JAMA | Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Effect of Use of a Bougie vs Endotracheal Tube With Stylet on Successful Intubation on the First Attempt Among Critically Ill Patients Undergoing Tracheal Intubation
A Randomized Clinical Trial

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IMPORTANCE For critically ill adults undergoing emergency tracheal intubation, failure to intubate the trachea on the first attempt occurs in up to 20% of cases and is associated with severe hypoxemia and cardiac arrest. Whether using a tracheal tube introducer ("bougie") increases the likelihood of successful intubation compared with using an endotracheal tube with stylet remains uncertain.

OBJECTIVE To determine the effect of use of a bougie vs an endotracheal tube with stylet on successful intubation on the first attempt.

DESIGN, SETTING, AND PARTICIPANTS The Bougie or Stylet in Patients Undergoing Intubation Emergently (BOUGIE) trial was a multicenter, randomized clinical trial among 1102 critically ill adults undergoing tracheal intubation in 7 emergency departments and 8 intensive care units in the US between April 29, 2019, and February 14, 2021; the date of final follow-up was March 14, 2021.

INTERVENTIONS Patients were randomly assigned to use of a bougie (n = 556) or use of an endotracheal tube with stylet (n = 546).

MAIN OUTCOMES AND MEASURES The primary outcome was successful intubation on the first attempt. The secondary outcome was the incidence of severe hypoxemia, defined as a peripheral oxygen saturation less than 80%.

RESULTS Among 1106 patients randomized, 1102 (99.6%) completed the trial and were included in the primary analysis (median age, 58 years; 41.0% women). Successful intubation on the first attempt occurred in 447 patients (80.4%) in the bougie group and 453 patients (83.0%) in the stylet group (absolute risk difference, −2.6 percentage points [95% CI, −7.3 to 2.2]; P = .27). A total of 58 patients (11.0%) in the bougie group experienced severe hypoxemia, compared with 46 patients (8.8%) in the stylet group (absolute risk difference, 2.2 percentage points [95% CI, −1.6 to 6.0]). Esophageal intubation occurred in 4 patients (0.7%) in the bougie group and 5 patients (0.9%) in the stylet group, pneumothorax was present after intubation in 14 patients (2.5%) in the bougie group and 15 patients (2.7%) in the stylet group, and injury to oral, glottic, or thoracic structures occurred in 0 patients in the bougie group and 3 patients (0.5%) in the stylet group.

CONCLUSIONS AND RELEVANCE Among critically ill adults undergoing tracheal intubation, use of a bougie did not significantly increase the incidence of successful intubation on the first attempt compared with use of an endotracheal tube with stylet.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03928925

JAMA. doi:10.1001/jama.2021.22002
Published online December 8, 2021.

Supplemental content

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Approximately 1.6 million critically ill adults undergo tracheal intubation annually in the US.[1,2] Failure to intubate the trachea on the first attempt occurs in up to 20% of tracheal intubations in the emergency department (ED) or intensive care unit (ICU) and is associated with an increased risk of severe hypoxemia, cardiac arrest, and death.[3,4]

Two devices are commonly used to facilitate tracheal intubation: a stylet or a tracheal tube introducer (referred to as a "bougie").[5] A stylet is a malleable metal rod placed inside the endotracheal tube to facilitate its passage into the trachea. A bougie is a thin plastic rod that is passed into the trachea, over which the endotracheal tube is inserted. Historically, most emergency tracheal intubations in the US have been performed using a stylet, with use of a bougie reserved for difficult intubations.[5,6] However, 3 recent observational studies and 1 randomized trial found that routinely using a bougie rather than a endotracheal tube with a stylet was associated with an increased incidence of intubation on the first attempt.[7-9] The only randomized clinical trial directly comparing the devices during tracheal intubation of critically ill adults was limited by its conduct in a single site in which clinicians routinely used the bougie on the first intubation attempt before the trial.[10] Despite that limitation, recent expert recommendations encourage routine use of a bougie for tracheal intubation.[11,12]

The Bougie or Stylet in Patients Undergoing Intubation Emergently (BOUGIE) trial was conducted to compare the effect of using a bougie vs an endotracheal tube with stylet on outcomes of tracheal intubation in EDs and ICUs across multiple health systems. The hypothesis was that use of a bougie would result in a higher incidence of successful intubation on the first attempt, compared with use of a stylet.

Key Points

Question In critically ill adult patients undergoing tracheal intubation, does use of a tracheal tube introducer ("bougie") increase the incidence of successful intubation on the first attempt, compared with use of an endotracheal tube with stylet?

Findings In this randomized clinical trial that included 1102 critically ill adults, successful intubation on the first attempt was 80.4% with use of a bougie and 83.0% with use of an endotracheal tube with stylet, a difference that was not statistically significant.

Meaning Among critically ill adults undergoing tracheal intubation, use of a bougie did not significantly increase the incidence of successful intubation on the first attempt compared with use of an endotracheal tube with stylet.

