ORIGINAL RESEARCH PAPER
Volume - 12 | Issue - 03 | March - 2023 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

COMPARISON OF INTRATHECAL MIDAZOLAM VERSUS INTRATHECAL FENTANYL AS AN ADJUVANTS IN SPINAL ANAESTHESIA TO BUPIVACAINE FOR INFRAUMBILICAL SURGERIES, A RANDOMIZED INTERVENTIONAL CLINICAL STUDY

Anesthesiology

Dr. Vikram Singh Meena Resident doctor, Department of Anaesthesiology, SMS medical college and attached hospitals, Jaipur, Rajasthan

Dr. Satish Chand Meena* Associate professor, Department of emergency medicine, SMS medical college and attached hospitals, Jaipur, Rajasthan. *Corresponding Author

Dr. Suresh Chand Resident doctor, Department of Anaesthesiology, SMS medical college and attached hospitals, Jaipur, Rajasthan

ABSTRACT

Background- This study is regarding the use of non-opioid adjuvants to intrathecal local anesthetics. Opioids are commonly used as an adjuvant; however, the use of opioids is associated with potential respiratory depression and other side effects. The purpose of this study is to find out non-opioid alternative as an adjuvant to local anesthetics for analgesia in spinal anesthesia. **Methods-** This study was conducted in SMS Hospital, Jaipur, Department of Anaesthesiology. 72 patients, scheduled to undergo different infraumbilical surgeries were chosen randomly and pre-anesthetic check-ups was done same day. Patients of either sex, age ranging between 20-60 years, belonging to ASA grade 1 and II were chosen for study. Informed consent was obtained from each patient. **Results-** Mean duration of sensory and motor block in Group A and group B was 278.92,194.14 and 194.42,52.17 respectively(P<0.001S). Total duration of analgesia(min) was not significant (P=0.137NS). Maximum number of the cases 91.67% in Group A were observed in the 4score followed by 8.33% in 5 score. As compared to in other group B, maximum number of the cases were observed 61.11% in the 4. And followed by 30.56in5 and rest 8,33% were in score 6. this observation was statistically. Hypotension cases were observed in 13.88% of Group A and lower 11.11% in Group B (p value = 1.00NS); Bradycardia cases were observed in 5.55% of Group A and 2.78% in Group B, also statistically not significant (P = 1.000NS). Pruritis was observed only in group B (13.88%) also statistically significant. **Conclusion-** Our study concluded that midazolam cause longer duration of motor and sensory block and visual analogue score is also lower postoperatively in initial hours, however, there was no difference in the total duration of effective analgesia between adjuvant intrathecal midazolam as compared to intrathecal fentanyl for patients undergoing infra umbilical surgery.

KEYWORDS

Midazolam, Fentanyl, Infra Umbilical Surgery

INTRODUCTION

Midazolam produces a synergistic effect on postoperative analgesia when administered intrathecally with bupivacaine.1-2 Previous reports have shown that administration of intrathecal midazolam with local anesthetics prolongs the duration of spinal anaesthesia and produces longer postoperative analgesia after lower abdominal and perianal surgeries. 3-4 None of these studies reported any serious adverse effects in patients receiving intrathecal midazolam. A large cohort study investigating the adverse neurological effects of intrathecal midazolam has also found no association between intrathecal midazolam and neurologic symptoms.[5] However, none of the studies to date compared the efficacy of intrathecal midazolam with fentanyl in infra umbilical surgeries. Therefore, this study is to find out non-opioid alternative as an adjuvant to local anesthetics for analgesia in spinal anesthesia.

METHODS

Study Design:
Hospital based double blinded randomized interventional study.

Study Period:
After approval of plan from Research Review Board till the completion of the desired number of cases.

Sample Size:
At 95% confidence interval with 80% power and 0.05 alpha error a sample size of 36 is required for each group (36*2=72 total) with anticipated minimum mean VAS score difference of 0.8 at rescue analgesia to reject null hypothesis of equality of two drugs name midazolam and fentanyl group.

Sampling Technique:
nonprobability sampling

Study Universe:
patients undergoing infraumbilical surgery.

Randomization:
Randomization was done by computerized random number table method where a total of 72 envelopes, 36 in each group were prepared by another person who was blinded about the study. After recruitment, every patient was allowed to draw one envelope and grouped accordingly.

Double Blinding:
Observer who measures study variable should be different from anesthesiologist who was give the study drug. Both the agent is transparent solutions and looks the same hence, neither the doctor nor the participant was aware of group allocation and drugs received. The patient was informed that he was given a drug, but the specific agent was not revealed to him. This was eliminating subject and observer bias.

Study Groups
The study was conducted in the following two groups of patients. Each group consisted of 72 patients (n=36/group).

