

Comparison of I-gel insertion using propofol-fentanyl vs propofol-dexmedetomidine in pediatric day surgery

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ABSTRACT

Objective: Supraglottic airway devices are pivotal tools for airway management in anesthesia. The I-gel, a widely used second-generation airway device, is recognized for ease of insertion and low complication rate. This study aims to compare the ease of insertion of I-gel and associated insertion conditions when used with Fentanyl and Dexmedetomidine in combination with Propofol.

Methods: After obtaining approval of ethical committee, a total of 60 patients were enrolled a tertiary care hospital and divided into two groups. Group F received 2 mcg/kg of intravenous fentanyl and propofol; Group D received 1 mcg/kg of intravenous dexmedetomidine infusion in 10 minutes and propofol. The ease of I-gel insertion and jaw relaxation was assessed using the modified Lund and Stovener criteria and Young's criteria, respectively. The physiologic variables, adverse events like apnea, desaturation, cough, jaw movement; and additional requirement of propofol bolus doses were recorded at baseline, first, third, fifth and tenth minutes after insertion.

Results: No significant differences were observed in jaw relaxation, ease of I-gel insertion, and adverse events. The apnea duration was shorter in Group D (12.1 ± 2.3 min vs 15.1 ± 2.8 , $p < 0.001$). Respiratory rate was significantly lower in Group F. It was easier to insert I-gel in Group D ($p = 0.213$). Ramsay Score was higher and Aldrete score was lower in Group D ($p < 0.001$).

Conclusion: Dexmedetomidine as an adjuvant to propofol is a safe alternative to combination of propofol and fentanyl in pediatric surgeries. Although both drugs maintain a stable hemodynamic profile, dexmedetomidine demonstrates superior efficacy in preserving respiratory stimulus.

Keywords: I-gel, supraglottic airway device, hemodynamic, upper airway reflexes, dexmedetomidine, fentanyl

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INTRODUCTION

Airway management in patients receiving general anesthesia is an essential skill. Failure to secure the airway can lead to catastrophic outcomes (1). Among anesthetic agents, propofol is the most used agent, especially in the placement of supraglottic airway devices (SGADs) such as the I-gel, classic laryngeal mask airway proseal LMA, and others (2,3). Second-generation SGADs like the I-gel are single-use devices equipped with an integrated biting block, a narrow-bore gastric drain tube, and a soft gel-like cuffless mask. Prior studies have demonstrated that I-gel is a reliable device and has a low morbidity rate (4).

The design of SGADs vary among different types, influencing the pressure exerted on the pharynx and larynx and the ease of insertion (5). For non-paralyzed patients, achieving adequate depth of anesthesia is crucial for jaw relaxation during I-gel insertion. Care must be taken to avoid complications such as coughing, head or limb movements, and laryngospasm. Propofol is effective in suppressing pharyngeal and laryngeal reflexes but may cause dose-dependent cardiorespiratory depression (6). To address these concerns, propofol is commonly combined with opioids, which may help mitigate associated adverse effects.

The I-gel insertion rate improves with the use of opioids. However, they also pose some disadvantages like delayed anesthetic recovery, inhibition of respiratory stimulus, , and muscle rigidity (7). Dexmedetomidine, a chemically active dextro-isomer of medetomidine, is commonly used as an intravenous anesthetic adjunct due to its anesthetic and analgesic effects at lower doses of 0.5–2 mcg/kg. It also allows dose reduction of propofol during induction and maintenance (8,9,10). Dexmedetomidine is an alpha-2 agonist with anxiolytic, sympatholytic, sedative, analgesic, and hypnotic properties (11). Recent literature reports that dexmedetomidine, when used as an adjuvant to propofol, improves insertion conditions and reduces pressor response during SGAD insertion (12,13).

We hypothesized that dexmedetomidine in combination with propofol may provide better responses for I-gel insertion conditions compared to fentanyl. Thus,

we aimed to compare the optimal combination of propofol with dexmedetomidine and fentanyl. The primary objective is to evaluate jaw relaxation and I-gel insertion conditions using the Modified Scheme of Lund and Stovener criteria. The secondary objective is to monitor hemodynamic parameters, including heart rate, mean arterial pressure, duration of apnea, and the total requirement of propofol.

