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Original Research Article

Comparison of dexmedetomidine, fentanyl, ketamine nebulization as an adjuvant to lignocaine for awake fibreoptic intubation: A randomised control trial

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ABSTRACT

Background: Awake fibreoptic intubation (AFOI) is a crucial technique in managing difficult airways, and local anaesthetic nebulization is the most commonly used method for anesthetizing the airway. This study focuses on comparing the efficacy of dexmedetomidine, fentanyl, and ketamine nebulization when used as adjuvants to lignocaine during AFOI.

Aim & Objective: This study aims to compare the effect of nebulised dexmedetomidine, fentanyl, and ketamine as an adjuvant to 4% lignocaine. The primary objective is to determine the cough score during the procedure and secondary objective is to look for sedation and any adverse effects.

Materials and Methods: 84 participants who required awake fibreoptic intubation of any gender and between the ages of 18 and 65 were divided into 4 equal groups at random: Along with nebulised 4% lignocaine, group A received dexmedetomidine (1 mcg/kg), group B received fentanyl (2 mcg/kg), group C received ketamine (2 mg/kg), and group D received normal saline. Each group contained 21 people. Cough scores and Glottis visibility were observed and additionally Ramsay sedation score (RSS) and any other side effects were monitored.

Results: No cough was observed in 76.2% of Groups A and B, 66.7% in Group C and 0% in group D which was statistically, a very high significant difference, amongst the participants in four groups P = 0.000 (p<0.05). The glottis was open in 100% in Group C, 90.5% in Group A, 85.7% in Group B, and 71.4% in Group D with significant statistical difference amongst the groups(p = 0.006) (p<0.05). Participants who were anxious, agitated and restless were 100% in group D, 38.1% in Group C, 14.3% in Group A, and 4.8% in Group B, with significant difference. p = 0.000 (p<0.05). No adverse effects were noted in any of the group participants.

Conclusion: Nebulised dexmedetomidine and fentanyl produced satisfactory airway preparation for awake fibreoptic intubation when compared to ketamine and plain lignocaine, although sedation was higher in the fentanyl group.

1. Introduction

The gold standard technique for managing difficult airways in anaesthetic practice is awake fibreoptic intubation (AFOI).[1] It is principally done in patients suspected to have a difficult airway, has had an intubation attempt fail, or have an unstable cervical spine injury where the finest positioning for laryngoscopy is tough to attain.[2] And, since awake fibreoptic intubation makes patients uncomfortable, it is crucial to anaesthetize the upper airway satisfactorily before undertaking awake fibreoptic guided intubation. This will ensure patient comfort and cooperation by avoiding

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coughing, gag reflex, and adverse hemodynamic changes.[1] In order to achieve this, anaesthesiologist employs a variety of approaches which includes nebulization, airway blocks, local anaesthetic spray, etc.

A selective alpha-2 agonist, dexmedetomidine has sedative, anxiolytic, analgesic, and salivary secretion-inhibiting action.[3] The analgesic effect of fentanyl administration by intravenous route has long been recognized. Local administration of ketamine via the nasal, oral, and rectal routes has been found to be both efficient and valid in the nociperception and anti-inflammatory cascade.[4] Several studies have been conducted on nebulised lignocaine,[1,5–8] dexmedetomidine,[5–8] and fentany[5] but none on nebulised ketamine for awake fibreoptic intubation. Nebulisation with dexmedetomidine is found to be more comfortable and also provides optimum environment for bronchoscopy.[5] We chose to compare dexmedetomidine with fentany,[1] ketamine and placebo as adjuvant nebulisation drug to lignocaine.

2. Materials and Methods

After receiving approval from the Institutional scientific research board (SRB/AOTT/01/2022) and the Institutional ethics committee 2 (YEC2/1163), the Clinical Trial Registry of India (CTRI/2023/01/049238) enrolment was established. Then written informed consent was obtained from the patients a day before the procedure. This randomized, double-blinded, prospective study was conducted on 84 patients scheduled to undergo surgeries needing awake fibreoptic intubation during general anaesthetic procedures. Sample size was estimated for one-way ANOVA using G*power software. To determine the required sample size we assumed a moderate effect size of 0.4 based on the within –subject standard deviation of primary outcome i.e. cough score, which is expected to be around 0.68 in pilot data from Kumari P et al.[5] The effect size of 0.4 represents a clinically meaningful difference between the groups, considering the practical implications of awake fiberoptic intubation. At 5% level of significance, 85% power and effect size 0.4 assuming within standard deviation to be 0.68 as per parent article Kumari P et al.,[5] considering cough score as primary objective, minimum sample size in each group was 21 and total sample size required for the study was 84.

