The introduction of a high-fidelity simulation program for training pediatric critical care personnel reduces the times to manage extracorporeal membrane oxygenation emergencies and improves teamwork

Matteo Di Nardo[1], Piero David[2], Francesca Stoppa[1], Roberto Lorusso[3], Massimiliano Raponi[4], Antonio Amodeo[5], Corrado Cecchetti[1], Yigit Guner[6], Fabio S. Taccone[7]

[1]Pediatric Critical Care Unit, Children's Hospital Bambino Gesù, IRCCS, Rome, Italy; [2]Cardiac Anaesthesia and Intensive Care Unit-Sant'Andrea Hospital, Rome, Italy; [3]Department of Cardio-Thoracic Surgery, Heart&Vascular Centre, Maastricht University, Maastricht, The Netherlands; [4]Medical Direction, Children's Hospital Bambino Gesù, IRCCS, Rome, Italy; [5]ECMO and VAD Unit, Children's Hospital Bambino Gesù, IRCCS, Rome, Italy; [6]Department of Surgery, Irvine Medical Center, University of California, Orange, CA, USA; [7]Department of Intensive Care, Hôpital Erasme, Université Libre de Bruxelles, ULB, Brussels, Belgium

Contributions: (I) Conception and design: M Di Nardo, F Stoppa, FS Taccone; (II) Administrative support: C Cecchetti, R Lorusso, M Raponi; (III) Provision of study materials or patients: M Di Nardo, A Amodeo; (IV) Collection and assembly of data: F Stoppa; (V) Data analysis and interpretation: P David, M Di Nardo, Y Guner; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Dr. Matteo Di Nardo. Pediatric Critical Care Unit, Children's Hospital Bambino Gesù, IRCCS, P.zza S. Onofrio 4, 00165 Rome, Italy. Email: matteo.dinardo@opbg.net.

Background: Extracorporeal membrane oxygenation (ECMO) is used to support patients with severe respiratory and/or cardiac failure unresponsive to conventional treatments. Despite being one of the most complex supportive therapy used in intensive care unit, there is a still a lack of training programs dedicated to improve both clinical and nonclinical skills. The aim of the current study was to evaluate if the introduction of an ECMO high-fidelity simulation curriculum among personnel reduces the times to manage bedside emergencies and improves the behavioral skills.

Methods: This retrospective study was performed from 2011 to 2016 in a 6-beds general pediatric intensive care unit (PICU) of a tertiary children's hospital. The study population was the PICU personnel. From the beginning of 2011 to the end of 2013, ECMO education was provided without a simulation program. A high-fidelity simulation program instead, was provided from December 2013. Times to manage the most common ECMO emergencies (pump failure, oxygenator change and air embolism management) as well as the behavioral skills of the personnel were evaluated before and after the simulation intervention only in novice learners to reduce the bias related to the natural improvement associated with the bedside practice.

Results: There were a total of 30 ECMO runs and 27 ECMO emergencies over the study period. Ten ECMO emergencies occurred during the pre-simulation period and 17 in the post-simulation period. The median time to change an oxygenator in case of failure was 5.3 (4.80–6.02) min during the pre-simulation period *vs.* 3.9 (3.50–4.15) min in the post-simulation period (P=0.02). The median time to manage an air embolism emergency was 22 (20.00–23.50) min during the pre-simulation period *vs.* 15 (13.75–16.50) min in the post-simulation period (P=0.048). Only one episode of pump failure occurred in either the pre-simulation and post-simulation periods. In the pre-simulation period the median cumulative behavioral score was 40 (35.00–44.75) whereas it was 48 (44.5–49.00) in the post-simulation period (P<0.01).

Conclusions: The introduction of a high-fidelity simulation program for pediatric ECMO improved both the times to effective interventions and behavioral skills.

Keywords: Simulation; extracorporeal membrane oxygenation (ECMO); education; training

Introduction

In the last decade, ECMO has seen a "renaissance" in its use with an increase in the number of adult ECMO runs to treat severe acute respiratory failure, cardiogenic shock and refractory cardiac arrest (1,2). In contrast, the use of ECMO in neonates and children has seen a reduction due to the improvement of conventional medical therapy (3). Thus, neonatal and pediatric ECMO is considered a low-volume and high-risk procedure, compounded by the fact that technical emergencies (i.e., pump or oxygenator failure, etc.) are associated with a mortality rate of 25% (4-6) in the neonatal/pediatric age group. It is therefore paramount to maintain the experience and minimize any external iatrogenic factors that could negatively influence the patient's outcome.

