Clinical Practice of Pre-Assembling and Storing of Extracorporeal Membrane Oxygenation Systems

Patrick Winnersbach,* Alexander Wallraff,† Marlene Schadow,‡ Rolf Rossaint,* Rüdger Kopp,§ Christian Bleilevens,* and Lasse J. Strudthoff‡

According to the Extracorporeal Life Support Organization (ELSO) guidelines, pre-assembled and already primed extracorporeal membrane oxygenation (ECMO) systems can be safely stored for up to 30 days under specific conditions. This study gives a detailed overview of existing pre-assembly practices. An anonymous online survey was conducted among chief perfusionists at German ECMO centers. Forty-four of a total of 83 ECMO centers (53%) completed the survey. Thirty-three percent do not preassemble ECMO systems. Seventy-seven percent (n = 34) reported having preassembled ECMO systems readily available (30% dry preassembly/20% wet preassembly/27% wet preassembly with circulation). Half of the participating centers (50%) reported having a standard operating procedure (SOP) and the majority (57%) of chief perfusionists expressed a need for an evidence-based SOP. A maximum storage time for wet preassembled ECMO systems is established in 88% of departments. On average, wet preassembled systems are discarded after 20 days, which is below the ELSO's safe limit of 30 days. Overall, this survey reveals a heterogeneous approach regarding the practice of provisioning preassembled ECMO systems. The demand for an evidence-based SOP for the preassembly and storing of ECMO systems becomes evident, necessitating the determination of hygienic standards, regular training, and a reliable maximum storage period. *ASAIO Journal* 2024; 70:979–986

From the *Department of Anesthesiology, University Hospital RWTH Aachen University, Aachen, Germany; †Department of Heart Surgery, University Hospital RWTH Aachen, Aachen, Germany; ‡Medical Faculty, Department of Cardiovascular Engineering, Institute of Applied Medical Engineering, RWTH Aachen University, Aachen, Germany; and §Department of Intensive Care, University Hospital RWTH Aachen University, Aachen, Germany.

Submitted for consideration March 2024; accepted for publication in revised form April 2024.

Disclosure: The authors have no conflicts of interest to report.

This research was funded by the German Research Foundation, grant number DFG RO 2000/26-2.

C.B. and L.J.S. contributed equally to this work.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML and PDF versions of this article on the journal's Web site (www.asaiojournal.com).

Correspondence: Patrick Winnersbach, Department of Anesthesiology, University Hospital RWTH Aachen University, Aachen, Germany. Email: pwinnersbach@ukaachen.de.

DOI: 10.1097/MAT.0000000000002232

Key Words: extracorporeal membrane oxygenation, hygiene, online survey, perfusionist, prepriming, preassembly, SOP, training

It is common practice in many departments performing extracorporeal membrane oxygenation (ECMO) to store preassembled ECMO circuits, either dry or wet (primed). Especially the storing of wet preassembled systems is a topic controversially discussed.[1] This study evaluates the current clinical practices regarding the provision of dry and wet preassembled ECMO systems qualitatively and quantitatively by means of an anonymous multicenter survey.

Nowadays, the just-in-time setup of ECMO systems has become challenging due to training,[2] procedural changes,[3] improved experience,[4] and the suddenness of ECMO-enhanced resuscitation (eCPR).[5,6] Therefore, it seems reasonable to hold preassembled ECMO circuits available to increase readiness for emergency ECMO application, conserve time and personnel resources during acute emergency situations, and facilitate meticulous preparations outside the emergency context.[7] Also, preassembled circuits that are eventually not used due to termination or change of therapy may be kept in stock for another appropriate patient, saving resources.

Indeed, the leading ECMO society, the Extracorporeal Life Support Organization (ELSO) defines in their guidelines[8]:

> "The circuit may be maintained in a primed condition, safely, for 30 days."

Apart from the storage duration, several open questions like the priming fluid, hygiene and sterility measures, and storage conditions, have not yet been sufficiently addressed.

To our knowledge, there are no universal standard operating procedures (SOPs) specifying the general handling of preassembled ECMO systems. Thus, we hypothesized that a broad spectrum of different preparation strategies are in place at German ECMO centers. To shed some light on the extent, this study presents a large multicenter survey at German ECMO centers. It gives a detailed overview of existing strategies and practices regarding the provision and handling of preassembled ECMO systems.

Materials and Methods

An anonymous online survey was conducted among chief perfusionists at German ECMO centers. The survey was initiated and designed by an interdisciplinary working group (perfusion, anesthesiology, intensive care, medical engineering, biology) and endorsed by the German Society for Cardiovascular Engineering (DGfK).

A group of local nonparticipating perfusionists pre-evaluated the survey regarding professional correctness, usability, and

technical functionality. The survey comprised 42 questions thereof 14 open questions and 28 multiple-choice questions, 13 with unrestricted multiple selections. The complete survey can be found in the Supplemental Digital Content, http://links.lww.com/ASAIO/B278.

