Original Article

# Effect of addition of intrathecal magnesium sulphate to 0.5% hyperbaric bupivacaine and 0.5% isobaric levobupivacaine on duration of analgesia in parturients undergoing elective caesarean section: A prospective randomised study

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## Abstract

**Background and Aims:** Addition of magnesium sulfate to local anesthetics improves the quality of spinal anesthesia for caesarean section. The aim of this study was to compare the effects of intrathecal 0.5% hyperbaric bupivacaine with 75-mg magnesium sulfate ($MgSO_4$) and 0.5% isobaric levobupivacaine with 75-mg $MgSO_4$ on the duration of analgesia in parturients undergoing elective caesarean section.

**Material and Methods:** This prospective randomized double-blind parallel-group study was conducted in 60 parturients undergoing elective caesarean section who were randomly allocated to Group I or Group II to receive either 2 ml of 0.5% levobupivacaine with 75-mg $MgSO_4$ or 2 ml of 0.5% hyperbaric bupivacaine with 75-mg $MgSO_4$ intrathecally. The duration of postoperative analgesia along with sensory and motor block characteristics and hemodynamics were studied.

**Results:** The duration of analgesia did not show a significant difference in the two groups ($P = 0.175$). The sensory onset time was faster in Group I (3.5 ± 1.3 min) as compared to that in Group II (4.8 ± 2 min; $P = 0.004$). The onset of motor blockade was not different in the two groups ($P = 0.265$), but there was a significant delay ($P = 0.002$) in motor recovery in Group II (267 ± 130.6 min) as compared to Group I (225 ± 85.4 min). Hemodynamics were comparable in the two groups.

**Conclusion:** Intrathecal levobupivacaine with $MgSO_4$ produces a similar duration of postoperative analgesia as compared to hyperbaric bupivacaine with $MgSO_4$. Early motor recovery allowing early ambulation postoperatively makes isobaric levobupivacaine with $MgSO_4$ a good alternative for caesarean sections.

**Keywords:** Caesarean, levobupivacaine, magnesium sulfate, spinal anesthesia

## Introduction

Hyperbaric bupivacaine, which is commonly used as local anesthetic for caesarean section, has a remarkable safety record, but its use may cause adverse effects like sudden cardiac arrest after spinal anesthesia due to extension of sympathetic block.[1-3] Intrathecal isobaric solutions are less sensitive to positional changes thus producing more predictable spread. Levobupivacaine, which is the S enantiomer of bupivacaine, has lower cardiovascular and central nervous system toxicity.[4] Levobupivacaine produces a more selective neuraxial blockade than racemic bupivacaine as it produces a shorter duration of motor blockade.[5] The duration of analgesia is prolonged when magnesium is used intrathecally during labor for labor analgesia.[6,7]

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In the postoperative period, prolonging the analgesia encourages early mobilization of patients, but prolonged motor blockade with the long acting local anesthetic discourages the patients from early ambulation in spite of having adequate analgesia. Studies comparing intrathecal hyperbaric bupivacaine with intrathecal levobupivacaine for spinal anesthesia in caesarean sections have shown an early motor recovery in patients receiving isobaric levobupivacaine.[8-10] A study done by Rashad *et al*.[11] showed that addition of $MgSO_4$ to hyperbaric bupivacaine prolongs postoperative analgesia. Based on the findings of the above studies, we hypothesized that intrathecal levobupivacaine with $MgSO_4$ might prolong the duration of postoperative analgesia with early motor recovery, thereby encouraging early postoperative ambulation. There are no studies that compare the use of $MgSO_4$ as adjuvant to isobaric levobupivacaine and hyperbaric bupivacaine. This study was therefore aimed primarily at comparing $MgSO_4$ as adjuvant to either hyperbaric bupivacaine or isobaric levobupivacaine to determine the duration of analgesia along with sensory and motor block characteristics.

## Material and Methods

The present study was a prospective randomized double-blind parallel-group study. The trial was registered in the Clinical Trial Registry India with number CTRI/2018/12/016660 prior to patient enrolment. The study was conducted between January 2019 and August 2019 after institutional ethics committee approval. Sixty parturients posted for elective caesarean section under spinal anesthesia were enrolled in the study after getting written informed consent. Parturients in the age group of 19–40 years, with gestational age 37–42 weeks, American Society of Anesthesiologists (ASA) physical status II, and height of 150–170 cm were included in the study. Those with any endocrine disorders, twin gestation, pregnancy-induced hypertension, and parturients with contraindication for neuraxial block were excluded from the study. The parturients were randomly allocated using a computer-generated randomization table to two groups [Figure 1]. Allocation concealment was done by sequentially numbered opaque envelopes. These were used to assign randomization on the day of surgery.

