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A Comparative Study of Intraperitoneal Ropivacaine with Dexamethasone or Magnesium Sulfate for Post Operative Analgesia after Laparoscopic Cholecystectomy: A Prospective Randomized Double-Blind Trial.

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Abstract

Background: Pain is the most common complaint of patients undergoing laproscopic cholecystectomy. Intraperitoneal instillation of local anesthetic with adjuvants in laparoscopic cholecystectomy is an effective approach for postoperative analgesia. Aim: The aim of this study was to determine the postoperative analgesic effect of intraperitoneal instillation of ropivacaine alone, ropivacaine with dexamethasone, or ropivacaine with magnesium sulfate in patients undergoing laparoscopic cholecystectomy. ***Materials and Methods***: After obtaining institute's ethical clearance and informed consent from patients, 90 patients were assigned to three groups (30 patients in each group) in this double blinded randomized clinical trial. Group RS received intraperitoneal instillation of 0.5% Ropivacaine (20 ml) + normal Saline (10 ml), Group RD received 0.5% Ropivacaine (20 ml) + 8 mg Dexamethasone (2 ml) + normal Saline (8 ml), Group RM received 0.5% Ropivacaine (20 ml) + 50 mg/kg Magnesium Sulfate + normal saline diluted to 30 ml. The haemodynamic parameters, time of first rescue analgesia, total analgesic consumption and visual analogue scale (VAS) score were recorded for 24 hours postoperatively. Patients with VAS score ≥4 received intravenous tramadol 100 mg as rescue analgesia. ***Results***: Patients of group RD showed lower VAS score and stable heart rate as compared to group RM and group RS ($p<0.05$). For group RS, RD and RM the total analgesic consumption was 200.0 ± 46.4 mg, 70.0 ± 27.39 mg and 101.6 ± 15.99 mg respectively and the duration of first rescue analgesia was 95.25±14.31 minutes, 502.75±30.47 minutes and 324.60±19.02 minutes respectively ($p<0.05$). No adverse events were noted. ***Conclusion***: Intraperitoneal instillation of ropivacaine with dexamethasone provides better pain relief, longer duration of analgesia and stable haemodynamic parameters as compared to ropivacaine with magnesium sulfate and ropivacaine alone.

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INTRODUCTION

Nowadays, laparoscopic cholecystectomy has substituted the conventional open method of cholecystectomy as the treatment of choice for cholelithiasis. [1] Residual carbon dioxide causes stretching & inflammation of the peritoneal cavity, with irritation of the phrenic nerve being the main reason for the postoperative pain. [2] Therefore patients often suffer from considerable postoperative pain during the first 24 hours. Pain prolongs the hospital stay and increases morbidity. Ropivacaine is an amino amide-linked highly potent local anesthetic, which blocks the nerve fibers reversibly by inhibiting sodium ions that leads to prolonged sensory & motor blockade. [3] Its actions are potentiated by potassium ion channels inhibition.[4] Intraperitoneal instillation of local anesthetics after laparoscopic procedure reduces postoperative pain, analgesic requirement, stress responses and lengthens the period for requirement of first postoperative analgesic.[5-7] Magnesium Sulfate primarily antagonizes the N-methyl-D-aspartate (NMDA) receptors by regulating calcium ion channel influx in the central nervous system responsible for its analgesic properties.[8] Peripheral nerve terminals expressing multiple glutamate receptors may contribute to peripheral nociceptive sensations [9], which elucidates the possibility of the use of peripheral NMDA receptor antagonism by magnesium sulfate to relieve pain [10]. Dexamethasone being highly selective & potent glucocorticoid decreases the inflammation by inhibiting synthesis of cytokines, lymphocytes, and prostaglandins. It suppresses leukocyte migration & capillary permeability and stabilizes cell & lysosomal membranes. In the present study, we have compared intraperitoneal instillation of ropivacaine alone, with dexamethasone or with magnesium sulfate to study their analgesic efficacy after laparoscopic cholecystectomy, assuming that the combination of both the drugs will provide stronger analgesia.

