Drug Design, Development and Therapy

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CLINICAL TRIAL REPORT

Comparison of Hemodynamic Status with Three Different Doses of Lidocaine as an Adjunct to Propofol-Remifentanil During Endotracheal Intubation in Elderly Female Patients: A Prospective Randomized Study

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Background: Lidocaine was reported to stabilize the hemodynamic status and reduce the incidence of postinduction hypotension in elderly patients. However, the optimal dose of lidocaine as an adjuvant to propofol-remifentanil during endotracheal intubation in elderly female patients remains uncertain. In this study, we aimed to determine the optimal dose of lidocaine as an adjuvant for propofol-remifentanil in elderly female patients.

Methods: Two hundred and forty patients were randomly assigned to one of three groups in a ratio of 1:1:1, each receiving a different dosage of lidocaine: 0.5 mg/kg, 1.0 mg/kg, or 1.5 mg/kg, with propofol-remifentanil for endotracheal intubation. Patients' hemodynamic parameters were continuously monitored 10 minutes after the induction of anesthesia. Hypotension, defined as a mean arterial pressure <70% of the baseline value and/or <65 mm Hg, and treated with norepinephrine 4 μg, repeated as necessary. Norepinephrine consumption (primary outcome), mean arterial pressure, heart rate, and propofol consumption were recorded.

Results: The incidence of hypotension was 51.4% (37/72), 13.0% (9/69), and 13.8% (9/65) in Groups 0.5, 1.0, and 1.5, respectively. The median (25th and 75th quartiles) consumption of norepinephrine was 4 (0–4) μg, 0 (0–0) μg, and 0 (0–0) μg across the groups, respectively; there was a significant difference among the groups (p = 0.0006). The incidence of hypertension was 15.7% (11/72), 5.8% (4/69), and 6.2% (4/65) across the groups, respectively.

Conclusion: In summary, under the conditions of this study, we propose that 1.0 mg/kg lidocaine may be considered as an optimal dose when used as an adjuvant to propofol-remifentanil for endotracheal intubation.

Clinical Trial Registration: Chinese Clinical Trial Registry number: ChiCTR2400092990 https://www.chictr.org.cn/bin/project/edit?pid=231367.

Keywords: lidocaine, propofol, hypotension, elderly, anesthesia

Introduction

Intraoperative hypotension is a common and detrimental complication that may increase the risk of postoperative complications and mortality due to reduced organ perfusion.[1–3] Approximately one-third of all hypotensive episodes occurring during surgery can be attributed to post-induction hypotension.[4] At present, elderly adults represent an increasingly significant proportion of the surgical population and are at higher risk for perioperative complications, particularly hypotension.[5]

Received: 20 May 2025
Accepted: 11 July 2025
Published: 29 July 2025

Propofol, a sedative-hypnotic agent widely used as one of the most common intravenous anesthetics for inducing and maintaining general anesthesia, is favored for its rapid onset of action and smooth recovery profile. However, it may be associated with adverse effects such as bradycardia, injection-site discomfort, and hypotension, particularly in elderly patients.[6]

Lidocaine is a local anesthetic agent with various systemic applications. Studies suggested that lidocaine can exhibit a propofol-sparing effect in clinical sedation.[7,8] In addition, lidocaine-based regimens were also reported to reduce the risk of post-propofol-induced hypotension in elderly patients compared to fentanyl-based regimens and to improve the hemodynamic status in elderly patients.[9] However, the optimal dose of lidocaine as an adjuvant for propofol-remifentanil in elderly patients during the endotracheal intubation remains unclear. In this study, we aimed to compare the effects of 0.5, 1.0, and 1.5 mg/kg lidocaine in combination with propofol-remifentanil on the effect of hemodynamic variations, in order to determine the optimal dose of lidocaine. Our hypothesis was that the effect of lidocaine on stabilizing hemodynamic status exhibits a dose-dependent relationship in elderly female patients during endotracheal intubation.