Methods

Trial Design and Oversight

This multicenter, parallel-group, unblinded, pragmatic, randomized clinical trial compared use of a bougie with use of an endotracheal tube with stylet for tracheal intubation of critically ill adults. The trial was approved with waiver of informed consent by the central institutional review board at Vanderbilt University Medical Center and the local institutional review board at each trial site through reliance agreement or primary review. The trial was overseen by an independent data and safety monitoring board and registered before initiation of enrollment. Enrollment began on April 29, 2019, was paused from February 28, 2020, until August 24, 2020, during the COVID-19 pandemic, and concluded on February 14, 2021. The protocol and statistical analysis plan (Supplement 1) were submitted for publication before enrollment concluded.[13]

Trial Sites and Patient Population

The trial was conducted at 15 sites, including 7 EDs and 8 adult ICUs in 11 hospitals across the US. Patients were eligible if they were undergoing tracheal intubation with the planned use of sedation and a nonhyperangulated (eg, Macintosh [curved] or Miller [straight]) laryngoscope blade. Patients were excluded if they were pregnant, were incarcerated, had an immediate need for tracheal intubation without time for randomization, or if the clinician performing the intubation procedure (referred to as the "operator") determined that use of a bougie or a stylet was either required or contraindicated. Details of the trial sites and complete lists of inclusion and exclusion criteria are provided in Supplement 2.

Randomization

Patients underwent randomization in a 1:1 ratio to intubation using a bougie or an endotracheal tube with stylet, according to a computer-generated list using randomly permuted blocks of 2, 4 and 6, stratified according to trial site. Trial-group assignments were placed in sequentially numbered opaque envelopes and remained concealed until after enrollment. Given the nature of the intervention, operators and research personnel were aware of trial-group assignments after randomization.

Trial Interventions

Before beginning enrollment, operators received structured education regarding best practices in use of a bougie and endotracheal tube with stylet via a standardized training video[14] and in-person training from the site principal investigator.

During the trial, for patients assigned to the bougie group, operators were instructed to use a bougie for the first attempt at tracheal intubation. Operators were instructed to pass the bougie into the trachea, have an assistant load the endotracheal tube (without a stylet) onto the bougie, advance the tube over the bougie through the vocal cords to the desired depth, and withdraw the bougie and the laryngoscope.

For patients assigned to the stylet group, operators were instructed to use an endotracheal tube with a malleable stylet for the first attempt at tracheal intubation. The trial protocol recommended shaping the stylet straight with a distal bend of 25° to 35°.[14]

As a pragmatic trial, delivery of the assigned intervention occurred within routine clinical care, and trial group assignment determined only whether a bougie or an endotracheal tube with stylet was used during the first attempt at tracheal intubation. All other aspects of the procedure were deferred

to the operator, including laryngoscope selection, choice of induction medication, and use of a bougie or a stylet during subsequent attempts at intubation if the first attempt was unsuccessful.

Data Collection

A trained, independent observer collected data on the outcomes of the procedure, including the number of intubation attempts, time between induction of sedation and intubation, peripheral oxygen saturation at induction, and the lowest oxygen saturation between induction and 2 minutes after tracheal intubation. Immediately after each intubation, the operator reported the laryngoscope used, the Cormack-Lehane grade of glottic view,[15] whether successful intubation occurred on the first attempt, the presence of difficult airway characteristics (including obesity, body fluid obscuring the glottis, cervical spine immobilization, and facial trauma), the occurrence of complications, and the operator's prior intubation experience, classified as the total number of prior tracheal intubations performed and the total number of prior tracheal intubations performed using a bougie.

Research personnel collected from the medical record data on baseline characteristics, management before and after laryngoscopy, and clinical outcomes. Race and ethnicity were reported by patients or their surrogates as part of clinical care. They were collected from the electronic health record by research personnel using fixed categories to facilitate assessment of the representativeness of the trial population and the generalizability of trial results.

Outcomes

The primary outcome was successful intubation on the first attempt, defined as a single insertion of a laryngoscope blade into the mouth and *either* a single insertion of a bougie into the mouth followed by a single insertion of an endotracheal tube into the mouth *or* a single insertion of an endotracheal tube with stylet into the mouth. The single prespecified secondary outcome was the incidence of severe hypoxemia, defined as an oxygen saturation less than 80% during the interval between induction and 2 minutes after tracheal intubation. Exploratory procedural outcomes, procedural complications, and clinical outcomes are described in Supplement 2.

Sample Size Calculation

Details regarding the determination of the sample size have been reported.[13] Assuming that 84% of patients in the stylet group would experience successful intubation on the first attempt[16] and anticipating that less than 5% of patients would be missing data for the primary outcome, enrollment of 1106 patients was determined to provide 80% power at a 2-sided α level of .05 to detect an absolute difference of 6% in the primary outcome between groups. A difference of this magnitude has been considered clinically meaningful in the design of prior airway management trials.[10,17,18]

Statistical Analysis

The primary analysis was an unadjusted comparison of the primary outcome between patients in the 2 trial groups using the χ^2 test, with results reported as an absolute risk difference and 95% CIs. Patients were analyzed according to the group to which they were randomly assigned. The primary analysis included all randomized patients except those withdrawn from the study for prisoner status identified after intubation. Sensitivity analyses used alternate definitions of the trial population and primary outcome, including (1) an analysis that defined successful intubation on the first attempt using only laryngoscopy attempts, (2) an analysis that considered intubations with crossover in the assigned intervention as not achieving successful intubation on the first attempt, (3) an analysis that limited the population to intubations performed by operators who had completed at least 10 previous intubations, and (4) an analysis that limited the population to intubations performed by operators who had completed at least 5 previous intubations using a bougie (Supplement 2).

