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RESEARCH ARTICLE

EFFICACY OF REHABILITATION PROTOCOL FOR PATIENTS IN THE INTENSIVE CARE UNIT RECEIVING EXTRACORPOREAL MEMBRAN OXYGENATION

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ABSTRACT

Background: Extracorporeal membrane oxygenation (ECMO) is a therapeutic intervention utilized for patients suffering from cardio-respiratory failure. ECMO, the highest level of life support, allows for different perfusion strategies to temporarily support patients as they recover or to facilitate as a bridge to transplantation (heart or lung).**(1)**Patients receiving ECMO are at high risk for significant physical impairment and pose unique challenges for physical therapy. Consequently, there is a need for innovative examples of successful physical therapy in these patients as preliminary data regarding feasibility and safety. O**bjective:** to investigate the effect of rehabilitation protocol for patients in the intensive care unit receiving extracorporeal membrane oxygenation. **Patients and Methods:** 20 patients of both sexes receiving ECMO. Assessing data divide into acute assessing data (before and after session) and before sessions and after 2 week of daily physiotherapy session. Rehabilitation protocol started once the patient became vital stable after cannulation on ECMO. NMES for 30 minutes, limbs exercises and chest physiotherapy continued for 2 weeks after cannulation one session daily. Chest x-ray (CXR) used to asses alveolar consolidation, arterial blood gases(ABG) used to asses oxygenation and medical research council (MRC) used to asses muscle power. All patients were assessed pre and post the study and also pre and post session. **Results:** There was a significant improvement in MRC and CXR with improvement percentage 16.89% and 39.67% respectively at endpoint compared to baseline within study group and non-significant improvement in SaO2 and PaO2 with percent 2.04% and 10.03% respectively. Regarding the acute assessing data there was a significant improvement in CXR, SaO2 and PaO2 with improvement percentage 18.53%,2.82%,9.75% respectively and non-significant improvement in MRC with percent 0.35%. **Conclusion:** rehabilitation protocol can improve muscle power, prevent muscle atrophy and improve chest condition.

INTRODUCTION

Extracorporeal membrane oxygenation (ECMO) is an advanced form of temporary life support, to aid respiratory and/or cardiac function. It has been used since the early 1970s and is based on cardiopulmonary bypass technology and diverts venous blood through an extracorporeal circuit and returns it to the body after gas exchange through a semi-permeable membrane. ECMO can be used for oxygenation, carbon dioxide removal and haemodynamic support. Additional components allow thermoregulation and haemofiltration. The two most common forms of ECMO are veno-venous (VV) and veno-arterial (VA). In VV-ECMO, used to support gas exchange, oxygenated blood is returned to a central vein. In VA-ECMO, used in cases of cardiac or cardiorespiratory failure, oxygenated blood is returned to the systemic arterial circulation, bypassing both the heart and lungs (2) Patients receiving ECMO are at high risk for significant physical impairment and pose unique challenges for physical therapy. Consequently, there is a need for innovative examples of successful physical therapy in these patients as preliminary data regarding feasibility and safety. While patients have severely restricted lung compliance and poor lung volumes the focus is on secretion clearance. Treatment techniques may involve manual techniques, suctioning, positioning and physiotherapy assisted bronchoscopies. As lung compliance improves, methods to increase and optimize lung volumes will commence. Physiotherapy plays a vital role to promote lung function and manage secretions. There are more ventilator-free days for patients who receive early physiotherapy compared to standard care (3).

Patients referred for respiratory ECMO have often been seen by the physiotherapy teams at their local hospital as they present with a rapid deteriorating respiratory symptom requiring physiotherapy management, continuous positive airway pressure or non-invasive ventilation support before intubation (4). Physiotherapy in ICU involves mobilisation activities, functional positioning, passive- and active-assisted movements of extremities, sitting, bedside standing, walking with support, early mobilisation, postural drainage, clear airway secretions, percussion and vibration, as well as assisted and resisted exercise. The rationale for mobilisation in ICU includes prevention of bed rest-related problems, optimisation for early recovery, improving functional ability as quickly as possible and improving mood and psychology with engagement in goal setting and attainment (5). The respiratory physiotherapy interventions that are recommended for critically ill patients hospitalised in the ICU are presented in Table 1. For clinical practice, we divided the recommended physiotherapy interventions into two groups; interventions for patients who are able (active interventions) and interventions for those who are not able (passive interventions) to follow instructions, determined primarily by the level of consciousness. The main goal of RP is minimising the adverse effects of critical illness and intubation on the respiratory system restoring respiratory and physical independence, preventing the need for subsequent dependence on mechanical ventilation and subsequent hospitalisations and improving patient's quality of life (6)

