Derivation of a Procedural Performance Checklist for Bifemoral Veno-Venous Extracorporeal Membrane Oxygenation Cannula Placement in Operational Environments

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ABSTRACT

Background: Veno-venous extracorporeal membrane oxygenation (VV ECMO) is a low-frequency, high-intensity procedure used for severe lung illness or injury to facilitate rapid correction of hypoxemia and respiratory acidosis. This technology is more portable and extracorporeal support is more frequently performed outside of the hospital. Future conflicts may require prolonged causality care and more specialized critical care capabilities including VV ECMO to improve patient outcomes. We used an expert consensus survey based on a developed bifemoral VV ECMO cannulation checklist with an operational focus to establish a standard for training, validation testing, and sustainment. **Methods:** A 36-item procedural checklist was provided to 14 experts from multiple specialties. Using the modified Delphi method, the checklist was serially modified based on expert feedback. **Results:** Three rounds of the study were performed, resulting in a final 32-item checklist. Each item on the checklist received at least 70% expert agreement on its inclusion in the final checklist. **Conclusion:** A procedural performance checklist was created for bifemoral VV ECMO using the modified Delphi method. This is an objective tool to assist procedural training and validation for medical providers performing VV ECMO in austere environments.

KEYWORDS: *VV ECMO; checklist; prolonged casualty care; ARDS*

Introduction

Veno-venous extracorporeal membrane oxygenation (VV ECMO) is used for patients with respiratory failure and acute respiratory distress syndrome (ARDS) who have failed conventional ventilator management.[1] VV ECMO facilitates rapid correction of hypoxemia and respiratory acidosis from hypercarbia while also reducing injurious ventilator settings.[2,3] VV ECMO could increase the survivability of patients with severe thoracic injury who cannot be immediately evacuated and facilitate stabilization and further procedures.[6,7] The use of VV ECMO for medical and trauma indications is increasing throughout the United States and the world. Notably, the technology is durable and portable, making broader access to extracorporeal support possible.[4–6] The United States military has an experienced ECMO transport and management team.[8] Future conflicts with contested airspace may necessitate prolonged casualty care and use of critical care modalities such as VV ECMO by the forward medical teams already in place. Injured Special Operations Forces may be at particular risk of delays in evacuation, given potential contested routes of evacuation to higher roles of care; however, they may benefit from innovation and implementation of more forward ECMO capabilities. Feasibility studies of training for forward implementation of VV ECMO are currently underway, with preliminary data presented at the 2023 Extracorporeal Life Support Organization (ESLO) in Seattle, Washington. Checklists are used in a variety of training programs to aid in education and validation of safety and procedural competence.[9–11] As part of training, checklists provide a standard and ensure the sustainment of knowledge.

Patients can be cannulated peripherally for VV ECMO via the internal jugular/femoral vein or bifemoral technique. The bifemoral technique offers the advantage of rapid access and placement of cannulas while allowing access to the patient's head, neck, and chest for other procedures.[12] Less space is also required for setup and preparation, making this technique useful in time, resource, and space-limited environments. We used an expert consensus survey based on a developed bifemoral VV ECMO cannulation checklist with an operational focus to establish a standard for training, validation testing, and skills sustainment.

Methods

This study was conducted at a high-volume ECMO center. It was reviewed by the institutional review board and found to be exempt from human subject research. While there is no standard definition of the appropriate number of experts to include in a modified Delphi study, 10–20 experts are typically recommended.[13–15] We identified a panel of 30 experts from the fields of critical care medicine, vascular surgery, trauma surgery, interventional cardiology, cardiac surgery, and emergency medicine, with demonstrated special interest in operational military medicine, percutaneous access, and ECMO cannulation. The experts were then individually contacted by email and serially invited to participate in each round of review until

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a total of 14 responses were obtained, like in previous studies.[15,16] All expert participants and study investigators were blinded to the identity of the other participants to minimize bias.

Initial Checklist Development

First, four investigators (MK, EP, DA, and RK) developed an initial checklist of 36 items they felt were crucial to ultrasound-guided bifemoral VV ECMO cannulation in operational, resource-limited environments. This 36-item checklist was created based on the experience of the investigators as well as a literature review. Multiple guidelines were used for the development of the checklist.[12,17,18] These guidelines differed somewhat in their recommendations, and efforts were made to represent the areas of agreement in the initial checklist. No specific guidelines existed for resource-limited considerations in bifemoral VV ECMO cannulation. After the creation of the initial checklist, expert review was conducted in three rounds.