In additional analyses adjusting for baseline covariates, a generalized linear mixed-effects model using a logit link function was fit for the primary outcome, with random effects for operator and study site and fixed effects for trial group and the following prespecified baseline covariates: age, sex, race and ethnicity, body mass index, the operator's prior number of tracheal intubations, and location (ED vs ICU). A second model also included use of a video laryngoscope, presence of difficult airway characteristics, and the Cormack-Lehane grade of glottic view.[15] In adjusted analyses, missing data for baseline covariates was imputed using multiple imputations. Effect modification was assessed by including an interaction term between prespecified baseline covariables and trial group assignment in the above models (Supplement 2).

After the enrollment of 553 patients, the data and safety monitoring board conducted a single interim analysis to review adverse event data and compare the incidence of successful intubation on the first attempt between groups using a Haybittle-Peto stopping boundary for efficacy of $P < .001$. For the final analysis of the primary outcome, a 2-sided P value less than .05 was considered to indicate statistical significance. Between-group differences in secondary and exploratory outcomes were reported using complete-case analysis with the use of point estimates and 95% CIs. The widths of the CIs have not been adjusted for multiplicity and should not be used to infer definitive differences in treatment effects between groups. Findings for these analyses should be interpreted as exploratory.

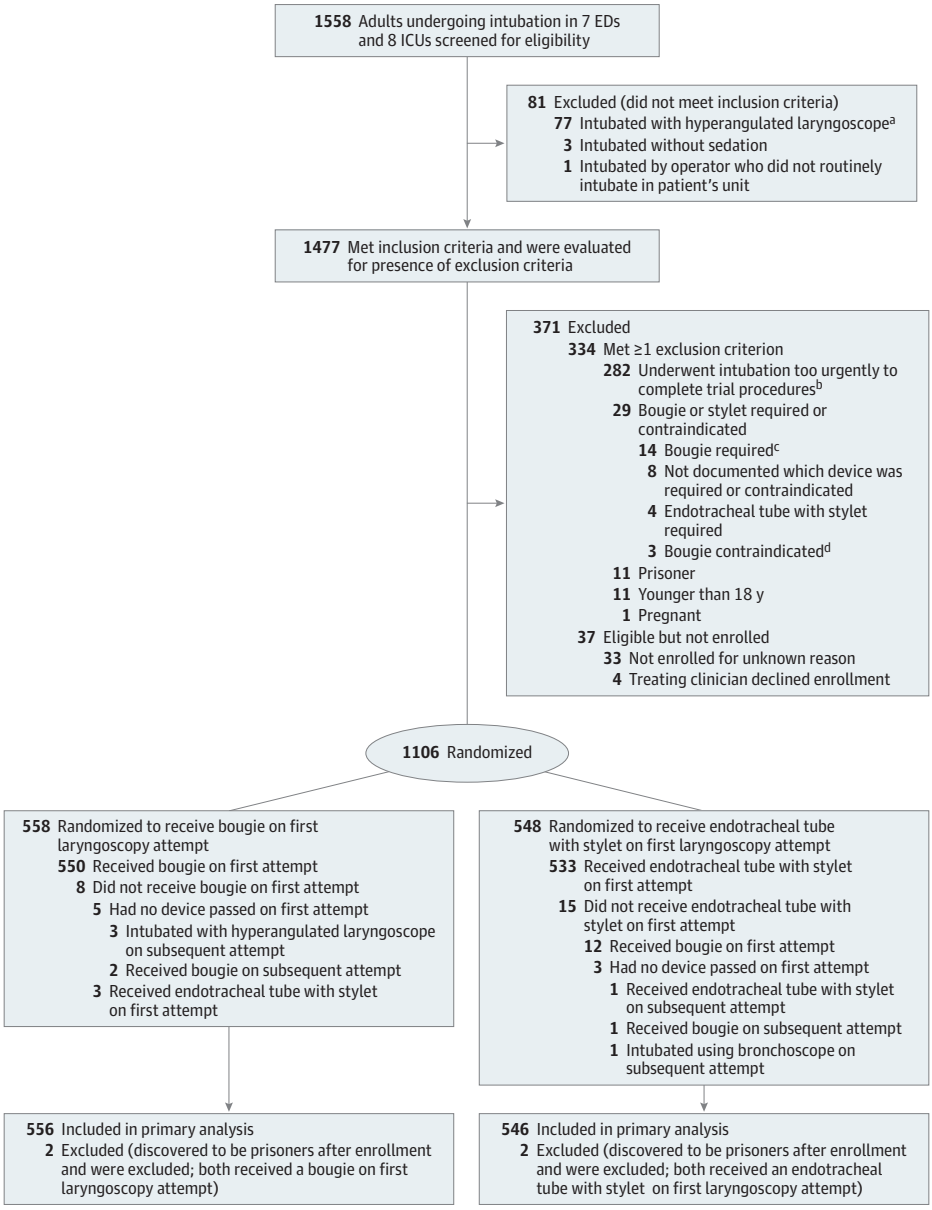
All analyses were performed using R version 4.1.0 (R Foundation for Statistical Computing).

Results

Patients

Of the 1558 patients screened, 1106 (71.0%) were enrolled. Four patients were determined to be prisoners after enrollment and were excluded from subsequent data collection and analysis. The remaining 1102 patients were included in the primary analysis (**Figure 1**). The median age was 58 years, and 41.0% were women. Altered mental status (44.6%) and acute respiratory failure (31.5%) were the most common reasons for

Figure 1. Flow of Participants Through the Trial



ED indicates emergency department; ICU, intensive care unit.

