The Utility of High-Fidelity Simulation for Training Critical Care Fellows in the Management of Extracorporeal Membrane Oxygenation Emergencies: A Randomized Controlled Trial

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Objective: Although extracorporeal membrane oxygenation volume has increased, proficiency in the technology requires extensive training. We compared traditional water-drill–based extracorporeal membrane oxygenation training with simulation-based extracorporeal membrane oxygenation training with the hypothesis that simulation-based training is superior.

Design: Randomized controlled trial.

Setting: Academic medical center.

Subjects: Pulmonary/critical care fellows.

Interventions: Participants had a preintervention simulated extracorporeal membrane oxygenation emergency (Sim1—recirculation) then randomized into simulation and traditional groups. Each group participated in three teaching scenarios, via high-fidelity simulation or via water-drills. After 6 weeks and after 1 year, participants returned for two simulated extracorporeal membrane oxygenation emergencies (Sim2—pump failure and Sim3—access insufficiency). Sim2 was a case encountered during teaching, whereas Sim3 was novel. A critical action, necessary for resolution of each scenario, was preidentified for timing.

Measurements and Main Results: Primary outcome was time required to perform critical actions. Twenty-one fellows participated in the study (simulation, 10; traditional, 11). Groups had similar scenario scores ($p = 0.4$) and times to critical action ($p = 0.8$) on Sim1. At 6 weeks, both groups had similar scenario scores on Sim2 ($p = 0.5$), but the simulation group scored higher on Sim3 ($p = 0.03$). Times to critical actions were shorter in the simulation group during Sim2 (127 vs 174 s, $p = 0.004$) and Sim3 (159 vs 300 s; $p = 0.04$). These findings persisted at 1 year.

Conclusions: In novice critical care fellows, simulation-based extracorporeal membrane oxygenation training is superior to traditional training. Benefits transfer to novel scenarios and are maintained over the long term. Further studies evaluating the utility of simulation in other learner groups and for maintenance of proficiency are required. (*Crit Care Med* 2017; 45:1367–1373)

Key Words: extracorporeal membrane oxygenation; medical education; respiratory failure; simulation

Extracorporeal membrane oxygenation (ECMO), a treatment modality for refractory cardiorespiratory failure, has seen a resurgence in use with ECMO volume increasing more than 10-fold over the past decade among adult patients (1, 2). This renewed interest follows advances in technology (3, 4), expanding indications (5–9), and a growing body of evidence (10–13).

The management of patients requiring ECMO support remains technically challenging requiring a thorough knowledge of cardiopulmonary physiology, familiarity with complex circuit components, and an ability to rapidly respond to complications (3, 14–16). A systematic review of ECMO cases identified clinician error as a cause for complications (16), while another recommended practitioner education to reduce adverse events (14).

A survey of 173 ECMO centers found that only half had established training programs (17). The Extracorporeal Life Support Organization, an international society focused on ECMO research and education, recommends practitioner education via lectures with water-drills or animal testing (18). Water-drills, however, offer limited opportunity for real-time troubleshooting while the use of animals is difficult and expensive (19).

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Simulation-based training has emerged as a valuable tool in critical care education (20–23) offering the opportunity to practice technical skills repeatedly and to become proficient in high-risk, low-frequency events while avoiding harm to patients (24–27). Patients on ECMO are typically dependent on the circuit for life support and are at risk for complications (14) associated with reduced survival (2, 28, 29). As such, simulation-based education may be ideally suited for teaching ECMO management.

Prior articles have reported on the feasibility (28, 30–32) and benefit (19, 33–35) of simulation-based ECMO education but have been limited by a lack of control groups. To address this limitation, we utilized a randomized controlled approach to test the hypothesis that high-fidelity simulation-based ECMO training is superior to traditional water-drill–based ECMO training.

MATERIALS AND METHODS

Study Design

This was a prospective randomized controlled trial. Study protocol was approved by the Institutional Review Board (IRB) of the Manhattan Veteran's Administration (VA) medical center (IRB number: 01474), and written informed consent was obtained from all subjects. The use of ECMO for cardiorespiratory failure is off-label.

