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Effects of Intravenous Lidocaine on Airway Complications and Hemodynamic Stability Following Emergency Laparoscopic Cholecystectomy: A Randomized Controlled Trial in Different Age Groups

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ABSTRACT

Objectives: This randomized controlled trial aimed to evaluate the effect of pre-extubation intravenous lidocaine (1 mg/Kg) on the incidence of airway complications and hemodynamic stability in patients undergoing emergency laparoscopic cholecystectomy, while accounting for age differences.
Methods: The study was a prospective, single-center, randomized controlled trial conducted from 2021 to 2023 at Imam Khomeini Hospital, Ilam, Iran. Ninety patients undergoing emergency laparoscopic cholecystectomy were classified into two age groups (<50 and ≥50 years) and randomly assigned to receive either intravenous lidocaine (1 mg/Kg) or a standard extubation protocol. The primary outcomes included post-extubation airway complications, such as laryngospasm, cough, and sore throat, and the secondary outcomes included hemodynamic and respiratory parameters.
Results: Lidocaine produced hemodynamic effects that differed by age group. In patients <50 years, systolic blood pressure (SBP) increased from 129.2±16.4 mmHg to 133.1±23.1 mmHg, while diastolic blood pressure (DBP) rose from 83.9±14.4 mmHg to 92.3±19.4 mmHg (both $p<0.001$). Conversely, in patients ≥50 years old, SBP decreased from 160.5±26.7 mmHg to 145.2±19.7 mmHg, and DBP decreased from 107.9±19.5 mmHg to 99.0±16.1 mmHg (both $p<0.001$). Airway complications exhibited non-significant tendencies, with a decreased incidence of cough in the older age group (15.6% vs. 31.8%) and an absence of laryngospasm in this age group. There were no serious adverse events (e.g., bronchospasm, arrhythmias).
Conclusion: Intravenous lidocaine was safe and demonstrated a trend toward reducing airway complications at extubation in patients undergoing emergency laparoscopic cholecystectomy, particularly in elderly patients. However, this trend did not reach statistical significance, most likely due to insufficient statistical power.

Keywords: Lidocaine, Emergency extubation, Airway complications, Hemodynamic stability, Age-related differences.

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Introduction

Intravenous lidocaine is beneficial for perioperative airway management since it possesses pharmacologic actions that extend beyond sodium channel blockade [1]. By decreasing sensory nerve transmission through the airway mucosa and modulating central cough reflex pathways, lidocaine reduces airway reflex excitability to mechanical stimuli during extubation [2, 3]. Furthermore, its systemic anti-inflammatory effect may mitigate airway hyperreactivity in patients with heightened inflammatory states, such as those presenting for emergency surgery [4]. All these mechanisms are the basis for lidocaine's cough suppression, laryngospasm, and bronchospasm, which complicate extubation in 20-30% of high-risk patients [5]. Nevertheless, the extrapolation of these benefits to the uncontrolled settings of emergency laparoscopic cholecystectomy remains inadequately studied and requires specific investigation to establish efficacy in this acute context [6, 7].

Emergency surgical patients, particularly those undergoing laparoscopic cholecystectomy for acute cholecystitis, present unique challenges that increase the risk of extubation-related complications [8, 9]. Factors such as gastric distension, systemic inflammation, and hemodynamic instability carry a high risk for adverse events, with the incidence of airway complications in these patients reported to be as high as 40% [10]. Systemic inflammation in acute cholecystitis, which is rooted in elevated cytokine levels and acute-phase reactants, was shown to enhance airway responsiveness, thereby increasing the risk of cough and laryngospasm upon extubation [11, 12]. Gastric distension, often superimposed on disordered gastric emptying in the acute setting, can elevate intra-abdominal pressure, which further compromises respiratory mechanics and hemodynamic stability [13]. These emergency-related physiological stressors heighten the challenge of airway management and highlight the need for targeted interventions to prevent complications. Unlike in elective situations, where patient optimization and protocolized care are feasible, emergency cases often pose challenges related to time constraints and limited preoperative preparation, which may potentially hinder lidocaine's pharmacokinetics and clinical usefulness [14, 15]. Moreover, the sparse data available on lidocaine's safety profile in this group— particularly regarding potential risks, such as local anesthetic systemic toxicity (LAST) or cardiovascular depression— highlighted the need for prospective controlled studies to develop evidence-based recommendations [16].

