

Virtual ACS 2021 Surgeons and Engineers: A Dialogue on Surgical Simulation Meeting

Research

Non-inferiority assessment of a self-study, self-debriefing mixed reality simulator for central venous access

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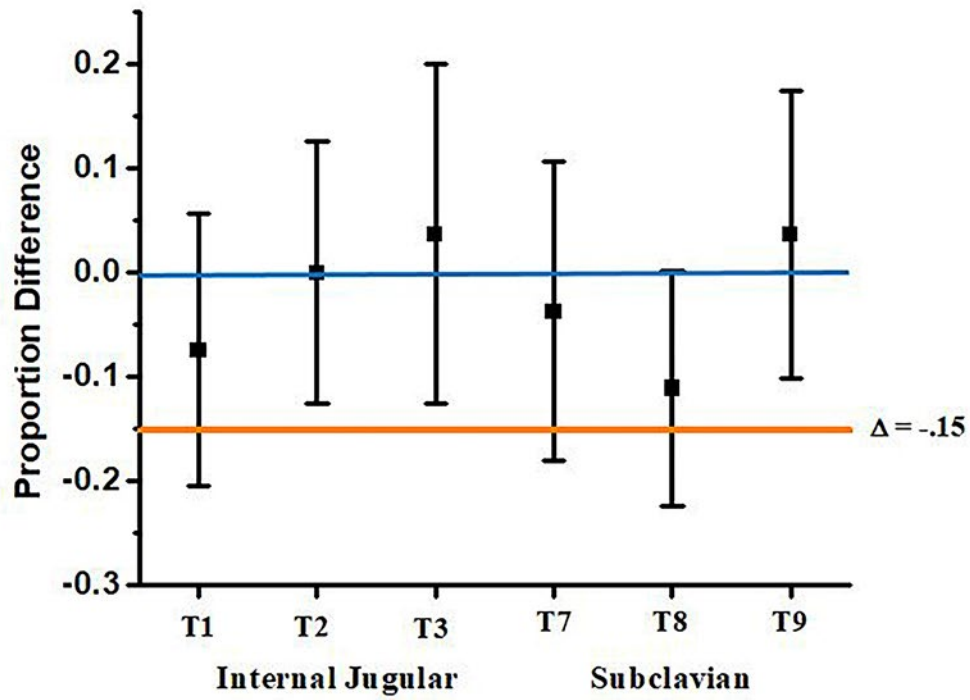
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Introduction: Simulators are more often idle than not. We developed a simulator with an optional integrated tutor (IT) for self-study/self-debriefing when instructors are unavailable. We hypothesize that our IT has similar, rather than superior, effects, i.e., can be non-inferior to an Anesthesiology human instructor (HUM) in helping trainees acquire procedural skills on a simulator.

Methods: We conducted a power analysis/sample size calculation for a non-inferiority analysis on the difference in two independent proportions, assuming $\alpha=0.05$, power=0.80, a high success rate expected for both groups (95%) and a non-inferiority margin of 15%. We assessed 54 randomly assigned trainees (IT=27; HUM=27) on central venous access (CVA) performance via both internal jugular (IJ) and subclavian (SC) approaches. We assessed baseline performance for ultrasound (US)-guided IJ access and landmark-based infraclavicular SC access. Participants were taught both methods of obtaining CVA on the same simulator by the IT or HUM. After instruction, we evaluated participants on 3 trials per approach. US-guided short and long axis techniques were required for IJ. Competency was defined as obtaining central venous access in 3 consecutive attempts without pneumothorax or arterial puncture. The non-inferiority analysis (Farrington-Manning test, SAS 9.4) for the proportion difference assumed a non-inferiority margin of 15% ($H_0: IT-HUM \leq -0.15$ vs. $H_a: IT-HUM > -0.15$). All trials were of normal anatomical difficulty.

Results: Because the non-inferiority margin, -0.15 , does not fall within the confidence interval, we conclude that IT is non-inferior to HUM for trials 2, 3, and 9 (Table)

Conclusions: Having established non-inferiority, we then used the simulator, together with its IT, to train 198 surgery, anesthesiology, EM residents; CCM, Neurology fellows; and SICU APPs to competency in US-guided IJ CVA (May-August 2018) as part of an ongoing patient outcome study. An integrated tutor makes simulation-based training more accessible when instructors are unavailable.



Trial	Approach	Success IT	Success HUM	Difference	Fisher's Exact p-value
1	IJ, long axis	88.89	96.30	-0.0741	0.61
2	IJ, short axis	96.30	96.30	0.0000	1.00
3	IJ, long axis	88.89	85.19	0.0370	1.00
7	SC	88.89	92.59	-0.0370	1.00
8	SC	88.89	100.00	-0.1111	0.24
9	SC	96.30	92.59	0.0370	1.00