

## Comparative Study Of 0.5% Hyperbaric Bupivacaine Versus 0.5% Hyperbaric Bupivacaine with Fentanyl on the Characteristics of Spinal Anaesthesia for Lower Abdominal Surgeries – A Prospective Randomized Study

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### Abstract:

**Introduction:** Regional Anaesthesia particularly spinal Anaesthesia is one of the most commonly used technique world wide. Risk of **Neuropathies** of 5% Lidocaine, Bupivacaine and Ropivacaine are the alternatives for routine use. The duration of the drugs were 2-4 hrs and maximal allowable volume and doses are associated with high incidence of side effects despite suitable precautions. A number of Opioid adjuvants are used to spinal anaesthesia with reduced doses of local anaesthetics to prolong the post operative analgesia, avoiding residual motor paralysis and potential side effects of Opioids given through other routes (IM/IV) for post operative pain relief. Fentanyl Citrate an opioid has been used as an adjuvant in various clinical trials. The aim of the study was to compare the subarchnoid block characteristics with low dose fentanyl with intrathecal bupivacaine.

**Methodology:** After institutional ethics committee approval and written informed consent, 50 Patients of ASA I&II belonging to both sexes posted for elective lower abdominal and orthopedic surgeries. They were randomly allocated into 2 groups, 25 each. Group A received 0.5% hyperbaric bupivacaine 2.5ml with 0.9% normal saline 0.5ml. Group B received 0.5% hyperbaric bupivacaine 2.5ml with fentanyl 0.5ml 25µg. Total volume made up to 3ml to achieve subarchnoid block, Sensory block, motor block, haemodynamic characteristics adverse effects, duration of post operative analgesia statistical analysis and results were noted in two groups. Statistical analysis was done with one way analysis of variance. Duration of Sensory, Motor blockade significantly longer in group B. ( $P < 0.01$ ). Time to first request of analgesia was significantly longer in group-B than group-A ( $P < 0.001$ )

**Conclusion:** Addition of Fentanyl Citrate to intrathecal bupivacaine prolonged the duration of sensory, motor and post operative analgesia without causing significant deleterious effects on the patients.

**Keywords:** Analgesia, Bupivacaine., Fentanylcitrate, Intrathecal ,Post operative.

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### I. Introduction

Spinal Anaesthesia is the most commonly used technique for lower abdominalS surgeries including orthopaedic surgeries, as it is very economical and easy to administer and safe. However using local anaesthetics alone for subarchnoid block associated with relatively short duration of action. Addition of adjuvants like midazolam, ketamine, clonidine etc, to intrathecal bupivacaine significantly prolongs the duration of spinal anaesthesia and also improved the quality of spinal blockade in various clinical studies<sup>1,2</sup>. A common problem during lower abdominal and orthopaedic surgeries under spinal anaesthesia is visceral pain, nausea and vomiting<sup>3</sup>. This problem can be overcome by the addition of anti-emetics preoperatively and the addition of adjuvants to improve the quality of block<sup>4</sup>. Low dose fentanyl an opioid has been proved in various clinical studies to increase the duration of sensory and motor blockade, duration of analgesia and quality of subarchnoid blockade<sup>5</sup> with minimal side effects. The aim of the study was to compare the characteristics of sensory and motor blockade and time to first request of analgesia, haemodynamic changes and adverse effects following intrathecal bupivacaine versus intrathecal bupivacaine with fentanyl.

### II. Methodology

After institutional ethics committee approval written informed consent 50 patients of ASA Grade-I & II belonging to both the sexes were scheduled for lower abdominal and orthopaedic surgeries included in the prospective randomized controlled study.

**Exclusion Criteria:**

1. ASA Grade >III
2. Patients below 16 years and above 35 years of age.
3. Patients with H/O severe systemic diseases, metabolic disorders, neurological, congenital & cardiovascular disorders.
4. Patients with H/O allergy to study drugs i.e., bupivacaine, fentanyl.
5. Patients with H/O any contra indications to spinal anaesthesia.

Two investigators involved in the study. The observer and anaesthesiologist who did intra operative and post operative monitoring were blinded to study. Patients were randomized into 2 groups 25 each into Group A & B.

Baseline parameters like HR,PR,NIBP,SPO<sub>2</sub> were recorded in all the 2 groups. After shifting the patient to operating room routine monitors like NIBP, SPO<sub>2</sub> and ECG were applied to the patient. An emergency resuscitation equipment were kept ready. 18G I V canula was secured and all patients were preloaded with 10ml per Kg of lactated Ringer’s solution. The patients were placed either in the left lateral or right lateral position, under strict aseptic precautions the lumbar puncture was carried out in midline through L<sub>3</sub>-L<sub>4</sub> intrespace with 25G quink babcocks needle. Group A(n=25) patients received 0.5% hyperbaric bupivacaine(2.5ml) with 0.9% normal saline(0.5ml). Group B(n=25) patients received 0.5% hyperbaric bupivacaine(2.5ml) with fentanyl 25µg (0.5ml) In all the groups the total volume administered was made upto 3ml to achieve subarchnoid block. Intra operatively bradycardia was treated with 1mg of I V atropine. Hypotension was treated with rapid boluses of I V fluids and incremental doses of 6mg of ephedrine. The following parameters were observed.