Targeted respondents were chief perfusionists at German ECMO centers, who were contacted *via* the mailing list of the DGfK. The invitational email informed about the purpose of the study, the investigators, the approximate time required, and the data management, all according to the CHERRIES criteria for online surveys.[9] The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the ethical committee of the University Hospital of the RWTH Aachen (file no EK 24-118). The completion of the survey was interpreted as informed consent to the anonymous data analysis. The survey was conducted from April 25 to June 13, 2023, using the online survey platform Typeform.[10] Completeness checks before submitting were carried out and the selection of at least one response option was enforced. Only complete questionnaires were analyzed.

Results

Forty-four of the 83 ECMO centers registered with the DGfK replied (53%). Among the responding chief perfusionists, 89% had more than 10 years of professional experience in their field.

Figure 1A shows the institutional standards regarding ECMO system preassembly. Twenty-three percent (n = 10) of the participating centers do not preassemble systems in advance. Seventy-seven percent (n = 34) reported holding preassembled ECMO systems readily available at all times. The extent of preassembly can be subdivided into the dry preassembly of the system (30%, n = 13), wet preassembly/de-airing of the system with fluid (20%, n = 9) and wet preassembly with additional continuous circulation of the fluid (27%, n = 12).

Figure 1B shows identical yet rearranged data from Figure 1A, relative to the annual caseload of the institution. All centers performing more than 100 ECMO applications per year preassemble and store ECMO systems, with a majority of 86% performing wet preassembly. Regarding centers with 50–100 cases per year, a minority of 10% (n = 1) does not preassemble the ECMO systems. In contrast, nearly half of the centers (44%) with 20–50 cases per year and half of the centers (50%) with less than 20 cases per year do not preassemble ECMO systems.

Figure 2 shows the rationale for holding (Figure 2A) and not holding (Figure 2B) preassembled ECMO systems available. Ninety-four percent of the participants who keep preassembled systems are aiming to avoid time pressure in emergency situations, whereas 71% report a lack of a permanently available "On-call"-service. The main reasons for not preassembling ECMO systems in advance are the expenses upon potential disposal and the long time of storage. No participants reported that the Departments of Hygiene prohibited the storage of preassembled ECMO systems.

Assembly Time

Figure 3A summarizes the data on the estimated dry and wet assembly time for the standard ECMO system used in each center. The sole procedure of dry assembly the ECMO system requires 8.6 minutes on average, whereas the subsequent procedure of de-airing (priming) requires 5.4 minutes. The total assembly time (dry + de-airing) for an ECMO system is plotted in Figure 3B, which is 14 minutes on average. Figure 3B also illustrates the preparation time according to the center's preparation approach. Centers that do not preassemble their systems in advance require an average of 11 minutes for the setup, whereas centers that normally perform dry or wet preassembly of their systems require an average of 13 and 15 minutes, respectively. Centers performing wet preassembly with and without circulation are combined, as starting the circulation has no substantial influence on the assembly time.

Training and Standard Operating Procedure

Figure 4 presents responses concerning training practices and the existence of an SOP for the safe preassembly of ECMO systems.

Figure 4A: the top graph shows that 59% of the participating departments implement regular training. The bottom graph shows the same data differentiated by the extent of ECMO system preassembly. Notably, only about 50% of departments that hold preassembled systems available provide regular training

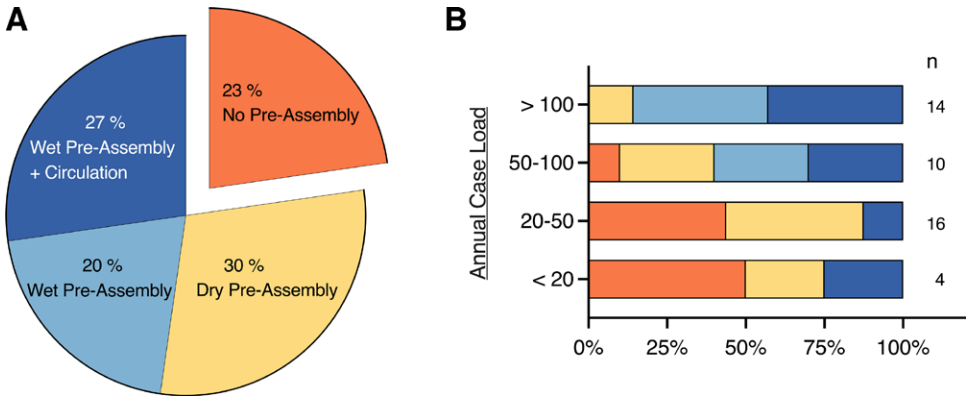

Figure 1. A: Proportional distribution of institutional standards regarding ECMO system preassembly among participating centers. **B**: Rearranged data in relation to the annual case load of the center. ECMO, extracorporeal membrane oxygenation.

