A comparative evaluation of dexmedetomidine and magnesium sulfate during awake fiber optic orotracheal intubation in patients scheduled for cervical spine surgeries: A prospective study

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ABSTRACT

Background: Fiber optic intubation has become an integral part in management of anticipated difficult airways. Various anesthetic drugs have been used to assist awake fiber optic intubation (AFOI) for producing conscious sedation to provide a calm, cooperative, and responsive patient without respiratory depression for successful awake fibre optic intubation. **Aims and Objectives:** The aim of the present study was to compare the efficacy of dexmedetomidine and magnesium sulfate during awake fiber optic orotracheal intubation in patients scheduled for cervical spine surgeries. **Materials and Methods:** A randomized, prospective, and comparative study design was conducted in 60 patients in JAH group of hospitals. All patients were randomly divided into two groups: Group A (n = 30) patients received dexmedetomidine (1 µg/kg) and Group B (n = 30) patients received magnesium sulfate (40 mg/kg) in 100 ml normal saline over 10 min. The fiber optic orotracheal intubation was performed and primary outcome was level of sedation assessed using Ramsay sedation score. Other parameters of study included cough score and intubation score to compare intubating conditions. The secondary outcomes of study included variations in hemodynamic parameters heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SPO_2 during drug infusion at 2-min interval, immediately after intubation and every 10 min after intubation till 30 min. **Results:** Group A (Dexmedetomidine) had better sedation score, cough score, and intubation score with stable hemodynamic variables than Group B (Magnesium Sulphate) with statistically significant results. **Conclusion:** Patients receiving dexmedetomidine had better sedation providing more optimum conditions for AFOI with stable hemodynamic parameters and lesser adverse effects during the procedure than magnesium sulfate.

Key words: Awake fiber optic intubation; Cervical spine surgery; Dexmedetomidine; Magnesium sulfate

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INTRODUCTION

Airway management is considered as most vital step during any anesthetic procedure for surgery. The conventional laryngoscopy performed for orotracheal intubation in patients with anticipated difficult airway may be challenging even to most trained anesthesiologists. In cases with unstable cervical spine, performing maneuvers such as head tilt and chin lift may be hazardous. The application of rigid cervical collar in these cases further limits the extent of mobility.[1] Induction of general anesthesia with resulting loss of muscle tone and reflexes further adds

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to the complications during the procedure.[2] AFOI is a breakthrough technique for successful intubation in these patients.

However, orotracheal intubation using a fiber optic bronchoscope requires an optimum level of conscious sedation which minimizes awareness during the procedure and provides calm and cooperative patient who is able to follow verbal commands allowing opening of obstructed airway in case of any obstruction.[3] Adequate sedation along with topical anesthesia of the airway may minimize undue discomfort, anxiety, and sympathetic surge during AFOI.[4] Numerous sedative drugs, including benzodiazepines, opioids, ketamine, propofol, and dexmedetomidine, have been used alone or in combination to bring the state of conscious sedation as an adjunct to facilitate AFOI.[3,5] Dexmedetomidine is a potent selective alpha-2 adrenergic agonist having sedative, analgesic, anxiolytic, and anti-sialagogue properties with minimal respiratory depression.[4] Magnesium plays an important role in a multitude of physiologic process. Its mechanism of blocking the calcium channels and N-methyl-D-aspartate receptors has been of great use in anesthesia. It also has potent analgesic, anticonvulsant, and sedative properties with cardiac and neurological protective effects.[6] The present study was done to assess and compare the level of sedation achieved during awake fiber optic intubation (AFOI) with dexmedetomidine and magnesium sulfate in patients undergoing cervical spine surgeries. The study also includes assessment of intubating conditions and hemodynamic changes during the procedure among the two groups.

Aims and objectives

The aim of the study was to evaluate the efficacy of dexmedetomidine and magnesium sulfate for level of sedation, intubating conditions, and hemodynamic changes during awake fiber optic orotracheal intubation in adult patients scheduled for cervical spine surgeries.

Primary objectives

The primary objective of the study was to compare the level of sedation with dexmedetomidine and magnesium sulfate using Ramsay sedation score during AFOI.

Secondary objectives

The secondary objectives of the study are as follows:

1. To assess the intubating conditions by cough score and intubation score
2. To compare the effect dexmedetomidine and magnesium sulphate on pulse rate, blood pressure and oxygen saturation
3. To study the adverse effects and complications, if any.

