AIRWAY/ORIGINAL RESEARCH

Routine Use of a Bougie Improves First-Attempt Intubation Success in the Out-of-Hospital Setting

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Study objective: The bougie is typically treated as a rescue device for difficult airways. We evaluate whether first-attempt success rate during paramedic intubation in the out-of-hospital setting changed with routine use of a bougie.

Methods: A prospective, observational, pre-post study design was used to compare first-attempt success rate during out-ofhospital intubation with direct laryngoscopy for patients intubated 18 months before and 18 months after a protocol change that directed the use of the bougie on the first intubation attempt. We included all patients with a paramedic-performed intubation attempt. Logistic regression was used to examine the association between routine bougie use and first-attempt success rate.

Results: Paramedics attempted intubation in 823 patients during the control period and 771 during the bougie period. The firstattempt success rate increased from 70% to 77% (difference 7.0% [95% confidence interval 3% to 11%]). Higher first-attempt success rate was observed during the bougie period across Cormack-Lehane grades, with rates of 91%, 60%, 27%, and 6% for Cormack-Lehane grade 1, 2, 3, and 4 views, respectively, during the control period and 96%, 85%, 50%, and 14%, respectively, during the bougie period. Intubation during the bougie period was independently associated with higher first-attempt success rate (adjusted odds ratio 2.82 [95% confidence interval 1.96 to 4.01]).

Conclusion: Routine out-of-hospital use of the bougie during direct laryngoscopy was associated with increased first-attempt intubation success rate. [Ann Emerg Med. 2020;**=**:1-9.]

Please see page XX for the Editor's Capsule Summary of this article.

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INTRODUCTION

Background

In the United States, paramedics commonly perform intubation for critically ill patients in the out-of-hospital setting. However, intubation is technically challenging and can be associated with a number of complications.¹ The likelihood of complications increases with the number of attempts required to successfully perform the procedure.^{2,3} Factors mediating performance, such as individual experience, frequency of paramedic exposure to critically ill patients, and the degree of skill in performing intubation, vary greatly among emergency medical services (EMS) systems.⁴ Consequently, the rates of correctly placing the endotracheal tube on the first attempt differ among nonphysician providers in the out-of-hospital setting, with rates as low as 52% reported for patients in cardiac arrest.^{5,6}

Importance

Despite being easy to use and inexpensive, the bougie is used in only 3.5% of emergency department (ED)

intubation attempts and is typically treated as a rescue device for difficult airways.' First-attempt success rates may improve with routine use of the bougie, especially when the initial laryngoscopic view is poor.^{8,9} In several randomized controlled trials of patients in the operating room, bougie use has been demonstrated to improve first-attempt intubation success rates with simulated or otherwise difficult airways.¹⁰⁻¹² Routine use of the bougie has also been shown to increase the likelihood of first-attempt success during intubation when used by emergency physicians in the hospital.¹³⁻¹⁵ In the out-of-hospital environment, the bougie is a well-established rescue device for difficult airways. However, prior evidence supporting routine use of the device in this setting is limited.^{8,9} An evaluation of routine bougie-assisted intubation by helicopter nurse/paramedic crews suggested the safety of the device's use.¹⁶ To date, no studies to our knowledge have evaluated the efficacy of routine use of the bougie with the first intubation attempt by ground-based paramedics in the out-of-hospital setting.

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Editor's Capsule Summary

What is already known on this topic Paramedics sometimes use the bougie as a rescue device for difficult out-of-hospital intubation, but its effect on routine use is unknown.

What question this study addressed

This observational study of nearly 1,600 patients measured the first-attempt intubation success rate and number of attempts before and after a protocol change directing routine use of a bougie.

What this study adds to our knowledge

Routine use of a bougie was associated with higher first-attempt success rate and fewer number of attempts across all grades of direct laryngoscopic views.

How this is relevant to clinical practice

This article supports the routine use of a bougie for out-of-hospital intubation.

