Original Article

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Postoperative Analgesia in Laparoscopic Cholecystectomy following Intraperitoneal Magnesium Sulphate: A Prospective Cohort Study

Anaesthesia Section

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ABSTRACT

Introdution: Postoperative pain and discomfort after laparoscopic cholecystectomy is partly because of distension, tearing, separation of parietal peritoneum and surgical manipulation. Intraperitoneal administration of Magnesium Sulphate ($MgSO_4$) is thought to desensitise the after effects of pneumoperitoneum in addition to providing analgesia.

Aim: To analyse the effect of intraperitoneal magnesium sulphate on postoperative analgesia and occurrence of shoulder pain after laparoscopic cholecystectomy.

Materials and Methods: The present study was a prospective cohort study which was conducted at the Government Medical College, Kozhikode, Kerala, India, from February 2019 to December 2020, included 60 adult patients scheduled for elective laparoscopic cholecystectomy under general anaesthesia were selected and they were divided into two groups, group M and group N. Patients in group M received 30 mg/kg $MgSO_4$ which was instilled into the gall bladder bed intraperitoneally by the surgeon after resection of gall bladder and patients who did not receive $MgSO_4$, were included in group N. Postoperative pain was assessed using Visual Analogue Scale (VAS) and VAS score> 3 was managed with Intravenous (i.v.) paracetamol 15 mg/kg. If pain was not relieved by this, i.v. tramadol 50 mg was supplemented. Time to first rescue analgesic, the total analgesic requirement and the incidence of shoulder pain in 24 hours were noted. Haemodynamics, recovery profile, incidence of Postoperative Nausea and Vomiting (PONV), any adverse events, were also noted and analysed.

Results: Mean pain scores (VAS) were significantly lower in group M and time to first analgesic requirement was longer in group M (4.23±2.31 hours) compared with group N (1.07±0.67 hours), PONV was significantly higher in group N. Sedation scores were significantly high in group M and there were no significant differences in haemodynamic and recovery profile and incidence of shoulder pain in both the groups.

Conclusion: Intraperitoneal instillation of $MgSO_4$ provides effective postoperative analgesia and reduces nausea and vomiting in patients undergoing laparoscopic cholecystectomy without any significant side-effects.

Keywords: Gall bladder, Nausea and vomiting, Postoperative pain

INTRODUCTION

Minimally invasive laparoscopic surgeries are now increasingly preferred over open procedures. Laparoscopic cholecystectomy has multiple advantages like less metabolic response to stress, maintenance of diaphragm and pulmonary function, less postoperative complications, lower incidence of postoperative ileus, early mobilisation, shorter hospital stay, reduced postoperative pain and better acceptance in terms of cosmetics. With these advantages, laparoscopic cholecystectomy is being increasingly done as day care procedure, despite effective postoperative analgesia remaining a major deterrent. Rosero EB and Joshi GP, in a large multicentric study on ambulatory laparoscopic cholecystectomy, found out that postoperative pain was one of the main diagnoses for readmission [1]. Moreover, it has been hypothesised that persistent pain after laparoscopic cholecystectomy may predict development of chronic pain (example post cholecystectomy syndrome) [2].

The fact that acute pain after laparoscopic cholecystectomy is complex in nature and does not resemble pain after other laparoscopic procedures suggests that effective analgesic treatment should be multimodal [3]. Various options like parenteral analgesics (opioid and non opioid), infiltration with Local Anaesthetics (LA), epidural and intrathecal opioids and LA, intercostal nerve blocks, subcostal and transverse abdominal plane block are employed.

Parenteral opioids are the main stay in postoperative pain management in laparoscopic cholecystectomy. Opioids, due to its inherent adverse effects like nausea, vomiting, ileus and respiratory depression can be undesirable and can cause morbidity, prolonged hospital stay and patient dissatisfaction. Newer modes of analgesia with different routes of administration and opioid avoidance can be a welcome change in laparoscopic cholecystectomy.

