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Original Article

Anaesthesia Section

Magnesium Sulphate as an Adjuvant to Ropivacaine in Bilateral Transversus Abdominis Plane Block for Laparoscopic Cholecystectomy: A Randomised Double-blind Clinical Study

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ABSTRACT

Introduction: Magnesium sulphate has the potential to treat and prevent pain by acting as an antagonist at N-methyl-D-Aspartate (NMDA) receptors. Many researchers found that magnesium sulphate as adjuvant to local anaesthetics reduces analgesic requirements in the postoperative period.

Aim: To evaluate magnesium sulphate as an adjuvant to ropivacaine in ultrasound guided bilateral Transversus Abdominis Plane (TAP) block with respect to postlaparoscopic cholecystectomy pain.

Materials and Methods: The present randomised double-blind clinical study was conducted in the Department of Anaesthesiology, SKIMS Medical College, Srinagar, Jammu and Kashmir, between January 2022 and June 2022. Total 80 patients of American Society of Anesthesiologists (ASA) grade I and II were divided into two groups. Group A (n=40) patients received ropivacaine with magnesium and group B (n=40) patients received ropivacaine only. Pain was measured using the Visual Analogue Scale (VAS). Total rescue analgesia consumption during 24 hours, time to first request of rescue analgesia, postoperative nausea vomiting, sedation score and patient satisfaction score were recorded. Mann-Whitney U test was used for VAS score and patient satisfaction score.

Results: Mean age of patients was higher in group A (47.95±13.853 years) than group B (46.45±11.940 years). Group A had 12 males and 28 females while in group B, there were 11 males and 29 females in group B. Group A showed better analgesic profile in the form of lower mean VAS, which were statistically significant (p-value <0.05). However, time to first request of rescue analgesia (743.5±58.214 minutes in group A vs 668.50±214.375 minutes in group B; p-value=0.162) and total dose of rescue analgesia consumption were comparable in both groups (p-value >0.05). Also the sedation score (2.325±0.2529 in group A vs 2.295±0.2562 in group B; p-value=0.600) and patient satisfaction score (PSS) between the two groups (81.05±8.638 in group A vs 80.53±7.517 in group B; p-value=0.665) were statistically not significant. Incidence of postoperative nausea and vomiting was comparable in both groups (p-value=0.924).

Conclusion: Addition of magnesium sulphate to ropivacaine in ultrasound guided bilateral TAP block significantly reduced pain scores in patients undergoing laparoscopic cholecystectomy.

Keywords: Analgesics, Local anaesthesia, Pain score, Patient satisfaction

INTRODUCTION

Laparoscopic cholecystectomy is one of the most commonly performed surgeries and is associated with significant pain, postoperatively [1]. In the past, various methods of postoperative pain control have been tried which include intravenous patient-controlled analgesia, patient controlled thoracic epidural analgesia, intraperitoneal injection of local anaesthetics, low-pressure pneumoperitoneum, warmed air supply, etc. But, the complications related to these methods actually outweighed the benefits [1].

Intravenous analgesia involves the side-effects of systemic opioids like respiratory depression, nausea vomiting and urinary retention [2]. Epidural analgesia carries the risk of dural puncture, infection and epidural haematoma [3]. Intraperitoneal injection leads to short duration of analgesia and insufficient pain control [4,5]. Transversus Abdominis Plane (TAP) block, first described by Rafi AN, blocks the sensory nerves in neurofascial plane from T6 to L1 dermatome, thus limiting the complications [6]. Ultrasound accurately visualises the needle and the anatomical structures thus making TAP block a very safe and effective technique for postoperative pain alleviation [7]. It diminishes the use of NSAIDs and opioids, thus lowering side-effects associated with them [6,7].

To prolong the duration of analgesic effect and reduce the side-effects of Non Steroidal Anti-Inflammatory Drugs (NSAIDs) and opioids, various adjuvants like dexamethasone, epinephrine dexmedetomidine, clonidine, magnesium sulphate, have been used [8,9]. Among these adjuvants magnesium has a very important place. It has been suggested that magnesium has got the potential to treat and prevent pain by acting as an antagonist at N-methyl-D-aspartate (NMDA) receptors [9]. Role of magnesium as adjuvant to local anaesthetics in reducing analgesic requirements in the postoperative period has been demonstrated in various clinical studies involving surgeries like hysterectomy, caesarean section, brachial plexus block [10-12].