Goals of This Investigation

Our study aimed to determine whether there was an association between routine use of a bougie and firstattempt success during intubation performed by paramedics using direct laryngoscopy in the out-of-hospital setting. We hypothesized that routine use of the bougie would lead to higher rates of first-attempt intubation success without significantly changing complication rates.

MATERIALS AND METHODS

Study Design

We performed a prospective, observational, intentionto-treat, pre-post analysis after a policy change. This study was reviewed and approved by the University of Washington institutional review board.

Setting

The Seattle Fire Department is the sole provider of EMS in Seattle. The structure of the tiered Seattle Fire Department response has been described previously.¹⁷ All paramedics are proficient in rapid sequence intubation using sedative and neuromuscular blocking agents. They perform intubation with direct laryngoscopy with Macintosh blades. Video laryngoscopy is not used in the system. Seattle Fire Department paramedics perform at least 10 intubations annually. If they are unable to accomplish this number of intubations in the out-ofhospital setting, they perform it in the operating room to maintain proficiency. Since 2005, the bougie has been available for use as a rescue device for difficult airways and has been used at the discretion of the individual paramedic. Additionally, the Seattle Fire Department serves as the primary clinical site for the paramedic students of the University of Washington Michael K. Copass Paramedic Training Program. A cohort of paramedic students performs intubation between December and June of each year under the close supervision of the paramedics.

Selection of Participants

All patients with attempts at advanced airway management by paramedics in Seattle between July 1, 2015, and September 30, 2018, were included in our study. The study period included the 18 months before the implementation of the bougie protocol, referred to as the "control period," and the 18 months after the 3-month training period, referred to as the "bougie period." Cases were excluded by the following criteria: patient younger than 16 years, use of a supraglottic device or cricothyrotomy without laryngoscopy, or initial intubation attempt by a paramedic student. Paramedic student intubations were excluded because the 2 study periods overlapped with 3 different paramedic training classes of differing sizes asymmetrically, resulting in variable exposure of the students to intubation. The characteristics of patients and intubation attempts when the initial attempt was by a paramedic student are shown in Table E1 (available online at http://www.annemergmed.com). All individual paramedics who performed at least one intubation attempt during one of the study periods were included.

Interventions

Beginning January 1, 2017, paramedics were instructed to use the bougie for the first attempt of intubation for all cases, regardless of perceived airway difficulty. Use of the bougie on the first attempt was promoted for both rapid sequence intubation and intubation without medications for patients in cardiac arrest. This revised airway management protocol was implemented during 3 months to ensure that in-person didactic and skills education sessions on the use of the bougie could be completed with all active paramedics. Regular reminders to the paramedics to use the bougie on all intubation attempts were given throughout the study period by e-mail and during monthly staff meetings.

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Methods of Measurement

The quality improvement staff maintains a prospectively collected, out-of-hospital airway management registry. Shortly after clinical encounters, paramedics complete a digital airway survey using Research Electronic Data Capture tools hosted at the Institute of Translational Health Sciences at the University of Washington (Figure E1, available online at http://www.annemergmed. com).¹⁸ ECG, end tidal carbon dioxide (ETCO₂) capnography, pulse oximetry (SpO₂), and audio recordings were captured throughout intubation attempts by LIFEPAK 15 manual defibrillators (Stryker/Physio-Control, Redmond, WA). Paramedics were trained to verbally identify treatments as they were being delivered, such as drug doses, adjuncts used, and the beginning and end of intubation attempts. A team of highly experienced abstractors reviewed the audio and monitor waveform recordings and adjudicated differences with the paramediccompleted airway survey to maintain consistent, accurate, and complete data in the airway registry.

