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Original research article

Study of effect of magnesium sulphate with bupivacaine in Transverse Abdominis Plane block after laparoscopic surgeries: A single blind randomised controlled trail

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Abstract

Background and Aims: The transverse Abdominis plane (TAP) block is a regional anesthesia technique that provides analgesia to the parietal peritoneum and anterior abdominal wall. This study was done to see the adjuvant efficacy of magnesium sulphate to 0.25% bupivacaine in Transverse Abdominis Plane block for laparoscopic surgeries and to know its effect on duration of analgesia and hemodynamics.

Methods: After obtaining clearance and approval from Institutional Ethical Committee, patients fulfilling Inclusion criteria who give informed consent were included in the study.82 patients were randomly assigned to one of two groups, namely, bupivacaine(0.25%) + normal saline group (B) and bupivacaine(0.25%) + magnesium sulphate group(0.5gm) (M). In both groups the preemptive ultrasound guided subcostal TAP block was performed on both sides using 20ml volume. Premedication and anaesthesia technique was standardized in both groups. Hemodynamic parameters were collected immediately after induction, at the start of surgery, and each 10min later and postoperatively. Visual analogue score, and postoperative nausea vomiting were recorded at 0, 1, 2,6,12 and 24hr after surgery, Ramsay sedation was recorded at 0,1,2 and 6h. Paracetamol infusion was given as rescue analgesic. **Results:** The demographic parameters, ASA status were comparable between the groups. In Group B Median VAS score at baseline was 0 and at 24hrs was 6. Similarly in Group M Median VAS score at baseline was 0 and at 24 hrs. was 4. There was significant difference in median VAS score between two groups from 1 hr. to 14 hrs. and at 24 hrs. At all these intervals of follow-up Median VAS score was high in Group B. Mean Duration of analgesia in Group B was 5.78 ± 1.00 min and in Group M was 12.43 ± 1.46 min.

Conclusion: magnesium sulphate as an adjuvant in TAP block for laparoscopic surgeries using 0.25% Bupivacaine has prolonged the duration of analgesia than compared to TAP block for laparoscopic surgeries with 0.25% Bupivacaine without any adjuvant.

Keywords: Transverse Abdominis plane block, magnesium sulphate, bupivacaine, laparoscopic surgeries, visual analogue score

Introduction

Adjuvants are agents possessing little effect by themselves, but potentiate the actions of other drugs when given at the same time. Co-administration of these agents often allows for synergistic effect with local anesthetic.N-methyl D-aspartate (NMDA) receptor is the major affecting site for the effects of magnesium. Magnesiumis an antagonist of the NMDA receptor, acting as a noncompetitive antagonist, blocking ion channels in a voltage dependent fashion^[1]. This receptor is found in many parts of the body, including the nerve endings, and plays a well-defined role in modulating pain and a number of inflammatory responses. NMDA receptor antagonists could prevent central sensitization that occurs due

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to the peripheral nociceptive stimulation.

Laparoscopic surgeries are commonly performed procedures that are associated with a moderate degree of postoperative pain especially on the first postoperative day. Adequate postoperative analgesia allows early patient ambulation, decreases analgesic requirements, and duration of stay in hospital^[2].

Transversus Abdominis Plane (TAP)^[3] block is a recent analgesic technique that has proved its efficacy in perioperative period. TAP block seems to be an ideal approach in alleviating post-operative pain in patients undergoing laparoscopic surgeries, especially when used as part of multimodal analgesia regimen. The technical simplicity, reliable analgesia makes TAP block, a preferred option for lower abdominal surgeries as has been reported by the American Society of Regional Anesthesia^[4].

The duration of TAP block is limited to the effect of administered local anaesthetics. Evidence supporting the presence of N-methyl-D-aspartate (NMDA) receptors in skin and muscles have led to the use of magnesium sulphate (MgSO₄) via different routes for brachial plexus block and via neuraxial route. Therefore, we intended this study to evaluate the role of MgSO₄ as an adjuvant to bupivacaine in ultrasound (USG)-guided TAP block in for post-operative analgesia in patients scheduled for laparoscopic surgeries.

Aims

- 1. To assess the efficacy of magnesium sulphate as an adjuvant to Bupivacaine for postoperative analgesia of patient.
- 2. To assess the efficacy of TAP block to conventional analgesics.

Methodology

After approval from institutional ethics committee, this prospective randomized comparative study was conducted from November 2016 to May 2018 in patients undergoing laparoscopic cholecystectomy under general anaesthesia. Patients in the age group of 20 to 60 years who planned surgeries lasting for >60min under general anesthesia with ASA (American society of anesthesiologists) grade I & II were included in the study. Patients who are refusing to participate in the study, with uncontrolled hypertension, diabetes, cardio-respiratory disorders, neuro-psychiatric disorders, hepatic or renal dysfunction, obesity (BMI >30), history of alcohol or drug abuse and with ASA grade III or more were excluded from the study.