Magnesium is a physiological calcium channel blocker and non competitive antagonist of NMDA receptors. It has been used with a local anesthetic solution in different regional anaesthesia techniques to decrease the onset time of the block and to increase the quality and duration of anaesthesia [13-15]. The possible mechanism for the analgesic action of magnesium is the voltage-dependent antagonism of NMDA receptors, which plays a well-defined role in modulating pain and a number of inflammatory responses, leading to the prevention of central sensitisation from peripheral nociceptive stimulation and a decrease in acute pain after tissue injury [16]. The analgesic effect of

magnesium on peripheral nerves was explained by Akutagawa T et al., According to his surface charge theory, modulation of the external magnesium concentration bathing a nerve bundle resulted in the enhancement of the nerve blockade due to local anaesthetics [17].

But there are no studies which have studied magnesium as adjuvant to ropivacaine for postlaparoscopic cholecystectomy pain. Hence, the aim of the present study was to evaluate magnesium as adjuvant to ropivacaine in ultrasound guided bilateral transversus abdominis plane block with respect to postlaparoscopic cholecystectomy pain.

MATERIALS AND METHODS

This randomised double-blinded clinical study was conducted in the Department of Anaesthesiology, SKIMS Medical College, Bemina, Srinagar, Jammu and Kashmir, India, between January 2022 and June 2022. After obtaining ethics committee approval [IEC/60/2021 dated November 30, 2021], the study was registered in the Clinical Trials Registry India (CTRI/2021/12/038916). A written informed consent was obtained from all the patients.

Inclusion criteria: Patients aged between 18-65 years belonging to American Society of Anaesthesiologists (ASA) grade I and II, enrolled for laparoscopic cholecystectomy under general anaesthesia were included in the study.

Exclusion criteria: Patients with coagulation disorders, infection, allergy to the local anaesthetics and magnesium sulphate were excluded from the study.

Sample size calculation: Sample size was estimated using nMaster software (version 2, CMC, Vellore). Sample size estimation was based on estimating the difference between two means. It was calculated on the basis of difference in Mean VAS scores of pain at 4 hours, as found in the study by Rana S et al., [11]. In this study, researcher found the Mean VAS for pain at 4 hr among bupivacaine and bupivacaine+magnesium sulphate groups as 2.4±1.43 and 1.4±1.7. Anticipating similar differences, with 95% confidence interval, a minimum sample size of 38 per group was found to be sufficient. Anticipating a drop out due to failure of anaesthesia, it was finalised as 40 per group.

The sample size was calculated using below mentioned formula:

$$n=2\ S_p^2[Z_{1-\alpha/2}+Z_{1-\beta}]^2/\mu_d^2,$$

Calculations:

$$(\text{Pooled Standard deviation})^2=((1.7)^2+(1.43)^2)/2)=2.47$$

$$n=2(2.47)(1.96+0.84)^2/(1)^2=38$$

Where, $s_p^2=S_1^2+S_2^2/2$

S_p=Pooled Standard deviation

S_1=Std Deviation of only Bupivacaine=1.43

S_2=Std Deviation of Bupivacaine + magnesium sulphate=1.7

μ_d=Mean difference between the samples=1

$Z_{1-\alpha/2}$=Value of Z at desired confidence level (95% confidence level)=1.96

$Z_{1-\beta}$=Value of Z at power of 80%=0.84

Total 80 patients were randomised into two groups with 40 patients in each group, using closed envelope technique (group A and group B). The random number table was used to generate the allocation sequence.

Procedure

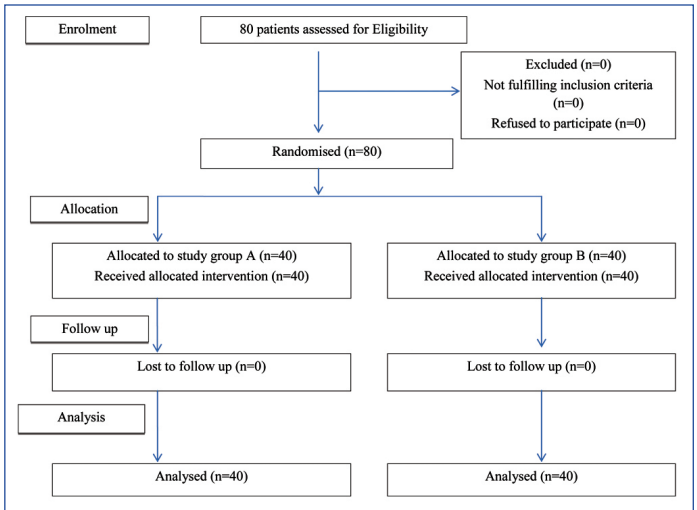
Anaesthesia induction was same in the two groups with 2 µg/kg fentanyl, 2 mg/kg propofol and 0.5 mg/kg atracurium. Anaesthesia was maintained with sevoflurane in 0.4 oxygen/nitrous oxide mixture. All patients were monitored with continuous electrocardiogram, pulse oximetry, capnography and non invasive blood pressure. In both the groups, the pre-emptive ultrasound guided TAP block was performed on both sides using either of the following drugs after the induction of general anaesthesia.

