Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/670v9g57

MAGNESIUM SULPHATE VERSUS DEXMEDETOMIDINE AS AN ADJUVANT TO BISPECTRAL INDEX GUIDED BALANCED GENERAL ANESTHESIA FOR LAPAROSCOPIC CHOLECYSTECTOMY: A NON-RANDOMIZED, DUAL-ARM, PROSPECTIVE STUDY

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ABSTRACT

Background: Magnesium sulphate and dexmedetomidine have been successfully used as an adjuvant to balanced general anesthesia. This study was designed to compare propofol-sparing effects, effects on haemodynamic changes and recovery profile due to intravenous magnesium sulfate and dexmedetomidine.

Methods: A prospective observational comparative study was conducted on 60 patients belonging to American Society of Anesthesiologists physical status 1to3, of either sex, in the age group of 18-60 years, undergoing laparoscopic cholecystectomy. Thirty patients who received magnesium-sulphate 40 mg/kg bolus in 100ml normal saline 15 minutes before induction followed by 10 mg/kg/h continuous infusion intra-operatively were included in group M, thirty patients who received dexmedetomidine 1 µg/kg bolus in 100ml normal saline followed by 0.5 µg/kg/h continuous infusion intra-operatively were included in group D. Induction and maintenance was done with propofol and atracurium. Vital parameters, neuromuscular blockage, bispectral-index (BIS) values, extubation time, time to follow verbal commands, modified Aldrete score and Ramsay Sedation Scale score were observed.

Results: Propofol requirement was significantly reduced in group D ($P<0.001$). Extubation time, time to follow verbal command, time to achieve BIS-value 80 & Aldrete score ≥ 9 were significantly faster in group M($P<0.05$). RSS scores were significantly lower in group M ($P<0.05$). Intra-operative hemodynamics were comparable ($P>0.05$) with minimal side-effects in both groups.

Conclusion: Intravenous dexmedetomidine decreases propofol requirements intra-operatively, while intravenous magnesium-sulfate has a better recovery profile with less post-operative sedation. Intra-operative hemodynamics were comparable and side-effects were minimal in both groups.

Keywords: (Magnesium sulphate, Dexmedetomidine, Propofol, Bi-spectral index, Laparoscopic cholecystectomy, Recovery profile, Ramsay Sedation Scale score, Modified Aldrete score) (https://meshb.nlm.nih.gov/MeSHonDemand).

Key Message: Pre-emptive magnesium sulphate and dexmedetomidine along with BIS monitoring optimizes propofol requirements, making it cost-effective and reducing environmental pollution caused by costly inhalation-agents.

Novel observation: We have discovered that a greater reduction of BIS value was seen with pre-emptive dexmedetomidine than with pre-emptive magnesium sulphate.

INTRODUCTION

Laparoscopic cholecystectomy is now routinely done because of benefits like minimal access procedure with less blood loss, less post-operative pain, faster post-operative recovery, shortened hospital stays and better cosmetic results.[1] However, during general anesthesia events like laryngoscopy, tracheal intubation and extubation provokes transient but marked sympatho-adrenal response resulting in hypertension and tachycardia.[1]

Pneumoperitoneum during laparoscopic surgery causes increased intra-abdominal pressure and release of catecholamines and vasopressin, leading to significant hemodynamic changes like decrease in cardiac output, increase in arterial pressure and systemic vascular resistance leading to hypertension and tachycardia.[1]

Various adjuvants and drug combinations in balanced anesthesia technique have been used to achieve minimal disturbances in hemodynamic parameters and attenuation of this sympatho-adrenal response. The balanced anesthesia technique maximizes safety and minimizes side effects related to large doses of individual drugs while maintaining adequate depth of anesthesia.[2]

Monitoring of depth of anesthesia can be done by Bi-spectral index (BIS) monitoring. Intra-operative BIS values are maintained between 40-60 to maintain deep hypnotic state, unresponsiveness to verbal or surgical stimuli and to prevent intra-operative awareness in surgical patients.[2,3,4]

Propofol has advantages like rapid onset, rapid elimination, rapid metabolism, non-cumulative properties and speedy recovery profile but as it lacks analgesic properties, higher doses may be needed for the maintenance of anesthesia causing major adverse cardio-respiratory events such as myocardial depression, metabolic acidosis and impaired platelet aggregation.[2,5]