84 patients requiring awake fibreoptic intubation were assessed for eligibility. The patients were selected by a simple random sampling method. The inclusion criteria were as follows: (i) Age group between 18 and 65 years, (ii) American Society of Anaesthesiologist (ASA) physical status of I-II. Patients were excluded if they had (i) previous airway surgery, (ii) nasal trauma (iii) allergy to local anaesthetic. Enrolment extended from December 2022 until June 2023. By using a computer-generated random number, the patients were randomly divided into 4 groups of 21 participants each. Prior to assigning a group, as illustrated in flow chart (Diagram 1), the random allocation sequence was hidden in opaque, sealed envelopes. An anaesthesiologist who was not involved in the study prepared the drug mixture with volume standardized to 8 ml using saline, as per the sealed envelopes and started the nebulisation. Participants and the co-investigator who performed the broncoscopy were blinded to the group allotment. Pantoprazole 40mg IV, Ondansetron 4 mg IV, and Glycopyrrolate 0.2 mg IM injections were administered in the preoperative area once the intravenous line was secured. Nasal packing was done using lignocaine with adrenaline (the dosage of lignocaine was maintained below the toxic levels). We chose drug dose of 1mcg/kg dexmedetomidine and 2mcg/kg fentanyl as adjuvant to lignocaine nebulisation in AFOI based on previous study by Kumari P et al.[5] Previous study by Prasant NV[4] used ketamine nebulisation for post operative sore throat, we chose dose of nebulized ketamine to be 2mg/kg.

Patients were assigned to one of four groups and nebulized with a total of 8 ml of a drug mixture. Group A received a solution containing 4 ml of 4% lignocaine combined with 1 mcg/kg of dexmedetomidine. Group B was administered 4 ml of 4% lignocaine along with 2 mcg/kg of fentanyl. Group C received 4 ml of 4% lignocaine mixed with 2 mg/kg of ketamine. Lastly, Group D was given 4 ml of 4% lignocaine with 4 ml of normal saline as a control.

A FLAEM AIRMATE® nebulizer with an oxygen flow rate of 8-10 L/min was used to deliver this drug mixture approximately 20 minutes prior to awake fibreoptic intubation. To help the nebulized medicine entrain into the patient's airway over the course of 15 minutes, patients were advised to breathe deeply through their nose and mouth. The nebulization drugs were administered by an anaesthesiologist not involved in this study. The patients were unaware of the drug they had received.

Electrocardiography (ECG), non-invasive blood pressure (NIBP) and pulse oximetry (SpO2) were all used in the operating room to monitor the patient. The co-investigator anaesthesiologist, who was blinded to the study groups, carried out the AFOI using an OLYMPUS® fibreoptic bronchoscope. The endotracheal tubes utilized were of size 7.0 mm for female patients and 8.0mm for male patients. Nasal prongs were used the entire time to administer adequate oxygen. Baseline vitals were noted. During AFOI, vital signs such as heart rate (HR), non-invasive blood pressure (NIBP), and oxygen saturation (SpO2) were monitored to check for any adverse events.

