

Effect of a Nursing Protocol on Clinical Outcomes of Patients' with Respiratory Failure Post-weaning from Mechanical Ventilation

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Abstract: The nurse plays an important role in caring for patients with respiratory failure Disease post-weaning from Mechanical Ventilation to improve of the respiratory function for better health status. **Aim:** The aim of this study was to evaluate the effect of a nursing protocol on clinical outcomes of patients with respiratory failure disease post-weaning from mechanical ventilation. **Subjects and Methods:** Design: A quasi experimental design was used. Setting: This study was conducted at Chest Intensive Care Unit affiliated to Ain Shams University Hospital. Sample: A purposive sample included 60 adult patients, diagnosed with respiratory failure disease, immediately post-weaning from mechanical ventilation. Tools of data collection: Patient's structured interview questionnaire, Clinical outcome assessment tool, the respiratory exercises observational checklist, Range of motion exercises observational checklist, Modified Borg Fatigue Scale, Dyspnea scale, and Hamilton anxiety scale. **Results:** The patients' clinical outcomes among the study and control group were improved from the second day to the fourth day. Also, there was a statistically significant difference regarding total patients' knowledge and practice pre- and post nursing intervention protocol between study and control group. **Conclusions:** Nursing protocol affected positively on the clinical outcomes of patients with respiratory failure disease post-weaning from mechanical ventilation. **Recommendations:** It was recommended to replicate of the current study on a larger probability sample to achieve generalization of the results and wider utilization of the nursing protocol.

Keywords: respiratory failure disease, Nursing protocol, Clinical outcomes, Mechanical ventilation.

1. INTRODUCTION

Acute respiratory failure is a clinical condition in which the pulmonary system fails to maintain adequate gas exchange. It is the most common type of organ failure seen in critical care unit, with approximately 56% of the patients in the critical care unit experiencing. The mortality rate for patients with acute respiratory failure 30% to 40%, with more than one third of patients not surviving to discharge (Hirsch, 2013).

Acute respiratory failure is a significant cause of morbidity and mortality. **In the United States**, the annual incidence of acute respiratory failure has been reported to be as high as 137 hospitalizations per 100,000 residents. Additionally, acute respiratory failure is very common in the intensive care unit (ICU) with as many as 56% of all ICU patients having this diagnosis at some point during their hospital course. Mortality rates also remain high with as many as 30-35 % of patients succumbing in hospital (Kirton, Frankel & Rabinovici, 2016).

In Egypt the incidence of acute respiratory failure in intensive care unit (ICU), a study of more than 1,400 patients found that 44% of patients diagnosed with acute respiratory failure who required admission to the intensive care unit (ICU) died in the hospital. However, a recent analysis of past studies on the mortality of patients with acute respiratory failure

showed that there have been improvements. Acute respiratory failure may be a cause for as many as 10% to 15% of admissions to medical ICUs (**Morton & Fontaine, 2013**).

Acute respiratory failure from a deficiency in the performance of the pulmonary system. It is impairment of the function of the respiratory system to maintain normal O₂ and CO₂ values when breathing room air. It occurs secondary to another disorder that has altered the normal function of the pulmonary system in such a way as to decrease the ventilator drive, decrease muscle strength, decrease chest wall elasticity, decrease the lungs capacity for gas exchange, increase airway resistance, or increase metabolic oxygen requirements (**Lough, Stacy, & Urden, 2017**).

Two significant symptoms of respiratory failure frequently complained by the patients are dyspnea and fatigue. Any patient who feels tired for more than 1 month is considered as affected by chronic fatigue. Chronic fatigue is important and common sensation in patients with respiratory failure that interferes with the quality of life but almost neglected. As the disease advances, hard breathing followed by dyspnea and increasing limitation of the patient's ability to perform daily activities are worsened, and even for doing simple work during the day, the patient gets out of breath and is affected with early fatigue (**Smeltzer, Bare, Hinkle & Cheever, 2014**).

Mechanical ventilation is a significant clinical and economic problems and detrimental to the individual as it is associated with increased risk of respiratory muscle weakness, critical illness myopathy, nosocomial infection and airway trauma. Prolonged mechanical ventilation is also associated with an increase in mortality, morbidity and intensive care unit (ICU) length of stay, as well as reduced functional status and quality of life. In addition prolonged mechanical ventilation is expensive, consuming a large fraction of hospital resources, with a healthcare burden that may continue after hospital discharge (**Lewis, 2014**).

In intensive care, weaning is the term used for the process of withdrawal of mechanical ventilation to enable spontaneous breathing to be re-established. Inspiratory muscle weakness and reconditioning are common in patients receiving mechanical ventilation, especially that of prolonged duration and respiratory failure patients. Inspiratory muscle training could limit or reverse these unhelpful sequelae, facilitate more rapid and successful weaning (**Linton, 2015**).

There is no cure for respiratory failure disease, thus treatment focuses on managing the disease and control the symptoms. Pulmonary Rehabilitation programs are standard treatment that leads to alleviate symptom and increase performance. Pulmonary rehabilitation uses a multidimensional method combining education and exercise in order to influence the levels of activity, symptoms and complaints which could lead to an improvement in gas exchange, exercise tolerance and quality of life (**Bucher, Heitkemper, Dirksen, & Lewis, 2013 & Roberts, Kwong, Harding, Heitkemper & Bucher, 2016**). The goal of respiratory exercises in patients with respiratory failure is for the patients to replace their ineffective respiratory techniques with effective ones and to discharge the lungs from secretions through deep respiratory exercises and effective coughing. Inspiratory muscle training (IMT) may improve inspiratory muscle strength and probably will diminish the sensation of respiratory effort (**Lewis et al., 2014**).

