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"AN OBSERVATIONAL STUDY TO COMPARE TWO DOSES OF INTRATHECAL MIDAZOLAM WITH BUPIVACAINE FOR POST OPERATIVE ANALGESIA IN PATIENTS UNDERGOING ELECTIVE HAEMORRHOIDECTOMY "

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ABSTRACT

Introduction: This observational study is designed to find out the lower doses of intrathecal midazolam (preservative free) when used as adjuvant with hyperbaric bupivacaine for post operative analgesia in patients undergoing elective haemorrhoidectomy.

Method: 60 patients were randomly classified into two groups according to the dose of adjuvant added to local anesthetic. 30 patients in group BM1 will receive 2ml 0.5% hyperbaric bupivacaine + 1mg preservative free midazolam (0.1ml) with 0.1ml normal saline. And the other 30 patients in group BM2 will receive 2ml 0.5% hyperbaric bupivacaine + 2mg preservative free midazolam (0.2ml).patients were observed for duration of sensory block, motor block, postoperative analgesia and analgesic requirement in first 24 hours.

Result : Duration of analgesia was significantly less in the BM1 group than in the BM2 group.

Conclusion: The addition of 2 mg of intrathecal midazolam with bupivacaine prolonged the postoperative analgesia as compare to 1mg intrathecal midazolam.

KEYWORDS : spinal anaesthesia; bupivacaine; intrathecal midazolam; haemorrhoidectomy.

Introduction

pain management is not only a human feeling, but it is a key aspect of postoperative care, as acute pain, regardless of its site, can adversely affect nearly every organ function, and so affects the postoperative morbidity and mortality (Morgan et al., 2006).[1] Spinal anaesthesia with local anaesthetic is a favourable technique during both emergency and elective surgeries[2] but only local anaesthetics provide shorter duration of action .Hence many Adjuvant are used to hasten the onset and to prolong duration of post operative analgesia.

Midazolam has been reported to have antinociceptive and effective analgesic properties in both animal[3,4] and humans[5,6]. Discovery of benzodiazepine receptors in spinal cord, triggered the use of intrathecal midazolam for analgesia

This observational study is designed to find out the lower doses of intrathecal midazolam (preservative free) with minimal side effect when used as adjuvant with hyperbaric bupivacaine for post operative analgesia in patients undergoing elective haemorrhoidectomy.

MATERIAL & METHODS

This study was conducted in Dhiraj general hospital in Department of Anaesthesiology, after institutional ethical committee approval on 60 patients aged between 20 and 55 years of both gender scheduled for undergoing elective haemorrhoidectomy under spinal anaesthesia.

Patients were divided into 2 groups with 30 patients in each group. Group BM1 – received 10mg 0.5% hyperbaric bupivacaine + 1mg preservative free midazolam made 2.2 ml with normal saline. And Group BM2 –received 10mg 0.5% hyperbaric bupivacaine + 2mg preservative free midazolam made 2.2ml .

ASA I & ASA II patients undergoing spinal anaesthesia and patients in the age range 20 - 55 years were included in the study.

Patients with systemic diseases, anaemia, sever hypovolemia, shock, septicemia, hypertension , coagulation disorders or on anticoagulant therapy, local infection at the site of proposed puncture for spinal anaesthesia, spinal deformities, known allergy to the trial drug and those who are not willing for spinal anaesthesia were excluded from the study.

Preaneasthetic check up was done one day prior to the surgery. Patient was evaluated for any systemic diseases and laboratory investigations were recorded. The procedure of spinal anaesthesia was explained to the patients and written and informed consent obtained. All patients were kept NBM for atleast 8 hours.

On the day of surgery, the patient was shifted to the operating room. On arrival of patient in the operating room standard monitoring was applied; ECG, non invasive arterial blood pressure, pulse rate and arterial oxygen saturation was monitored. Baseline vitals were recorded – Pulse, B.P, SpO_2. IV line was secured and preloading was done with 10ml/kg of ringer lactate. Patients were premedicated with Inj. Glycopyrrolate 0.2mg IV and Inj. Ondansetron 4 mg IV.

Patient was positioned in the sitting position. Painting & draping of patient back was done with povidine iodine solution, study drug was injected in L3. - L4 intervertebral space with 23 G spinal needle after free flow of cerebrospinal fluid. The patient was placed supine immediately after injection.

All patients of both groups were monitored for:

Sensory block: Onset, level using pinprick test, Motor block: Onset and duration of block using modified Bromage scale, Pulse rate, Systolic blood pressure, Diastolic blood pressure, SpO_2, were monitored at: 0, 5, 10, 15, 20, 30, 45, 60, 75, 90, 120 minutes.