- Group I—2 cc of 0.5% isobaric levobupivacaine combined with 0.15 ml of 50% $MgSO_4$ (75-mg $MgSO_4$).
- Group II—2 cc of 0.5% hyperbaric bupivacaine combined with 0.15 ml of 50% $MgSO_4$ (75-mg $MgSO_4$).

On arrival to the operating room baseline heart rate, blood pressure and $SpO_2$ was recorded. Preloading was done with 10 ml/kg of Ringer's lactate as per institutional practice. Spinal anesthesia was administered using 25 G Quincke needle at the L2–L3 or L3–L4 interspace in left lateral position. To facilitate blinding, the medication was prepared and injected by an anesthesiologist not involved in the study. Heart rate, noninvasive blood pressure, $SpO_2$, and respiratory rate were monitored and the level of sensory and motor block was assessed every 1 min for first 10 min and every 5 min till the completion of surgery. Intraoperatively time taken to achieve loss of sensation to pin prick at T4 level and motor blockade was checked by modified Bromage score as used by Breen *et al*.[12]

The time taken to achieve Bromage 3 was recorded as onset of motor blockade. Hemodynamics in the form of systolic blood pressure (BP), diastolic BP, and mean arterial pressure (MAP) were also assessed. Bradycardia, defined as heart rate less than 60 beats/min, was treated with intravenous (IV) atropine 0.6 mg. Hypotension, defined as a fall in MAP by more than 20% from baseline or MAP less than 60 mmHg, was treated with IV ephedrine 6 mg and IV fluids. Nausea and vomiting if any was treated with IV ondansetron 4 mg.

The assessment of sensory and motor block was continued postoperatively till complete recovery of both motor and sensory functions. The time taken for sensory block to regress to T12 level was taken as sensory recovery time. Time to attain Bromage 0 was taken as motor recovery time. The time to first request for analgesia to be given when visual analog scale (VAS) was more than 4 or when parturient demanded was assessed and was taken as the duration of analgesia. Postoperatively, heart rate, noninvasive blood pressure, and visual analog scale (VAS) which range from 0–10, with 0 representing no pain and 10 representing unbearable pain and side effects (shivering, hypotension, and bradycardia) were observed and recorded for every 15 min till 1 h and hourly till 12 h. Paracetamol (15 mg/kg) was administered IV if VAS was more than 4 or when patient demanded. If patient continued to have pain even after IV paracetamol, IV tramadol at a dose of 50 mg was administered.

Statistical analysis done in the study was by descriptive and inferential methods. Duration of analgesia has been taken as the outcome measure for sample size calculation. A study by Rana *et al*.[13] in 2017 showed a postoperative duration of analgesia with intrathecal hyperbaric bupivacaine with $MgSO_4$ of 252.6 ± 40.7 min and 239.8 ± 38.4 min for the group receiving hyperbaric bupivacaine with fentanyl. The sample size calculated with a significance level of 95% and 80% power of study, to detect a difference of 30% in the mean duration of analgesia, was at least 30 parturients in each group. The results on continuous measurements

