

Comparative Evaluation of Nebulized Fentanyl versus Dexmedetomidine as an Adjuvant to Lignocaine for Flexible Fiberoptic Awake Nasal Intubation in Surgeries under General Anaesthesia: A Randomized Controlled TrialArvind Khare¹, Beena Thada², Gopika R.³¹Senior Professor & Head of Department, Department of Anaesthesiology, Jawaharlal Nehru Medical College and Associated Group of Hospitals, Ajmer, Rajasthan, India²Professor, Department of Anaesthesiology, Jawaharlal Nehru Medical College and Associated Group of Hospitals, Ajmer, Rajasthan, India³Postgraduate Student, Department of Anaesthesiology, Jawaharlal Nehru Medical College and Associated Group of Hospitals, Ajmer, Rajasthan, India

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Conflict of interest: Nil

Abstract

Background: Awake fiberoptic intubation (AFOI) requires effective topical anaesthesia, adequate sedation and preserved airway reflex suppression. Lignocaine nebulization alone is often insufficient, and adjuvants such as fentanyl and dexmedetomidine have been used to optimize intubating conditions. Comparative data between these two adjuvants during flexible fiberoptic awake nasal intubation (AFNI) under general anaesthesia remain limited.

Methods: In this prospective, randomized, double-blind study, 100 adult patients (ASA I–II) with a predicted difficult airway scheduled for elective ENT, maxillofacial, plastic, orthopaedic or spinal surgery under general anaesthesia were randomized to receive nebulization with either 4% lignocaine (4 mL) plus fentanyl 2 µg/kg (Group F, n = 50) or 4% lignocaine (4 mL) plus dexmedetomidine 1.5 µg/kg (Group D, n = 50), diluted with normal saline to 8 mL, over 20 minutes prior to AFNI. The primary outcome was the cough score during intubation; secondary outcomes included time to intubation, vocal cord position, post-intubation comfort score, Ramsay sedation score, haemodynamic parameters, post-surgery satisfaction score, and adverse effects.

Results: Baseline demographics were comparable between groups. A cough-free intubation occurred in 60% of Group D versus 34% of Group F (p = 0.033). Group D showed a shorter mean intubation time (3.58 ± 1.60 vs. 4.68 ± 1.80 min; p = 0.0017), more favourable vocal cord relaxation (62% vs. 36% fully relaxed; p = 0.029), better post-intubation comfort (64% vs. 32% cooperative; p = 0.007), higher post-surgery satisfaction (50% vs. 30% excellent; p = 0.043) and deeper Ramsay sedation scores (p = 0.038). Heart rate, systolic, diastolic and mean arterial pressures rose less during intubation in Group D, with significant differences between groups at 6, 8 and 10 minutes (p < 0.05). Oxygen saturation and adverse-effect rates were comparable between groups (p = 0.245).

Conclusion: Nebulized dexmedetomidine (1.5 µg/kg) as an adjuvant to lignocaine provided superior cough suppression, faster intubation, better patient comfort and satisfaction, deeper sedation, and greater haemodynamic stability than nebulized fentanyl (2 µg/kg), with a comparable safety profile, during flexible fiberoptic awake nasal intubation under general anaesthesia.

Keywords: awake fiberoptic intubation; dexmedetomidine; fentanyl; nebulization; lignocaine; difficult airway; cough score; haemodynamic stability.