1. Sensory block was assessed by using Pinprick method. Onset time and duration of sensory blockade was recorded.
2. Motor block was assessed by using bromage scale (Table-I). Onset time and duration of motor blockade was noted between 2 groups.
3. Haemodynamic parameters like HR, BP were noted between the 2 groups.
4. Time to first request of analgesia (the duration of post operative analgesia) was compared between the 2 groups.
5. Adverse effects were also noted between the groups. The possible adverse effects like hypotension, bradycardia, nausea, vomiting, sedation, pruritis, urinary retention, respiratory depression etc., were noted.

**Table – 1: Bromage Scale**

BROMAGE SCALE	
0	Free movement of legs and feet, with ability to raise extended leg
1	Inability to raise extended leg and knee flexion is decreased but full flexion of feet and ankle is present
2	Unable to flex knees but some flexion of feet and ankle is possible
3	Unable to move feet, legs or toes

**Statistical Analysis:**

Demographic data was analysed by using fischer’s exart test. Sensory and motor characteristics analysed by using one way analysis of variants of student-t test. Time to first request of analgesia was assessed by using student-t test. It was expressed in Mean, Standard deviation, Absolute numbers and percentage. P<0.001 was considered significant.

**Results**

50 patients were included in the study, all patients were completed the study. Results were analysed based on various parameters such as Age, Sex, Weight, Height, Onset and duration of action of sensory and motor, the highest sensory dermatomal level reached, duration of post operative analgesia and side effects in both the groups.

**Age Distribution:**The age distribution in Group A was 20-50 years with mean age 37.52 years where as in Group B 18-48years with mean age 32.28 years (Table – 2).

**Table – 2: Age Distribution**

Age in years	Group A	Group B
Minimum	20	18
Maximum	50	8
Mean	37.52	32.28
20-29	8	10
30-39	6	8
40-49	11	7
Total	25	25

**Sex Distribution:** 38 Patients were males and 12 patients were females. The significantly higher males are due to the fact that the study included high percentage of orthopaedic patients who are males (Table – 3).

**Table – 3: Sex Distribution**

SEX	Group A	Group B
Males	17	21
Females	8	4
Total	25	25

**Weight Distribution:** The Mean weight in group A was 60.68 whereas in group B 62.32 were comparable (Table -4).

**Table – 4: Weight Distribution**

Weight in Kgs	Group A	Group B
Range	48-72	50-84
Mean	60.68	62.32

Height range in Group A was between 160-178cms with mean height 170.76cms whereas in Group B was between 160-181 cms with mean height 172cms were comparable in both the Groups. This study included 23 cases were orthopaedic and two cases were General Surgery in Group A. Whereas 16 cases were Orthopaedic and 9 cases were General Surgery in Group B.

There were no significant differences in the baseline haemodynamic parameters like PR, BP in all the two groups. P>0.01 statistically not significant. After intrathecal bupivacaine there is invariable fall in systolic blood pressure in all the two groups between first 15-20 minutes followed by gradual recovery. The onset of sensory blockade was 2-4 minutes in group B with mean 2.6 minutes whereas in group A 3-7 minutes with mean 4.64 minutes. P<0.001 is highly significant. (Table-5)

**Table – 5: Sensory And Motor Block Characteristics**

	RANGE (minutes)		MEAN		P-VALUE
	Group A	Group B	Group A	Group B	
Onset of action – sensory	3-7	2-4	4.64	2.6	<0.001
Duration of action – sensory	203- 382	285- 555	250.06	428.44	<0.001
Onset of action – motor	5-9	4-9	6.84	5.16	
Duration of action – motor	160-200	170-215	182.76	199.96	<0.01
Duration of postoperative analgesia	35-210	220-435	117.2	312.32	<0.001

P<0.001 highly significant.

Highest sensory dermatomal level seen at T6 level in both the groups.

Onset of action of motor blockade slightly faster in group B with range 4-9 minutes with mean 5.16, whereas in group A range 5-9 minutes with mean 6.84. Duration of sensory blockade range 285-555 minutes with mean 428.44 in group B, whereas in group A range is 203-382 minutes with mean 250.06. P < 0.001 highly significant. The range of motor blockade in group A was 160-200minutes with mean value of 182.76, whereas in group B range is 170-215minutes with mean value 199.96, prolonged in some extent than group A. P<0.001 (Table-5). The duration of post operative analgesia in group A range was 35-210 minutes with mean value 117.2 whereas in group B it was in the range of 220-435 minutes with mean value of 312.32. P<0.001 highly significant (Table-5). Time taken to two segment regression in group A with mean value of 170.76 minutes whereas in group B 175.84 minutes. P>0.01 not significant.

