

Comparison of Intravenous Magnesium Sulphate and Dexmedetomidine for Attenuation of Cardiovascular Stress Response during Laryngoscopy and Endotracheal Intubation: A Double-blinded Randomised Clinical Trial

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ABSTRACT

Introduction: Laryngoscopy and intubation provokes sympathetic tachycardia and hypertension. These transient changes may precipitate adverse effects in patients with undiagnosed comorbidities. Magnesium sulphate and dexmedetomidine attenuate this response, but direct comparisons at clinical doses remain limited.

Aim: To compare magnesium sulphate 30 mg/kg and dexmedetomidine 1 µg/kg for attenuating cardiovascular responses to laryngoscopy and endotracheal intubation.

Materials and Methods: This double-blind, randomised clinical trial was conducted at Shija Hospitals and Research Institute, Imphal, Manipur, India from May 2021 to May 2022. A total of 80 adults with American Society of Anaesthesiologists physical status (ASA PS) I or II were randomly allocated equally to receive intravenous magnesium sulphate (30 mg/kg) or dexmedetomidine (1 µg/kg), infused over 10 minutes, beginning 15 minutes before intubation. The parameters assessed included demographic characteristics, haemodynamic variables including Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP), recorded at baseline, after drug infusion, after induction and at 1, 5, 10 and 15 minutes after intubation, and postoperative adverse events categorical variables were analysed using the Chi-square test, while

quantitative variables were compared using Student's t-test. The p-value <0.05 was considered statistically significant.

Results: The two groups were comparable at baseline. The mean age was 34.80±10.16 years in Group A and 38.55±10.77 years in Group B (p-value =0.113). Group A included 19 males and 21 females, compared with 18 males and 22 females in Group B. The distribution of ASA PS was also similar between groups, with 29 and 31 patients classified as ASA PS I and 11 and nine patients as ASA PS II in Groups A and B, respectively. HR was lower with dexmedetomidine at all postinduction time points at T2 (p-value=0.004), T3 (p-value=0.036), T4 (p-value=0.043), T5 (p-value=0.002). At 15 minutes, Group A versus Group B values were: HR, 78.70±16.50 versus 68.83±11.37 beats/min (p-value=0.003); SBP, 116.15±13.77 versus 114.05±17.61 mmHg (p-value=0.550); DBP, 72.50±14.60 versus 72.65±13.55 mmHg (p-value=0.962); and MAP, 87.20±19.67 versus 86.48±14.00 mmHg (p-value=0.851). No clinically significant bradycardia, hypotension or postoperative adverse effects occurred.

Conclusion: Both drugs effectively attenuated the haemodynamic response to intubation. Dexmedetomidine provided better control of HR than magnesium sulphate. Blood Pressure (BP) responses were comparable between the two groups. Neither drug caused clinically significant adverse effects.

Keywords: Adrenergic alpha-2 receptor agonists, Blood pressure, Haemodynamics, Heart rate

INTRODUCTION

Endotracheal intubation refers to the insertion of a tube into the trachea through the oral or nasal route. The process of laryngoscopy and intubation causes a pressor response associated with intense sympathetic activity which is marked by tachycardia, hypertension and arrhythmias [1]. This cardiovascular response to intubation is a reflex phenomenon and was first described by Reid LC and Brace DE in 1940 [2]. The vagus (X) as well as the glossopharyngeal nerve (IX), which transmit afferent inputs from the epiglottis and infraglottic area to stimulate the vasomotor centre, mediate the response. This triggers peripheral sympathetic adrenal response with release of adrenaline and noradrenaline [3].

In adults, this intense sympathetic response occurs within five seconds of laryngoscopy, reaches maximum at one minute after intubation and lasts for five to 10 minutes [4]. SBP typically rises by 25 to 50 mmHg. Such transient but marked increases in HR and BP

may be tolerated by ASA PS I patients; but in patients with limited myocardial reserve - tachycardia and hypertension may result in myocardial ischaemia, myocardial infarction, arrhythmias and could also precipitate cardiac failure [5]. The hypertensive response may also produce adverse effects in patients with raised intracranial pressure, intraocular pressure, pheochromocytoma and vascular lesions such as intracranial arteriovenous malformations or aortic aneurysms [6].

Various methods have been used to attenuate the haemodynamic stress response, i.e., (1) deepening the plane of anaesthesia with inhalational and intravenous anaesthetic agents; (2) decreasing the duration of laryngoscopy to less than 15 seconds; and (3) using drugs such as lidocaine, sedatives, vasoactive drugs, opioids, barbiturates, benzodiazepines, beta-blockers, calcium channel blockers and vasodilators [7]. But none of these strategies have been able to achieve ideal outcomes from all perspectives.