MATERIALS AND METHODS

This was a cross-sectional comparative study conducted prospectively at a tertiary care hospital over a period of two years (January 2020 to December 2022). Ethical committee approval was obtained prior to patient recruitment (ECR/300/Inst/AP/2013/RR-16).

The inclusion criteria comprised patients aged 2–10 years with ASA physical status I or II, whose parents or guardians provided written informed consent. Eligible children were scheduled for elective short surgical procedures, defined as operations lasting less than 60 minutes. Exclusion criteria were ASA grade III or higher, age below 2 or above 10 years, lack of parental/guardian consent, presence of cardiac disorders, emergency surgeries, and patients with a full stomach.

Patients were randomly assigned into two groups using computer-generated single-sequence randomization (Figure 1):

- 1) Group F received 2.5 mg/kg of intravenous (iv) propofol and 2 mcg/kg of iv fentanyl, followed by I-gel insertion.
- 2) Group D received 1 mcg/kg of iv dexmedetomidine infused over 10 minutes, followed by 2.5 mg/kg of iv propofol, and then I-gel insertion.

All patients received premedication with 0.01 mg/kg of iv atropine, and 10 mg/kg of iv paracetamol during the intraoperative period. The ease of I-gel insertion was assessed based on the level of jaw relaxation using "Young's criteria" (I-Absolutely relaxed jaw, II-Moderately relaxed jaw, III-Poorly relaxed jaw) and the Modified Scheme of Lund and Stovener criteria (Excellent: No gagging or coughing, no laryngospasm, no patient movement; Good: Mild to moderate gagging

or coughing, no laryngospasm, mild to moderate patient movement; Poor: Moderate to severe gagging or coughing, no laryngospasm, moderate to severe patient movement; Unacceptable: Severe gagging or coughing, laryngospasm, severe patient movement). If any of the conditions occurred during the initial attempt at l-gel insertion, an additional dose of 0.5 mg/kg of iv propofol was administered, and the number of boluses was recorded.

The study also measured the respiratory rate and apnea time. Apnea time was defined as the interval between the last spontaneous breath following propofol administration and the first spontaneous breath observed thereafter, using the 8-level Modified Ramsay Sedation Scale.

Changes in heart rate and blood pressure during l-gel insertion were documented at baseline (before any medication, at the operating table), after the infusion of the study drug, after propofol induction, and at 1, 3, 5, and 10 minutes following l-gel insertion.

Patients were evaluated postoperatively using Aldrete Score. Recovery from anesthesia was evaluated with five clinically relevant parameters: muscle activity, respiration, circulation, consciousness, and color. Each category is assigned a score of 0, 1, or 2, with

a maximum total score of 10. A score of 8 or higher indicates that a patient is suitable for discharge.

After surgery, the l-gel was removed once the patient could open their mouth upon command. It was then examined for any bloodstains. Both the front and back of the l-gel cuff were inspected for regurgitation of gastric contents using litmus paper, which changes color in the presence of acidic pH. Any adverse events, such as bradycardia, hypotension, coughing, laryngospasm, bronchospasm, or desaturation, were documented and addressed appropriately. Postoperative measurements included recovery time, sedation status, respiratory rate, heart rate, and non-invasive blood pressure.

Statistical analysis

Statistical analysis was performed using SPSS for Windows, version 25 (SPSS Inc., Chicago, IL). Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables as counts and percentages. Normality of data distribution was assessed prior to analysis. Between-group comparisons of continuous variables were performed using independent samples t-test for normally distributed data, and Mann-Whitney U test for non-normally distributed variables. Categorical variables