Table 1. Respiratory physiotherapy interventions

Active interventions	Passive interventions
• Hyperinflation (Deep breathing exercises, Incentive spirometry) • Drainage of endobronchial secretions • Hydration and airway humidification • Suctioning • Mechanical insufflation-exufflation • Manual techniques (postural drainage, percussion, vibrations) • High frequency oscillations (IPV, HFCWO) • Positive expiratory pressure (PEP) • NIV • Positioning • Mobilization • Respiratory muscle training (RMT)	• Hyperinflation (manual or with ventilator) • Recruitment manoeuvers • Drainage of endobronchial secretions • Hydration and airway humidification • Suctioning • Mechanical insufflation-exufflation • High frequency oscillations (IPV, HFCWO) • Positioning • Mobilization • Passive exercise • Electro muscular stimulation (EMS)

Patients: This study was carried out between 1/10/2019 and 1/2/2021 on twenty patients of both sex (8males and 12 females) with pulmonary disease (ARDS, Respiratory failure and COPD) receiving extracorporeal membrane oxygenation in intensive care unit. The study is a prospective observational study on patients who were admitted to Critical Care Department, Cairo University hospitals. This study is conducted prospectively to assess the efficiency of rehabilitation protocol for patients in critical care unit receiving ECMO. We used CXR to asses alveolar consolidation, ABG for oxygenation and MRC for muscle power assessment.

Measurements

Chest X-ray: Chest x-ray it was used to measure the development of the patient's chest condition by determine number of quadrants affected according to Murray lung injury score.

Arterial Blood Gases analysis

- Arterial oxygen tension {PaO2}
- Arterial carbon dioxide tension {PaCO2}
- Arterial saturation {SaO2}

Manual muscle test (MMT)

The Medical Research Council (MRC) is commonly used as a measurement tool to assess muscle strength within the ICU. Grading follows the Medical Research Council (MRC) system in this evaluation is considered the strength of 3 muscle groups for each limb (shoulder abductors elbow flexors, wrist dorsiflexors, hip flexors, knee extensors and ankle dorsiflexors) with a score from 0 to 5 assigned to each one. Both the upper and lower limb muscles were assessed and reevaluated before and after the intervention.

Summation of scores gives MRC-sum score, ranging from 0 to 60.Maximum score 60: (4 limbs, maximum of 15point per limb) (Normal). From 0 (min) to 36: quadriplegia to sever quadriparesis

From 36 to 48: mild quadriparesis. From48 to 60 (max): normal strength (7). Assessment of patients by (ABG, CXR and MRC) has been taken before and after session as an acute reading, also before and at end of the study.

Treatment Procedures: One session was implemented per day for the study group for 2weeks. Rehabilitation protocol was completely dependent on patient conscious level.The 1st stage was patient sedative so we started the protocol by all passive procedures as percussion, vibration and MHI for air way clearance applied by putting the patient in posture drainage then suction at end of session. For maintaining joint range of motion, we applied passive limb exercises and positioning. NMES applied on quadriceps and dorsiflexors for 30 minutes daily to preserve muscle tone and prevent disuse atrophy. Once the patient became conscious and oriented, we started active, active assisted and active resisted exercises to improve muscle power and prepare the patient for mobilization. RMT and incentive spirometer used to improve respiratory muscle power applied for awake ECMO patients from sitting position and asking the patient to take deep breath as much as possible for 3 to 5 times.