The initiation of an ECMO program is based on many human and logistic efforts since this procedure requires extensive multidisciplinary coordination as well as well-trained personnel. The "ideal ECMO Team" would then need an immediate "in-hospital" availability of human resources, such as a surgeon able to perform urgent cannulation, a perfusionist experienced in rapidly priming a circuit and an ECMO specialist able to set up baseline ECMO parameters to stabilize the patient. All of these issues necessitate a structured organization by a team leader to minimize confusion and positions overlap in a moment of significant time pressure (2,7).

The Extracorporeal Life Support Organization, an international society focused on ECMO research and education, proposed for the ECMO education didactic lectures with water-drills or animal labs (8,9) and recently introduced the use of high-fidelity simulation programs to improve technical and behavioral skills related to the ECMO management (10). Simulation-based training has emerged as a valuable tool in critical care education offering the opportunity to improve technical skills and reduce the risk of human errors (1,2,11). Previous studies (5,12-16) have reported the feasibility and benefits perceived by trainees in simulation-based ECMO educational programs, but limited data showed the positive impact of simulation to improve both technical and behavioral skills at bedside (17-19). To address this issue, we hypothesized that the introduction of an ECMO specific high-fidelity simulation program would reduce the response times to manage ECMO emergencies and improve behavioral skills.

Methods

This retrospective study was performed in the 6-beds general pediatric intensive care unit (PICU) of the Children's Hospital Bambino Gesù, Rome, Italy, from the beginning of the year 2011 to the end of 2016. The study population is composed of the personnel working in PICU (12 nurses, 5 physicians, 4 perfusionists). The study was approved by the local Institutional Scientific Board of Bambino Gesù Children's Hospital (within the Annual Research Program "Ricerca Corrente 2017", ref number 201702Q003968). Since the study did not involve patient data, the institutional board waived the need for informed consent.

In our hospital, the respiratory ECMO runs are managed in the general PICU since 2010. Cardiac ECMO runs instead are managed in the cardiac PICU since 1988.

Since 2010, an ECMO course per year composed of 34 hours (24 hours of didactic lessons and 10 hours of water drills) was established to train physicians, nurses and perfusionists (*Figure 1A*). This ECMO curriculum included also a period of supervised bedside training of almost 32 hours for the "new" ECMO specialists. Re-trainings were performed with water drills and seminars every 3 months from 2011 to 2013.

At the end of 2013, this educational curriculum was completely modified with the introduction of a high-fidelity simulation program as an alternative training tool for all team members including any new and all previously trained "experienced" personnel. This modification was due to the contemporary concern about the positive value as educational tool of high-fidelity simulation (1,2,15,16). The new ECMO course consisted of 32 hours of training per year. The personnel attended both the didactic lessons (16 hours) and the simulation scenarios (16 hours). The simulation scenarios covered all the topics introduced with the didactic lessons. After the course, the "new" ECMO specialists attended 32 hours of bedside training. Re-trainings were performed every 3 months only with high-
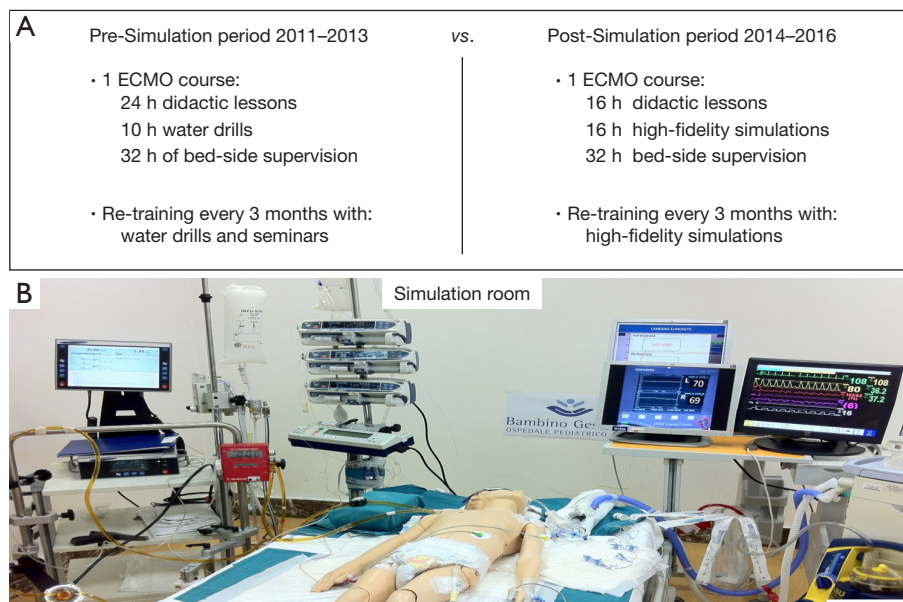
Figure 1 (A) Comparison of the didactic activities in the period 2011–2013 and 2014–2014; (B) simulation room in the Children's Hospital Bambino Gesù. ECMO, extracorporeal membrane oxygenation.

fidelity simulations and were associated to seminars.