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Introduction

Airway management is central to the safe conduct of general anaesthesia, and difficult airway situations remain a leading cause of anaesthesia-related morbidity.[1] Awake fiberoptic intubation (AFOI) is regarded as the gold-standard technique for securing an anticipated difficult airway, as it preserves spontaneous ventilation and allows

continuous patient cooperation while the airway is visualized and instrumented under direct vision.[2,3] Successful AFOI requires dense topical anaesthesia of the airway from the nares to the trachea together with a level of sedation that blunts airway reflexes without compromising ventilation or cooperation.[4,5] Nebulized lignocaine achieves

widespread mucosal anaesthesia with a favourable safety profile compared with regional nerve blocks, but its effect alone is often insufficient to abolish cough and haemodynamic responses to airway instrumentation.[6,7] Adjuvant drugs delivered by the same nebulized route have therefore been explored to potentiate topical anaesthesia while avoiding the risks associated with intravenous sedative boluses.[8,9]

Fentanyl, a potent short-acting opioid, blunts airway and sympathetic reflexes and provides rapid analgesia, but carries a risk of respiratory depression, particularly relevant in an awake, spontaneously breathing patient.[10] Dexmedetomidine, a highly selective α_2 -adrenoceptor agonist, provides sedation, anxiolysis and analgesia with comparatively preserved respiratory drive, and nebulized dexmedetomidine achieves useful bioavailability via the nasal and buccal mucosa.[11,12] Both drugs have individually been used as nebulized adjuvants to lignocaine in prior studies of fiberoptic bronchoscopy and intubation, but head-to-head comparisons specific to flexible fiberoptic awake nasal intubation (AFNI) under general anaesthesia are limited, and the optimal adjuvant remains unsettled.[13–15]

We therefore designed this randomized, double-blind study to compare nebulized fentanyl and dexmedetomidine, each combined with lignocaine, for AFNI in surgeries under general anaesthesia. The primary objective was to compare the cough score during intubation; secondary objectives were to compare the time required for intubation, vocal cord position, post-intubation comfort, sedation level, haemodynamic stability, post-surgery patient satisfaction and adverse effects.

Materials and Methods

Study design and setting: This prospective, randomized, double-blind, parallel-group study was conducted in the Department of Anaesthesiology at a tertiary care teaching hospital after approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants. The study adhered to the principles of the Declaration of Helsinki and is reported in accordance with the CONSORT 2010 statement.

Participants: Adult patients of either sex, aged 18–65 years, ASA physical status I or II, with a predicted difficult airway, scheduled for elective ENT, maxillofacial, plastic, orthopaedic or spinal surgery under general anaesthesia with a planned duration of under 120 minutes, and requiring AFNI, were eligible.

Exclusion Criteria: ASA physical status III or higher; known coronary artery disease, prior myocardial infarction or ischaemic heart disease;

pregnancy; known hypersensitivity to the study drugs; inability to provide informed consent; uncontrolled hypertension or diabetes, heart block, haemodynamic instability, current beta-blocker therapy, bleeding diathesis, or refractory hypoxaemia.

Randomization and Blinding: Patients were allocated in a 1:1 ratio to Group F or Group D using a computer-generated random number table, with allocation concealed in sequentially numbered, opaque, sealed envelopes opened immediately before nebulization. An anaesthesiologist not involved in data collection or analysis prepared the study drug according to group allocation. The patient, the anaesthesiologist assessing cough episodes and recording outcome parameters, and the anaesthesiologist performing the fiberoptic intubation were all blinded to group allocation.

Interventions: Group F (n = 50) received nebulization with 4% lignocaine 4 mL plus fentanyl 2 μ g/kg, diluted with normal saline to a total volume of 8 mL. Group D (n = 50) received nebulization with 4% lignocaine 4 mL plus dexmedetomidine 1.5 μ g/kg, diluted with normal saline to 8 mL. Nebulization was administered over 20 minutes in both groups using a standard nebulization mask. Glycopyrrolate 0.2 mg intravenously and intranasal xylometazoline 0.1% in both nostrils were administered 30 minutes before the procedure in all patients. Supplemental oxygen (2 L/min) was delivered via nasal prongs throughout. AFNI was then performed with a flexible fiberoptic bronchoscope (11301 BNX, 5.5 $\times$ 65 cm). Intermittent intravenous midazolam 1 mg was permitted as rescue sedation for cough or gag reflex in either group.

