

การศึกษานำร่องแบบสุ่มที่มีกลุ่มควบคุมเพื่อดูอัตราการใส่ท่อช่วยหายใจสำเร็จตั้งแต่ครั้งแรกเปรียบเทียบระหว่างกลุ่มที่ได้รับหรือไม่ได้รับยาชา Lidocaine เฉพาะที่ในทางเดินหายใจส่วนต้น

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บทคัดย่อ

แพทย์เวชปฏิบัติทั่วไปในประเทศไทยส่วนใหญ่ใส่ท่อช่วยหายใจที่แผนกฉุกเฉินด้วยเทคนิคการให้ยาสงบประสาท การศึกษานำร่องนี้มีวัตถุประสงค์เพื่อประเมินความเป็นไปได้ในการศึกษาอัตราใส่ท่อช่วยหายใจสำเร็จตั้งแต่ครั้งแรกเปรียบเทียบระหว่างกลุ่มที่ใช้ยาชา Lidocaine เฉพาะที่กับทางเดินหายใจส่วนต้นเทียบกับกลุ่มที่ไม่ใช้ การศึกษาสองกลุ่มแบบสุ่มที่มีกลุ่มควบคุม ที่แผนกฉุกเฉิน โรงพยาบาลสมเด็จพระเจ้าตากสินมหาราช ระหว่างเดือนตุลาคม 2565 ถึง เมษายน 2566 ผู้ป่วยอายุ 18 ปีขึ้นไป ที่มีข้อบ่งชี้ในการใส่ท่อช่วยหายใจทางปากถูกคัดเข้าและสุ่มเข้าแต่ละกลุ่มด้วยจดหมายปิดผนึก กลุ่มควบคุมได้รับการใส่ท่อช่วยหายใจด้วยเทคนิคการให้หรือไม่ให้ยาสงบประสาท กลุ่มทดลองได้รับยาชา Lidocaine เฉพาะที่ที่ทางเดินหายใจส่วนต้นร่วมด้วย การศึกษาความเป็นไปได้วัดจากอัตราการคัดผู้ป่วยเข้าสู่การศึกษา ได้รับการรักษาตามที่ถูกจัดสรร และความสมบูรณ์ของข้อมูล ผลลัพธ์ทางคลินิกหลักคือ อัตราการใส่ท่อช่วยหายใจสำเร็จตั้งแต่ครั้งแรก และผลลัพธ์รองคือ ภาวะแทรกซ้อนระหว่างการใส่ท่อช่วยหายใจ ผู้ป่วย 259 รายที่ได้รับการใส่ท่อช่วยหายใจแต่คัดออก 179 ราย ตรงเกณฑ์เข้าสู่การศึกษา 80 ราย สุ่มเข้ากลุ่มทดลองและกลุ่มควบคุม กลุ่มละ 40 ราย คัดผู้ป่วยได้ตามเป้าหมายใน 6 เดือน ได้รับการรักษาตามที่ถูกจัดสรรร้อยละ 97.5 ความสมบูรณ์ของข้อมูลอยู่ที่ร้อยละ 91.3 จากตั้งไว้ที่ร้อยละ 95.0 อัตราการใส่ท่อช่วยหายใจสำเร็จตั้งแต่ครั้งแรกสูงกว่าในกลุ่มยาชาพบร้อยละ 72.5 เทียบกับ ร้อยละ 60 (ค่าความแตกต่างร้อยละ 12.5, ความเชื่อมั่นร้อยละ 95 = 8.0-33.0) ระดับออกซิเจนระหว่างใส่ท่อช่วยหายใจต่ำกว่าร้อยละ 90 พบบ่อยกว่าในกลุ่มได้รับยาชาพบร้อยละ 22.5 เทียบกับ ร้อยละ 10 (ค่าความแตกต่างร้อยละ 12.5, ความเชื่อมั่นร้อยละ 95 = 3.4-28.4) มีผู้ป่วยระดับออกซิเจนก่อนใส่ท่อช่วยหายใจต่ำกว่าร้อยละ 90 ถูกคัดสู่การศึกษา ขณะแพทย์ใส่ท่อช่วยหายใจพบว่าการให้ยาชา Lidocaine หยอดในท่อนอนในผู้ป่วยที่กระสับกระส่ายและไม่ให้ความร่วมมือนั้นยาก การศึกษาในอนาคตที่มีจำนวนตัวอย่างมากขึ้นที่จะบอกความแตกต่างทางสถิติของผลลัพธ์ทางคลินิกที่สนใจมีความเป็นไปได้ ด้วยการปรับเกณฑ์การคัดออก กระบวนการเก็บข้อมูล และเทคนิคการให้ยาชา