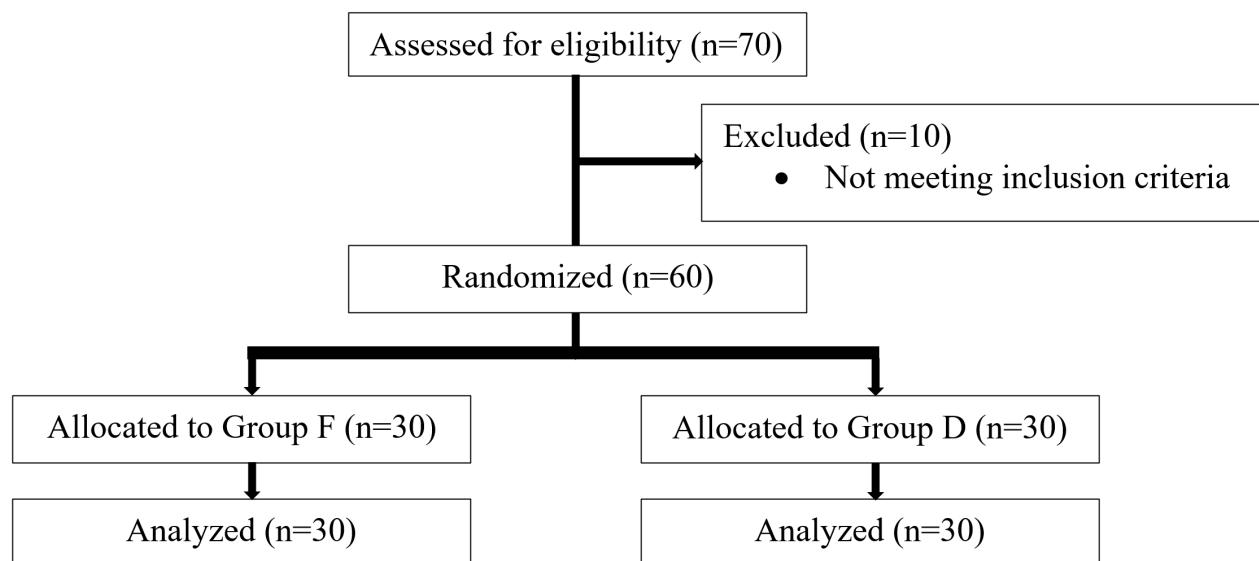


Figure 1. Flow diagram of the study.

were analyzed using the Fisher's exact test. Timepoint-specific comparisons of heart rate, mean arterial pressure, and respiratory rate at each timepoint (T1-T5) were compared with independent samples t-tests. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 60 patients were enrolled in this study. Baseline demographics were similar. Briefly, Group D was slightly older (5.08 ± 0.5 vs 4.5 ± 2.4 years; mean difference 0.58 years, 95% CI -0.33 to 1.49; Welch's $p=0.20$), and the gender proportion did not differ significantly (26/30 vs 24/30; Fisher's $p=0.73$). The mean surgical duration was 42 ± 8 minutes for Group D and 45 ± 10 minutes for Group F. Procedures included herniotomy, circumcision, hydrocele repair, and superficial soft tissue excisions. None of the patients exhibited poorly relaxed jaws (Table 1).

Table 1. Comparison of jaw relaxation prior to i-gel insertion based on Young's criteria

Jaw relaxation	Group F (n = 30)	Group D (n = 30)	Total	p-value
Excellent	17 (56.6%)	18 (60%)	35	0.720*
Good	13 (43.3%)	10 (33.3%)	23	
Poor	0 (0%)	2 (6.0%)	2	

*Fisher's exact test.

Table 2. Comparison of i-gel insertion conditions based on Modified Lund and Stovener criteria

Ease of insertion	Group F (n = 30)	Group D (n = 30)	p-value
Excellent	25 (83.3%)	29 (96.7%)	0.213*
Good	4 (13.3%)	1 (3.3%)	
Poor	-	-	
Unacceptable	1 (3.3%)	-	

*Fisher's exact test.

Table 3. Insertion metrics for i-gel airway—groupwise comparison of size, insertion time, and attempts

	Group F (n = 30)	Group D (n = 30)	p-value*
i-gel size	2.06 ± 0.4	1.9 ± 0.2	0.169
Insertion time (seconds)	12.03 ± 2.9	11.73 ± 2.2	0.659
Number of attempts	1.07 ± 0.25	1.17 ± 0.46	0.302

*Fisher's exact test.