Magnesium sulphate reduces sympathetic outflow, inhibits N-methyl-D-aspartate receptors and decreases catecholamine release from the adrenal medulla and adrenergic nerve endings [8]. Dexmedetomidine is a highly selective alpha-2 adrenergic receptor agonist that decreases norepinephrine release at the neuroeffector junction and inhibits sympathetic neurotransmission, thereby reducing HR and BP [9].

Although several pharmacological approaches have been evaluated, a limited number of recent studies have directly compared intravenous magnesium sulphate and dexmedetomidine at clinically relevant doses in patients undergoing elective surgery [6,10-12]. Other studies have compared one or both agents with clonidine, fentanyl, lignocaine, esmolol, labetalol, placebo or different routes of dexmedetomidine administration [13-18].

Interindividual variability in response to anaesthetic and adjuvant drugs is well recognised. ADRA2A genotype contributes substantially to interindividual variability in the cardiovascular response to dexmedetomidine, which affects the BP response [19] and, in a Chinese Han population receiving 1 µg/kg, HR response [20]. A direct comparison between ethnic groups found large interindividual variability but no significant between-ethnicity difference [21], which indicated that regional response profiles cannot be assumed and require empirical evaluation [19-21].

Published direct-comparison data from North-East India remain limited, which restricts assessment of whether findings from other clinical settings are reproducible in this regional population [6,10-12]. North-East Indian populations occupy a distinguishable position within India's complex ancestral structure [22], and regional anthropometric context is relevant when interpreting perioperative data. The present study therefore evaluated intravenous magnesium sulphate and dexmedetomidine within a standardised anaesthetic protocol at a tertiary hospital in Imphal, Manipur, India. To the authors' knowledge, this represents the first direct comparison of these two agents in a North-East Indian surgical population.

The study aimed to compare the efficacy of intravenous magnesium sulphate 30 mg/kg and dexmedetomidine 1 µg/kg in attenuating the cardiovascular stress response to laryngoscopy and endotracheal intubation.

MATERIALS AND METHODS

This randomised, double-blind study was conducted in the Department of Anaesthesiology and Critical Care, Shija Hospitals and Research Institute, Imphal, Manipur, India from May 2021 to May 2022. The study was approved by the Institutional Ethics Committee and Scientific Research Committee of Shija Hospitals and Research Institute (Ref. No. SHRI/c/h/DNB/07/2021, dated 22 April 2021). Written informed consent was obtained from every participant before enrolment. The study was not registered in a clinical trial registry.

Sample size: The sample size was estimated with reference to MAP values reported by Panchal M et al., for dexmedetomidine and magnesium sulphate (94.52±16.07 and 104.70±16.20 mmHg, respectively) [10]. For a two-sided alpha error of 0.05 and 80% power, the formula for comparison of two independent means

$$n = \{[Z\alpha/2 + Z\beta]^2 \times (SD1^2 + SD2^2)\} / (\mu1 - \mu2)^2$$

Substitution gave $n = \{(1.96 + 0.84)^2 \times (16.07^2 + 16.20^2)\} / (104.70 - 94.52)^2 = 39.39$ participants per group.

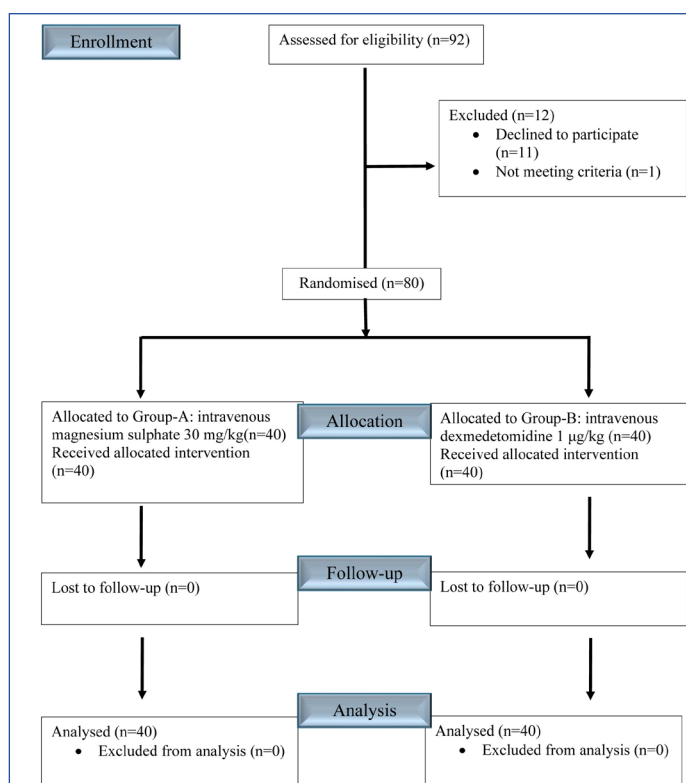
This was rounded to 40 participants per group, giving a total sample of 80.