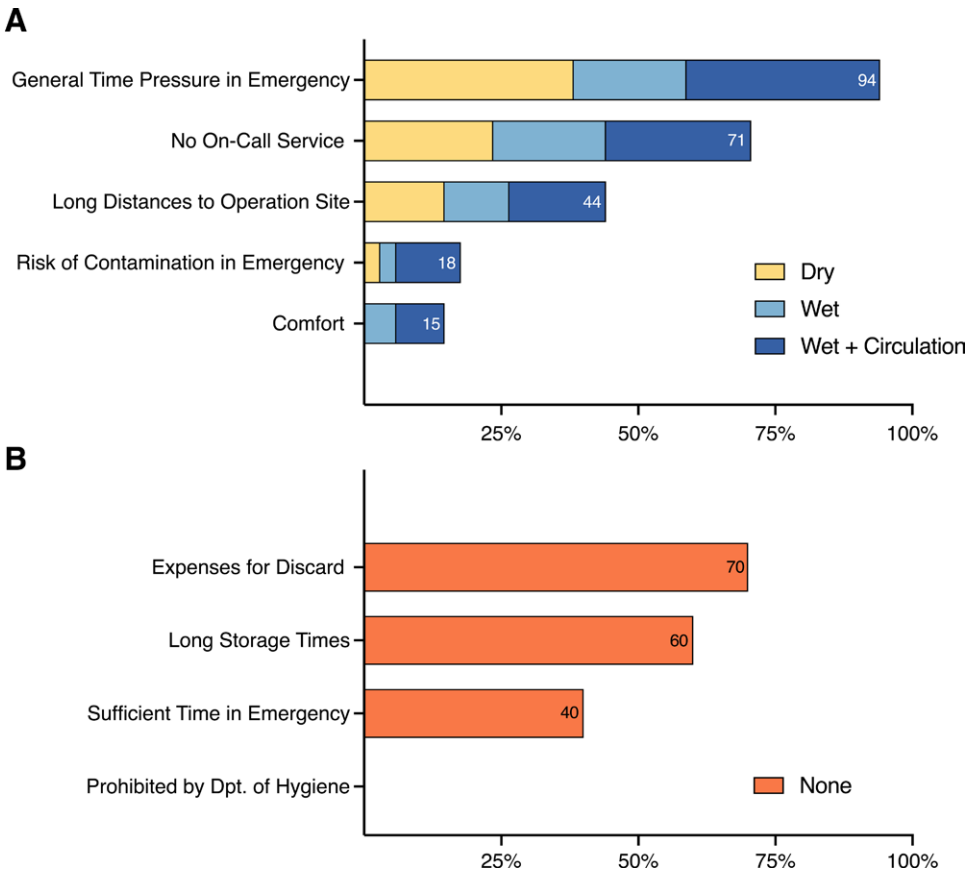

Figure 2. Reasons for holding preassembled ECMO systems available in relation to the degree of preassembly (**A**) and for not holding preassembled ECMO systems available (**B**). Multiple-choice questions with unrestricted multiple selections. ECMO, extracorporeal membrane oxygenation.

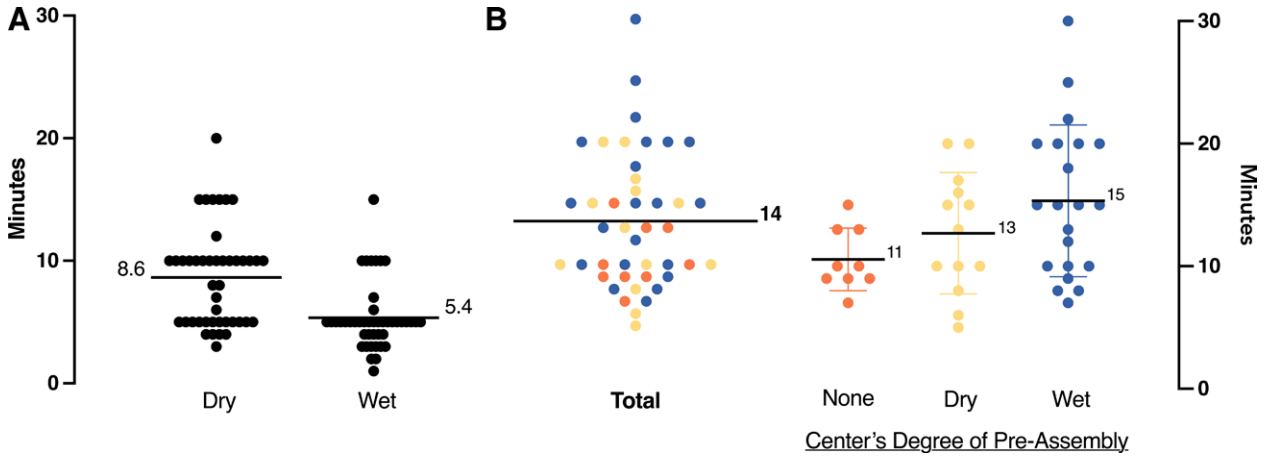

Figure 3. A: Required time for dry and wet assembly of ECMO systems. **B**: Required time for the total assembly of an ECMO system (dry assembly + de-airing), and subdivided by the degree of preparation that the respective center implemented as their standard. The horizontal bars represent mean values. ECMO, extracorporeal membrane oxygenation.

