Section: Anesthesia

Original Research Article

EFFECT OF LOW-DOSE (SINGLE-DOSE) MAGNESIUM SULPHATE ON POSTOPERATIVE ANALGESIA IN PATIENTS UNDERGOING TOTAL ABDOMINAL HYSTERECTOMY RECEIVING BALANCED GENERAL ANESTHESIA

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ABSTRACT

Background: Adequate perioperative pain management helps to relieve the patients' suffering, allow early mobilization after surgery, reduce the length of hospital stay and have better satisfaction. The objective is to determine the analgesic effect of a single low-dose (50mg/kg) intravenous magnesium as an adjunct to standardized opioid regimen in patients undergoing total abdominal hysterectomy under balanced general anesthesia as quantified by NRS at 0, 6, 12, 24 hours after surgery. **Materials and Methods:** This prospective, double-blinded, randomized, control study was conducted among ASA I-II female patients who had undergone elective TAH surgery under balanced general anesthesia at Manipal Hospital, Old Airport Road, Bangalore, a multi-specialty tertiary care hospital. Duration of study was from August 2023 - January 2024. **Result:** A consistent and statistically significant difference in MAP (mmHg) between the two groups across various time intervals (PACU 0 hours, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours) was observed. A consistent and statistically significant difference in heart rates between Group M and group C across various time intervals (baseline, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours) except at PACU 0 hr was observed. The mean SBP in group M was significantly lower at 0 hour in PACU (P 0.05). Though the SBP was lower in magnesium group at other time intervals it was not statistically significant. Later, after 24 hours of surgery statistically significant lower SBP was found in group M patients. At 6 hours (P=0.006), 12 hours (P 0.011) and 24 hours (P <0.001) there was significant reduction in DBP in group M. There was a consistent and statistically significant difference in NRS (PACU) score between the two groups across various time intervals (baseline, PACU 0 hours, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours). **Conclusion:** Low dose magnesium sulphate is an effective pre-emptive analgesic on postoperative analgesia in patients undergoing total abdominal hysterectomy receiving balanced general anaesthesia as per reduced heart rate, mean arterial pressure and blood pressure reduction along with lower pain scores noted in group given magnesium sulphate in comparison with control group. A lower consumption of Fentanyl an opioid given for postoperative pain management was also noted in group receiving magnesium sulphate was also noted in the study.

INTRODUCTION

It is estimated that around 75% of patients undergoing surgical procedures experience acute post-operative pain which is usually medium to high in severity.[1] Among these less than 50% of patients report receiving adequate post-operative pain relief.[2] Subjective success of any surgical procedure depends on patients' satisfaction which in turn is influenced by efficacy of analgesia both in immediate as well as long term period following the surgery. When acute post-operative pain is not managed effectively it leads to neurological, cardiovascular, and thromboembolic sequalae caused due to immobility associated with pain, eventually leading to prolonged hospitalisation. In case of abdominal hysterectomy, inadequately treated operative pain can lead to chronic pain syndrome called hysterectomy chronic pelvic pain syndrome.[3]

Pre-emptive analgesia is defined as an intervention given before incision or surgery.[4] Advances in research in the basic science of pain in combination with evidence-based clinical research have led to the understanding that in surgical procedures, surgical incision alone does not result in central sensitization, but other factors including preoperative pain, additional painful noxious intraoperative inputs like retraction, post-operative inflammatory processes, related peripheral and central neuromodulators and ectopic neural activity, all cause augmentation of acute pain and long term post-portative pain as a consequence of central sensitization. Magnesium sulphate has been reported to be effective in perioperative pain treatment and in blunting somatic, autonomic and endocrine reflexes provoked by noxious stimuli.[5]

Abdominal hysterectomy is a major surgery associated with interim inflammatory response, resulting in moderate to severe postoperative pain perception. Pain management in these surgeries aims to provide adequate analgesia with minimal side effects. Opioids are the most used perioperative analgesics but may be associated with side effects such as nausea, vomiting, itching, tolerance, dependence, and addiction. We hypothesized that even a single low dose of magnesium given pre-emptively will provide adequate analgesia and will reduce peri-operative opioid requirements in patients undergoing total abdominal hysterectomy under balanced general anaesthesia.