MATERIALS AND METHODS

The present study was conducted at department of anaesthesiology of a tertiary care centre after obtaining clearance from the institutional ethics committee (1658/UPUMS/DEAN (M)/ETHICAL/2020-21/EC.NO:73/2019-20). In this randomized double-blind study, 90 patients of American Society of Anesthesiologists (ASA) physical status class I and II, aged between 18-40 years with BMI 18-29 kg m-2 undergoing elective laparoscopic cholecystectomy, requiring general anesthesia were enrolled and divided into three groups of 30 patients each. Patients who refused to participate in the study, patients allergic to study drugs, pregnant and lactating females, patients with obesity (BMI >29 kg m-2), history of alcohol and drug abuse, having hepatic, cardiac, renal dysfunction were excluded from the study. Patients of group RS received 0.5% ropivacaine (20 ml) + 0.9% normal saline (10 ml), group RD received 0.5% ropivacaine (20 ml) + 8 mg dexamethasone (2ml) + 0.9% normal saline (8ml), and group RM received 0.5% ropivacaine (20 ml) + 50 mg kg-1 magnesium sulfate diluted to 30 ml with 0.9% normal saline. Pre-anesthetic checkup with the examination of all relevant systems was done. All routine investigations were done and evaluated. On the night before surgery, patients were kept nil per oral for 6 hr, premedicated with tablet alprazolam 0.5 mg, and written informed consent was taken. All patients were demonstrated about VAS scores for the assessment of postoperative pain. In the operating room, an intravenous line was secured and ringer lactate infusion was started at 6 ml kg-1 hr-1. Monitors were attached to measure the heart rate, non-invasive blood pressure, pulse oximetry, and respiratory rate and baseline vitals were recorded. Patients involved in the study were randomized using sealed opaque envelope technique which were opened by an anesthesiologist not involved the study and preparation of study drug. All patients were premedicated with intravenous midazolam 1.0 mg, glycopyrrolate 0.2 mg, and fentanyl 2 µg kg-1. After 3 minutes of preoxygenation, all the patient were induced with intravenous propofol 1-2.5 mg kg-1 followed by vecuronium 0.1 mg kg-1 to facilitate endotracheal intubation. Intubation of the trachea is done with an appropriate-sized cuffed endotracheal tube. Maintenance of anesthesia was carried out by 67% N2O with 33% O2 and isoflurane 0.75% using controlled ventilation. Neuromuscular blockade was maintained with intermittent intravenous vecuronium 0.02 mg kg-1. An anesthesiologist, who was blinded to the study drug, did monitoring of vital parameters. Heart rate, systolic & diastolic blood pressure, mean arterial

pressure, arterial oxygenation saturation, and end-tidal CO2 were recorded after induction, immediately after intubation, and just after extubation. At end of the surgery, the study drug was instilled through trocar over the gall bladder bed and hepatodiaphragmatic space by an operating surgeon who was unaware of the study drugs. To obtain thorough diffusion of study drugs, 5 minutes of trendelenburg position was maintained. Reversal of neuromuscular blockade was achieved with intravenous neostigmine 0.05 mg kg-1 and glycopyrrolate 0.01 mg kg-1. The patient was extubated on return of spontaneous respiration. In the postoperative period heart rate, systolic & diastolic blood pressure, mean arterial pressure, arterial oxygen saturation, VAS score, ramsay sedation score, time of first rescue analgesia administered, and total dose of rescue analgesia were recorded at 0, 1, 2, 4, 6, 8, 12, and 24 hours. Patients with a VAS score ≥4, received rescue analgesia in the form of intravenous tramadol 100 mg.

The quantitative variables are expressed as mean±sd and compared between groups using unpaired t-test/Mann-Whitney Test and within groups across follow-ups using paired t-test. Qualitative variables are compared between groups using the Chi-square test. A p-value <0.05 was considered statistically significant. Statistical analysis was performed using IBM Statistical Package for Social Sciences (SPSS) version 20.0.

RESULTS

The demographic profile of the patients on intergroup comparison among three groups were found comparable (p>0.05). [Table 1]

Table 1: Demographic profile of the patients among all the three groups

Parameter	Group RS	Group RD	Group RM	p-value		
				RS vs RD	RS vs RM	RD vs RM
Mean age (years)	32.83±6.27	32.47±6.24	32.87±5.64	0.411	0.491	0.398
Duration of surgery (minutes)	67.80±10.9	67.97±9.66	67.27±6.36	0.475	0.409	0.371
ASA-PS grade (I/II)	6/24	8/22	11/19	0.349		
Gender (Male/Female)	7/23	7/23	13/17	0.149		

On intergroup comparison the VAS scores at 0, 1st and 2nd hour was lower in group RD and group RM, compared to group RS and the results were statistically significant (p<0.05). At 6th and 8th hour, higher VAS scores were recorded in group RM as compared to group RD and group RS and the difference was statistically significant (p<0.05). At the 12th, and 24th hour, the VAS score was found comparable (p>0.05) on intergroup comparison among all three groups [Table 2].

