



## Comparison of the bleeding cricothyrotomy model to SimMan for training students and residents emergency cricothyrotomy

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### Abstract

**Introduction:** A cricothyroidotomy is an emergency procedure that few emergency medicine residents see or perform during their training. Therefore, there is a need for low cost, high fidelity models for training. In this study, we explore a new training model for cricothyroidotomies (the bleeding CRIC [cost-effective realistic interactive cricothyroidotomy]) to determine if this new task-trainer is non-inferior compared to the current standard of training.

**Methods:** Authors conducted a randomized control non-inferiority study. There were seventeen residents and medical students enrolled by convenience sample to partake in the study. The participants were randomized by block randomization to be taught how to perform a cricothyroidotomy on either the new task trainer or the current standard task trainer and then were asked to perform the procedure on a pig trachea model. Primary outcome measures were scores on a previously validated objective assessment tool and secondary outcomes were comfort levels and realism scores based on pre and post survey results which were analyzed with ANOVA.

**Results:** There was found to be no statistically significant difference between the groups in assessment scores, time to completion, or comfort levels pre- and post-intervention. There was a statistically significant difference in that the participants gave higher realism scores in post-test analysis to the Bleeding CRIC compared to the SimMan. Both groups demonstrated that they had significantly improved comfort levels from baseline post-intervention.

**Conclusion:** Overall, the new task trainer was rated by learners to feel more realistic than the current standard. This study demonstrates non-inferiority of the new task trainer and further studies with larger sample sizes should be conducted to determine its true efficacy.

**Keywords:** Graduate, Medical education, Simulation training, High fidelity simulation training

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### Introduction

A cricothyroidotomy is an emergent procedure done to establish an airway in a patient who cannot be intubated or ventilated (1). It is a procedure that requires appropriate training and practice as it is only done in emergency situations.

Residents are often unable to receive training on live patients as the procedure is rare and often the more senior physicians perform the procedure (2-4). It is estimated that 0.5 to 2.5 per 10,000 cases will require a surgical airway (1). Nearly half of all emergency medicine residents will

never see a cricothyroidotomy during training, and less than one quarter will perform one (1, 5). Task trainers are essential for residents to receive appropriate training, however, these task trainers are often unrealistic or expensive (6). One of the most commonly used task trainers is part of the Lederal SimMan, a mechanical manikin used for simulation training. An artificial skin can be placed over his neck and a cricothyrotomy can be practiced on the site. One of the primary limitations of this task trainer is the cost of the artificial skin and that it is not intended to be used multiple times (7-10).

As such, it is important to evaluate new task trainers that can provide a realistic simulation experience and decrease the cost of medical education. Dr. Alisa Wray and John Ray developed a task trainer, the bleeding CRIC (cost-effective realistic interactive cricothyroidotomy) using materials easily purchased on the Internet. The task trainer is relatively inexpensive and simple to produce. This study explores this new cricothyroidotomy task trainer to determine if it improves the user's comfort and success in performing cricothyroidotomies while being non-inferior to the existing standard task trainer.

## Methods

This study is a randomized controlled non-inferiority study evaluating the efficacy for learning cricothyroidotomy on either bleeding CRIC or SimMan. Twenty volunteer participants were recruited and randomized using block randomization. We created participant numbers in advance, used block randomization to randomize those participant numbers into blocks of four and then assigned participant numbers at random once participants were consented.

The authors created the bleeding CRIC task trainer from materials readily available on the Internet or in the hospital, including ventilator tubing, a hot glue gun, tape, a life-size styrofoam wig head, Dragon Skin 10 Medium (TM) by Smooth-On, stage blood, polyester fiberfill and silicone glue. Instructions are available on <http://www.cricproject.com/cricbuild.html>. The SimMan used for the study was a Lederal (TM) SimMan (R). The authors ordered fresh frozen pig larynges from an online scientific supply company and defrosted them prior to the study. Human cadavers were not financially feasible for the study. We conducted the study at the UC Irvine School of Medicine Simulation Center during a scheduled monthly resident simulation day.

15 UC Irvine emergency medicine residents and 5 UC Irvine fourth year medical students were present at the simulation education day.

All residents and students participated in the teaching and training as a part of their normal education activities however participation in the study was optional. Three students and residents present at the simulation education day opted not to participate. We provided study information sheets and explained the study prior to the start of the session. A total of seventeen students and residents participated in the study. Authors randomized them using block randomization (with block sizes of 4) and all participants completed all aspects of the study as shown in Figure 1.

