Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

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Supplemental methods

A. IRB approval and waiver of informed consent

Critically ill adults undergoing tracheal intubation in the emergency department (ED) or intensive care unit (ICU) are at significant risk for morbidity and mortality from their critical illness. In the United States, most patients undergoing emergency tracheal intubation in routine clinical care receive either a bougie or an endotracheal tube with stylet on the first attempt, thus experiencing any benefits or risks of these two approaches as a part of clinical care, outside the context of research. The only patients eligible for the BOUGIE trial were patients for whom their treating clinician considered use of either a bougie or an endotracheal tube with stylet to be safe and reasonable approaches to tracheal intubation of the patient (otherwise the patient was excluded). Thus, for patients who were undergoing tracheal intubation with either a bougie or an endotracheal tube and stylet as a part of clinical care, and whose treating clinician felt that either approach was a safe and reasonable approach for their care, making the decision between the two approaches using randomization (by trial group assignment) was felt to pose no more than minimal additional risk, compared to the risks the patient would experience in clinical care without participation in the research.

Additionally, obtaining informed consent for participation in the study would be impracticable. In addition to the time-sensitive nature of tracheal intubation in the ED or ICU, critically ill patients requiring intubation are frequently unconscious or delirious due to their critical illness. Further, legally authorized representatives are commonly unavailable during the brief period between the decision to intubate and the completion of the procedure, and the need for emergency tracheal intubation and distress of the patient or LAR from the patient's critical illness precludes a meaningful informed consent process even when an LAR is present. Delaying emergency tracheal intubation for a critically ill adults to attempt a meaningful informed consent process would be unsafe, impracticable, and unethical. Despite the availability of a formal informed consent document for the procedure itself, time allows discussion of risks and benefits in less than 10% of airway management events in the study settings.

Because the BOUGIE trial was considered to pose minimal incremental risk and obtaining informed consent was considered to be impracticable, the trial was conducted under a waiver of informed consent. This approach is consistent with previous randomized trials comparing the effectiveness of alternative approaches to tracheal intubation commonly used in current clinical care.^{1–8} The trial was approved by the central Institutional Review Board (cIRB) at Vanderbilt University Medical Center (reference number 182123) and a local institutional review board at Lincoln Medical Center (reference number 19-024), with the remainder of site IRBs ceding review to the cIRB.

B. Characteristics of the study intensive care units

Characteristic	Vanderbilt	Vanderbilt	UAB	Ochsner	LSU MICU	UW ICU	Iowa MICU	HCMC MICU
	MICU	Neuro ICU	MICU	MICU				
Annual admissions	2,940	2,800	2,000	3,500	2,600	6,900	2,800	900
Number of beds	35	23	24	33	24	89	26	28
Annual number of tracheal intubations	200	200	200	400	300	1000	250	160
Personnel present at intubation								
Critical Care Attending	Always	Almost Always	Almost Always	Always	Almost Always	Sometimes	Sometimes	Sometimes
Critical Care Fellow	Always	Almost Always	Almost Always	Almost Always	Sometimes	Sometimes	Always	Sometimes
Internal Medicine Resident	Rarely	Never	Sometimes	Rarely	Rarely	Never	Never	Never
Emergency Medicine Attending	Never	Never	Never	Never	Never	Sometimes	Never	Sometimes
Emergency Medicine Fellow	Never	Never	Never	Never	Never	Sometimes	Never	Rarely
Emergency Medicine Resident	Never	Never	Never	Never	Never	Sometimes	Never	Sometimes
Anesthesiology Attending	Never	Always	Never	Sometimes	Never	Almost Always	Rarely	Never
Anesthesiology Fellow	Never	Almost Always	Never	Never	Never	Sometimes	Rarely	Never
Anesthesiology Resident	Never	Always	Never	Sometimes	Sometimes	Almost Always	Sometimes	Never
Certified Nurse Anesthetist	Never	Never	Never	Never	Sometimes	Almost Always	Never	Never
Advanced Practice Provider	Sometimes	Never	Rarely	Rarely	Rarely	Never	Rarely	Never
Laryngoscopes available								
Macintosh Video Laryngoscope	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hyperangulated Video Laryngoscope	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Direct Laryngoscope	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pre-medication								
Lidocaine	Never	Never	Never	Never	Never	Rarely	Rarely	Never
Atropine	Never	Never	Never	Never	Never	Never	Never	Never
Midazolam	Never	Rarely	Sometimes	Sometimes	Never	Sometimes	Rarely	Never
Fentanyl	Rarely	Almost Always	Rarely	Sometimes	Never	Sometimes	Sometimes	Rarely
Bougie manufacturer	Sunmed	Sunmed	SunMed	SunMed	Smiths Medical	SunMed	SunMed	SunMed
Bougie length (cm)	70	70	70	70	70	70	70	70
Bougie - Coudé tip present	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

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Bougie - packaged straight or curved	Straight	Straight	Straight	Straight	Straight	Straight	Straight	Straight
Bougie bent before intubation	Sometimes	Almost Always	Sometimes	Sometimes	Almost	Rarely	Sometimes	Sometimes
		_			Always	_		
How often was a bougie used on the first	Rarely	Rarely	Sometimes	Rarely	Sometimes	Rarely	Rarely	Always
attempt before the BOUGIE trial?								
How often was a bougie used for rescue	Sometimes	Sometimes	Almost	Sometimes	Sometimes	Sometimes	Rarely	Almost Always
in this unit before the BOUGIE trial?			Always				-	
Endotracheal tube manufacturer	Shiley	Shiley	Covidien	Shiley	Shiley	Shiley	Novaplus	Parker

ICU, intensive care unit; MICU, medical ICU

UAB, University of Alabama at Birmingham; LSU, Louisiana State University; UW, University of Washington, Harborview; HCMC, Hennepin County Medical Center