in contrast to 80% of the departments not holding preassembled systems available. Thirty-two percent of chief perfusionists hold the opinion that regular training makes preassembly obsolete (Figure 4B, top graph). This belief is most prevalent (60%) among departments that do not preassemble ECMO systems in advance (bottom graph). Further, the proportion of chief perfusionists stating that regular training could replace preassembly decreases with increasing extent of the standard preassembling procedure.

Half of participating centers (50%) reported having an SOP for the provision of preassembled system (Figure 4C). A majority (57%) of chief perfusionists expressed a need for an evidence-based and universally applicable SOP for preassembling and storing of ECMO systems (Figure 4D).

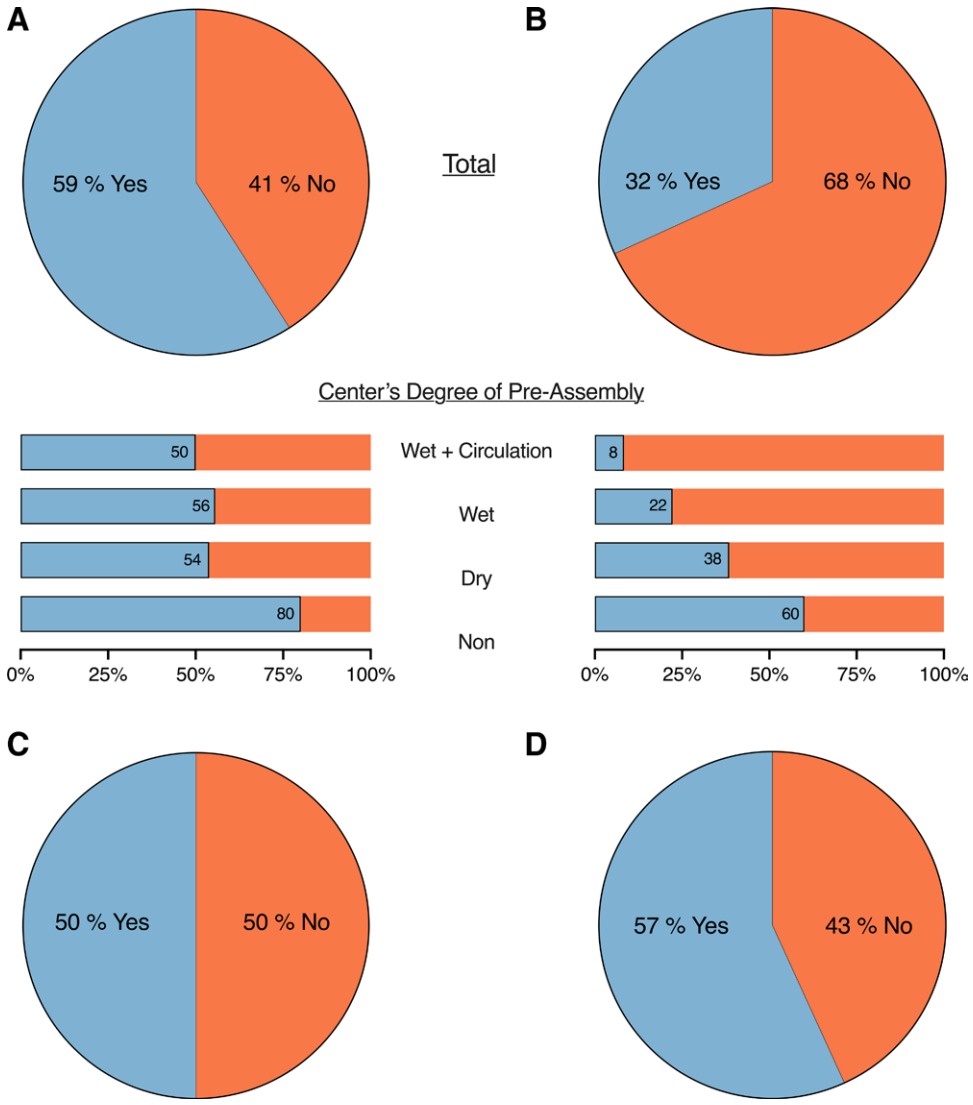

Figure 4. A: Share of centers providing regular training on the safe setup and priming of ECMO systems (top graph) and its display in relation to the center' standard preparation procedure (bottom). **B**: Share of chief perfusionists convinced that regular training on the safe setup and priming of ECMO systems could make preassembly obsolete (top graph) and its display in relation to the center' standard preparation procedure (bottom). **C**: Percentage share of centers having an SOP and (**D**) chief perfusionist expressing the need for an evidence-based, universally applicable SOP for the preassembling and storing of ECMO systems. ECMO, extracorporeal membrane oxygenation; SOP, standard operating procedure.