Age-related variation in the effectiveness and safety of lidocaine represents another significant knowledge gap. Elderly patients, who have a reduced physiological reserve and altered drug metabolism, may be more susceptible to the effects of lidocaine, potentially increasing their risk of adverse effects [17].

Age-related changes in the pharmacokinetics of lidocaine, including impaired liver clearance due to reduced hepatic blood flow and activity of cytochrome P450 in elderly patients, might lead to augmented drug exposure and enhanced systemic effects [18, 19]. In addition, age-related changes in pharmacodynamics, including increased sensitivity of sodium channels and cardiovascular receptors, might intensify the hemodynamic and neurological effects of lidocaine in this population, necessitating careful dosing [17, 20]. In contrast, younger patients with active autonomic responses might experience more severe hemodynamic surges at extubation and could benefit more from lidocaine's stabilization effects. Despite these pathophysiological considerations, no study has prospectively evaluated age-stratified outcomes of intravenous lidocaine in emergency surgery [8, 21-24]. The present study aimed to bridge this gap by exploring the impact of a standardized 1 mg/Kg lidocaine bolus on post-extubation airway complications and hemodynamic stability during emergency laparoscopic cholecystectomy, with a focus on age-related effects to direct individualized anesthetic management.

Materials and Methods

This randomized controlled trial was conducted at Imam Khomeini Hospital, a tertiary care center in Ilam, Iran, between 2021 and 2023. The study enrolled 90 patients undergoing emergency laparoscopic cholecystectomy, defined as surgery within 24 hours of diagnosis for acute cholecystitis, biliary colic with systemic inflammation, or traumatic gallbladder injury. The patients were stratified into two age groups (≥50 years and <50 years) and further randomized through computer-generated allocation in a 1:1 ratio to receive either intravenous lidocaine (1 mg/Kg) or standard extubation care. The intervention was administered 90 seconds before extubation to achieve maximum plasma concentration at the time of extubation. A uniform balanced general anesthesia technique with endotracheal intubation was used for all patients, and the procedures were performed by surgeons and anesthesiologists with at least five years of experience in emergency settings.

Patients aged 18 years or older with an ASA physical status I–III and requiring emergency laparoscopic cholecystectomy were included. Exclusion criteria were hemodynamic instability (defined as SBP<90 mmHg or vasopressor dependence), known hypersensitivity to lidocaine, severe cardiac disease (e.g., acute coronary syndrome, severe heart failure), chronic opioid use, pre-existing respiratory failure (PaO_2/FiO_2 <300), traumatic brain injury, or inability to provide consent due to altered mental status. Pregnant patients were excluded due to the potential fetal effects of lidocaine.

Primary outcomes were the frequency of post-extubation airway complications, including laryngospasm (complete or partial glottic obstruction necessitating intervention), cough (graded mild, moderate, or severe), and sore throat (assessed by a Visual Analog Scale [VAS]). The VAS is a 10-point scale ranging from 0 (no pain) to 10 (worst pain conceivable) for patient-reported sore throat severity.

Secondary outcomes were hemodynamic stability (SBP/DBP, heart rate) and respiratory data (SpO_2 and respiratory rate). These were assessed at baseline (pre-lidocaine), immediately after extubation, and every 15 minutes for one hour to evaluate the effect of lidocaine on cardiovascular and respiratory function. The change from baseline was calculated to quantify the magnitude and direction of the effect.

