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Original Research Article

Comparison of intravenous dexmedetomidine alone versus dexmedetomidine ketamine combination on sedation intubation response safety profile and patient satisfaction during awake fiberoptic nasotracheal intubation

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ABSTRACT

Background: Awake fiberoptic intubation requires adequate airway anaesthesia along with good sedation to achieve patient cooperation during intubation without respiratory depression and hypoxia.
Aim and Objectives: The purpose of this study was to compare dexmedetomidine alone and dexmedetomidine with ketamine in order to achieve an ideal regimen during awake fiberoptic intubation by providing sedation, good intubating conditions, better hemodynamic stability, and patient satisfaction.
Materials and Methods: This prospective, randomised, double-blind clinical trial included 60 patients who were scheduled for elective surgery under general anaesthetic and required nasotracheal intubation. Patients were randomly assigned to two groups of 30 each, with ages ranging from 18 to 65 years and ASA grades I and II. All patients received an inj. dexmedetomidine bolus at 1 mcg/kg over 10 min. followed by a study drug depending on the group. In Group A, patients will receive an inj. ketamine 15 mg bolus and a 20 mg/hr ketamine infusion, whereas those in Group B will receive a normal saline bolus and infusion till completion of intubation. Sedation by Ramsay sedation scale (RSS), intubation response (by coughing score and grimace score), hemodynamic stability was observed during awake fiberoptic intubation, and patients' satisfaction by visual analogue score (VAS) and recall of events were assessed post operatively at 24 hours.
Results: In Group A with greater hemodynamic stability compared to Group B, RSS and Post-Operative Vas Score were more successfully attained.
Conclusion: A combination of dexmedetomidine and ketamine provides the optimum sedation, hemodynamic stability, and patient satisfaction during awake fiberoptic intubation.

1. Introduction

The act of creating and securing a patent airway is referred to as airway management. Even an experienced airway manager may suffer problems during tracheal intubation, thus it is essential to have access to alternate procedures and tools. In these situations, a variety of modalities, including flexible fiberoptic scopes, supraglottic airway devices, and video laryngoscopes, may be employed. It is a useful tool for dealing with both planned and unplanned situations that make the airway hard.

Conditions like known or expected problematic airways, contraindications to neck extension (unstable cervical fracture, severe cervical stenosis, vertebral artery insufficiency, Chiari malformation), and limited mouth opening scenarios are examples of fiber-optic intubation indications (temporomandibular joint disease, mandibulo maxillary fixation, severe facial burns). Obtundation of airway reflexes and sedative techniques are two crucial

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components of efficient awake fiberoptic intubation preparation. When intubation and ventilation are not feasible in difficult airway circumstances, we should avoid hypoxemia.[1,2]

Medication used during awake fiberoptic intubation causes respiratory depression and apnea in higher doses. As a result, it is critical to use the right sedative regimen for awake fiberoptic intubation in order to avoid respiratory depression, allow patients to maintain spontaneous breathing, and have their full cooperation when the fiberoptic scope is introduced into their airway.[3]

The alpha-2 adreno receptor agonist dexmedetomidine has a high level of specificity and selectivity. Conscious sedation, anxiolytic, analgetic, sympatheticolytic, and antisecretory effects are widely documented for this substance. It is easily arousable and has minor respiratory depression.[4]

Low doses of ketamine added to dexmedetomidine provide an additional analgesic effect and assist avoid bradycardia and hypotension caused by dexmedetomidine, while dexmedetomidine attenuates the unfavourable rise in airway secretion brought on by ketamine. Combining Ketamine and Dexmedetomidine will result in more steady hemodynamic response, greater sedation, and easier intubation because Ketamine and Dexmedetomidine have opposing effects on cardiac autonomic receptors and the central nervous system.[5]

We selected to compare Dexmedetomidine alone with Dexmedetomidine with Ketamine in order to give the best circumstances for awake fiberoptic intubation in terms of sedation, intubation response, safety profile, and patient satisfaction.

2. Materials and Methods

The current prospective, randomised, double-blind clinical study was conducted between September 2019 and October 2020 after receiving permission from the scientific research committee and the institutional ethics committee for human research and registration in the clinical trials registry of India (CTRI/2020/01/022959). Following written informed permission to participate in the trial, a total of 60 patients between the ages of 18 and 65, with ASA status I and II, who were scheduled for elective surgical procedures involving nasotracheal intubation under general anaesthesia were included in the study.

