with Fentanyl in comparison to 0.5% Bupivacaine alone is haemodynmically stable and provide longer duration of analgesia in caesrean section. These above observation were consistent with our study results.

***Upasana Bhatia et al*[14]** Conducted a study in 2015 and found that low dose Fentanyl (25mcg) used as the adjuvant to intrathecal 0.5% hyperbaric Bupivacaine provides various advantages such as better intra operative analgesia, effective analgesia in post operative period. As it has synergistic action with bupivacaine, it helps in reduction of the dose of bupivacaine for spinal anesthesia; this reduces the incidence of side effects associated with it and assures better quality of anaesthesia. These above observation were consistent with our study results.

**ADVERSE EFFECT**

In our study we found that, out of 29 patients in Group 1, 34.5% had nausea,31.0% had vomited and 34.5% had post operating shivering and out of 29 patients in Group 2, 55.2% had nausea, 44.8% had vomited and 58.6% had post operating shivering, and out of 29 patients .The adverse effects are more in patients in Group 2 after postoperatively as compared to Group 1 patients but there was no significant difference in adverse effects after p ostoperatively in patients of Group 1 and Group 2.

***Bharati Devi Sharma Regmi et al*[15]** Conducted a study in 2019 and found that low dose bupivacaine with Fentanyl provides adequate spinal anesthesia in cesarean section with less number of hypotension, nausea & vomiting in comparison to conventional dose of bupivacaine alone. These above observation were consistent with our study results.

***Manisha et al*[16]** Conducted a study in 2023 and found that addition of 25mcg Fentanyl to low dose

Bupivacaine heavy for spinal anaesthesia reduces the incidences of hypotension, with no observed adverse effects. These above observation were consistent with our study results.

**Conclusion:** The primary outcome of this study indicated that the low-dose Bupivacaine with Fentanyl group showed greater stability in hemodynamic parameters compared to the conventional Bupivacaine dose group, with only a negligible decrease in blood pressure observed.The onset of both motor and the sensory blockade occurred more rapidly in the Group 1, receiving the low-dose Bupivacaine and Fentanyl. The low-dose Bupivacaine with Fentanyl group also demonstrated an increased duration of sensory blockade and a reduced duration of motor blockade. This combination appears to be an effective alternative to the conventional low-dose Bupivacaine alone for procedures such as cesarean sections and infraumbilical surgeries, where early ambulation, shorter hospital stays, effective postoperative pain relief, and reduced morbidity are desired.
The low-dose Bupivacaine with Fentanyl combination ensures better hemodynamic stability than the conventional Bupivacaine alone dose. Therefore, using this combination for spinal anesthesia is a more favorable option for cesarean sections and infraumbilical surgeries.

**References:**

1. MS Hussain. comperative study of intrathecal low dose Bupivacaineand Fentanyl vs vs conventional dose of Hyperbaric Bupivacaine for caesarean section. Bangladesh Journals Online, AKMMC J. 2018; (1) : 57-62
2. Dr. Manisha, Dr. Kadam S, Dr. Monnaiah K. Low dose bupivacaine along with fentanyl in spinal anesthesia with conventional dose of bupivacaine: Hemodynamic changes. European Journal of Molecular & Clinical Medicine. 2023; 10(04): 221-26
3. Girgin N, Gurbet A, Turker G, Bulut T, Demir S, Kilic N, et al. the combination of low dose Levobupivacaine and Fentanyl for Spinal Anaesthesia in Ambulatory Inguinal Herniorrhaphy. J IntMed Res. 2008 Dec; 36(6): 1287-92
4. Gupta P and Singh N. Sample size estimation. How to write thesis and thesis protocol. Jaypee Brothers publisher, India 2014; 1:89-90
5. Yadav R, Keyal N.K, Mahato R. A Comparative study of Bupivacaine and Bupivacaine with Fentanyl for subarachnoid block. Med- Phoenix: Journal of National Medical College. 2023; 8(2): 29-33
6. Yousef E, Ateia I, Mansour N, Abdelsameaa S. Impact of Ozone gel, PRF & A- PRF on Pain and Trismus during Tissue Healing after Extraction of Mandibular Third Molars. Egyptian Dental Journal. 2021 Jul 1;67(3):2075-89.
7. Crossley AWA, Mahajan RP. The intensity of postoperative shivering is unrelated to axillary temperature. Anaesthesia. 2007 22;49(3):60-71
8. Halvadia, S. H., Halvadia, H. B., Joshi, R. M., & Upadhyaya, D. P. (2013). Low Dose Bupivacaine - Fentanyl Vs. Conventional Dose Of Bupivacaine In Spinal Anesthesia For Orthopaedic Procedures In Elderly Patients: Low Dose Bupivacaine - Fentanyl Vs. Conventional Dose Of Bupivacaine. National Journal of Integrated Research in Medicine, 4(1), 50–56.
9. Venkata H.M, Pasupuleti S, Pabba U. G, Porika S, Talari G. A randomized controlled prospective study comparing a low dose Bupivacaine and Fentanyl mixture to a conventional dose of hyperbaric Bupivacaine for caesarean section. Saudi J Anaesth. 2015 Apr-Jun; 9(2): 122-27
10. Prajapati J, Parmar H. Low dose Bupivacaine and Bupivacaine with Fentanyl for spinal anesthesia for transurethral resection of prostrate. IAIM, 2015; 2(9): 11-19
11. Akam T.A.H.A, Hussain E.M. Comparative study of small dose Bupivacaine- Fentanyl vs. Normal dose of Bupivacaine in spinal Anesthesia for patient above 60 years old undergoing surgery. Medico-legal update. 2020; 20(4): 1672-76
12. VM Rama R, Murupudi N.R, Cherukuri B, Ameena Bibi S. A Study of intrathecal low dose

Bupivacaine and Fentanyl versus conventional dose of Bupivacaine alone for elective caesarean section. MedPulse International Journal of Anesthesiology. September 2021; 19(3): 86-90

13. Ghimire B, Khanal K, Ghimire K.K, Bajracharya A. Comparison of intrathecal hyperbaric Bupivacaine alone and hyperbaric Bupivacaine with Fentanyl in lower limb surgery. Nepal Journal of Health Sciences 4(1): 92-99
14. Bhatia U, Parmar S. Comparative study of intrathecal Hyperbaric Bupivacaine and Hyperbaric Bupivacaine with Fentanyl for quality of Anesthesia and duration of Post operative pain relief. GCSMC J Med Sci. 2015; 4(1): 44-48
15. Regmi B.D.S, Deo G.P, Srestha S, Srestha S, Mishra R.T. Low dose hyperbaric Bupivacaine with Fentanyl in spinal Anesthesia in elective caesarean section. Journal of Chitwan Medical College. 2019; 9(2): 79-82
16. Dr. Manisha, Dr. Kadam S, Dr. Monnaiah P. Low dose Bupivacaine along with Fentanyl in spinal anesthesia with conventional dose of Bupivacaine: Hemodynamic changes. European Journal of Molecular & Clinical Medicine. 2023; 10(04): 221-26