Round 1

The initial checklist was distributed using Research Electronic Data Capture (REDCap), a secure web-based software program designed to support data capture for research studies.[19,20] Each expert participant received an individualized link to the survey by email. The participants were asked to rank each item on the checklist according to how important they felt it was for inclusion on a procedural checklist. Each item in the checklist was ranked with a 9-item Likert-type scale used to rank each item according to its importance: irrelevant (must be discarded), extremely unimportant, very unimportant, unimportant, neutral, important, very important, extremely important, and mandatory (must be included).

Expert participants were allowed to provide their own items for inclusion in the checklist. Participants were also able to make suggestions for item removal. Finally, participants had an opportunity to comment on any of the items and provide suggested edits or necessary discussion points.

The composite results were collected by one investigator (EP) who calculated mean scores for each item. The group of researchers then reviewed each response. An item with a mean score of ≤3 was discarded from the checklist. An item with a mean score of ≥7 was included, while a mean score of <7 but >3 was discussed by the investigators to reach a consensus regarding exclusion, inclusion, or the need for modification. These items were edited as indicated by participants' responses and were included or excluded based on the investigators' consensus. Any additional items created by participants were added to the checklist for inclusion in the second round.

Round 2

Round 2 of the survey was then sent to the expert participants until 14 responses were collected. They were again asked to rank each item according to the above scale. As in round 1, participants had the option to include their items, make suggestions for removal, and make edits to the existing items. The results were similarly reviewed, and items were edited according to participants' comments.

Round 3

Finally, a third version of the checklist was sent to the participants for review. In this version, experts classified an item as "include" or "discard." Any item with more than 30% discard responses was discarded, and a final checklist with at least 70% expert consensus was yielded.

Results

This study was conducted from February 1 to June 1, 2023. This was a blinded study; the exact specialties of the 14 respondents are not known. The specialty backgrounds surveyed are listed in Table 1. Each round was stopped after 14 responses were obtained. The initial checklist developed by investigators was distributed with a 9-point Likert scale (Table 2). No items in either rounds 1 or 2 had mean values <3 (Figure 1). Twenty-three items from round 1 and 28 items from round 2 had scores ≥7 and were included. Ten items from round 1 and 7 items from round 2 had values >3 but <7. These items were reviewed by investigators for necessity and clarity (EP, DA, and RK). One item from round 1 (item 9) and two items from round 2 (items 10, 15) were removed. During the first two rounds, nine edits were made to the existing items (items 1, 5, 6, 14, 16, 19, 24, 27, and 28). There were no additional checklist items that were added, as all edits were incorporated into existing items.

TABLE 1 *Specialty Background of Expert Participants (n=14)*

Specialty	No. of participants
Emergency medicine–critical care	7
Pulmonary–critical care	1
Surgery–critical care	3
Trauma surgery	7
Vascular surgery	4
Cardiac surgery	2
Interventional cardiology	2

After three items were removed and the suggested edits were made, the 33-item checklist was distributed to the expert participants to rate each item as either include or discard (round 3). One item received less than 70% consensus for inclusion (item 7) and it was discarded (Figure 2). This step resulted in a 32-item checklist (Table 3).

Discussion

Using the modified Delphi method, we created a procedural performance checklist based on expert consensus for VV ECMO cannulation in austere environments. To our knowledge, this is the only checklist currently available for this procedure, and it will help standardize training for bifemoral cannulation in resource-limited situations.

Specific Inclusions, Exclusions, and Edits

The investigators removed three items. First, local anesthesia at the cannula insertion site was removed (item 9). Though regional anesthesia is important, patients requiring VV ECMO in the operational environment will likely be unresponsive and receiving intravenous analgesia and sedation.[21] Local anesthesia may also not be readily available.[22] Given the variability of the availability and use of local anesthesia, this item was removed. Next, site-specific cannula assignments was removed (item 10). Though the right femoral vein may be the preferred location for the return cannula, given the inferior vena cava anatomy and linear approach to the right atrium, this placement was not essential to the performance of cannula placement so it was removed.[18] Finally, placement of the return