The participant's IP number, age, sex, weight (kg), height (cms), ASA PS I/II were noted; cough score, and glottic visibility during the time of intubation were recorded. Episodes of coughing were monitored from the time of bronchoscopy till the endotracheal tube reaches the tracheal carina. The cough score was classified as 1 = No cough,

2 = Slight (≤ 2 cough), 3 = Moderate (3-5 coughs), and 4 = Severe (>5 coughs). Glottis visibility was monitored and graded as open or closed.[6] Secondary outcomes like sedation score and other adverse effects during the time of AFOI were also recorded. Sedation scores were assessed using the Ramsay sedation score (RSS): Score 1 = Anxious, agitated or restless; Score 2= cooperative, oriented, and tranquil; Score 3 = sedated, but responds to command; Score 4 = asleep, brisk glabellar reflex, responds to loud noise; Score 5 = asleep, sluggish glabellar reflex responds to loud noise; and Score 6 = asleep with no response to a painful stimulus.[5] Vitals were monitored to check for adverse effects. All these data were recorded by the co-investigator anaesthesiologist who was unaware of the group allocation and handed over to the principal investigator.

All participant-recorded data were statistically analysed using SPSS 27 software. Continuous variables are expressed as means ± standard deviation. Categorical variables are expressed as frequency and percentage (%). A Chi-square test was used for the comparison of cough score, glottis visibility score, Ramsay sedation score, and gender-wise effect of drug among the 4 groups. A one-way ANOVA test is used to compare the age-wise distribution of the study participants in the groups. P values < 0.05 were considered to be statistically significant.

3. Results

In the present study, a total of 84 individuals were considered and divided into four groups: Lignocaine with Dexmedetomidine (Group A), Lignocaine with Fentanyl (Group B), Lignocaine with Ketamine (Group C), and Lignocaine with saline (Group D). Each group consisted of 21 patients (n = 21), who were eligible and enrolled accordingly. The participant's progress through the study is shown according to Consort guidelines 2010 in (Diagram 1) as a consort flow diagram:

The mean age (Table 1) of the study participants in the groups was found to be 48.7±13.4 years in lignocaine with dexmedetomidine group, 39.2±12.3 years in lignocaine with fentanyl group, 43.1±12.0 years in lignocaine with ketamine group and 45.1±10.8 years in plain lignocaine group respectively. P value was 0.094. Hence, statistically no significant difference was observed in age-wise distribution of the study participants in four groups (p>0.05).

The percentage of females and males (Table 2) in the lignocaine with dexmedetomidine group (Group A) was 4.8% & 20.2%, 6.0%, and 19.0% in lignocaine with fentanyl group (Group B), 11.9%, and 13.1% in lignocaine with ketamine group (Group C), and in plain lignocaine group (Group D) it was found to be 10.7% in females and 14.3% in males. (p = 0.134) hence using the Chi-Square no significant statistical difference was observed in the gender-wise distribution of the study participants in four groups (p>0.05).

On comparison of the cough scores amongst patients in various groups, it was observed that 16 (76.2%) in Group A, 16 (76.2%) in Group B, 14 (66.7%) in Group C and 0 (0%) in Group D had no cough. While 5 (23.8%) in Group A, 5 (23.8%) in Group B, 7 (33.3%) in Group C, and 21 (100%) in Group D were found to have a cough with a cough score ranging from mild to moderate. No cough was observed highest in lignocaine with dexmedetomidine group and fentanyl group each (76.2%). One participant in lignocaine with dexmedetomidine had a severe cough (4.8%). None of the participants in the plain lignocaine group were free of cough. 76.2% of participants were observed with slight cough in the plain lignocaine group. One patient in group B was excluded due to technical problem during the procedure. On using the Chi-square test, statistically very high significant difference was observed in the prevalence of cough among patients in four groups p = 0.000 (p<0.05)(Table 3).

Table 4 show that the percentage of patients with an open glottis varied across the study groups. In Group A (Lignocaine with Dexmedetomidine), 19 out of 21 patients (90.5%) had an open glottis, while in Group B (Lignocaine with Fentanyl), 18 out of 21 patients (85.7%) experienced the same. Group C (Lignocaine with Ketamine) had the highest percentage, with all 21 patients (100%) showing an open glottis. In contrast, Group D (Lignocaine with Saline) had the lowest, with only 15 out of 21 patients (71.4%) demonstrating an open glottis. The percentage of patients with an open glottis was significantly higher in Groups A, B, and C compared to Group D. The Chi-Square test revealed a statistically significant difference in glottis opening among the groups (p = 0.006), indicating that the adjuvants used with lignocaine had a significant impact on improving glottis visibility during the procedure.