After Institutional Ethical Committee approval Informed and written consent was obtained for all the selected patients. They were randomly allocated to Group B and Group M. Randomization was done using numbers generated by www.random.org.

Group B:Received 0.25% bupivacaine + normal saline as the control.

Group M:Received 0.25% bupivacaine + magnesium sulphate (0.5gm) as the adjuvant.

A routine pre anaesthetic checkup was done assessing for history and general condition of the patient, Airway assessment by Mallampati grading, Nutritional status, height and weight of the patient, A detailed examination of the cardiovascular system, Respiratory system and Central nervous system with Examination of the spine was done. Routine investigations were carried out.

Patients were premedicated with tabletalprazolam 0.5 mg and tablet ranitidine 150 mg orally at bed time. They were kept nil per oral from 10 pm onwards on the previous night. On the day of surgery intravenous (i.v.) line was secured with an 18-gauge cannula and patients were preloaded with Ringer lactate 500 ml half an hour before anaesthesia.

In the operating room, patients will be put on standard monitoring like non-invasive blood pressure, pulse oximetry, end-tidal CO2, heart rate, electrocardiogram, and entropy and baseline readings taken. Five minutes prior to induction, patients will be administered fentanyl 1-2mcg/kg i.v. Patient was preoxygenated with 100% oxygen for 3min. Anesthesia induction was the same in the two groups (propofol 1.5 mg/kg, fentanyl $2\mu/\text{kg}$ and atracurium 0.5 mg/kg), then isoflurane inhalational anesthesia for maintenance in 0.4 oxygen/air mixture.

In both M group and B group, the preemptive ultrasound guided subcostal TAP block was performed on both sides using 20ml volume (0.25% bupivacaine + 2ml normal saline in B group0.25% bupivacaine +0.5gm of MgSo4 in M group). Surgical sterilization started 5 min after the block and surgery started 5 min later. Hemodynamic data (HR, MAP, SBP, DBP and SpO₂) was collected immediately after induction, at the start of surgery, and each 10min later. At the end of surgery, and after the closure of surgical ports, anesthesia was terminated, and extubation was done when patients fulfilled the required

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criteria. Postoperative hemodynamic data (HR, MAP, SBP, DBP and SpO₂), visual analogue scale (VAS) score, and postoperative nausea vomiting (PONV) were recorded at 0,1,2,6,12 and 24hr after surgery. Paracetamol infusion (15 mg/kg) was given whenever postoperative VAS score \geq 4 for any patient in the two study groups.

The sample size was calculated based on the DCR 4 Guidelines. Mean postoperative VAS score was adopted as a primary variable and power of 80% was achieved accepting a Standardized Effect Size of 65%, the total sample size of 74was included in the study. 10% Dropout rate was added to this, thus making an effective sample size of 82; i.e. 41 patients in each group.

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Independent t test or Mann Whitney U test was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively. Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram and line diagram. P value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Results

All the patients included in the study received the assigned intervention and were followed up tillthe end of study. There were no exclusions or drop outs. Patient demographic characteristics were comparable in both groups(age, gender, BMI). Number of patients belonging to ASA class I and II and duration of surgery were uniformly distributed between both the groups.(table 1)

In Group B, mean HR at baseline was 77.41± 6.55bpm and at 24 hrs was 84.05± 4.21bpm. In Group M, mean HR at baseline was 73.85± 5.28bpm and at 24 hrs was 77.34± 5.20bpm (fig1). In Group B, mean SBP at baseline was 123.37 ± 9.29mmhg and at 24 hrs was 121.56± 7.98mmhg. In Group M, mean SBP at baseline was 120.05± 12.41mmhg and at 24 hrs was 119.12± 10.63mmhg (fig 2). In Group B, mean DBP at baseline was 76.10± 7.69mmhg and at 24 hrs was 74.73± 9.44mmhg. In Group M, mean DBP at baseline was 75.51± 9.3 mmhg and at 24 hrs was 75.51± 8.44mmhg (fig3). In Group B, mean MAP at baseline was 91.32± 8.03mmhg and at 24 hrs was 91.34± 5.62mmhg. In Group M, mean MAP at baseline was 89.46± 10.28mmhg and at 24 hrs was 89.76± 9.04mmhg (fig4). In Group B, mean SpO2 at baseline was 98.32± 0.72mmhg and at 24 hrs was 98.10± 0.77mmhg. In Group M, mean SpO2 at baseline was 98.27± 0.71mmhg and at 24 hrs was 98.20± 0.81mmhg (fig5).

