Managing Patients on Extracorporeal Membrane Oxygenation Support During The COVID-19 Pandemic – A Proposal for A Nursing Standard Operating Procedure

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Research article

Keywords: extracorporeal membrane oxygenation, ECMO, simulation, COVID-19, nursing, pandemic

Posted Date: October 16th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-89378/v1

Version of Record: A version of this preprint was published at BMC Nursing on October 30th, 2021. See the published version at https://doi.org/10.1186/s12912-021-00736-7.

Abstract

Background: Extracorporeal membrane oxygenation (ECMO) therapy is proven to be efficient in a selected critically ill patient population and is showing promising results in refractory hypoxemia in the novel coronavirus disease (COVID-19). However, it necessitates specialized clinicians and advanced technological resources. While COVID-19 is an ongoing global emergency, there is no evidence-based practice in preparedness. This article proposes an innovative and optimized nursing care protocol, the Standard Operating Procedure (SOP), that increase safety, and prevents overuse of personal protective equipment (PPE) without interfering with therapy during ECMO in COVID-19 patients.

Methods: A high-fidelity simulation scenario was developed. It included practicing safe and proper PPE donning and doffing during work organization, ECMO cannulation and ECMO-related procedures, and routine daily nursing care and management of patients on ECMO over nine hours.

Results: Results were collected in three parts – proposal of nursing standardized operating procedures. They provide including work organization, work load references, competences and infrastructural conditions. Additionally, the cannulation equipment checklist proposal and daily routine nursing algorithm with other procedures during extracorporeal support were created.

Conclusions: High-fidelity medical simulation can play an important role in staff training, improvement in previously gained proficiency, and development of optimal SOP for nursing care and management during ECMO in patients with COVID-19. Optimal SOPs may further guide multidisciplinary teams including intensive care units and interventional departments.

Introduction

Although there are numerous publications [1–3] related to nursing management of extracorporeal membrane oxygenation (ECMO), no guidelines exist about its application during a disaster, such as the global coronavirus disease 2019 (COVID-19) pandemic [4]. Moreover, the guidelines are unspecified for clinical nursing management of ECMO, and the use of personal protective equipment (PPE) during COVID-19 in ECMO [5]. Consequently, ECMO centres are strained to develop own institutional procedures. The dynamic evolution of the pandemic provides a growing that allows for innovations to optimisations of procedures [6–12].

Background

Extracorporeal membrane oxygenation can help a selected critically ill patient population [13] in modern critical care. However, its implementation in epidemic conditions – such as the COVID-19 disease – is only possible with appropriate both human and hardware resources [14, 15]. Due to its invasiveness, ECMO is a high-risk application with possible sudden and severe complications such as air entrapment in the ECMO circuit, and dislodgement, dislodgment of cannulae [5, 16]. Accordingly, the constant presence of at least two ECMO-trained clinicians is necessary for emergent life-saving interventions.

From December 2019 to March 2020, COVID-19 evolved from a cluster of pneumonia cases in China into the first coronavirus-caused pandemic [17], surpassing 30.5 million cases and 950,000 deaths in nine months and is still not under control [18]. It is accepted that the COVID-19 virus transmits human-to-human through respiratory droplets by coughing and sneezing, and aerosols [11]. The disease is highly contagious, with a relatively long incubation period, asymptomatic state, and viral shedding post-recovery. The lack of effective antiviral treatment and vaccine leave prevention and supportive therapies the only potentially helpful strategies available at this time. Although estimates are that only 3–5% of all cases progress into critical illness [19], it is significant given the high numerator. Invasive mechanical ventilation is necessary for a significant number of COVID 19-cases, in both hospitalized and critically ill (2.3–33.1% and 29.1–89.9%, respectively) [12]. The World Health Organization (WHO) provisionally recommends ECMO in cases with refractory hypoxemia unresponsive to lung-protective ventilation emphasizin*g access to expertise in extracorporeal membrane oxygenation* [20].

To apply ECMO in critically ill patients with COVID-19, a careful analysis of the balance between the potential benefits of ECMO and the available ECMO-trained human resources, staff safety, epidemiological restrictions, and hospital equipment and infrastructure is necessary [14, 15, 21]. Up-to-date, there are 2,571 applications of ECMO in COVID-19 reported into the Extracorporeal Life Support Organization (ELSO) registry [22].

Aim:

The purpose of this paper is to disseminate a proposal for a nursing SOP applicable to ECMO patients with COVID-19, or other epidemic conditions.

Procedure participants:

Participants were medical and nursing clinicians, caring for patients with COVID-19 on ECMO.