Storage, Usage, and Discard

A maximum storage period for preassembled dry (Figure 5A) and wet (Figure 5B) ECMO systems exists in 74% and 88% of the departments, respectively.

Figure 5C shows the plotted maximum storage period for dry and wet preassembled ECMO systems. On average, preassembled systems must be discarded dry after 27 days and wet after 20 days, respectively. Responses are clustered around the 30 day mark. Differentiating the data by the annual case numbers (right) shows that experienced centers with greater than 100 cases permit longer maximum storage durations than centers with fewer cases.

Wet preassembled systems are typically used within an average of 9.5 days (Figure 6) with distinct differences with respect to the centers' annual caseload. In centers with greater than 100 cases, wet systems are used on average after 4 days, with a narrow standard deviation. In contrast, centers with less than 20 annual cases use their wet preassembled ECMO systems after a mean of 21 days, with a broad standard deviation.

Hygiene

Figure 7A shows that hand disinfection before circuit assembly and the use of face masks during the procedure are adopted by 98% and 89% of participating centers, respectively. Seventy-seven percent use surgical caps, whereas 61% use gloves (48% unsterile, 13% sterile). Forty-eight percent have performed examinations before on wet preassembled and stored ECMO systems, aiming to detect any potential contamination (Figure 7B). Asking for a more detailed description of these examinations, free text responses indicated no evidence of any contamination after various periods of storage (Figure 7C).