Methods

This randomized double-blinded study was conducted in Jiaxing University Affiliated Women and Children Hospital after getting the permission of the Ethics Committee in the hospital. The clinical trial was registered on the Chinese Clinical Trial Registry on November 27, 2024 (ChiCTR2400092990, https://www.chictr.org.cn/showproj.html?proj=231367). All patients included in this study were fully informed and required to provide written informed consent. We enrolled the first patient in this study on December 1, 2024, marking the initiation of our research protocol. This study complies with the Declaration of Helsinki.

Patients with American Society of Anesthesiologists (ASA) physical status I to III, aged over 60 years, with a body mass index (BMI) ranging from 18 to 35 kg/m², and undergoing laparoscopic gynecologic surgery under general anesthesia were recruited. Exclusion criteria included heart disease (eg, ejection fraction <50%, conduction block, or arrhythmia), metabolic equivalent <4, uncontrolled hypertension despite treatment with medications such as ACE inhibitors or ARBs, allergy to any study drug, and suspected difficult airway management.

Patients were randomly assigned to one of three groups in a ratio of 1:1:1, each receiving a different dosage of lidocaine: 0.5 mg/kg, 1.0 mg/kg, or 1.5 mg/kg in Group 0.5, Group 1.0, and Group 1.5, respectively. The randomization sequence was generated using computer-generated random numbers in Microsoft Excel (Microsoft, Redmond, WA, USA). An independent research assistant, who was not involved in the clinical care of participants, prepared the randomization assignments and sealed them in opaque, sequentially numbered envelopes prior to the study commencement. These envelopes were opened only upon the enrollment of each participant to maintain allocation concealment.

Upon arrival in the operating room, routine monitoring according to the study protocol was initiated, including invasive blood pressure measurement, continuous electrocardiographic monitoring, pulse oximetry, and bispectral index (BIS). An 18-gauge intravenous cannula was inserted into a forearm vein; however, no prehydration protocol was administered to the patient. The baseline data for blood pressure and heart rate were obtained by averaging three consecutive measurements taken at 3-minute intervals after the patient had a short rest period.

The LiDCOplus monitor (LiDCO Ltd., Cambridge, UK) was employed, and before the administration of anesthesia, all patients underwent an assessment for fluid responsiveness. This evaluation utilized a stroke volume variability (SVV) threshold of ≥13%.[10] During the assessment, patients were instructed to maintain regular, calm respiration at a rate of 8 breath/minute for one minute.[11] The fluid-responsive patient was administered a fluid bolus of 8 mL/kg Ringer's acetate over a 10-minute period, and this intervention was repeated until the SVV decreased to less than 13%.

Patients in Group 0.5, Group 1.0, and Group 1.5 received 0.5, 1.0 and 1.5 mg/kg lidocaine solution, respectively. The study solution was prepared in advance by a designated anesthesiologist (LQ. X) under sterile conditions in an identical 20 mL syringe. Although this anesthesiologist was aware of patient allocation, she was not involved in any other aspects of the study. All patients initially received a target effect-site concentration of 2 μg/mL of propofol for inducing loss of consciousness. If necessary, the concentration was increased incrementally 0.25 μg/mL until the desired effect (loss of verbal response, eyelashes reflex and BIS value <60) was achieved. Remifentanil was administered at a target effect-site concentration of 2 ng/mL, and rocuronium at 0.6 mg/kg, immediately following the confirmation of patient loss of consciousness. Following two

minutes of mask ventilation, the endotracheal tube was inserted. When performing endotracheal intubation, if the heart rate or invasive blood pressure increased by 20% above the baseline value, an immediate intravenous bolus of propofol 30 mg was administered by an anesthesiologist, repeated if necessary. Patients who experienced difficult intubation, defined as requiring more than one attempt or exceeding a predefined time threshold as assessed by the attending anesthesia specialist, were excluded from the final analysis. The patient's ventilation mode was configured with a tidal volume of 8 mL/kg and a respiratory rate of 12 breaths/minute. The end-tidal partial pressure of carbon dioxide (EtCO2) was maintained at 40 mm Hg through adjustments to the tidal volume and respiratory rate as needed.