Dexmedetomidine acts on central α-2A and imidazoline type 1 receptors leading to sedative, anxiolytic, analgesic, sympatholytic and anti-nociceptive effects.[2,6] It decreases surgical stress response and decreases anesthetic and opioid requirements intra-operatively.[2,7,8]

Magnesium sulphate is a non-competitive N-Methyl-D-Aspartate (NMDA) receptor antagonist.[9,10] When co-administered with propofol, it potentiates anesthetic and hypotensive effect of propofol.[2] Thus, it reduces total dose requirement of propofol. Magnesium inhibits release of norepinephrine at nerve endings leading to decrease in catecholamines release from adrenal medulla, resulting in attenuation of pressor response.[9,11,12]

In this study, we have evaluated effects of intravenous magnesium sulphate and dexmedetomidine as an adjuvant to BIS guided balanced general anesthesia technique to compare intra-operative propofol requirement, recovery profile, post-operative sedation and intra-operative hemodynamics.

MATERIAL & METHODS

After getting approval from **institutional ethics committee** (GMCS/STU/ETHICS/Approval/10604/21–dated-on-28-04-2021) and **CTRI registration** (https://ctri.nic.in; CTRI/2021/09/036199; 3rd September 2021; 26th September 2021), a prospective comparative observational study was conducted on 60 patients belonging to American Society of Anesthesiologists physical status (ASA PS) 1,2 and 3, 18–60 years of age group, of either sex, giving written informed consent, scheduled to undergo laparoscopic cholecystectomy under general anesthesia who received pre-emptive intravenous (IV) magnesium sulphate or dexmedetomidine along with induction and maintenance of anesthesia with propofol and atracurium.

Patients with body mass index (BMI) >30 kg/m^2, major cardiovascular, hepatic, renal or neuromuscular disorders, pregnancy, epilepsy, postural hypotension, anticipated difficult airway and

patients on calcium channel blockers, beta-blockers, opioids, sedatives or allergic to study drugs were excluded from the study.

Detailed pre-anesthetic examination was performed and all routine investigations were recorded day before surgery. All patients were pre-medicated with glycopyrrolate 0.004 mg/kg, midazolam 0.02 mg/kg and tramadol 2 mg/kg IV half an hour before surgery.

After taking patients to operation theatre, patients who received pre-treatment with magnesium sulphate 40 mg/kg in 100 ml normal saline IV over 10-15 minutes before anesthesia followed by continuous infusion at 10 mg/kg/h IV intra-operatively were included in **group M (n=30)** and those who received pre-treatment with dexmedetomidine 1 µg/kg in 100 ml normal saline IV over 10-15 minutes before anesthesia followed by continuous infusion at 0.5 µg/kg/h IV intra-operatively were included in **group D (n=30)**.

Induction of anesthesia was done after pre-oxygenation with 100% oxygen for 3 minutes followed by lignocaine (2%) 1 mg/kg IV, propofol 2-2.5 mg/kg IV in titrated doses to achieve BIS 40 and atracurium 0.6 mg/kg IV. Train of Four (TOF) response was observed by stimulation of ulnar nerve every 30 seconds till TOF=0 followed by laryngoscopy and tracheal intubation.

Maintenance of anesthesia was done with 1:1 mixture of oxygen and nitrous oxide, propofol infusion 4-6 mg/kg/h IV to keep BIS values between 40 to 60 [further doses of propofol were adjusted to maintain hemodynamic parameters like heart rate (HR) & mean arterial pressure (MAP) ±20% from baseline] and atracurium 0.2 mg/kg IV was given intermittently when TOF≥2, on presence of respiration, sudden movement of patients or change in end tidal CO_2 ($EtCO_2$) waveforms.

Pulse oximetry, non-invasive blood-pressure (NIBP), electrocardiogram (ECG), capnography, neuromuscular monitoring with INMED NS 100 and BIS monitoring with Covidien digital BIS monitor were done intra-operatively. Magnesium sulphate or dexmedetomidine infusion was discontinued at the time of gall bladder removal and propofol infusion was discontinued at the time of skin closure. At the end of surgery, reversal of neuromuscular block was done with neostigmine 0.05 mg/kg IV and glycopyrrolate 0.008 mg/kg IV, given after completion of surgery when TOF>2.

