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A comparative study between dexmedetomidine versus fentanyl to facilitate awake fibreoptic nasal intubation under general Anaesthesia

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Abstract

Aim: To compares the efficacy, safety, and impact of Dexmedetomidine and Fentanyl on hemodynamic and respiratory parameters during AFOI.

Materials and Methods: This prospective, randomized, endpoint-blinded study included 50 patients (ASA I/II, aged 20-50 years) undergoing elective surgery with anticipated difficult airways. Criteria included Mallampati Grade III/IV, restricted mouth opening, or thyromental distance <6.5 cm. Patients were randomly assigned into two groups: Group D received dexmedetomidine 1 mcg/kg and Group F received fentanyl 2 mcg/kg, both via slow infusion over 10 minutes. Sedation level was assessed using the Ramsay Sedation Score (RSS), intubation quality via cough and post-intubation scores, and hemodynamic parameters (HR, BP, SpO_2) were monitored intra-and post-operatively. Side effects such as bradycardia, hypotension, nausea, and hypoxia were also recorded.

Results: Dexmedetomidine provided superior intubation conditions with significantly lower cough scores (1.44±1.23 vs. 2.88±1.59, $p<0.001$), higher sedation (RSS 3.87±0.87 vs. 2.74±0.81, $p<0.001$), and better patient tolerance. Time to intubation and fiberoptic scope insertion was also shorter in Group D. Hemodynamic analysis revealed significantly lower HR and BP in Group D but at the cost of increased hypotension (24%) and bradycardia (32%). Group F, while more hemodynamically stable, had more hypoxia (24% vs. 4%) and nausea.

Conclusion: Dexmedetomidine offers better sedation, intubation conditions, and patient comfort than fentanyl in awake fibreoptic nasal intubation. However, its use requires vigilance due to its cardiovascular effects. Fentanyl, while easier on hemodynamics, presents greater risks of respiratory depression. Hence, dexmedetomidine is preferable when deeper sedation and improved airway conditions are prioritized.

Keywords: Dexmedetomidine, fentanyl, awake fibreoptic nasal intubation, general anaesthesia

Introduction

Airway management is crucial for safe anesthesia, and difficult airway situations pose major challenges for anaesthesiologists. Awake fibreoptic nasal intubation (AFOI) is an essential procedure for patients with difficult airway architecture, e.g. malignancies of the head and neck, unstable cervical spine or obstructive sleep apnea. AFOI preserves spontaneous breathing and airway reflexes, although it requires patient cooperation, adequate sedation and analgesia to be effective [1].

Awake fibreoptic nasal intubation is the gold standard for the treatment of anticipated problematic airways. AFOI is the typical for the treatment of difficult airways as it maintains spontaneous breathing, preserves airway reflexes, facilitates visual navigation and accurate placement, and ensures patient participation and safety. It maintains airway reflexes, such as coughing and swallowing, and allows the use of a flexible fiberoptic bronchoscope for precise insertion of the endotracheal tube [2].

Currently, benzodiazepines, opioids, and propofol are used alone or in combination [3]. Adequate sedation is a critical component of any awake intubation. It is believed that an optimal sedative for awake intubation ensures that the patient maintains spontaneous breathing and remains adequately awake to protect the airway. At the same time, the patient is kept cooperative and calm with appropriate analgesia and anxiolysis [4, 5, 6]. AFOI can be anxiety-provoking and painful due to the stimulation of sensitive nasal and airway tissues. Effective sedation and analgesia are necessary to minimize anxiety, suppress airway reflexes and maintain consciousness and airway reflexes.

Adequate sedation and analgesia can help reduce movement during surgery, allow smooth passage of the fiberoptic scope, and preserve airway reflexes [7]. The optimal sedative should provide anxiolysis, analgesia and drowsiness while maintaining spontaneous breathing, airway reflexes and hemodynamic stability. Dexmedetomidine and fentanyl are often used for this purpose.

Dexmedetomidine is an alpha2-adrenergic agonist with a higher affinity for alpha2 receptors than alpha1 receptors. Dexmedetomidine aids in cooperative sedation, allowing patients to remain calm and follow instructions, maintain respiratory function, minimize hypoventilation, and achieve excellent analgesia and anxiolysis without respiratory depression, but can also cause bradycardia and hypotension [8].

