

activity at 1 month follow up was also similar between groups. Study groups had similar rates and lengths of ICU admission, as well as hospital length of stay. Additionally, adverse events rates at 2h, during admission and at 1 month follow-up were similar.

The authors concluded the study showed no evidence for superior efficacy of levetiracetam compared to phenytoin and that both agents appear effective in treating convulsive status epilepticus in pediatric populations. Given that > 70% of cases resolved within 2 hours in patients who received one or both drugs, it appears that rates of intubation could be significantly reduced by giving the alternative 2nd line agent. The authors acknowledged this was a superiority trial, so levetiracetam cannot be considered statistically equivalent to phenytoin. Furthermore, they recognized that the different infusion times could bias the results in favor of phenytoin due to the occurrence of natural seizure decay or onset of benzodiazepine effect. The results cannot be generalized to patients who regularly take levetiracetam or phenytoin since these populations were excluded from the study. There is potential for physician bias since they were not masked to the assigned therapy, but they did use video analysis to mitigate this possibility. Additionally, EEG was not used and patients with non-epileptic events may have been included.

[Ryan Matthews, MD
Amanda Young, MD

University of Arkansas for Medical Science, Little Rock, AR]

Comment: Overall, this randomized controlled trial suggests it is reasonable to choose either phenytoin or levetiracetam as a 2nd line agent, followed by adding the other agent if seizures persist. This can likely prevent unnecessary intubations as patients who received both drugs had high rates of seizure cessation and stabilization. It is important to note that children already on one of these agents were excluded. Additionally, this trial was open label so there added risk of bias. Although both agents appear effective, further studies are needed to demonstrate equivalent therapeutic benefit.

□ COMPARISON OF THE EFFICACY OF A BOUGIE AND STYLET IN PATIENTS WITH ENDOTRACHEAL INTUBATION: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS.



Sheu YJ, Yu SW, Huang TW, et al. *Journal of Trauma and Acute Care Surgery*. 2019;86(5):902–908

Endotracheal intubation (ETI) is a common procedure in the emergency department, one in which first-attempt success is vital to preventing peri-intubation adverse events. Endotracheal intubation is often performed with assistance from either a flexible bougie or malleable stylet placed into the endotracheal tube. A recent article in the *Journal of the American Medical Association* found that the bougie had a higher first-attempt success rate. This meta-analysis took this recent study and compared it to other randomized controlled trials evaluating first-attempt success, intubation duration, and safety of using a bougie versus using a stylet.

This meta-analysis collected data from randomized controlled trials (RCT) performed prior to October 2018 using

search databases including PubMed, Embase, and the Cochrane Library. The RCTs comparing the success rates of stylet and bougie were included in this analysis and had to clearly list inclusion and exclusion criteria, as well as first attempt success rates, intubation technique, and duration of intubation. The intubation attempts had to be performed on living patients, as data pertaining to manikins and cadavers were excluded. Data pertaining to the analysis from the prior RCTs was collected by two of the study authors, with disagreements and inconsistencies reviewed by a third author. The authors used the Cochrane Risk of Bias tool to evaluate the quality of the studies, assigning a grade for the overall risk of bias to each study. The data were stratified by study design, population characteristics of the patients studied, inclusion and exclusion criteria, and outcomes regarding duration of intubation, first attempt success rate, and complications. The primary outcome of the meta-analysis was first attempt intubation success rate, and secondary outcomes were intubation duration and esophageal intubation rate. The analysis used a confidence interval of 95% and significance was indicated by $p < 0.05$.

The initial search process yielded 370 studies. After removal of duplicate and ineligible studies as well as studies meeting exclusion criteria, 5 trials remained that were eligible for inclusion. Of these five trials representing 1038 patients, three were performed in the preoperative setting, one performed in the emergency department, and one performed in the pre-hospital environment. The distribution of the need for intubation was 633 (60.98%) for medical issues in the emergency department, 230 (22.16%) for elective surgeries, 124 (11.95%) secondary to trauma which were performed in the emergency department, and 51 (4.91%) patients in a pre-hospital setting for which data could not be obtained. Four of the five trials used an identical stylet (one trial used a stylet manufactured to 60 degrees), and the specific technique for using the bougie differed slightly due to different manufacturers of the bougie. The five studies all used modified Mallampati scores (four classifications) and two different systems for laryngeal grades (Cormack and Lehane, Cook's) to predict the ease of intubation. Issues regarding methodological quality were reported from the individual studies and included deviation from initial intended intervention (early termination of using the bougie secondary to unfamiliarity by the performing clinician), as well as concerns about the randomization process and bias in the measurement of outcomes.

For the primary outcome of first-pass intubation rate, there was no difference between bougie or stylet (RR, 1.03; 95% CI, 0.85–1.24). The definition of the duration of intubation, or time it took to secure the airway, varied slightly in all five of the trials', but overall there was no difference between bougie or stylet (mean difference in seconds, 6.01; 95% CI, -0.07 to 12.09). Esophageal intubation rate was reported in four of the trials and there was also no difference found for this outcome (RR, 0.59; 95% CI, 0.13–2.59). Numerous other complications and their rates were reported between the five trials including dental trauma, witnessed aspiration, iatrogenic bleeding, hypoxemia, and pneumothorax, but there was no significant difference in rates between the two methods, and there was no overall statistical difference in complications between the two methods (RR, 1.03; 95% CI, 0.75-1.42).

