JAMA | Original Investigation

Effect of Use of a Bougie vs Endotracheal Tube and Stylet on First-Attempt Intubation Success Among Patients With Difficult Airways Undergoing Emergency Intubation
A Randomized Clinical Trial

Brian E. Driver, MD; Matthew E. Prekker, MD; Lauren R. Klein, MD; Robert F. Reardon, MD; James R. Miner, MD; Erik T. Fagerstrom, BA; Mitchell R. Cleghorn, BS; John W. McGill, MD; Jon B. Cole, MD

IMPORTANCE The tracheal tube introducer, known as the bougie, is typically used to aid tracheal intubation in poor laryngoscopic views or after intubation attempts fail. The effect of routine bougie use on first-attempt intubation success is unclear.

OBJECTIVE To compare first attempt intubation success facilitated by the bougie vs the endotracheal tube + stylet.

DESIGN, SETTING, AND PATIENTS The Bougie Use in Emergency Airway Management (BEAM) trial was a randomized clinical trial conducted from September 2016 through August 2017 in the emergency department at Hennepin County Medical Center, an urban, academic department in Minneapolis, Minnesota, where emergency physicians perform all endotracheal intubations. Included patients were 18 years and older who were consecutively admitted to the emergency department and underwent emergency orotracheal intubation with a Macintosh laryngoscope blade for respiratory arrest, difficulty breathing, or airway protection.

INTERVENTIONS Patients were randomly assigned to undergo the initial intubation attempt facilitated by bougie (n = 381) or endotracheal tube + stylet (n = 376).

MAIN OUTCOMES AND MEASURES The primary outcome was first-attempt intubation success in patients with at least 1 difficult airway characteristic (body fluids obscuring the laryngeal view, airway obstruction or edema, obesity, short neck, small mandible, large tongue, facial trauma, or the need for cervical spine immobilization). Secondary outcomes were first-attempt success in all patients, first-attempt intubation success without hypoxemia, first-attempt duration, esophageal intubation, and hypoxemia.

RESULTS Among 757 patients who were randomized (mean age, 46 years; women, 230 [30%]), 757 patients (100%) completed the trial. Among the 380 patients with at least 1 difficult airway characteristic, first-attempt intubation success was higher in the bougie group (96%) than in the endotracheal tube + stylet group (82%) (absolute between-group difference, 14% [95% CI, 8% to 20%]). Among all patients, first-attempt intubation success in the bougie group (98%) was higher than the endotracheal tube + stylet group (87%) (absolute difference, 11% [95% CI, 7% to 14%]). The median duration of the first intubation attempt (38 seconds vs 36 seconds) and the incidence of hypoxemia (13% vs 14%) did not differ significantly between the bougie and endotracheal tube + stylet groups.

CONCLUSIONS AND RELEVANCE In this emergency department, use of a bougie compared with an endotracheal tube + stylet resulted in significantly higher first-attempt intubation success among patients undergoing emergency endotracheal intubation. However, these findings should be considered provisional until the generalizability is assessed in other institutions and settings.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT02902146

JAMA. 2018;319(21):2179-2189. doi:10.1001/jama.2018.6496
Published online May 16, 2018.

Supplemental content

CME Quiz at jamanetwork.com/learning and CME Questions page 2229

Author Affiliations: Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, Minnesota (Driver, Prekker, Klein, Reardon, Miner, Fagerstrom, McGill, Cole); Department of Medicine, Division of Pulmonary and Critical Care, Hennepin County Medical Center, Minneapolis, Minnesota (Prekker); University of Minnesota School of Medicine, Minneapolis (Cleghorn).

Corresponding Author: Brian E. Driver, MD, Department of Emergency Medicine, 701 Park Ave, Mail Stop R2, Minneapolis, MN 55415 (briandriver@gmail.com).

It has been estimated that in 2014 endotracheal intubation was performed 310 000 times in US emergency departments (EDs).[1] This procedure is potentially life-saving for patients who are critically ill, yet has inherent risk.[2] A multicenter registry of ED intubations, reporting data from 2002-2012, found that approximately 12% of intubations resulted in an adverse intubation-related event.[3] Of factors within an emergency physician's control, successful endotracheal intubation on the initial attempt is important to reduce the likelihood of adverse events.[4] A large ED intubation registry described first-attempt intubation success rates of 85%, despite increasing adoption of video laryngoscopy.[3] The 15% first-attempt failure rate highlights an opportunity to improve the safety and efficiency of this critical procedure.

The tracheal tube introducer (known as the bougie), a simple, inexpensive device first described by Macintosh[5] in 1949 to facilitate orotracheal intubation, may improve first-attempt success.[6] However, the bougie has been used in less than 5% of ED first attempts[3] and reserved primarily for patients with poor laryngeal views or as a rescue device when initial intubation attempts fail.[7] Routine bougie use was associated with increased first-attempt success in a retrospective study in the ED[6]; however, to our knowledge, there have not been randomized clinical trials assessing its efficacy.

Accordingly, the Bougie Use in Emergency Airway Management (BEAM) trial was designed to evaluate the bougie in a randomized comparison with an endotracheal tube + stylet in ED patients with at least 1 characteristic predictive of difficult laryngoscopy or intubation because these patients would be most likely to benefit from the bougie. It was hypothesized that the bougie would facilitate higher first-attempt intubation success than the endotracheal tube + stylet among ED patients with a difficult airway characteristic (primary outcome) and all ED patients undergoing orotracheal intubation (secondary outcome).

Key Points

Question In patients admitted to the emergency department with difficult airway characteristics undergoing orotracheal intubation with a Macintosh laryngoscope blade, does a bougie facilitate higher first-attempt intubation success than an endotracheal tube + stylet?

Findings In this randomized clinical trial that included 757 adults, bougie use resulted in significantly higher first-attempt intubation success than an endotracheal tube + stylet (96% vs 82%) for those with a difficult airway characteristic.

Meaning Although bougie use led to a higher likelihood of first-attempt intubation success, further research is needed to assess generalizability to other institutions and settings.

