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ORIGINAL RESEARCH

Effect of Intravenous Lidocaine (1.0 mg/Kg) on Propofol ED50 and ED95 for Successful Double-Lumen Laryngeal Mask Airway Placement in Hysteroscopy Patients: A Randomized Controlled Trial

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Purpose: It has been demonstrated that administration of intravenous lidocaine promotes laryngeal mask airway (LMA) placement. This research aimed to evaluate the effect of intravenous lidocaine at a dosage of 1.0 mg/kg on the 50% and 95% effective doses (ED50 and ED95) of propofol required for the successful placement of a double-lumen LMA during propofol-fentanyl-based anesthesia in patients undergoing hysteroscopy.

Patients and Methods: Eighty patients who underwent hysteroscopy were screened and randomly enrolled in either lidocaine group (group L, n=40) or the saline group (group S, n=40). The propofol induction dose per patient was established via an up-and-down sequential method. Under the guidance of bispectral index (BIS) value monitoring, the propofol doses required for the successful placement of a double-lumen LMA in 50% and 95% of the patients in the two groups (ED50 and ED95) were compared. The total propofol induction dose, awakening duration, and adverse outcomes were documented and analyzed.

Results: The propofol's ED50 was notably lower in the L group than in the S group (1.15±0.27 mg/kg versus 1.83±0.26 mg/kg; $p<0.05$, Cohen's d=2.56). The ED95 (95% confidence interval) of propofol was 2.04 (1.23–2.85) mg/kg in the L group and 2.64 (1.95–3.33) mg/kg in the S group, with a small effect size for the difference (Cohen's d=0.25). The total propofol induction dose in the L group was lower than that in the S group ($p<0.05$). There existed no variations in terms of awakening duration or incidence of adverse events.

Conclusion: In patients who underwent hysteroscopy, post-propofol intravenous lidocaine at 1.0 mg/kg markedly reduced the propofol's ED50 in propofol-fentanyl-based anesthesia for successful placement of a double-lumen LMA without significant adverse reactions.

Keywords: lidocaine, propofol, laryngeal mask airway, median effective dose

Introduction

The successful first-time insertion of the laryngeal mask airway (LMA) is crucial for patient safety and comfort, as a failed attempt could heighten the likelihood of laryngospasm, oxygen deficiency, and post-procedure throat irritation.[1] Propofol and fentanyl combined anesthesia is commonly used to provide deep enough sedation and adequate analgesia for LMA insertion. However, high doses of propofol may be associated with circulatory depression, and high doses of fentanyl can lead to an increased incidence of apnea after surgery.[2–6] Recent literature indicates that intravenous lidocaine provides sedative and analgesic effects, which could reduce the propofol requirement for anesthesia induction.[7–9] It has

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also been proven that administration of intravenous lidocaine could improve conditions for LMA insertion.[10,11] Second-generation double-lumen LMA is known to have a modified design to offer greater sealing pressure and decrease pulmonary aspiration risk, leading to its widespread use.[12–14] Thus, this dose finding study aimed to evaluate intravenous lidocaine's impact on propofol's ED50 and ED95 in induction for successful placement of a double-lumen LMA in propofol-fentanyl-based anesthesia in patients undergoing hysteroscopy, which, as far as we know, has not been investigated in prior studies. In our previous study, we showed that intravenous lidocaine administration at 1.0 mg/kg notably decreased propofol's ED50, comparable to a 1.5 mg/kg dose.[15] Thus, the dose of intravenous lidocaine in this study was 1.0 mg/kg. We hypothesized that intravenous injection of lidocaine at 1.0 mg/kg could markedly lower the propofol's ED50 and ED95 in induction for LMA insertion and could also achieve hemodynamic stability compared to propofol fentanyl anesthesia alone.

Materials and Methods

Trial Registration

The research design received approval from the Ethics Committee of West China Second University Hospital, Sichuan University, and was documented within the Chinese Clinical Trial Registry (ChiCTR2300069522). The research was conducted in accordance with the Declaration of Helsinki between March 2023 and March 2024 and written informed consent was acquired from 80 participants before the study began.