MATERIALS AND METHODS

The present study was carried out on 60 patients scheduled for cervical spine surgeries of ASA Grade 1 and 2 between age group 18 and 65 years in Department of Anaesthesiology, J.A. Group of Hospitals of G.R. Medical college, Gwalior (M.P.) after approval from the Institutional Ethics Committee during January 2021–June 2022 after getting written informed consent from the patients. The study was conducted in randomized, prospective, and double-blind manner.

On the basis of the previous study,[7] estimated sample size for two sample comparison of mean test with assumption: 95% level of confidence and 80% power of test; mean±SD was (1.97±0.53) and (2.43±0.66) and the sample size was calculated as 27 increased to 30 for each group.

$$n = \frac{\left(S1^2 + S2^2\right)\left(Z_{\alpha/2} + Z_{1-\beta}\right)^2}{\left(x_1 - x_2\right)^2}$$

Inclusion criteria

The following criteria were included in the study:

- Patients who gave consent to participate in study
- Patients between 18 and 65 years of age
- ASA physical Grade I–II
- Patients undergoing elective cervical spine surgeries.

Exclusion criteria

The following criteria were excluded from the study:

- Patient's refusal
- ASA Grade III and IV
- Heart rate <50 bpm and Systolic blood pressure (SBP) <90 mmHg
- Patients with other associated facial, skull base and/or mandibular fractures.

Sixty patients fulfilling the eligibility criteria of ASA Grade I and II of either sex were randomly divided into two groups of 30 patients each by sealed envelope technique where patients were asked to select an envelope containing the group allocated to them. The study was carried out in a double blinded fashion. The patients on whom study was conducted were blinded as they did not know what drug they were administered. The drugs for infusion were prepared by an anesthesiologist who was not involved in the study and hence the investigator who conducted the study was also blinded.

- Group "A" (n=30): Patients who received an intravenous infusion of dexmedetomidine (1 μg/kg) in 100 ml normal saline 10 min before induction
- Group "B" (n=30): Patients who received an intravenous infusion of magnesium sulfate (40 mg/kg) in 100 ml normal saline 10 min before induction.

After taking thorough history and detailed general examination, complete procedure was explained to the patients. Overnight fasting was ensured before procedure. After pre-anesthetic evaluation, patient was shifted in pre-operative room and Inj. glycopyrrolate 0.2 mg intramuscular 45 min before surgery was given. All patients were nebulized with 3 ml of 4% lignocaine through nebulizer.

On arrival of the patient in the operation room, an intravenous access with 18 G cannula was established and crystalloid infusion was started. All the standard vital parameters were recorded (Pulse rate, non-invasive blood pressure (SBP, diastolic blood pressure [DBP], mean arterial pressure [MAP]), ECG, temperature, $ETCO_2$, and SPO_2).

Inj midazolam 0.05 mg/kg iv was given followed by topicalization of the airway with lignocaine10% spray up to a maximum dose of 5 mg/kg based on total lignocaine dose calculated as per weight of the patient. An intravenous infusion of 1 μg/kg dexmedetomidine in normal saline in Group A and infusion of 40 mg/kg magnesium sulfate in normal saline in Group B was given over 10 min.

