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Evaluation of the effects of intravenous magnesium sulphate on haemodynamic parameters in patients undergoing laproscopic cholecystectomy

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ABSTRACT

Background: Within a decade since the first case of laparoscopic cholecystectomy was performed, it had become the gold standard for managing acute cholecystitis. However, laparoscopy has disadvantages of its own, mostly, secondary to the creation of pneumoperitoneum. *Aim*: To evaluate (and compare with Normal Saline) the effectiveness of intravenous Magnesium Sulphate (0.5mg/kg) on the haemodynamic parameters among patients undergoing laparoscopic cholecystectomy. *Material and methods*: This was a single centre, double-blinded, 1:1, parallel, placebo-controlled randomised control trial comparing magnesium sulphate (0.5mg/kg) and normal saline among a total of 40 participants. The duration of surgery, level of sedation, heart rate, and systolic- and diastolic blood pressure among the participants were measured. *Results*: The mean, median and the range of 'duration of laparoscopy' in the intervention and the control group were almost equal. The median sedation score was lower in the magnesium sulphate group in comparison to the normal saline group. The mean heart rate in the magnesium sulphate group was lower than the control group and this difference was statistically significant. The SBP increased in both groups following pneumoperitoneum, however, the maximum increase in SBP among participants given MgSO4 was 10%. Comparatively, in the normal saline group, the maximum increase in SBP was 16 %. No participants in either the intervention or the control group had an episode of arrhythmia, bradycardia, or hypotension in either group. *Conclusion:* Magnesium sulphate reduced the intensity of changes in haemodynamic parameters in comparison to normal saline during pneumoperitoneum.

Keywords: Magnesium Sulphate, Laparoscopy, Cholecystectomy

1. INTRODUCTION

Surgery is an invasive procedure, subjecting the body to all kinds of stress, affecting all organ systems (Hargest, 2020). A couple of centuries ago, it became apparent to physicians that smaller incisions induce less operative stress (Lau et al., 1997). This realization led to the development of laparoscopy and other minimally invasive procedures (Lau et al., 1997). Laparoscopy, despite its wide acceptance, increasing popularity and cost-effectiveness, has challenges of its own. In addition to the systemic risks of anaesthetic, common complications associated with laparoscopic cholecystectomy include bleeding, visceral injury, diarrhoea, retained gallstones, and injury to the bile ducts (Daliya, 1988). Anaesthetic management of a laparoscopic procedure is further complicated by the following factors (Kovac, 1996; Ortega et al., 1996; Cunningham, 1998): Increased intra-abdominal pressure, secondary to the creation of pneumoperitoneum; Metabolic changes, secondary to carbon dioxide absorption into the bloodstream; Patient's altered position.

The intensity of change in the various haemodynamic parameters during a laparoscopic procedure depends on several factors viz. intra-abdominal pressure, carbon dioxide absorption, patient's position, circulating volume and pre-existing morbidities (Cunningham, 1998). Therefore, several organizations recommend that during any laparoscopic procedure the range of intra-abdominal pressure should be between 15-20 mm Hg (Raval et al., 2020). Since the 1990s, surgeons across the world reported that after a prolonged laparoscopic surgery several patients had oliguria that resolved following de-sufflation (O'Malley and Cunningham, 2001). Physiologists and Nephrologists believe that the direct impact of raised intra-abdominal pressure of the renal system rather than changes in hemodynamic parameters are responsible for oliguria (O'Malley and Cunningham, 2001). An increase in ICP is associated with the creation of pneumoperitoneum. Moreover, the increase in ICP is worsened by putting the patient in the Trendelenburg position (Yashwashi et al., 2020). However, putting the patient in either supine or reverse Trendelenburg position does not minimize the increase in ICP. Therefore, particular care is required among patients with an intracranial lesion, for increased ICP during pneumoperitoneum (Yashwashi et al., 2020). The creation of pneumoperitoneum pushes the diaphragm upward thereby decreasing the functional residual capacity, and pulmonary compliance, and increasing the dead space (Wirth et al., 2017). Among a subset of patients viz. pulmonary fibrosis, obesity or restricted chest movements, these changes can have a detrimental effect during and after the laparoscopic procedure (Wirth et al., 2017).