Nurses, who take care of the individuals suffering from chronic diseases, must be considered to improving their quality of life by applying pulmonary rehabilitation protocol. So, the nurse plays the important role with respiratory failure disease patient through improve health status, physical functioning, psychosocial wellbeing, life satisfaction and happiness. Patients with respiratory failure disease and other chronic lung diseases are less active than those with other long-term conditions through the pulmonary rehabilitation protocol (**Linton, 2015**).

Nursing intervention in pulmonary rehabilitation may include postures, limb exercise and percussion/vibration and breathing exercise techniques. Early mobilization and nursing education may be effective on health status for patients with respiratory failure disease in ICU. This protocol of a nursing intervention is to enhance the overall patient's functional capacity and to restore his/her respiratory and physical independence, thus decreasing the risks of bed-rest associated complications. Also, when started early helps prevent weaning delay, limited mobility, total dependence on the ventilator, hospital stay and re-again acute exacerbation (**Gonce, & Fontaine, 2013; Goldsworthy, 2016**).

Nursing protocol for respiratory rehabilitation also includes breathing through a mouthpiece against resistance during pulmonary rehab, arm and chest exercises, simple walking, and assess spirometer test results, arterial blood gases, and progressive respiratory failure disease symptoms such as shortness of breath or dyspnea sensation, coughing and fatigue.

This protocol improves their exercise tolerance, quality of life and ability to self-manage their condition (**Wilson, Scully, Jack & Rebeiro, 2014; Lough, Stacy & Urden, 2017**).

Significance of study:

Acute respiratory failure is a major cause of death and disability world wide, the incidence was 88.6 per 100,000/year. Respiratory failure is dangerous condition because it may lead to sudden death. Mechanical ventilation, intended for use as a temporary, life saving which, is indicated for patients with acute respiratory failure who are unable to maintain normal gas exchange, and was implemented using a variety of modes and techniques. Proper nursing management is very important to promote patients' condition and safe patients' life, the nurses' insufficient knowledge, practice and positive attitude are to be the most significant factors affecting morbidity and mortality of these patients. The epidemiology of these events is therefore important for both the understanding of the disease process and in assessing therapeutic outcomes. In Egypt, the number of patients admitted with respiratory failure combined with acute exacerbation to ICU chest at Ain Shams University hospitals in year 2016 was approximately 200 patients according to Ain Shams University hospital medical records. Realistic aims for respiratory failure management include slowing or halting disease progression, relieving symptoms to reduce disability, and decreasing the frequency and severity of exacerbations; therefore the aim of this study is to evaluate the effect of nursing protocol on improving respiratory failure patients' knowledge, practice and clinical outcomes.

Aim:

The aim of this study was to evaluate the effect of a nursing protocol on clinical outcomes of patients with respiratory failure post-weaning from mechanical ventilation. The aim of this study was achieved through the following:

1. Assessment patients' knowledge and practices pre intervention.
2. Plan and implement of a nursing protocol.
3. Evaluate the effect of nursing protocol intervention on patients' knowledge and practice post- intervention.
4. Evaluate the effect of a nursing protocol on patients' clinical outcomes post intervention.

Hypothesis of the study

It was hypothesized that:

1. The study group will have an improvement regarding patients' knowledge and practice post weaning from mechanical ventilator compared to the control group.
2. The study group will have an improvement regarding patients' respiratory function post weaning from mechanical ventilator compared to the control group.
3. The study group will have a lower intensity of dyspnea, fatigue and anxiety post weaning from mechanical ventilator compared to the control group.
4. There will be a statistically significant difference between patients' outcomes at the beginning and at the end of a protocol of nursing intervention among the study group compared to the control group.

A nursing protocol:

It included specific nursing actions in a given situation to ensure consistency and quality of care. A protocol describes nursing intervention for respiratory failure patient post weaning from mechanical ventilation for improving patient's respiratory function and minimizing dyspnea, fatigue and anxiety. A protocol describes nursing intervention which included enhancing patients' knowledge and practice regarding: I- breathing exercises including diaphragmatic, pursed-lip, deep breathing and coughing exercise, II- use of spirometer, III- relaxation technique as pursed and diaphragm breathing exercise and guided imagery, IV- assisted mobilization and upper and lower limb exercise, V- secretion clearance techniques including coughing exercise and chest percussion as indicated.

Outcomes measures

Comparisons were done between both groups (study & control) regarding outcomes measures either primary or secondary. Primary outcomes included the improvement of patient's knowledge and practice. Secondary outcomes included the improvement of patients' respiratory function as respiration rate, arterial blood gas analysis results and intensity of patients' dyspnea, fatigue and anxiety.

2. SUBJECTS AND METHODS

Subjects and methods for this study were portrayed under the four main designs as the following:

- 1- Technical design.
- 2- Operational design.
- 3- Administrative design.
- 4- Statistical design.

I- Technical design:

The technical design included research design, setting, subjects and tools of data collection used in this study.

- Research design

A quasi experimental study design was utilized to accomplish this study.

- Setting:

This study was conducted in Chest Intensive Care Unit at Ain Shams University Hospital. It consisted of 3 section each section have 5 bed for patient each bed connected with monitor and mechanical ventilator and there were 5 room for lab and one for sterilization and one for chest X ray one for doctor and other for nursing staff.

-Subjects:

A purposive sample of 60 patients from whom admitted in the previous mentioned setting at the time of data collection were recruited in this study. The sample size was estimated with STATA 10 program. The estimated required sample size was 50 patients, to achieve power of study $=1-\beta=0.90$ and Alpha $\alpha=0.05$ (sig. 95%).

Patients were subdivided into 2 groups:

Study group: (30 patients who were received a nursing protocol and a routine care in the chest ICU).

