Effect of care protocol on the knowledge, practice and clinical outcomes of patients with chronic obstructive pulmonary disease

Dina M. Mohamed, Salwa S. Ahmed, Asmaa H. Mohamed, Asmaa A. Abdel Rahman*

Faculty of Nursing, Ain Shams University, Cairo, Egypt

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ABSTRACT

Background: Care protocol for patients with chronic obstructive pulmonary disease is considered as a strategy for promoting their knowledge, practice and clinical outcomes. Aim: This study aimed to evaluate the effect of care protocol on knowledge, practice and clinical outcomes of patients with COPD through the following: A. Assessment of knowledge, practice and clinical outcomes of patients with chronic obstructive pulmonary disease (COPD). B. Developing and implementing care protocol for patients with COPD. C. Evaluating the effect of care protocol on knowledge, practice and clinical outcomes of patients with COPD.

Methods: Study design: A quasi-experimental design was utilized to conduct this study. Setting: The study was conducted at chest department and outpatient clinic at Ain Shams University Hospitals. Subjects: A purposive sample of 50 patients with chronic obstructive pulmonary disease was included in the study. Data collection tools: (1) Patients’ assessment sheet. (2) Patients’ observational checklists. (3) Clinical outcomes assessment sheet.

Results: There were statistically significant differences between mean scores of the pre and post test regarding patients’ knowledge, practice and clinical outcomes except for respiratory muscle training.

Conclusions: Application of care protocol for patients with COPD has positive effect on improving knowledge, practice and clinical outcomes regarding dyspnea, fatigue, sleep quality, mood. Recommendations: Applying care protocol for all patients with chronic obstructive pulmonary disease in the chest units and up-dating its content periodically in order to improve knowledge, practice and clinical outcomes for those patients.

Key Words: Care protocol, Clinical outcomes, Chronic obstructive pulmonary disease

1. INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable disease characterized by progressive airflow limitation. It is a type of obstructive lung disease in which chronic incompletely reversible airflow limitation and inability to breathe out fully (air trapping) exist. The poor airflow is the result of breakdown of lung tissue (known as emphysema) and small airways disease (known as obstructive bronchiolitis).[1]

COPD is the fourth most common cause of death in the world. It disproportionately affects those of lower socioeconomic status and older adults, creating reluctance to diagnose and
treat patients. It has been a major public health problem and will remain a challenge for clinicians within the twenty-first century. Worldwide, COPD is in the spotlight because of its morbidity, mortality and high prevalence. The burden of the disease is great for both those who are affected and for society.\(^2\) COPD is highlighted as a major public health problem in Egypt. The prevalence of COPD among high-risk individuals in Egypt was estimated to be about 10% as per GOLD according to a study done by Said, Ewis, Omran, Magdy, and Saleeb (2015).\(^3\)

The major risk factor for developing COPD is cigarette smoking; COPD is more than four times as prevalent among smokers as non-smokers. It affects about 15% of smokers and just 3% of nonsmokers. Occupational chemicals and dusts: prolonged exposure to various dusts, vapors, irritants, and/or fumes in the workplace. Air pollution, high levels of urban air pollution are harmful to people with existing lung disease. A host risk factor for COPD is aging, frequent lung infection and deficiency of \(\alpha\)-1 antitrypsin.\(^4\)

Complications of COPD include respiratory infections. People with COPD are more susceptible to colds, the flu and pneumonia. Heart problems, COPD increase the risk of heart disease, including heart attack. Lung cancer, smokers with chronic bronchitis has a greater risk of developing lung cancer than do smokers who don’t have chronic bronchitis. Pulmonary hypertension, difficulty breathing contributes to development of depression.\(^5\)

The primary goals of COPD management are slowing disease progression, relieving symptoms, improving exercise tolerance, preventing and treating complications, promoting patient’s participation in care, preventing and treating exacerbation, improving quality of life and reducing mortality risk.\(^6\) Chronic disease self-management, preventive health programs and care protocols mainly focus on promoting informed lifestyle choices, risk-factor modification, and active patient self-management of chronic diseases. Such a process relies heavily on better information and communication.\(^6\)

1.1 Significance of the study
COPD is an incurable devastating disease, with symptoms such as chronic cough, phlegm, wheezing, shortness of breath and increased infections of the respiratory passage. In addition, severely ill patients with COPD often have other symptoms, including congestive heart failure, brittleness of the bones, muscular weakness, malnutrition, weight loss, cognitive dysfunction, fatigue and depression.\(^7\) COPD severely limits their quality of life over time and it is considered one of the most challenging medical issues because of its influence on personal, public health and its impact on the economy; therefore the aim of this study is to evaluate the effect of care protocol on improving knowledge, practice and clinical outcomes of patients with COPD.