Lund and Stovener Criteria was statistically similar (Table 2). However, numerically, a higher percentage of patients had excellent insertion conditions in Group D compared to Group F. In one patient in Group F, the insertion condition was evaluated as unacceptable.

i-gel size, duration of i-gel insertion, and number of attempts were similar (Table 3).

Number of propofol bolus doses were lower in Group D (Fisher's exact test, 4×2 : $p = 0.009$; Table 4). When dichotomized as any vs none, Group F required more often boluses (50% vs 10%; odds ratio 9.0, 95% CI 2.24–36.17; absolute risk difference 40%, 95% CI 19–61%) (Table 4).

Apnea duration was 2.9 min shorter in Group D (mean difference -2.94, 95% CI -4.06 to -1.82; $p < 0.001$). The incidence of desaturation, laryngospasm, and

cough was similar in both groups (Table 5).

Table 4. Number of additional propofol bolus doses required throughout the surgery

# of propofol bolus doses	Group F (n = 30)	Group D (n = 30)	p-value
None	15 (50%)	27 (90%)	0.009*
1	8 (26.7%)	2 (6.7%)	
2	6 (20%)	1 (3.3%)	
3	1 (3.3%)	0	

*Fisher's exact test.

Table 5. Intraoperative adverse events

	Group F (n = 30)	Group D (n = 30)	p-value*
Duration of apnea (minutes)	15.07 ± 2.82	12.13 ± 2.28	<0.001
Desaturation	1 (3.3%)	-	0.313
Laryngospasm	1 (3.3%)	-	0.313
Cough	5 (16.7%)	1 (3.3%)	0.085

*Fisher's exact test.

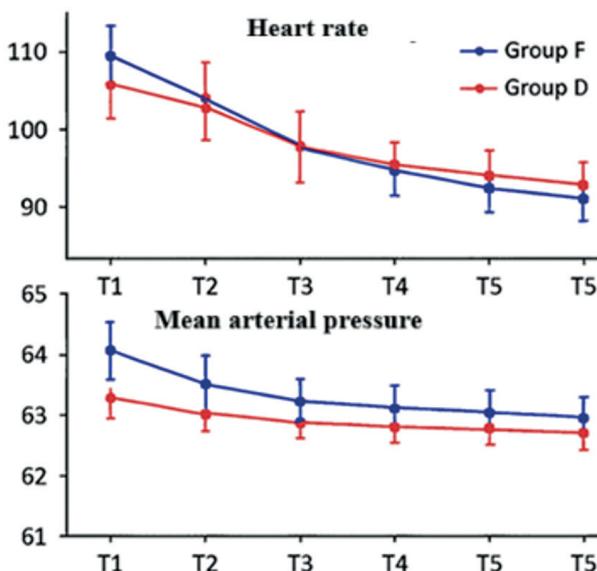


Figure 2. Comparison of heart rate and mean arterial pressure.

Trends of heart rate and mean arterial pressure were similar in both groups (Figure 2). SpO₂ remained ≥99% in both groups at all timepoints (all p ≥ 0.09).

Respiratory rate was lower in Group F at every timepoint (all p < 0.001; Table 6), with between-group mean differences of 7.5–8.6 breaths/min across T1–T5.

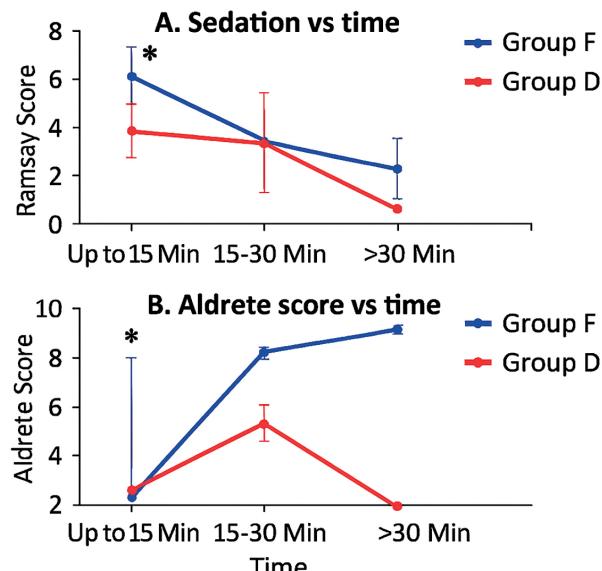


Figure 3. Comparative differences in Ramsay sedation scores and Aldrete recovery.