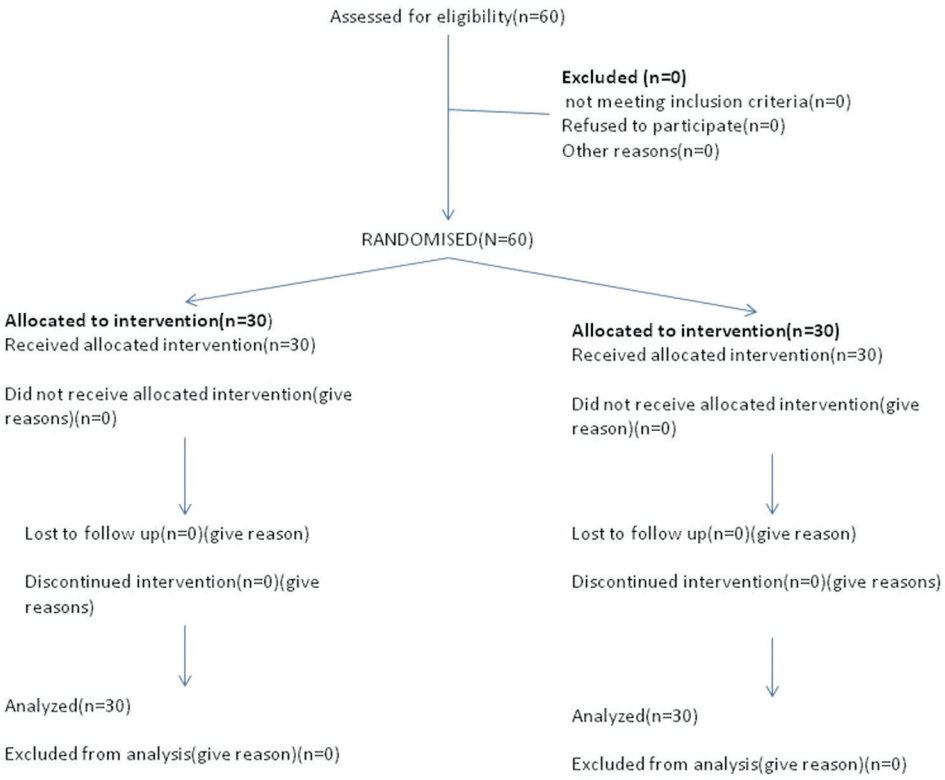


**Figure 1:** CONSORT flow diagram for the study

have been presented as mean ± SD (Min–Max) and those on categorical measurements are presented in number (%). Significance is assessed at 5% level. The study parameters measured on continuous scale were compared between the two groups with Student's *t*-test (two-tailed, independent). Chi-square test was used to compare the study parameters on categorical scale. The proportion of patients in either group with continuing postoperative analgesia as a function of time was shown as Kaplan Meier curves and analyzed using log rank test. The Statistical software namely SPSS 22.0 and R environment ver. 3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables, etc.

## Results

The demographic and baseline data of the two groups are shown in Table 1. The mean duration of analgesia in Group I was 405.0 ± 173.8 min and in Group II 485.0 ± 229.8 min. The Kaplan Meier graph shows the proportion of parturients in each group with continuing pain relief as a function of time [Figure 2]. A log rank test between pairs of curves showed no significant difference ($P = 0.123$). The percentage of parturients with effective analgesia 5 h after spinal anesthesia showed no difference between the two groups. The parturients in group I showed a significantly faster onset of sensory

**Table 1: Demographic and baseline characteristics of the two groups**

| Variable | Group I (*n*=30) | Group II (*n*=30) |
|---|---|---|
| Age (years) | 23.2±5.1 | 24.3±4.9 |
| Height (cm) | 150.0±6.0 | 152.0±7.1 |
| Weight (kg) | 62.3±12.4 | 65.4±10.2 |
| Duration of surgery (min) | 42.6±7.3 | 47.5±8.7 |
| Gestation (weeks) | 37.5±0.6 | 38.2±0.4 |

*Values are presented as mean±SD*

blockade as compared to those in Group II ($P = 0.004$). The parturients in Group I recovered earlier from sensory blockade than those in Group II ($P < 0.001$) [Table 2]. All parturients in group I had sensory recovery within 6 h of spinal anesthesia, whereas 26.7% of parturients in Group II had sensory recovery after 6 h of spinal anesthesia. The time taken for onset of motor blockade was similar in the two groups ($P = 0.265$) [Table 2]. Parturients in Group I recovered faster from motor blockade than those in Group II ($P = 0.002$) [Table 2]. All parturients in Group I had motor recovery within 6 h of spinal anesthesia, but in Group II, 10% of patients recovered after 6 h of spinal anesthesia. There was no incidence of bradycardia in the two groups [Table 3]. Twelve out of thirty patients had hypotension in Group I as compared to thirteen out of thirty patients in Group II ($P = 0.79$). In the present study, it was observed that incidence of shivering was 10% in parturients receiving

