Section: Anaesthesiology

Original Research Article

ANALGESIC EFFICACY OF MAGNESIUM SULPHATE VERSUS DEXAMETHASONE IN PATIENTS UNDERGOING CAESAREAN SECTION UNDER SPINAL ANAESTHESIA: A DOUBLE BLIND RANDOMISED CONTROL STUDY

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ABSTRACT

Background: Spinal anaesthesia is at the core of conduct of caesarean section. Aim of this study was to compare analgesic efficacy of magnesium sulphate with dexamethasone in patients undergoing caesarean section under spinal anaesthesia with bupivacaine. **Materials and Methods:** After obtaining approval from the Institutional Ethics Committee, this prospective, randomized double blinded study was conducted in sixty-eight pregnant females. The patients were divided into two groups with Group M receiving 50 mg/kg magnesium sulphate intravenous infusion while Group D received Eight mg dexamethasone intravenous infusion. Time for first analgesia, requirement of postoperative rescue analgesics, duration of sensory - motor blockade and hemodynamic parameters were compared in both the groups. Categorical variables are presented as number and percentage (%) while the continuous variables are presented as mean ± standard deviation and median (interquartile range). Independent t test was used for continuous variables and chi square test was used for categorical variables. **Result:** The demographic profile of the patients was comparable with no statistical difference between two groups (P >0.05). The mean duration of sensory and motor block was higher in Group M than in Group D. The VAS scores were significantly different between the two groups at 3 hrs, 9hrs, 12hrs, 18hrs, and 24 hrs postoperatively. Group D had significantly more requirement of rescue analgesic as compared to Magnesium sulphate group. **Conclusion:** Pre operative administration of intravenous magnesium sulphate significantly reduces postoperative pain in patients undergoing cesarean section under spinal anesthesia when compared to intravenous dexamethasone.

INTRODUCTION

Spinal anaesthesia is at the core of conduct of caesarean section. It not just provides anaesthesia, it also helps in early bonding of mother and child, paving the way for early restoration of normalcy despite female undergoing a surgical procedure. Adequate pain management facilitates early ambulation and reduces postoperative complications such as thromboembolic events and postoperative pulmonary complications leading to an overall improved patient satisfaction. But the effect of spinal anesthesia is limited, forcing the requirement of various analgesics to manage the postoperative pain quite early, as compared to other methods like epidural analgesia. To delay the requirement of various analgesics various adjuvants have been used intrathecally (fentanyl, morphine, clonidine) as well as intravenously (lignocaine, dexamethasone, magnesium sulphate). Magnesium sulphate appears to have analgesic effect in patients undergoing anaesthesia by exerting an antagonistic effect at the N-methyl-D-aspartate (NMDA) receptor in addition to calcium-channel blocking properties.[1] On the other hand, Dexamethasone exerts its effect via anti-inflammatory properties and decreasing surgical stress response.[2]

The primary objective of the study was to compare the postoperative analgesic efficacy in terms of time for first analgesia and requirement of postoperative rescue analgesics. The secondary objectives of the study were to compare the duration of sensory blockade and motor blockade in each group, to

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determine the hemodynamic parameters in each group, and to determine side effects, if any.

MATERIALS AND METHODS

After obtaining approval from the Institutional Ethics Committee, this prospective, randomized double blinded study was conducted. Sixty-eight pregnant females were allocated in ratio of 1:1 according to parallel design, with evaluation of superiority of one drug over another. Patients belonging to ASA physical status II posted for elective caesarean section in our hospital were included in the study after explaining the protocol and informed written consent. Patients who refused to participate in the study, had significant neurological, psychiatric, neuromuscular, cardiovascular, pulmonary, renal or hepatic diseases, had history of allergy to drugs under study, history of treatment with magnesium or calcium channel blockers, history of opioids, steroid or analgesic abuse and cases where general anaesthesia was required due to any reason were excluded from the study. The patients were divided into two groups with Group M consisting of patients who received 50 mg/kg magnesium sulphate intravenous infusion with 100 ml 0.9%NaCl over 10 minutes while Group D consisted of patients who received eight mg dexamethasone intravenous infusion with 100 ml 0.9%NaCl over 10 minutes.

