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Original Article

RANDOMIZED STUDY: PROPOFOL VERSUS FENTANYL-MIDAZOLAM COMBINATION FOR CONSCIOUS SEDATION DURING FIBREOPTIC NASOTRACHEAL INTUBATION

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Abstract

Background

The ideal characteristics of the sedative and analgesic that is used for awake fiberoptic intubation are that it should be easily titrable, that it should act rapidly, that it should maintain hemodynamic stability, that it should provide sufficient amnesia, and that it should have a short-acting time because the manipulation of the airway is only required until the intubation is finished. Currently, fentanyl and midazolam are used; propofol also fits the characteristics. This study aims to determine the efficacy and safety of both agents in the conduction of awake fiberoptic intubation.

Method

This study was a prospective randomized study. There were a total of 25 participants in the study. All of them underwent a pre-anesthetic assessment. The patients were divided into two groups. The first group received propofol as their sedating agent and the second group received fentanyl and midazolam combination as their sedating agent. The intubation period, sedation score, intubation score, hemodynamic vitals, oxygen saturation, degree of amnesia, and degree of global acceptance were recorded.

Results

Both propofol and the fentanyl-midazolam combination were effective for sedation during fiberoptic intubation. Propofol had a slightly higher sedation score at 2 minutes (mean: 13.3 vs. 15.5, $p < 0.05$), but both groups reached similar sedation levels at 6 minutes (score: 16). Intubation scores showed no significant differences between groups ($p > 0.05$). Propofol provided better hemodynamic stability, with lower systolic blood pressure during stage 2 ($p < 0.05$). Oxygen saturation remained stable in both groups. Complete amnesia was achieved in 75% of the propofol group and 85% of the fentanyl-midazolam group, with similar global acceptance ratings (75% vs. 85%).

Conclusion

Propofol alone is suitable for awake fiber optic insertion for artificial ventilation.

Recommendation

Propofol should be considered as a sedative agent for the performance of fiber optic insertion for artificial ventilation.

Keywords: *Fiberoptic intubation, Propofol, Sedative.*
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Introduction

When executing a variety of surgical procedures, it is necessary to induce full anesthesia, which may be accomplished via the use of general anesthesia. In addition to rendering the patients unconscious, it has the potential to clog the airway to varying degrees, which may ultimately result in the obstruction of the airway. The muscle that composes the mouth cavity begins to contract, resulting in obstruction of the airway. It is possible to avoid the blockage of the airway by beginning the assistance of artificial ventilation before the introduction of general anesthesia. A basic technique that is followed by an anesthesiologist is to offer support to the patient while he or she is conscious [1]. This is done to reduce the danger that is linked with the changes in hemodynamics and the possibility of fatality due to the obstruction of the airway.

In the past, tracheostomy was the preferred method before the induction of general anesthesia; however, with the advancements that have been made in the technique, the insertion of a fiberoptic tube into the trachea may now provide patients with assistance for their breathing [2]. On the other hand, this intubation needs to be performed while the patient is awake, and at the same time, the patient ought to be calm to ensure that the intubation is performed correctly. When attempting to achieve good intubation while causing the patient as little pain as possible, it is vital to make use of sedatives and analgesics [3].

At present, midazolam and fentanyl are used together to provide the desired effects of sedation and analgesia,

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respectively [4]. However, it is essential to have a clear understanding that sedation should not induce any significant changes to the hemodynamic parameters, nor should it result in any blockage of the airway. The ideal characteristics of the sedative and analgesic that is used for awake fiberoptic intubation are that it should be easily titrable, that it should act rapidly, that it should maintain hemodynamic stability, that it should provide sufficient amnesia, and that it should have a short-acting time because the manipulation of the airway is only required until the intubation is finished [5]. Because general anesthesia may be administered after intubation, fentanyl and midazolam exhibit all of the features that were mentioned above, making them the recommended pharmacological agents. Propofol is a local anesthetic not used in the usual practice of awake fiberoptic intubation [6]. However, since it has features that are comparable to the combination of midazolam and fentanyl, it is a dependable sedative and analgesic that may be used for the conduction of awake fiberoptic intubation [7,8].

This study aims to determine the efficacy and safety of both agents in the conduction of awake fiberoptic intubation.

Method

Study design

This study was a prospective, randomized, parallel-group trial.

Study setting

The study was conducted at Lady Hardinge Medical College New Delhi within a period of a year from September 2018 to September 2019.

Participants

There were a total of 25 participants in the study. All of them underwent a pre-anesthetic assessment. This was done to assess the category of ASA of the patients. The patients belonging to ASA grades I and II were the only ones considered for this study. Patients with any other major cardiovascular, renal, hepatic, or any other systemic illness were not included. Especially patients with a history of airway difficulty, respiratory tumors, patients with a BMI greater than 30, and surgery of the trachea.