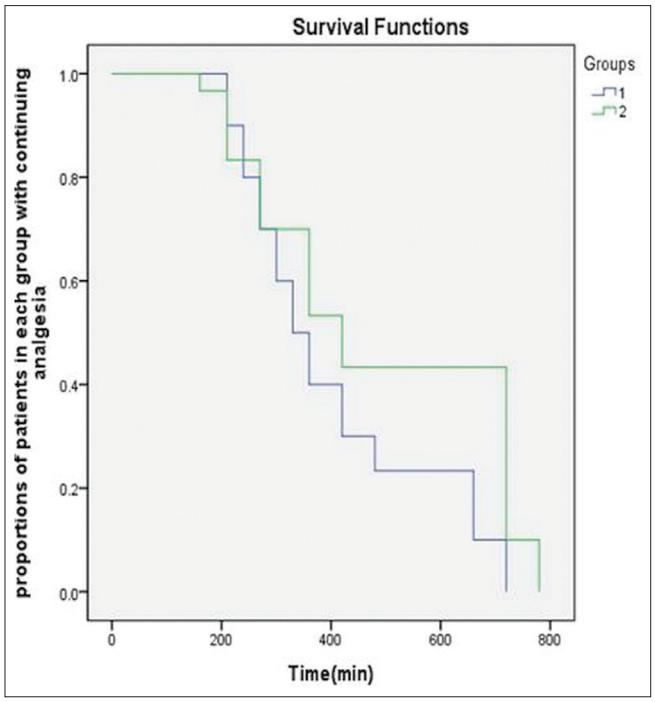


**Figure 2:** Kaplan Meier analysis that depicts the proportion of patients with continuing pain relief as a function of time. A log rank test showed no significant difference ($P = 0.123$)

intrathecal isobaric levobupivacaine with $MgSO_4$ as compared to 27% in parturients receiving hyperbaric bupivacaine with $MgSO_4$ [Table 3]. This difference was not statistically significant ($P = 0.095$).

## Discussion

The results of the present study indicate that isobaric levobupivacaine with $MgSO_4$ produces similar duration of postoperative analgesia when compared with hyperbaric bupivacaine with $MgSO_4$ for spinal anesthesia in parturients undergoing caesarean section. This finding is similar to the findings by Fattorini *et al.*[14] and Dar[10] who compared plain isobaric levobupivacaine and hyperbaric bupivacaine for lower limb orthopedic surgeries and caesarean sections, respectively. Various studies have compared use of intrathecal hyperbaric bupivacaine with isobaric levobupivacaine with or without adjuvants.[11,13–19] Magnesium is an ion that inhibits calcium entry into the cells by noncompetitive blockade of the dorsal horn N-methyl-aspartate (NMDA) receptor, which modulates or prevents central pain sensitization.[20] Jabalameli *et al.*[17] studied three different doses of magnesium sulfate namely 50, 75, and 100 mg, with hyperbaric bupivacaine for caesarean section and found that 75 mg is ideal for intrathecal injection as it increases the duration of postoperative analgesia and prolongs the sensory and motor block without increase in maternal and neonatal side effects. Based on the above findings, we decided to use intrathecal $MgSO_4$ at a dose of 75 mg.

**Table 2: Mean time taken for onset and recovery of block in the two groups**

| Variables | Group I ($n$=30) | Group II ($n$=30) | $P$ |
|---|---|---|---|
| Onset (minutes) | | | |
| Sensory | 3.5±1.3 | 4.8±2.0 | 0.004 |
| Motor | 3.8±2.4 | 3.2±1.5 | 0.265 |
| Recovery (minutes) | | | |
| Sensory | 231.5±69.8 | 264.6±130.6 | <0.001 |
| Motor | 225.0±85.4 | 267.0±44.1 | 0.002 |
| Duration of analgesia (minutes) | 405.0±173.8 | 485.0±229.8 | 0.175 |
| APGAR score at 1 min | 8.3±0.6 | 8.1±0.8 | 0.401 |

*The values have been presented as mean±SD and analyzed using Student's t-test*

**Table 3: Number of patients with adverse effects in the two groups**

| Adverse effects | Group I ($n$=30) | Group II ($n$=30) | $P$ |
|---|---|---|---|
| Bradycardia | 0 (0%) | 0 (0%) | - |
| Hypotension | 12 (40%) | 13 (43.3%) | 0.79 |
| Shivering | 3 (10%) | 8 (27%) | 0.095 |

*Values are presented as number and percentage and analyzed using Chi-square test*

The finding of early onset of sensory blockade in parturients receiving intrathecal levobupivacaine with $MgSO_4$ as compared to those receiving hyperbaric bupivacaine with $MgSO_4$, in our study, is in contrast to studies comparing plain levobupivacaine and hyperbaric bupivacaine where no significant difference was observed between the onset of action of sensory blockade.[9,21] Studies have shown that addition of intrathecal MgSO4 to hyperbaric bupivacaine causes a delay in onset of sensory blockade[22,23] Buvanendran *et al.*[6] in 2002 studied the effect of administration of 50 mg of intrathecal magnesium and 25 mcg of fentanyl versus plain fentanyl in parturients requiring labor analgesia. They also measured the baricity of magnesium sulfate mixed with fentanyl using refractometry and found it (and fentanyl) to be slightly hypobaric with respect to cerebrospinal fluid (CSF). There are no studies that measure the changes in baricity of levobupivacaine after addition of $MgSO_4$. Further randomized controlled studies are required after verification of baricity of magnesium containing solutions including isobaric levobupivacaine and hyperbaric bupivacaine to account for variability between studies.