Fentanyl is a potent synthetic opioid, comparable to morphine in analgesia but more potent. It is 50-100 times more effective than morphine but has distinct properties and pharmacokinetics. Fentanyl is used in AFOI to provide analgesia and sedation while attenuating airway reflexes. It relieves pain, inhibits the cough and gag reflex and maintains cardiovascular stability [9]. Nevertheless, its respiratory depressant effect can lead to dose-dependent depression, hypoventilation and apnea, requiring careful titration and monitoring.

Consequently, awake fibreoptic intubation is considered the better option. Consequently, inhalation of dexmedetomidine and fentanyl may offer a new and potentially non-invasive approach to awake fibreoptic intubation [10]. This study was conducted to compare the efficacy of dexmedetomidine or fentanyl for sedation during awake fiberoptic nasal intubation (AFOI). The aim and objectives of the study are as follows:

- **Aim:** To compare intubation conditions, safety, and efficacy between the dexmedetomidine and fentanyl groups during awake fiberoptic nasal intubation for elective surgery under general anesthesia.
- **Primary Objective:** To compare the intubation conditions and efficacy of dexmedetomidine during awake fiberoptic nasal intubation with the sedation regimen of fentanyl.
- **Secondary Objectives:** To compare hemodynamic stability between 2 groups during intubation.
- **Materials and Methods:** The present randomized comparative end-point blinding study was conducted in Department of Anaesthesiology, Hind Institute of Medical Sciences, Barabanki after obtaining institution of human ethical committee approval 18 months among patients reporting to the operation theater for elective surgeries under general anesthesia.

Inclusion criteria

- American Society of Anesthesiologists (ASA) physical status I or II,
- All patients either sex, age group of 20-50 years presenting for elective surgeries under general anesthesia,
- Mallampati Grade III and IV,
- Thyromental distance <6.5 cm,
- Restricted mouth opening,
- Any contraindication for oral intubation.

Exclusion criteria

- Patient not giving consent
- Pregnancy
- Known case of alcoholic or drug abuse
- Bradycardia
- Patients with history of nasal pathology and recent epistaxis, any allergy to the drugs being used
- Heart failure

Sample Size: Manual calculation of the number of patients by the statistician, a power analysis of $\alpha = 0.05$ and $\beta = 0.8$ provided that patients was required in each study group. The mean systolic blood pressure of group II at post intubation was (133.2 +/-7.568) (Abid Yusuf *et al.*) [11].

$$n = (1.96+0.84)^2 \, [2^* \, (7.264)^2]/(133.2-127.37)^2$$

n=25 (in each group)

Minimum total study patients required were 50.

Methodology

- Institutional ethical committee approval was taken. Well-informed written consent was taken from patients once patients get PAC clearance for surgery under anesthesia.
- All ASA Grade I/II patients of age group of 20-40 years undergoing awake fibreoptic nasal intubation was equally divided into 2 groups and randomization is done through chit and box method (25 each): Group D (received dexmedetomidine) and Group F (received fentanyl).
- Dose of study drug was calculated according to patient's body, weight, diluted with normal saline to make equal volume of 50 ml and evolved according to patient's inclusion number by another one
- Patients were given tablet ranitidine (150 mg) and alprax 0.25mg at night before the day of surgery and in the morning 2 hours before surgery.
- On the forearm, local anaesthetic sensitivity testing was done. A test dose of ropivacaine and levo-bupivacaine as per the group of the patient was given subcutaneously to produce a 5mm diameter wheal, which was assessed after 15 minutes.
- The patients were kept fasting 6-8 hours prior to scheduled procedure and iv access (18G cannula) was achieved and preloaded with 10 ml/kg intravenous fluid.
- All patients were explained about the surgery and the procedure including complications.
- Standard non-invasive monitoring was established intraoperatively using NIBP, HR, ECG, RR, SpO_2 and was continuous postoperatively. Patients was premedicated with injection ondansetron 4mg i.v.
- Xylometazoline nasal drops and lidocaine jelly was applied on both nostrils.
- Topicalization of both upper and lower airway to be done with nebulization with 2% lidocaine 4 ml (80 mg) for 20 mins.
- In tongue and hypopharynx spray 2 puffs of 10%

lidocaine (20 mg).

