

CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC  
SINUS SURGERY: RANDOMIZED PROSPECTIVE COMPARISON OF  
MAGNESIUM SULPHATE AND DEXMEDETOMIDINE

By

**DR. NAYANTRA. K .P.**

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**IN**

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Under the guidance of

**Dr.VIJAYA V KATTI**

PROFESSOR

DEPARTMENT OF ANESTHESIOLOGY

**BLDE (Deemed to be University)**

**SHRI B.M.PATIL MEDICAL COLLEGE**

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**“CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS  
SURGERY: A RANDOMISED PROSPECTIVE COMPARISON OF MAGNESIUM  
SULPHATE AND DEXMEDETOMIDINE”**

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## ABBREVIATIONS

FESS	Functional endoscopic sinus surgery
MAP	Mean arterial pressure
NMDA	N methyl D aspartate
MgSo <sub>4</sub>	Magnesium sulphate
D group	Dexmedetomidine group
M group	Magnesium sulphate group
PACU	Post anaesthesia care unit
VAS	Visual analog score
ASA	American society of anaesthesiologist
NIBP	Noninvasive blood pressure monitoring
EtCo <sub>2</sub>	End tidal carbon dioxide
HR	Heart rate
SBP	Systolic blood pressure
DBP	Diastolic blood pressure
SPO <sub>2</sub>	Partial pressure of oxygen saturation
RSS	Ramsay sedation score
NRS	Numerical rating score
ECG	Electrocardiogram
Mg/kg	Milligram per kilogram
Mcg/kg	Microgram per kilogram

## **ABSTRACT**

### **Background and aims**

The treating of nasal sinus diseases with functional endoscopic sinus surgery (FESS) is a well-established and popular method. In this endoscopic procedure, the sinus ostia and air cells are opened under direct visualization. The aim of the surgery is to reestablish sinus breathing and smooth functioning. This procedure offers around 90% improvement in symptoms. This is done under general anaesthesia or under local anaesthesia. Intentional induction of hypotension has helped in limiting intraoperative blood loss dramatically. A bloodless surgical field improves field visibility and lowers the possibility of damaging nearby structures. This is achieved by reducing the baseline mean arterial pressure (MAP) by 30% or by maintaining MAP at 60-70 mmHg. The main concern is severe bleeding when under general anaesthesia (GA) during functional endoscopic sinus surgery (FESS). Better operative field sight and less danger of harm to nearby structures are also benefits of a bloodless operating field. The study is carried out to evaluate and compare the efficacy of dexmedetomidine and magnesium sulphate (MgSO<sub>4</sub>) for attaining the target MAP and thereby attaining controlled hypotension in FESS.

### **Methods**

In this prospective randomised clinical trial, 70 patients, aged 18 to 60 years of either sex, who were admitted for FESS surgeries under General Anesthesia with ASA Grade I & II were randomly divided into two groups with 35 patients in group dexmedetomidine and 35 patients in group magnesium sulphate. The primary objective of the study was to compare the time required to reach the target MAP and to compare the number of patients requiring a minimum and maximum infusion doses of study drugs. Secondary objectives of the study

were to evaluate the surgical field quality and to compare the adverse effects and recovery characteristics of the two drugs studied.

## **Result**

Demographic profile regarding age, gender, BMI, ASA grade and duration of surgery in both the groups were comparable and showed no significant results. The target MAP 60–70 mmHg was achieved significantly earlier in group D as compared with group M. Compared to group M, majority of patients in group D reached their desired MAP with a minimal infusion of the study medication.

## **Conclusion**

MgSO<sub>4</sub> and Dexmedetomidine are both equally efficient at causing carefully monitored hypotension during FESS but Dexmedetomidine achieves target MAP earlier with lower infusion dosages, offers a better surgical field and causes less haemorrhage during surgery. The dexmedetomidine group experienced extended sedation and post-operative recovery.

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# **CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A RANDOMISED PROSPECTIVE COMPARISON OF MAGNESIUM SULPHATE AND DEXMEDETOMIDINE**

## **INTRODUCTION**

Nasal sinus diseases can mostly be treated with “functional endoscopic sinus surgery (FESS)” which is a well-proven method <sup>[1]</sup>. The FESS procedure uses a microdebriding tool to remove the diseased tissue while the surgeon preserves the good mucosa. Significant postoperative bleeding is the main obstacle to clear visibility and can compromise the efficiency and safety of this surgical procedure. Due to bleeding, both the anaesthesiologist and the surgeon encounter significant difficulties. It impairs vision, prolongs surgery, demands additional blood transfusions and exacerbates edema and ecchymosis after surgery [2]. You can prevent the aforementioned challenges by using controlled hypotension.

It most frequently refers to a drop in systolic pressure below 80–90 mm Hg, a drop in mean arterial pressure up to 60–65 mm Hg, or a 30% drop from baseline MAP <sup>[3]</sup>.

Surgeon's ability to advance depends on anaesthesia's ability to do so and the use of hypotensive anaesthesia as a surgical adjuvant is a prime example. Controlled hypotension, also known as



“hypotensive anaesthesia”, is a type of anaesthesia in which systemic blood pressure is purposefully brought down while patient is under anaesthesia; instead of a predetermined target pressure, the amount of the reduction should be in line with the patient's initial blood pressure.

American Society of Anaesthesiologists defines class 1 patients as having a minimal mean arterial blood pressure (MAP) of 60 to 70 mmHg as clinically acceptable. The MAP can be decreased by 30% compared to the initial MAP of the patient.

Hypertension can cause a variety of consequences, including haemorrhage that needs blood transfusions, cerebrospinal fluid (CSF) leak, increased intracranial pressure, ocular issues. To reduce surgical blood loss and problems and improve the vision of the operating field, a technique known as controlled hypotension lowers arterial blood pressure in a planned yet regulated way <sup>[4]</sup>.

The American Society of Anaesthesiologists class 1 patients must have a minimum mean arterial pressure (MAP) of 60 to 70 mmHg to be considered clinically acceptable. The MAP can be 30% lower than the patient's baseline MAP.

The optimal drug for controlled hypotension must possess a number of qualities, including ease of administration, rapid clearance without hazardous metabolites, minor effects on essential organs, predictability and dose dependence.

During head and neck surgeries and middle ear surgeries, deliberate hypotension has been utilised as a strategy to reduce intraoperative bleeding and enhance the operating field for improved visualisation <sup>[5]</sup> .

Intentional hypotension has been induced using a variety of pharmaceuticals. When performing middle ear surgery, vasodilators like nitroglycerine, nitroprusside, alpha alpha 2 adrenergic agonists like dexmedetomidine and clonidine, beta adrenergic blockers like esmolol and propranolol, alpha-

and beta-adrenergic antagonists like labetalol, inhalational anaesthetics like isoflurane <sup>[6]</sup>.

Atipamezole is an alpha<sub>2</sub> receptor antagonist that can, in a dose-dependent way, reverse the effects of sedation and sympatholysis. Magnesium sulphate has been used to treat a variety of conditions, including eclampsia, arrhythmias, refractory hypokalemia, shivering, status asthmaticus, premature labour, as well as analgesia, controlled hypotension and attenuation of hemodynamic response during intubation and extubation. It works by blocking NMDA receptors and calcium channels.

After phosphorus, calcium and potassium, in the human body, magnesium is the fourth most prevalent salt. In the past, purposeful hypotension induction was accomplished with magnesium sulphate. By limiting calcium's outflow from the sarcoplasmic reticulum and increasing prostacyclin synthesis while lowering angiotensin converting enzyme activity, it has a hypotensive effect and a vasodilator effect.

The magnesium has significant analgesic impact during surgery, also causes hypotension. The antagonistic activity of magnesium on N-methyl D-aspartate receptors accounts for its analgesic effects <sup>[7]</sup>. Transmembrane G protein-

binding adrenoreceptors are the site of binding for the highly potent and selective alpha<sub>2</sub>-receptor agonist dexmedetomidine. It is different from other sedatives because it has analgesic effects that are known to have sympatholytic, anxiolytic and opioid-sparing characteristics in anaesthesia <sup>[8]</sup>. It also produces sedation without causing respiratory depression.

The reduction in arterial blood pressure, heart rate, cardiac output and norepinephrine release are all attributed to dexmedetomidine's central and peripheral sympatholytic actions. By facilitating the activation of the Na<sup>+</sup>-K<sup>+</sup> ATPase and Ca<sup>++</sup> ATPase enzymes, which participate in transmembrane ion exchange during the depolarization and repolarization phases, magnesium sulphate is an effective treatment for controlled hypotension.

Additionally, it stabilises intracytoplasmic organelles and the cell membrane. Additionally, Mg<sup>2+</sup> lowers blood pressure by blocking N-type Ca<sup>++</sup> channels at nerve endings, which prevents norepinephrine from being released [9].

This study examined the effectiveness of dexmedetomidine and magnesium sulphate in inducing controlled hypotension to create a bloodless surgical field during “functional endoscopic sinus surgery (FESS)” and its effects on analgesic need, discharge and surgical recovery.