C. Characteristics of the study emergency departments

Characteristic	Vanderbilt	UAB ED	U of CO ED	Wake Forest	UW ED	Denver Health	Lincoln ED
	ED			ED		ED	
Approximate annual ED visits	72,000	65,000	102,000	100,000	53,000	60,000	144,000
Number of beds	58	51	92	41	49	53	56
Estimated annual number of tracheal	750	900	300	600	300	500	400
intubations							
Personnel present at intubation							
Critical Care Attending	Never	Never	Never	Never	Never	Never	Sometimes
Critical Care Fellow	Never	Never	Never	Never	Never	Never	Rarely
Internal Medicine Resident	Never	Never	Never	Never	Never	Never	Rarely
Emergency Medicine Attending	Always	Always	Always	Always	Always	Always	Always
Emergency Medicine Fellow	Rarely	Never	Sometimes	Never	Sometimes	Rarely	Rarely
Emergency Medicine Resident	Almost Always	Almost Always	Always	Always	Always	Always	Almost Always
Anesthesiology Attending	Never	Never	Never	Rarely	Sometimes	Rarely	Rarely
Anesthesiology Fellow	Never	Never	Never	Never	Rarely	Never	Never
Anesthesiology Resident	Never	Never	Never	Rarely	Sometimes	Never	Never
Certified Nurse Anesthetist	Never	Never	Never	Never	Sometimes	Never	Never
Advanced Practice Provider	Rarely	Never	Sometimes	Sometimes	Never	Never	Never
Laryngoscopes available							
Macintosh Video	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Laryngoscope							
Hyperangulated Video	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Laryngoscope							
Direct Laryngoscope	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Pre-medication							
Lidocaine	Rarely	Never	Rarely	Never	Rarely	Rarely	Rarely
Atropine	Rarely	Never	Rarely	Never	Sometimes	Rarely	Rarely
Midazolam	Rarely	Rarely	Rarely	Rarely	Sometimes	Rarely	Rarely
Fentanyl	Rarely	Rarely	Rarely	Rarely	Sometimes	Rarely	Rarely
Bougie manufacturer	SunMed	SunMed	SunMed	SunMed	SunMed	SunMed	SunMed
Bougie length (cm)	70	70	70	70	70	70	70
Bougie - Coudé tip present	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bougie - packaged straight or curved	Straight	Straight	Straight	Straight	Straight	Straight	Straight
Bougie bent before intubation	Rarely	Almost Always	Sometimes	Sometimes	Sometimes	Sometimes	Almost Always
How often was a bougie used on the first	Sometimes	Sometimes	Rarely	Rarely	Rarely	Rarely	Sometimes
attempt before the BOUGIE trial?							

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How often was a bougie used for rescue	Sometimes	Almost Always	Almost Always	Sometimes	Sometimes	Almost Always	Sometimes
attempts in this unit before the BOUGIE			-				
trial?							
Endotracheal tube manufacturer	Covidien	Shiley	Shiley	Vyaire	Shiley	Shiley	Covidien

ED, emergency department UAB, University of Alabama at Birmingham; U of CO, University of Colorado; UW, University of Washington, Harborview.

D. Inclusion and exclusion criteria

Inclusion criteria:

- 1. Patient is located in a participating unit of an adult hospital
- Planned procedure is tracheal intubation with sedative administration (or tracheal intubation without sedative administration in patients with decreased level of consciousness, cardiac arrest, or respiratory arrest)
- 3. Planned operator is a clinician expected to routinely perform tracheal intubation in the participating unit
- 4. Planned laryngoscopy device is a non-hyperangulated laryngoscope blade

Exclusion criteria:

- 1. Patient is pregnant
- 2. Patient is a prisoner
- 3. Urgency of intubation precludes safe performance of study procedures
- 4. Operator feels an approach to intubation other than use of a bougie or use of an endotracheal tube with stylet would be best for the care of the patient
- 5. Operator feels use of a bougie is required or contraindicated for the care of the patient
- 6. Operator feels use of an endotracheal tube with stylet is required or contraindicated for the care of the patient

The original inclusion criteria specified that patients must be at least 18 years old to be eligible. Because the age of critically ill patients presenting to the ED requiring emergency tracheal intubation is sometimes unknown (e.g., a patient with cardiac arrest presenting by ambulance without family) and patients who have the anatomic appearance of adults are likely to receive the same effects from a bougie as true adults, with approval from the cIRB at Vanderbilt University Medical Center, this criterion was revised on January 16, 2020 to be limited to patients located in a participating unit of an adult hospital. Ultimately, 4 patients were enrolled, 2 in the bougie group and 2 in the stylet group, who were subsequently discovered to be either 16 or 17 years old.

E. Exploratory outcomes

Complete details of the statistical analysis plan have been published previously.9

Pre-specified exploratory outcomes included:

- Cormack-Lehane grade of glottic view, from grade 1 (best) to grade 4 (worst)
 - 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.
- Number of laryngoscopy attempts
- Number of attempts at passing the bougie
- Number of attempts at passing the endotracheal tube
- Duration of intubation: The start of the procedure was defined as either the time of first sedative administration or, among patients who do not receive a sedative, the time of initiation of laryngoscopy. The end of the procedure was defined as the time of the final placement of an endotracheal tube within the trachea.
- Whether the video laryngoscope screen was viewed, among intubations where the operator used a video laryngoscope.
- Incidence of airway complications, including:
 - Esophageal intubation
 - Operator-reported aspiration during the procedure
 - Airway trauma (injury to oropharyngeal, glottic, or thoracic airway structures)
- Cardiac arrest within 1 hour following intubation
- Incidence of peri-intubation cardiovascular collapse, defined as one or more of:
 - New systolic blood pressure < 65 mmHg between induction and 2 minutes following intubation
 - New or increased vasopressor between induction and 2 minutes following intubation
 - Cardiac arrest within 1 hour of intubation
 - Death within 1 hour of intubation
- ICU-free days in the first 28 days (range: 0 to 28)

- Defined as the number of days, between enrollment and 28 days after enrollment, in which the patient is alive and not admitted to an intensive care unit service after the patient's final discharge from the intensive care unit. Patients who are never discharged from the intensive care unit receive a value of 0. Patients who die before day 28 receive a value of 0. For patients who return to an intensive care unit and are subsequently discharged prior to day 28, ICU-free days are counted from the date of final intensive care unit discharge. All data are censored hospital discharge or 28 days, whichever comes first.
- Ventilator free days in the first 28 days (range: 0 to 28)
 - Defined as the number of days, between enrollment and 28 days after enrollment, during which the patient is alive and with unassisted breathing and remains free of assisted breathing. If a patient returns to assisted breathing and subsequently achieves unassisted breathing prior to day 28, ventilator free days will be counted from the end of the last period of assisted breathing to day 28. If the patient is receiving assisted ventilation at day 28 or dies prior to day 28, ventilator free days are 0. If a patient is discharged while receiving assisted ventilation, ventilator free days are 0. All data is censored hospital discharge or 28 days, whichever comes first.
- All-cause, in-hospital mortality at 28 days

Post-hoc exploratory outcomes included:

• Pneumothorax present on the first chest radiograph obtained in the 48 hours after tracheal intubation.