Following successful intubation, general anaesthesia was induced with propofol 2 mg/kg and vecuronium 0.1 mg/kg, and maintained with oxygen–nitrous oxide (50:50) and sevoflurane up to 2% v/v with intermittent vecuronium 0.02 mg/kg; neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.5 mg at the end of surgery.

Outcome Measures

Primary Outcome: Cough score during intubation, graded from the time the bronchoscope contacted the patient to completion of intubation as: 1 = no cough, 2 = slight (≤ 2 coughs), 3 = moderate (3–5 coughs), 4 = severe (> 5 coughs).

Secondary outcomes: (i) time from passage of the bronchoscope through the nostril to the first capnographic reading after intubation; (ii) vocal cord position at intubation (1 = relaxed/open, 2 = moving/partially open, 3 = adducted/closed); (iii) post-intubation patient comfort (1 = cooperative, 2

= restless/minimal resistance, 3 = severe resistance requiring immediate general anaesthesia); (iv) Ramsay sedation score after nebulization; (v) heart rate, systolic, diastolic and mean arterial pressures and SpO₂ recorded at baseline, at 5, 10, 15 and 20 minutes during nebulization, immediately before the procedure, and at 2, 4, 6, 8, 10, 15 and 30 minutes during and after intubation; (vi) post-surgery patient satisfaction score (1 = excellent to 4 = poor), recorded 2 hours after surgery; and (vii) adverse effects, including hypotension, bradycardia, hypertension, tachycardia, nausea/vomiting and respiratory depression.

Sample Size: Based on a previous report of a 65% baseline incidence of cough with lignocaine nebulization and an anticipated 38% relative reduction with the addition of an adjuvant, a sample size of 50 patients per group was calculated to provide 80% power at a two-sided α of 0.05.[16]

Statistical Analysis: Categorical variables are expressed as frequency and percentage and were

compared using the chi-square test. Continuous variables are expressed as mean $\pm$ standard deviation and were compared using the independent-samples t-test. A two-sided p value < 0.05 was considered statistically significant. Analyses were performed using standard statistical software.

Results

Of 110 patients assessed for eligibility, 10 were excluded (6 did not meet inclusion criteria, 4 declined participation), and 100 patients were randomized (50 per group).

All randomized patients completed the study and were included in the final analysis (Figure 1).

Baseline Characteristics: Groups F and D were comparable for age (45.8 ± 5.3 vs. 46.6 ± 8.4 years; $p = 0.590$), weight (66.1 ± 5.7 vs. 67.6 ± 6.5 kg; $p = 0.214$), sex distribution ($p = 0.393$), ASA grade ($p = 0.657$) and duration of surgery (89.1 ± 11.6 vs. 90.8 ± 11.0 min; $p = 0.456$) (Table 1).

Table 1: Baseline demographic and clinical characteristics

Characteristic	Group F (n = 50)	Group D (n = 50)	p value
Age (years), mean $\pm$ SD	45.8 ± 5.3	46.6 ± 8.4	0.590
Weight (kg), mean $\pm$ SD	66.12 ± 5.68	67.64 ± 6.46	0.214
Male sex, n (%)	18 (36.0)	14 (28.0)	0.393
ASA grade I, n (%)	35 (70.0)	37 (74.0)	0.657
Duration of surgery (min), mean $\pm$ SD	89.11 ± 11.64	90.80 ± 10.95	0.456

SD = standard deviation; ASA = American Society of Anesthesiologists.

Primary and secondary intubation-related outcomes: A cough-free intubation was achieved in 60.0% of Group D compared with 34.0% of Group F, with a significantly lower overall cough score distribution in Group D ($p = 0.033$) (Table 2). The mean time required for intubation was significantly shorter in Group D (3.58 ± 1.60 min) than in Group F (4.68 ± 1.80 min; $p = 0.0017$). Vocal cords were fully relaxed at intubation in 62.0% of Group D versus 36.0% of Group F ($p =$

0.029). Post-intubation comfort was rated cooperative in 64.0% of Group D versus 32.0% of Group F ($p = 0.007$).