The carbon dioxide used for the creation of pneumoperitoneum is actively absorbed into the body and produces several physiological effects independent of the mechanical effects of pneumoperitoneum (Joris et al., 1993). Clinically, a decline in blood pH, secondary to carbon dioxide absorption or otherwise can cause cardiac depression, leading to bradycardia and reduction in force of myocardium contraction (Liu et al., 2021). In direct contrast to this phenomenon, a rise in carbon dioxide concentration directly stimulates the sympathetic system thereby, promoting cardiac contractility and vasoconstriction (Zhu et al., 2009). Cullen and Eger (1974) showed that all these physiological changes were seen only with CO2 insufflation and not N2O insufflation, thereby, implying that these changes are secondary to the CO2 absorption rather than either hypoventilation or the creation of pneumoperitoneum.

In conclusion, the changes in haemodynamic parameters observed during a laparoscopy procedure are determined by an array of factors including comorbidities of the patients. Therefore, to ensure a laparoscopic procedure goes as per plan, an anaesthetic must rely on more than one strategy. Firstly, conduct a thorough pre-anaesthetic check-up. Secondly, a range of pharmacological agents is available to counteract pathophysiological changes encountered during a laparoscopic procedure (Cunningham, 1998; O'Malley and Cunningham, 2001). The choice of pharmacologic agents depends upon the procedure (type, duration, hospital stay), patient (age, co-morbidities, preferences etc.,) and properties of the drug (onset, duration, potency, and side effects).

Magnesium is an emerging drug in anaesthesia; it is the fourth most common ion with positive charge in the body, second-most common intracellular cation (after potassium), and a physiological antagonist of calcium (Sathishkumar and Adhikary, 2011). In pharmacologically administered doses, magnesium sulphate inhibits the catecholamines' release from the adrenal medulla and nerve endings, thereby effectively blunting the rise in blood pressure secondary to noxious stimuli (Nandal et al., 2021). Hence, magnesium sulphate is used as an antihypertensive drug in a variety of disorders. Furthermore, some researchers have even claimed that magnesium sulphate given intravenously in high doses could attenuate the rapid rise in blood pressure observed following endotracheal intubation and the creation of pneumoperitoneum during laparoscopy (Tan et al., 2019). Collectively, these properties make magnesium sulphate an attractive option for laparoscopy.

Therefore, it is impertinent to evaluate the clinical effectiveness of magnesium sulphate in controlling the changes in haemodynamic parameters encountered during laparoscopic cholecystectomy. Therefore, the present study was designed to evaluate (and compare with Normal Saline) the effectiveness of intravenous Magnesium Sulphate on the haemodynamic parameters following the creation of pneumoperitoneum among patients undergoing laparoscopic cholecystectomy.

2. METHODS AND MATERIAL

Study Design

A single centre, parallel-group, 1:1, double-blind, placebo-controlled, randomised control study.

Study Setting

Department of Anaesthesiology, Jawaharlal Nehru Medical College, affiliated with Datta Meghe Institute of Medical Sciences, Sawangi, Wardha. It is a tertiary care institute.

Study Duration

Total 27 months; from October 2019 to December 2021.

Study Outcomes

(i) Heart Rate, (ii) Systolic- and Diastolic Blood Pressure, and (iii) Sedation. The level of sedation was measured using the Ramsay sedation scale (Al-Qamari and Ault, 2011).

End Point of Study

(i) A participant decided to withdraw from the study, (ii) Participants suffered any adverse/unwanted event (due to any reason) or (iii) After completion of the surgery.

Comparative groups

All the participants were allocated to two groups using block randomization: (i) Group M (Intervention/Treatment group): Participants in the intervention group were given intravenous MgSO4 (50milligrams/kilograms) at the rate of 240 ml/hr through infusion pump, 5 minutes before pneumoperitoneum. (ii) Group C (control group): Participants in the control group were given 20 ml of normal saline alone at the rate of 240ml/hr.

Participants' recruitment

The participants recruited after verifying that they fulfilled the following criteria:

Inclusion

Patients are scheduled for laparoscopic cholecystectomy for their ailment(s).
Patients between 18- 70 years of age
Patients of all genders.
Patients who were categorized as belonging to grades I and II of the American Society of Anaesthesiologists (ASA).
Patients whose serum magnesium level was within normal limits.
Patients agree to provide written informed consent.

Exclusion Criteria

Patient aged either <18 or > 70 years,
Bodyweight >75kgs
Patients with known allergies to medicines to be used during the procedure,
Patients with pre-existing kidney, endocrine, or metabolic disease(s),
Patients with hypertension, diabetes mellitus, ischemic heart disease, or asthma,
Patients with hypermagnesemia,
A patient who refused to take part in the study.

Sample Size

The smallest required sample size for the study was estimated following the recommendation of *Zhong B* (2009) for a randomised controlled trial. Using the formula for randomised control trial, the minimum sample size was calculated as 40 (20 participants in each group).