Study Subjects

Study subjects were recruited from pulmonary/critical care fellows at New York University (NYU) Medical Center in their first ($n = 7$), second ($n = 8$), or third ($n = 7$) year of training during the 2014–2015 academic year. Study start coincided with establishment of the NYU ECMO program in an effort to recruit novice learners. The program treated 12 ECMO patients during the study period.

Study Setting

The simulation laboratory at the Manhattan VA medical center was used for all sessions.

Water-Drill Setup

An ECMO circuit composed of a Centrimag pump (Thoratec, Pleasanton, CA), a Quadrox-iD oxygenator (Maquet, Wayne, NJ), and a 27-French Avalon Elite dual-lumen cannula (Maquet, Wayne, NJ) was used for the water-drills. To maintain continuous flow in the circuit, cannula tip was sealed within an R-38 bladder reservoir (Medtronic, Minneapolis, MN) (**Fig. S1**, Supplemental Digital Content 1, http://links.lww.com/CCM/C589; **legend**, Supplemental Digital Content 5, http://links.lww.com/CCM/C593). This setup allowed for realistic values of circuit pressures, blood flow, and gas flow.

Simulation Setup

The simulation room was set up to simulate an ICU (**Fig. S2**, Supplemental Digital Content 2, http://links.lww.com/CCM/C590; legend, Supplemental Digital Content 5, http://links.lww.com/CCM/C593). While the traditional group worked with the circuit in isolation, the simulation group worked with the circuit connected to a SimMan3G (Laerdal, Wappingers Falls, NY) via a simulated right internal jugular cannulation. The mannequin was also intubated and connected to a Servo-i ventilator (Maquet, Wayne, NJ) and to a Laerdal vitals monitor (Laerdal). In addition to realistic circuit variables, this setup also incorporated patient vital signs and ventilator settings. Simulation setup is further detailed in **Supplemental Digital Content—Document 1** (Supplemental Digital Content 3, http://links.lww.com/CCM/C591).

ECMO Scenarios

We developed scenarios to reflect complications an ECMO practitioner is expected to troubleshoot (**Supplemental Digital Content—Document 2**, Supplemental Digital Content 3, http://links.lww.com/CCM/C591). A critical action, necessary for scenario resolution, was prespecified for timing. Based on prior work showing time from recognition of an ECMO emergency to isolation from the ECMO circuit required 51 ± 73 seconds and subsequently increasing ventilatory support required 51 ± 58 seconds (28), we chose a maximal scenario time of 300 seconds, allowing additional time to recognize the emergency and to resume support.

Study Interventions

Study design flow diagram is shown in **Figure 1**. Participants had a baseline written knowledge examination (**Supplemental Digital Content—Document 3**, Supplemental Digital Content 3, http://links.lww.com/CCM/C591) followed by individual participation in a scored simulated ECMO emergency scenario (Sim1—recirculation). This was followed by three ECMO lectures: 1) ECMO basics; 2) ECMO circuit; and 3) ECMO complications. Participants were randomized via computer algorithm into simulation and traditional groups. Both groups (in teams of 2–3) participated in three ECMO emergency scenarios (oxygenator failure, pump failure, and air embolus), via high-fidelity simulation or via water-drills, followed by standardized debriefings. At scenario start, both groups received identical introductions including a short history, initial vital signs, and circuit settings. During the scenario, while both groups had real-time circuit variables, the simulation group additionally had real-time vital signs and ventilatory settings. Participants evaluated their educational experience using a nine-question five-point Likert-scale survey (**Supplemental Digital Content—Document 4**, Supplemental Digital Content 3, http://links.lww.com/CCM/C591). After 6 weeks and after 1 year, participants returned for a written knowledge examination (identical to the baseline examination) followed by individual participation in two scored simulated ECMO emergency scenarios (Sim2 and Sim3). Sim2 (pump failure) was identical to a case encountered during training, whereas Sim3 (access insufficiency) was novel.