Magnesium is the fourth most common cation in the body and the second most abundant intracellular cation in the body after potassium. $MgSO_4$ reduces postoperative pain by reduction of an influx of calcium into the cells and by antagonising N-methyl-D-Asparatate (NMDA) receptors, vital components for pain processing as well as neuronal signalling in the central nervous system. This receptor blockade decreases postoperative pain by virtue of blocking both visceral and somatic fibres. Pathways of visceral sensation are diffusely organised peripherally as well as centrally and NMDA receptors are involved in nociceptive visceral input processing [4]. The mechanism of analgesia in intraperitoneal route may be by blocking multiple glutamate subtype of NMDA receptors expressed on peripheral nerve terminals present on the gall bladder resection bed and port site as these receptors contribute to peripheral nociceptive sensation [5,6]. Many studies have explored the feasibility of intraperitoneal administration of $MgSO_4$ with LA and LA with opioids concluding that addition of LA with $MgSO_4$, resulted in longer duration of analgesia and prolonged the time for rescue analgesics [7,8].

However, there are less studies on $MgSO_4$ alone instilled intraperitoneally and no consensus with regard to dose, timing and manner of administration. The present study evaluated the analgesic

effects of $MgSO_4$ alone in laparoscopic cholecystectomy, a surgery with complex pain characteristics. Aim of the present study was to analyse the effect of intraperitoneal $MgSO_4$ on postoperative analgesia and occurrence of shoulder pain after laparoscopic cholecystectomy.

MATERIALS AND METHODS

The present study was a prospective cohort study which was conducted at the Government Medical College, Kozhikode, Kerala, India, from February 2019 to December 2020. The approval from Institutional Research and Ethics Committee (IREC) (GMCKKD/RP 2019/IEC/82) was obtained on 21st January 2019.

Written informed consents were taken from all patients. Ninety patients who underwent laparoscopic cholecystectomy were assigned to two groups. Patients who received intraperitoneal instillation of 30 mg/kg of $MgSO_4$ were included in group M and those who did not receive were included in group N, till the sample size of 30 was reached in each group.

Inclusion criteria: Patients who belonged to American Society of Anaesthesiologist Physical Status (ASA PS) I and II between the age of 20-60 years and of Body Mass Index (BMI) 18-30 kg/m^2 were included in the study.

Exclusion criteria: Pregnant and lactating females, patients with history of autonomic dysfunction, renal or neurological disorders, patients with chronic pain on opioids and patients taking beta blockers were excluded from the study.

Sample size calculation: Sample size calculation was done using the formula $n=(Z\alpha+Z\beta)^2\times SD^2\times 2/d^2$ where $Z\alpha=1.96$, $Z\beta=0.84$, SD=standard deviation, d=effect size (0.31) [9]. Standard Deviation (SD) was 24.87 and sample size was calculated to be 30 [10].

Study Procedure

All patients were assessed preoperatively by detailed history, physical examination and laboratory evaluation including baseline serum magnesium level. On the day before surgery, procedure was explained to each patient. All patients were kept nil per oral overnight and premedicated in the previous night with tablet alprazolam 0.25 mg and tablet ranitidine 150 mg and tablet metoclopramide 10 mg. They were advised fasting of eight hours for solids and two hours for clear liquids.

Standard anaesthetic technique was followed for all patients in both the groups. On arrival to the operation theatre, after application of preinduction monitors (ECG, pulse oximeter, non invasive blood pressure, $ETCO_2$) an 18 G i.v. line was secured. After noting all baseline vital parameters, all patients were premedicated with injection glycopyrrolate 0.004 mg/kg, injection midazolam 0.02 mg/kg, and injection fentanyl 2 μg/kg i.v.

After preoxygenation general anaesthesia with injection propofol 2.5 mg/kg i.v. was given as inducing agent and injection succinylcholine 1.5 mg/kg i.v. as muscle relaxation for intubation. Patient was intubated with appropriate size cuffed endotracheal tube. Anaesthesia was maintained with oxygen in nitrous oxide and isoflurane mixture and muscle relaxation obtained with injection Atracurium. Ventilation was adjusted to maintain normocapnia ($ETCO_2$ between 35-38).

