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THE STUDY TO EVALUATE THE SAFETY AND EFFICACY OF DEXMEDETOMIDINE DURING AWAKE FIBREOPTIC OROTRACHEAL INTUBATION IN PATIENTS SCHEDULED FOR CERVICAL SPINE SURGERIES: A PROSPECTIVE PLACEBO CONTROLLED DOUBLE BLINDED STUDY

Neurosurgery

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ABSTRACT

Introduction: Fibreoptic intubation has become an integral part in management of anticipated difficult airways. Various anaesthetic drugs have been used to assist Awake fibreoptic intubation(AFOI) for producing conscious sedation to provide a calm ,cooperative and responsive patient without respiratory depression for successful awake fiberoptic intubation. **Aims And Objective:** The aim of the present study was to study the safety and efficacy of dexmedetomidine during awake fibreoptic orotracheal intubation in patients scheduled for cervical spine surgeries. **Material And Methods:** A randomized, prospective, placebo controlled comparative study design was conducted in sixty patients in JAH group of Hospitals. All patients were randomly divided into two groups : Group A (n=30) patients received dexmedetomidine (1µg/kg) in 0.9% 100 ml Normal Saline and Group B (n=30) patients received 0.9% 100 ml Normal Saline, each over 10 minutes as an intravenous infusion in a randomized blinded manner. The fibreoptic 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, SBP, DBP, MAP and SPO2 during drug infusion at 2 minutes interval, immediately after intubation and every 10 minutes after intubation till 30 minutes. **Results:** Dexmedetomidine had better sedation score, cough score and intubation score with stable hemodynamic variables than Group B(Normal Saline) with statistically significant results. **Conclusion:** Patients receiving dexmedetomidine had adequate and appropriate level of sedation providing more optimum conditions for AFOI with stable hemodynamic parameters and lesser adverse effects during the procedure.

KEYWORDS

Awake fibreoptic intubation, cervical spine surgery, dexmedetomidine.

INTRODUCTION

Airway management is considered as most vital step during any anaesthetic procedure for surgery. The conventional laryngoscopy performed for orotracheal intubation in patients with anticipated difficult airway may be challenging even to most trained anaesthesiologists. 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. Induction of general anaesthesia with resulting loss of muscle tone and reflexes further adds to the complications during the procedure.[2] AFOI is a breakthrough technique for successful intubation in these patients.

However, orotracheal intubation using a fibreoptic bronchoscope requires an optimum level of conscious sedation which minimizes awareness during the procedure and provides calm and co-operative patient who is able to follow verbal commands allowing opening of obstructed airway in case of any obstruction.[3] Adequate sedation along with topical anaesthesia 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 (NMDA) receptors has been of great use in anaesthesia. It also has potent analgesic, anticonvulsant, and sedative properties with cardiac and neurological protective effects.[6] The present study was done to assess the safety and efficacy in terms oflevel of sedation achieved during awake fibreoptic intubation with dexmedetomidine in patients undergoing cervical spine surgeries.The study also include assessment of intubating conditionsand hemodynamic changes during the procedure among the two groups.

Aims: To evaluate the safety and efficacy of dexmedetomidine for level of sedation,intubating conditions and hemodynamic changes during awake fibreoptic orotracheal intubation in adult patients scheduled for cervical spine surgeries.

Primary Objective

To study and assess the level of sedation with dexmedetomidine using Ramsay sedation score during AFOI.

Secondary Objectives

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

Methodology

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

On the basis of 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.

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

Inclusion Criteria

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

Exclusion Criteria

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

60 patients fulfilling the eligibility criteria of ASA grade I & 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 anaesthesiologist 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 (1µg/kg) in 100 ml 0.9% normal saline 10 minutes before induction.

Group'B' (n=30): Patients who received an intravenous infusion of 100 ml 0.9% normal saline 10 minutes before induction.

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

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

Inj midazolam 0.05mg/kg iv and Inj Fentanyl 2µg/kg was given followed by topicalization of the airway with lignocaine10% spray up to a maximum dose of 5mg/kg based on total lignocaine dose calculated as per weight of the patient. An intravenous infusion of 1µg/kg dexmedetomidine in 100 ml 0.9% normal saline in Group A and infusion of 100 ml 0.9% normal saline as placebo in Group B was given over 10 minutes.

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 fibreoptic 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 fibreoptic orotracheal intubation was performed using AMBU Scope™ 4 Broncho Regular 5.0/2.2 Flexible Endoscope. Once the vocal cords were visualized, 2% xylocard was injected through the instillation port of fibrescope on vocal cords and glottis. The fibrescope 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 fibrescope was withdrawn. Placement of endotracheal tube was confirmed with capnography and auscultation and general anaesthesia was induced with Inj.propofol 2mg/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 to 3[9](0=no cough, 1=single cough, 2=persistent cough lasting <5 seconds, 3=persistant cough lasting ≥5 seconds or bucking) and tolerance to intubation by intubation score[9] as score 1(cooperative), 2(minimal resistance), and 3(severe resistance). Anaesthesia 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 (0.1mg/kg) doses. Monitoring of heart rate, systolic and diastolic blood pressure, mean arterial pressure, SpO2 (0,2,4,6,8 and 10 minutes during drug infusion), immediately after intubation and every 10 minutes till 30 minutes (10, 20,30 minutes) 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 0.5mg 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/minute. Oxygen insufflation was done through oxygen port of fibrescope to correct any hypoxic episode (fall in SPO_2 <90%).If this was not enough, additional bag and mask with temporary removal of fibrescope was done. A postoperative assessment was done for sore throat and hoarseness in the patient.