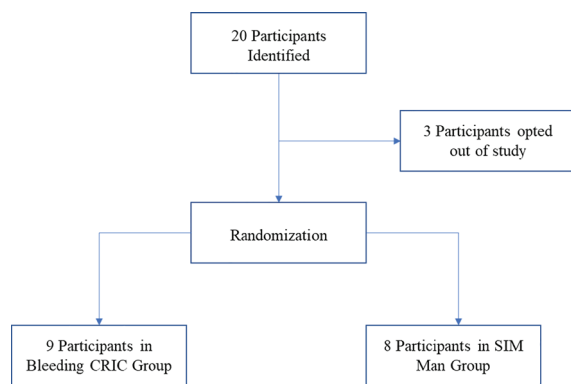


Figure 1: Participant Inclusion

The primary outcome was participant completion of a cricothyroidotomy on the pig model evaluated by a previously validated Objective Structured Assessment of Technical Skills (OSATS) (11). Secondary outcomes were the participants' comfort levels measured by the visual analog scale before and after training and evaluation (12). Pre-surveys also included questions regarding the number of cricothyroidotomy simulations previously performed, as well as the number of real cricothyroidotomies previously performed. Post-surveys asked the participants to rate the realism of the pig trachea, Bleeding CRIC, and SimMan via a previously validated visual analog scale which was a 100mm line with two end-points ranging from 'not at all' to 'extremely.'

1) All students and residents at the simulation training day received a brief verbal explanation of the study and a study information sheet.

2) The participants were assigned a number to ensure data collection was anonymous.

3) The participants completed a pre-instruction survey.

4) The authors randomized the participants, by block randomization, to receive cricothyroidotomy instruction on either the bleeding CRIC or SimMan task trainer.

5) A single instructor taught the participants how to perform a cricothyroidotomy on their assigned task trainer.

6) A single evaluator, who was blinded to the method of instruction, tested the participants on a pig trachea and evaluated them using a validated OSATS (11).

7) The participants crossed over and practiced performing a cricothyroidotomy on the task trainer they were not randomized to. This allowed all participants to experience performing a cricothyroidotomy on the SimMan, the bleeding CRIC and the pig trachea model.

8) The participants completed post-instruction survey.

A power calculation was performed based on a previously shown novice mean of 3.2 points per minute with a standard deviation of at least 1 point per minute (11). Using a two-sided t-test with an alpha of 0.05 and a power of 90%, we needed a total sample size of 43. Unfortunately, we were unable to have this number with our available study population.

The data was collected, tabulated, and coded by a research assistant not involved in any teaching aspects of the study. The means and standard deviations were calculated for OSATS scores and visual analog scores. The means for OSATS and visual analog scores were compared between the groups using a t-test (Microsoft Excel version 16.16.9). ANOVA was performed to analyze the realism scores among the three task trainers.

**Ethical approval:** The institutional review board at the University of California, Irvine approved this study.

## Results

There were 8 participants randomized into the SimMan group and 9 participants randomized into the bleeding CRIC group. There were no statistically significant differences between the groups in the level of training (Chi-square=0.81,

$p=0.84$ ). A summary of the number of medical students and residents in each group can be found in Table 1. There was also no difference between pre-intervention comfort levels between the two groups; the SimMan group mean was 41.1 (95% CI 25.6-56.7), and the CRIC group mean was 32.3 (95% CI 13.1-51.6) ( $t=0.81$ ,  $p=0.43$ ).

The summary of outcomes can be found in Table 2. The mean time to complete the cricothyroidotomy on the pig trachea was 1:41.00 (95% CI 0:50.93-2:30.98) for the bleeding CRIC group and 2:25.20 (95% CI 00:47.36-4:03.09) for the SimMan group ( $t=0.98$ ,  $p=0.34$ ). The average OSATS score was 10/12 for the bleeding CRIC group (95% CI 7.9-12) and 9.25/12 (95% CI 7.7-10.8) for the SimMan group ( $t=-0.66$ ,  $p=0.52$ ). The mean post-intervention comfort levels were 60.67 (95% CI 43.8-77.5) for the bleeding CRIC group and 64.25 (95% CI 52.4-76.1) for the SimMan group with no statistically significant difference between the two groups ( $t=0.39$ ,  $p=0.70$ ). Both groups showed a statistically significant increase in comfort levels from baseline post-intervention (bleeding CRIC: 32.33 to 60.66;  $t=-2.55$ ,  $p=0.021$ ; SimMan: 41.13 to 64.25;  $t=-2.80$ ,  $p=0.014$ ). There was also a statistically significant difference between the realism that participants attributed to each task trainer ( $F=5.14$ ,  $p<0.01$ ). The participants believed that the bleeding CRIC task trainer felt more realistic (mean=70.24) than the SimMan (mean=51.88) ( $t=3.09$ ,  $p=0.004$ ).