Significant differences were observed in both Ramsay Sedation Scores and Aldrete Recovery Scores between Group F and Group D during the early postoperative period (Figure 3).

Table 6. Trend of respiratory rate

Timepoint	Respiratory rate		p-value*
	Group F (n = 30)	Group D (n = 30)	
T1	11.23 ± 0.093	19.38 ± 0.521	<0.001
T2	10.02 ± 0.12	18.23 ± 0.801	<0.001
T3	9.21 ± 0.352	17.83 ± 0.675	<0.001
T4	9.48 ± 1.174	17.02 ± 0.140	<0.001
T5	8.32 ± 1.815	16.50 ± 1.21	<0.001

Data are presented as mean ± standard deviation.

*Independent samples t-test.

Sedation Scores (Ramsay)

At <15 minutes, Group D demonstrated deeper sedation (mean ± SD: 7.37 ± 0.49) compared to Group F (6.33 ± 1.18) with a mean difference of 1.04 (95% CI: 0.58 to 1.50); $p < 0.001$. Between 15–30 minutes, sedation remained higher in Group D (5.50 ± 0.51) than in Group F (2.93 ± 2.27), with a mean difference of 2.57 (95% CI: 1.65 to 3.49). At >30 minutes, both groups recovered fully with minimal sedation levels (1.00 ± 0.00, Figure 3A).

Recovery Scores (Aldrete)

Group F recovered faster, with significantly higher Aldrete Scores at <15 minutes (6.47 ± 0.51) compared to Group D (4.43 ± 0.50), with a mean difference of 2.04 (95% CI: 1.61 to 2.47); $p < 0.001$. Between 15–30 minutes, Group F fully recovered (10.00 ± 0.00), while some patients did not recover in Group D (6.47 ± 0.51), with a mean difference of 3.53 (95% CI: 3.23 to 3.83). At >30 minutes, both groups recovered completely (10.00 ± 0.00) (Figure 3B).

DISCUSSION

This study demonstrated that the insertion conditions of the l-gel with either fentanyl or dexmedetomidine as an adjunct to propofol showed no significant difference. However, a numerically higher percentage of patients who received dexmedetomidine had excellent insertion conditions compared to patients who received fentanyl. One patient in Group F experienced unacceptable insertion conditions.

Dexmedetomidine was initially approved by the FDA in 1999 for sedation in intubated and mechanically ventilated adult patients in intensive care settings. In 2008, its approval was expanded to include non-intubated adults undergoing procedural sedation. However, its use in pediatric patients has been under evaluation. While studies have been conducted to assess its efficacy and safety in children, the FDA has not yet granted full approval for pediatric procedural sedation. A recent submission proposed its use for sedation in non-intubated pediatric patients aged 1 month to 16 years undergoing non-invasive procedures. The FDA has required further studies to ensure its safety and efficacy in this population.

Given that dexmedetomidine's pediatric approval process is still under review, this study contributes valuable clinical insights into its airway tolerance and sedation efficacy in children. If further regulatory evaluations align with our findings, this study could support its inclusion in pediatric sedation protocols and assist in refining dosing recommendations for optimized patient outcomes.

Rustagi et al. (14) evaluated l-gel insertion conditions following propofol induction with dexmedetomidine or fentanyl premedication. They used modified scheme of Lund and Stovener criteria to assess overall insertion conditions. Similar insertion conditions were observed between the two groups.

Moderately relaxed jaw, coughing, and movement were observed more frequently in patients from Group F in this study. Also, the incidence of coughing and movement was notably higher in Group F, with

a statistically significant difference in occurrence of coughing between the two groups. Rustagi et al. reported a higher incidence of apnea with fentanyl (18/40) compared to dexmedetomidine (3/40). In this study, the duration of apnea also differed significantly between the groups.

