Section: Anesthesiology

Original Research Article

A COMPARATIVE STUDY BETWEEN BUPIVACAINE AND BUPIVACAINE WITH MAGNESIUM SULPHATE IN SPINAL ANAESTHESIA FOR LOWER ABDOMINAL SURGERIES

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ABSTRACT

Background: Spinal anaesthesia using hyperbaric bupivacaine is widely employed for lower abdominal surgeries; however, the limited duration of postoperative analgesia remains a concern. The addition of adjuvants such as magnesium sulphate has been explored to enhance the quality and duration of spinal block due to its N-methyl-D-aspartate (NMDA) receptor antagonistic properties. Undertaken to compare the spinal block characteristics and postoperative analgesic efficacy of intrathecal hyperbaric bupivacaine alone versus hyperbaric bupivacaine combined with magnesium sulphate. **Objectives**: In this study 0.5%hyperbaric bupivacaine (15mg) 3ml with 0.2ml normal saline was compared with 0.5%hyperbaric bupivacaine (15mg) 3ml with preservative free 50% magnesium sulphate (100mg) 0.2ml.Two groups were compared in terms of onset and duration of sensory and motor block, duration of effective analgesia was assessed by time interval between the onset of block to the time for request for first rescue analgesia or by VAS(visual analogue scale) pain score of ≥4. Hemodynamic changes and any obvious side effects were also taken into consideration. **Materials and Methods:** The prospective, randomized, double blinded study was carried out in general surgery and gynecology OT complex of Bankura Sammilani Medical College and Hospital (a tertiary care teaching hospital of West Bengal) from 18 months after approval of synopsis by the University. The patients were randomly allocated into two equal groups, Group B (n=30) received 0.5%hyperbaric bupivacaine(15mg) 3ml with normal saline 0.2ml intrathecally and Group M (n=30) received 0.5%hyperbaric bupivacaine(15mg) 3ml with preservative free 50% magnesium sulphate(100mg) 0.2ml intrathecally. **Results:** Both groups were comparable with respect to demographic parameters, body weight, height, duration of surgery, and baseline as well as intraoperative hemodynamic variables. The onset of sensory and motor block was significantly delayed in Group M compared to Group B. However, the duration of sensory and motor block was significantly prolonged in the magnesium sulphate group. The duration of effective postoperative analgesia was also significantly longer in Group M than in Group B. Additionally, the incidence of shivering was significantly lower in patients receiving intrathecal magnesium sulphate. No significant adverse effects or hemodynamic instability were observed in either group. **Conclusion:** The present study demonstrates that the addition of intrathecal magnesium sulphate to 0.5% hyperbaric bupivacaine improves the quality of subarachnoid block compared to bupivacaine alone. Although the onset of sensory and motor blockade is delayed, magnesium sulphate significantly prolongs the duration of sensory and motor block and provides prolonged postoperative analgesia. The incidence of postoperative shivering is also reduced with the use of magnesium sulphate. Thus, intrathecal magnesium sulphate is an effective adjuvant to hyperbaric bupivacaine for enhancing the efficacy of spinal anaesthesia.

INTRODUCTION

It is easier to find men who will volunteer to die,than to find those who are willing to endure pain with patience."

Anaesthesiologists are responsible for proper pain management during the perioperative period. They are the leaders in the development of acute postoperative pain services, application of evidence-based practice of acute postoperative pain and creation of innovative approaches to acute pain management, all of which are a natural part of anaesthesiologist's function as a "perioperative physician", consultant and therapist throughout an institution and as a highly skilled expert in the operating room. Provision of effective analgesia for surgical and other medical patients is an important component of this multidimensional role.[1]

Pain has been best defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[2] Pain is not only very distressing to the patients but also causes sympathetic over activity in the postoperative period, often prolonging hospital stay, increasing cost and unanticipated re-admission in hospital. By reducing the physiological and psychological response to tissue injury, satisfactory perioperative analgesia improves the surgical outcome with reduced morbidity, organ dysfunction, need for hospitalization and convalescence, which is a prerequisite for early recovery.[3]

