Supplementary Online Content

Driver BE, Prekker ME, Klein LR. 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. *JAMA*. doi:10.1001/jama.2018.6496

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

eTable 1. Trial Outcome Analysis Accounting for Clustering by Physician

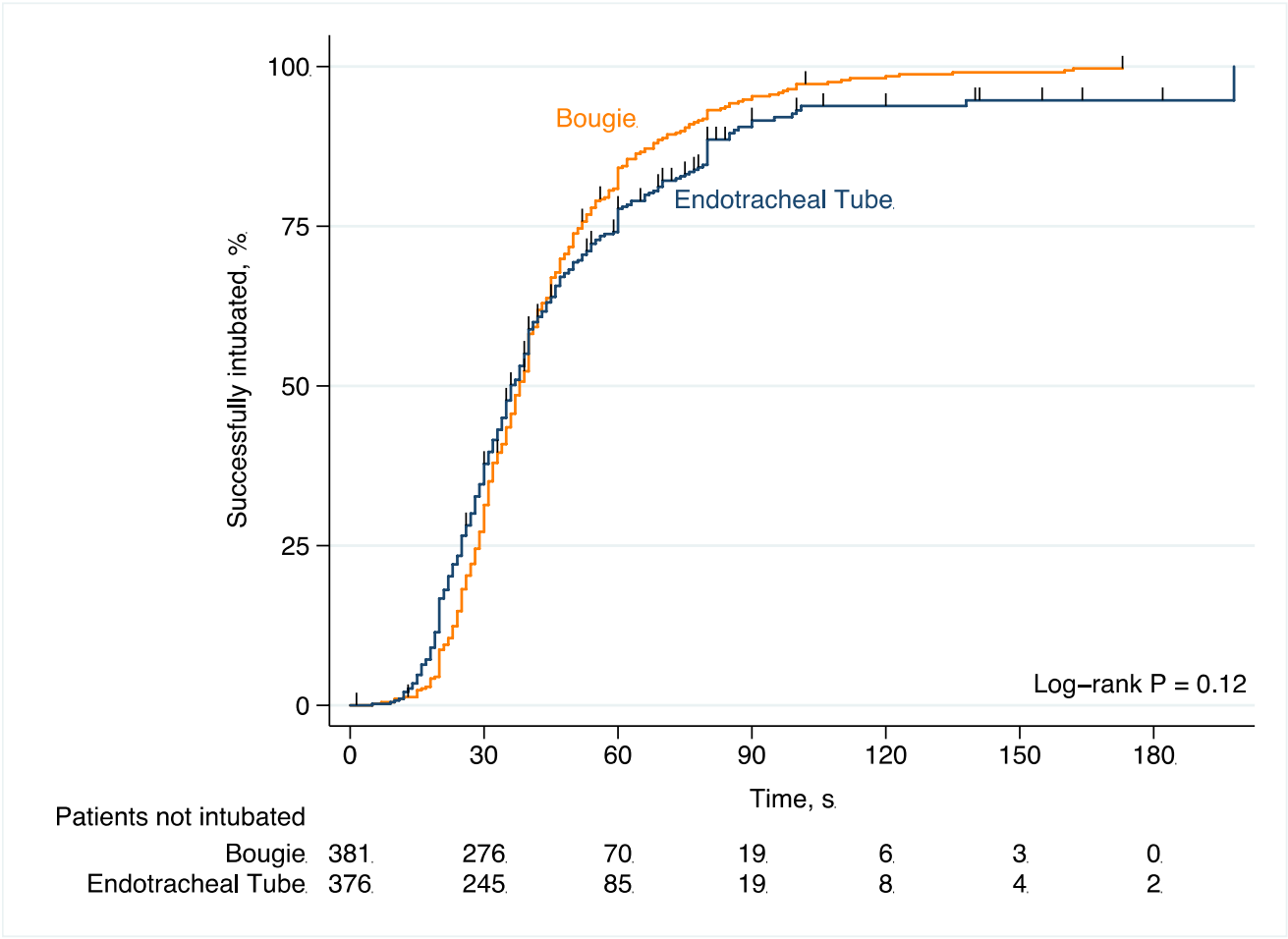
Outcome	Bougie (N=381)	Endotracheal Tube (N=376)	Difference (95% CI)	P-value	Interaction P-value
Primary outcome					
First attempt success, any difficult airway characteristic (N=380)	191/198 (96; 93 - 99)	150/182 (82; 76 - 88)	14% (7% - 21%)	<0.001	0.35
Planned Secondary outcomes					
Patients with any difficult airway characteristic (N=380)					
First attempt success without hypoxemia*	156/191 (82; 76 - 87)	123/177 (69; 63 - 76)	12% (2% - 22%)	0.015	0.61
First attempt duration†, median (IQR)	39 s (29 - 52 s)	40 s (27 - 63 s)	-1 s (-6 s to 3 s)	0.31	0.17
All Patients (N=757)					
First attempt success, overall	373 (98; 96 - 99)	328 (87; 83 - 90)	11% (6 - 15%)	<0.001	n/a
First attempt success without hypoxemia*	317/371 (85; 81 - 89)	282/366 (77; 72 - 81)	8% (2 - 15%)	0.02	n/a
First attempt duration†, median (IQR)	38 s (29 - 51 s)	36 s (25 - 54 s)	1 s (-1 s to 4 s)	0.95	n/a