Pre-anaesthetic check-up (PAC) was carried out in all patients posted for elective cesarean section and informed written consent was obtained from all the patients during checkup. All patients were kept nil per os as per ASA protocol. On the day of Caesarean section, standard peri-operative monitoring was done as per American Society of Anesthesiologists (ASA) protocol including heart rate (HR), non-invasive blood pressure (NIBP), electrocardiogram (ECG), pulse-oximetry (SpO2) and temperature. Variables were continually recorded every 5 minutes upto 30 minutes followed by every 10 minutes till completion of surgery. A broad gauge cannula was secured preoperatively and and injection Lactated ringer was infused @10 ml/kg for co-loading. Deep tendon reflex of all patients was examined pre-operatively.

Patients were randomly allocated to either of the two groups and administered drugs as per protocol 15 minutes prior to spinal anesthesia. Anaesthesiologist and nursing officer administering the drug were not involved in the study. Under strict aseptic precautions, in lateral decubitus position, patient was administered 10 mg hyperbaric bupivacaine in Spinal anesthesia at L3-L4 level with 25 G Whitacre needle. Time of completion of the subarachnoid block was taken as time 0 and all variables were measured at prespecified intervals. Time of onset of sensory and motor block was recorded. The adequacy of motor block was assessed by Bromage scale. The onset of motor block was defined as the time from intrathecal injection to Bromage 3 block. Sensory block was measured by Modified Hollman score. The onset of sensory block was defined as time from intrathecal injection to bilateral T6 level of sensory blockade. Patients were assessed for loss of sensation to pin prick over dermatomes at every 2 minutes for 10 minutes. The duration of sensory block was defined as the time from intrathecal injection to regression of the sensory block to T10 and motor recovery was considered when the modified Bromage score was zero. The duration of analgesia was defined as the period from intrathecal injection to the first complaint of pain by the patient. Surgery was allowed to begin once full surgical anaesthesia was established. Patients were monitored for pain using visual analogue scale (VAS) intra-operatively and post-operatively for a period of 24 hrs. The total duration of the surgery was also observed. Intraoperatively, patients were also observed intra-operatively for adverse drug reactions and haemodynamic parameters. Variation of hemodynamic parameters ≥20% was observed and managed accordingly. In case of hypotension, 200 ml bolus of IV fluid was given as primary management while IV 6mg Ephedrine 6mg was administered, if the hypotension persisted. Similarly, Inj. Atropine 0.02mg/kg was administered intravenously, in case of bradycardia. Inj Oxytocin was administered according to standard institutional protocol after clamping of umbilical cord. APGAR scores of baby was also noted at one and five minutes.

Post-operatively, patients were assessed at 1, 2, 3, 6, 9, 12, 18 and 24 hrs for hemodynamic parameters, VAS scores, adverse effects and need of rescue medication. Standard monitoring including heart rate (HR), Systolic blood pressure (SBP), Diastolic blood pressure (DBP) and urine output was monitored postoperatively, till a period of 24 hrs. Rescue analgesia in the form of Inj. Paracetamol 15mg/kg IV was given on patient demand or VAS score>3.

Time for first rescue analgesia and total number of rescue analgesia was recorded. Deep tendon reflexes were continuously monitored postoperatively after blockade was over. The side effects like postoperative hypotension, shivering, excessive blood loss, nausea and vomiting were also observed. Any complications encountered during post-operative periods were managed as per institutional protocol.

The sample size was calculated based on previous studies by Rezae et al,[3] The superiority margin was taken at 2.7 hrs with the alpha error at 5% and power of study being 80%. The sample size was calculated to be 34 patients in each group i.e. a total of 68 patients. The data was recorded in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of JASP software. Categorical variables are presented as number and percentage (%) while the continuous variables are presented as mean ± standard deviation and median (interquartile range). Independent t test was used for continuous variables and chi square test was used for categorical variables. For statistical significance, p value of less than 0.05 was considered as significant.