### **AIMS AND OBJECTIVES OF THE STUDY**

The study's aim is to assess the effectiveness of dexmedetomidine against magnesium sulphate (MgSO<sub>4</sub>) for controlled hypotension during functional endoscopic sinus operations.

#### **PRIMARY OBJECTIVES:**

1. To compare time required to attain target MAP.
2. To compare the number of participants who needed the lowest and highest doses of the study drug.

#### **SECONDARY OBJECTIVES:**

1. To compare the surgical field's quality.
2. To compare adverse effects and recovery characteristics of the two drugs studied.

## Review of literature

1. Ossama H. et al in 2019 conducted a study to assess the effectiveness of magnesium sulphate and dexmedetomidine in causing induced hypotension and improving exposure of surgical field in middle ear surgeries. It also compared how their use impacted postoperative pain and recovery time. There were 88 adult patients who underwent middle ear surgery. Two equal groups of patients were randomly assigned. Patients were divided into two groups: those receiving dexmedetomidine (D group) or magnesium sulphate (M group). Fentanyl 1 mcg/kg and propofol 2 mg/kg intravenous were used to induce anaesthesia. Both study drugs were successful in achieving the required MAP. The quality of the surgical field was not different between the two groups. Only eight patients in the M group and seven patients in the D group needed analgesics following surgery and there was no difference in postoperative pain between the two groups. Patients in group D had a noticeably extended recovery period ( $p < 0.05$ ). Both dexmedetomidine and magnesium sulphate were shown to successfully cause deliberate hypotension in patients following middle ear surgery, however magnesium sulphate was linked to a quicker recovery and earlier discharge from the PACU, according to their findings. <sup>[7]</sup>.
2. Omyma S.M. Khalifa et al in 2015 carried out a study to contrast the effectiveness of dexmedetomidine, magnesium sulphate, or glyceryl trinitrate in producing deliberate hypotension in “FESS” and its effect on post surgical recovery, discharge and postoperative requirement for analgesia. While both magnesium sulphate and dexmedetomidine achieved the targeted mean arterial pressure (55-65 mm Hg), better haemodynamic stability was displayed by the DEX group. Blood loss during surgery and surgical field quality were equivalent in either groups.

Magnesium sulphate and dexmedetomidine both had the benefit of having an established analgesic and sedative effect, but at the cost of a slower recovery from anaesthesia and discharge from the "PACU".

They concluded that Dexmedetomidine, magnesium sulphate, or glyceryl trinitrate induced deliberate hypotension, with superior hemodynamic stability in dexmedetomidine. Analgesic and sedative effects were obtained with dexmedetomidine and magnesium sulphate, but with longer recovery and discharge times<sup>[8]</sup>.

3. Bayoumy et al. in 2020 conducted a study to contrast dexmedetomidine with magnesium sulphate regarding their efficacy as a hypotensive agent in FESS in adult patients to obtain a bloodless surgical field. Sixty patients were randomly assigned into two groups, D group for dexmedetomidine (n = 30) and M group for magnesium sulphate (n = 30). In D group, patients received 1 µg/kg dexmedetomidine in 100 ml saline solution as the loading dose 10 min before induction and 0.5–1 µg/kg/h infusion via syringe pump during surgery. In M group, patients received 40 mg/kg magnesium sulphate in 100 ml saline solution over 10 min as the intravenous loading dose 10 min before induction, with a subsequent 10–15 mg/kg/h infusion. If there is an increase in the arterial blood pressure greater than the targeted MAP (55–65 mmHg), nitroglycerine infusion was started by 0.5 µg/kg/min. The surgeon estimated the quality of the surgical field and recorded it. The total blood loss was measured. In recovery, time to reach Aldrete score  $\geq 9$  was recorded to fulfill the discharge criteria. Pain score was assessed by the (NRS) numerical rating score. The time needed to first analgesia requirement was recorded. Sedation score was recorded using Ramsay sedation score<sup>[9]</sup>.
4. Chhabra A in 2020 conducted a research study to compare the efficacy of dexmedetomidine and magnesium sulphate (MgSO<sub>4</sub>) for controlled hypotension in FESS. They found the In group D, the mean time to reach the goal mean arterial pressure (MAP) was

lower ( $10.59 \pm 2.04$ ) compared to group M's ( $21.32 \pm 4.65$  min )(P 0.001). While 82.35% of patients in group M needed 4% sevoflurane together with an infusion of more than 12-15 mg/kg/hr of MgSO<sub>4</sub> to achieve the goal MAP in 10-20 min, target MAP was achieved in 5-15 min in 73.52% of patients (Group D) with an infusion dose of 0.2-0.4 g/kg/h of dexmedetomidine.. Conclusion: Dexmedetomidine is superior to MgSO<sub>4</sub> in achieving target MAP in lesser time with minimum infusion dose <sup>[10]</sup>.

5. Bafna U et al in 2020 conducted a study to compared the hypotensive effectiveness and safety of dexmedetomidine and magnesium sulphate in patients undergoing elective FESS. Sixty adult patients posted for elective FESS were randomly assigned to two groups. Group A received a loading dose of dexmedetomidine 1 µg/kg, followed by infusion of 1 µg/kg/h and Group B received a loading dose of magnesium sulphate 40 mg/kg, followed by 15 mg/kg/h infusion. Surgical field quality, emergence time, sedation score, Visual Analog Scale score, recovery profile and vital signs were recorded. Mean arterial pressure (MAP) was kept above 65 mmHg during induced hypotension. Results: Both the groups achieved the target MAP (65–70 mmHg) and improved the surgical field visibility with reduced blood loss. Hemodynamics was superior in the dexmedetomidine group with the additional advantage of postoperative conscious sedation and analgesia (P < 0.05). None of the groups showed any statically significant adverse effects (P > 0.05). Conclusions: Both dexmedetomidine and magnesium sulphate are safe agents for controlled hypotension for improving surgical field quality. Dexmedetomidine provides an additional benefit of reducing the analgesic requirements and providing postoperative sedation <sup>[11]</sup>.
6. Gupta K K et al in 2022 compared the effectiveness of dexmedetomidine and propofol infusion for hypotensive anaesthesia in patients undergoing “FESS” in a research. They found that throughout the procedure, group D's mean arterial pressure and heart rate were

substantially lower than those of group P. Group P saw much more blood loss. ( $100.73 \pm 18.12$  ml) than group D ( $85.70 \pm 18.56$  ml).

Intraoperatively, only one incidence of bradycardia and hypotension was observed in group D (2.5%) compared to group P. Conclusion being that both dexmedetomidine and propofol are efficacious and safe drugs for facilitating controlled hypotension during FESS; however, dexmedetomidine provides better hemodynamic control and is associated with lesser blood loss without any significant adverse effects <sup>[12]</sup>.

7. Kapoor C et al in 2020 did a study to assess the effectiveness of magnesium sulphate against dexmedetomidine during functional endoscopic sinus surgery, to minimise blood loss and enhance operative site visualisation through controlled hypotension. It also compares the following: satisfaction of the surgeon, time taken to achieve desired mean arterial pressure, total requirement of muscle relaxants, attenuation of hemodynamic response to tracheal manipulation, postoperative sedation and adverse effects. A randomized, prospective study was conducted on 40 patients (18-65 years) with ASA (American Society of Anaesthesiologists) physical status I or 2 posted for FESS. Patients were randomly allocated into 2 groups: (1) group D, received  $1 \mu\text{g}/\text{kg}$  dexmedetomidine 10 minutes prior to induction, followed by  $0.5\text{-}1 \mu\text{g}/\text{kg}/\text{hr}$  as maintenance dose and (2) group M, received  $40 \text{ mg}/\text{kg}$  of magnesium sulphate 10 minutes prior to induction followed by  $10\text{-}15 \text{ mg}/\text{kg}/\text{hour}$  as maintenance dose. The goal was to achieve a 20%-30% decrease from baseline mean arterial pressure (MAP). The surgeon was more satisfied and there was less blood loss in Group D. Patients in Group D group required frequent administration of atracurium. Conclusion was that dexmedetomidine proved to be a superior agent to provide controlled hypotension <sup>[3]</sup>.

## **Materials and methods**

Following a loading dose of dexmedetomidine 1 g/kg diluted in 100 ml of 0.9% normal saline provided over 10 min, an infusion at 0.2 to 0.7 g/kg/h was administered using an infusion pump.

To prepare the medicine for infusion, dilute 100 g (1 ampoule) in 49 ml of 0.9% normal saline NS to a final volume of 50 ml with a final concentration of 2 g/ml.

A loading dose of MgSO<sub>4</sub> 40 mg/kg diluted in 100 ml of 0.9% normal saline was administered over the course of 10 min. An infusion at 10 to 15 mg/kg/h was then administered using an infusion pump. For infusion 5 gm (5 ampoules i.e., 10 ml) was diluted in 40 ml of 0.9% NS to make a final volume of 50 ml and a final concentration of 100 mg/ml.