Table 2: Visual analogue scale (VAS) score

Time (in hours)	Group RS	Group RD	Group RM	p-value		
				RS vs RD	RS vs RM	RD vs RM
0	4.73±1.53	2.37±0.49	2.30±0.47	<0.05	<0.05	0.296
1	3.83±1.26	2.30±0.47	2.27±0.45	<0.05	<0.05	0.390
2	3.37±0.96	2.40±0.93	2.17±0.38	<0.05	<0.05	0.105
4	2.30±0.47	2.13±0.35	2.23±0.43	0.061	0.284	0.163
6	2.00±0	2.03±0.18	3.73±0.83	0.161	<0.05	<0.05
8	2.53±0.78	2.30±0.47	2.93±0.83	0.082	0.029	<0.05
12	2.17±0.38	2.17±0.38	2.27±0.45	0.500	0.178	0.178
24	1.40±0.5	1.47±0.51	1.57±0.5	0.305	0.101	0.223

Systolic blood pressure, diastolic blood pressure, mean arterial pressure, arterial oxygen saturation and end-tidal CO2 were statistically comparable (p>0.05) in all groups throughout the postoperative period.

On intergroup comparison of heart rate (HR) at 0,1st and 2nd hour, lower heart rate was recorded in group RD and group RM, when compared with group RS, and results were statistically significant (p<0.05). At the 6th and 8th hour, higher values of heart rate were recorded in group RM as compared to group RD & group RS and the result was statistically significant (p<0.05).

At 12th and 24th hour, heart rate was found comparable (p>0.05) on intergroup comparison among all three groups [Table 3].

Table 3: Comparison of heart rate among the groups across time period

Time (in hours)	Group RS	Group RD	Group RM	p-value		
				RS vs RD	RS vs RM	RD vs RM
Baseline	74.90 ± 6.29	74.67 ± 7.36	72.47 ± 5.4	0.448	0.057	0.096
After induction	82.97 ± 5.92	82.53 ± 7.03	80.77 ± 5.7	0.399	0.074	0.145
Immediately after intubation	86.87 ± 5.03	86.87 ± 5.56	85.13 ± 4.29	0.305	0.078	0.212
Just after extubation	89.13 ± 5.16	87.40 ± 4.87	88.83 ± 4.27	0.093	0.404	0.115
0	82.87 ± 3.92	76.63 ± 5.44	77.07 ± 3.47	<0.05	<0.05	0.357
1	78.27 ± 3.99	73.60 ± 4.47	74.73 ± 3.08	<0.05	<0.05	0.129
2	79.27 ± 4.75	70.80 ± 4.05	71.93 ± 3.98	<0.05	<0.05	0.140
4	72.60 ± 3.37	70.77 ± 5.76	71.87 ± 5.14	0.069	0.258	0.258
6	71.00 ± 3.55	69.67 ± 6.08	75.33 ± 5.64	0.152	<0.05	<0.05
8	70.20 ± 4.65	69.27 ± 5.79	76.73 ± 5.24	0.247	<0.05	<0.05
12	74.13 ± 4.49	75.53 ± 3.22	74.73 ± 5.0	0.277	0.313	0.137
24	75.27 ± 5.11	73.53 ± 3.66	74.33 ± 4.93	0.068	0.237	0.239

The duration until the first dose of rescue analgesia was 324.60 ± 19.02, 502.75 ± 30.47 and 95.25±14.31 minutes in group RM, RD and RS respectively. This was significant (p<0.05) from statistical point of view. [Table 4]

The total dose of analgesic consumption was highest in group RS (200±46 mg), compared to group RM (101.6±15.9 mg) and minimum in group RD (70.0±27.3 mg) and difference was statistically significant (p<0.05) [Table 4].

Table 4: Mean time for rescue analgesia and total dose of analgesia required

Parameter	Group RS	Group RD	Group RM	p-value		
				RS vs RD	RS vs RM	RD vs RM
Time for first rescue analgesia administration (minutes)	95.25±14.31	502.75 ± 30.47	324.60 ± 19.02	<0.05	<0.05	<0.05
Total dose of rescue analgesia administered (mg)	200.00 ± 46.00	101.60 ± 15.90	70.00 ± 27.30	<0.05	<0.05	<0.05

DISCUSSION

Prophylactic use of medications for prevention and control of pain and its complications is the primary concern in the care of patients after laparoscopic cholecystectomy. Multimodal analgesia both parental and intraperitoneal instillation may me more useful with fewer side effect to combat the postoperative pain of laparoscopic cholecystectomy. In this randomized double-blind study, we demonstrated that intraperitoneal instillation of 0.5% ropivacaine with dexamethasone 8 mg (Group RD) at the end of surgery, significantly ($p<0.05$) reduces the VAS pain score, changes in postoperative hemodynamic parameters, time to first rescue analgesia and total analgesic consumption, compared to the group receiving 0.5% ropivacaine with 50 mg kg-1 magnesium sulfate (Group RM) and 0.5% ropivacaine alone (Group RS).

