Section: Anaesthesia

Original Research Article

COMPARISON OF EFFECT OF INTRATHECAL FENTANYL 25µG WITH 0.5% HYPERBARIC BUPIVACAINE AND ONLY 0.5% HYPERBARIC BUPIVACAINE

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ABSTRACT

Background: To prolong the duration of sensory anaesthesia and analgesia in post-operative period during spinal anaesthesia, different adjuvants have been experimented in addition to the local anaesthetic agent. The present study was undertaken to evaluate and compare the onset and duration of sensory block, motor block and duration of post-operative pain relief by using intrathecal 0.5% hyperbaric bupivacaine with fentanyl 25µg versus only 0.5% hyperbaric bupivacaine in selected groups.

Materials and Methods: We recruited 70 patients who were posted for surgeries below the umbilicus level for our prospective randomized trial. Individuals who met the specified criteria were randomly selected using a simple random sampling method, followed by process of obtaining informed consent. Patients in Group A were administered fentanyl 25µg with 0.5% hyperbaric bupivacaine, while patients in Group B were only given 0.5% hyperbaric bupivacaine intrathecally. Factors, such as the start and length of sensory and motor block, as well as postoperative pain relief, were carefully monitored. After the surgery, the patient's blood pressure was closely monitored, and the time it took for them to receive pain relief was recorded, when their hemodynamics reached a certain level and VAS score exceeded 5 or more than that.

Results: The study revealed that patients in Group A experienced a significantly longer duration of postoperative pain relief compared to Group B (Z value 17. 35). The results of start and duration of sensory and motor block showed no significant findings. In our study, the occurrence of post-operative complications was minimal.

Conclusion: The combination of fentanyl 25µg and 0.5% hyperbaric bupivacaine in spinal anesthesia has no significant impact on the start and duration of sensory and motor blockage but it does extends the postoperative pain relief.

Keywords: Spinal Anaesthesia, Intrathecal Fentanyl, Hyperbaric Bupivacaine, Analgesia, Pain relief, VAS score.

INTRODUCTION

Neuraxial blockade is the preferred method of anaesthesia for surgeries on lower abdomen and lower limb. It is remarkable for its ability to produce intense and extensive analgesia from a tiny dose of local anaesthesia. It is easy to perform, guided by a definite end point and enjoys a high success rate in producing rapid onset of action. It provides effective pain relief for a short duration in post-operative period and thus early analgesic intervention is needed in postoperative period due to which various adjuvants have been studied.

Advantages include simplicity, rapidity and reliability. Disadvantages include higher incidence of hypotension, limited control of level and duration of anaesthesia and possibility of post dural puncture headache.

Local anaesthetic like Bupivacaine is commonly used in spinal anaesthesia but its duration of spinal anaesthesia may be short and limited.

Since postoperative anesthesia is not only desired but also essential for all surgical procedures, a variety of drugs were employed in conjunction with local anesthetic to extend the duration of sensory anesthesia and postoperative pain management.

Now a days drugs like Benzodiazepines,[1] Epinephrine,[2] Morphine,[3] Buprenorphine,[4] Fentany,[1,5] Neostigmine,[6,7] Dexmedetomidine,[8] Clonidine6 have been tried by various authors to potentiate the effect of local anaesthesia drug in spinal anaesthesia.

Fentanyl citrate is safer and commonly used drug among opioids. It is a lipophilic opioid having fast onset of action and short duration of action. When it is added to intrathecal hyperbaric bupivacaine, it prolongs duration of post-operative analgesia.

Fentanyl acts at the μ(mu)-opioid receptor and some studies suggest that The quality of the intrathecal block is improved when fentanyl is given to hyperbaric bupivacaine.

However, it also has negative side effects, such as respiratory depression and itching.

In the current study, intrathecal 0.5% Hyperbaric bupivacaine + fentanyl 25μg was used in the respective groups to examine the length of post-operative pain alleviation and the onset and duration of sensory and motor block.