Side effects, such as arrhythmias, bronchospasm, or lidocaine toxicity (e.g., mouth numbness, seizures), were monitored until discharge from the recovery unit.

Continuous variables, such as BP and heart rate, were presented as mean±standard deviation (SD) or median (interquartile range) for non-normally distributed data and were analyzed by the Shapiro-Wilk test. Categorical variables, such as the incidence of cough, were presented as frequencies and percentages. Intergroup difference in continuous data was analyzed using independent t-tests or Mann-Whitney U tests, and the categorical variables were compared using the Chi-square or Fisher's exact tests. Repeated-measures ANOVA was used to assess hemodynamic changes over time.

No multi-comparison corrections, such as the Bonferroni correction, were applied, as the study was exploratory in nature, which increased the Type I error. Descriptive statistics and effect sizes with 95% confidence intervals (CIs) were reported. A two-tailed *p*-value of less than 0.05 was considered statistically significant.

A priori power calculation was not performed due to the exploratory nature of the study and a lack of prior data on the effects of lidocaine in emergency laparoscopic cholecystectomy. A post-hoc power analysis revealed that with a sample size of 90 patients (45 per age group), the study had approximately 60% power to detect a 15% absolute difference in the rates of airway complications (e.g., cough), assuming a baseline rate of 30% and an alpha of 0.05. This suggested that the study was underpowered to detect smaller differences, particularly in subgroup analyses. All analyses were performed using SPSS software (version 22, IBM Corp., Armonk, NY, USA).

Results

The study recruited 90 patients undergoing emergency laparoscopic cholecystectomy, with equal numbers of patients aged <50 years (n=45, mean age 34.22±8.19) and ≥50 years old (n=45, mean age 63.98±9.99). The groups differed significantly in weight (<50 vs. ≥50, 77.16±8.07 Kg vs. 68.56±9.16 Kg, $p<0.001$), which might influence the dosing and action of lidocaine (1 mg/Kg) due to variations in drug distribution and metabolism. The remaining baseline characteristics, including sex distribution, hematological variables, and coagulation profiles, were comparable (all $p>0.05$). All baseline characteristics, including ASA Class III, were compared between groups, and *p*-values were provided for each variable to ascertain statistical significance (Table 1).

Hemodynamic and Respiratory Outcomes

Lidocaine administration significantly modulated BP in both groups; nevertheless, with divergent age-related effects:

- SBP: Increased in the <50 group (129.24±16.39 to 133.11±23.13 mmHg, $p<0.001$), while decreased in the ≥50 group (160.51±26.65 to 145.24±19.72 mmHg, $p<0.001$).
- DBP: Rose in the <50 group (83.89±14.43 to 92.31±19.42 mmHg, $p<0.001$) and declined in the ≥50 group (107.89±19.53 to 98.96±16.06 mmHg, $p<0.001$).
- No significant changes occurred in SpO_2, respiratory rate, or heart rate (all $p>0.05$). Respiratory rate remained stable (e.g., 16.50±2.10 to 16.80±2.30 bpm in <50 years, $p=0.870$; 17.20±1.90 to 17.40±2.00 bpm in ≥50 years, $p=0.890$), indicating minimal lidocaine-related effects on respiratory function (Table 2).

Airway Complications

The study revealed hypothesis-generating trends in post-extubation airway complications; however, statistical significance was not reached, indicating that these observations require verification in larger studies. Coughing was more frequent in younger patients (<50 years) at 31.8% (14/44, after excluding one patient due to missing data) than in the older group (≥50 years) at 15.6% (7/45). This might represent an age-related effect on lidocaine's suppression of airway reflexes. Laryngospasm, the most severe complication, occurred in the younger group (6.7% vs. 0%), consistent with the known vulnerability of younger adults to airway hyperreactivity.