F. Modeling of the primary outcome

In order to understand the effect of use of a bougie vs use of an endotracheal tube with stylet on the primary outcome of successful intubation on the first attempt after accounting for (1) pre-specified baseline covariates, (2) correlation of patients within each study site, and (3) pre-specified baseline covariates that can only be assessed after randomization, we fit two multivariable models.

We fit a generalized linear mixed-effects model using a logit link function with the primary outcome as the dependent variable, operator and study site as random effects, and fixed effects of study group and the following pre-specified baseline covariates: age, sex, race, body-mass index, operator experience quantified as the operator's total number of prior intubations, and location of intubation (ED vs ICU). Age, body-mass index, and intubation experience were modeled with a nonlinear relationship to the outcome using restricted cubic splines with 3 knots. Location of knots were 10th, 50th, and 90th quantiles. The effect estimates were made by comparing the 75th percentile to the 25th percentile.

We also constructed a model with the following additional factors that may be interpreted as baseline covariates but which are unable to be assessed until after randomization: use of a video vs direct laryngoscope; presence of ≥ 1 difficult airway characteristic (body fluids obscuring glottic view, obesity, cervical immobilization, or facial trauma), and Cormack-Lehane grade 2, 3, or 4 laryngeal view.

Data on the primary outcome were available for all patients. Multiple imputations were used to impute missing baseline covariates in adjusted analyses using the R function "aregImpute" in Hmisc package. Variables used in the imputation model include: height, weight, hypoxemic respiratory failure as indication for intubation, obesity, trauma as a presenting diagnosis, sepsis or septic shock, altered mental status, pre-intubation cardiac arrest, acute respiratory distress syndrome, pneumonia, gastrointestinal bleeding, COVID-19, sedative agent, neuromuscular agent, oxygen saturation at induction, systolic blood pressure at induction, use of vasopressors in the hour prior to intubation, and laryngoscope type (direct or video).

G. Effect modification (Subgroup analyses)

Complete details of the plan to evaluate for effect modification have been previously published.⁹ Possible effect modification was assessed using a formal test of interaction between group assignment and the proposed effect modifier in the same multivariable model used for adjusted analysis of the primary outcome. The model included the following baseline covariates: age, sex, race, body-mass index, operator experience quantified as the operator's total number of prior intubations, and location of intubation (ED vs ICU). Age, body-mass index, and intubation experience were modeled with a nonlinear relationship to the outcome using restricted cubic splines with 3 knots. The following baseline variables were examined to determine if they modified the effect of study group on the primary outcome:

- 1. Operator Experience at the time of each enrollment
 - a. Total number of previous intubations performed by operator
 - b. Number of previous intubations performed by operator using a bougie
 - c. Proportion of previous intubations performed by the operator that were performed using a bougie
- 2. Location (ED vs ICU)
- 3. Indication for intubation (trauma vs medical)
- Difficult airway, defined as one or more of the following difficult airway characteristics: obesity (body mass index > 30 kg/m²), cervical immobilization, or facial trauma.
- 5. Time period (before the COVID pandemic vs during or after the COVID pandemic)

In addition to the variables above, which can be assessed prior to enrollment, we performed exploratory analyses examining additional potential effect modifiers that are intended to represent baseline variables, but which are collected after enrollment, and therefore have the potential to be affected by study group assignment. These included:

- 1. Laryngoscope type (Direct laryngoscope [without video capability] vs video laryngoscope [with video capability])
- 2. Presence body fluids obscuring glottic view (Yes vs No)
- 3. Cormack Lehane grade of view (1 vs 2-4).

H. Sensitivity analyses of the primary outcome

To assess the robustness of the findings for the primary outcome, we repeated the main analysis of the primary outcome with the following alternate populations or alternate definitions of successful intubation on the first attempt:

1. Excluding intubations performed with hyperangulated blades: This analysis excluded patients for whom a hyperangulated laryngoscope blade was used on the first attempt at intubation.

2. Counting crossovers as failures: This analysis assigned failure for the primary outcome for all patients for whom the operator crossed over from the assigned device to the non-assigned device.

3. Including only patients with complete observer data: This analysis included only cases in which primary outcome data from the independent observer was complete (i.e., excluding cases in which the operator's self-report of whether there was successful intubation on the first attempt was used to calculate the primary outcome for that patient).

4. Excluding cases in which the operator had ≤ 10 total prior intubations: Because prior intubating experience may influence success with both devices, this analysis excluded cases where the operator had ≤ 10 total prior intubations.

5. Excluding cases where the operator had \leq 5 total prior intubations using a bougie: Because prior experience with using a bougie may influence successful intubation in the bougie group, this analysis excluded cases where the operator had \leq 5 prior intubations while using a bougie.

6. Defining successful intubation on the first attempt as intubation with one insertion of the laryngoscope blade: This analysis defined successful intubation on the first attempt as successful tracheal intubation during the first insertion of the laryngoscope blade, regardless of the number of insertions of a bougie or endotracheal tube.

I. Handling of missing data

No patient was missing data for the primary outcome. When data were missing for the secondary or exploratory outcomes, we performed complete-case analysis, excluding cases where the data for the analyzed outcome were missing. In adjusted analyses, missing data for baseline covariates was imputed using multiple imputations.

Multiple imputations used the R function "aregImpute" in Hmisc package. Variables used in the imputation model include: height, weight, hypoxemic respiratory failure as indication for intubation, obesity, trauma as a presenting diagnosis, sepsis or septic shock, altered mental status, pre-intubation cardiac arrest, acute respiratory distress syndrome, pneumonia, gastrointestinal bleeding, COVID-19, sedative agent, neuromuscular agent, oxygen saturation at induction, systolic blood pressure at induction, use of vasopressors in the hour prior to intubation, and laryngoscope type (direct or video).