Control group: (30 patients who received only a routine care in the chest ICU, while they did not receive a nursing protocol).

Inclusion Criteria:

Adult patients diagnosed with respiratory failure disease, immediately post-weaning from mechanical ventilation, haemodynamically stable, alert and able to co-operate with training, undergoing the same medical intervention.

Exclusion criteria:

Exclusion criteria were neoplastic disease or the presence of other disease that could contribute to dyspnea or exercise limitation (as cardiovascular, neuromuscular, or other respiratory diseases), patients who had other chronic diseases and recognized with psychotic confusion.

-Tools of data collection:

Five different tools were used to collect data pertinent to this study as the following:

I. Patient's structured interview questionnaire:

It was developed by the researcher based on related literature (Linton, 2016; Burns, 2014; Lewis, et al.2014; Timy& Smith, 2014; Lough, Stacy&Urden, 2014). It was written in simple Arabic language, and filled by the researcher. It included three parts:

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Part 1: It aimed to assess the patient's demographic characteristics including (age, sex, level of education, marital status, residence, income and occupation).

Part 2- It was used to assess and collect clinical data about patient's medical history as diagnosis, respiration rate and result of ABG, (PH, PaO₂, PaCO₂ & oxygen saturation), body mass index, smoking and family history of respiratory failure.

Part 3: It was consisted of 20 yes or no questions which distributed into two division, the 1st was consisted of 8 questions which was used to assess patients' knowledge regarding respiratory failure disease (as definition, complications, aim of mechanical ventilation and side effect of mechanical ventilation); while, the 2nd was consisted of 12 questions which was used to assess patients' knowledge regarding the types and benefits of breathing exercise; spirometer; relaxation techniques and assisted mobilization and benefits of limb exercise as indicated post weaning from mechanical ventilator.

Scoring system:

The total score of knowledge was 20 degrees. The score one was given for each correct answer and zero for incorrect answer. For each area of knowledge, the scores of the items were summed-up and the total score for every patient's was calculated. After that, the mean of the total score of knowledge for all patients was calculated.

II- Observational checklists:

It was developed by the researcher based on related literature (**Lewis et al., 2014; Taylor, Lillis & Lynn, 2013**). It was written in simple Arabic language, and filled by the researcher. It included three parts:

Part 1: *The respiratory exercises observational checklist:* which included four items, namely, lip-pursing respiration, diaphragm respiration, effective coughing and use of spirometer?

Part 2: *Range of motion exercises observational checklist:* which included upper limb exercises (elbow & shoulder) and lower limb exercises (knee & hip).

Part 3: *The relaxation exercises observational checklist:* which included, pursed and diaphragm breathing exercise and guided imagery.

The scoring system: The total score of patient's practice was 48 marks. The step observed to be done correctly was scored "1" and the step not done or incorrectly done was scored "0". For each area of practice, the scores of the items were summed-up and the total score for every patient's was calculated. After that, the mean of the total score for all patients was calculated.

III- Modified Borg Dyspnea scale:

Dyspnea was measured using a Modified Borg Scale which was adopted from **Borg, 1982** and translated into Arabic. Translation and re-translation from English to Arabic was done for this tool to assure accuracy for content validity. Modified Borg Scale has been found to have acceptable reliability and validity in patients undergoing MV. Modified Borg Scale is a rapid assessment and monitoring for patients with acute bronchospasm. However, tools for measuring dyspnea or the state of being short of breath are often limited to peak flow, blood gas analysis, and asking patients multiple questions about their breathing at a time when they find speaking difficult. So, Modified Borg Scale was used to provide quick, easy, and rapid information about a patient's state of dyspnea in all post treatment assessment notes on patients with exacerbations who were seen in the emergency department and urgent care clinic.

Scoring system: Each item is scored on a scale of 0 (not present) to 10 (maximal), with a total score range of 0–10, where < 2 indicates mild severity of dyspnea, 3-4 is moderate severity of dyspnea and > 5 is severe dyspnea.

IV-Visual Analogue Fatigue Scale (VAFS):

The visual fatigue rating scale was adopted from **Lee, Hicks & Nino-Murcia, 1991** and translated into Arabic. Translation and re-translation from English to Arabic was done for this tool to assure accuracy for content validity. Reliability and validity of this scale is approved internationally and have demonstrated a high internal reliability ranging from 0.94 to 0.96. Various researches have used this scale to rate fatigue severity in patients. The visual fatigue rating scale the patient to provide a single rating of his /her fatigue – related problem on a 0 – to – 10 scale. The 0 point indicates

no fatigue – related problem and the 10 point indicates as it could be. The number chosen by the patient signifies the severity of the fatigue – related problem for the patient.

Scoring system

The intensity of fatigue was ranked on a horizontal scale of 0 (—no fatigue) to 10 (—worst possible fatigue). Fatigue screening numerical rating scale scores as no fatigue (0), mild fatigue (1–3), moderate fatigue (4–6), or severe fatigue (7–10).

V- Hamilton Anxiety Rating Scale:

It concerned with assessment of the severity of anxiety among the studied subjects, it was adopted from (**Hamilton, 1959**) and translated into Arabic language. Translation and re-translation from English to Arabic was done for this tool to assure accuracy for content validity. It included 14 statements and the patients were asked to read each sentence quietly and rate their present anxiety, on a scale of 0 (not present) to 4 (severe).