MATERIALS AND METHODS

The study was conducted on 70 ASA grade I and II patients scheduled for procedures below the umbilicus level under spinal anesthesia after we received approval from the Institutional Ethical Committee and signed consent from each patient. This prospective, randomized, double-blind trial was conducted at our institute from October 2022 to March 2024.

Inclusion & Exclusion Criteria:

Patients undergoing surgeries below umbilicus level, of age between 20-60 years, whose weight in range of 42-86 kg, and height was between 145-180 cm, belonging to ASA I and II were included in study.

Patient refusal, ASA III and IV patients, Spinal anesthesia contraindications include bleeding diathesis, hypovolemia, and infection at the intrathecal injection site, allergy to bupivacaine and fentanyl, Patients undergoing obstetric procedures were not included in our study.

Sample Size:

$$n = \left[\frac{Z_{\frac{\alpha}{2}}.\sigma}{E}\right]^2$$

Where n= Sample Size

Z= Standard Normal Variate α= Level of significance

σ = Standard Deviation of Population

(from literature review/ past studies the rough estimate is 15) E=Error level= 5%

At 5% level of significance Z α/2 =1.96

Hence the estimated sample size is 34.57 which is approximately 35.

For the study two groups each of size 35 are investigated.

Statistical Analysis: Data analysis was done using SPSS (statistical package for the social science) Version 20 for windows.

All quantitative data (continuous variable like Sensory block time, Motor block time, Post-operative VAS score) presented in mean ± SD at decimal point. The data thus obtained was statistically analyzed using Z test (for quantitative data (as n>30) & Chi square test (for qualitative data).

A p-value of <0.05 and Z-test of >2 considered statistically significant.

Pre Anaesthetic Assessment: One day prior to surgery for all selected patients including detailed history, investigations, drug therapy and drug allergy was taken. A clinical examination of the patient was performed including general and systemic examination. All patients were kept fasting for 6 hours prior to surgery.

Visual Analogue Score (VAS) was explained to patients preoperatively.

All patients were allocated by randomization using closed opaque envelope technique in 2 groups as mentioned below,

GROUP A: (case group n=35) got 0.5 ml (25μg) of fentanyl and 3.5 ml of 0.5% hyperbaric bupivacaine in the subarachnoid area.

GROUP B: (control group n=35) got 0.5 ml of normal saline and 3.5 ml of 0.5% hyperbaric bupivacaine in the subarachnoid area.

Intravenous access was secured in preoperative area and intravenous infusion was commenced.

All baseline vital parameters like heart rate, MAP, SpO2 were noted and documented.

The patients were premedicated with Ondansetron 8mg& Ranitidine 50mg intravenously and then patients were shifted to operation theatre (OT).

In OT, patients were connected to monitors and vital data were recorded. Then patients were prepared for spinal anaesthesia.

Before the beginning of anaesthetic procedure, the patient was subjected to Group A or Group B by opening of the envelopes. The randomization was kept blind to the observer who monitored the patient in intraoperative and postoperative period. The person who has observed and recorded data for assessment has no knowledge of the regime of Group A or Group B that the particular patient receive.

Spinal anaesthesia was performed in sitting position with proper aseptic precautions. Local skin wheal was raised with 2ml of 0.5% lignocaine at the site of lumbar puncture. Then lumbar puncture was performed with 23 Gauge Quincke's spinal needle in

L3-L4 space. After successful subarachnoid puncture, drug solution was injected slowly according to randomization, without the knowledge of observer who was supposed to document the observations. The time of intrathecal injection was noted.

Up to the conclusion of the procedure, the patient's heart rate, electrocardiogram, mean arterial pressure (MAP), and SpO2 were continuously monitored.

Sensory block was evaluated by loss of sensation using pin prick technique bilaterally at lateral part of foot (S1). Time of onset of analgesia was recorded.