J. Results of the interim analysis

After the enrollment of 553 patients, the data and safety monitoring board conducted a single interim analysis to compare the incidence of successful intubation on the first attempt between groups using a Haybittle–Peto stopping boundary for efficacy of P<0.001. At the time of the single interim analysis, successful intubation on the first attempt had occurred in 237 patients (85%) in the bougie group and 223 patients (82%) in the stylet group (P=0.31).

Supplemental Figures

eFigure 1. Cumulative proportion of patients successfully intubated.

Shown is the cumulative proportion of patients successfully intubated over time (in seconds) following the induction of anesthesia. The figure displays data for the 1,073 patients for whom information on the time from induction to intubation was available.





eFigure 2. Calibration plot for the first model used for adjusted analysis of the primary outcome

Predicted Probability

This figure shows the calibration plot for the model fit for the first adjusted analysis of the primary outcome, a generalized linear mixed-effects model using a logit link function with the primary outcome as the dependent variable, operator and study site as random effects, and fixed effects of study group and the pre-specified baseline covariates. Additional details of the model are included in Supplemental Methods section F. Results of the model are shown in eTable 9.



eFigure 3. Calibration plot for the second model used for adjusted analysis of the primary outcome

Predicted Probability

This figure shows the calibration plot for the model fit for the second adjusted analysis of the primary outcome, a generalized linear mixed-effects model using a logit link function with the primary outcome as the dependent variable, operator and study site as random effects, and fixed effects of study group and the pre-specified baseline and semi-baseline covariates. Additional details of the model are included in Supplemental Methods section F. Results of the model are shown in eTable 9.





Panel A shows the relationship between an operator's number of previous tracheal intubations and the probability of successful intubation on the first attempt in the bougie group (red) and the stylet group (blue). Panel B shows the relationship between an operator's number of previous tracheal intubations using a bougie and the probability of successful intubation on the first attempt, by group. Shaded bands denote 95% confidence intervals. A histogram on the x-axis shows the distribution of previous operator experience. Operators' previous intubating experience did not appear to modify the effect of trial group assignment on the primary outcome.

eFigure 5. Successful intubation on the first attempt by site.

Shown is the unadjusted absolute risk difference in the primary outcome of successful intubation on the first attempt between use of a bougie and use of an endotracheal tube and stylet for patients at each of the 15 trial sites. Horizontal bars represent the 95% confidence intervals around the absolute risk difference. The number of patients in each group and the incidence of the primary outcome in each group with 95% confidence intervals are shown. ED = Emergency Department; ICU = Intensive Care Unit.



eFigure 6. Cumulative proportion of patients successfully intubated on the first attempt.

In contrast to eFigure 1, this figure shows the cumulative proportion of patients successfully intubated on the *first attempt* over time (in seconds) following the induction of anesthesia. The 202 patients not successfully intubated on the first attempt are not shown in this figure, nor are 24 patients who achieved the primary outcome but had missing data on the duration of tracheal intubation.



Supplementary Tables

eTable 1. Chronic comorbidities.

Comorbidity	Bougie group N=556	Stylet group N=546
Respiratory conditions – no. (%)		•
Chronic obstructive pulmonary disease	81 (14.6)	74 (13.6)
Obstructive sleep apnea	20 (3.6)	24 (4.4)
Asthma	19 (3.4)	24 (4.4)
Pulmonary or pleural malignancy	12 (2.2)	11 (2.0)
Interstitial lung disease	10 (1.8)	10 (1.8)
Pulmonary hypertension	9 (1.6)	9 (1.6)
Neuromuscular weakness	8 (1.4)	7 (1.3)
Recurrent aspiration	2 (0.4)	3 (0.5)
Cystic fibrosis	1 (0.2)	0
Other respiratory condition	19 (3.4)	14 (2.6)
Non-respiratory conditions – no. (%)		· · · ·
Hypertension	190 (34.2)	200 (36.6)
Diabetes mellitus	111 (20.0)	111 (20.3)
Hepatic cirrhosis	56 (10.1)	71 (13.0)
Atrial fibrillation	51 (9.2)	47 (8.6)
Congestive heart failure	50 (9)	47 (8.6)
Coronary artery disease	49 (8.8)	54 (9.9)
Cerebrovascular accident	46 (8.3)	40 (7.3)
Chronic kidney disease	44 (7.9)	50 (9.2)
Solid malignancy, non-pulmonary	39 (7.0)	38 (7.0)
End stage renal disease	26 (4.7)	13 (2.4)
Solid organ transplant	24 (4.3)	11 (2.0)
Hematologic malignancy	19 (3.4)	18 (3.3)
Traumatic brain injury	3 (0.5)	7 (1.3)
Spinal cord injury	3 (0.5)	4 (0.7)
Stem cell or bone marrow transplant	2 (0.4)	2 (0.4)
Other non-respiratory condition	94 (16.9)	102 (18.7)

Condition	Bougie group N=556	Stylet group N=546
Glasgow coma score, median (IQR)	11 (7-14)	10 (6-14)
Neurologic – no. (%)	· · · ·	• • • • •
Altered mental status	372 (66.9)	393 (72.0)
Seizure	51 (9.2)	53 (9.7)
Intracranial hemorrhage	42 (7.6)	45 (8.2)
Stroke	35 (6.3)	27 (4.9)
Traumatic brain injury	20 (3.6)	21 (3.8)
Meningitis or encephalitis	3 (0.5)	6 (1.1)
Spinal cord compression	2 (0.4)	3 (0.5)
Myasthenic crisis	2 (0.4)	0
Cardiac – no. (%)		
Cardiac arrest	21 (3.8)	20 (3.7)
Decompensated heart failure	19 (3.4)	11 (2.0)
Myocardial infarction	14 (2.5)	19 (3.5)
Hypertensive urgency or	10 (1.8)	13 (2.4)
emergency		
Cardiogenic shock	6 (1.1)	8 (1.5)
Pulmonary – no. (%)		
Hypoxemic respiratory failure	191 (34.4)	202 (37.0)
Hypercarbic respiratory failure	73 (13.1)	60 (11.0)
Pneumonia	58 (10.4)	45 (8.2)
Acute respiratory distress syndrome	30 (5.4)	19 (3.5)
Chronic obstructive pulmonary	18 (3.2)	13 (2.4)
disease exacerbation		
Aspiration	11 (2.0)	10 (1.8)
Upper airway obstruction	4 (0.7)	2 (0.4)
Asthma exacerbation	0	1 (0.2)
Gastrointestinal – no. (%)		
Gastrointestinal bleeding	51 (9.2)	48 (8.8)
Acute liver failure	15 (2.7)	12 (2.2)
Bowel obstruction	6 (1.1)	2 (0.4)
Pancreatitis	5 (0.9)	5 (0.9)
Hepatorenal syndrome	4 (0.7)	7 (1.3)
Bowel perforation	1 (0.2)	3 (0.5)

