Pilot Study of a Novel Gelatin-based Model for Venovenous Extracorporeal Membrane Oxygenation Cannula Insertion Simulation

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Venovenous (VV) extracorporeal membrane oxygenation (ECMO) is a form of mechanical support used in respiratory failure refractory to conventional medical management. Because VV ECMO cannulation is an uncommonly performed, time-sensitive, and high-stakes procedure (1), simulation can be used to improve the procedural competency of trainees. Simulation-based training (SBT) has been shown to improve proficiency of vascular cannulation (2–5), yet there are few low-fidelity, low-cost, portable models that allow physicians-in-training to practice venous cannulation with an ECMO cannula. Most ECMO simulators are high-fidelity, software-based, interactive models (6–9). Because of the cost-prohibitive nature of such models, some nonhuman tissue models were developed

(Received in original form December 4, 2020; accepted in final form April 14, 2021)

Author Contributions: R.P.R., C.C., M.J.S., and L.M.D. added substantial contributions to the conception, design, data acquisition, analysis, and interpretation of the work. A.B., C.C.-B., and M.D.W. added substantial contributions to the data acquisition, analysis and interpretation of the work. All authors assisted with drafting the work and revising it for content, approved the final version to be published, and vouch for data accuracy and integrity of the work.

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This article has a data supplement, which is accessible from this issue's table of contents at www.atsjournals.org.

ATS Scholar Vol 2, Iss 3, pp 297–303, 2021

DOI: 10.34197/ats-scholar.2020-0167BR

for use in procedural skills laboratories for vascular access training, with promising improvements in procedural comfort and skill being shown (10). However, noncommercial simulators in the medical education literature are generally used to teach trainees management of intact ECMO circuits (11–13) or generally combine cannulation SBT with circuit management training (14, 15). Therefore, although these simulators may serve specific roles in ECMO SBT, they may not be as useful for the acquisition of skills related to venous cannula insertion. To address this educational need, we conducted an observational pilot study in which we developed a low-fidelity, low-cost, portable, gelatin-based model intended for use by trainees in preparation for VV ECMO initiation.

METHODS

Study Design

We designed a single-center, observational pilot study to measure the attitudes of physicians experienced in VV ECMO cannulation toward our novel gelatin-based model. All research was approved by the Emory Institutional Review Board (institutional review board number IRB00106018), and informed consent was obtained from all participants.

Study Subjects

Subjects were enrolled from a single center (Emory University Hospital) between November 2019 and October 2020 and were identified prospectively as being credentialed to cannulate. Of 13 potential clinicians identified, 11 were enrolled in the study. For demographic information, *see* Table E1 in the data supplement.

Gelatin-based Model Construction

Gelatin-based model design (Figure 1) was adapted from a protocol as previously described (16–21). A detailed description of model construction can be found in Figure E1A.

Survey Design and Validation

After obtaining author consent, attitude-gauging questions were adapted from a previously published survey (22). The adapted survey, composed of 5-point Likert-type-scale response items and a free-text response question, was reviewed by two content experts in ECMO, one content expert in model-based simulation, and one content expert in medical education and survey design by using a modified Delphi technique (23, 24) in an attempt to maximize content validity (25). Survey items were revised on the basis of this feedback. Internal reliability (25) was assessed by using cognitive interviews (26), which were conducted with three critical care medicine trainees to confirm that survey items were interpreted as written. The adapted survey was finalized and incorporated into the study protocol (Figure E1B).

ECMO Simulation Protocol

A protocol (Figure E1C) was used to provide a more uniform testing experience for each subject. Using a script (Figure E1D), subjects were asked to insert a VV ECMO cannula (23-Fr or 25-cm Bio-Medicus cannula; Medtronic) into the model using ultrasound guidance. Subjects were instructed to give verbal feedback by using a "think-aloud" protocol, and responses were recorded (27, 28) to collect data regarding the validity of the response process (25). The simulation concluded once the subject either obtained venous access or had sufficient time with the model to give feedback. Subjects were given the survey form, and responses were recorded.

