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Original Research Article

IN ATOMIZATION, ADDITION OF DEXMEDETOMIDINE TO LIGNOCAINE CAN BE A BETTER ALTERNATIVE THAN LIGNOCAINE ALONE IN AIRWAY PREPARATION FOR AWAKE FIBREOPTIC INTUBATION- A RANDOMIZED CONTROLLED TRIAL

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Abstract

Background: Airway management during awake fiberoptic intubation (AFOI) is crucial, especially in patients with difficult airways. This prospective randomized controlled study aimed to evaluate the addition of dexmedetomidine to lignocaine (L/D) as an alternative to lignocaine alone (L) for airway preparation during AFOI, with a focus on patient comfort, intubating conditions, cough and gag reflex suppression, and hemodynamic stability. **Materials and Methods:** Seventy adult patients with anticipated or confirmed difficult airways were randomized into two groups. Group A received L/D for atomization, while Group B received L only. Both the groups received transtracheal injection of 3 ml of 4% lignocaine. Quality of intuationwas assessed using patient's comfort score, Intubating condition grade score, cough and gag score and cord visibility score. Hemodynamic parameters were also recorded. **Result:** Patients in Group A, who received the combination of dexmedetomidine and lignocaine, reported significantly higher comfort levels compared to those in Group B, where lignocaine alone was used for airway preparation during AFOI. This difference in comfort levels was highly significant, with a chi-square value of 45.2 ($p < 0.0001$). Dexmedetomidine and lignocaine, achieved significantly better intubating condition grade scores compared to those in Group B. The difference in intubating condition grades was highly significant, with a chi-square value of 37.227 ($p < 0.0001$). Patients in Group A, who received the combination of dexmedetomidine and lignocaine, were more likely to have "Relaxed" cord visibility during AFOI compared to those in Group B, where lignocaine alone was used for airway preparation. The difference in cord visibility scores was statistically significant ($p = 0.001$).While hemodynamic differences were observed, they were statistically significant. **Conclusion:** The combination of dexmedetomidine and lignocaine for airway preparation in AFOI offers improved patient comfort, favorable intubating conditions, and effective suppression of airway reflexes, without compromising safety. This approach has the potential to enhance patient acceptance and the quality of care during AFOI in cases of difficult airways.

INTRODUCTION

Airway management is a critical aspect of anesthesia and critical care medicine, particularly in situations where patients require awake fiberoptic intubation (AFOI). AFOI is a valuable technique for securing the airway in patients with anticipated or established difficult airways, such as those with

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upper airway tumors, faciomaxillary trauma, post burn neck contructure and cervical spine instability. Adequate airway preparation is essential to minimize patientdiscomfort, to optimize intubating conditions, and to ensure procedural success.

Traditionally, topical airway anesthesia for AFOI has been achieved using lignocaine, a commonly usedlocal anesthetic agent. Lignocaine is effective in blunting airway reflexes, reducing coughing and gagging, and facilitating the passage of the fiberoptic scope. However, blunting of reflexes is achived to a certain level but not upto the mark. There is scope for improvement in its effectiveness and patient tolerance.[1,2]

In recent years, an alternative approach has gained attention ie, the addition of dexmedetomidine to lignocaine for airway preparation in AFOI. Dexmedetomidine is a highly selective alpha-2 adrenergic agonist with sedative, anxiolytic, and analgesic properties. It has been used successfully in various clinical scenarios, including procedural sedation and as an adjunct in regional anesthesia, due to its ability to provide both analgesia and sedation without causing respiratory depression.[3]

The rationale behind combining dexmedetomidine with lignocaine in airway preparation is to enhance patient comfort, reduce airway reflexes, and to improve the overall quality of the intubation experience. This approach may offer advantages over lignocaine alone by providing superior sedation and analgesia.[4]

Several studies have explored the efficacy and safety of this combination and a randomized controlled trial is a robust research design to evaluate its potential benefits. This study evaluates whether the addition of dexmedetomidine to lignocaine can indeed provide a better alternative to lignocaine alone in airway preparation for AFOI.

Aims & Objectives

To observe whether addition of dexmedetomidine to lignocainecan be a better alternative than lignocaine alone in airway preparation for awake fibreoptic intubation (AFOI).

