Section: Anaesthesia

Original Research Article

COMPARISON OF FENTANYL, TRAMADOL AND MIDAZOLAM WITH HYPERBARIC BUPIVACAINE FOR POST OPERATIVE PAIN RELIEF IN SUBARACHNOID BLOCK IN LOWER LIMB AND UPPER ABDOMINAL SURGERIES

Jatin Kohli[1], Vineet Tyagi[2], Salma Shazia[3]

[1]Post Graduate Resident, Department of Anaesthesia, Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, India
[2]Associate Professor, Department of Anaesthesia, Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, India
[3]Assistant Professor, Department of Anaesthesia, Muzaffarnagar Medical College, Muzaffarnagar, Uttar Pradesh, India

Received : 11/10/2024
Received in revised form : 22/11/2024
Accepted : 08/12/2024

Keywords:
Subarachnoid Block, bupivacaine, midazolam, fentanyl, tramadol, post operative analgesia.

Corresponding Author:
Dr. Vineet Tyagi,
Email: vineetngmc@gmail.com

DOI: 10.47009/jamp.2024.6.6.79

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (6); 410-414

Abstract

Background: Intrathecal route of administration of local anesthetic agent have been the most effective and definitive method of providing anaesthesia and post operative analgesia. Addition of adjuvant to local anaesthetic agent for subarachnoid blockage results into potentiation of blockade effect and prolongation of postoperative analgesia. It is helpful in reducing the usage of post-operative analgesic and dosage of Bupivacaine. The aim is to evaluate and compare the potency and duration of post operative analgesic action of intrathecal drugs – Fentanyl, Tramadol and Midazolam with Hyperbaric Bupivacaine. **Materials and Methods:** 200 patients were chosen for the study and were divided into 4 groups. Group B received Bupivacaine (0.5%) heavy (3ml) + (0.4 ml) of 0.9% saline, Group BF received bupivacaine (0.5%) heavy (3ml) + fentanyl (20 ug/0.4ml), Group BT received bupivacaine (0.5%) heavy (3ml) + tramadol (25 mg/ 0.5ml), group BM received bupivacaine (0.5%) heavy (3ml)+ midazolam (2mg/0.4ml) (preservative free). Duration and onset of sensory and motor block was recorded along with VAS and Bromage score. **Result:** Mean Onset of sensory block was fastest in group BM (2.62 mins) followed by BF(2.74 mins), BT(2.79 mins) and B(3.08 mins). Mean Regression to S1 Dermatome was 157.4, 194.19, 183.45 and 228.13 minutes in group B, BF, BT and BM respectively. Mean duration of motor blockade was 143.89, 182.27, 174.41 and 190.5 minutes in group B, BF, BT and BM respectively. VAS score was least in group BM followed by BF and maximum in group B. **Conclusion:** The bupivacaine-midazolam prolonged the duration of sensory and motor blockade, improved analgesia, has lower pain score, and prolonged duration of postoperative analgesia as compared to all the other drugs used in this study. So, addition of intrathecal midazolam to bupivacaine is a better choice.

INTRODUCTION

Any expertise in anaesthesia requires knowledge of pain relief during surgery and also into the postoperative period.[1] Spinal anaesthesia was first performed by Corning in 1885 and first used deliberately by Bier in 1898.[2]

Subarachnoid block is one of the most widely practiced and effective regional approach for elective and emergency caesarean sections, lower abdominal surgeries, lower limb orthopedic and urological procedures.[3] A common problem during abdominal surgeries under spinal anaesthesia is visceral pain, nausea, and vomiting. The addition of opioids to local anaesthetic solution has disadvantages, such as pruritus and respiratory depression.[4]

Till recently, bupivacaine 0.5% heavy was the only drug used for spinal anaesthesia after the discontinuation of Lidocaine's intrathecal use. However, postoperative pain control is a major problem because spinal anaesthesia using only local anaesthetics is associated with relatively short duration of action, and thus early analgesic intervention is needed in the postoperative period. Addition of adjuvant to local anaesthetic agent for subarachnoid blockage results into potentiation of blockade effect and prolongation of postoperative

ISSN (O): 2687-5365; ISSN (P): 2753-6556

analgesia.[5] A number of adjuvants such as Fentanyl, Tramadol and Midazolam and others have been studied to prolong the effect of spinal anaesthesia.[6,7] We conducted this study to compare the intrathecal fentanyl, Tramadol and midazolam combination with hyperbaric bupivacaine for quality of anaesthesia and post-operative analgesia in patients undergoing upper abdominal and lower limb surgeries.