Modified Bromage Scale as given below utilized to decide the grade of motor block. Grading was carried out every two minutes after the local anesthetic was injected subarachnoidly. The entire grading process took ten minutes. The third grade was regarded as a whole motor block.

Any intraoperative complication was noted.

Duration of surgery was considered from the time of spinal anaesthesia till the time of dressing was done.

After 4 hours of commencement of spinal anaesthesia, the patient was questioned about pain perceived. Subsequently patient was asked the same question about feeling of pain every hour for the next 8 hours and then 2nd hourly. At any stage when patient confirmed the feeling of pain, he/she was asked to give VAS score for documenting the severity of pain. The total duration from the time of giving subarachnoid block, to the instance when patient complained of pain was calculated.

At the same time interval like assessment of pain the patient was also assessed for regression of motor tone. The pulse rate, MAP, SpO2 were recorded concurrently.

Whenever VAS was 5 or above, systemic analgesic was administered to patient. In our study, we used Inj. Diclofenac Sodium (75mg) intramuscularly. The duration of first analgesic need from the time of administration of spinal anaesthesia was documented. Any postoperative adverse effects or complications were looked for before discharge.

RESULTS

The charts and tables are designed from the data obtained from every patient and compiled from master chart. Data is expressed as Mean ± SD.

Table 1: Demographic characteristic of our study

Sr. No.	Characteristic	Group A	Group B
1	Age in years	42.7±13.7	43.5±10.7
2	Height in cm	158.3±6	159.6±7.03
3	Weight in kg	55.4±6.8	58.4±8.08
4	Sex of patients(M:F)	17:18	18:17
5	ASA grade (I : II)	17:18	20: 15
6	Duration of surgery	119±25	105±19.7

Table 2: Comparison of onset of sensory block & motor block

	Group A	Group B	Z	
Starting of sensory Block(min) Mean ± SD	3.3 ± 0.8	3 ± 0.7	1.67	Insignificant
Starting of motor Block (min) Mean ± SD	4.7 ± 1.04	5 ± 0.8	-1.35	Insignificant

Comparison of startring of sensory block on statistical analysis the difference was not significant (Z value 1.67). Regarding comparison of starting of motor block, The calculated Z value of -1.35, suggesting the observed difference has no significance at 95% confidence limit.

Table 3: Comparison of heart rate & mean arterial pressure in 1st hour (at different time interval in minutes)

Measured at time interval from the start of intrathecal block		5 min Mean ± SD	10 min Mean ± SD	20 min Mean ± SD	30 min Mean ± SD	45 min Mean ± SD	1 hour Mean ± SD
Heart Rate	Group A	77 ± 10.1	74 ± 12.3	73 ±11.4	75 ± 10.2	75 ± 9.4	76 ± 8.7
	Group B	89 ± 8.6	83 ± 8.8	79 ± 9	78 ± 7.4	78 ± 8.1	79 ± 7.4
Z value		-5.35	-3.52	-2.44	-1.4	-1.43	-1.56
Mean Arterial Pressure	Group A	87 ± 11.2	83 ± 8.4	82 ±9.3	81 ± 9.4	83 ± 8.8	83 ± 8.3
	Group B	92 ± 5.9	79 ± 4.9	78±4.4	78 ± 4.8	79 ± 4.6	79 ± 4.9
Z value		-2.34	2.43	1.19	1.68	2.38	2.46
Z value > 2 suggestive of significance							

Assessment of pain: The subjective measurement of pain was documented in form of VAS - Visual Analogue Scale in each group.