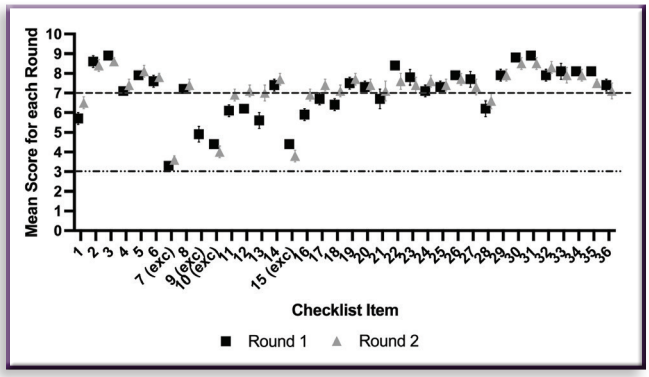
TABLE 2 *Initial Procedural Performance Checklist for Bifemoral Veno-Venous Extracorporeal Membrane Oxygenation (ECMO)*

1. Utilize two sterile personnel for this procedure.
2. Assess the patient for any contraindications prior to procedure.
3. Prime and prepare ECMO circuit. Flush cannulas with sterile saline and tighten all stopcocks and caps on the cannulas.
4. Assess femoral vein anatomy bilaterally and evaluate using ultrasound prior to starting procedure.
5. Clean hands. Put on sterile gloves. Use sterile probe cover for ultrasound.
6. Clean insertion sites with chlorhexidine.
7. Drape blue towels. Make every effort to maintain a sterile field and equipment throughout procedure.
8. Using ultrasound, identify the needle insertion site that will allow cannulation of the femoral vein cephalad to the insertion of the saphenous vein but below the inguinal ligament bilaterally.
9. Anesthetize the area over the insertion sites (as clinically indicated).
10. The right femoral vein site is the preferred location for the return cannula while the left femoral vein location is the preferred location for the drainage cannula. Cannulation is ideally performed with two people for access and wire control. Ideally, the right femoral vein would be used for the return cannula and the left femoral vein for the drainage cannula.
11. Insert introducer needle with syringe under ultrasound guidance to the 12 o'clock position of the right femoral vein. Micropuncture use can be considered.
12. Visualize insertion of the needle into the right femoral vein and confirm with return of blood into the syringe.
13. Remove syringe. Place 160cm 0.035 J-tip wire through introducer needle or micropuncture wire and sheath.
14. Confirm placement of wire within the right femoral vein using ultrasound guidance. Remove needle, leaving wire in place OR if micropuncture was used, remove sheath, leaving wire in place. If the patient is attached to continuous telemetry monitoring, ectopy may also be observed, indicating wire in the right ventricle. Retract the wire until ectopy is no longer observed.
15. Use ultrasound to confirm wire placement for the return cannula at the level of the inferior vena cava/right atrial junction.
16. Sequentially dilate the return cannula site over wire. 1/3 to 1/2 of dilator should be placed with each dilation. Ensure wire can easily move back and forth after each dilation. Dilate to one size smaller than planned cannula size.
17. Advance return cannula with introducer until position in right atrium is confirmed with ultrasound guidance.
18. Remove wire and introducer from return cannula and clamp the end.
19. Flush return cannula with sterile saline and clamp the end.
20. Insert introducer needle with syringe under ultrasound guidance to the 12 o'clock position of the left femoral vein. Micropuncture use can be considered.
21. Visualize insertion of the needle into the left femoral vein and confirm with return of blood into the syringe.
22. Remove syringe. Place 160cm 0.035 J-tip wire through introducer needle or micropuncture wire and sheath.
23. Confirm placement of wire within the left femoral vein using ultrasound guidance. Remove needle, leaving wire in place OR, if micropuncture was used, remove sheath, leaving wire in place.
24. Sequentially dilate the drainage cannula site over wire. 1/3 to 1/2 of dilator should be placed with each dilation. Ensure wire can easily move back and forth after each dilation. Dilate to one size smaller than planned cannula size.
25. Advance drainage cannula with introducer until the last hole is through skin and not visible. Retract introducer to designated line and advance the drainage cannula.
26. Remove wire and introducer from drainage cannula and clamp the end.
27. Flush drainage cannula with sterile saline and clamp the end.
28. Once both cannulas are in place in each femoral vein, administer an IV bolus of heparin. Heparin bolus may be withheld if anticoagulation is contraindicated as determined by the proceduralists (high risk of bleeding complications, active and ongoing correction of coagulopathy, etc).
29. Place circuit tubing on the field identifying drainage and return tubing and placing next to drainage and return cannulas.
30. Connect drainage cannula to circuit with air-free technique.
31. Connect return cannula to circuit with air-free technique.
32. Ensure no air entrainment in the circuit.
33. Initiate circuit flow, remove clamps closest to cannulas, and then remove clamps closest to circuit.
34. Note cannula positions.
35. Secure cannulas with purse string non-absorbable suture where cannula enters the skin and at least 3 additional securing sutures on the legs per cannula.
36. Cover cannula sites with sterile dressings.