In the study mean VAS score in group B is 0 at baseline and 6 at 24hr, while for group M it is 0 at baseline and 4 at 24 hr (TABLE 2). Mean Duration of analgesia in Group B was 5.78 ± 1.00 min and in Group M was 12.43 ± 1.46 min (TABLE 3).

Parameters		Group B	Group M	P Value
Age(years)		38.85 ± 9.88	38.46± 10.50	0.388
Sex	Female	20	23	
	Male	21	18	
BM	I (kg/m2)	21.8 ± 2.27	22.76±2.81	0.096
ASA	Grade i	18	22	0.082
	Grade ii	23	19	0.062
Duratio	on of surgery	60.51 ± 35.03	56.59 ± 25.94	0.566

Table 1: Demographic parameters and duration of surgery

Table 2: VAS Score comparison between two groups at different time intervals

	Group						
	Group B			G	P value		
	Mean	SD	Median	Mean	SD	Median	
Basal	0	0	0	0	0	0	0.155
0 Min	0	0	0	0	0	0	1.000
1 hr.	1	1	2	0	0	0	<0.001*
2 hr.	2	1	2	1	1	1	<0.001*
4 hr.	5	0	5	2	1	2	<0.001*
6 hr.	6	1	6	3	1	3	< 0.001*

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12 hr.	6	1	6	4	1	4	<0.001*
14 hr.	6	1	6	3	1	4	<0.001*
16 hr.	6	1	6	3	1	2	<0.001*
18 hr.	6	1	6	3	1	3	<0.001*
20 hr.	6	1	6	4	1	3	<0.001*
22 hr.	6	1	6	4	1	4	<0.001*
24 hr.	6	1	6	4	1	4	<0.001*

^{*}Mann Whitney U test

Table 3: Duration of Analgesia comparison between two groups

		Gr	oup	P value
		Group B	Group M	r value
	Mean	5.780	12.439	
Duration of	SD	1.0065	1.4671	<0.001*
Analgesia	Minimum	4	9	<0.001**
	Maximum	8	16	

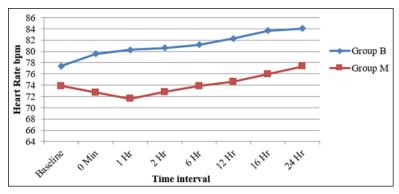


Fig 1: Line diagram showing Heart rate comparison between two groups at different time intervals

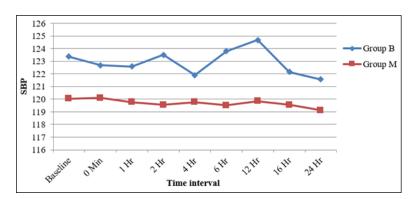


Fig 2: Line diagram showing SBP comparison between two groups at different time interval

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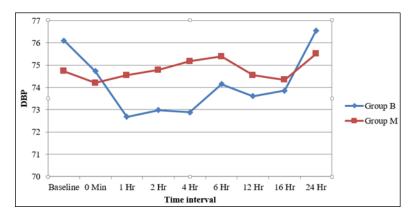


Fig 3: Line diagram showing DBP comparison between two groups at different time intervals

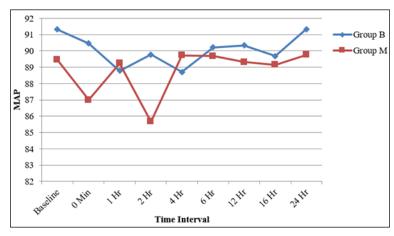


Fig 4: Line diagram showing MAP comparison between two groups at different time intervals

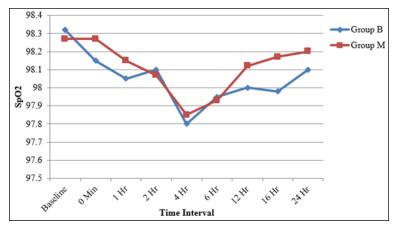


Fig 5: Line diagram showing SpO₂ comparison between two groups at different time intervals

Discussion

Studies on TAP block using various techniques were done in various subsets of surgeries like prostatectomy, large bowel resection, open or lap appendicectomy, C-sections, total abdominal hysterectomies, cholecystectomies, hepatic and renal surgeries and abdominoplasties. Our study was in a subset of patients posted for laparoscopic surgeries, where the surgical incision for trochar introduction is above or at the level of umbilicus.