### **Preliminaries:**

- Written informed consent will be taken.
- Nil per oral status will be confirmed.
- Intravenous access will be secured with a 18 gauge I.V cannula.

### **Pre anaesthetic evaluation:**

Preoperative visits include a thorough review of the patient's medical history, a general physical examination and a systemic evaluation. We extracted any relevant medical ailment history.

Assessments of the respiratory, cardiovascular and airway systems was performed.

This study only involved ASA grade I and patients undergoing FESS surgery under GA who are between the ages of 18 and 60 and of either sex.



The day of the procedure an 18 gauge IV cannula was used to begin 10 ml/kg of ringer lactate. In order to further reduce bleeding and topical vasoconstriction, cotton wool plugs soaked in 1:1000 epinephrine and local anaesthesia (LA) were placed in the nasal cavity for 5 to 10 minutes 10 minutes before to the start of the procedure. Baseline vital signs were recorded using electrocardiography (ECG), pulse oximeter, non-invasive blood pressure (NIBP) and capnogram. 70 adult patients who had signed up for elective FESS were divided into two groups at random. Dexmedetomidine was given to Group D as a loading dose of 1 g/kg, followed by an infusion of 0.2-0.7 g/kg/h and magnesium sulphate was given to Group M as a loading dosage of 40 mg/kg, followed by an infusion of 10-15 mg/kg/h. Vital signs, emergence time, sedation score, VAS score, recovery profile and surgical field quality were all noted. During induced hypotension, mean arterial pressure (MAP) was maintained at or above 65 mmHg.

### **INTRAOPERATIVE PERIOD**

At specific times, such as baseline, after pre-medication, after the study drug, after induction, after intubation and at intervals of every five minutes for the first 15 minutes, monitoring of the heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), oxygen saturation (SpO<sub>2</sub>) and the end-tidal carbon dioxide (EtCO<sub>2</sub>) was obtained. Recordings continued every five minutes after the target MAP was reached until the surgery's conclusion and after extubation.

In both groups, the extubation time—the interval between the termination of anaesthesia and the extubation of the trachea—were recorded and compared. All patients were moved to the post-anaesthesia care unit after extubation (PACU).

## **POST-OPERATIVE PERIOD**

Patients were seen and vitals were recorded at 5 minutes, 30 minutes and 60 minutes following extubation of trachea in the PACU for post-operative recovery scoring (modified Aldrete score) and sedation ratings (“Ramsay Sedation Score (RSS)”). When the Aldrete score was below 9, patients were deemed fit for release from the PACU. Any post-operative side effects were noted and documented, including dry mouth, shivering, nausea and vomiting.

### **Procedure**

After meeting the eligibility requirements, 70 patients were enrolled in the trial and randomly divided into two equal groups: the dexmedetomidine group (n = 35) and the magnesium sulphate group (n = 35). Using sealed, opaque, sequentially-numbered envelopes with a 1:1 random distribution, randomization was carried out. Patients scheduled for FESS under general anaesthesia who had ASA grades I and II and were of both sex in the age group between 18 and 60 were included in the study. Patients who declined consent, those who were younger than 18 or older than 60, pregnant females and those who are hypertensive, patients with “ischemic heart disease”, “cerebrovascular insufficiencies”, “neuromuscular diseases”, “diabetic neuropathies”, “peripheral vascular disease”, “renal and hepatic” impairments were removed.

Patients with coagulopathies and those taking drugs that interfered with blood coagulation were also eliminated. Every patient received a typical preoperative assessment, which comprised a history taking, physical examination and routine tests (“complete blood picture, kidney function tests, liver function tests, pro thrombin time and partial thromboplastin time”). Verbal numerical rating scale (NRS) data was provided to patients (0: no pain, 10: severe pain). The body weight of each patient was noted in the records. All the patients were fasted in accordance with accepted practices and were premedicated 30 minutes prior to surgery using

inj midazolam 0.07 mg/kg i.v, ranitidine 50 mg i.v and ondansetron 40 mg i.v. patient's hemodynamic parameters were monitored in the operating room after the monitors, five lead electrocardiography (ECG), non-invasive blood pressure and pulse oximetry were connected. Prior to induction, patients in D group received loading dose of 1 mcg/kg dexmedetomidine in 100 ml saline solution and throughout surgery, they received 0.5–1 g/kg/h infusion using a syringe pump. Patients in group M were given a 10-minute intravenous loading dose of 40 mg/kg magnesium sulphate in 100 ml of normal saline, followed by a 10-15 mg/kg/h syringe pump infusion during the surgery (the range of the maintenance rate was attached to the syringe in accordance to the weight of the subject before handling it to the attending anaesthesiologist). Every patient received the same anaesthetic regimen of fentanyl 2 mcg/kg and propofol 1-2 mg/kg, with atracurium 0.5 mg/kg used to ease endotracheal intubation with the appropriate size cuffed tube. 1-2% isoflurane was used to keep the anaesthesia in place. The O<sub>2</sub>/air mixture FiO<sub>2</sub> 0.6 was used to mechanically ventilate all patients in a volume-controlled mode. To keep normocapnia, capnography was developed for end-tidal CO<sub>2</sub> measurement. Following the induction of anaesthesia, the mean arterial pressure and EtCO<sub>2</sub> were measured continuously. Prior to the loading dosage, baseline measurements of heart rate (HR) and mean arterial pressure (MAP) were taken and later measured during anaesthesia at 15, 30, 60, 90 and 120 minutes and postoperatively on conclusion of operation, immediately after extubating and 30 minutes after. If MAP rises over the desired MAP (55 to 65 mm Hg), NTG infusion is initiated at a rate of 0.5 g/kg/min. The amount of nitroglycerin utilised for each patient was calculated as the medication infusion rate when intended MAP was attained. At the conclusion of surgery, the surgeon's satisfaction with the quality of the surgical field was judged when the MAP reached the required span (55-65 mmHg) and was sustained a minimum of 10 minutes: 1 = poor, 2 -moderate, 3 -good and 4 -excellent (Bayram et al. 2015). Total amount of blood lost was determined and the subsequent grading schemes were used:

0 = no bleeding; 1 = faint bleeding; 2 = minor bleeding; 3 = minor haemorrhage; frequent aspiration; 4 = moderate bleed; visible only with aspiration; and 5 = severe bleed with continuous aspiration. By the time the endoscopic sinus surgery was complete, the studied medication infusions and the isoflurane were ceased, remaining neuromuscular block was treated with neostigmine 0.04 mg/kg and glycopyrrolate 0.01 mg/kg. When patient responded to verbal directions by opening their eyes, they were extubated. The length of time it took for the patient to recover and be discharged from the postanaesthetic care unit (PACU) to the ward was noted (Table 1). (“Aldrete 1995”),[13]

**Table:1 Aldrete score**

Respiration	<b>2</b>	<b>1</b>	<b>0</b>
	Deep breaths and cough	Dyspnoea or shallow breaths	Patient in apnoea
O2 saturation	<b>2</b>	<b>1</b>	<b>0</b>
	Maintaining > 92% on room air	Requires oxygen inhalation to maintain O2 saturation > 90%	Saturation < 90% with O2 supplementation
Level of consciousness	<b>2</b>	<b>1</b>	<b>0</b>
	<u>Completely awake</u>	Arousable on call	No response
Circulation	<b>2</b>	<b>1</b>	<b>0</b>
	Baseline BP $\pm$ 20 mm Hg	Baseline BP $\pm$ (20–50) mmHg	Baseline BP $\pm$ 50 mmHg
Activity level	<b>2</b>	<b>1</b>	<b>0</b>
	Can move all 4 extremities voluntary or on command	Capable of moving 2 extremities voluntary or on command	Unable to move any limbs

The pain score was determined using “NRS numerical rating scores” (“Childs et al. 2005”). The “Ramsay sedation scoring” (Table 2) [14] (“Ramsay et al. 1974”) was used to measure the patient's level of sedation at 15, 30 and 60 minutes post extubation. Duration of time required for providing the

initial dose of analgesia was documented. There were records of all complications during and after surgery.

Table 2: Ramsay sedation score

Sedation score	Response
1	Anxious and agitated or restless or both
2	Co-operative, oriented and tranquil
3	Responding to command only
4	Brisk response to glabellar tap or loud auditory stimulus
5	Sluggish response to light glabellar tap or loud auditory stimulus
6	No response to stimulus

- Mild sedation is indicated by a sedation score of 1 or 2
- Moderate sedation is indicated by a sedation score of 3 and 4
- Deep sedation is indicated by a sedation score of 5 and 6

Patients who had bradycardia were given inj atropine 0.01 mg/kg and warming blankets were provided to patients who started shivering. MAP of less than 50 mm Hg was deemed to represent hypotension and it was treated with incremental doses of 10 mg ephedrine IV. The primary outcome was the measurement of the “bleeding score” and the secondary outcomes included the mean arterial

MAP and HR required to achieve a bloodless field under induced hypotension, surgeon's satisfaction, the length of procedure, anaesthesia recovery with use of the "Aldrete scoring system", sedation with the "Ramsay sedation scoring system" and the requirement for first rescue analgesia post operatively using numerical rate scoring.