eTable 2. Active medical conditions at the time of intubation.

Indication – no. (%)	Bougie group N=556	Stylet group N=546
Altered mental status	246 (44.2)	246 (45.1)
Hypoxic respiratory failure	116 (20.9)	107 (19.6)
Hypercarbic and hypoxic respiratory failure	35 (6.3)	41 (7.5)
Hypercarbic respiratory failure	28 (5.0)	17 (3.1)
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)
Metabolic acidosis	3 (0.5)	3 (0.5)
Respiratory arrest	2 (0.4)	1 (0.2)
Hemoptysis	1 (0.2)	2 (0.4)
Other	15 (2.7)	22 (4.0)

eTable 3. Primary indication for tracheal intubation.

Difficult Airway Characteristic – no. (%)	Bougie group N=556	Stylet group N=546
One or more difficult airway	259 (46.6)	263 (48.2)
characteristics – no. (%) ^a		
Obesity ^b	158 (28.4)	158 (28.9)
Glottic view obscured by body	50 (9.0)	56 (10.3)
fluids or blood ^c		
Cervical collar before intubation ^c	48 (8.6)	56 (10.3)
Obstructive sleep apnea ^d	20 (3.6)	24 (4.4)
Limited neck mobility ^d	17 (3.1)	15 (2.7)
Vomiting ^d	12 (2.2)	7 (1.3)
Upper gastrointestinal bleeding	11 (2.0)	11 (2.0)
complicating intubation ^d		
Witnessed aspiration ^d	9 (1.6)	7 (1.3)
Facial trauma ^c	6 (1.1)	13 (2.4)
Upper airway mass, infection, or	6 (1.1)	4 (0.7)
trauma ^d		
Limited mouth opening ^d	5 (0.9)	3 (0.5)
Epistaxis or oral bleeding ^d	2 (0.4)	5 (0.9)
Head and neck radiation ^d	1 (0.2)	0
Other ^d	33 (5.9)	25 (4.6)

eTable 4. Difficult airway characteristics.

a. Patients could have more than one.

b. Obesity is defined as body-mass index $> 30 \text{ kg/m}^2$ or, when the body-mass index was not available, based on a diagnosis of obesity in the medical record.

c. Reported by the operator immediately after completion of the intubation procedure

d. Collected through chart review by study staff

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eTable 5. Operator characteristics.

Characteristic	Bougie group N=556	Stylet group N=546
No. of unique operators	244	264
No. of enrollments per operator		
Median (IQR)	1 (1-3)	1 (1-2)
Range	1 to 12	1 to 15
Operator specialty ^a – no. (%)		
Emergency Medicine	354 (63.7)	339 (62.1)
Critical Care	189 (34.0)	194 (35.5)
Anesthesia	10 (1.8)	11 (2.0)
Other or unknown	4 (0.8)	6 (1.1)
Operator training level – no. (%)		
Resident	344 (61.9)	335 (61.4)
Fellow	187 (33.6)	186 (34.1)
Attending physician	13 (2.3)	13 (2.4)
Other or unknown ^b	12 (2.2)	12 (2.2)
Prior intubation experience ^c		
No. of previous intubations, median (IQR)	60 (35-100)	60 (40-100)
No. of previous intubations performed using a bougie, median (IQR)	10 (4-20)	10 (4-20)

a. Some operators reported more than one specialty.b. Other intubator training level included nurse anesthetist, nurse practitioner, and physician assistant.

c. This is the operator's self-reported intubation experience at the time of enrollment

eTable 6. Characteristics of the intubation procedure with marginal estimates

Measure	Bougie group n=556	Stylet group n=546	Absolute difference or median difference (95% CI)
Before induction			
Plan to use a direct laryngoscope - no. (%)	142/551 (25.8)	151/543 (27.8)	-2.0% (-7.5% to 3.4%)
Preoxygenation performed - no. (%)	552 (99.3)	544 (99.6)	-0.4% (-1.4% to 0.7%)
Preoxygenation with positive pressure - no. (%)	154 (27.7)	133 (24.4)	3.3% (-2.0% to 8.7%)
Oxygen saturation at induction, median (IQR) - % ^a	100 (97-100)	100 (97-100)	0 (0 to 1)
Oxygen saturation < 90% at induction – no. (%)	33/533 (6.2)	32/528 (6.1)	0.1% (-2.9% to 3.1%)
Induction through initiation	of laryngoscopy –	no. (%)	
Sedative administered	545 (98.0)	532 (97.4)	0.6% (-1.4% to 2.5%)
Neuromuscular blocking agent administered	539 (96.9)	531 (97.3)	-0.3% (-2.5% to 1.9%)
Laryngoscopy and Intubation	n		
Initial laryngoscope used – no.	(%)		
Direct laryngoscope	132 (23.7)	142 (26.0)	-2.3% (-7.6% to 3.0%)
Macintosh video	421 (75.7)	403 (73.8)	1.9% (-3.4% to 7.2%)
laryngoscope			
Other	3 (0.5)	1 (0.2)	0.4% (-0.5% to 1.2%)
First device to enter mouth after	r the laryngoscope	– no. (%)	
Bougie	548 (98.6)	12 (2.2)	96.4% (94.6% to 98.1%)
Stylet	3 (0.5)	531 (97.3)	-96.7% (-98.4% to -95.0%)
No device passed	5 (0.9)	3 (0.5)	$0.\overline{3\%}$ (-0.8% to 1.5%)

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

eTable 7. Additional characteristics of the intubation procedure.