Regional anaesthesia is a safe effective and cheap anaesthesia with an added advantage of long duration of postoperative analgesia. It reduces the risk of airway complications and avoids hemodynamic changes associated with laryngoscopy and intubation.[4] Many opioids are available to serve as an additive to local anaesthetics to prolong the duration and intensify the subarachnoid block. However significant side effects of opioids such as pruritus, urinary retention, respiratory depression, hemodynamic instability, occasionally severe nausea and vomiting may limit their use. Magnesium sulphate, a very old drug having its initial use in preeclampsia, cardiac arrhythmias and bronchial asthma, now has been explored as an anaesthetic and analgesic sparing drug in anaesthesia practice. Magnesium blocks NMDA receptors. NMDA antagonism can prevent the induction of central sensitization from peripheral nociceptive stimulation. Magnesium can be a useful adjuvant to bupivacaine. Antinociceptive effects of magnesium are primarily based on the regulation of calcium influx into the cell i.e. natural physiological calcium antagonism.

In previous studies it was demonstrated that intrathecally administered magnesium prolonged spinal opioid analgesia both in rats and in humans. The addition of magnesium to spinal anaesthesia improved postoperative analgesia in an orthopedic setting.[5]

Hence a prospective, randomized, double blinded study will be conducted by using 0.5%hyperbaric bupivacaine (15mg) 3ml with 0.2ml normal saline and 0.5%hyperbaric bupivacaine (15mg) 3ml with preservative free 50% magnesium sulphate (100mg) 0.2ml intrathecally to compare the effects on spinal block characteristics, postoperative analgesia, hemodynamics and adverse effects. The objective of this study was to compare the onset and duration of sensory and motor block, duration of effective postoperative analgesia, hemodynamic changes, and incidence of side effects between intrathecal 0.5% hyperbaric bupivacaine alone and 0.5% hyperbaric bupivacaine combined with magnesium sulphate.

MATERIALS AND METHODS

Study Design: Prospective, randomised, double blinded controlled study.

Study Setting and Timelines: The present prospective, randomized, double blinded study was carried out in general surgery and gynaecology OT complex of B.S.M.C&H (a tertiary care teaching hospital of West Bengal).

Place of Study: Bankura Sammilani Medical College and Hospital, Department of Anaesthesiology, Department of General Surgery and General Surgery OT complex, Depatment of Gynaecology and respective OT complex.

Period of Study: 18 months after approval of synopsis by the University.

Study population

In this study 60 patients of either sex belonging to ASA I & II in age group of 18-60 years and body weight between 45-80 kg were included. The patients were randomly allocated into two groups of 30 each according to drug administered.

Sample size / design:

60 patients of either sex belonging to ASA I & II in age group of 18-60 years and body weight between 45-80 kg were included. The patients were randomly allocated into two groups of 30 each according to drug administered.

Group B (n=30) received 0.5%hyperbaric bupivacaine(15mg) 3ml with normal saline 0.2ml intrathecally.

Group M (n=30) received 0.5%hyperbaric bupivacaine(15mg) 3ml with preservative free 50% magnesium sulphate(100mg) 0.2ml intrathecally

CASE, CONTROL: As such not relevant to this study.

Group B (n=30) received 0.5%hyperbaric bupivacaine (15mg) 3ml with normal saline 0.2ml intrathecally.

Group M (n=30) received 0.5%hyperbaric bupivacaine(15mg) 3ml with preservative free 50% magnesium sulphate(100mg) 0.2ml intrathecally.

Inclusion Criteria

1. Patients with ASA physical status I & II.
2. Patients of age group between 18 to 60 years.
3. Patients of either sex.

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4. Patients scheduled for elective lower abdominal surgeries under spinal anaesthesia.

Exclusion Criteria

1. Patient refusal.
2. Any contraindication to spinal anaesthesia
3. Infection at the site of injection
4. Coagulopathy
5. Neurological disorders
6. Stenotic heart diseases
7. Spinal deformity
8. Haemodynamically compromised patients
9. Known allergy to study drugs.
10. Patients on chronic analgesic therapy or antiplatelet drugs and anticoagulants.
11. Pregnancy.
12. Patients using any drug that modifies pain perception.
13. Patients with psychiatric disease, inability to comprehend VAS.
14. Patients having the level of sensory block below T10 after 15 minutes of subarachnoid block or those needed any analgesic supplementation or general anaesthesia during the operative procedure.