A nasogastric tube was introduced and the laparoscopic procedure was carried out in a standard fashion. Intra-abdominal pressure was maintained around 12-14 mmHg. After the removal of gall bladder, in group M, 30 mg/kg of $MgSO_4$ diluted to 30 mL with 0.9% normal saline was instilled intraperitoneally by surgeon through the port and the patient was kept at Trendelenburg position for 10 minutes. After skin closure local infiltration was given with 3 mL 0.25% bupivacaine at each port site. In group N also, where patients did not receive intraperitoneal $MgSO_4$, port site infiltration was given using same drug and dose at the end of surgery.

Neuromuscular blockade was reversed with intravenous neostigmine 0.05 mg/kg with glycopyrrolate 0.01 mg/kg and patient was extubated, after ensuring complete reversal. The level of sedation was noted using Ramsay Sedation score and serum magnesium level was checked after 30 minutes of extubation [11]. Vitals were monitored and kept stable throughout the procedure and the postoperative period. Patient was assessed postoperatively for incisional, visceral pain and shoulder pain at the 1st, 2nd, 3rd, 6th, 12th and 24th hour of postoperative period using Visual Analogue Scale (VAS) score. It was assessed by noting the patient's facial expression and over all reaction to the intensity of pain and assigning appropriate number ranging from 0-10; '0' means no pain to 10 means worst possible pain which was plotted on a horizontal straight line 10 cm length and asking the patient to mark his/her pain on that scale. Postoperative pain (VAS >3) was managed with Inj. paracetamol 15 mg/kg i.v. infusion, if pain not relieved or VAS>3 even after administration of paracetamol or if patient complained of pain (VAS>3) before six hours of paracetamol administration, injection tramadol 50 mg i.v. was given intravenously, as second line rescue analgesic.

Time to request first analgesic, total analgesic requirement in the first 24 hours, the incidence and type of pain, especially shoulder pain at the end of 24 hours, recovery characteristics which included extubation time in minutes (from the end of anaesthesia to extubation), time of emergence (time to first response to a simple verbal command following discontinuation of isoflurane), time to achieve full Modified Aldrete Score which was considered fit for discharge from Post Anaesthesia Care Unit (PACU) were monitored [12]. Haemodynamic parameters like Heart rate (HR), systolic, diastolic mean arterial pressures were noted up to 30 minutes after $MgSO_4$ administration. PONV was evaluated using four-point nausea score (0-none, 1-mild, 2-moderate, 3-severe). Sedation was assessed with Ramsay Sedation Score. Complications such as cardiovascular, respiratory and neurological side-effects or allergic reactions if any, were looked for in the intraoperative and postoperative period.

STATISTICAL ANALYSIS

Statistical analysis was done using IBM SPSS (Statistical Package for the Social Sciences) Statistics for Windows, version 18.0. Armonk, NY: IBM Corp. Continuous variables such as age, weight, duration of surgery were represented as mean with standard deviation and association between these variables were analysed using Student's t-test. The quantitative data was analysed using the unpaired student's t-test for significance. The categorical variables such as sex, ASA PS were represented as numbers with percentages. Association between these variables was tested using Chi-square test. The VAS scores were represented as mean with standard deviation and association between the two groups was tested by Mann-Whitney U test. The p-value <0.05 was considered as statistically significant.

RESULTS

A total of 60 patients, 30 in each group, were included in the study. Patients in both groups were comparable with respect to demographic parameters like age, sex, and weight. Duration of surgery and ASA PS were also comparable [Table/Fig-1]. Baseline serum magnesium concentrations were comparable in the two groups (p=0.83). Postoperative serum magnesium concentrations in group M were not significant as compared with group N and with baseline.

Time to first analgesic requirement was longer in group M than in group N and the difference was statistically significant with p-value of <0.001. Incidence of shoulder pain was found to be below 10% and statistically insignificant between the two groups [Table/Fig-2].