Inclusion criteria: Patients aged 18-60 years with ASA PS I or II, weight 40-70 kg, Body Mass Index (BMI) ≤29.9 kg/m², Mallampati grade I or II, and a duration of laryngoscopy and endotracheal

intubation of <30 seconds who provided written consent were included in the study.

Exclusion criteria: Patients with ASA PS III or higher, age <18 or >60 years, Mallampati grade III or higher, anticipated difficult intubation, pregnancy or lactation, coronary artery disease, valvular heart disease, ischaemic heart disease, cardiac conduction abnormalities, uncontrolled diabetes mellitus or hypertension, HR <60 beats/min, SBP <100 mmHg, a history of drug reactions, BMI ≥30 kg/m² or refusal to participate were excluded from the study.

Randomisation: The allocation sequence was generated using randomizer.org, which performed simple randomisation in a 1:1 ratio. Allocation was concealed using serially numbered sealed envelopes prepared by an anaesthesiologist who was not otherwise involved in the study. Participants were enrolled by the DNB trainee anaesthesiology, and assignment followed the sequence contained in the envelopes. The study drugs were prepared and labelled by the uninvolved anaesthesiologist, diluted to the same volume of 100 mL and infused over 10 minutes. Participants and the anaesthesiologist recording haemodynamic variables were blinded to group allocation. The data analyst was aware of group allocation. The anaesthetic technique, monitoring and measurement time points were standardised for both groups [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram of participant enrolment, allocation, follow-up and analysis.

Group A received intravenous magnesium sulphate 30 mg/kg, and Group B received intravenous dexmedetomidine 1 µg/kg. Each drug was diluted in 100 mL normal saline and infused over 10 minutes, beginning 15 minutes before intubation. The selected magnesium sulphate and dexmedetomidine doses were based on Panda NB et al., and Sagioglu AE et al., respectively [23,24].

After a 5-minute stabilisation period, baseline haemodynamic variables and continuous electrocardiography were recorded. Patients received ondansetron 4 mg and butorphanol 1 mg intravenously, followed by preoxygenation with 100% oxygen for three minutes, propofol 2 mg/kg intravenously, and succinylcholine 1.5 mg/kg intravenously. The trachea was intubated with an appropriately sized cuffed endotracheal tube, and anaesthesia was

maintained with sevoflurane, air and oxygen, and atracurium. The co-primary outcome measures were between-group differences in HR, SBP, DBP and MAP after induction and intubation. Measurements were recorded at baseline (T0), after completion of drug infusion (T1), one minute after induction (T2), and 1, 5, 10 and 15 minutes after intubation (T3, T4, T5 and T6, respectively); T0 and T1 served as reference measurements. After extubation, patients were observed in the postoperative care unit for bradycardia, hypotension, nausea, vomiting, difficulty in breathing, excessive sedation and other untoward effects related to the study drugs or anaesthesia. These safety events were described separately.

STATISTICAL ANALYSIS

Data were entered using Epi Info version 3 and analysed using Statistical Package for the Social Sciences (SPSS) version 28.0, as reported by the investigators. Categorical variables were compared using the Chi-square test, while quantitative variables were compared using the Student's t-test. A p-value <0.05 was considered statistically significant.

RESULTS

The groups were comparable in age, weight, height, BMI, sex distribution and ASA PS (all p-value >0.05) [Table/Fig-2].

Parameter	Group A (n=40)	Group B (n=40)	Test statistic	p-value
Age (years)	34.80±10.16	38.55±10.77	t=1.60	0.113
Weight (kg)	58.88±8.43	58.68±9.17	t=0.10	0.919
Height (cm)	158.05±4.37	158.45±3.77	t=0.44	0.662
BMI (kg/m ²)	23.51±2.84	23.32±3.25	t=0.28	0.778
Male	19 (47.5)	18 (45.0)	$\chi^2=0.000$	1.000
Female	21 (52.5)	22 (55.0)		
ASA physical status I	29 (72.5)	31 (77.5)	$\chi^2=0.056$	0.797
ASA physical status II	11 (27.5)	9 (22.5)		

[Table/Fig-2]: Comparison of demographic characteristics between Group A and Group B.