1.2 Aim of the study
This study aimed to evaluate the effect of care protocol on knowledge, practice and clinical outcomes of patients with COPD through the following: (1) Assessment of knowledge, practice and clinical outcomes of patients with COPD. (2) Developing and implementing care protocol. (3) Evaluating the effect of care protocol on knowledge, practice and clinical outcomes of patients with COPD.

1.3 Research hypothesis
The current study hypothesized that: Implementation of care protocol will affect the knowledge, practice and clinical outcomes of patients with chronic obstructive pulmonary disease positively.

2. METHODS
2.1 Research design
The design of this study was a quasi-experimental design (one group pre-test-post-test design).

2.2 Setting
The study was conducted at chest department and outpatient clinic at Ain Shams University Hospitals in Cairo, Egypt.

2.3 Subject
A purposive sample of 50 patients with chronic obstructive pulmonary disease were selected according to certain inclusion criteria as follow: Adult patients, from both genders with different educational levels, free from other chronic diseases, who didn’t receive any educational programs related to disease management and agreed to participate in the study. The sample size selection was based on power analysis according to the number of patients with COPD who were admitted to chest department at Ain Shams university hospital within year 2012 (150 patients) with type I error with significant level \(\alpha = 99\%\), type II error by power test \(\beta = 95\%\).

2.4 Tools for data collection
Four tools for data collection were used as follow:

2.4.1 Patients’ assessment tool
This tool was developed by the researcher in an Arabic language. It includes the following two parts:
Part 1 includes patients’ demographic characteristics (age, gender, residence, level of education, occupation, etc).
Part 2 includes clinical data about patients’ medical history (duration of illness, number of previous hospitalization, exposure to irritant/pollutant, etc).

2.4.2 Patients’ knowledge assessment questionnaire regarding COPD

This questionnaire was developed by the researcher in an Arabic language after reviewing the related literatures to assess patients’ knowledge level.

**Scoring system:** Regarding scoring system of the patients’ knowledge assessment questionnaire:
- It included 70 items.
- The responses for each statement were either (true or false).
- The correct answer was given (1 grade).
- The incorrect answer was given (zero).
- The total grade was (70 grades).
- The total score of the knowledge assessment questionnaire for every patient was calculated after that; the mean of the total score for all patients was calculated.

2.4.3 Patients’ observational checklists

These checklists were developed by the researcher in an Arabic language after reviewing related literatures to assess patient’s practices related to breathing exercises, coughing exercise and using of inhaler.

**Scoring system:** The response to each item in the procedures was categorized into (done correctly and not done). One grade was given for each correct step and zero for each incorrect step. The total scores for the observational checklists were (24 grades) distributed as follow:
- Diaphragmatic breathing exercise (6)
- Pursed lip breathing exercise (3)
- Coughing exercise (6)
- Use of inhaler (9)

The total score of all checklists for every patient was calculated then the mean of the total score for all patients were calculated.

2.4.4 Clinical outcomes assessment tools

Assessment of patients’ outcomes was done using the following tools:

(A) Medical Research Council Dyspnea Scale (MRC):

This scale was adopted from Fletcher (1959) to assess the level of activity that produces dyspnea for patients.

**Scoring system:** The MRC is a five point scale grading the severity of dyspnea associated with activities of daily living. It ranges from grade zero to 4.
- Grade “zero” means patient wasn’t troubled with breathlessness.
- Grade “1” (Slight) means patient troubled by shortness of breath when hurrying on the level or walking up a slight hill.
- Grade “2” (Moderate) means patient walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level.
- Grade “3” (Severe) means patient stops for breath after walking about 90 meter or after a few minutes on the level.
- Grade “4” (Very severe) means patient is too breathless to leave the house or breathless when dressing or undressing. Patients were asked to decide on the level of activity that produces dyspnea.

Number and percentage of patients in every level were calculated pre and post implementation of the COPD care protocol.

(B) Iowa fatigue scale (IFS):

This scale was adopted from Watson, Bentler and Hartz (2003) to assess the severity of patient’s fatigue.