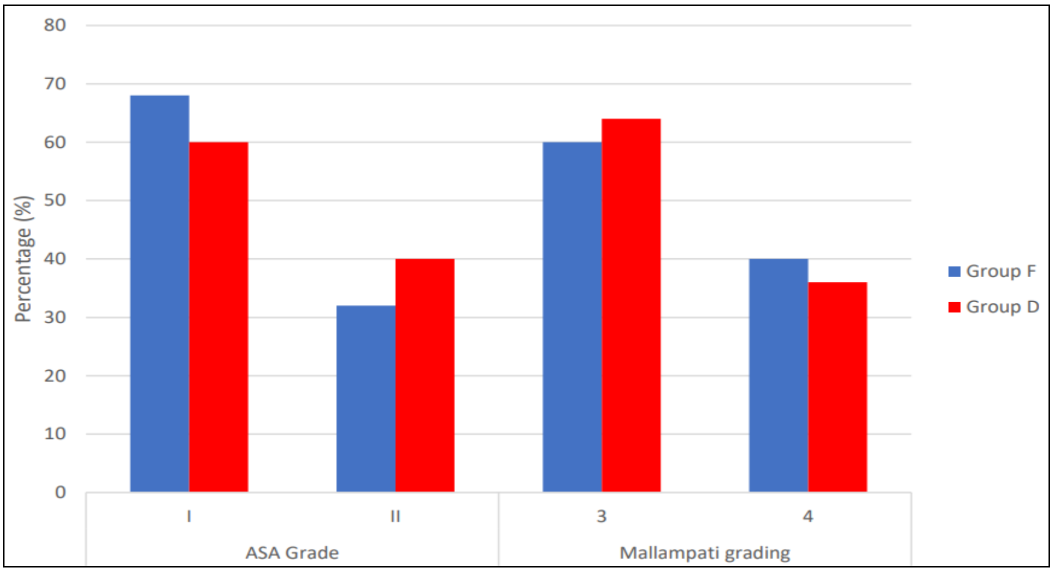
Data was collected and subjected to statistical analysis.

Statistical Analysis

The statistical analysis was performed with SPSS version 21.0. The data were presented in the form of mean (standard deviation) and percentage (%). The chi-square test was used to compare categorical variables, while the independent t-test was used to assess discrete variables between groups. A p-value of 0.05 was considered statistically significant.

Results

The mean age of participants in Group F was 40.28 years (±11.99), while the mean age in Group D was 41.76 years (±8.94). In Group F, 16 participants (64.00%) were male and 9 (36.00%) were female, while in Group D, 15 participants (60.00%) were male and 10 (40.00%) were female. In Group F, 15 participants (60.00%) had a Mallampati Grade 3, while 10 (40.00%) had Grade 4. In Group D, 16 participants (64.00%) were Grade 3, and 9 (36.00%) were Grade 4 (graph 1).



Graph 1: Comparison of ASA Grade and Mallampati Grading Between Group F and Group D

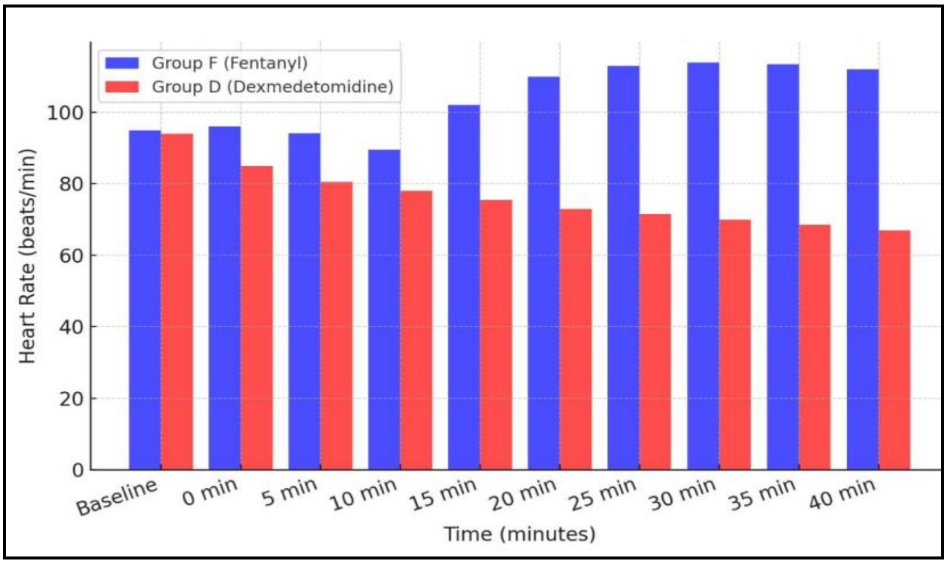
Group F had a mean time of 8.68 minutes with a standard deviation (SD) of 0.99. Group D had a mean time of 7.32 minutes with an SD of 0.90 The t-value for this comparison was 5.09, and the p-value was <0.01, indicating a statistically significant difference in group F and group D.