Informed Consent

A tri-lingual (Marathi, Hindi, & English) consent form was drafted following the prescribed guidelines for research on human participants. The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. The participants were informed and explained that they have the right to withdraw from the study at any point in time. Thereafter, willing participants were asked to sign the consent form.

Randomization and Allocation Concealment

An independent statistician (no involvement in the study) used statistical software Stata version 15.1 to generate random numbers. The allotment of the participants to either the normal saline or the magnesium sulphate group was achieved using a computer-generated programme based on a permuted block design (n=6). The details of the allocated groups were concealed from the principal investigator and research team by supplying random numbers in opaque and sealed envelopes. Impregnated tapes were used to render the envelope impermeable to intense light.

Blinding

Double-blind study, both participants and the investigator were blinded to the study group. Both, the intervention, and the placebo were supplied by the manufacturer in an identical packet, moreover, the colour, smell, volumes etc., of the drugs were matched. An operation theatre nurse independent of the study prepared and gave the drug to the participants. Unblinding was done only in case of a serious adverse event.

Data Collection

The data were collected in a paper-based questionnaire. The questionnaire had 4 parts as follows: (i) Demographic details (ii) Pre-anaesthetic check-up details (iii) Pre- and Intra-operative details, (iv) post-operative details.

Statistical Analysis Plan

The primary outcome was the degree of variation/change in vital parameters viz. heart rate and blood pressure at various time points from the baseline values. Secondary outcomes were the levels of sedation among the participants in the two groups. We aimed to assess whether data supplied evidence of the superiority of magnesium sulphate to placebo for the primary outcome. We followed the scientific convection for detecting a significant difference between two groups of P-value < 0.05.

Null Hypothesis (H_0): Change in haemodynamic parameters were of equal magnitude in both the study group.
Alternate Hypothesis (H_A): Change in haemodynamics were of different magnitude in both groups.

3. RESULTS

While recruiting participants for the present study, we screened a total of 54 participants. Out of 54 patients, 14 (25.9%) were excluded: 10 did not meet the inclusion criteria and 4 participants refused to participate in the study (Figure 1). Table 1 illustrates the participatsnt details. The mean duration of laparoscopy in the intervention and the control group was exactly equal (85.35 minutes). The median duration of surgery in the two groups was also the same (84.5 minutes). As Table 1, the sedation level among the participants was measured using Ramsay's sedation score for the first 6 hours after the surgery. Each of the 50.0% of participants in the intervention group had a Sedation Score of I and II, respectively. Comparatively, in the normal saline group, most of the participants (60%) had a sedation of score of 2. The distribution of sedation scores among the participants was statistically non-significant (Chi = 0.751, p = 0.376).

Table 1 Key variables and secondary outcomes among participants (n = 40)

Variables	Group		P-value
	MgSO4 (n, %)	NS (n, %)	
Gender			
Female	13 (65.0)	13 (65.0)	1.00
Male	7 (35.0)	7 (35.0)	
ASA Grade			
I	10 (50.0)	8 (40.0)	0.376

II	10 (50.0)	12 (60.0)	
Sedation Score			
1	10 (50.0)	8 (40.0)	0.376
2	10 (50.0)	12 (60.0)	
Duration of LC	85.35 (16.4)	85.35 (15.6)	1.00
Weight	43.15 (13.7)	49.2 (15.8)	0.205