Methods

Trial Design and Setting

This randomized clinical trial was conducted from September 2016 through August 2017 in the ED of an urban, academic level I trauma center with 109 000 annual ED visits. All endotracheal intubations are performed by either emergency medicine residents (usually postgraduate year 3 or higher) or attending emergency physicians. All residents receive extensive training in endotracheal intubation with both an endotracheal tube + stylet and bougie, including didactics, hands-on sessions with all direct and video laryngoscopes, simulation sessions, and intubation of patients during rotations in community EDs earlier in training. The Hennepin County Medical Center institutional review board approved the trial protocol, available in Supplement 1.

Patients undergoing emergency endotracheal intubation are generally not able to provide informed consent. As use and nonuse of the bougie were both standard of care in this ED, and any differential risk between the groups was deemed to be minimal, this trial was conducted under the US 45 Code of Federal Regulations, Section 46.116, Waiver of Informed Consent for Emergency Research. If the patient was able to communicate or an appropriate surrogate decision maker was present, the opportunity to object to study enrollment was offered.

Patient Selection

Patients 18 years and older consecutively admitted to the ED who would undergo orotracheal intubation were eligible if the attending emergency physician planned to use a Macintosh laryngoscope blade on the first attempt; both direct and video laryngoscopy were allowed. Prisoners, patients known or assumed to be pregnant, and patients with known distortion of the upper airway or glottic structures (eg, angioedema, epiglottitis, laryngeal mass, or malignancy) were excluded. In the latter group, the bougie has been shown to be advantageous and it was considered to be unethical to include them in the trial.[8] Bougie use with hyperangulated blades was not studied because it can be difficult to pass the bougie, and it is more common to use a steel stylet.[9]

It has been estimated that approximately 60% of patients in the ED undergoing endotracheal intubation have anatomic or other features associated with difficulty obtaining an adequate laryngeal view and passing the endotracheal tube.[4,10] After completion of the procedure, the intubating emergency physician recorded whether any of the following difficult airway characteristics were present: body fluid(s) obscuring the laryngeal view, airway obstruction or edema, obesity, short neck, small mandible, large tongue, facial trauma, or cervical spine immobilization.[4,10,11] These characteristics were not defined formally and physicians determined their presence subjectively. Patients with at least 1 of these characteristics were analyzed as the primary trial end point. Querying the intubating physician after intubation was necessary because it is not possible to ascertain all difficult airway characteristics before intubation. This approach facilitated analysis of the effect of the bougie in patients with and without difficult airway characteristics.

Randomization and Trial Procedures

Eligible patients were randomly assigned in a 1:1 ratio to orotracheal intubation using either the bougie or endotracheal

tube + stylet for the initial attempt. Randomization was performed before the start of the trial with the use of a computer-generated assignment sequence in permuted blocks of random sizes of 2, 4, 6, 8, and 10. In an attempt to balance the number of patients with a difficult airway characteristic in both intervention groups, the randomization had 2 strata: those with obesity or cervical immobilization and those without obesity or cervical immobilization. Intervention assignments were placed inside a folded sheet of paper in sequentially numbered, opaque envelopes. A research associate opened the next envelope in the appropriate strata to determine intervention allocation after patient enrollment and before laryngoscopy.

The intubation procedure, including patient positioning, preoxygenation strategy, use of neuromuscular blockade (ie, rapid sequence intubation), cricoid pressure, choice of Macintosh-style laryngoscope, and whether to view the video screen, was at the discretion of the emergency physician. The ED had 2 laryngoscopes with reusable Macintosh-style blades capable of both direct and video laryngoscopy (C-MAC Macintosh blade [KARL STORZ] and GlideScope Titanium MAC [Verathon]); a nonvideo, direct Macintosh laryngoscope was also available. The bougie used for this study is a 70-cm long, 15 French (5-mm diameter), malleable, semirigid, straight, single-use bougie with a coudé tip (SunMed). Bougie bending was not stipulated; intubating physicians chose whether and how to bend the bougie.

In all patients, the best possible view of the larynx was obtained using direct or video laryngoscopy. In the bougie group, the operator attempted to pass the bougie into the trachea. If successful, an assistant loaded the endotracheal tube over the bougie and the operator guided the tube through the vocal cords and into the trachea to the desired depth while keeping the laryngoscope in the mouth.[12] If resistance was encountered when passing the endotracheal tube over the bougie (presumably from the bevel-tip of the tube catching on the arytenoid cartilages), the tube was retracted 2 centimeters, rotated 90° counterclockwise, and readvanced into the trachea.[12,13] In the endotracheal tube + stylet group, the operator attempted to intubate the trachea with an endotracheal tube + stylet with a "straight-to-cuff" shape and a bend angle of 25° to 35°.[14] If difficulty in passage was encountered, the intubator could withdraw, rotate, or reshape the tube and stylet as needed. The stylet was left in place until the tube was advanced to the desired position in the trachea. In both groups, if the trachea was not intubated with the initial device, any change in equipment was at the discretion of the operator, including crossover to bougie or endotracheal tube + stylet. Correct tube position was confirmed with waveform capnography.

Measurements

A trained research associate prospectively collected process and outcome data from patient randomization until 1 minute following the end of the first intubation attempt, including the duration of the first attempt using a handheld stopwatch and whether the attempt was successful. After the procedure, the intubating physician recorded additional data on a standardized collection form (Supplement 2), including the presence of specific difficult airway characteristics. In addition, the physician reported whether a clicking sensation was felt as the bougie passed over tracheal rings, and whether a "hold-up" sign was felt as the bougie stopped in a bronchus.[15]

Because of inherent difficulties with blinding of an intubation device, physicians and research assistants were not blinded. Discrepant reporting of first-attempt success between the research associate and intubating physician were adjudicated by an investigator who retrospectively reviewed video of the intubation captured on motion-activated, ceiling-mounted cameras used in the ED critical care bays for quality assurance and improvement. A trained and blinded abstractor reviewed the final postintubation chest radiograph read for all patients to determine if a pneumothorax was present. Pneumothoraces were considered to be possibly related to intubation unless the patient had chest trauma with rib fractures or had received chest compressions in the setting of cardiac arrest.