MATERIALS AND METHODS

This prospective, double-blinded, randomized, control study was conducted among ASA I-II female patients who had undergone elective TAH surgery under balanced general anesthesia at Manipal Hospital, Old Airport Road, Bangalore, a multi-specialty tertiary care hospital. Duration of study was from August 2023 - January 2024

Sample size calculation: Was estimated by using the difference in Mean Remifentanil (mg kg21 min21) used between Group S and Group M from the study by Ryu et al21, as 0.12 ± 0.012 and 0.11 ± 0.012. Using these values at a 95% Confidence limit and 80% power sample size of 50 was obtained in each group by using the below-mentioned formula and Med calc sample size software.

Considering the 10% non-participation rate (2 cases) 23+2 = 25 cases will be included in each group.

Patients were allocated to 2 groups by computerized random number table. This was intimated to the anesthesia assistant in sealed envelopes, who prepared the study medication in two 50ml syringes. The study group M had received magnesium sulphate 50 mg/kg over a period of 10 minutes just before induction (group M, n=25) and the control group had received equal volumes of normal saline (group C, n=25). Both the anesthesia consultant managing the case and the observer collecting the data were blinded to the group allocation.

Inclusion criteria

Adult female patients (18-65 years) of ASA 1 and 2 categories undergoing elective TAH surgery under balanced general anesthesia.

Exclusion criteria

Patients with known allergy to magnesium sulphate, renal, hepatic, or cardiovascular dysfunction, neurological disorders, atrioventricular conductance disturbance, and history of opioid abuse.

Method of collecting data: The institutional ethics committee had approved, that patients between 18 and 65 years of age, belonging to the American Society of Anesthesiologists (ASA) grade I/II undergone elective TAH surgery under balanced general anesthesia and who satisfied the inclusion and exclusion criteria were recruited for the study. Written informed consent was taken from all the recruited patients.

Preoperative assessment: Pre-anesthesia evaluation was done prior to the surgery and includes

1. Demographic data
2. Detailed history of comorbid illnesses and drug therapy
3. General examination
4. Systemic examination
5. Airway assessment will be carried out and documented

Relevant lab investigation to rule out exclusion criteria and as per the surgical procedure was carried out.

