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To Evaluate the Outcome of Use of Inhalers in Patient with Chronic Obstructive Pulmonary Disease (COPD) Following Training

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ABSTRACT

Background: *Chronic obstructive pulmonary disease (COPD) is a common respiratory condition associated with high morbidity and mortality. A correct diagnosis of COPD can decrease symptoms, reduce frequency and severity of exacerbations, improve health status, improve exercise capacity, and prolong survival. Inhaler devices are mainstay in management of chronic obstructive pulmonary disease and their proper usage requires continuous training. A thorough literature search has shown limited data on the outcome of various techniques and devices used in COPD; hence this study is being done to study the outcome of use of inhalers in patients with COPD following training.*

Methods: *This prospective, observational study was conducted on patients suffering from COPD as per Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria. The patients were given instructions and training correctly all patients were called after one month and spirometry parameters were assessed after one month. Spirometry and St. George Respiratory Questionnaire was administered to all participants.*

Results: *A total of 60 patients were enrolled in study with the mean age of 49.37±17.65 years. 19 patient suffering from COPD also had concurrent diseases associated. Revolizer was used by 60% of patients. There was a significant ($p<0.05$) improvement in FEV1 and PEF after 1 month of proper use of inhalation technique. All patients showed a statistically significant ($p<0.05$) improvement in symptoms score in SGRQ.*

Conclusion*: A significant improvement in FEV_1, Ratio of FEV_1/FVC and PEF was observed after 1 month, there was also improvement in Quality of life of patients.*

Key words: *inhalers, respiration, devices, quality of life, spirometry*

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common respiratory condition that is characterized by limitation of airflow.[1] Chronic obstructive pulmonary disease is a type of obstructive lung disease where the patient has long-term poor airflow. The main symptoms of COPD include shortness of breath and cough with sputum production which typically worsens over time.[2] COPD affects more than 5 percent of the population and is associated with high morbidity and mortality.[3] It is the third leading cause of death in the United States, killing more than 120,000 individuals each year.[4] Establishing a correct diagnosis of COPD is important because appropriate management can decrease symptoms (especially dyspnoea), reduce the frequency and severity of exacerbations, improve health status, improve exercise capacity, and prolong survival.[5]

Inhaler devices are a mainstay in the management of chronic obstructive pulmonary disease and their proper usage requires continuous training.[6] The correct use of inhaler devices is one of the most important aspects to be taken into account when evaluating the progress of disease treatment among individuals with COPD, and guidelines emphasize the

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importance of assessing inhalation technique to improve the efficiency of drug delivery.[6] Efficient delivery of inhaled medication is essential for the success of COPD therapy.[6,7] A wide range of inhaler devices are available, including pressurized metered dose inhalers (pMDIs), dry powder inhalers (DPIs), nebulizers, and soft mist inhalers (SMI), all of these devices have their own advantages and disadvantages.[8] A thorough literature search has shown limited data on the outcome of various techniques and devices used in COPD; hence this study is being done to study the outcome of use of inhalers in patients with COPD following training.

METHODS

This prospective, observational study was conducted in the Department of Pulmonary medicine for a period of two months from May 2017 to June 2017. All patients visiting the inpatient as well as the outpatient department of pulmonary medicine and suffering from chronic pulmonary obstructive disease as per Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria were included in the study after they give written informed consent.

COPD patients who received verbal instructions on the correct inhalation techniques for their particular inhaler device for more than 3 months only from their pharmacist or those who have received instructions from their doctor and those who used inhaler according to the instructions leaflet provided with the inhaler were included in the study. The patients using other kinds of inhaler devices; those who received face-to-face training program on inhalation technique from COPD clinic; and acute exacerbation or hospitalization within the previous 6 weeks were excluded from the study.