In our study, all 30 patients receiving intrathecal levobupivacaine with $MgSO_4$ had sensory recovery within 6 h of administration of spinal anesthesia, whereas only 22 patients out of 30 patients had sensory recovery within first 6 h in bupivacaine with $MgSO_4$ group. This finding of early sensory recovery in parturients receiving intrathecal levobupivacaine with $MgSO_4$ is similar to the findings in a study done by Guler *et al.*[8] where a comparison of isobaric levobupivacaine with hyperbaric bupivacaine was done for

caesarean section and it was observed that sensory and motor block durations are shorter in parturients receiving isobaric levobupivacaine as compared to hyperbaric bupivacaine. Although the duration of analgesia in the present study showed no significant difference in the two groups, the sensory recovery time was faster in the parturients receiving levobupivacaine with $MgSO_4$. The mode of assessment of sensory recovery was based on loss of pin prick sensation at T12 level. The assessment of duration of analgesia was based on VAS scale or demand for analgesia by the parturient, which is a subjective criterion. This explains the difference in the comparisons between the sensory recovery time and the postoperative duration of analgesia.

In the present study, the onset of motor blockade [Table 2] was similar in parturients receiving isobaric levobupivacaine (3.8 ± 2.5 min) and those receiving hyperbaric bupivacaine (3.2 ± 1.6 min). However, Guler *et al.*[8] found delay in onset of motor blockade in group receiving levobupivacaine with fentanyl compared to bupivacaine with fentanyl for spinal anesthesia in parturients undergoing caesarean sections.

In our study, parturients receiving levobupivacaine with $MgSO_4$ showed significantly shorter duration of motor blockade as compared to those receiving hyperbaric bupivacaine with $MgSO_4$. Studies have shown that levobupivacaine and ropivacaine produce early regression of motor blockade as compared with bupivacaine[14,18] The results of our study are comparable to the study by Guler *et al.*,[8] Babu *et al.*,[9] and Dar *et al.*[10] The early recovery of motor blockade facilitated early ambulation in the parturients who received levobupivacaine with $MgSO_4$. Bradycardia was not observed in any of the parturients in the two groups [Table 3]. Studies comparing hemodynamics with intrathecal isobaric and hyperbaric bupivacaine for caesarean sections have shown lesser incidence of bradycardia with isobaric levobupivacaine.[8,24] Conventional local anesthetic doses in spinal anesthesia for caesarean section cause hypotension in 70%–80% of the cases.[25] In the present study, the incidence of hypotension was similar in the two groups [Table 3]. Banihashem *et al.*[26] compared plain hyperbaric bupivacaine and hyperbaric bupivacaine with $MgSO_4$ and observed that there are no significant hemodynamic variations in the two groups.

In the present study, the incidence of shivering was similar in the two groups. Addition of $MgSO_4$ intrathecally with hyperbaric bupivacaine has been proven to produce lesser incidence of shivering as compared to plain hyperbaric bupivacaine in patients undergoing caesarean section.[27] Reem *et al.* in 2018 studied the effect of adding epidural $MgSO_4$ in a dose of 500 mg with 0.5% levobupivacaine in parturients receiving epidural anesthesia[28] and observed that the incidence of shivering was lesser in parturients receiving epidural levobupivacaine with $MgSO_4$ as compared to those receiving epidural plain levobupivacaine. The neonatal APGAR scores at 1 min were similar in the two groups [Table 2]. Further assessment of neonatal outcome using cord blood pH was not done in the present study. This is one of the limitations of our study. Another limitation is the difference in baricity of the local anesthetics used in the study. A study with a different dose of intrathecal $MgSO_4$ or a larger sample size might have shown a significant difference in duration of analgesia.

In conclusion, intrathecal levobupivacaine with $MgSO_4$ produces a similar duration of postoperative analgesia as compared to hyperbaric bupivacaine with $MgSO_4$. Early motor recovery allowing early ambulation postoperatively makes isobaric levobupivacaine with $MgSO_4$ a good alternative for caesarean sections.

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## Conflicts of interest
There are no conflicts of interest.

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