Patients

This prospective trial enrolled patients planed for hysteroscopy with anesthesia at the West China Second Hospital of Sichuan University. Patients aged 18 to 60 years, with the American Society of Anesthesiologists (ASA) physical status I or II and Mallampati score I or II and fasted for at least 6 hours (solids) and 2 hours (liquids) prior to surgery were enrolled. The exclusion criteria: patients weighing <40 kg or with body mass index (BMI) <18 kg/m^2 or >28 kg/m^2; patients with allergies to propofol, fentanyl, local anesthetics, or other related drugs; patients with anticipated difficult airway, recent history of upper respiratory tract infections, and gastroesophageal reflux diseases; patients with significant hepatic or renal impairment, cardiovascular, respiratory, endocrine, metabolic, or neurological disorders; patients using long-term analgesics, sedatives, or drugs altering local anesthetics metabolism within 7 days; participants in other clinical studies with experimental drugs within 3 months prior; patients with alcohol or drug dependency. All the participants were apprised of the study's objectives.

Randomization and Blinding

In short, 80 patients were allocated into L and S groups via a software-generated randomization with dual-block allocation. Each number was concealed in a sealed envelope. The anesthesiologist handling medication preparation and administration knew the group allocations. The data-collecting investigator, participants, surgeon, and nurses remained unaware of the allocations.

Study Protocol

Once patients were within the surgical suite, Ringer's lactate infusion (2 mL/kg/h) was initiated, and the peripheral capillary oxygen saturation (SpO_2), electrocardiogram, invasive blood pressure, and bispectral index (BIS) values were observed until patients recovered from anesthesia and moved to the post anesthesia recovery area. SpO_2, invasive blood pressure, heart rate (HR), and BIS were recorded at four time points: prepared on the examination table for medication (T_0), immediately prior to LMA insertion (T_1), immediately after LMA insertion (T_2), and after LMA removal (T_3). The patients received mask oxygen at 10 L/min for 3 min prior to anesthesia induction. All medications were formulated at ambient temperature and administered promptly. Lidocaine (Sinopharm Rongsheng Pharmaceutical Co., China) at 1.0 mg/kg was mixed with saline to a total of 10 mL in a 10-mL syringe. An equivalent amount of saline was filled in a syringe of the same capacity. Intravenous injections of 5 mg dexamethasone and 10 mg metoclopramide were administered to reduce postoperative nausea and vomiting prior to anesthesia induction. Anesthesia induction began with

a single 2.0 μg/kg fentanyl (Yichang Humanwell Pharmaceutical Co., China) bolus. After two minutes, propofol (Corden Pharma S.P.A., Italy) was administered at 0.4 mL/s to all participants, followed by lidocaine or saline solution given over about 30 seconds per group assignment. Initial patient in each group received 2.0 mg/kg propofol, with subsequent doses adjusted up or down by 0.2 mg/kg based on prior patient response. The BIS monitored the sedation depth. Once the BIS value fell below 60, the anesthesiologist began the placement of the double-lumen LMA (Zhejiang Haisheng Medical Equipment Co., Ltd., China). All procedures were conducted by the same anesthesiologist. If the BIS value remained ≥60 after initial propofol dose or if bodily movement was observed during the placement of the double-lumen LMA, the outcome was regarded ineffective; alternatively, it was regarded effective. For effective outcomes, the propofol dosage in the subsequent patient was reduced by 0.2 mg/kg. For ineffective outcomes, the propofol dosage was raised by 0.2 mg/kg. If the BIS value was ≥60 after induction, or if bodily movement was noted throughout the LMA placement, propofol 0.5 mg/kg was administered, until successful placement of the double-lumen LMA. From anesthesia induction to successful insertion of the double-lumen LMA, if HR fell below 50 beats per minute, atropine at 0.5 mg was injected. Hypotension was classified as a decrease more than 20% in the mean arterial pressure (MAP), diastolic blood pressure (DBP), or systolic blood pressure (SBP) from baseline, or SBP <80 mmHg. Upon hypotension, ephedrine 3–10 mg was given when necessary. The total induction dose of propofol, surgery duration, awakening duration, and visual analog scale (VAS) score of the sore throat after removal of the LMA was also documented.

Measurements

The primary outcomes were propofol's ED50 and ED95 for induction. The secondary outcomes included bodily movement, hypotension, bradycardia, sore throat VAS score, total propofol induction dose, surgery duration, and awakening duration.