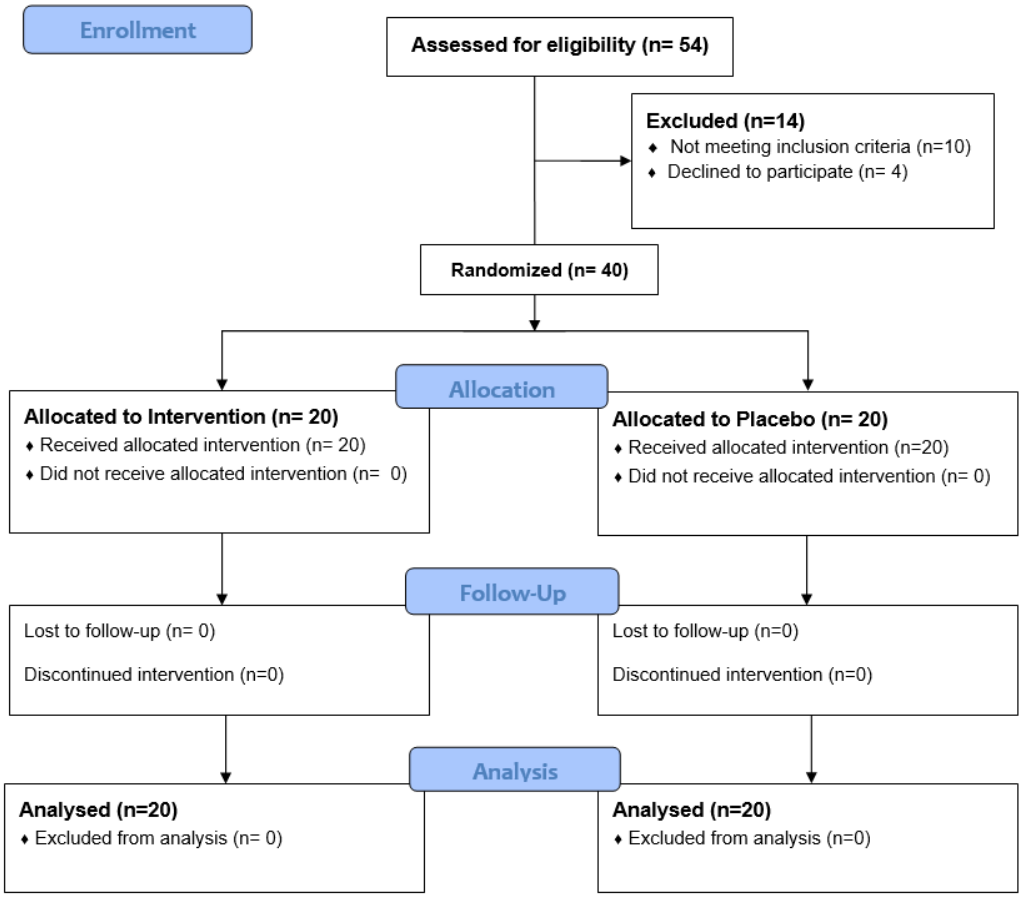

Figure 1 CONSORT Flow Diagram

Table 2 shows the trend in the Heart Rate among the participants in both groups. At the baseline, the mean heart rate was lower among the patients given normal saline (P-value= 0.092). Comparatively, for most of the period after the creation of pneumoperitoneum, the heart rate was lower in the magnesium sulphate group in comparison to the normal saline group. More importantly, the difference in heart rate between the intervention and control arm was statistically significant at 10, 15, 45 and 60 minutes after the creation of pneumoperitoneum (Table 2). Most importantly, not even a single participant either in the intervention or control arm had an episode of arrhythmia, bradycardia, or tachycardia.

In the magnesium sulphate group, the maximum increase in heart rate (1.67%) was noticed immediately after the creation of pneumoperitoneum followed by 1.63% at 45 minutes (Figure 2). The maximum decline in heart rate (minus 0.77) was seen at 10 minutes after pneumoperitoneum. In the NS group, the maximum change (increase) from the baseline was observed 45 minutes after pneumoperitoneum (15.6%). The heart rate increased gradually for most of the period after the creation of pneumoperitoneum. A decline in heart rate, as seen in group M, was not seen at any time point among participants in group C (Figure 2).

Table 2 The mean Heart Rate among participants at prescribed time points (n=40)

Time Point (in minutes)	Heart Rate				P-value
	MgSo4		NS		
	Mean	SD	Mean	SD	
BASELINE	88.8	15.01	82.5	9.74	0.092
0 minutes	89.7	14.04	84.1	8.05	0.1391
5 Minutes	87.3	11.32	88.2	7.66	0.3914
10 Minutes	87.0	11.51	92.9	6.03	0.0249
15 Minutes	88.5	12.73	93.6	7.52	0.0640
20 Minutes	88.1	12.04	91.6	12.24	0.1837
30 Minutes	87.1	11.03	92.4	12.38	0.0827
45 Minutes	89.1	10.44	94.9	10.06	0.0410
60 Minutes	88.4	10.62	93.8	8.90	0.0448