Data Collection

Scoring sheets with important scenario-specific tasks were developed based on preestablished criteria (28, 31, 32, 35)

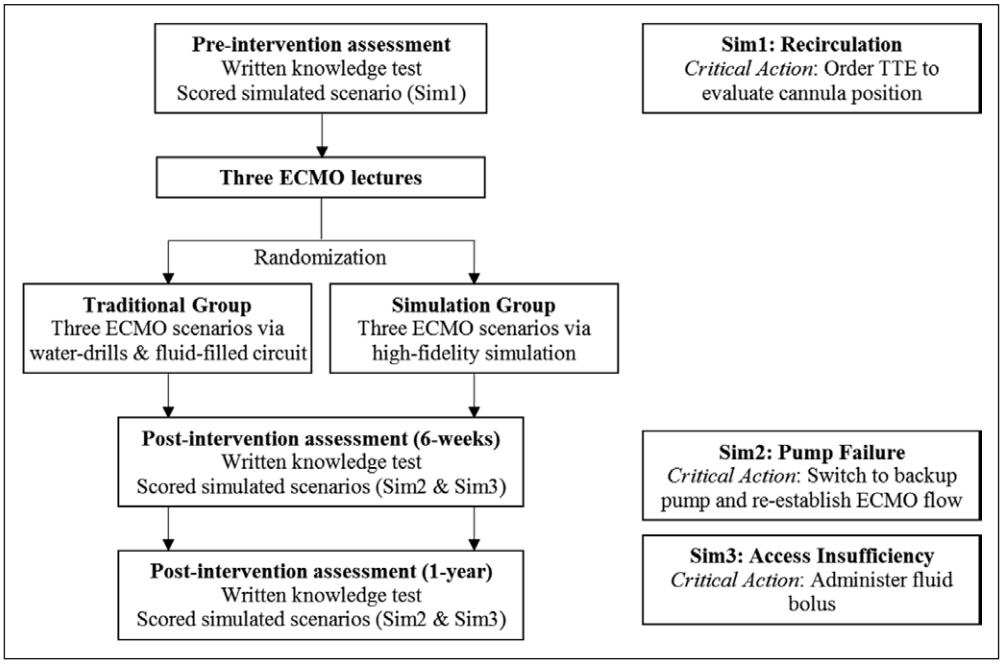

Figure 1. Study design flow diagram. After a preintervention written knowledge examination and scored simulated extracorporeal membrane oxygenation (ECMO) emergency scenario (Sim1) followed by three ECMO lectures, participants were randomized into traditional and simulation groups. Both groups participated in three ECMO emergency scenarios, via high-fidelity simulation in the simulation group and via water drills with a fluid-filled circuit in the traditional group, followed by identical debriefings. After 6 wk and after 1 yr, participants returned for a postintervention written knowledge examination followed by two scored simulated ECMO emergency scenarios (Sim2 and Sim3). For each of the scored scenarios, a critical action, necessary for resolution of the emergency scenario, was preidentified for timing. The primary outcome was the time required to perform the critical action specific to each simulated scenario at the 6-wk and 1-yr evaluations.
TTE = transthoracic echocardiography.

(**Supplemental Digital Content—Document 5**, Supplemental Digital Content 3, http://links.lww.com/CCM/C591). Tasks included cognitive skills demonstrating understanding of the complication and technical skills demonstrating the ability to troubleshoot the scenario. Scoring was performed real time by one simulation faculty observer (B.S.K.) blinded to subject randomization group. Each element of the evaluation form was scored via a binary (performed or not performed) scoring tool. The time required to perform critical actions was documented. Scenarios ran until the ECMO emergency resolved or 300 seconds had passed. If the critical action was not performed, the time recorded was 300 seconds (maximal scenario time).

Outcome Measures

Primary outcome was time required to perform scenario-specific critical actions at the 6-week and 1-year evaluations. Secondary outcomes were scores on the written knowledge test, the simulated scenarios, and the surveys.

Statistical Analyses

Continuous variables were expressed as median with interquartile range and compared using the Mann-Whitney *U* test (for two independent groups) or Wilcoxon signed-rank test (for longitudinal continuous data). Discrete variables were expressed as percentages and compared using Fisher exact test. A *p* value of less than 0.05 was taken as significant. No corrections were made for multiple comparisons. Statistical analyses were performed using SPSS (IBM Statistical Package for Social Sciences v22.0; Chicago, IL) and graphs were produced using Prism (v6.01; GraphPad, La Jolla, CA).