After the induction of anesthesia, mean arterial pressure (MAP) and heart rate were monitored and recorded at 1-minute intervals. Any episode of hypotension, defined as a mean arterial pressure <70% of the baseline value and/or <65 mm Hg, was treated with an initial dose of 4 μg of norepinephrine, which could be repeated if hypotension persisted for more than 2 minutes. Severe post-induction hypotension, defined as a mean arterial pressure of 60 mm Hg, was managed with an initial dose of 6 μg of norepinephrine. If the severe hypotension persisted for 1 minute, the same dose was repeated. Bradycardia, defined as an HR <45 beats/minute, was managed by administering a 0.5 mg intravenous bolus of atropine. During the surgical procedure, fluid maintenance was managed through the administration of Ringer's lactate solution, infused at a rate of 2 mL/kg/h. Ten minutes after general anesthesia induction, the hemodynamic and anesthetic management was managed based on the attending anesthetists' clinical discretion.

When designing the study, we hypothesized that a higher dose of lidocaine might be more effective than a lower dose in stabilizing patients' hemodynamic status, potentially leading to a reduced incidence of postinduction hypotension. Because the protocol allows anesthesiologists to treat hypotension with norepinephrine actively, we considered that a difference in norepinephrine consumption was likely to be a more sensitive measure of differences between groups. Therefore, the primary outcome was set to be the dose requirement of norepinephrine. Secondary outcomes were as follows: the incidence of hypotension following induction, the number of hypotensive episodes, the frequency of severe hypotension post-induction, hypertension (defined as MAP >120% of the baseline value), bradycardia, and tachycardia (defined as HR >120% of the baseline value) were continuously monitored during the period from anesthesia induction to 10 minutes post-induction.

Statistical Analysis

The sample size was calculated via PASS Software version 15.0 (NCSS, Kaysville, UT, USA). In a pilot investigation involving 10 patients, the mean norepinephrine dosage administered to individuals who received a combination of 0.5 mg/kg lidocaine and propofol-remifentanil for anesthesia induction was 6 ± 5 μg. To detect a 3 μg difference in the norepinephrine requirement between groups with a significance level (α) of 0.05 and a power of 90%, at least 60 patients are required. To account for potential dropouts, we increased the sample size to 80 participants in each group.

The Kolmogorov–Smirnov test was employed to identify the normality of distribution for continuous variables. Data that followed a normal distribution were expressed as mean (SD) and analyzed using one-way analysis, and pairwise comparisons were conducted using the post-hoc Bonferroni test. In contrast, data that did not follow a normal distribution were represented as median (IQR) and assessed using the Kruskal–Wallis test, with the post Dunn's test being applied to analyse pairwise comparisons. Categorical data, including the incidence of hypotension, were analyzed using the Cochran–Armitage trend test. When the overall test suggested significant differences among groups, pairwise comparisons were performed using χ^2 tests. Categorical data, such as the incidence of side effects, were analyzed using χ^2 tests. For data measured repeatedly over time, a summary measures approach was employed for analysis. The area under the curve (AUC) for values plotted against time was calculated using the trapezoidal rule. P values less than 0.05 were considered to indicate statistical significance (two-tailed). All statistical analyses were performed using GraphPad Prism version 5.0 (GraphPad Software, Inc., San Diego, CA, USA).

Results

In total, 250 patients scheduled for laparoscopic gynecologic surgery under general anesthesia were recruited and assessed for eligibility. Among them, two patients declined to participate in the clinical trial, eight patients did not meet the inclusion criteria, and the remaining 240 eligible patients were enrolled in the study and randomly allocated to

three groups at a ratio of 1:1:1. However, 34 patients were excluded from the final analysis due to unexpected variations in airway conditions and incomplete data (Figure 1). The final analysis was conducted on 206 patients, whose characteristics are summarized in Table 1. The distribution of fluid responders (2, 3, and 2 in Groups 0.5, 1.0, and 1.5, respectively) was similar across the groups, with all responders requiring a single bolus of fluid (Table 1). The consumption of propofol for induction of loss-of-consciousness and during study period in Group 1.0 and Group 1.5 compared to Group 0.5 is presented in Table 1.