Statistical analysis: Data were screened, for normality assumption test and homogeneity of variance. Normality test of data using Shapiro-Wilk test was used, that reflect the data was normally distributed ($P>0.05$) after removal outliers that detected by box and whiskers plots. Additionally, Levene's test for testing the homogeneity of variance revealed that there was no significant difference ($P>0.05$). So, the data are normally distributed and parametric analysis is done. The statistical analysis was conducted by using statistical SPSS Package program version 25 for Windows (SPSS, Inc., Chicago, IL). Numerical data are expressed as mean and standard deviation for age, MRC, arterial blood gases, and CXR variables. Categorical data (gender) are expressed as number (percentage). Paired t-test used to compare between baseline vs. endpoint and before session vs. after session within study group for MRC, arterial blood gases, and CXR variables. All statistical analyses were significant at level of probability less than an equal 0.05 ($P \leq 0.05$).

RESULTS

A total of 20 patients participated in this study. The mean value of age was 38.67 ±15.03year for patients participated in the study group. The gender distribution revealed the number (percentage) of males and females' patients were 8 (40%) and 12 (60%), respectively, in study group (Table 1).

Table 1. Demographic data for the study group

Items	Age (year)	Gender	
		Males	Females
Study group (n=21)	38.67 ±15.03	8 (40%)	12 (60%)

Numerical data are expressed as mean ±standard deviation

Categorical data are expressed as number (percentage). The statistical analysis between baseline and endpoint within study group (Table 2 and Figure 1) revealed there were significantly increased in MRC (P=0.021; P<0.05) and decreased in CXR (P=0.0001; P<0.05) at endpoint compared to baseline within study group with improvement percentage 16.89 and 39.67%, respectively. However, no significant difference in PCO_2 (P=0.683; P>0.05), PaO_2 (P=0.072; P>0.05), and SaO_2 (P=0.162; P>0.05) between baseline and endpoint within study group with improvement percentage 1.97, 10.03, and 2.04%, respectively.

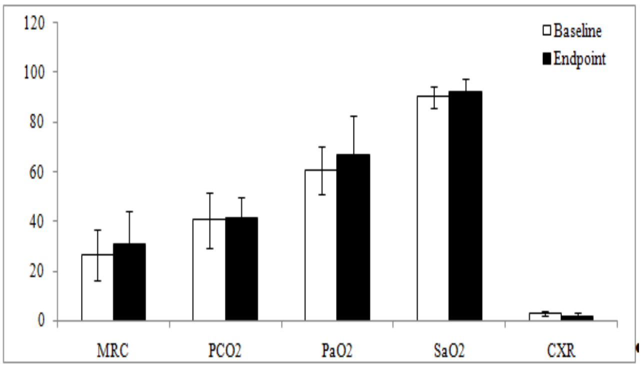

Figure 1. Mean values of measured outcomes variables between baseline and endpoint

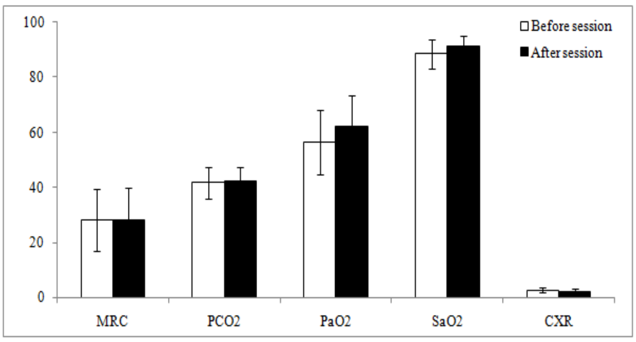

Figure 2. Mean values of measured outcomes variables between before and after sessio

The statistical analysis between before and after session within study group (Table 3 and Figure 2) revealed there were significantly increased in PaO_2 (P=0.017; P<0.05) and SaO_2 (P=0.006; P<0.05) and decreased in CXR (P=0.001; P<0.05) at after session compared to before session within study group with improvement percentage 9.75, 2.82, and 18.53%, respectively. However, no significant difference in MRC(P=0.329; P>0.05) and PCO_2 (P=0.678; P>0.05) between before and after session within study group with improvement percentage 0.35 and 0.91%, respectively.