Results presented as Mean  $\pm$  SD, counts and percentages and diagrams. For normally distributed continuous variables between two groups was compared using independent t-test. For not normally distributed variables Mann Whitney U test was used. Categorical variables between the two groups were compared using the Chi square test.  $P < 0.05$  will be considered statistically significant. All statistical tests were performed in two-tailed.

## **Results**

There were no significant statistical differences in this study regarding gender, age, weight, ASA grade, or surgery duration between both the groups. (Table 3).

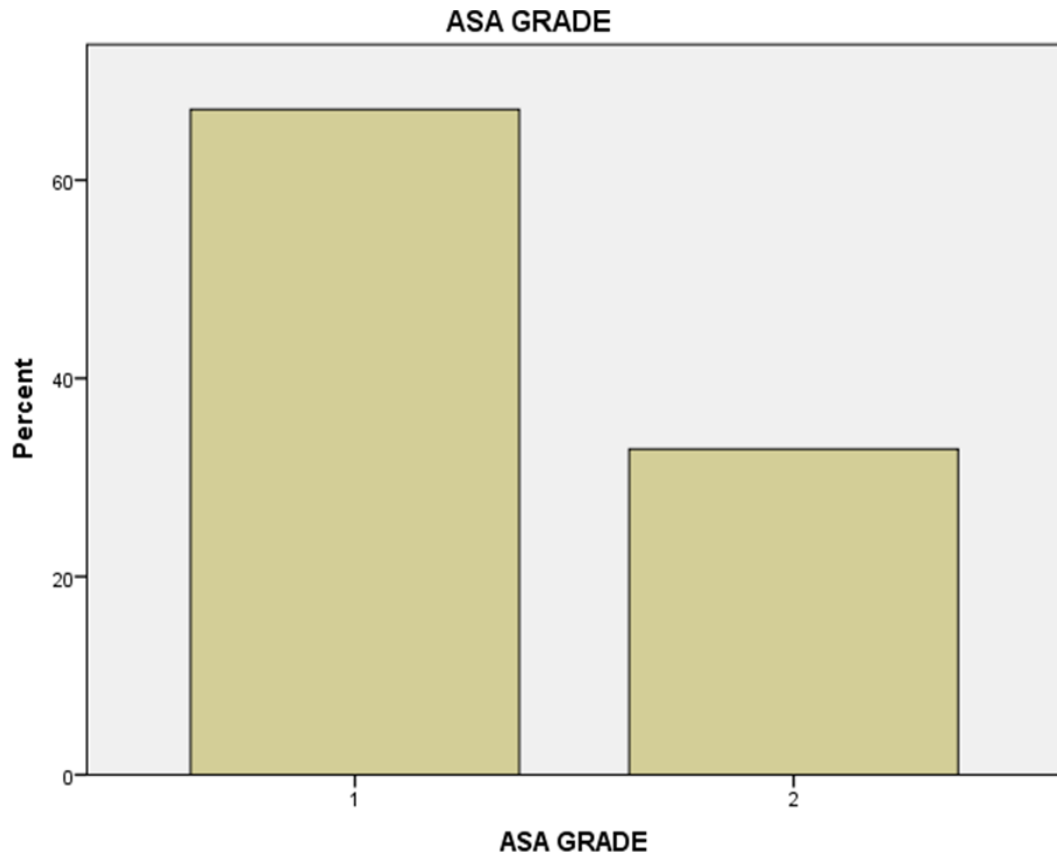
**Table: 3** Comparison between the groups in accordance to the demographic variables**Frequency Table**

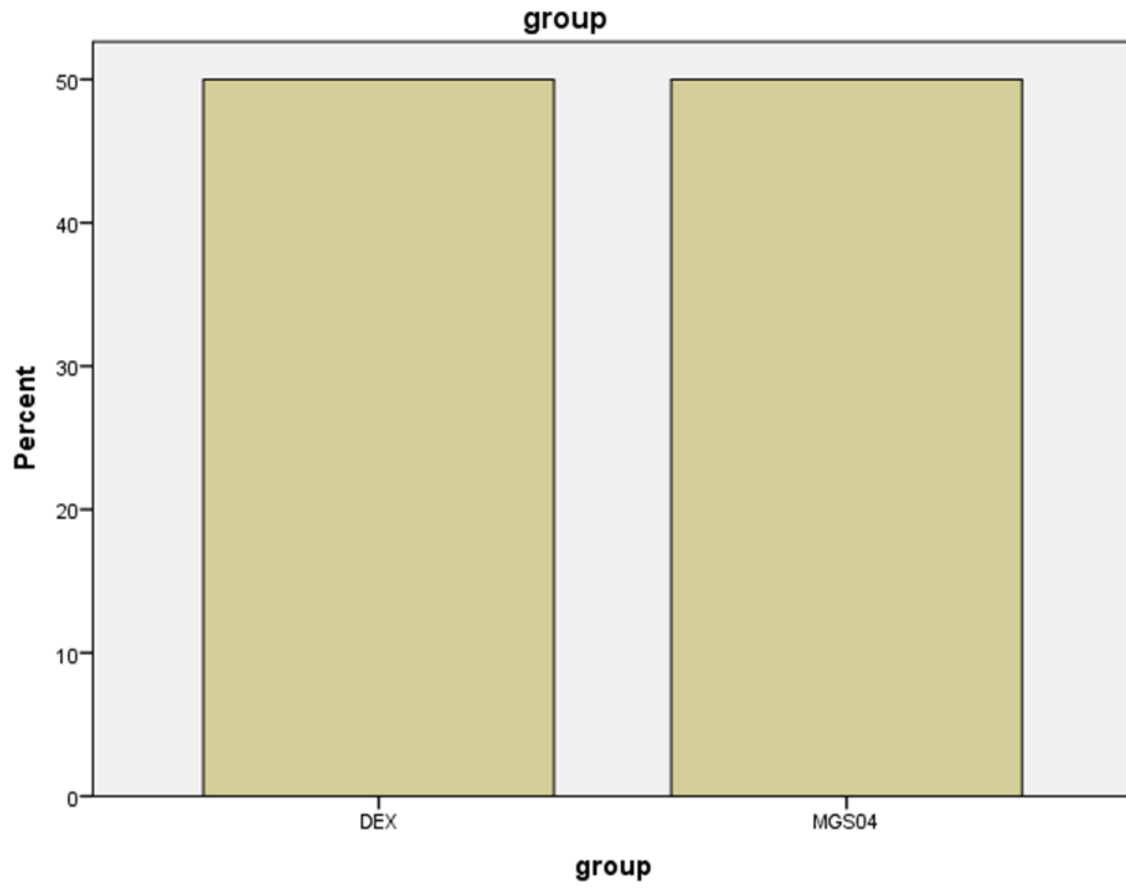
<b>SEX</b>	Frequency	Percent
Female	31	44.3
Male	39	55.7
Total	70	100.0