Sample Size

Based on the stopping criterion of the up-and-down sequential method,[16] enrollment should continue until at least six ineffective-to-effective result pairs were achieved in each group. A priori sample size calculations were not possible. Other anesthesia studies using this approach generally include 20–40 participants.[17,18] In our trial, each group consisted of 40 subjects.

Statistical Methods

Statistical analyses were conducted with R software (version 4.3.3).[19] The normality of continuous variables was evaluated using Shapiro–Wilk test. Normally distributed continuous data were reported as mean ± standard deviation (SD) and analyzed using Student's *t*-test, while continuous data with non-normal distribution were reported as median (interquartile range) and analyzed using the Wilcoxon rank-sum test. Categorical variables, expressed as n (%), were evaluated using the chi-square test when at least 80% of expected frequencies were ≥5, or Fisher's exact test when this condition was not met. Significance was set at $p<0.05$ for all comparisons.

To determine the primary endpoint, propofol's ED50 and ED95 were estimated using multiple computational approaches for validation, incorporating the results from the Dixon-Massey method, two-parameter log-logistic (LL.2), and two-parameter Weibull (W2.2) models. The ED50 was initially estimated using the Dixon-Massey up-and-down sequential allocation method, which is a non-parametric approach commonly applied in anesthetic dose-response studies. This method calculates the ED50 as the average of ineffective-effective crossover midpoints, providing a preliminary estimation based on sequential dose allocation. To ensure robustness in the dose-response estimation, this study also employed two nonlinear regression models, the LL.2 and W2.2 model. LL.2 was selected as the primary model for dose-response characterization owing to its standard pharmacological applications, while W2.2 was employed for sensitivity analysis, specifically refining estimation in the high-dose range. This multi-model approach enhances the reliability of dose-response estimation and ensures a comprehensive analysis across different dose ranges. Model performance was compared using the Akaike Information Criterion (AIC), Bayesian Information Criterion (BIC), residual standard deviation (SD), and ED50 and ED95 confidence interval widths (CI widths). Dose-response curve visualization was performed based on the W2.2 modeling results because of its superior performance in high-dose range estimation.

Results

Altogether, 105 participants were enrolled in the research and screened. Among them, 25 were excluded: 16 due to surgery cancellation, 8 due to withdrawal of consent, and 1 lost to contact, and the remaining 80 participants were incorporated into the final analysis and randomly divided into the L and S groups (Figure 1). No notable differences were identified between the groups regarding baseline characteristics, including age, height, BMI, ASA classification, maximum mouth opening, Mallampati score, SPO_2 (T_0), HR (T_0), SBP (T_0), DBP (T_0), MAP (T_0), and BIS value (T_0) (Table 1). Figure 2 displays the up-and-down dosing sequences and patient responses.

For dose-response estimation, the Dixon-Massey method, LL.2, and W2.2 model were applied. A comparative analysis of the AIC, BIC, Residual SD, and CI widths was conducted to evaluate the model performance. Table 2 shows the model fit statistics for the dose-response estimation. W2.2 demonstrated a narrower ED95 CI width, which improved the estimation precision in the high-dose range. The final dose-response curve was plotted based on the W2.2 model results, as it provided a more precise visualization of dose-effect trends at higher doses (Figure 3). Table 3 presents propofol's ED50 and ED95 (with 95% CI) for both groups, using the Dixon-Massey method, LL.2 model, and W2.2 model. Cohen's d was calculated to quantify the ED50 and ED95 difference between the L and S groups, with a threshold of 0.8 typically regarded as a large effect size in pharmacological studies.[20] Using the Dixon-Massey method, the ED50 of propofol was 1.15±0.27 mg/kg in the L group and 1.83±0.26 mg/kg in the S group, with a significant difference ($p<0.001$, Cohen's d=2.56). The LL.2 and W2.2 models yielded similar ED50 estimates. While W2.2 provided superior ED95 estimation: 2.04 (1.23–2.85) mg/kg in the L group; 2.64 (1.95–3.33) mg/kg in the S group, the ED95 difference showed a small effect (Cohen's d=0.25). The dose-response curve, visualized using W2.2, highlighted distinct dose requirements between the groups (Figure 3).

