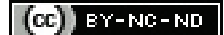


Comparison of Effect of Clonidine and Magnesium Sulphate on Attenuation of Haemodynamic Response to CO₂ Pneumoperitoneum in Patients undergoing Laparoscopic Surgeries- A Randomised Clinical Study

APARNA BAGLE¹, KRUSHA SURESH SHAH², SPOORTI PUJARI³, TANYA GULIA⁴, CHANDRAKALA SINGH⁵



ABSTRACT

Introduction: Laparoscopy, a minimally invasive technique causes several physiological fluctuations. There can be deleterious sympathetic responses during Carbon Dioxide (CO₂) insufflation, which is done to create a pneumoperitoneum.

Aim: To assess the impact of clonidine and magnesium sulphate on sympathetic response to carbon dioxide insufflation in patients undergoing laparoscopic surgeries.

Materials and Methods: A double-blinded randomised clinical study was conducted in Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India, from June 2020 to September 2021, included 52 patients, posted for elective laparoscopic surgeries. Patients were randomised into two groups i.e, group M (n=26) received 30 mg/kg of magnesium sulphate and group C (n=26) received 1 µg/kg of clonidine after premedication. The vital parameters like heart rate, systolic, diastolic and mean arterial pressure, end tidal carbon dioxide, saturation were observed and noted at predetermined interval in perioperative period. Also, Visual Analogue Score (VAS) and

sedation score were recorded in the recovery room. The statistical software SPSS version 16.0 was used. The p-value <0.05 was considered as significant.

Results: The mean age in group C and group M was 35.46±8.5 years and 35.38±9.02 years (p-value=0.751). Both groups were compared for change in heart rate, systolic, diastolic and mean blood pressure changes after pneumoperitoneum and showed no significant variations in both groups at different time intervals (p-value >0.05). Also, both groups showed less than 20% variation from the baseline parameters, thus, effectively attenuating the pressor response. The VAS and sedation score were comparable in both the groups and showed no significant variations in both groups at different time intervals.

Conclusion: Intravenous administration of clonidine 1 µg/kg, or magnesium sulfate 30 mg/kg prior to pneumoperitoneum was effective in suppressing the pressor response during laparoscopic procedures. At the above used dosages, groups C and M showed insignificant difference in the measured parameters, thus, proving to be equally effective in blunting the pressor response.

Keywords: Carbon dioxide insufflation, Haemodynamic surge, Pressor response, Visual analogue score

INTRODUCTION

French gynaecologist Mouret was the first to perform laparoscopic cholecystectomy [1]. The demand for laparoscopic surgeries is on the surge due to minimal incision which results in less pain, early ambulation and thus short stay in the hospital [2,3].

Creation of pneumoperitoneum is essential for laparoscopic procedures. For this, the surgeons insufflate gases, like carbon dioxide, which causes several physiological fluctuations. There is a rise in the abdominal pressure which leads to elevation of the diaphragm, thus, compressing both small and big blood vessels. Compression of inferior vena cava leads to decreased venous return as well as pooling of blood in the legs which ultimately causes decreased cardiac output by approximately 50%. Positioning, like reverse trendelenburg or patients with compromised cardiovascular reserve are at a higher risk. Moreover, there is a rise in the intrathoracic pressure. Carbon dioxide insufflation creates a state of hypercarbia which causes vasopressor effects due to release of catecholamines and vasopressin, leading to raised blood pressure and heart rate.

Pharmacological agents like nitroglycerine, α-blockers, β-blockers, opioids etc. help in attenuation of heart rate and blood pressure, thereby, enabling better outcome during the surgeries [4,5].

Clonidine, being a selective α-2 adrenergic receptor agonist, causes bradycardia and hypotension accompanied with a fall in systemic

vascular resistance and decreased cardiac output; thereby blunting the haemodynamic response [6].

Magnesium sulphate deters the release of catecholamines from adrenal gland as well as adrenergic terminals. By action on blood vessels, it leads to vasodilatation, whereas, at higher doses it can attenuate the release of vasopressin, thereby causing further vasodilation [7,8].

