"ATTENUATION OF PRESSOR RESPONSE TO PNEUMOPERITONEUM IN LAPAROSCOPIC SURGERIES, COMPARISON BETWEEN MAGNISIUM SULPHATE AND DEXMEDETOMIDINE: A RANDOMISED CONTROL STUDY"

By

Dr. RATAN A NALATWADMATH

DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANAESTHESIOLOGY

Under the Guidance of

Dr. KIRAN N

Professor

MD

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PRIOR PERMISSION TO START OF STUDY

The Institutional Ethics Committee of Sri Devaraj Urs Medical College, Tamaka, Kolar has examined and unanimously approved the synopsis entitled **"Attenuation Of Pressor Response To Pneumoperitoneum In Laparoscopic Surgeries, Comparison Between Magnisium Sulphate And Dexmedetomidine . A Randomised Control Study."** being investigated by **Dr.Ratan A Nalatwadmath & Dr. Kiran . N** in the Department of Anaesthesiology at Sri Devaraj Urs Medical College, Tamaka, Kolar. **Permission is granted by the Ethics Committee to start the study.**

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ATTENUATION OF PRESSOR RESPONSE TO PNEUMOPERITONEUM IN LAPAROSCOPIC SURGERIES, COMPARISON BETWEEN MAGNISIUM SULPHATE AND DEXMEDETOMIDINE: A RANDOMISED CONTROL STUDY ABSTRACT Background: Laparoscopic surgeries, favored for their minimally invasive nature and quicker recovery, often involve the creation of a pneumoperitoneum using carbon dioxide (CO_2). Aim: To evaluate and compare the effectiveness of magnesium sulfate and dexmedetomidine in controlling the hemodynamic pressor response to pneumoperitoneum during laparoscopic surgeries. Materials and Methods: "This study was conducted on 56 patients undergoing laparoscopic surgeries under general anesthesia at R.L. Jalappa Hospital from May 2023 to October 2024. Patients were randomly divided into two groups: Group B got 1 mcg/kg dexmedetomidine and Group A received 50 mg/kg magnesium sulfate, all of which were administered in 100 ml of normal saline over 20 minutes before to induction. Systolic and diastolic blood pressure, heart rate, and mean arterial pressure were measured at baseline and at regular intervals during the procedure. SPSS 20.0 was utilized to conduct the statistical analysis." Results: Both groups were demographically comparable. Dexmedetomidine (Group B) resulted in significantly lower systolic, diastolic, and mean arterial pressures at the 1st minute and maintained a more stable heart rate throughout surgery. Magnesium sulfate (Group A) showed higher early intraoperative blood pressure and heart rate, though later stabilized. I Conclusion: Both dexmedetomidine and magnesium sulfate effectively attenuate the pressor response during laparoscopic surgeries. However, dexmedetomidine offers superior hemodynamic stability and may be preferred in patients at higher cardiovascular risk. Keywords: Pneumoperitoneum, Pressor response, Dexmedetomidine, Magnesium sulfate, Hemodynamic parameters, Laparoscopic surgery. II INTRODUCTION Laparoscopic procedures are gaining widespread use because they are less invasive and allow quicker patient recovery. Nonetheless, a key concern during such operations is the hemodynamic stress response, characterized by increased heart rate and blood pressure resulting from the creation of pneumoperitoneum. This is typically achieved by insufflating the abdominal cavity with carbon dioxide (CO_2).1 This leads to a

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ABSTRACT

Background: Laparoscopic surgeries, favored for their minimally invasive nature and quicker recovery, often involve the creation of a pneumoperitoneum using carbon dioxide (CO_2). Aim: To evaluate and compare the effectiveness of magnesium sulfate and dexmedetomidine in controlling the hemodynamic pressor response to pneumoperitoneum during laparoscopic surgeries.

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Results: Both groups were demographically comparable. Dexmedetomidine (Group B) resulted in significantly lower systolic, diastolic, and mean arterial pressures at the 1st minute and maintained a more stable heart rate throughout surgery. Magnesium sulfate (Group A) showed higher early intraoperative blood pressure and heart rate, though later stabilized.

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ABBREVIATIONS

ACLS – Advanced Cardiovascular Life Support

ASA – American Society of Anesthesiologists

BP – Blood Pressure

CO – Cardiac Output

CO_2 – Carbon Dioxide

CRP – C-reactive protein

DBP – Diastolic Blood Pressure

ECG – Electrocardiogram

FDA – Food and Drug Administration

HR – Heart Rate

IAP – Intra-Abdominal Pressure

ICU – Intensive Care Unit

IVC – Inferior Vena Cava

MAP – Mean Arterial Pressure

MBP – Mean Blood Pressure

$MgSO_4$ – Magnesium Sulfate

NMJ – Neuromuscular Junction

PNP – Pneumoperitoneum

PTH – Parathyroid Hormone

RAAS – Renin-Angiotensin-Aldosterone System

SBP – Systolic Blood Pressure

SD – Standard Deviation

SPSS – Statistical Package for the Social Sciences

SVR – Systemic Vascular Resistance

TNF-alpha – Tumor Necrosis Factor-alpha

TPN – Total Parenteral Nutrition

VAS – Visual Analog Scale

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ABSTRACT

Background: Laparoscopic surgeries, favored for their minimally invasive nature and quicker recovery, often involve the creation of a pneumoperitoneum using carbon dioxide (CO_2). Aim: To evaluate and compare the effectiveness of magnesium sulfate and dexmedetomidine in controlling the hemodynamic pressor response to pneumoperitoneum during laparoscopic surgeries.

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Conclusion: Both dexmedetomidine and magnesium sulfate effectively attenuate the pressor response during laparoscopic surgeries. However, dexmedetomidine offers superior hemodynamic stability and may be preferred in patients at higher cardiovascular risk.

Keywords: Pneumoperitoneum, Pressor response, Dexmedetomidine, Magnesium sulfate, Hemodynamic parameters, Laparoscopic surgery.

INTRODUCTION

INTRODUCTION

Laparoscopic procedures are gaining widespread use because they are less invasive and allow quicker patient recovery. Nonetheless, a key concern during such operations is the hemodynamic stress response, characterized by increased heart rate and blood pressure resulting from the creation of pneumoperitoneum. This is typically achieved by insufflating the abdominal cavity with carbon dioxide (CO_2).[1] This leads to a rise in plasma catecholamine and vasopressin levels. The elevated intra-abdominal pressure and upward displacement of the diaphragm can negatively impact cardiovascular function, including reduced cardiac output and increased arterial pressure, resulting in tachycardia and hypertension. In patients with pre-existing conditions such as hypertension, ischemic heart disease, or elevated intracranial pressure, these changes can pose significant risks.[2,3] Therefore, effective measures to attenuate the pressor response during laparoscopic surgeries are necessary to minimize the risk of adverse cardiovascular events.

The need for this study arises from the fact that both magnesium sulfate and dexmedetomidine have been shown to be effective in attenuating the pressor response during laparoscopic surgery.[4,5] As a calcium channel blocker, magnesium sulfate has vasodilatory effects and helps reduce blood pressure. A very selective α-2 adrenergic agonist, dexmedetomidine has analgesic, sedative, and anxiolytic properties. Hence, a comparative study is required to determine the relative effectiveness of these two medicines in reducing the pressor response during laparoscopic surgery.[6,7] The findings of this randomised controlled study may aid in selecting the most effective pressor response attenuator of hemodynamic parameters during laparoscopic surgery, which could have important therapeutic implications for better patient outcomes and less morbidity.

AIMS & OBJECTIVES

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"To evaluate the effectiveness of Magnesium sulphate and Dexmedetomidine in reducing the pressor response to hemodynamic parameters to Pneumoperitoneum in laparoscopic surgeries"

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Pneumoperitoneum refers to the artificial insufflation of gas into the peritoneal cavity during laparoscopic surgeries. It provides a clear surgical field by creating space between intra-abdominal organs and the abdominal wall. However, it induces physiological and hemodynamic changes, significantly affecting cardiovascular and respiratory function.[8,9] After peritoneal access is achieved, the abdomen is inflated, usually with carbon dioxide (CO2) gas, though alternatives like nitrous oxide and helium have been explored without confirmed safety. CO2 can be used cold or heated, but heating provides minimal clinical benefit and is not cost-effective, as shown in a Cochrane review of 22 trials.[10,11]

Initially, CO2 flow is set at a low rate, with a Veress needle limiting flow to 3 L/min. The pressure starts below 10 mmHg and gradually rises; a rapid increase may indicate displacement or blockage. Adjusting the needle's position or ensuring proper tubing alignment can help resolve issues. If pressure remains high, repositioning the needle or trocar is necessary.

Once intra-abdominal insufflation is confirmed, gas flow is increased while monitoring pressure, typically set between 12-15 mmHg. Lower pressures have been used successfully in some procedures, like lap cholecystectomy, reducing postoperative shoulder pain without increasing complications. The required gas volume depends on anesthesia depth, neuromuscular blockade, and patient size, confirmed through manual and visual examination.[12]

Increased intra-abdominal pressure triggers physiological responses, including elevated heart rate and vascular resistance, with reduced venous return and cardiac output. These effects are generally well tolerated in healthy patients (ASA class 1 or 2) if pressure stays

below 15 mmHg. CO2 absorption can lead to hypercapnia and respiratory acidosis, but the body compensates by increasing CO2 elimination via the lungs. Monitoring end-tidal CO2 and adjusting ventilation prevent complications. Temporary oliguria may occur due to renal compression but resolves after pneumoperitoneum release.[13–15]

Effect of Pneumoperitoneum on Pressor Response

The establishment of pneumoperitoneum leads to a **pressor response**, characterized by **increased BP and HR.**[16,17] The degree of these hemodynamic changes depends on factors such as:

- **Insufflation pressure** (typically 12–15 mmHg)
- **Duration of pneumoperitoneum**
- **Patient comorbidities** (e.g., cardiovascular disease)
- **Anaesthetic technique**

Key hemodynamic effects include:

1. **Increased Mean Arterial Pressure (MAP)** – Due to **systemic vasoconstriction and increased afterload**
2. **Increased Systemic Vascular Resistance (SVR)** – Induced by sympathetic activation
3. **Potential Bradycardia or Tachycardia** – Depending on autonomic reflexes and vagal stimulation
4. **Decreased Cardiac Output (CO)** – Due to reduced **venous return** from the inferior vena cava compression
5. **Transient Hypertension** – Related to catecholamine release

Mechanism of Altered Pressor Response Due to Pneumoperitoneum

Pneumoperitoneum alters the **pressor response** through multiple mechanisms[18,19]:

1. Mechanical Effects on Venous Return and Cardiac Output

- **• The inferior vena cava (IVC) is compressed by elevated intra-abdominal pressure (IAP), which lowers venous return (preload) and may also lower cardiac output.**
- High IAP also leads to **increased afterload**, causing **myocardial workload elevation**.

