



A COMPARATIVE EVALUATION OF THE EFFICACY OF BUPIVACAINE AND BUPIVACAINE +MIDAZOLAM IN INTERSCALENE BLOCK FOR CLAVICULAR FRACTURE SURGERIES: A RANDOMIZED SINGLE BLINDED STUDY

Anaesthesiology

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ABSTRACT

BACKGROUND AND OBJECTIVES : Adjuncts to local anaesthetics for brachial plexus block may enhance the quality and duration of analgesia. Midazolam, a water-soluble benzodiazepine, is known to produce antinociception and enhance the effect of local anaesthetics when given epidurally or intrathecally. The purpose of this study was to assess the effect of Midazolam added to brachial plexus block by interscalene approach.

METHODS : A prospective, randomized, single blinded study was conducted on 100 ASA I or II adult patients undergoing upper limb surgeries under interscalene brachial plexus block. Patients were randomly divided into two groups. Patients in Group B (n = 50) were administered 30mL of 0.125% Bupivacaine and Group BM (n = 50) were given 30mL of 0.125% Bupivacaine with Midazolam 0.05 mg/kg. The onset time and duration of sensory and motor blockade were recorded. Haemodynamic variables (i.e., heart rate, noninvasive blood pressure, oxygen saturation), sedation scores and rescue analgesic requirements were recorded for 24 hr postoperatively. Results : The onset of sensory and motor block was significantly faster in Group BM compared to Group B (P < 0.05). Rescue analgesic requirements were significantly less in Group BM compared to Group B (P < 0.05). Haemodynamics and sedation scores did not differ between groups in the post-operative period.

CONCLUSION : Midazolam (0.05mg/kg) in combination with 30mL of Bupivacaine (0.125%) hastened onset of sensory and motor block, and improved postoperative analgesia when used in brachial plexus block, without producing any adverse events.

KEYWORDS

clavicular fracture, Interscalene block; Midazolam; Bupivacaine.

INTRODUCTION:

Interscalene blocks provide a useful alternative to general anaesthesia for upper limb surgeries¹. They achieve near-ideal operating conditions by producing complete muscular relaxation, maintaining stable intra-operative haemodynamics and the associated sympathetic block^{2,3}. The sympathetic block decreases postoperative pain, vasospasm and edema.

Of various local anaesthetics, Bupivacaine is used most frequently, as it has a long duration of action varying from 3 to 8 hours.⁴ However there are many limiting factors like delayed onset, patchy or incomplete analgesia, sometimes short duration etc.

Midazolam, a water-soluble benzodiazepine is known to produce antinociception and to enhance the effect of local anaesthetic when given epidurally or intrathecally. Midazolam was first synthesized by Fryer and Walser in 1976. It is the most commonly administered benzodiazepine in the perioperative period for preoperative medication and intravenous "conscious" sedation. The five principal pharmacologic effects are: sedation, anxiolysis, anticonvulsant actions, spinal cord-mediated skeletal muscle relaxation and anterograde amnesia. Midazolam produces this effect by its action on gamma aminobutyric acid-A (GABA-A) receptors. GABA receptors have also been found in peripheral nerves.

So the present study is being undertaken in a randomized single blinded manner to evaluate the onset time and analgesic efficacy of Midazolam- Bupivacaine combination compared to plain Bupivacaine (0.125%) for interscalene block for clavicular fractures.

AIMS AND OBJECTIVES:

The present study was undertaken to compare the effectiveness of adding midazolam (0.05mg/kg) to bupivacaine (0.125%) in interscalene technique of brachial plexus block for clavicular fracture surgeries with plain bupivacaine (0.125%).

Following parameters were studied:

- 1) Onset of sensory and motor blockade
- 2) Duration of sensory and motor blockade
- 3) Sedation score intra and post operatively
- 4) Number of rescue analgesics in post Operative 24hrs.

MATERIALS AND METHODS:

The present study was carried out in the Department of Anaesthesia, IGIMS, Patna. After obtaining ethical clearance from the Institutional Ethics Committee and obtaining written consents from the participants, 100 adult cases ranging in age from 30 to 50 years with ASA Grade I & II requiring clavicular fracture surgeries under

interscalene block were selected for this study. Cases were allocated by computer generated randomization into two groups containing 50 cases each. Cases in Group B received 30ml of 0.125% Bupivacaine and those in Group BM received 0.125% bupivacaine +midazolam (0.05mg/kg)

INCLUSION CRITERIA:

- 1) ASA CLASS I & II
- 2) Age between 15 to 55 years.

EXCLUSION CRITERIA:

- 1) Known cause of hypersensitivity reaction to Midazolam or other morphonomimetics.
- 2) Patients with medical complications like severe anemia, severe hypovolemia, shock, septicemia.
- 3) Abnormal BT, CT or on anticoagulant therapy.
- 4) Local infection at the site of proposed puncture for interscalene block.