All values are no. (%; 95% confidence interval) except for first attempt duration; the 'Difference' column displays the difference in proportion or median and the 95% confidence interval. The interaction column displays "n/a", not applicable, for analyses that included all patients, since these were not subgroup analyses. The columns "Bougie" and "Endotracheal Tube" are unchanged in this analysis, and the "Difference," P-value, and interaction P-value columns have been re-calculated to account for clustering by physician. The intraclass coefficient was estimated to be <0.001 (95% confidence interval <0.001 to 0.03); the upper bound of the 95% confidence interval was used in the analysis.

*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 less than 90%, an absolute decrease in saturation of more than 10%) during or within 1 minute after completion of the intubation attempt. Valid pulse oximetry waveform during intubation was not available for all patients.

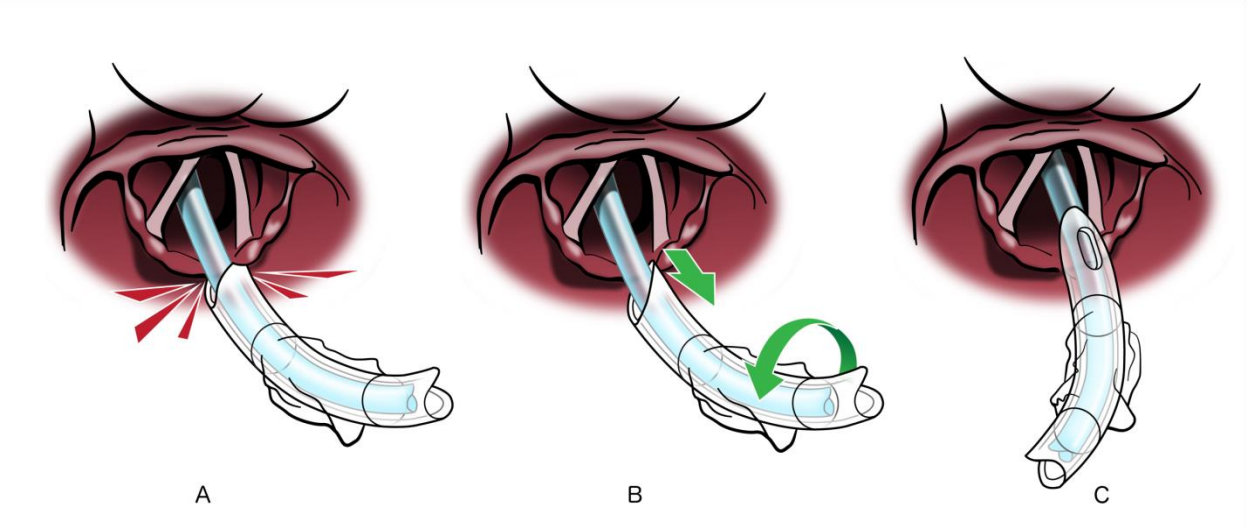
†Intubation duration was defined as the time elapsed from when the laryngoscope blade entered the mouth to when the blade was removed from the mouth.

eFigure 1: Kaplan-Meier Curve for Duration of the First Intubation Attempt for All Patients



This figure displays estimates of the time until successful intubation by group for all patients. The hazard ratio for first attempt success the bougie group was 1.12 (95% CI 0.97 -1.30), with endotracheal tube plus stylet group as reference. Vertical ticks mark the time point when the intubation attempt for one or more patients ended in failure. The assumption of proportional hazards over time was not upheld.

eFigure 2. Maneuver to correct bevel orientation if resistance is encountered during endotracheal tube passage



A) Resistance is sometimes encountered at the level of the arytenoids during endotracheal tube passage. To correct this, B) withdraw the tube 1-2 cm and rotate 90 degrees counterclockwise, then C) readvance the endotracheal tube with the bevel in a more favorable position.