Scoring system: Each item was scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where <17 indicates mild anxiety, 18–24 indicates moderate anxiety and ≥ 25 indicates severe anxiety. 10

A nursing protocol:

It was designed by the researchers to improve patients' outcomes post weaning from mechanical ventilation based on the related literature (**Linton, 2016; Burns, 2014; Lewis, et al.2014; Lough, Stacy&Urden, 2014**). A nursing protocol was revised by a group of four experts in Chest diseaseat faculty of Medicine, Ain Shams University and five experts in Medical surgical nursing at faculty of Nursing, Ain Shams University for the content validity. Based on the experts' opinion, some modifications were done, and then the final form was developed. A protocol describes nursing intervention for respiratory failure patient post weaning from mechanical ventilation for improving patient's respiratory function and minimizing dyspnea, fatigue and anxiety. A protocol describes nursing intervention which included enhancing patients' knowledge and practice regarding: I-breathing exercises including diaphragmatic, pursed-lip, deep breathing and coughing exercise, II-use of spirometer to measure maximum inspiratory pressure(MIP), III- relaxation technique as pursed and diaphragm breathing exercise and guided imagery, IV- assisted mobilization and upper and lower limb exercise, V- secretion clearance techniques including coughing exercise and chest percussion as indicated.

- Operational Design:

It included preparatory phase, content validity and reliability, pilot study and field work.

• The preparatory Phase:

It included reviewing of related literature, and theoretical knowledge of various aspects of the study using books, articles, internet, periodicals and magazines to develop data collection tools, the educational guidelines content and media.

• Validity and Reliability

Testing content and face validity of the proposed tools by inspecting the items to determine whether the tools measure what supposed to measure. The stage developed by a jury of 5 experts from different academic categories (professors and assistant professors) of the medical –surgical nursing at the faculty of nursing, Ain Shams University. The experts reviewed the tools for clarity, relevance, comprehensiveness, simplicity and minor modification was done. **Testing reliability** of the proposed tools was done statistically by Crombach alpha test.

Ethical consideration:

The aim of the research was explained to the participants. Verbal consent was obtained from each patient to participate in the study, after clarifying the procedures of the study. Participants were informed about their right to refuse participation and to withdraw at any time without any consequences. Confidentiality of data was ensured.

• Pilot Study:

Pilot study carried out for 8 patients diagnosed with respiratory failure post-weaning from mechanical ventilator, in the previous mentioned setting to test clarity, applicability of tools used in this study before performing the actual study.

Based on the result of the pilot study, no modifications were done. The patients who included in the pilot study were included in the study sample.

- **Field Work:**

The actual field work of this study started at the beginning of (July 2018) and had been completed of (December 2018). This period of time was divided into:

- **Implementation phase:**

Before conducting the study, an exploratory visit was done in the previously mentioned study setting in order to estimate the rate of admission and suitable time for collecting data. Personal communication was done with nurses and physician to explain the purpose of the study and gain their best possible cooperation. The data gathering in this research are done through interview (question and answer) and data documented from the patients' files. The researchers had referred to the predetermined research study setting and selected the samples based on the previous inclusion and exclusion criteria. The researchers were available 4 days per week at the morning or afternoon shifts in the ICU alternatively. The Patients who met the study criteria were included in the study after explaining the purpose of the study and obtaining a verbal consent. First, the researchers greeted the patients, introduced themselves and explained the aim of the study then start implementation phase and received a protocol of care in addition to the routine nursing care of the ICU.

Pre assessment was done as the same for two groups at the first meeting of the patient which involved assessment of patients' demographic characteristics, clinical data, patients' knowledge and practice, respiratory function as respiratory rate and ABGs results, dyspnea, anxiety and fatigue. Filling the tools were took about (30-40) minutes. The researcher used the available data documented from the patients' files to ensure accuracy of data and save effort of the patient as demographic characteristics, clinical data as respiratory rate and ABGs results. Then, implementation of the protocol of nursing care was implemented at the previously mentioned study settings for each patient of the study group separately, each patient took about 2-3 sessions, each session took about 25-30 minutes in the first day (after 24 hours after weaning from mechanical ventilation). An instructional media was used which included the guidelines handout and visual materials as pictures and videos. The session was stopped if the patients had any of the following signs: respiratory rate was more than 38 breaths per minute, arterial oxygen saturation below 90% and heart rate more than 100/min. After training the respiratory exercises and range of motion exercises through face to face procedure, the patients instructed to perform them 3-4 times a day during the patient's stay at ICU. Every day in the patient's ICU stay, the researchers visited the patient to ensure that the patients follow the protocol of care, evaluate and document the effect on the selected variables under the study.

- **Evaluation phase:**

The evaluation phase was done through the first 4 days after the day of weaning (24 hours post weaning) from the mechanical ventilation for patients with respiratory failure and the questionnaire was again asked to be completed together with the fatigue severity scale, anxiety scale and dyspnea scale. The evaluation phase was emphasized on estimating the effect of a protocol of nursing intervention on outcomes of patients with respiratory failure post weaning from mechanical ventilator through comparing the outcomes measures of the pre and post intervention.

Administrative design:

An official permission was obtained from the Director of Chest intensive care unit affiliated to Ain Shams University. Meeting and discussions were held between the researchers and nursing administrative personnel to make them aware about the aims and objectives, as well as to get better cooperation during the implementation phase. It was important to have their full support, especially to encourage patients to participate positively in the study.

- **A statistical design:**

Statistical methods for data analysis

All Data were collected, tabulated and subjected to statistical analysis. Statistical analysis is performed by SPSS in general (version 21), also Microsoft office Excel is used for data handling and graphical presentation. Quantitative variables are described by the Mean, Standard Deviation (SD) and the Range (Maximum – Minimum). Qualitative

categorical variables are described by proportions and Percentages. Two way analysis of variance repeated measure mixed model ANOVA is used to assess the effect of change with time and the effect of group type on the measured variables. Paired sample t test are used for testing Pre –post measurements within the same group. Comparison of the mean changes (Post—Pre) between groups is performed using independent samples t test. For categorical variables Chi squared test is used and Fisher exact test in case of small number per cell. Pearson correlation coefficient is used for quantitative variables. Significance level is considered at $P < 0.05$ (S); while for $P < 0.01$ was considered highly significant (HS). Two Tailed tests are assumed throughout the analysis for all statistical tests.