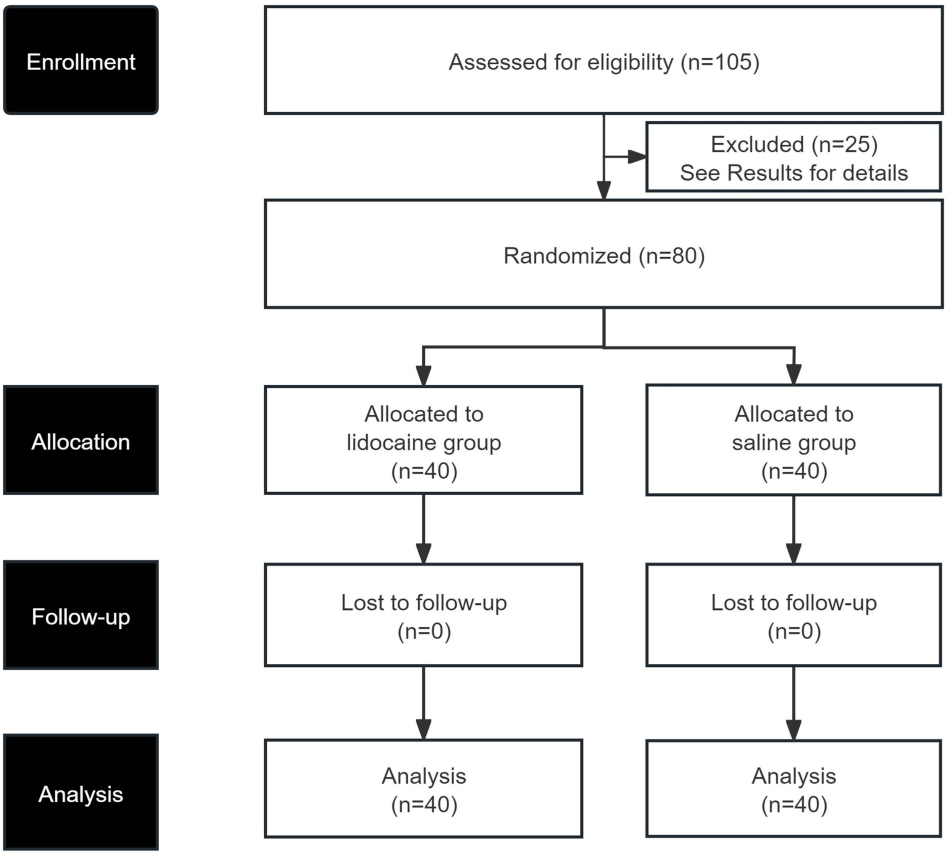

Figure 1 Flow diagram of included participants.

Table 1 Baseline Demographic and Clinical Data of Study Participants (n=40 per Group)

	L Group	S Group	P value
Age (years)	35.50 [30.75, 41.00]	32.00 [30.00, 35.00]	0.068
Height (cm)	159.52 (4.08)	158.48 (3.73)	0.233
BMI (kg/m^2)	21.29 [19.87, 23.28]	21.28 [20.03, 23.69]	0.690
ASA classification			1.000
I	37	38	
II	3	2	
Maximum mouth opening (cm)			0.055
3	1 (2.5%)	0 (0.0%)	
3.5	21 (52.5%)	28 (70.0%)	
4	18 (45.0%)	10 (25.0%)	
4.5	0 (0.0)	2 (5.0%)	
Mallampati score			0.815
I	13 (32.5%)	15 (37.5%)	
II	27 (67.5%)	25 (62.5%)	
SPO_2 (T_0)	100.0 [100.0, 100.0]	100.0 [100.0, 100.0]	0.399
HR (T_0)	71.72 (9.77)	73.35 (9.11)	0.444
SBP (T_0)	110.00 [104.75, 114.00]	108.50 [103.00, 115.00]	0.813
DBP (T_0)	70.45 (7.48)	69.42 (7.23)	0.535
MAP (T_0)	81.50 [78.00, 87.00]	82.00 [77.00, 86.00]	0.813
BIS (T_0)	95.50 [93.00, 97.00]	95.00 [92.00, 97.00]	0.120

Notes: Data are reported as the median [Q1, Q3] for variables with non-normal distribution, mean (SD) for variables with normal distribution, and n (%) for categorical variables. Statistical significance was set at $p<0.05$.