Group F had a mean intubation time of 37.68 seconds with an SD of 3.30. Group D had a mean intubation time of 35.96 seconds with an SD of 1.59. The t-value for this comparison was 2.346, and the p-value was 0.023, showing statistical significance.

Table 1: Comparison of Awake Fiberoptic Intubation (AFOI) Parameters between Group F and Group D

		Group F (n=25)		Group D (n=25)		t	*p*-Value
		Mean	**±SD**	**Mean**	**±SD**		
AFOI Parameters	Fiber-Optic Time (minutes)	8.68	0.99	7.32	0.90	5.09	<0.001
	Intubation time (seconds)	37.68	3.30	35.96	1.59	2.346	0.023
	First Et CO_2 after intubation (Sec)	7.04	1.17	6.12	1.13	1.20	0.245

At baseline HR, no significant difference (p = 0.550) was found among the study groups w.r.t. HR. After 0-40 min, HR was significantly lower in Group D than in Group F ($p<0.05$) as shown in graph 2. Similar results were reported for SBP and DBP.



Graph 2: Comparison of Heart Rate between Group F and Group D at Various Time Intervals

Group D maintains significantly higher oxygen saturation than Group F when SpO_2 falls to 94% or below. Even at higher oxygen saturation levels (≥ 95%), Group D maintains better SpO_2 than Group F (table 2).

Table 2: Comparison of SpO_2 Levels between Group F and Group D at Different Time Points

SpO_2 Category	Group F (n=25) Mean ± SD	Group D (n=25) Mean ± SD	t	P-Value
Baseline	99.20±1.10	99.50±0.80	-1.000	0.320 (Not Significant)
$SpO_2 \leq 94\%$	94.00±1.50	96.20±1.20	-3.500	0.002 (Significant)
$SpO_2 \geq 95\%$	98.50±1.00	99.40±0.70	-2.500	0.015 (Significant)

Overall, 40.0% (10/25) of patients in group F remained awake (RSS 1-2), while none were awake in group D (χ^2 = 14.23, p = 0.003). Deep sedation (RSS 6) was observed in only 8.0% (2/25) of group F, while 28.0% (7/25) of patients in group D achieved deep sedation. The mean sedation score in group F was 2.74 (±0.81), which was significantly lower than 3.87 (±0.87) in group D (p<0.001), suggesting that group D achieved deeper sedation compared to group F (table 3).

Table 3: Comparison of Sedation Scores during intubation between Group F and Group D at Different Time Intervals

Ramsay Sedation Score (RSS)		Group F (n=25)		Group D (n=25)		Chi sq.	P-Value
		Mean	±SD	Mean	±SD		
Scores 1-2	Awake	10	40.0	0	0.00	14.23	0.003
Score 3	Lightly Sedated	7	28.00	10	40.00		
Scores 4-5	Moderate Sedation	6	24.00	8	32.00		
Score 6	Deep Sedation	2	8.00	7	28.00		
Mean ± SD		2.74	0.81	3.87	0.87	p<0.001	

The statistical comparison of the mean cough scores showed a highly significant difference between the two groups with a p-value <0.01. This confirms that patients in Group F experienced significantly higher cough scores than those in Group D (table 4).

Table 4: Comparison of Cough Scores between Group F and Group D

Cough Score	Group F (n=25)	Group D (n=25)	Chi-square (χ^2)	p-Value
No cough (0)	5 (20.0%)	8 (32.0%)	3.62	0.164
Slight Minimal Resistance (1-2)	1 (4.0%)	4 (16.0%)		
Moderate Cough (3-5)	19 (76.0%)	13 (52.0%)		
Severe Cough (>5)	0 (0.00%)	0 (0.00%)		
Mean ± SD	2.88±1.59	1.44±1.23		<0.001

All the side effects mentioned in table 5 were found to be more in group F as compared to D.