คำสำคัญ: ยาชาลิโดเคน; แผนกฉุกเฉิน; อัตราความสำเร็จในการใส่ท่อช่วยหายใจตั้งแต่ครั้งแรก; การใส่ท่อช่วยหายใจ

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Comparing the first-pass success rate of oral intubation in patients who received or did not receive add-on topical lidocaine in the upper airway: A pilot randomized controlled trial

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Abstract

The intubation with sedatives method is commonly employed by general practitioners in the emergency department (ED) in Thailand. This pilot study aimed to assess the feasibility of conducting a larger definitive trial on the first-pass success rate of oral intubation in patients who received or did not receive add-on topical lidocaine in the upper airway. This parallel two-arm pilot randomized controlled trial took place in the emergency department of Somdejphrajoataksinmaharaj Hospital, spanning from October 2022 to April 2023. Participants included patients aged 18 years and older with an indication for oral intubation with a laryngoscope, screened using eligibility criteria for enrollment. Patients were randomized and assigned to either of the two study arms through sealed envelopes. The control arm received oral intubation with or without sedation, while the intervention arm received topical lidocaine applied to the upper airway in addition to the therapy in the control arm. Feasibility was assessed based on the recruitment rate, adherence to group assignment, and data completeness. The primary outcome was the first-pass success rate, while secondary outcomes were peri-intubation complications. During this period, 259 patients were intubated in the ED, but 179 patients were excluded. A total of 80 patients were randomly assigned to each group, with 40 patients in the intervention arm and 40 patients in the control arm. The study achieved its recruitment rate goal within 6 months, and adherence to the protocol was 97.5%. However, data completeness fell below expectations at 91.3% compared to the target of 95.0%. The first-pass success rate was 72.5% in the intervention group and 60.0% in the control group (Difference 12.5%; 95% CI, 8.0-33.0). Peri-intubation desaturation below 90% was more prevalent in the intervention group, with 22.5% versus 10.0% in the control group (Difference 12.5%; 95% CI, 3.4-28.4). Some patients with oxygen saturation below 90% at the end of preoxygenation were enrolled. Physicians performing intubation found it challenging to administer lidocaine in a supine position to agitated and uncooperative patients. Conducting a larger sample size in the future study, which could reveal statistical differences in clinical outcomes, is feasible by modifying exclusion criteria, improving the data collection process, and refining the method of topical lidocaine administration.

Keywords: topical lidocaine; emergency department; first-pass success rate; endotracheal intubation

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Introduction

Airway management is an important resuscitation skill for emergency physicians. Even though there are a lot of intubation methods, rapid sequence intubation (RSI) is the most frequently used method by emergency physicians for critically ill patients in the emergency department (ED).¹ The utilization of the RSI technique in Thailand's emergency departments ranged from 50% to 60% when compared to other methods in secondary and tertiary hospitals.^{2,3} The intubation with sedative drug technique is often used by general practitioners and other specialists in the ED.^{4,5} The benefit of this method is that patients still have spontaneous breathing and intact airway reflex to avoid a situation of can't intubation and can't ventilate. The first-pass intubation rates were higher in the group using the RSI technique compared the group of sedative drugs without neuromuscular blocking agents.⁵⁻⁷ The frequency of peri-intubation complications, particularly hypoxia, increase with the number of intubation attempts.⁸ Applying a laryngoscope in conscious patients activates the sympathetic and parasympathetic nervous systems. As a result of these responses, the saliva production increases, triggering a gag reflex and a cough reflex, making intubation more difficult.⁹ Awake intubation is a technique recommended for the management of difficult airways, and it is usually performed in an operating room. The basic concept of this technique is the use of topical anesthesia to