Surgery-related characteristics and adverse outcomes are presented in Table 4, with no significant differences detected in surgery duration or awakening duration between the L and S groups ($p>0.05$). The average total propofol dose needed for successful double-lumen LMA placement was significantly lower in the L group than in the S group ($p<0.05$), though no notable differences were observed in the incidence of hypotension ($p>0.05$) and no patients developed hypoxia,

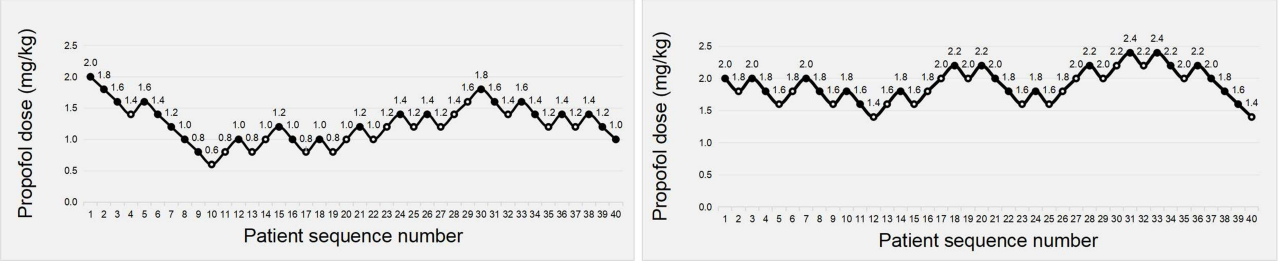

Figure 2 Dixon up-and-down graphs for the two groups. "●" indicates ineffective, and "○" indicates effective. The left panel corresponds to the lidocaine group, while the right panel corresponds to the saline group.

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Table 2 Model Fit Statistics for Dose-Response Estimation

Model	AIC	BIC	Residual SD	ED50 CI Width	ED95 CI Width
LL.2 (L group)	50.57	53.94	0.46	0.86–1.30	0.94–3.96
LL.2 (S group)	52.31	55.69	0.47	1.64–2.04	1.80–4.07
W2.2 (L group)	50.60	53.98	0.46	0.87–1.35	1.23–2.85
W2.2 (S group)	52.56	55.93	0.47	1.64–2.08	1.95–3.33

Notes: AIC and BIC were used to evaluate relative model performance, where smaller values suggest an improved fit. The residual SD quantifies model stability, with smaller values suggesting a lower deviation from the observed data. The CI widths represented the uncertainty of the ED50 and ED95 estimates, with narrower widths indicating greater precision.

nausea, or vomiting. In a subset of patients with BIS values <60, LMA insertion was unsuccessful or accompanied by bodily movement, with a lower incidence in the L group ($p<0.05$, Table 5).

Discussion

Our study found that intravenous lidocaine 1.0 mg/kg administered after propofol induction significantly reduced the ED50 and total induction dose of propofol. Although propofol's ED95 was estimated using LL.2 and W2.2 models, limited high-dose data may compromise CI precision, and no significant statistical difference was observed for ED95.

The laryngeal mask airway, a supraglottic airway device, has multiple advantages compared to the endotracheal tube, including simpler insertion, decreased risk of tracheal trauma, reduced postoperative sore throat, and enhanced respiratory and hemodynamic stability during insertion.[21–25] Compared to facemasks, the benefits include an improved oxygen saturation level and decreased hand exhaustion for anesthetists. Moreover, the LMA is incorporated into the airway management protocols of the ASA and the UK's Difficult Airway Society.[26–28] The second-generation double-lumen LMA is known to have a modified design to offer greater sealing pressure and a built-in drain tube that enable expelled gastric content to bypass the pharynx to reduce pulmonary aspiration risk.[26] The LMA is commonly used for short-