Variables collected in the airway registry included individual paramedic performing each intubation attempt, patient demographic data, indications for intubation, medications given, adjuncts used on each attempt, and the best Cormack-Lehane grade view for each attempt.¹⁹ Rapid sequence intubation was defined as a patient with spontaneous circulation who received an intubation attempt after sedation and neuromuscular blocking agents had been given. Ongoing cardiopulmonary resuscitation (CPR) was defined as a patient who received the intubation attempt while he or she was pulseless and who received chest compressions during the attempt. Patients who received neuromuscular blocking agents with ongoing CPR were included in the ongoing CPR group. The final airway device used was noted, whether an endotracheal tube, i-gel supraglottic device (Intersurgical Ltd, Berkshire, UK), surgical cricothyrotomy, or bag-valve-mask ventilation. The number of attempts before successful device placement was recorded, with an attempt defined as the laryngoscope blade's passing the teeth. Barriers to successful intubation, as perceived by the intubating paramedic, were also collected. Finally, the reviewers recorded complications such as unrecognized esophageal intubation or hypoxia. The airway registry defines hypoxia as any oxygen saturation reading of less than 90% between the initial intubation attempt and 2 minutes postplacement of the tracheal tube or rescue airway device. An unrecognized esophageal tube placement was defined as an endotracheal tube placed in the esophagus for at least 5 minutes before removal. These cases were identified in the field by paramedics or on review of the ETCO2 waveform and audio download by quality improvement staff.

Outcome Measures

The primary outcome was first-attempt intubation success, which was defined as successful placement of the

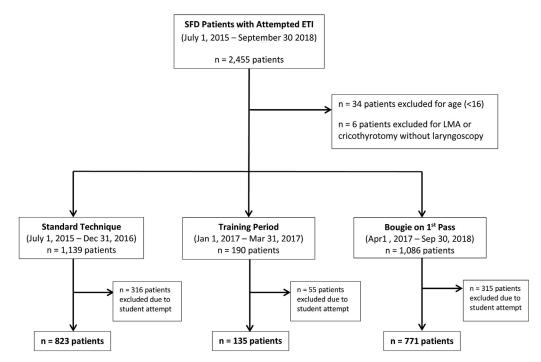


Figure 1. Flow of patients through the study. ETI, Intubation; SFD, Seattle Fire Department; LMA, laryngeal mask airway.

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endotracheal tube in the trachea on the first laryngoscopy attempt. A laryngoscopy attempt was defined as the laryngoscope blade's passing the teeth regardless of whether the placement of an endotracheal tube or bougie was also attempted. Secondary outcome measures included the overall number of attempts required for successful intubation and the presence of hypoxia during the intubation attempt.

Primary Data Analysis

Point estimates and 95% confidence intervals (CIs) were reported when determined to be appropriate. We used logistic regression to examine the association between first-pass success and important covariates, including Cormack-Lehane grade 1 view, flat position, male sex, age in years, trauma associated with the event, whether the patient was receiving chest compressions during the first attempt, and study period. We report odds ratios and 95% CIs. Standard errors of the regression coefficient were adjusted for potential correlated error caused by repeated measurements for paramedics with the Huber-White sandwich estimator. We assessed model fit with the Hosmer-Lemeshow statistic. SPSS (version 19.0; IBM Corp, Armonk, NY) and Stata (version 16.1; StataCorp, College Station, TX) software packages were used for statistical analysis.

RESULTS

Characteristics of Study Subjects

Between July 1, 2015, and September 30, 2018, 2,455 patients received an intubation attempt by paramedics or paramedic students. After exclusionary criteria were applied, 823 patients received an intubation attempt by a paramedic in the 18-month control period (July 1, 2015, through December 31, 2016) and 771 patients during the 18-month bougie period (April 1, 2017, through September 30, 2018) (Figure 1).

During the control period, 8.9% of patients had intubation attempted with a bougie on the first attempt compared with 81.3% of patients in the bougie period (Table 1). The majority in all study periods were male patients (67.9% versus 62.9%), and the most common indication for intubation was cardiac arrest. The mean age of the patients was similar for both cohorts. During the study period, 74 paramedics in the control period and 69 in the bougie period performed at least one intubation attempt included in our analysis. The median number of attempts per paramedic was 16 (interquartile range 7 to 21) and 15 (interquartile range 11 to 20) between periods, respectively. A total of 82 paramedics performed at least 1 intubation attempt during 1 of the Table 1. Baseline characteristics.