2. Sympathetic Nervous System Activation

- Pneumoperitoneum triggers **baroreceptor activation**, stimulating the **sympathetic nervous system (SNS)** and leading to **increased systemic vascular resistance (SVR) and arterial blood pressure**.
- **Catecholamine (epinephrine/norepinephrine) release** further **amplifies vasoconstriction**, leading to an exaggerated **pressor response**.

3. Vagal Reflex Activation

- **Peritoneal stretch receptors** can stimulate the **vagus nerve**, sometimes leading to **bradycardia** and even severe cases of **asystole**.
- This occurs more frequently in patients with **high vagal tone** or when **CO_2 insufflation is rapid**.

4. Hypercapnia-Induced Vasoconstriction

- CO_2 absorption during pneumoperitoneum causes **hypercapnia**, leading to:

- **Respiratory acidosis** (↓ pH, ↑ $PaCO_2$)
- **Stimulation of central chemoreceptors**, increasing **sympathetic drive**
- **Elevated systemic blood pressure** due to **vasoconstriction**

5. Hormonal and Renin-Angiotensin System Activation

- Pneumoperitoneum induces the **renin-angiotensin-aldosterone system (RAAS)**, increasing:
  - **Angiotensin II levels** → potent **vasoconstrictor**
  - **Aldosterone secretion** → leading to **fluid retention and increased BP**

PHARMACOLOGY OF MAGNESIUM SULPHATE

Magnesium sulfate is a widely used medication in hospitals, serving multiple therapeutic purposes. It has several FDA-approved indications, as well as various off-label applications in clinical practice.

FDA-Approved Uses[20,21]:

- Treatment of constipation
- Management of hypomagnesemia
- Seizure prevention in eclampsia and preeclampsia
- Treatment of acute nephritis in pediatric patients
- Correction of cardiac arrhythmias caused by hypomagnesemia
- Used for soaking minor cuts and bruises[22,23]:

Magnesium Metabolism

Knowledge of intracellular magnesium function is necessary to comprehend the therapeutic implications of magnesium sulfate. Through nutrition, the gastrointestinal system absorbs magnesium, a positively charged divalent cation. The kidneys, which regulate reabsorption and excretion, are principally responsible for controlling its serum levels. While circumstances such as hypercalcemia and hypermagnesemia result in increased magnesium excretion, the parathyroid hormone (PTH) encourages magnesium reabsorption in the cortical thick ascending limb of the nephron. About half of the body's total magnesium is kept in bone, and the normal range for blood magnesium is 0.7 to 1 mmol/L (1.4 to 2.0 mEq/L).

Magnesium Imbalances

Hypermagnesemia (Serum Magnesium > 2 mmol/L)

Hypermagnesemia is uncommon unless **renal insufficiency** or **excessive magnesium intake** occurs. High magnesium levels cause **neuromuscular blockade and vasodilation** by inhibiting **calcium influx at voltage-gated channels**, preventing **acetylcholine release** at the neuromuscular junction. This results in **muscle relaxation and reduced excitability**.

Symptoms:

- **Muscle weakness**
- **Respiratory depression**
- **Hyporeflexia**
- **Hypotension**
- **ECG abnormalities**: Prolonged **P-R interval, Q-T interval, or widened QRS complex**, potentially leading to **heart block**

Hypomagnesemia (Serum Magnesium < 0.7 mmol/L)[24]

Symptoms:

- **Muscle spasms and hyperreflexia**
- **Increased neuromuscular irritability**
- **ECG changes**: Widened **P-R interval, QRS complex**, and **peaked T waves**

These effects highlight the **critical role of magnesium in neuromuscular function and cardiovascular stability**.

Administration of Magnesium Sulfate

Magnesium sulfate can be administered through various routes,

- **Oral (PO)**
- **Intramuscular (IM)**.
- **Intraosseous (IO)**.
- **Intravenous (IV)**
- Total parenteral nutrition (TPN).

The route of administration determines its effect—**oral magnesium** acts as a **laxative**, while **parenteral magnesium** is broken down into **elemental magnesium** to replenish and maintain **serum magnesium levels**.

Adverse Effects of Magnesium Sulfate

At **therapeutic doses**, magnesium sulfate has minimal side effects, with **facial flushing and warmth** being the most commonly reported symptoms. These effects typically resolve on their own. However, certain risks exist:

- **Neuromuscular Effects:** In patients with **neuromuscular disorders** (e.g., **myasthenia gravis**), magnesium sulfate may **worsen muscle weakness** even at lower doses.
- **Cardiovascular Effects: Rapid or high-dose administration** can cause **transient hypotension** due to its **vasodilatory properties**, though this effect is usually temporary.

- **Hypermagnesemia Risks:** Continuous **magnesium sulfate infusions** require **serum level monitoring** to prevent **absent reflexes, cardiac conduction abnormalities, and muscle weakness** associated with **supratherapeutic levels**.

Contraindications

Magnesium sulfate should be **avoided** in:

- **Patients with a known hypersensitivity** to the drug.
- **Individuals with heart block**, as it can further **impair cardiac conduction**.
- **Preeclampsia/eclampsia patients before delivery**: However, discontinuing magnesium sulfate prematurely may **increase the risk of seizures**, so clinical judgment is necessary.[25]

PHARMACOLOGY OF DEXMEDETOMIDINE[26]

It is the dextro-enantiomer of medetomidine and is a α2 receptor agonists which is part of the imidazole subclass.

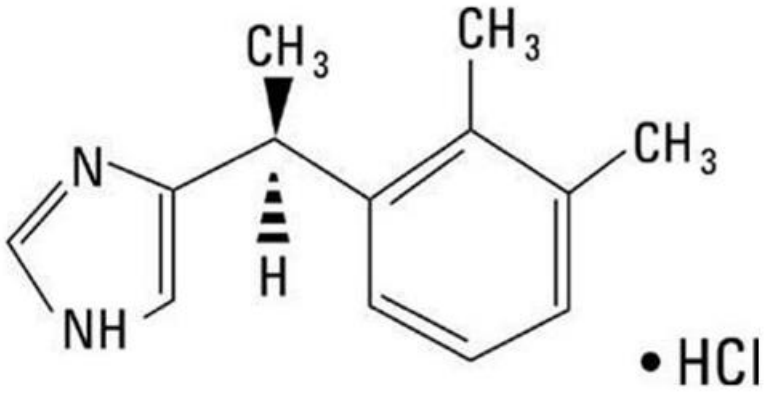

Figure 1: Chemical structure of Dexmedetomidine

Mechanism of action

"α2A, α2B, and α2C are the three human subtypes of alpha-2 adrenergic receptors, which

are G protein-coupled receptors that cross the cell membrane. Whereas α2B and α2C are mostly prevalent in the brain and spinal cord, the α2A subtype is primarily found in peripheral tissues." While presynaptic α2 receptors block norepinephrine release, which might lessen vasoconstriction, postsynaptic α2 receptors in the periphery cause vasoconstriction in blood vessels. The sympatholytic, sedative, and pain-relieving (antinociceptive) actions of α2 agonists are facilitated by these receptors.

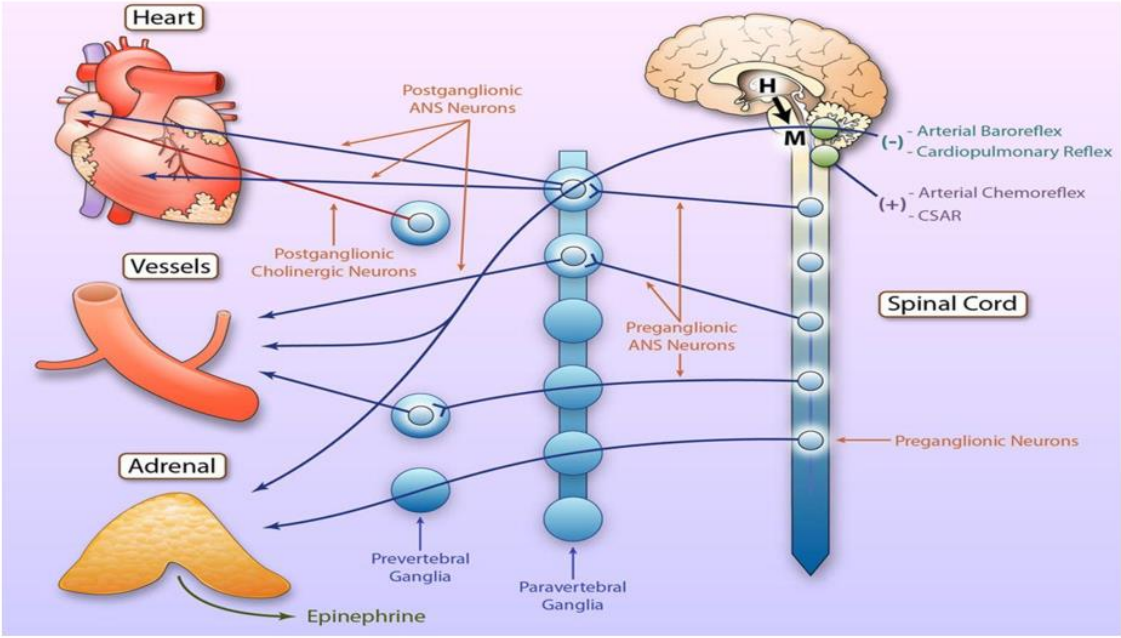

Figure 2: Physiology of alpha -2 adrenoceptors

The alpha – 2 adrenergic receptors:

SUBTYPE	LOCATION
Alpha 2 A	Periphery
Alpha 2 B	Brain, spinal cord
Alpha 2 C	Brain, spinal cord

Pharmacokinetics

Dexmedetomidine is quickly carried throughout the body after intravenous administration, where it is mostly metabolized in the liver and excreted in the urine and feces. 94% of the time, dexmedetomidine binds to proteins. After an 8-hour infusion, dexmed has a context-sensitive half-life of 4 to 250 min ues and an elimination half-life of approximately 2 hours. There are 118 liters in the distribution volume. It is anticipated that 39 liters per hour will be cleared.[6]

Dosage and administration:

"IV loading dose 0.5-1 µg/kg (10mins) followed by maintenance dose of 0.2 to 0.7 µg/kg/hr."