Trial Outcomes

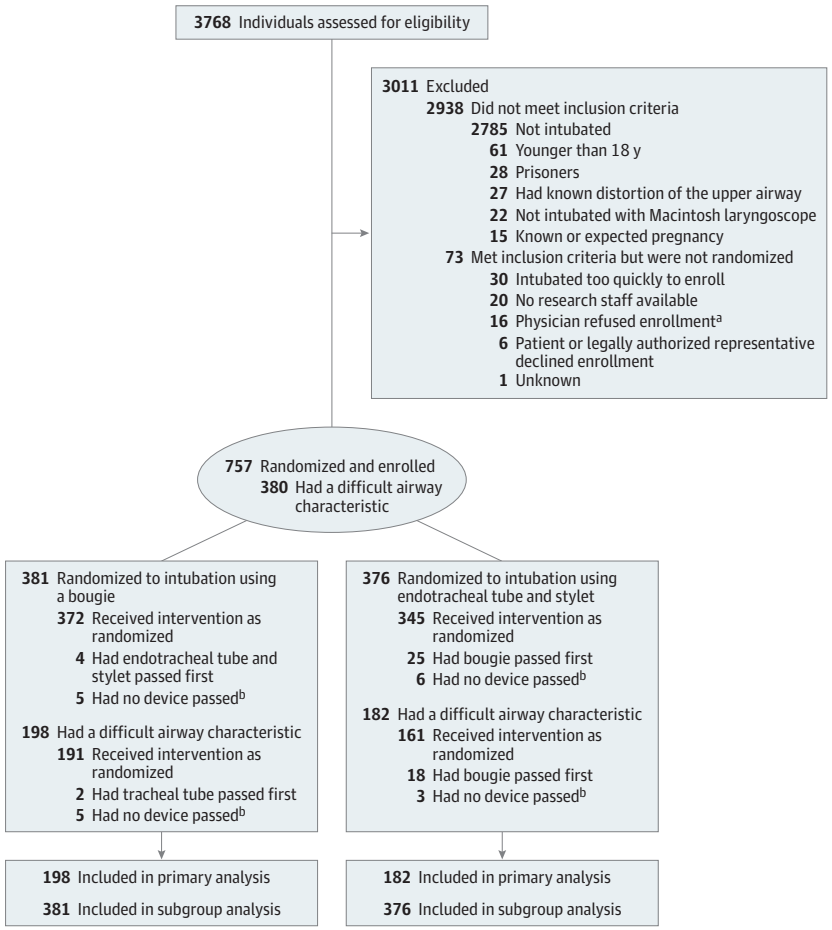
The primary outcome was first-attempt intubation success, defined as successful endotracheal tube placement with the first device passed (bougie or endotracheal tube + stylet) during the first laryngoscope insertion. If neither a bougie nor endotracheal tube + stylet were inserted into the mouth during the first laryngoscope insertion, the attempt was counted as a failure. Secondary outcomes included hypoxemia, first-attempt duration, and esophageal intubation. Hypoxemia was defined as an oxyhemoglobin saturation less than 90% (or, if the attempt began with a saturation <90%, an absolute decrease in saturation of >10%) by continuous pulse oximetry. The duration of an intubation attempt was defined as the time elapsed between insertion and removal of the laryngoscope blade from the patient's mouth.

Statistical Analysis

This study was powered to detect a between-group difference in first-attempt intubation success among patients with at least 1 difficult airway characteristic (a subset of all enrolled patients). A minimum clinically important difference in first-attempt intubation success has not been defined in the literature to guide trial planning. Therefore, based on a previously published study of bougie use in the ED, we estimated that a sample of 374 patients with difficult airway characteristic(s) would provide 80% power to detect an absolute difference of 9% in first-attempt intubation success (95% vs 86%)[6] with a 2-sided α of .05. No a priori sample size calculation was performed for the analysis that included all enrolled patients, which included patients without a difficult airway characteristic, as we anticipated the difference in first-attempt success for patients without predicted difficulty would be less than 5%, which would require a sample size not feasible for this study. The number of patients with a difficult airway characteristic was monitored and the trial stopped when more than 374 such patients were enrolled. All enrolled patients were included in the final analysis.

The principal trial analyses were performed in the intention-to-treat population. The primary analysis of those with a difficult airway characteristic, the secondary analysis of the overall study cohort, and secondary outcomes were compared

Figure 1. Flow of Patients Through the Study



Difficult airway characteristics were defined as body fluids obscuring the laryngeal view, airway obstruction or edema, obesity, short neck, small mandible, large tongue, facial trauma, or the need for cervical spine immobilization.

[a] Of the 16 patients who were refused randomization by the physician, data are available for 15. The bougie was used in all 15 cases, with first-attempt success in 14 of 15 patients (93%). Reasons for protocol deviations and refusal included anticipated difficult airway and perceived need for more rapid intubation. Of the 25 patients in the endotracheal tube + stylet group with a protocol deviation (a bougie was passed first rather than an endotracheal tube + stylet), 23 had first-attempt success (92%).

[b] These patients, after laryngoscope insertion, did not have passage of a bougie or endotracheal tube + stylet attempted. All were considered to have first-attempt failure and were intubated on subsequent attempts.

by calculating the difference in the proportions or median difference, as appropriate, between groups, and the associated 95% CI. Hodges-Lehmann median between-group differences and the associated 95% CIs were calculated for continuous variables. Tests of significance were completed using the χ^2 test for binary outcomes and the Wilcoxon rank sum test for continuous outcomes, using a 2-sided threshold of .05. Because the primary outcome analysis was performed on the subgroup of patients with a difficult airway characteristic, we tested for the effect modification of this variable with a test of interaction. In addition, the duration of the first intubation attempt was analyzed using Kaplan-Meier estimates and a log-rank test; hazard ratios were estimated using an unadjusted Cox proportional hazards model. Schoenfeld residuals and data visualization were used to test for proportionality.