Post-surgery satisfaction was excellent in 50.0% of Group D versus 30.0% of Group F, with no patient in Group D reporting poor satisfaction compared with 10.0% in Group F ($p = 0.043$). The Ramsay sedation score after nebulization was shifted toward deeper sedation levels in Group D (score 4 in 34.0% vs. 16.0%; $p = 0.038$).

Table 2: Comparison of intubation-related and patient-reported outcomes

Outcome	Group F (n = 50), n (%)	Group D (n = 50), n (%)	p value
Cough score 1 – no cough	17 (34.0)	30 (60.0)	0.033
Cough score 2 – slight (≤ 2)	24 (48.0)	15 (30.0)	
Cough score 3 – moderate (3–5)	9 (18.0)	5 (10.0)	
Vocal cords relaxed/open	18 (36.0)	31 (62.0)	0.029
Vocal cords moving/partial	25 (50.0)	16 (32.0)	
Vocal cords adducted/closed	7 (14.0)	3 (6.0)	
Post-intubation comfort – cooperative	16 (32.0)	32 (64.0)	0.007
Post-intubation comfort – restless	23 (46.0)	17 (34.0)	
Post-intubation comfort – severe resistance	11 (22.0)	1 (2.0)	
Satisfaction – excellent	15 (30.0)	25 (50.0)	0.043
Satisfaction – good	20 (40.0)	18 (36.0)	
Satisfaction – fair/poor	15 (30.0)	7 (14.0)	
Ramsay sedation score 3–4 (sedated)	32 (64.0)	42 (84.0)	0.038
Time to intubation (min), mean $\pm$ SD	4.68 ± 1.80	3.58 ± 1.60	0.0017

Haemodynamic Parameters: Baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and mean arterial pressure (MAP) were comparable between groups (all $p > 0.05$). Both groups showed a modest decline in HR and blood pressure following nebulization, with no significant between-group difference. During and after intubation, all haemodynamic parameters rose

in both groups, but the rise was significantly attenuated in Group D, with the largest between-group differences observed at 6, 8 and 10 minutes after intubation (Table 3).

SpO₂ remained stable throughout the study period in both groups, with no significant between-group difference at any time point.

Table 3: Comparison of haemodynamic parameters at baseline and during the intubation period

Parameter	Time point	Group F, mean $\pm$ SD	Group D, mean $\pm$ SD	p value
Heart rate (bpm)	Baseline	84.56 $\pm$ 5.40	83.40 $\pm$ 6.40	0.329
Heart rate (bpm)	8 min post-intubation	82.56 $\pm$ 5.27	78.68 $\pm$ 5.47	0.0005
Heart rate (bpm)	10 min post-intubation	82.65 $\pm$ 6.40	77.65 $\pm$ 5.40	0.0001
SBP (mmHg)	Baseline	120.30 $\pm$ 5.61	121.26 $\pm$ 5.11	0.373
SBP (mmHg)	10 min post-intubation	122.23 $\pm$ 5.32	118.23 $\pm$ 6.22	0.0008
DBP (mmHg)	Baseline	80.20 $\pm$ 4.15	81.43 $\pm$ 5.11	0.189
DBP (mmHg)	10 min post-intubation	81.85 $\pm$ 5.91	78.42 $\pm$ 4.25	0.001
MAP (mmHg)	Baseline	88.62 $\pm$ 4.25	89.45 $\pm$ 5.12	0.379
MAP (mmHg)	10 min post-intubation	87.78 $\pm$ 6.04	84.25 $\pm$ 5.32	0.002
SpO ₂ (%)	Baseline	99.18 $\pm$ 0.81	99.28 $\pm$ 0.75	0.523
SpO ₂ (%)	10 min post-intubation	98.20 $\pm$ 0.82	99.33 $\pm$ 0.73	0.404

SD = standard deviation; SBP = systolic blood pressure; DBP = diastolic blood pressure; MAP = mean arterial pressure; SpO₂ = peripheral oxygen saturation. Full time-course data (baseline, 5/10/15/20 min nebulization, immediately pre-procedure, and 2/4/6/8/10/15/30 min post-intubation) are available from the authors on request.