cannula under ultrasound guidance was removed (item 15) as this was felt to be redundant with subsequent return cannula placement guidance. The remaining items had mean scores of >3 and <7 in the first two rounds of review and the investigators considered them to be essential to the checklist.

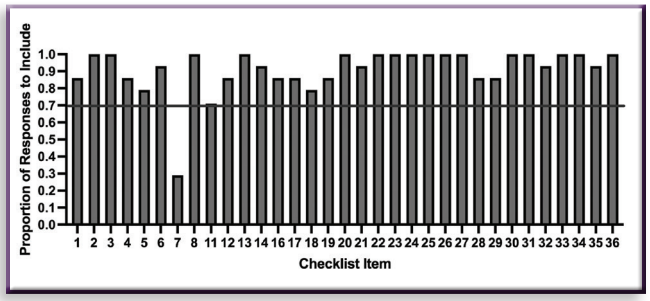
No additional checklist items were suggested by the expert participants; however, edits to the existing items were suggested. All edits were incorporated into rounds 1 and 2 and were included in the final round of scoring. First, given potential resource limitations, the word "consider" was added (1). Hand sanitizer may or may not be available in the operational environment, so this was removed (item 5). In addition, cleaning supplies may differ based on group and team, so chlorhexidine was removed (item 6). The final checklist was updated to include having the guidewire directed toward the right atrium for the return cannula, given the possibility of migration into a hepatic vein and malposition resulting in lower flows (14).[23] Making a skin incision at the wire entry site prior to dilation was added, as this is an important component of percutaneous access that was not initially included (items 16 and 24).[24] Cannula flushing was updated to include using

FIGURE 1 *Mean expert participant scores of each checklist item for rounds 1 and 2.*



The x-axis represents the mean score for each round with error bars representing standard deviations. The y-axis represents the individual checklist item. The horizontal lines represent a mean score of 3 and a mean score of 7.

FIGURE 2 *Proportion of expert responses to include a given item on the final checklist.*



The x-axis represents the mean score for each round with error bars representing standard deviations. The y-axis represents the proportion of responses to include a given item. The horizontal line represents a proportion of 0.7 (70%) to include a given item.

TABLE 3 *Final Procedural Performance Checklist for Bifemoral Veno-Venous Extracorporeal Membrane Oxygenation (ECMO)*