<b>ASA GRADE</b>	Frequency	Percent
1	47	67.1
2	23	32.9
Total	70	100.0

<b>group</b>	Frequency	Percent
DEX	35	50.0
MGS04	35	50.0
Total	70	100.0





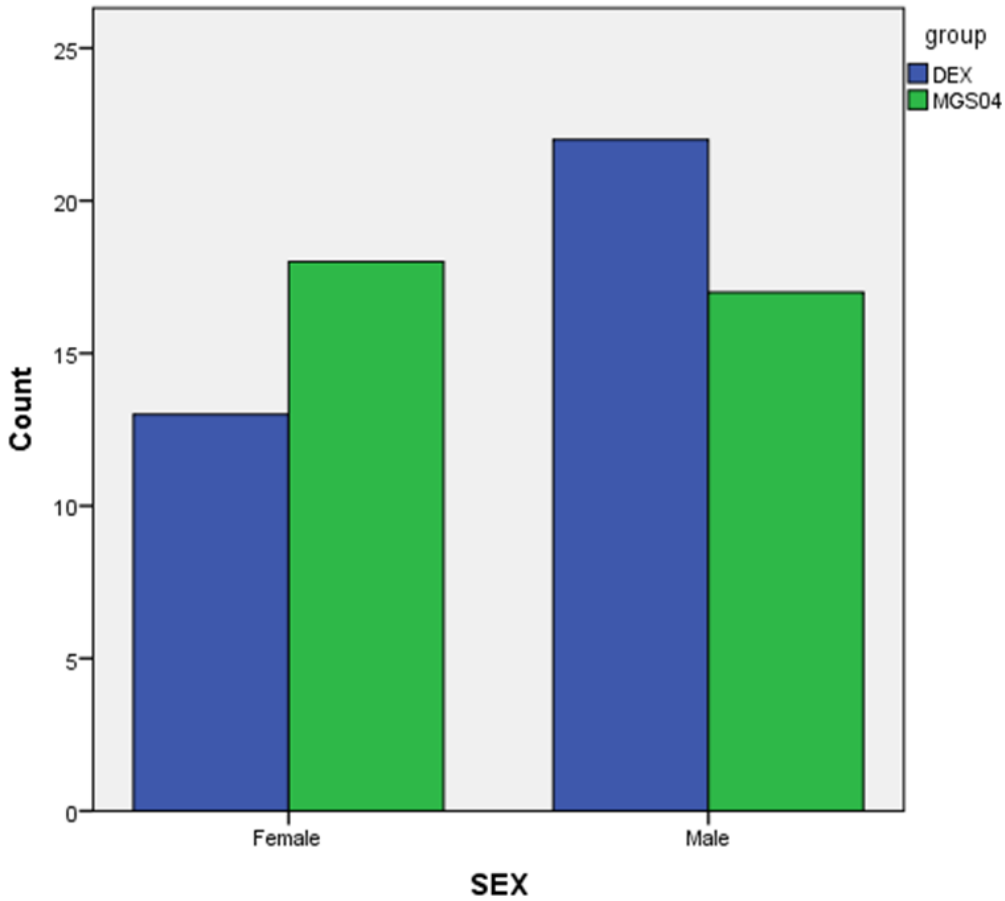


## SEX v/s group

Crosstab

		group		Total	Chi-square value	p-value
		DEX	MGS04			
SEX	Female	Count	13	18	1.447	0.229
	% within group	37.1%	51.4%	44.3%		
Male	Count	22	17	39		
	% within group	62.9%	48.6%	55.7%		
Total	Count	35	35	70		
	% within group	100.0%	100.0%	100.0%		

Bar Chart



Variables	Group	N	Mean	SD	Mann-Whitney U test value	p-value
AGE	DEX	35	36.429	11.793	720	0.208
	MGS04	35	33.086	13.832		
ASA GRADE	DEX	35	1.4	0.497	700	0.209
	MGS04	35	1.257	0.443		
WEIGHT (KG)	DEX	35	59.543	8.49	708	0.255
	MGS04	35	57	7.34		
HEIGHT (CM)	DEX	35	158.057	6.791	761	0.080
	MGS04	35	155.029	6.78		
total duration of surgery (mins)	DEX	35	144.286	25.586	578.5	0.682
	MGS04	35	146.286	24.981		

## Assumption Checks

### Test of Normality (Shapiro-Wilk)

		W	p
AGE	DEX	0.955	0.161
	MGS04	0.859	< .001
ASA GRADE	DEX	0.623	< .001
	MGS04	0.546	< .001
WEIGHT (KG)	DEX	0.890	0.002
	MGS04	0.960	0.236
HEIGHT (CM)	DEX	0.933	0.035
	MGS04	0.943	0.070
total duration of surgery (mins)	DEX	0.806	< .001
	MGS04	0.810	< .001

At baseline, prior to the loading dose, at induction and later at 15min, 30mins, 60mins, 90mins, or 120 min, or post extubation, there were no significant difference between the two group's mean arterial pressures (MAP), but at 30 minutes after surgery, the MAP in the D group was statistically lower than that in the M group ( $p = 0.039$ ). (Table 4).

## COMPARISON OF HEART RATES BETWEEN THE GROUPS

**Group Descriptives**

	Group	N	Mean	SD	SE	Coefficient of variation
HR baseline	DEX	35	89.714	16.570	2.801	0.185
	MGS04	35	84.057	12.968	2.192	0.154
HR after premedication	DEX	35	88.343	18.727	3.165	0.212
	MGS04	35	82.543	14.902	2.519	0.181
HR after study drug	DEX	35	85.429	17.095	2.890	0.200
	MGS04	35	81.343	13.911	2.351	0.171
HR after induction	DEX	35	82.029	12.332	2.085	0.150
	MGS04	35	79.371	10.605	1.793	0.134
HR after intubation	DEX	35	81.886	11.227	1.898	0.137
	MGS04	35	80.714	10.280	1.738	0.127
HR after 5 mins	DEX	35	77.600	11.698	1.977	0.151
	MGS04	35	77.829	10.168	1.719	0.131
HR after 10 mins	DEX	35	72.686	11.866	2.006	0.163
	MGS04	35	75.829	10.473	1.770	0.138
HR after 15 mins	DEX	35	68.057	11.662	1.971	0.171
	MGS04	35	74.314	9.845	1.664	0.132

**Independent Samples T-Test**

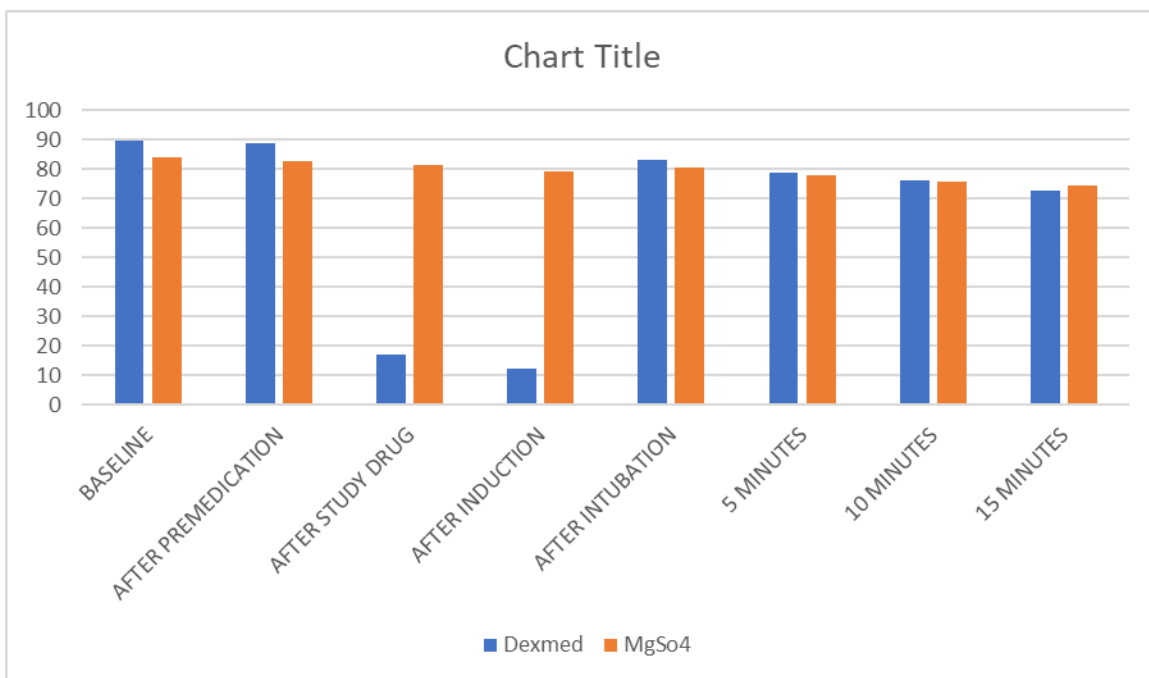
	W	df	p
HR baseline	736.500		0.146
HR after premedication	753.000		0.099
HR after study drug	697.500		0.320
HR after induction	675.500		0.462
HR after intubation	651.000		0.654
HR after 5 mins	563.000		0.564
HR after 10 mins	459.500		0.073
HR after 15 mins	370.500		0.004

*Note.* Mann-Whitney U test.

There was no statistical significance in the reduction in heart rate between the groups at baseline, after premedication, post administration of study drug, on induction or intubation and upto 10 minutes after administration