Procedure: We assessed the commonly used controller devices, i.e., the pressurized metered-dose inhaler (pMDI), the pMDI with a volumetric spacer, the Accuhaler®, and the Handihaler®. Stable COPD patients previously diagnosed in accordance with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria and who had been using one of the four types of inhaler devices longer than 3 months prior to the study were screened for enrolment. Enrolled patients were assessed for inhalation technique compliance at their routine medical (pre-training) visits by a qualified respiratory nurse without prior notification. This assessment was performed in an infirmary room before the meeting with a physician. The use of each inhaler device was evaluated in a practical manner by asking patients to demonstrate their inhalation technique using their prescribed devices. They were asked to say each step as they perform, so that all of the steps could be clearly observed. We developed a checklist to measure essential steps required for adequate drug delivery for each device based on the instructions provided by the manufacturer and from previous studies. When one or more errors were made regarding essential steps, we considered it unlikely that a significant amount of medicine would be inhaled. The technique of inhalation was observed and each incorrect step was recorded.

After the assessment, patients were given instructions, face-to-face demonstrations regarding the correct use of the controller devices, and training until they could use the devices correctly. One month later (post-training visit), all patients were requested to demonstrate their inhalation techniques and re-evaluation was done.

Parameters: Spirometry of all the subjects was done to measure forced expiratory volume in 1 second (FEV_1) and ratio of FEV_1 to forced vital capacity.

The numbers and types of inhaler controller devices were recorded and any exacerbation within the previous year was also noted. Exacerbation was defined as a worsening of two or more major symptoms for 2 or more consecutive days as determined by a physician (dyspnea, sputum volume, sputum purulence), and requiring treatment with either systemic corticosteroids or antibiotics, or combinations of the two as necessary.

Patients were evaluated for potential factors associated with incorrect inhalation technique including age, sex, severity of disease classified by GOLD, dyspnea assessed by modified Medical Research Council score, level of education (primary school, secondary school, or higher), use of multiple devices, and whether treatment by a pulmonologist had been provided in the previous 2 years.

St. George respiratory questionnaire: Patients were administered St. George Respiratory Questionnaire, it is designed to measure health impairment in patients suffering from asthma and COPD. It has two parts, part 1 produces symptom score (effect of respiratory symptoms, their frequency and severity), and part 2 the activity (activities that cause/ are limited by breathlessness) and impacts (social and psychological disturbances) score. It is designed for self-administration and should be completed in a quiet area, free from distraction and elicits the patient's opinion. Scores range from 0 to 100 percent, where 100 represents worst possible health status and 0 indicates best possible health status.[9].

Statistical Analysis: The data was tabulated as mean ± standard deviation (SD). Results were analyzed using non parametric tests (Chi-Square Test), parametric tests (two tailed student t-test) and correlation (Pearson correlation coefficients) analysis. A $p<0.05$ was considered statistically significant.

RESULTS

A total of 60 patients fulfilling in the inclusion and exclusion criteria were enrolled in the study after they giving written informed consent. A total of 45 males and 15 females participated in the study. The mean age of patients was 49.37±17.65 years. The other baseline characteristics of patients are demonstrated in Table 1. The baseline spirometry parameters are also shown in Table 1.

Table 1 :- Baseline characteristic of patients

Characteristics	n=60
Age (Mean±SD) (years)	49.37±17.65
Sex (M:F)	45:15
Body Mass Index (Mean±SD) (Kg/m^2)	21.69±4.43
Height (Mean±SD) (cms)	158.78±7.80
Weight (Mean±SD) (Kg)	54.98±10.90
FEV1 (Pre) (Mean±SD) (L)	1.28±0.71
FEV1 (Post) (Mean±SD) (L)	1.41±0.85
FEV1/FVC (Pre) (Mean±SD) (%)	61.48±11.60
FEV1/FVC (Post) (Mean±SD) (%)	62.81±14.4
PEF (Pre) (Mean±SD) (L)	3.21±1.79
PEF (Post) (Mean±SD) (L)	3.32±1.46

Patient suffering from COPD also had concurrent diseases associated with it, out of total 60 patients 19 patients were suffering from chronic disease with patients suffering from diabetes mellitus, hypertension, previous history of tuberculosis and pleural effusion. One patient also had restrictive lung disease. The most common disease associated with the patients was tuberculosis as 10 patients gave a prior history of the disease. The pattern of disease associated with COPD is shown in Figure 1.