Various articles;

"To evaluate the impact of magnesium sulfate on the reduction of hemodynamic stress response, Showket AD et al. (2015) conducted a research. The train-of-four response did not exhibit statistical significance, but Group I's heart rate, systolic, diastolic, and mean arterial pressures were considerably lower ($p<0.05$). Group I had a longer extubation time, but the difference was not statistically significant. In laparoscopic abdominal procedures, magnesium sulfate efficiently reduces the hemodynamic stress response."[27]

Zarif P. et al. (2016) evaluated dexmedetomidine vs magnesium sulfate as an adjuvant to an anesthetic medication. The greatest total mean readings were found in Group C. Groups D and M had considerably longer times to obtain an Aldrete score of ≥9, and they also had significantly greater recovery times and sedation ratings. In summary, there was no discernible difference between the two medications in their ability to successfully lower pressor responses during laparoscopic cholecystectomy.[28]

In a research by Kataria AP et al. (2016), the effectiveness of fentanyl and

dexmedetomidine on pressor response was evaluated. Group I had greater control over heart rate (HR) and mean arterial pressure (MAP) during laryngoscopy, intubation, and pneumoperitoneum (PNP) than Group II. Additionally, Group I had better pain management, less sedation, and a more seamless extubation. Conclusion: During laparoscopic cholecystectomy, dexmedetomidine outperformed fentanyl in terms of hemodynamic stability and analgesia, confirming its efficacy in reducing pressor reactions.[29]

Ahmed IM et al. (2018) evaluated the effectiveness of dexmedetomidine and magnesium sulfate in reducing hypertension during lap surgery. Heart rate and mean arterial pressure were significantly different in the magnesium sulfate, dexmedetomidine, lignocaine, and control groups at the time of drug administration, after intubation, during the pneumoperitoneum at 5-minute intervals, post-pneumoperitoneum, and 10 minutes postoperatively ($P<0.001$). In conclusion, lignocaine was less successful than magnesium sulfate and dexmedetomidine in lowering the need for opioids during laparoscopic cholecystectomy and managing the hypertensive reaction to pneumoperitoneum.[30]

Desai DJ et al. (2019) evaluated the effectiveness of dexmedetomidine against magnesium sulphate in lap operations. "In both groups, MAP and hr decreased after magnesium sulfate and dexmed infusions, and these effects continued when propofol was administered. Throughout the intraoperative phase, both measures stayed below baseline even though they rose following intubation and pneumoperitoneum. During laparoscopic cholecystectomy, magnesium sulfate (40 mg/kg) and dexmedetomidine (1 µg/kg) both successfully reduced the hemodynamic response to anesthetic and surgical manipulation, with magnesium sulfate offering superior hemodynamic stability."[31]

"In a randomized clinical research, Nirmala D et al. (2019) assessed the efficacy of

dexmedetomidine and magnesium sulphate for attenuation response. HR and MAP were significantly lower in Group D, but recovery time and sedation ratings were greater in Group M. Furthermore, Group M took much longer than Group D to get an Aldrete score of ≥9. Magnesium sulfate and dexmedetomidine both successfully reduced the stress reaction to pneumoperitoneum and surgery. Dexmedetomidine, on the other hand, improved hemodynamic stability and sped up postoperative recovery."[32]

Rishardhan P. et al. (2021) determined the effects of Dexmed and MgSo4 on pressor response attenuation. This makes it a better anesthetic adjuvant than dexmedetomidine in laparoscopic surgery among 60 patients. Furthermore, the magnesium sulfate group had lower visual analog scale (VAS) ratings and improved maintenance of hemodynamic parameters (apart from heart rate).[33]

Bagle A. et al. (2022) evaluated the impact of MgSo4 and clonidine on the attenuation of hemodynamic response. Groups C and M had mean ages of 35.46±8.5 and 35.38±9.02 years, respectively (p=0.751). "With less than 20% deviation from baseline, both groups' HR, systolic, diastolic, and MAP changes during pneumoperitoneum did not vary significantly (p>0.05), successfully attenuating the pressor response. Additionally, there were no appreciable differences in the visual analog scale (VAS) and sedation scores. Conclusion: There was no discernible difference in the effects of intravenous clonidine (1 μg/kg) and magnesium sulfate (30 mg/kg) in suppressing the pressor response during laparoscopic operations."[34]

Mohamed A. et al. (2022) evaluated the effects of MgSo4 and clonidine in premedication for response to stress. Group C recovered far more quickly than Groups M and S. Conclusion: Preoperative intravenous infusion of magnesium sulfate and clonidine successfully decreased blood cortisol levels, slowed the hemodynamic response to pneumoperitoneum, and decreased the need for analgesics and postoperative discomfort.

In terms of heart rate regulation and quicker recovery, clonidine outperformed magnesium sulfate.[9]

Singh S. et al. (2024) evaluated the effects of magnesium sulfate versus dexmedetomidine perioperative administration on patients' hemodynamic response. The groups' demographic profiles were similar. There was no pressor reaction after PLMA insertion, and mean arterial pressure (MAP) dropped after medication delivery in both groups, with Group D seeing a larger drop. Following peritoneal insufflation, diastolic blood pressure increased similarly in both groups, although Group D's heart rate was continuously lower. Conclusion: During laparoscopic cholecystectomy, dexmedetomidine was superior to magnesium sulfate in regulating hemodynamic responses.[35]

According to a research by Jaisawal S. et al. (2024), the demographic information for the two groups was similar. Blood sugar, TNF-alpha, CRP, and cortisol levels rose in all groups, but after 30 minutes and 4 hours, Group M's levels were considerably higher than Group D. When it came to reducing surgical stress during laparoscopic cholecystectomy, dexmedetomidine worked better.[36]

MATERIALS & METHODS

MATERIAL & METHOD

Source of data

"This study was conducted on 48 patients undergoing laparoscopic surgeries done under general anaesthesia at R.L.Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar during the period from May 2023 to November 2024"

Study Design: Single blinded randomized control trial.

Sample Size: 56

Duration of study: From May 2023 to October 2024

Sampling Method: Random sampling.

Method of collection of data:

- Patients undergoing laparoscopic surgeries under general anaesthesia will be randomly selected.
- Taken Informed consent.
- Result values were recorded using a proforma.

Inclusion Criteria

- Age 20 - 60 yrs
- Patients undergoing laparoscopic surgeries under general anaesthesia.
- ASA 1 and 2

Exclusion Criteria

- Abnormal ECG, difficult airway
- Pre-existing disease effecting NMJ
- pre-existing cardiac, hepatic, renal, cerebral diseases
- Seizure disorder, electrolyte abnormality
- Psychiatric disorders

Sampling procedure

- Patient Detailed history of the was taken.
- Complete physical examination was done.
- Checked for Routine investigations
- IV was secured and fluids were connected.
- Divided Patients into two groups randomly.

Group A: Infusion of 50mg/kg of MgSo4 in 100 ml NS over 20 minutes prior to induction of Anaesthesia

Group B: Infusion of 1 mcg/kg of Dexmedetomidine in 100 ml Normal Saline over 20 minutes prior to induction of Anaesthesia

A baseline evaluation of SBP, DBP, MBP, HR were obtained Intraoperatively, under aseptic precautions patient is stabilized under general anaesthesia. After administration of anaesthesia all the variables were recorded at 1st minute, 5th min, 10th min, and there

after every 30 mins until extubation

Sample size estimation

"As per Prithvi R, et al.,[33] the study observed mean ± SD of DBP in group A as 74.95± 10.98 and group B as 83.52±11.81. The mean difference is 8.57and SD is 11.395. At 5percent level of significance and 80percent power the sample size estimated is 28 in each group. Sample size is estimated using formula":

FORMULA:

$$n = \frac{2\times(z_{\alpha/2}+z_{\beta})^2\times\sigma^2}{d^2}$$

Where , $z_{\alpha/2} = 1.92$, $z_{\beta=0.84}$

Parameters to be observed

- HR
- SBP
- DBP
- MBP

Ethical clearance was obtained from institutional ethics committee.

STATISTICAL ANALYSIS

Statistical analysis of the data were performed using SPSS 20.0, descriptive statistics of SBP, DBP, MBP, and HR were expressed using mean ± SD. Catagorical variables were expressed as frequency and percentage. Pre and Post comparison within group were done using Paired T test. Between the group comparison in all the parameters was done using unpaired t test. A value < 0.05 was considered statistically significant.

RESULTS

RESULTS

There were 56 patients in the current study, 28 of them were in groups A and B.

"Group A: 50 mg/kg of MgSo4 was infused in 100 ml of normal saline 20 minutes before anesthesia was induced. Group B: 20 minutes before anesthesia was induced, 1 mcg/kg of dexmedetomidine was infused in 100 ml of normal saline."

Table 1: Comparison of mean age between the groups

	Group A		Group B		p-value
	Mean	SD	Mean	SD	
Age in yrs	44.2	15.6	44.8	13.3	0.869

Patients in Group A were 44.2 years old on average with a standard deviation of 15.6, whereas those in Group B were 44.8 years old on average with a standard deviation of 13.3.