Method

Literature research:

A literature search was performed using the following MeSH key words: COVID + ECMO + NURSE; CORONAVIRUS + ECMO + NURSE using two search engines, PubMed and Google Scholar. There are several publications on ECMO nursing, mainly recommendations from regional centres [1–3,23–25). There are ELSO guidelines available, but are limited to the use of PPE during ECMO in patinets with COVID-19 [5, 10, 13]. No publications dedicated to nursing management of patients with COVID-19 ECMO were found.

Simulation:

On a single day, over 12 hours, of which three were used for preparation and nine to run the scenarios, authors carried out the simulation in an isolated ICU room in the Centre of Medical Simulation, Poznan University of Medical Sciences.

Based on evidence and our experience, we developed innovations in three main areas, including (A) work organization, (C) ECMO cannulation and ECMO-related procedures, and (B) daily nursing care and management of patients on ECMO and COVID-19.In addition, with the assistance of international experts in ECMO and critical care nursing, we made significant revisions to the initial SOP in use at our institution.

The simulation was designed and ran by two trainers, two experienced intensive care nurses, one perfusionist, and two physicians (an intensivist and a cardiac surgeon) with prior training and experience in ECMO and over 10-year experience in simulation training.

The simulation was carried out using a high-fidelity Laerdal 3G SimMan (Laerdal Medical, Orpington, UK) with an incorporated “artificial vessel” loop in a high-fidelity simulated intensive care unit (ICU) isolation room. Additional equipment used included an invasive mechanical ventilator and a vital sign monitor, infusion pumps, and an ECMO device (Cardiohelp) with a complete ECMO setup such as introducers, cannulae, and an HLS Set Advanced set (Maquet, Getinge, Rastatt, Germany). The communication was done using a radio station (Baofeng – 888S (BaofengTech, USA).

We designed a scenario (Table 1) to test the operational readiness of the ICU environment and staff by monitoring correct PPE use during the care of an ECMO patient. The scenario was run during a nine-hour simulation of a routine work in an ICU with nurses changing in the „cold and hot zone” (three-hour nursing care “shift” in working period time), and involving five medical additional staff members as participants and two simulation trainers. In our case, the simulation was used as an introduction to developing a nursing protocol for ECMO during COVID-19, therefore its logistics lack the typical structure of a medical simulation.

Table 1
Summary of the simulation scenario.

Scenario	
Setup	An intubated patient with COVID-19 in the ICU isolation room
Problem	Despite proper treatment and previous prone clinical status does not improve
Task	The team needs to be able to: A. implement VV ECMO B. take care of patient to fulfil the 6-hour nursing period including personnel change between “cold and hot zones” C. daily nurse routine activity including ECMO therapy monitoring D. intrahospital transportation E. other actions during ECMO support
ICU – intensive care unit; VV – venovenous; ECMO – extracorporeal membrane oxygenation.	

After the simulation, the participants joined a debriefing session lead by the two simulation trainers. The debrief consisted of a discussion, creation of a checklist, and a proposal of a daily nursing routine. They were asked to discuss their experiences with each scenario, identify potential technical problems, hidden risks, equipment failures and threats, as well as any difficulties related to PPE. Issues regarding human factors were also discussed including personal fears, communication and teamwork. Then each participant was asked to create an equipment checklist, followed by a proposal of essential nursing responsibilities in SOP during epidemic conditions (SOP for nursing management with extracorporeal techniques).

No statistical analyses were planned, and all data was qualitatively assessed.

Ethics:

Complying with the requirements of the Local Bioethical Committee of Poznan University of Medical Sciences, since the structure of this simulation did not involve patients, no ethical approval was sought.

Results

The results of the participants’ proposals based on their 9-hour simulated ICU work are combined into a final SOP covering three different areas including work organization (Appendices A), management and care of patients on ECMO with COVID-19 (Appendices B), and ECMO cannulation and ECMO-related procedures (Appendices C).

Discussion

Simulation is an excellent proven skill tester, knowledge and technical controller, and a re-evaluation tool. In our' previous works, we used high-fidelity simulations as a tool for creating rare, new, difficult, and complicated procedures. In ECMO, simulation is used to introduce to create standards for a new procedure. It is used in two ways, as (i) an introduction to develop a procedure or a program with initial teaching for newly starting ECMO programs, or as (ii) a validation tool for ECMO competency based on real-experience scenarios for established ECMO programs. In our case, it was the former, inevitably lacking a typical structure of the latter (e.g., medical simulation, knowledge evaluation of participating clinical staff before and after simulation, debriefing). However, it provided an essential element in developing an ECMO program at a regional ECMO Centre. We provide crucial commentaries in the Appendices (A, B, and C) focusing on all aspects of nursing care, including noted underlying discrepancies and made innovations. We believe, no general discussion is necessary for SOPs prepared this way.