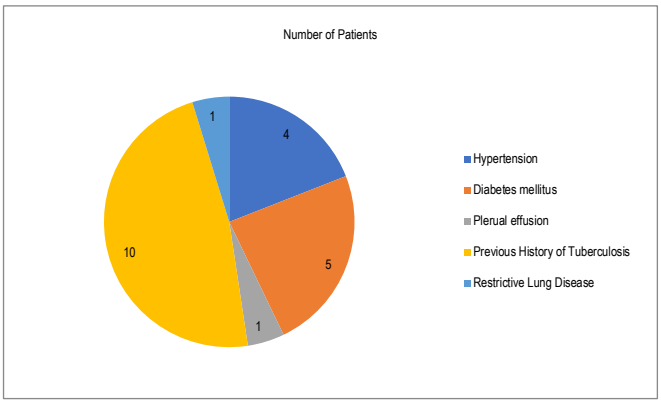

Fig1. Chronic Disease associated with COPD

Patients were on inhalational therapy and the various devices used for inhalational therapy are shown in Figure 2. Revolizer was the most common inhalational device used by patients, used by more than 60% of patients.

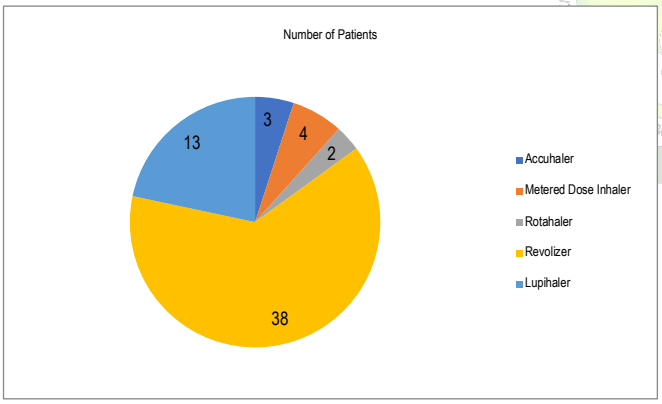

Fig 2. Inhalational Devices used by Patients

Spirometry parameters after one month

The patients were given instructions, face-to-face demonstrations regarding the correct use of the controller devices, and training until they could use the devices correctly all patients were called after one month and spirometry parameters were assessed after one month (Table 2). One month later (post-training visit), all patients were requested to demonstrate their inhalation techniques and re-evaluation was done. There was a significant ($p<0.05$) improvement in FEV1 and PEF after 1 month of proper use of inhalation technique.

SGRQ:

All patients showed a statistically significant ($p<0.05$) improvement in symptoms score as compared to baseline as is evident by lower scores in SGRQ as is shown in Figure 3. The scores improvement in patients after 1 month of use through proper training of inhalational technique is shown in Figure 3.

Table 2. Spirometry findings at baseline and 1 month

Parameters	At baseline	At 1 month	p value
FEV1 (Pre) (Mean±SD) (L)	1.28±0.71	1.45±0.65	<0.05*
FEV1 (Post) (Mean±SD) (L)	1.41±0.85	1.55±0.79	<0.05*
FEV1/FVC (Pre) (Mean±SD) (%)	61.48±11.60	64.92±10.29	>0.05
FEV1/FVC (Post) (Mean±SD) (%)	62.81±14.4	65.52±14.82	>0.05
PEF (Pre) (Mean±SD) (L)	3.21±1.79	3.50±1.73	<0.05*
PEF (Post) (Mean±SD) (L)	3.32±1.46	3.65±1.42	<0.05*