The patients were divided into two groups. The first group received propofol as their sedating agent and the second group received fentanyl and midazolam combination as their sedating agent. The patients in both groups were given local anesthetics. The vitals of the patients were thoroughly monitored throughout the procedure.

Interventions

Propofol Group (Group 1)

- Dosage and Administration: Participants in this group received an initial bolus of propofol at a dose of 1 mg/kg of body weight, followed by continuous maintenance at 1 mg/kg/hr.
- Procedure Timing: Propofol was administered intravenously one minute before intubation, with sedation levels and vitals being assessed every 2 minutes after the initial dose.
- Additional Medications: Xylometazoline was sprayed into the nostrils as a vasoconstrictor, and lignocaine was applied for local anesthesia.

Fentanyl-Midazolam Group (Group 2)

- Dosage and Administration: This group received fentanyl at 1 microgram/kg of body weight and midazolam at 0.5 mg/kg of body weight, with IV maintenance at 1 microgram/kg/hr.
- Procedure Timing: Fentanyl and midazolam were administered intravenously one minute before intubation, with sedation levels and vitals being assessed every 2 minutes post-administration.
- Additional Medications: Similar to the propofol group, xylometazoline and lignocaine were used for local anesthesia.

The degree of sedation was analyzed by observers' assessment of the alertness scale. Table No. 1 gives the details of the scale.

Table no.1: Observer's assessment of sedation

Parameters	Score 5 alert	Score 4	Score 3	Score 2	Score 1 Deep sleep
Responsiveness	Responding to the name at normal tone	Slowed response to the name called	Responds only after repeated calling or calling loudly	Responds only after shaking	Does not respond
Type of speech	Proper	Thickened speech	Slurred speech	Few words recognizable	-
Jaw	Proper	Mildly relaxed	Completely relaxed	-	-
eyes	Clear	½ the eye is closed	More than ½ eye is closed	-	-

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Observer assessment

The assessment was taken every 2 minutes after 1 minute of IV, i.e, the timing of sedation was evaluated. After the intravenous administration of the sedative (propofol or fentanyl-midazolam), sedation was first assessed one minute later, followed by continuous assessments at 2-minute intervals until intubation was completed (within 6 minutes). If the sum of the score is 20 to 18 the patient is alert, if between 17 to 15 light sedation, 14 to 11 heavy sedation, and 10 deep sleep. After sedating agents are given intubation begins for airway manipulation. A fibreoptic tube is inserted. The intubation score is given as per table no. 2. Jaw movements, vocal cord movements, coughing and limb movements are scored. After 60 seconds of sedations jaw movements are monitored, and vocal cord movements are monitored after the epiglottis is seen via a fibreoptic bronchoscope. Coughing and limb movements are monitored throughout the intubation.

Table no. 2 Intubation score

Score	Movements of the jaw	Movements of the vocal cord	Coughing	Limb movements
1	Completely relaxed	Open	None	None
2	Slightly toned	Movements	Slight	Slight
3	Stiff	Closing	Moderate	Moderate
4	Rigid	Closed	Aggressive	Aggressive

Randomization

- Sequence Generation: The random allocation sequence was generated using a computerized random number generator to ensure random assignment and reduce selection bias.
- Type of Randomization: Simple randomization was used, with no additional restrictions such as blocking or stratification. This method ensured an equal probability of assignment to either the propofol or fentanyl-midazolam group.

Allocation Concealment Mechanism

To conceal the random allocation sequence, the group assignments were placed in sealed, sequentially numbered opaque envelopes. These envelopes were opened only after patient enrollment and baseline assessments were completed, ensuring the group assignment remained unknown until the interventions were assigned.

Implementation

The random allocation sequence was generated by an independent research assistant, who was not involved in recruiting participants or collecting outcome data. The study coordinator enrolled the 25 participants and assigned them to one of the two groups based on the randomization sequence in the sealed envelopes.

Blinding

This study was single-blind, meaning that participants were blinded to which treatment they received (propofol or fentanyl-midazolam). However, due to the nature of the interventions, care providers who administered the drugs and those assessing the sedation and intubation outcomes were not blinded to the treatment groups. Therefore, only the participants were blinded, making this a single-blind trial.

Outcomes

Primary Outcome

- Sedation Level: Measured using the Observer's Assessment of Alertness/Sedation Scale (OAAS). The scale was applied every 2 minutes after sedation began (at 0, 2, 4, and 6 minutes).