Parameter	Control Period, n=823 (Jul 2015– Dec 2016)	Bougie Period, n=771 (Apr 2017– Sep 2018)
Age, mean (SD), y	55.8 (20.1)	57.4 (19.6)
Male sex	559 (67.9)	485 (62.9)
Indication		
Medical, RSI	333 (40.5)	279 (36.2)
Medical, ongoing CPR	335 (40.7)	378 (49.0)
Trauma, RSI	127 (15.4)	84 (10.9)
Trauma, ongoing CPR	28 (3.4)	30 (3.9)
Final result of the intubation attempt		
Endotracheal tube	806 (97.9)	753 (97.7)
i-gel Laryngeal mask airway	13 (1.6)	15 (1.9)
Cricothyrotomy	2 (0.2)	1 (0.1)
Bag-valve-mask ventilation	1 (0.1)	2 (0.3)
Unknown	1 (0.1)	0
Intubation characteristics		
Positioning (head elevated)	147 (17.9)	166 (21.5)
Bougie used on first attempt	73 (8.9)	627 (81.3)
Cormack-Lehane grade		
laryngoscopic view*		
RSI		
1	311 (67.8)	209 (57.6)
2	62 (13.5)	81 (22.3)
3	72 (15.7)	60 (16.5)
4	14 (3.1)	13 (3.6)
Ongoing CPR*		
1	191 (53.4)	151 (37.2)
2	47 (13.1)	82 (20.2)
3	82 (22.9)	130 (32.0)
4	38 (10.6)	43 (10.6)
Paramedic intubation exposure		
No. of paramedics with ≥ 1 ETI attempt	74	69
Median ETI attempts per provider (IQR)	16 (7-21)	15 (11-20)

RSI, Rapid sequence intubation; IQR, interquartile range.

Data are presented as No. (%) unless otherwise indicated.

*Six cases had a missing Cormack-Lehane grade view in the control period. Two cases had a missing Cormack-Lehane grade view in the bougie period, and both had first-attempt success.

study periods. The variation of out-of-hospital intubation encounters by paramedic during the study period is shown in Figure E2 (available online at http://www.annemergmed.com).

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Main Results

The first-attempt success rate increased between the control and bougie periods from 70% to 77% (difference 7.0% [95% CI 3% to 11%]). Higher first-attempt success was observed during the bougie period across all Cormack-Lehane grades, with rates of 91%, 60%, 27%, and 6% for Cormack-Lehane grade 1, 2, 3, and 4 views, respectively, during the control period and 96%, 85%, 50%, and 14%, respectively, during the bougie period (Table 2). Firstattempt success was higher in the bougie period compared with the control period, with similar effect sizes across Cormack-Lehane grades when patients were in cardiac arrest and receiving chest compressions during the intubation attempt and when rapid sequence intubation was performed (Figure 2). The mean number of attempts required for successful intubation decreased during the study period from 1.4 attempts per patient during the control period to 1.3 during the bougie period (difference -0.10 attempts [95% CI -0.03 to -0.17]) (Table 2).

Compliance with the protocol was 81.3% in the bougie period. However, the case mix changed over time (Figure 3). Patients were more likely to be in cardiac arrest during the initial intubation attempt in the bougie period (n=408, or 52.9%) versus the control period (n=363, or 44.1%). Logistic regression controlling for factors documented in Table 3 demonstrated lower first-attempt success when intubation occurred during ongoing cardiac arrest and with increasing patient age. This analysis

Table 2.	Intubation	attempts and	first-attempt success.
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demonstrated higher first-attempt success when a Cormack-Lehane grade 1 view was present, with flat patient positioning, and when the intubation occurred during the bougie period. The bougie period was independently associated with higher first-attempt success (adjusted odds ratio 2.82 [95% CI 1.96 to 4.01]).