Characteristic	Bougie group n=556	Stylet group n=546	Absolute difference or median difference (95% CI)				
Before induction							
Bilevel positive pressure or high flow nasal cannula in the hour before intubation, not including preoxygenation – no. (%)	140 (25.2)	124 (22.7)	2.5% (-2.7% to 7.7%)				
Preoxygenation device ^a – no. (%)							
Nasal Cannula	186 (33.5)	200 (36.6)	-3.2% (-9.0% to 2.6%)				
High flow nasal cannula	68 (12.2)	62 (11.4)	0.9% (-3.1% to 4.9%)				
Non-rebreather mask	286 (51.4)	291 (53.3)	-1.9% (-7.9% to 4.2%)				
Bag mask (no ventilation)	37 (6.7)	48 (8.8)	-2.1% (-5.5% to 1.2%)				
Bag mask (with ventilation)	68 (12.2)	63 (11.5)	0.7% (-3.3% to 4.7%)				
Bilevel positive pressure	86 (15.5)	71 (13.0)	2.5% (-1.8% to 6.8%)				
Other	15 (2.7)	21 (3.8)	-1.1% (-3.4% to 1.1%)				
None	4 (0.7)	2 (0.4)	0.4% (-0.7% to 1.4%)				
Induction							
Systolic blood pressure at induction, median (IQR) – mm Hg ^b	134 (115-153)	128 (110- 150)	6 (2 to 11)				
Sedative medication for induction ^a	1						
Etomidate – no. (%)	383 (68.9)	375 (68.7)	0.2% (-5.4% to 5.9%)				
Median Dose (IQR) - mg	20 (20-20)	20 (20-20)	0 (0 to 0)				
Ketamine – no. (%)	136 (24.5)	133 (24.4)	0.1% (-5.1% to 5.3%)				
Median Dose (IQR) - mg	150 (100-150)	150 (100- 150)	0 (0 to 0)				
Propofol – no. (%)	13 (2.3)	16 (2.9)	-0.6% (-2.7% to 1.5%)				
Median Dose (IQR) - mg	80 (50-105)	80 (70-100)	0 (-40 to 40)				
Midazolam – no. (%)	22 (4.0)	17 (3.1)	0.8% (-1.5% to 3.2%)				
Median Dose (IQR) - mg	2 (2-3.8)	2 (2-4)	0 (-2 to 1)				
Fentanyl – no. (%)	7 (1.3)	8 (1.5)	-0.2% (-1.8% to 1.3%)				
Median Dose (IQR) - mcg	100 (50-100)	100 (50-200)	0 (-150 to 50)				
Lorazepam – no. (%)	3 (0.5)	3 (0.5)	-0.0% (-0.9% to 0.9%)				
Median Dose (IQR) - mg	3 (2-4)	6 (6-10)	-4 (-8 to -2)				
Neuromuscular blockade ^a							
Succinylcholine – no. (%)	217 (39.0)	224 (41.0)	-2.0% (-8.0% to 4.0%)				
Median Dose (IQR) - mg	120 (100-150)	120 (100- 150)	0 (-30 to 20)				

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Rocuronium – no. (%)	324 (58.3)	306 (56.0)	2.2% (-3.8% to 8.3%)
Median Dose (IQR) - mg	100 (70-100)	100 (70-100)	0 (0 to 0)
Cisatracurium – no. (%)	0	1 (0.2)	-0.2% (-0.7% to 0.4%)
None – no. $(\%)^c$	17 (3.1)	15 (2.7)	0.3% (-1.7% to 2.3%)
Between induction and laryngoscop	y – no. (%)		
Positive pressure ventilation between induction and laryngoscopy	203 (36.5)	210 (38.5)	-2.0% (-7.8% to 3.9%)
Laryngoscopy			
Initial laryngoscope used – no. (%)			
Direct laryngoscope, curved blade	112 (20.1)	126 (23.1)	-2.9% (-8.0% to 2.1%)
Direct laryngoscope, straight blade	11 (2.0)	13 (2.4)	-0.4% (-2.3% to 1.5%)
Direct laryngoscope, blade shape unknown	9 (1.6)	3 (0.5)	1.1% (-0.3% to 2.5%)
C-MAC Macintosh Blade	298 (53.6)	276 (50.5)	3.0% (-3.0% to 9.1%)
McGrath MAC Macintosh Blade	85 (15.3)	86 (15.8)	-0.5% (-4.9% to 4.0%)
GlideScope Titanium MAC blade	38 (6.8)	41 (7.5)	-0.7% (-3.7% to 2.4%)
Hyperangulated video laryngoscope	3 (0.5)	0	0.5% (0.0% to 1.1%)
Other ^d	0	1 (0.2)	-0.2% (-0.7% to 0.4%)

All values are no. (%) unless otherwise specified

a. Patients could receive more than one preoxygenation device, sedative, and neuromuscular blocking agent.

b. Systolic blood pressure data at induction were missing in 41 patients (3.7%): 27 in the bougie group and 14 in the stylet group.

c. Patients who were comatose (e.g., those experiencing cardiac arrest) could be intubated without a sedative and neuromuscular blocker

d. One patient underwent intubation using a flexible bronchoscope.