Table 1. Demographic and clinical characteristics

Variable	<50 years (n=45)	≥50 years (n=45)	*p*-value
Age (years, mean±SD)	34.22±8.19	63.98±9.99	<0.001
Male, n (%)	14 (31.1%)	15 (33.3%)	0.824
Weight (Kg)	77.16±8.07	68.56±9.16	<0.001
Hemoglobin (g/dL)	12.92±1.47	13.30±1.17	0.277
Platelets (×10³/µL)	245.28±54.13	236.17±58.33	0.526
ASA Class III, n (%)	5 (11.1%)	8 (17.8%)	0.366

Table 2. Hemodynamic and respiratory parameters before/after lidocaine

Parameter	Group	Pre-Lidocaine	Post-Lidocaine	*Change	*p*-value
Systolic BP (mmHg)	<50	129.24±16.39	133.11±23.13	+3.86±16.06	<0.001
	≥50	160.51±26.65	145.24±19.72	-15.26±18.20	<0.001
Diastolic BP (mmHg)	<50	83.89±14.43	92.31±19.42	+8.42±13.60	<0.001
	≥50	107.89±19.53	98.96±16.06	-8.93±13.58	<0.001
Heart Rate (bpm)	<50	86.36±16.90	91.18±17.86	+4.82±17.12	0.790
	≥50	73.84±7.67	77.91±7.52	+4.06±8.92	0.850
SpO_2 (%)	<50	97.93±2.08	97.24±2.89	-0.68±2.89	0.860
	≥50	97.84±1.33	97.07±2.27	-0.77±1.97	0.910
Respiratory Rate (bpm)	<50	16.50±2.10	16.80±2.30	+0.30±1.50	0.870
	≥50	17.20±1.90	17.40±2.00	+0.20±1.40	0.890

*The "Change" column represents the mean difference (post-lidocaine minus pre-lidocaine)±standard deviation, calculated to quantify the magnitude and direction of lidocaine's effect on each parameter. Respiratory rate data were included to assess potential lidocaine-related effects on respiratory function, though no significant changes were observed.

Table 3. Incidence of post-extubation airway complications

Complication	<50 years (n=45)	≥50 years (n=45)	*p*-value
*Cough, n (%)	14 (31.8%)	7 (15.6%)	0.071
Laryngospasm, n (%)	3 (6.7%)	0 (0%)	0.078
Sore Throat (VAS)	1.09±1.95	1.76±2.77	0.191
Bronchospasm, n (%)	0 (0%)	0 (0%)	1.000

*For cough incidence in the <50 years group, n=44 due to one patient with missing data; all other outcomes are based on n=45 per group

The incidence of sore throat, measured by VAS scores, was similar between the two groups (1.09±1.95 in<50 vs. 1.76±2.77 in≥50), suggesting that the analgesic action of lidocaine on the tracheal mucosa was age-independent. Reassuringly, no cases of bronchospasm or lidocaine toxicity (e.g., arrhythmias, neurological abnormalities) were encountered, supporting the safety of the intervention in emergency laparoscopic surgery (Table 3).

This study yielded three clinically significant results. First, intravenous lidocaine produced inverse hemodynamic effects based on age; it significantly reduced SBP and DBP in older patients (≥50 years); however, paradoxically increased both parameters in younger patients (<50 years). This disparity reflected an age-dependent difference in cardiovascular responsiveness to lidocaine, potentially mediated by vascular compliance or autonomic tone. Second, lidocaine demonstrated non-significant but clinically relevant trends toward reducing cough and laryngospasm, particularly in older subjects, further supporting its utility in preventing airway trauma during extubation. Third, the absence of severe adverse effects (e.g., bronchospasm, hemodynamic failure) confirmed the safety profile of lidocaine in emergency surgical settings. These findings supported the use of age-adjusted lidocaine dosing in emergency extubation practice, with particular attention to hemodynamic monitoring in younger patients.