DISCUSSION

This study designed to evaluate the efficacy of rehabilitation protocol for patients in the intensive care unit receiving ECMO. Rehabilitation protocol include both chest physical therapy for (air way clearance and respiratory muscle training) and also limbs exercises and mobilisation. Twenty patients (12 women and 8 men) were enrolled in this study with their age ranged from 20 to 50 years old. All patients received their medical treatment, physical therapy one session every day for 2 weeks and assessed for safety criteria before, during and after session. Physical therapy for ECMO patients started after cannulation even if we did passive or active procedures without any delay to avoid farther muscle weakness or chest consolidation due to accumulation of secretions. Sometimes we postponed starting our protocol in time after cannulation according to safety criteria. Patient safety is a critical issue in implementing physical therapy interventions for patients requiring ECMO. Starting physical therapy after cannulation depended on patient's vital stability as not all the patients started from day one of cannulation. Once the patient became vital stable, low level of vasopressor and physicians had no restrictions about starting our protocol we got start and took our base line data and draw our plan. The measured variables were SaO2, PaO2 and PCo2 by ABG, chest x-ray by Murray lung injury score and muscle strength by MRC.

In this study we took:

- Comparative data between base line data and end of the study
- Acute assessing data before and after session.

Comparative data between base line data and end of the study

Before starting the protocol, we collected a base line data of ABG, chest x-ray and MRC, then applying all the physical therapy procedures for 2 weeks one session per day and took end of the study data. In the present study, the results of the end of the study showed significant improvement as following: - significant improvement in MRC and chest x-ray about 16.89%, 39.67% respectively, and showed non-significant in PCO2, SaO2, and PaO2 at the end of the study. After 2 weeks of continuous physical therapy for chest and muscle training started from 2nd day of cannulation in most cases and others delayed in starting until became vital stable to start. MRC improvement reflected improved muscle power due to early intervention of NMES during sedation and disturbed conscious level which helped in maintaining muscle tone, applied on quadriceps and on dorsiflexors for 30 minutes to avoid muscle atrophy. NMES also used with sever muscle weakness due to long period of corticosteroids which mainly affecting muscle power as a one of muscle facilitation methods. Passive limbs exercise done in phase one helped us to preserve ROM and prevent joint stiffness, stretching for the dorsiflexors and positioning of bilateral lower limbs to prevent muscle shortening complications. Gradually progression in exercises from active assisted exercises for peripheral muscles to active

Table 2. Comparison between baseline and endpoint for all measured outcomes variables within study group

Variables	Baseline (n=21)	Endpoint (n=21)	Change	Improvement %	*P*-value
MRC	26.52 ±10.12	31.00 ±13.27	4.48	16.89%	0.021*
PCO_2	40.59 ±11.19	41.39 ±8.20	0.80	1.97%	0.683
PaO_2	60.79 ±9.51	66.89 ±15.76	6.10	10.03%	0.072
SaO_2	90.17 ±4.42	92.01 ±5.57	1.84	2.04%	0.162
CXR	3.00 ±0.89	1.81 ±1.16	1.19	39.67%	0.0001*

Data are expressed as mean ±standard deviation; MRC: Medical research council; CXR: chest radiograph score; P-value: probability value; *Significant (P<0.05)

Table 3. Comparison between before and after session for all measured outcomes variables within study group

Variables	Before session (n=21)	After session (n=21)	Change	Improvement %	*P*-value
MRC	28.19 ±11.36	28.29 ±11.43	0.10	0.35%	0.329
PCO_2	41.71 ±5.60	42.09 ±5.48	0.38	0.91%	0.678
PaO_2	56.51 ±11.51	62.02 ±11.35	5.51	9.75%	0.017*
SaO_2	88.61 ±5.31	91.11 ±4.09	2.50	2.82%	0.006*
CXR	2.86 ±0.85	2.33 ±1.01	0.53	18.53%	0.001*