Extubation was done after appearance of TOF=4 and after achievement of regular smooth respiration with adequate tidal volume and spontaneous eye opening, patients were assessed for sustained head lift for 5 seconds and sustained hand grip. Time of extubation was noted.

At the end of surgery, patients were observed for recovery characteristics such as time required for extubation, time to follow verbal command, time to BIS 80 and time to achieve modified Aldrete score ≥9. Ramsay Sedation Scale (RSS) score at 5 minutes and 30 minutes was observed post-operatively. Peri-operative complications like nausea, vomiting, hypotension, hypertension, bradycardia, tachycardia, hypoxia, arrhythmias if present were noted.

Statical Analysis

Sample size calculation was done using G-power software with power calculation based on two-sided test with power of 0.80 and the significant level $\alpha = 0.05$ considering mean maintenance dose of propofol for group M as 180.34 ± 29.63 mg and for group D as 155.60 ± 34.63 mg as per previously published study. [16] The calculated minimum required sample size was 56 with 28 in each group.

Data collected were expressed as a mean ± SD. Quantitative variables were compared by student `t-test' and qualitative variables were compared using chi-square test. *P*-value <0.05 was considered statistically significant. *P*-value >0.05 was considered statistically non-significant. The analysis was done using EPI software (version 3.01).

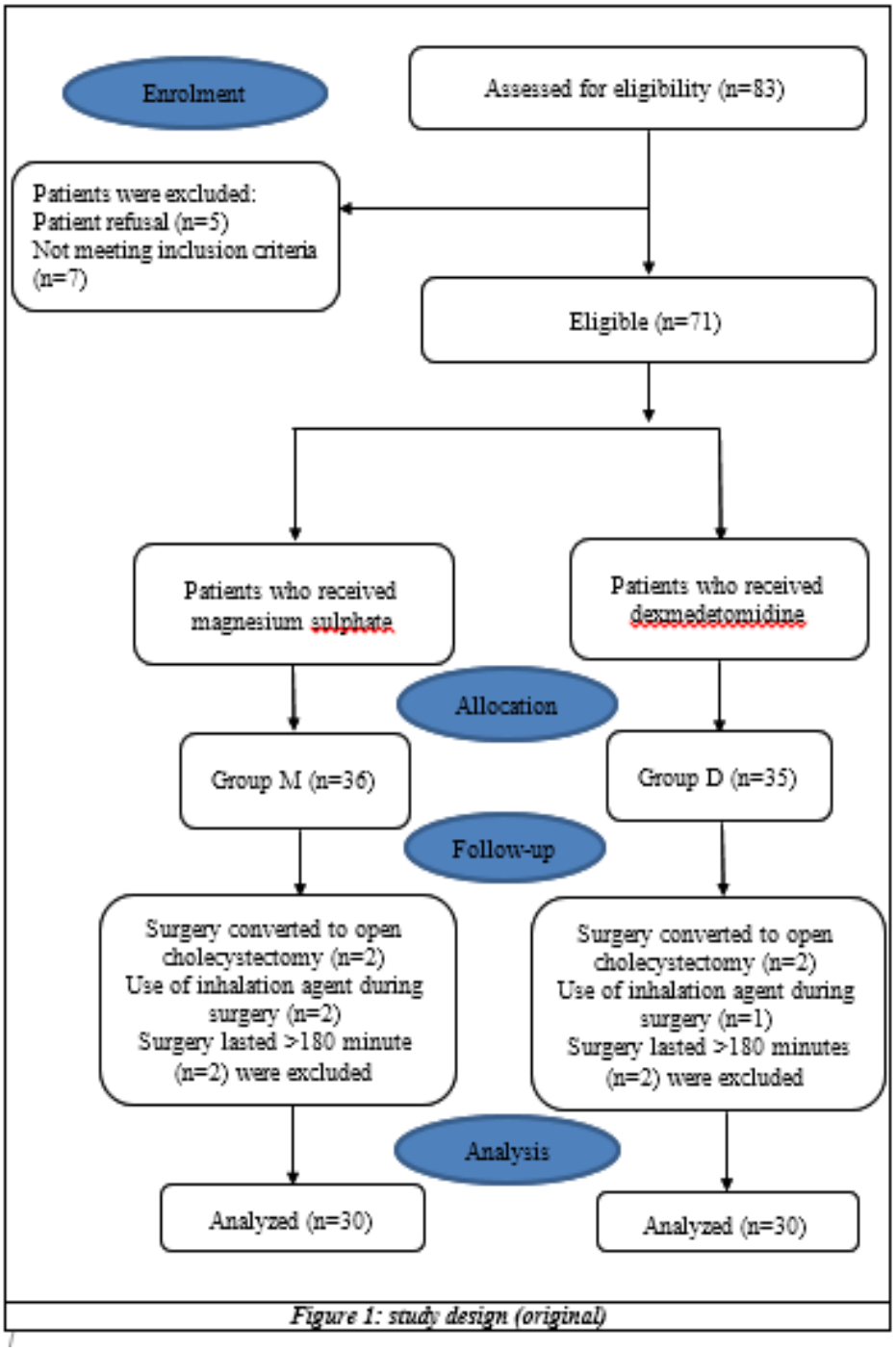

Figure 1: study design (original)

RESULTS

We included total of 30 patients each to magnesium and dexmedetomidine group. No significant difference was found in demographic data between both groups. The majority of patients were females.[Table 1]

Characteristics	**Group M (n=30)**	**Group D (n=30)**	**p-value**
Age (years)	38.23 ± 11.59	40.9 ± 10.62	0.35
Gender (M: F)	3:27	2:28	0.64
BMI (kg/m^2)	23.28 ± 3.59	23.02 ± 3.50	0.77