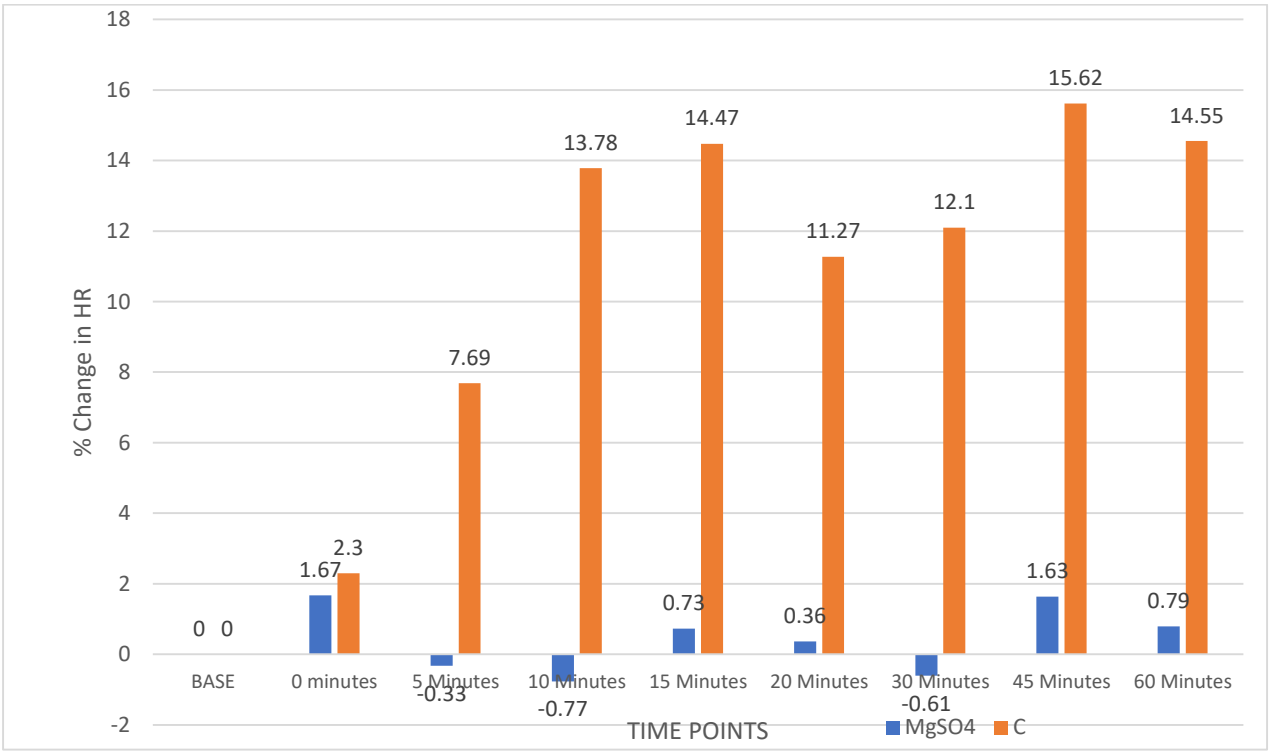

Figure 2 Percentage change in Heart Rate

Table 3 Systolic Blood Pressure among participants at various time points (n=40)

Time Points (in minutes)	Mean Systolic BP				P-value
	MgSO4		NS		
	Mean	SD	Mean	SD	
BASELINE	119.10	9.3	118.05	8.0	0.7056
0 minutes	122.0	13.7	121.0	9.3	0.7897
5 Minutes	123.55	11.5	122.70	7.2	0.7818
10 Minutes	122.85	3.1	130.60	12.3	0.0621
15 Minutes	127.0	11.2	131.30	16.9	0.3484
20 Minutes	128.60	11.4	136.45	13.5	0.0450
30 Minutes	131.05	12.3	135.05	14.4	0.3528
45 Minutes	127.30	13.6	134.05	16.4	0.0160
60 Minutes	128.85	11.2	134.55	12.4	0.0370

Table 3 shows the trend in the SBP among the participants in both groups. The mean SBP of the participants in the intervention and the control arm was almost similar (P-value = 0.705) at baseline. The SBP increased in both groups following pneumoperitoneum, however, comparatively for a greater part of the observation period the increase in SBP was of lower magnitude in group MgSO4.

As from Table 3, in the intervention group M, the mean systolic BP increased from 119.10 mm Hg at baseline to a maximum of 131 mm Hg after 30 minutes of pneumoperitoneum. The mean SBP was 128 mm at the end of 60 minutes after the creation of pneumoperitoneum. In the normal saline group, the mean systolic BP (mmHg) increased from 118 mm Hg at baseline to a maximum of 136 mm Hg, 20 minutes after pneumoperitoneum. The mean SBP in group C participants at the end of observation was 134 mm Hg. Although, the SBP at baseline was almost similar in the two groups, however, the difference in SBP at the end of observation was statistically significant between the intervention and the control arm. Further, as can be seen from the table 3, at all the prescribed time points during observation, the SBP was consistently lower among the participants belonging to the intervention group. Moreover, the difference in the mean SBP among the participants of the two groups was significant on more than one occasion.