suppress gag reflex and cough reflex to facilitate intubation.¹⁰ To the current knowledge, there are no previous studies on the use of topical anesthesia to facilitate intubation in the ED in Thailand. This study hypothesized that the use of topical lidocaine would increase the success rate of oral intubation with sedation alone. Since the nature of patients in the ED differs from those who are intubated in the operating room, the decision to intubate in the ED is often made quickly with a short period of time for preparation. Patients may experience confusion, agitation, and impaired consciousness due to hypoxia or central nervous system diseases. Topical application of lidocaine may increase the time required to prepare patients before endotracheal tube insertion more than usual. Therefore, a pilot study was conducted to evaluate the feasibility before proceeding to the future definitive trial. Feasibility outcomes were recruitment rate, acceptability of the trial protocol, and data completeness with problems found while conducting the trial protocol. First-pass intubation success rate will be used to synthesize data to determine the sample size of the main trial.

Objectives

This study was aimed at evaluating the feasibility of conducting a larger definitive trial of the first-pass success rate of topical lidocaine-aided oral intubation when compared to oral intubation with or without sedation.

Material and Methods

Trial design

This study was conducted in the ED of Somdejphrajoataksinmaharaj Hospital, Thailand. The ED has an annual census of 48,000 visits. There were 4 certified emergency physicians and physicians in their first to third year of training under the Thai Internship Program and working in shifts at the ED. Ethical approval for this pilot study (No.16/2565) was obtained from the Somdejphrajoataksinmaharaj Hospital Ethics Committee.

Participants

Inclusion criteria were the patients who were at least 18 years old with an indication for oral intubation with a laryngoscope. Exclusion criteria were that 1) the physicians intended to intubate with the RSI technique or use sedative drug with an induction effect, such as propofol or etomidate, or they intended to use ketamine and midazolam at a dose greater than 0.2 mg/kg; 2) the patients had blood or vomit in oral cavity prior to the initiation of intubation; 3) the patients were known or suspected to be pregnant; 4) the patients were allergic to lidocaine; 5) the patients refused to participate in the study; 6) the intubators were not physicians, such as medical students; 7) the physicians had determined that the patients were in an unstable condition and delaying intubation until the intervention protocol was complete would put the patients at risk for a cardiac arrest; 8) the patients suffered from cardiac arrests. On-duty physicians at the ED

screened the patients requiring endotracheal intubation for eligibility criteria and enrollment. If the treating physicians determined that the patients were capable of judgment or had surrogate decision makers, verbal consent for enrollment was obtained; otherwise, patients were enrolled without consent.

Intervention

Oral intubation with or without sedation was defined as a method of intubation via the oral route. The patients might or might not be given sedative drugs without a neuromuscular blockage agent. Topical lidocaine-aided oral intubation was defined as an intubation procedure in which the patients are given topical lidocaine in the upper airway in addition to oral intubation with or without sedation. The intubation process began with monitoring blood pressure, ECG, pulse oximeter, and administration of oxygen at least 3 minutes before attempting oral intubation. The type of laryngoscope, type of introducer stylet, positioning of the patient, methods of preoxygenation, and type of sedation depended on the treating physicians. For the patients in the control arm, the time to start applying the laryngoscope depended on the treating physicians but preoxygenation was needed for at least 3 minutes. A stopwatch was used to record time in the intervention arm. At zero minute, a treating physician or a nurse sprayed 10% lidocaine over the oropharynx, tonsils and the base of the tongue. A patient weighing less than or equal to 60 kg received 10 puffs of 10% lidocaine,