Postincident audio and monitor waveform recordings demonstrated that hypoxia at any point during rapid sequence intubation, as previously defined, declined between the control period and the bougie period (29.8% versus 19.0%; difference -10.8% [95% CI -18.0% to -4.9%]) (Table 4). There were 3 unrecognized esophageal endotracheal tube placements in the control period and 2 in the bougie period. Four patients in both the control and bougie periods had a new cardiac arrest within 10 minutes of the intubation attempt.

LIMITATIONS

Our study has limitations. Although data were collected prospectively, our study design was an observational, prepost analysis after an intervention. The results may be confounded by the ongoing quality improvement efforts focused on out-of-hospital airway management within the Seattle Fire Department, which include regular education on airway management best practices and continuous feedback with individual paramedics regarding challenging cases. The system currently does not use Miller blades or

Parameter	Control Period (n=823)	Bougie Period (n=771)	Difference (95% CI)
Overall			
Mean ETI attempts (SD)	1.4 (0.7)	1.3 (0.7)	0.10 (0.03 to 0.17)
First-attempt success, % (95% CI)	70 (66 to 73)	77 (74 to 80)	7 (3 to 11)
Cormack-Lehane airway grade*			
1 (Full view)			
Mean ETI attempts (SD)	1.1 (0.4)	1.0 (0.3)	0.10 (0.05 to 0.15)
First-attempt success, % (95% CI)	91 (89 to 94)	96 (94 to 98)	5 (2 to 8)
2 (posterior cartilage)			
Mean ETI attempts (SD)	1.5 (0.8)	1.2 (0.4)	0.30 (0.15 to 0.45)
First-attempt success, % (95% CI)	60 (50 to 69)	85 (80 to 91)	25 (15 to 36)
3 (epiglottis only)			
Mean ETI attempts (SD)	2.0 (1.0)	1.7 (0.9)	0.30 (0.15 to 0.50)
First-attempt success, % (95% CI)	27 (20 to 34)	50 (43 to 57)	23 (13 to 33)
4 (no laryngeal structures)			
Mean ETI attempts (SD)	2.3 (0.7)	2.2 (0.9)	0.10 (-0.26 to 0.46)
First-attempt success, % (95% CI)	6 (0 to 12)	14 (5 to 24)	8 (-4 to 21)

*Six cases had a missing Cormack-Lehane grade view in the control period, of which 5 had first-attempt success. Two cases had a missing Cormack-Lehane grade view in the bougie period, and both had first-attempt success.

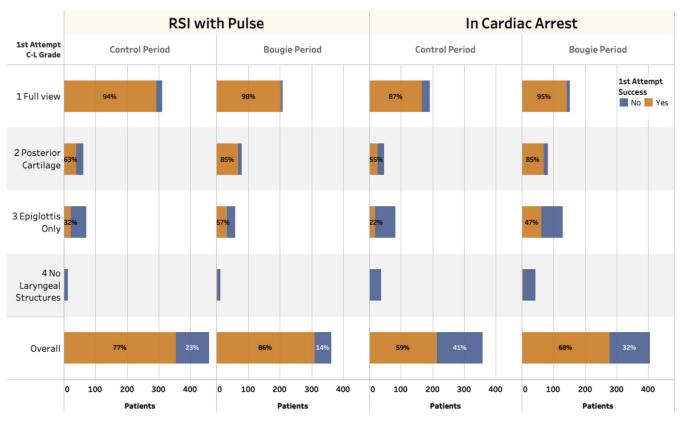


Figure 2. Initial Cormack-Lehane grade versus first-attempt success rate.

video laryngoscopy. Reporting on the Cormack-Lehane grade view was not independently verifiable. However, the distribution of Cormack-Lehane grade views in patients undergoing rapid sequence intubation and those receiving chest compressions during the intubation attempt was similar to that reported in an anesthesiologist-staffed helicopter EMS program.²⁰ We could not consistently measure intubation attempt duration. Measurement of hypoxia was missing in 18% of the patients. Finally, the full influence of routine bougie use may not have been assessed accurately because there was an 81.3% adherence to the airway management protocol during the bougie period.