Statistical Analysis Plan: Statistical analysis was performed with the SPSS, version 20.0 for Windows Statistical Software Package (SPSS Inc., Chicago, IL, USA). Categorical data, i.e. ASA grade and the incidence of adverse events (hypotension, bradycardia, respiratory depression, nausea and vomiting) were presented as numbers and proportion of these data were compared in all two groups and the difference in proportion was inferred by Chi-square test. Demographic data (age, weight), duration of surgery, VAS score, total duration of analgesia, requirement of rescue analgesia and all other numeric data were expressed as mean ± standard deviation and these data were compared in all two groups and difference in means were inferred by unpaired t- test of significance. For significance P value ≤ 0.05 was considered as significant for both types of data.

RESULTS

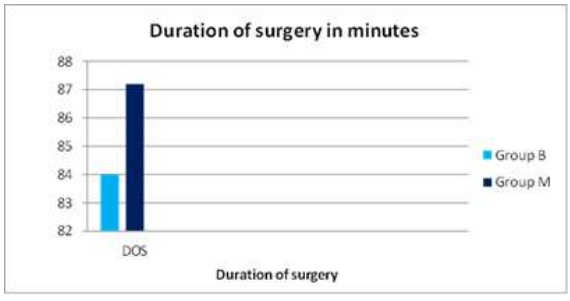

Figure 1: Showing duration of surgery of both group

Figure 1 shows that mean duration of surgery of group B was 84 min and group M was 87.20 min. There was no statistically significant difference in mean values between the two groups as p- value >0.05.

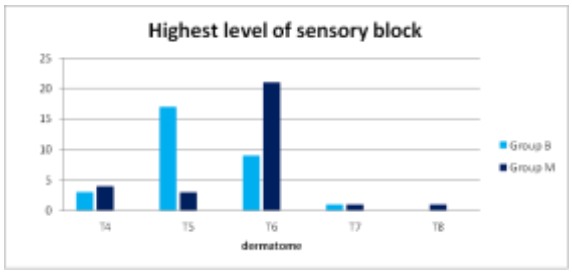

Figure 2: Showing highest level of sensory block in both group

Figure 2 showing highest level of sensory blockade in both group. Majority of patients in group B had T5 level where in group M it was T6. This was statistically significant (p value 0.025).

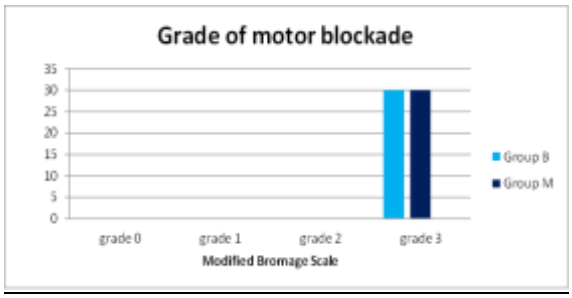

Figure 3: Showing Grade of motor blockade (Modified Bromage scale)

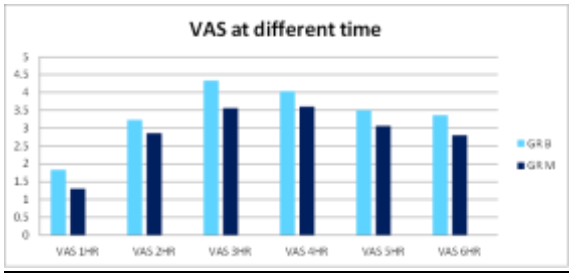

Figure 4: showing VAS at different time during postoperative period

Figure 4 Shows descriptive statistics of Visual analogue score (VAS) of both groups in post operative period. Statistically significant change (p <0.05) in VAS was found at 1hour, 2 hours, 3hour, 4hour and 5hour.

