WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 8, Issue 3, 857-883. Research Article ISSN 2277– 7105

# ASSESSMENT OF INHALATION TECHNIQUES & ITS EFFECT ON THE QUALITY OF LIFE IN ASTHMA & COPD PATIENTS THROUGH AUTHORIZED QUESTIONNAIRE

**[1]Deepika Reddy Basireddygari, [2]Sonika Chandragiri, [3]Ladhida Puthan Purayil, [4]Sathish Kumar Sure, *[5]Dr. S. Anusha Rao MBBS, MD and [6]Dr. V. Jayasankar Reddy M. Pharm, PhD**

[1,2,3,4]Pharm. D. Krishna Teja Pharmacy College, Tirupati.
[5]Department of Pulmonology, SVIMS, Tirupati.
[6]HOD, Department of Pharmacology.

Article Received on
05 Jan. 2019,
Revised on 27 Jan. 2019,
Accepted on 18 Feb. 2019
DOI: 10.20959/wjpr20193-14281

***Corresponding Author**
**Dr. S. Anusha Rao MBBS, MD**
Department of Pulmonology, SVIMS, Tirupati.

## ABSTRACT

Inhalation is the preferred route of delivery for drugs intended for Asthma and COPD. The main aim of the study is to identify the patients' performance of the inhaler technique, the most common errors made by patients and to profile the individuals who make such errors. It is a prospective observational study carried out for a period of five months in department of TB&RD in a tertiary care hospital. Three questionnaire forms 'ACTQ', 'CAT', 'mMRC' and ABCD classification is used for the assessment of Asthma and COPD symptom control for a 12-week study period. Assessment of Asthma control was based on ACT questionnaire as per GINA, with baseline (mean±sd) score at week 1 was 10.84±2.50 followed by 20.92±1.38 at week 12. Assessment of COPD based on CAT questionnaire with baseline (mean±sd) score at 1st week 18.86±6.39 followed by 12.00±3.15 at week 12, mMRC questionnaire with baseline (mean±sd) score at 1st week 1.96±1.15 followed by 0.83±0.69 at week 12 and ABCD classification during 1st week was of 10% with D, 30% patients with C, 37% patients with B, 23% with A. During 12th week, 3% with D, 23% patients with C, 44% patients with B, 30% with A. These results shows the significant improvement in the quality of life of the patients. Among 100 patients 94% patients made mistakes in the inhalation technique. Only 6% of the patients have done proper inhalation technique. Our study therefore concludes that face-to-face training significantly decreased incorrect inhalation techniques in patients using pMDIs and DPIs.

## INTRODUCTION

Inhalation is the preferred route of delivery for drugs intended for Asthma and COPD. The major advantage of inhaled therapy is that medications are delivered directly into the airways, which reduces risk of side effects and amount of medication required.[1,2,3] The mechanisms of action, effectiveness and the significance of inhaled corticosteroids (ICS) as well as short-acting and long-acting B2-agonists in the management of asthma and chronic obstructive pulmonary disease (COPD) are well-established. However, the importance of the mode of delivery of these agents, which is the inhaler device, is still disregarded.[4] There are many reasons that might explain why the disease condition remains poorly controlled. Such reasons include: poor compliance with therapy, wrong inhaler choice by physician and improper inhalation technique.[1,3]

Good-quality outcomes in the disease condition hinge not just on the availability of medications but also on their appropriate use by patients. Both the efficacy of a medication and patient adherence to the therapeutic regimen influence the effectiveness of a treatment.[6] It has been recently demonstrated that inhaler misuse is associated with decreased disease control treated with an ICS, where for ICS to be effective, good inhaler technique and adequate adherence are important.[5&7] Large systematic reviews of bioequivalence have found that, when properly used, MDI and DPI devices are not different in delivering inhaled medications, and then patients will have the same disease control.[7,8]

Many inhaler devices have been developed, and each has specific instructions for usage to ensure suitable drug dose delivery to the airways. Although a number of different devices have enabled technological improvements in airway drug delivery, important limitations still remain.[9] Patient-related determinants such as sex, age, education level and severity of obstruction were associated with incorrect technique.[11,12,3,13-15] The type of inhaler device is also an important determinant of incorrect technique.[11,16,17] Individuals' ability to use inhalers and their attitude to the disease, therapy and acceptability of the selected device should be taken into account when selecting the device if compliance with therapy is to be achieved. Compliance and inhaler technique should be assessed at every consultation.[18-20]

Therefore, it is necessary on the part of the physicians, nurses, and other health care providers, to understand the issues related to performance and correct use of these inhaler devices, and also to understand the difficulties faced by patients while using them.

**Different types of inhaler devices used are as follows**

1. Pressurised metered dose inhalers (MDIs) and Spacer devices
2. Breath-actuated inhalers - MDIs and Dry Powder Inhalers (DPIs)
3. Nebulisers

**Asthma**

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable reversible expiratory airflow limitation shown in figure 1.[102]

The various types of asthma are atopic asthma, non-atopic asthma, drug-induced asthma, occupational asthma, exercise-induced asthma and nocturnal asthma.

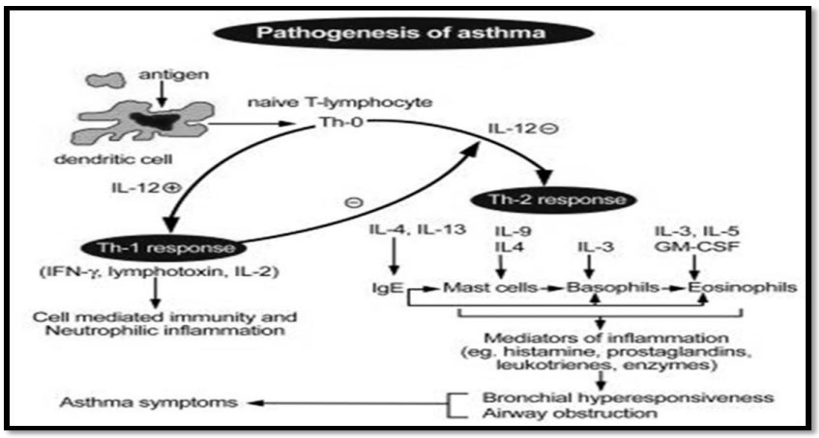



**Figure. 1: Four distinct subsets of CD4 lymphocytes, Th1, Th2, regulatory T cells (TReg), and T17 cells can differentiate from precursor T cells at the time of antigen presentation and influence cytokine production. Th1 cells drive cell-mediated immune responses and are characterized by the production of IFN-, TNF-a, and IL-2 without production of IL-4, IL-5, IL-9, and IL-13.**

**Chronic Obstructive Pulmonary Disease (COPD):** Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.[111] The chronic airflow limitation that is characteristic of COPD is caused by a mixture of small airways disease (e.g., obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person shown in figure 2 and 3.[111]

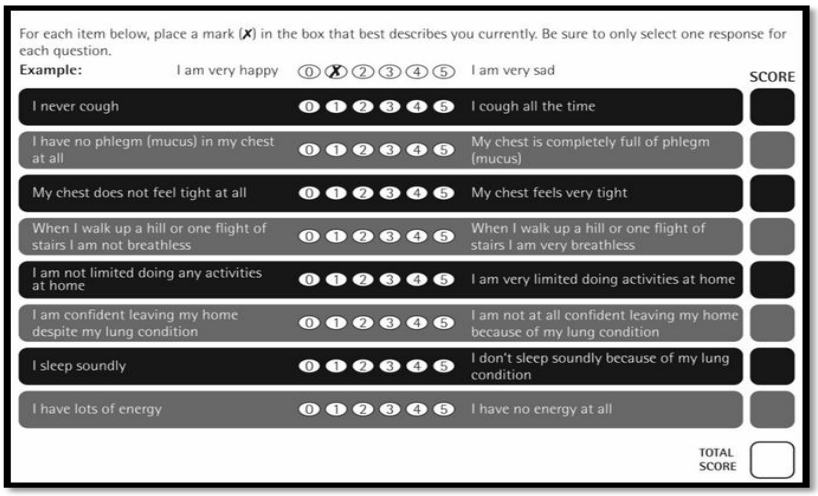



**Figure. 2: CAT Assessment.**

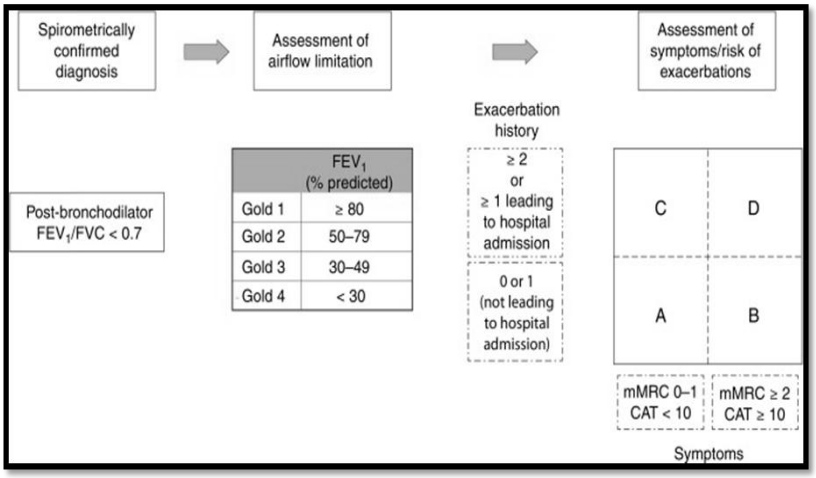



**Figure. 3: The refined ABCD assessment tool.**

## METHODOLOGY

## MATERIALS AND METHODS

**Study Design:** Prospective Observational study

**Study Site:** Department of Pulmonology, SVIMS, Tirupati

**Duration of The Study:** 5 months

**Study Population:** 100 patients

### Inclusion Criteria

1. Patient aged ≥18 years of either sex
2. Patients using Inhalation medications
3. The patients attending follow up

**Exclusion Criteria**

1. Patients under the age of 18 years
2. Irregular and loss of follow up / drug therapy.
3. Pregnant women
4. Patients not willing to participate in the study