3. RESULTS

Table (1): Comparison between patients in the control and the study group regarding their demographic characteristics.

Patients' characteristics	Control Group N=20		Study Group N=20		Test	P value	
	No	%	No	%			
Age/years							
<40	10	33.3%	12	40.0%	$\chi^2 = 0.14$	0.7307	
40 – 60	11	36.7%	12	40.0%			
Above 60	9	30.0%	6	20.0%			
Mean \pm SD	43.55 \pm 12.14		46.35 \pm 12.78		t = 0.30	0.8624	
Gender							
Male	15	50.0%	20	66.7 %	$\chi^2 = 1.67$	0.1845	
Female	15	50.0%	10	33.3%			
Education							
Illiterate	5	16.7%	3	10.0%	$\chi^2 = 0.91$	0.7220	
Read and write	8	26.7%	6	20.0%			
Secondary	10	33.3%	13	43.3%			
Higher	7	23.3%	8	26.7%			
Residence							
Rural	7	23.3%	5	16.7%	$\chi^2 = 0.48$	0.4902	
Urban	23	76.6%	25	83.3%			
Marital status							
Widow & divorced	6	20.0%	7	23.3%	$\chi^2 = 0.10$	0.6357	
Married	24	80.0%	23	76.6%			
Smoking							
Passive	15	50.0%	16	53.3%	$\chi^2 = 2.07$	0.3558	
Active moderate	8	26.7%	6	20.0%			
Active heavy	7	23.3%	8	26.7%			

Regarding characteristics of patients in the control and study group, table (1) showed that, the mean age of control group was 43.55 ± 12.14 , while, the mean age of the study group was 46.35 ± 12.78 . Regarding gender, 50.0 % of patients of control group and 66.7 % of patients of the study group were males. As regards educational level, only 16.7% of the control group and 10.0% of the study group were illiterate. In relation to residence, 76.6% and 83.3% of patients in the control and study group resided in urban areas respectively. Regarding marital status, 80.0% of the control group and 76.6% of the study group were married. Finally, concerning smoking, 23.3 % of patients of control group and 26.7 % of patients of the study group were active heavy smokers.

Table (2): Comparison between the control and the study group regarding Patients' knowledge and practice Pre- & post- nursing protocol intervention.

Variables	Control Group N=30				Study Group N=30				Independent T test	P value	
	Satisfactory		Un satisfactory		Satisfactory		Un satisfactory				
	No	%	No	%	No	%	No	%			
Knowledge	pre	9	30%	21	70%	7	23.3%	23	76.7%	0.54	0.59
	post	12	40%	18	60%	24	80%	6	20%	-13071	0.0000
Practice	pre	8	26.7%	22	73.3%	10	33.3%	20	66.7%	0.36	0.73
	post	9	30%	21	70%	22	73.3%	8	26.7%	-16.23	0.0000

Table (2) represents the patients' satisfactory level of knowledge and practice in both the control and study group pre- & post- intervention of the nursing protocol, it is clear from this table that, there were no statistically significant difference pre- interventions. While, there were highly statistically significant difference post- intervention with obvious improvement of the patients' satisfactory level of knowledge and practice in the study group in compared to the control group.

Table (3): Correlation of patients' knowledge and practice in pre- and post- a nursing protocol intervention in the control and study group.

Patients' practice	Patients' knowledge			
	PRE		POST	
	Control	Study	Control	Study
Pearson Correlation Coefficient	-.276	-.185	-.357	0.677
P value	0.257 P > 0.05 NS	0.334 P > 0.05 NS	0.188 P > 0.05 NS	0.00 P < 0.05 HS

Table (3) showed that, there were no statistically significant correlations between patients 'total knowledge and practice in the control group pre & post the nursing protocol intervention. While, post the nursing protocol intervention, there was a statistically significant correlation between patients 'total knowledge and practice in the study group only (P<0.05).

Table (4): Two way analysis of variance repeated measure Mixed Model ANOVA for assessment of the change with time and the effect of group type on the measured variables

Variable	Time	Control Group N=30		Study Group N=30		Two Way Repeated measure ANOVA	
		Mean	SD	Mean	SD	Time Effect	Group difference
						P Value	P Value
RR	D1	21.86	2.09	21.36	2.30	P < 0.001 HS	P > 0.05 NS
	D2	19.47	1.88	18.77	2.12		
	D3	19.09	2.15	18.75	2.51		
	D4	18.13	2.91	17.32	3.29		
PO2	D1	77.60	6.34	77.75	6.85	P < 0.001 HS	P < 0.05 S
	D2	78.70	5.70	81.70	4.86		
	D3	79.35	5.71	85.45	4.26		
	D4	80.00	5.95	87.85	3.92		
	D1	44.25	4.52	43.85	4.93		