Since the introduction of high-fidelity simulations in our program, 12 simulation sessions where performed to re-train personnel till December 2016. At the end of 2013 we also had new PICU staff because of personnel retirements. Seven new nurses without previous ECMO experience (7 new nurses on a total of 12 nurses), 2 new physicians without previous ECMO experience (2 new physicians on a total of 5 physicians) and 2 new perfusionists with limited ECMO experience (2 new perfusionists on a total of 4 perfusionists) were included in our PICU.

All simulations were conducted using a simulation room equipped with same materials (ventilator, defibrillator, emergency medications) present in PICU. Basic vital signs and physiologic data including central venous pressure, arterial blood pressure, end-tidal carbon dioxide tracing and an electrocardiogram were displayed in real time on a bedside monitor in accordance with clinical scenario (*Figure 1B*). Simulations were built up with preprogrammed scenarios using the Laerdal SimBaby software (Laerdal Italia SRL). This approach was used to assure that all the trainees could receive the same learning experience during the simulation sessions. All the simulations were videotaped and discussed in a debriefing session with a simulation instructor. During the debriefing all the learning objectives of the scenario were reviewed and were reinforced positive

team behaviors, as well as areas for improvement (11,12).

Measurements and definitions

We defined the pre-simulation period from January of 2011 to December of 2013 and the post-simulation period from January 2014 to December 2016 according to the introduction of the simulation program.

Emergency intervention time "at bedside" was defined as the time in minutes from the exact moment the call was placed to the pager reported on the clinical charts to the actual resolution of the ECMO emergency identified as the re-start of the ECMO flow reported in the perfusionist charts. The ECMO emergencies evaluated retrospectively were: pump failure, oxygenator change and air embolism management.

In the pre-simulation period, all personnel were novice learners whereas in the post-simulation period we had both novice and experienced personnel. However, "only" ECMO emergencies managed by novice personnel in the post-simulation period were included and evaluated in the study. The introduction at the end of 2013 of a different educational program with high-fidelity simulations associated to the renewal of the personnel allowed us to make a more homogeneous comparison of the two study periods including only novice learners.

	Know your environment	
Seems confused in the environment, unfamiliar with the circuit, unable to find clamps and/or syringes	Grading 1 2 3 4 5	Recognizes the circuit alarms, quickly finds and uses the clamps
	Anticipate and plan for crises	
Seems slow to anticipate problems, slow to recognize the need for respiratory support once off bypass	Grading 1 2 3 4 5	Anticipate the plan, when off bypass promptly recognizes the need for respiratory support
	Assume a leadership role	
Seems timid and unable to take control of the situation	Grading 1 2 3 4 5	Assumes a leadership role, takes charge of the crisis
	Communicate effectively	
Mumbles, speaks quietly, gives open air commands; is unable to explain the problem to the incoming personnel	Grading 1 2 3 4 5	Communicates effectively, gives clear, concise, well directed commands; is able to quickly explain the problem to the incoming personnel
	Distribute workload optimally	
Gets pulled away from the pump, does not assign tasks, gets distracted with menial tasks	Grading 1 2 3 4 5	Distributes the workload optimally is not the phone caller when should be the pump nurse, gives the bedside nurse a job, assigns a job to the RT
	Allocate attention wisely	
Gets distracted by the patient and pump alarms, is unable to troubleshoot the problem with the pump	Grading 1 2 3 4 5	Allocates his or her attention wisely, focuses on the pump and the patient, is not distracted by alarms or panicking personnel
	Utilize all available information	
Ignores the provided history (patient moving or pump bumped), doesn't listen to bedside nurse	Grading 1 2 3 4 5	Utilizes all available information, including the history and the changing information provided by the patient and the pump
	Utilize all available resources	
Ignores other personnel, doesn't elicit help from the team	Grading 1 2 3 4 5	Utilizes all available resources, including the other members of the team
	Call for help early enough	
Doesn't call for help in a timely manner, doesn't make use of all available resources	Grading 1 2 3 4 5	Uses all resources; calls for help early, asks for the RT, the ECMO doctor, the surgeon
Maintain professional	**Maintain professional behavior**	
Behaves inappropriately or unprofessionally	Grading 1 2 3 4 5	Maintains professional behavior, uses appropriate terminology

Figure 2 Behavioral skills evaluated using a 5-point Likert scale. ECMO, extracorporeal membrane oxygenation; RT, respiratory therapist.