Mean pain scores were significantly lower in group M when compared with group N during the first six postoperative hours [Table/Fig-3].

Parameters	Mean±SD		p-value
	Group M	Group N	
Age in years^	40.77±10.31	43.70±11.31	0.298
Genders M/F (No, %)*	7 (23.3)/23 (76.7)	14 (46.7)/16 (53.3)	0.058
Weight in kg^	55.33±5.99	55.87±6.14	0.735
Duration of surgery (min)^	57.07±10.27	52.70±9.34	0.051
ASA Class I/II (Number, %)*	29 (96.7)/1 (3.3)	27 (90)/3 (10)	0.301

[Table/Fig-1]: Demographic features and duration of surgery.
*Data expressed in numbers, ^Data expressed in mean±standard deviation. p-value <0.05 considered as statistically significant

Variables	Group M Mean±SD	Group N Mean±SD	p-value
Time of 1st rescue analgesia-hours^	4.23±2.31	1.07±0.67	<0.001*
Incidence of shoulder pain* (Number, %)	1 (3.3)	3 (10)	0.612

[Table/Fig-2]: Time for first rescue analgesic in hours and incidence of shoulder pain.
*Data expressed in numbers, ^Data expressed in mean±standard deviation. p-value less than 0.05 considered as statistically significant

Postoperative period VAS^	Group M Mean±SD	Group N Mean±SD	p-value*
1st hour	2.3±1.02	3.63±1.21	<0.001
2nd hour	1.77±1.33	3±0.69	<0.001
3rd hour	2.1±0.99	3±0.64	<0.001
6th hour	2.57±1.07	2.17±0.53	0.072
12th hour	1.4±0.89	1.57±0.50	0.378
24th hour	0.97±0.18	1.43±0.50	<0.001

[Table/Fig-3]: Mean pain scores in VAS during 24 hours.
^Visual analogue scale, *Mann-Whitney U test. p-value <0.05 considered as statistically significant

Postoperative nausea was high in the group N than group M, especially during the 1st two hours of postoperative period. There was no incidence of vomiting in group M as compared with four patients in group N. This was statistically significant with a p-value of 0.008. Sedation scores were slightly high in the magnesium group M than group N which was statistically significant during the 2nd and 3rd hour of postoperative period. Recovery characteristics in terms of extubation time and emergence time were not significantly different. Also, there was no significant difference in time to reach the full Aldrete score. As regards haemodynamic parameters, baseline mean arterial pressure and heart rate in the two groups were comparable. There were no perioperative side-effects in both the groups.

DISCUSSION

Magnesium sulphate, one of the major cations in the body, has been used through various routes as an adjuvant analgesic. Normal serum magnesium values range between 1.6-2.5 mg/dL. As $MgSO_4$ has a half-life of 30 minutes, the serum magnesium level was determined 30 minutes after intraperitoneal instillation of the study solution, and the mean magnesium level reached up to 2.26±0.8 mg/dL in comparison to the preoperative baseline value of 1.86±0.17 in the current study.

The efficacy of intraperitoneal instillation of local anesthetics both alone and in combination with other drugs including $MgSO_4$ has been demonstrated in numerous studies on laparoscopic cholecystectomy, but there is no consensus regarding the dose, concentration, site, and manner of administration [7,8,10,13,14]. The present study was devised to evaluate the analgesic and recovery characteristics of instilling $MgSO_4$ alone intraperitoneally. Blood magnesium level and the sedation score in the PACU were also studied to conclude a safe and effective level of $MgSO_4$ after peritoneal instillation.

Results of the present study showed that $MgSO_4$ improved the postoperative analgesic profile. There was significantly lower postoperative pain in group M compared with group N. Mean pain scores (VAS) were significantly lower in group M compared with group N, during the first six postoperative hours. Time to first analgesic requirement was also significantly longer in the present study.