**Study Materials**

1. Patient informed consent form.
2. Patient data collection profoma.
3. Asthma Control Test Questionnaire.
4. Modified British Medical Research Council Questionnaire (mMRC).
5. COPD Assessment Test (CAT).
6. Refined ABCD Assessment tool.
7. Assessment of COPD and Assessment of Asthma.

**Data Collection:** The data collected by using the proforma which includes Baseline Demographic, Clinical, Procedural details of Past medical history, Personal history and habits, Systemic examination of CVS, Respiratory System, PFT.

**Ethical Justification**

The institutional ethical committee clearance obtained then proceeded with the study. An informed written consent will be taken from the patients after explaining the nature of the study. The patients will not be forced for participation if they are not willing.

**Statistical Analysis**

Percentages calculated for all categorical variables considering the literature prevalence. Data entered into MS - excel spread sheets. Mean and standard deviation calculated for all continuous variables. SPSS version 20 (Statistical software) utilized for data analysis. Paired t-test for comparing the categorical data. Here we considered null hypothesis and alternate hypothesis for statistical purpose. p value of $\leq 0.05$ considered statistically significant.

**RESULTS**

**Distribution of Patients:** In our study, a total of 100 patients were enrolled. On diagnosis, they were divided into Asthma and COPD. 70%(70) were Asthma patients and 30%(30) were COPD patients as represented in the figure 4.

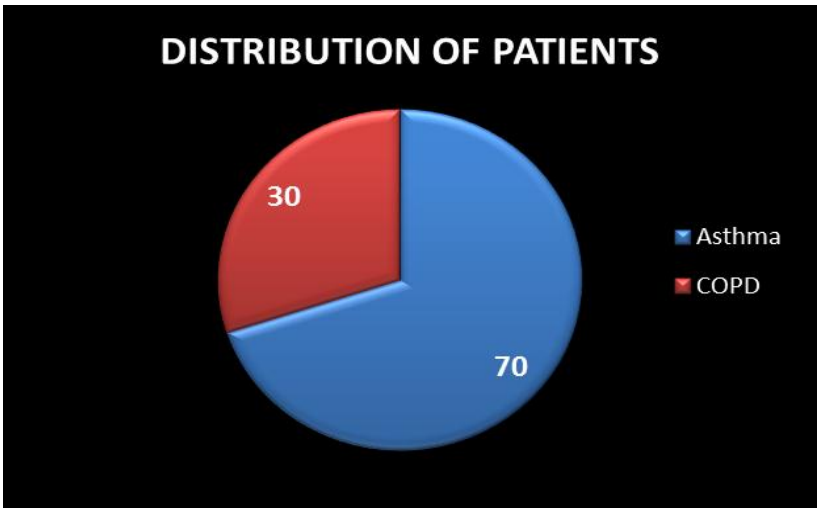
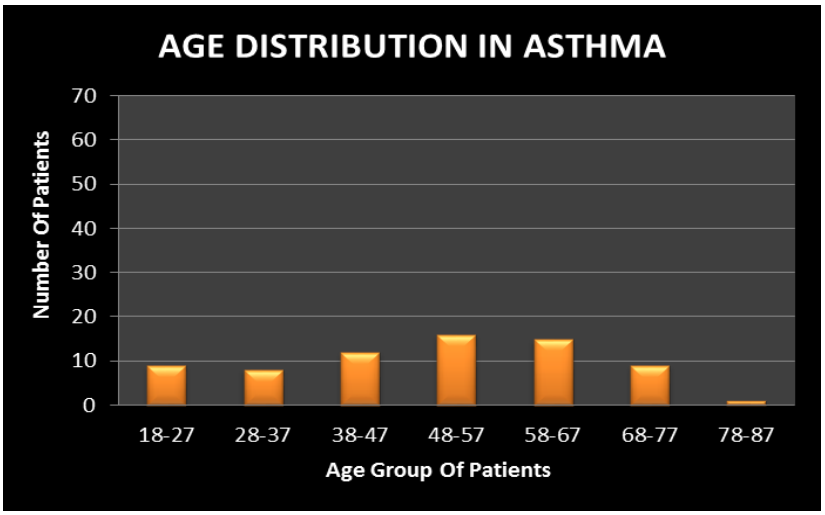



**Figure. 4**: **Distribution of patients.**

### 5.2 Age Distribution

Asthma was most commonly observed in our study for 23%(16) in the age group of 48-57 years followed by 22%(15) in the age group of 58-67 years, 17%(12) in the age group of 38-47 years, 13%(9) in the age group of 18-27 years, 13%(9) in the age group of 68-77 years, 11% (8) in the age group of 28-37 years and 1%(1) in the age group of 78-87 years was shown in figure 5. The mean ± SD age of patients was 49±16.09 years.




**Graph. 5: Age distribution of patients in Asthma.**

COPD was most commonly observed in our study for 33%(10) in the age group of 51-60 years followed by 27%(8) in the age group of 61-70 years, 17%(5) in the age group of 71-80 years, 13%(4) in the age group of 31-40 years and 10%(3) age group of 41-50 years was shown in figure 6. The mean±SD age of patients was 57.7±11.8 years.

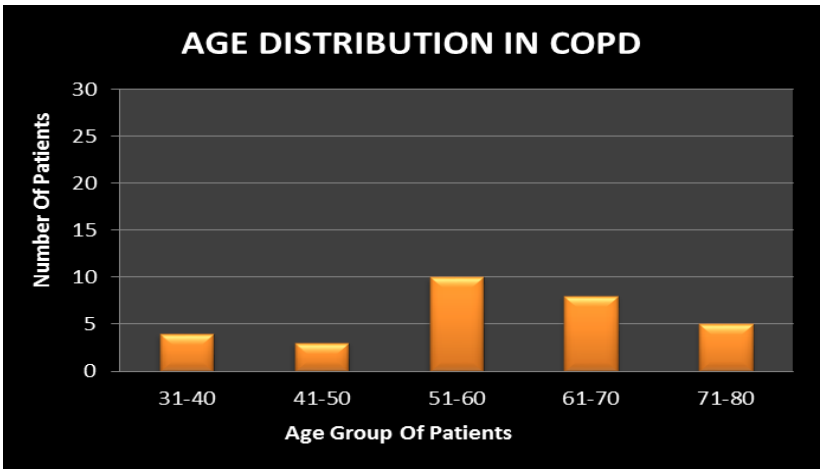



**Figure. 6: Age distribution of patients in COPD**

**1.3 Gender Distribution:** In our study of 70 Asthma patients, 53% (37) were females and 47% (33) were males was shown in figure 7.

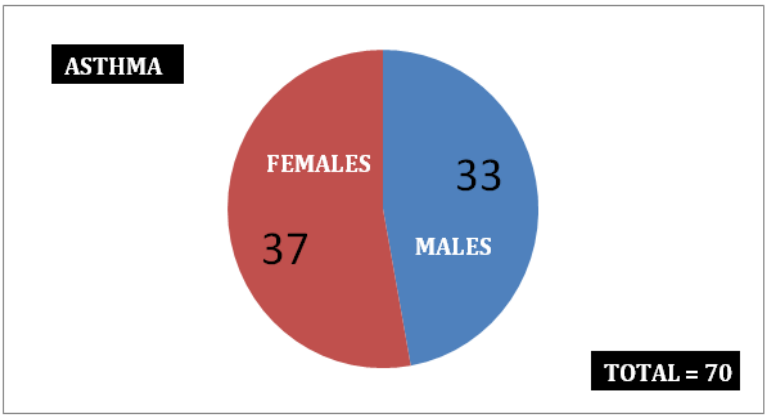
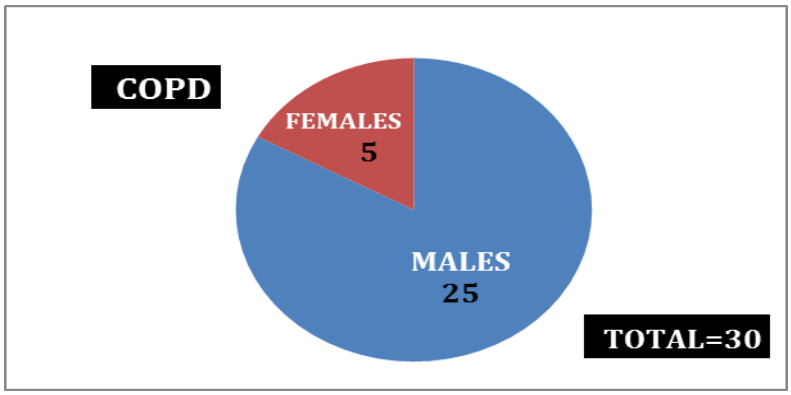



**Figure. 7: Gender distribution of patients in Asthma.**

In our study of 30 COPD patients, 83%(25) were males and 17%(5) were females was shown in figure 8.