Data are expressed as mean ±standard deviation; MRC: Medical research council; CXR: chest radiograph score; P-value: probability value; *Significant (P<0.05)

then active resisted exercises. Strengthening exercises applied for a long period to allow muscle building, increase size of muscle or even maintain the muscle power. Starting early as much as possible after cannulation gave a good result as we started before muscle atrophy or shortening occurred. Trunk control exercises and balance training started once the patient became full conscious and oriented, that helped us for mobilizing the patient and transferring from bed to wheel chair. Patient mobility is a result of improvement in muscle power to the level allowed the patient to participate in movement. The results of this study agreed with (8) who stated that NMES is able to elicit muscle contractions in unconscious or sedated and therefore uncooperative patients. As it is possible to initiate this form of treatment in the early phase of critical illness, even if the patient has to remain heavily sedated, it was reasoned to be a promising therapeutic option to target muscular pathophysiological processes in their beginning stages. Also, the results of this study coincided with the results achieved by (9) who showed that more recently the effects of NMES were studied with muscle ultrasounds in 26 critically ill patients; Gerovasilli et colleagues confirmed that this intervention is well tolerated and found out that it may help in preserving the muscle mass. The results of this study supported by a previous study which reported that Physiotherapy in ICU involves mobilisation activities, functional positioning, passive- and active-assisted movements of extremities, sitting, bedside standing, walking with support, early mobilisation, postural drainage, clear airway secretions, percussion and vibration, as well as assisted and resisted exercise. The rationale for mobilisation in ICU includes prevention of bed rest-related problems, optimisation for early recovery, improving functional ability as quickly as possible and improving mood and psychology with engagement in goal setting and attainment (5). (10)found that Muscle-building exercise plans with early mobilization help in rapid recovery by the prevention of critical illness polyneuropathy. Muscle wasting, which occurs early and rapidly during the first week of illness, can also be prevented and reversed. Awake patients, when engaged in physiotherapy, have an improved psyche due to involvement in goal setting and attainment. Physiotherapy planning depends on sedation levels, oxygen requirements, muscle power, patient cooperation, cannula sites, and team availability.

In our study not all patients were awake from the beginning of the protocol so we started with all passive procedures to prevent any regression due to immobility, complications of MV and secretions accumulation. Long period of sedation and disturbed conscious level were affecting reversely on outcomes of physical therapy. The significant improvement in chest x-ray in this study was due to reduction of secretion accumulation, air way clearance and reduction of mechanical ventilation duration. The continuous chest physiotherapy in form of posture drainage, percussion, vibration and manual hyperinflation helped us for draining secretion (10) performed the study for all patients were maintained in an almost upright position in bed (Fowler's position as tolerated). Upright posture, periodic lateral position, mobilization, and sitting out of bed, after early tracheostomy, were our mobilization algorithm. An optimal patient position improves lung compliance, decreases V/Q mismatch, and encourages loosening of the secretions. Prone ventilation on ECMO requires deeper sedation and even NMBAs, which would delay awakening the patient; hence, they did not use the prone position for ECMO patients routinely.

The non-significant result in Pco2, Sao2 and Pao2 after 2 weeks was due to changes in ECMO settings along the period of our protocol like reduction of oxygen flow as a plan of weaning or decrease sweep gas and also, complications occurred for some patients such as surgical emphysema, pneumothorax and sepsis. Some patients complicated with pulmonary embolism so stopped at least for 3 days then continue and others complicated with DVT which lead to exclude the affected limb. All these complications affected on the results specially the thrombosis in the ECMO oxygenator. Some patients initiated on VV ECMO may need prolonged care to allow the native lung to recover. They may become impossible to wean due to irreversible organ damage and may need bridging to lung transplant.

Acute assessing data before and after session: On the other side the results of acute assessing data before and after session showed significant improvement as following: - significant improvement in Pao2, Sao2, and CXR about9.75%, 2.82%, 18.53% respectively, and showed non-significant in MRC and PCO2.