Unplanned subgroup analyses were performed for variables of clinical interest. These analyses were exploratory in nature, and a test of interaction for each subgroup was performed. No corrections were made for multiple comparisons. In addition, because individual physician intubation ability can affect first-attempt success, a post hoc analysis accounting for clustering by physician was also completed.

Missing data were left as such, and imputation was not performed. A data and safety monitoring board was established; 1 interim analysis evaluating for futility was completed at the midpoint of the trial (Supplement 2). Because this interim analysis assessed only for futility and not superiority, no adjustments were made to the significance threshold. Stata (StataCorp), version 15.1, was used for data analysis.

Results

Trial Patients

A total of 380 patients with a difficult airway characteristic were enrolled. **Figure 1** shows the flow of patients into the trial. In total, 757 patients were enrolled and randomized to be intubated using either the bougie (381 patients, including 198 with a difficult airway characteristic) or an endotracheal tube + stylet (376 patients, including 182 with a difficult airway characteristic). There were 51 unique emergency physicians who intubated at least 1 patient in the trial; 44 physicians intubated patients randomized to the bougie group on the first intubation attempt, whereas 40 physicians intubated patients randomized to the endotracheal tube + stylet group. The median number of intubations per physician was 8 (interquartile range, 1-26; range, 1-61). Adherence to the randomized allocation was 98% in the bougie group and 92% in the endotra-

cheal tube + stylet group. The 2 groups were well balanced in terms of patient characteristics and clinical indications for intubation (**Table 1**) and intubation process measures (**Table 2**).

Primary Outcome

Among the 380 patients with at least 1 difficult airway characteristic, first-attempt intubation success was higher in the bougie group (96%) than in the endotracheal tube + stylet group (82%); absolute between-group difference, 14% (95% CI, 8%-20%). An analysis accounting for clustering by physician did not significantly change the study results (eTable 1 in Supplement 2).

Secondary Trial Outcomes

Among the study population as a whole, first-attempt intubation success in the bougie group (98%) was higher than the endotracheal tube + stylet group (87%); absolute difference, 11% (95% CI, 7%-14%). For patients without any difficult airway characteristics, first-attempt intubation success in the bougie group was 99% compared with 92% in the endotracheal tube + stylet group (absolute difference, 8% [95% CI, 4%-12%]). There was no significant interaction between bougie use and presence of difficult airway characteristics on the outcome of first-attempt intubation success (P = .36). **Table 3** provides secondary outcomes of this trial.

In exploratory analyses, the effect of the bougie over a endotracheal tube + stylet in facilitating first-attempt intubation success was also present in several subgroups, including patients requiring cervical in-line immobilization (100% vs 78%, respectively), obese patients (96% vs 75%), and patients with incomplete glottic views on laryngoscopy corresponding to Cormack-Lehane grades 2 to 4 (97% vs 60%) (Table 3).

Kaplan-Meier estimates of time until first-attempt intubation success for patients with a difficult airway characteristic are displayed in **Figure 2**. There was a significant difference in intubation times between the 2 groups (log-rank P = .02; hazard ratio for first-attempt intubation success in the bougie group, 1.29 [95% CI, 1.04-1.60], with endotracheal tube + stylet group as reference). Kaplan-Meier estimates including all patients are displayed in eFigure 1 in Supplement 2. There was no significant difference between groups (log-rank P value, 0.12; hazard ratio for the bougie group, 1.12 [95% CI, 0.97-1.30], with endotracheal tube + stylet group as reference). Analysis of scaled Schoenfeld residuals and data visualization demonstrated that the assumption of proportional hazards was not upheld. In an unplanned, post hoc subgroup analysis including only patients with a successful first attempt, the bougie use resulted in a longer median first-attempt duration than the endotracheal tube (38 seconds vs 34 seconds; absolute difference, 4 seconds [95% CI, 2-7]) (Table 3).

Other Outcomes

In total, the bougie was used in 444 patients; tracheal clicks (tactile vibrations felt by the operator as the bougie tip scrapes along the tracheal rings) were reported in 404 intubations (91%). Although it was not mandated that the operator verify a hold-up sign upon bougie advancement (caused by the distal bougie wedging in a bronchus at a bougie depth of about 30 cm, thus confirming correct placement; if no hold-up occurs by 35 cm, this indicates esophageal placement), the hold-up sign was reported in 283 intubations (64%). During intubation over a bougie, the endotracheal tube tip met resistance on the arytenoid cartilages in 31 patients (7%); in all but

Table 1. Baseline Characteristics of Patients Admitted to the Emergency Department Undergoing Orotracheal Intubation Using a Bougie vs an Endotracheal Tube + Stylet

Characteristic	Bougie Group, No. (%) (n = 381)	Endotracheal Tube + Stylet Group, No. (%) (n = 376)
Age, mean (SD), y	46 (18)	46 (18)
Men	272 (71)	255 (68)
BMI, mean (SD)[a]	28 (7)	28 (7)
Heart rate, mean (SD), beats/min[b]	108 (25	107 (25)
Systolic blood pressure, mean (SD), mm Hg[b]	135 (30)	134 (32)
Oxygen saturation, median (IQR), %[b]	99 (95-100)	99 (96-100)
<90%[b]	44/352 (13)	40/344 (12)
<80%[b]	21/352 (6)	11/344 (3)
Indication for intubation		
Medical	318 (83)	315 (84)
Altered mental status	185 (49)	173 (46)
Cardiac arrest	32 (8)	23 (6)
Septic shock	21 (6)	27 (7)
Seizure	20 (5)	28 (7)
Asthma, COPD, heart failure, pneumonia	16 (5)	23 (7)
Other	44 (14)	41 (13)
Trauma	63 (17)	61 (16)
Traumatic brain injury	29 (8)	23 (6)
Other	34 (9)	38 (10)
Difficult airway characteristic present	198 (52)	182 (48)
Blood or vomit in airway	83 (22)	67 (18)
Obesity[c]	57 (15)	68 (18)
Cervical immobilization	49 (13)	36 (10)
Large tongue	31 (8)	34 (9)
Short neck	28 (7)	28 (7)
Facial trauma	20 (5)	12 (3)
Small mandible	14 (4)	18 (5)
Airway obstruction or edema	8 (2)	4 (1)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); COPD, chronic obstructive pulmonary disease; IQR, interquartile range.