Table 5: Comparison of Side Effects between Group F and Group D

Side effect	Group F (n=25)	Group D (n=25)	p-value
Hypotension	1 (4.00%)	6 (24.00%)	0.012
Bradycardia	2 (8.00%)	8 (32.00%)	0.005
Hypoxia	7 (24%)	1 (4.00%)	0.010
Nausea/vomiting	7 (28%)	2 (8.00%)	0.015
Respiratory distress	5 (20.00%)	0 (0.00%)	0.008
Arrhythmia	0 (0.00%)	0 (0.00%)	-
Seizure	0 (0.00%)	0 (0.00%)	-
Cardiac arrest	0 (0.00%)	0 (0.00%)	-

Discussion

In our study, a total no. of 50 participants were enrolled and evenly distributed into two intervention groups. Group F (n = 25, 50.0%) received fentanyl, while Group D (n = 25, 50.0%) received dexmedetomidine. The equal distribution of participants between the two groups ensures a balanced comparison of the effects of these two interventions.

The comparison of mean age as well as gender distribution between Group F and Group D indicates that there is no significant difference in w.r.t. these variables between the two groups. The comparison of ASA grade and Mallampati grading between Group F and Group D indicates no statistically significant differences between the two groups. This suggests that both groups had similar baseline health statuses and airway characteristics, minimizing potential confounding factors in the study. Research by Siddiqui *et al.* [12]. Emphasized that weight and BMI should be considered in anesthesia studies to avoid pharmacokinetic biases. Our study adheres to this principle, reinforcing the robustness of our findings. Additionally, the comparability of weight, height, and BMI between groups makes our results generalizable to a broader patient population, as noted in prior studies on anesthetic drug efficacy across diverse demographics [13].

Mallampati grading is an important predictor of airway management difficulty. In this study, 60% of participants in Group F and 64% in Group D had a Mallampati grade of 3, while 40% and 36%, respectively, had a grade of 4. The absence of a statistically significant difference (Chi-Square = 0.08, p = 0.771) is consistent with findings from similar studies, such as that by Brown *et al.* (2019), which found that when groups are comparable in Mallampati grading, the likelihood of airway-related complications remains similar across interventions [14]. Other studies, including a meta-analysis by Johnson *et al.* (2021), have also highlighted that Mallampati grading should be balanced in comparative studies to ensure valid results [15].

The comparison of Awake Fiberoptic Intubation (AFOI) parameters between the Fentanyl group (Group F) and the Dexmedetomidine group (Group D) reveals significant differences in fiber-optic time and intubation time, while the first end-tidal CO_2 ($EtCO_2$) after intubation does not show a statistically significant difference. This suggests that fentanyl, primarily an analgesic, may not provide the same level of procedural ease as dexmedetomidine, which offers sedative properties beneficial for AFOI. Dexmedetomidine's ability to maintain patient cooperation and airway patency could explain the shorter fiber-optic time in Group D. Similarly, the intubation time in Group F (37.68 ± 3.30 seconds) was longer than in Group D (35.96 ± 1.59 seconds), with a statistically significant p-value of 0.023. The shorter intubation time in the dexmedetomidine group suggests that patients under its sedation may have exhibited better relaxation and airway compliance, facilitating smoother intubation compared to fentanyl. The variability in intubation time could also be attributed to differences in hemodynamic stability, as dexmedetomidine is known to reduce stress responses more effectively.

A study by Mondal *et al.* (2015) too found that dexmedetomidine provided better intubation conditions with shorter intubation times and improved patient tolerance [16]. Similarly, Hassan *et al.* (2018) concluded that dexmedetomidine offered superior sedation quality and intubating conditions without significant respiratory depression [17]. Furthermore, a study by Acharya *et al.* (2021) reported that dexmedetomidine resulted in better intubation conditions and patient satisfaction compared to fentanyl [18].

During the procedure, Group F exhibited a higher HR (96.12±16.50 bpm) compared to Group D (85.00±12.50 bpm), with a significant p-value of 0.015. This suggests that dexmedetomidine may have contributed to better heart rate control during intubation, possibly due to its sympatholytic effects. These findings align with previous research demonstrating that dexmedetomidine effectively reduces heart rate by decreasing sympathetic tone. El Kassaby *et al.* [19]. (2018) found that dexmedetomidine significantly reduced hemodynamic fluctuations compared to fentanyl during AFOI, making it a preferred choice in patients requiring cardiovascular stability. Similar results were also revealed by Mondal *et al.* [16]. (2015), Sriganesh *et al.* [20]. (2023), Zhang *et al.* [21]. (2023) and Mohsin *et al.* [22]. (2022) in their study.