Pneumoperitoneum by carbon dioxide causes complex physiological changes leading to the sympathetic nervous system & renin-angiotensin-aldosterone system activation and catecholamines release. Increased carbon dioxide absorption can cause hypercarbia and respiratory acidosis. The resulting sympathetic stimulation results in tachycardia and hypertension. Various other physiological and mechanical changes are associated with pneumoperitoneum. In our study, blood pressures (systolic, diastolic and mean) were all comparable ($p>0.05$). The study conducted by Singh A et al. [11] and Anurag Yadava et al. [12] also revealed similar findings. Similarly, mean duration of surgery, arterial oxygen saturation and end-tidal CO2 were also found comparable ($p>0.05$). Wael Sadaqa et al., Tripat Kaur Bindra et al., and Dinesh Singh et al. also concluded results similar to our study [13,14,15].

In our study, Group RD and RM showed a significant reduction in VAS score at zero, 1st and 2nd hour compared to group RS. Behnaz Nouri et al. found in her study that group dexamethasone recorded significantly ($p<0.05$) lower VAS scores at the immediate, 2nd, 6th, 12th and 24th hour postoperatively, and the results were similar to those of our study in which group RD showed a significant reduction in VAS score up to the 24th hour [16]. In another study conducted by Maharjan Sk et al, the group receiving intraperitoneal 0.25% bupivacaine plus 50 mg kg-1 magnesium sulfate provided better pain relief in the first 24 hours and the results were similar to our study in which group RM showed significantly ($p<0.05$) lower VAS score [17]. Similar results were also seen in a study conducted by Mona B. El Mourad et al. and Zahra Asgari et al. [18,19].

At the 4th hour, intergroup comparison of the groups revealed that the VAS scores was found statistically non-significant ($p>0.05$). A study conducted by, Mona B. El Mourad et al. reported that a group receiving intraperitoneal magnesium sulfate, at a dose of 30 mg kg-1 provides pain relief for up to 4 hours with lower consumption of rescue analgesia. Similar results were seen in our study receiving ropivacaine with magnesium sulfate (Group RM) [18]. With Group RS, most of the patients have already received rescue analgesia during the initial hours, therefore at 4th hour intergroup comparison was found comparable among all groups. At the 6th hour, the VAS score was significantly ($p<0.05$) higher in Group RM as compared to group RS and group RD. 50% of patients received rescue analgesia. A study conducted by Smriti Anand et al. reported the mean duration of analgesia to be approx 5 hours whereas in our study it was 324.60 ± 19.02 minutes for group RM. Such a longer duration of analgesia was due to the difference in local anaesthetic & its concentration and dosage of magnesium sulfate used which was 0.5% ropivacaine plus 50 mg kg-1 magnesium sulfate in our study compared to 0.25% bupivacaine plus 30 mg kg-1 magnesium sulfate [20].

At the 8th hour, the VAS score was significantly ($p<0.05$) higher in group RM compared to group RS and group RD. 50% of patients received rescue analgesia. In study conducted by, Maharjan Sk et al. group receiving magnesium sulfate showed pain relief upto 8th hour and results were similar to our study [17]. Similar results were also reported by Zahra Asgari et al. [19]. In our study, at the 12th and 24th hour the VAS scores in all groups were comparable ($p>0.05$). Similar results were also reported by Behnaz Nouri et al. and Radhe Sharan et al. [16,22].

In our study, group RD and group RM showed stable heart rate at zero, 1st and 2nd hour along with lower VAS score, compared to group RS and the result was statistically significant ($p<0.05$). At the 6th and 8th hour, group RM showed raised heart rate along with an increase in VAS scores and the results were statistically significant ($p<0.05$). At the 4th, 12th and 24th hour, an intergroup comparison showed that the difference was statistically non-significant ($p>0.05$). Contrary to our study, Wael Sadaqa et al. reported no increase in heart rate between group morphine and group magnesium sulfate [13]. Similar results were reported in a study conducted by Mona B. El Mourad et al. [18]. The time for the first rescue analgesia administration was 95.25±14.31, 502.75 ± 30.47 and 324.60±19.02 minutes for group RS, group RD and group RM respectively and the results were statistically significant ($p<0.05$). Maharjan Sk et al., Zahra Asgari et al. and Sunil Chiruvella et al. also found results similar to our study [17,19,23].

CONCLUSION

We conclude that intraperitoneal instillation of ropivacaine with dexamethasone after laparoscopic cholecystectomy provides better pain relief, stable hemodynamics, and longer duration of analgesia with the lowest consumption of rescue analgesia as compared to ropivacaine with magnesium sulfate and ropivacaine alone.

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