Student's t-test was used for quantitative variables, and the Chi-square test with Yates' continuity correction was used for gender and ASA physical status.

HR did not differ significantly between the groups at baseline (p=0.891) or after completion of the study-drug infusion (p=0.064). From one minute after induction (T2) through 15 minutes after intubation (T6), mean HR was significantly lower in Group B than in Group A. At T6, mean HR was 78.70±16.50 beats/min in Group A and 68.83±11.37 beats/min in Group B (p-value=0.003) [Table/Fig-3].

Time point	Group A (n=40)	Group B (n=40)	p-value
T0 (Baseline)	89.00±16.31	89.45±12.74	0.891
T1 (After drug infusion)	88.13±18.03	81.60±12.58	0.064
T2 (1 min after induction)	84.73±14.76	76.40±10.41	0.004*
T3 (1 min after intubation)	80.23±13.15	74.40±11.21	0.036*
T4 (5 min after intubation)	77.35±12.33	72.15±10.19	0.043*
T5 (10 min after intubation)	76.30±11.57	68.83±8.81	0.002*
T6 (15 min after intubation)	78.70±16.50	68.83±11.37	0.003*

[Table/Fig-3]: Comparison of Heart Rate (HR) between Group A and Group B at predefined time points.

Values were compared using the Student's t-test

There were no statistically significant between-group differences in SBP, DBP or MAP at any recorded time point (all p-value >0.05) [Table/Fig-4].

No episode of clinically significant bradycardia requiring pharmacological intervention or significant hypotension occurred in either group. No patient experienced postoperative nausea, vomiting, difficulty in breathing or excessive sedation.

Measure	Time point	Group A (n=40)	Group B (n=40)	p-value
SBP (mmHg)	T0	134.15±15.02	132.53±14.33	0.623
	T1	125.93±21.62	127.80±14.05	0.647
	T2	120.65±14.38	117.70±14.95	0.371
	T3	119.16±12.56	116.68±16.53	0.452
	T4	116.50±12.88	115.00±13.20	0.608
	T5	117.38±12.63	114.98±12.57	0.396
	T6	116.15±13.77	114.05±17.61	0.550
DBP (mmHg)	T0	79.32±9.57	78.68±11.10	0.783
	T1	79.23±10.73	76.33±10.99	0.236
	T2	75.00±11.68	70.98±13.58	0.159
	T3	73.50±11.31	70.68±10.21	0.232
	T4	72.40±12.31	70.05±10.47	0.361
	T5	72.00±13.82	70.90±9.91	0.683
	T6	72.50±14.60	72.65±13.55	0.962
MAP (mmHg)	T0	97.60±9.57	96.60±11.71	0.677
	T1	94.79±11.03	93.50±11.18	0.620
	T2	90.20±19.75	86.50±12.82	0.323
	T3	88.70±17.66	86.00±11.46	0.418
	T4	87.10±18.44	85.58±10.68	0.653
	T5	86.10±19.77	85.60±10.25	0.887
	T6	87.20±19.67	86.48±14.00	0.851

[Table/Fig-4]: Comparison of Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and Mean Arterial Pressure (MAP) between Group A and Group B at predefined time points.

Values were compared using the Student's t-test. SBP: Systolic blood pressure; DBP: Diastolic blood pressure; MAP: Mean arterial pressure; T0: Baseline; T1: After drug infusion; T2: 1 minute after induction; T3-T6: 1, 5, 10 and 15 minutes after intubation, respectively

DISCUSSION

The present study showed that both intravenous magnesium sulphate 30 mg/kg and dexmedetomidine 1 µg/kg attenuated the haemodynamic response to laryngoscopy and endotracheal intubation. The groups were comparable in baseline demographic characteristics. HR was significantly lower in the dexmedetomidine group from one minute after induction through 15 minutes after intubation; at 15 minutes, the values were 68.83±11.37 beats/min in Group B and 78.70±16.50 beats/min in Group A (p-value=0.003). SBP, DBP and MAP did not differ significantly between the groups at any recorded time point, and no clinically significant bradycardia, hypotension or postoperative adverse effects were observed.