Intraoperative hemodynamic outcomes are summarized in Table 2. The incidence of hypotension was 51.4% (37/72), 13.0% (9/69), and 13.8% (9/65) in Groups 0.5, 1.0, and 1.5, respectively. A significant trend was observed in the incidence of hypotension across different lidocaine doses ($p = 0.0007$). The median (25th and 75th quartiles) consumption of norepinephrine was 4 (0–4) μg, 0 (0–0) μg, and 0 (0–0) μg across the groups, respectively; there was a significant difference among the groups ($p = 0.0006$). Patients in Group 0.5 required a significantly higher dose of norepinephrine compared to patients in Group 1.0 and Group 1.5, with adjusted p-values of 0.0030 and 0.0028, respectively. The temporal variations in MAP and HR in the first 10 minutes after induction for the three groups are depicted in Figure 2. The analysis indicated that there was no significant difference in MBP across the groups over time ($P > 0.005$). There were 4 (5.6%) patients in Group 0.5, 4 (5.8%) patients in Group 1.0 and none in Group 1.5 experienced severe hypotension.

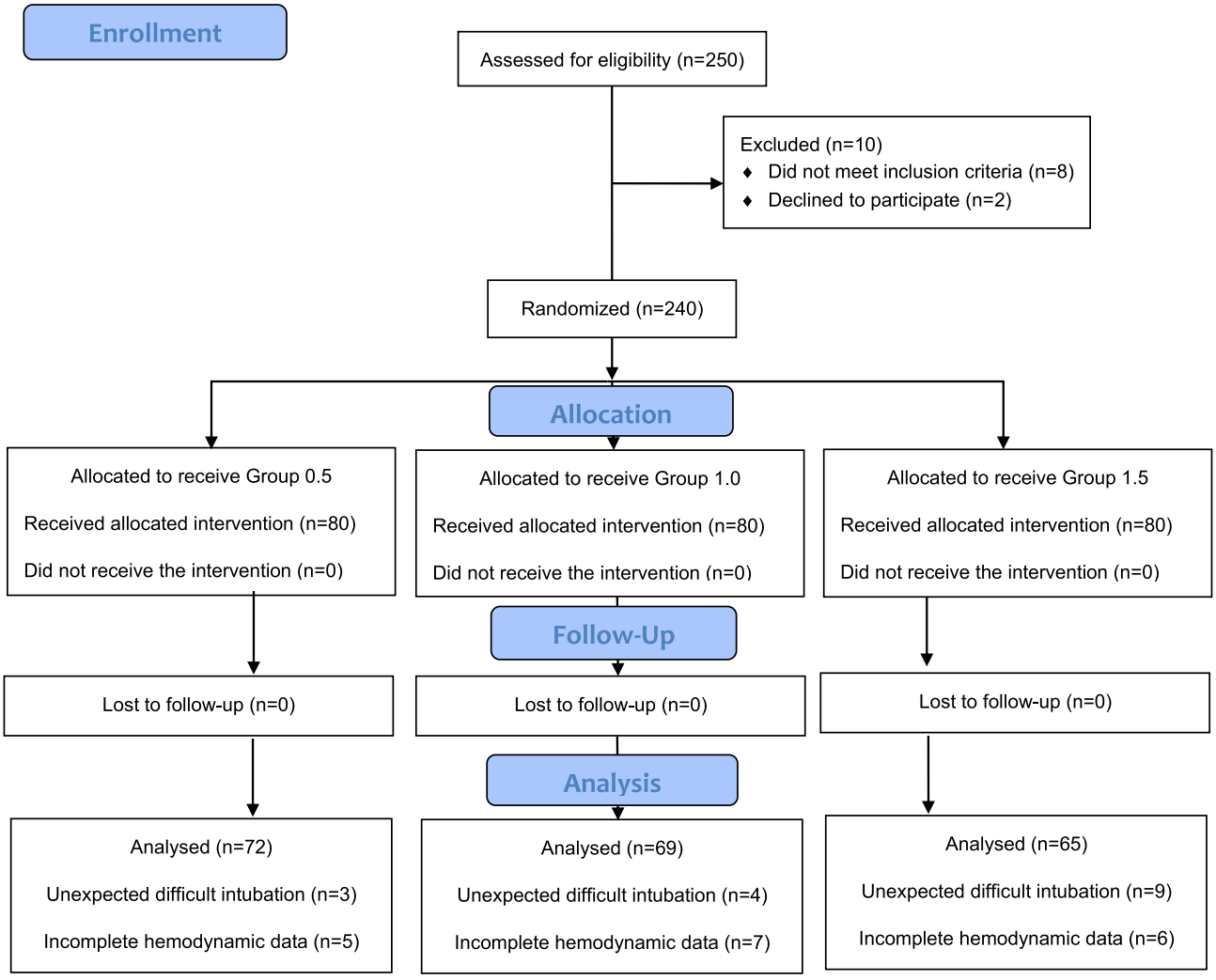

Figure 1 CONSORT diagram presenting patient recruitment and flow.

Table 1 Demographic Data, Baseline Hemodynamic Characteristics, and Perioperative Data

	Group 0.5 (n=72)	Group 1.0 (n=69)	Group 1.5 (n=65)
Age (years)	66.1 (6.2)	65.0 (5.7)	66.5 (5.4)
Height (cm)	156.5 (5.0)	157.3 (4.3)	157.2 (4.1)
Weight (kg)	59.4 (9.4)	56.9 (8.2)	60.2 (6.8)
Baseline heart rate (bpm)	72.2 (7.1)	72.1 (7.8)	72.1 (8.7)