Table 5 illustrates the varying levels of sedation across the four groups, measured using the Ramsay Sedation Scale (RSS). In Group A (Lignocaine with Dexmedetomidine), 3 participants (14.3%) were anxious, agitated, or restless (RSS = 1), while the majority, 18 participants (85.7%), were cooperative, oriented, and tranquil (RSS = 2). Group B (Lignocaine with Fentanyl) showed similar results, with 1 participant (4.8%) classified as anxious or restless (RSS = 1) and 20 participants (95.2%) as sedated but responsive to commands (RSS = 3). In Group C (Lignocaine with Ketamine), 8 participants (38.1%) were anxious or restless (RSS = 1), and 13 (61.9%) were cooperative or sedated (RSS=2 or 3). Group D (Lignocaine with Saline), however, showed a stark contrast, where all 21 participants (100%) were anxious, agitated, or restless (RSS = 1), with none achieving higher sedation scores. Notably, the fentanyl group demonstrated the highest level of sedation with 85.7% of participants sedated but responsive to commands (RSS = 3). A statistically significant difference in Ramsay Sedation

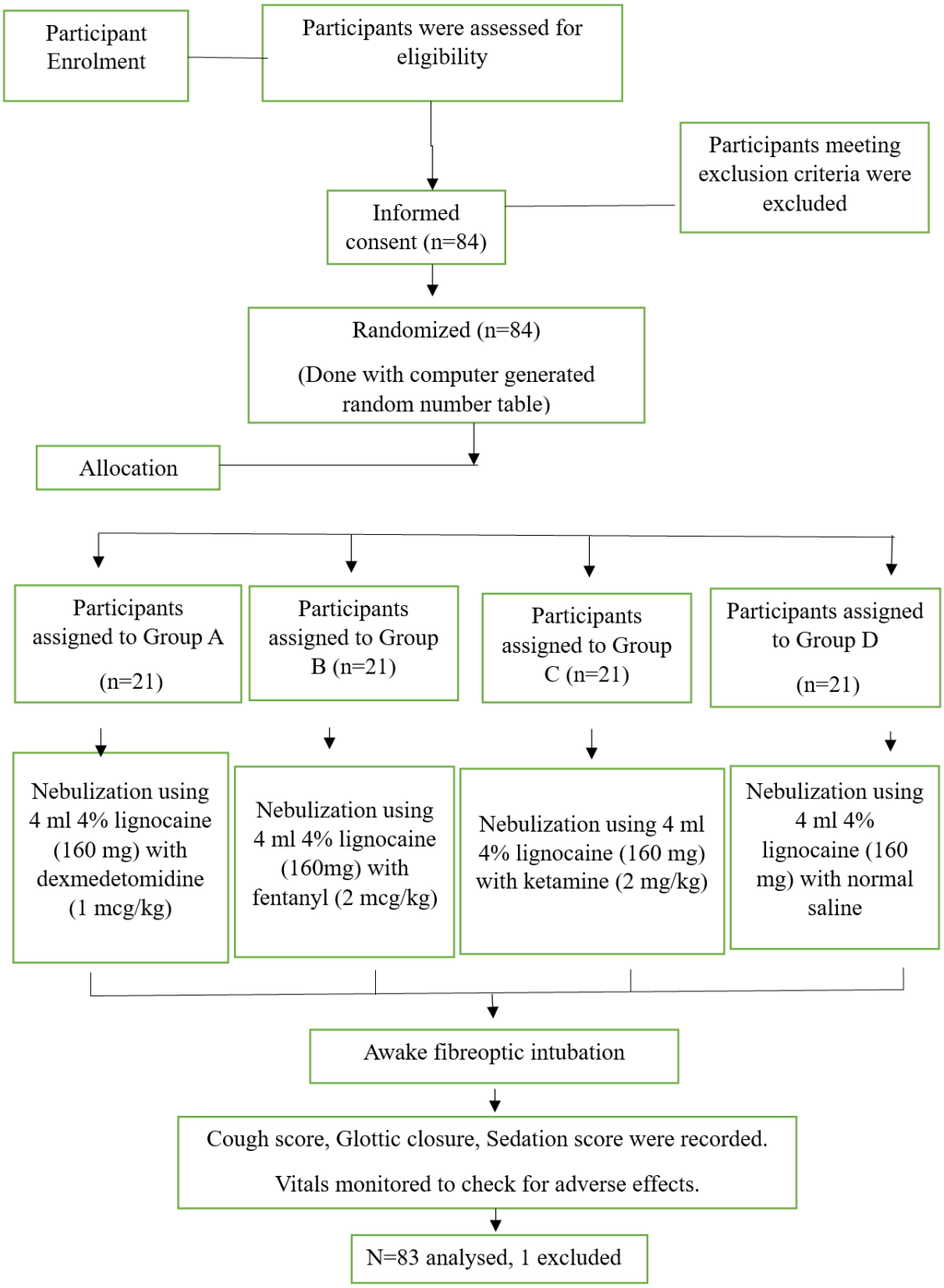

Diagram 1: Consort flow diagram

Scores was observed across the four groups, as indicated by the Chi-Square test (p = 0.000), confirming that the sedative effects of the adjuvant drugs were more effective than plain lignocaine in achieving adequate sedation levels during the procedure.

4. Discussion

Our study observed that when nebulized with adjuvants drugs like dexmedetomidine, fentanyl, and ketamine, coughing during fibreoptic was lesser in comparison to lignocaine alone (p 0.000)(Table 3). Patients who received fentanyl nebulization had a higher value of Ramsay sedation score when compared to dexmedetomidine and ketamine. (p = 0.00). Sedation with fentanyl was higher because it is highly lipophilic in nature and gets absorbed easily through the nebulization route.[9,10]

4.1. Cough score

Dexmedetomidine is a sedative, anxiolytic and analgesic drug without causing respiratory depression. The agonist activity on the peripherally located alpha 2 receptor in the bronchi causes the relaxation of smooth muscles and bronchodilatation thereby reducing the cough reflex in patients.[11] Hence in our study, we used nebulized dexmedetomidine as an adjuvant drug to lignocaine. A case series was reported by Kumar A et al.