Adverse Effects: Hypotension occurred in 2 (4.0%) patients in Group F and 3 (6.0%) in Group D; bradycardia occurred in 2 (4.0%) patients in Group D and none in Group F; nausea and vomiting occurred in 4 (8.0%) patients in Group F

and 2 (4.0%) in Group D. No episodes of hypertension, tachycardia or respiratory depression were recorded in either group. The overall between-group difference in adverse effects was not statistically significant ($p = 0.245$) (Table 4).

Table 4: Comparison of adverse effects

Adverse effect	Group F (n = 50), n (%)	Group D (n = 50), n (%)
Hypotension	2 (4.0)	3 (6.0)
Bradycardia	0 (0.0)	2 (4.0)
Nausea and vomiting	4 (8.0)	2 (4.0)
Hypertension	0 (0.0)	0 (0.0)
Tachycardia	0 (0.0)	0 (0.0)
Respiratory depression	0 (0.0)	0 (0.0)

Chi-square test, $p = 0.245$ for overall comparison.

Discussion

In this randomized, double-blind trial comparing nebulized fentanyl and dexmedetomidine as adjuvants to lignocaine for AFNI in surgeries under general anaesthesia, dexmedetomidine was associated with a significantly lower cough score, shorter intubation time, more favourable vocal cord position, better post-intubation comfort, higher post-surgery satisfaction, deeper sedation, and greater haemodynamic stability, with a comparable incidence of adverse effects. The superior cough suppression observed with dexmedetomidine is consistent with its pharmacological profile: dexmedetomidine provides sedation, anxiolysis and analgesia through central α_2 -adrenoceptor agonism without significant respiratory depression, and peripheral α_2 agonism in the airway may additionally contribute to attenuation of airway reflexes.[17]

Similar findings of reduced cough with nebulized dexmedetomidine compared with fentanyl have been reported in studies of awake fiberoptic bronchoscopy and intubation, although absolute cough-free rates vary with the dose used and the specific procedure.[18,19]

The shorter intubation time in the dexmedetomidine group likely reflects better airway tolerance and reduced patient movement, consistent with previous comparative studies of nebulized adjuvants during AFOI.[20] Similarly, more favourable vocal cord relaxation and post-intubation comfort scores with dexmedetomidine have been described elsewhere and may relate to its combined sedative and reflex-suppressant actions without the respiratory depression that can complicate opioid-based sedation.[21,22]