In various studies like the one conducted by Kalra NK et al., used a higher doses like 1.5 µg/kg clonidine and 50 mg/kg magnesium sulfate [9]. There was evidence of delayed response to command which was statistically significant. In a study conducted by Mallick S et al., used infusion of magnesium sulfate with a loading dose of 30 mg/kg followed by 10 mg/kg/hr infusion and compared this to dexmedetomidine 1 µg/kg followed by infusion of 0.5 µg/kg/hour [10]. They concluded, that, both these drugs attenuated the haemodynamic surge. Sheth PP et al., compared 50 mg/kg magnesium sulfate and 1.5 µg/kg clonidine and concluded that, sedation score was higher in the postoperative room [11].

In the previous studies magnesium sulfate was used in the dose of 50 mg/kg and clonidine 1.5 µg/kg. These doses were associated with increased sedation score. So, the present study was designed to find the minimum effective dosage of 30 mg/kg of magnesium sulphate and 1 µg/kg of clonidine drugs with least side effects. The

primary outcome measures were change in heart rate, systolic, diastolic and mean arterial blood pressure after carbon dioxide insufflation. The secondary objectives of the study were to rule out any side effects of the study drugs like bradycardia, hypotension, postoperative Visual Analogue Score (VAS) and sedation.

MATERIALS AND METHODS

The double-blinded randomised clinical study was conducted in Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India, from June 2020 to September 2021. The approval from the Institution Ethics Committee (Research Protocol No. IESC/PGS/2019/153) was obtained. Total 52 patients, undergoing laparoscopic surgeries, were included. Written informed consent was taken from all patients.

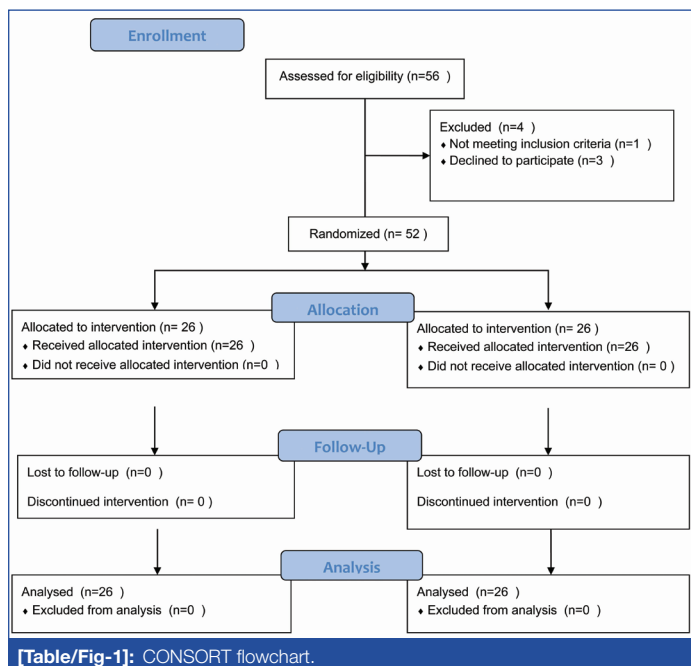
Sample size calculation: In a study conducted by Paul S et al., the mean and standard deviation of heart rate after pneumoperitoneum among two groups was 79.4 ± 10.6 and 90.2 ± 10.4 . Considering the difference in the mean heart rate in this study, WINPEPI software was used, with confidence interval 95% and power of study 95% [12]. Total sample size calculated was 52 (26 in each group). The patients were then, randomly allocated to respective groups of 26, using lottery method.

Inclusion criteria: All patients of either gender aged between 18-65 years and physical status American Society of Anaesthesiologists (ASA) status I and II were included in the study.

Exclusion criteria: Patients with cardiovascular, neurological, renal and respiratory co-morbidities, allergies to any drug used in the study and hypermagnesemia were excluded from the study.