[7] where dexmedetomidine 1 mcg/kg with 4% lignocaine was used through the inhalation route for AFOI and found that all patients were comfortable throughout the procedure. Sancheti A G et al.[8] conducted a study where patients who received dexmedetomidine by nebulisation (0.5mcg/kg) with transtracheal inhalation (0.5mcg/kg) had better tolerance and lower cough scores than those who received it intravenously (1 mcg/kg). They concluded that dexmedetomidine by nebulization and transtracheal route provided optimal conditions for AFOI with good patient tolerance and lower cough scores as compared to the intravenous route alone. Another study by Wei Gu et al.[6] compared nebulized dexmedetomidine, intravenous dexmedetomidine, and no dexmedetomidine and found that the incidence of moderate to severe coughing was 15%, 50%, and 55%, respectively. Also, nebulized dexmedetomidine had a significant reduction in cough score and required less vasoconstrictor consumption. This was in accordance with our study where no cough was observed in 76.2% of the nebulized dexmedetomidine group when compared to the plain lignocaine group (0%) (p <0.00). This finding may be due to the fact that dexmedetomidine can potentiate the effects of local anaesthetic.[12]

Pulmonary administration of aerosolized fentanyl using Smart Mist provided a similar plasma concentration of fentanyl when compared to IV injection. Systemic pharmacokinetics were similar to previously reported with no trends to dose dependence in either route. Adverse effects were the same in both groups.[13] Kumari P et al.[5] compared dexmedetomidine vs fentanyl as adjuvant to lignocaine nebulisation and found that dexmedetomidine group had lower cough scores, and higher satisfaction and comfort score.. Contrarily, we observed similar cough scores in dexmedetomitine and fentanyl group (76.2%). Significant difference in cough scores was seen with ketamine and saline group. (p 0.00). A study by Grover et al.,[14] they inferred that nebulised dexmedetomidine, Mgso4 were superior to fentanyl in blunting the stress response to direct laryngoscopy and intubation, but the dose of fentanyl used was 1 mcg/kg which was lesser than in our study. There is paucity of literature for use of nebulised fentanyl in AFOI.