The maximum change in SBP among participants given MgSO4 was an increase of 10% noticed about 30 minutes after the creation of pneumoperitoneum (Figure 3). Comparatively, in the normal saline group, the maximum change was an increase of 16 % recorded some 20 minutes after pneumoperitoneum (Figure 3).

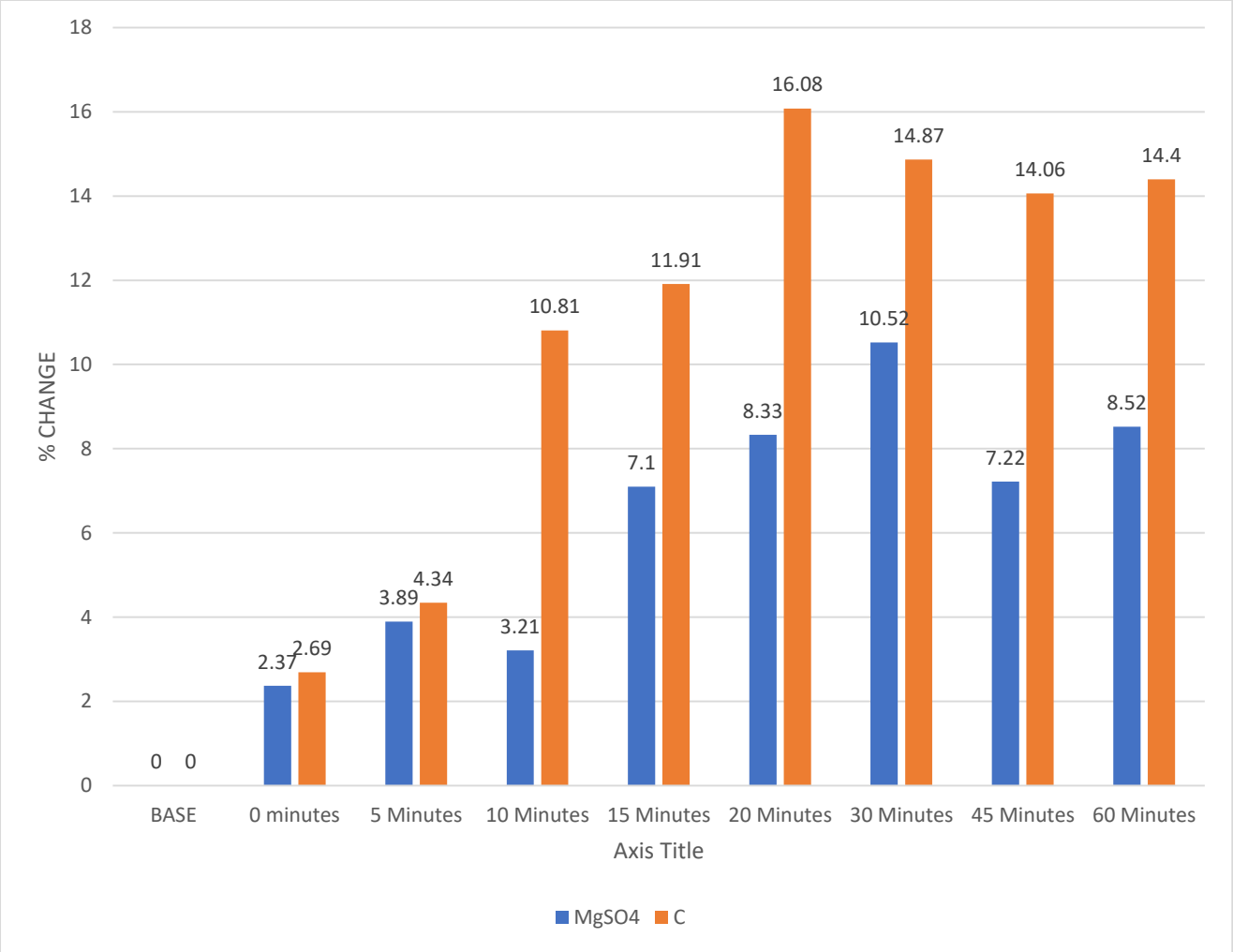

Figure 3 The percentage change in SBP from the baseline

Table 4 shows the trend in the DBP among the participants in both groups. In the intervention arm: the DBP increased from 78.0 at baseline to a maximum of 84 mm Hg, 30 minutes after pneumoperitoneum and then declined gradually to ultimately settle at 79.60 mm Hg, 60 minutes after pneumoperitoneum. As can be seen from Table 4, the change in DBP from baseline to maximum observed value was statistically insignificant (p = 0.062). In the control arm: the DBP increased from 76.8 mm Hg at baseline to a