2.1. Exclusion criteria

Patient's refusal, patient's on anti coagulants or who have thrombocytopenia or coagulopathies; nasal trauma, polyps, and deformity; pregnant and nursing mothers; patients with hypertension, bradyarrhythmia, psychiatric illness; and patients with raised intracranial pressure.

2.2. Sample size

As the study conducted was time-bound, taking five cases in a month from September 2019 to October 2020, a total of 60 cases were enrolled. They were divided into two groups, with 30 patients in each group (group A and B), using the sealed envelope method.

2.3. Grouping of patients

All the patients in group A and group B received a loading dose of INJ. Dexmedetomidine (1 mcg/kg) in 100 ml of normal saline over 10 minutes followed by the study drug according to group;

Group A: In this group, patients received Inj. Ketamine 15 mg as a bonus of 5 ml followed by an Inj. Ketamine 20 mg/hour infusion till completion of intubation.

Group B: Patients in this group were given a 5 mL bolus of normal saline, followed by an infusion of normal saline until the intubation was completed.

Patients and/or their family were fully informed of the study's goal, technique, and potential negative effects. They were taught about the visual analogue scale of pain intensity, which includes a horizontal line scale of 0 to 10 (no pain to extremely severe pain) and a vertical line to represent how much pain they had during the operation at 24-hours post-operatively.

2.4. Patient preparation

Patients were kept nil by mouth 6-8 hours prior to surgery. On arrival to operation theatre appropriate sized IV cannula was inserted; IV fluids were started according to the requirement. Baseline vital parameters of every patient including heart rate (HR), systolic (SBP) and diastolic blood pressure (DBP), SpO_2 were noted.

Nasal patency confirmed & 2-3 drops of 0.1% xylometazoline nasal drops were instilled in both nostrils. Patients were Nebulized with 2% Lignocaine 15 minutes prior to procedure, 2-3 puffs of 10% lignocaine was sprayed on oropharynx and base of tongue. Patients were pre-medicated with Inj. Glycopyrrolate 5 mcg/kg IV and Inj. Ondansetron 0.1 mg/kg IV (5 minutes before loading dose of drug) loading dose of Dexmedetomidine started and airway block was given. Superior laryngeal nerves were blocked bilaterally at the level of greater cornu of hyoid bone with 2ml of 2% lignocaine on each side & recurrent laryngeal nerve block by transtracheal approach at cricothyroid membrane with 2ml 2% lignocaine. (Total 6 ml volume).

Alongside before the procedure, the fiberoptic bronchoscope was prepared for intubation by connecting the light cord and functional suction catheter to the suction port. An oxygen source was connected, and a lubricated endotracheal tube was threaded over the fiberscope before insertion. Patients were assessed for Ramsay sedation scale

(RSS) after receiving the loading dose and continuing study drug infusion according to group. After confirming RSS of >/2, fiberoptic intubation was done through the nasal approach. The distance from the ala of the nose to the tragus was measured and that length of the bronchoscope was inserted along the floor of the nose. The epiglottis was visible at a marked distance and the scope was gradually advanced, keeping the epiglottis in the centre of view. The vocal cords were visualised and the bronchoscope was further advanced. After visualising the carina, the loaded endotracheal tube Flexometallic or armoured endotracheal tubes were slipped over the scope to the trachea, and the tube was positioned four tracheal rings above the carina, and the scope was withdrawn. Placement of the endotracheal tube was confirmed by fiberoptic scope, recording end tidal carbon dioxide (etCO2), and the tube was fixed. Following that, traditional general anaesthesia was administered. Propofol (2-2.5 mg/kg) was injected, followed by the muscle relaxant Vecuronium (0.1 mg/kg).

For maintenance, O_2+N_2O (50:50) with sevoflurane and vecuronium bromide 0.02 mg/kg was used for maintenance. N_2O and anaesthetic agents were terminated before 10 minutes of operation, and patients were ventilated with 100% oxygen. After resuming spontaneous breathing, the remaining neuromuscular block was reversed by injections of neostigmine (50 mcg/kg) and glycopyrrolate (10 mcg/kg). Patients were ventilated with 100% oxygen at a fresh gas flow of 4–6 litres per minute throughout this time. Patients were extubated after a consistent spontaneous breathing pattern was established and they could open their eyes on command. Patients were subsequently transferred to the post-anesthesia care unit (PACU).