[a] Among 77 patients intubated with a hyperangulated laryngoscope, 32 were at a single trial site at which operators preferred a hyperangulated blade when video laryngoscopy was to be performed. The indication for the selection of a hyperangulated blade for the remaining 45 patients was not recorded.

[b] Among 282 patients who underwent intubation too urgently to complete trial procedures, 28 were at trial sites that recorded the reason for the urgency. Of these, 17 patients were experiencing cardiac arrest, 3 had ongoing hematemesis, 3 had severe hypoxemia, 1 had an acute cerebrovascular accident requiring urgent transport, 1 had massive hemoptysis, 1 had a tension pneumothorax, 1 was experiencing a seizure, and 1 had a traumatic injury requiring an emergency procedure.

[c] Reasons a bougie was required: 3 patients with a history of a prior difficult intubation, 3 with body fluids obscuring the glottic view, 1 with morbid obesity, and 7 with unknown reason.

[d] Reasons a bougie was contraindicated: 1 patient with recent lung transplant and concern for damage to the anastomoses; 2 with unknown reason.

tracheal intubation, and 42.0% of patients had 1 or more difficult airway characteristics. A total of 556 patients (50.5%) were assigned to the bougie group and 546 patients (49.5%) to the stylet group (**Table 1**; eTables 1-4 in Supplement 2).

Operators

The specialty, level of training, and prior experience of the operator performing the tracheal intubation procedure are reported in Table 1 and in eTable 5 in Supplement 2. The most common operator specialty was emergency medicine (62.9%), and most operators were resident physicians (61.6%). In each group, operators had performed a median of 60 total prior tracheal intubations, with a median of 10 (IQR, 4-20) prior intubations using a bougie.

Laryngoscopy and Tracheal Intubation

A video laryngoscope was used for 421 patients (75.7%) in the bougie group and 403 patients (73.8%) in the stylet group. A total of 548 patients (98.6%) in the bougie group received a bougie on the first laryngoscopy attempt; 531 patients (97.3%) in the stylet group received an endotracheal tube with stylet on the first laryngoscopy attempt. Additional characteristics of the intubation procedure are shown in **Table 2**, Figure 1, and eTables 6-8 in Supplement 2.

Primary Outcome

Data for the primary outcome were available for all patients. Successful intubation on the first attempt occurred in 447 patients (80.4%) in the bougie group and in 453 patients (83.0%)

Table 1. Baseline Characteristics

Characteristic	Group, No. (%)	
	Bougie (n = 556)	Stylet (n = 546)
Age, median (IQR), y	58 (42-69)	58 (44-67)
Sex		
Female	223 (40.1)	229 (41.9)
Male	333 (59.9)	317 (58.1)
Race or ethnicity, No./total No. (%)[a]		
American Indian or Alaska Native	2/547 (0.4)	3/541 (0.6)
Asian	12/547 (2.2)	13/541 (2.4)
Black, non-Hispanic	137/547 (25.0)	127/541 (23.5)
Hispanic	49/547 (9.0)	55/541 (10.2)
Native Hawaiian or Other Pacific Islander	0/547	1/541 (0.2)
White, non-Hispanic	340/547 (62.2)	336/541 (62.1)
Other	34/547 (6.2)	35/541 (6.5)
Body mass index, median (IQR)[b]	26.1 (22.7-31.3)	26.6 (22.7-31.3)
Indication for intubation[c]		
Altered mental status	246 (44.2)	246 (45.1)
Acute respiratory failure	181 (32.6)	166 (30.4)
Emergency procedure	36 (6.5)	31 (5.7)
Seizure	26 (4.7)	22 (4.0)
Agitation	14 (2.5)	17 (3.1)
Cardiac arrest	13 (2.3)	14 (2.6)
Upper airway obstruction	13 (2.3)	12 (2.2)
Hemodynamic instability	8 (1.4)	11 (2.0)
Other	19 (3.4)	27 (4.9)
Location of intubation procedure		
Emergency department	350 (62.9)	335 (61.4)
Intensive care unit	206 (37.1)	211 (38.6)
≥1 difficult airway characteristics[d]	228 (41.0)	235 (43.0)
Obesity[e]	158 (28.4)	158 (28.9)
Body fluid obscuring glottis	50 (9.0)	56 (10.3)
Cervical spine immobilization	48 (8.6)	56 (10.3)
Facial trauma	6 (1.1)	13 (2.4)
Primary diagnosis of trauma	96 (17.3)	100 (18.3)
Active medical conditions[f]		
Acute encephalopathy	372 (66.9)	393 (72.0)
Sepsis or septic shock	174 (31.3)	195 (35.7)
Pneumonia	58 (10.4)	45 (8.2)
Gastrointestinal tract hemorrhage	51 (9.2)	48 (8.8)
Acute respiratory distress syndrome	30 (5.4)	19 (3.5)
Cardiac arrest	21 (3.8)	20 (3.7)
COVID-19	17 (3.1)	17 (3.1)
APACHE II score, median (IQR)[g]	17 (12-22)	17 (12-23)

Abbreviation: APACHE II, Acute Physiology and Chronic Health Evaluation II.

[a] Race and ethnicity were reported by patients or their surrogates as part of clinical care and collected from the electronic health record by research personnel using the fixed categories shown in the table. Patients could report more than 1 race. "Other" was recorded when a patient's race or ethnicity was not represented by any of the available categories. Data on race were missing for 14 patients (1.3%) (9 in the bougie group and 5 in the stylet group).