**Graph. 8: Gender distribution of patients in COPD.**

### 1.4 Social History

In our study among patients diagnosed with Asthma, 11%(8) of patients were observed to be smokers and 17%(12) were alcoholics was shown in figure 9.

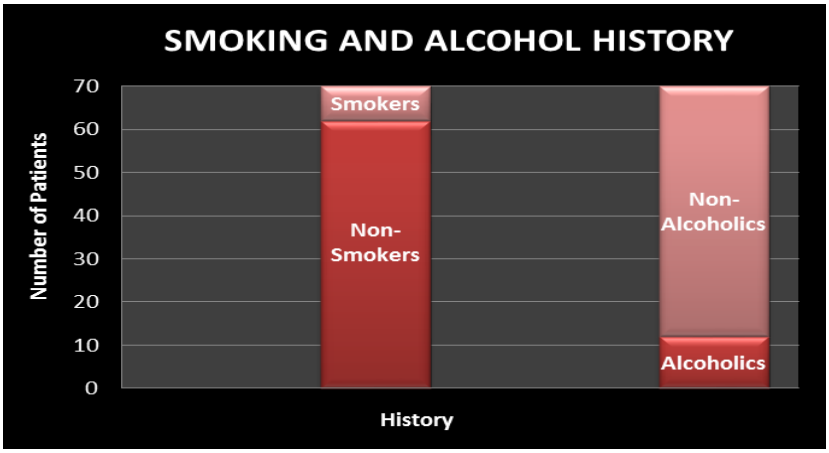



**Figure. 9: Social History in Asthma Patients.**

In our study among patients diagnosed with COPD, 80%(25) of patients were observed to be smokers and 40%(12) of patients were alcoholics was shown in figure 10.

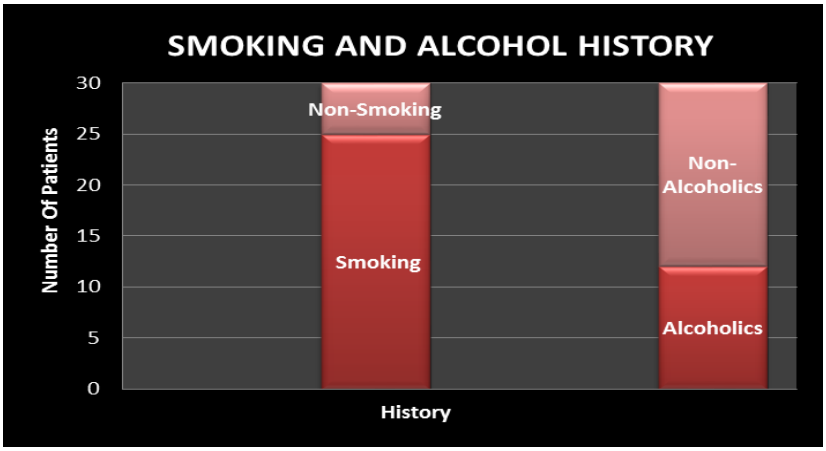



**Figure. 10: Social History in COPD Patients.**

### 1.5 Occupation

The occupation of Asthma patients were observed of 30%(21) Agriculturalist, 22%(15) were Homemaker, 18% (13) were Employee, 12%(8) are students, 5%(4) were in Carpentry and 13%(9) were in other occupation was shown in figure 11.

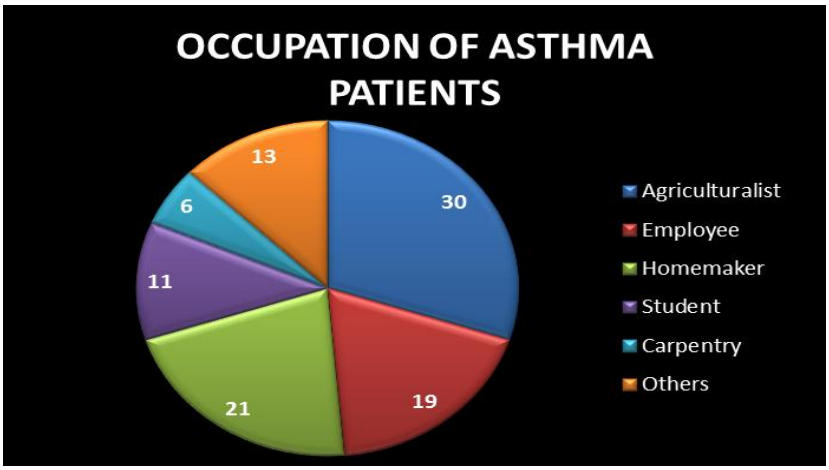



**Figure. 11: Occupation of Asthma Patients.**

The Occupation of COPD patients were observed of 35%(10) Agriculturalist, 17%(5) were Homemaker, 15%(4) were Employee, 5%(2) were Traffic police, 10%(3) were in Carpentry, 10%(3) were Miner and 8%(3) were in other occupation was shown in figure 12.

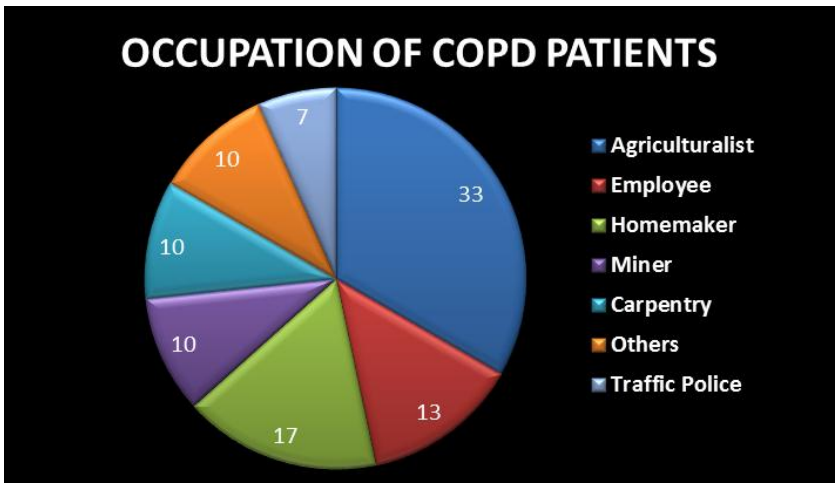



**Figure. 12: Occupation of COPD Patients.**

### 5.6 Socio-Economic Status

Socio-economic status categorized as Upper were 7%(5), Upper middle were 14%(10), Lower middle were 50%(35), Upper lower were 9%(6) and Lower were 20%(14) was shown in figure 13. This was derived by Modified Kuppuswamy scale.

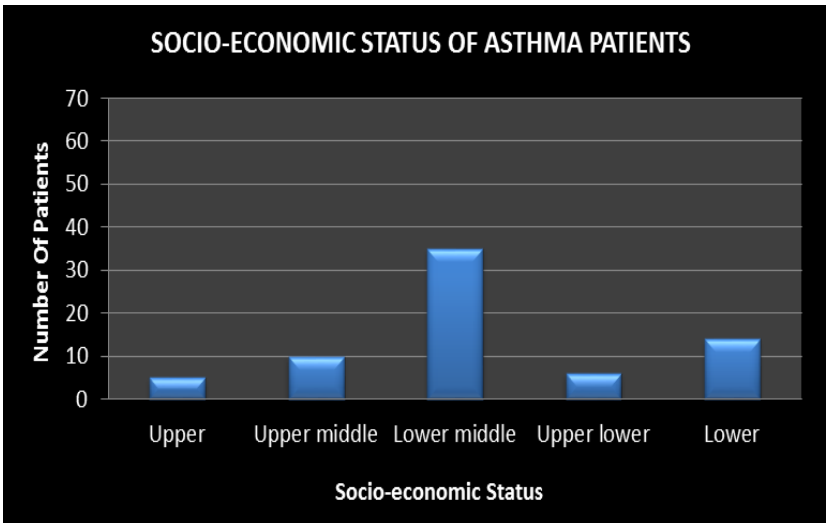



**Figure. 13: Socio-economic Status of Asthma Patients.**

Socio-economic status categorized as Upper were 10%(3), Upper middle were 20%(6), Lower middle were 30%(9), Upper lower were 25%(7) and Lower were 15%(5) was shown in figure 14. This was derived by Modified Kuppuswamy scale.