*p<0.05, hence significant using student 't' test and Mann-Whitney U Test

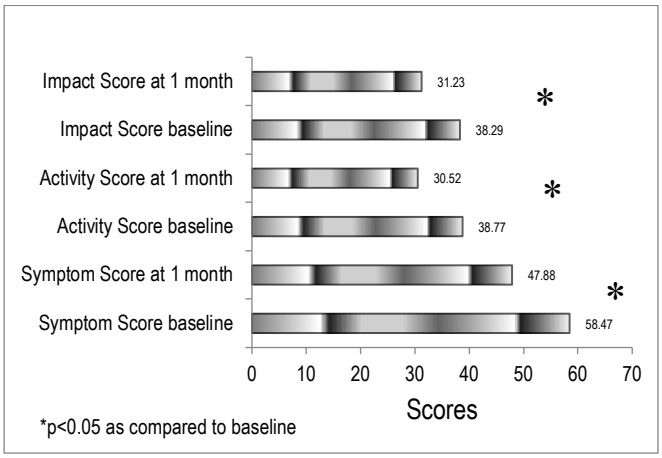

Fig 3. Symptoms Score

DISCUSSION

Chronic obstructive pulmonary disease (COPD) is a common respiratory condition that is characterized by limitation of airflow associated with symptoms of shortness of breath and cough with sputum production which typically worsens over time.[2] Its affects more than 5 percent of the population and is the third leading cause of death in the United States, killing more than 120,000 individuals each year.[4] Patient training and education in inhaler use and inhalation therapy is directly related to the efficacy of therapy. Our study tried to assess outcome of use of different inhalers and their techniques in patients with COPD. The results of our study showed that Revolizer was the most common inhalational device that was used by the patients, followed by Lupihaler. There was significant improvement in FEV1, Ratio of FEV1/FVC and PEF after 1 month, to the time when the patients were trained to use different inhalational techniques. There was improvement in Quality of life of patients also as evident by the decrease in score of SGRQ in all parameter i.e. activity, symptom and impact score.

An online survey done to assess COPD patients and Healthcare practitioners over options and preferences for inhalational devices attributed that certain key factors were essential for preferences of inhaler devices. For patients perspective it was fewer steps to operate the inhaler, confirmations that dose had been correctly and easier coordination were important; whereas for HCP it was patient's satisfaction and ease of use. Our study highlighted this particular aspect that if patients were properly trained for inhalational technique and they demonstrated it successfully; it led to significant improvement in symptoms as well as quality of life of patients.[10]

Another study highlighted upon the fact that effectiveness of inhaled medication is limited by patient's ability to use the device properly. Correct inhaler techniques should be taught

learnt and required educational and motivational programs for patients and HCPs. Education must include practical demonstration, periodic reassessment, and re-education as correct technique and motivation deteriorate with time. The impact of this study is obvious in our study also as the patients were observed for correct technique and were trained for correct use which was to be demonstrated by them, this led to significant improvement in symptoms of the patients and better impact as compared to baseline.[11]

A study done to assess the problems with inhaler use cited patients education as a critical factor in use and misuse of medication inhaler. Inhaler technique is considered easy and they do not receive adequate training for its use; many patients do not use the device well enough to benefit from prescribed medication. HCPs are unable to describe or perform critical steps for using inhaler leading to waste of resources. The impact of this study is visible in our study as our focus was on proper training, technique demonstration and minimizes waste of resources, which resulted in significant improvement in patients at the end of 1 month.[12]

One study done to assess the patient's preferences for inhaler devices in COPD demonstrated that patients satisfaction was higher with Respimat Soft Mist Inhaler as compared to pressurized meter dose inhaler and other devices available. The result of our study are different from this study as in our study we did not compare the satisfaction level of patient with different type of inhalers, the focus of our study was on proper training and demonstration of the technique by the patient which lead to a significant improvement in the quality of life of patients.[13]

There are certain limitations to our study, firstly, the sample size is small, a bigger sample size could have been better but provided with the time constrain of finishing this study within 2 months and the patients were on follow up after 1 month, it would not be possible. Secondly, the comparison between various devices could have given a different parameter to this study, but for comparing different devices we would have required a larger sample size and time constrain would have impeded us. Thirdly, we only focused ourselves on demonstration and training of technique being used by the patients.

CONCLUSION

To conclude our study showed that there was significant improvement in FEV1, Ratio of FEV1/FVC and PEF after 1 month, to the time when the patients were trained to use different inhalational techniques. There was also improvement in Quality of life of patients also as evident by the decrease in score of SGRQ in all parameter i.e. activity, symptom and impact score.

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