while a patient weighing more than 60 kg received 15 puffs. A tongue depressor was used to facilitate the administration of lidocaine in the patients who were unconscious or did not follow the command to open their mouths. The patients could be in an upright or supine position. One minute after applying the lidocaine spray, the patients would be set to lie down in a position if not before. The 1% lidocaine without adrenaline was drawn up into a syringe and gently trickled into the back of the tongue at a dose of 0.2 mL/kg or 20 mL, whichever was less. For a patient with limited mouth opening, the catheter over a needle number 16 would be connected to a syringe to facilitate the delivery of 1% lidocaine into their mouth. If the patients weighed more than or equal to 40 kg, the total maximum dose of lidocaine administered to them would not exceed 4.5 mg/kg. The physicians could apply a laryngoscope only after at least 5 minutes of having sprayed 10% lidocaine. If a patient was found to have a life-threatening condition during intubation and the treating physician believed that changing the technique would increase the patient's chance of success and benefit more than the intubation technique to which the patient had been assigned, the treating physician would change their intubation method and might also ask a more experienced physician to intubate the patient. A nurse in the airway management team was assigned to record the time and observe the lowest oxygen saturations. After the procedure, the physician performing the intubation

recorded the patient's demographics, methods of preoxygenation, doses and types of sedative used, type of ETT introducer stylet, type of laryngoscope used, the number of attempts, peri-intubation complication, and problems found during conduct the protocol.

Outcome

Successful pilot study was defined as the recruitment of 80 trial participants over a 6-month period, 95% completeness of data, and 95% adherence to the group assignment. The primary end point was the first-pass success intubation rate. Successful intubation was defined as the correct placement of the endotracheal tube in the trachea, as confirmed by the pulse oximetry, chest auscultation, observation of chest movement, absence of epigastric sounds, misting of the endotracheal tube, and with or without end-tidal CO₂ capnometer measurement. The first-pass success intubation was defined as placing the laryngoscope under the alveolar ridge without removing a laryngoscope blade before successfully inserting the endotracheal tube through the vocal cords. The secondary end point was peri-intubation complications, such as hypoxia and cardiac arrests during attempts. Desaturation-1 was defined as a drop in oxygen saturation below 90% during the intubation attempts in the patients with oxygen saturation above 90% at the end of preoxygenation. Desaturation-2 was defined as a drop in oxygen saturation of more than 10% from the oxygen saturation at the end of preoxygenation.

Sample size

This study hypothesized that the use of topical lidocaine to facilitate oral intubation would increase first-pass success rates by at least 10%. To detect a clinically significant difference of 10% in successful intubation in this randomized control trial with a power of 80% and a two-sided alpha level of 0.05, 774 patients were required. The recommended sample size for pilot study were 72 patients.¹¹ This study increased the sample size by 10% in case there would be patients who might be switched to another intubation method after group assignment or whose data were incomplete. Finally, the total number in each group was 40 patients.

Randomization and blinding

Computer-generated sets of random assignments in a 1:1 ratio using a permuted block of 8 by a research support unit (which did not perform data collection) were created before the start of the study, which were then sealed in consecutively numbered opaque envelopes. The envelopes could not be opened until the patients were finally enrolled in the study. Because of the difference in methods, it was not possible to blind the patients and physicians.

Statistical analysis

Categorical data were described with frequency and percentage, tested by Fisher's exact probability test. Normally distributed continuous data were described with mean and standard deviation, tested by independent

t-test. In all analyses, statistical uncertainties are expressed in 95% two-sided confidence intervals. A p value of <0.05 will indicate statistical significance. This study measured feasible parameter with frequency and percentage of complete data and missing variable. The variables were preliminarily analyzed using bivariable analyses and performed with STATA 16.1.