Statistical Analysis

Data was composed in a suitable spreadsheet i.e., EXCEL and SPSS and analysed 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 was described as a frequency (percentage) distribution as well as in Mean±SD. Data was presented through suitable statistical graphs. All the observations and particulars of each patient were recorded in a proforma.

OBSERVATION AND RESULTS

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

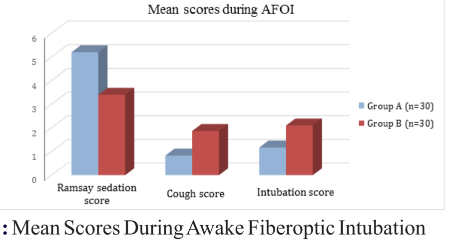
MPG: Mallampati Grading

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).

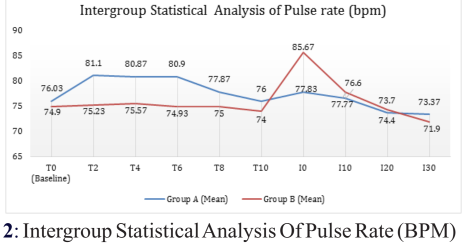
Table 2: Mean Scores During Awake Fiberoptic Intubation

Scores	GroupA (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**

The mean Ramsay Sedation Score in group A was higher as compared to group B, with p value of 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).

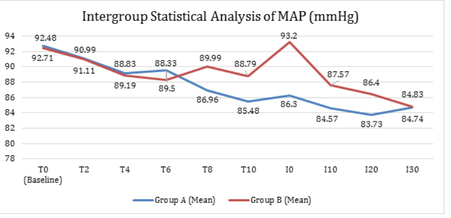


Graph 1: Mean Scores During Awake Fiberoptic Intubation



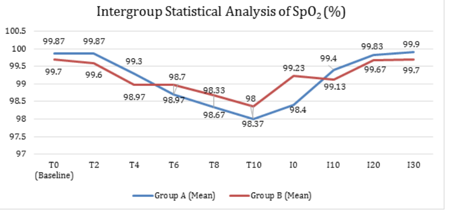
Graph 2: Intergroup Statistical Analysis Of Pulse Rate (BPM)

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. Also, 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).



Graph 3: Intergroup Statistical Analysis of MAP (mmHg)

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 4: Intergroup Statistical Analysis of SpO2 (%)

The intergroup analysis of mean SPO2 at different intervals of time showed that the mean SPO2 of both groups were comparable except at I0. However, the SPO2 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).

Graph 5: Adverse effects during Awake fiberoptic intubation

All the adverse effects had p value < 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 noninvasive 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.

Succesful and smooth use of fiberoptic bronchoscope in these situationsrequires 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, 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]

Thus, it was expected to provide stable hemodynamics during AFOI.[12] The present study was conducted to evaluate the level of sedation, intubating conditions and hemodynamic parameters among dexmedetomidine in patients undergoing cervical spine surgeries.

Demographic Parameters depicted by Table no.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 value >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 normal saline(Group B) (3.4±0.56), with statistically significant difference(p=0.00).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 T et al.,** [7] which determined that group receiving dexmedetomidine had lower BIS and higher RSS with better sedation as compared to patients receiving normal saline and fentanyl during awake fibreoptic intubation in patients scheduled for elective anterior corpectomy and cervical fixation.

Chopra P etal.,[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 prior to 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 SD et a.,l**[16] demonstrated the effectiveness of dexmedetomidine in sedating patients with oral cancers for awake fibreoptic 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 present study, mean cough score observed was lower in patients receiving dexmedetomidine (0.83±0.46) than in patients receiving magnesium sulphate (1.87±0.43) with p value of 0.00 and mean intubation score assessed was lower with dexmedetomidine (1.17±0.38) than magnesium sulphate (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 sulphate. 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 favourable outcomes during intubation.[13]

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

The hemodynamic parameters were more stable during intubation (I0 in Graph 2,3,4,5 and 6) in dexmedetomidine group while group B patients had greater variations with increase in heart rate, systolic,diastolic blood pressures 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 mean arterial pressure 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 P 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 T et al.,**[7] showed that dexmedetomidine had greater hemodynamic stability with lower mean heart rate and systolic blood pressure with dexmedetomidine than fentanyl and magnesium sulphate, thus supporting our study.

Five out of 30 patients with magnesium sulphate had incidences of sore throat and hoarseness as compared to 1 patient in dexmedetomidine group indicating greater degree of resistance with magnesium sulphate as compared to smooth conduct of fibreoptic intubation in dexmedetomidine group.Though, dexmedetomidine is not known to cause respiratory depression, 1 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 prior to 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 a.,l**[20] which also had comparable incidences of adverse effects including hypotension, hypertension, bradycardia, tachycardia and hypoxia between dexmedetomidine- midazolam and sufentanil - midazolam groups.

Also, in the study done by **Tsai et a.,l**[21] post-operative incidences of adverse events like sore throat and hoarseness were comparable among dexmedetomidine and propofol group during awake fibreoptic nasotracheal intubation.

To summarize, Dexmedetomidine provides optimum intubation conditions with greater sedation and stable hemodynamics for successful awake fibreoptic intubation.

Limitations

Limitations of our study was the small sample size. Often a larger trail testing selected gives greater differences and more significant results.
Scope: Comparing other drugs to find out the most effective, feasible and optimum drug for smooth awake fibreoptic intubation.

CONCLUSION

The present study concluded that dexmedetomidine is convincingly a superior and better drug in terms of providing better conscious sedation, optimum intubating conditions with greater hemodynamic stability and lesser incidences of adverse effects during awake fibreoptic orotracheal intubation.

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