These surgeries involved less organ manipulation and dissection resulting in less visceral pain, making TAP block an ideal modality for postoperative pain relief. Prolonged duration of analgesia after a TAP

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block may be related to a relatively poorly vascularized plane, delaying the drug absorption and clearance

The use of TAP block has succeeded as an analgesic technique after Laparoscopic surgeries in the last decade^[5-9]. Also, adding MgSo4 as an adjuvant to local anesthetics in regional procedures has proofed its efficacy in many clinical trials. Other studies used MgSo4 as an adjuvant to various regional techniques such as brachial, intra-articular, epidural, or even intrathecal blocks where MgSo4 had a beneficial effect on postoperative analgesia and analgesic requirements^[10-12].

The mechanism of action by which TAP MgSo4 potentiates the analgesic effect of local anesthetics still is not clear and may be related to systemic and or local actions. The analgesic effects of Magnesium are primarily based on antagonism of calcium influx into nerve fiber, and NMDA receptor blocking activity^[5-11] thus interfering with the release of neurotransmitter substances at synaptic junctions or may potentiate the action of local anesthetics^[12]. Also, magnesium ions are known to elevate the firing threshold in both myelinated and unmyelinated axons. Divalent cations have been suggested to reduce the fixed negative surface charge on the outside of nerve membranes and thereby increase the transmembranes potential (i.e., cause a hyper polarization)^[12-13].

To compare the efficacy of blind TAP block with USG guided TAP block a study was done by Yoon Suk Ra¹⁴ in 2010 which concluded that the USG-TAP block showed a significantly lower VAS than that of the Group Control(blind TAP block), as assessed at 20 min, 30 min, 60 min, 6hr, 12hr and 24hr after the operation. the amount of analgesics used in the recovery room after the operation were also remarkably lower than the Group Control, indicating that the USG-TAP block had a good analgesic effect after laparoscopic cholecystectomy until 24 hours. In our study, USG-guided TAP block was used where local anaesthetics is deposited at the anatomical landmark under vision which is more sensitive method and increases the efficacy of the block.

S torchard et al. [15] have concluded that Subcostal TAP block resulted in a significant reduction in serial visual pain analogue score values and significantly reduced the fentanyl requirement in recovery by >35% compared to the group that received local port-site infiltration (median 0.9 vs. 1.5 μ cg/kg). Furthermore, Subcostal TAP block was associated with nearly a 50% reduction in overall 8hrs equivalent morphine consumption. Since port site infiltration covers only somatic pain whereas subcostal TAP block covers both somatic& stretch pain and also autonomic reflexes is inhibited by subcostal TAP block and henceincreasethe duration of analgesia. In our study subcostal approach TAP block was done where the block spreads from T6-L1 which covers pain above umbilicus while classic approach covers sensory block from T9/10 which covers pain below umbilicus [16].

This study revealed a significant analgesic benefit of administration of MgSO₄ 500mg combined with 20 ml 0.25% bupivacaine as a single injection ultrasound-guided TAP block, for postoperative analgesia.AL-Rafay^[1]havecompared effect of magnesium sulphate500mgwith 0.25% bupivacaine for TAP block for laparoscopic cholecystectomy observed that increase in mean duration of analgesia for 19hrs and decrease in consumption of morphine. Lee *et al.*^[17] magnesium sulfate at a dose of 200 mg (2 mL of 10% solution magnesium sulfate) to normal saline when added to 0.5% bupivacaine with epinephrine in an interscalene nerve block for arthroscopic rotator cuff repair; they found a statistically significant prolongation of analgesia in the magnesium group than in the saline group (852 to 476minutes vs. 708 to 398minutes, respectively). In our study magnesium sulphate 500mg was used for tap blockin all laparoscopic surgeries where the surgical port insertion is variableand had showedduration of analgesia for 12.4 Hrs, while in the study by AL-Rafay^[1]TAP block was performed only in lap cholecystectomy where the surgical port insertion is same in all the study groups.

In our study due to adjuvant effect of magnesium sulphate of 500mg and lower concentration of bupivacaine i.e. 0.25% bupivacaine had showed to increase in duration of analgesia to range from661.8to 829 minutes. While study by Lee *et al.* [17] used 200mg of MgSO₄ and showed analgesic duration range 852 to 476minutes.

Rana *et al.* ^[18] a bilateral TAP block was performed on patients undergoing abdominal hysterectomy under subarachnoid block, with 18 mL bupivacaine 0.25% alone or in combination with 150 mg magnesium sulfate. Reduced pain score and rescue analgesic consumption as well as increased duration of analgesia for 12hrs. In the above study effect TAP block in combination with central neuraxial blockade enhanced analgesia while in our study the mean duration of analgesia is enhanced due to TAP block using bupivacaine with magnesium sulphate as an adjuvant.

Conclusion

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To conclude, our study has shown that with the use of magnesium sulphate as an adjuvant using 0.25% Bupivacaine in TAP block for laparoscopic surgeries has prolonged the duration of analgesia after laparoscopic surgeries.

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