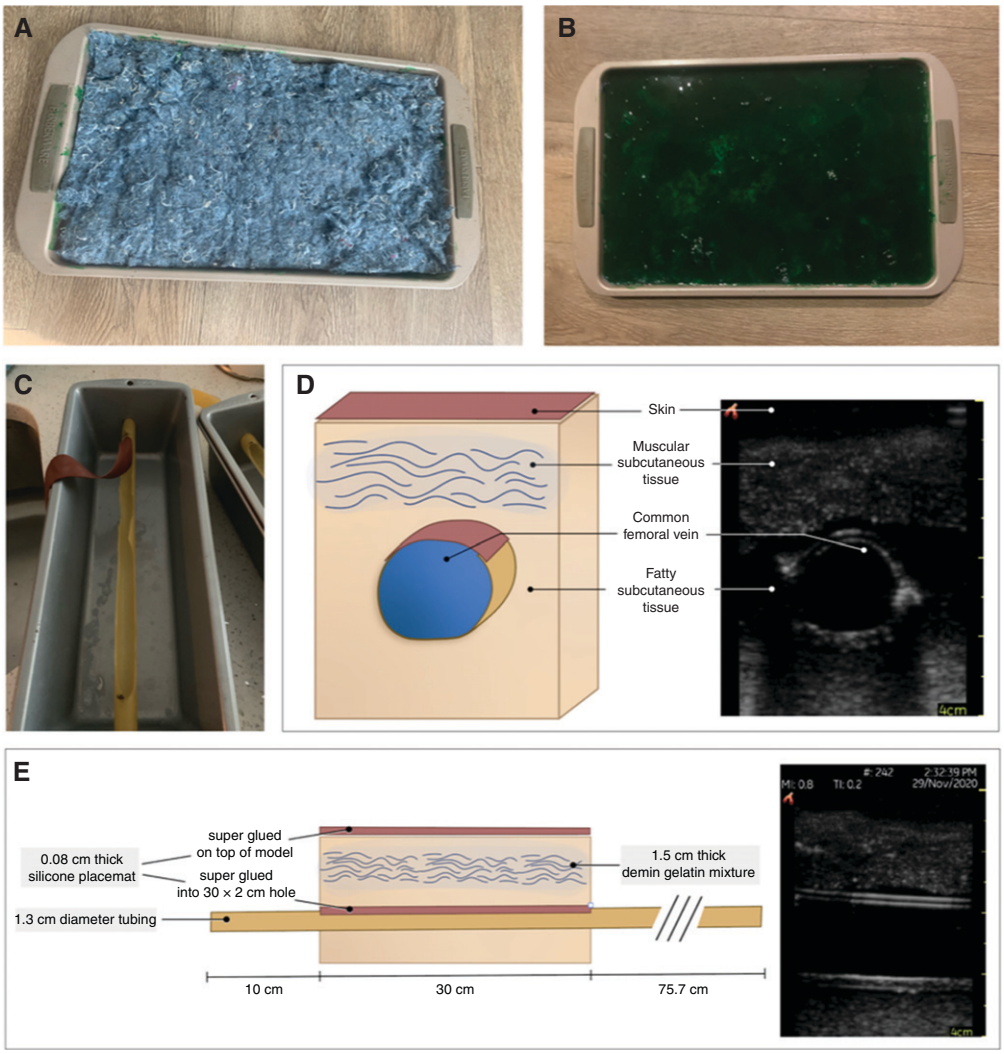


Figure 1. Images of the gelatin-based model. (*A*) Photograph of the model showing the recycled denim layer overlying the gelatin mixture. (*B*) Photograph of the completed model without silicone "skin" on top. (*C*) Photograph of the model showing tubing running through the center of the baking tin without any gelatin mixture added. (*D*) Cross-sectional illustration of the completed model (left) and an axial ultrasound image of the model with corresponding simulated layers (right). (*E*) Longitudinal illustration of the completed model (left) and an ultrasound image of the model (right).

Statistical Analysis

Statistical analysis was performed using Prism 8 (version 8.4.3; GraphPad). Demographic data in Table E1 were presented as medians with interquartile ranges (IQRs) for continuous variables or percentages for discrete variables. Likert-type-scale data were treated as ordinal variables and presented with percentages.