On completion of the drug infusion, level of sedation achieved was evaluated by Ramsay sedation scale (RSS)[8] (1 – anxious and agitated, 2 – cooperative and oriented, 3 – respond to commands only, 4 – exhibit brisk response to light glabellar tap or loud auditory stimulus,5 – exhibit sluggish response to light glabellar tap or loud auditory stimulus, and 6 – unresponsive). The fiber optic bronchoscope loaded with an appropriately sized endotracheal tube was kept prepared. With adequate level of sedation (RSS≥2) achieved, mouth gag was applied to the patient and fiber optic orotracheal intubation was performed using AMBU Scope™ 4 Broncho Regular 5.0/2.2 Flexible Endoscope. Once the vocal cords were visualized, 2% of xylocard was injected through the instillation port of fiber scope on vocal cords and glottis. The fiber scope was maneuvered across vocal cords into the trachea. After visualization of carina, endotracheal tube was slided down the bronchoscope and position 2–3 cm above carina. Cuff was inflated and fiber scope was withdrawn. Placement of endotracheal tube was confirmed with capnography and auscultation and general anesthesia was induced with Inj.propofol 2 mg/kg i.v. and Inj.fentanyl 2 μg/kg i.v. and Inj.atracurium loading dose (0.25 mg/kg) i.v. During fiberscopy, intubation conditions were evaluated by the cough score on a scale of 0–3[9] (0=no cough, 1=single cough, 2=persistent cough lasting <5 s, and 3=persistant cough lasting ≥5 s or bucking) and tolerance to intubation by intubation score[9] as score 1 (cooperative), 2 (minimal resistance), and 3 (severe resistance). Anesthesia was maintained by giving nitrous oxide: oxygen (66:33) along with inhalation anesthetic agents (isoflurane) to prevent awareness and non-depolarizing muscle relaxants (Inj. atracurium) maintenance (0.1 mg/kg) doses. Monitoring of heart rate, systolic and DBP, MAP, and SpO_2 (0, 2, 4, 6, 8, and 10 min during drug infusion), immediately after intubation and every 10 min till 30 min (10, 20, and 30 min) was done for secondary outcomes in evaluation. After completion of surgery, patient's neuromuscular blockade was reversed with inj. neostigmine 0.04–0.08 mg/kg IV and inj. glycopyrrolate 0.5 mg IV. Once adequate reversal was obtained, patient was extubated and shifted to recovery room for further monitoring.

Airway obstruction during procedure was assessed using airway obstruction score[10] (1=no airway obstruction, 2=airway obstruction relived by neck extension, and 3=airway obstruction requiring jaw thrust). A score of ≥2 was considered to be eventful. Baseline values of HR, SBP, DBP, MAP, and SPO_2 were used to identify adverse events during procedure. Bradycardia was defined as heart rate <50 beats/min which was treated with atropine. Hypotension was taken as any recordings of SBP, DBP, or MAP of <20% from baseline values treated with crystalloid infusion followed by mephentramine injection if needed. A respiratory depression was recorded if respiratory rate was <8/min. Oxygen insufflation was done through oxygen port of fiber scope to correct any hypoxic episode (fall in SPO_2 <90%). If this was not enough, additional bag and mask with temporary removal of fiber scope were done. A post-operative assessment was done for sore throat and hoarseness in the patient.

Statistical analysis

Data were composed in a suitable spreadsheet, that is, EXCEL and SPSS and analyzed using SPSS software version 22.0. To compare the two groups after checking the assumption for the normality either Chi-square test or unpaired "t"-test were applied. Significance level was 95% confidence level (P<0.05). Data were described as a frequency (percentage) distribution as well as in Mean±SD. Data were presented through suitable statistical graphs.

All the observations and particulars of each patient were recorded in a proforma.

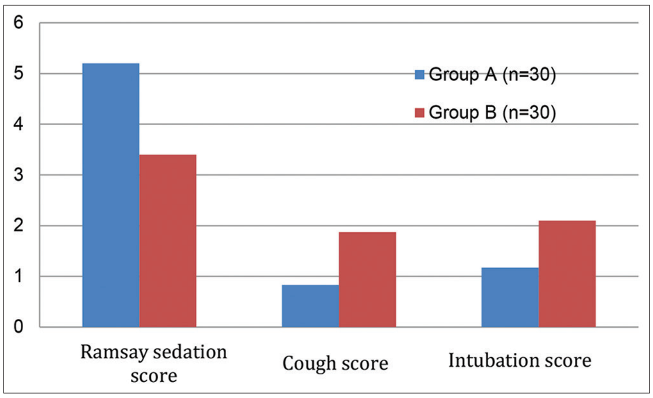
RESULTS

The 60 patients in two groups included in the study were compared with respect to demographic variables: age, weight, gender, ASA grade, and mallampati grading. The two groups were comparable and there was no statistically significant difference among the two groups with respect to these variables (Table 1).

The mean Ramsay Sedation Score in Group A was higher as compared to group B, with P=0.00 (<0.05) and thus was found to be highly statistically significant. Mean cough scores (P=0.00) and mean intubation scores (P=0.00) were higher in Group B than in Group A and the difference was found to be highly statistically significant (Table 2).

During intergroup analysis of mean pulse rate at different intervals of time, the mean pulse rate of both groups was comparable at T0 (Baseline). However, the pulse rate variations at T2, T4, and T6 were higher in Group A. Furthermore, the mean pulse rate variations immediately after intubation were higher in Group B than in Group A and the difference was statistically significant (P<0.05) as compared to baseline (Graph 2).

