Critical Review Form
Therapy

Turgeon AF, Nicole PC, Trépanier CA, Marcoux S, Lessard MR. Cricoid pressure does not increase the rate of failed intubation by direct laryngoscopy in adults. Anesthesiology. 2005 Feb;102(2):315-9.

Objectives: **" to evaluate the effect of CP on the rate of failed orotracheal intubation and on the conditions of intubation in adult patients under general anesthesia." (p. 315)**

Methods: **This randomized, controlled trial was conducted over a 7-month period at the Centre Hospitalier *Affilié* Universitaire de Québec. Adult patients undergoing elective surgery under general anesthesia with orotracheal intubation were eligible for inclusion. Exclusion criteria included contraindications to the induction medication or cricoid pressure, upper respiratory tract abnormalities or known difficulty ventilating by mask, history of a difficult intubation, pregnancy, surgery requiring a double-lumen endotracheal tube, symptomatic GERD, morbid obesity, and "definite indications for cricoid pressure."**

Patients were randomized to either receive cricoid pressure (CP) during endotracheal intubation or to receive "sham" cricoid pressure (SCP). If intubation could not be completed within 30 seconds, the attempt was recorded as a failure and patients then crossed over to the other group for a second intubation attempt. If intubation could not be completed within another 30-second window (second attempt), the airway was then managed according to the difficult airway algorithm. If the oxygen saturation decreased to less than 90% at any time during the intubation attempts, the protocol was terminated and the attempt was recorded as a failure. The primary endpoint was failure to intubate within the 30-second attempt.

A total of 700 patients were enrolled; 344 were randomized to the CP group and 356 were randomized to the SCP group. The mean age in the two groups was 42.3 and 44.3 years, respectively. About half of patients in both groups were male.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis?**	
1.	Were patients randomized?	Yes. Patients were randomized to receive either cricoid pressure or sham cricoid pressure. This appears to have been done in a 1:1 fashion.
2.	Was allocation concealed? In other words, was it possible to subvert the randomization process to ensure that a patient would be “randomized” to a	Yes. "The randomization sequence was prepared with the Maple software (version 6.0; Maplesoft, Waterloo, Ontario, Canada) and sealed in prenumbered opaque

	particular group?	envelopes." (p. 316)
3.	Were patients analyzed in the groups to which they were randomized?	Yes. "...data were analyzed according to the patient's group allocation" (p. 316) consistent with an intention to treat analysis. A secondary analysis of patients who failed initial intubation was undertaken; in this analysis, patients "crossed over" to the opposite treatment. Their initial intubation failure was still analyzed according to their initial group allocation. For the initial intubation attempt, all patients received the intervention to which they were randomized.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. Patients were similar with respect to age, gender, BMI, Mallampati class, ASA physical status,
B.	**Did experimental and control groups retain a similar prognosis after the study started?**	
1.	Were patients aware of group allocation?	No. Patients were under general anesthesia at the time of the intervention and hence would not have been aware of which treatment they were receiving. There is no way performance bias on the part of the patients could have influenced the outcomes.
2.	Were clinicians aware of group allocation?	No. "In the SCP group, the cricoid cartilage was identified and the fingers were positioned as in the CP group but no pressure was applied. A screen was hung over the upper part of the patient's neck to keep both the anesthesiologist and the data collector unaware of the patient's CP or SCP status." (p. 316)
3.	Were outcome assessors aware of group allocation?	Uncertain. The primary outcome was failure to intubate within 30 seconds. It is not entirely clear who kept the time using the chronometer and whether they were blinded or not. The outcome is, however, fairly objective, and observer bias is unlikely to have influenced the outcome.
4.	Was follow-up complete?	Yes. Outcome data was available for all 700 patients randomized.
II.	**What are the results ?**	

1.	How large was the treatment effect?	• There was no significant difference between the number of patients who could not be intubated during the first 30-second attempt between the CP and SCP groups: 4.4% vs. 3.7% (RR 1.2, 95% CI .058 to 2.5). • The time to successful intubation was slightly longer in the CP group vs. the SCP group, though the difference was not statistically significant: mean 12.4 ± 4.3 vs. 11.4 ± 4.0 minutes. • The rate of failed intubation during the second, crossover attempt was similar between the groups.
2.	How precise was the estimate of the treatment effect?	See above.
III.	**How can I apply the results to patient care?**	
1.	Were the study patients similar to my patient?	No. This study was conducted in the operating room with patients undergoing elective procedures using general (presumably inhaled) anesthetics. The overall incidence of aspiration in this group would likely be much lower than among patients being emergently intubated in the ED using rapid sequence intubation (RSI). Additionally, the authors excluded many patients, including those with GERD and morbid obesity, that we would have no option but to intubate if it was required (external validity).
2.	Were all clinically important outcomes considered?	No. The primary outcome of this study (failed intubation within 30 seconds) was a surrogate outcome of uncertain clinical significance. The authors did consider the more patient-oriented outcomes of significant hypoxia or development of healthcare-associated pneumonia or development of ARDS (though it likely would have been underpowered to detect clinically meaningful differences in these).
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain. This study suggests no difference in 30-second intubation rates during elective intubation in the operating room with or without the use of cricoid pressure. Unfortunately, the primary outcome evaluated is of very uncertain

		clinical significance and the study was vastly underpowered to detect a clinically important difference in more meaningful outcomes. Additionally, the patients in this study are too different from those seen in our practice to generalize these results to the ED.

Limitations:

1. **The authors failed to adhere to the standards for reporting provided in the CONSORT statement. Specifically, they fail to report:**
    a. **The dates over which the study was performed.**
    b. **Estimated effect sizes with corresponding 95% confidence intervals.**
    c. **A review of the studies limitations.**
2. **The primary outcome in this study was a surrogate outcome of very uncertain clinical significance. While additional patient-oriented outcomes were considered, the study was vastly underpowered to detect a clinically significant difference in these outcomes.**
3. **The patients and setting in this study are very different from our practice environment, and it is unclear if these results would be externally valid when considering emergent intubation using RSI in the ED.**

Bottom Line:

This randomized, controlled, double-blinded study comparing cricoid pressure to a sham cricoid procedure during elective intubation of low-risk patients in the operating room found no significant different in 30-second intubation failure rates between the two groups (RR 1.2, 95% CI .058 to 2.5). The study's primary limitation is external validity, specifically that this group of patients and the practice setting are too different from what we encounter to generalize the results to ED patients undergoing RSI for emergent intubation.