Conduct of study and method of measurement of outcome of interest: All patients were fasted for at least 6 hours before surgery. On arrival at the operating room, the sealed envelope which mentions the group allocated to the patient was handed over to the anesthesia technician present in the OT who in turn had prepared the study drug. Standard mandatory monitors (electrocardiogram, non-invasive blood pressure monitor, pulse-oximeter) were connected to the patient. In addition, a neuromuscular monitor (TOF) was connected. Intravenous access was secured with an 18/20G intravenous cannula. Baseline vital parameters were noted. Group M (magnesium sulphate group) received 50 mg/Kg of magnesium sulphate in 100 ml of normal saline before induction over a period of 10 minutes. Group C control (normal saline) received 100 ml of 0.9% sodium chloride solution before induction over a period of 10 minutes. After pre-oxygenation with 100% oxygen for 3 to 5 minutes, patients were induced with Inj Propofol (2-2.5 mg/kg) and Fentanyl 2mcg/kg. Muscle relaxation was achieved with Atracurium 0.5mg/kg or Rocuronium 0.6 –0.9mg/kg to facilitate oro-tracheal intubation. End-tidal gas monitors were connected. Following intubation with an appropriate-sized cuffed endotracheal tube, mechanical ventilation was started to adjust end-tidal CO2 between 30-32 mm Hg. Muscle relaxation was maintained with Atracurium boluses of 0.1 mg/kg or infusion of 0.3mg/kg/h targeting TOF count of zero. Preemptive analgesia was given with paracetamol 15- 20 mg/kg. Intraoperative analgesia was maintained with Fentanyl 0.5-1 mcg/kg/h as bolus or infusion. Anaesthesia was maintained with either Sevoflurane to achieve a minimal alveolar concentration of 1–1.5 MAC or propofol infusion as total intravenous anesthesia (TIVA) or TCI, Thus, controlled general anesthesia was administered to maintain hemodynamics within 20% of baseline values. Additional doses of fentanyl, if administered, were noted. At skin closure, patients were reversed with Neostigmine 50mcg/ kg Glycopyrrolate 10 mcg/kg or sugamadex 2mg/kg after onset of spontaneous breathing and appearance of TOF count of 2 or more. Patients were extubated when clinical criteria for reversal of neuromuscular blockade and TOF >0.9 were fulfilled. All patients were shifted to the post-anesthesia care unit (PACU) where they were assessed for pain using a numeric rating scale (NRS). The pain was assessed at 0,6,12 and 24 hours after surgery. Postoperatively vital parameters readings were noted. Analgesics such as Pentazocine (15 mg intravenous boluses) or 0.5mcg/kg boluses of Fentanyl were administered to patients with NRS>4. Incidences of post-operative nausea and vomiting were noted. Signs of magnesium toxicity (weakness, loss of deep tendon reflexes) were watched for. In case of any suspicion of magnesium toxicity, serum magnesium levels were sent from the PACU and patients were treated accordingly. The patient's sedation status was assessed and scored. The patient was shifted to the ward after 1 hour of assessment in the PACU. Pain assessment was done inwards 6,12and 24 hours after surgery by an independent observer and total analgesic consumption (fentanyl, morphine, tramadol, pentazocine, diclofenac, or any other) was noted.

In a Numerical Rating Scale (NRS), patients were asked to circle the number between 0 and 10. Zero usually represents ‘no pain at all’ whereas the upper limit represents ‘the worst pain ever possible.[6]

Baseline parameters:

1. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, and Spo2.
2. Total fentanyl consumption.

Postoperative parameters (PACU):

1. Heart rate, blood pressure, and Spo2.
2. Pain assessment by using a numerical rating scale at 0,6,12 and 24 hours after surgery.
3. Sedation score.
4. Incidence of post-operative nausea and vomiting.
5. Signs of magnesium toxicity (weakness, loss of deep tendon reflexes).
6. Total analgesic consumption (pentazocine/ fentanyl/ tramadol/ morphine/ diclofenac) in the first 24 hours after surgery.

Statistical Analysis: NRS score was considered as the primary outcome variable. Overall analgesic consumption in the first 24 hours of the postoperative period, hemodynamic stability, sedation score, and any complications in the post-anesthetic care unit (PACU) were considered Secondary outcome variables. The study group (Cases vs. controls) was considered as the Primary explanatory variable. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, and frequency and proportion for categorical variables.

All Quantitative variables were checked for normal distribution within each category of an explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-Wilk test was also conducted to assess normal distribution. Shapiro Wilk test p-value of >0.05 was considered as a normal distribution. Categorical outcomes were compared between study groups using the Chi-square test /Fisher's Exact test was used). Data was analyzed by using SPSS software, V.22.[7]

RESULTS

Patients receiving Magnesium were included in Group M and those receiving normal saline were included in Group C. All the included patients were able to complete the study.

Table 1: Comparison of demographics between the two groups (N=50)

	Group M (N=25) (Mean± SD)	**Group C (N=25) (Mean± SD)**	
Age (years)	47.92 ± 9.26	56.2 ± 5.62	<0.001*
Height(cm)	159.52 ± 3.65	152.52 ± 4.46	<0.001*
Weight (Kg)	63.44 ± 8.48	61.76 ± 7.14	0.452
BMI	24.92 ± 3.21	26.47 ± 3	0.084
ASA Grade			
1	13 (52%)	23 (92%)	0.002*
2	12 (48%)	2 (8%)	