The authors noted some validity concerns for the included studies as well as significant heterogeneity when the studies were combined. Additional limitations mentioned were that the studies included all patients being 12 years or older, different levels of experience with intubations between clinicians and pre-hospital providers, all but one study having fewer than 100 patients in their sample size, absence of analysis of different complications, and the use of the railroaded bougie method instead of a preloaded bougie (i.e., use of a preloaded bougie has demonstrated better success rates in recent studies). The authors state there is a multiplicity of clinical factors that contribute to the success rate of ETI regardless of the use of bougie or stylet. They found no statistically significant difference between ETI with a bougie or stylet, including the success rate of ETI during the first attempt, the duration of intubation, and the rate of esophageal intubation. They conclude that the two methods of intubation are similar and that choice of method should be left to individual comfort and experience.

[Seth Bartholomew, MD

Amanda Young, MD

Emergency Medicine, University of Arkansas for Medical Sciences]

Comment: This is the first meta-analysis comparing the use of bougie to stylet during endotracheal intubation. No differences were found for all outcomes between the two approaches, however there were methodological concerns for the included studies and significant heterogeneity, not only in the individual study methods but also the results. Additionally, only 2 of the included studies included emergency department patients, which limits the applicability for emergency physicians.

□ THE RESTRICTIVE IV FLUID TRIAL IN SEVERE SEPSIS AND SEPTIC SHOCK (RIFTS): A RANDOMIZED PILOT STUDY.



Corl KA, Prodromou M, Merchant RC, et al. *Critical Care Medicine*. 2019

The ideal amount of intravenous (IV) fluids to give septic patients is still controversial despite extensive research into the topic. Currently, it is generally accepted that initially these patients benefit from a 30 mL/kg bolus, however guidelines regarding further fluid resuscitation are less elucidated. Furthermore, there has been some research to suggest too much IV fluid resuscitation could worsen outcomes.

The goal of this study was to compare restrictive IV fluid resuscitation to standard care in adult patients with severe sepsis and septic shock over the first 72 hours of treatment. Patients either in the emergency department or the medical ICU were identified if they either met the Sepsis 2 International Consensus Criteria for sepsis or the treating physician determined their primary medical problem was caused by severe sepsis or septic shock. Exclusion criteria included receiving more than 60 mL/kg IV fluids prior to randomization, being diagnosed with another disease process that could explain their current clinical picture other than sepsis, having a fluid wasting disease process, being diagnosed with a disease process that required high volume fluid resuscitation, requiring emergent

surgery or extracorporeal membrane oxygenation, or being incarcerated or pregnant. The primary outcome measured was 30-day all-cause mortality. Secondary outcomes measured were 60-day all-cause mortality, intensive care unit (ICU) length of stay (LOS), hospital LOS, ventilator free days, ventilator hours, vasopressor free days, vasopressor hours, electrolyte abnormalities, and adverse events (myocardial infarction, acute kidney injury, organ failure, repeat intubations, disseminated intravascular coagulation, acute limb ischemia). Patients were randomized into the two groups by a computer-based program and group assignments were concealed from the researchers but not from the treating physicians. The fluid restrictive group was only allowed to have 60 mL/kg of resuscitative IV fluids over the first 72 hours of treatment. The control group could receive any amount of resuscitative fluids the physician deemed appropriate for their treatment. Fluid volumes from medications, vasopressors, blood products, or other similar infusions were not restricted and were not considered part of the resuscitative fluids.

Five hundred and thirteen adult patients were identified over a 14-month period. Four hundred patients were excluded before randomization and 4 additional patients were found to have an exclusion criterion after randomization, leaving 109 patients in the analysis. The restrictive IV fluid group received a significantly lower volume of resuscitative IV fluids (47.1 vs 61.1 mL/kg, 95% CI[3.5-24.5], $p=0.01$) compared to the usual group under an intention to treat analysis, but with no significant difference in either 30 or 60 day mortality, organ failure, vasopressor free days, vasopressor duration of use, ventilator free days, or LOS in the ICU or hospital. Although there was no difference in the number of ventilator-free days, the restrictive group did see a statistically significant decrease in the number of hours they required mechanical ventilation (16.8 vs 37.8 hours, $p=0.02$).

Several limitations were discussed. Sample size was small and patients and physicians were not blinded to treatment group. Given the lack of blinding, the authors speculated the Hawthorn effect may have influenced care since the restrictive group received statistically significantly less non-resuscitative fluids even though those fluids were not restricted in the protocol. Additionally, there was no baseline measurement of fluid status. Lastly, even the control group in this study received less fluids overall compared to other similar studies investigating fluid resuscitation in septic patients, so it is possible that both study groups could actually be considered restrictive.

The authors concluded that in this pilot study, restrictive IV fluid resuscitation did not show detrimental outcomes in septic patients, with a potential decrease in the number of hours patients require mechanical ventilation.

[Meredith Von Dohlen, MD

Jerrilyn Jones, MD, MPH

University of Arkansas Medical Sciences, Little Rock, AR]

Comment: This study suggests that septic patients may have a similar mortality and morbidity with a smaller volume of IV fluids. There were several flaws, however, that limit our applicability of this study to clinical practice. Most notably, the study