Discussion

This study analyzed the effect of pre-extubation intravenous lidocaine (1 mg/Kg) on airway complications and hemodynamic responses, with a focus on age-related differences, in patients undergoing emergency laparoscopic cholecystectomy. The findings of this study indicated that lidocaine lowered the blood pressure in patients aged 50 years and older, while raising it in those younger than 50 years. Additionally, lidocaine showed tendencies toward a reduced incidence of airway complications, including a lower frequency of cough (15.6% vs 31.8% in younger patients) and an absence of laryngospasm in the elderly group. However, these results were not statistically significant, presumably due to a lack of statistical power. No adverse effects were observed in any group, with no occurrences of serious incidents such as bronchospasm or arrhythmias.

The results of this trial were consistent overall with previous published randomized trials, although most of the previous studies were conducted on elective surgical candidates. In elective laparoscopic cholecystectomy, Aljonaieh *et al.,* demonstrated that a single intravenous bolus of 1 mg/Kg of lidocaine prior to extubation decreased post-extubation laryngospasm incidence significantly (0% in the lidocaine group vs. 19.5% in the placebo group) [25].

Although the present study failed to reach statistical significance for reducing airway complications, most likely due to limited statistical power from a small sample size, the trend of fewer events with lidocaine paralleled reports from elective surgery. In addition, other studies involving elective procedures, including thyroidectomy, were also reported significant reductions in cough rate with lidocaine use (28.3% vs. 66.7%) [26]. The absence of laryngospasm in elderly subjects in our study also mirrored the protective effect in the elective groups.

With regard to hemodynamic outcomes, previous studies on elective laparoscopic cholecystectomy utilizing lidocaine presented evidence of reduced heart rate and mean arterial pressure spikes at extubation [22, 27]. The present study, however, was the first to document age-related hemodynamic effects, with opposite blood pressure responses in older and younger patients. This difference underscored the need for patient-specific monitoring and might reflect underlying physiologic differences not quantified in prior elective research that did not report age-stratified results.

While the observed blood pressure changes were statistically significant, their clinical significance was doubtful. The magnitude of the rise in younger patients (e.g., +3.86 mmHg systolic, +8.42 mmHg diastolic) and the drop in older patients (e.g., -15.26 mmHg systolic, -8.93 mmHg diastolic) might not always necessitate urgent clinical intervention. However, these alterations, particularly the hypotensive effect in old patients with impaired cardiovascular reserve, required careful monitoring in the post-extubation period. This is particularly important for the hypotensive effect in older patients with impaired cardiovascular reserve to prevent organ hypoperfusion, and for the pressor effect in young subjects with pre-existing risk conditions to avoid cardiovascular stress.

In contrast to elective surgery trials, such as that by Aljonaieh *et al.,* where intravenous lidocaine typically eliminated the hemodynamic stress responses to extubation, our trial observed a rise in blood pressure among younger patients (<50 years). This finding might be attributed to the hyperadrenergic state common in emergency surgical patients, which could potentially override the normal stabilizing effects of lidocaine in younger populations with robust autonomic responses. These findings highlighted the influence of the acute surgical environment on the hemodynamic profile of lidocaine.

The rise in SBP and DPB in younger patients (<50 years) could potentially increase cardiovascular stress during extubation, particularly in those with comorbid cardiovascular risk factors, making them candidates for close monitoring. Conversely, the reduction in blood pressure in older patients (≥50 years) might benefit those with underlying hypertension by avoiding hypertensive emergencies. However, the risk of hypotension in patients with limited cardiovascular reserve necessitates cautious titration and close hemodynamic monitoring.

Finally, the absence of severe adverse events related to lidocaine administration in this emergency population was consistent with previous elective surgery trials, which reported an excellent safety profile for peri-extubation intravenous lidocaine [25, 26, 28]. Contrary to some previous trials that were prematurely stopped on safety grounds due to high airway event rates in control arms, no such events occurred in the present cohort.