maximum of 85.9 mm Hg 10 minutes after pneumoperitoneum. Thereafter, the DBP declined slightly to 82.9 mm Hg at 60 minutes. Among the participants given MgSO4, the maximum increase (8.5%) from the baseline was noticed at the 30 minutes of pneumoperitoneum. In the normal saline group, the maximum change from the baseline was recorded after 10 minutes of creating pneumoperitoneum (12.4%). At endline, the DBP was 2.62% and 8.34% higher in group M and group C, respectively. At 10, 15, 45, and 60 minutes after pneumoperitoneum.

Table 4 Diastolic Blood Pressure among participants at prescribed time points (n=40)

Time Point (in minutes)	Mean DBP				P-value
	Group M		Group C		
	Mean	SD	Mean	SD	
BASELINE	78.0	7.6	76.85	6.5	0.6119
0 minutes	78.05	12.5	78.90	5.3	0.7828
5 Minutes	80.55	9.3	81.50	7.9	0.7309
10 Minutes	80.95	7.1	85.90	4.9	0.0153
15 Minutes	82.15	6.9	84.20	8.3	0.4046
20 Minutes	81.90	11.1	85.45	9.7	0.2903
30 Minutes	84.05	9.0	85.65	10.7	0.6123
45 Minutes	81.15	7.6	83.95	9.2	0.3055
60 Minutes	79.60	7.0	82.95	8.5	0.1850

4. DISCUSSION

Laparoscopic surgeries have replaced convectional surgeries as the new norm for cholecystectomy. However, the laparoscopic procedure does come with some disadvantages of its own. As mentioned earlier, the creation of pneumoperitoneum provides unpleasant stimuli to multiple organ systems. An individual with pre-existing morbidities viz. hypertension, coronary occlusion, or atherosclerosis is especially prone to unwanted outcomes during or after laparoscopy. To limit the adverse consequence of pneumoperitoneum, several drugs from different classes have been evaluated for safety and efficacy. In this regard, magnesium sulphate has become quite popular because of its numerous remarkable properties, safety, and acceptable adverse effect profile.

The mean duration of laparoscopy in the intervention and the control group was exactly equal (85.35 minutes) (p=1.00). Likewise, Ghodratry et al., (2017) observed the mean duration of surgery in group M and group C was 94.6 and 93.06 minutes, respectively. Likewise, Safavi et al., (2015) observed that the mean duration of surgery in group M and group C was 89.2 and 91.6 minutes, respectively.

In comparison, Jee et al., (2009) noted the mean duration of surgery in group M and group C was 51.9 and 54.3 minutes, respectively. In comparison, Mahajan et al., (2018) noted mean duration of surgery in group M and group C was 102.5 and 103.75 minutes, respectively. Each of the 50.0% of participants in the intervention group had a Sedation Score of I and II, respectively. Comparatively, in the normal saline group, most of the participants (60%) had sedation of score of 2 (Chi = 0.751, p = 0.376). Like our study, Ghodatry et al., (2017) measured the level of sedation using the Ramsay Sedation Score. They reported that the mean sedation score in group M and group C was 1 and 2, respectively. Sunil et al., (2014) reported that the mean sedation score in group M and group C was 2 and 3, respectively. On the other hand, Kalra et al., (2011) measured the level of sedation using the time to obey a verbal command. They reported that the meantime to respond to verbal commands was 8.8 and 10.7 minutes, respectively. Similarly, Ray et al., (2010) reported that the meantime to respond to verbal commands was 8.8 and 10.7 minutes, respectively.

At baseline, the mean heart rate was slightly lower among the participants given normal saline, however, statistically, this difference was non-significant (P-value= 0.092). Comparatively, for most of the period after the creation of pneumoperitoneum, the heart rate was less in the magnesium sulphate group in comparison to the normal saline group. More importantly, the difference in heart rate between the intervention and control arm was statistically significant at 10, 15, 45 and 60 minutes after the creation of pneumoperitoneum. Jee et al., (2009) reported that the difference in heart rate remained statistically insignificant at baseline, at the time of the creation of pneumoperitoneum, and five minutes after that. They observed that 10 minutes after, the difference in heart rate between the two groups became statistically significant. The maximum difference in heart rate was noticed 10 minutes after pneumoperitoneum. Also, the heart rate was significantly higher in the control group than in the magnesium group after the

completion of surgery (Jee *et al*., 2009). Sengupta et al., (2013) reported no significant difference in the heart rate between the groups at baseline and before the creation of pneumoperitoneum.