RESULTS

Baseline Characteristics

Twenty-one of 22 fellows participated in the study (**Table 1**) with 10 in the simulation group and 11 in the traditional group. This included seven first-year, eight second-year, and six third-year fellows. The majority of fellows had no ECMO experience with only one having cared for an ECMO patient in the prior year. Of the 21 participants, 15 were available for 1-year evaluation, six among the traditional group and nine among the simulation group. At that point, eight of the 15 fellows had cared for an ECMO patient with even distribution among study groups (simulation: $n = 5/9$; traditional: $n = 3/6$; $p = 1.0$).

Survey Scores

The simulation group rated their educational experience more favorably than did the traditional group (4.2 [3.9–4.3] vs 3.6 [3.1–3.7] on a five-point Likert-scale; $p = 0.002$). Highest ratings were for scenario effectiveness ($p = 0.02$) and practice applicability ($p < 0.001$) (**Fig. S3**, Supplemental Digital Content 4, http://links.lww.com/CCM/C592; legend, Supplemental Digital Content 5, http://links.lww.com/CCM/C593).

Written Examinations

Preintervention written examination scores (**Fig. 2**) were similar between groups (42% [30–51%] vs 35% [25–45%], simulation vs traditional; $p = 0.2$). At 6 weeks, both groups demonstrated improvement in scores ($p < 0.05$ for both comparisons). Compared with preintervention scores, at 1-year testing, the simulation group maintained an improved score (70% [55–75%]; $p = 0.004$), whereas the traditional group did not (45% [40–50%]; $p = 0.69$).

Simulated Scenarios

Scenario scores (**Fig. 3**) on Sim1 were similar between groups (27% [18–36%] vs 36% [18–36%], simulation vs traditional; $p = 0.4$). At 6 weeks, scores were similar between groups on Sim2 (75% [59–91%] vs 63% [50–88%], simulation vs traditional;

TABLE 1. Baseline Characteristics of Participants

Variables	All Participants ($n = 21$)	Traditional Group ($n = 11$)	Simulation Group ($n = 10$)	p
Age (yr), median (IQR)	33 (32.0–34.0)	33 (33.0–34.0)	32.5 (29.8–33.5)	0.14
Male gender, *n* (%)	9 (43)	5 (45)	4 (40)	0.83
Fellowship year, *n* (%)				
1	7 (30)	2(18)	5 (50)	
2	8 (38)	5 (45)	3 (30)	
3	6 (29)	4 (36)	2 (20)	
Median (IQR)	2.0 (1.0–3.0)	2.0 (2.0–3.0)	1.5 (1.0–2.3)	0.19
Cared for ECMO patient in past year, *n* (%)				
Yes	1 (5)	0 (0)	1 (10)	
No	20 (95)	11 (100)	9 (90)	0.48
Cared for ECMO patient previously, *n* (%)				
Yes	2 (10)	0 (0)	2 (20)	
No	19 (90)	11 (100)	8 (80)	0.21

ECMO = extracorporeal membrane oxygenation, IQR = interquartile range.

$p = 0.5$), but the simulation group scored higher on Sim3 (50% [25–67%] vs 33% [17–33%]; $p = 0.03$). At 1 year, scores were again similar between groups on Sim2 (75% [50–75%] vs 63% [52–91%], simulation vs traditional; $p = 0.9$), but the simulation group continued to score higher on Sim3 (58% [42–75%] vs 25% [17–46%]; $p = 0.02$).

Critical Actions

Times to critical action are displayed in **Figure 4**. For Sim1, the critical action was performed by two of 10 participants in the simulation group and three of 11 participants in the traditional group ($p = 1.0$). Times were similar between groups ($p = 0.8$).