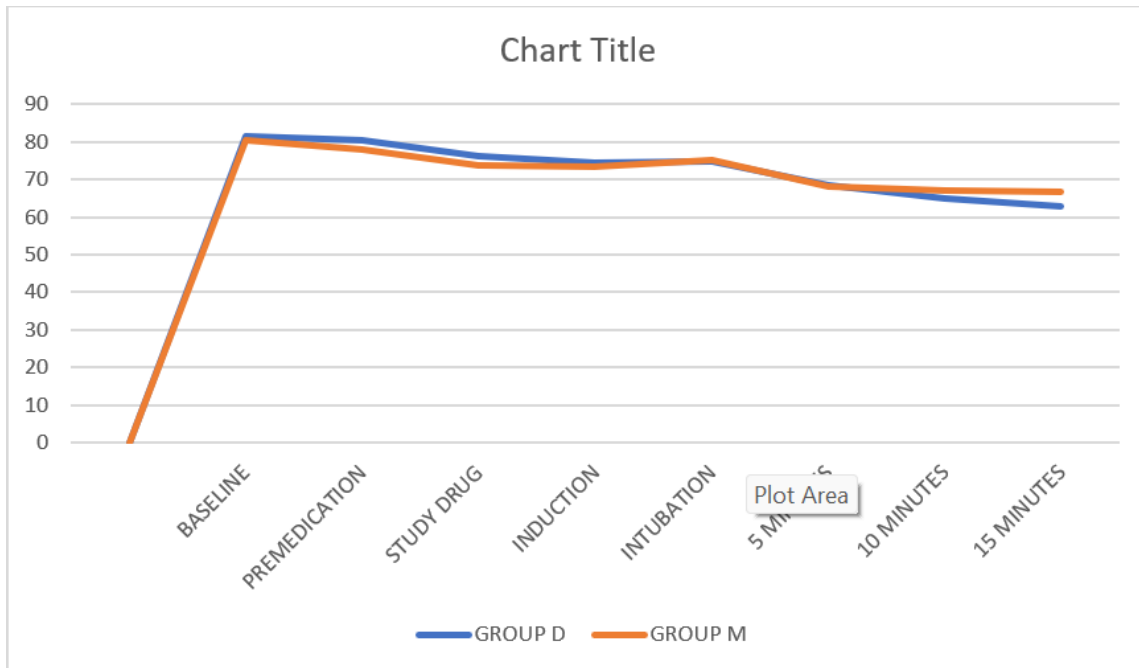
Heart rate was significantly reduced at 15 minutes after administration of the drug and later .  
 Dexmedetomidine induced a significant reduction in HR which was statistically validated

COMPARISON OF SYSTOLIC BLOOD PRESSURE BETWEEN THE TWO GROUPS						
	GROUP DEXMEDETOMIDINE		GROUP MgSO4		MANN WHITNEY U TEST	P VALUE
	MEAN (MEDIAN)	+/- S.D.	MEAN (MEDIAN)	+/- S.D.		
BASELINE	89.714	16.570	84.057	12.968	763.000	0.063
AFTER PREMEDICATION	88.629	18.985	82.543	14.902	758.500	0.074
AFTER STUDY DRUG	17.138	2.897	81.343	13.911	583.000	0.726
AFTER INDUCTION	12.315	2.082	79.371	10.605	542.500	0.399
AFTER INTUBATION	83.343	11.178	80.714	10.280	455.500	0.058
5 MINUTES	78.743	11.607	77.829	10.168	416.500	0.017
10 MINUTES	76.286	11.631	75.829	10.473	372.500	0.004
15 MINUTES	72.743	10.587	74.314	9.845	346.000	0.001



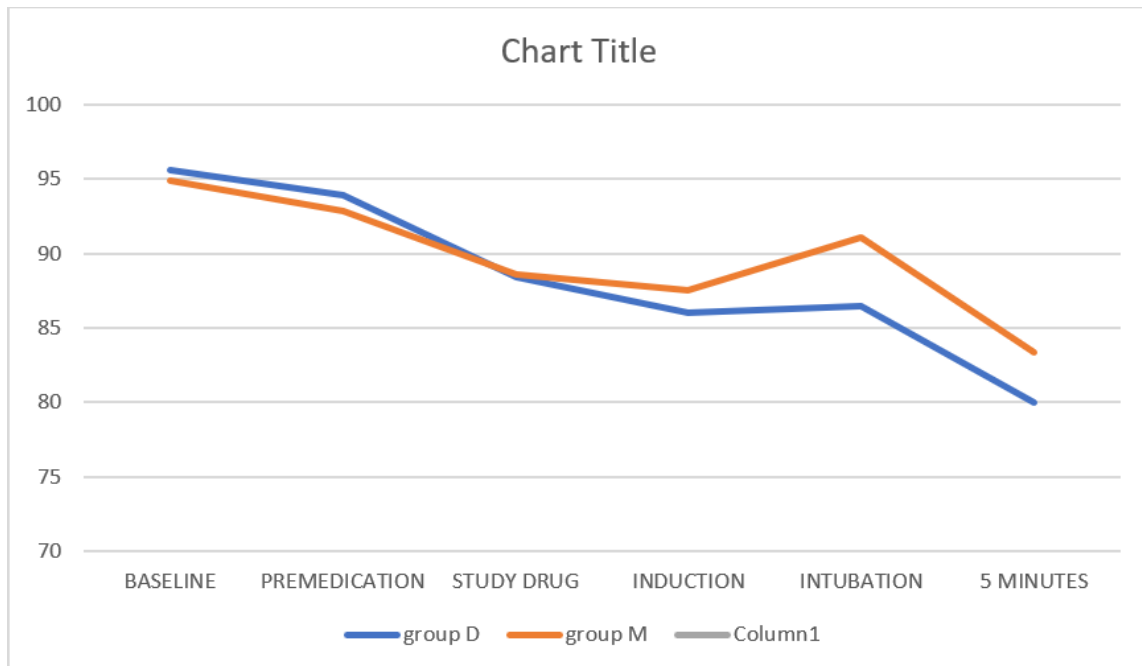
COMPARISON OF DIASTOLIC BLOOD PRESSURE BETWEEN GROUP D AND GROUP M						
	GROUP D		GROUP M			
	MEAN (MEDIAN)	+/-SD	MEAN (MEDIAN)	+/- SD	MANN WHITNEY U TEST	P VALUE
BASELINE	81.600	6.687	80.286	8.824	646.000	0.676
PREMEDICATION	80.400	9.230	78.057	11.943	706.000	0.256
STUDY DRUG	76.171	8.723	73.714	9.433	706.500	0.254
INDUCTION	74.257	8.586	73.457	10.242	634.500	0.791
INTUBATION	74.600	11.094	75.143	10.330	583.000	0.725
5 MINUTES	68.486	8.545	68.029	9.015	622.000	0.912
10 MINUTES	64.829	7.656	66.886	8.920	517.500	0.244
15 MINUTES	62.771	7.967	66.571	8.125	438.500	0.033

COMPARISON OF DIASTOLIC BLOOD PRESSURE BETWEEN THE GROUPS



COMPARISON OF MEAN ARTERIAL PRESSURE BETWEEN THE GROUPS						
	GROUP D		GROUP M		MANN WHITNEY U TEST	P VALUE
	MEAN/ MEDIAN	+/- S.D	MEAN/ MEDIAN	+/- S.D		
BASELINE	95.6	5.22	94.886	7.653	670.500	0.497
PREMEDICATION	93.886	7.263	92.886	11.628	604.000	0.925
STUDY DRUG	88.4	7.064	88.6	7.597	551.000	0.471
INDUCTION	86	8.788	87.571	8.552	471.000	0.096
INTUBATION	86.457	9.992	91.114	8.348	438.000	0.040
5 MINUTES	80	8.36	83.4	7.785	471.000	0.096
10 MINUTES	75.429	7.747	80.8	8.217	378.000	0.005
15 MINUTES	73.771	7.57	79.2	7.384	380.500	0.006

MAP COMPARISON IN BOTH GROUPS





A statistically significant reduction in MAP was found in group D compared to group M at the time of intubation and later at 10 minutes and 15 minutes.

When it came to the usage of nitroglycerin, which was only necessary in eight cases for the M group, there was a statistically significant difference between the two groups ( $p = 0.008$ ). The M group used a total dose of 145.48 g of nitroglycerin. At baseline, there were no statistically significant differences in HR between the two groups, but in comparison to the M group, the D group saw a significant decline in HR at 15, 30, 60, 90 and 120 minutes throughout the operation, afterward, at the conclusion of the procedure, post-extubation and after 30 minutes. (Table 5).

30 min post-operatively	68.23 ± 4.78	75.87 ± 5.31	3.607	0.035*
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M group greatly outperformed D group in terms of bleeding score (Table 6).

**Table: 6** Comparison of the bleeding scores between the groups

Bleeding score	(Group D) (n = 35)	(GroupM) (n = 35)	p-value
<b>0</b>	3 (3.3%)	0 (0.0%)	0.212
<b>1</b>	5 (10.0%)	0 (0.0%)	0.217
<b>2</b>	15 (50.0%)	9 (20.0%)	0.039*
<b>3</b>	8 (26.7%)	6 (13.3%)	0.017*
<b>4</b>	2 (6.7%)	12 (40.0%)	0.028*
<b>5</b>	2 (3.3%)	8 (26.7%)	0.031*

In comparison to the M group, there is a statistically significant reduction in blood loss ( $p = 0.019$ ).

In comparison to the M group, the D group had much higher surgeon satisfaction (Table 7).

**Table: 7** Comparison of surgeon satisfaction between the two groups

<b>Surgeon satisfaction</b>	D group (n = 35)	M group (n = 35)	X <sup>2</sup>	p value
<b>Bad</b>	5 (3.3%)	9 (20.0%)	5.249	0.022*
<b>Moderate</b>	6 (16.7%)	16 (46.7%)	9.053	0.003*
<b>Good</b>	9 (30.0%)	7 (23.3%)	3.481	0.049*
<b>Excellent</b>	15 (50.0%) <	3 (10.0%)	17.190	0.001**

The D group took substantially longer than the M group to obtain an Aldrete score of less than 9 (p = 0.023). Ramsay sedation score (RSS) was statistically substantially different between two groups at fifteen, thirty and sixty minutes after extubation (p 0.001) because it was significantly higher in group D than group M (Table 8).