Among the intergroup analysis of MAP at different intervals of time, both groups were comparable at T0 (Baseline). However, the variations in MAP immediately after intubation were higher in Group B than in Group A and the difference was highly statistically significant (P<0.05) as compared to baseline(Graph 3).



Graph 1: Mean scores during Awake fiber optic intubation

Table 1: Demographic profile of study participants

Demographic parameter	Group A (n=30)	Group B (n=30)	P-value
Age (years)	42.9±11.33	45.53±9.58	0.335
Weight (Kg)	58.1±7.61	55.9±6.88	0.245
Gender (Male/Female)	20/10	24/6	0.241
ASA (I/II)	2/28	3/27	0.640
MPG (1/2)	14/16	13/17	0.795

P>0.05 - Statistically insignificant,*P<0.05 - Statistically significant,**P<0.005 - Highly statistically significant, MPG: Mallampati grading

The intergroup analysis of mean SPO_2 at different intervals of time showed that the mean SPO_2 of both groups were comparable except at I0. However, the SPO_2 variations immediately after intubation were higher in Group B than in Group A and the difference was statistically significant (P<0.05) as compared to baseline (Graph 4).

All the adverse effects had P<0.05 among two groups and were found to be comparable (Graph 5).

DISCUSSION

The thrust to move away from invasive techniques of airway management (Tracheostomy/Tracheotomy) to non-invasive techniques with introduction of conventional laryngoscopy for orotracheal intubation was a major shift in medicine practice. However, in conditions such as cervical spine injuries, conventional maneuvers such as head tilt and chin lift for laryngoscopy may be difficult to perform.

Successful and smooth use of fiber optic bronchoscope in these situations requires an adequately sedated individual with optimal intubation conditions. The amount of sedation achieved needs to be carefully titrated as deep sedation may lead to hypoventilation whereas inadequate sedation may provoke anxiety and discomfort. Hence, the search of an ideal agent for conscious sedation ensuring a calm and cooperative patient maintaining stable hemodynamics without causing respiratory depression is continued.

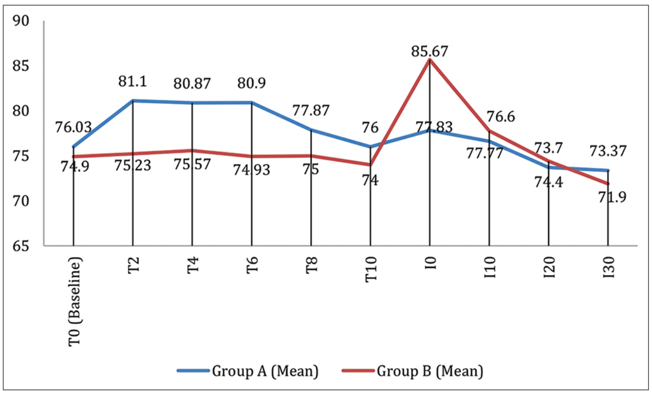
Dexmedetomidine is a potent selective alpha 2 adrenergic agonist having sedative, analgesic, anxiolytic, and anti-sialagogue properties with minimal respiratory depression.[4] It has the advantage of providing adequate sedation without causing respiratory depression, thus it seems to satisfy optimum conditions required in all aspects.[11]

Magnesium sulfate has potent analgesic, anticonvulsant, and sedative properties with cardiac and neurological protective effects. The stress of intubation associated with catecholamines release is decreased by magnesium. Thus, it was expected to provide stable hemodynamics during AFOI.[12] The present study was conducted to evaluate the

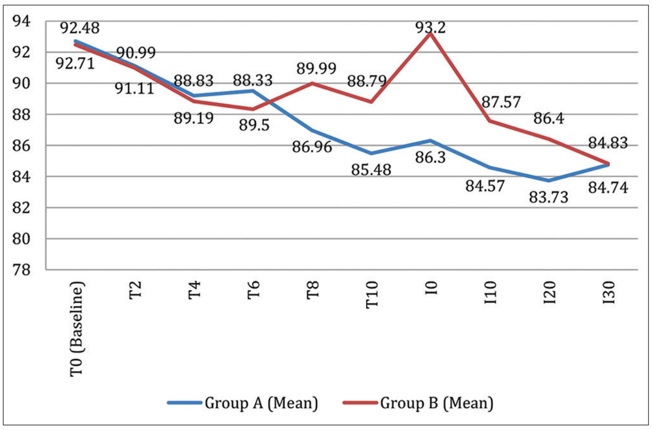
Table 2: Mean scores during awake fiber optic intubation