MATERIALS AND METHODS

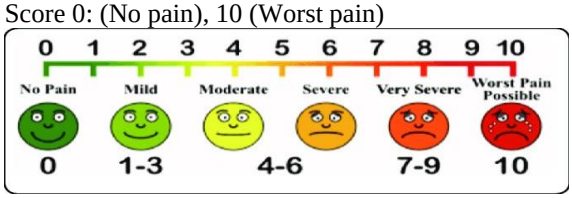
This hospital based observational study was conducted at The Department of Anaesthesiology, Muzaffarnagar Medical College, Uttar Pradesh, after the approval of Institutional Ethical Committee and informed consents from the patients. 200 adults of either sex, posted for elective lower limb and abdominal surgery under subarachnoid block were included in the study and randomly allocated into four groups of 50 each. Group B (received Bupivacaine 0.5% heavy 3ml + 0.4 ml of 0.9% saline), Group BF (received bupivacaine 0.5% heavy 3ml + fentanyl 20 ug/0.4ml), Group BT (received bupivacaine 0.5% heavy 3ml + tramadol 25 mg/ 0.5ml), Group BM (received bupivacaine 0.5% heavy 3 ml+ midazolam 2 mg/0.4ml preservative free). Patients of ASA grade III or higher, with local skin infections at site of injection or having coagulopathy / bleeding disorder are excluded from the study.

Methodology

Vital signs including Blood Pressure (BP), Oxygen Saturation (SPO2), End tidal Carbon Dioxide (ETCO2), Respiratory Rate (RR), Heart Rate (HR), and Electrocardiography (ECG) were closely monitored. Additionally, the Visual Analogue Scale (VAS) Score, Sedation Score, and Bromage Score were assessed. The onset of sensory and motor blockade was recorded. Adverse effects such as nausea, vomiting, respiratory depression, urinary retention, shivering, and pruritus were observed and managed appropriately (using vasopressors, antiemetics, etc.). Baseline measurements were taken before administering the block, followed by measurements at 5-minute intervals for the first 30 minutes and then at 15-minute intervals until the end of the surgical procedure. Subsequently, the patient was transferred to the Post-Anaesthesia Care Unit. In the Post-Anaesthesia Care Unit (PACU), trained anaesthesia personnel and other paramedical staff assessed vital parameters and conducted specialized monitoring, including sedation scores, pain Visual Analog Scale (VAS) scores, Bromage scores, and evaluation of adverse effects such as urinary retention, respiratory depression, pruritus, and postoperative nausea and vomiting (PONV). These assessments were performed at specific time intervals: 1st, 2nd, 4th, 6th, 8th, 12th, and 24th postoperative hours. When patients required analgesia during the postoperative period, rescue analgesics were administered based on patient demand or pain VAS scores (rescue analgesia). Diclofenac (75 mg) was given intramuscularly if the pain VAS score was between 4 and 5, and for severe breakthrough pain (VAS > 5), pentazocine (30 mg) was administered intramuscularly.

A. Visual Analogue Scale (VAS)

Score 0: (No pain), 10 (Worst pain)



B. Bromage Scale (Motor Blockade) – (0-3)

0 = Able to straight leg raise against resistance (No motor block)

1 = Unable to straight leg raise but able to flex knee

2 = Unable to flex knee but able to dorsiflex ankle

3 = Unable to move hip, knee or ankle

C. Sedation Score (0-3)

0 = Patient is awake and talkative

1 = Patient is awake but uncommunicative

2 = Patient is drowsy, quiet and easily arousable

3 = Patient is asleep

As the subarachnoid block effects waned, patients were encouraged to hydrate and attempt voiding using standardized protocols. Once patients were capable of oral fluid intake (without contraindications), the intravenous (IV) drip was discontinued. A 24-hour follow-up assessment was conducted, after which patients were transferred to the general ward. Data were collected and underwent statistical analysis.

Data was collected and subjected to statistical analysis.

Statistical Analysis: With the assistance of a statistician, the data was tabulated in an excel spreadsheet. For statistical analysis, the measures per group's means and standard deviations were employed (SPSS 24.00 for Windows; SPSS Inc., Chicago, USA).One way ANOVA was used to statistically evaluate the data for each evaluation point. The t test and chi square test were used to assess the difference between the all groups, and $p < 0.05$ was chosen as the significance level.