**Scoring system:** Iowa fatigue scale includes 11 items. Each item had 5 responses ranging (Not at all = 1, a little = 2, moderately = 3, quite a bit = 4 & extremely = 5). The total score for the scale was calculated using the following equation for every patient: Total = Q1.php + (6-Q2) + Q3 + (6-Q4) + Q5 + Q6 + (6-Q7) + Q8 + Q9 + (6-Q10) + (6-Q11).

Patients were categorized into fatigue and severe fatigue as follow:
- 30-39 categorized as fatigue.
- 40-55 categorized as severe fatigue.

The mean and standard deviation of the total score for all patients pre and post implementation of the COPD care protocol were calculated.

(C) Short Form of the Profile of Mood States (POMS):

POMS-SF is an adaptation to the original 65-item POMS. This scale was adopted from Shelly, Michael and Jamie (1995) and translated into simple Arabic language by the researcher to assess feelings people had within the last week including the day in which the data were collected. The POMS-SF consists of 37 items which describe mood on a 5-point likert scale (0 = not at all, 1 = a little, 2 = moderately, 3 = quite a bit, 4 = extremely). Respondents rate six mood subscales, including tension, depression, anger, vigour, fatigue and confusion. Depression had 8 items (4, 8, 12, 14, 20, 23, 28 & 33), vigor had 6 items (5, 9, 13, 24, 32 & 35), anger
had 7 items (2, 7, 19, 11, 21, 25 & 31), tension–anxiety had 6 items (1, 10, 15, 16, 22 & 27), confusion had 5 items (6, 17, 30, 34 & 36) and fatigue had 5 items (3, 18, 26, 29 & 37).

Scoring system: The patients’ scores for every subscale were calculated:

- Depression (0-32)
- Anger (0-28)
- Tension (0-24)
- Confusion (0-20)
- Fatigue (0-20)
- Vigor (0-24)

The total score of mood disturbance scale (124) was done by adding scores for tension, depression, anger, fatigue and confusion and then subtracting vigor score. Mean and standard deviation for all patients’ scores were done pre and post implementation of the COPD care protocol.

(D) Pittsburgh Sleep Quality Index (PSQI): This scale was adopted from Buysse, Reynolds, Monk, Berman and Kupfer (1989) to assess the severity of sleep-onset and sleep maintenance difficulties.

Scoring system: The scale included (10) items. Item (1 to 4) were open questions, items (5, 6 & 7) had 4 responses (Not during the past month, less than once a week, once or twice a week, three or more times a week). The eighth item had 4 responses (No problem at all, only a very slight problem, somewhat of a problem & a very big problem). The ninth item had 4 responses (very good, fairly good, fairly bad & very bad). In scoring the PSQI, seven component scores are derived, each scored zero (no difficulty) to 3 (severe difficulty). The component scores are summed to produce a global score (range 0 to 21). Higher scores indicate worse sleep quality. Item 10, which is the second page of the scale, does not contribute to the PSQI score.

The mean and standard deviation for all patients’ scores were calculated pre and post implementation of the COPD care protocol. These tools were translated into an Arabic language, and then retranslated into English to assure its accuracy.

2.5 Pilot study

A pilot study was carried out on 10% of patients to test the applicability of the study and to test clarity of the designed questionnaires, as well as to estimate the time needed for each tool. The modifications were done for the used tools then the final form was developed. Patients of the pilot study were excluded from the study’s subjects.

2.6 Ethical considerations

The research approval was obtained from the faculty of nursing research ethics committee before initiating the study. The researcher clarified the purpose and aim of the study to patients included in the study. Oral consent was obtained from patients to ensure willingness to engage in the study. The researcher maintained anonymity and confidentiality of subjects’ data. Patients were informed that they are allowed to withdraw from the study at any time without penalty.

2.7 Field work

Field work included two phases: implementation phase and evaluation phase.

2.7.1 Implementation phase

- This phase started by selecting patients with chronic obstructive pulmonary disease who met the inclusion criteria and explaining the nature of the study as well as taking their approval to participate in the study prior to data collection.
- The patients’ telephone numbers were obtained at the first time for contacting them at the evaluation phase in order to complete data collection process.
- The patients’ assessment tool and the patients’ knowledge assessment questionnaire were used to assess patients’ medical history and patient knowledge regarding COPD and its management to identify the patients’ educational needs. These tools were filled in by the researcher; it had taken about 30-45 minutes to be filled in according to the health condition of every patient.
- Patients were observed by the researcher once before implementation of care protocol using observational checklists to assess their practice regarding diaphragmatic breathing, pursed lip breathing, coughing exercise and inhaler use. It had taken 20 minutes for every patient.
- The clinical outcomes assessment tools were filled in by the researcher. It had taken 30 minutes for every patient.
- Teaching sessions were conducted for every patient individually. The booklet was handed for every patient and the contents of the booklet were explained over
4-5 sessions according to patients’ condition with 45 minute for every session. The first teaching session included: the nature of the disease. The second one was about dyspnea control and the third about saving energy and decreasing fatigue severity. The fourth teaching sessions regarding preventing disease exacerbation and sleep difficulty control. Patients were allowed to ask questions in case of misunderstanding while listening and expressing interest for them.