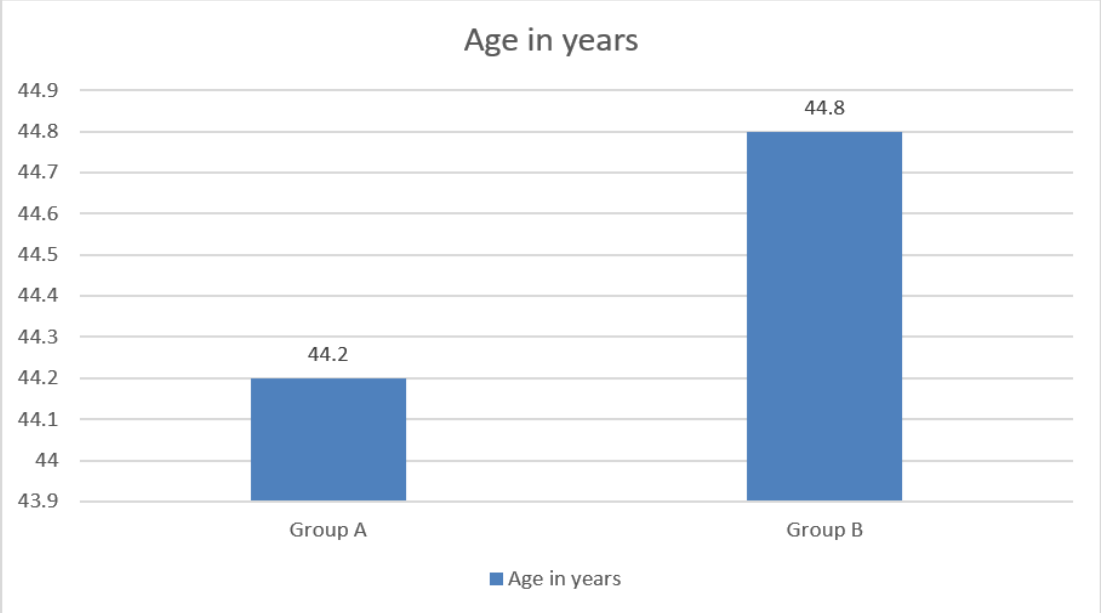

Figure 3: Comparison of mean age between the groups

Table 2: Gender distribution between the groups

		Group A		Group B		Chi-square (p-value)
		Count	N %	Count	N %	
Gender	Female	19	67.9%	20	71.4%	0.08 (0.771)
	Male	9	32.1%	8	28.6%	

Gender distribution is found to be comparable with no significant difference.

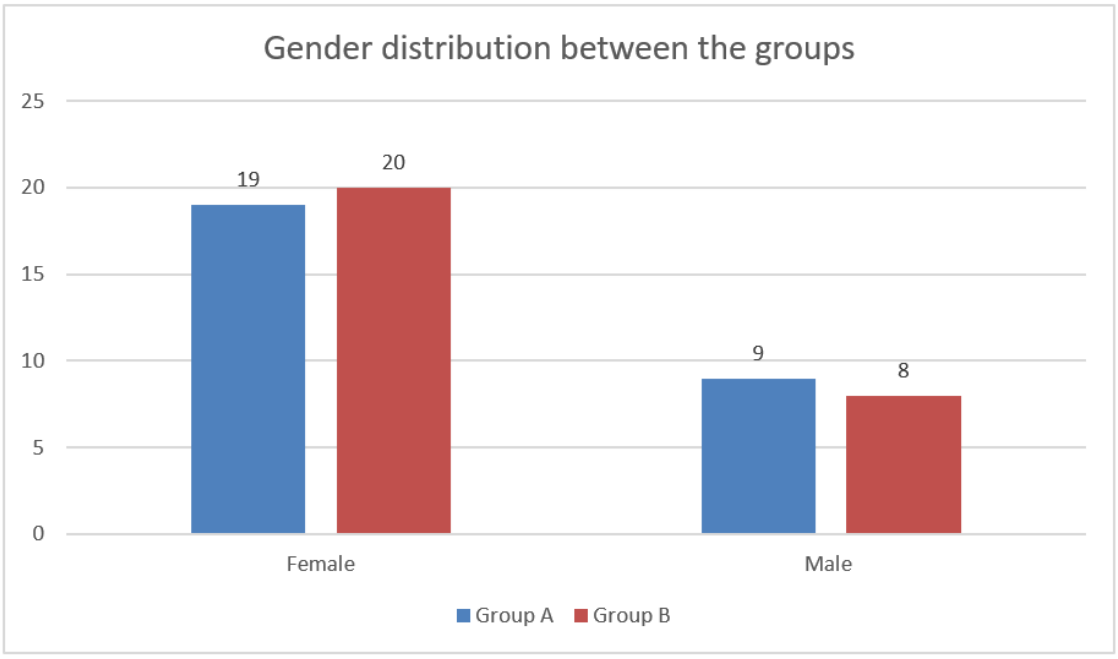

Figure 4: Gender distribution between the groups

Table 3: Mean systolic blood pressure between group at different time interval

Systolic blood pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0 mins	132.14	10.15	131.50	12.96	0.837
1st min	135.39	9.42	126.86	6.76	0.01*
5th min	124.29	8.91	116.71	7.66	0.01*
10th min	119.3	8.4	118.8	8.6	0.827
30 min	121.50	7.60	119.43	7.77	0.318
60 min	122.82	4.92	119.64	7.44	0.065
End of surgery	129.29	6.60	122.43	6.43	0.01*

At the 1st minute, 5th min and end of surgery, Group A exhibited significantly higher SBP compared to Group B (p = 0.01 for both),

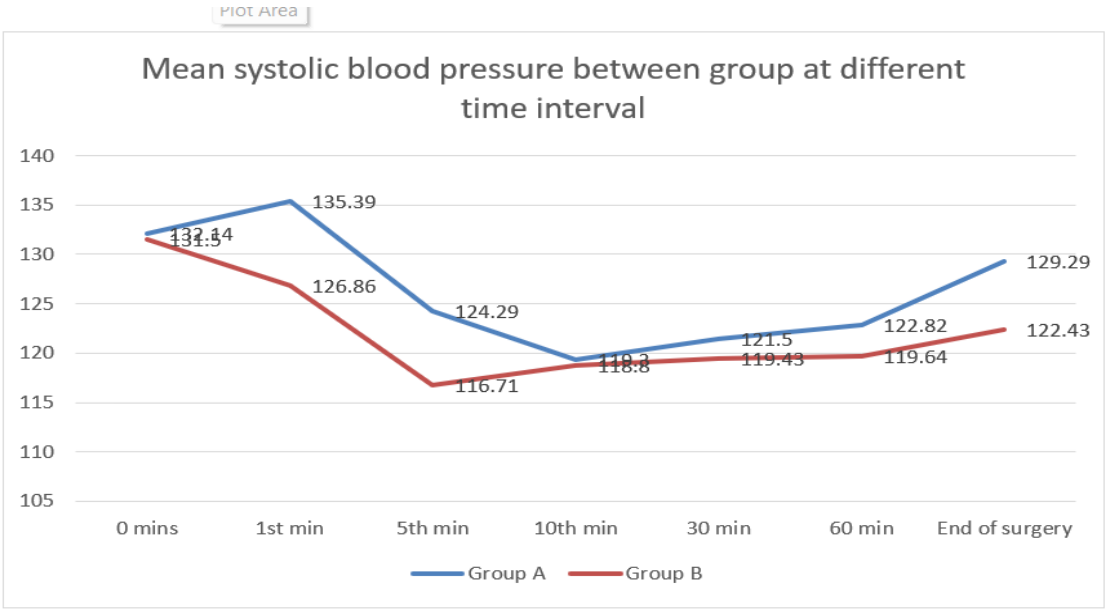

Figure 5: Mean systolic blood pressure between group at different time interval

Table 4: Mean diastolic blood pressure between group at different time interval

Diastolic blood pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0 mins	76.00	8.34	80.21	9.83	0.089
1st min	83.46	7.59	77.57	11.56	0.02*
5th min	74.96	7.74	71.79	9.34	0.171
10th min	71.68	7.33	71.71	7.62	0.98
30 min	72.11	6.71	72.14	8.16	0.98
60 min	73.46	5.85	73.14	6.02	0.84
End of surgery	75.64	6.67	74.07	7.29	0.404

The DBP was comparable between each group at all the interval of time, except at 1st min. At the 1st minute, Group A had a significantly higher DBP compared to Group B (p = 0.02).

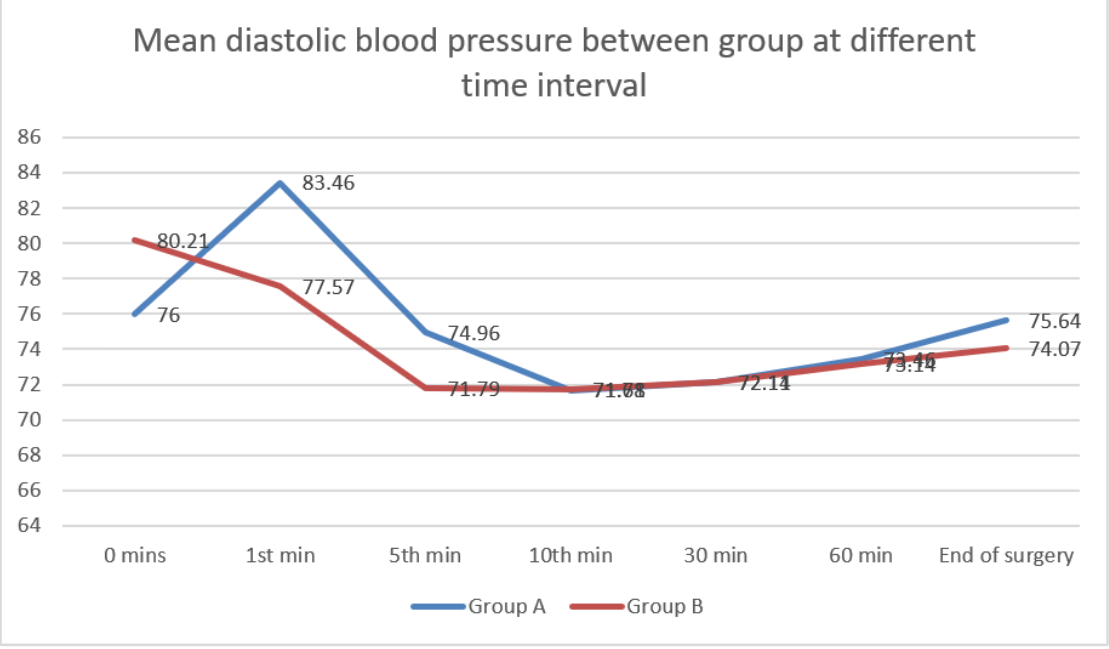

Figure 6: Mean diastolic blood pressure between group at different time interval

Table 5: Mean blood pressure between group at different time interval

Mean blood pressure	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0 mins	94.43	8.02	97.29	10.58	0.26
1st min	100.43	7.37	93.89	9.12	0.01*
5th min	90.36	7.21	86.75	7.95	0.08
10th min	87.14	5.97	86.50	9.11	0.75
30 min	88.36	5.33	87.86	6.92	0.76
60 min	89.54	4.16	88.61	5.12	0.45
End of surgery	92.93	6.37	90.11	6.49	0.107

Overall the heart rate was comparable between the group at varied time interval. At the 1st minute, Group A exhibited a significantly higher MBP compared to Group B (p = 0.01).