The mean age of patients in the control group was significantly more (p<0.001). The mean height of patients in the control group was significantly less (p<0.001). The mean of weight was a little high in cases compared to controls but not statistically significant (p 0.458). The mean of BMI was a little less in cases compared to controls but not statistically significant (p 0.084). There were more patients belonging to ASA- 1 category in the control group (P= 0.002). [Table 1]

Post-Anesthesia Care Unit: The baseline heart rate in Group C was higher. There was a consistent and statistically significant difference in heart rates between the 2 groups across various time intervals (PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours) except at PACU 0 hr. Patients in group M generally had lower heart rates than controls. Though the difference existed at baseline, the degree of statistical significance at later time intervals was higher. [Figure 1]

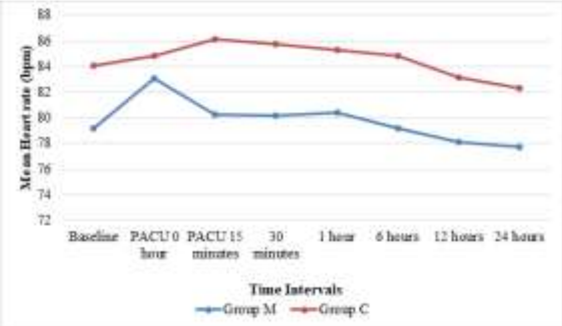

Figure 1: Comparison of mean heart rate (beats/minutes) between the two groups at different time periods.

The mean SBP in group M was significantly lower at 0 hour in PACU (P= 0.05). Though the SBP was lower in magnesium group at other time intervals it was not statistically significant. Later, after 24 hours of surgery, we found statistically significant lower SBP in group M patients (P =0.002) [Figure 2]

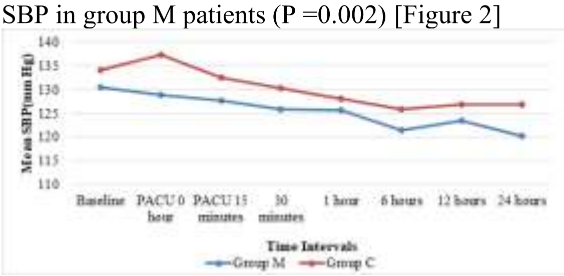

Figure 2: Comparison of mean of SBP (mmHg) between the two groups at different time periods.

There was no difference in DBP values between the two groups up to one hour of observation in post-operative period. Thereafter at 6 hours (P=0.006), 12 hours (P 0.011) and 24 hours (P <0.001) there was significant reduction in DBP in group M. [Figure 3]

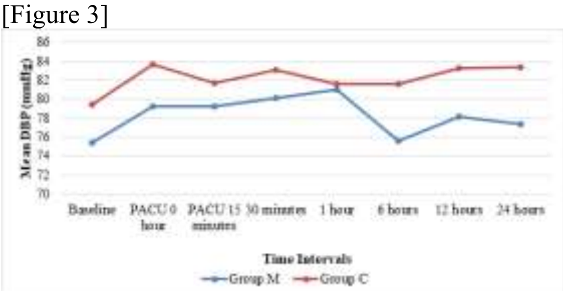

Figure 3: Comparison of mean DBP (mmHg) between the two groups at different time periods.

There was a consistent and statistically significant difference in MAP (mmHg) between the two groups across various time intervals (PACU 0 hours, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours). Group M patients had lower MAP than controls. The difference in baseline MAP (mmHg) between the two groups was not significant. [Figure 4]

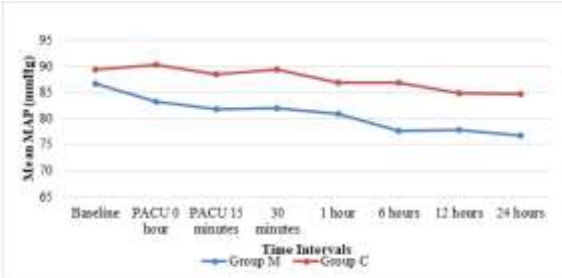

Figure 4: Comparison of mean MAP (mmHg) between the two groups at different time periods.