Ketamine, an NMDA receptor antagonist has a 20-40% bioavailability when administered via nebulization route. Previous studies done by Prasant NV et al.[4] and Ahuja V et al.[15] have demonstrated that nebulized ketamine decreases the incidence and severity of post-operative sore throat. A study by Daneil dove et al.[16] showed that sub dissociative dose of nebulised ketamine administered by breath actuated nebuliser decreased moderate-severe acute painful conditions in emergency units. However, nebulised ketamine was not used for awake fibreoptic intubation. Hence in our study, we used adjuvant ketamine nebulization for awake fibreoptic intubation. We observed that 14 (66.7%) patients had no cough and 7 (33.3%) patients had mild to moderate cough in the ketamine group when compared to the plain lignocaine group where 21 (100%) of patients had mild to moderate cough and 0% had no cough. 100% of the participants had glottis open on visualization by bronchoscopy. Ketamine group patients had higher cough score compared to fentanyl and dexmedetomidine probably due to poor bioavailability. Further studies need to be done to ascertain these findings.

4.2. Glottis view

Wei Gu et al.[6] also found that there was no significant change in glottis view when dexmedetomidine was compared to plain lignocaine owing to no effect on muscle relaxation by dexmedetomidine group. But in our study, the glottic open was seen among 90.5% in the dexmedetomidine group and 71.4% in the plain lignocaine group. This revealed a statistically significant difference in the percentage of patients seen with glottic open (p = 0.006) (Table 4). 85.7% of fentanyl patients have glottis open on visualization and 100% of ketamine patients had glottis open on visualization by bronchoscopy. There is dearth of data regarding use of nebulised ketamine for AFOI and glottis visibility thereby necessitating further research.

Table 1: Age-wise distribution of the study participants in the groups

Group	N	Mean	Std Deviation	Minimum	Maximum	P value
Lignocaine with dexmeditomidine (Group A)	21	48.76	13.438	23	64	
Lignocaine with fentanyl (Group B)	21	39.29	12.338	19	63	0.094
Lignocaine with ketamine (Group C)	21	43.14	12.010	16	65	
Lignocaine with saline (Group D)	21	45.10	10.821	24	65	
Total	84	44.07	12.450	16	65	

Table 2: Gender-wise distribution of patients in various drug groups

		Group A	Group B	Group C	Group D	Total	P value
Females	number	4	5	10	9	28	
	%	4.8%	6%	11.9%	10.7%	33.3%	
Males	number	17	16	11	12	56	0.134
	%	20.2%	19%	13.1%	14.3%	66.7%	
Total	total	21	21	21	21	84	
	%	25%	25%	25%	25%	100%	

Table 3: Comparison of cough score in different groups

			Group				Total	P value
			1	2	3	4		
Cough Score	No cough	Count	16	16	14	0	46	.000*
		%	76.2%	76.2%	66.7%	0.0%	54.8%	
	Slight cough	Count	3	2	7	16	28	
		%	14.3%	9.5%	33.3%	76.2%	33.3%	
	Moderate cough	Count	1	2	0	5	8	
		%	4.8%	9.5%	0.0%	23.8%	9.5%	
	Severe cough	Count	1	0	0	0	1	
		%	4.8%	0.0%	0.0%	0.0%	1.2%	
	Failed intubation (due to nasal mass)	Count	0	1	0	0	1	
		%	0.0%	4.8%	0.0%	0.0%	1.2%	
Total		Count	21	21	21	21	84	
		%	100.0%	100.0%	100.0%	100.0%	100.0%	

*cell frequency are pooled

Table 4: Comparison of glottis visibility in different groups

			Group				Total	P value
			1	2	3	4		
Glottic Closure	Open	Count	19	18	21	15	73	.006*
		%	90.5%	85.7%	100.0%	71.4%	86.9%	
	Closure	Count	2	2	0	6	10	
		%	9.5%	9.5%	0.0%	28.6%	11.9%	
	Failed	Count	0	1	0	0	1	
		%	0.0%	4.8%	0.0%	0.0%	1.2%	
Total		Count	21	21	21	21	84	
		%	100.0%	100.0%	100.0%	100.0%	100.0%	