[a] BMI was calculated by chart review using a measured weight and height.

[b] Initial vital signs were the first vital signs after enrollment but before intubation. Not all had initial vital signs available due to not being connected to the monitor or unreliability of the oximetry waveform: 61 (29 in bougie group; 32 in endotracheal tube + stylet group), 185 (94 in bougie group; 91 in endotracheal tube + stylet group), and 43 (19 in bougie group; 24 in endotracheal tube + stylet group) patients had no heart rate, systolic blood pressure, and oxygen saturation, respectively, available before intubation.

[c] Sixty-four patients in the bougie group and 68 patients in the endotracheal tube + stylet group had a BMI of ≥30 but were not classified as obese by the intubating physician; these 132 patients had a mean BMI of 34. Those considered obese by the intubating physician had a mean BMI of 37.

Table 2. Intubation Process Measures Among Patients Admitted to the Emergency Department Undergoing Orotracheal Intubation Using a Bougie vs an Endotracheal Tube + Stylet

Measure	Bougie Group, No. (%) (n = 381)	Endotracheal Tube + Stylet Group, No. (%) (n = 376)	Difference, % (95% CI)	*P* Value
Preoxygenation				
Non-rebreather mask	267 (70)	276 (73)	−3 (−10 to 3)	.31
Non-rebreather mask at flush rate oxygen, No. of patients/total patients with non-rebreather masks (%)	204/267 (76)	210/276 (76)	0 (−7 to 7)	.93
Bag and mask ventilation	47 (12)	37 (10)	2 (−2 to 7)	.27
Noninvasive positive pressure ventilation	18 (5)	24 (6)	−2 (−5 to 2)	.32
Extraglottic device	27 (7)	17 (5)	3 (−1 to 6)	.13
Preintubation sedative, any[a]	338 (89)	341 (91)	−2 (−6 to 2)	.37
Etomidate	332 (87)	333 (89)	−1 (−6 to 3)	.54
Ketamine	4 (1)	4 (1)	0 (−1 to 1)	.99
Preintubation neuromuscular blockade, any[b]	366 (96)	367 (98)	−2 (−4 to 1)	.23
Succinylcholine	214 (56)	229 (61)	−5 (−12 to 2)	.19
Rocuronium	147 (39)	137 (36)	2 (−5 to 9)	.54
Patient position for intubation				
Sniffing position[c]	222 (58)	244 (65)	−7 (−14 to 0)	.06
Neutral cervical spine	117 (31)	96 (26)	5 (−1 to 12)	.11
Cervical spine extension without sniffing position	39 (10)	32 (9)	2 (−2 to 6)	.42
Oxygen saturation at start of intubation attempt, median (IQR), %[d]	100 (98-100)	100 (98-100)	0 (0 to 0)	.60
<90%, No. of patients/total patients with data (%)[d]	22/360 (6)	27/343 (8)	−2 (−6 to 2)	.36
<80%, No. of patients/total patients with data (%)[d]	13/360 (4)	8/343 (2)	1 (−1 to 4)	.32
Apneic oxygenation with nasal cannula[e]	221 (58)	227 (60)	−2 (−9 to 5)	.51
Operator[f]				
Emergency medicine senior resident or fellow (postgraduate year 3 or higher)	318 (83)	334 (89)	−5 (−10 to 0)	.03
Emergency medicine junior resident (postgraduate year 2 or below)	57 (15)	37 (10)	5 (0 to 10)	.03
Emergency medicine faculty	8 (2)	5 (1)	1 (−1 to 3)	.42
Laryngoscope used				
C-MAC Macintosh blade	362 (95)	366 (97)	−2 (−5 to 0)	.10
GlideScope Titanium MAC blade	12 (3)	8 (2)	1 (−1 to 3)	.38
Macintosh direct laryngoscope	7 (2)	2 (1)	1 (0 to 3)	.10
Video screen use for video laryngoscopy, No. of patients/total patients with data (%)[g]				
Screen never used	218/377 (58)	182/372 (49)	9 (2 to 16)	.02
Screen viewed for entire attempt	78/377 (21)	90/372 (24)	−4 (−9 to 2)	.25
Screen viewed during passage of tube or bougie into glottis	75/377 (20)	98/372 (26)	−6 (−12 to 0)	.04
Best Cormack-Lehane view, No. of patients/total patients with data (%)[h]				
Grade 1 (best view)	269/373 (72)	269/359 (75)	−3 (−9 to 4)	.39
Grade 2	74/373 (20)	62/359 (17)	3 (−3 to 8)	.39
Grade 3	27/373 (7)	23/359 (6)	1 (−3 to 4)	.66
Grade 4 (worst view)	3/373 (1)	5/359 (1)	−1 (−2 to 1)	.44
First device entered into mouth after laryngoscope				
Bougie	372 (98)	25 (7)	91 (88 to 94)	<.001
Endotracheal tube + stylet	4 (1)	345 (92)	−91 (−94 to −88)	<.001
Laryngoscope withdrawn before attempted passage of bougie or endotracheal tube + stylet	5 (1)	6 (2)	0 (−2 to 1)	.75

Abbreviation: IQR, interquartile range.

[a] Of the 78 patients without sedative administration, 53 (68%; 31 and 22 in the bougie and endotracheal tube + stylet groups, respectively) had received sedation prehospital or were in cardiac arrest. Sedatives other than ketamine or etomidate are not listed.

[b] Drugs other than succinylcholine and rocuronium are not listed.

[c] The sniffing position was defined as flexion of the neck and extension of the atlanto-occipital joint to align the external auditory meatus with the sternal notch.

[d] Twenty-one patients in the bougie group and 33 patients in endotracheal tube + stylet group did not have an oxygen saturation at the start of the attempt due to an unreliable oximetry waveform.

[e] Nasal cannula left in place during intubation.

[f] This lists the final intubating physician. During the course of intubation, a change of intubating physician occurred 8 times total, 4 times per group.

[g] Video screen use was determined by the intubating physician, and documented on the postintubation data form. There were 4 missing values in each group.