Patients in Group M had a consistent and statistically significant decrease in NRS (PACU) score in PACU at all time intervals. [Figure 5]

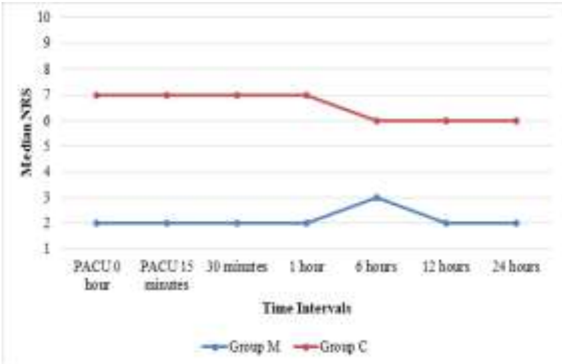

Figure 5: Comparison of Median NRS (PACU) score between the two groups at different time periods.

Sedation was assessed in the PACU using modified Ramsay score. Patients receiving magnesium were more sedated at 0 hour PACU. (P value <0.001*). After 15 minutes in the PACU, there was no difference in the sedation levels between the two groups. [Figure 6]

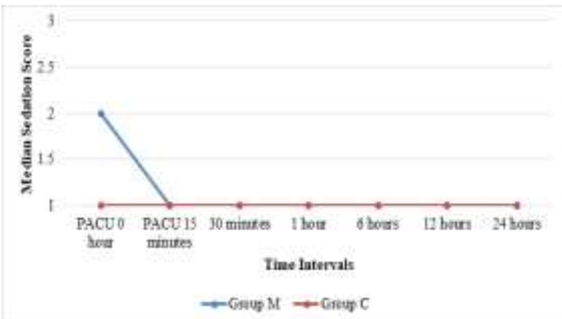

Figure 6: Comparison of mean sedation score (PACU) between the two groups at different time periods.

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The mean total fentanyl consumption in Group M during the intraoperative period was lesser compared to control group. However, this difference was not statistically significant (p=0.505). [Figure 7]

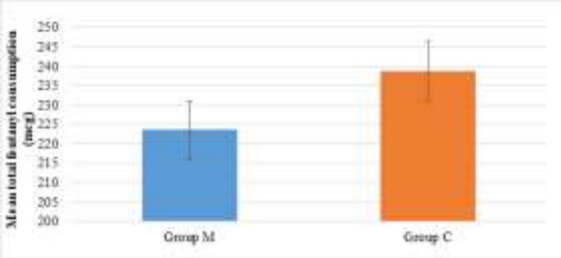

Figure 7: Comparative bar chart of mean total fentanyl (intra-op) consumption (mcg) between the two groups.

Group M-Magnesium Group C: Control P<0.05* considered statistically significant.

In patients receiving magnesium, 3 (12%) had PONV compared to 1 (4%) participant in the control group. This difference in PONV between the two groups was not found to be statistically significant. (p-value=0.297).

We found that 64% of patients in Magnesium group and 32% controls needed diclofenac rectal suppository. Intramuscular pentazocine 30mg was administered to 68% of control patients compared to 36% of patients in Magnesium group. The analysis showed that there was a significant difference between the two groups in terms of total analgesic consumption in the first 24 hours after surgery.

DISCUSSION

A total of 50 subjects were included in the final analysis. Among the study population, 25 (50%) participants were given magnesium sulphate (Group M) and the other 25(50%) of participants were controls who were given normal saline instead (Group C). The mean of height, weight, and BMI were a little high in cases compared to controls but not statistically significant whereas age was high in controls compared to cases.