Results

The patients were enrolled between mid-October 2022 and mid-April 2023. During this time, 259 patients older than 18 years were intubated in the ED. After a review of eligibility criteria, 179 patients were excluded. A total of 80 patients were randomly assigned to either the intervention or the control arm (see the study flow diagram). All patients in the control arm were intubated according to the protocol. In the intervention arm, two patients did not receive the complete protocol. One of them received only lidocaine spray before intubation because the patient's condition deteriorated and there was a risk of a cardiac arrest. Meanwhile, after receiving a 1% lidocaine drip into the posterior tongue, the other patient became extremely agitated and refused to receive more. Baseline characteristics, equipment, methods of preoxygenation, type of sedative drugs and dosage, and operators are shown in Table 1. The majority of parameters were the same in both groups; only the methods of preoxygenation and the use of sedatives were different. The two most commonly used

methods of preoxygenation in both groups were oxygen mask with reservoir bag and positive ventilation with an AMBU bag with mask. In the intervention group, 12.5% of the patients received a nebulizer for bronchodilation, but none in the control group received it. The patients in the control group received more sedatives than those in the intervention group (87.5% versus 32.5%). Feasible outcomes are shown in Table 2. This study succeeded in recruiting 80 patients within 6 months. The aim of adherence to the intubation protocol was met; however, data completeness was below expectations. The primary and secondary outcome are shown in Table 3. The outcome of the first-pass success rate was favorable in the intervention group. The different proportion in the primary outcome was 12.5% (95% CI, 8.0%-33.0%). The secondary outcome was found only in

the desaturation-1 condition, and the different proportion was 12.5% (95% CI, 3.4%-28.4%). More desaturation events were detected in the intervention group. This study collected the problems during the implementation of the intervention from the comments in the case record forms. First, half of the intubators who performed oral intubation with topical lidocaine to the patients who were in a supine position reported that they found it difficult to administer 1% lidocaine to the patients who were agitated and not fully cooperative. Some patients spit out the lidocaine after it had been dripped onto the posterior tongue. Second, fifty percent of the intubators felt that the total time from the start of the protocol to the application of a laryngoscope was too long for the patients in emergency conditions.