Patient	Device assigned	Device used on	Reason for not using	Number of	Number of	Number of	Lowest
		the first	the assigned device	laryngoscope	bougie	endotracheal	oxygen
		laryngoscope		insertions	insertions	tube insertions	saturation
		insertion					(%)
Crossovers fr	om the assigned d	evice to the non-assi	igned device.				
Patient 1	Tube + stylet	Bougie	Poor glottic view	2	2	2	67
Patient 2	Tube + stylet	Bougie	Poor glottic view	1	1	1	98
Patient 3	Tube + stylet	Bougie	Poor glottic view	1	2	1	85
Patient 4	Tube + stylet	Bougie	Poor glottic view	1	1	1	100
Patient 5	Tube + stylet	Bougie	Poor glottic view	1	1	1	100
Patient 6	Tube + stylet	Bougie	Poor glottic view	1	1	1	95
Patient 7	Tube + stylet	Bougie	Poor glottic view	1	1	1	94
Patient 8	Tube + stylet	Bougie	Poor glottic view	1	1	1	92
Patient 9	Tube + stylet	Bougie	Poor glottic view	1	1	1	78
Patient 10	Tube + stylet	Bougie	Poor glottic view	1	1	1	99
Patient 11	Tube + stylet	Bougie	Poor glottic view	1	1	1	97
Patient 12	Tube + stylet	Bougie	Operator error	1	1	1	96
Patient 13	Bougie	Tube + stylet	Bougie not available	1	0	1	Unknown
Patient 14	Bougie	Tube + stylet	Physician preference	1	1ª	2	92
Patient 15	Bougie	Tube + stylet	Unknown reason	3	1 ^a	2	96
Neither devic	e passed during th	e first laryngoscope	insertion				
Patient 16	Tube + stylet	Neither	Poor glottic view	2	2	1	88
Patient 17	Tube + stylet	Neither	Poor glottic view	2	0	1	84
Patient 18	Tube + stylet	Neither	Malfunction of video	2	0	1	72
			laryngoscope				
Patient 19	Bougie	Neither	Switched to	1	0	1	35
		(used rigid stylet	hyperangulated blade				
		and tube instead)					
Patient 20	Bougie	Neither	Poor glottic view	2	1	1	100
Patient 21	Bougie	Neither	Poor glottic view	2	0	1	100
Patient 22	Bougie	Neither	Poor glottic view	2	0	1	96
Patient 23	Bougie	Neither	Poor glottic view	2	1	1	78

eTable 8. Patients who did not receive the assigned device on the first laryngoscope attempt

a. Bougie used for rescue after intubation with the endotracheal tube with stylet was not successful.

Variable	Odds ratio	95% Confidence interval
Bougie group : Stylet group	0.88	0.64 to 1.22
Age (years)	1.14	0.99 to 1.32
Female sex	1.16	0.83 to 1.62
Ethnicity		
Black, non-Hispanic	0.89	0.61 to 1.29
Hispanic	1.43	0.77 to 2.67
Other	1.67	0.77 to 3.59
Body-mass index (kg/m ²)	1.00	0.88 to 1.12
Operator's number of previous	1.14	1.05 to 1.24
intubations		
ICU : ED	0.66	0.45 to 0.95

eTable 9. Multivariable models for successful intubation on the first attempt.

This table shows the results of the multivariable model. We fit a generalized linear mixed-effects model using a logit link function with the primary outcome as the dependent variable, operator and study site as random effect, and fixed effects of study group and the variables listed above. Age, BMI, and intubation experience were modeled with a nonlinear relationship to the outcome using restricted cubic splines with 3 knots. The effect estimates were made by comparing the 75th percentile to the 25th percentile.

A second model including use of a video vs direct laryngoscope, presence of ≥ 1 difficult airway characteristic (obesity, body fluids obscuring glottic view, cervical immobilization, or facial trauma), and Cormack-Lehane grade 2, 3, or 4 laryngeal view, produced a similar result for the effect of use of a bougie vs use of a stylet on the outcome of successful intubation on the first attempt (OR 0.82; 95% CI 0.59 to 1.14).

Analysis	Sample size	Bougie	Stylet group	Absolute	P value
		group		(95% CI)	
		No. with succ	ess / total no. in		
		analy	<u>sis (%)</u>		
Repeating the primary	1099	445/553	453/546	-2.5%	0.28
analysis but excluding		(80.5)	(83.0)	(-7.2% to 2.3%)	
intubations performed with a					
hyperangulated blade.	1100		110/515	0.00/	0.50
Repeating the primary	1102	446/556	443/546	-0.9%	0.70
analysis but considering		(80.2)	(81.1)	(-5.8% to 5.9%)	
device to the non assigned					
device to the non-assigned					
intubate on the first attempt					
Repeating the primary	1082	439/545	444/537	-2.1%	0.37
analysis but including only		(80.6)	(82.7)	(-6.9% to 2.7%)	
data on the primary outcome		, , , , , , , , , , , , , , , , , , ,	· · · ·		
reported by the independent					
observer and excluding the 20					
cases in which data from the					
independent observer were					
unavailable and the operator					
self-report was used to					
determine whether successful					
intubation on the first attempt					
had occurred.	1011	415/505	101/505	1.60/	0.40
Repeating the primary	1011	415/505	424/506	-1.6%	0.49
analysis but excluding cases		(82.2)	(83.8)	(-6.4% to 3.2%)	
in which the operator had ≤ 10					
Peneoting the primary	684	288/242	202/242	1 50/2	0.50
analysis but excluding cases	004	(84.2)	(85.7)	(-7.1% to 4.2%)	0.39
in which the operator had < 5		(04.2)	(05.7)	(7.170 to 4.270)	
total prior intubations using a					
bougie.					
Repeating the primary	1102	487/546	484/546	-1.1%	0.59
analysis with the alternative		(87.6)	(88.6)	(-5.1% to 2.9%)	
definition of successful					
intubation on the first attempt					
of "intubation with only one					
insertion of the laryngoscope					
blade into the mouth".					

eTable 10. Pre-specified sensitivity analyses.