- Group M received 30 mg/kg of magnesium sulfate in 20 mL normal saline over a period of 10 minutes.
- Group C received 1 µg/kg of clonidine diluted in 20 mL normal saline over a period of 10 mins.

The study drug preparation was done by an anaesthesiologist who was not involved in administration of anaesthesia and patient care. Patient care, monitoring and data collection was done by another anaesthesiologist, who was not involved in the study [Table/Fig-1].



Procedure

After a thorough pre anaesthetic check-up, patients were taken inside the operation theatre. Preoperative pulse, non invasive blood pressure, Electrocardiogram (ECG) and oxygen saturation were noted. Peripheral venous access was established and intravenous (i.v.) fluid (Ringer's Lactate) was given at 10 mL/kg. All patients received premedication with injection midazolam 0.02 mg/kg, injection fentanyl 2 µg/kg,

and injection glycopyrrolate 4 µg/kg body weight intravenously. After premedication study drug was given. Patients were pre-oxygenated with 100% O₂ for 3 minutes before induction. Induction was done in both the groups with inj. propofol 2 mg/kg body weight i.v and injection vecuronium 0.1 mg/kg i.v. to facilitate endotracheal intubation. After intubation bilateral air entry was confirmed by auscultation, End tidal Carbon Dioxide (EtCO₂) reading was noted and the endotracheal tube was firmly secured using adhesive tape. Anaesthesia was maintained with oxygen and air mixture 50:50, sevoflurane 1.5 to 2.5% and vecuronium 0.1 mg/kg intermittent boluses. During surgery ringer lactate was infused in accordance with deficit, maintenance and blood loss. Carbon dioxide pneumoperitoneum was created and intra-abdominal pressure was maintained between 12-14 mmHg. Patients were ventilated with Intermittent Positive Pressure Ventilation (IPPV). Tidal volume and respiratory rate were adjusted to maintain EtCO₂ between 35-45 mmHg.

Monitoring of Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Mean Arterial Pressure (MAP), Oxygen saturation (SpO₂) and EtCO₂ was done on a multichannel monitor and noted at baseline, after premedication, after study drug, at one, three and five minutes, after creation of pneumoperitoneum at 5, 10, 20, 30, 50, 70, 90, 120 mins till the end of the surgery. All patients were given injection ondansetron 4 mg, injection diclofenac sodium 75 mg intravenously 30 mins prior to the end of surgery. Also local infiltration with 0.125% bupivacaine was given at the port site for postoperative analgesia.

After completion of surgery, 100% oxygen was administered. Residual neuromuscular blockade was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 8 µg/kg. A patient was then extubated. In recovery room, all patients were observed for vital parameters. Pain and sedation score was assessed on arrival and after 30 mins, 1 hour, 2 hours, 3 hours, and 4 hours in the recovery room with the help of VAS and Ramsay Sedation score, respectively. Also all patients were observed for any other side effects such as nausea, vomiting and shivering.

STATISTICAL ANALYSIS

Variables like age, weight, heart rate, mean arterial pressure and Saturation (SpO₂), VAS and sedation score are expressed as Mean±Standard Deviation (SD), and compared across the groups using unpaired t-test. The statistical software Statistical Package for Social Sciences (SPSS) version 16.0 was used. The p-value <0.05 was considered as significant.

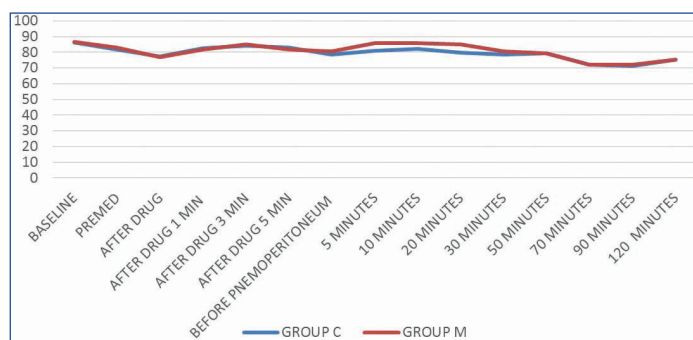
RESULTS

The demographic profile like age, sex and factors like the type and duration of surgeries were comparable in both the groups [Table/Fig-2].