ASA PS (II: III)	16:14	15:15	0.79
Duration of surgery (hour)	1.98 ± 0.5	1.97 ± 0.56	0.93

Table 1: Demographic characteristics as mean±SD or ratio

The average induction and maintenance dose requirement of propofol was significantly reduced in group D compared to group M (P=0.002) (P<0.001). [Table 2]

Propofol requirement	**Group M (n=30)**	**Group D (n=30)**	**p – value**
	Mean ± SD	**Mean ± SD**	
Induction dose (mg/kg)	2.26 ± 0.21	2.06 ± 0.26	0.002
Maintenance dose (mg/kg/h)	5.57 ± 0.53	4.36 ± 0.62	<0.001

Table 2: Intra-operative propofol requirements

After reversal time required for extubation, time required to follow verbal command, time to achieve BIS value 80 and time required to achieve modified Aldrete Score of ≥9 was significantly less in group M compared to group D (P<0.05).
RSS score at 5-minute and 30-minute post-extubation was less in group M, the difference was statistically highly significant (P=0.0005) (P=0.035). [Table 3]

	Group M	**Group D**	**p- value**
Recovery profile (time in minutes)	**Mean ± SD**	**Mean ± SD**	
Time for extubation	4.83 ± 2.29	6.3 ± 3.16	0.04
Time to follow verbal command	5.03 ± 2.36	6.53 ± 3.31	0.04
Time to achieve BIS 80	6 ± 2.65	9.46 ± 4.03	<0.001
Time for modified Aldrete Score ≥9	6.87 ± 2.51	11.6 ± 4.67	<0.001
RSS Score			
After 5 minutes	3.23 ± 0.43	3.67 ± 0.47	0.0005
After 30 minutes	1.9 ± 0.30	2.13 ± 0.50	0.035

Table 3: Recovery profile and post-operative sedation

Baseline mean heart rate (MHR) and mean arterial pressure (MAP) were comparable in both the groups (P>0.05). A significant decrease in mean heart rate in both the groups compared to baseline values throughout the observation period (P<0.05) except 1 minute after intubation in group M (P=0.72). On intergroup comparison, the mean heart rate was comparable in both the groups throughout the surgery (P>0.05) except at 60 minutes to 90 minutes where it was found significantly reduced in group D compared to group M (P<0.05). [Figure 2]