Table 1: Showing Onset of Sensory block upto T10 level, Onset of complete Motor block (modified bromage scale 3) after giving Spinal anaesthesia (Mean ± SD)

Variables	GR B	GR M	p-Value	Significance
OTNSB (onset of sensory block)	5.50±1.00	6.23±0.67	0.002	Significant
OTNMB (onset of motor block)	7.63±0.99	8.33±1.09	0.012	Significant

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Table 1 shows that the difference in mean onset of sensory block upto T10 level between both the group was statistically significant (p value 0.002). Also, the difference in mean onset of complete motor block was statistically significant (p value 0.012). It indicates that addition of magnesium delays the onset of both sensory and motor block.

Table 2: Showing time (min) taken for sensory regression to S2 level, Modified Bromage scale-0 and time (min) to give rescue analgesia (Mean ± SD)

Variables	GR B	GR M	p-Value	Significance
SRS2	171.16±14.71	206.66±13.66	0.000	Significant
MRBR0	149.76±11.17	167.36±16.22	0.000	Significant
TTRA	167.90±17.02	252.13±20.48	0.000	Significant

Table 2 summarizes descriptive statistics of duration of sensory and motor block and duration of analgesia. The difference in mean duration of sensory regression and motor regression between both groups was statistically significant (p 0.000). The difference in mean duration of giving rescue analgesia was also statistically significant (p 0.000) indicating that magnesium prolonged the duration of sensory and motor block as well as duration of analgesia.

Table 3: Showing post-operative side effects in both group

	VARIABLES	YES	NO	P-VALUE	SIGNIFICANCE
HYPOTENSION	**Group B**	3(10%)	27(90%)	0.448	Not Significant
	Group M	5(16.7%)	25(83.3%)		
BRADYCARDIA	**Group B**	4(13.3%)	26(86.6%)	0.209	Not Significant
	Group M	9(30%)	21(70%)		
PONV	**Group B**	5(16.7%)	25(83.3%)	0.532	Not significant
	Group M	8(26.6%)	22(73.3%)		
SHIVERING	**Group B**	12(40%)	18(60%)	0.039	Significant
	Group M	4(13.3%)	26(86.6%)		

Table 3 shows that, Postoperative side effects were comparable between the two groups except for shivering. Hypotension was observed in 3 patients (10%) in Group B and 5 patients (16.7%) in Group M, with no statistically significant difference between the groups (p = 0.448). Bradycardia occurred in 4 patients (13.3%) in Group B and 9 patients (30%) in Group M; however, this difference was not statistically significant (p = 0.209). Postoperative nausea and vomiting (PONV) were noted in 5 patients (16.7%) in Group B and 8 patients (26.6%) in Group M, and the difference was not statistically significant (p = 0.532). In contrast, the incidence of shivering was significantly higher in Group B, occurring in 12 patients (40%), compared to only 4 patients (13.3%) in Group M, and this difference was statistically significant (p = 0.039).

DISCUSSION

Adequate pain management is essential to facilitate rehabilitation and enabling the patients to return their normal activity more quickly. Postoperative pain management is one of the main challenges for anaesthesiologists and even with the help of multimodal analgesia techniques, patients still remain undertreated. Many opioids are available to serve as an additive to local anaesthetics to prolong the duration and intensify the subarachnoid block. However significant side effects of opioids such as pruritus, urinary retention, respiratory depression, hemodynamic instability, occasionally severe nausea and vomiting may limit their use4. Because magnesium is a noncompetitive antagonist of NMDA receptor, it has the potential to prevent central sensitization from peripheral nociceptive stimulation. The aim of this study was to compare the analgesic efficacy, onset and duration of sensory and motor blockade of bupivacaine heavy (0.5%) and bupivacaine heavy (0.5%) with preservative free 50% magnesium sulphate through subarachnoid route in patients undergoing elective lower abdominal surgery. Perioperative haemodynamic changes and any obvious side effects were also taken into consideration and were observed.

In this study, 60 patients of either sex belonging to ASA I & II in the age group of 18–60 years and body weight between 45–80 kg were included. The patients were randomly allocated into two groups of 30 each according to the drug administered. Group B received 0.5% hyperbaric bupivacaine (15 mg) 3 ml with normal saline 0.2 ml intrathecally, and Group M received 0.5% hyperbaric bupivacaine (15 mg) 3 ml with preservative free 50% magnesium sulphate (100 mg) 0.2 ml intrathecally.