[b] Data on body mass index (weight in kilograms divided by the square of the height in meters) were missing for 60 patients (5.4%) (31 in the bougie group and 29 in the stylet group).

[c] Abstracted from review of the procedure note and medical record. A full list of indications is reported in eTable 3 in Supplement 2.

[d] Patients could have more than 1 difficult airway characteristic. Characteristics were reported by the operator. Additional difficult airway characteristics collected by chart review are reported in eTable 4 in Supplement 2.

[e] Defined as body mass index 30 or greater or, when body mass index was not available, the presence of a diagnosis of obesity in the electronic health record.

[f] Research personnel obtained data on active medical conditions by review of the electronic health record using prespecified categories. Patients could have more than 1 active medical condition.

[g] Scores on the APACHE II range from 0 to 71, with higher scores indicating a greater severity of illness. Data on APACHE II score were missing for 4 patients (0.4%) because of cardiac arrest with termination of resuscitation in the emergency department (2 in the bougie group and 2 in the stylet group).

in the stylet group, for a risk difference of −2.6 percentage points (95% CI, −7.3 to 2.2; $P = .27$) (**Table 3**; eFigure 1 in Supplement 2). Successful intubation on the first attempt did not significantly differ between groups in an adjusted analysis (adjusted odds ratio, 0.88 [95% CI, 0.64 to 1.22]) (eFigures 2 and 3 and eTable 9 in Supplement 2) or multiple sensitivity analyses, including one defining successful intubation on the first attempt based only on the number of laryngoscope insertions (87.6% vs 88.6%; absolute risk difference, −1.1 percentage points [95% CI, −5.1 to 2.9]) (eTables 10 and 11 in Supplement 2). The odds of successful intubation on the first attempt did not differ significantly between groups in any of the prespecified subgroups, including among more experienced operators, among patients with difficult airway characteristics, or when a video laryngoscope was used (**Figure 2**; eFigures 4 and 5 and eTable 12 in Supplement 2).

Secondary Outcome

A total of 58 patients (11.0%) in the bougie group experienced an oxygen saturation less than 80%, compared with 46 patients

Table 2. Characteristics of the Intubation Procedure

Characteristic	Group, No. (%)	
	Bougie (n = 556)	Stylet (n = 546)
Operator		
Resident	344 (61.9)	335 (61.4)
Fellow	187 (33.6)	186 (34.1)
Attending physician	13 (2.3)	13 (2.4)
Other[a]	12 (2.2)	12 (2.2)
Before induction		
Preoxygenation method[b]		
Nonrebreather mask	286 (51.4)	291 (53.3)
Standard nasal cannula	186 (33.5)	200 (36.6)
Bag-mask device	104 (18.7)	111 (20.3)
Bilevel positive airway pressure	86 (15.5)	71 (13.0)
High-flow nasal cannula	68 (12.2)	62 (11.4)
None	4 (0.7)	2 (0.4)
At induction		
Oxygen saturation[c]		
Median (IQR), %	100 (97-100)	100 (97-100)
<90%, No./total No. (%)	33/533 (6.2)	32/528 (6.1)
Systolic blood pressure, median (IQR), mm Hg[d]	134 (115-153)	128 (110-150)
Sedative administered for induction[e]	545 (98.0)	532 (97.4)
Neuromuscular blocking agent administered[e]	539 (96.9)	531 (97.3)
After induction		
Laryngoscope used on first laryngoscopy attempt		
Direct laryngoscope	132 (23.7)	142 (26.0)
Video laryngoscope	421 (75.7)	403 (73.8)
Storz C-MAC, No.	298	276
McGrath MAC, No.	85	86
Glidescope titanium, No.	38	41
Other[f]	3 (0.5)	1 (0.2)
Device used on first laryngoscopy attempt		
Bougie	548 (98.6)	12 (2.2)
Endotracheal tube with stylet	3 (0.5)	531 (97.3)
Neither[g]	5 (0.9)	3 (0.5)

[a] Included nurse anesthetist, nurse practitioner, and physician assistant.

[b] More than 1 preoxygenation method could be used in each patient. Standard nasal cannula refers to delivery of 100% oxygen at a flow rate of 1 to 15 L per minute. High-flow nasal cannula refers to delivery of up to 100% humidified oxygen at a flow rate of 30 to 70 L per minute.

[c] Data on oxygen saturation at induction were missing in 41 patients (3.7%) (23 in the bougie group and 18 in the stylet group).

[d] Data on systolic blood pressure at induction were missing in 41 patients (3.7%) (27 in the bougie group and 14 in the stylet group).

[e] A full list of induction and neuromuscular blocking agents is reported in eTable 7 in Supplement 2.

[f] Included 3 patients who underwent intubation with a video laryngoscope with a hyperangulated blade and 1 who underwent intubation using a flexible bronchoscope. Results of a sensitivity analysis excluding patients intubated with use of a hyperangulated blade are reported in eTable 10 in Supplement 2.

[g] In 5 patients in the bougie group and 3 in the stylet group, the operator inserted the laryngoscope into the mouth and removed it without an attempt to pass either a bougie or an endotracheal tube on the first attempt. See Figure 1 for devices used after the first laryngoscope insertion.

(8.8%) in the stylet group (absolute risk difference, 2.2 percentage points [95% CI, −1.6 to 6.0]) (Table 3).