*cell frequency are pooled

Table 5: Comparison of Ramsay sedation score in different groups

			Group				Total	P value
			1	2	3	4		
Ramsay sedation score	Anxious, agitated or restless	Count	3	1	8	21	33	.000*
		%	14.3%	4.8%	38.1%	100.0%	39.3%	
	Cooperative, oriented and tranquil	Count	17	1	13	0	31	
		%	81.0%	4.8%	61.9%	0.0%	36.9%	
	Sedated but responds to commands	Count	1	18	0	0	19	
		%	4.8%	85.7%	0.0%	0.0%	22.6%	
	Failed	Count	0	1	0	0	1	
		%	0.0%	4.8%	0.0%	0.0%	1.2%	
Total		Count	21	21	21	21	84	
		%	100.0%	100.0%	100.0%	100.0%	100.0%	

*cell frequency arepooled

4.3. Sedation

81% of patients in the dexmedetomidine group were cooperative, oriented, and tranquil (RSS = 2). 85.7% of participants in the fentanyl group were sedated and responding to commands (RSS = 3) and 61.9% of ketamine patients were cooperative, oriented, and tranquil (RSS = 2). The results were in accordance with the study by H.S. Abdel-Ghaffar et al.[17] Unlike fentanyl (agonist at opioid receptor) and ketamine (NMDA receptor antagonist), dexmedetomidine is an alpha 2 agonist that primarily acts on locus coeruleus which induces EEG activity similar to natural sleep.[18] Hence, dexmedetomidine patients were less likely to be disoriented, uncooperative, or deeply sedated. Similar results were found in the study by Singariya G et al.[19] where they found that children were comparatively calm and sedated with better mask acceptance and fewer respiratory complications in the dexmedetomidine group compared to the ketamine group. Fentanyl group were more sedated when compared to the dexmedetomidine and ketamine group (p 0.000). (Table 5). A study done by Chen C et al.[20] found that pre-anaesthetic inhaled ketamine can provide effective sedation in low doses for elective surgery in children when compared to oral ketamine. In our study, 61.9% of participants fell into Ramsay sedation score 2 (cooperative oriented and tranquil) and 38.1% were Ramsay sedation score 1 (agitated, anxious, and restless).

By using various nebulisation adjuvant the dose of lignocaine can be decreased. Unlike lignocaine, these adjuvants are potent sedatives and analgesics. Hence they could be useful in providing optimum environment for awake broncoscopy assisted intubation and can be extended to non operative room procedures like indirect laryngoscopy, diagnostic broncoscopy.

The limitations of our study were single centred study and inherent heterogeneity in patient population. We did not record the trend in hemodynamics, only if there had been adverse events were being noted. Serum concentration of lignocaine and other drugs were not monitored. Our secondary outcomes may have been underpowered as we were unable to detect delayed adverse events in patients as patient received general anaesthesia following AFOI. Therefore, further studies might be required to determine delayed adverse reaction of drugs in patients, in addition to monitoring drug serum concentrations.

The strengths of our study were that we compared different adjuvants by nebulization route only because of the ease of administration, need of minimally skilled expertise personnel, circumvent the adverse effects of bradycardia, hypotension, and respiratory depression and to achieve optimal preparation of the patient for awake fibreoptic intubation. Ketamine nebulisation for AFOI has been tried for the first time. Awake fibreoptic intubation was performed by same anaesthesiologist in all the patients to limit confounding factors. As per the available web resources no studies have reported about the role of ketamine nebulisation for AFOI.

5. Conclusion

Nebulized dexmedetomidine and fentanyl produced satisfactory airway preparation for awake fibreoptic intubation when compared to ketamine and plain lignocaine, although sedation was higher in fentanyl group. All patients in ketamine group had glottis open. Further studies are required to confirm the role of nebulised ketamine in AFOI. No adverse effects were observed in nebulization route unlike IV which is historically known to produce adverse effects needing intervention many a times. Hence, these nebulisation adjuvants can be used by minimally skilled personnel in resource limited areas.

6. Source of Funding

None.

7. Conflict of Interest

None.

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