Magnesium as pre-emptive analgesic: Magnesium as a pre-emptive analgesic has the potential to be more effective than a similar analgesic treatment initiated after surgery.[8] Consequently, immediate postoperative pain may be reduced, and the development of chronic pain may be prevented. This study confirmed the effect of low-dose magnesium sulphate (50mg/kg) bolus as a pre-emptive analgesic as patients receiving Magnesium had better postoperative analgesia and lower intraoperative fentanyl consumption

Magnesium and effect on hemodynamics: In addition to its opioid-sparing properties, magnesium has been shown to improve hemodynamic stability intraoperatively. Forget and Cata examined the role of IV magnesium in mitigating hemodynamic responses to major noncardiac surgery. Their meta-analysis showed that magnesium significantly reduced heart rate variability compared with placebo, but there was no effect on blood pressure. Although heart rate stability is associated with adequate analgesia under anesthesia, it is difficult to differentiate whether heart rate stability was truly due to the antinociceptive effects of magnesium or if it was instead a direct effect of the antiarrhythmic effect of magnesium.[9] In our study, we noted and compared postoperative hemodynamic changes between the 2 groups across various time intervals (PACU 0 hours, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours) and observed a consistent and statistically significant difference in MAP (mmHg) between the two groups. Group M patients generally had lower MAP than controls (Table 5 and figure 4). A consistent and statistically significant difference in heart rates between Group M and group C across various time intervals (baseline, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours) except at PACU 0 hour was observed. Patients in group M generally had lower heart rates than controls. Though the difference existed at baseline, the degree of statistical significance at later time intervals was higher. These results are similar to those noted in studies by Ryu et al,[10] and Seyhan et al,[11] which reported lower MAP and HR values in patients who received $MgSO_4$.

Magnesium and neuromuscular blockade: Pretreatment with $MgSO_4$ reduces the intubating dose of a nondepolarising NMBA, accelerates the onset of muscular block, increases the clinical duration of non depolarising neuromuscular block and delays recovery from neuromuscular blockade.[12] According to Czarnetzki et al, pretreatment with a single intravenous dose of $MgSO_4$ 60 mg kg^{-1} does not decrease the efficacy of reversal agent.[13] Han et al evaluated the impact of pretreatment with intravenous $MgSO_4$ on the dose requirements of rocuronium to establish deep (post tetanic count ≤ 3) or moderate neuromuscular blockade (TOF ≥1) for laparoscopic abdominal surgery, whether it facilitated reduction of the intra-abdominal insufflation pressure, improved surgical conditions and even surgical outcome. According to their findings, pretreatment with $MgSO_4$ 50 mg kg^{-1} allowed 20% reduction of the rocuronium dose needed to maintain deep neuromuscular blockade.[14] Considering this effect of $MgSO_4$, neuromuscular monitoring (GE Health care E-NMT-00®) was done in all patients in our study. Administration of maintenance dose of muscle relaxants, reversal and extubation was neuromuscular monitoring guided. In our study, we did not encounter any delay in neuromuscular recovery.

Magnesium use and mean total intraoperative fentanyl consumption: The mean total fentanyl consumption for Magnesium group during the intraoperative period was 223.68 ± 83.240 micrograms, and for the control group was 238.80 ± 75.723 micrograms. Though the mean total intraoperative fentanyl consumption was less in Group M, this difference was not statistically significant. This finding was in line with many other studies. A meta-analysis of 13 studies with 694 patients undergoing a variety of surgical procedures found that a magnesium bolus (30–50 mg/kg) and infusion (8–15 mg/kg/hr) decreased opioid consumption without compromising hemodynamic stability.[15]