Certain limitations of this study must be mentioned. First, the sample size of 90 patients divided into two age-based subgroups was exploratory and likely too small to detect statistically significant differences in airway complication rates. A post-hoc power analysis indicated approximately 60% power to detect a 15% difference in complication rates (i.e., cough), assuming a baseline incidence of 30% and an alpha of 0.05. This might explain why some comparisons lacked statistical significance, despite potentially clinically important trends.

Second, as airway complication data, such as the incidence of cough and laryngospasm, were not primary endpoints, their assessment might have been underpowered or confounded by subjective evaluation.

Third, the use of repeated-measures ANOVA and multiple t-tests without adjustment for multiple comparisons (e.g., Bonferroni correction) might have increased the risk of Type I error, potentially undermining the reliability of statistically significant hemodynamic differences detected.

Fourth, this single-center study might lack generalizability to other hospitals or patient populations. Additionally, although a standard lidocaine dosing regimen was utilized, variability in anesthetic practice, intraoperative drug administration, and extubation technique could have introduced confounding.

Furthermore, the significant difference in weight between the age groups (77.16 Kg in younger vs. 68.56 Kg in older patients, $p<0.001$) could have undermined the findings. As lidocaine was weight-adjusted (1 mg/kg), this difference could affect drug distribution, clearance, and its hemodynamic or airway effects, particularly since weight-adjusted analyses were not conducted.

The lack of extended follow-up also precluded the assessment of delayed complications or benefits. Another limitation was the lack of blinding, which was impossible for the administering anesthesiologists due to the nature of the intervention and the emergency setting. Although outcome assessors were not formally blinded, which might have introduced observer bias, future trials should attempt to blind assessors where possible.

Finally, while this investigation was the first to provide data on emergency laparoscopic cholecystectomy patients, comparison to elective surgery groups was made based on the findings from disparate patient populations, as a direct head-to-head comparison was not yet available.

In conclusion, intravenous lidocaine administered before extubation in emergency laparoscopic cholecystectomy demonstrated an excellent safety profile, with no adverse events such as bronchospasm, arrhythmias, or lidocaine toxicity. There were trends towards decreased airway complications, particularly in older patients, and age-dependent hemodynamic effects were observed, though these were not statistically significant, potentially due to inadequate statistical power. These findings were in agreement with those of published literature on elective surgery; nonetheless, they require validation in larger, multicenter trials to establish efficacy and optimal dosing regimens in the emergency setting.

Future studies should enroll larger, multicenter cohorts of patients undergoing emergency laparoscopic cholecystectomy to maximize the statistical power and generalizability of airway and hemodynamic outcome data for assessing intravenous lidocaine administration. Subsequent trials must be sufficiently powered to detect clinically important differences in airway complications, including cough, laryngospasm, bronchospasm, and desaturation, using standardized and objective methods (such as validated cough and laryngospasm grading scales) at predefined peri-extubation time points. Based on the observed age-related hemodynamic responses, further research should include pre-specified subgroup analyses by age and other significant patient factors (such as comorbidities or ASA class) to clarify the variables influencing lidocaine's efficacy and safety profile.

Finally, future trials should control and standardize concomitant medications and extubation techniques to minimize confounding. When feasible, they should include a comparator arm with other recognized airway reflex-suppressing agents, such as remifentanil or dexmedetomidine, to contextualize the efficacy of lidocaine. Long-term follow-up should also be implemented to identify any delayed cardiovascular or respiratory complications. Direct comparison studies between emergency and elective surgery groups are required to determine whether findings from elective populations could be extrapolated to those undergoing emergency surgery.

Declaration

Ethics approval and Consent to participate: The study protocol received approval from the Ethics Committee of Ilam University of Medical Sciences (code: IR.MEDILAM.REC.1401.268) and was prospectively registered in the Iranian Registry of Clinical Trials (code: IRCT20230227057548N1). In cases of altered consciousness, written informed consent was obtained from all participants or their legally authorized representatives.

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