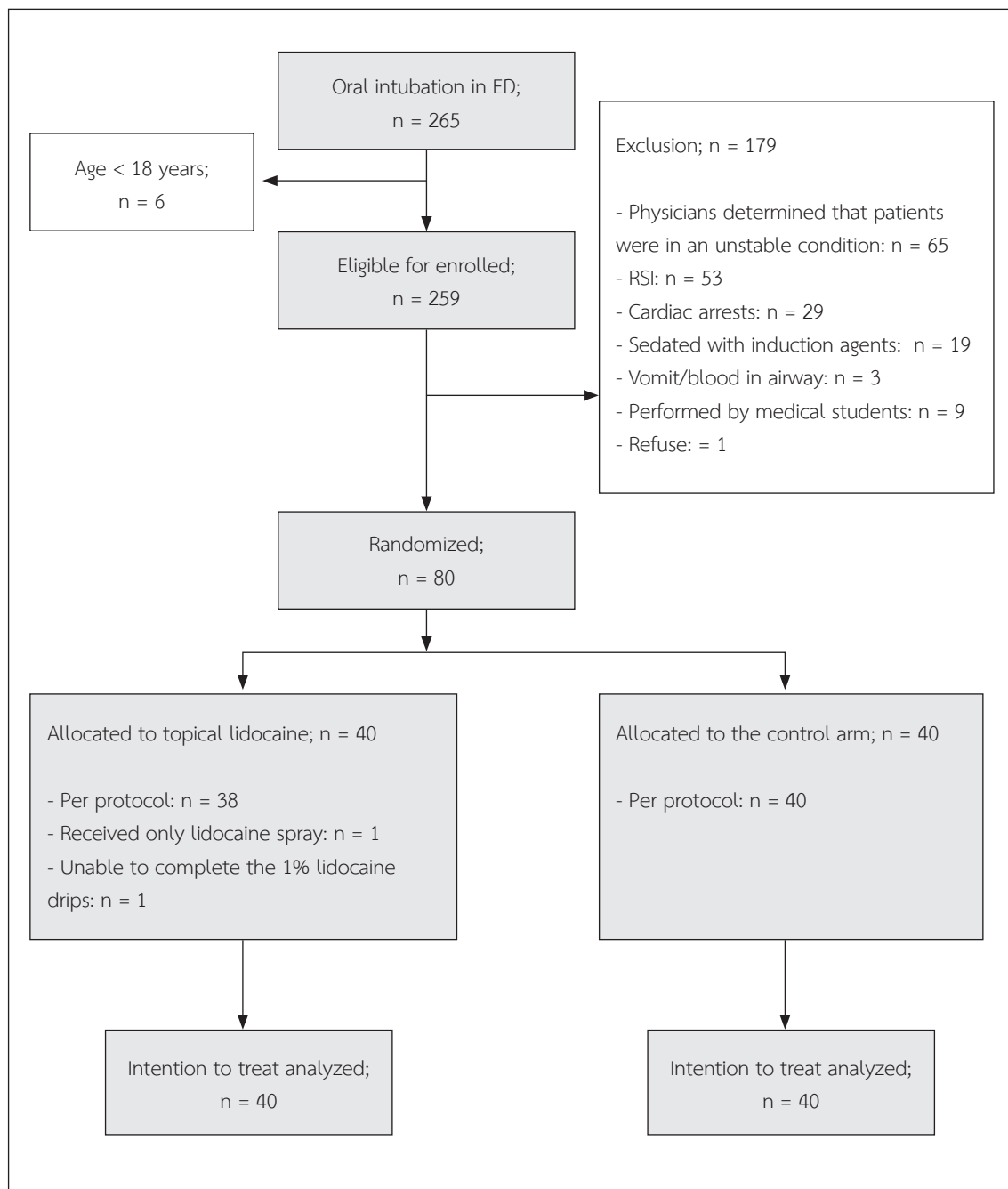


Figure 1 Study flow diagram

Table 1 Baseline demographics of the patients randomized to topical lidocaine aided oral intubation and without topical lidocaine

General characteristics	With topical lidocaine n = 40 n (%)	Without topical lidocaine n = 40 n (%)	p-value
Gender			
Male	23 (57.5)	26 (65.0)	0.647
Female	17 (42.5)	14 (35.0)	
Age, (years) mean±SD	65.6±15.3	66.1±14.7	0.876
Weight, (Kg) mean±SD	54.4±11.2	56.8±12.7	0.368
Glasgow coma score			
3-8	9 (22.5)	6 (15.0)	0.080
9-12	2 (5.0)	9 (22.5)	
13-15	29 (72.5)	25 (62.5)	
Type of patients			
Non-trauma	37 (92.5)	40 (100.0)	0.241
Trauma	3 (7.5)	0 (0)	
Indication for intubation			
Protect airway	9 (22.5)	9 (22.5)	1.000
Failure of oxygenation or ventilation	31 (77.5)	31 (77.5)	
Predicted difficult airway	11 (27.5)	9 (22.5)	0.797
Facial trauma	0 (0)	0 (0)	1.000
Beard or moustache	0 (0)	2 (5.0)	0.494
Large tongue	1 (2.5)	4 (10.0)	0.359
Large incisors	6 (15.0)	3 (7.5)	0.481
Obstruction e.g., hematoma	3 (7.5)	0 (0)	0.241
Neck mobility limited	2 (5.0)	1 (2.5)	1.000
Preoxygenation modality			
Oxygen mask with reservoir bag	20 (50.0)	30 (75.0)	0.049
Bag mask ventilation	9 (22.5)	6 (15.0)	
Nebulizer of bronchodilator	5 (12.5)	0 (0)	
High flow nasal cannula	3 (7.5)	2 (5.0)	
Nasal cannula	1 (2.5)	2 (5.0)	