Cases in which RSS was not achieved >/2 after 2 minutes of study drug infusion completion; cases in which patient's saturation fell despite receiving 100% oxygen for more than 2 minutes; and cases in which patient was unable to intubate after two attempts of fiberoptic bronchoscopy were excluded from the study.

The following monitoring parameters were monitored:

Sedation: Before fiberoptic intubation, the Ramsay Sedation Scale (RSS),[6] which comprises six scores, was measured after 10 minutes of drug infusion. (After the last loading doses of dexmedetomidine and ketamine, respectively, were given to groups A and B).

Table 1: Ramsay sedation scale

Score	Response
1	Anxious or restless or both
2	Cooperative, focused, and calm
3	Only responding to orders
4	Rapid reaction to the stimulus (light glabellar tap or loud auditory stimuli)
5	Slow reaction to the stimuli
6	No reaction to the stimuli

Intubation Response: Grimacing score and coughing score[5] were used to evaluate it. There are four levels of coughing score: score 1 is no cough; score 2 is a light cough (no more than two coughs in a sequence); score 3 is a moderate cough (3-5 coughs in a sequence); and score 4 is a severe cough (more than 5 coughs in a sequence). Grimaces were graded based on how they looked on the face. A score of 1 meant the grimace was mild, a score of 2 meant it was moderate, and a score of 3 meant it was severe.

Haemodynaemic Stability: Heart rate (HR), systolic and diastolic blood pressure (SBP), and SpO_2 were all noted at baseline and after a drug loading dose, at 2 minutes, 4 minutes, 6 minutes, 8 minutes, and 10 minutes prior to fiberoptic intubation, and then at 2 minutes, 5 minutes, and 10 minutes following fiberoptic intubation.

After 24 hours, all patients had their satisfaction with pain and recollection from AFOI evaluated. Using a 10 cm visual analogue scale, it was evaluated. Patients were instructed to put a vertical mark on the horizontal scale that represented the degree of discomfort they had felt during fiberoptic intubation after being informed of the scoring methodology. (Figure 1)

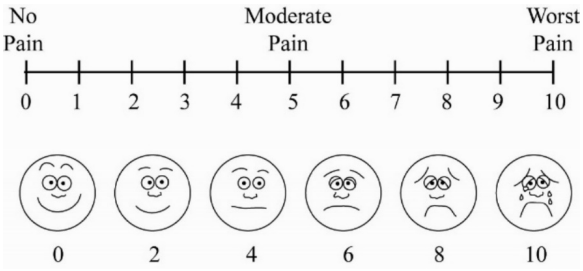

Fig. 1: Visual analogue scale

We asked every patient whether they could recollect everything that happened during fiberoptic intubation, including pre-anesthetic preparation, topical anaesthetic, endoscopy, and intubation.

Complications: Hypoxia (saturation 90%), bradycardia (heart rate 50 min), tachycardia (heart rate > 120/ min), respiratory depression (respiratory rate 8/min), hypertension (>20 percent from baseline rise in blood pressure), hypertension (>20 percent from baseline fall in blood pressure), bradycardia (heart rate 50/min), and tachycardia (heart rate > 120/min) were observed from the start of drug infusion, at completion of loading drug infusion, and during fiberoptic intubation.

Using the MedCalc application, the data for the various parameters was statistically analysed using the student t test for all continuous variables and the chi-square test for qualitative (nonparametric) data. A P- value was used to determine the significance of statistical analysis; P values of >0.05 were deemed non-significant, <0.05 were deemed significant, and <0.001 were deemed extremely significant.

3. Observations and Results

This study enlisted the participation of 60 patients. Two groups were comparable in terms of demographic characteristics and procedure types. On the Ramsay sedation scale, there was a significant difference between the two groups. The mean Ramsay sedation score for Group A was 3 ± 1.41 after a 10-minute loading drug infusion and before fiberoptic intubation, whereas Group B was 2.1 ± 0.70. The difference in mean RSS between the two groups was statistically significant (P < 0.05).