1.	Consider utilizing two sterile personnel for this procedure.
2.	Assess the patient for any contraindications prior to procedure.
3.	Prime and prepare ECMO circuit. Flush cannulas with sterile saline and tighten all stopcocks and caps on the cannulas.
4.	Assess femoral vein anatomy bilaterally and evaluate using ultrasound prior to starting procedure.
5.	Put on sterile gloves. Use sterile probe cover for ultrasound as available.
6.	Clean insertion sites.
7.	Using ultrasound, identify the needle insertion site that will allow cannulation of the femoral vein cephalad to the insertion of the saphenous vein but below the inguinal ligament bilaterally.
8.	Insert introducer needle with or without syringe under ultrasound guidance to the 12 o'clock position of the right femoral vein. Micropuncture use can be considered.
9.	Visualize insertion of the needle into the right femoral vein and confirm with return of blood into the syringe, if used.
10.	Remove syringe, if used. Place 180cm 0.035 J-tip wire through introducer needle or micropuncture sheath.
11.	Confirm placement of wire within the right femoral vein and directed toward the right atrium using ultrasound guidance. Remove needle, leaving wire in place OR. if micropuncture was used, remove sheath, leaving wire in place. If the patient is attached to continuous telemetry monitoring, ectopy may also be observed, indicating wire in the right ventricle. Retract the wire until ectopy is no longer observed.
12.	Insert introducer needle with or without syringe under ultrasound guidance to the 12 o'clock position of the left femoral vein. Micropuncture use can be considered.
13.	Visualize insertion of the needle into the left femoral vein and confirm with return of blood into the syringe, if used.
14.	Remove syringe, if used. Place 180cm 0.035 J-tip wire through introducer needle or micropuncture sheath.
15.	Confirm placement of wire within the left femoral vein using ultrasound guidance. Remove needle, leaving wire in place OR. if micropuncture was used, remove sheath, leaving wire in place.
16.	Once both wires are in place in each femoral vein, administer an IV bolus of heparin. Heparin bolus may be withheld if anticoagulation is contraindicated as determined by the proceduralists (high risk of bleeding complications, active and ongoing correction of coagulopathy, etc).
17.	Perform skin incision at wire. Sequentially dilate the return cannula site over wire. 1/3 to 1/2 of dilator should be placed with each dilation. Ensure wire can easily move back and forth during each dilation. Dilate to one size smaller than planned cannula size.
18.	Advance return cannula with introducer until position in right atrium is confirmed with ultrasound guidance.
19.	Remove wire and introducer from return cannula, back bleed the cannula, and clamp the end.
20.	Flush return cannula with sterile saline (may be heparinized if desired) and clamp the end.
21.	Perform skin incision at wire. Sequentially dilate the drainage cannula site over wire. 1/3 to 1/2 of dilator should be placed with each dilation. Esnure wire can easily move back and forth after each dilation. Dilate to one size smaller than planned cannula size.
22.	Advance drainage cannula with introducer until the last hole is through skin and not visible. Retract introducer to designated line. Advance drainage cannula.
23.	Remove wire and introducer from drainage cannula, back bleed the cannula, and clamp the end.
24.	Flush drainage cannula with sterile saline (may be heparinized if desired) and clamp the end.
25.	Place circuit tubing on the field identifying drainage and return tubing and placing next to drainage and return cannulas.
26.	Connect drainage cannula to circuit with air-free technique.
27.	Connect return cannula to circuit with air-free technique.
28.	Esnure no air entrainment in the circuit.
29.	Initiate circuit flow, remove clamps closest to cannulas and then remove clamps closest to circuit.
30.	Note cannula positions.
31.	Secure cannulas with purse string non-absorbable suture where cannula enters the skin and at least additional securing sutures on the legs.
32.	Cover cannula sites with sterile dressings.

either a sterile saline or heparinized flush based on clinical indication and mediation availability (items 19 and 27). Finally, consideration of systemic heparinization was moved after wire placement and before dilation and cannula placement to ensure enough time for systemic effect between administration and cannula placement, given the prothrombotic potential for initial insertion (28).[25]

Importance of Checklists in Training and Validation

The development of a bifemoral VV ECMO cannulation checklist that can be used in the operational environment is important. First, this checklist provides an initial framework for the development of training platforms for advanced medical teams without VV ECMO experience. Having a procedural checklist can improve learners' understanding of instructions.[26,27] Second, checklists can benefit patient care through uniform training and communication.[28] This can be especially important in austere environments where conditions are not as optimal as they are in the hospital. VV ECMO cannulation is a low-volume, high-intensity procedure that requires standardization to optimize team performance. Therefore, implementation of this checklist into operational VV ECMO training of advanced medical teams may improve procedural success and outcomes. Future studies should be devoted to team performance of VV ECMO cannulation when using the checklist.

Limitations

One limitation of this study is the potential bias in specialty responses. We emailed 30 experts individually for each round and stopped collecting responses when we reached 14 responses. While this was done to blind the expert participants to each other and blind the investigators to the participants, it is possible that some specialties were not represented in each round. However, we attempted to minimize any bias this would create by choosing experts with extracorporeal support procedural knowledge and operational experience and interest. In addition, our checklist includes ultrasound guidance for both placement of cannulas and confirmation of positioning. Given that ultrasound is a separate skillset that requires specific training, we did not provide additional details on ultrasound techniques or views required.

Conclusions

Checklists are used in training and to optimize procedure technique; consequently, they improve the performance of medical skills and patient care. We developed a VV ECMO bifemoral cannulation checklist, specifically designed for advanced medical teams working in austere operational environments, to be used in training and the performance of the procedure. Further studies on the use of the checklist and patient outcomes are required.

Author Contributions

EP performed study design, data collection, and manuscript development. RB performed concept development and manuscript editing. RK performed concept development and provided expert review. DH performed expert review. MK performed data collection and expert review. SG performed concept development, data analysis, and manuscript revision.

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