PCO2	D2	41.90	4.70	41.15	4.73	P < 0.001 HS	P > 0.05 NS
	D3	40.00	3.45	38.40	3.15		
	D4	38.45	2.46	36.10	1.41		
SO2	D1	89.25	1.62	89.70	2.20	P < 0.001 HS	P < 0.05 S
	D2	89.60	1.47	91.05	2.70		
	D3	90.40	1.27	91.95	2.56		
PH	D4	90.70	1.17	93.10	2.02	P < 0.05 S	P > 0.05 NS
	D1	7.38	0.07	7.38	0.07		
	D2	7.39	0.06	7.40	0.05		
MIP	D3	7.40	0.05	7.41	0.03	P < 0.001 HS	P > 0.05 NS
	D4	7.39	0.05	7.41	0.03		
	D1	340.00	150.09	350.00	153.90		
Dyspnea	D2	420.00	115.17	475.00	140.96	P < 0.001 HS	P > 0.05 NS
	D3	567.50	142.60	635.00	183.60		
	D4	612.50	122.34	722.50	156.84		
Fatigue	D1	4.50	1.36	4.10	1.39	P < 0.001 HS	P > 0.05 NS
	D2	3.80	1.06	3.50	0.89		
	D3	3.20	0.70	2.75	0.85		
	D4	2.85	0.49	2.30	0.57	P < 0.001 HS	P > 0.05 NS
	D1	4.60	1.14	4.50	0.72		
	D2	3.95	0.94	3.75	0.81		
	D3	3.15	0.81	2.95	0.55	P < 0.001 HS	P > 0.05 NS
	D4	2.95	0.83	2.40	0.82		

Table 4 shows that, there were statistically significant change with time from D1 to D4 regarding all measured outcome variables. However, concerning to the difference between the two groups, there were statistically significant difference for PO2 and SO2, while did not attain statistical significant difference in other variables.

Table (5): Comparison between the control and the study group regarding the mean difference (D4 - D1) in all outcome variables.

Variable	Difference	Control Group N=30		Study Group N=30		Independent T test	P Value
		Mean	SD	Mean	SD		
RR	D4 - D1	-3.73	2.41	-4.04	2.29	0.41	0.68407
PO2	D4 - D1	3.40	3.17	10.10	5.16	-4.95	0.00002
PCO2	D4 - D1	-5.80	3.05	-7.75	4.27	1.66	0.10469
SO2	D4 - D1	1.45	1.23	3.40	1.54	-4.43	0.00008
PH	D4 - D1	0.01	0.04	0.03	0.08	-0.91	0.37041
MIP	D4 - D1	272.50	121.91	372.50	136.18	-2.45	0.01915
Dyspnea	D4 - D1	-1.65	1.09	-2.10	1.02	1.35	0.18565
Fatigue	D4 - D1	-1.65	0.67	-2.70	0.57	5.33	0.00000`
Anxiety	D4 - D1	-2.40	1.57	-4.50	1.85	3.87	0.00041

Table 5 showed that, there were statistically significant difference between the two groups in relation to the mean difference at the beginning (D1) and at the end of the nursing protocol intervention (D4) regarding Po2, So2, MIP, fatigue and anxiety. While, there were no statistically significant difference between the two groups in relation to RR, PCo2, PH and dyspnea in spite of the presence of improvement in mean difference of the study group in comparison to the control group.

Table (6): Comparison of levels of dyspnea, fatigue and anxiety between the two groups at Day 1 pre- a nursing protocol intervention.

Variable	Control No=30		Study No=30		Fisher Exact Probability	
	No	%	No	%		
Dyspnea	mild	3	10%	5	16.7%	1.00 P > 0.05 NS
	moderate	15	50%	10	50 %	
	severe	12	40%	10	33.3%	
Fatigue	mild	3	10 %	9	30%	1.00 P > 0.05 NS
	moderate	12	40 %	6	20 %	
	severe	15	50 %	15	50 %	
Anxiety	mild	5	16.7%	5	16.7%	1.00 P > 0.05 NS
	moderate	16	55%	15	50%	
	severe	9	30%	10	33.3%	

Table 6 showed that, there were no statistically significant difference between the control and the study group regarding levels of dyspnea, fatigue and anxiety at Day 1 pre- a nursing protocol intervention. Also, this table presents that, 50% of the control group and 50% of the study group had moderate level of dyspnea and 50% of the control group and 50% of the study group had sever level of fatigue. However, 55% of the control and 50%the study group had moderate anxiety.

Table (7): Comparison of levels of dyspnea, fatigue and anxiety between the two groups at Day 4 post- a nursing protocol intervention

Variable	Control		Study		Chi squared	P Value	
	No	2	No	%			
Dyspnea	Mild	8	26.7%	17	56.7%	8.29	0.0040 P < 0.01 HS
	Moderate	16	53.3%	13	43.3%		
	Severe	6	20.0%	0	0.0%		
Fatigue	Mild	16	53.3%	20	66.7%	0.78	0.0037 P > 0.05 HS
	Moderate	9	30.0%	10	33.3%		
	Severe	5	16.7%	0	0.0%		
Anxiety	Mild	8	26.7%	20	66.7%	4.04	0.0032 P > 0.05 HS
	Moderate	14	46.6%	8	26.7%		
	Severe	8	26.7%	2	6.6%		

Table 7 showed that, there were statistically significant difference between the control and the study group regarding levels of dyspnea at Day 4 post- a nursing protocol intervention. While, this table presents that, there were no statistically significant difference between the control and the study group regarding levels of fatigue and anxiety level at Day 4.

Table (8): Correlation of patients ' anxiety and both of dyspnea and fatigue post a nursing protocol intervention in the two groups.

	Control		Study	
	Dyspnea	Fatigue	Dyspnea	Fatigue
Anxiety	.422	.241	.806	0.447
P value	0.064 P > 0.05 NS	0.306 P > 0.05 NS	0.000 P < 0.05 HS	0.002 P < 0.05 HS

Table (8) showed that, there were no statistically significant correlations between patients ' anxiety and both of dyspnea and fatigue in the control group post the nursing protocol intervention. While, there were statistically significant positive correlation between them in the study group only(P<0.05).