Table 4: Comparison of vas score in both groups at various time interval in hour

	MEAN VAS		SD			
Time (hour) after sensory block	A	B	A	B	P Value	
4	4	5	1.06	0.6	<0.05	Significant
5	4	5	0.9	0.7	<0.05	Significant
6	5	4	0.65	0.7	<0.05	Significant
8	5	4	0.7	0.8	<0.05	Significant
10	4	4	1.06	0.7	>0.05	Insignificant
12	3	4	0.7	0.9	<0.05	Significant

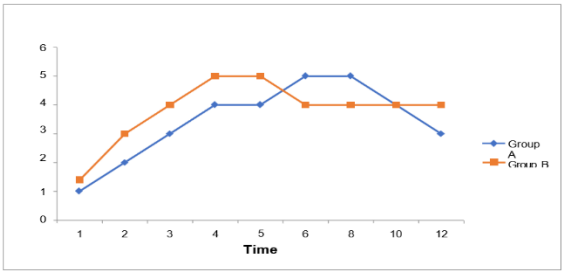

Figure 1: MEAN VAS

The [Figure 1] depicts the line diagram of mean VAS in both the groups. As it is clearly evident that the line curve in Group A which received Fentanyl is shifted to the right. This suggests that the equivalent VAS for pain was observed at a longer duration in Group A as compared to Group B. However, the peak mean VAS score was same around 5 in both the groups although at different time intervals.

Table 5: Comparison of duration of analgesia

	Group A	Group B
Duration of Analgesia (min) Mean ± SD	576 ± 93.3	280 ± 38.48
Z	17.35	
	Highly Significant	

[Table 5] suggested the duration of analgesia was statistically significant and longer in Group A as compared to Group B. The calculated Z value of 17.35, suggests that the observed difference is highly significant at 95% confidence limit (P value <0.05).

Table 6: Comparison of duration of sensory & motor block

	Group A	Group B	Z	
Duration of Sensory Block (min) Mean ± SD	190 ± 30.94	200 ± 19.57	-1.61	Insignificant
Duration of Motor Block (min) Mean ± SD	217 ± 33.98	220 ± 24.91	-0.41	Insignificant

[Table 6] suggests that the observed difference has no significance at 95% confidence limit.

Comparison of complications in both the groups:
Group A experienced a slightly higher incidence of pruritus (14.285%) than Group B.
In both groups, the remaining problems did not reach statistical significance.

DISCUSSION

Addition of fentanyl as an adjuvant prolonged the bupivacaine spinal block. Fentanyl when used in lower dose is safe and prolongs the postoperative pain relief of intrathecal bupivacaine. There is scarcity of studies comparing safety and effectiveness of fentanyl with bupivacaine. In light of this, we examined the safety, effectiveness, and post-operative pain management of intrathecal fentanyl (25µg) used as an adjuvant with 0.5% hyperbaric bupivacaine in patients having procedures below the umbilicus level.

Demographic Data [Table 1]: Regarding age, height and weight, gender distribution, and ASA grade, there was no discernible difference between the two groups.
The mean surgical operating time varied significantly.
Additionally, demographic factors (age, height, sex, ASA grade, and length of operation) [Table 7] were found to be comparable by Bajwa et al. (2017).[9]

Table 7: demographic characteristic of Bajwa et.al. (2017)

Characteristics	BF group (n=50) (mean± SD)	BC group (n=50) (mean± SD)
Age (year)	42.53 ± 15.43	44.76 ± 14.20
Height (cm)	154.75 ± 9.54	153.25 ± 8.59
Weight (kg)	64.54 ± 12.50	61.80 ± 8.38
Sex of patients (Male : Female)	16:18	18:16
ASA grade	1-2	1-2
Duration of Surgery (minutes)	120.47 ± 54.63	128.65 ± 7.10

Table 8: Comparison of Sensory and Motor blockade and Analgesic duration

Parameters	Groups				Z
	A		B		
	Mean	SD	Mean	SD	
Start of sensory blockade	3.3	0.8	3	0.7	1.67
Start of motor blockade	4.7	1.04	5	0.8	-1.3
Duration of sensory blockade	190	30.94	200	19.57	-1.61
Duration of motor blockade	217	33.98	220	24.91	-0.41
Duration of pain relief	576	93.3	280	38.48	17.35
Z >2, p<0.05 suggestive of statistical significance					

In our study, The duration of analgesia was longer in Group A than in Group B, but the start and duration of sensory and motor blockage were similar in both groups. Group A required rescue analgesia after a longer period of time than Group B (p<0.0001).