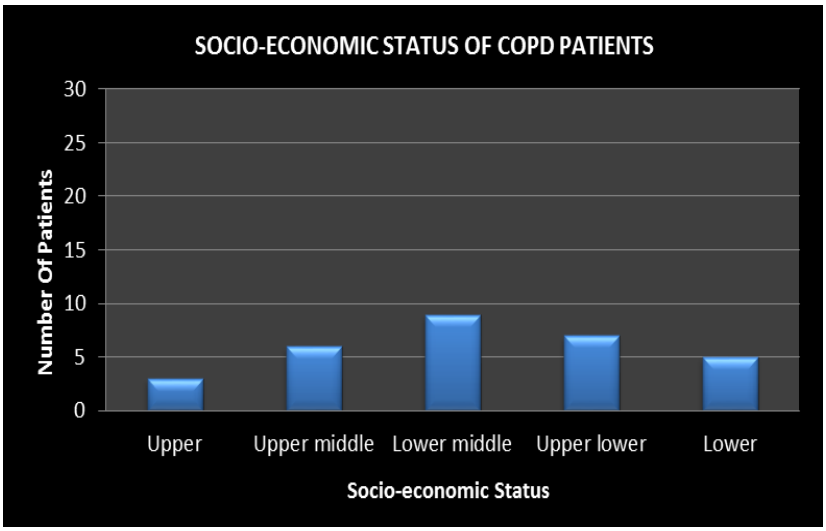



**Figure. 14: Socio-economic Status of COPD Patients.**

### 5.7 Comorbidities

In our study, comorbidities observed in the patients with Asthma were of 19%(13) with both hypertension and diabetes mellitus, 14%(10) with hypertension only, 8%(6) with diabetes milletus only, 5%(3) with Hypertension, Diabetes mellitus & Coronary artery disease(CAD), 10%(7) with other comorbid conditions and 44%(31) with no comorbid conditions was shown in Table 1.

**Table 1: Comorbidities in Asthma Patients.**

| Comorbidities | Frequency | Percent |
|---|---|---|
| Hypertension only | 10 | 14 |
| Diabetes mellitus only | 06 | 08 |
| Both Hypertension and diabetes mellitus only | 13 | 19 |
| Hypertension, Diabetes mellitus & CAD | 03 | 05 |
| Others | 07 | 10 |
| No | 31 | 44 |

In our study, comorbidities observed in the patients with COPD were of 47%(14) with both hypertension and diabetes mellitus, 30%(9) with hypertension only, 3%(1) with diabetes milletus only, 10%(3) with other comorbid conditions and 10%(3) with no comorbid conditions was shown in Table 2.

**Table. 2: Comorbidities in COPD Patients.**

| Comorbidities | Frequency | Percent |
|---|---|---|
| Hypertension | 09 | 30 |
| Diabetes mellitus | 01 | 03 |
| Hypertension and Diabetes mellitus | 14 | 47 |
| Others | 03 | 10 |
| No | 03 | 10 |

**X-RAY FINDING**

In our study, patients were enrolled also basing the reports of diagnosis of clinical symptoms (such as cough, wheezing, breathlessness, chest tightness, mucus and dyspnea), radiographic features and pulmonary function test (PFT), Complete haemogram. The Chest x-ray findings of the 70 Asthma patients were observed to be 46%(32) with Hyperinflation condition, 30%(21) with Bronchial wall thickening and 24%(17) with Normal condition was shown in Table 3.

**Table. 3: Chest Xray Findings of Asthma Patients.**

| Chest x-ray finding | Percent |
|---|---|
| Hyperinflation | 30 |
| Bronchial wall thickening | 24 |
| Normal finding | 46 |

The Chest x-ray findings of the 30 COPD patients were observed to be 27%(8) with Hyperinflation condition, 17%(5) with Increased Bronchovascular Marking, 11%(3) with Bullous lesions, 7%(2) with Cardiomegaly and 38%(12) with Normal condition was shown in Table 4.

**Table. 4: Chest Xray Findings of COPD Patients.**

| Chest x-ray finding | Percent |
|---|---|
| Hyperinflation | 27 |
| Increased Bronchovascular Marking | 17 |
| Bullous lesions | 11 |
| Cardiomegaly | 7 |
| Normal finding | 38 |

**Pulmonary Function Test (Pft)**

In our study, the pulmonary function test of 100 (70 = asthma, 33 = COPD) patients with similar baseline characteristics were evaluated with Pre FEV1 was 72.7% ± 16.7% and 53.6% ± 6.2%; Post $FEV_1$ was 82.4% ± 17.3% and 30.4% ± 5.6% for Asthma and COPD respectively. 70 patients with bronchdilator response greater than or equal to 12% and 30 with less than 12% were confirmed to be with Asthma and COPD respectively was shown in Table 5 & Table 6.This was confirmed as per GINA and GOLD guidelines for Asthma and COPD respectively.

**Table 5: Pulmonary Function Test in Asthma Patients.**

| ASTHMA | MEAN±SD |
|---|---|
| Bronchodilator Response (Mean±SD) | 13.6 ± 3.1 |
| FEV1 % predicted (Mean±SD) | 72.7% ± 16.7% |
| FEV1 % post (Mean±SD) | 82.4% ± 17.3% |

**Table 6: Pulmonary Function Test in COPD Patients.**

| COPD | MEAN±SD |
|---|---|
| Bronchodilator Response (Mean±SD) | 5.14 ± 0.95 |
| FEV1 % predicted (Mean±SD) | 53.6% ± 6.2% |
| FEV1 % post (Mean±SD) | 30.4% ± 5.6% |

**Inhaler Device**

In our study, the most commonly used inhaler devices were metered dose inhalers. Among 100 patients enrolled, 50%(50) were using MDI with spacer, 15%(15) of patients were using MDI without spacer and 35%(35) of patients were using dry powder inhalers was shown in figure 15.

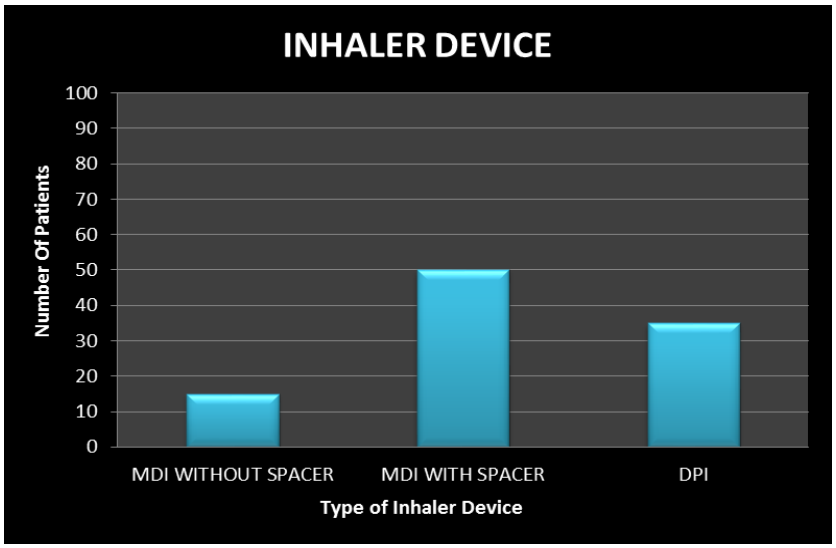



**Figure. 15: Type of Inhaler used by Patients.**

**Nature of Error Observed**

Most common errors made by the patients were "Not Exhaling prior to inhalation and No Breath Hold for 2 to 8 seconds" 25%(25), "Not Shaking inhalers, No Exhale prior to inhalation, No Breath Hold for 2 to 8 seconds" 18% (18), "Not Shaking inhalers and No Breath Hold for 2 to 8 seconds" 13% (13), "Not Shaking inhalers and No Exhale prior to inhalation" 12% (12), "Not Shaking inhalers" 11%(11), "No Breath Hold for 2 to 8 seconds" 10% (10), Not Exhaling prior to inhalation" 5%(5) and 6%(6) patients made no errors. The nature of errors represented in the and figure 16.