4. DISCUSSION

Acute respiratory failure is a sudden and life threatening deterioration in pulmonary gas exchange, resulting in carbon dioxide retention and inadequate oxygenation. Acute respiratory failure remains a major cause of morbidity and mortality in the intensive care unit (**Morton& Fontaine, 2013**).

Nowadays, the respiratory disability patient who needs medical and nursing management need also a set of complementary and progressive measures, which would aim at improving the clinical condition and global physical condition. So, the researchers had led to increase the efficiency of complex respiratory rehabilitation therapies to prevent the occurrence of acute exacerbation or improving the symptomatology improving the patients' outcomes post weaning from mechanical ventilation, improving the quality of life and maintain in daily activity for a longer period of time (**Damaris, 2012**). The aim of this study was to evaluate the effect of nursing protocol intervention on clinical outcome of patients with respiratory failure disease post-weaning from mechanical ventilation.

Concerning the characteristics of the studied patients with respiratory failure, the present study revealed that, the mean age of control group was 43.55 ± 12.14, while, the mean age of the study group was 46.35 ± 12.78. These results are in disagreement with **Rohet al (2012)**, in a research study titled that "A weaning protocol administered by critical care nurses for the weaning of patients from mechanical ventilation" and who mentioned that, approximately two thirds of the studied subjects were at age between 40-60 years.

Regarding gender, 50.0 % of patients of control group and 66.7 % of patients of the study group were males, this finding may be due to the higher prevalence of smoking among this gender. This finding was with supported by **Rohet al (2012)**, who stated that the more than half of patients were males, While, **Talwar et al (2014)**, wasn't in the same line who reported that more than half of the study subjects were female.

In relation to educational level, less than one fifth of the control group and study group were illiterate. This may be due to conduction of the study in governmental hospital in which there high percentage of low social economic class patients. These results are similar to with **Gaafar, El-salam, Tawfeek, Gumaa, & Mohammed, (2012)**, who found that slightly more than one third of the studied patients had low educational level in their study.

One of the noticeable findings of this study was that, In relation to residence, more than three quarter of patients in the control and majority of the study group resided in urban areas respectively. So, this result convey that these patients are more likely to have the disease because the urban areas had more pollution than rural areas, crowdies and poor houses ventilation that those patients live in and confirm that outdoor and indoor pollutions are risk factors for developing the disease. This is in accordance with **Damaris (2012)**, who reported that about two thirds of the study subjects resided in urban areas.

As regards to marital status, the results of the present study revealed that, majority of the control group and more than three quarter of the study group was married. This finding is supported by **Walterspacher et al. 2017** titled "Activation of respiratory muscles during weaning from mechanical ventilation", in Germany, who mentioned that, more than half of the study subjects were married. This may reflect the load, as well as the higher levels of anxiety and depression experienced by the

patients through their families. The married patients are a burden on their partners because of the limitations in their expected roles toward their families.

Ward and Fulbrook (2016) emphasized on, Since, the nurses are directly responsible for taking care of the patients, and, spend more time with the patients than other treatment staff, it is expected that they try more than others to apply what they learn in training and encouraging the patients. Training of respiratory exercises through face to face procedure while implementing treatment procedures may have significant effects on controlling and improving the symptoms, raising the level of awareness of the knowledge and practice.

In relation to the primary outcomes which included the improvement of patient's knowledge and practice. Concerning the patients' knowledge about respiratory failure and its management through the nursing

protocol intervention, the results of this study revealed that there was a highly statistically significant difference between study and control group post implementation of a nursing protocol intervention with obvious improvement of the patients' knowledge in the study group. This may be due to the most of the patients were educated and the protocol intervention gave the study subjects the confidence and sense of control over their disease that allow them to commit to the information and instructions through the nursing protocol intervention and follow it to avoid or decrease exacerbation attacks. On the same line, **Mohamed, EL Basiouny & Salem, (2014)** in a research study titled 'Response of Mechanically Ventilated Respiratory Failure Patients to Respiratory Muscles Training' added that, none of the studied patients had satisfactory level of knowledge pre intervention. However, the majority of them had satisfactory level of knowledge post guidelines intervention with a statistically significant difference post implementation of intervention in their study and the pulmonary rehabilitation raised awareness for all of the study subjects regarding disease management strategies. Participants were impressed with the range of and strategies which learned in the program. Pulmonary rehabilitation helps the study subjects to overcome their disease to engage in health behavior change to overcome the limitations imposed by respiratory failure.

Regarding patients' total practice, there was a highly statistically significant difference satisfactory level of practice between control and study group post- intervention with obvious improvement of the patients' practice. This may be due to the commit and continuous performance of breathing, coughing, physical exercises and using of spirometer that affect positively on dyspnea, fatigue and anxiety level. These findings were supported with **Kalliopi, Guro, Jennifer and Leanne. 2016** titled "Understanding nurses' decision-making when managing weaning from mechanical ventilation", in Scotland and Greece, who revealed that there were highly statistically significant differences between mean score of total practice pre and post implementation of a care patients.

Concerning correlation between total Patients' knowledge and practice for patients with respiratory failure post implementation of nursing intervention protocol, there were statistically significant correlation between total practice and total knowledge between control and study group. This result was supported with **Walterspacher et al. 2017**, in their research study who found significant effects of education intervention protocol on patients' performance, this study showed a significant improvement of the body of knowledge for the study subjects affected positively on their performance.