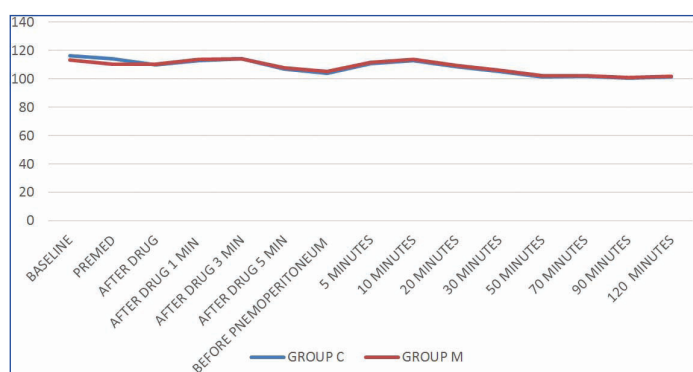
Variables	Group C (n=26)	Group M (n=26)	p-value
Age (years)	35.46±8.5	35.38±9.02	0.751*
Weight (kg)	60.4±14.72	59.75±9.21	0.867*
Height (cm)	162.4±6.17	164.5±8.19	0.1332*
Gender			
Male	14	11	0.803*
Female	12	15	
ASA status			
Status I	11	12	0.623*
Status II	15	14	
Duration of surgery (hours)	1.43±0.39	1.48±0.45	0.752*
Type of surgery			
Laparoscopic appendectomy	13	10	0.532*
Laparoscopic hysterectomy	4	3	
Laparoscopic cholecystectomy	9	13	

[Table/Fig-2]: Demographic profile.
*Unpaired t-test; *Chi-square test

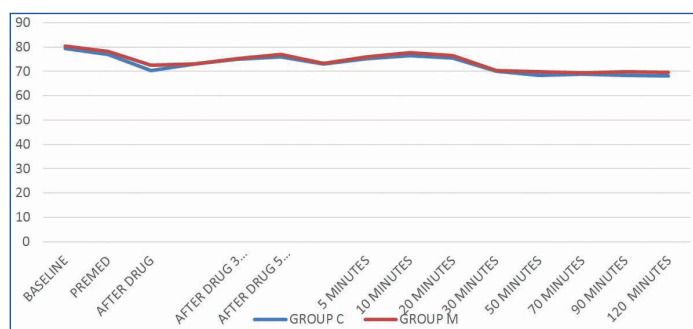
The MAP, SBP, DBP, and HR were comparable between the two groups [Table/Fig-3-6]. The VAS score, as shown in [Table/Fig-7], shows no clinical significance in the both the compared groups at all time intervals. Sedation score, as mentioned in [Table/Fig-8], showed no significant difference and was comparable at all time intervals.



[Table/Fig-3]: Mean Heart Rate (beats per minute) in both the groups.



[Table/Fig-4]: Mean systolic blood pressure (mmHg) in both the groups.



[Table/Fig-5]: Mean diastolic blood pressure (mmHg) in both the groups.

Mean arterial pressure (mmHg)	Group C	Group M	p-value (unpaired t-test)
Baseline	86.11±8.86	87.65±9.47	0.298
Premedication	84.44±8.48	84.88±9.51	0.687
After drug administration			
At 1 minutes	82.42±7.67	84.24±21.18	0.548
At 3 minutes	78.47±8.47	82.48±9.98	0.205
At 5 minutes	77.21±8.64	79.87±9.84	0.238
Before pneumoperitoneum	76.24±8.25	79.16±8.45	0.229
After creation of pneumoperitoneum			
At 5 minutes	76.46±8.49	78.88±8.95	0.269
At 10 minutes	78.32±8.63	79.38±8.42	0.533
At 20 minutes	77.92±7.65	78.64±7.38	0.542
At 30 minutes	78.29±6.24	79.64±6.03	0.096
At 50 minutes	77.79±7.48	78.42±9.51	0.243
At 70 minutes	77.24±8.25	77.96±8.45	0.14
At 90 minutes	76.46±7.49	77.86±7.95	0.267
At 120 minutes	78.32±8.63	78.88±8.42	0.553

[Table/Fig-6]: The comparison of mean arterial blood pressure in mmHg.