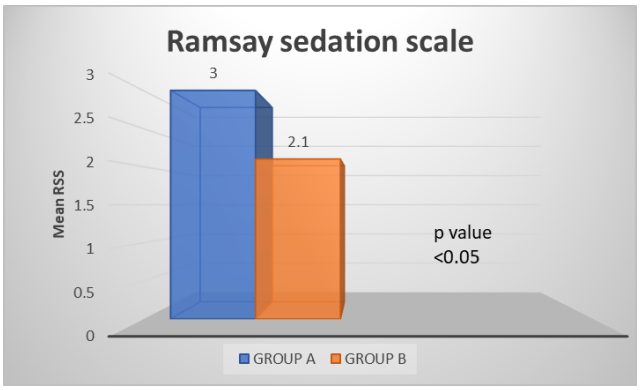

Fig. 2: Mean Ramsay sedation scale

Coughing and grimacing ratings were used to compare the two groups' intubation reactions. The mean coughing scores in Groups A and B were 1.8 ± 0.59 and 2.3 ± 0.49, respectively, with a statistically significant difference between the two groups. The mean Grimace Scores in Groups A and B were 1.3 ± 0.34 and 1.36 ± 0.34, respectively. There was little difference between the two groups. Intubation circumstances were good in both groups. Heart rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation (SpO2) were assessed and compared for hemodynamic stability across the two groups. There was a small rise in pulse rate from baseline in group A at 2 minutes, 5 minutes, and 10 minutes after intubation. At any period, there was no significant change in heart rate, systolic and diastolic blood pressure (at 2 min, 4 min, 6 min, 8 min, and 10 min after the loading dose of drug). However, in group B, heart rate, systolic blood pressure, and diastolic blood pressure all decreased at each interval (at 2 min, 4 min, 6 min, 8 min, and 10 min after the loading dose of drug, and there was a slight rise at 2 min and 5 min after intubation that was significant and returned to baseline value at 10 min after intubation).

The intergroup comparison showed significant differences in heart rate, systolic blood pressure, and diastolic blood pressure between the two groups at each interval; however, they stabilised and were equivalent after 10 minutes. (p > 0.05).

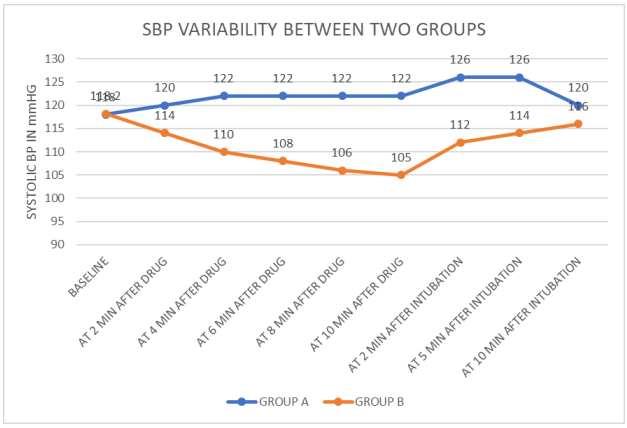

Fig. 3: Mean SBP variation between two groups

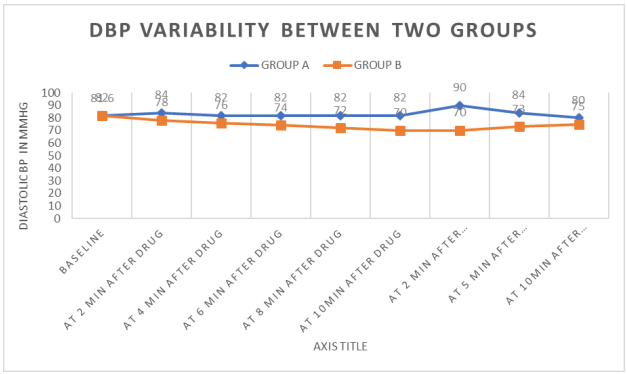

Fig. 4: Mean DBP variation between two groups

SBP and DBP were more stable in Group A, and no noticeable intra-group variation existed between Groups A and B. The saturation levels in both groups did not decrease much, and there was no statistically significant difference between the two groups (p>0.05). There had been no problems in either group during the experiment. A visual analogue score (VAS score) post-op evaluation was required 24 hours following surgery. The mean VAS in Group A was 2.23 ± 0.97, whereas it was 3.0 ± 0.83 in Group B. The mean VAS between the two groups was 0.05, which was statistically significant.(Figure 5)

Recall of events in Group A was present in 2/30 (6.66%) vs 5/30 (16.6%) in Group B. Statistically, there was no difference between the two groups in how they remembered events during the whole process.