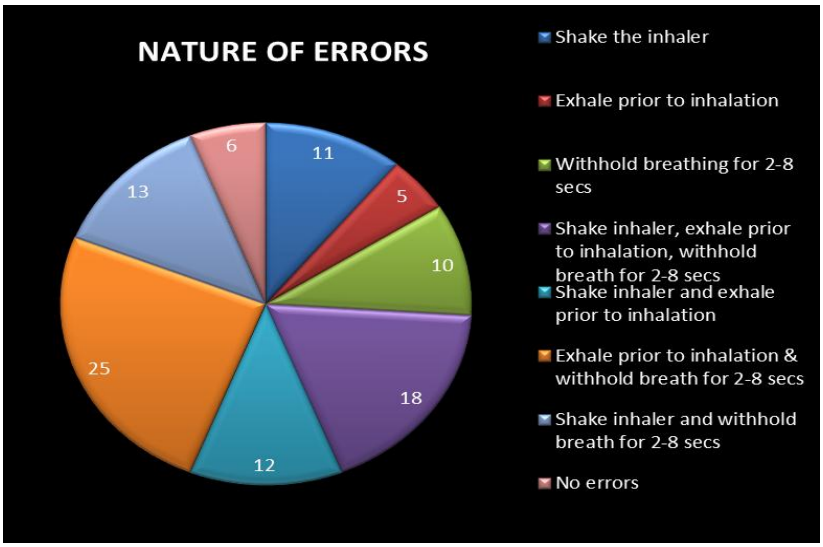



**Figure. 16: Inhalation Technique Errors by Asthma and COPD patients.**

**Assessment of Asthma and Copd**

Patients involved in our study, after meeting the diagnosis criteria, were assessed to know the patients' symptom control and the severity of the disease condition. It was taken in the form of scores to analyse the condition using Asthma Control Test Questionnaire (ACTQ) and COPD Assessment Test (CAT), Modified Medical Research Council Questionnaire (mMRC), ABCD Classification tool for Asthma and COPD respectively. Scores of each patient was collected after taking the consent from the patients, at first visit of the study followed by next 3 visits of every 4 weeks interval and given counseling as per their usage of Inhalers prescribed. score recorded 1st week was considered as baseline and it is compared with the scores recorded at 4$^{th}$ week, 8$^{th}$ week and 12$^{th}$ week.

**5.11 Assessment Of Asthma**

In our study, the Mean±SD and p-value of Asthma patients (70) for ACTQ calculated and represented in the Table 5.13. This was calculated by using Paired t-test. The graphical representation of mean±sd for ACTQ score shown in the figure 17 and figure 18.

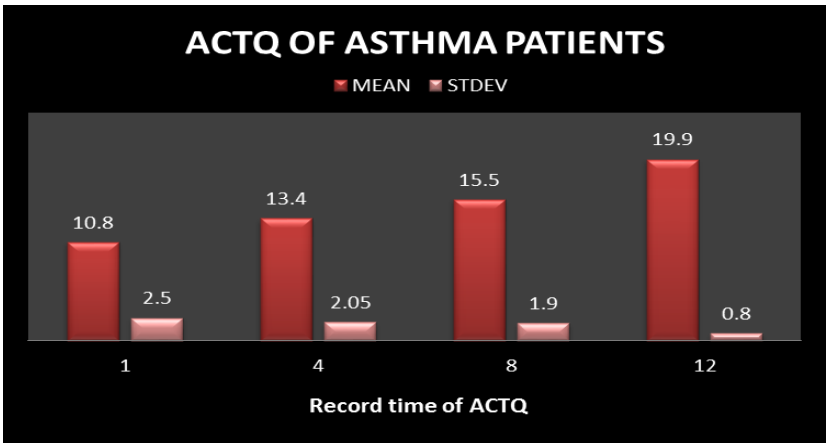



**Figure. 17: ACTQ of patients at 1$^{st}$, 4$^{th}$, 8$^{th}$ & 12$^{th}$ week.**

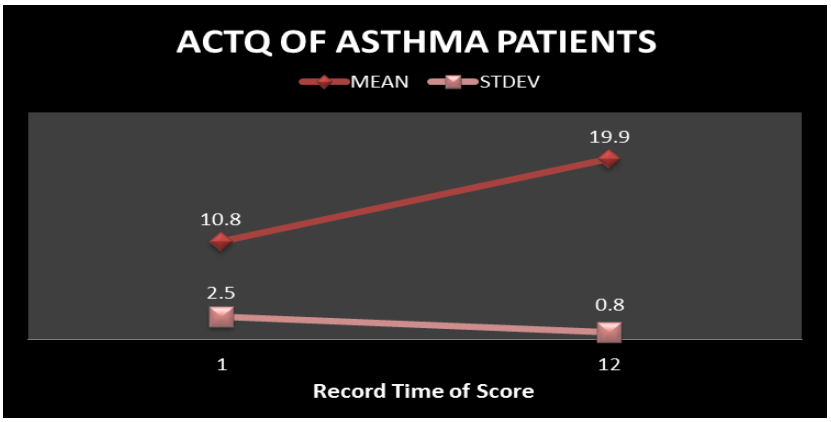



**Figure. 18: ACTQ of patients at 1$^{st}$ & 12$^{th}$ week.**

Improvement of disease control significantly increased from visit 1 to visit 2 (43.3% and 53.6% respectively) and from visit 2 to visit 3 (53.6% and 62.2% respectively) and from visit 3 to visit 4 (62.2% and 79.8% respectively) and from visit 1 to visit 12, p<0.0001.

**Assessment of Copd**

In our study, the Mean±SD and p-value of COPD patients (30) for ACTQ calculated and represented in the Table 5.14. This was calculated by using Paired t-test. The graphical representation of mean±sd for CAT score shown in the figure 20 and figure 19.

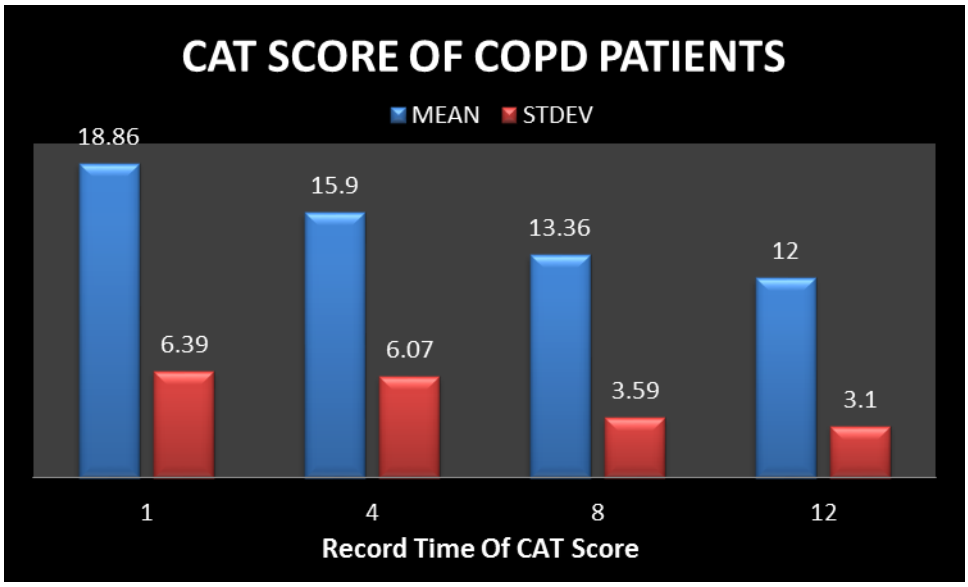



**Figure 19: CAT score of Patients at 1st, 4th, 8th & 12th week.**

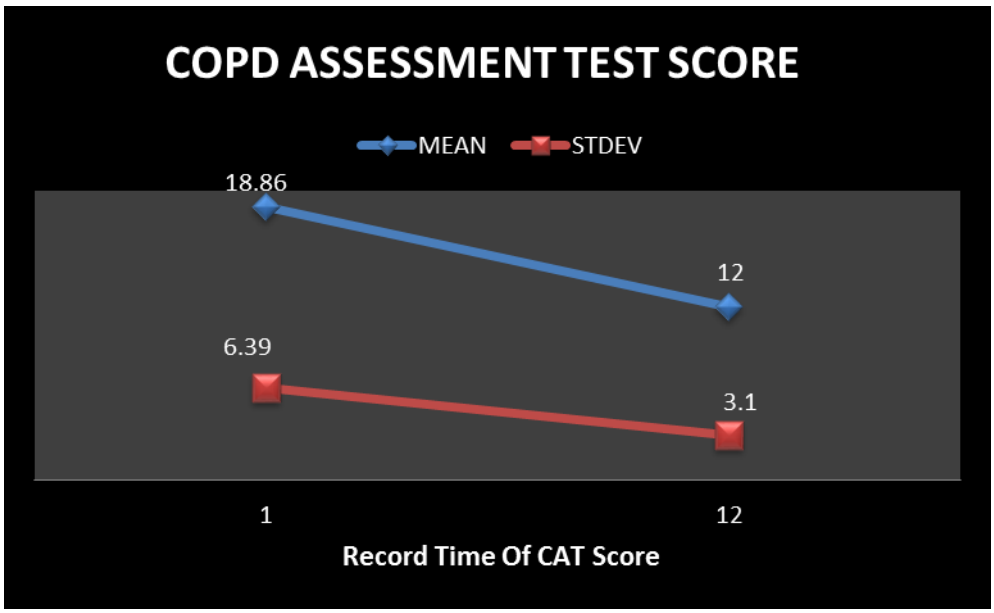



**Figure 20: CAT score of Patients at 1st & 12th week**

In our study, the Mean±SD and p-value for mMRC score of COPD patients (30) calculated. This was calculated by using Paired t-test. The graphical representation of mean±sd for CAT score shown in the figure 21 and figure 22.