Furthermore, they reported that the heart rate in the intervention arm was significantly lower throughout the laparoscopic procedure, after the release of pneumoperitoneum and after extubation in comparison to the control group. Baid et al., (2020) also reported that the heart rate was similar in both groups 5 minutes after the infusion of magnesium sulphate. Further, they observed that the increase in HR in the control group after the creation of the pneumoperitoneum was not seen in the magnesium group. Ghodatry et al., (2017) reported that they did not observe any statistically significant difference in heart rate between the magnesium and normal saline group. However, they observed that the participants in the magnesium group had smaller variation in heart rate, the change was of smaller magnitude and distributed uniformly throughout the observation.

In the present study, although, the SBP at baseline was almost similar in the two groups, however, the difference in SBP at the end of observation was statistically significant between the intervention and the control arm. We observed that the SBP increased sharply after pneumoperitoneum. Moreover, the increases in SBP were sustained during the entire pneumoperitoneum period. This was true for both the control group as well as the magnesium group. However, in the magnesium group, the sharp increase in SBP as seen in the normal saline group immediately following was blunted to a considerable extent. In the intervention group M, the mean systolic BP increased from 119.10 mm Hg at baseline to a maximum of 131 mm Hg after 30 minutes of pneumoperitoneum. In the normal saline group, the mean systolic BP (mmHg) increased from 118 mm Hg at baseline to a maximum of 136 mm Hg, 20 minutes after pneumoperitoneum.

Our findings are similar to the observations reported by Jee et al., (2009) in their study. They reported that in comparison to the baseline values, in the comparison group, the SBP was higher at 5-, 10-, 20-, and 30-min post-pneumoperitoneum. Sengupta et al., (2013) also reported that the mean arterial pressure in group M was significantly lower during and after the release of pneumoperitoneum, and even after extubation. Further, a bit like our findings, Sengupta et al., (2013) also observed that the maximum difference in blood pressure between the two groups was seen fifteen minutes after pneumoperitoneum. However, Ghodatry et al., (2017) did not observe any significant difference in mean arterial pressure between the magnesium and control groups. Nevertheless, they also observed that participants in the magnesium group had a minimal increase in the MAP.

As mentioned earlier, there are multiple reasons for raised blood pressure during a laparoscopic procedure. Different mechanisms combinedly cause a sudden surge in the circulating values of plasma catecholamines and vasopressin (Raman and Cadeddu, 2012). The resulting increase in catecholamines stimulates the adrenoreceptors located in the cardiovascular system to increase heart rate, SBP, DBP and MAP (Raman and Cadeddu, 2012). Several in-vivo studies have reported that magnesium attenuates catecholamines release (Laurant et al., 2000). An increase in SBP during the intraoperative period of more than 20% of the baseline values can significantly increase the risk of myocardial infarction (Iwase *et al*., 1992). Several studies including ours have empirically shown that infusion of magnesium sulphate can effectively attenuate adverse haemodynamic stress response to the creation of pneumoperitoneum, thereby protecting unwanted cardiovascular events, especially among patients having hypertension or cardiac diseases. There were zero incidences of either hypotension or hypertension in either group.

5. CONCLUSION

The mean, median, and the range for the variable 'duration of laparoscopy' in the intervention and the control group were almost the same. The median sedation score was less in the magnesium sulphate group in comparison to the normal saline group. The mean heart rate in the intervention group was lower than the control group and this difference was statistically significant. No participants in either the intervention or the control group had an episode of arrhythmia, bradycardia, or tachycardia. The SBP increased in both groups following pneumoperitoneum, however, comparatively for a greater part of the observation period the increase in SBP was of lower magnitude in group M. There were zero incidences of either hypotension or hypertension in either group.

Author Contributions

Dr Eshana Rasheed: Propoposal writing, Review of Literature, Questionnaire design, Data collection, Data analysis, Paper writing, Revisions

Dr Anjali Modak: Propoposal writing, Questionnaire design, Data analysis, Paper writing, Revisions

Dr Neeta Verma: Propoposal writing, Data analysis, Paper writing, Revisions

Dr Sheetal Madavi: Data analysis, Paper writing, Revisions

Dr Nikhil Bhalerao: Data analysis, Paper writing, Revisions

Ethical approval

The study was approved by the Medical Ethics Committee of Datta Meghe Institute of Medical Sciences, Sawangi, Wardha. Ethical approval code:-DMIMS (DU)/IEC/Sept-2019/8366).

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Conflicts of interest

The authors declare that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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