The incidence of nausea, vomiting, pruritus and respiratory depression were not seen either of the groups could be due to very low dose of fentanyl citrate. There was considerable fall in blood pressure is seen in many patients in both the groups, they were responded well with measures like oxygenation with Facemask, intravenous fluids, footend elevation and vasopressors. Many patients recorded a fall in pulse rate in both the groups, some patients recorded values below 60/minute received atropine 0.5mg I.V (Table-6).

**Table – 6: Adverse Effects**

Intra operative complication	GROUP A		Group B	
	Patients	%	Patients	%
Hypotension	15	60	14	56
Bradycardia	10	40	8	32
Sedation	--	---	19	76
Nausea & vomiting	--	--	--	--
Urinary retention	2	8	3	12
Pruritus	--	--	--	--
Respiratory depression	--	--	--	--

Mild sedation in the grades of II & III were recorded in group B, whereas no patient exhibited sedation in group A, assessed by **E.Wilson et. Al 1990** (Table-7).

**Table – 7**

Sedation Score	Group B
Grade – I	6
Grade – II	12
Grade – III	7
Grade – IV	-
Grade – V	-
Total	25

Opioid agents produce analgesia by binding to specific receptors located primarily in brain and spinal cord regions involved in the transmission and modulation of pain. Fentanyl is highly selective for  $\mu$  opioid receptors. Receptor binding initiates a series of physiologic functions resulting in cellular hyper polarization and inhibition of neuro -transmitter release, effects that are mediated by second messengers<sup>6,7,8</sup>.

### III. Discussion

Regional Anaesthesia, particularly spinal anaesthesia is most commonly used technique worldwide for lower abdominal and orthopaedic surgeries. Using local anaesthetics alone will provide less duration of analgesia. In order to improve the quality of analgesia as well as to provide extended post operative analgesia, various adjuvants are being added to intrathecal local anaesthetics. Of which opioids have gained prominence due to their multiple beneficial effects like prolonged post operative analgesia, stable haemodynamics, reducing post operative analgesic requirements, facilitate early ambulation and reduced hospital stay. The procedure should not cause complications, simple, easy and not time consuming. Should be prevent discomfort due to multiple pricks of IM/IV injections and relieve more work load on nursing staff.

The time of sensory onset was shorter in fentanyl group (Group B). This study was well correlated with previous work done by Singh H; Yang J; Canadian Journal of Anaesthesia 42(11): 987-99<sup>9</sup>.

The duration of post operative analgesia was significantly higher in Fentanyl group were well correlated with studies done by Dr.B.N.Biswas, Dr.A.Rudra, Dr.B.K.Bose, Dr.S.Nath, Dr.S.Chakrabarty, Dr.S.Bhattacharjee. Indian J. Anaesth 2002; 46(6): 469-472<sup>10</sup>

The study conducted by Amr Abdelfatah – The post operative analgesic effect of intrathecal fentanyl versus midazolam in Knee Arthroscopy<sup>11</sup>. Intrathecal fentanyl vs. midazolam. 173/ Eg J Anaesth 2003; 19:173-177. Our study was well correlated with the study.

Effect of addition of Fentanyl (10,20,30 or 40 mcg), intrathecally to 0.5% hyperbaric bupivacaine, on perioperative analgesia and subarchnoid block characteristics in lower abdominal surgeries<sup>12</sup>. A dose response study Anaesthesiology 2002; 96: A885(2002)(A-885) Lee et al. Anaesthesiology 2000; 92: Suppl A77.

Our study was well correlated with study done by G.Sudarshan, B.L.Browne, JNS.Mathews and I.D.Conacher Intrathecal fentanyl for post-thoracotomy pain British Journal of Anaesthesia, Vol 75, Issue 1 19-22<sup>13</sup>. Our study was also well correlated with study done by J.B.Whiteside, D.Burke and J.A.Wildsmith 2003 Comparison of ropivacaine 0.5% (in glucose 5%) with Bupivacaine 0.5% (in glucose 8%) for spinal anaesthesia for elective surgery British Journal of Anaesthesia, 2003, Vol.90,No.3 304-308<sup>14</sup>.

### IV. Conclusion

Addition of low dose (25 $\mu$ g) of fentanyl citrate to 0.5% hyperbaric bupivacaine improves the quality of spinal anaesthesia and increase the duration of post operative analgesia without significant deleterious effects on the patients.

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