Appropriate level of PPE:

The PPE used by personnel working in the "hot zone" during routine care was defined by the local epidemiological institutional policies and the availability of PPE.

The WHO provides a guide for both prevention and protection. Studies demonstrated that for performing aerosol-generating procedures, the proper level of PPE includes a respirator, eye protection goggles, a gown with long sleeves, and a full-length apron [7, 8, 20, 25]. The correct use of PPE by healthcare professionals for COVID – 19 is key for limiting the spread of infection. Detailed guidelines for the use of PPE during ECMO have been included in the latest ELSO COVID guidelines [5]. A full-face mask with an absorber, a level 3 protection (Scott-Vision 4000 with Pro2000 filter, 3M, USA), is safe and comfortable (Fig. 4). Full-face mask prevents evaporation and does not decrease voice reception. With its horizontal and vertical curvature, and excellent optical properties, it does not distort the view. During simulation, the full-face masks with a side filter connector provided a better protection than a bottom (chin) one, as it covers and touches the front of the protective clothing.

Critical care in an isolation room:

Our simulation has demonstrated two key factors important for the management of patients with COVID-19, the ability to properly communicate and strategically minimize the number of clinicians in the patient's room. The balance between providing an efficient therapy and safety of personnel requires strict control with PPE, compliance with respecting the hot and cold zones [8], and adherence to standards of involving only the necessary number of clinicians in the isolation room [20, 26].

Lessons learned from previous epidemics and pandemics are strategies of implementing modified systems including notifications, isolation precautions, infection prevention, and environmental cleanliness of ICUs [6, 8, 11, 27]. Minimizing the frequency in opening the door of the patient's room was significant during the simulation. Improving the nurse-to-patient ratio to 1:1 or 2:1 decreases the frequency the nurse moves in and out of the room [31]. Assigning one nurse for each zone, efficient

nursing communication and the larger isolation room helped improve efficiency in therapy. Exceptions are situations that require the presence of additional clinicians (e.g., CPR, prone positioning or transferring).

For collecting equipment, using a checklist was a new and efficient approach (Appendices C and Table 2).

Specific care related to ECMO:

Managing a patient with COVID-19 also on ECMO requires additional multidisciplinary staff with expertise in managing ECMO. Moreover, the unknown of the novel pandemic mandates modifying standards related to use of PPE, and the increased patient workload. Optimization, maintenance and adherence to isolation specific to COVID-19 is necessary to reduce the risk of transmission of infection to the highly specialized ECMO team. Their well-being is crucial for providing ECMO support to the most critically ill COVID-19 patients [9].

Pandemic-specific nursing management:

In the proposed SOP, nurses that play an integral role in the ECMO team, including monitoring of the ECMO device and patient hemodynamic within ECMO [10, 28], as well as efficiently responding to ECMO emergencies following specific infection control related to COVID-19, which can lead to a significant physical and mental stress [8]. Ongoing training including appropriate use of PPE, daily management of ECMO and readiness for ECMO emergencies helps less experienced clinicians in preventing burnout and improves preparedness for any upcoming pandemic [10]. For equipment collection direct checklists should be utilized.

Innovation:

It seems reasonable to build isolation rooms with easy viewing, with continuous monitoring and communication ability from outside the room, especially during procedures. Another solution can be to design a control room with continuous monitoring of the patient with projection two cameras, at minimum.

Communication:

We have learned that the use of PPE required for patients with COVID-19 causes additional anxiety and discomfort to staff. Nursing care and communication among team members is an added challenge [26]. The introduction of facilities over intercom, continuous availability and assistance of a nurse from the “cold zone”; names written on aprons of the auxiliary staff; writing essential information on a window, glass or board helps reducing stress and inconveniences. Our simulation also demonstrates the usefulness of full-face masks and wireless radio systems between the zones for communication.

Training and simulation:

Providing ECMO therapy requires education and training of clinicians including high-fidelity simulation (ELSO). Moreover, due to the current global state of the pandemic, added attention is necessary. Medical

simulation in ECMO has been used for almost 20 years [10, 26]; it created new procedures and built ECMO-dedicated teams [16, 29, 30].

When applying ECMO to patients with COVID-19, constant diligence in critical care and ECMO device monitoring are fundamentals of nursing care. It is necessary to train nurses in monitoring the ECMO circuit including the blood colour in the ECMO tubing, pre- and post- oxygenator pressures and interventional clamping of the ECMO tubing in an ECMO emergency [31]. We have known from our previous experimental simulations that nurses' actions helped to detect early any potential emergencies and ad hoc interventions preceding support from "cold zone".