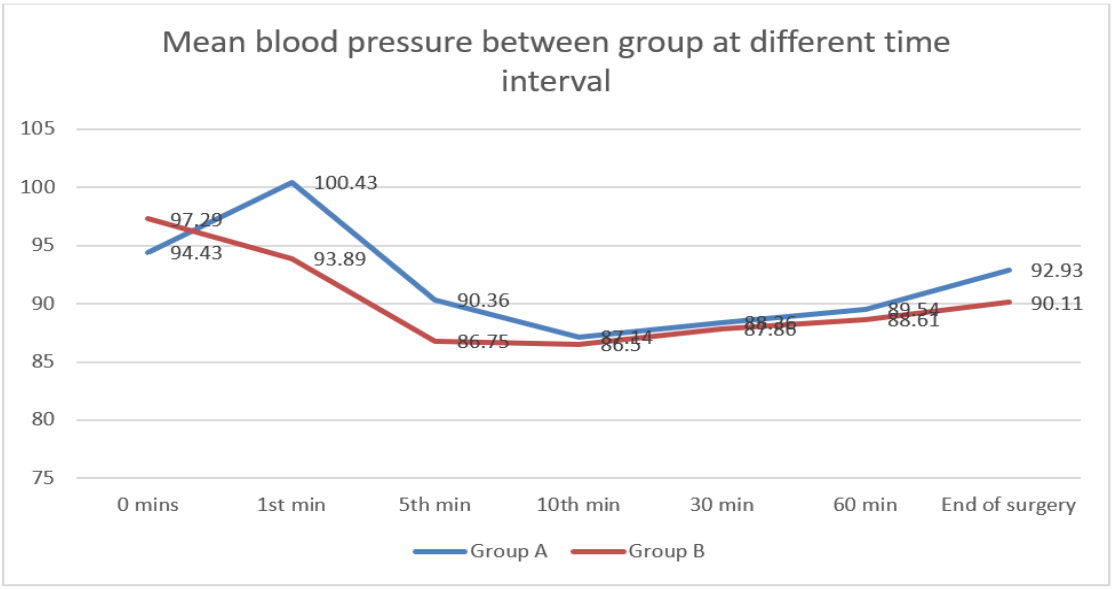

Figure 7: Mean blood pressure between group at different time interval

Table 6: Mean heart rate between group at different time interval

Heart rate	Group A		Group B		p-value
	Mean	SD	Mean	SD	
0 mins	88.82	12.02	83.89	11.34	0.120
1st min	91.68	10.26	72.36	8.98	0.01*
5th min	85.36	8.71	67.07	7.82	0.01*
10th min	83.96	8.18	66.21	7.72	0.01*
30 min	84.25	7.54	67.04	5.89	0.01*
60 min	85.04	7.13	69.75	6.49	0.01*
End of surgery	89.18	5.91	71.46	5.69	0.01*

Heart rate (HR) measurements between Group A and Group B showed significant differences at multiple time points. At baseline (0 minutes), the heart rate was slightly higher in Group A compared to Group B, but the difference was not statistically significant ($p = 0.120$). However, from the 1st minute onwards, Group A consistently exhibited a significantly higher heart rate than Group B ($p = 0.01$ at all measured time intervals). This pattern continued throughout the procedure, including at the 5th, 10th, 30th, and 60th minutes, as well as at the end of surgery. These findings suggest that Group A maintained a higher heart rate compared to Group B throughout the procedure, indicating a notable hemodynamic variation between the two groups.

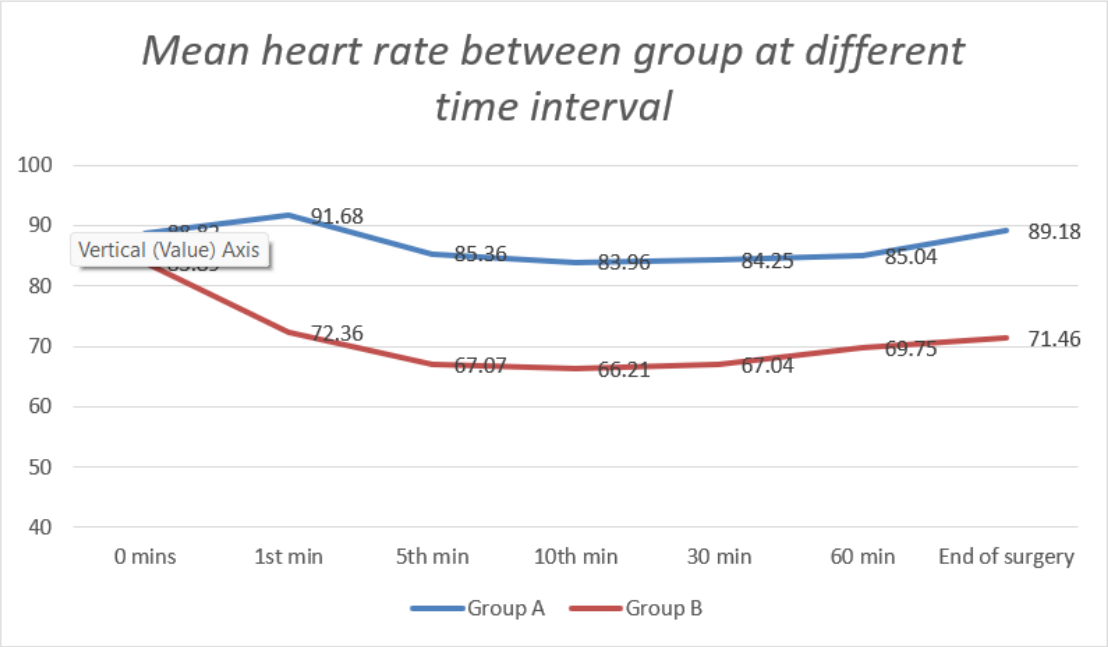

Figure 8: Mean heart rate between group at different time interval

DISCUSSION

DISCUSSION

As because of its minimal invasiveness, decreased post-Op discomfort, shorter hospital stays, and quicker recovery periods, laparoscopic operations have completely changed the surgical practice. Notwithstanding these benefits, the pressor reaction brought on by the formation of pneumoperitoneum is one of the main intraoperative difficulties related to laparoscopic surgeries. In order to create pneumoperitoneum, carbon dioxide (CO_2) is frequently insufflated into the peritoneal cavity. While this is necessary for surgical vision and space, it can cause major physiological abnormalities.

These hemodynamic alterations pose a considerable risk, particularly in patients with underlying conditions like HTN, IHD, or elevated intracranial pressure, potentially leading to serious perioperative complications. Hence, mitigating the pressor response during laparoscopic surgeries is crucial to improving patient safety and surgical outcomes. Pharmacological agents such as Magnesium Sulfate and Dexmedetomidine have demonstrated efficacy in attenuating these hemodynamic fluctuations. Magnesium Sulfate acts as a calcium channel blocker, inducing vasodilation and reducing vascular resistance. “Dexmed, a highly selective α-2 adrenergic agonist, provides anxiolysis, sedation, and analgesia while exerting sympatholytic effects that help stabilize heart rate and blood pressure”. Despite their individual benefits, there is limited comparative data evaluating their relative effectiveness in this context.

This randomized controlled study is thus designed to compare the efficacy of Magnesium Sulfate and Dexmedetomidine in blunting the pressor response to pneumoperitoneum during laparoscopic surgeries. The findings aim to guide anesthetic management strategies, optimizing patient safety by selecting the most effective agent for maintaining stable intraoperative hemodynamics.

"Present study included total of 56 patients with 28 in group A and group B. **Group A:** Infusion of 50mg/kg of MgSo4 in 100 ml Normal Saline over 20 minutes prior to induction of Anaesthesia. **Group B:** Infusion of 1 mcg/kg of Dexmedetomidine in 100 ml Normal Saline over 20 minutes prior to induction of Anaesthesia. There is no significant difference in mean age between the groups, with 44.2yr in group A and 44.8yrs in group B patients. There is comparable gender distribution between the group, with female preponderance in both the groups."

In study by Rishardhan P et al., among 60 patients, the distribution of ASA I and II categories was similar between groups A (66.67percent, 33.33percent) and B (63.33percent, 36.67percent), with both groups being comparable in demographic variables. [33] "Also in study by Bagle A et al., the mean age in Group C and Group M was 35.46±8.5 years and 35.38±9.02 years, respectively (p=0.751)." [34]

"Group B had a considerably reduced mean systolic blood pressure at the beginning, middle, and conclusion of the procedure. The mean difference in systolic blood pressure was similar at different time intervals. At the first minute, group A's mean diastolic blood pressure was determined to be substantially higher than group B's. The mean difference in systolic blood pressure was similar at different time intervals. At the first minute, group A's mean blood pressure was determined to be substantially higher than group B's. The mean difference in systolic blood pressure was similar at different time intervals".