The behavioral skills reported in *Figure 2* were evaluated "*in situ*" for each person involved in the management of the emergency and scored using a 5-point Likert scale (12). Scores were reported on a separate medical registry, which belongs to the Health Directorate of our hospital. Subjects were rated on 10 different behavioral items on a scale from 1 (poor) to 5 (excellent) for a possible total score of 50 points. The "*in situ*" evaluation of the behavioral skills is a required and established practice of the Bambino Gesù Risk Management Program. All medical emergencies occurring in our PICU are scored immediately after their management and recorded in separate registry. This evaluation is performed by one of the two doctors in charge not involved in the management of the crises. The use of

a very simple Likert scale associated to repeated courses of risk management for all the medical personnel working in PICU provided a homogeneous scoring system among doctors.

Statistical analysis

We retrospectively collected demographic and clinical data. We compared the duration of emergency interventions and behavioral skill scores in the pre-simulation period (January 2011 to December 2013) to the post-simulation period (January 2014 to December 2016). Further analyses were made between the two groups for confounding variables that could potentially affect the results. These analyses evaluated the following variables: the primary diagnosis leading to ECMO, the type of ECMO (venoarterial vs. venovenous ECMO), the surgical technique (percutaneous vs. surgical) and daytime vs. night-time/weekend emergency management. Continuous data were shown as median and interquartile ranges [IQR1 and IQR3]. Categorical data were described as absolute frequencies and percentage. Mann-Whitney U test was used to analyse non-parametric variables, student t-test was used to analyse normally distributed variables. Normal distribution and homogeneity of variances were analysed using Shapiro-Wilk test and Bartlett test. Categorical differences were tested using the Yates's chi-squared test or the Fisher exact method depending on the size of the observed frequencies. A P values of <0.05 was considered statistically significant. Statistical analyses were performed using Epi Info, version 7.1.5 (Centres for Disease Control and Prevention, Atlanta, GA, 2015) and "R" statistical software (version 3.2.5; R Foundation for Statistical Computing, 2016).

Results

During the study period ranging from January 2011 to December 2016, a total of 30 ECMO runs occurred in our institution. Twelve ECMO runs were performed during the pre-simulation period, while 18 in the post-simulation period. Of these 18 ECMO runs, only 14 were included in the evaluation because managed only by novice personnel.

Demographic and clinical characteristics of the patients are summarized in *Table 1*. A total of 27 ECMO emergencies in 30 patients were recorded from 2011 to 2016. No patients had more than one emergency. Ten emergencies occurred during the pre-simulation period and 17 occurred in the post-simulation period. Of these 17

emergencies, only 12, which were managed only by novice personnel, were included in the analysis.

When comparing the two periods (pre-simulation vs. post-simulation), we did not find any statistically significant difference in patient age, weight, gender, distribution of neonatal vs. paediatric cases, distribution of diseases treated, type of ECMO support (VA vs. VV), number of emergencies managed, mode of cannulation (percutaneous vs. surgical), night and weekend time management of the ECMO emergencies (*Table 1*). Also, the distribution of the emergencies treated (pump failure, air embolism, oxygenator failure) was similar among the two periods. There was no survival difference between the pre and post-simulation period for the ECMO runs evaluated in the study (50% vs. 57.1%) (P=0.72).

The median time to change an oxygenator was 5.30 (4.8–6.02) min during the pre-simulation period whereas in the post-simulation period was 3.90 min (3.50–4.15) (P=0.02). The median time to manage an air embolism emergency was 22 (20–23.50) min during the pre-simulation period whereas in the post-simulation period was 15 (13.75–16.50) min (P=0.048). Given the infrequent occurrence of pump failure (1 episode in each period), we did not make a comparison of pump replacement times.

Behavioural skills were evaluated using a "cumulative score" (defined as the median of all behavioral scores pre and post-simulation). In the pre-simulation period the median cumulative behavioural score was 40 (35–44.75) whereas it was 48 (44.5–49) in the post-simulation period (P<0.01).