eTable 11	. Post-hoc	sensitivity	analyses.
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Analysis	Sample size	Bougie group	Stylet group	Absolute difference (95% CI)	P value
		No. with succ anal	cess / total no. in ysis (%)		
Repeating the primary analysis among patients with body mass index $> 40 \text{ kg/m}^2$	71	26/38 (68.4)	29/33 (87.9)	-19.5% (-40.8% to 1.9%)	0.05
Repeating the primary analysis, limited to sites with an attending always present at the tracheal intubation procedure.	950	387/481 (80.5)	392/469 (83.6)	-3.1% (-8.2% to 2.0%)	0.21
Repeating the primary analysis, limited to sites with an attending <i>not</i> always present at the tracheal intubation procedure.	152	60/75 (80.0)	61/77 (79.2)	0.8% (-12.8% to 14.4%)	0.91
Repeating the primary analysis, limited to ICU intubations performed with a video laryngoscope	241	101/122 (82.8)	101/119 (84.9)	-2.1% (-12.2% to 8.0%)	0.66
Repeating the primary analysis, limited to ICU intubations performed with a direct laryngoscope	176	56/84 (66.7)	68/92 (73.9)	-7.2% (-21.9% to 7.4%)	0.29
Repeating the primary analysis, limited to ED intubations performed with a video laryngoscope	587	255/302 (84.4)	245/285 (86.0)	-1.5% (-7.6% to 4.6%)	0.60
Repeating the primary analysis, limited to ED intubations performed with a direct laryngoscope	98	35/48 (72.9)	39/50 (78.0)	-5.1% (-24.2% to 14.0%)	0.56
Repeating the primary analysis among cases where a resident physician was the operator	679	279/344 (81.1)	285/335 (85.1)	-4.0% (-9.9% to 2.0%)	0.17
Repeating the primary analysis among cases where a fellow physician was the operator	375	145/187 (77.5)	147/188 (78.2)	-0.7% (-9.6% to 8.3%)	0.88

Subgroup	Bougie group	Stylet group	Adjusted odds ratio (95% CI)	P value for interaction		
COVID-19 pandemic ^a						
Before	308/380	301/366	0.98			
pandemic	(81.1)	(82.2)	(0.66 to 1.47)	0.55		
After pandemic	139/176	152/180	0.79			
_	(79.0)	(84.4)	(0.44 to 1.41)			
Body fluids obscuring the glottic view						
No	418/506	419/490	0.85			
	(82.6%)	(85.5%)	(0.59 to 1.23)	0.37		
Yes	29/50	34/56	1.30			
	(58.0%)	(60.7%)	(0.56 to 3.05)			

eTable 12: Additional Subgroup Analyses of the Primary Outcome

a. Patients enrolled on or before February 28, 2020, were considered to have been enrolled before the Coronavirus disease 2019 pandemic.

eTable 13. Additional procedural outcomes.

Characteristic	Bougie group n=556	Stylet group n=546	Absolute difference (95% CI)
Number of total laryngoscop	e insertions – no. (%)		
One insertion	487 (87.6)	484 (88.6)	-1.1% (-5.1% to 2.9%)
Two insertions	61 (11.0)	47 (8.6)	2.4% (-1.3% to 6.0%)
Three or more insertions	8 (1.4)	15 (2.7)	-1.3% (-3.2% to 0.6%)
Number of total bougie inser	tions – no. (%)		· · · · ·
Zero insertions	4 (0.7)	489 (89.6)	-88.8% (-91.7% to -86.0%)
One insertion	500 (89.9)	48 (8.8)	81.1% (77.5% to 84.8%)
Two insertions	40 (7.2)	7 (1.3)	5.9% (3.4% to 8.4%)
Three or more insertions	12 (2.2)	2 (0.4)	1.8% (0.3% to 3.3%)
Number of total endotrachea	l tube insertions – no.	(%) ^a	
One insertion	528 (95.0)	471 (86.3)	8.7% (5.1% to 12.3%)
Two insertions	26 (4.7)	61 (11.2)	-6.5% (-9.8% to -3.1%)
Three or more insertions	2 (0.4)	14 (2.6)	-2.2% (-3.8% to -0.6%)
Video screen viewing – no. (%	(0)	· · · · ·	, , , , , , , , , , , , , , , , , , ,
Video screen viewed when a video laryngoscope was used	387/416 (93.0)	363/402 (90.3)	2.7% (-1.3 to 6.8%)
Other Complications – no. (%	(0)		
Bradycardia (heart rate < 40 bpm)	4 (0.7)	2 (0.4)	0.4% (-0.7% to 1.4%)

a. Endotracheal tube insertions includes either direct insertion of the endotracheal tube with stylet into the trachea or advancement of the endotracheal tube over a bougie that had been placed in the trachea. Patients in the bougie group were more likely to experience multiple insertions of the bougie followed by a single advancement of an endotracheal tube over the bougie whereas patients in the stylet group were more likely to experience multiple attempts to directly insert an endotracheal tube with stylet into the trachea.

Event number	Severity	Relatedness	Narrative
1	Serious	Not Related	The patient was randomized to the endotracheal tube with stylet. The first attempt was not successful. The second attempt was successful with use of a bougie. After intubation, the patient was hemodynamically stable with a normal oxygen saturation.
			Fifteen minutes after intubation a Blakemore tube was placed in the esophagus for upper gastrointestinal hemorrhage with inflation of the gastric and esophageal balloons. The patient immediately developed high airway pressures, hypoxemia, hypotension, and was found to have a pneumothorax. Upper gastrointestinal endoscopy revealed an esophageal rupture, which was attributed to Blakemore tube placement and inflation of esophageal balloon.
			In the operating room, in addition to the esophageal rupture, a tear in the posterior trachea was observed. The patient died the following day.
			The treating team believed that both the esophageal and tracheal injury were caused by the Blakemore tube, as evidenced by the stability of the patient until the Blakemore tube was placed.

eTable 14. Adverse events.

Characteristics	Bougie group n=109	Stylet group n=93	Absolute difference (95% CI)
Reason for failure on the first	attempt at intul	oation – no. (%)	
Inadequate view of vocal cords	31 (28.4)	29 (31.2)	-2.7% (-16.4% to 10.9%)
Difficulty passing the endotracheal tube	17 (15.6)	55 (59.1)	-43.5% (-56.6% to -30.5%)
Difficulty passing the bougie	37 (33.9)	0	33.9% (24.1% to 43.8%)
Other	7 (6.4)	4 (4.3)	2.1% (-5.1% to 9.3%)
Unknown	17 (15.6)	5 (5.4)	10.2% (1.0% to 19.4%)
Devices used after failure on t	he first attempt	at intubation ^a – no. (%)
Bougie	86 (78.9)	47 (50.5)	28.4% (14.6% to 42.1%)
Endotracheal tube with stylet	24 (22.0)	48 (51.6)	-29.6% (-43.4% to -15.8%)
Bronchoscope	1 (0.9)	2 (2.2)	-1.2% (-5.7% to 3.2%)

eTable 15. Management when intubation did not occur on the first attempt

a. Patients could receive more than one device for subsequent attempts

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