The study by Kataria AP et al. "found that the dexmedetomidine group had better control over mean systolic and diastolic pressure as well as mean arterial pressure. Dexmedetomidine outperformed fentanyl in terms of hemodynamic stability and analgesia during laparoscopic cholecystectomy, confirming its efficacy in reducing pressor responses."[29]

"The magnesium sulfate, dexmedetomidine, lignocaine, and control groups showed a significant difference in mean arterial pressure and blood pressure at the time of drug administration, after intubation, during the pneumoperitoneum at 5-minute intervals, post-pneumoperitoneum, and 10 minutes postoperatively (P<0.001), according to Ahmed IM et al.[30] The pressor response was successfully attenuated in the research by Bagle A et al., as both groups had less than 20 percent deviation from baseline and no significant differences in heart rate, systolic, diastolic, and mean blood pressure changes following pneumoperitoneum (p>0.05). Additionally, there were no appreciable differences in the visual analog scale (VAS) and sedation scores. Conclusion: There was no discernible difference in the effects of intravenous clonidine (1 μg/kg) and magnesium sulfate (30 mg/kg) in suppressing the pressor response during laparoscopic operations."[34]

In a related research by Singh S et al., no pressor response after PLMA insertion was seen, and mean arterial pressure (MAP) dropped in both groups after medication delivery, with Group D seeing a larger drop. with T6, T7, and T8, however, Group M saw a substantially greater rise in MAP with peritoneal insufflation (31.9 percent, 27.9 percent, and 35.6 percent over baseline, respectively). Although both groups' systolic blood pressure (SBP) decreased after the operation, Group M's SBP was still considerably higher than Group D's (p<0.05). "Following peritoneal insufflation, diastolic blood pressure increased similarly in both groups, although Group D's heart rate was continuously lower. Conclusion: During laparoscopic cholecystectomy, dexmedetomidine was superior to magnesium sulfate in regulating hemodynamic responses."[35]

In concordance, the HR and MAP were higher in Group M in study by Jaisawal S et al. Dexmed was more effective in attenuating surgical stress during laparoscopic

cholecystectomy.[36]

But according to a research by Rishardhan P et al., magnesium sulfate was more successful in reducing the stress response to laparoscopic surgery and intubation while simultaneously extending post-operative pain relief. Because of this, it is a better anesthetic adjuvant for laparoscopic surgery than dexmedetomidine. Furthermore, the magnesium sulfate group had lower visual analog scale (VAS) ratings and improved maintenance of hemodynamic parameters (apart from heart rate).[33]

"There is significant higher mean heart rate in group A patients at 1^{st}, 5^{th}, 10^{th}, 30^{th}, 60^{th} min and end of surgery compared to group B."($p<0.05$)

The mean heart rate was well controlled in the dexmedetomidine group in study by Kataria AP et al., Dexmedetomidine proved superior to fentanyl in maintaining hemodynamic stability and providing better analgesia during laparoscopic cholecystectomy, reinforcing its effectiveness in attenuating pressor responses.[29]

Ahmed IM et al. found that during and after pneumoperitoneum, there were substantial heart rate changes between the magnesium sulfate, dexmedetomidine, lignocaine, and control groups ($P<0.001$). During laparoscopic cholecystectomy, lignocaine was less successful in lowering the need for opioids and managing hypertensive reactions than magnesium sulfate and dexmedetomidine.[30]

"Both magnesium sulfate (40 mg/kg) and dexmedetomidine (1 μg/kg) successfully reduced the hemodynamic response to anesthesia and surgical manipulation during laparoscopic cholecystectomy, with magnesium sulfate offering superior hemodynamic stability, in similar with the current study by Desai DJ et al.[31] Also in study by Nirmala D et al., both dexmed and MgSo4 effectively attenuated the stress response and

pneumoperitoneum. However, dexmedetomidine provided improved hemodynamic stability and facilitated earlier postoperative recovery.[32] Showket AD et al., found that Magnesium sulfate effectively attenuates the hemodynamic stress response in laparoscopic abdominal surgeries."[27]

SUMMARY

SUMMARY

- This research included a total of fiftysix patients with 28 in group A and group B.
- **Group A:** Infusion of 50mg/kg of MgSo4 in 100 ml NS over 20 min prior to induction of Anaesthesia. **Group B:** Infusion of 1 mcg/kg of Dexmed in 100 ml NS over 20 min prior to induction of Anaesthesia
- Mean was comparable with 44.2yr in group A and 44.8yrs in group B patients.
- There is comparable gender distribution between the group, with female preponderance in two the groups.
- The mean SBP was found to be significantly lower in group B at 1^{st} min, 5^{th} min and at end of surgery. At other time interval, the mean difference of systolic blood pressure was comparable.
- DBP was significantly higher in group A at 1^{st} min compared to group B. At other time interval, the mean difference of systolic blood pressure was comparable.
- The MBP was significantly higher in group A at 1^{st} min compared to group B. At other time interval, the mean difference of SBP was comparable.
- There is significant higher mean HR in group A patients at 1^{st}, 5^{th}, 10^{th}, 30^{th}, 60^{th} min and end of surgery compared to group B.($p<0.05$)

CONCLUSION

CONCLUSION

Demographic variables including mean age and gender distribution were comparable between the groups, ensuring homogeneity. Hemodynamic analysis revealed that Dexmedetomidine (Group B) resulted in significantly lower systolic, diastolic, and MAP at the 1st mine after pneumoperitoneum, as well as a more stable heart rate throughout the intraoperative period. Group A, treated with Magnesium Sulphate, showed relatively higher heart rates and blood pressure readings in the early intraoperative phase but maintained acceptable stability thereafter.

Despite the more pronounced depressant effect of Dexmedetomidine on HR and blood pressure, both agents found to be effective in controlling the hemodynamic responses to pneumoperitoneum. Therefore, both Magnesium Sulphate and Dexmedetomidine can be considered valuable adjuncts in minimizing the stress response during laparoscopic procedures, with Dexmedetomidine offering an added advantage of superior hemodynamic stability.

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ANNEXURES

ANNEXURE

PROFORMA

STUDY: **ATTENUATION OF PRESSOR RESPONSE TO PNEUMOPERITONEUM IN LAPAROSCOPIC SURGERIES, COMPARISON BETWEEN MAGNISIUM SULPHATE AND DEXMEDETOMIDINE . A RANDOMISED CONTROL STUDY.**

Investigators: Dr Ratan. A. Nalatwadmath / Dr Kiran.N

1. Name of the patient: 2. Age/Sex:

3. Ward: 4. IP No:

5. ASA grade:

- **General physical examination:**

Pulse rate: respiratory rate: BP: Temperature:

Pallor/icterus/cyanosis/clubbing/lymphadenopathy/edema

- **Systemic examination:**

RS - **CVS -**

CNS - **P/A -**

- **Investigations:**

Blood group: Hb: WBC: Platelets:

RBS: Blood urea: Sr. Creatinine: Sodium:

Potassium: ECG:

- **Diagnosis:**

- **Surgery:**

- **Group A:** Infusion of 50mg/kg of MgSo4 in 100 ml Normal Saline over 20 minutes prior to induction of Anaesthesia
- **Group B:** Infusion of 1 mcg/kg of Dexmedetomidine in 100 ml Normal Saline over 20 minutes prior to induction of Anaesthesia

Group: _____

TIME	SBP	DBP	MBP	HR
Baseline				
1st min				
5th min				
10th min				
30 mins				
60mins				
End of surgery				

PATIENT INFORMATION SHEET

TITLE:-Attenuation Of Pressor Response To Pneumoperitoneum In Laparoscopic Surgeries, Comparison Between Magnisium Sulphate And Dexmedetomidine . A Randomised Control Study.

Investigators: Dr. Ratan. A. Nalatwadmath/ Dr Kiran.N
Study location: R.L.Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

Details -patients undergoing laparoscopic surgeries

This study aims to reduce the pressor response to hemodynamic parameters caused by Pneumoperitoneum during the laproscopic surgeries. Patient and the attenders will be completely explained about the procedure being done i.e. giving Dexmedetomidine(1mcg/kg) or MgSo4(50mg/kg) as premedication 30 mins prior to laparoscopic surgery, and the hemodynamic parameters will be monitored during the surgery

Please read the information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, then relevant information and history will be taken. This information collected will be used only for dissertation and publication.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. There is no compulsion to agree to this study. . Participation in this study doesn't involve any added cost to the patient. The care you will get will not change if you don't wish to participate. There will not be any monetary benefits/incentives for taking part in this study. You are required to sign/ provide thumb impression only if you voluntarily agree to participate in this study.

For further information contact

Dr Ratan. A. Nalatwadmath

Post graduate in Anaesthesiology, SDUMC Kolar

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Dr Kiran.N

Professor in Anaesthesiology

Dept of Anaesthesiology, SDUMC Kolar

Mobile no : 9740468460

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಸಂಸ್ಥೆಯ ಹೆಸರು: ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜ

ಅಧ್ಯಯನ:. ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಸರ್ಜರಿಗಳಲ್ಲಿ ನ್ಯೂಮೋಪೆರಿಟೋನಿಯಮ್‌ಗೆ ಪೆಸ್ಸರ್ ಪ್ರತಿಕ್ರಿಯೆಯ ಕ್ಷೀಣತೆಯ ಮೇಲೆ ಯಾದೃಚ್ಛಿಕ ನಿಯಂತ್ರಿತ ಟ್ರಯಲ್, ಮ್ಯಾಗ್ನಿಷಿಯಮ್ ಸಲ್ಫೇಟ್ ಮತ್ತು ಡೆಕ್ಸ್‌ಮೆಟ್‌ಮಿಯ ನಡುವಿನ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ

ತನಿಖಾಧಿಕಾರಿಗಳು: ಡಾ. ರತನ್. ಎ. ನಲತವಾಡಮಠ / ಡಾ ಕಿರಣ್ .ಎನ್

ಅಧ್ಯಯನದ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರ ಲಗತ್ತಿಸಲಾದ ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು ಟಮಕ, ಕೋಲಾರ.

ವಿವರಗಳು: ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ ಒಳಗಾಗುವ ರೋಗಿಗಳು

ಲ್ಯಾಪ್ರೊಸ್ಕೋಪಿಕ್ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಸಮಯದಲ್ಲಿ ನ್ಯುಮೊಪೆರಿಟೋನಿಯಂನಿಂದ ಉಂಟಾಗುವ ಪೆಸ್ಸರ್ ಪ್ರತಿಕ್ರಿಯೆಯನ್ನು ಕಡಿಮೆ ಮಾಡಲು ಈ ಅಧ್ಯಯನವು ಗುರಿಯನ್ನು ಹೊಂದಿದೆ. ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗೆ 30 ನಿಮಿಷಗಳ ಮೊದಲು ಡೆಕ್ಸ್‌ಮೆಡೆಟೊಮಿಡಿನ್ (1mcg/kg) ಅಥವಾ MgSo4 (50mg/kg) ಅನ್ನು ಪೂರ್ವಭಾವಿಯಾಗಿ ನೀಡುವುದರ ಬಗ್ಗೆ ರೋಗಿಗೆ ಮತ್ತು ಹಾಜರಾದವರಿಗೆ ಸಂಪೂರ್ಣವಾಗಿ ವಿವರಿಸಲಾಗುವುದು ಮತ್ತು ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ಸಮಯದಲ್ಲಿ ಹಿಮೋಡೈನಮಿಕ್ ನಿಯತಾಂಕಗಳನ್ನು ಮೇಲ್ವಿಚಾರಣೆ ಮಾಡಲಾಗುತ್ತದೆ.