[h] Grade 1: all or most of the glottic opening seen; grade 2: only the posterior portion of the glottis or only arytenoid cartilages are visible; grade 3: only the epiglottis but no portion of the glottis is visible; grade 4: neither the glottis nor the epiglottis can be seen. There are missing data for 8 patients in the bougie group and 17 patients in the endotracheal tube + stylet group.

Table 3. Trial Outcomes Among Patients Admitted to the Emergency Department Undergoing Orotracheal Intubation Using a Bougie vs an Endotracheal Tube + Stylet

Outcome	Bougie Group		Endotracheal Tube + Stylet Group		Difference (95% CI)	*P* Value	Interaction *P* Value[a]
	No. With Event/ Total No. of Patients	% (95% CI)	No. With Event/ Total No. of Patients	% (95% CI)			
Primary Outcome							
First-attempt intubation success, patients with any difficult airway characteristic (n = 380)	191/198	96 (93 to 99)	150/182	82 (76 to 88)	14 (8 to 20)	<.001	.36
Planned Secondary Outcomes							
Patients with any difficult airway characteristic (n = 380)							
First-attempt intubation success without hypoxemia[b]	156/191	82 (76 to 87)	123/177	69 (63 to 76)	12 (3 to 21)	.006	.61
First-attempt duration, median (IQR), s[c]	39 (29 to 52)		40 (27 to 63)		−1 (−6 to 3)	.50	.17
All patients (N = 757)							
First-attempt intubation success, overall	373/381	98 (96 to 99)	328/376	87 (83 to 90)	11 (7 to 14)	<.001	NA
First-attempt intubation success without hypoxemia[b]	317/371	85 (81 to 89)	282/366	77 (72 to 81)	8 (3 to 14)	.003	NA
First-attempt duration, median (IQR), s[c]	38 (29 to 51)		36 (25 to 54)		1 (4 to −1)	.24	NA
Unplanned Subgroup Analyses							
First-attempt intubation success by individual difficult airway characteristic[d]							
Blood or vomit in airway (n = 150)	79/83	95 (88 to 99)	55/67	82 (71 to 90)	13 (3 to 23)	.01	.31
Cervical immobilization (n = 85)	49/49	100 (93 to 100)	28/36	78 (61 to 90)	22 (9 to 36)	.001	.25
Obesity (n = 125)	55/57	96 (88 to 100)	51/68	75 (63 to 85)	21 (10 to 33)	.001	.63
First-attempt intubation success, no difficult airway characteristic (n = 377)	182/183	99 (97 to 100)	178/194	92 (87 to 95)	8 (4 to 12)	<.001	.36
First-attempt intubation success when C-MAC used, all patients	356/362	98 (96 to 99)	321/366	88 (84 to 91)	11 (7 to 14)	<.001	.46
First-attempt intubation success by Cormack-Lehane view, all patients							
Grade 1	265/269	99 (96 to 100)	258/269	96 (93 to 98)	3 (0 to 5)	.07	.04
Grade 2	72/74	97 (91 to 100)	41/62	66 (53 to 78)	31 (19 to 44)	<.001	.13
Grade 3	26/27	96 (81 to 100)	11/23	48 (27 to 69)	48 (27 to 71)	<.001	.17
Grade 4	3/3	100 (29 to 100)	2/5	40 (5 to 85)	60 (17 to 100)	.09	.78
First-attempt intubation success by actual first device entered into mouth after laryngoscope, all patients[e]	392/402	98 (95 to 99)	309/355	87 (83 to 90)	10 (7 to 14)	<.001	NA
First-attempt duration if first attempt successful, median (IQR), s[c]	38 (29 to 51)		34 (23 to 47)		4 (2 to 7)	<.001	.03

Abbreviations: IQR, interquartile range; NA, not applicable.

[a] The interaction *P* value column displays NA for analyses that included all patients.

[b] Oxyhemoglobin saturations were recorded in real time by research associates. Hypoxemia was defined as an oxyhemoglobin saturation <90% (or, if the attempt began with a saturation <90%, an absolute decrease in saturation of >10%) during or within 1 min after completion of the intubation attempt. Valid pulse oximetry waveform during intubation was not available for all patients.

[c] Intubation duration was defined as the time elapsed from when the laryngoscope blade entered the mouth to when the blade was removed from the mouth.

[d] Short neck, small mandible, airway obstruction or edema, facial trauma and large tongue subgroups are not displayed because there were too few patients with these characteristics to make a valid comparison between groups.

[e] Those that had the laryngoscope withdrawn before attempted passage of the bougie or endotracheal tube + stylet were considered to have the randomized device passed first for this analysis.

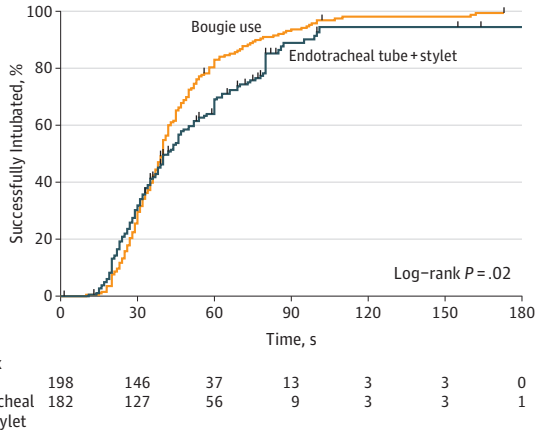
1 of these patients, the tube was rotated 90° counterclockwise and advanced without resistance into the trachea. In 1 patient, the tube could not be advanced, both tube and bougie were removed, and intubation was ultimately successful with a bougie on a subsequent attempt.

Among the 56 patients (7%) in both groups who were not intubated on the first attempt, subsequent attempt(s) were successful with the help of several rescue techniques including the bougie in 49 patients, the intubating laryngeal mask airway in 1 patient, and cricothyrotomy in 1 patient (**Table 4**).