Scores	Group A (n=30)	Group B (n=30)	t-value	P-value
Ramsay sedation score	5.2±0.48	3.4±0.56	13.273	0.000**
Cough score	0.83±0.46	1.87±0.43	-8.936	0.000**
Intubation score	1.17±0.38	2.1±0.31	-10.506	0.000**

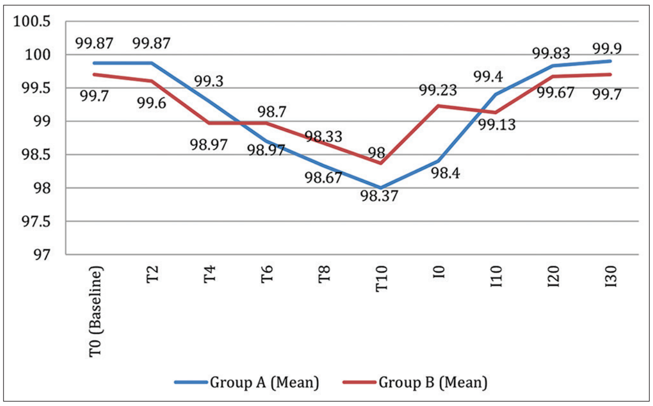
P>0.05 – statistically insignificant,*P<0.05 – statistically significant,**P<0.005 – highly statistically significant



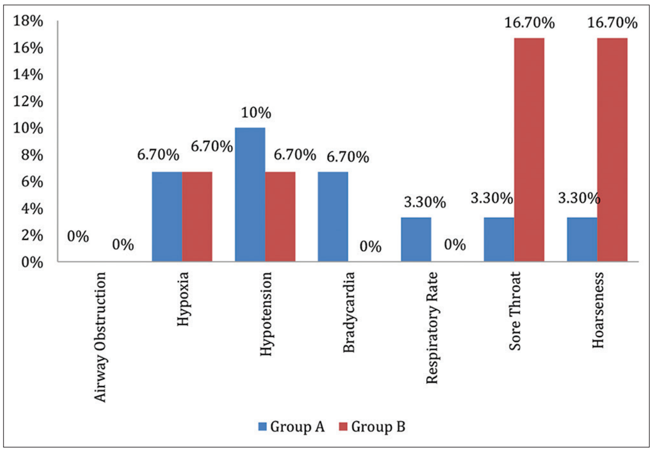
Graph 2: Intergroup statistical analysis of pulse rate (bpm)



Graph 3: Intergroup statistical analysis of MAP (mmHg)



Graph 4: Intergroup statistical analysis of SpO_2 (%)



Graph 5: Adverse effects during awake fiber optic intubation

level of sedation, intubating conditions, and hemodynamic parameters among dexmedetomidine and magnesium sulfate in patients undergoing cervical spine surgeries.

Demographic parameters depicted by Table 1 including age and weight, gender, ASA Grade, and Mallampati grading were comparable in both groups and the difference was found to be statistically insignificant (P>0.05).

The level of sedation as assessed by Ramsay sedation score was RSS≥2 in all patients, but patients receiving dexmedetomidine (Group A) achieved a higher score (5.2±0.48) than patients receiving magnesium sulfate (Group B) (3.4±0.56), with statistically significant difference (P=0.00) [Graph1]. This unique advantage of superior sedation with dexmedetomidine (α_2 agonist) was attributed to its action on pontine locus ceruleus while the patient is still arousable and cooperative.[13]

Our study was also supported by a previous study conducted by Radwan et al.,[7] which determined that group receiving dexmedetomidine had lower BIS and higher RSS with better sedation as compared to patients receiving magnesium sulfate and fentanyl during AFOI in patients scheduled for elective anterior corpectomy and cervical fixation.

Chopra et al.,[14] and Niyogi et al.,[4] also found that dexmedetomidine infusion provided optimum level of sedation as compared to saline infusion. Decreased need of midazolam in dexmedetomidine group to achieve RSS ≥2 before intubation was observed in Chopra et al., study, while none of the patients receiving dexmedetomidine in the Niyogi et al., study required supplementary fentanyl as opposed to 60% patients in placebo group.