4. Discussion

Before awake fiberoptic intubation, patients must be prepared (AFOI). The preparation includes, in addition to compliance, airway patency, appropriate sedation, anxiolysis, and airway anaesthesia.[1] Dexmedetomidine is a highly selective, centrally acting alpha-2 adrenoceptor agonist. The addition of a modest dosage of ketamine to

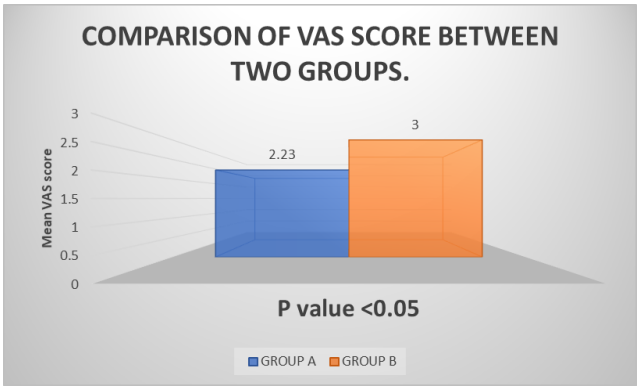

Fig. 5: Mean VAS between two groups

dexmedetomidine results in a combination that is effective for conscious sedation with enhanced hemodynamic stability and patient satisfaction. Its effects include sedative, hypnotic, anxiolytic, sympatholytic, anti-secretory, and analgesic.

The two groups shared the same demographic information, surgical procedures, and baseline vital signs. Group A had a greater sedation score than Group B. While grimace ratings were comparable in both groups, 25 of 30 patients in group A and 8 of 30 patients in group B had positive cough values of less than 2, indicating a significant difference. Group A was more successful than Group B in achieving hemodynamic stability. There were no problems in either group. Even though there wasn't a statistically significant difference in how well people remembered what happened after surgery, group A had a lower visual analogue score, which means they were more comfortable.

Sinha et al. (2014)[5] observed increased sedation scores in the combination Dexmedetomidine/Ketamine group compared to Dexmedetomidine alone, which is significant with no significant change in intubation condition. This is consistent with our results. The difference in mean heart rate between groups B and A was substantial, although the intragroup variation in group A was low. When the MAP between the two groups was compared, there was a significant decrease. Group I (Dexmedetomidine+ketamine) showed a much stronger memory of the patient procedures than Group II (Dexmedetomidine alone). They thought it was because ketamine stimulates the central nervous system, which can cause hallucinations.

Mondal et al. (2015)[1] observed that the RSS score was extremely significant and that the Dexmedetomidine group obtained a higher degree of sedation than the Fentanyl group. They also observed that the dexmedetomidine group was more hemodynamically stable. Dexmedetomidine has effects on blood flow because it decreases sympathetic outflow from the heart, decreases sympathetic tone that is controlled by the heart, and increases vagal tone.

In their Niyogi et al. (2017)[3] study on the effectiveness of dexmedetomidine during AFOI, the researchers showed that the drug alters blood pressure in a dose-dependent, biphasic manner. The initial rise in blood pressure following the loading dose may be caused by vasoconstriction brought on by the direct stimulation of alpha1 receptors, while the subsequent drop in blood pressure may be caused by inhibition of sympathetic tone. In the control group, they observed a substantial increase (p value < 0.001). There were no problems with hemodynamic instability or saturation loss. A VAS was used to measure the patient's post-procedure comfort 24 hours later. The dexmedetomidine group scored lower (40–60) than the control group (50–90), which was statistically significant (p < 0.001).

5. Conclusion

Dexmedetomidine is an effective sedative for individuals undergoing awake fiberoptic intubation. It permits effective sedation and intubation without significant respiratory depression. By having an additive impact on sedation, analgesia, and forgetfulness as well as haemodynamic stability, the addition of low dosage ketamine offers additional benefits.

6. Source of Funding

None.

7. Conflict of Interest

None.

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