ದಯವಿಟ್ಟು ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಒಪ್ಪಿದರೆ, ನಂತರ ಸಂಬಂಧಿತ ಮಾಹಿತಿ ಮತ್ತು ಇತಿಹಾಸವನ್ನು ತೆಗೆದುಕೊಳ್ಳಲಾಗುತ್ತದೆ. ಸಂಗ್ರಹಿಸಿದ ಈ ಮಾಹಿತಿಯನ್ನು ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಮಾತ್ರ ಬಳಸಲಾಗುತ್ತದೆ

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾದ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುತ್ತದೆ ಮತ್ತು ಯಾವುದೇ ಹೊರಗಿನವರಿಗೆ ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ. ನಿಮ್ಮ ಗುರುತು ಬಹಿರಂಗಗೊಳ್ಳುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾವುದೇ ಬಲವಂತವಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯು ರೋಗಿಗೆ ಯಾವುದೇ ಹೆಚ್ಚುವರಿ ವೆಚ್ಚವನ್ನು ಒಳಗೊಂಡಿರುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ಚಿಕಿತ್ಸೆಯ ವಿಧಾನ ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಯಾವುದೇ ವಿತ್ತೀಯ ಪ್ರಯೋಜನಗಳಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ

ಭಾಗವಹಿಸಲು ನೀವು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಒಪ್ಪಿಕೊಂಡರೆ ಮಾತ್ರ ನೀವು ಹೆಬ್ಬೆರಳು ಅನಿಸಿಕೆ ಸಹಿ / ಒದಗಿಸುವ ಅಗತ್ಯವಿದೆ.

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ

ಡಾ. ರತನ್. ಎ. ನಾಲ್ವತ್ವಾಡಮಠ
ಸ್ನಾತಕೋತ್ತರ ಪದವಿ, ಅರಿವಳಿಕೆ ವಿಭಾಗ
ಮೊಬೈಲ್ ಸಂಖ್ಯೆ: 9449548789
ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜ, ಟಮಕ, ಕೋಲಾರ.

ಡಾ ಕಿರಣ್. ಎನ್
ಪ್ರಾಧ್ಯಾಪಕ, ಅರಿವಳಿಕೆ ವಿಭಾಗ,
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ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜ, ಟಮಕ, ಕೋಲಾರ.

INFORMED CONSENT FORM

Name of the institution: SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH.

Name of the principal investigator: Dr. Ratan. A. Nalatwadmath

Name of the guide: Dr. Kiran.N

Name of the subject/participant:

STUDY: A RANDOMISED CONTROLLED TRAIL ON ATTENUATION OF PRESSOR RESPONSE TO PNEUMOPERITONEUM IN LAPAROSCOPIC SURGERIES, A COMPARITIVE STUDY BETWEEN MAGNISIUM SULPHATE AND DEXMEDETOMIDINE

Date:

I, _____ aged _____ ,after being explained in my own language about the purpose of the study and the risks and complications of the procedure, hereby give my valid written informed consent without any force or prejudice for using MgSo4 or Dexmedetomidine in attenuation of pressor response due to Pneumoperitoneum in laparoscopic surgerieses under general anaesthesia. The nature and risks involved have been explained to me to my satisfaction. I have been explained in detail about the study being conducted. I have read the patient information sheet and I have had the opportunity to ask any question. Any question that I have asked, have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereby give consent to provide my history, undergo physical examination, undergo the procedure, undergo investigations and provide its results and documents etc. to the doctor / institute etc. For academic and scientific purpose, the operation / procedure, etc. may be photographed. All the data may be published or used for any academic purpose. I will not hold the doctors / institute etc. responsible for any untoward consequences during the procedure / study. I am aware that there wont be any monetary benefits for taking part in this study.

A copy of this Informed Consent Form and Patient Information Sheet has been provided to the participant.

_____ _____

(Signature & Name of Pt. Attendant) (Signature/Thumb impression & Name of patient)

(Relation with patient)

Witness 1:

Witness 2:

_____

(Signature & Name of Research person /doctor)

ಮಾಹಿತಿಯುಕ್ತ ಸಮ್ಮತಿಪತ್ರ

ಸಂಸ್ಥೆಯ ಹೆಸರು: ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜ.
ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿ ಹೆಸರು ; **ಡಾ. ರತನ್. ಎ. ನಾಲ್ವತ್ವಾಡಮಠ**

ಮಾರ್ಗದರ್ಶಿ ಹೆಸರು; ಡಾ ಕಿರಣ್. ಎನ್

ರೋಗಿಯ ಹೆಸರು;

ದಿನಾಂಕ:

ಅಧ್ಯಯನ: . ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್ ಸರ್ಜರಿಗಳಲ್ಲಿ ನ್ಯೂಮೋಪೆರಿಟೋನಿಯಮ್‌ಗೆ ಪ್ರೆಸ್ಸರ್ ಪ್ರತಿಕ್ರಿಯೆಯ ಕ್ಷೀಣತೆಯ ಮೇಲೆ ಯಾದೃಚ್ಛಿಕ ನಿಯಂತ್ರಿತ ಟ್ರಯಲ್, ಮ್ಯಾಗ್ನಿಷಿಯಮ್ ಸಲ್ಫೇಟ್ ಮತ್ತು ಡೆಕ್ಸ್‌ಮೆಟ್‌ಮಿಯ ನಡುವಿನ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ

ನಾನು, _____ ವಯಸ್ಸಿನ _____,

ಅಧ್ಯಯನದ ಉದ್ದೇಶ ಮತ್ತು ಕಾರ್ಯವಿಧಾನದ ಅಪಾಯಗಳು ಮತ್ತು ತೊಡಕುಗಳ ಬಗ್ಗೆ ನನ್ನದೇ ಆದ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ವಿವರಿಸಿದ ನಂತರ, ಲ್ಯಾಪರೊಸ್ಕೋಪಿಕ್‌ನಲ್ಲಿ ನ್ಯೂಮೋಪೆರಿಟೋನಿಯಮ್‌ನಿಂದಾಗಿ ಪ್ರೆಸ್ಸರ್ ಪ್ರತಿಕ್ರಿಯೆಯನ್ನು ಕ್ಷೀಣಿಸಲು ಮೆಗ್ನೀಸಿಯಮ್ ಸಲ್ಫೇಟ್ ಅಥವಾ ಡೆಕ್ಸ್ಮೆಡೆಟೊಮಿಡಿನ್ ಅನ್ನು ಬಳಸಲು ಯಾವುದೇ ಬಲ ಅಥವಾ ಪೂರ್ವಾಗ್ರಹವಿಲ್ಲದೆ ನನ್ನ ಮಾನ್ಯ ಲಿಖಿತ ತಿಳುವಳಿಕೆಯನ್ನು ನೀಡಿ. ಸಾಮಾನ್ಯ ಅರಿವಳಿಕೆ ಅಡಿಯಲ್ಲಿ ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಗಳು. ಒಳಗೊಂಡಿರುವ ಸ್ವಭಾವ ಮತ್ತು ಅಪಾಯಗಳನ್ನು ನನಗೆ ತೃಪ್ತಿಪಡಿಸಲು ವಿವರಿಸಲಾಗಿದೆ. ನಡೆಸುತ್ತಿರುವ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ನನಗೆ ವಿವರವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ನಾನು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಲು ನನಗೆ ಅವಕಾಶವಿದೆ. ನಾನು ಕೇಳಿದ ಯಾವುದೇ ಪ್ರಶ್ನೆಗೆ ನನ್ನ ತೃಪ್ತಿಗೆ ಉತ್ತರಿಸಲಾಗಿದೆ. ಈ ಸಂಶೋಧನೆಯಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವವನಾಗಿ ಭಾಗವಹಿಸಲು ನಾನು ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ಸಮ್ಮತಿಸುತ್ತೇನೆ. ನನ್ನ ಇತಿಹಾಸವನ್ನು ಒದಗಿಸಲು, ದೈಹಿಕ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಲು, ಕಾರ್ಯವಿಧಾನಕ್ಕೆ ಒಳಗಾಗಲು, ತನಿಖೆಗೆ ಒಳಗಾಗಲು ಮತ್ತು ಅದರ ಫಲಿತಾಂಶಗಳು ಮತ್ತು ದಾಖಲೆಗಳನ್ನು ಇತ್ಯಾದಿಗಳನ್ನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳಿಗೆ ಒದಗಿಸಲು ನಾನು ಈ ಮೂಲಕ ಒಪ್ಪಿಗೆ ನೀಡುತ್ತೇನೆ. ಶೈಕ್ಷಣಿಕ ಮತ್ತು ವೈಜ್ಞಾನಿಕ ಉದ್ದೇಶಕ್ಕಾಗಿ, ಕಾರ್ಯಾಚರಣೆ / ಕಾರ್ಯವಿಧಾನ, ಇತ್ಯಾದಿ. ಛಾಯಾಚಿತ್ರ. ಎಲ್ಲಾ ಡೇಟಾವನ್ನು ಪ್ರಕಟಿಸಬಹುದು ಅಥವಾ ಯಾವುದೇ ಶೈಕ್ಷಣಿಕ, ಪ್ರಬಂಧ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಬಹುದು. ಕಾರ್ಯವಿಧಾನ / ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗೆ ನಾನು ವೈದ್ಯರು / ಸಂಸ್ಥೆ ಇತ್ಯಾದಿಗಳನ್ನು ಜವಾಬ್ದಾರರನ್ನಾಗಿ ಮಾಡುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ

ಪಾಲ್ಗೊಳ್ಳುವುದರಿಂದ ಯಾವುದೇ ವಿತ್ತೀಯ ಪ್ರಯೋಜನಗಳು ಇರುವುದಿಲ್ಲ ಎಂದು ನನಗೆ ತಿಳಿದಿದೆ. ಈ ತಿಳುವಳಿಕೆಯುಳ್ಳ ಒಪ್ಪಿಗೆ ನಮೂನೆಯ ಪ್ರತಿಯನ್ನು ಮತ್ತು ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆಯನ್ನು ಭಾಗವಹಿಸುವವರಿಗೆ ಒದಗಿಸಲಾಗಿದೆ