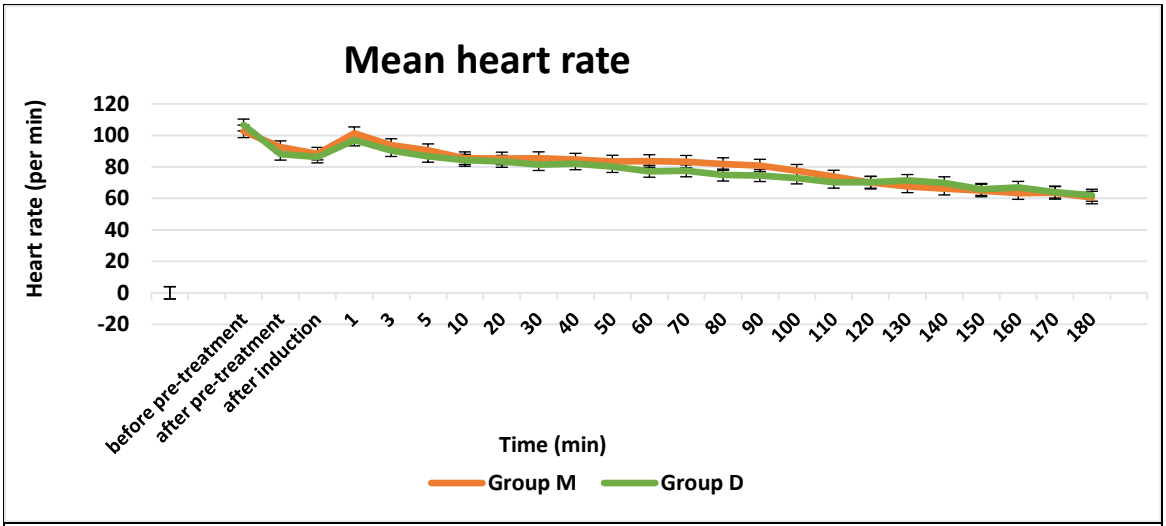

Figure 2: Intra-operative mean heart rate (MHR) variations

A significant decrease in MAP in both the groups from the baseline values throughout the observation period (P<0.05) except at 1 minute and 3 minutes after intubation in group M (P>0.05) & at 1 minute after intubation in group D (P>0.05). On inter-group comparision, mean arterial pressure was significantly reduced after pre-treatment, after induction, at 20 minutes, 30 minutes, 50 minutes, 100 minutes and 120 minutes intra-operatively in group M compared to group D (P<0.05). [Figure 3]

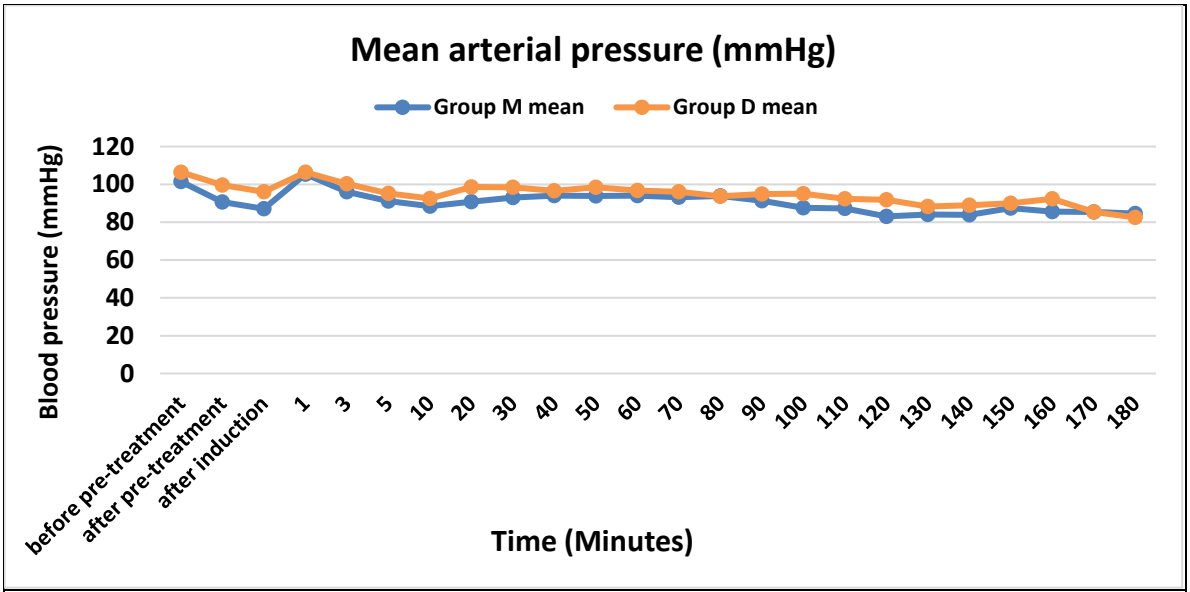

Figure 3: Intra-operative MAP variations (mean±SD)

Intra-operatively and post-operatively, none of the patients had any side-effects like hypotension, tachycardia, hypertension, bradycardia, excessive sedation, loss of knee jerk, desaturation or respiratory depression. Only 3 patients in group M and 1 patient in group D had nausea and vomiting.