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RESULTS

The clinical study comprising of 68 patients posted for elective cesarean section with ASA physical status I & II was done to evaluate postoperative analgesic effect of single dose of intravenous magnesium sulphate infusion versus single dose of dexamethasone infusion in patients undergoing caesarean section under spinal anaesthesia. The demographic profile of the patients age, weight and height were comparable with no statistical difference between two groups (P >0.05) [Table 1]. There was significant hemodynamic change during intraoperative period at 15, 20 and 25 minutes with more incidence of hypotension and tachycardia occurring in group M than group D but no difference was observed during postoperative period [Figure 1]. The APGAR score was comparable between the two study groups (p= >0.05), indicating that none of the drugs under study had any adverse effect on the delivered babies. The mean duration of sensory and motor block was higher in Group M than in Group D [Table 2]. The VAS scores were significantly different between the two groups at 3 hrs, 9hrs, 12hrs, 18hrs, and 24 hrs postoperatively [Figure 2]. The difference in the mean number of post-operative analgesic doses in 24 hours between the study groups was statistically significant (p-value <0.001).

Table 1: Comparison of Demographic profile, Duration of Surgery and APGAR scores in both the groups

Variable	Group M(n=34)	Group D(n=34)	P value
Age (Yrs)	26.48 ± 3.96	26.71 ± 4.80	0.568
Weight (Kg)	63.71 ± 8.56	63.32 ± 8.78	0.596
Height (cm)	158.61 ±2.98	159.36 ± 4.57	0.667
ASA physical status (I/II)	19/15	16/18	0.256
Duration Of Surgery (min)	49.64 ± 12.83	48.91 ± 13.18	0.972
APGAR score 1 min	7.25 ± 0.73	7.54 ± 0.75	0.823
APGAR score 5 min	10 ± 0	10 ± 0	*

*Can not be computed, as std deviation is Zero

Table 2: Comparison of Sensorimotor properties in both the groups

Variable	Group M(n=34)	Group D(n=34)	P value
Duration of Sensory block	172.9 ± 6.58	143.16 ± 8.62	<.001
Duration of motor block	162.65 ± 6.13	134.16 ± 8.13	<.001
Duration of analgesia	240.65 ± 30.05	225 ± 24.60	0.165
Number of rescue analgesics	2.87 ± 0.56	4 ± 0.73	<.001

Table 3: Side effects in both the groups.

Variable	Group M	Group D	P value
Shivering(present/Absent)	23/11	19/15	<0.001
PONV (Yes/No)	10/24	8/26	0.024

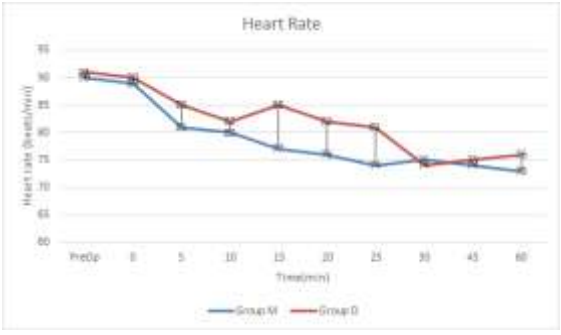

Figure 1: Comparison of Heart rate (per minute) at between group M and Group D.

Figure 2: Comparison of VAS score between group M and D.

DISCUSSION

Spinal anesthesia provides excellent anesthesia as well as perioperative analgesia. Various studies have been conducted to prolong the effects of spinal anesthesia with the use of adjuvants. The present study was done to compare effect of magnesium sulphate (50mg/kg) with dexamethasone (8mg) given pre-emptively in 68 pregnant patients posted for elective Caesarean section. Previous studies investigating the analgesic efficacy of magnesium sulphate and dexamethasone have shown mixed results. A study was conducted by Mahgoub et al,[4] to compare the duration of postoperative analgesia after adding either magnesium sulfate or dexamethasone to levobupivacaine for performing supraclavicular brachial plexus block in patients undergoing upper-limb surgeries. They concluded that there was no significant difference in postoperative analgesia between dexamethasone and magnesium sulfate when added to levobupivacaine as adjuvants. In our study, we observed that Group M required less postoperative rescue analgesics than Group D, thereby providing better postoperative analgesia. The studies conducted by Shah et al and