- At the end of these sessions, the researcher emphasized the importance of follow up visits and informed them that they will be evaluated during this follow up visits after three months post sessions.
- Data collection and teaching sessions were conducted in morning and afternoon shifts starting at September 2014 till the end of May 2015.

2.7.2 Evaluation phase
Post implementation of the care protocol, all tools except patients’ medical history assessment tool were refilled again. Evaluation of the effect of care protocol on patient’s knowledge, practice and clinical outcomes was done by comparing the results pre and post the implementation of the care protocol by using the same data collection tools after 3 months.

2.8 Data analysis
The collected data were analyzed using the statistical package for social science (SPSS) version 18. Quantitative data were presented as mean and standard deviation (SD), t-test was used to determine the differences. Qualitative data were presented as percentage (%). The significance of the observed difference was obtained at $p = .05$.

3. RESULTS
Regarding demographic characteristics of the study subjects, Table 1 clarifies that, approximately one third of the studied subjects (32%) felt at age group between 40-50 years old, also (32%) of them, their ages between 50-60 years. As regard to patients’ gender, most of them (88%) were males. Regarding educational level of the studied subjects, two fifths of them (40%) were able to read and write. Moreover, more than three quarters of the subjects (78%) were married.

Regarding patients’ occupation, less than three fifths of the subjects (58%) exposed to irritating work. In addition, more than half (54%) of the studied subjects were living in urban areas and less than half of them (46%) were smokers.

In relation to the differences between mean scores of patients’ knowledge related to COPD pre and post implementation of COPD care protocol, Table 2 reveals the highly statistically significant differences between mean scores of the pre and post knowledge scores regarding COPD definition, causes, clinical manifestations, complications, treatment, and care protocol items (physical exercise, energy conservation, smoking cessation, dyspnea control, relaxation techniques, nutrition) and between the mean scores of the total knowledge pre and post implementation of COPD care protocol.

<table>
<thead>
<tr>
<th>Patients’ characteristics</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 40</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>40-&lt;50</td>
<td>16</td>
<td>32</td>
</tr>
<tr>
<td>50-&lt;60</td>
<td>16</td>
<td>32</td>
</tr>
<tr>
<td>60-≤70</td>
<td>11</td>
<td>22</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>44</td>
<td>88</td>
</tr>
<tr>
<td>Female</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>9</td>
<td>18</td>
</tr>
<tr>
<td>Read &amp; write</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Diploma</td>
<td>14</td>
<td>28</td>
</tr>
<tr>
<td>Bachelor</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>39</td>
<td>78</td>
</tr>
<tr>
<td>Unmarried</td>
<td>11</td>
<td>22</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Office work</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Literalt work</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Irritating work</td>
<td>29</td>
<td>58</td>
</tr>
<tr>
<td>Unemployed</td>
<td>14</td>
<td>28</td>
</tr>
<tr>
<td>Residence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>23</td>
<td>46</td>
</tr>
<tr>
<td>Urban</td>
<td>27</td>
<td>54</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Quit</td>
<td>22</td>
<td>44</td>
</tr>
</tbody>
</table>

Note. As reported by patients.

As regards to the differences between mean scores of patients’ practice pre and post implementation of COPD care protocol, Table 3 represents that, there were highly statistically significant differences between mean scores of the pre and post tests scores as regards to diaphragmatic breathing, pursed lip breathing, coughing exercise, use of inhaler, and total practice.

In relation to the difference between mean scores of profile of mood state for patients with COPD pre and post implementation of COPD care protocol, Table 4 shows that, there were highly statistically significant differences between mean scores of anger, tension, fatigue, vigor subscales and the total of mood disturbance pre and post implementation of COPD care protocol ($p \leq .001$).
By testing the difference between mean scores of sleep quality of patients with COPD pre and post implementation of care protocol, Table 5 shows that there was highly statistically significant difference between mean scores of sleep quality for patients with COPD pre and post implementation of COPD care protocol, with significant decrease in mean score.