The patient is placed in a semi-sitting or supine position with the head turned away from the side to be blocked.

The patient is asked to elevate the head slightly to bring the clavicular head of the sternocleidomastoid muscle into prominence

The index and middle fingers of the nondominant hand are placed immediately behind the lateral edge of the sternocleidomastoid muscle. The patient is instructed to relax so that the palpating fingers can be moved medially behind this muscle and finally lie on the belly of the anterior scalene muscle.

The palpating fingers are then rolled laterally across the belly of the anterior scalene muscle until they fall into the interscalene groove (formed by scalene anterior and posterior muscles).

With both fingers in the interscalene groove, a 1.5-in., 22-gauge, short-bevel needle is inserted between the fingers at the level of C6 in a direction that is perpendicular to the skin in every plane.

After a motor response is obtained, aspiration is carried out to rule out intravascular or intrathecal placement. While the patient is monitored closely for signs of local anaesthetic toxicity or inadvertent subarachnoid injection, 30 mL of local anesthetic is slowly injected.

All patients would be monitored for anaesthesia and analgesia upto 24 hours post-operatively. Injection ketamine would be given as rescue analgesic when patient complains of pain.

Number of rescue analgesics in 24 hours of post-operative period would also be recorded.

Quantitative data will be analysed by student's 't' test.

Qualitative data will be analysed by Chi-square test
P value < 0.05 would be considered statistically significant.

Table 1 : Time for onset of sensory block (min)

Study group	Onset time (min)	Mean difference	t* value	P value	Significance
B	19.08 ± 1.7	7.82	24.13	P < 0.001	HS
BM	11.26 ± 1.5				

* Student's unpaired t test

HS – Highly significant

The statistical analysis by student's unpaired 't' test showed that, the time for onset of sensory block in group BM was significantly faster when compared to group B (P < 0.05)

Table 2 : Time for onset of motor block (min)

Study group	Onset time (min)	Mean difference	t* value	P value	Significance
B	15.30 ± 2.09	5.74	16.38	P < 0.001	HS
BM	9.56 ± 1.32				

The statistical analysis by unpaired student's 't' test showed that, the time for onset of motor block was significantly faster when compared to group B (P < 0.05).

Table 3 : Duration of sensory block (hours)

Study group	Duration of block (hrs)	Mean difference	t* value	P value	Significance
B	5.84 ± 0.49	7.96	42.2	P < 0.001	HS
BM	13.81 ± 1.23				

Patients of both groups were observed for 24 hours. Time was noted when the patient asked for rescue analgesics. The statistical analysis by students unpaired 't' test showed that the duration of sensory block in group BM was significantly longer when compared to group B (P < 0.05).

Table 4 : Duration of motor block (hours)

Study group	Duration of block (hrs)	Mean difference	t* value	P value	Significance
B	5.13 ± 0.45	0.12	1.32	P > 0.05	NS
BM	5.25 ± 0.45				

NS – not significant

The statistical analysis by students unpaired 't' test showed that the difference between duration of motor block in group BM and group B was not significant (P > 0.05).

Table 5 : Number of rescue analgesics in post-op 24 hours

No. of RA in 24 hours post-op	BUPIVACAINE	BUPIVACAINE+ MIDAZOLAM
1	0	37 (74%)
2	38 (76%)	13 (26%)
3	12 (24%)	0

$\chi^2 = 61.25$ P < 0.0001 Highly Significant.

This difference in number of rescue analgesic doses required by patient of both groups is statistically significant by chi-square test ($\chi^2 = 61.25$, P < 0.05).

DISCUSSION:

In our study we found that the onset of sensory and motor blocks was significantly faster in patients who received a combination of Midazolam and Bupivacaine. This could be due to a local anaesthetic property of Midazolam and its synergistic action with that of local anaesthetics⁶. The somatotrophic arrangement of fibres in a nerve bundle at the level of the trunks in which motor fibres are located more peripherally than sensory fibres^{6,7}. Hence, a local anaesthetic injected perineurally will begin to block motor fibres before it arrives at the

centrally located sensory fibres. Our results showed that sensory block tended to last longer as compared to motor block as large fibres require a higher concentration of local anaesthetic than small fibres. The minimal effective concentration of local anaesthetic for large (motor) fibres is greater than for small (sensory) fibres. Thus, motor function return before pain perception and duration of motor block is shorter than the sensory block

CONCLUSION:

From our study, we conclude that, the addition of Midazolam (0.05 mg / kg) as adjuvant to bupivacaine (0.125%) has faster onset of sensory block, faster onset of motor block, longer duration of sensory block, less number of rescue analgesics in post – op 24 hrs Comfortable sedation intraoperatively without any need for airway assistance. No significant difference in duration of motor block and haemodynamic variables i.e., pulse rate, systolic BP, diastolic BP and O₂ saturation.

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Conflict of interest – None declared

Ethical approval – The study was approved by the institutional ethics committee

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