Magnesium and effect on postoperative pain: A meta-analysis evaluating the effectiveness of IV magnesium as an analgesic adjunct revealed significant reduction in postoperative opioid consumption, and early (0 to 4 hours) and late (24 hours) pain scores. Intraoperative magnesium administration across the studies included in the meta-analysis used magnesium bolus doses ranging from 30 to 50 mg/kg, followed by variable infusions at rates ranging from 8 to 25 mg/kg/h.[16] In our study we gave bolus 50 mg/kg magnesium sulphate in 100ml normal saline before induction over a period of 10 minutes and pain scores was assessed post operatively at 0 hour, 15minutes, 30 minutes, 1 hour, 6 hours, 12 hours and 24 hours using NRS score. There was a consistent and statistically significant difference in NRS (PACU) score between the two groups across various time intervals (baseline, PACU 0 hours, PACU 15 minutes, 30 minutes, 1 hour, 6 hours, 12 hours, and 24 hours). Patients receiving magnesium had lower NRS (PACU) scores than controls. This observation along with the reduction of mean arterial pressure, heart rate, and blood pressure in patients receiving magnesium shows that single, low-dose magnesium sulphate given pre-emptively in patients undergoing total abdominal hysterectomy receiving balanced general anaesthesia resulted in better analgesia. This observation is similar to that reported in a similar study by Taheri et al,[17] which concluded that low doses of magnesium sulphate at 50 mg·kg−1 in 100 mL of normal saline solution alleviates postoperative pain throughout the first day after TAH under balanced general anaesthesia significantly and reduces opioid consumption as well. Ryu et al,[10] in a randomized double-blinded study assessed the effect of Mg sulphate on the intraoperative anaesthetic requirement and postoperative analgesia in gynaecologic patients who underwent TIVA (total intravenous anaesthesia) and concluded that IV Mg sulphate improves the quality of postoperative analgesia during TIVA. The difference is that in the study by Ryu et al, TIVA was used whereas balanced sevoflurane based general anaesthesia was used in the present study.

Magnesium and postoperative opioid consumption: In the postoperative period (first 24 hours), patients with NRS <5 were administered diclofenac rectal suppository and those with NRS>5 were given intramuscular single dose pentazocine (30 mg) as per surgical team rescue analgesic protocols. In our study, 36% of patients receiving Magnesium and 68% of controls needed intramuscular single dose pentazocine (30 mg). Patients who did not receive magnesium had significantly higher opioid (pentazocine) consumption in the first 24 hours (p=0.024). These findings are in sync with study by Kara et al that have demonstrated better postoperative analgesia with an initial bolus (30 mg/kg) followed by infusion (0.5 g/hr) of IV magnesium.[18] Likewise, Levaux C et al showed that an IV magnesium bolus (50 mg/kg) at induction improved pain and decreased opioid consumption following lumbar spine surgery.[19]

Magnesium and effect on PONV: Among the patients who received magnesium, 3 (12%) participants had post-operative nausea and vomiting, while only 1 (4%) participant in the control group had post-operative nausea and vomiting. The antinociceptive effect and opioid sparing properties of Magnesium should have resulted in reduced PONV as demonstrated by a few trials.[20] In our study, we found more patients with PONV in Group M. This difference was, however, statistically insignificant. (p=0.297).

Magnesium and postoperative sedation: Patients who received magnesium were found to be more sedated and less agitated on arrival to PACU (0 hour), which was a statistically significant difference (P value <0.001). This could be because of the central neurological calming effect of magnesium. There was no significant difference in the sedation score (PACU) between the cases and controls 15 minutes to 24 hours (P value> 0.05) in the postoperative period. Elsersy et al and Ryu JH et al have also noted similar decreased postoperative agitation and better recovery profiles in their respective studies.[21,22]

CONCLUSION

Our study observations lasting for 24 hours after surgery, reached the conclusion that low-dose magnesium sulphate (50mg/kg) is an effective pre-emptive analgesic in patients undergoing total abdominal hysterectomy receiving balanced sevoflurane based general anaesthesia as reflected by significant reduction in heart rate and mean arterial pressure along with lower post-operative pain scores when compared with control group. A lower consumption of intraoperative fentanyl was also noted in the group receiving magnesium sulphate. Patients who did not receive magnesium had significantly higher opioid (pentazocine) consumption in the first 24 hours (p=0.024) postoperatively. Patients receiving magnesium were found to be significantly less agitated and more sedated compared to control group on arrival to PACU (0 hour) (P value <0.001).

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