Regarding the difference between levels of dyspnea for patients with COPD pre and post implementation of care protocol, Table 6 shows that there was statistically significant difference between levels of dyspnea for COPD patients pre and post implementation of COPD care protocol.

Table 2. Differences between mean scores of patients’ knowledge related to COPD pre and post implementation of COPD care protocol

<table>
<thead>
<tr>
<th>Knowledge items</th>
<th>Pre Mean</th>
<th>Pre SD</th>
<th>Post Mean</th>
<th>Post SD</th>
<th>Paired t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition &amp; causes of COPD (5)</td>
<td>2.00</td>
<td>1.088</td>
<td>3.10</td>
<td>0.647</td>
<td>6.395</td>
<td>.000*</td>
</tr>
<tr>
<td>Clinical manifestations (19)</td>
<td>7.02</td>
<td>3.236</td>
<td>14.52</td>
<td>3.221</td>
<td>11.465</td>
<td>.000*</td>
</tr>
<tr>
<td>Complications (5)</td>
<td>1.18</td>
<td>1.380</td>
<td>2.98</td>
<td>1.943</td>
<td>5.324</td>
<td>.000*</td>
</tr>
<tr>
<td>Treatment (21)</td>
<td>10.56</td>
<td>4.970</td>
<td>15.88</td>
<td>2.639</td>
<td>6.229</td>
<td>.000*</td>
</tr>
</tbody>
</table>

Care Protocol items (20)

<table>
<thead>
<tr>
<th>Item</th>
<th>Pre Mean</th>
<th>Pre SD</th>
<th>Post Mean</th>
<th>Post SD</th>
<th>Paired t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical exercise</td>
<td>1.24</td>
<td>0.771</td>
<td>2.48</td>
<td>0.580</td>
<td>8.421</td>
<td>.000*</td>
</tr>
<tr>
<td>Energy conservation</td>
<td>1.86</td>
<td>1.471</td>
<td>3.48</td>
<td>0.505</td>
<td>7.207</td>
<td>.000*</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>1.50</td>
<td>1.313</td>
<td>2.42</td>
<td>0.642</td>
<td>4.388</td>
<td>.000*</td>
</tr>
<tr>
<td>Dyspnea control</td>
<td>1.56</td>
<td>0.812</td>
<td>3.14</td>
<td>0.670</td>
<td>10.625</td>
<td>.000*</td>
</tr>
<tr>
<td>Relaxation techniques</td>
<td>1.20</td>
<td>0.948</td>
<td>2.18</td>
<td>0.523</td>
<td>6.664</td>
<td>.000*</td>
</tr>
<tr>
<td>Nutrition</td>
<td>1.32</td>
<td>1.504</td>
<td>2.44</td>
<td>0.644</td>
<td>4.993</td>
<td>.000*</td>
</tr>
<tr>
<td>Total knowledge (70)</td>
<td>29.44</td>
<td>10.721</td>
<td>52.62</td>
<td>8.642</td>
<td>11.564</td>
<td>.000*</td>
</tr>
</tbody>
</table>

Table 3. Differences between mean scores of patients’ practice pre and post implementation of COPD care protocol

<table>
<thead>
<tr>
<th>Item</th>
<th>Pre Mean</th>
<th>Pre SD</th>
<th>Post Mean</th>
<th>Post SD</th>
<th>Paired t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diaphragmatic breathing (6)</td>
<td>1.38</td>
<td>1.483</td>
<td>3.42</td>
<td>0.642</td>
<td>8.536</td>
<td>.000*</td>
</tr>
<tr>
<td>Pursed lip breathing (3)</td>
<td>0.70</td>
<td>0.814</td>
<td>2.20</td>
<td>0.728</td>
<td>10.057</td>
<td>.000*</td>
</tr>
<tr>
<td>Coughing exercise (6)</td>
<td>1.16</td>
<td>1.683</td>
<td>2.80</td>
<td>0.926</td>
<td>5.747</td>
<td>.000*</td>
</tr>
<tr>
<td>Use of inhaler (9)</td>
<td>1.44</td>
<td>1.343</td>
<td>6.34</td>
<td>1.912</td>
<td>14.913</td>
<td>.000*</td>
</tr>
<tr>
<td>Total practice (24)</td>
<td>4.60</td>
<td>3.601</td>
<td>19.12</td>
<td>3.762</td>
<td>18.517</td>
<td>.000*</td>
</tr>
</tbody>
</table>