RESULTS

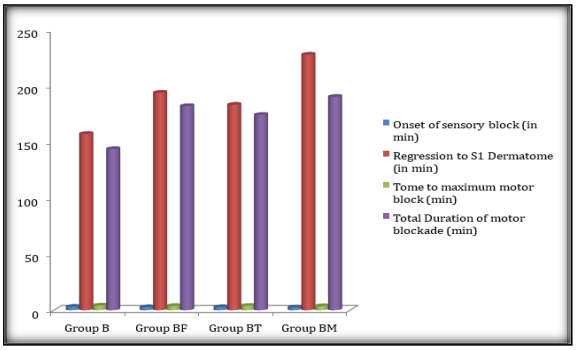


Figure 1: Motor and sensory block

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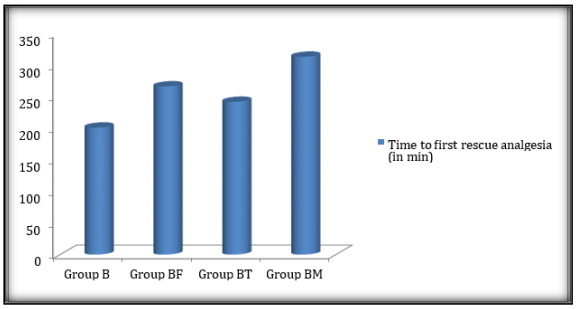

Figure 2: Time to first request and total consumption of postoperative rescue analgesia

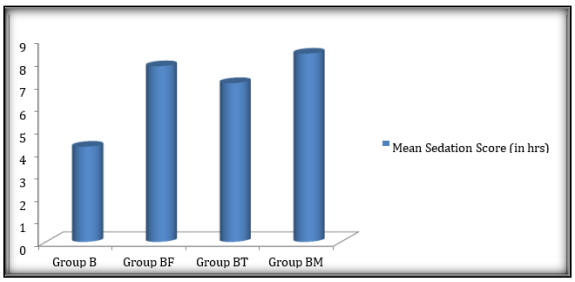

Figure 3: Comparison of sedation score

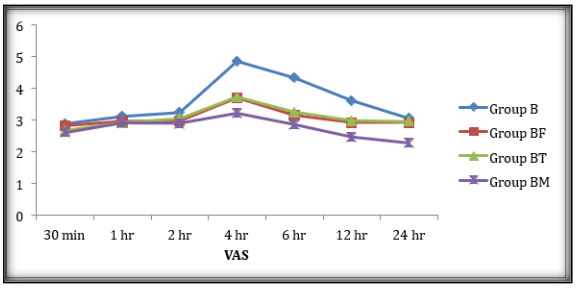

Figure 4: VAS comparison

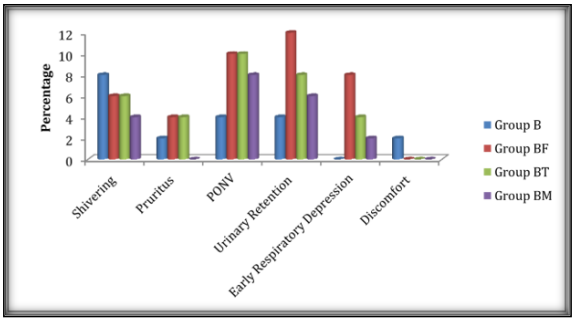

Figure 5: Comparison of complications among the study groups

Table 1: Motor and sensory block characteristics.

Interval	Group B		Group BF		Group BT		Group BM		p value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Onset of sensory block (in min)	3.08	0.57	2.74	0.62	2.79	0.48	2.62	0.71	0.005*
Regression to S1 Dermatome (in min)	157.4	17.81	194.19	21.38	183.45	20.89	228.13	25.96	0.002*
Time to maximum motor block (min)	4.21	0.94	3.82	1.01	3.97	0.92	3.66	1.05	0.009*
Total Duration of motor blockade (min)	143.89	14.65	182.27	19.21	174.41	17.80	190.5	18.42	<0.01*

*: statistically significant

Table 2: Time to first rescue analgesia

Interval	Group B		Group BF		Group BT		Group BM		p value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Time to first rescue analgesia (in min)	200.8	12.42	265.91	10.30	241.56	13.47	312.78	11.76	<0.01*

*: statistically significant

Time to first rescue analgesia was required earlier in group B (200.8 min) followed by BT (241.56 min), BF (265.91 min) and BM (312.78 min) with statistically significant difference p<0.05.

Table 3: Comparison of sedation score

Group	Sedation Score (in hrs)		p value
	Mean	SD	
Group B	4.23	1.5	<0.01*
Group BF	7.81	2.2	
Group BT	7.06	1.7	
Group BM	8.37	1.4	

*: statistically significant

Table 4: VAS score comparison

Interval	Group B		Group BF		Group BT		Group BM		p value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
30 min	2.88	1.07	2.81	1.35	2.67	1.34	2.59	1.13	0.19
1 hr	3.11	0.96	2.95	1.01	2.92	0.97	2.90	1.1	0.27
2 hr	3.23	0.81	2.96	1.01	3.04	1.02	2.89	1.1	0.11
4 hr	4.84	0.90	3.69	0.96	3.72	0.99	3.21	0.87	0.005*