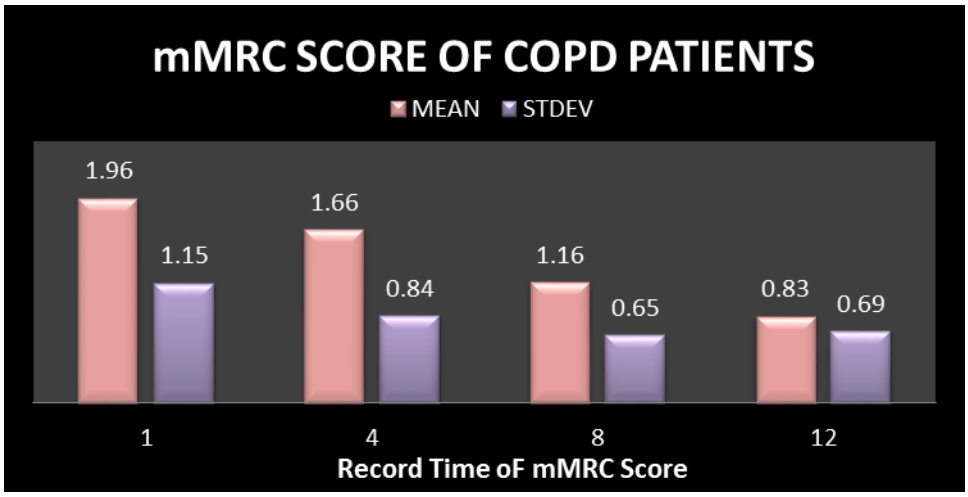



**Figure 21: mMRC score of Patients at 1st, 4th, 8th & 12th week**

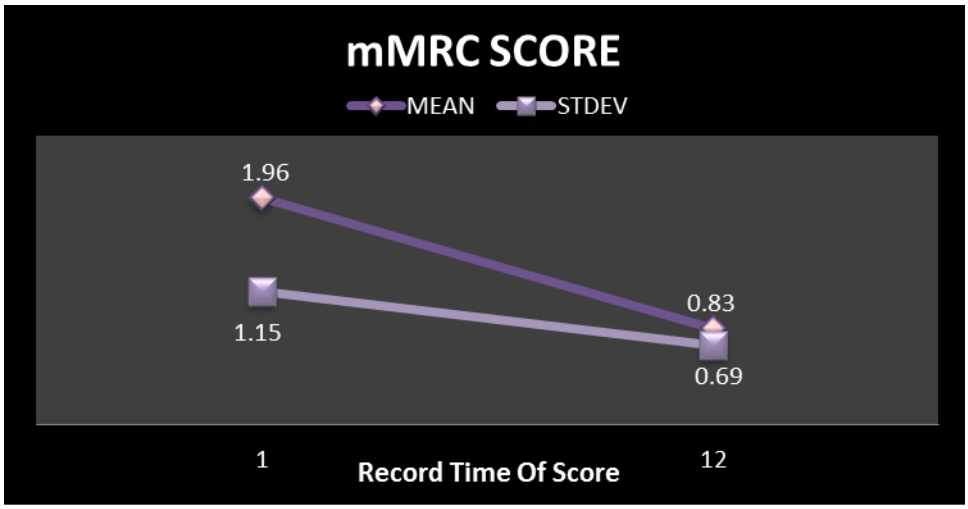



**Figure 22: mMRC score of Patients at 1st and 12th week**

The ABCD Classification of the COPD patients (30) 1st week with A were 23%(7), 37%(11) patients with B, 30%(9) patients with C, 10%(3) patients with D. And at 12th week, the number of patients with A were 30%(9), 44%(13) patients with B, 23%(7) patients with C, 3%(1) patients with D was shown in Table 7. There was gradual improvement in the quality of life of the patients as there partial decrease in the scores from the first day to 12th week. ABCD classification done based on New Gold Guidelines, 2017.

**Table. 7: ABCD Classification on 1st & 12th week.**

| ABCD Classifiaction of COPD patients | No. of patients at 1st week | No. of patients at 12th week |
|---|---|---|
| A | 23%(7) | 30% (9) |
| B | 37%(11) | 44% (13) |
| C | 30%(9) | 23% (7) |
| D | 10%(3) | 3% (1) |

## DISCUSSION

Incorrect technique when using inhaled medicines is very common among patients with asthma or chronic obstructive pulmonary disease. Regardless of the type of inhaler device prescribed, patients of any age are unlikely to use inhalers correctly unless they are given clear instruction, including a physical demonstration and have their inhaler technique checked regularly.

In our study, the patients were observed on the usage of inhalation technique that were prescribed to them after getting consent. They were given counseling on their usage and assessed for a 12-week period with every fourth week as follow up and its effect on the quality of life was closely monitored. The asthma control in selected asthma patients was assessed by using the questionnaire form, asthma control test questionnaire (ACTQ). And the severity of COPD in the selected COPD patients was assessed by using the questionnaire forms, COPD Assessment Test (CAT), Modified Medical Research Council Questionnaire (mMRC) and ABCD Classification tool.

In our study, out of 100 enrolled patients, 70% were Asthma patients and 30% were COPD patients (Graph 5.1 and Table 5.1). In the study conducted by Lokender kumar *et al.*, (2014) in which a total of 300 cases of bronchial asthma or COPD patients.

In our study, out of 70 Asthma patients 53% were females and 47% were males (Graph 5.4 and Table 5.4). The Mean±SD of enrolled patients was 49±16.09 years. Among the selected patients, more number of patients (23%) was observed in 48-57 years age group followed by the age group of 58-67 years (22%) (Graph 5.2 and Table 5.2). In the study conducted by Bharti Chogtu *et al*.,(2017) the mean age of patients was 51.54±14.6 years and 57.3% were females,42.7% were males.

Out of 30 COPD patients 83% were males and 17% were females (Graph 5.5 and Table 5.5). The Mean±SD of enrolled patients was 57.7±11.8 years. Among the selected patients, more number of patients (33%) was observed in 51-60 years age group (Graph 5.3 and Table 5.3).

In the study by Pothirat C *et al.*,(2015) the mean age of patients was 71.2 ± 9.2 and 64.1% were males, 35.9% were females.

In our study, from the social history of enrolled asthma patients 11% of the patients were smokers and 83% were non-smokers. 17% of patients were alcoholics and 80% were non-alcoholics (Graph 5.6). These results were showing compliance with the study by Ra et al., (2017) in which 17.9% of the patients were smokers, 17% were alcoholics.

From the social history of enrolled COPD patients 80% of patients were smokers and 20% were non-smokers. 40% of patients were alcoholics and 60% were non-alcoholics (Graph 5.7). In our study, asthma patients in occupation of agriculture were 30%, homemaker 21%, employees 19%, students 11%, carpentry 6% and others 13% (Graph 5.8). In the study by Bharti Chogtu *et al.,(*2017) home makers were 45.5%, professionals 16.9% and others 22.7%.

COPD patients in occupation of agriculture were 33%, homemaker 17%, employees 13%, carpentry 10%, Miners 10%, traffic police 7% and others 10% (Graph 5.9). In the study by Bharti Chogtu *et al.,(*2017) home makers were 45.5%, professionals 16.9% and others 22.7%. The distribution of patients in different occupations was based on locality the study was conducted. In our study patients in agriculture as occupation were observed to be most affected persons followed by home makers. In the study conducted by Sapkota D *et al.*, (2016) house hold were 80% and service/ labour were 20%.

The distribution of patients in different occupations was based on the locality the study was conducted. In our study patients in agriculture as occupation were observed to be most affected persons followed by home makers.

In our study, the socio-economic status of the asthma patients was categorized as Upper which were of 7%, Upper middle were 14%, Lower middle 50%, Upper lower 9% and Lower were 20% (Graph 5.10). In the study done by Lokender kumar et al.,(2014) documented that lower 9.3%, upper lower 49.7%, lower middle 33% and upper middle 8%.

The socio-economic status of the COPD patients was categorized as Upper which were 10%, Upper middle were 20%, Lower middle 30%, Upper lower 25% and Lower were 15% (Graph 5.11). In the study done by Lokender kumar *et al.*,(2014) documented that lower 9.3%, upper lower 49.7%, lower middle 33% and upper middle 8%.This was categorized based on Modified Kuppuswamy Classification.