VAS score recorded at time interval	Group C	Group M	p-value (unpaired t-test)
30 mins	3.65±0.74	3.75±0.95	0.218
1 hour	4.11±0.81	4.21±0.96	0.673
2 hour	4.38±0.89	4.59±0.86	0.865
3 hour	4.73±1.11	4.96±1.15	0.347
4 hour	5.07±1.09	5.54±1.01	0.113

[Table/Fig-7]: Visual Analogue Score (VAS) score in both the groups.

Sedation score recorded at time interval	Group C	Group M	p-value (unpaired t-test)
30 mins	1.23±0.54	1.34±0.48	0.560
1 hour	1.12±0.32	1.22±0.42	0.180
2 hour	1.31±0.22	1.23±0.38	0.357
3 hour	1.17±0.18	1.14±0.21	0.446
4 hour	1.04±0.12	1.07±0.04	0.232

[Table/Fig-8]: Ramsay Sedation Score in both the groups.

DISCUSSION

Laparoscopic surgeries are minimally invasive, less painful and thus shorten the hospital stay. Pneumoperitoneum can cause increase in heart rate, rise in blood pressure accompanied with positional changes, anaesthesia and retention of CO₂ due to insufflation. This has increased the challenge to maintain haemodynamic stability for the anaesthetist.

Clonidine is a selective α-2 adrenergic receptor agonist. It causes fall in heart rate and blood pressure along with decrease in systemic vascular resistance. It also reduces the cardiac output. These effects help to reduce a surge in the haemodynamic response during creation of pneumoperitoneum. Magnesium sulfate decreases release of catecholamines. It causes vasodilatation and can suppress the release of vasopressin at higher doses thereby causing further vasodilation. This will help in attenuation of haemodynamic response during laparoscopy.

Paul S et al., compared 30 mg/kg magnesium sulfate with a placebo group and observed a significant attenuation of pressor response in the former group for pneumoperitoneum [12]. Pareek A et al., compared 50 mg/kg magnesium sulfate, 1 µg/kg clonidine and normal saline to attenuate the haemodynamic response due to pneumoperitoneum in laparoscopic cholecystectomy. The study concluded that, at these doses clonidine and magnesium were better at blunting the response as compared to normal saline whereas both these drugs were equally effective when compared to each other. So, the lowest dose of magnesium sulfate (30 mg/kg) and clonidine (1 µg/kg) which was effective in previous studies was chosen for the present study to minimise the side effects [13].

Haemodynamic parameters: In the present study, on comparing the mean heart rate, systolic and diastolic blood pressure, mean arterial pressure, it was concluded that amidst both the groups there was insignificant variance in the two groups during the perioperative period.

Kalra NK et al., studied patients, who received 1.5 µg/kg clonidine or 50 mg/kg magnesium sulfate. They concluded that heart rate showed insignificant difference between the two groups. There was a measurable decrease in systolic blood pressure in the group administered with 1.5 µg/kg clonidine at an interval of 10 and 30 mins post pneumoperitoneum as compared to group that received 50 mg/kg magnesium. The 30 and 40 minutes post pneumoperitoneum the diastolic blood pressure was significantly lesser in the group which received clonidine as compared to those who received 50 mg/kg magnesium sulfate [9]. Statistically significant difference in the time required to respond to commands like eye opening between the

two groups was observed. There was no significant difference in both systolic and diastolic blood pressures in both the groups in the present study. Also, there was no delay in response as compared with the above study.