Similar to the present study, the interventional study group of Ali RM et al., where they used 20 mL of 10% $MgSO_4$ instilled intraperitoneally after the creation of pneumoperitoneum and before any dissection, showed the efficacy of instilling $MgSO_4$ as evidenced by comparable VAS scores with the current study, especially during the first six hours of postoperative period [14]. The time to first analgesic requirement was longer in group M (9.2±3 hours) than in control group C (2.4±1.3 hours) when compared with the present study where only 4.23±2.31 hours of analgesia was observed in magnesium group M and 1.07±0.67 hours in group N. This difference may be due to drug administration early in the intraoperative period which might have resulted in prevention of central sensitisation, before the surgical stimulus.

Lee DH et al., found that 80% of patients suffered from shoulder pain in the first 24 hours [15]. Other reported incidences of shoulder pain vary between 25-60% in laparoscopy [16,17]. The incidence was less than 10% in the present study. This could be due to careful emptying of pneumoperitoneum and saline irrigation and suctioning before $MgSO_4$ instillation. Washing the diaphragmatic surface by a sizeable amount of saline dilutes carbonic acid, a strong diaphragmatic irritant formed by carbon dioxide in moist peritoneal surfaces and reduces the severity of diaphragmatic irritation.

Maharjan SK and Shrestha S, compared intraperitoneal instillation of bupivacaine, alone and in addition to $MgSO_4$ in 60 patients posted for laparoscopic cholecystectomy [18]. They concluded that combined instillation of intraperitoneal bupivacaine plus $MgSO_4$ at the end of surgery rendered better analgesic control and less consumption of analgesics in first 24 hours in comparison to the sole bupivacaine group. Saadawy IM et al., in a double blinded study, reported that, both i.v. lignocaine and $MgSO_4$ 50 mg/kg improved postoperative analgesia and postoperative opioid requirements in patients undergoing lap cholecystectomy [19]. Abdel-Raouf M and Amer H, studied the postoperative analgesic effects of intraperitoneal NMDA receptor antagonists $MgSO_4$ and ketamine delivered intraperitoneally in patients undergoing laparoscopic cholecystectomy. They concluded that intraperitoneal co-administration of either magnesium sulphate or ketamine with bupivacaine 0.25% at the end of surgery is effective in reducing postoperative shoulder pain and analgesic requirement following laparoscopic cholecystectomy [20].

The effect on nausea and vomiting after intraperitoneal $MgSO_4$ administration in laparoscopic cholecystectomy as observed in the present study was similar to the findings in a study done by Ali RM et al., [14]. In the present study, there was significant reduction in nausea and vomiting in group M in comparison to group N. NMDA receptors are present in both emetic pathways and structures associated with final common pathway for vomiting. Magnesium, by virtue of being a NMDA blocker has the potential to become a broad-spectrum antiemetic [21]. However, there is not much literature available on the direct effects of $MgSO_4$ on nausea and vomiting, currently.

Patient recovery characteristics and haemodynamic parameters like HR and mean arterial pressures in present study were comparable and no significant difference was noted between both groups. Even though sedation scores were significantly high in group M in the second and third postoperative hour, all the patients were easily arousable during this period. Also, none of the patients had a sedation score of more than 3.

Intraperitoneal instillation of $MgSO_4$ appears to be a safe and valid technique which aids in reducing postoperative pain after laparoscopic cholecystectomy, as evidenced from the findings of the current study and conclusions drawn from similar studies exploring the feasibility of intraperitoneal $MgSO_4$. A dose of 30 mg/kg also

appears to be sufficient in combating the common but troublesome problem of nausea and vomiting, associated with laparoscopic surgeries.

Limitation(s)

The present study included only ASA I and II patients. A study on patients with multiple co-morbidities would be able to shed more light on the effects of intraperitoneal instillation of $MgSO_4$, especially the direct antiemetic action.

CONCLUSION(S)

Intraperitoneal instillation of $MgSO_4$ in laparoscopic cholecystectomy provides effective postoperative analgesia, without any significant side-effects as evidenced by lower pain scores in the first 24 hours and reduced total analgesic consumption in a 24-hour period. It also reduces the incidence of nausea and vomiting, significantly.

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