Discussion

Extracorporeal life support is one of the most complex techniques available in the critical care setting, requiring both technical and non-technical skills to deal with unforeseen events and complications (16).

Currently ECMO education is not a formal part of any medical or surgical subspecialty's training curriculum (17-19), therefore ECMO training is usually accomplished with courses performed with didactic lectures, water drills, animal labs and periods of supervised mentorship. These teaching strategies overemphasize cognitive skills, underemphasize technical skills and completely ignore behavioural skills (1,2,6). The Extracorporeal Life Support Organization (ELSO) has developed guidelines for training and continuing education of ECMO specialists, which outline institutional requirements for effective ECMO

3414

Di Nardo et al. Simulation training of ECMO emergencies

Table 1 Characteristics of patients and ECMO runs stratified by time period. Data are presented as counts (percentage) or median (IQR 1–3), where not otherwise specified

Variables	Pre-simulations	Post-simulations	P value
Total ECMO runs, n (row %)	12 (40.0)	18 (60.0)	–
Total ECMO emergency interventions, n (row %)	10 (37.0)	17 (63.0)	–
Total ECMO survival, n (group %)	6 (50.0)	10 (55.5)	0.76
Evaluated ECMO runs, n (row %)	12 (46.0)	14 (54.0)	–
ECMO survival, n (group %)	6 (50.0)	8 (57.1)	0.72
VA ECMO, n (group %)	7 (58.3)	6 (42.8)	0.43
Age (months)	2.95 (1.75–3.50)	5.50 (2.00–15.00)	0.12
Weight (kg)	4.10 (3.65–4.50)	5.20 (4.00–12.00)	0.17
Female gender, n (group %)	5 (41.7)	6 (42.9)	0.95
Neonatal cases, n (group %)	4 (33.3)	4 (28.6)	0.79
Neonatal infective respiratory failure, n (neonatal %)	2 (50.0)	2 (50.0)	1.00
Pediatric viral ARDS, n (pediatric %)	4 (50.0)	6 (60.0)	0.62
Percutaneous cannulation, n (group %)	11 (91.7)	11 (78,6)	0.36
Night or/and weekend time, n (group %)	6 (50.0)	6 (42.9)	0.72
Evaluated emergency interventions, n (incidence %)	10 (83.3)	12 (86)	0.87
Pump failure, n (incidence %)	1 (8.3)	1 (7.1)	0.91
Oxygenator change, n (incidence %)	6 (50.0)	7 (50.0)	1.00
Air embolism, n (incidence %)	3 (25.0)	4 (28.6)	0.84
Cumulative behavioral score	40 (35.0–44.75)	48 (44.5–49.0)	0.001
Emergency intervention time (min)			
Pump failure time (min)	14.40	7	NA
Oxygenator change time (min)	5.30 (4.80–6.02)	3.90 (3.50–4.15)	0.02
Air embolism time (min)	22 (20.00–23.50)	15 (13.75–16.50)	0.048

ECMO, extracorporeal membrane oxygenation; VA, veno-arterial; NA, not applicable; ARDS, acute respiratory distress syndrome.

use (8,9). In the 5th edition of the *ELSO Red Book*, these guidelines have been re-visited introducing the role of high-fidelity simulations to train specialists for skills acquisition in routine and emergency situations (10).

Simulation has become a very common method of training medical and nursing personnel to learn specific technical skills and behavioural skills. Previous studies (6,11-16) have demonstrated the efficacy of high-fidelity simulation to improve teamwork in stressful situations (urgent cannulation, extracorporeal cardiopulmonary resuscitation (ECPR), troubleshooting regarding equipment malfunctions and other bedside emergencies). However, despite the accepted role of this method in other medical fields, there has been a limited evaluation of the impact of ECMO high-fidelity simulations at bedside (1,2,17-19).

The main objective of our study was to evaluate, using a retrospective approach, if the introduction of a high-fidelity simulation program improves the performance of novice personnel. This hypothesis was tested by comparing the duration of the emergency interventions and the measurement of the behavioural skills score between the two-study periods. When comparing pre-simulation *vs.* post-simulation period, we found a reduction in the times used to manage clinical crises including the oxygenator change due to rapid failure or the circuit change because of air embolism. The same positive impact of high-fidelity

simulation was found when we evaluated the cumulative behavioural skills score between the two study periods.