MATERIALS AND METHODS

Study Design: A prospective randomized controlled study was conducted to investigate the efficacy and safety of adding dexmedetomidine to lignocaine as an alternative to lignocaine alone in airway preparation for awake fiberoptic intubation (AFOI). The study was designed to compare the two intervention groups, with randomization to ensure an unbiased allocation of patients.

Study Setting: The study was carried out in the Plastic Surgery Operation Theatre and the Postoperative Recovery Room at the Institute of Postgraduate Medical Education & Research (IPGME&R), SSKM Hospital, which is a tertiary care teaching hospital in Kolkata. This operation theatre was chosen for the frequent occurrence of AFOI guided cases, availability of necessary equipment's and trained personnel.

Period of Study: The study was conducted over a period of seven months, from December 2022 to June 2023, to ensure an adequate sample size and to account for any potential seasonal variations in patient caseload.

Inclusion Criteria

Adult patients (aged 18 and above) scheduled for elective awake fiberoptic intubation.

Patients with anticipated or confirmed difficult airways.

ASA Grade I & II scheduled for elective reconstructive plastic surgery requiring awake fibreoptic intubation (AFOI)

Patients who provided informed consent for participation in the study.

Exclusion Criteria

Patients with a known allergy to study drugs

Pregnant patients.

Patients with a history of severe cardiovascular disease, respiratory disease, or hepatic impairment.

Patient with full stomach, bleeding disorder, raised intraocular pressure, raised intra cranial pr. Cerebral aneurysm.

Patients who declined to participate in the study.

Randomization: Patients meeting the inclusion criteria were randomized into two groups using computer-generated random numbers. The allocation sequence was concealed in sealed envelopes to ensure allocation concealment. Group Areceived airway preparation with a combination of dexmedetomidine and lignocaine while Group Breceived airway preparation with lignocaine alone.

Intervention

Group A: Atomization with lignocaine and dexmedetomidine under moderate sedation

Group B: Under moderate sedation atomization with lignocaine only.

Sample Size: The sample size was calculated to achieve 80% power and a significance level of 0.05, based on previous studies and an expected effect size. The required sample size was estimated to be 35 patients in each group assuming a 10% drop-out rate.

Data Collection: Demographic information, medical history, and baseline vital signs were recorded for each patient. The primary outcome measures included patient comfort during AFOI, and the success rate of fiberoptic intubation. Secondary outcome measures included hemodynamic stability, cough reflex suppression, and time to successful intubation.

Methodology: After receiving informed consents from all study patients , they were explained about the anaesthesia procedure. An experienced anaesthesist assessed airway of all patients and intubation difficulty by conventional laryngoscopy was demarketed. Thorough preanaesthetic evaluation was done in all patients including history regarding the illness, comorbidities and surgery. Difficult airway was assessed by mouth opening,

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Mallampati grading ,thyromental distance, temporomandibular joint, neck mobility and evaluation of dentition. They were given tablet ranitidine 150 mg and diazepam 5mg orally night before and in the morning four hours before surgery. Following a period of fasting lasting at least 6 hours, the patients were transported to the operation room. In all patients, routine monitoring techniques such as non-invasive blood pressure (NIBP), pulse oximeter (SPO2), and electrocardiogram leads (ECG) were employed inside the confines of the operating room. An 18-gauge intravenous (IV) cannula was inserted and secured, and Ringer Lactate solution was initiated. Following the measurement of baseline heart rate (HR), blood pressure (BP), and SPO2, all patients were administered intravenous injections of midazolam at a dosage of 1-2mg, injection ondansetron 4mg and glycopyrolate at a dosage of 0.2 mg. Additionally, an intravenous injection of fentanyl at a dosage of 1μg/kg was administered to induce a state of cooperation, orientation, and tranquility (Ramsay sedation scale of 2) in the patients.