Chu et al.,[15] and Bergese et al.,[16] demonstrated the effectiveness of dexmedetomidine in sedating patients with oral cancers for awake fiber optic nasotracheal intubation. They found that dexmedetomidine group provided better intubation conditions and patients tolerance with higher levels of amnesia and patient satisfaction. Comparable upper airway patency to awake patients implied dexmedetomidine to be a better and superior drug for AFOI.

In the present study, mean cough score observed was lower in patients receiving dexmedetomidine (0.83±0.46) than in patients receiving magnesium sulfate (1.87±0.43) with P=0.00 and mean intubation score assessed was lower with dexmedetomidine (1.17±0.38) than magnesium sulfate (2.1±0.31) with P=0.00, both of which suggested better intubation conditions at the time of intubation with dexmedetomidine than with magnesium sulfate. Inhibition of sympathetic supply of upper airways by dexmedetomidine results in blunting of airway reflexes, with more comfort to patients during intubation allowing easy intubation and favorable outcomes during intubation.[13]

This was supported by the studies done by Yousuf et al.,[17] and Mondal et al.,[18] who compared the effectiveness of dexmedetomidine for sedation and safety during AFOI having difficult intubation. The cough score and post-intubation score were favorable in patients receiving dexmedetomidine with statistically significant difference with P<0.001 and P=0.0001, respectively.

The hemodynamic parameters were more stable during intubation (I0 in Graph 2-6) in dexmedetomidine group while Group B patients had greater variations with increase in heart rate, systolic, DBP, and SPO_2 during and immediately after intubation with statistically significant difference in both groups while the baseline values were comparable among both groups. The variations in MAP were found to be highly statistically significant. The stable hemodynamic profile seen with dexmedetomidine was attributed to attenuation of sympathetic response done during AFOI.[13]

Similar results were seen by Mondal et al.,[18] and Singh et al.,[19] who compared the efficacy of dexmedetomidine and fentanyl during AFOI in patients scheduled for elective laparoscopic surgeries. He concluded that dexmedetomidine was more effective than fentanyl in providing better hemodynamic stability and lesser incidences of desaturation during AFOI. Radwan et al.,[7] showed that dexmedetomidine had greater hemodynamic stability with lower mean heart rate and SBP with dexmedetomidine than fentanyl and magnesium sulfate, thus supporting our study.

Five out of 30 patients with magnesium sulfate had incidences of sore throat and hoarseness as compared to one patient in dexmedetomidine group indicating greater degree of resistance with magnesium sulfate as compared to smooth conduct of fiber optic intubation in dexmedetomidine group. Although dexmedetomidine is not known to cause respiratory depression, one out of 30 patients had an episode of respiratory depression in our study; however, the difference was insignificant between both groups (P>0.05). One of the drugs selected for study is having bradycardia and hypotension as side effects, but their incidences were found to be comparable in both groups (P>0.05) without any significant difference. This could be due to patients' characteristics having initial state of bradycardia and hypotension before drug infusion.

The overall incidences of adverse effects were found to be comparable and statistically insignificant among both groups. In study done by Li C-W et al.,[20] which also had comparable incidences of adverse effects including hypotension, hypertension, bradycardia, tachycardia, and hypoxia between dexmedetomidine-midazolam and sufentanil-midazolam groups.

Furthermore, in the study done by Tsai et al.,[21] post-operative incidences of adverse events such as sore throat and hoarseness were comparable among dexmedetomidine and propofol group during awake fiber optic nasotracheal intubation.

To summarize, dexmedetomidine provides better intubation conditions with greater sedation and stable hemodynamics than magnesium sulfate for successful AFOI.

Scope

Comparing other drugs to find out the most effective, feasible, and optimum drug for smooth AFOI.

Limitations of the study

Limitations of our study were the small sample size. Often a larger trail testing selected gives greater differences and more significant results.

CONCLUSION

The present study concluded that dexmedetomidine is convincingly a superior and better drug as compared to magnesium sulfate in terms of providing better conscious sedation and optimum intubating conditions with greater hemodynamic stability and lesser incidences of adverse effects during awake fiber optic orotracheal intubation.

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Authors' Contributions:
EB- Concept and design of the study and prepared first draft of manuscript; **SS-** Interpreted the results; reviewed the literature, and manuscript preparation; **SvS-** Concept, coordination, statistical analysis and interpretation, and preparation of manuscript; and **NT-** Revision of the manuscript.

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