Technique of subcostal TAP Block [18]: The transducer was placed linearly alongside the lower margin of the rib cage as medial and cranial as possible for the subcostal TAP block. The rectus abdominis muscle and its posterior rectus sheath were visualised along with the transversus abdominis muscle deep to the posterior rectus sheath. The target was the fascial plane between the posterior rectus sheath and the transversus abdominis muscle. The needle was inserted above the rectus abdominis close to the midline and advanced from medial to lateral direction. The endpoint of injection was the spread of local anaesthetic between the posterior rectus sheath and the anterior margin of the transversus abdominis muscle.

Group A: Pateints received 19.5 mL ropivacaine 0.2% (Ropin, Neon Laboratories Limited) in combination with 0.5 mL magnesium sulphate 50% (Fresenius Kabi Pvt. Ltd.)

Group B: Patients received 19.5 mL ropivacaine 0.2% in combination with 0.5 mL normal saline.

The block was performed under ultrasound guidance (SonoSite-Edge II ultrasound machine) by a qualified anaesthesiologist, unaware of the type of the solution to be injected. Participants were also unaware of the drug solution administered [Table-Fig-1].



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

Visual analogue scale: The patient's pain was measured and recorded using the Visual Analogue Scale (VAS) [19]. The scale ranges from 0 to 10 where 0 denotes no pain and 10 stands for the worst imaginable pain. If a patient reported a VAS pain score of greater than three, rescue analgesic (injection Diclofenac 75 mg iv infusion) was given. Total rescue analgesic consumption during 24 hours, time to first dose of rescue analgesia were recorded.

Postoperative Nausea and Vomiting (PONV): Three-point rating scale used for PONV [20]:

1: no postoperative nausea and vomiting,

2: nausea without vomiting,

3: nausea with vomiting.

Haemodynamic data: Haemodynamic data (heart rate and mean arterial pressure) were recorded at baseline, immediately after induction, at the start of surgery, and each 15 minute later. VAS score were recorded at 1, 2, 6, 12, and 24 hours after the surgery by doctor/nurse, without knowledge of group assignment.

Sedation score: Sedation was assessed by Ramsay Sedation Scale where sedation score ranged from 1 to 6 [21]:

1: Anxious and irritable or dysphoric or both

2: Co-operational, oriented and quiet

3: Responsive to command

4: Asleep, quickly responsive to light tap or loud auditory stimulus

5: Asleep, slowly responsive to light tap or loud auditory stimulus

6: Asleep, no response to light tap or loud auditory stimulus.

Patient satisfaction score: Patient satisfaction score ranged from 0-100 points with 0 indicating the worst level of satisfaction and 100 indicating the best level of satisfaction [22].

STATISTICAL ANALYSIS

Data were collected, tabulated, and analysed using Statistical Package for Social Sciences (SPSS) version 24.0. Continuous data were tested for normality and expressed as mean±standard deviation. Chi-square test was used for gender distribution and PONV score. Independent t-test was used for age distribution, weight distribution and sedation scores. Mann-Whitney U-test was used for VAS score and PSS score.

RESULTS

The mean age was 47.95±13.85 years in group A and 46.45±11.94 years in group B but the difference was not statistically significant (p-value=0.605). Mean weight was comparable between the two groups (p-value=0.835). Group A had 12 (30%) male vs 28 (70%) femlaes but in group B there were 11 (27.5%) male and 29 (72.5%) female, but the difference was not statistically significant (p-value=0.999) [Table/Fig-2].