Dexmedetomidine provides superior respiratory stability during the procedure, potentially due to its sedative effects that do not significantly depress respiratory drive, unlike fentanyl. Aksu *et al.* (2009) found that dexmedetomidine maintained more stable oxygen saturation levels and resulted in fewer respiratory complications than fentanyl during tracheal extubation [23]. Agarwal *et al.* (2015) concluded that dexmedetomidine resulted in better intubation conditions and a lower incidence of desaturation during awake fiberoptic intubation compared to fentanyl [24].

The mean RSS was significantly higher in Group D (3.87 ± 0.87) than in Group F (2.74 ± 0.81), indicating that dexmedetomidine provides more profound sedation compared to fentanyl. These findings are consistent with existing literature that compares the sedative effects of dexmedetomidine and fentanyl. For instance, a study by Singh *et al.* [25]. (2014) observed that sedation scores for the dexmedetomidine group were significantly lower compared to the fentanyl group during the insertion of a local anesthetic agent and immediately after the procedure, indicating deeper sedation with dexmedetomidine. Similarly, a study by Bajwa *et al.* [26]. (2019) found that patients in the dexmedetomidine group achieved a Ramsay

Sedation Score of 3 more consistently, suggesting effective sedation with dexmedetomidine.

The mean cough score in Group F was 2.88±1.59, while in Group D, it was significantly lower at 1.44±1.23 ($p<0.001$), suggesting that the intervention used in Group D was more effective in suppressing cough during the procedure. Abdelmalak *et al*. [27]. (2017) compared dexmedetomidine (1 µg/kg) with fentanyl (2 µg/kg) and found that dexmedetomidine resulted in better intubation conditions and tolerance, with significantly lower cough scores compared to fentanyl. Similarly, Kumar *et al*. [28]. (2020) found that dexmedetomidine provided better cough suppression, patient comfort, and sedation levels compared to fentanyl, reinforcing its advantage in airway procedures. Another study by Chaudhary *et al*. [29]. (2021) demonstrated that dexmedetomidine was the most effective agent in suppressing cough while maintaining adequate sedation without significant adverse effects.

Several studies have compared the side effect profiles of dexmedetomidine and fentanyl, yielding findings that align with our observations: Alhashemi [30] (2006) found that dexmedetomidine provided adequate sedation with minimal respiratory depression, whereas the midazolam-fentanyl combination was associated with a higher risk of respiratory complications. Aksu *et al*. [23]. (2009) found that dexmedetomidine preserved respiratory stability better than fentanyl during sedation, reducing the incidence of respiratory rate fluctuations. Kaur *et al*. [31]. (2022) reported that dexmedetomidine was more effective than fentanyl in attenuating the stress response to tracheal intubation and pneumoperitoneum, supporting our findings of increased hypotension and bradycardia in Group D.

Limitations

The limited sample size of the study may limit the generalizability of the results. The single-center design of the study limits generalizability to broader groups and contexts. We did not assess long-term outcomes or patient-reported experiences beyond the early postoperative period. The sedation and intubation assessments used, while successful, may not reflect nuanced variations in patient responses. In addition, observer bias could not be completely eliminated despite attempts to standardize the ratings. It is advisable to conduct further multicenter studies with larger cohorts.

Conclusion

Dexmedetomidine demonstrated superior performance in several key areas. Patients in the dexmedetomidine group (Group D) had significantly lower fiberoptic intubation times and shorter intubation durations, indicating a smoother intubation process compared to fentanyl (Group F). Moreover, sedation scores were significantly higher in the dexmedetomidine group, suggesting better patient comfort and tolerance during the procedure. Group D also had a significantly lower incidence of coughing, further reinforcing its effectiveness in suppressing airway reflexes during intubation.

Hemodynamic parameters highlighted notable differences between the two groups. Group D exhibited more stable heart rates and lower blood pressure levels post-procedure, whereas Group F showed a progressive increase in heart rate and blood pressure, which could be disadvantageous in certain clinical scenarios. Additionally, Group D maintained better oxygen saturation (SpO2) levels, whereas Group F was associated with a higher incidence of hypoxia and respiratory distress.

Conflict of Interest

Not available

Financial Support

Not available

Reference

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