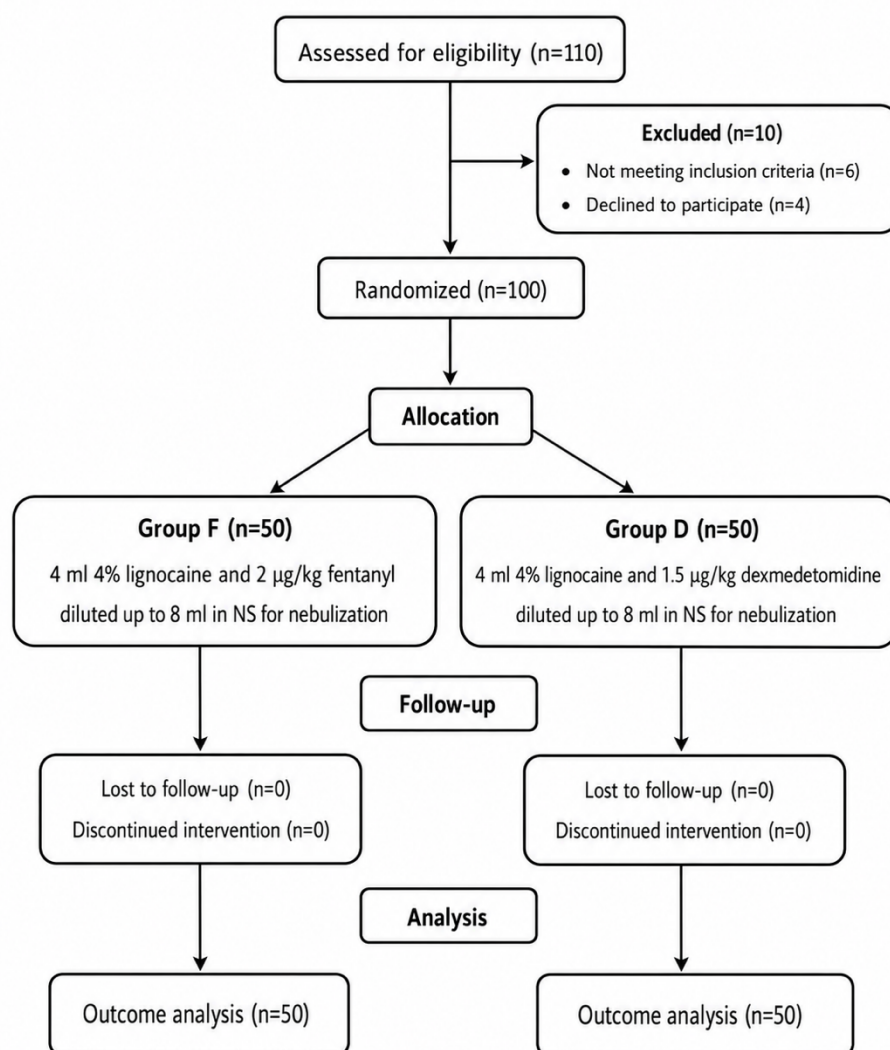
CONSORT FLOW CHART

Figure 1: CONSORT flow diagram of patient enrolment, randomization, and follow-up. Of 110 patients assessed for eligibility, 10 were excluded (6 did not meet inclusion criteria, 4 declined participation). 100 patients were randomized (50 to Group F, receiving nebulized 4% lignocaine 4 mL with fentanyl 2 µg/kg; 50 to Group D, receiving nebulized 4% lignocaine 4 mL with dexmedetomidine 1.5 µg/kg, each diluted with normal saline to 8 mL). No patients were lost to follow-up or discontinued the intervention; all 100 patients were included in the outcome analysis.

The attenuated rise in heart rate and blood pressure during intubation in the dexmedetomidine group is in keeping with its well-described sympatholytic action, mediated by presynaptic inhibition of norepinephrine release and postsynaptic reduction of central sympathetic outflow.[23] This haemodynamic stability has been a consistent finding across studies comparing nebulized dexmedetomidine with other adjuvants for attenuation of the stress response to airway instrumentation.[24,25] Oxygen saturation remained well preserved in both groups, suggesting that, at the doses used, neither adjuvant produced clinically significant respiratory compromise.

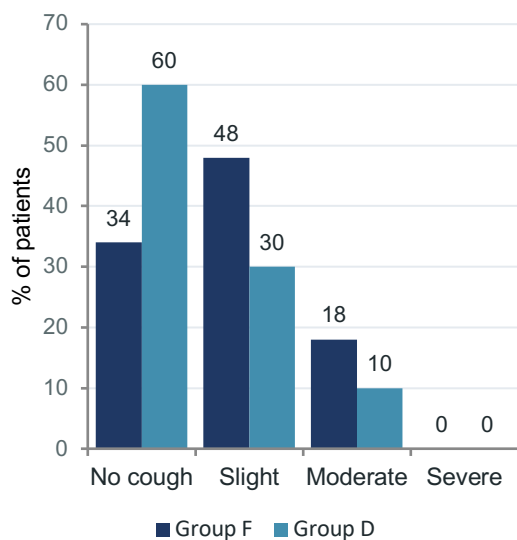
The comparable adverse-effect profile between groups, with only modest and non-significant

differences in hypotension, bradycardia and nausea/vomiting, supports the safety of both nebulized regimens within the dose ranges studied. This finding is broadly consistent with prior reports, although some studies have noted dose-dependent bradycardia or hypotension with higher doses of intravenous dexmedetomidine, an effect that was not clinically evident with the nebulized route used here.[26,27]