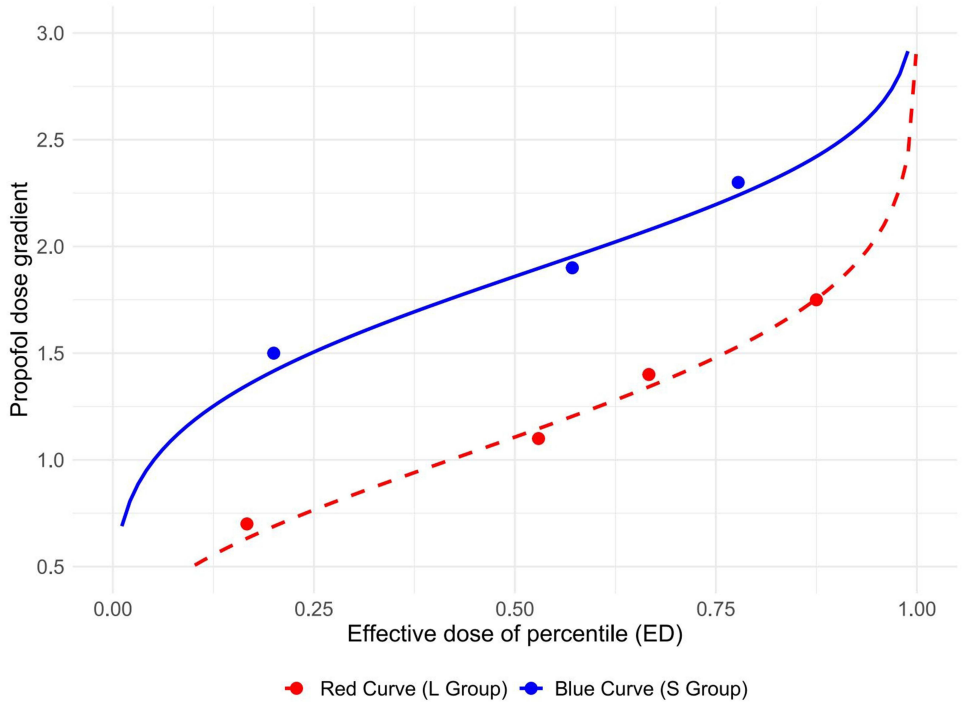

Figure 3 Dose-effect analysis of lidocaine and propofol on patients' responses in the two groups.

Table 3 ED50 and ED95 of Propofol (95% CI) in Two Groups Using Dixon-Massey, LL.2, and W2.2 Methods

ED (mg/kg)	L Group	S Group	Student's t test P value	Cohen's d
ED50 (Dixon-Massey)	1.15 (0.27)	1.83 (0.26)	<0.001*	2.56#
ED50 (LL.2)	1.08 (0.86–1.30)	1.84 (1.64–2.04)		1.11#
ED50 (W2.2)	1.11 (0.87–1.35)	1.86 (1.64–2.08)		1.02#
ED95 (LL.2)	2.45 (0.94–3.96)	2.94 (1.80–4.07)		0.11
ED95 (W2.2)	2.04 (1.23–2.85)	2.64 (1.95–3.33)		0.25

Notes: *p<0.05, significant difference between groups. "#" represents a large effect size was observed, with Cohen's d>0.8.

Table 4 Surgery-Related Characteristics and Adverse Outcomes

	L Group	S Group	P value
Bodily movement			0.344
No	29 (72.5%)	24 (60.0%)	
Yes	11 (27.5%)	16 (40.0%)	
Hypotension			0.599
No	11 (27.5%)	8 (20.0%)	
Yes	29 (72.5%)	32 (80.0%)	
Bradycardia			1.000
No	40 (100%)	39 (97.5%)	
Yes	0 (0.00%)	1 (2.50%)	
VAS score of sore throat			0.889
0	8 (20.0%)	10 (25.6%)	
1	5 (12.5%)	6 (15.4%)	
2	11 (27.5%)	9 (23.1%)	
3	16 (40.0%)	14 (35.9%)	
Surgery duration (min)	11.50 [9.00, 18.25]	14.00 [7.50, 21.50]	0.891
Total induction dose of propofol (mg/kg)	77.4 [60.8, 96.6]	112 [99.2, 129]	<0.001*
Awakening duration (min)	8.72 (1.83)	9.51 (2.25)	0.091

Notes: Data are reported as the median [Q1, Q3] for variables with non-normal distribution, mean (SD) for variables with normal distribution, and n (%) for categorical variables. Statistical significance was set at *p<0.05.

duration surgical procedures under general anesthesia that does not require muscle relaxants. In our institute, a double-lumen LMA has been used for years, and size 3 LMA has been successfully applied in the majority of female patients during hysteroscopy.