Our ECMO program started in 2010 (pre-simulation period) and to train our personnel we used the traditional ECMO training proposed by the ELSO guidelines for training and continuing education (8,9), therefore our ECMO course (34 hours) was performed with lectures and water drills, and 32 hours of mentorship at bedside, while re-trainings were performed every 3 months with water drills and seminars. All team members evaluated in the pre-simulation period were novice learners without previous experience of respiratory ECMO. Only the cardiac surgeons and the perfusionists had a previous knowledge of cardiac ECMO.

At the end of 2013 there was a critical change in our working team due to the retirement of some PICU staff, therefore new physicians, nurses and perfusionists were enrolled in the "new" ECMO team. Contemporary to this personnel renewal, we also introduced high-fidelity simulations as a teaching tool in our ECMO program. The evaluation in the post-simulation period of "only" novice personnel allowed us to "reduce" the biases due to the natural improvement of technical and behavioural skills over time with bedside practice. However, in any educational intervention, it is almost impossible to state that other learning opportunities (learning from experienced colleagues, reading, self-practising, etc.) do not contribute to improve the skills of the students.

Other investigators have also reported the improvements of technical and behavioural skills with the utilization of high-fidelity ECMO simulation training. Anderson *et al.* (12) found that ECMO practitioners reduced errors in emergency scenarios after a simulation-based training, but not the times to critical actions, whereas Burkhart *et al.* (14) reported that simulation-based training improved the emergency circuit management among thoracic-surgery residents working with a post-cardiotomy ECMO model. Zakhary *et al.* (2) reported the improvement of times to critical action with simulation-based training. These results differed from the ones reported by Anderson *et al.* (12) because in the randomized controlled trial of Zakhary *et al.* (2) novice learners were included suggesting that the benefits of high-fidelity simulation may be reduced when evaluating an experienced group. Allan *et al.* (13) also reported the improvement of surgical skills evaluated as time elapsed to cannulation in 10 cardiothoracic surgery residents and fellows with the use of high-fidelity simulations.

There is paucity of data on the positive effect of high-fidelity simulation to bedside ECMO management. Burton *et al.* (17) described for the first time the clinical results of simulation-based training for ECMO clinical specialists. Brazzi *et al.* (18) reported a more important impact of high-fidelity simulation on the delivery care. They used didactic lectures and simulations to rapidly train 193 ECMO physicians in 14 centers in response to the 2009 H1N1 pandemic. After their training program, no survival difference was detected between the centers with previous ECMO experience and those without (71% *vs.* 64%, P=0.35). Su *et al.* (19) reported the "clinical" efficacy of a high-fidelity simulation program to train personnel to manage ECPR situations. She showed a significant reduction of ECPR deployment times (51 *vs.* 40 minutes, P=0.018) when comparing pre and post intervention periods.

Our study, performed with the same retrospective approach of Su *et al.* (19), showed, using a simulation-based training, a significant reduction of the times used to manage ECMO emergency crises and a significant improvement of behavioral skills score when comparing pre-simulation period *vs.* post-simulation period. Our study confirmed the positive impact of high-fidelity simulations on personnel performance regarding the management of ECMO at bedside; furthermore, for the best of our knowledge, this study was the first to evaluate the behavioral skills of the ECMO team in real clinical scenarios as opposed to a simulation environment.

Our study has also several limitations. The most important are: the retrospective nature and the small sample size evaluated. In our study the small sample size was due: firstly, to the reduction of the ECMO runs in the last years because of the improvement of the medical management of the neonatal and pediatric respiratory failure (3); secondly, to the fact that many ECMO runs that occurred in the post-simulation period were not included in the study because were not managed by novice learners. However, this aspect according to our opinion highlights the positive performances acquired by novice learners during the second study period using high-fidelity simulation. Even is this small sample size did not allowed to evaluate any improvement in patient outcomes between the two study periods, this was not an objective of the study.

We also acknowledge that high volume ECMO centers reported lower mortality both in adult and children when compared with low volume ECMO centers (20-22), however this aspect is no more actual when dealing

with neonates and children because the ECMO runs are reducing (3). Thus, we strongly believe that a standardized ECMO education with high-fidelity simulation is mandatory in low volume ECMO centers to homogeneously train all personnel.

In conclusion, our study demonstrated the incremental improvement in behavioural skills and measured outcomes among novice learners with the introduction of a high-fidelity simulation program. We believe that further prospective and randomized studies should be performed to determine whether simulation training improves clinical outcomes and translates to reduced complication rates in patients supported with ECMO.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by the local Institutional Scientific Board of Bambino Gesù Children's Hospital (within the Annual Research Program "Ricerca Corrente 2017", ref number 201702Q003968).

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