The dose of intrathecal magnesium sulphate has not yet been fixed. The search in literature revealed that different studies have been conducted using different doses of magnesium sulphate. Banihashem et al. (2015),[6] observed delayed onset of sensory blockade with intrathecal magnesium sulphate, while postoperative analgesia was longer in the magnesium group. Katiyar et al. (2015),[7] concluded that addition of magnesium sulphate at 100 mg dose as an adjuvant to intrathecal bupivacaine significantly prolonged the duration of analgesia. Hence, preservative free 50% magnesium sulphate 100 mg was selected as an adjuvant in the present study.

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The onset of sensory block up to T10 dermatome and the onset of complete motor block were significantly delayed in the magnesium group compared to the bupivacaine-only group. Rashad et al. (2015),[8] Nath et al. (2012),[9] Shukla et al. (2011),[10] and Amr et al. (2013),[11] also observed a statistically significant delay in the onset of sensory and motor blockade following intrathecal magnesium sulphate. The findings of the present study are consistent with these studies. The delayed onset of blockade may be attributed to the difference in pH and baricity of the intrathecal solution containing magnesium.

The peak height of sensory blockade was lower in the magnesium group compared to the control group, and this difference was statistically significant. Ozalevli et al. (2005),[12] also found that the highest level of sensory block was significantly lower in patients receiving intrathecal magnesium sulphate. Samir et al. (2013),[13] reported a similar finding, although it was not clinically significant. The reduced peak height of sensory block may be due to altered baricity of the magnesium-containing solution.

All patients in both groups achieved complete motor blockade (Modified Bromage Scale grade 3), indicating that the addition of magnesium sulphate did not compromise the quality of motor block.

The duration of sensory block, motor block and postoperative analgesia was significantly prolonged in the magnesium group. Sensory regression to S2 dermatome and motor regression to Modified Bromage Scale 0 occurred significantly later in patients receiving intrathecal magnesium sulphate. These findings are consistent with studies by Amr et al. (2013),[11] Shukla et al. (2011),[10] and Rashad et al. (2015).[8]

In the present study, the duration of effective analgesia was assessed by the time to first request for rescue analgesia or when the Visual Analogue Scale score was ≥4. Prolonged duration of analgesia was observed in the magnesium group. Similar findings were reported by Samir et al. (2013),[13] Tabdar et al. (2013),[14] Amr et al. (2013)11, Rashad et al. (2015),[8] and Katiyar et al. (2015).[7] However, Banihashem et al. (2015),[6] did not observe a significant effect of intrathecal magnesium on postoperative pain, which may be due to the lower dose of magnesium sulphate used in their study.

Postoperative pain scores assessed using the Visual Analogue Scale were significantly lower in the magnesium group during the early postoperative period up to the fifth postoperative hour, after which the scores became comparable between the two groups. These findings correlate with studies by Amr et al. (2013),[11] Samir et al. (2013),[13] and Arcioni et al. (2007).[15]

With regard to postoperative complications, hypotension, bradycardia and postoperative nausea and vomiting were comparable between the two groups. No patient developed pruritus, urinary retention or respiratory depression. The incidence of shivering was significantly lower in the magnesium group compared to the control group, and Elsonbaty et al. (2013)16 also found magnesium sulphate to be effective in reducing postoperative shivering.

CONCLUSION

The present study concludes that the addition of intrathecal magnesium sulphate to 0.5% hyperbaric bupivacaine provides superior quality of subarachnoid block compared to 0.5% hyperbaric bupivacaine alone. Although magnesium sulphate delays the onset of both sensory and motor blockade, it significantly prolongs the duration of sensory and motor block and offers excellent intraoperative analgesia along with extended postoperative analgesia. Furthermore, the use of magnesium sulphate is associated with a reduced incidence of shivering, thereby minimizing the need for additional pharmacological interventions. Overall, the combined use of magnesium sulphate with 0.5% hyperbaric bupivacaine enhances the efficacy and quality of spinal anaesthesia.

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