- **Group A(n=36)** – Patients were receiving 13 mg of 0.5% hyperbaric bupivacaine (2.6 ml) + midazolam 2mg (0.4 ml) total volume 3.0 ml
- **Group B(n=36)** –Patients were receiving 13 mg of 0.5% hyperbaric Bupivacaine (2.6 ml) +fentanyl 20mcg. (0.4 ml) total volume 3.0 ml

Eligibility Criteria
Inclusion Criteria

1. Patients age group between 20-60 years.
2. Weight of patient between 40 -70 kg.
3. Height of patient >145 cm.
4. Undergoing elective infraumbilical surgery under spinal anesthesia.
5. Patient belonging to ASA I, II

Exclusion Criteria

1. Uncooperative patient
2. Patient not willing to participate in this study
3. Patient with compromised airway or morbid obesity
4. Patient with general contraindications for spinal anesthesia
5. History of convulsion, allergy to the drug used, bleeding disorder, severe neurological deficit.
6. Patient with history of hypertension, respiratory, cardiac, hepatic, or renal diseases (necessitating classification in ASA class 3rd or above)

7. Patient in which spinal anesthesia failed.

Statistical analyses were done using computer software (SPSS Trial version 23 and primer). The qualitative data were expressed in proportion and percentages and the quantitative data (Continuous data) were expressed as mean and standard deviations. The difference in proportion was analysed by using chi-square are test and the difference in means among the groups was analysed using the student's t test.5% probability level was considered as statistically significant i.e., p<0.05 for all statistical analysis.

RESULTS

Table 1. Socio-demographic profile

Variable	Group A	Group B	p-value
Mean age in yrs.	31.26±7.36	30.29±7.02	0.636
Male: female	19:17	18:19	0.99
ASA (I: II)	30:6	31:5	0.99

Both groups were comparable

Table No.2. Comparisons of cases according to sensory and motor block

Group	Group A			Group B			p-values
	N	Mean	SD	N	Mean	SD	
Total Duration of Sensory Block(min)	36	278.92	15.995	36	199.14	16.81	<0.001S
Total Duration of Motor Block(min)	36	194.42	16.434	36	152.17	20.14	<0.001S
First Complain of Pain/time for first rescue analgesia(min)	36	283.17	15.397	36	251.25	28.221	<0.001S
No. Of rescue analgesia given in first 24 Hrs	36	1.22	0.42	36	1.25	0.44	1.00 NS
Total duration of analgesia(min)	36	259.56	17.310	36	253.75	15.450	0.137 NS
Two segment regression time(min)	36	158.28	8.362	36	156.69	7.01	0.386 NS

The given table showed comparison of groups according to sensory and motor block.

Mean for total duration of sensory and motor block in Group A and group B was 278.92±15.995, 199.14±16.81 and 194.42±16.424, 152.17±20.14 respectively(P<0.001S). Total duration of analgesia(min) was not significant (P=0.137NS)

Table No.3. Distribution of cases according to VAS scoring at first complain of pain.

VAS scoring at first complain of pain	Group A		Group B		P-values
	No.	%	No.	%	
4	33	91.67	22	61.11	0.008S
5	3	8.33	11	30.56	
6	0	0.00	3	8.33	
Grand Total	36	100.00	36	100.00	

The given table showed the VAS scoring at first complain of pain maximum number of the cases 91.67% in Group A were observed in the 4-score followed by 8.33% in 5 score.

As compared to in other group B, maximum number of the cases were observed 61.11% in the 4. And followed by 30.56 in 5 and rest 8,33% were in score 6. this observation was statistically significant (p=0.002)

Table 4. Comparison of cases according to VAS in postoperative period

TIME (hrs.)	Group A			Group B			p-values
	N	Mean	Std. Deviation	N	Mean	Std. Deviation	
0.5	36	0.00	0.00	36	0.25	0.65	0.023S
1	36	0.00	0.00	36	0.31	0.71	0.011S
1.5	36	0.11	0.46	36	1.83	0.70	p<0.001S
2	36	2.00	0.00	36	2.36	0.76	p<0.001S
2.5	36	2.17	0.56	36	4.00	0.00	p<0.001S
3	36	2.28	0.70	36	4.00	0.00	p<0.001S
3.5	36	4.00	0.00	36	4.00	0.00	N/A
4	36	4.00	0.00	36	4.00	0.00	N/A

As shown in Table, comparison of mean visual analogue score among both study groups at different time intervals. Comparison of mean visual analogue score in both study groups showed statistically significant results as p value<0.05.