## Discussion

The authors conducted the study to determine if the bleeding CRIC task trainer demonstrated non-inferiority to the current standard of teaching. Although we did not reach our goal subject number, the results from the study suggest there be no difference in outcomes for the participants taught on the bleeding CRIC task trainer versus those taught on the SimMan. In the evaluation phase, the participants taught on the bleeding CRIC task trainer completed

**Table 1:** Numbers of participants in each group based on level of training

Group	Total	MS	R1	R2	R3
SIM man	8	1	2	3	2
Bleeding Cric	9	1	4	2	2

**Table 2:** OSATS and survey results between groups

Group	Pre-comfort levels	OSATS	Completion time	Post-comfort levels
SIM man	41.13±25.06 (95% CI 25.6-56.7)	9.25±2.69 (95% CI 7.7-10.8)	02:25.2±01:05.1 (95% CI 00:47.36-4:03.09)	64.25±21.93 (95% CI 52.4-76.1)
Bleeding Cric	32.33±18.59 (95% CI 13.1-51.6)	10±1.83 (95% CI 7.9-12)	01:41.0±01:57.1 (95% CI 0:50.93-2:30.98)	60.66±12.15 (95% CI 43.8-77.5)
P value for difference	0.43	0.52	0.34	0.7

Mean (Standard Deviation)

the cricothyroidotomy in less time and with a better OSATS score on average than those taught on SimMan; however, the difference was not statistically significant. Both groups did demonstrate a significant improvement in comfort levels from baseline. Lastly, the participants reported that the bleeding CRIC felt more realistic compared to the SimMan.

Similar studies have been conducted to evaluate new teaching models on resident and medical student education. One study evaluated the efficacy of new cricothyroidotomy teaching model by having one hundred twenty final year medical students complete pre- and post-teaching session surveys on confidence levels as well as having 30 of the students complete an objective skills assessment similar to our current study (13). They found that there was a significant improvement in post-session confidence levels and all 30 students were deemed competent in performing cricothyroidotomy despite no comparison group. Likewise, another study evaluated a high-fidelity epistaxis task trainer on training junior surgical residents for epistaxis management (13). They enrolled 13 residents in a cohort study and found that there was a statistically significant improvement in global rating scores across all measured items after the intervention compared to pre-intervention scores. Both studies concluded that their teaching models led to an improvement in educational outcomes for their participants. Our study was designed to include a comparison group and used pre and post surveys as well as a previously validated objective assessment tool similar to these two studies to strengthen our conclusions.

Our study however was limited largely due to the small sample size of residents. As this is a preliminary study, we determined the sample size to be satisfactory to report given it showed some significant results. The results trended toward better outcomes for the bleeding CRIC group with a few outliers. Had there been a larger sample, we may have seen more significant results. Further research should be conducted with larger sample sizes to determine the true differences between the two task trainers. More studies should be performed to determine whether the bleeding CRIC task trainer can be a viable model to implement in cricothyroidotomy training.

Importantly, the creation of a bleeding CRIC task trainer costs approximately \$88 for the initial purchases that create 40+ attempts at a cricothyroidotomy. In comparison a traditional SIM manikin or task trainer can cost more than \$2,000 (13). Our results suggest that outcomes between the two are not different, but the former

can provide significant cost savings for users.

## Conclusion

The study data shows promising results for the bleeding CRIC task trainer as it can be seen as non-inferior to the SimMan and trended towards superiority in realism. Given that the bleeding CRIC is substantially less expensive to produce and use than the SimMan, it may be useful to continue to investigate this new task trainer. If the data continues to show at least non-inferiority, this tool can be used for cricothyroidotomy training and not only reduce expenses, but also significantly enhance the training experience.

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## Conflict of Interest Disclosure

The Bleeding CRIC task trainer was produced by the current study's lead author, Dr. Alisa Wray. Dr. Wray has a free open access website [www.cricproject.com](http://www.cricproject.com) that explains how to build this model; she has received no revenue from this task trainer. There is no financial gain or conflicts of interest to report.

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