**Table :8** Comparison between both groups regarding the Ramsay sedation score

Ramsay sedation score	D group (n = 35)	M group (n = 35)	X <sup>2</sup>	p value
RSS at 15 min postoperatively	4.75 ± 0.33	2.42 ± 0.17	15.651	<0.001**
RSS at 30 min postoperatively	3.82 ± 0.30 <	2.26 ± 0.16	14.040	0.001**
RSS at 60 min postoperatively	3.20 ± 0.29	2.12 ± 0.15	12.572	< 0.001**

Compared to the M group, the D group took substantially longer for the first postoperative analgesic demand. Two incidences of hypotension (MAP 50 mmHg), which was treated with mephentramine increments of 3 mg in the dexmedetomidine group, were noted, although this was statistically insignificant. With no statistically significant difference, atropine 0.6 mg was administered to five patients with HR less than 50 beats/minute in dexmedetomidine group and to one patient in the magnesium sulphate group. In regards to the magnesium group, there were just two small incidences of nausea and vomiting. Ondansetron 40 mg intravenously was used to treat them. Magnesium caused shivering in two cases and those people received warm blankets.

## **Discussion**

“Functional endoscopic sinus surgery (FESS)”, a surgical procedure, is performed using a fiberoptic endoscope which uses a brilliant camera. A simple drop of blood could effectively block the surgical area, so bleeding should be kept to a minimum to ensure a dry operating field, a number of techniques have been employed, including topical vasoconstriction agents, fowler position,” alpha 2 adrenergic” and “beta adrenergic” inhibitors as well as pre operative steroids. The mentioned techniques have considerable negative side effects. Combining total intravenous anaesthesia with propofol, remifentanyl and esmolol is another acceptable solution to this issue <sup>[15]</sup>. For induced hypotension in FESS, oral nifedipine was employed in other investigations as a premedication <sup>[16]</sup>. Dexmedetomidine and magnesium sulphate were employed in the current investigation. Dexmedetomidine's central and peripheral sympatholytic impact is manifested by a reduction in heart rate, cardiac output, MAP and norepinephrine release. It is a potent and highly selective central alpha 2-receptor agonist. Additionally, compared to other sedatives, it has a special sedative quality in that it induces sleep without causing respiratory depression. Additionally, it owns potent analgesic

(opioid-sparing) and calming properties. By stimulating the membrane “Ca<sup>++</sup> ATPase” and “Na-K ATPase” participating in trans-membrane ion transfers while in the depolarization & repolarization stages, magnesium sulphate causes induced hypotension. Furthermore, Mg<sup>++</sup> prevents norepinephrine from being released.

By increasing prostacyclin synthesis and decreasing angiotensin-converting enzyme activity, it also functions as a vasodilator. We discovered in this study that dexmedetomidine was superior to magnesium sulphate in attaining targeted hypotension in the subjects undergoing “FESS”.

Dexmedetomidine has strong analgesic effect and generally lesser side effects than magnesium sulphate in controlling blood pressure as nitroglycerin was added to the M group to achieve the targeted MAP. This improved the surgical field's quality, increased surgeon satisfaction and reduced bleeding. In numerous other investigations, controlled hypotension has been treated with dexmedetomidine and magnesium. Dexmedetomidine and nitroglycerin were tested in a study by Patel et al. to create controlled hypotension; the former had advantage of retaining greater hemodynamic stability in comparison to latter <sup>[17]</sup>. Dexmedetomidine and esmolol were tested in a study by Bajwa et al. as hypotensive medications; when compared to esmolol, Dexmedetomidine reduced heart rate and blood pressure while also enhancing the operating room environment. <sup>[18]</sup> In the study by Ghodratty et al., magnesium and remifentanil were contrasted. Both medications have similar hemodynamic qualities and similar effects on controlling hypotension <sup>[19]</sup>. Dexmedetomidine and magnesium both produced regulated hypotension in the current trial and the surgery's hypotensive result was satisfactory. Many researchers looked at metabolic as well as hormonal responses in people with induced hypotension with MAP values in the spectrum of 55 to 65 mmHg; tissue ischemia was not found to a matter of concern. In order to prevent patient cerebral hypoxia, we chose to keep the MAP between 55 and 65 mmHg. Patients in group D in current study had lesser HRs compared to those in group M during procedure, which would have contributed to better

surgical field condition in the D group. Only one patient of group M required atropine administration whereas five patients in group D did. Four patients in the “dexmedetomidine group” experienced bradycardia in a research by Byram and colleagues, as opposed to 1 patient in the magnesium group [20]. While in a study by Sie'skiewicz and his colleagues, They reported that by lowering the HR, it was possible to improve operating room conditions without having to reduce MAP to dangerously low levels (assuming HR was kept low at roughly 60 beats per minute). [21]. They studied how mean arterial pressure and intraoperative haemorrhage correlated to low heart rates in patients undergoing functional endoscopic sinus surgeries. In terms of bleeding score, group D performed worse than group M. Patients in the group with higher levels of surgical satisfaction for operational field visibility were D group. In addition to the reduced effects of BP and HR, the decreased bleeding and improved surgical site in the D group may have also been caused by peripheral vasoconstriction. In the “Faranak et al.” research study, compared to the magnesium group, the dexmedetomidine group had a lower bleeding score and higher surgeon satisfaction, which produced comparable results [22]. Dexmedetomidine provided higher surgeon satisfaction than magnesium in a study by “Bayram et al”. evaluating the efficiency of MgSO<sub>4</sub> and dexmedetomidine in producing hypotension during “FESS” operations (“Bayram et al. 2015”). In a research comparing labetalol and dexmedetomidine in preventing bleeding during "FESS," Eghbal and associates” found that labetalol group had greater visibility of the operating field and reported higher levels of surgeon satisfaction. Patients in the dexmedetomidine group in the current trial were more sedated while they were in the PACU and it took them a lot longer than patients in the magnesium group to achieve an Aldrete score of less than nine.

These findings are in agreement with the research by Faranak et al., where the dexmedetomidine group's patients appeared more tranquillized in “PACU” and required longer to attain a modified Aldrete score of nine than the magnesium group's patients [22].

When dexmedetomidine rather than esmolol was used to produce hypotension during “FESS”, the sedation score in Erdem et al.'s was similarly greater <sup>[24]</sup> in a study by Lee et al. comparing the administration of remifentanyl and dexmedetomidine as hypotension inducing agent during surgery, it was discovered that subjects receiving remifentanyl reached modified Aldrete score of 9 more quickly, while those receiving dexmedetomidine experienced more profound sedation. [25]. In the present study, the D group required an analgesic sooner after the procedure than the M group, on average. Dexmedetomidine appears to have a more potent analgesic effect than magnesium. Dexmedetomidine has analgesic, sedative and anti-anxiety properties without causing respiratory depression because it has a stronger selectivity of spinal cord and locus coeruleus alpha alpha 2 adrenergic receptor agonist whereas magnesium sulphate is an NMDA receptor antagonist that has analgesic effects <sup>[26]</sup>. The findings of the current trial and that of Faranak et al. were similar, with dexmedetomidine cohort requiring less analgesia than the magnesium group. According to study done by Dong et al., dexmedetomidine reduced the requirement for opioid painkillers and provided adequate pain relief in the postoperative period when it was introduced to spine surgery patients using a sufentanil-based analgesia regimen for pain management following surgery. <sup>[27]</sup> Yu and coworkers investigated effects of I/V MgSO<sub>4</sub> for postoperative pain control in orthopaedic surgeries which came to the conclusion that preoperative intravenous magnesium sulphate administration could lower postoperative pain and postoperative analgesic intake <sup>[28]</sup>. One of the study's major benefits was the way it was designed. A randomised controlled trial was conducted that was adequately computerised in its allocation concealment. In contrast to past studies of a similar sort, the current study recorded the duration before the first analgesic requirement in both groups. This study's major flaw is the absence of a control group. This study's use of ASA one or two-classified

participants falling in the age group of 18 and 60 may be another source of weakness, preventing one from extrapolating the conclusions to other subgroups. Other adverse effects that might occur occasionally may not have been detected due to the small sample size. No patients experienced any serious neuromuscular blockade or toxicity symptoms. Postoperative magnesium sulphate levels were not assessed.

## **Conclusion**

Dexmedetomidine displays better efficiency than MgSo<sub>4</sub> at attaining targeted hypotension in subjects undergoing FESS, which is the main finding. The surgical field was of greater quality, the surgeon was more satisfied and there was less bleeding with dexmedetomidine than with magnesium sulphate, which required more nitro-glycerine. Dexmedetomidine also provides a stronger analgesic effect than magnesium and a shorter postoperative requirement for analgesics.