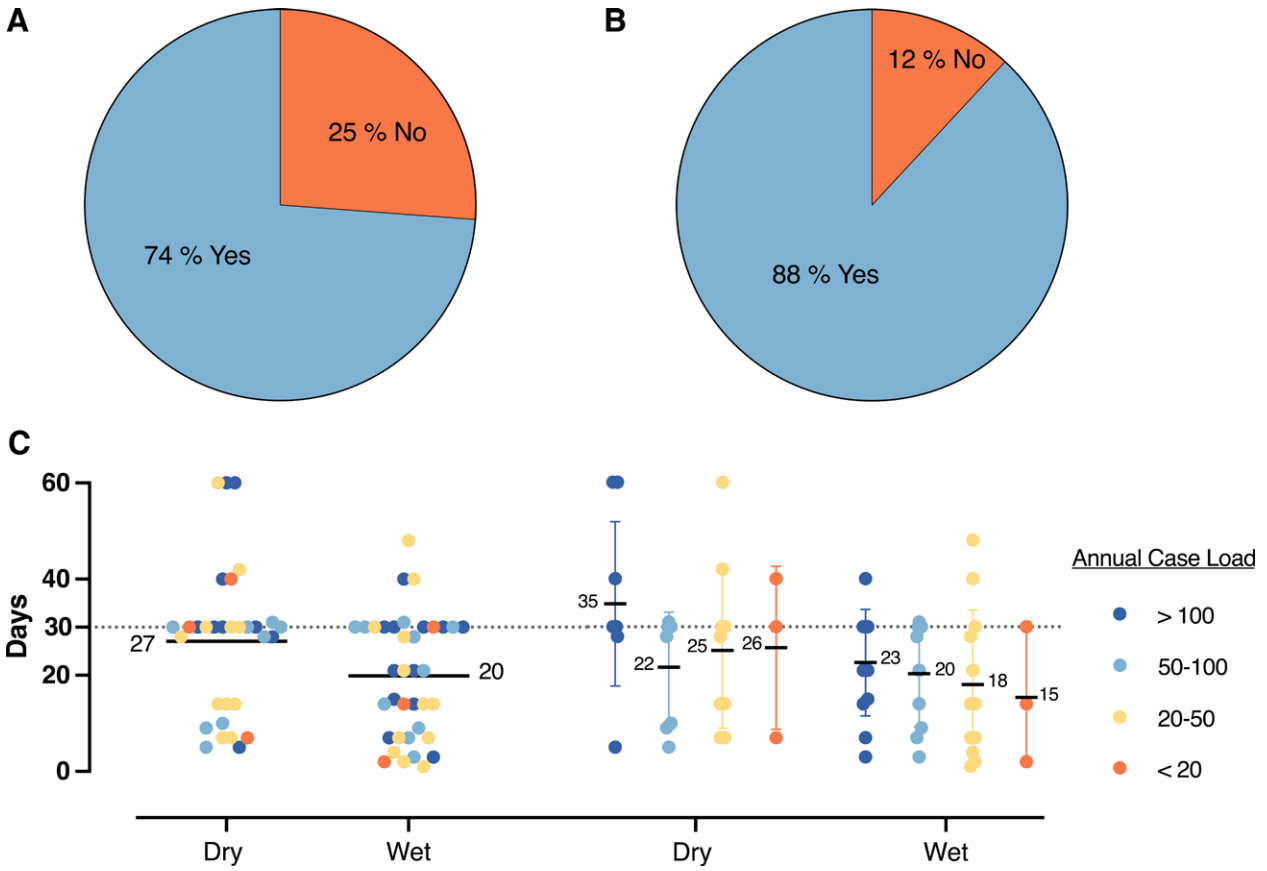

Figure 5. Percentage share of centers having a maximum storage period for preassembled dry (**A**) and wet (**B**) ECMO systems. Permitted maximum storage period in individual centers for dry or wet preassembled ECMO systems and division according to the centers annual case numbers (**C**). The horizontal bars represent mean values. The dotted line highlights the 30 day limit. ECMO, extracorporeal membrane oxygenation.

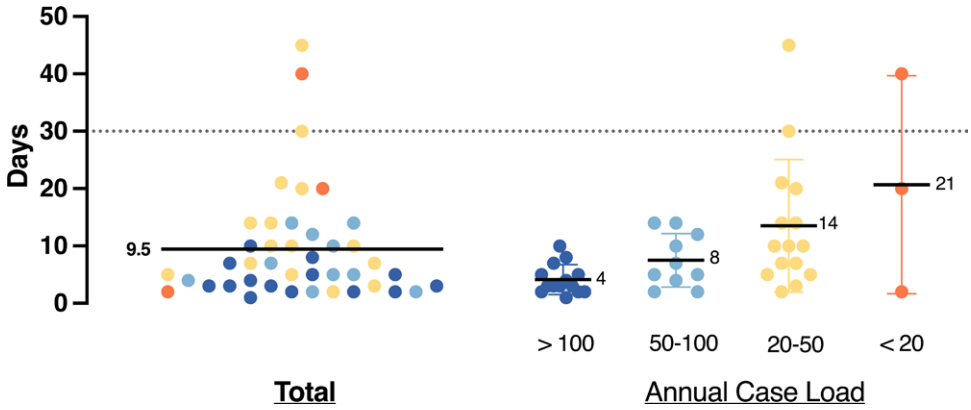

Figure 6. Average storage times of wet preassembled ECMO systems until usage, displayed as total overview and divided according to the centers annual case numbers. The horizontal bars represent mean values. The dotted line highlights the 30 day limit. Centers that do not store ECMO systems at all (n = 2), even in nonusage scenarios after emergency assembly, are not included. ECMO, extracorporeal membrane oxygenation.

Discussion

To our knowledge, this is the first survey investigating the practice of holding preassembled ECMO systems in provision. A response rate of 53% of the chief perfusionists at German ECMO centers is distinctly above the average of comparable online surveys[11] and suggests a robust dataset. Also, the vast experience of the study participants ensures that experts in the field provided reliable data.

Standard Approach Depends on Annual Case Numbers

Investigating the extent of circuit preassembly in relation to the department's caseload, departments with high annual case

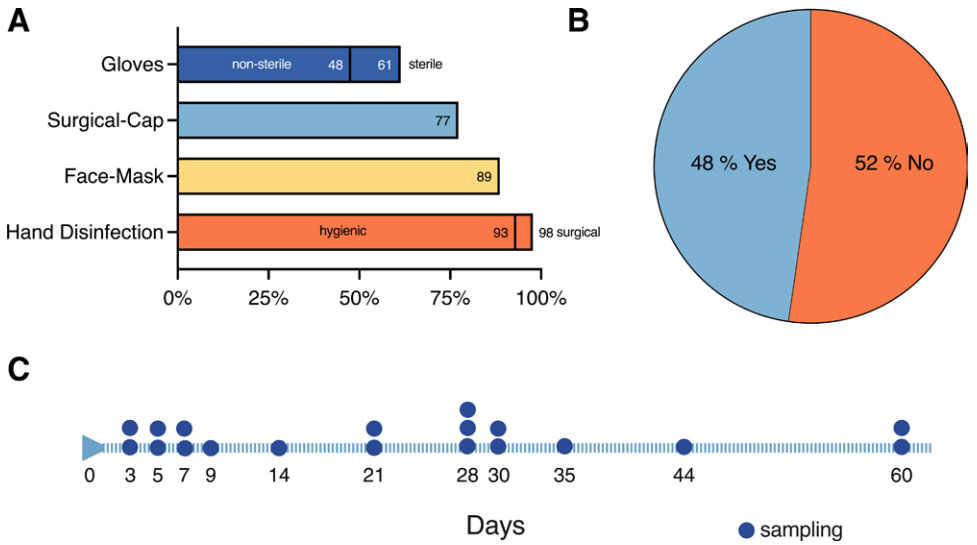

Figure 7. A: Various hygienic measures used for the dry and wet preassembly of ECMO systems and (**B**) testing for contamination of EMCO system in participating centers. **C**: Timespan until samples were taken from the preassembled systems for contamination testing varies between the participating centers. Created with BioRender.com. ECMO, extracorporeal membrane oxygenation.