Limitation

The application of the approach used in this simulation is feasible only at centres with similar structure. Of note, because each hospital's critical care department has different organizational structure and training of personnel, they can face unique problems, especially during a pandemic state. Departments should follow the latest guidelines, modify our recommendations and their own protocols.

Conclusion

High-fidelity simulation can enhance previous existing expertise in preparation of a standard operation procedure. Although an unprecedented pandemic creates unpredictable barriers, we demonstrated the possibility of implementing an initial simulation strategy resulting in a nursing SOP proposal for the most critically ill with COVID-19 undergoing ECMO. This simulation project may guide intensive care and operations departments regarding aspects of care that may require significant focus and possible modifications before admitting COVID-19 patients or in a future pandemic. We recommend for each unit managing COVID-19 patients on ECMO to develop and implement *in situ* simulation to identify unit- or institution-specific hidden risks and create individualized protocols aligned with available recommendations and guidelines, as well as to modify to own circumstances and implement our proposal.

Terms:

"cold zone" - epidemiologically clean zone

"hot zone" - epidemiologically contaminated zone

Abbreviations

ABM	acid-base management
ACT	activated clotting time
APTT	activated partial thromboplastin time
COVID-19	coronavirus disease
CVP	*central venous pressure*
ECMO	extracorporeal membrane oxygenation
ECMO VA	ECMO venoarterial
ECMO VV	ECMO venovenous
ELSO	Extracorporeal Life Support Organization
ETT	endotracheal tube
FFP	filtering facepiece
HR	heart rate
MACC	mechanical automated chest compression
MAP	mean arterial pressure
MPC	medical product characteristics
POCT	point of care testing
SARS-CoV-2	Coronavirus
SOP	standard operating procedure
SpO_2	oxygen saturation
PPE	personal protective equipment
TISS	Therapeutic Intervention Scoring
VAE	ventilator associated events

Declarations

Ethics approval and consent to participate

Following the requirements of Local Bioethical Committee of Poznan University of Medical Sciences, since our simulation did not involve patients based on its structure, ethical approval was not sought for this simulation.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

This research received no specific grant from any funding agency from a public, commercial, or not-for-profit sector.

Authors' contributions

MP, MD, KB, ML, AD, MW, PZ, MLa prepared the simulation scenario, performed all tasks with ECMO therapy. LSz, SS performed the literature search. All authors prepared SOP for ECMO and nursing management and constructed Appendices A, B, C. MT, JS, TF, LS, PS, AS, KH, BA, BP, JS, MJ provided expert critical input and guide for the proposed SOPs. All authors read and approved the final manuscript.

Acknowledgements

We would like to express the special thanks to international experts in critical medicine and ECMO for their significant contribution in the development of this document:

Monika Tukacs (Department of Cardiothoracic Intensive Care Unit/Nursing, NewYork-Presbyterian/Columbia University Irving Medical Center, New York, NY, USA)

Tammy Friedrich (Mayo Clinic, Rochester, MN, USA)

Justyna Swol (General Hospital Nuremberg, University Hospital of Paracelsus Medical University, Dept. of Respiratory Medicine, Allergology and Sleep Medicine, Intensive Care Unit, Nuremberg, Germany)

Lukasz Szarpak (Bialystok Oncology Center, Bialystok, Poland)

Paulina Skorupa (Department of Cardioanesthesia and Intensive Care, Medical University of Silesia, Zabrze, Poland)

Aleksandra Steliga, Kazimiera Hebel, Blazej Andrejanczyk (Chair of Nursing and Medical Rescue, Pomeranian Academy, Slupsk, Poland)

Jacek Smereka (Department of Medical Rescue, Wroclaw Medical University, Wroclaw, Poland)

Marek Jemielity, Bartlomiej Perek (Department of Cardiac Surgery and Transplantology, Poznan University of Medical Sciences, Poznan, Poland)

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Tables

Due to technical limitations, table 2 is only available as a download in the Supplemental Files section.

Figures

Figure 1

Preparation for ECMO cannulation. ECMO Team in PPE in the isolated ICU room. (authors' material)

Figure 2

Venous femoral cannulation, percutaneous ultrasound navigated. (authors' material)

Figure 3

VV ECMO run in isolated ICU room. (authors' material)

Figure 4

Full-face mask with absorber (Scott-Vision 4000 with Pro2000 filter, 3M, USA). Personnel name marked on apron. (authors' material)

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- AppendicesA.docx
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- AppendicesC.docx
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