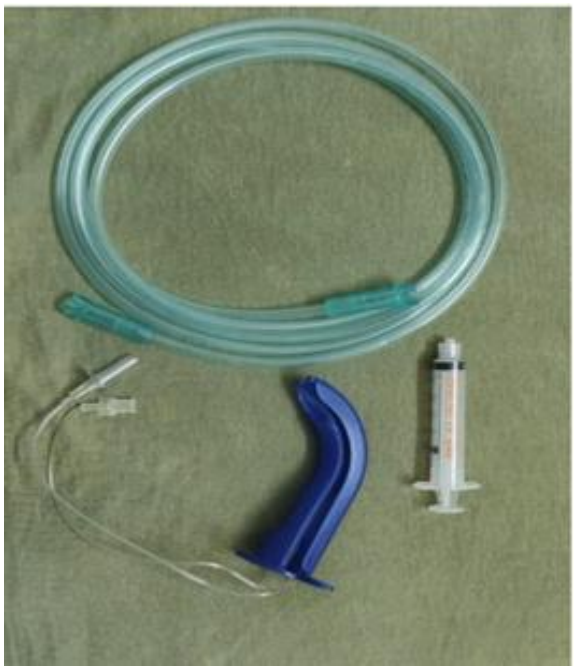

Figure 1: The LMA MADgic airway with syringe and oxygen tubing

The study had two groups of patients who received two drops of xylometazoline nasal solutions, two sprays of 10% lignocaine in each nostril, as well as 1 ml of a 2% Lignocaine jelly.The patients in Group A were administered a solution containing9ml of 2% lignocaine and dexmedetomidine 2mcg/ kg maximum 100mcg, for atomization whereas the patients in Group B were administered a 10 ml solution containing2% lignocaine only for atomization. MA Dgic Laryngo-Tracheal Mucosal Atomizer, connected to a lignocaine- filled syringe and a oxygen tubing, delivering fine particles of atomized drug was directed towards posterior pharyngeal wall and palate duringthe inspiratory phase to anaesthetize the airway. Oxygen flow through MADgic LMA working on venturiprinciple was maintained at a rate of 4-6litre/ min. The oral cavity,palate, tongue, and throat are first atomized with local anesthetic. Subsequently LMA MADgic is introduced inside the oral cavity facing towards the glottis aperture. In order toachive anesthesia of the pharynx, glottis and subglottic region the participants were instructed to inhale full vital capacity breaths of oxygen mixed with atomized lignocaine ± dexmedetomidine.The perception of a decrease in vocal pitch and/or numbness in the back of the tongue were regarded as indicators of sufficient topical anaesthesia.

Recurrent laryngeal nerve block with transtracheal instillation of 3 ml of 4% lignocaine was performed in both the groups.

After three minutes of optimal topical anaesthesia and adequate sedation, nasal fibre optic intubation was done in two groups with supplemental oxygen administered via nasal cannula @ 4L/min through mouth.

Supplemental local anaesthesia (LA) with 2% lignocaine was administered with 1 ml aliquots through the working channel of the flexible optical bronchoscope (FOB) accordingly.A fiberoptic bronchoscope (FOB) fitted with an adequate size endotracheal tube was introduced nasally and propagated forward till it confirmed position of fiberscope in trachea placing endotracheal tube about (2- 2.5) cm above carina. Male patients were given nasal endotracheal tube with an internal diameter ranging from 7 to 7.5 mm, whereas 6.5 to 7 mm for female patients. The duration of intubation was determined by measuring the time elapsed from the initiation of bronchoscopy through the nose until the placement of the tube in the trachea was confirmed by auscultation as well as end-tidal capnography.

The vital parameters, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and peripheral oxygen saturation (SpO2), were documented prior to sedation, during intubation, at one minute and five minutes following intubation. Parameters such as quality of intubation as judged by cough and gag reflex score, duration of intubation, comfort score, grades of intubating condition as well as cord visibility(relaxed, partially relaxed or adducted) were documented. The optimal dosage of lignocaine for airway anaesthesia lacks clear consensus among several authors, with suggested total dosages ranging from 4 to 9 mg/kg.[5]

It is crucial to engage in vigilant monitoring for signs and manifestations of lignocaine toxicity which encompass ECG changes, bronchoconstriction, tinnitus, peri-oral tingling, metallic taste, light-headedness and dizziness. Excessive administration of Lignocaine can lead to the development of several adverse effects including

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hypertension, tachycardia, seizures, and cardiovascular collapse.[5] The observed manifestations of lignocaine toxicity were documented. Following the establishment of an airway, the administration of general anaesthesia was carried out according to protocol, with a dosage of propofol 2 mg/kg and rocuronium at a dosage of 0.3 mg/kg.[6]

Statistical Analysis: Statistical analysis was performed using SPSS software ver-26, Descriptive statistics, such as mean, standard deviation, and frequency, were used to summarize the data. Inferential statistics, including student's t-tests and chi-squared tests, were applied to assess differences between the two groups. Intubation grades and patient comfort scores were analysed using the mann- whitney U test. The results were presented in tables and graphs for clarity.p-values < 0.05 were considered statistically significant and <0.01 highly significant.