Regarding secondary outcomes which involved the improvement of patients' respiratory function as respiration rate and arterial blood gas analysis results. The present finding highlighted that the positive improvement through the time from 1st day to 4th day after weaning from mechanical ventilation in all patient's respiratory function variables and there were statistically significant change with time from D1 to D4 regarding all measured outcome variables between study and control group. This is in contraindicated with **Gaafar, El-salam, Tawfeek, Gumaa, & Mohammed, (2012)**. Impact of Weaning Protocol on Outcome of Mechanical Ventilation in Adults. who stated that very significant improvement in all ABG parameters and in RR and tidal volume (TV). This may be due to those patient still in ICU and they are the critical cases and need more accommodation and frequent observation during implementation of the protocol through the day.

However, concerning to the respiratory rate difference, there was statistically significant change with time from D1 to D4 between study and control group. These may be due to effect of breathing, coughing exercises and using of incentive spirometry. This result is supported by **Ward & Fulbrook 2016** titled "Nursing Strategies for Effective Weaning of the Critically

Ill Mechanically Ventilated Patient", in Australia, who stated that, the mean respiratory rate changes through the respiratory muscle exercises sessions, and the respiratory rate decreased.

As regards arterial blood gases, the results revealed that there were statistically significance differences between patients in study and control groups in relation to the means difference of PO₂ and SO₂ at the beginning and ending of intervention (D4-D1). Also, These findings are in agreement with **Shakouri, Salekzaman, Taghizadih, Jadid&Soleymani (2015)**, who studied the effect of Pulmonary rehabilitation post ICU weaning from mechanical ventilator, it was found that mean difference of PO₂ concentration (of ABG parameters) in experimental group was significantly more than that in control group, while it was observed no difference in the other parameters of ABG between two groups. This may be due to effect of nursing protocol intervention in which patient training of physical, breathing exercises and using of incentive spirometer that provide effective inspiratory effort. Also, these results in similar to **Spiva, et. al. 2015** in their quasi-experimental research study, who reported that, with repeated measure with intervention, oxygen saturation levels significantly improved compared to the comparison group during mechanical ventilation weaning trials.

Jan, Goldworthy and Thomas (2016) stated that, patients who have been mechanically ventilated, the inspiratory muscles remain weak and fatigable following ventilator weaning, which may contribute to dyspnea and limited functional recovery. Training of respiratory exercises through face to face procedure while implementing treatment procedures may have significant effects on controlling and improving the symptoms. This will be achieved by the efforts and perseverance of nurses and members of the treatment team and through supervision on the implementation of training programs for patients.

Regarding the effect of a nursing protocol intervention on patients' dyspnea, the result of the current study revealed that, there was statistically significant change in the patients' dyspnea with time from D1 to D4 in study and control groups, there was a statistically significant difference between the study group and control regarding levels of dyspnea at Day 4 reflecting the effect of a protocol intervention in contrast to Day 1.

The previous present study result is supported with the study of **Bissett, Leditschke, Neeman, Boots and Paratz (2016)** which aimed to assess the effect of inspiratory muscle training to enhance recovery from mechanical ventilation, it was found that Inspiratory muscle training following successful weaning increases inspiratory muscle strength and quality of life, but there were no statistically significant differences in physical function or dyspnea.

Talwar et al. (2014) stated that, fatigue is a known symptom of advanced lung disease and impacts quality of life and psychological health. Many of these patients undergo pulmonary rehabilitation as part of their therapy. Understanding the effect of pulmonary rehabilitation on fatigue in these patients is important. Concerning the patients' fatigue, the results of the current study revealed that, there was statistically significant change in the mean score of patients' fatigue with time from D1 to D4 in study group, there was a statistically significant difference between the pre and post implementation of the nursing protocol.

Concerning the patients' anxiety, the results of the current study revealed that, in relation to the mean difference at the beginning (D1) and at the end of the nursing protocol intervention (D4), there was a statistically significant difference between study and control group. This may be due to the effect of a protocol intervention given to the study group. This is supported with **Spiva et al. (2015)** who found that regular practice of relaxation techniques as guided imagery, breathing exercise and taped message have been shown to reduce trait anxiety levels and stress, and the use of relaxation during a period of increased breathlessness could help patients reduce state anxiety and fear when breathlessness increases. Some studies provide evidence of positive outcomes with different relaxation techniques, for example, with a taped message and guided imagery.

The results of the present study showed that, there were statistically significant correlations between patients' anxiety and both of dyspnea and fatigue in the study group and control group post the nursing protocol intervention. This may be due to training of respiratory exercises through face to face procedure while implementing the nursing protocol may have significant effects on controlling and improving the symptoms as dyspnea and fatigue which reflected on minimizing patients' anxiety.

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Findings of this study in similar with **Talwar et al. (2014)**, who suggested that co-morbid anxiety and depression are associated with increased fatigue, shortness of breath, and frequency of pulmonary-specific symptoms. The extent to which anxiety and depression exacerbate pulmonary symptoms could not be determined, as heightened anxiety and depression could be a cause or consequence of elevated pulmonary symptoms.

Finally, the results of this study support the hypothesis that the nursing intervention protocol has positive effect on patients' knowledge, practice and clinical outcomes (respiratory functions, dyspnea, fatigue and anxiety levels). Additionally, a positive improvement was found among patients in the study group post nursing protocol intervention.

5. CONCLUSION

It is clear from this study that the nursing protocol intervention improves the patients' knowledge and practice and decrease dyspnea, fatigue and anxiety levels and also improves the pulmonary function through the time (difference between D1 – D4).

6. RECOMMENDATIONS

-To date only strong recommendations can be made this protocol before the weaning will help patients no take more days on ventilator and successful weaning strategies.

-Early physiotherapy and breathing exercises may be effective in ICU for patient with respiratory failure.

- Educational program for teaching nurses to apply weaning protocol for patients on mechanical ventilator.

- Teaching nurses to improve patients knowledge and practice about their disease from day 1 of admission to ICU.

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