In our study, in the asthma patients 44% patients were without any comorbidities, 19% patients were with both hypertension and diabetes mellitus, 14% patients were only hypertension, 10% patients with only diabetes mellitus, 5% of patients with hypertension, diabetes mellitus and coronary artery disease and 10% with other comorbidities (Table 5.6). In the study conducted by sasikala kumaravel et al 71% of the patients were with comorbids and 29% of the patients were without comorbidities. In the study by Bharti Chogtu *et al*.,(2017) documented that 50% were with no comorbidities, 22.4% with hypertension, 15% with diabetes mellitus, 1% with GERD and 20% with others.

In our study, in the COPD patients 47% patients were with both hypertension and diabetes mellitus, 30% with only hypertension, 3% with only diabetes mellitus, 10% with no comorbidities and 10% with other comorbidities (Table 5.7).

The diagnosis of asthma in our study is based on clinical symptoms, chest radiographic features and pulmonary function test (PFT) and complete haemogram. In our study the chest radiograph was performed to all 100 patients.

In asthma patients 46% were with normal findings, 30% with pulmonary hyperinflation and 24% with bronchial wall thickening (Table 5.8). No sputum AFB reported for all the enrolled asthma patients.

In COPD patients 38% were with normal findings, 27% with pulmonary hyperinflation, 17% with increased bronchovascular markings and 24% with bronchial wall thickening, 11% with bullous lesions, 7% patients with cardiomegaly (Table 5.9).

In our study, PFT for 100 (70 = asthma, 33 = COPD) patients with similar baseline characteristics were evaluated at day 0 before commencing for 12-week study.

In asthma patients, the mean ± sd of FEV1% predicted was 72.7% ± 16.7% and bronchdilator response 13.6 ± 3.1 (Table 5.10). This was confirmed as per GINA guidelines. In the study done by Bharti Chogtu *et al*., (2017) in which FEV1 was ≥ 70% in 97 (30%) patients. Mean FEV1 in 1s was 56.31± 20.22.As per GINA guidelines 2017, in adults increase in FEV1 of >12% and more than > 200mL from baseline, 10-15minutes after 200-400mcg albuterol or equivalent (greater confidence if increased is >15%and>400mL) and when FEV1 is low, confirming that FEV1/FVC is reduced (normally >0.75-0.85 in adults) then the patient meet the criteria for asthma confirmatory diagnosis.

In COPD patients, the mean ± sd of FEV1% predicted was 53.6% ± 6.2% and bronchdilator response 5.14 ± 0.95 (Table 5.11). In the study done by pothirat C *et al*., (2015) in which 103 patients were enrolled with moderate –to- severe COPD (51.9% ± 22.5% predicted FEV1).

In our study, the most commonly used inhalers were metered dose inhalers with spacers (50%), metered dose inhalers without spacers (15%) and dry powder inhalers (35%) (Graph 5.12.1).

The inhalation technique errors made by the MDI users was of 36% whereas DPI users it was 60%. Patients who used MDI made significantly fewer mistakes than patients using DPI. The study conducted by Ilse van Beerendonk *et al*., (1998) states the same and in the study by Mohammad Zain Farooq *et al*., (2016) metered dose inhalers were (83.2%) and dry powder inhalers(16.8%).

Independent of the inhaler, our study showing the strongest association between inhaler misuse and older age patients of 36%(25) in Asthma and 50%(15) in COPD.

In our study, among 100 patients 94% patients made mistakes in the inhalation technique. Only 6% of the patients have done proper inhalation technique. Most of the young age people done no errors because educational and socio-economic status. There is no difference in errors between men and women. In the study done by Ilse van Beerendonk *et al*.,(1998) in which 281 patients (88.9%) made atleast one mistake in the inhalation technique.

The most common errors made by patients while performing inhalation technique were not shaking the inhalers before use, donot exhale prior to inhalation, donot withhold breath for 2 to 8 seconds. 11% of patients donot shake the inhalers before use, 5% of patients donot exhale prior to inhalation, followed by 10% patients who donot Withhold breathing for 2 to 8 seconds, 18% patients donot Shake inhalers, donot exhale prior to inhalation and donot Withhold breathing for 2 to 8 seconds and 12% patients donot Shake inhalers and Withhold breathing for 2 to 8 seconds, 25% patients exhaling prior to inhalation, Withhold breathing for 2 to 8 seconds and finally 13% patients donot Shake inhalers and Withhold breathing for 2 to 8 seconds and only 6% patients with no errors during performing inhalation technique. Paula Duarte de oliveira, *et al*,(2014) also reported similar results in which Patient performance of inhaler technique assessed in different ways using inhalation steps: pre inhalation, inhalation and post-inhalation. In our study 70% of the people have done at least

one step incorrectly. In the study done by chaicharn pothirat, *et al.*, (2015) in which seventy-seven patients (74.8%) perfomed at least one step incorrectly. Some patients have done 100% error, they found to be self educated about the inhalation technique (Table 5.12.2) and (Graph 5.12.2). In the study done by Lokender Kumar, *et al.*, (2014) in which self-educated patients committed 100% error. While those trained by a doctor made 56.3% error.

Asthma control is defined as the extent to which the various manifestations of asthma have been reduced or removed by treatment. Futhermore, good adherence to the therapeutic regimen may offer good asthma-related outcomes.

In our study, two category of questionnaire forms were used to evaluate the symptom control and the severity in patients for asthma and COPD. They are asthma control test questionnaire (ACTQ) and COPD Assessment Test (CAT), Modified Medical Research Council Questionnaire (mMRC), ABCD Classification tool for Asthma and COPD respectively.

ACTQ, a short and relatively simple, validated, patient based, five-item questionnaire that is one of the assessment tools for asthma control recommended by GINA. The total ACT scores and responses to individual questions in asthma control and quality of life were assessed for the questions as per the symptoms after the proper instruction of correct inhalation technique.

The ACTQ consists of five questions rated on a scale from 1 to 5. The results of individual questions were added up to a total score, with a range between 5 (completely uncontrolled asthma) and 25 (completely controlled asthma). Patients were placed into the following four different categories based on their results: score<16 (uncontrolled); score ≥16≤19 (poorly controlled) and score if 25 (completely controlled).

In our study, the mean ± sd for the baseline ACT score for the enrolled Asthma patients at 1st week was 10.8± 2.5 and in follow ups at week-4 it was 13.4±2.05, at week-8 was 15.5±1.9 and at week-12 was 19.9±0.8. The mean ± sd of ACTQ scores increased from 1st week for every follow up by the end of the study i.e., from 10.8±2.5 to 14.9±1.8 (Graph 5.13 & Graph 5.14). The average mean ± sd of three follow ups increased from 1st week (16.26±1.58). This shows that the number of patients from partly controlled were significantly improved to well controlled with significant p<0.0001 by the end of the study (Table 5.13). In the study done by Bharti Chogtu *et al*., (2017) patients with improper technique of inhaler device had lower

QOL scores with respect to all the domains in comparison with those having proper technique($p < 0.001$).

The COPD Assessment Test (CAT) is an 8-item uni-dimensional measure of health status impairement in COPD. The goals of COPD assessment test were to determine the level of airflow limitation, its impact on the patient's health status and risk of future events (such as exacerbations, hospital admissions, or death), in order to, eventually guide therapy. The results of individual questions were added up to a total score, explains the severity. The interpretation of CAT score: score>30 (Very High), score>20 (High), score 10-20 (Medium) and score <10 (Low).

The total CAT scores and responses to individual questions in the COPD severity and quality of life were assessed for the questions as per the symptoms after the proper instruction of correct inhalation technique.

In our study, the mean ± sd for the baseline CAT score for the enrolled COPD patients at 1st week was 18.86±6.39 and in follow ups at week-4 it was 15.9±6.07, at week-8 was 13.36±3.59 and at week-12 was 12±3.1 (Graph 5.15 & Graph 5.16). The mean ± sd of CAT scores decreased from 1st week for every follow up by the end of the study i.e., from 18.86±6.39 to 15.03±4.53. The average mean ± sd of three follow ups decreased from 1st week (13.75±3.92). This shows that the number of patients from highly severe were significantly improved to less severe with significant $p<0.0001$ by the end of the study (Table 5.14). In the study done by pothirat C *et al.*, (2015) in which p value for CAT score was 0.075.

Modified British Research Council (mMRC) Questionnaire was considered adequate for assessment of symptoms and relates well to other measures of health status and predicts future mortality risk. It is a simple, five-option grading system. It measured patients' limitation base on a scale of 0-4 and used the final value to determine how much disability was caused by shortness of breath.

The mMRC grade, the response to it and quality of life were assessed after the proper instruction of correct inhalation technique.