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Shalu et al, both describes the prolonging of analgesic effect with use of Magnesium sulphate and Dexamethasone when compared to control cases.[5,6]
The duration of motor blockade was prolonged in group M as compared to group D. The result was in concordance with a study conducted by Hwang et al who made similar observations in arthroscopic knee surgeries under spinal anaesthesia.[7] Zhong et al,[8] also made similar observations that intravenous magnesium sulphate administered in a dosage of 50mg/kg significantly prolonged the duration of sensory and motor block as compared to the control group($p < 0.05$).[7] Parthasarathy et al,[9] conducted a study to evaluate the efficacy of single-dose intravenous dexamethasone on postoperative pain and observed that the mean duration of motor block was increased in patients receiving dexamethasone as an IV adjuvant. The results were statistically significant, in contrast to study by Shalu et al,[6] who did not observe any prolongation with dexamethasone.
The duration of sensory blockade in group M was almost 30 min more than group D and the difference was statistically significant with $p < 0.05$. Previous studies by Zhong et al,[8] and Shalu et al,[6] made similar observations with use of magnesium sulphate (261.3min ± 64.7min) and dexamethasone (162.50 min) with control groups in their respective studies.
Magnesium sulphate induces hypotension directly by vasodilatation as well as indirectly by sympathetic blockade and inhibition of catecholamine release. Transient fall in Mean arterial pressure was observed at 20 mins, and 25 minutes ($p=0.026$) Hypotension was managed with 200 ml IV fluid bolus followed by Inj Ephedrine 6 mg IV if required. None of patients in any of the groups had any episode of bradycardia warranting treatment. This is in accordance with previous studies like Maulik et al,[9] and Shalu et al.
The APGAR scores were evaluated and recorded in the first and fifth min by a paediatrician and were statistically insignificant. These results were in concordance with previous studies like Zhong et al,[8] who studied the effect of intravenous magnesium sulfate in preeclamptic patients under spinal anesthesia with bupivicaine 0.5% (heavy) and observed that intravenous magnesium sulphate administered in a dosage of 50mg/kg had no adverse effect on the baby. Patnaik et al,[10] did not observe any significant effect of dexamethasone on neonatal outcome.
In our study, we observed that patients in Group D had less perioperative shivering episodes as compared to Group M ($p=0.001$). Destaw et al,[11] made similar observations while comparing dexamethasone and pethidine for prevention of post-spinal anesthesia shivering. Patients in group D did not complain of nausea and vomiting. They had better tolerance to feed than Group M, postoperatively. Dexamethasone exerts antiemetic effect by inhibiting the release of prostaglandins and serotonin in the gastrointestinal tract and endorphin in the nervous system. Similar observations were made by Cardoso et al,[12] concluding that dexamethasone reduced the cumulative incidence of nausea, vomiting and pain after cesarean section under spinal anesthesia.
In our study, we did not observe any adverse effect related to the drugs, in mother as well as baby, which was in concordance with a study by previous researchers.[10,13]
Our study was marred with a few limitations. We did not measure serum magnesium and cerebrospinal fluid magnesium concentration. However, it has been studied that most of total body magnesium (99%) is intracellular and estimation of plasma magnesium does not represent magnesium content of body tissues. Therefore, there is lack of correlation between plasma magnesium concentration and total body magnesium content. A larger study population and sample size would have ensured better validation of results. As the study was performed in a small geographic location, the results of this study may not be representative of population in different geographic areas.

CONCLUSION

As per our observations we have concluded that administration of intravenous magnesium sulphate 50 mg/kg preoperatively significantly reduces postoperative pain in patients undergoing cesarean section under spinal anesthesia than intravenous dexamethasone Eight mg. In the present study we did not find any evidence of adverse effect owing to the use of magnesium sulphate or dexamethasone because of small sample size. However, further studies should be carried regarding different dosages of magnesium and dexamethasone, comparison with established analgesic drugs of other classes and other routes of administration of magnesium sulphate such as (spinal, epidural and as adjuvant with local anaesthetic for regional nerve blocks).

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