Ethical Considerations: The study was conducted in accordance with the Declaration of Helsinki and received ethical approval from the Institutional Review Board of IPGME&R. Informed consent was obtained from all participants, and their confidentiality and rights were protected throughout the study.

RESULTS

Patients in Group A, who received the combination of dexmedetomidine and lignocaine, reported significantly higher comfort levels compared to those in Group B, where lignocaine alone was used for airway preparation during AFOI. This difference in comfort levels was highly significant, with a chi-square value of 45.2 ($p < 0.0001$). [Table 1]

Patients in Group A, who received the combination of dexmedetomidine and lignocaine, achieved significantly better intubating condition grade scores compared to those in Group B, where lignocaine alone was used for airway preparation during AFOI. The difference in intubating condition grades was highly significant, with a chi-square value of 37.227 ($p < 0.0001$). [Table 2]

Patients in Group A, who received the combination of dexmedetomidine and lignocaine, experienced significantly less coughing and gagging during AFOI compared to those in Group B, where lignocaine alone was used for airway preparation. The difference in cough and gag scores was highly significant, with a chi-square value of 34.409 ($p < 0.0001$). [Table 3]

Patients in Group A, who received the combination of dexmedetomidine and lignocaine, were more likely to have "Relaxed" cord visibility during AFOI compared to those in Group B, where lignocaine alone was used for airway preparation. The difference in cord visibility scores was statistically significant ($p = 0.001$). [Table 4]

Heart Rate: In Group A (L/D), the average heart rate during intubation was 92.54±6.45 beats per minute. In Group B (L), the average heart rate was 109.23±8.11beats per minute. The difference in heart rate between the two groups was statistically significant ($p = 0.002$).

Systolic Blood Pressure: In Group A (L/D), the average systolic blood pressure was 129.23±5.33 mmHg. In Group B (L), the average systolic blood pressure was 136±5.33 mmHg. The difference in systolic blood pressure between the two groups was statistically significant ($p = 0.005$).

Diastolic Blood Pressure: In Group A (L/D), the average diastolic blood pressure was 76.84±4.11mmHg. In Group B (L), the average diastolic blood pressure was 82.45±4.11mmHg. The difference in diastolic blood pressure between the two groups was statistically significant ($p = 0.009$).

Mean Arterial Pressure: In Group A (L/D), the average mean arterial pressure was 96.12±4.11 mmHg. In Group B (L), the average mean arterial pressure was 101±3.45 mmHg. The difference in mean arterial pressure between the two groups was statistically significant ($p = 0.001$). [Table 5]

Table 1: Comparison of Comfort Score Between the two Groups.

Score	Value	Group A (L/D)n (%) (n=35)	Group B (L)n (%) (n=35)	PValue
1	Excellent, calmpatient	23	0	Chi- square-45.2 p Value-<0.0001
2	Good, comfortable,patient	6	2	
3	Moderately comfortable, Need to pacifythe patient	4	28	
4	Poor,uncomfortable	2	3	
5	Agitated patient	0	2	

Table 2: Comparison of Intubating Condition Grade Score Between the two Groups.

Score	Value	Group A (L/D)n (%) (n=35)	Group B (L)n (%) (n=35)	PValue
1	Optimal	24	0	Chi- square-37.227p Value- <0.0001
2	Suboptimal	8	21	
3	Difficult	3	12	
4	Failure	0	2	

Table 3: Comparison of Cough and Gag Score Between the Two Groups

Score	Value	Group A (L/D) n (%) (n=35)	Group B (L) n (%) (n=35)	P Value
1	None	10	0	Chi- square-34.409 p Value-
2	Minimal coughing and gagging, <3 times, like clearing throat	18	4	

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3	Mild cough and gag lasting < 1 min	5	19	<0.0001
4	Persistent Coughing & Gagging	2	10	
5	Need of Rescue Topical Anaesthesia	0	2	

Table 4: Comparison of Cord Visibility Score Between the two Groups.