Kamble SP et al., compared 30 patients each in group C (clonidine 1 µg/kg), group M (magnesium sulfate 50 mg/kg), and group NS (normal saline 10 mL). Heart rate was significantly lower in magnesium group and systolic blood pressure was significantly higher in normal saline group as compared to magnesium and clonidine group. Between the later groups systolic pressure was, at 5 mins post pneumoperitoneum, significantly reduced in magnesium group as compared to clonidine group [14]. Thus, concluding that clonidine and magnesium sulfate were both effective in attenuation of pressor response. This is similar to present study.

Reddy JS, in their research compared the efficacy of single intravenous dose of magnesium sulphate (50 mg/kg) and clonidine (1 µg/kg) for suppression of sympathetic response. They concluded that MgSO₄ attenuated the heart rate better than those who received clonidine and diastolic pressure was significantly reduced in the magnesium group at 5, 10, 20 minutes after the pneumoperitoneum and even postoperatively [15].

Pareek A et al., group C, group M, group Normal Saline (NS) which received 50 mg/kg magnesium sulphate, 1 µg/kg clonidine and normal saline, respectively. They concluded that there was significant bradycardia amidst groups C and M. In group NS the heart rate was significantly higher than the other two groups. There was insignificant difference in systolic blood pressure and MAP. On comparing these groups with normal saline, showed a significant reduction in blood pressure as a result of pneumoperitoneum was noted in groups C and M [13].

Paul S et al., compared 30 mg/kg magnesium sulfate with placebo group. Preoperatively and prior to pneumoperitoneum MAP in both groups was comparable. This was followed by a statistically significant reduction in MAP during the entire course of surgery and even post extubation. Thus, study concluded that magnesium sulfate was effective in lowering MAP during pneumoperitoneum [12].

Tripathi et al., observed a significant drop in diastolic blood pressure occurred in the patients that were administered 2 µg/kg clonidine, as compared to placebo 20 minutes after pneumoperitoneum [16]. Dutta PK, piloted a study to observe the effectiveness of 50 mg/kg magnesium sulfate with placebo to attenuate the arterial blood pressure in abdominal laparoscopic surgeries and observed a surge in diastolic as well as systolic blood pressure in control group [17]. Observing the results in both these studies, clonidine and magnesium sulfate proved to attenuate the elevation of blood pressure to pneumoperitoneum as compared to placebo group.

In the present study, the VAS and sedation score was comparable in both the study groups and all patients were calm and alert. A recent study by Shafiq T et al., used 50 mg/kg magnesium sulfate versus placebo for haemodynamic surge prevention in patients undergoing laparoscopic cholecystectomy. They concluded that there was significant reduction in the haemodynamic surge due to pneumoperitoneum in patients that received magnesium sulfate [18].

Kalra NK et al., concluded that magnesium 50 mg/kg and clonidine 1.5 mcg/kg blunted the haemodynamic stress response [9]. Sheth PP et al., concluded that, the sedation score was significantly higher in group M (50 mg/kg) as compared to group C (1.5 µg/kg) in the first two hours in the postoperative period [11]. Increase in the sedation score can be attributed to the higher doses they have used in their studies. In the present study, the sedation

score was comparable in both the groups without significant delay in recovery.

Monitoring of all the patients in recovery for the adverse effects like decrease in heart rate, fall in blood pressure, postoperative nausea and vomiting, shivering was done. There was no such adverse event seen in either group M or group C. Studies by Kalra NK et al., and Sheth PP et al., concluded a delayed response and increased sedation score [9,11].

Limitation(s)

The present study was conducted on American Society of Anaesthesiologists (ASA) grades I and II patients and a small sample size. Hence, it is not possible to extrapolate the results to all patient populations. So, further studies on elderly patients and those with compromised cardiac function are required to recommend its use in such high risk patients.

CONCLUSION(S)

Intravenous administration of clonidine 1 µg/kg and magnesium sulfate 30 mg/kg prior to pneumoperitoneum was effective in suppressing the pressor response during laparoscopic procedures. However, at the above used dosages, 1 µg/kg of clonidine and 30 mg/kg of magnesium sulphate showed insignificant difference in the measured factors, thus proving to be equally effective in blunting the pressor response.

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