These limitations are balanced by the study strengths. Our ability to review audio and waveform downloads enabled us to independently verify the number of attempts, devices used, oxygen saturation plethysmography, and other measures related to each attempt. The resulting airway registry data are of high fidelity, with limited self-reporting bias. To our knowledge, our study represents the largest evaluation of routine bougie use to date in the out-of-hospital setting.

DISCUSSION

Our study demonstrated that in a mature EMS system with paramedics who regularly perform intubation by

direct laryngoscopy, routine use of the bougie was associated with higher first-attempt intubation success and a reduction in the overall number of attempts to achieve successful endotracheal tube placement. The effect size of this improvement was most pronounced in Cormack-Lehane grade 2 and 3 airways, but improvements were also demonstrated in Cormack-Lehane grade 1 airways. The bougie may offer an advantage in patients with Cormack-Lehane grade 1 airways with smaller oral anatomy in which the endotracheal tube may otherwise obstruct a clear view of the glottic opening. Routine use of the bougie for every intubation attempt may also improve providers' skill in manipulating the device, as well as their understanding of tactile feedback with correct placement, such as the click of tracheal rings and the holdup sign.²¹ Using the bougie for Cormack-Lehane grade 1 airways may foster these skills and improve success when a challenging Cormack-Lehane view is encountered on a subsequent patient.

Our results challenge the traditional out-of-hospital teaching in the United States, which maintains that the bougie should be used as a rescue device or when a good laryngoscopic view cannot be obtained. The guidelines on out-of-hospital anesthesia published by the Association of Anaesthetists of Great Britain and Ireland recommend the

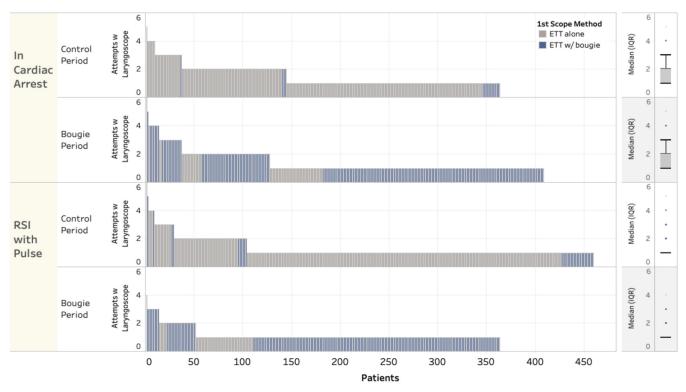


Figure 3. Use of bougie on first attempt compared with number of attempts at laryngoscopy.

routine use of the bougie on all out-of-hospital intubations.²² Similarly, routine bougie use is the practice of many out-of-hospital care teams in the United Kingdom and Australasia.^{22,23} Our results support this same

Table 3. Factors associated with first-attempt success: results from logistic regression (n=1,572).

	Odds Ratio (95% CI)		
Variable	Unadjusted	Adjusted*	
Cormack-Lehane grade I view	15.2 (10.43-22.43)	17.83 (11.71-27.15)	
Bougie period	1.43 (1.21-1.82)	2.82 (1.96-4.01)	
Flat position	2.65 (1.88-3.75)	1.67 (1.08-2.57)	
Male sex	1.37 (1.08-1.75)	1.21 (0.92-1.59)	
Age per 1-y increase, y	0.99 (0.98-0.99)	0.99 (0.98-1.00)	
Trauma patient	1.35 (0.97-1.86)	0.92 (0.59-1.44)	
In cardiac arrest during first ETI attempt	0.43 (0.43-0.53)	0.60 (0.43-0.84)	