Parameters		Group A	Group B	p-value
Gender	Male	12 (30%)	11 (27.5 %)	0.999*
	Female	28 (70%)	29 (72.5%)	
Mean age (years)		47.95±13.853	46.45±11.940	0.605#
Mean weight (kg)		64.40±9.803	64.83±8.348	0.835#

[Table/Fig-2]: Intergroup comparison of gender, mean age and mean weight.
*Chi-square test; #Independent t-test; p-value <0.05 was considered as statistically significant

On comparing the mean heart rate and mean arterial pressure between the two groups at baseline, after induction, at the start of surgery and every 15 minutes thereafter, the difference observed was statistically not significant (p-value >0.05) [Table/Fig-3,4].

Time interval	Heart rate		p-value (Chi-square test)
	Group A (Mean±SD)	Group B (Mean±SD)	
Baseline	85.63±13.40	85.47±10.03	0.473
After induction	85.10±14.31	84.10±7.23	0.129
Start of surgery	85.30±11.84	84.63 ±8.52	0.476
30 min	85.03±11.58	83.77±5.87	0.063
45 min	85.63±15.07	84.30±9.03	0.245
60 min	83.80±6.98	84.13±6.87	0.617
75 min	85.33±13.11	83.67±8.78	0.060
90 min	84.60±10.72	84.32±1.36	0.580

[Table/Fig-3]: Intergroup comparison of mean heart rate (beats/min).
p-value <0.05 was considered as statistically significant

Time interval	Mean arterial pressure		p-value (Chi-square test)
	Group A (Mean±SD)	Group B (Mean±SD)	
Baseline	94.28±7.36	92.96±6.89	0.057
After induction	93.12±8.72	93.32±8.83	0.816
Start of surgery	93.20±7.12	93.02±5.14	0.890
30 min	93.54±8.05	94.12±5.00	0.677
45 min	92.54±5.12	93.01±3.52	0.461
60 min	92.77±4.60	93.33±8.09	0.682
75 min	93.27±6.31	94.93±6.57	0.854
90 min	94.60±7.03	94.93±0.54	0.508

[Table/Fig-4]: Intergroup comparison of mean arterial pressure (mmHg).
p-value <0.05 was considered as statistically significant

Mean VAS score was lower in group A than group B at all intervals of time post-operatively. The difference in VAS scores was statistically significant at all intervals except at six hours. Within each group, mean VAS score was found to increase significantly from 1 hr to 12 hours. After that it decreased from 12 hours to 24 hours [Table/Fig-5].

Time interval	Visual analogue scale		p-value (Mann-Whitney U test)
	Group A (Mean±SD)	Group B (Mean±SD)	
1 hour	1.40±0.955	1.88±0.853	0.022
2 hours	1.98±0.768	2.35±0.662	0.026
6 hours	2.68±0.730	2.70±0.564	0.646
12 hours	3.18±1.035	3.65±0.949	0.008
24 hours	2.25±0.707	2.58±0.636	0.041
p-value	<0.001	<0.001	

[Table/Fig-5]: Intergroup and intragroup comparison of mean visual analogue scale.
p-value <0.05 was considered as statistically significant

Although, time to first rescue analgesia was longer in group A than group B, it was not statistically significant (p value=0.162). The amount of total diclofenac consumption during 24 hours postoperatively was also comparable in two study groups and was statistically not significant. Also, there were statistically no significant differences in relation to sedation score and patient satisfaction score between the two study groups [Table/Fig-6].

Postoperative Nausea Vomiting (PONV) score between the two groups was comparable (p-value=0.924) [Table/Fig-7].

Parameters		Group A	Group B	p-value
Sedation score		2.325±0.2529	2.295±0.2562	0.600
PSS		81.05±8.638	80.53±7.517	0.665
TTFDORA (minutes)		743.50±258.214	668.50±214.375	0.162
Diclofenac consumption (mg) in 24 hours	75 mg	28 (70%)	27 (67.5%)	0.999
	150 mg	12 (30 %)	13 (32.5%)	

[Table/Fig-6]: Intergroup comparison of Sedation Score, PSS, TTFDORA, Diclofenac consumption.
PSS: Patient satisfaction score; TTFDORA: Time to first dose of rescue analgesia; mg: Milligram; Sedation score=Independent t test; PSS=Mann Whitney U test; TTFDORA=Chi-square test; Diclofenac consumption=Chi-square test

PONV score	Group A (n, %)	Group B (n, %)	p-value (Chi-square test)
1	25 (62.5 %)	25 (62.5 %)	0.924
2	10 (25.0 %)	11 (27.5 %)	
3	5 (12.5 %)	4 (10 %)	

[Table/Fig-7]: Intergroup comparison of PONV score.
PONV: Postoperative nausea vomiting; p-value <0.05 was considered as statistically significant

DISCUSSION

Results of this study demonstrated that addition of magnesium sulphate (250 mg) as adjuvant to ropivacaine (0.2%) in TAP block for laparoscopic cholecystectomy had better analgesic profile as seen by lower VAS scores in group A.