When the sensory block reached at T_{12} level, surgeon was allowed to start the surgery. Data was collected regarding the onset of sensory block (Time taken from intrathecal injection to loss of pinprick sensation at T_{12}) and duration of sensory block (Time from intrathecal injection to 2 segment regression) Motor block was tested by Bromage scale, time of onset (Time from intrathecal injection to grade 3 motor block) and duration of motor block (Time from intrathecal injection to grade 0 motor block) was recorded. Side effects/complications was noted and treated. Bradycardia was defined as pulse rate < 60/min and treated with IV atropine sulfate 0.6mg. Hypotension was defined as systolic BP less than 20% of the basal value and treated with IV mephenteramine 6mg.

After completion of surgery patient was shifted to recovery room and watched for pulse, blood pressure, sensory leval and duration of motor blockade. Pain score was assessed by prince henry's visual rating scale in postoperative period. Duration of analgesia was calculated from the time of intrathecal injection to the time when visual rating scale was 2. Total number of analgesics required in the first 24 hours was recorded.

OBSERVATION & RESULTS

The distribution of patients with respect to age, height, weight, gender, ASA was statistically not significant in both the groups (p value > 0.05).

The mean time from intrathecal injection to onset of sensory analgesia at T12 level was 5.03 ± 0.76 minutes in group BM1 and 3.26 ± 0.58 minutes in group BM2 .The onset of sensory analgesia was significantly earlier in group BM2 as compared to group BM1, which

was highly significant (p value < 0.01).

The mean duration of sensory block was 154.96 ± 19.75 minutes in group BM1 & 199.33 ± 16.28 minutes in group BM2. It was significantly prolonged in Group BM2 as compared to Group BM1 (P<0.01).

The mean time from intrathecal injection to onset of motor block was 4.93 ± 0.73 minutes in group BM1 & 3.06 ± 0.63 minutes in group BM2 . It was significantly faster in Group BM2 as compared to Group BM1 which was highly significant.(p<0.01)

The mean duration of motor block was 165.03 ± 25.10 minutes in Group BM1 and 217.26 ±20.27 minutes in Group BM2. It was significantly prolonged in Group BM2 as compared to Group BM1 which was highly significant(p<0.01).

There was statistically no significant difference in pulse rate between the two groups (p value > 0.05), at any interval of time during intraoperative and post-operative period.

There was statistically no significant difference in systolic and diastolic blood pressure and SpO_2 between the two groups (p value >0.05) at any time interval during intra as well as post operative period.

Table 16: Mean Duration of analgesia

Duration of Analgesia.	Group BM1		Group BM2		P Value	Remarks
	Mean	SD	Mean	SD		
Time Interval (Min.)	251.00	18.11	345.33	32.74	<0.01	HS

HS – Highly significant

The mean duration of analgesia was 251.00 ± 18.11 minutes in Group BM1 and 345.33 ± 32.74 minutes in Group BM2. It was significantly prolonged in Group BM2 as compared to Group BM1 which was statistically highly significant.(p<0.01).

Table 17: Postoperative analgesic consumption in 24 hrs

Analgesic consumption in 24 hrs	Group BM1		Group BM2		P Value	Remark
	Mean	SD	Mean	SD		
Number of analgesia	2.4	0.50	1.23	0.43	<0.01	HS

HS- Highly significant
Analgesic consumption for 24 hours postoperatively was less in Group BM2 as compared to Group BM1 which was statistically highly significant (p< 0.01)
NO side effects were observed in either of the group.

DISCUSSION

One of the mainstay of balanced anaesthesia is relief of pain during operation and in post operative period. "Postoperative pain relief" is a growing concern for an anaesthesiologist,as an uneventful postoperative period make all surgery comfortable proposition for surgical patients.

Spinal anaesthesia using local anaesthetics alone has shorter duration of action with early requirement of analgesia for postoperative pain relief.

This study was conducted to find out the lower doses of intrathecal midazolam with minimal side effect when used as adjuvant with hyperbaric bupivacaine.

The addition of 2 mg of intrathecal midazolam prolonged the post operaive analgesic effect of bupivacaine than 1mg of intrathecal midazolam.

Similarly M. H. KIM et al (2001)[7] also observed prolonged duration of analgesia and less analgesic consumption for 24 hours postoperatively with intrathecal administration of 2 mg midazolam with bupivacaine than 1mg intrathecal midazolam with bupivacaine.

CONCLUSION: we conclude that 2mg intrathecal midazolam when added to bupivacaine provides faster onset of sensory and motor blockade with longer duration of analgesia and less analgesic consumption for 24 hours postoperatively then 1mg intrathecal midazlom when added to bupivacaine without any side effect.

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