Baseline mean artery pressure (mm Hg)	90.8 (6.1)	91.6 (6.8)	90.6 (4.1)
Preoperative fluid responder	2 (2.8)	3 (4.3)	2 (3.1)
Preoperative fluid volume in responders (mL) (n = 7)	664 (448, 880)	424 (488, 784)	588 (456, 720)
Propofol consumption for inducing loss-of-consciousness	66.0 (13.1)	68.7 (13.8)	67.3 (10.4)
Propofol consumption during study period (mg)	126.1 (13.5)	83.8 (14.1)	82.4 (10.7)

Note: Data presented as mean (standard deviation), median (25th and 75th quartiles), and frequency (%).

Table 2 Intraoperative Hemodynamic Outcomes

	Group 0.5 (n=72)	Group 1.0 (n=69)	Group 1.5 (n=65)	p-value
Total norepinephrine requirement, μg	4 (0, 4)	0 (0, 0)	0 (0, 0)	<0.0001
Incidence of hypotension, n (%)	37 (51.4)	9 (13.0)	9 (13.8)	<0.0001
No. hypotensive episodes per patient	1 (0, 1)	0 (0, 0)	0 (0, 0)	<0.0001
Incidence of severe hypotension, n (%)	4 (5.6)	4 (5.8)	0 (0)	0.12
Incidence of bradycardia	5 (6.9)	6 (8.7)	5 (7.7)	0.86
Incidence of hypertension	11 (15.3)	4 (5.8)	4 (6.2)	0.06
Incidence of tachycardia	15 (20.8)	9 (13.0)	5 (7.7)	0.03

Note: Data presented as median (25th and 75th quartiles), and frequency (%).

The incidence of hypertension was 15.7% (11/72), 5.8% (4/69), and 6.2% (4/65) across the groups, respectively. There was no significant difference in the incidence of hypertension among the groups (p = 0.06). There were 5, 6, and 6 patients in Groups 0.5, 1.0, and 1.5, respectively, who experienced bradycardia and required a bolus of atropine. The incidence of tachycardia significantly decreased with increasing lidocaine dose (p = 0.03).