Table 1 Continued

General characteristics	With topical lidocaine n = 40 n (%)	Without topical lidocaine n = 40 n (%)	p-value
Systolic blood pressure, (mmHg) mean±SD	130.3±36.3	137.7±33.8	0.353
Pulse rate, (bpm) mean±SD	110.8±18.2	115.4±21.9	0.307
O ₂ when making the intubation decision, (%) mean±SD (min, max)	89.7±12.1 (44, 100)	92.4±10.2 (58, 100)	0.281
O ₂ at end of preoxygenation, (%) mean±SD (min, max)	95.6±9.4 (44, 100)	98.4±4.5 (80, 100)	0.099
Type of laryngoscope			1.000
Direct laryngoscope (DL)	38 (95.0)	38 (95.0)	
Video laryngoscope (VL)	2 (5.0)	2 (5.0)	
Used sedative drugs	13 (32.5)	35 (87.5)	< 0.001
Type of sedative drugs			
Midazolam	0 (0)	1 (2.5)	1.000
Dosage, (mg) mean±SD	NA	5.0	
Diazepam	11 (27.5)	32 (80.0)	< 0.001
Dosage, (mg) mean±SD	13.6±6.7	14.4±6.2	0.740
Fentanyl	0 (0)	3 (7.5)	0.241
Dosage, (mcg) mean±SD	NA	83.3±28.9	
Ketamine	2 (5.0)	1 (2.5)	1.000
Dosage, (mg) mean±SD	50.0±0.0	50.0	
Primary operator			
Internship year-1	24 (60.0)	22 (55.0)	0.929
Internship year-3	2 (5.0)	2 (5.0)	
Emergency physician	14 (35.0)	16 (40.0)	

Table 2 Feasibility outcomes of the pilot trial

Feasibility outcome	Feasibility target	Result
Recruitment rate (months to recruit 80 patients)	6 months	6 months
Data completeness	95.0 %	91.3 %
Adherence to intubation protocol	95.0 %	97.5 %

Table 3 Primary and secondary outcome of the patients intubated with topical lidocaine and without topical lidocaine

Outcome	With topical lidocaine No. with event/total No. of patients (%)	Without topical lidocaine No. with event/total No. of patients (%)	Difference % (95% CI)
First-pass success	29/40 (72.5)	24/40 (60.0)	12.5 (8.0-33.0)
Cardiac arrest	0 (0)	0 (0)	0 (0)
Desaturation-1	9/40 (22.5)	4/40 (10.0)	12.5 (3.4-28.4)
Desaturation-2	0 (0)	0 (0)	0 (0)

Discussion

Feasibility criteria were met for recruitment rate and adherence to protocol; however, the data's completeness did not. There were some limitations to this study. This study was unable to blind the treating physicians and the patients since there was usually a short period of preparation before attempting intubation, most of the patients were in critical conditions, and the treating physicians typically needed to closely monitor patients by bedside during that time. The primary outcome and secondary outcome were recorded by the treating physicians after the procedure rather than in real time, which could be inaccurate. The reasons for the incomplete data were that they were recorded by team members who were involved in

intubation care. During the procedure, they paid more attention to treating the patients than gathering the data. Staff members who are not part of the intubation team should be designated to collect the data for the future main trial. Currently, there is no standardized, validated scoring system for predicting difficult intubation in emergency patients. One of the predictors of difficult intubation is the LEMON score.¹ In this study, we used simplified patient characteristics to define a patient at risk for difficult intubation. There were 3 components: 1) "look" (including: facial trauma, beard or mustache, large tongue, and large incisors); 2) "obstruction" of the airway; and 3) limited "neck" mobility. The large tongue and large incisors were highly subjective and prone to significant interobserver variability. The