Exploratory Outcomes

The median time interval from induction to tracheal intubation was 124 seconds (IQR, 97-180) in the bougie group and 112 seconds (IQR, 85-157) in the stylet group, for a median difference of 12 seconds (95% CI, 4 to 20) (eFigures 1 and 6 in Supplement 2). The incidence of airway complications, which included esophageal intubation, injury to airway structures, and witnessed aspiration during intubation, was 1.8% in each group. The incidence of postintubation pneumothorax was 2.5% in the bougie group and 2.7% in the stylet group (Table 3; eTables 13 and 14 in Supplement 2). A total of 68 patients (12.2%) in the bougie group experienced the composite outcome of cardiovascular collapse, compared with 91 patients (16.7%) in the stylet group (risk difference, −4.4 percentage points [95% CI, −8.8 to −0.1]). Death prior to day 28, censored at hospital discharge, occurred in 152 patients (27.3%) in the bougie group and 184 patients (33.7%) in the stylet group (absolute risk difference, −6.4 percentage points [95% CI, −12.0 to −0.8]).

Discussion

In this multicenter, randomized trial, use of a bougie for tracheal intubation of critically ill adults did not significantly increase the incidence of successful intubation on the first attempt, compared with use of an endotracheal tube with stylet.

Emergency tracheal intubation is a common and potentially lifesaving procedure, with limited prior data informing whether routine use of a bougie is superior to the common practice of using an endotracheal tube with stylet. Prior research has largely been limited to small studies enrolling patients undergoing elective procedures in the operating room in whom difficult airway conditions have been artificially created.[19,20] Only 1 prior randomized clinical trial

Table 3. Outcomes of Tracheal Intubation

Outcome	Group, No. (%)		Absolute risk difference or difference in medians (95% CI)[a]
	Bougie (n = 556)	Stylet (n = 546)	
Primary outcome			
Successful intubation on the first attempt[b]	447 (80.4)	453 (83.0)	−2.6 (−7.3 to 2.2)
Secondary outcome			
Lowest oxygen saturation <80%, No./total (%)	58/526 (11.0)	46/524 (8.8)	2.2 (−1.6 to 6.0)
Exploratory procedural outcomes			
Time from induction to intubation			
Median (IQR), s	124 (97-180) [n = 543]	112 (85-157) [n = 530]	12 (4 to 20)
Cormack-Lehane grade of glottic view, No./total No. (%)[c]			
Grade 1 (best view)	358/554 (64.6)	335/544 (61.6)	3.0 (−2.8 to 8.9)
Grade 2	153/554 (27.6)	163/544 (30.0)	−2.3 (−7.9 to 3.2)
Grade 3	30/554 (5.4)	35/544 (6.4)	−1.0 (−4.0 to 2.0)
Grade 4 (worst view)	13/554 (2.3)	11/544 (2.0)	0.3 (−1.6 to 2.2)
Exploratory procedural complications			
Intubation complications	10 (1.8)	10 (1.8)	0 (−1.6 to 1.6)
Esophageal intubation	4 (0.7)	5 (0.9)[d]	
Injury to oral, glottic, or thoracic structures	0	3 (0.5)[d]	
Witnessed aspiration during intubation	6 (1.1)	3 (0.5)	
Cardiovascular collapse within 1 h after intubation[e]	68 (12.2)	91 (16.7)	−4.4 (−8.8 to −0.1)
Cardiac arrest within 1 h after intubation	10 (1.8)	10 (1.8)	0 (−1.7 to 1.6)
New pneumothorax within 48 h after intubation (post hoc outcome)	14 (2.5)	15 (2.7)	−0.2 (−2.3 to 1.8)
Exploratory clinical outcomes			
Ventilator-free days, median (IQR)[f]	24 (0-27)	22 (0-26)	2 (0.5 to 6)
Intensive care unit-free days, median (IQR)[f]	21 (0-25)	18 (0-25)	3 (0 to 6)
Death before 28 d	152 (27.3)	184 (33.7)	−6.4 (−12.0 to −0.8)

[a] Continuous variables were compared between groups and difference in medians were presented. The 95% CIs of the difference in medians were calculated using the nonparametric bootstrap method stratified by group.

[b] In the primary analysis comparing successful intubation on the first attempt between groups with the use of a χ^2 test, the difference in successful intubation on the first attempt between groups was not statistically significant ($P = .27$). Details of management when intubation did not occur on the first attempt are reported in eTable 15 in Supplement 2.

[c] Considered an outcome because some operators might attempt to pass a bougie with a less favorable view. Data regarding Cormack-Lehane grade of glottic view were missing for 4 patients (0.4%) (2 in the bougie group and 2 in the stylet group).

[d] One patient in the stylet group had both esophageal intubation and injury to oral, glottic, or thoracic structures.

[e] Defined as the occurrence of 1 or more of the following: a new systolic blood pressure measurement less than 65 mm Hg between induction and 2 minutes after intubation; new or increased vasopressor administration between induction of sedation and 2 minutes after intubation; cardiac arrest within 1 hour of intubation; or death within 1 hour of intubation.