Variables	Cord Visibility Score			p Value
	Relaxed	Partially Relaxed	Adducted	
Group A	26	7	2	Chi- square-12.9210p Value- 0.001
Group B	11	18	6	

Table 5: Hemodynamic Parameters During Intubation Recorded (Mean ± SD)

HemodynamicParameters	Group A (L/D)n (%) (n=35)	Group B (L)n (%) (n=35)	p Value
Heart Rate	92.54±6.45	109.23±8.11	0.002
Systolic Blood Pressure	129.23±5.33	136±5.33	0.005
Diastolic Blood Pressure	76.84±4.11	82.45±4.11	0.009
Mean Arterial Pressure	96.12±4.11	101±3.45	0.001

DISCUSSION

The utilisation of a fibre-optic device to perform awake tracheal intubation was initially documented by Murphy in 1967. In this study, a choledochoscope was employed to assist in nasotracheal intubation for individuals encountering challenges with their airway. There exist various methods for administering anaesthesia to the airway in order to facilitate the execution of awake fiberoptic bronchoscopy (FOB) guided intubation. Commonly employed methods for achieving topical anaesthesia include nebulized local anaesthetic, gargles, lozenges, sprays, airway blocks, atomized local anaesthetic, and local anaesthesia administered through the working channel of a flexible bronchoscope. Alternative methods to painful, invasive nerve block techniques for assisting awake fibre-optic intubation in patients with expected difficult airway include the use of atomizers, nebulizers, and the 'spray-as-you-go' technique to topically anaesthetize the airway mucosa.[7]

While it is possible to combine the aforementioned approaches in many ways, we have selected one distinct technique with two different medications for the purpose of comparing their effectiveness and the level of comfort experienced by patients with one, nerve block technique common in both groups. There exists a scarcity of literature that examines and compares the effectiveness and comfort of atomization with two different medications within a population characterised by a challenging airway. Previous research has investigated the use of nebulized lignocaine for the purpose of anaesthetizing the upper airway and larynx. Wei Gu et al in 2019 showed that for awake fibreoptic bronchoscopy under moderate sedation, as a premedication, nebulized dexmedetomidine-lignocaine inhalation was well tolerated with less incidence of moderate to severe cough. The patients in the lignocaine-dexmedetomidine group experienced lowest incidence of moderate to severe cough compared with those in the, no dexmedetomidine group. Thus revealing nebulized dexmedetomidine has a protective effect against cough compared with intravenous route. Our study corroborates with above mentioned study. Most of the patients of dexmedetomidine-lignocaine group had cough & gag score 2 (51.42%) and lignocaine alone group had a score 3 (54.28%).Cullen et al,[8] conducted a study wherein they discovered that the administration of lignocaine via nebulization resulted in a reduction in the level of discomfort experienced during nasogastric tube insertion. In a study conducted by Techanivate A. in 2007, it was observed that the use of 2% lignocaine nebulization resulted in a sufficient upper airway anaesthesia for fiber-optic nasotracheal intubation.[9] In a study conducted by Williams KA et al.the authors achieved successful fiber-optic nasotracheal intubation in a cohort of 25 adult patients using a combination of nebulization and spray-as-you-go approach.[10]

In the present study, it was observed that there existed no statistically significant distinction between the two groups when examining demographic variables and baseline hemodynamic parameters. The hemodynamic variables, including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP), exhibited statistically significant changes during the process of intubation. Patients in thegroup A ie, lignocaine, dexmedetomidine group exhibit a lesser degree of elevation in heart rate (HR), systolic blood pressure (SBP) and mean arterial pressure (MAP) compared to patients in the group B ie, lignocaine alone group.

In the present study, the duration required to complete fiberoptic bronchoscopy (FOB) guided intubation was shown to be considerably longer in the lignocaine group compared to lignocaine, dexmedetomidine group. In their respective studies, Gupta B et al,[11] and Vasu KB et al,[12] observed that the duration required to complete fiberoptic bronchoscopy (FOB) guided intubation was notably longer in the nebulization group. Our result is dissimilar to the study conducted by Reasoner et al,[13] comparing nebulized lignocaine with airway nerve blocks to help in awake FOB guided intubation. They did not see any significant difference in the duration of FOB guided intubation as the nebulization was reinforced by transtracheal

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lignocaine injection. In our study, when conducting a comparison of hemodynamic variables at 1,2 and 3 minutes following intubation, it was observed that patients in the lignocaine group had a greater increase in heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) compared to those in lignocaine - dexmedetomidine group. In contrast, individuals in the lignocaine - dexmedetomidine group exhibited the most minimal elevation in heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP). In a study conducted by Kundra P et al,[14] it was observed that the average heart rate (HR) and blood pressure (BP) were notably elevated in the nebulization group, indicating a statistically significant difference. According to the study conducted by Pirlich N et al,[15] it was determined that the atomization method exhibited more effectiveness in terms of comfort, cough suppression, and intubation time compared to the bolus administration technique for awake fibre-optic intubation.