From Reardon RF, Carleton SC. Direct Laryngoscopy. In: Brown CA III, Sakles JC, Mick NW, eds. The Walls Manual of Emergency Airway Management. 5th ed. Philadelphia, PA: Wolters Kluwer; 2018: 139-156. Permission granted from Wolters Kluwer. Originally commissioned by Hennepin County Medical Center.

eAppendix 1. Interim Analysis

Per protocol section 8.6.2:

> An interim analysis will be performed after 500 patients are enrolled. The data will be analyzed for the primary outcome only.
>
> The trial will be stopped early only for futility. After the data from the first 500 patients is analyzed, a sensitivity analysis will be performed. An analysis will be performed with a sample size of 1000 patients (equal allocation in both arms) with the following assumptions:
>
> - First pass success rate with non-use the GEB remains the same in the second half of the trial
> - First pass success rate with use of the GEB is 15% higher (absolute difference, up to a success rate of 100%) than observed in the first half of the study
>
> If no difference is found in first pass success with this analysis, then the trial will be stopped early for futility.

After 507 patients were enrolled, first pass success rates were:

- First pass success with a bougie: 250/257 (97%)
- First pass success with an endotracheal tube and stylet: 213/250 (85%)

Using the assumptions above, the trial was not stopped for futility.

eAppendix 2. Postintubation Data Form

1. Was pre-hospital intubation attempted?

Yes	No

2. Training level of intubator (circle one):

G1	G2	G3	G4+/Fellow	Faculty	PA
Other (explain):					

3a. Indication for intubation:
(pick <u>ONE</u> best choice from medical <u>OR</u> one from trauma)

<u>Medical</u>

Airway obstruction (not anaphylaxis or angioedema)	Anaphylaxis	Angioedema	Asthma
Cardiac Arrest	CHF	COPD	GI bleed
Intracranial hemorrhage	Acute MI	Non-overdose AMS	Overdose
Pneumonia	Pulm embolism	Seizure	Stroke
Shock (sepsis)	Shock (cardiogenic)	Shock (PE)	Shock (other)

Other:_____

<u>Trauma</u>

Abdominal trauma	Burn/inhalation injury	Chest trauma	Combative/agitated
Facial Trauma	Head injury without hemorrhage	Head injury with hemorrhage	Neck Trauma
Polytrauma	Shock (hemorrhagic)	Shock (spinal trauma)	Traumatic arrest

Other:_____

3b. If trauma, select one:

Blunt	Penetrating

4. Identify the highest-level device used for pre-oxygenation (select one option)

0	None
1	Simple nasal cannula
2	Face mask (simple or non-rebreather)
3	Face mask + nasal cannula
4	High flow nasal cannula
5	BVM: one person technique
6	BVM: two person technique
7	CPAP or BiPAP
8	Extraglottic device (LMA or King)
9	Other (explain) :

5. Highest oxygen flow rate during preoxygenation (pick one)

15 LPM or less	Flush rate (flowmeter turned up maximally)

6. Was the elevation of the head of the bed 30˚ or more during pre-oxygenation?

Yes	No

7. Was the nasal cannula used during intubation attempts?

Yes	No

8. Sedative used for RSI (circle one):

No sedative	Etomidate	Ketamine	Midazolam	Propofol
Other (explain):				

9. Paralytic used for RSI (circle one):

No paralytic	Succinylcholine	Rocuronium	Vecuronium	Pancuronium

10. If both a sedative and paralytic were administered, which was administered first?

Sedative	Paralytic

11. Intubation position (select one):

	C-spine extension only
	Full sniffing position: C-spine extension plus head elevation (Ear to sternal notch)
	Neutral c-spine position
	Seated Upright

12. Were there any of the difficult intubation parameters listed below?
<u>CHECK/SELECT ALL THAT APPLY</u>

	Blood or vomit in airway
	Short neck
	Cervical immobilization during attempt
	Small mandible
	Obesity
	Airway obstruction/edema (foreign body, angioedema, anaphylaxis, infection)
	Facial trauma
	Large tongue

ATTEMPT #1

The intubation attempt:

- **BEGINS** when the laryngoscope blade (metal handle) is **inserted** into the patient's mouth
- **ENDS** when the laryngoscope blade (metal handle) is **removed** from the patient's mouth

13. Device used

	CMAC with Mac 3 or 4 blade
	Macintosh DL blade (no video)
	Glidescope with Macintosh blade
	Other (explain):