Rana S et al., in their study using magnesium sulphate (150 mg) with bupivacaine in TAP block for abdominal hysterectomy patients found prolonged duration of analgesia and less requirement for rescue analgesia in group receiving magnesium sulphate [11]. Another recent study by Al-Refaey K, et al., reported that patients receiving 500 mg magnesium added to bupivacaine in TAP block showed better postoperative analgesia in the form of longer duration, lesser analgesic requirements and nausea or vomiting [12].

Abd-Elsalam KA et al., used magnesium in TAP block for hysterectomy patients and found adding 200 mg of magnesium sulfate to bupivacaine in a USG guided TAP block caused a significant reduction in VAS score and postoperative opioid requirement, and prolonged the duration of analgesia [23]. In a study, conducted by Jalili S et al., but for open appendicectomy and using similar dose of

Authors name and reference no	Year and place of the study	Magnesium sulphate used in combination with which LA	Sample size	Findings
Rana S et al., [11]	2016, Himachal Pradesh, India.	Bupivacaine 0.25%	65	Prolonged duration of analgesia and less rescue analgesia in group receiving magnesium.
K Al-Refaey et al., [12]	2016, Mansoura, Egypt.	Bupivacaine 0.25%	90	Better postoperative analgesia in the form of longer duration, less analgesic requirements and nausea or vomiting.
Abd-Elsalam KA et al., [23]	2017, Assiut, Egypt.	Bupivacaine 0.25%	60	Reduced postoperative opioid requirements, prolonged the duration of analgesia, reduced VAS score.
Siam EM et al., [25]	2021, Alexandria, Egypt.	Bupivacaine 0.25%	50	Prolonged duration of analgesia and reduced rescue analgesia consumption.
Ammar AS et al., [26]	2018, Shebin Elkoam, Egypt.	Bupivacaine 0.375%	75	Prolonged duration of analgesia in magnesium group than adenosine group.
Present study	2022, Jammu and Kashmir, India.	Ropivacaine 0.2%	80	Better postoperative analgesic profile as seen by lower VAS scores than plain ropivacaine 0.2% in magnesium group. No increase in duration of block or reduction of rescue analgesia dose in the two groups.

[Table/Fig-8]: Comparison of studies with present study [11,12,23,25,26].

magnesium (250 mg), they concluded that addition of magnesium resulted in lower pain scores and less need for opioids [24]. In study by Siam EM et al., magnesium 150 mg added to bupivacaine in TAP block for inguinal herniorraphy prolonged duration of analgesia and reduced rescue analgesia consumption [25]. Ammar AS et al., studied quality and duration of adenosine and magnesium in TAP block and found that adding magnesium prolonged duration of analgesia more than adenosine [26]. Comparison of findings of previous studies [11,12,23,25,26] are shown in [Table/Fig-8].

It has been postulated that most neurological damages caused by magnesium sulphate were due to high dose and concentration >15% in most studies [27-29]. But in this study we used a low dose (250 mg in 20 mL on either side) and low concentration (1.25%) of magnesium sulphate which is far less than postulated toxic concentration.

Although, mean time of block duration was longer in group A than group B, it was statistically not significant (p-value=0.162). Rescue analgesia was needed in both the groups in same quantity (100% each) as the period of the present study was 24 hours postoperation but block lasted for less than 24 hours.

Limitation(s)

Serum magnesium levels were not measured to be correlated to efficacy of TAP block.

CONCLUSION(S)

Magnesium sulphate as an adjuvant to ropivacaine 0.2% in TAP block for laparoscopic cholecystectomy under general anaesthesia resulted in better postoperative analgesic profile as seen by lower VAS scores than plain ropivacaine 0.2%. However, there was no increase in duration of block or reduction of rescue analgesia dose on adding magnesium sulphate to ropivacaine. Further studies need to be done which can measure serum magnesium levels in the patients and correlate it with the efficacy of TAP block.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jul 26, 2022
- Manual Googling: Oct 31, 2022
- iThenticate Software: Nov 09, 2022 (15%)

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- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

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