In a study conducted by Vasu et al,[12] comparing atomization with transtracheal lignocaine injection, resulted in insignificant differences in HR, SBP,DBP & MAP in 1 and 5 min. after intubation. They also compared cough and gag scores between transtracheal injection and atomization and found atomization Group Patients to have higher Cough and gag score than airway nerve block group patients. Effectiveness of block was assessed by cough and gagscoring.

In our study to reduce the incidence of cough and gaging we applied transtracheal block in both the groups apart from atomization with two different drugs.

Graham DR et al in 1992,[16]documented that the bronchoscopy Preferred Trantracheal instillation of LA as compared to LA nebulization or LA instillation through the working port of fibre optic bronchoscope (FOB).

Reasoner DK et al,[17] did not find any difference in the quality of airway anaesthesia between nebulized LA and nerve blocks as assessed by a blind-observer/ bronchoscopes.

Urvashi Yadav et al in 2021 observed that topical anaesthesia was not efficient enough in the atomization group, may be due to raining- down effect of local anaesthetic into the trachea leading to poor comfort observed during awake fibreoptic intubation in atomised patients. Keeping this in our mind we have given transtracheal recurrent laryngeal nerve block in both the groups while comparing two different drugs by atomization.

The utilisation of cough and gag reflexes as a means to judge the efficacy of topical anaesthesia has been employed by numerous other studies as well. Regional blocks were deemed satisfactory if no instances of coughing or gagging occured during the process, and were regarded as optimal with a score of 1 while the utilization of rescue topical anaesthetic spray was found to be suboptimal, having a score of 5, closely resembling the scoring system utilised by Malcharek et al.[18] The majority of patients in both groups had scores ranging from 1 to 3, and there was no necessity for rescue interventions in either group. In our study, it was seen that two patients in the lignocaine group obtained a score of 5, while the majority of patients in this group had scores ranging from 3 to 4. Conversely, in lignocaine - dexmedetomidine group, no patients achieved a score of 5, instead the majority of patients in this group obtained scores ranging from 1 to 2.

Patients in Group A, who received the combination of dexmedetomidine and lignocaine, achieved significantly better intubating condition grade scores compared to those in Group B, where lignocaine alone was used. The difference in intubating condition grades was highly significant, with a chi-square value of 37.227 ($p < 0.0001$).

In the present study, Patients in Group A, who received the combination of dexmedetomidine and lignocaine, experienced significantly less coughing and gagging during AFOI compared to those in Group B, receiving lignocaine alone. The difference in cough and gag scores was highly significant, with a chi-square value of 34.409 ($p < 0.0001$).Patients in Group A, who received the combination of dexmedetomidine and lignocaine, were more likely to have "Relaxed" cord (74.28%) during AFOI compared to those in Group B (31.42%) where lignocaine alone was used.The difference in cord visibility scores was statistically significant ($p = 0.001$), with a chi-square value of 12.9210.

Our analysis aligns with the findings of Gupta et al,[11] about the grading of intubating conditions. There were no instances of desaturation, laryngospasm, or regurgitation observed among the patients during the surgery. The incidence of cough was higher in the lignocaine group, and two patients required rescue topical anaesthesia by administering local anaesthetic through the fiber-optic bronchoscope. While there was a statistically significant rise in heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial pressure (MAP) among individuals receiving nebulization, these changes did not have any therapeutic significance. All procedures were performed by skilled, experienced anaesthesiologists who regularly performthese two approaches for AFOI. This factor may account for the lack of significant problems observed across the groups and may not be replicable by individuals without expertise in the field.

CONCLUSION

The addition of dexmedetomidine to lignocaine for airway preparation during AFOI appears to be a superior approach compared to using lignocaine alone. This combination offers improved patient

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comfort, better intubating conditions, and effective suppression of cough and gag reflexes without compromising overall safety. These results have implications for enhancing the quality of care and patient experience in cases of anticipated or confirmed difficult airways, making the L/D combination a valuable option for AFOI procedures. Further research and clinical application of this approach may lead to more widespread adoption and improved outcomes for patients undergoing AFOI.

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