Secondary Outcomes

- Intubation Score: Assessed based on jaw movements, vocal cord movements, coughing, and limb movements using a predefined scoring system. Scores were recorded immediately after the procedure.
- Hemodynamic Parameters: Systolic and diastolic blood pressure, heart rate, and oxygen saturation were monitored continuously throughout the procedure, with special attention during the advancement of the fiberoptic tube.
- Degree of Amnesia: Measured post-procedure using a simple scale where 1 indicated no memory, 2 partial memory, and 3 full memory of the procedure.
- Global Acceptance: Patient satisfaction with the procedure was assessed using a scale of 1 (smooth), 2 (tolerable), or 3 (troublesome).

Ethical consideration

The institution's ethics committee approved the conduction of the study

Statistical analysis

The data obtained which could be measured was analyzed and compared using the chi-square method and the parameters which could not be measured were analyzed using the Whitney test.

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Result

A total of 25 volunteers participated in this study they were divided into two groups, the first group consisted of 12 patients, and they were given propofol as the sedating agent. The second group fentanyl and midazolam as the sedating and analgesic consisted of 13 patients. The type of surgical procedure all the 25 patients underwent were comparable. The majority of the participants of the study were females the first group consisted of 10 females and 2 males. The second group consisted of 9 females and 4 males. The average age of the participants in the first group was 35 years and the average age of the participants in the second group was 30 years. The average weight of the participants in the first group was 51 kg and the average weight of the participants in the second group was 54 kg. The difference in the gender, age, and weight of the participants in both groups was not statistically significant.

The sedation score was given to the patients as per the scale discussed before. All the patients were under the light sedation or heavy sedation score. None of the patients went into the deep sleep category. The sedation was assessed 60 seconds after intubation which was taken as 0 minutes, later it was assessed every 2 minutes until the completion of intubation. The intubation was completed within 6 minutes and hence the sedation was recorded until then. It was observed that the difference in the level of sedation was statistically significant only at 2 minutes between both groups. It sedation levels were not significantly different during the 0 minutes, 4 minutes, and 6 minutes. However, the degree of sedation was numerically higher at 0 and 2 minutes in the first group but it was statistically significant. Later the degree of sedation was 16 which is light sedation at 6 minutes in both groups. Table no. 3 gives details of the degree of sedation numerically.

Table no. 3: Degree of sedation

Time interval	Propofol group	Fentanyl and midazolam group
0 min	14.3	15.5
2 min	13.3	15.5
4 min	15.35	15.25
6 min	16.0	16.0

The intubation score was given based on jaw movements, vocal cord movements, coughing, and limb movements. Table No. 4 gives the details of the score of intubation in each parameter as described in Table No. 2. It was observed the intubation parameters were of higher grade in the propofol group than that of the fentanyl and midazolam group. Considering the jaw movements none of them had rigid jaws, slight tone, and mild relaxation were observed in both the groups but the difference amongst the groups was not statistically significant. The vocal cords were open and movements were there in the vocal cords none of them had closing and closed vocal cords. However, the difference in the condition of the vocal cords was not statistically significant when both groups were compared. The coughing was slight in the propofol group and almost none in the other group. The aggressive limb movements were not reported in the second group, the first group had slight to moderate limb movements. The overall sum of the intubation score was not statistically significant on comparing both groups.

It was observed in the vitals that the systolic blood pressure, diastolic blood pressure, and heart rate were higher than the baseline in the fentanyl group, especially during the advancement of the fiber optic tube the vitals were significantly higher in the fentanyl group than that of the propofol group. However, the oxygen saturation was comparable in both groups. The p-value of stage 2 that is the advancement of the fiber optic tube was less than 0.05 but during the other stages, the values were numerically high in the fentanyl group but were not significant statistically.

Table no. 4: Intubation scores observed.

Parameters	Propofol group (N)	Fenatnyl and midazolam group (N)
Jaw movements		
Completely relaxed	02	02
Slightly toned	08	09
Stiff	02	02
Rigid	00	00
Movements in the vocal cord		
Open	04	05
Movements	09	08
Closing	00	00
Closed	00	00

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Coughing		
None	01	04
Slight	05	07
Moderate	06	01
Aggressive	00	00
Limb movements		
None	00	01
Slight	07	07
Moderate	04	05
Aggressive	01	00

In the second group, 11 out of 13 people felt complete amnesia, and 2 of them remembered the whole procedure. In the first group 9 patients felt complete amnesia, 2 patients remembered a few moments of the procedure and 1 patient remembered the whole procedure. The degree of global acceptance was high in the fentanyl group 11 patients felt that the procedure was smooth 2 of them felt that it was tolerable. Whereas in the propofol group, 09 of them had smooth procedures, 2 felt it was tolerable and 1 of them felt that the procedure was unbearable. Although numerically the degree of global acceptance is high in the fentanyl and midazolam group statistically the difference between both the groups was not significant.