Table 4. Difference between mean scores of profile of mood state for patients with COPD pre and post implementation of COPD care protocol

<table>
<thead>
<tr>
<th>Items</th>
<th>Pre Mean</th>
<th>Pre SD</th>
<th>Post Mean</th>
<th>Post SD</th>
<th>t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression (0-32)</td>
<td>22.68</td>
<td>3.178</td>
<td>22.18</td>
<td>2.632</td>
<td>0.884</td>
<td>.381*</td>
</tr>
<tr>
<td>Anger (0-28)</td>
<td>22.22</td>
<td>2.728</td>
<td>18.36</td>
<td>2.877</td>
<td>6.789</td>
<td>.000**</td>
</tr>
<tr>
<td>Tension (0-24)</td>
<td>20.06</td>
<td>2.461</td>
<td>14.86</td>
<td>1.702</td>
<td>12.327</td>
<td>.000**</td>
</tr>
<tr>
<td>Confusion (0-20)</td>
<td>15.80</td>
<td>2.421</td>
<td>15.12</td>
<td>2.330</td>
<td>1.489</td>
<td>.143*</td>
</tr>
<tr>
<td>Fatigue (0-20)</td>
<td>17.96</td>
<td>1.772</td>
<td>15.54</td>
<td>2.305</td>
<td>6.277</td>
<td>.000**</td>
</tr>
<tr>
<td>Vigor (0-24)</td>
<td>3.18</td>
<td>2.238</td>
<td>5.28</td>
<td>1.429</td>
<td>5.430</td>
<td>.000**</td>
</tr>
<tr>
<td>Total mood disturbance (124)</td>
<td>94.86</td>
<td>14.622</td>
<td>81.46</td>
<td>8.180</td>
<td>5.797</td>
<td>.000**</td>
</tr>
</tbody>
</table>

*p ≤ .001 highly significant.
Concerning the difference between mean scores of fatigue for patients with COPD pre and post implementation of COPD care protocol, Table 7 shows that there was highly statistically significant difference between mean scores of fatigue for patients with COPD pre and post implementation of COPD care protocol.

Table 5. Difference between mean scores of sleep quality of patients with COPD pre and post implementation of care protocol

<table>
<thead>
<tr>
<th>Sleep quality score (0-21)</th>
<th>Pre Mean SD</th>
<th>Post Mean SD</th>
<th>t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15.34 1.493</td>
<td>10.42 2.391</td>
<td>13.53</td>
<td>.000*</td>
</tr>
</tbody>
</table>

*p ≤ .001 highly significant.

Table 6. Difference between levels of dyspnea for patients with COPD pre and post implementation of care protocol (n = 50)

<table>
<thead>
<tr>
<th>Dyspnea level</th>
<th>Pre No</th>
<th>%</th>
<th>Post No</th>
<th>%</th>
<th>Chi-square</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0</td>
<td>0 0</td>
<td></td>
<td>0 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td>0 0</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2</td>
<td>3 6</td>
<td>9</td>
<td>18</td>
<td>23.06</td>
<td>.001*</td>
<td></td>
</tr>
<tr>
<td>Level 3</td>
<td>20 40</td>
<td>33</td>
<td>66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 4</td>
<td>27 54</td>
<td>7</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*p ≤ .001 highly significant

Table 7. Difference between mean scores of fatigue for patients with COPD pre and post implementation of COPD care protocol

<table>
<thead>
<tr>
<th>Fatigue score</th>
<th>Pre Mean SD</th>
<th>Post Mean SD</th>
<th>t test</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>47.10 3.547</td>
<td>41.28 2.090</td>
<td>13.38</td>
<td>.000*</td>
</tr>
</tbody>
</table>

*p ≤ .001 highly significant.

4. DISCUSSION
Chronic obstructive pulmonary disease is a slowly progressive, devastating incurable respiratory disease that affects many people and severely limits their quality of life over time and it is considered one of the most challenging medical issues because of its influence on personal, public health and its impact on the economy. This study was carried out in order to determine the effect of care protocol on the clinical outcomes for patients with COPD.

The present study revealed that approximately two thirds of the studied subjects fall at age group between 40-60 years old. This results are in agreement with Salah, Hamdi and Shehata (2013) who mentioned that, the mean age of more than half of patients with COPD were 50 years of age or older. According to Badway, Hamed and Yousef (2016), the age of subjects who included in their study was between 40-59 years and they represent approximately three quarters of study subjects.

