Critical Review Form Therapy

A comparison of succinylcholine and rocuronium for rapid-sequence intubation of emergency department patients. *Acad Emerg Med*.

<u>Objectives:</u> "To compare rocuronium and succinylcholine for rapid-sequence intubation (RSI) in the emergency department (ED)." (p. 1362)

Methods: This prospective cohort study included all patients intubated from January 1, 1998 to December 31, 1998 in the ED at the University of California, Davis, Medical Center, an urban Level 1 trauma center with a three-year emergency medicine residency program. In July 1997, rocuronium was stocked in the ED and the emergency physicians attended an in-service on its use in RSI. The choice of sedative and paralytic was at the discretion of the physician providing care.

A data collection form was filled out by the intubator immediately following intubation, and included such data as the patient's name, age, and gender, the paralytic agent and dose used, reason for the choice of paralytic agent, the time from agent administration to paralysis, serum potassium level at the time of intubation, the need for bag-valve-mask (BVM) ventilation, pulse-oximetry readings during intubation, and any complications during intubation. The time to paralysis was measured by an independent observer using a stopwatch, and was defined as the time from administration of the paralytic to successful insertion of the laryngoscope blade into the patient's mouth; when direct measurement was not possible, time to onset of paralysis was estimated by the intubator immediately following the intubation. Additionally, there were three ten-point numerical descriptor scales used to describe: 1) the patient's body movement during intubation, 2) vocal cord movement during intubation, and 3) the physician's satisfaction with the extent of paralysis.

During the study period, 578 patients were intubated in the ED, 63% male, with an average age of 46 years. Fifty-five intubations (10%) were in children less than 16. The initial method of intubation was RSI in 521 patients (90%), with 382 of these (73%) receiving succinylcholine and 138 (26%) receiving rocuronium.

Guide		Comments		
I. Are the results valid?				
A.	Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?			
1.	Were patients randomized?	No. The choice of using succinylcholine vs. rocuronium was at the discretion of the treating physician. This could potentially lead to selection bias.		
2.	Was randomization concealed (blinded)?	No. The patients were not randomized.		
3.	Were patients analyzed in the groups to which they were randomized?	Yes. Patients were analyzed according to which paralytic they received, and there was no crossover noted.		
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Unknown. Demographic information and medical history was not provided for the two groups. Though not likely to affect the primary outcome, factors such as BMI, predicted airway difficulty, and level of training of the person performing the intubation would likely influence some of the outcomes (Kim 2012). As this study was not randomized, it is possible that the two groups began the study with different prognoses.		
В.	Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?			
1.	Were patients aware of group allocation?	Yes and no. While <u>blinding</u> of participants is generally recommended when feasible, these were patients being sedated and paralyzed for intubation and were unlikely to be aware of group allocation. They were unlikely to be subject to performance bias.		
2.	Were clinicians aware of group allocation?	Yes. Paralytic choice was at the discretion of the treating physicians. Performance bias could therefore be introduced.		
3.	Were outcome assessors aware of group allocation?	Likely yes. The primary outcome was assessed by "an independence observer." There is no mention that this observer was blinded, and as he or she was present at the intubation would likely be aware of paralytic choice.		
4.	Was follow-up complete?	No. Time to onset of paralysis was not documented for 32 patients (9%) who received succinylcholine and 12 patients (9%) who received rocuronium. Complete pulse-oximetry and BVM data were not recorded		
		for 86 (23%) patients who received succinylcholine and 35		

II.	What are the results (answer the questions posed below)?				
1.	How large was the treatment				
	effect?		Succinylcholine	Rocuronium	p-value
		Mean measured time to onset of paralysis	39 ± 13 seconds	44 ± 20 seconds	0.04
		Mean estimated time to onset of paralysis	35 ± 24 seconds	44 ± 27 seconds	0.007
		BVM needed for desaturation prior to first intubation attempt	0 (0%)	0 (0%)	1.00
		Body movement	Mean = 9.5 ± 1.1	Mean = 9.1 ± 1.5	0.01
		Vocal cord movement	Mean = 9.2 ± 1.6	Mean = 9.0 ± 1.6	0.15
		Physician satisfaction	Mean = 9.4 ± 1.3	Mean = 8.8 ± 2.0	< 0.01
		Complications	7/382 (1.8%)	6/138 (4.3%)	0.12
		Esophageal intubation	19/382 (5.0%)	9/138 (6.5%	0.51
		Main-stem intubation	4/382 (1.0%)	2/138 (1.4%)	0.66
		themselves question the clinical significance of such small time differences. Of the remaining outcomes, the only statistically significant differences were noted in body movement and physician satisfaction. Again the clinical significance of these small differences (9.5 vs. 9.1 and 9.4 vs. 8.8, respectively) is questionable.			
2.	How precise was the estimate of the treatment effect?	There was no estimate of treatment effect (relative risk, odds ratios). P-values for differences in the outcomes are provided above.			
III.	How can I apply the results to patient care (answer the questions posed below)?	doove.			
1.	Were the study patients similar to my patient?	Uncertain. The authors provide no demographic information or medical history. We would expect patients to be similar, given that the study was performed at an academic, tertiary care, Level I trauma center associated with an emergency medicine residency program.			
2.	Were all clinically important outcomes considered?	No. More <u>patient-important outcomes</u> could have been considered, including mortality, neurologic status, ICU and hospital length-of-stay, and cost.			
3.	Are the likely treatment benefits	Uncertain. There	=	_	
	worth the potential harm and costs?	favor of succinyle	monne) with rega	ius to time to ons	set of

paralysis and body movement, however these are of uncertain clinical significance. While physician satisfaction also revealed a significant difference in favor of succinylcholine, the impact of paralytic choice on other patient-important
outcomes would likely take precedence.

Limitations:

- 1) This was an observational, non-randomized trial in which physicians who selected the paralytic also assessed outcomes: estimated time to paralysis, body and vocal cord movement, and satisfaction (ascertainment bias).
- 2) Failure to follow <u>STROBE statement</u> criteria in reporting the results of observational trials:
 - a. Failure to identify primary outcome
 - b. Failure to provide characteristics of study participants (demographic information, clinical and social data).
- 3) Those outcomes for which statistically significant results were identified may be clinically insignificant.

Bottom Line

This non-randomized, prospective observational study of succinylcholine versus rocuronium for RSI in the ED revealed a statistically significant, but likely clinically insignificant increase in time to onset of paralysis with the use of rocuronium. While a statistically significant difference in body movement and physician satisfaction was observed, favoring succinylcholine, these results were subject to <u>ascertainment bias</u>, and again may not be clinically significant.