“evaluate 3-3-2” and “Mallampati” assessments were not performed because they were difficult to assess in combative, confused, and agitated patients.¹² Peri-intubation cardiac arrest was rare, occurring in approximately 1.0% of ED intubations. Pre-intubation hypotension, pre-intubation oxygen saturation <90%, and clinician-reported need for immediate intubation without time for full preparation were associated with a higher likelihood of peri-intubation cardiac arrest.¹³ In the study’s protocol for lidocaine-aided oral intubation, the time frame to apply the laryngoscope was set for at least 5 minutes after starting to spray 10% lidocaine because the peak anesthetic effect following topical application of lidocaine occurred within 2-5 minutes.¹⁴ The majority of the patients excluded from this study were those whose physicians determined that they were in an unstable condition and that delaying intubation until the intervention protocol was complete would put them at risk for cardiac arrests. This exclusion criterion was unclear since it depended on the treating physicians, and they might have excluded the patients who could benefit from using topical lidocaine. Moreover, some of the patients recruited still had end-preoxygenation oxygen saturation below 90%. These patients might experience cardiac arrests while the protocol was being performed. In regard to these findings and for reasons of safety, the researchers will clarify an unstable condition criterion in the future study to the following: 1) a patient who needs an immediate intubation attempt without use of drugs (crash

airway)¹, such as the patient who is in cardiopulmonary arrest or a state of near arrest; 2) a patient who is in a deep coma, or defined as the one who has the Glasgow coma score equal to 3 points and is likely to be unresponsive to direct laryngoscopy; and; 3) a patient with severe hypoxia, agonal, apnea, or hypopnea who requires noninvasive positive bag-mask ventilation to maintain the oxygen saturation level of at least 90% when the decision to intubate is made. The reason lidocaine dripping was administered onto the posterior tongue in a supine position was from the Chung et al. study.¹⁵ Most of the patients in their study tolerated the fiberoptic intubation without coughing. The patients in this study had normal consciousness, so they were promptly administered lidocaine of a full dose, and they were fully cooperative. They were unlike most ED patients who are critically ill and are not entirely in a cooperative state. Fifty percent of the intubators had difficulty giving 1% lidocaine to the patients who did not fully participate. To improve the cooperation of the physicians with the intervention, the researchers will propose an amendment to remove the 1% lidocaine dripping step to reduce cough reflex from the protocol in future trials. The 10% lidocaine spraying would help decreasing the gag reflex to facilitate intubation, and the time frame from spraying the 10% lidocaine until applying a laryngoscope would range from 3-5 minutes. The usage of sedative drugs was significantly lower in the lidocaine-aided group. However, the precise reasons for this observation remain

uncertain. Topical lidocaine may diminish the gag reflex and laryngoscope-related pain, potentially reducing the need for sedatives. This study revealed a different proportion in the first-pass success rate of 12.5% (95% CI, 8.0-33.0) in favor of the lidocaine-aided oral intubation group, while peri-intubation hypoxia was found more often in the lidocaine-aided oral intubation group of 12.5% (95% CI, 3.4-28.4). The reason that this study found peri-intubation hypoxia more in the lidocaine-aided oral intubation group could be due to the fact that the percent of patients who needed bag mask ventilation in preoxygenation process in lidocaine-aided group was comparatively higher. When applying topical lidocaine in upper airway, it interrupted a bag mask ventilation process, so the patients would not get oxygen supplement during lidocaine application. However, this pilot study was not designed to be adequately powered to detect a clinically significant difference.

Conclusion

The definitive study is considered feasible with a few modifications to the exclusion criteria, an improvement in the data collection process, and a refinement of the method for topical lidocaine administration. The results obtained from this pilot study will serve as a foundation for future trials.

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