Complications

Complications were infrequent and occurred with a similar frequency in both groups (**Table 5**). The incidence of hypoxemia

Figure 2. Duration of the First Intubation Attempt Until Successful Intubation Using a Bougie vs Endotracheal Tube + Stylet Among Patients With 1 or More Difficult Airway Characteristics



No. at risk

Bougie	198	146	37	13	3	3	0
Endotracheal tube + stylet	182	127	56	9	3	3	1

The hazard ratio for first-attempt success in the bougie group was 1.29 (95% CI, 1.04 to 1.60), with endotracheal tube + stylet group as reference. Vertical ticks mark the time point when the intubation attempt for ≥1 patients ended in failure. The assumption of proportional hazards over time was not upheld.

Table 4. Successful Technique After Failed First Attempt Among Patients Admitted to the Emergency Department Undergoing Orotracheal Intubation With a Bougie vs Endotracheal Tube + Stylet

Attempt Detail	Bougie Group (n = 8)	Endotracheal Tube + Stylet Group (n = 48)
Same (first) laryngoscopic insertion		
Bougie	0	34 (71)
Endotracheal tube + stylet	0	1 (2)[a]
Second laryngoscopic insertion		
Bougie	6 (75)	6 (13)
Endotracheal tube + stylet	0	3 (6)
Second attempt with different intubating device[b]	0	2 (4)
>2 Attempts[c]	2 (25)	2 (4)

[a] This patient had the bougie used first, which failed, and the endotracheal tube + stylet was used on the same attempt to successfully intubate the patient.

[b] One was rescued with an intubating laryngeal mask airway; 1 had a cricothyrotomy.

[c] Three of 4 were intubated on the third attempt with a bougie; the fourth had a tracheal abnormality and was intubated after several attempts with 4.0 mm stylet and endotracheal tube.

during intubation was similar between the bougie group (13%) and the endotracheal tube + stylet group (14%). No patients had an esophageal intubation in the bougie group, and 3 patients (1%) had esophageal intubation in the endotracheal tube + stylet group (Table 5).

Discussion

In this trial, orotracheal intubation with a bougie on the initial intubation attempt compared with intubation using a stylet and endotracheal tube led to improved first-attempt intubation success in patients with at least 1 difficult airway characteristic. In light of the significant association between first-attempt intubation success and fewer intubation-related adverse events in previous research,[4,16-19] the bougie may be beneficial as a primary intubation device rather than solely as a rescue adjunct.

Several hypotheses could explain the mechanism by which the bougie affects first-attempt intubation success. First, by virtue of its smaller diameter compared with the endotracheal tube, the bougie obscures less of the operator's view of the glottic inlet as it approaches, allowing the trachea to be intubated more easily and confidently. Second, the bougie has advantages when an incomplete view of the glottis is obtained (Cormack-Lehane grade 2-4), as was the case in nearly one-third of patients in this study. In this instance, the coudé tip can be placed under the epiglottis and can blindly enter the glottic opening[8,15,20-22]; clicking against tracheal rings during passage and holding up when the tip lodges in the bronchial tree, providing tactile feedback of proper placement.[15] The bougie likely has a higher chance of blindly accessing the glottic opening when compared with the larger-caliber endotracheal tube.

If emergency physicians in this trial had inadequate training or experience intubating with an endotracheal tube + stylet (because the majority of ED intubations at this institution utilized a bougie prior to this trial[6]), between-group differences in first-attempt intubation success could have been biased away from the null. The first-attempt success in the endotracheal tube and stylet group in this trial, however, compares favorably with success rates reported elsewhere using this same strategy. For example, in patients with 1 or more difficult airway characteristics, Sakles et al[23] reported a first-attempt success rate of 78% when a video laryngoscope was used compared with 82% in this study for endotracheal tube + stylet. In the same study,[23] Sakles et al, examining patients without any difficult airway characteristics, reported a first-attempt success rate of 91% when a video laryngoscope was used compared with 92% in this study for endotracheal tube + stylet. Describing more than 13 000 resident physician intubations in the ED (not distinguishing those with a difficult airway), Brown et al[3] reported first-attempt success of 86.9%, which is similar to the 87% observed in this trial among all patients randomized to an endotracheal tube + stylet. Furthermore, a meta-analysis of more than 42 000 ED intubations reported first-attempt success to be 84.1%.[24] Taken together, these comparisons argue against inferior institutional performance intubating with endotracheal tube + stylet in the current trial.

Because more than 96% of patients were intubated using the C-MAC Macintosh blade for the initial attempt, this study can essentially be seen as a comparison of first attempt intubation success using the C-MAC Macintosh blade with or without the bougie. First-attempt success using the C-MAC Macintosh blade in a large ED registry was 91%,[3] which contrasts to first-attempt success achieved in this study using C-MAC Macintosh blade with a bougie achieved in this study

Table 5. Intubation Complications Among Patients Admitted to the Emergency Department Undergoing Orotracheal Intubation Using a Bougie vs an Endotracheal Tube + Stylet

Complication	Bougie Group, No. of Patients (%) (n = 381)	Endotracheal Tube + Stylet Group, No. of Patients (%) (n = 376)	Difference, % (95% CI)	*P* Value
Any complication[a]	66 (17)	63 (17)	1 (−5 to 6)	.83
Hypoxemia, No. of patients/total patients with data (%)[b]	47/371 (13)	50/364 (14)	−1 (−6 to 4)	.67
Pneumothorax diagnosed after intubation	9 (2)	9 (2)	0 (−2 to 2)	.99
Pneumothorax postintubation without clear cause[c]	1 (<1)	3 (1)	−1 (−2 to 1)	.31
Lip laceration	7 (2)	3 (1)	1 (−1 to 3)	.21
Witnessed aspiration during intubation	3 (1)	1 (<1)	1 (−1 to 2)	.32
Iatrogenic bleeding from oropharynx or perilaryngeal structures	2 (1)	2 (1)	0 (−1 to 1)	.99
Dental trauma	1 (<1)	1 (<1)	0 (−1 to 1)	.99
Esophageal intubation	0	3 (1)	−1 (−2 to 0)	.08
Direct airway injury	0	0		

[a] Some patients had >1 complication and were only counted once in this composite variable.