DISCUSSION

Balanced general anesthesia with adjuvants like dexmedetomidine and magnesium sulfate reduces anesthetic consumption, provides good haemodynamic stability, decreases peri-operative complications and maintains adequate depth of anesthesia when used with BIS monitoring.[13]

Magnesium sulphate produces analgesia and sedation by inhibiting calcium influx, NMDA antagonism[14] and prevention of NMDA signalling in voltage-dependent manner and reducing the release of catecholamines.[24] Magnesium decreases acetylcholine secretion at pre-synaptic terminal in CNS thus reducing excitability of nerves.[2,23] Dexmedetomidine decreases neuronal activity and enhances vagal activity by activation of central α-2 receptors located in postsynaptic terminals in CNS leading to reduction in requirement of anesthetic agents. [7] Thus, both causes reduction in anesthetic requirement. BIS monitoring is an objective and qualitative guide to prevent intra-operative awareness.[4] By titrating propofol infusion according to BIS values (40 to 60), we can optimize dose of anesthetic agents accurately, avoid overdose of the anesthetic agent and decrease incidence of intraoperative awareness with use of magnesium sulphate and dexmedetomidine as adjuvants along with BIS monitoring reduces intra-operative propofol requirement.[2,21]

We observed that dexmedetomidine 1 µg/kg loading dose with intra-operative infusion at 0.5 µg/kg/h compared to magnesium sulphate 40 mg/kg loading dose with intra-operative infusion at 10 mg/kg/h causes significant reduction in mean induction and maintenance dose of propofol (P<0.05). Similarly, **Hesameddin Modir et al (2018)**[15], **Chiteshwar Walia et al (2018)** (P=0.013)[2] and **Vinit K. Srivastava et al (2016)**[16] observed that total propofol dose requirement for induction and maintenance of anesthesia was highly significantly reduced in dexmedetomidine group compared to magnesium group (P<0.001).

BIS-guided general anesthesia has reduced doses and exposure time,[21] causing a reduction in neurotoxicity and faster recovery from anesthesia with reduced risk of post-operative cognitive dysfunction and delirium during initial post-operative period.[2,27,28]

Recovery from anesthesia in the form of time required for extubation, to follow verbal command, to achieve BIS value 80 and to achieve modified Aldrete score of ≥9 was significantly prolonged with dexmedetomidine compared to magnesium sulphate (P<0.05). Similar findings were observed in previous studies. **Ahmed Mohammed Sonbol (2022)** [17] and **Hesameddin Modir et al (2018)**[15] observed that extubation time was significantly prolonged in dexmetetomidine group compared to magnesium sulphate group (P<0.001). **Hesameddin Modir et al (2018)** [15] (P<0.001) **and Mohammed Abdelsalam Menshawi et al (2022)[14]** (P<0.05) and **Alka Chhabra et al (2019)** [18] (P<0.001) observed that time to achieve modified Aldrete score ≥9 which was significantly prolonged in dexmetetomidine group compared to magnesium sulphate group.

Dexmedetomidine has a physiological sleep like phenomenon on EEG and an arousable sedation by acting on α-2 adrenoreceptor in locus coeruleus in brainstem leading to decrease in sympathetic outflow and increases parasympathetic outflow without causing respiratory depression or failure of ventilatory drive.[2,27] Whereas with the use of magnesium sulphate, narcotic trend has been demonstrated but with lower RSS scores leading to early discharge from PACU.[2,9] In our study, A significantly higher levels of post-operative sedation (**Ramsay sedation Scale score)** was observed in dexmetetomidine group in comparison to magnesium sulphate group (P<0.001) (P<0.05). **Mohammed Abdelsalam Menshawi et al (2022),**[14] **Alka Chhabra et al (2019)** [18] and **Chiteshwar Walia et al (2018)**[2] also observed that post-operative RSS Score was significantly higher in dexmedetomidine group compared to magnesium sulphate group respectively (P<0.05) (P=0.000) (P<0.001).