According to Lewis et al. (2014), as people age there is gradual loss of the elastic recoil of the lung. The lungs become more rounded and smaller. The number of functional alveoli decreases as peripheral airways lose supporting tissues. The thoracic cage becomes stiff and rigid and the ribs are less mobile. Changes in the elasticity of the lungs reduce the ventilatory reserve, and ability to clear secretions decreases with age. These facts support the finding of this study regarding age.

In the present study, most of the studied patients were males, this finding may be due to the higher prevalence of smoking among this gender and the frequent occupational exposures to irritating work as the finding of this study revealed that more than half of the study subjects had exposed to irritating work. This finding was supported by Zamzam, Azab, Ragab, El wahsh and Allam (2012), who stated that, the majority of patients were males in their study entitled “Quality of Life in COPD Patients”, while contradicted with Center of Disease Control and Prevention (2013), who reported that females are more likely to have chronic obstructive pulmonary disease than males.

One of the noticeable findings of this study was that, less than three fifths of the studied subjects exposed to irritating work. This is contradicted with Salah et al. (2013), who stated that only one fifth of the studied subjects were exposed to irritating work. As regard to marital status, the result revealed that more than three quarters of the subjects were married. This finding is to some extent in accordance with Cedano, Belasco, Traldi, Machado and Bettencourt (2012), who reported that more than half (55%) of the study subjects were married. This may reflect the load, as well as the higher levels of anxiety and depression that experienced by the patients through their role in caring for their families. The married patients are suffering because they may feel that, they were a burden on their partners because of the limitations in their expected roles toward their family.

Regarding residence, the current study showed that, more than half of the studied subjects were lived in urban areas. This is in accordance with Damaris (2012), who reported that near to two thirds (65%) of the study subjects resided in urban areas. This result shows the crowdedness, pollution and poor houses ventilation that those patients live in and confirm that outdoor and indoor pollutions are risk factors for...
developing the disease. But the same finding is contradicted with that of Badway et al. (2016),[16] who stated that one quarter of their study subjects were living in urban and three quarters were living in rural areas.

In the present study, less than half of the studied subjects were smokers. This finding coincides with the fact that, smoking is a major risk factor for COPD. The same finding was supported by Balcells et al. (2009),[21] who mentioned that 42.4% of their study subjects were current smokers.

Regarding patients’ knowledge about COPD and its management, the results of this study showed that there was highly statistically significant difference between mean score of total knowledge related to COPD pre and post implementation of COPD care protocol. This might be attributed to the fact that most of them were educated which allow them to commit to the instructions in the care protocol and follow it in order to decrease exacerbation of the disease. On the same line, Salah et al. (2013),[15] added that, none of the studied patients in their study had satisfactory level of knowledge pre intervention; however, the majority (88%) of them had satisfactory level of knowledge post intervention.

Also Price (2010)[22] reported that pulmonary rehabilitation raised awareness for all of the study subjects regarding disease management strategies. Participants were impressed with the range of and strategies they learned in the program. They expressed being completely unaware that, there was so much they could do to manage their disease. Participants expressed that they would not have achieved the same level of awareness regarding managing their COPD without the pulmonary rehabilitation program. Pulmonary rehabilitation gave participants the confidence and sense of control over their disease to engage in health behavior and change in order to overcome and/or manage the limitations imposed by COPD.

Regarding patients’ total practice, there were highly statistically significant differences between mean score of total patients’ practice pre and post implementation of COPD care protocol. This may be due to the continuous practicing of breathing exercise, coughing exercise which affect positively their performance by making their breathing more controlled and they become more efficient in removing sputum. These findings were in accordance with Salah et al. (2013),[15] who reported that there was highly significant improvement post guidelines implementation in their study about improving breathlessness and fatigue in patient with COPD.

COPD is a disease with multiple co-morbidities. Two of the most common and least-treated co-morbidities of COPD are anxiety and depression. Untreated and undetected anxiety and depressive symptoms may increase physical disability, morbidity, and health-care utilization.[23] The present study showed that, there was a highly statistically significant difference between mean scores of total mood disturbance pre and post implementation of COPD care protocol. This may be due to that, the care protocol implementation had positive effect on improving their level of dyspnea which subsequently improved their mood.

This finding is in agreement with the findings of a similar study by Lamers, Jonkers, Bosma, and Chavannes (2010),[24] who reported that patients receiving the minimal psychological intervention had significantly fewer depressive symptoms and fewer symptoms of anxiety at nine months than patients receiving usual care. Also, Maurer et al. (2010),[25] demonstrated that, both the anxiety and depression associated with COPD responded well to both pharmacologic and non-pharmacologic therapy in their study about anxiety and depression in COPD.