Table No.5 Distribution of cases according to Adverse effects

	Group A		Group B		P-values
	No.	%	No.	%	
Hypotension	5	13.88	4	11.11	1.000 NS
Bradycardia	2	5.55	1	2.78	1.000 NS
Vomiting	1	2.78	0	0	1.000NS
Pruritis	0	0.00	5	13.88	0.033S
Shivering	1	2.78	0	0	1.000NS
Nausea	1	2.78	2	5.55	1.000NS

The following table shows the adverse effects: hypotension cases were observed in 13.88% of Group A and lower 11.11% in Group B (p value = 1.00NS); Bradycardia cases were observed in 5.55% of Group A and 2.78% in Group B, also statistically not significant (P = 1.000NS). Pruritis was observed only in group B (13.88%) which is statistically significant. (p=0.033)

DISCUSSION

Spinal anaesthesia is the most used technique for infraumbilical surgeries, as it is cost effective and easy to administer. However, postoperative pain control is a major problem because spinal anaesthesia using only local anesthetics drugs is associated with relatively short duration of action and thus early rescue analgesic is needed in the postoperative period. Various drugs such as clonidine, midazolam, fentanyl and others have been studied for prolongation of the effect of spinal anaesthesia and duration of analgesia.[6-7]

Pain in the postoperative period must be managed judiciously and adequately. Postoperative pain may delay recovery, increase hospital stay and patient's expenditure. Good analgesic techniques minimize patient discomfort, facilitate early mobilization and discharge from hospital. It also prevents acute pain from developing into chronic pain.

Our study concentrated on two medications, which are fentanyl and midazolam. The main purpose of our study was to to find out non-opioid alternative as an adjuvant to local anesthetics for analgesia in spinal anesthesia. With above background present study was conducted at the department of Anaesthesiology, S.M.S. Medical College, Jaipur, after obtaining due permission from Institutional Ethics Committee.

Demographic Variables such as age, sex, body weight, height, duration of surgery was found to be insignificant.

Onset Of Sensory Block And Motor Block:

Our study shows that time taken for onset of both sensory and motor block is higher in midazolam group compared to fentanyl group and the difference is statistically significant. (P<0.05)

Duration Of Sensory And Motor Block:

Mean duration of sensory and motor block in midazolam group is significantly longer compared to fentanyl group. (P<0.05)

It was also found that the mean time to achieve the highest level of block (min) was significantly longer in midazolam group as compared to fentanyl group (P<0.05) but there was no significant difference in the mean time to two segment regression (min) between both group.

VAS score:

In our study the VAS scoring at first complaint of pain Maximum number of the cases 91.67% in midazolam were observed in the 4-score followed by 8.33% in 5 score.

As compared to in fentanyl group, maximum number of the cases were observed 61.11% in the 4. And followed by 30.56% in 5 and rest 8.33% were in score 6. This observation was statistically significant.

It was also found that difference between Visual Analogue Score between both group at 0.5 hrs., 1 hr., 1.5 hrs., 2 hrs., 2.5 hrs., 3hrs postoperatively was also significant (P<0.05)

Duration Of Analgesia And First Complain Of Pain:

In our study it was observed that Time of first complain of pain or time

to require first rescue analgesia is significantly higher ($p<0.05$) in midazolam group compared to fentanyl group but total duration of analgesia in each group was not significantly different.

Side Effects:

Study revealed that in both group there was no significant difference in various side effect like nausea and vomiting, hypotension, bradycardia, shivering. But the incidence of pruritis is higher in fentanyl group compared to midazolam group. None of the patients in both groups experienced respiratory depression in our study.

CONCLUSION

Our study concluded that midazolam cause longer duration of motor and sensory block and visual analogue score is also lower postoperatively in initial hours, however, there was no difference in the total duration of effective analgesia between adjuvant intrathecal midazolam as compared to intrathecal fentanyl for patients undergoing infra umbilical surgery.

REFERENCES

1. Larson MD. Anaesthesia. In: Miller RD, editor. History of Anaesthetic Practice. Philadelphia: Elsevier; 2005. p. 25–26
2. Choi, D. H., Ahn, H. J. and Kim, M. H. (2000): "Bupivacaine-sparing effect of fentanyl in spinal anesthesia for cesarean delivery." Reg Anesth Pain Med, 25(3): 240-245.
3. Miller's Anesthesia. 7th edition (2010).vol.1:21
4. Kissin I. Preemptive analgesia. Anesthesiology 2000;93:1138–43.
5. Bromley L. Pre-emptive analgesia and protective premedication. What is the difference? Biomed Pharmacother 2006;60:336–40
6. Islam MA, Khanum E, Karim MR, et al. Effect of Spinal Anaesthesia in Children of 4-10 Years. J Enam Med Col. 2017;7(1):10–14.
7. Yallapragada SV, Vemuri NN, Shaik MS. Effect of adding clonidine to intrathecal bupivacaine on the quality of subarachnoid block: a prospective randomized double-blind study. Anesth Essays Res. 2016;10(3):451