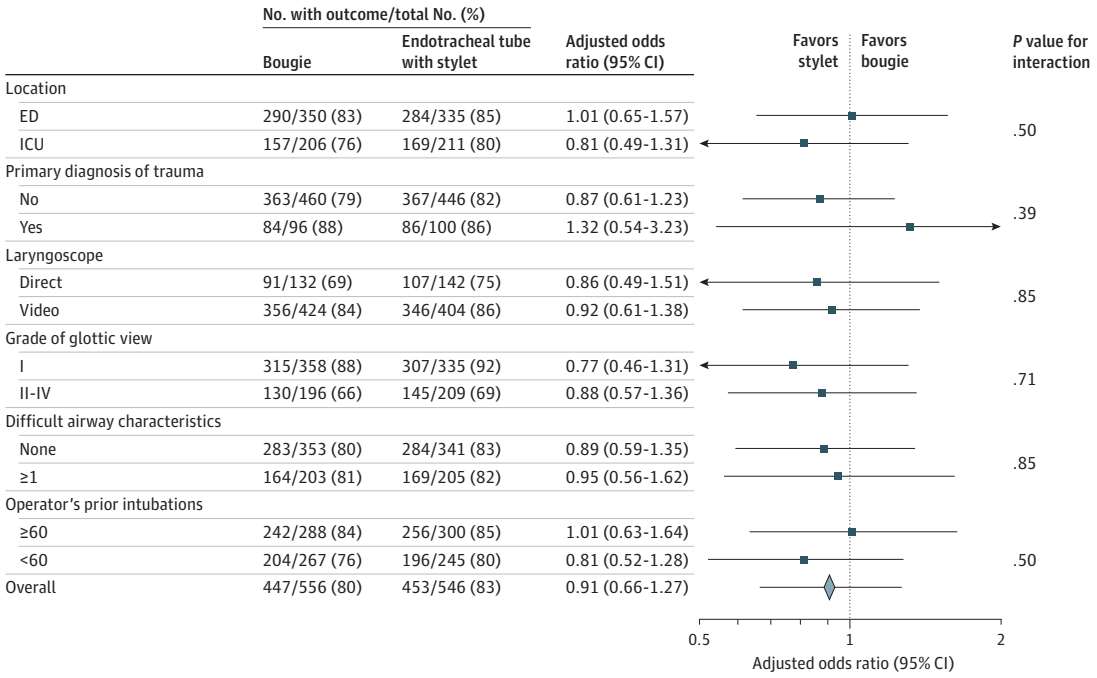
[f] Defined as the number of calendar days between enrollment and 28 days after enrollment on which the patient was alive and not receiving invasive mechanical ventilation after final receipt of invasive mechanical ventilation. Patients who died before day 28 received a value of 0. Intensive care unit-free days were calculated using the same approach.

compared the use of a bougie with the use of an endotracheal tube with stylet for tracheal intubation in settings outside of the operating room.[10] In that prior trial, conducted in a single academic ED, the rate of successful intubation on the first laryngoscopy attempt was 98% in the bougie group and 87% in the stylet group. In the current trial, the rate of successful intubation on the first attempt was lower, with no significant difference between trial groups. Because the current trial defined the primary outcome as a single insertion of both the blade and the bougie or tube, a prespecified sensitivity analysis of the current trial was performed using the primary outcome definition from the prior trial (successful intubation during the first insertion of a laryngoscope, regardless of the number of bougie or tube insertions), which demonstrated that approximately 88% of patients in each trial group experienced the outcome—comparable to the rate of 87% observed in the stylet group in the prior trial.

The difference in findings between the current trial and the prior trial might be explained by differences in patients, operators, or intubation context. Use of a bougie has been suggested to have the greatest effect for patients with difficult airway characteristics[10,21,22] or when the larynx cannot be fully visualized.[10,19,23-26] The current trial, however, did not demonstrate a benefit to use of a bougie among the 463 patients with difficult airway characteristics or among the 405 patients in whom the larynx was incompletely visualized. Similarly, the type of laryngoscope (direct vs video laryngoscope) did not appear to modify the effect of bougie use on successful intubation.

An operator's training and experience performing tracheal intubation, overall or with a specific device, may influence

Figure 2. Subgroup Analysis of the Primary Outcome



Shown are the odds ratios and 95% CIs for the primary outcome in the bougie group compared with the stylet group, after adjustment for prespecified baseline covariates. The Cormack-Lehane grade of glottic view[15] ranges from grade 1 (all or most of the glottic opening is seen) to grade 4 (neither glottis nor epiglottis are seen). The prespecified difficult airway characteristics included in this effect modification analysis were obesity (body mass index >30 [calculated as weight in kilograms divided by height in meters squared]), cervical immobilization, and facial trauma. ED indicates emergency department; ICU, intensive care unit.

the likelihood of successful intubation on the first attempt.[27,28] In the prior trial, all operators were resident or attending physicians in a single ED in which the majority of intubations before the trial were performed using a bougie rather than an endotracheal tube with a stylet.[7] The current trial included 322 operators from 15 EDs and ICUs, ranging from resident physicians who had never before performed tracheal intubation to attending physicians with thousands of prior intubations. The average operator had performed a median of 60 prior intubations, with a median of 10 of those performed using a bougie. In effect modification analyses, use of a bougie did not appear to be beneficial among operators who had performed a greater number of total prior intubations or a greater number of prior intubations using a bougie. These results suggest that, for operators who commonly use an endotracheal tube with stylet, introducing use of a bougie is unlikely to increase the rate of successful intubation on the first attempt. Whether results would have differed among operators who have already incorporated routine use of a bougie on the first attempt into their practice is unknown.[8-10]

The effect of a procedural intervention on outcomes depends on the context in which the procedure is performed. Tracheal intubation occurs in a context determined by the physical environment, organizational resources and practices, team composition and dynamics, operator training and cognitive performance, and other nontechnical factors.[29,30] The effects of bougie use observed may not generalize to contexts for tracheal intubation not represented in this trial.