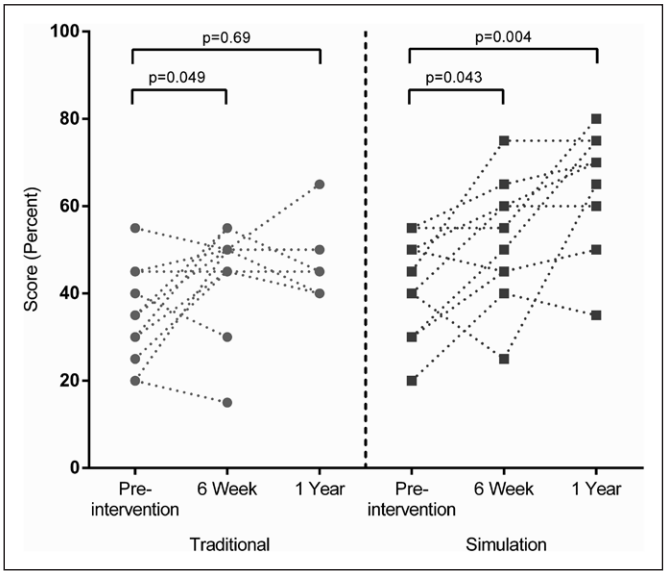

Figure 2. Written examination scores. Scores are displayed for individual participants over time. Preintervention scores were similar between groups ($p = 0.2$). Both groups demonstrated improvement at 6-wk evaluation, but only the simulation group maintained an improved score at 1-yr evaluation.

For Sim2, at 6-week evaluation, all participants attempted to switch to the backup pump. Median time to restore ECMO flow was shorter in the simulation group (127 [117–147] vs 174 [146–250] s; $p = 0.004$), a finding that remained significant after controlling for time to start pump switch ($p = 0.02$). At 1-year assessment, median time to restore ECMO flow remained significantly shorter in the simulation group (114 [102–134] vs 191 [178–238] s; $p = 0.002$), a finding that again remained significant after controlling for time to start pump switch ($p = 0.003$).

For Sim3, at 6-week evaluation, the critical action was performed by six of 10 participants in the simulation group and one of 11 participants in the traditional group ($p = 0.02$). At 1-year assessment, similar numbers of participants in each group administered a fluid bolus ($p = 0.09$), but median time was shorter in the simulation group (63 [25–87] vs 300 [95–300] s; $p = 0.03$).

DISCUSSION

The primary findings of this study are: 1) both traditional and simulation-based training offer benefit in ECMO education; 2) simulation-based training is more effective than traditional training; 3) the benefit appears to transfer to novel scenarios not encountered during training; and 4) the benefit is maintained over a 1-year period.

While the number of ECMO centers increases (2), proficiency in the technology continues to require extensive training (3, 14–16). Prior studies have suggested the potential benefit of simulation in ECMO education. Anderson et al (28) found that ECMO practitioners reduced errors in emergency