The greater attenuation of HR with dexmedetomidine was consistent with the direct comparisons reported by Chaithanya K et al., Panchal M et al., Ghodki DP and Sawle VM, and Mohan A and Saha G, in which dexmedetomidine provided better HR control than magnesium sulphate [6,10-12]. Shukla S et al., also demonstrated effective attenuation of the intubation response with dexmedetomidine when compared with fentanyl and magnesium sulphate [14]. In the present study, the between-group difference was evident at one minute after induction (84.73±14.76 versus 76.40±10.41 beats/min; p-value=0.004) and persisted at 1, 5, 10 and 15 minutes after intubation, indicating a more consistent chronotropic effect with dexmedetomidine.

In contrast to the HR findings, BP control was comparable between the two groups. At 15 minutes after intubation, SBP was 116.15±13.77 versus 114.05±17.61 mmHg (p-value=0.550), DBP was 72.50±14.60 versus 72.65±13.55 mmHg (p-value=0.962), and MAP was 87.20±19.67 versus 86.48±14.00 mmHg (p-value=0.851) in Groups A and B, respectively. Comparable BP responses have also been reported by Chaithanya K et al., Panchal M et al., and Ghodki DP and Sawle VM [6,10,11]. Borah B et al., reported a greater overall haemodynamic advantage with dexmedetomidine [13], while

studies using fentanyl, labetalol and alternative dexmedetomidine regimens have also produced differing magnitudes of attenuation [14,17,18]. These variations may reflect differences in comparator drugs, dose, timing of administration and background anaesthetic technique.

The difference in HR control is pharmacologically plausible. Dexmedetomidine is a highly selective alpha-2 adrenergic agonist that reduces norepinephrine release and sympathetic neurotransmission [9,25], whereas magnesium sulphate attenuates the pressor response through N-methyl-D-aspartate receptor antagonism, reduced sympathetic outflow and inhibition of catecholamine release [8]. The dexmedetomidine and magnesium sulphate doses were selected from previous dose-comparison studies [23,24] to provide haemodynamic attenuation while limiting dose-related hypotension and bradycardia. Although HR was lower with dexmedetomidine in the present study, no participant developed clinically significant bradycardia requiring pharmacological treatment, and no significant hypotension occurred in either group.

These findings have practical relevance for ASA PS I and II adults undergoing elective surgery. Dexmedetomidine may be considered when attenuation of peri-intubation tachycardia is a clinical priority, whereas magnesium sulphate provided comparable BP control and remained an effective alternative within the studied protocol. Pharmacogenetic studies demonstrate ADRA2A-related variability in the cardiovascular response to dexmedetomidine [20,21], but a direct ethnic comparison found no significant between-group difference [19]; Indian populations have a complex regional ancestral structure [22]. The present cohort had mean heights of 158.05 and 158.45 cm and mean BMI values of 23.51 and 23.32 kg/m² in Groups A and B, respectively and it characterises the anthropometric context of the North-East Indian study setting. Ethnicity was not recorded or analysed separately; therefore, the findings should be interpreted as regional clinical evidence rather than evidence of an ethnicity-specific pharmacological response. The results should not be extrapolated directly to patients with cardiovascular disease or other high-risk conditions because such patients were excluded. Larger multicentre studies that include higher-risk populations, prospectively record ethnicity, use prespecified safety outcomes, and evaluate clinically important adverse events are required.

Limitation(s)

The study was conducted at a single centre and included 80 patients with ASA PS I or II who were 18-60 years of age. Patients with cardiovascular disease, higher physical status and extremes of age were excluded; therefore, the findings may not be generalisable to higher-risk populations. The data analyst was aware of group allocation, which may have introduced analytical bias. Although all participants had Mallampati grade I or II, the group wise distribution was unavailable in the source records and could not be reconstructed. The sample was also not designed to compare uncommon adverse events.

CONCLUSION(S)

Both intravenous magnesium sulphate 30 mg/kg and dexmedetomidine 1 µg/kg attenuated the haemodynamic response to laryngoscopy and endotracheal intubation. Dexmedetomidine produced significantly lower HRs from one minute after induction through 15 minutes after intubation. SBP, DBP and MAP were comparable between groups, and no clinically significant bradycardia, hypotension or postoperative adverse effects occurred. In ASA physical status I and II adults, dexmedetomidine provided more consistent HR control; larger studies are needed in higher-risk patients.

Authors' contribution: PV- was involved in the conception, data collection and analysis of the study, TDS- was involved in the

manuscript preparation, critical revision and final approval, KM- was involved in conception, analysis and manuscript preparation.

Editorial disclosure: Prospective trial registration was not completed before participant enrolment. The journal recognises the unique clinical value of this data. Henceforth publication is permitted as an exception with transparent disclosure.

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