Limitations

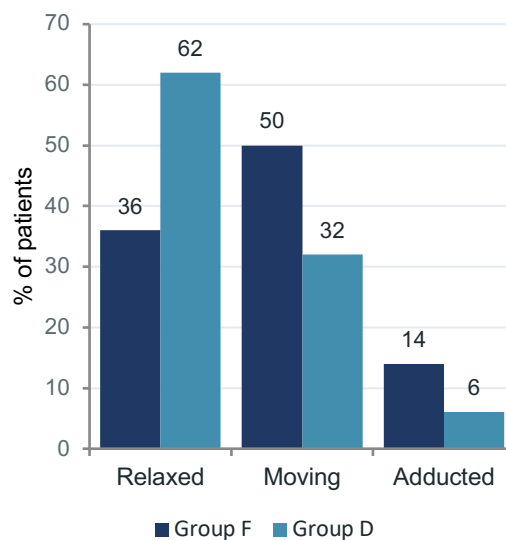
1. This was a single-centre study; multicentre validation with larger samples is needed to confirm generalizability.

- The study population was restricted to ASA I–II patients aged 18–65 years; findings may not extend to elderly or critically ill patients.
- Long-term outcomes and patient recall of the procedure were not assessed.
- The absence of a placebo (lignocaine-only) control group limits inference about the absolute contribution of each adjuvant over lignocaine alone.



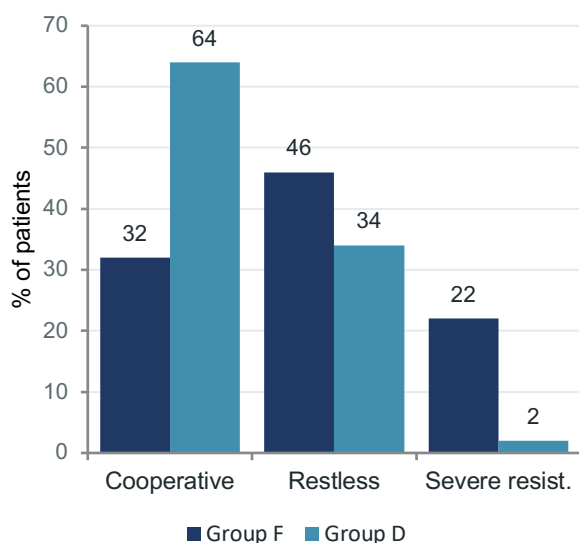
p = 0.033 (significant)

Figure 2: Cough Score During AFNI (%)



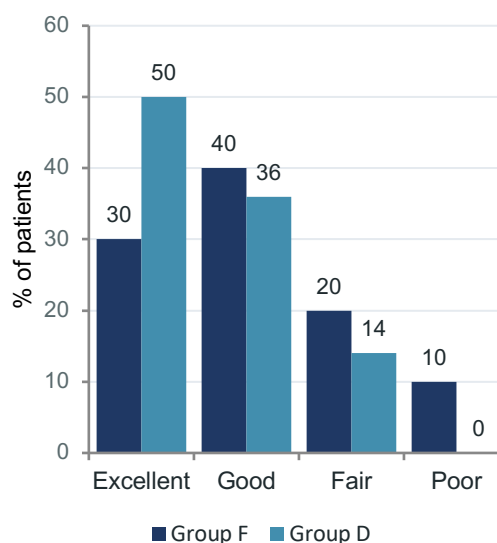
p = 0.029 (significant)