_____ _____

(ರೋಗಿಯ ಪರಿಚಾರಕ ಹೆಸರು ಮತ್ತು ಸಹಿ) (ರೋಗಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ/ಹೆಬ್ಬೆರಳ ಅನಿಸಿಕೆ)

(ರೋಗಿಯೊಂದಿಗಿನ ಸಂಬಂಧ)

ಸಾಕ್ಷಿ 1:

ಸಾಕ್ಷಿ 2: (ಸಹಿ ಮತ್ತು ಸಂಶೋಧನಾ ವ್ಯಕ್ತಿ / ವೈದ್ಯರ ಹೆಸರು)

MASTER CHART

MASTERCHART

GROUP- A MAGNEISIUM SULPHATE

SL.NO	UHID NO.	AGE[YRS]	GENDER	SYSTOLIC BLOOD PRESSURE							DIASTOLIC BLOOD PRESSURE							MEAN BLOOD PRESSURE						HEART RATE			
				0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery
1	371517	55	M	140	142	120	114	116	126	130	80	88	78	76	78	72	76	100	106	92	88	90	90	94	96	92	84	88	80	82	84
2	378038	49	F	120	140	124	114	118	120	130	70	84	78	72	70	82	86	86	102	93	86	86	94	100	84	88	82	89	94	88	90
3	372051	74	F	140	120	110	114	118	120	130	70	74	72	70	76	70	76	93	89	84	84	90	86	94	74	70	72	74	88	74	86
4	73422	25	F	130	140	126	110	100	120	120	84	86	70	80	72	82	76	99	104	88	90	84	94	90	94	88	90	86	84	86	90
5	364782	55	F	160	150	130	110	130	120	150	80	90	70	70	80	70	80	106	110	90	83	96	86	103	90	86	82	84	84	90	94
6	291728	23	F	120	113	116	120	119	120	118	76	79	83	73	74	76	74	85	88	72	80	76	84	76	103	88	68	82	80	84	82
7	57922	59	M	130	144	128	118	117	117	140	86	90	88	88	79	77	84	100	104	99	98	90	90	102	84	89	63	61	59	67	90
8	354444	40	M	140	146	110	112	120	120	130	84	92	76	80	78	72	80	103	110	87	91	92	88	97	86	98	92	94	82	86	90
9	351439	39	F	130	136	124	130	126	130	136	86	92	90	82	72	76	80	101	107	101	98	98	94	99	110	86	92	86	85	84	89
10	341866	22	F	136	144	130	110	122	120	130	74	86	76	70	72	76	74	95	105	94	83	89	91	93	82	98	88	89	84	91	86
11	336156	19	F	146	140	130	138	136	130	134	80	88	78	72	70	84	76	102	105	95	94	92	99	95	89	95	91	86	82	91	86
12	343328	26	F	128	138	130	118	124	122	130	78	86	72	68	60	74	70	95	103	91	85	81	90	90	71	85	94	91	91	89	91
13	290703	29	F	136	144	138	134	138	130	120	68	80	74	68	60	64	72	91	101	95	90	86	86	88	85	94	91	89	85	90	87
14	318708	56	F	134	128	134	126	130	126	132	80	88	72	68	76	74	78	98	101	93	87	94	91	96	89	91	97	95	95	86	89
15	312169	32	F	130	146	140	126	128	130	134	78	86	72	68	62	74	70	95	106	95	87	84	93	91	76	85	85	87	91	83	85
16	329381	61	F	126	134	140	126	114	120	126	70	78	64	60	64	68	74	89	97	89	82	81	85	91	71	84	75	94	86	88	98
17	312244	57	M	116	130	128	120	126	130	126	68	60	72	64	60	58	62	84	83	91	83	82	82	83	89	81	73	67	87	88	87
18	418450	51	M	124	130	124	136	128	134	130	60	86	74	70	76	74	66	81	101	91	92	93	94	87	65	79	85	81	79	85	82
19	438642	37	F	140	144	126	120	126	124	132	94	90	82	86	80	74	86	109	108	97	97	95	91	101	87	95	82	75	78	78	82
20	236785	46	M	138	132	116	112	118	122	124	84	76	62	60	74	70	74	102	95	80	77	89	87	91	83	95	86	82	86	78	89
21	425048	53	F	136	134	116	122	112	120	124	74	86	70	74	72	78	72	95	102	85	90	85	92	89	106	98	90	84	81	93	90
22	327281	55	M	130	122	116	110	124	120	130	66	74	70	62	60	64	60	87	90	85	78	81	83	83	96	108	92	98	94	92	110
23	333730	41	F	110	126	110	106	118	114	120	60	72	58	62	74	72	70	77	90	75	77	89	86	87	82	96	92	84	88	96	94
24	97111	78	M	126	140	128	120	116	120	124	72	88	74	68	74	78	80	90	105	92	85	88	92	95	108	116	92	82	80	84	86
25	99495	47	M	138	126	120	120	122	118	126	88	92	82	82	78	70	76	105	103	94	95	92	86	93	110	86	92	85	91	83	90
26	101777	33	F	136	142	132	126	120	126	134	78	88	92	72	82	76	84	97	106	105	90	95	93	100	90	119	94	82	86	94	98
27	548208	26	F	120	140	124	114	118	120	130	70	84	78	72	70	82	86	86	102	93	86	86	94	100	103	88	90	82	90	84	82
28	487029	49	F	140	120	110	114	118	120	130	70	74	72	70	76	70	76	93	89	84	84	90	86	94	84	89	76	74	69	67	90

ROUP- B DEXMEDET0MIDINE

SL.NO	UHID NO.	AGE[YRS]	GENDER			SYSTOLIC BLOOD PRESSURE							DIASTOLIC BLOOD PRESSURE							MEAN BLOOD PRESSURE							HEART RATE			
				0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery	0 MINS	1st MIN	5th MIN	10th MIN	30 MIN	60 MIN	End of surgery
1	375454	78	M	160	116	110	112	114	120	130	100	78	70	74	70	72	76	120	90	83	86	84	88	94	65	72	68	70	60	64	68
2	44547	25	F	144	124	120	124	122	136	130	88	82	82	80	72	74	82	107	96	95	95	89	95	98	90	82	76	70	72	72	78
3	317751	35	F	156	134	122	132	128	126	130	90	86	80	82	82	76	80	112	102	94	99	98	93	97	83	71	67	72	62	60	76
4	334678	35	F	124	110	106	126	124	112	120	72	62	68	70	74	72	80	89	78	81	89	91	85	93	91	81	74	77	69	70	76
5	348423	34	M	136	124	120	122	122	120	126	84	72	68	66	68	72	70	101	89	85	85	86	88	89	73	66	62	64	65	61	72
6	343948	49	F	142	128	134	130	124	120	124	90	74	72	72	84	80	76	107	92	93	91	97	93	92	85	75	71	71	68	72	71
7	340674	43	F	122	128	110	108	112	120	118	64	56	52	62	60	64	60	83	80	71	77	77	83	79	65	58	56	55	61	67	62
8	340331	56	M	110	118	106	102	100	102	108	62	54	52	52	58	56	68	78	75	70	69	72	71	81	89	71	74	64	70	72	71
9	329281	61	F	118	124	110	114	110	104	110	76	88	82	76	84	80	68	90	100	91	89	93	88	82	97	81	72	70	70	84	80
10	331839	51	F	134	130	128	128	132	126	128	86	90	84	84	86	80	84	102	103	99	99	101	95	99	79	64	58	61	62	62	68
11	381624	35	F	124	118	110	108	112	122	120	80	86	76	78	70	76	78	95	97	87	88	84	91	92	73	60	55	51	63	61	60
12	458818	36	F	116	124	114	116	116	120	124	76	78	64	68	70	74	78	89	93	81	84	85	89	93	67	60	59	51	66	63	69
13	402954	27	F	128	128	114	120	116	110	118	78	70	66	72	70	74	70	95	89	82	88	85	86	86	110	89	73	71	71	75	81
14	227489	50	F	134	128	110	108	112	120	118	88	84	72	68	70	74	72	103	99	85	81	84	89	87	97	81	73	64	74	71	70
15	387202	56	F	142	140	128	124	120	120	128	86	90	86	80	82	78	80	105	107	100	95	95	92	96	83	73	70	70	68	72	70
16	367833	54	F	128	136	116	116	128	120	122	84	88	74	70	72	74	76	99	104	88	85	91	89	91	86	78	62	77	71	70	76
17	315286	30	F	118	126	114	110	122	118	118	70	72	68	74	70	66	70	86	90	83	86	87	83	86	91	81	76	77	76	70	74
18	324095	51	F	124	130	116	124	118	126	120	74	78	70	64	66	78	80	91	95	85	84	83	94	93	75	61	60	58	55	69	66
19	316864	35	F	114	120	112	110	128	120	122	60	56	70	62	60	64	60	78	77	84	78	83	83	81	84	71	73	71	82	84	80
20	322566	66	F	146	132	122	128	124	126	128	90	82	74	78	68	70	74	109	99	90	95	87	89	92	91	80	73	70	65	71	70
21	416194	38	M	134	138	120	124	118	126	130	82	88	70	68	72	70	84	99	105	87	87	87	89	99	85	73	61	66	64	72	71
22	395886	51	F	136	124	108	116	128	120	122	86	84	70	68	68	72	70	103	97	83	84	88	88	87	74	60	53	57	59	67	65
23	439403	37	M	128	134	126	118	112	124	120	80	82	72	76	70	76	72	96	99	90	90	84	92	88	87	73	79	70	68	70	71
24	98394	35	M	154	132	124	134	126	122	132	90	86	82	76	76	80	84	111	101	96	95	92	94	100	91	81	74	77	69	70	76
25	99306	35	M	136	124	120	122	122	120	126	84	72	68	66	68	72	70	101	89	85	58	86	88	88	97	81	73	64	74	71	70
26	100445	46	F	122	128	110	108	112	120	118	64	56	52	62	60	64	60	83	80	71	77	77	83	79	65	58	56	55	61	67	62
27	554840	37	F	118	124	110	114	110	104	110	76	88	82	76	84	80	68	90	100	91	89	93	88	82	97	81	72	70	70	84	80
28	361493	69	M	134	130	128	128	132	126	128	86	90	84	84	86	80	84	102	103	99	99	101	95	99	79	64	58	61	62	62	68