Our findings were correlated with below mentioned studies:

- Jayshri Bogra, Namita arora et al,[10] (2005) studied synergistic effect of intrathecal fentanyl and bupivacaine in spinal anaesthesia in 120 parturients who underwent elective caesarean. They divided patients into six groups, identified as B8, B10 and B12.5; received 8, 10 and 12.5mg of bupivacaine and FB8, FB10 and FB12.5 received combination of 12.5 µg fentanyl respectively. They concluded bupivacaine-fentanyl combination leads to abolishment of the visceral pain, increased hemodynamic stability and increased duration of post-operative analgesia.
- Shashikala, Shrinivas et al,[11] (2014) conducted study in 90 healthy parturients undergoing elective caesarean, divided them in two groups in which one received 0.5%Hyperbaric bupivacaine alone and the other received 0.5%Hyperbaric bupivacaine with 12.5µg fentanyl citrate intrathecally. They observed statistically highly significant difference in duration of analgesia 165±29.8 minutes in hyperbaric bupivacaine alone and 259.4±35.5 minutes in fentanyl group.
- Amir Sabertanha, Gholam Reza Makhmalbaf et al,[12] (2023) conducted study on 40 patients undergoing lower limb surgery, divided them in two groups in which one received bupivacaine alone and the other group received bupivacaine plus dextrose 5% and fentanyl 25µg in subarachnoid space. They concluded that the mean time of anaesthesia onset and analgesia duration were significantly longer in bupivacaine plus fentanyl group than bupivacaine alone.

Hemodynamic Parameters: Heart Rate: In our study, heart rate were comparable in both groups and statistically insignificant. (Z >2)

Mean Arterial Pressure: In our study, the fall in Mean Arterial Pressure (MAP) in was significant at 10 minutes, 45 minutes and 60 minutes (Z < 2). MAP in both groups was equivalent and statistically insignificant throughout the rest period. (Z > 2)

Blood pressure and heart rate, two hemodynamic indicators, did not differ statistically significantly between the two groups, according to Bajwa et al.5

Adverse effects or Complications: The dose of Fentanyl selected in this study did not produce excessive sedation, as at no time sedation score exceeded 2 and no patient developed respiratory depression or fall in SpO2. In fact, the sedation produced by Since every patient stayed composed and quiet during the intraoperative and postoperative phases, fentanyl was determined to be beneficial. The two groups' sedation scores did not differ in a way that was statistically significant.

Our study is comparable with Nasr et al,[13] and Elzayyat et al,[14] with respect to sedation score.

No any patient developed shivering during intraoperative or post-operative period.

The incidence of nausea and vomiting was not significant in both groups. It should be noted that in this study Inj Ondansetron IV 8 mg was administered in all cases as part of premedication. Our study is comparable with Nasr et al,[13] Bansal et al,[15] Elzayyat et al,[14] and Chatrath et al,[16] with respect to these adverse effects.

Limitations

Patients with high risk factors were excluded from study. The generalization of the findings is the limitation in the study.

Being a teaching institute, the spinal anaesthesia is given by doctors of the different seniority. Whether this has any effect is not clear.

Recommendations

Further studies based on comparison between different doses can be considered.

Further studies based on comparison between normal risk patients and high risk patients can be considered.

CONCLUSION

Following conclusions were drawn from this study:

The need for rescue analgesia lasted much longer, delaying the administration of systemic analgesics.

The duration of sensory and motor block is not prolonged by fentanyl.

No notable negative consequences were noted.

Therefore, we draw the conclusion that intrathecal fentanyl, when used as an adjuvant to hyperbaric bupivacaine, is a safe and effective way to extend post-operative pain management with moderately controlled hemodynamics and negligible side effects.

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