In this study improvement in the chest condition observed clearly after session due to fixed parameter of ECMO which not changed during session and also level of sedation. Patients were assessed before starting our session to determine our target for this session and which type of exercise suitable for him, also the comparative data of ABG, chest x-ray and MRC were collected. Chest percussion, posture drainage, MHI, EEP and suction for the intubated patients helped in air way clearance which improved the chest condition, cough stimulation and RMT for extubated patients improved respiratory muscle power which is important for cough and improve lung capacity. CXR improved after session due to reduction of secretion accumulation by percussion, vibration, MHI and suction which improved air way clearance so decrease amount of alveolar consolidation. Sao2 and Pao2 improved with fixed ECMO parameter which meant improvement was due to RMT, breathing exercises and improvement in air way clearance. Another study referred that each ECMO patient has differing needs; therefore, there cannot be a set protocol. A detailed plan has to be made daily, depending on the patient factors such as sedation level, investigations, inotropes, ventilator, and ECMO flow requirements **(10).** The results of this study coincided with results of the study done by **(11)** which emphasized the importance of respiratory therapy when proposed to treat or prevent pulmonary complications in ECMO patients; in-bed positioning and postural exercises are vital components of such treatments, promoting lung ventilation and removal of secretions. In addition to the results of this study were supported by results which found that chest physiotherapy plays an important role in order to facilitate secretion clearance and lung function for a patient while on ECMO **(12)** Respiratory physiotherapy helps to decrease VAP, improve static lung compliance, enhance sputum clearance, and reduce atelectasis.

Patients on ECMO should be planned for physiotherapy daily with frequent re-evaluation and goal setting. There is strong evidence that this results in a speedy recovery, decreases the length of hospital stay, and improves the level of independence of the patient at hospital discharge **(10).** Also **(13)**conducted the study on A 32-year old previously fit and healthy male with Influenza A (H1N1) required ECMO for severe refractory respiratory failure. During ECMO, the patient was ventilated with a pressure controlled UPVS consisting of positive end expiratory pressure 15 cmH2O and set inspiratory pressure of 20 cmH2O, which generated TVs less than 50 ml (<1 ml kg1). chest physiotherapy during ECMO can be challenging because of the location of the cannulae (via jugular and femoral veins in this case) and anti-coagulation to maintain the patency of the circuit (which necessitates caution with suction and manual techniques). Deep sedation/paralysis impairs cough reflexes but excessive coughing can alter intra-thoracic pressure, resulting in reduced blood flow through the ECMO circuit, particularly in the intravascularly deplete patient. Finally, the UPVS employed during ECMO must be considered when utilizing increased positive pressure through VHI to aid secretion clearance. The effects of increasing inspiratory pressure during CPT whilst on ECMO support need further investigation. The non-significant result in the study of MRC in acute assessing data reflected no change in muscle strength from before and after session because of there is noimmediate effect of NMES or strengthening exercises. Improvement in muscle power need time to allow increase in muscle mass and improve muscle firing.

The results of this study supported by the study done by (14) who emphasized that beneficial results have been found over multiple NMES training sessions due to muscular adaptations to the stimulus. Repeated exposure to NMES will produce a training effect that decreases patient discomfort, muscular fatigue, and development of creatine kinase and other indirect measures of muscle damage. (15)performed a systematic review about safety and potential benefits of physical therapy in adult patients on extracorporeal membrane oxygenation support .The results of the studies listed in this systematic review demonstrate that multimodal PT approaches routinely used in the rehabilitation of adult patients on ECMO support are considered safe because of the absence of severe events and the small number of mild adverse events. Some studies have shown that these interventions might reduce the length of ICU stays and decrease threat of fatal outcomes, although the probability of reducing mortality has not been confirmed. Furthermore, preventing the deleterious effects of prolonged bed rest has many benefits, including the maintenance and/or gain of muscle strength, together with improved functional capacity relative to individuals who did not undergo PT and decreases in the incidence of myopathy and length of MV after LT. However, the number of these outcomes was not sufficiently large to provide an adequate level of evidence.

Ethical Consideration: The patients approached to ask if they are willing to engage in the research. The therapist explained all relevant information about (risks/benefits, voluntary participation, procedures). Patients and their relatives were given adequate time to reflect on the information, to ask any questions and to give free and voluntary consent. The patients' rights and confidentiality were conserved strictly. The study will be approved by the ethical committee of the Faculty of Physical therapy, Cairo University.

Informed Consent: Informed consent has been obtained from all individuals included in this study.

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Conflict of interest: The authors state no conflict of interest.

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