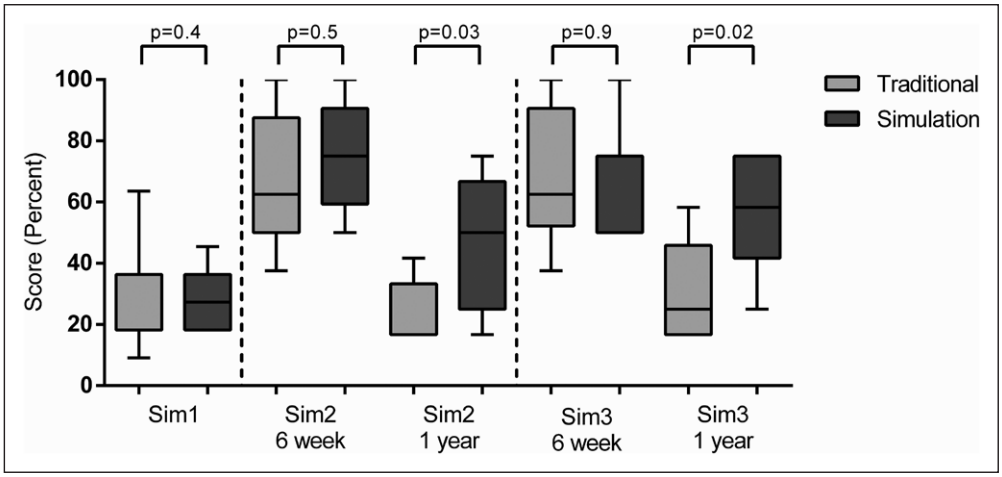

Figure 3. Simulation scenario scores. Sim1 (recirculation) was administered preintervention, whereas Sim2 (pump failure) and Sim3 (access insufficiency) were both administered at 6-wk and at 1-yr postintervention. Participants were scored in real time by a simulation faculty observer blinded to subject randomization. *Box plots* display median and interquartile range with whiskers from minimum to maximum.

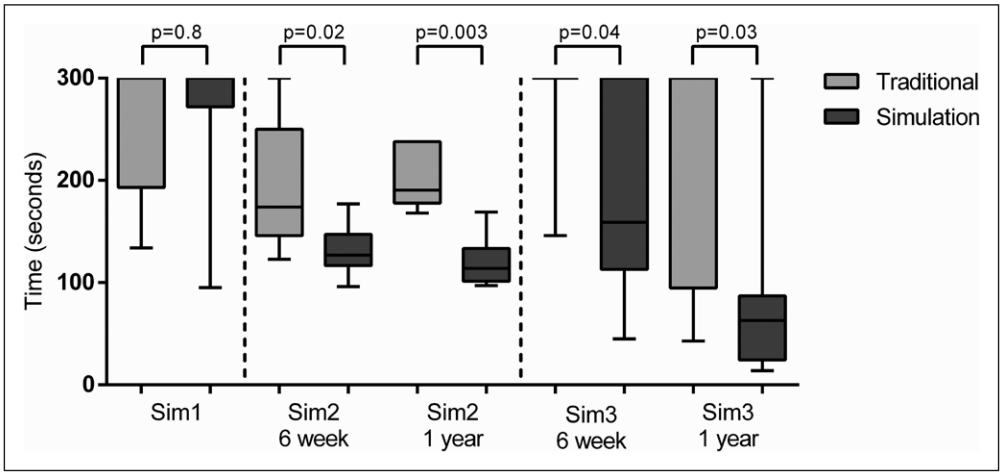

Figure 4. Times to critical action. For each scored simulated scenario, a critical action, necessary for resolution of the extracorporeal membrane oxygenation (ECMO) emergency, was prespecified for timing during evaluation. For Sim1 (recirculation), the critical action was to order an echocardiogram to assess cannula position. For Sim2 (pump failure), the critical action was to switch to the backup pump and restore ECMO flow. For Sim3 (access insufficiency), the critical action was to administer a fluid bolus. Maximal scenario times were 300 s. *Box plots* display median and interquartile range with whiskers from minimum to maximum.

scenarios after simulation-based training, whereas Burkhart et al (34) reported simulation-based training improved emergency circuit management among thoracic-surgery residents working with a postcardiotomy ECMO model. Although our findings support these studies, the inclusion of a control group based on the traditional training model offers insight into the added value of simulation.

In our population of ECMO naive learners, both traditional and simulation-based training offered benefit. At 6-week testing, written examination scores improved in both groups with simulation adding no benefit. At 1-year testing, however, the simulation group maintained an improved score whereas the traditional group declined to preintervention performance. This builds on other studies demonstrating improved long-term knowledge retention with simulation-based education (36, 37).

Preintervention (Sim1—recirculation) scenario scores were low, with only 30% of required tasks performed and with a minority of participants performing the critical action. This is consistent with another study of novice ECMO learners in which 60% of participants had difficulty with component identification and 40–78% failed to manage emergency scenarios (34). These findings likely reflect the initial unfamiliarity with a novel and complex technology.

After intervention, for the scenario encountered during training (Sim2—pump failure), both groups performed 70% of required tasks with no added benefit to simulation. The benefit of simulation-based training was seen in the time required to perform the critical action (pump switch) with the simulation group restoring ECMO flow 47 seconds faster at 6 weeks and 77 seconds faster at 1 year, differences that are both statistically and clinically significant. Of note, similar numbers of participants in each group attempted a pump switch indicating that the difference was not due to underrecognition of pump failure but likely represented improved technical skills. This finding is consistent with similar studies where simulation-based training improved response times for critical actions during advanced cardiac life support training (38) and operating-room emergencies (39).