We used logistic regression to examine the association between first-pass success and important covariates, including Cormack-Lehane grade 1 view (0=no, 1=yes), flat position (0=no, 1=yes), male sex (0=women, 1=men), age in years, trauma patient (1=yes, 2=no), whether the patient was receiving chest compressions during the first attempt (10=no, 1=yes), and study period (1=standard, 2=bougie). *Model fit *P*=.80 by Hosmer-Lemeshow statistic. Standard errors of the regression coefficient were adjusted for potential correlated error caused by repeated measurements for paramedics with the Huber-White sandwich estimator. approach in a ground-based EMS system with paramedics who regularly perform intubation with direct laryngoscopy.

Potential downsides of bougie use for intubation include prolonging laryngoscopy attempts, resulting in longer apnea time and increasing the rate of hypoxia or hypercarbia. Driver et al¹³ demonstrated that routine bougie use in the ED did not change first intubation attempt duration. Our study lacked video recordings, so we could not accurately measure attempt duration. However, during rapid sequence intubation cases, we measured lower rates of hypoxia throughout the intubation process in the bougie period compared with the control period, suggesting the safety of routine use. Another concern about routine bougie use is that the device may expose patients to tracheal, bronchial, and mediastinal injuries from the bougie itself.^{24,25} We did not identify any cases of bougierelated injuries during the 4-year study period.

Our results also highlight the difficulty in obtaining favorable Cormack-Lehane grade views in patients undergoing CPR in the out-of-hospital environment. Greater than 30% of the patients in cardiac arrest who received chest compressions during the intubation attempt in both study groups had Cormack-Lehane grade 3 or 4 views as their initial laryngoscopic view. This is a problem that may be mitigated with video laryngoscopy, which has been associated with more favorable Cormack-Lehane

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Table 4. Oxygenation and complications.

Parameter	Control Period (n=460)	Bougie Period (n=363)	Mean % Difference (95% Cl)
Oxygenation, No. (%)*			
$\begin{array}{l} \text{Maintained } \text{Sp}_2 \\ \text{at } {\geq} 90\% \end{array}$	227 (49.3)	233 (64.2)	14.8 (8.0 to 21.4)
Нурохіа	137 (29.8)	69 (19.0)	-10.8 (-16.5 to -4.9)
Unknown	96 (20.9)	61 (16.8)	-4.1 (-9.3 to 1.4)
Unrecognized esophageal placement [†] (%; 95% Cl)	3 (0.36; 0 to 0.77)	2 (0.26; 0 to 0.62)	-0.1 (-0.8 to 0.6)
New cardiac arrest within 10 min [†] (%; 95% Cl)	4 (0.49; 0.01 to 0.97)	4 (0.52; 0.01 to 1.03)	0.0 (-0.8 to 0.9)

*The cases included in the control and bougie periods represent patients who were receiving intubation while they had a pulse. This does not include patients who were in cardiac arrest during the intubation attempt.

[†]These percentages are out of all patients included in the study.

grade views in patients receiving CPR in the out-of-hospital environment.²⁰ More evaluation of this technology in the out-of-hospital setting is needed.

In summary, we found that routine use of the bougie was associated with increased overall first-attempt intubation success and a reduction in the number of attempts required for successful intubation in the out-ofhospital setting when deployed in a mature, paramedicbased EMS system that regularly performs intubation by direct laryngoscopy.

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Author contributions: AJL and MRS conceived and designed the study and implemented the protocol changes and training. AJL,

BH, CRC, KR, and MRS supervised the conduct of the data collection and analyzed the airway data and recordings. CM provided statistical advice on study design and analyzed the data. AJL drafted the article, and all authors contributed substantially to its revision. AJL takes responsibility for the paper as a whole.

All authors attest to meeting the four ICMJE.org authorship criteria: (1) Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND (2) Drafting the work or revising it critically for important intellectual content; AND (3) Final approval of the version to be published; AND (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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