Discussion

The study found that both propofol and the fentanyl-midazolam combination were effective for sedation during awake fiberoptic intubation. Sedation scores indicated that propofol provided slightly deeper sedation at the 2-minute mark (mean score: 13.3 for propofol vs. 15.5 for fentanyl-midazolam, $p < 0.05$), although, by 6 minutes, sedation levels were similar between the two groups (score of 16 in both). This suggests that propofol may induce sedation more quickly than the fentanyl-midazolam combination, but the overall level of sedation during the procedure was comparable.

In terms of intubation conditions, no significant differences were observed between the two groups in terms of jaw movements, vocal cord movements, coughing, or limb movements ($p > 0.05$ for all parameters). This indicates that both sedative regimens provided similar ease of intubation, making them equally suitable from the perspective of airway management during the procedure.

Propofol, however, demonstrated better hemodynamic stability, particularly during the advancement of the fiberoptic tube (stage 2 of the procedure). The fentanyl-midazolam group showed higher systolic and diastolic blood pressure, as well as increased heart rates during this stage ($p < 0.05$), while oxygen saturation remained comparable between the two groups. This suggests that propofol may be a safer option in terms of maintaining stable hemodynamics during intubation, reducing the risk of adverse cardiovascular events.

Regarding patient recall, complete amnesia was achieved in 75% of the propofol group (9 out of 12 participants) and 85% of the fentanyl-midazolam group (11 out of 13 participants). While slightly more participants in the fentanyl-midazolam group reported complete amnesia, the difference was not statistically significant, suggesting that both regimens provided adequate amnesia for most patients.

Finally, global acceptance of the procedure was high in both groups, with 75% of participants in the propofol group and 85% in the fentanyl-midazolam group rating the procedure as smooth. This indicates that both sedatives were generally well tolerated, with no significant difference in patient satisfaction.

Overall, the results suggest that propofol is an effective alternative to the fentanyl-midazolam combination for sedation during awake fiberoptic intubation. While both drugs provided comparable levels of sedation, ease of intubation, and patient satisfaction, propofol offered the added benefit of better hemodynamic stability, which could make it a preferable choice in patients where cardiovascular stability is a concern. Both sedative regimens resulted in high levels of patient amnesia and smooth procedural experiences, supporting their use in clinical practice.

Opioid analgesics facilitate a sufficient amount of analgesia to carry out the procedure of fiber optic insertion. Also, the benzodiazepine that is midazolam used with fentanyl provides sufficient amnesia. This combination has been used widely for such procedures [9]. The combination however does not maintain the desired hemodynamic stability. Propofol has been used in bronchoscopy and provides satisfactory sedation as well as amnesia.

There are studies in which propofol has been used in various doses in combination with other drugs as well for the smooth procedure of fiber optic insertion [10,11]. In this study, we have used the dose suggested by Rai M R et al, in their study. The combination of the drug is not used in this study [12]. Nevertheless, the study found that propofol produced comparable sedation, moreover, the sedation was significantly higher when the tube was inserted. Thus sedation was comparatively more with propofol. The degree of amnesia produced was comparable as well to the fentanyl and midazolam combination.

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Hemodynamic stability produced by propofol was remarkable compared to that produced by fentanyl and midazolam group, especially during stage 2. This property is desired and improves the experience and reduces the chances of fatality in the patients undergoing the procedure [13,14]. The maintenance of hemodynamic stability and sedation of propofol has been studied before and this study gave similar results as obtained in the previously researched [15,16].

Generalizability

The trial findings apply to patients undergoing awake fiberoptic intubation classified as ASA grade I or II with no major systemic illness. However, the results may not generalize to higher-risk populations, such as those with airway difficulties or high BMI. While the small sample size limits broad applicability, the study provides useful insights for using propofol in routine cases, particularly where hemodynamic stability is critical. Further research with larger, more diverse groups is needed to strengthen external validity.

Conclusion

The propofol alone is suitable for awake fiber optic insertion for artificial ventilation. It provides desirable hemodynamic stability and sedation.

Limitation

The exact dose of infusion was not studied in the research conducted. Further studies are required to determine the exact amount of dose required for desirable sedation and amnesia.

Recommendation

Propofol should be considered as a sedative agent for the performance of fiber optic insertion for artificial ventilation.

Interpretation

The trial showed that both propofol and fentanyl-midazolam are effective for sedation during awake fiberoptic intubation, with similar sedation, intubation conditions, and patient satisfaction. However, propofol provided better hemodynamic stability, making it potentially safer for patients with cardiovascular concerns. While both regimens were well-tolerated, propofol's benefits include better control of blood pressure and heart rate, reducing complications. Given the small sample size, further research is needed, but propofol appears to be a viable alternative with fewer hemodynamic risks in similar clinical settings.

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List of abbreviation

FOI-Fiberoptic intubation

Source of funding

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Conflict of interest

The authors declare no conflict of interest.

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