Our results regarding improved times to critical action with simulation-based training appear to differ from those reported by Anderson et al (28) where simulation-based ECMO training did not improve timed responses. In this study, however, participants were ECMO specialists with at least 1 year of ECMO experience suggesting that the technical benefits of simulation training may be reduced when evaluating an experienced group.

Of particular interest, during a novel scenario not encountered during training (Sim3—access insufficiency), more participants in the simulation group performed the critical action. This suggests underrecognition of access insufficiency in the traditional group, and the higher scenario scores in the

simulation group are supportive. It is not clear why this was the case, but a prior article noted that despite recent traditional training in ECMO management, study subjects still failed to perform critical tasks, raising concern regarding the efficacy of traditional training programs on teaching emergency management skills (28). It may be that simulation-based training, with the fully immersive and hands-on environment, engaged and active learners, and exposure to real-time circuit and physiologic variables, contributes to both improved knowledge acquisition and technical skill development.

We retested subjects 1 year after training to evaluate for extinction of competencies gained. Neither group demonstrated a decline in scenario scores. While time for pumpswitch and restoration of ECMO flow was also similar within groups over time, the simulation group continued to perform the task significantly faster. Similarly, while more participants in the traditional group recognized access insufficiency and administered a fluid bolus at 1-year compared with 6-week evaluation, the simulation group continued to perform this critical action faster. These findings suggest that although both forms of training have longevity at 1 year, the technical benefits of simulation-based training are also retained. This complements another study that reported that at 6-month retesting, previously novice learners who underwent simulation-based ECMO training demonstrated continued competence in simulated emergencies (35).

The simulation group rated their educational experience higher than the traditional group, confirming an earlier study reporting overwhelming preference for simulation-based ECMO training over traditional water-based training (30). This likely reflects the higher active (hands-on) learning opportunities simulation offers (30, 35), a central element of effective adult learning (40, 41).

This study has several strengths. First, to the best of our knowledge, this is the first randomized controlled trial evaluating the utility of simulation in ECMO education, thereby addressing a significant gap in the literature and limitation of prior articles. Second, the outcomes are objective, measurable, and clinically relevant. Third, although it was impossible to blind study participants regarding group assignment, we ensured all scoring was performed by a simulation faculty blinded to participant randomization. Finally, we evaluated subjects at 1-year postintervention, thereby demonstrating longevity to the results.

The present study should be interpreted in the context of certain limitations. First, this is a single-center study limiting generalizability. Second, simulation was used to assess study participants, potentially biasing the results toward the simulation group who may have become more familiar with the technology during training. Although we could have reevaluated the traditional group with water-drills, this would have limited our ability to compare the two groups. We opted to evaluate both groups via simulation to most closely mimic real-life scenarios. Additionally, our fellows receive extensive simulation-based education and are experienced and comfortable with the simulation environment and technology, possibly limiting this bias. Third, although we used predefined standardized scenario checklists based on prior studies, no validated scoring tools are available. We adapted those published previously and note that Fehr et al (32) reported that their checklists demonstrated good correlation with clinical experience. Fourth, we only studied novice critical care fellows managing venovenous ECMO emergencies; our findings may not be applicable to other learners or to venoarterial ECMO emergencies. Finally, although our results are encouraging regarding the utility of simulation in ECMO education, it remains to be seen if the benefits translate to improved clinical outcomes.

CONCLUSION

In novice critical care fellows, simulation-based ECMO training is effective and superior to traditional water-drill–based training with improved long-term scores on written knowledge examinations and reductions in times to critical actions for emergency circuit management. These benefits transfer to novel ECMO scenarios and are maintained over the long term. We anticipate simulation-based ECMO education to become more commonplace and societal recommendations on ECMO education to consider simulation a superior alternative to traditional techniques. Further studies evaluating the utility of simulation in other learner groups and for maintenance of proficiency are required.

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