Concerning total sleep quality, the results of the present study showed that there was highly statistically significant difference between mean scores of sleep quality for patients with COPD pre and post implementation of COPD care protocol, with significant decrease in mean score denoting positive change in sleep quality. This may be due to the positive effect of the care protocol implementation on patients’ performance particularly controlling breathing difficulties which affected their sleeping pattern positively.

This result to some extent is similar to Lan, Huang, Lee and Huang (2014),[26] who reported that, pulmonary rehabilitation resulted in significant improvement in sleep quality, as indicated by the scores of Pittsburgh Sleep Quality Index (PSQI) which decreased from 9.41 ± 4.33 to 7.82 ± 3.90. Furthermore, Özge, Ozge and Unal (2006),[27] found a correlation between an abnormally high carbon dioxide level in the blood (hypercapnia) and the frequency of sleep disturbances in patients with COPD. So, the care protocol was effective in decreasing hypercapnia that consequently affected the quality of sleep. While, McDonnell, Hogg, McDonnell and White (2014)[28] stated that pulmonary rehabilitation (PR) did not improve sleep quality in COPD as indicated by the scores of Pittsburgh Sleep Quality Index (PSQI).

According to Marciniuk et al. (2011),[29] dyspnea is a cardinal symptom of chronic obstructive pulmonary disease (COPD), and its severity and magnitude increases as the disease progresses, leading to significant disability and a negative effect on quality of life. In the same context, the result of this study revealed that, more than half of the study subjects had severe dyspnea. This may be due to the long duration and severity of the disease and not practicing breath-
ing exercise accurately and regularly. Also, may be due to, near half of the study sample are smokers. The same finding is corresponding to Bilgic, Tel, & Zorlu, (2012),[30] who mentioned that, all of the patients said to have dyspnea and the analysis made using dyspnea scale (MRC) revealed that 73.3% of the patients had severe dyspnea.

The current study illustrated that, there was statistically significant difference between levels of dyspnea for COPD patient’s pre and post implementation of COPD care protocol. This may be due to the effective continuous practicing of breathing exercise which has a positive effect on improving respiratory muscles. This finding is congruent with the finding of a study conducted by Damaris (2012),[20] to assess the effect of respiratory rehabilitation on improving the COPD patient’s symptomatology and their quality of life; the findings concluded that there was decrease in the dyspnea severity after rehabilitation. Also, the result was supported by Pablo et al. (2002),[31] who mentioned that, there was improvement in the MRC scale of dyspnea after the pulmonary rehabilitation program.

Fatigue is a distressing, complex, multidimensional sensation common in individuals with chronic obstructive pulmonary disease which negatively impacts functional performance and quality of life. The results of the present study revealed that the most of the study subjects had severe fatigue. This may be related to their age and severity of the disease and dyspnea. This result was supported by Wong, Goodridge, Marciniuk, & Rennie (2010),[32] who mentioned that, almost all of the study subjects (95.3%) experienced high levels of fatigue in their study about fatigue among patients with COPD participating in a pulmonary rehabilitation program.

Also, the results of the present study revealed that, there was highly statistically significant difference in mean scores of fatigue for patients with COPD pre and post implementation of COPD care protocol. This may be due to patient’s compliance with the guidelines concerning energy conservation. This finding was supported by Salah et al. (2013),[15] who reported that, the mean scores of fatigue were decreased post guidelines implementation compared to pre guidelines implementation with highly statistically significant differences.

5. CONCLUSION
The results of this study concluded that, application of care protocol for patients with COPD has positive effect on improving their knowledge about COPD and its management (physical exercise, energy conservation, smoking cessation, dyspnea control, relaxation techniques, and nutrition), practices related to breathing exercise, coughing exercise and inhaler use and subsequently improving their clinical outcomes regarding dyspnea, fatigue, sleep quality and mood.

6. RECOMMENDATION
Care protocol for patients with chronic obstructive pulmonary disease should be applied in chest units periodically in order to improve knowledge, practice and clinical outcomes for those patients. Further researches are recommended on new approaches in the area of management of patients with chronic obstructive pulmonary disease and evaluate its effect on patients’ clinical outcomes.

CONFLICTS OF INTEREST DISCLOSURE
The authors declare that there is no conflict of interest.

REFERENCES