Discussion

This study demonstrated that the addition of 1.0 mg/kg or 1.5 mg/kg lidocaine to a propofol-remifentanil regimen in elderly female patients significantly reduced the incidence of postinduction hypotension, thereby minimizing the requirement for norepinephrine to manage this complication compared to 0.5 mg/kg lidocaine. Moreover, the incorporation of 1.0 mg/kg or 1.5 mg/kg lidocaine led to a statistically significant decrease in the amount of propofol needed during endotracheal intubation relative to 0.5 mg/kg lidocaine. The reactive hypertension was decreased with increased dose of lidocaine. No significant differences were observed in the effects of lidocaine between the doses of 1.0 and 1.5 mg/kg. Therefore, we propose that 1.0 mg/kg lidocaine can be considered an optimal dose as an adjuvant to propofol-remifentanil during endotracheal intubation.

Considering that postinduction hypotension is predominantly caused by anesthetic agents[4] and its incidence increases with advancing age,[12,13] it is crucial to develop an anesthesia induction method that provides adequate sedation while preserving stable hemodynamics throughout endotracheal intubation and the surgical procedure, especially for elderly patients. Previous studies have shown that 1mg/kg lidocaine decreases the incidence of propofol-induced hypotension during anesthesia induction compared to 1 μg/kg fentanyl.[9] Additionally, lidocaine exhibits a sparing effect on anesthetic agents without inducing significant hemodynamic depression.[14,15] Therefore, we hypothesized that the administration of lidocaine as an adjuvant to propofol-remifentanil could potentially mitigate the risk of postinduction hypotension and stabilize the hemodynamic status during endotracheal intubation. However, the optimal dose of lidocaine for this purpose remains unclear,

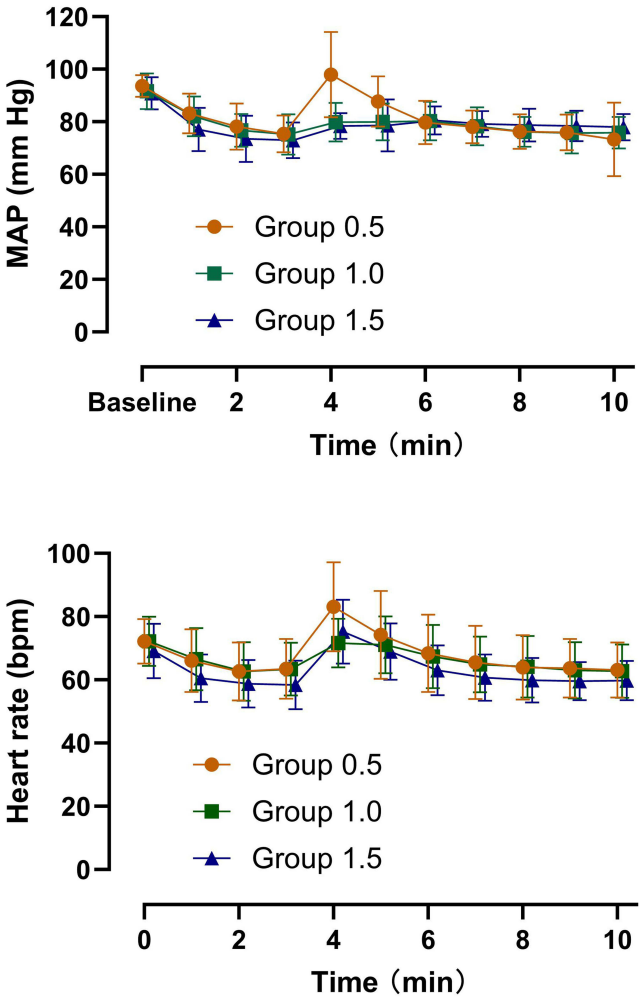

Figure 2 The temporal variations in MAP and HR in the first 10 minutes after induction for the three groups.

particularly in elderly female patients. Therefore, the primary strength of this study lies in providing valuable information to guide the clinical selection of an appropriate lidocaine dose in elderly female patients for this purpose.