Smooth insertion of the LMA is crucial for anesthesiologists to provide effective and efficient airway management, which requires sufficient anesthesia depth to fully relax the mouth and jaw and suppress the airway reflexes. Propofol is commonly used for anesthesia induction owing to its quick onset and short half-life; however, it has no analgesic effect. Its use alone cannot provide favorable conditions for LMA insertion. Therefore, it is necessary to combine propofol with

Table 5 BIS-Related Characteristics

	L Group	S Group	P value
BIS (T_0)	95.50 [93.00, 97.00]	95.00 [92.00, 97.00]	0.120
BIS (T_1)	44.17 (6.85)	40.15 (7.04)	0.011*
BIS (T_3)	81.00 [78.00, 84.25]	81.00 [78.50, 83.00]	0.708
Failed LMA insertion with BIS <60			0.006*
0	35 (87.5%)	23 (57.5%)	
1	5 (12.5%)	17 (42.5%)	

Notes: Data are presented as median [Q1, Q3] for variables with non-normal distribution, mean (SD) for variables with normal distribution, and n (%) for categorical variables. *p<0.05, significant difference between groups.

opioid drugs or muscle relaxants to improve the sedation and analgesic effects. However, a large dose of opioid drugs can prolong postoperative recovery time, and muscle relaxants may increase the risk of reflux aspiration. In clinical practice, an appropriate dose of opioid drugs combined with propofol is a commonly used anesthetic method for LMA placement. However, extensive use of propofol can lead to unstable hemodynamics. Thus, in propofol-fentanyl-based anesthesia, a potential effective adjunct to mitigate the response to LMA insertion and decrease propofol requirements is required.

Recent research indicates intravenous lidocaine's analgesic and sedative effects, such as reduced propofol injection pain, lower opioid requirement, and less postoperative chronic pain. It has also been proven that administration of intravenous lidocaine can improve the conditions for LMA insertion. For instance, Hee Jung Baik et al demonstrated that intravenous lidocaine at 1.5 mg/kg significantly improved conditions for LMA insertion during propofol target-controlled infusion in patients undergoing minor surgery by reducing cough and laryngospasm. Foo et al suggested that, for intravenous lidocaine, an initial dose not exceeding 1.5 mg/kg based on optimal body mass was considered to be safe in their consensus guidelines.[29] In our previous outpatients study, we showed that intravenous lidocaine 1.0 mg/kg markedly lowered propofol's ED50 for induction without significant side effects, comparable to a 1.5 mg/kg dose. Hence, this research aimed to evaluate the impact of intravenous lidocaine 1.0 mg/kg on propofol's ED50 and ED95 induction doses for the successful placement of a double-lumen LMA in propofol-fentanyl-based anesthesia in patients undergoing hysteroscopy, which, as far as we know, remains unexamined in prior research.

With a distribution half-life ranging from 5 to 8 minutes, intravenous lidocaine disperses from circulation to peripheral tissues.[30] Thus, we delivered lidocaine post-propofol to sustain effective plasma levels. Our research showed that intravenous lidocaine post-propofol at 1.0 mg/kg markedly lowered the ED50 and total induction dose of propofol. We found that in a subset of patients, even when the BIS value was <60, insertion of the LMA was either unsuccessful or accompanied by bodily movement. An analysis of the incidence of this occurrence revealed a lower rate in the L group. These findings may indicate lidocaine's analgesic and antihyperalgesic properties. No differences in adverse event rates were observed between L and S groups. Thus, we advocate intravenous lidocaine at 1.0 mg/kg dose as an effective adjunctive treatment for propofol-fentanyl-based anesthesia for the placement of the double-lumen LMA.

Our research had some limitations. First, we exclusively recruited female patients with ASA I or II status, potentially limiting generalizability as ASA III and IV patients could be more prone to cardiovascular suppression from propofol. Second, lidocaine was given as a single bolus injection without continuous infusion. Third, although the ED95 of propofol was estimated using both the LL.2 and W2.2 models, limited high-dose data may reduce CI precision, warranting caution when extrapolating. Further research is required to enhance the accuracy of the data.

Conclusion

Our current results indicated that among participants undergoing hysteroscopy under propofol-fentanyl-based anesthesia, intravenous lidocaine at 1.0 mg/kg post-propofol markedly lowered propofol's ED50 and total dose of propofol. However, the ED95, a co-primary outcome, showed no significant difference, likely due to limited high-dose data. Larger studies with higher propofol doses are needed to clarify lidocaine's effect on ED95.

Data Sharing Statement

The study data can be acquired from the corresponding author upon inquiry.

Acknowledgments

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Disclosure

The authors declare no competing interests in this study.

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