Dexmedetomidine demonstrated better maintenance of oxygen saturation compared to fentanyl, despite inducing deeper sedation. Fentanyl was associated with more cases of oxygen desaturation, likely due to its opioid-induced respiratory depression, which differs pharmacologically from dexmedetomidine. Although fentanyl had a shorter duration of action, resulting in less impact on apnea time beyond the initial sedation phase, patients receiving fentanyl-propofol should be closely monitored for oxygen desaturation, particularly in high-risk populations.

Rustagi et al. also observed that emergence times were shorter in patients receiving fentanyl compared to patients receiving dexmedetomidine, with more propofol bolus doses required in the former group. Similarly, this study also showed that the number of propofol boluses required in Group F was significantly higher compared to Group D. This can be attributed to the effects of dexmedetomidine, which prolongs sedation and lowers the overall propofol requirement.

Rustagi et al. also observed that the respiratory rate was higher in patients receiving dexmedetomidine. This finding aligns with the findings of Ramaswamy et al. (15). Similarly, this study indicated that the respiratory rate was significantly higher in Group D compared to Group F. Hanci et al. (16) compared the effects of fentanyl and dexmedetomidine when combined with propofol and lidocaine for tracheal intubation. Their study found that heart rate was significantly lower in patients receiving dexmedetomidine, while mean arterial pressure was significantly lower in patients receiving fentanyl.

Uzumcugil et al. (13) observed greater reductions in systolic and mean arterial blood pressure in patients receiving fentanyl. In contrast, this study did not observe any significant differences in heart rate or mean arterial pressure at different time intervals. This finding is consistent with the findings of Choudhary et

al. (17), which examined the insertion of Proseal LMA (a supraglottic device like classical LMA, with a second bore for gastric access) and reported hemodynamic stability in both groups. This study also found no significant differences in terms of I-gel size or number of insertion attempts. Based on these results, it is recommended that either protocol can be used without major concerns for hemodynamic instability.

This study found no significant difference in desaturation and laryngospasm, but a significant difference in the Ramsay Score. The mean Ramsay Score within the first 30 minutes was significantly higher in Group D. Prolonged sedation in Group D suggests improved patient comfort and reduced movement, both of which are advantageous for procedures requiring minimal patient response.

This study found a significantly lower Aldrete Score in Group D within the first 30 minutes. This indicates prolonged post-anesthesia effects, necessitating extended monitoring before discharge. Clinically, this suggests that dexmedetomidine-propofol patients may require additional monitoring time before discharge, whereas fentanyl-propofol patients can be discharged sooner, especially in outpatient settings.

Limitations

The findings of this study are limited by the small sample size, single-center design, subjective anesthesia assessment, lack of patient-reported comfort, and the absence of continuous capnography as an objective measure of apnea. Future research should aim to integrate objective sedation monitoring devices including capnography, larger and more diverse populations; and comprehensive evaluations of patient factors to improve the clinical applicability of findings.

CONCLUSIONS

This study compared I-gel insertion conditions using propofol-fentanyl versus propofol-dexmedetomidine in pediatric daycare surgeries at a tertiary care hospital. Jaw relaxation was similar between groups, and overall insertion conditions were statistically comparable. However, Group D demonstrated a higher rate of excellent placement and no unacceptable

scores. Group D required significantly fewer propofol boluses but exhibited higher Ramsay Sedation Scores and lower Aldrete Scores, consistent with deeper sedation and delayed recovery. With no significant differences in hemodynamic or respiratory parameters, dexmedetomidine as an adjunct to propofol appears to be a promising alternative to fentanyl in this setting.

Ethical approval

Ethical committee approval was obtained prior to patient recruitment (ECR/300/Inst/AP/2013/RR-16).

Author contribution

Surgical and Medical Practices: NA, JH; Concept: SP; Design: NA, HJ; Data Collection or Processing: NA, JH; Analysis or Interpretation: NA, JH; Literature Search: NA; Writing: NA, SP. All authors reviewed the results and approved the final version of the article.

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Conflict of interest

The authors declare that there is no conflict of interest.

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