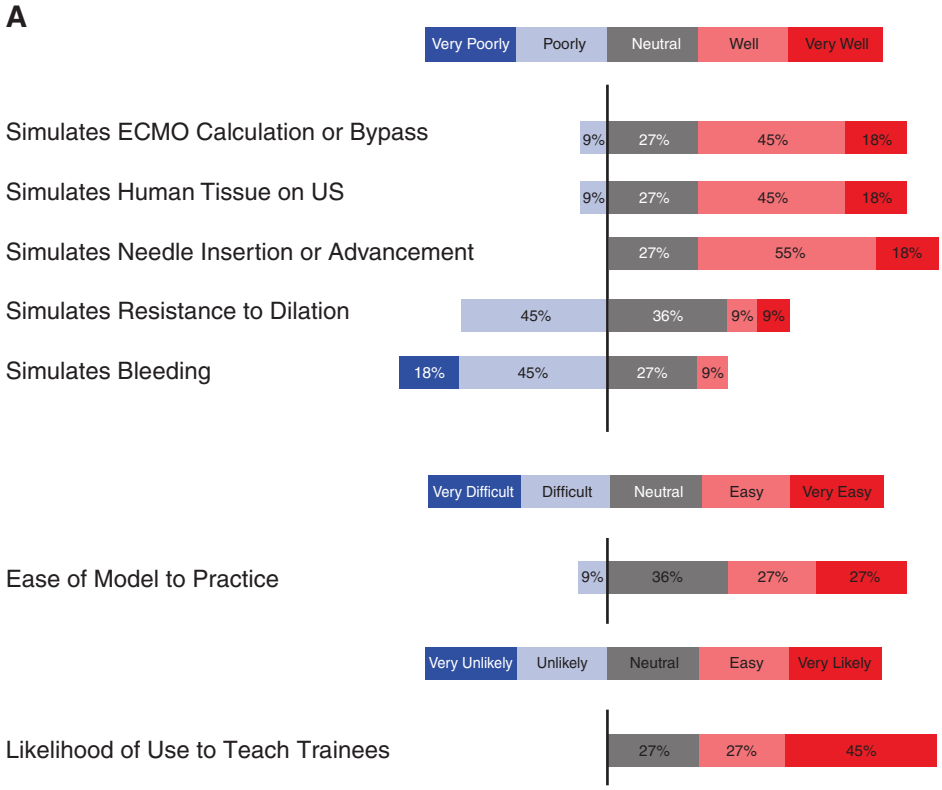
RESULTS

Survey Responses

Subjects were overall fairly experienced in ECMO cannulation, having performed a median of 9 VV ECMO cannulations (IQR, 7–12) and a median of 2 (IQR, 1.5–4) venoarterial ECMO cannulations in the last year.

Subjects found that the gelatin-based model simulated the venous access portion of

A



B

"Think Aloud" Protocol Themes

Model Characteristic	Feedback
Gross Model Structure	Model should be anchored to table
Skin	Eliminate bubbles under skin Needs groin or thigh landmarks
Vessel	Ultrasound appearance has high fidelity Should bleed back more Simulated blood should be red Gross vessel structure should be tortuous to make it more Challenging
Passing the Guidewire	Easy for the most part Catches on the "lumen If It's been used before
Dilation	Type of dilators used should be Avalon, as others are too flimsy Some experts thought resist thence to dilation was appropriate, others thought it was "too easy"

Figure 2. Survey and "think-aloud" protocol responses. (*A*) Distribution of responses to survey questions regarding model fidelity, ease of use, and likelihood of use to teach trainees. (*B*) Summary feedback based on think-aloud protocol responses. ECMO = extracorporeal membrane oxygenation; US = ultrasound.

VV ECMO cannulation well; 64% of respondents rated the model as simulating venous access "well" or "very well" on a 5-point Likert-type scale (Figure 2A). Similarly, 64% of subjects rated the similarity to human tissue as visualized on ultrasound by responding that it was simulated well or very well. The most highly rated feature of the model was the simulation of needle insertion and advancement, with 73% of respondents rating the model as simulating this step of the procedure well at the least. Although the majority of responses were positive, subjects did note some limitations of the model. In particular, subjects found that the model did not closely approximate the sensation of sequential dilation of tissue or the amount of bleeding during sequential dilation well. Despite these limitations, the majority (73%) of subjects reported that they were "likely" or "very likely" to use this model to teach trainees if it were readily available and 55% of respondents reported the model was at least "easy" to practice with.

Think-Aloud Responses

To triangulate the validity of the responses to our simulated ECMO procedure and to improve the relevance of this pilot study to other medical educators, we used a think-aloud protocol during the procedure and analyzed the responses after the conclusion of the study. Most subjects noted how realistic the single vessel appeared on ultrasound for cannulation while they were exploring the model and suggested adding another tube to represent the artery to better mimic human anatomy for improvement (Figure 2B).

DISCUSSION

Simulation in medical education has become an invaluable tool in SBT but is currently limited by the availability of simulation centers and model costs. We performed a pilot study to investigate the utility of a novel, low-fidelity, low-cost, portable, gelatin-based model for the instruction of VV ECMO cannulation. This study has several important limitations. Because the nature of our study was investigational, we enrolled a small number of participants at a single academic center. Although the methodology was rigorous, there may have been a bias toward rating the model positively. Although the ECMO program at Emory University Hospital is experienced, there are a limited number of physicians credentialed to perform ECMO cannulations, which led to sampling bias. Finally, although we took additional steps to validate our survey responses, the use of a Likert-type scale minimizes the applicability of our study to medical education. Subsequent studies should aim to incorporate an improved iteration of this model by using feedback we gained over the course of this project. These studies should develop and validate an ECMO cannulation assessment instrument and should use this tool to evaluate the use of our model in clinical skill acquisition. Overall, we believe that our model represents a timely and useful tool that can be applied broadly across different training environments.

Acknowledgment

The authors thank Drs. Ulemu Luhanga, Taryn Taylor, and Imran Iftikhar for their contributions to the design of this study.

Author disclosures are available with the text of this article at www.atsjournals.org.

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