Magnesium sulphate and dexmedetomidine prevents sympathetic responses related to surgery and laryngoscopy. [20,22] Magnesium decreases heart rate and blood pressure by directly acting on adrenal gland and adrenergic nerve terminals leading to blockage of release of catecholamines [20] and indirectly through negative feedback system.[2,24,25] It also decreases vasopressin-stimulated vasoconstriction and acts directly on blood vessels leading to vasodilation.[2] Dexmedetomidine is a selective α-2 receptors (α2: α1- 1620:1) located on vascular pre-junctional terminals. It inhibits the release of nor-epinephrine through negative feedback mechanism leading to decrease in sympathetic outflow which results in decrease in blood pressure.[20] It also has a vagomimetic and peripheral ganglion blocking action leading to decrease in heart rate and blood pressure.[2]

In our study, baseline MHR and MAP were comparable in both the groups (P=0.31) (P=0.06). MHR and MAP were significantly decreaseed from baseline values with both magnesium sulphate and dexmedetomidine (P<0.05) except immediately after intubation when it was comparable with baseline (P>0.05). On intergroup comparison, MHR in dexmedetomidine group significantly reduced from 60-90 minutes (P<0.05) whereas MAP in magnesium sulphate group was significantly reduced at 20,30,50, 100 and 120 minutes intra-operatively (P<0.05). Similarly, **Pierre Zarif et al (2016)**[1] **and Chiteshwar Walia et al (2018)**[2] found a comparable decrease in MHR in both groups from baseline value (P>0.05). **Passaint Fahim Hassan et al (2022)**[7] also observed a significant decrease in mean heart rate in both groups from baseline values which was comparable in both groups up to 30 minutes (P>0.05) thereafter fall in heart rate was significant in group D (P<0.05). **Hesameddin Modir et al (2018)**[15] observed that no significant difference between two groups in blood pressure from post induction to 60 minutes post operation (P>0.05). **Pierre Zarif et al (2016)**[1] found that both study drugs have provided better blood pressure stabilization with MAP was not significantly different in between both the groups (P>0.05). In contrast**, Chiteshwar Walia et al (2018)**[2] observed that post-infusion and post-intubation MAP values were non-significantly lower in dexmedetomidine group compared to magnesium sulphate group.

In our study, none of the patients had any side-effects intra-operatively. Post-operatively, only 3 patients in group M and 1 patient in group D had nausea and vomiting. **Alka Chhabra et al (2019)**[18] observed that intra- and post-operative adverse effects were not significant in both the groups

(*P*>0.05). **Devyani J. Desai et al (2019)**[19] observed no incidence whereas **Chiteshwar Walia et al (2018)**[2] found similar incidence of complications in both groups.

The strength of the present study is that all intra-operative factors were kept constant (such as duration and position of surgery, induction and maintenance of anesthesia, analgesia and mode of ventilation) for accurate assessment as well all the readings were recorded by single observer to minimize inter-observer bias. There are some limitations to our study that we did not measure Serum magnesium level, randomization and blinding were not done, selection bias cannot be eliminated and there was no control group to compare effect of individual drug. This study offers several advantages like reduced anesthetic requirement, better attenuation of stress response, cost-effective as inhalation agents are avoided, prevention of intra-operative awareness, maintenance of anesthesia with intravenous anesthetic agents leading to decrease environmental pollution caused by inhalation agents. For future prospect, further studies can be done with different doses of magnesium sulphate and dexmedetomidine to identify most effective dose.

CONCLUSION

We have concluded that magnesium sulphate and dexmedetomidine both can be safely co-administered with propofol under balanced anesthesia. Dexmedetomidine had better propofol sparing effect whereas magnesium sulphate had shorter recovery profile and lesser post-operative sedation. Both agents have provided good hemodynamic stability with minimal side effects. Balanced anesthesia with adjuvants like dexmedetomidine and magnesium sulphate along with intravenous anesthetics is cost effective and prevents environmental pollution due to inhalational agents.

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