numbers tend to preassemble their ECMO systems in advance and *vice versa*. These findings match the main reasons given for the decision to not hold preassembled ECMO systems available, which are "Expenses for Discard" and "Long Storage Times." It is consistent that centers with a low case load have longer storage times of ECMO systems before usage and therefore fear expenses for their discard.

Further, two stereotypical types of departments can be characterized:

First, departments with high annual case numbers (>100) tend to preassemble their ECMO systems in advance. The time needed for preassembly is high, because training is of minor interest, as preassembled ECMO systems are normally readily available. Average storage times in large centers are low due to a fast turnover, therefore expenses for disposal of preassembled ECMO systems are low.

Second, departments with a low annual caseload (<20) characteristically do not preassemble their ECMO systems in advance. Due to implemented regular training, the set-up time is low and sudden setup in an emergency is no obstacle. The disposal of wet preassembled ECMO systems is a frequent event due to the lower turnover.

Premature Disposal and Exceeded Storage Periods

From an economic and ecological perspective, preassembled ECMO systems should not be disposed before the defined maximum storage period.[12] At the same time, maximum storage durations of ECMO systems must not be exceeded as evidence for the safe use is insufficient.

On first sight, premature disposal or exceeded storage periods seems not to be an issue, considering that the mean maximum storage period of unused, already wet preassembled ECMO systems is 20 days (Figure 5C) and the mean average storage time is 9.5 days (Figure 6A). Both durations are considerably below the ELSO's recommended safe limit of 30 days.[8]

A more profound analysis reveals that especially departments with lower annual case numbers discard their preprimed systems early, within 15 days (below 20 annual cases) and 18 days (20–50 annual cases) on average (Figure 5C). Examining the individual maximum storage duration of the departments, over one third of departments discard their systems within 15 days or less, potentially producing unnecessary cost and waste.

Likewise, the reporting of the average storing time does not rule out individual systems being stored for more than 30 days. Six centers (14%) report an average storage time exceeding 20 days, suggesting a likelihood of individual systems in these centers surpassing the 30 day safe limit. Two centers (5%) even report an average storage time exceeding 30 days (Figure 6). Altogether, the data suggest that storage times for individual systems exceeding the 30 day safe limit are likely.

Training Is Predominant in Centers Not Preparing Extracorporeal Membrane Oxygenation Systems

Eighty percent of departments that do not regularly preassemble their ECMO systems offer regular training sessions for the safe dry and wet preassembly. In distinct contrast, only 53% of departments preassemble their ECMO systems in advance offer regular training (Figure 4A). Considering the swift ECMO system assembly times of departments not preassembling ECMO systems in advance (11 min), in contrast to departments performing dry (13 minutes) or wet (15 minutes) preassembly, depicted in Figure 3B, one can derive that regular training facilitates a faster preassembly of ECMO systems.

Demand for an Evidence-Based Standard Operating Procedure

Fifty percent of participating ECMO centers do not have an SOP for the preassembly and storing of ECMO systems, and 57% of participating chief perfusionists express the need for an evidence-based, universally applicable SOP (Figure 4B). This survey suggests the demand for such a guideline.

For a broad acceptance in the community, an SOP must meet the diverse requirements of the ECMO centers as presented in this study.

Further, the hygienic conditions for the preassembly and storing of ECMO systems need to be defined. For the preassembly, hygienic hand disinfection, and a face mask are indispensable as basic hygienic standards.[13]

The implementation of regular, supervised, and mentored training and simulation can lead to a safer and swifter dry and wet assembly of ECMO systems. Safer, in the context of hygienic aspects, which are essential for the assembly of a sterile ECMO system. The monitoring of the hygienic conditions during regular training sessions and the revision of hygienic standards can refine the awareness and importance of hygienic aspects.[14] Swifter, in the context of a structured and time-saving, but accurate dry and wet circuit assembly. A supervised and mentored training can identify problems in the preassembly process of ECMO systems and improve the process by giving feedback and advice.[15]

Last, reliable maximum storage periods for dry and wet preassembled ECMO systems must be determined. Several chief perfusionists referred to the ELSO guidelines on infection control.[8] Consequently, responses on the maximum storage period before disposal are clustered around the 30 day mark (Figure 5C). Indeed, several studies endorse the safe utilization of wet preassembled ECMO systems after weeks of storage:

Bistrussu *et al.*[16] aimed for validating wet preassembly and aseptical storage of ECMO circuits at 8°C using Plasmalyte which recirculates at low pump speed. No contaminations were detected after 14 days. The same group subsequently tested oxygenators with contemporary PMP hollow fibers.[17] After 14 days, neither microorganism growth, plasticizer migration, nor a decrease in O_2-transfer could be detected, whereas the CO_2 transfer decreased by 25%. Walczak *et al.*[18] conducted similar experiments for 30 days, with microporous membranes and zero-flow. They detected no microorganism growth. Naso *et al.*[19] stored wet preassembled circuits for 35 days at 37°C. Circuits with 0.5 lpm flow were compared against stalled circuits. Additionally, two further circulating circuits with intentional Escherichia coli (*E. coli)* contamination were tested for bacterial growth. No growth could be detected in either of the sterile circuit groups. The bacterial growth in the voluntarily contaminated circuits was exponential followed by a decline in bacterial burden to zero after 21 days.[19] Weinberg *et al.*[20] studied the bacterial contamination during nonsimulated clinical use in circuits primed with saline solution and stalled for 4 weeks. No bacterial growth was detected. Tan *et al.*[21] tested ECMO circuits even for 65 days. Slightly acidified Isolyte-S priming fluid (pH = 6.7) was kept in the circuits at room temperature. They did not find any bacterial growth.[21] More recently, Deptula *et al.*[22] conducted a larger experiment series designed to prove safe preassembly of extracorporeal circuits of different groups. They tested open cardiopulmonary bypass circuits and closed ECMO circuits in three different priming-statuses for different durations. They concluded that open and closed dry circuits can be safely used after 60 days storage duration. Crystalloid-primed, open circuits can be safely used for 5 days, closed circuits for 6 weeks. For all tests, they assessed gas transfer efficacy and *E. coli* growth (with and without voluntary initial contamination).[22] Many further studies exist specifically for cardiopulmonary bypass, which differs in circuit components (open reservoir, porous membrane, simpler coating, *etc*.) and clinical applications (elective deployment, short term usage, *etc*.) and is therefore difficult to translate to ECMO.[23–28]

These studies may answer some questions to a certain degree, however, most of them do not describe the hygiene standards they applied during the preassembly of the ECMO systems further than "aseptic" or even "sterile" conditions.[16,19,20,22,24]

In some studies, the risk of pathogen proliferation during the holding period is also investigated. For this purpose, a certain amount of *E. coli* is intentionally placed in the system.[19,22] It should be noted that although *E. coli* is used as a standard pathogen in the event of contamination, it does not provide information on the proliferation of clinically relevant pathogens. Common nosocomial infections during ECMO treatments, like *Pseudomonas* or fungi[29] have significantly lower cultivation requirements, and could therefore potentially proliferate in conditions *E. coli* would show no growth at all.

Other questions remain unanswered entirely. For example, procedural details, the effect of storage on the surface coatings, or the migration of substances from or through circuit-polymers into the priming fluid[30–35] have not yet been addressed or entirely resolved. Regarding the aspects of impaired oxygen or carbon dioxide transfer and coating wash-off due to the practice of prepriming, data is limited or non-existent. Thus, despite these studies and the integration of the 30 day limit into the ELSO guidelines, the evidence is limited. Consequently, the development and implementation of a standardized test protocol are imperative to enhance the existing evidence concerning the wet preassembly and storing of ECMO systems.

Limitations

The survey is limited on German ECMO centers operating with perfusionists. A response rate of 53% is reliable, compared to other online surveys, but nevertheless only represents half of the centers aimed for. As the survey addresses the preassembling of ECMO systems, chief perfusionist at centers not preassembling ECMO systems could have judged their response as unimportant and therefore did not respond, resulting in a sampling bias. The time parameters of this survey, like the assembly time for an ECMO system or the time until usage of an ECMO system, are estimated by chief perfusionists. Consequently, there is a potential for bias, given that durations are estimated rather than precisely measured. The survey did not ask for suggestions for improvement or ideal storage conditions.

Conclusions

The overarching finding of this survey is the heterogeneity at German ECMO centers regarding holding preassembled ECMO systems. The wet preassembling of ECMO systems (with or w/o circulation) emerged as the prevailing practice, implemented by 47% of the participating departments. The dry preassembly of the ECMO systems without de-airing is implemented as standard procedure by 30% of departments, whereas 23% do not store preassembled ECMO systems, entirely.

Further substantial findings are the nonuniform implementation of SOPs and training for the assembly of ECMO systems in the participating centers. The average storage durations are considerable below the ELSO's recommended safe limit of

30 days. In addition, relations were identified between the annual caseload of departments and their standard practices regarding preassembly, regular training and simulation, storage duration, and the time required to preassemble an ECMO system.

Overall, the study shows the demand for an evidence-based SOP for the preassembly and storing of ECMO systems.

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