In the present study, we observed that the incidence of hypotension during the study period was lower in patients who received 1.0 and 1.5 mg/kg lidocaine compared to those who received 0.5 mg/kg lidocaine. Additionally, the incidence of hypertension induced by tracheal intubation was significantly lower in patients administered 1.0 and 1.5 mg/kg lidocaine. However, no significant difference was found in the incidence of hypotension and hypertension between patients receiving 1.0 and 1.5 mg/kg lidocaine. Our findings suggest that a dose of 1.0 and 1.5 mg/kg lidocaine may provide a more stable hemodynamic profile for elderly female patients; however, increasing the lidocaine dose from 1.0mg/kg to 1.5mg/kg did not provide additional benefit.

In this study, we found that the incidence of hypotension was 13% in patients who received 1.0 mg/kg of lidocaine, which was significantly higher than that reported by Amin et al, where no patients experienced postinduction hypotension.[9] In our study, remifentanil was administered per-protocol at an effect-site concentration of 2.0 ng/mL following loss of consciousness, which might explain the higher incidence of hypotension compared to the infusion of lidocaine-propofol alone. However, in their study, the incidence of reactive hypertension following tracheal intubation was nearly twice as high as that observed in our study. This suggests that endotracheal intubation using pure lidocaine combined with propofol at the studied dose may result in inadequate anesthesia depth, thereby increasing the risk of clinical complications, particularly in elderly patients with fragile cardiovascular and cerebral vascular systems.

Therefore, clinical anesthesia providers should carefully weigh the advantages and disadvantages when selecting different induction protocols for endotracheal intubation.

It should be noted that the incorporation of 1.0 mg/kg or 1.5 mg/kg lidocaine resulted in a statistically significant reduction in the amount of propofol required during endotracheal intubation, according to the design protocol, when compared to 0.5 mg/kg lidocaine. One possible explanation for this distinction is that lidocaine exerts a direct inhibitory effect on the central nervous system,[15] thereby potentiating the efficacy of hypnotic agents through GABA receptor activation.[16,17] Our results demonstrated that this effect was dose-dependent. Similar to the results of other studies,[9,14,18] we found that the propofol-sparing effect of lidocaine was not apparent during the induction phase of anesthesia but during endotracheal intubation. This suggests that this sparing effect is also because lidocaine exhibits an antinociceptive action.[14,19]

We acknowledged some limitations in this study. One limitation is that the pilot study demonstrated a higher norepinephrine consumption compared to the main study, likely due to a greater frequency of hypotensive episodes during the pilot phase. However, the inter-group difference of 4 μg in norepinephrine usage, which exceeds our assumed dose difference of 3 μg, suggests that the actual sample size required to achieve 90% statistical power would be smaller than 60 patients per group. Another limitation is that the study exclusively included elderly female patients without heart disease (eg, ejection fraction <50%, conduction block, or arrhythmia), metabolic equivalent >4, and under-controlled hypertension. Consequently, the generalizability of these findings to broader populations is restricted. Finally, although patients who experienced difficult intubation, defined as requiring more than one attempt or exceeding a predefined time threshold as assessed by the attending anesthesia specialist, were excluded from the final analysis, different anesthesiologists may take different amounts of time to complete intubation, which may slightly affect the results.

In summary, under the conditions of this study, we propose that 1.0 mg/kg lidocaine may be considered as an optimal dose when used as an adjuvant to propofol-remifentanil during endotracheal intubation.

Abbreviations

ASA, American Standards Association; BMI, Body mass index; BIS, Bispectral index; SVV, stroke volume variability; MAP, mean arterial pressure.

Data Sharing Statement

The datasets generated during and/or analyzed during the current study are not publicly available due to the privacy policy but are available from the corresponding authors on reasonable requests.

Acknowledgments

The authors thank all the staff at the Department of Operating Room of Jiaxing University Affiliated Women and Children Hospital, Jiaxing, China, for their help in this study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

There is no funding to report.

Disclosure

The authors declare that they have no competing interests.

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