ISSN (O): 2687-5365; ISSN (P): 2753-6556

6 hr	4.32	0.78	3.14	1.35	3.25	1.08	2.85	0.98	0.002*
12 hr	3.61	0.83	2.91	1.14	2.98	0.92	2.45	1.02	0.001*
24 hr	3.05	0.87	2.92	1.08	2.95	0.90	2.26	1.17	0.009*

*: statistically significant

Table 5: Comparison of complications

Interval	Group B		Group BF		Group BT		Group BM		p value
	N	%	N	%	N	%	N	%	
Shivering	4	8	3	6	3	6	2	4	0.62
Pruritus	1	2	2	4	2	4	0	0	0.71
PONV	2	4	5	10	5	10	4	8	0.85
Urinary Retention	2	4	6	12	4	8	3	6	0.70
Early Respiratory Depression	0	0	4	8	2	4	1	2	0.43
Discomfort	1	2	0	0	0	0	0	0	0.89

Most common complication was PONV. All the complications were comparable among all the study groups [Table 5, Figure 5].

DISCUSSION

A key element of surgical recovery is the efficient management of pain. It functions by attenuating somatic, endocrine, and autonomic reflexes, potentially reducing perioperative morbidity. The current hospital-based observational study involved 200 patients who were scheduled for upper abdomen and lower limb procedures at Muzaffarnagar Medical College and Hospital.

Hemodynamic Parameters (SBP, DBP, MAP, Heart Rate, SPO2) were comparable in our study groups as p value was > 0.05.

Sensory Block: In the present study; onset of sensory block was fastest in group BM (2.62 mins) followed by BF (2.74 mins), BT (2.79 mins) and B (3.08 mins) with statistically significant difference as p<0.05. Similar findings were concluded by Kurmanadh et al,[8] compared the effects of intrathecal midazolam (1 mg) and fentanyl (25 micrograms) as additives to intrathecal hyperbaric bupivacaine (0.5%) for spinal anaesthesia and concluded that intrathecal combination of bupivacaine and midazolam (223.6 ± 35.5 sec) offers same advantages in terms of onset of sensory blockade with fewer side effects as compared to bupivacaine and fentanyl (227.9 ± 25.6 sec).

Total duration of motor blockade (mins): Total duration of motor blockade (min) was 143.89, 182.27, 174.41 and 190.5 minutes in group B, BF, BT and 68 Discussion BM respectively. Hence total duration of motor blockade (mins) was maximum prolonged in group BM followed by BF, BT and B with statistically significant difference as p<0.05. Similar findings were concluded by Gupta Anshu et al,[9] in 2015 conducted a study which was designed to study the efficacy of intrathecal midazolam in potentiating the analgesic duration along with sensorimotor blockade and concluded that it increases the onset of sensory block in fentanyl(25µg) & midazolam(1mg) in combination with bupivacaine(4.04 ± 0.86 min) as compared to fentanyl with bupivacaine (4.54 ± 0.93 min) , increases the onset of motor block in fentanyl(25µg) & midazolam(1mg) in combination with bupivacaine (7.64±0.31 min) as compared to fentanyl with bupivacaine (7.68±0.46 min) as well as duration of motor block in fentanyl & midazolam with bupivacaine (201.2±11.57 min) as compared to fentanyl with bupivacaine (192.2±21.17 mins) and without any haemodynamic compromise with significant potentiation of the duration of analgesia with the addition of intrathecal midazolam to the bupivacaine fentanyl mixture (470.68±37.51 min) as compared to bupivacaine fentanyl combination (420.8±32.39 min).

Time to first rescue analgesia: Time to first rescue analgesia was required earlier in group B (200.8 mins) followed by BT (241.56 mins), BF (265.91 mins) and BM (312.78 mins) with statistically significant difference as p<0.05. Similar findings were concluded by Ebied et al,[10] in their study described that intrathecal midazolam safely potentiates postoperative analgesic effect of bupivacaine-midazolam (210.9 ± 54.5 mins) in spinal anaesthesia as compared to bupivacaine-fentanyl combination (150.8 ±41.9 mins).

Mean VAS till 2hours was found to be comparable among the study groups. At 4 hours, VAS score was revealed least in group BM followed by BF and maximum in group B. Similar findings were reported at 6hr, 12hr and 24hr. Similarly Abdelrady et al,[11] reported that median the VAS scores were lesser in midazolam than fentanyl group.

CONCLUSION

In our present study we conclude that addition of midazolam to bupivacaine gives prolonged onset and duration of sensory & motor blockade and duration of analgesia as compared to fentanyl and tramadol with minimal side effects. So, addition of intrathecal midazolam to bupivacaine is a better choice for subarachnoid block in patients posted for upper abdomen and lower limb surgeries.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556