Several exploratory findings of this trial should be viewed as hypothesis-generating. First, the time from induction of sedation to intubation was numerically 12 seconds longer in the bougie group, the clinical significance of which is uncertain. Second, airway injury and pneumothorax were uncommonly observed in both groups, contrary to the notion that use of a bougie increases the risk of iatrogenic airway injury,[31] but the trial was underpowered for definitive assessment of these rare safety outcomes. Third, the risks of periprocedural cardiovascular collapse and death by day 28 were numerically lower in the bougie group. Because use of a bougie did not influence procedural process measures, the mechanism by which bougie use would influence these outcomes is unclear and these differences may be attributable to chance.

Limitations

This study has several limitations. First, the trial excluded patients for whom the urgency of intubation precluded performance of trial procedures, patients intubated using a hyperangulated laryngoscope, and patients for whom use of a bougie was specifically indicated. Thus, the results of the trial may not apply to patients being intubated under specific urgent circumstances (eg, cardiac arrest), patients being intubated with a hyperangulated laryngoscope, or patients known to have

abnormal airway anatomy. Second, although operator experience did not appear to modify the relationship between use of a bougie and successful intubation on the first attempt, most operators in this trial had limited previous experience intubating using a bougie, and some had limited experience performing intubation overall. Therefore, the results may not apply to operators with extensive experience intubating or intubating using a bougie. Third, the nature of the trial intervention precluded blinding of operators or observers. Fourth, the between-group comparisons may be underpowered to rule out clinically important differences in specific subgroups. Fifth, this trial evaluated use of a bougie on the first tracheal intubation attempt and does not inform the use of a bougie after a failed first intubation attempt.

Conclusions

Among critically ill adults undergoing tracheal intubation, use of a bougie did not significantly increase the incidence of successful intubation on the first attempt compared with use of an endotracheal tube with stylet.

ARTICLE INFORMATION

Accepted for Publication: November 19, 2021.

Published Online: December 8, 2021. doi:10.1001/jama.2021.22002

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Author Contributions: Drs Driver and Casey had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The first authors (Drs Driver and Semler) contributed equally. The last authors (Drs Prekker and Casey) contributed equally.
Concept and design: Driver, Semler, Self, Hughes, Russell, Wang, Janz, Rice, Prekker, Casey.
Acquisition, analysis, or interpretation of data: All authors.
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Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Semler, Wang, Lindsell, Casey.
Obtained funding: Casey.
Administrative, technical, or material support: Driver, Semler, Self, Ginde, Trent, Smith, Vonderhaar, West, Mitchell, Hughes, Landsperger, Jackson, Howell, Robison, Gaillard, Whitson, Barnes, Latimer, Koppurapu, Russell, Janz, Rice, Prekker, Casey.
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Conflict of Interest Disclosures: Dr Semler reported receiving grants from the National Heart, Lung, and Blood Institute (NHLBI) (K23HL143053). Dr Ginde reported receiving grants from the National Institutes of Health (NIH), Department of Defense, Centers for Disease Control and Prevention (CDC), AbbVie, and Faron Pharmaceuticals. Dr Trent reported receiving grants from NHLBI and CDC. Dr Mitchell reported receiving grants from Washington State Department of Health used for support of state-level disaster coordination efforts. Dr Hughes reported receiving consulting fees from Sedana Medical. Dr Alvis reported holding patent, equity, and executive position in VoluMetrix, a venous waveform medical device company, and Goldfinch Health, an enhanced recovery company. Dr Russell reported receiving grants from NIH/NHLBI (1 K08 HL148514-01), a Chest/Alpha-1 Foundation Biomedical Research Grant, and funding for the I-SPY COVID clinical trial from Quantum Leap Healthcare. Dr Lindsell reported receiving grants to his institution from National Center for Advancing Translational Sciences (NCATS), NIH, CDC, and Department of Defense; receiving support for research services (to his institution) from Endpoint Health, bioMerieux, and Entegrion Inc; and holding a patent for risk stratification in sepsis and septic shock issued to Cincinnati Children's Hospital Medical Center. Dr Rice reported serving as Director of Medical Affairs for Cumberland Pharmaceuticals Inc, as consultant for Cytovale Inc, and as a data and safety monitoring board member for Sanofi. No other disclosures were reported.

Funding/Support: Dr Semler was supported in part by the NHLBI (K23HL143053). Dr Russell was supported in part by the NIH/NHLBI (T32HL105346-07). Dr Rice was supported in part by the NIH (UL1 RR024975). Dr Casey was supported in part by the NIH (K12HL133117 and K23HL153584). Data collection used the Research Electronic Data Capture (REDCap) tool developed and maintained with Vanderbilt Institute for Clinical and Translational Research grant support (UL1 TR000445 from NCATS/NIH).

Role of the Funder/Sponsor: The NHLBI, NIH, and NCATS had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Group Information: Full lists of the BOUGIE Investigators and the members of the Pragmatic Critical Care Research Group are available in Supplement 3.

Meeting Presentation: Presented in part as a Critical Care Reviews livestream on December 8, 2021.

Data Sharing Statement: See Supplement 4.

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