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## SUMMARY

We performed this randomized prospective study titled “**CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A RANDOMISED PROSPECTIVE COMPARISON OF MAGNESIUM SULPHATE AND DEXMEDETOMIDINE**” in B.L.D.E. (DEEMED TO BE) UNIVERSITY SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE, VIJAYAPURA, KARNATAKA to compare and contrast the efficacy of Dexmedetomidine and magnesium sulphate in inducing hypotension and providing a bloodless surgical field in “FESS surgeries”. We also studied the time required by both the drugs to reach the target mean arterial pressure and its adverse effects and recovery characteristics.

Seventy patients in the age group of 18 to 60 of either sex who belonged to ASA category 1 and 2 who were electively posted for “FESS” surgeries were enrolled in the study and randomly assigned into two groups.

- “Group dexmedetomidine” : 35 patients were enrolled in this group and injection dexmedetomidine was used as the agent to induce hypotension.
- “Group magnesium sulphate”: 35 randomly selected patients were included in this group and MgSo<sub>4</sub> was utilised to produce hypotension.

**Demographic profile:** either group shared characteristics such as age, sex, weight, height and ASA grade and were scheduled for similar surgery.

This prospective randomised investigation was conducted in a study period of one and half year from December 2020 to August 2022 in “B.L.D.E. (DEEMED TO BE UNIVERSITY) SHRI B. M. PATIL MEDICAL COLLEGE”.

Results were recorded using a present Performa. Preanesthetic evaluation was done, patients were kept fasting for 6 hours prior to surgery. Written informed consent was taken and the procedure was explained to the patient in their own understandable language.

Any adverse effects that occurred were noted and treated promptly.

It was come to the observation that “Group dexmedetomidine” was superior to “group magnesium sulphate” in inducing targeted hypotension in subjects and provided superior surgical field which lead to better surgeon satisfaction in the same group. It also succeeded in providing greater analgesia compared to “MgSo4 group”

The study proves the superiority of dexmedetomidine over magnesium sulphate in inducing controlled hypotension in “FESS surgeries” and therefore recommends its use.

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8. Stoelting pharmacology of anaesthesiology.

9. Millers anesthesia

### **SAMPLE INFORMED CONSENT FORM**

BLDE (DU)'s Shri B M Patil Medical College

Hospital and research centre, vijayapura

**TITLE OF THE PROJECT:** "CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A RANDOMISED PROSPECTIVE COMPARISON OF MAGNESIUM SULPHATE AND DEXMEDETOMIDINE"

**PRINCIPAL INVESTIGATOR:** DR. NAYANTARA K.P

Department of Anaesthesiology

BLDE (DU)'s Shri B M Patil Medical College

Hospital and research centre, Vijayapura

PG GUIDE: DR. VIJAY V KATTI

Associate Professor,

Department of Anaesthesiology

BLDE (DU)'s Shri B M Patil Medical College

Hospital and research centre, vijayapura

**PURPOSE OF RESEARCH:**

I have been informed that this, study is CONTROLLED HYPOTENSION FOR  
FUNCTIONAL ENDOSCOPIC SINUS SURGERY: A RANDOMISED PROSPECTIVE  
COMPARISON OF MAGNESIUM SULPHATE AND DEXMEDETOMIDINE”

I have been explained about the reason for conducting this study and selecting me/my ward  
as a subject for this study. I have also been given free choice for either being included or not  
in the study.

**PROCEDURE:**

I understand that I will be doing “CONTROLLED HYPOTENSION FOR FUNCTIONAL  
ENDOSCOPIC SINUS SURGERY: A RANDOMISED PROSPECTIVE COMPARISON  
OF MAGNESIUM SULPHATE AND DEXMEDETOMIDINE”



**RISKS AND DISCOMFORTS:**

I understand that I/my ward may experience hypotension while doing the procedure and I understand that necessary measures will be taken to reduce these complications as and when they arise.

**BENEFITS:**

I understand that I/my wards participation in this study will help in finding out.

“CONTROLLED HYPOTENSION FOR FUNCTIONAL ENDOSCOPIC SINUS

SURGERY: A RANDOMISED PROSPECTIVE COMPARISON OF MAGNESIUM

SULPHATE AND DEXMEDETOMIDINE”

**CONFIDENTIALITY:** I understand that medical information produced by this study will become a part of this hospital records and will be subjected to the confidentiality and privacy regulation of this hospital. Information of a sensitive, personal nature will not be a part of the medical records, but will be stored in the investigator’s research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission

**REQUEST FOR MORE INFORMATION:**

I understand that I may ask more questions about the study at any time. Dr NAYANTARA K.P is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation. If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me. And that a copy of this consent form will be given to me for keep for careful reading.

**REFUSAL OR WITHDRAWL OF PARTICIPATION:**

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that Dr NAYANTARA K.P will terminate my participation in this study at any time after he has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly to my participation in this study, if such injury were reported promptly, then medical treatment would be available to me, but no further compensation will be provided.

I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to \_\_\_\_\_, the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date:

Dr.VIJAY.V.KATTI

(Guide)

Dr. NAYANTARA K.P

(Investigator)

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr NAYANTARA K.P has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

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(Participant) Date

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(Witness to above signature) Date



## MONITORING

TIME	HR(bpm)	SBP(mm hg)	DBP(mm hg)	MAP (mm hg)	SPO2	ETCO2
Baseline						
After premedication						
After study drug						
After induction						
After intubation						
5 min						
10 min						
15 min						

DATE:

STAFF SIGNATURE:

BIODATA

GUIDE NAME : DR. VIJAY V KATTI

DATE OF BIRTH : 12/01/1976

EDUCATION: M.B.B.S  
BLDEA's SHRI B.M. PATIL MEDICAL  
COLLEGE AND RESEARCH CENTRE,  
VIJAYAPURA – 586103

M.D ANAESTHESIOLOGY  
BLDEA's SHRI B.M. PATIL MEDICAL  
COLLEGE AND RESEARCH CENTRE,  
VIJAYAPURA – 586103

K.M.C. REG. NO. : 51716

DESIGNATION : ASSOCIATE PROFESSOR  
DEPARTMENT OF ANAESTHESIOLOGY

TEACHING : 16 YEARS

ADDRERSS : ASSOCIATE PROFESSOR  
DEPARTMENT OF ANAESTHESIOLOGY  
BLDE (DU)'s SHRI B.M.PATIL MEDICAL  
COLLEGE AND RESEARCH CENTRE,  
VIJAYAPURA – 586103

PHONE : (08352)262770 EXT 2052

MOBILE NO 9844585900

E mail : drvijaykatti@gmail.com

INVESTIGATOR

NAME : DR. NAYANTARA K.P

QUALIFICATION : M.B.B.S.

K.M.C. REG. NO. 121137

ADDRESS : DEPARTMENT OF ANAESTHESIA  
BLDE (DU)'S SHRI B.M.PATIL MEDICAL  
COLLEGE AND RESEARCH CENTRE,  
VIJAYAPURA – 586103

Contact Number : 8123395650

E-mail : nayantarakp118@gmail.com



NAME : DR. NAYANTARA K.P  
QUALIFICATION : M.B.B.S.  
K.M.C. REG. NO. 121137  
ADDRESS : DEPARTMENT OF ANAESTHESIA  
BLDE (DU)'S SHRI B.M.PATIL MEDICAL  
COLLEGE AND RESEARCH CENTRE,  
VIJAYAPURA – 586103  
  
Contact Number : 8123395650  
E-mail : nayantarakp118@gmail.com



## ETHICAL COMMITTEE CLEARANCE CERTIFICATE



IEC/No-09-2021  
22-01-2021

**B.L.D.E. (DEEMED TO BE UNIVERSITY)**

(Declared vide notification No. F.9-37/2007-U.3 (A) Dated. 29-2-2008 of the MHRD, Government of India under Section 3 of the UGC Act, 1956)

The Constituent College

**SHRI. B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE**

### INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Institutional ethical committee of this college met on 11-01-2021 at 11 am to scrutinize the synopsis of Postgraduate students of this college from Ethical Clearance point of view. After scrutiny the following original/corrected and revised version synopsis of the Thesis has been accorded Ethical Clearance

**Title:** Controlled hypotension for functional endoscopic sinus surgery a randomized double blinded comparison of magnesium sulphate and dexmedetomidine.

**Name of PG student:** Dr Nayantara K P Department of Anaesthesiology

**Name of Guide/Co-investigator:** Dr Vijay V Katti, Associate Professor of Anaesthesiology

  
DR. S.V. PATIL  
CHAIRMAN, IEC

**Institutional Ethical Committee**  
**B L D E (Deemed to be University)**  
**Shri B.M. Patil Medical College,**  
**VJAYAPUR-526103 (Karnataka)**

**Following documents were placed before Ethical Committee for Scrutinization:**

1. Copy of Synopsis / Research project
2. Copy of informed consent form
3. Any other relevant documents.