14. For the CMAC and Glidescope (with Macintosh blade), how was the video screen used during the intubation?

	Screen was never used
	During entire attempt
	During passage of ETT or bougie into glottis (do not count passage of ETT over bougie)
	N/A – Blade inserted and removed before attempting intubation

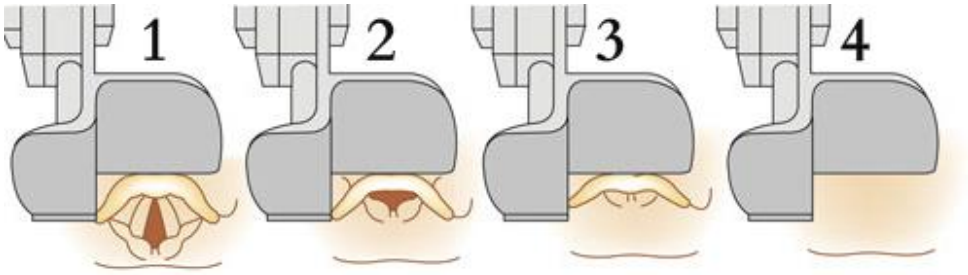
15. What was passed first for this attempt?

	Bougie
	Endotracheal tube
	N/A – Blade inserted and removed before attempting intubation

16. Was the attempt with the first device (bougie or ET tube) successful, or did the intubator have to switch? Select the best option below.

- ☐ Bougie successful
- ☐ Endotracheal tube successful (just endotracheal tube without use of bougie)
- ☐ Switch from bougie to endotracheal tube
  - This **does not include** when the tube is passed over the bougie. Select this box only if the intubator had to fully remove the bougie and then use **just** an endotracheal tube without the use of a bougie.
- ☐ Switch from endotracheal tube to bougie
- ☐ N/A – Blade inserted and removed without attempting Bougie / ETT

17. Intubating Conditions for first attempt (circle one):



18. Were these intubating conditions seen by DL or video? (select <u>one</u>)

DL	Video

ATTEMPT #2 (if first attempt fails)

The intubation attempt:

- **BEGINS** when the laryngoscope blade (metal handle) is **inserted** into the patient's mouth
- **ENDS** when the laryngoscope blade (metal handle) is **removed** from the patient's mouth

19. Device used

	CMAC with Mac 3 or 4 blade
	Macintosh DL blade (no video)
	Glidescope with Macintosh blade
	Other (explain):

20. For the CMAC and Glidescope (with Macintosh blade), how was the video screen used during the intubation?

	Screen was never used
	During entire attempt
	During passage of ETT or bougie into glottis (do not count passage of ETT over bougie)
	N/A – Blade inserted and removed before attempting

21. What was passed <u>first</u> for this rescue attempt?

	Bougie
	Endotracheal tube
	N/A – Blade inserted and removed before attempting intubation

22. Was the attempt with the first device (bougie or ET tube) successful, or did the intubator have to switch? Select the best option below.

- ☐ Bougie successful
- ☐ Endotracheal tube successful (just endotracheal tube without use of bougie)
- ☐ Switch from bougie to endotracheal tube
  - This **<u>does not include</u>** when the tube is passed over the bougie. Select this box only if the intubator had to fully remove the bougie and then use **<u>just</u>** an endotracheal tube without the use of a bougie.
- ☐ Switch from endotracheal tube to bougie
- ☐ N/A – Blade inserted and removed without attempting Bougie / ETT

23. If the second attempt was not successful, describe the remainder of the intubation course.

_____

_____

_____

_____

24. If a bougie was used, did you feel either of the following?

(select all that apply):

	Tracheal clicks
	Hard stop at carina
	Or: Bougie not used

25. *If the bougie was used*, <u>did the endotracheal tube get caught</u> at the arytenoids when passing it (during any attempt)?

	No
	Yes, the tube was rotated 90 degrees and passed successfully
	Yes, and we were unable to intubate and had to remove the bougie
	N/A – Bougie not used

26. How was the ETT placement confirmed? (Select all that apply):

	Quantitative/waveform CO2
	Auscultation
	Sonographic Sliding signs
	None

27. Complications: (select all that apply)

	Direct airway injury
	Witnessed aspiration during intubation attempt
	Cardiac arrest that began during intubation or within 5 minutes after intubation
	Cardiac arrest or death in the ED, at any time
	Iatrogenic bleeding
	Pharyngeal laceration
	Dental trauma
	Lip laceration
	Esophageal intubation