CRITICAL REVIEW FORM:
THERAPY ARTICLES

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Citation:

Driver BE, et al. BOUGIE Investigators and the Pragmatic Critical Care Research Group. 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. JAMA. 2021 Dec 28;326(24):2488-2497.

Study Objective: "To determine the effect of use of a bougie vs an endotracheal tube with stylet on successful intubation on the first attempt"

Study Methodology:
RCT – patients randomly assigned to use of bougie or use of ETT w stylet
Multicenter (15 sites – ED's & ICU's), unblinded. All US sites with EM training programs.
Randomized – 1:1 via random block allocation and assignments in opaque envelopes
Measure first-pass success rates in both groups
Deferred to operator – laryngoscope size, RSI meds, method of subsequent attempts
Measures – intubation attempts, time between induction + intubation, SpO2 at induction, lowest SpO2
Operators reported laryngoscope, grade of view, intubation success, difficult airway, complications, intubation experience

GUIDE	COMMENTS
I. Are the results valid?	
A. Did experimental and control groups begin the study with a similar prognosis	Yes – all required placement of definitive airway
1. Were patients randomized?	Yes – computer generated block-allocation of 2,4 and 6 assigned in a 1:1 distribution.
2. Was randomization concealed (blinded)? In other words, was it possible to subvert the randomization process to ensure that a patient would be "randomized" to a particular group?	Yes. Group assignments were placed in opaque envelopes and concealed until enrollment.
3. Were patients analyzed in the groups to which they were randomized?	Yes – authors used intention-to-treat analysis "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 The primary analysis included all randomized patients except those withdrawn from the study for prisoner status identified after intubation." A small number in each group were intubated via alternate method on first attempt but were included in the ITT analysis.

4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	Generally, yes. on review of pre-intubation characteristics patients were similar (Table 1). The majority of both groups had AMS (44.2% vs 45.1%) or Acute Resp Failure (32.6% vs. 30.4%)
5. Were patients aware of group allocation?	No, they were being intubated
6. Were clinicians aware of group allocation?	Yes, because they had to perform either method for intubation
7. Were outcome assessors aware of group allocation?	Yes, due to nature of study and the need for data collection at or immediately post intubation blinding was not possible.
8. Was follow-up complete?	Yes. Outcome was limited and no follow-up required.
What are the results ?	• Primary – No difference between use of bougie vs stylet in first-pass success of intubation. (80.4%) with ET tube + stylet (83.0%) groups: risk difference -2.6%, 95% CI -7.3 to 2.2%. Secondary – No increased risk of significant hypoxemia (SpO2 <80%) in either group Exploratory: - 12 second increased time to intubation with bougie - No difference in PTX (underpowered) - Lower risk of CV collapse and death at 28d in bougie group, but unclear if true risk reduction or because of chance as bougie did not affect first-pass success or other procedure measures
1. How large was the treatment effect?	Absolute risk difference -2.6 w/ CI -7.3 to 2.2
2. How precise was the estimate of the treatment effect? (CI's?)	No difference as CI crosses 0
III **How can I apply the results to patient care?**	

1. Were the study patients similar to my patient?	Median BMI 26.1 & 26.6 otherwise all US based locations similar training centers. ~2/3 patients Caucasian – I think our local population would have higher number of Black patients in addition to other ethnicities
2. Were all clinically important outcomes considered?	I would say so – first-pass intubation is critical to efficient and quality definitive airway care. Also, several potential adverse events of intubation were considered including PTX within 48 hours, CV collapse post-RSI, vent-free and ICU-free days, and death
3. Are the likely treatment benefits worth the potential harm and costs?	I would say there are no real potential harms or costs from style of intubation. Given this study showed no difference, it would be beneficial for operators to choose their preferred method.

Limitations:

- Unblinded – unavoidable in operators
- Unclear which methods used on subsequent intubation attempts if failure on first
- Patient exclusions:
    - High urgency for intubation precluding trial procedure may have missed the group of patients most likely to benefit from bougie assisted airwaws.
    - Hyperangulated blade use
    - Bougie specifically indicated
- Most operators had limited experience using bougie
    - Could postulate that if operators had equal experience w/ both stylet and bougie that this may reasonably alter outcomes
- Many operators with limited intubating experience (i.e. residents)
    - Could have different outcome(s) in trial limiting to only experienced or only novice operators
- Underpowered for comparison of subgroups

Clinical Bottom Line:

Overall, I felt this was a relatively well-designed study. I think there is some limitation in determining the “better” method of intubation in a study that includes a variety of experience in operators as well as varying experience with the bougie itself. For example, it is not unreasonable to estimate that a seasoned attending physician with minimal prior experience with a bougie would have much higher success with the stylet method. However, they do cite a p-value of 0.50 with comparison of groups with prior intubations of <60 and >60.

In my opinion, this study solidifies the notion that prior experience and comfortability best dictates method of choice and success in first pass intubation.