Figure 3: Vocal Cord Position During AFNI (%)



p = 0.007 (significant)

Figure 4: Post-Intubation Comfort Score (%)



p = 0.043 (significant)

Figure 5: Post-Surgery Satisfaction Score (%)

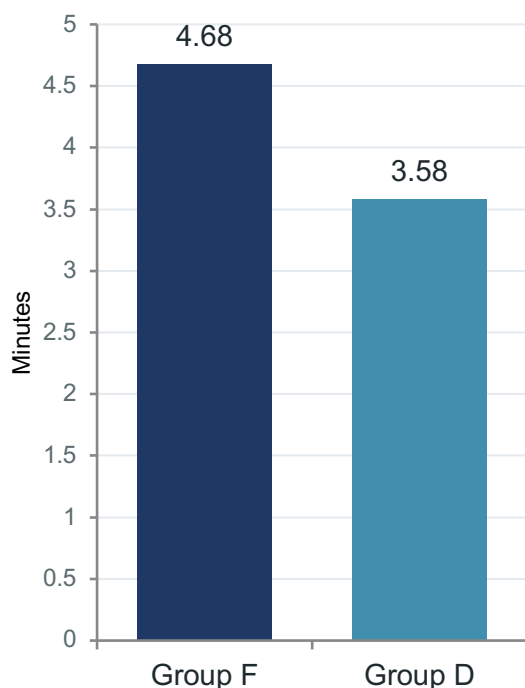


Figure 6: Mean Time Required for AFNI (min)

Conclusion

Nebulized dexmedetomidine (1.5 µg/kg) as an adjuvant to lignocaine provided superior intubating conditions compared with nebulized fentanyl (2 µg/kg) for flexible fiberoptic awake nasal intubation under general anaesthesia, with significantly lower cough scores, more favourable vocal cord relaxation, shorter intubation time, better post-intubation comfort, higher patient satisfaction, and greater haemodynamic stability, alongside a comparable safety profile. Nebulized dexmedetomidine may therefore be preferred over fentanyl as an adjuvant to lignocaine for AFOI, although fentanyl may remain a reasonable alternative in specific clinical contexts, such as when additional analgesia is a priority.

Declarations

Ethics approval and consent to participate: This study was approved by the Institutional Ethics Committee [02555/Acad-iii/MCA/2024] and was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions: GR: study design, data collection, analysis, manuscript drafting. AK: conception, supervision, critical revision of the

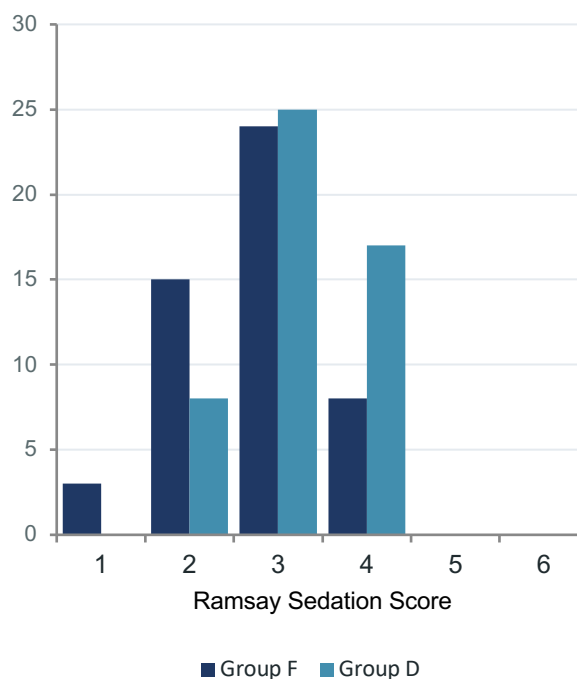


Figure 7: Comparison Of Ramsay Sedation Score (patients)

manuscript. Both authors read and approved the final manuscript.

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