[b] Oxyhemoglobin saturations were recorded in real time by research associates. Hypoxemia was defined as an oxyhemoglobin saturation <90% (or, if the attempt began with a saturation <90%, an absolute decrease in saturation of >10%) during or within 1 min after completion of the intubation attempt. Valid pulse oximetry waveform during intubation was not available for all patients. A valid pulse oximetry waveform was not available for all patients.

[c] Clear causes included chest trauma with rib fractures or patients who received chest compressions as part of cardiopulmonary resuscitation. None of these 4 patients had the etiology of the pneumothorax definitively identified.

(98%). This supports the finding that the bougie could have incremental benefit in improving first-attempt success in the ED and suggests an expanded role for expansion of the role of the bougie beyond difficult airways[15,21,22,25] and rescue after failed attempts.[7,25-27] To our knowledge, first-attempt success in the ED as high as 98% has not previously been reported using any combination of airway devices or algorithms, though introduction of a new intubation protocol combining the C-MAC video laryngoscope and the bougie in a helicopter system improved first-attempt success to above 98%.[28]

The trial data may be interpreted as supporting greater ease of use of the bougie compared with the endotracheal tube + stylet. A greater proportion of operators using the bougie vs the endotracheal tube never viewed the video laryngoscopy screen during the procedure (Table 2). Similarly, although bougie use requires the additional step of placing the endotracheal tube over the bougie, the duration of the first attempt with bougie use was shorter (based on the results of the Cox proportional hazard model) for patients with a difficult airway characteristic and similar when considering all patients. Because laryngeal views were comparable between groups, these findings suggest that passing the device into the trachea is simpler with a bougie compared with an endotracheal tube + stylet.

Challenges may be anticipated when learning or performing bougie-assisted orotracheal intubation. The endotracheal tube can encounter resistance at the arytenoid cartilages when being passed over a bougie. This was observed in 7% of intubations in the bougie group, but was remedied by slight withdrawal of the tube, 90° counterclockwise rotation, and readvancement in all cases except 1 (Figure S1 in Supplement 2).[12,13] The coudé tip of the bougie can occasionally impinge on the anterior larynx after passing through the glottis; this is remedied by slight withdrawal of the bougie, rotation of the tip posteriorly, and advancement.[13] Few instances of bougie-related complications have been reported in the literature,[29-33] and the bougie is generally viewed as a safe device[34,35]; this trial supports this view, with complications being rare in both groups without clear causative links. Use of the hold-up sign, however, may increase the risk of pneumothorax, especially if the bougie does not have a coudé tip, which allows penetration of the bougie into smaller, more fragile bronchi.[32,36] Because of the danger of the hold-up sign, it should not be sought when the intubator knows the bougie has been correctly placed into the trachea, either by visualization of the bougie anterior to the arytenoid cartilages or detection of tracheal clicks. If sought, the intubator should do so gently.

Limitations

This study has several limitations. First, these data are from a single institution with a history of bougie use,[13,37] hence the results may not be generalizable to physicians less familiar with its use. Second, difficult airway characteristics were based on a subjective assessment of the patient before and during intubation and may be subject to a wide range of interpretation; although interphysician agreement estimates for these difficult airway characteristics have not been established, prior work has demonstrated increased first-attempt failure and intubation-associated complications when at least 1 characteristic is present.[4,11] Third, because not all difficult airway characteristics were ascertainable before intubation, we could not stratify randomization by difficult airway characteristics; therefore the primary analysis represented a postrandomization subgroup

analysis. However, first-attempt success with bougie use was higher than the endotracheal tube + stylet in subgroups both with and without a difficult airway characteristic. Fourth, this trial used a single-use, straight bougie with a coudé tip. These results may not generalize to bougies packaged in a curled position, which may be more difficult to advance into the glottis.[38]

Fifth, 7% of patients randomized to the endotracheal tube + stylet group were intubated using a bougie on the first attempt (protocol violation); this was ascribed to anticipated difficulty or need for rapid intubation. This bias toward the null had little consequence on the trial results, as intubation success for protocol violations changing from endotracheal tube to bougie was higher than first-attempt success for the endotracheal tube + stylet group. Sixth, it was not possible to conceal group allocation by blinding the emergency physicians and research assistants to the device used for the initial intubation attempt. Biased assessment of outcomes by research assistants was minimized by objective definitions of primary and secondary outcomes, such as first-attempt success and time to intubation. Differential treatment of the groups by unblinded emergency physicians is also of lesser concern, as first-attempt success in the endotracheal tube + stylet group in this trial was similar to previous studies. Seventh, the assumption of proportional hazards between groups for first-attempt duration was not upheld, which limits interpretation for this outcome. Eighth, patients who underwent intubation with hyperangulated laryngoscopes were excluded; thus, the results do not generalize to these devices.

Conclusions

In this emergency department, use of a bougie compared with an endotracheal tube + stylet resulted in significantly higher first-attempt intubation success among patients undergoing emergency endotracheal intubation. However, these findings should be considered provisional until the generalizability is assessed in other institutions and settings.

ARTICLE INFORMATION

Accepted for Publication: April 24, 2018.

Published Online: May 16, 2018. doi:10.1001/jama.2018.6496

Author Contributions: Dr Driver had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Driver, Klein, Reardon, Miner, Fagerstrom, Cole.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Driver, Klein, McGill, Cole.
Critical revision of the manuscript for important intellectual content: Driver, Prekker, Klein, Reardon, Miner, Fagerstrom, Cleghorn, Cole.
Statistical analysis: Driver, Klein.
Obtained funding: Miner.
Administrative, technical, or material support: Driver, Reardon, Miner, Fagerstrom, Cleghorn.
Supervision: Driver, Reardon, Miner, McGill, Cole.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Miner reported grant funding from Securisyn Medical. No other disclosures were reported.

Meeting Presentation: This article was presented at the Society for Academic Emergency Medicine on May 16, 2018.

Additional Contributions: We thank the Hennepin County Medical Center residents and Research Associate Program for their contribution to research in emergency medicine. They did not receive compensation for their contributions.

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