In our study, the mean ± sd for the baseline mMRC grade for the enrolled COPD patients at 1st week was 1.96±1.15 and in follow ups at week-4 it was 1.66±0.84, at week-8 was

1.16±0.65 and at week-12 was 0.83±0.69 (Graph 5.17 & Graph 5.18). The mean ± sd of CAT scores decreased from 1st week for every follow up by the end of the study i.e., from 1.96±1.15 to 1.4±0.83. The average mean ± sd of three follow ups decreased from 1st week (1.21±0.72). This shows that the number of patients from highly severe were significantly improved to less severe with significant $p<0.0001$ by the end of the study (Table 5.15). In the study done by pothirat C *et al*., (2015) in which patients with lower quality of life (mMRC score >=2) were more likely to have incorrect inhalation technique.

The severity of COPD at initial stages is assessed by Revised ABCD Classification. It incorporates patient-reported outcomes and highlights the importance of exacerbation prevention in the management of COPD. In our study, ABCD scores for all 30 patients diagnosed with COPD collected time of diagnosis, and after counseling the inhaler technique to patient during follow ups at $4^{th}$ week, $8^{th}$ week and $12^{th}$ week. During $1^{st}$ week, the number of patients with A were 23%, 37% patients with B, 30% patients with C, 10% patients with D. During 12 th week, the number of patients with A were 30%, 44% patients with B, 23% patients with C, 3% patients with D. There was gradual improvement in quality of life of patients (Table 5.16). ABCD classification done in COPD patients based on New Gold Guidelines, 2017.

## 7. CONCLUSION

In our study, the age of asthma and COPD patients ranged from 18 -87 years with a mean age of 49.0 for asthma and 57.7 for COPD. The predominant age group was 48-57 years for asthma and 51-60 years for COPD. 32% in the study has history of smoking and all the smokers in the study were males. Hypertension plus diabetes was the most common associated medical condition for asthma (19%) and for COPD (47%) followed by hypertension for asthma (14%) and for COPD (30%). The diagnosis of asthma and COPD was based on clinical symptoms, PFT and x-ray findings. Sputum AFB was done to all the enrolled patients and reported negative. Normal findings and pulmonary hyperinflation were the most common radiographic features in 76% of asthma patients, pulmonary hyperinflation and increased bronchovascular markings were the most common radiographic feature in 50% of COPD patients. The baseline mean± sd for bronchial response in asthma and COPD patients was 13.6±3.1 and 5.14±0.95, FEV1% predicted for asthma and COPD was 56.31±20.22 and 51.9±22.5 respectively.

Assessment of Asthma control was based on ACT questionnaire as per GINA, with baseline (mean±sd) score at week 1 was 10.84±2.50 followed by 20.92±1.38 at week 12. Assessment of COPD based on CAT questionnaire with baseline (mean±sd) score at 1$^{st}$ week 18.86±6.39 followed by 12.00±3.15 at week 12, mMRC questionnaire with baseline (mean±sd) score at 1$^{st}$ week 1.96±1.15 followed by 0.83±0.69 at week 12 and ABCD classification during 1$^{st}$ week was of 10% with D, 30% patients with C, 37% patients with B, 23% with A. During 12$^{th}$ week, 3% with D, 23% patients with C, 44% patients with B, 30% with A. In our study, the most commonly used inhalers were MDIs with spacers (50%), MDIs without spacers (15%) and DPIs (35%). 36% patients using MDI and 60% patients using DPI made errors in inhalation technique. Among 100 patients 94% patients made mistakes in the inhalation technique. Only 6% of the patients have done proper inhalation technique. Independent of the inhaler, our study showing the strongest association between inhaler misuse and older age patients of 50%.

Our study therefore concludes that inhalation technique in Asthma and COPD patients without face–to-face training was mostly unsatisfactory, especially in patients with low education levels. Face-to-face training significantly decreased incorrect inhalation techniques in patients using pMDIs and DPIs. The most common errors made by patients when using inhalers were not exhaling prior to inhalation and failure to breath-hold after inhalation. Special attention should be given to education regarding inhaler techniques for patients of lower socio-economic status and with less formal education, as well as for those of advanced age and also DPI user's, because they were at a greater risk of committing errors in their use of inhalers.

Poor control of asthma and insufficient information about inhaler were strong predictors for faulty technique of inhaler use. Improper technique in higher age groups makes it obligatory to stress on proper inhalation technique in this subset of patients. Asthma and COPD patients on inhalation medications should have routine assessment of their inhaler technique at every visit and corrected if found to be poor.

Majority of patients using inhalation devices made errors while using the device. Proper education to patients on correct usage may not only improve control of the symptoms of the disease but might also allow dose reduction in long term. Our study concludes in the patient sample that the most patients failed to use their inhaler correctly. Regular instructions and

checkups of inhalation technique were the responsibility of the physician and should be a standard and routine procedure.

**ACKNOWLEDGEMENT**

Completion of this doctoral dissertation was possible with the support of several people.

We would like to express our sincere gratitude to all of them. First of all, it is our Honour to be a part of Krishna Teja Pharmacy College, the esteemed institution and we would like to express our gratitude to **Dr. C. Sucharitha garu**, Honourable Chairperson, Krishna Teja Group of Institutions. **Dr. P. JayaChandra Reddy**, Principal, **Dr. V. Prabhakaran garu**, Vice Principal, Krishna Teja Pharmacy College for providing all the facilities & support necessary for the dissertation work. It was a wonderful experience to be the part of the Institution.

We are extremely grateful to our research guide, **Dr. S. Anusha Rao MBBS,MD**, Department of Pulmonology, SVIMS for her valuable guidance, scholarly inputs and consistent encouragement received throughout the research work. She was with an amicable and positive disposition, she always made herself available to clarify our doubts despite her busy schedules and we consider it as a great opportunity to do the thesis under his notable guidance.

We express our gratitude to **Dr. V. Jayasankar Reddy** $_{\text{M Pharm, PhD}}$, HOD, Department of Pharmacology for our project which was possible only because of the unconditional support provided by him. We are very much thankful and privileged to do our project under his guidance and to learn from his research expertise. We thank, for all his help and support.

The thesis would not have come to a successful completion, without the help of the other doctors, **Dr. k. Preethi MBBS,MD** and staff of Pulmonology Department.

Finally it is the time to express our warm gratitude to our family, friends and relatives for continuous support and encouragement to finalise the Project work.

**REFERENCES**

1. Virchow, J.C., et al., Importance of inhaler devices in the management of airway disease. Respir Med., 2008; 102(1): 10-19.

2. Khassawneh, B.Y., et al., Handling of inhaler devices in actual pulmonary practice: metered-dose inhaler versus dry powder inhalers. Respir Care, 2008; 53(3): 324-328.
3. vanBeerendonk, I., et al., Assessment of the inhalation technique in outpatients with asthma or chronic obstructive pulmonary disease using a metered-dose inhaler or dry powder device. J Asthma, 1998; 35(3): 273-279.
4. Barnes, P.J., Achieving asthma control. Curr Med Res Opin, 2005; 21 Suppl 4: p. S5-9.
5. Molimard, M., et al., Assessment of handling of inhaler devices in real life: an observational study in 3811 patients in primary care. J Aerosol Med., 2003; 16(3): 249-254.
6. Horne, R., Compliance, adherence, and concordance: implications for asthma treatment. Chest, 2006; 130(1 Suppl): 65S-72S.
7. Roy, A., et al., Inhaler device, administration technique, and adherence to inhaled corticosteroids in patients with asthma. Prim Care Respir J., 2011; 20(2): 148-154.
8. Cochrane, M.G., et al., Inhaled corticosteroids for asthma therapy: patient compliance, devices, and inhalation technique. Chest, 2000; 117(2): 542-550.
9. Dolovich MB, Ahrens RC, Hess DR, et al. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians; American College of Asthma, Allergy, and Immunology. Chest., 2005; 127: 335–371. [PubMed]
10. Cochrane MG, Bala MV, Downs KE, Mauskopf J, Ben-Joseph RH. Inhaled corticosteroids for asthma therapy: patient compliance, devices, and inhalation technique. Chest, 2000; 117: 542–550.
11. Goodman DE, Israel E, Rosenberg M, Johnston R, Weiss ST, Drazen JM. The influence of age, diagnosis, and gender on proper use of metered-dose inhalers. Am J Respir Crit Care Med., 1994; 150(Pt 1): 1256–1261.
12. Rootmensen GN, van Keimpema AR, Jansen HM, de Haan RJ. Predictors of incorrect inhalation technique in patients with asthma or COPD: a study using a validated videotaped scoring method. J Aerosol Med Pulm Drug Deliv., 2010; 23: 323–328.
13. Wieshammer S, Dreyhaupt J. Dry powder inhalers: which factors determine the frequency of handling errors? Respiration, 2008; 75: 18–25.
14. Diggory P, Fernandez C, Humphrey A, Jones V, Murphy M. Comparison of elderly people's technique in using two dry powder inhalers to deliver zanamivir: randomized controlled trial. BMJ. 2001; 322: 577–579.
15. Jarvis S, Ind PW, Shiner RJ. Inhaled therapy in elderly COPD patients; time for re-evaluation? Age Ageing, 2007; 36: 213–218.

16. Harvey J, Williams JG. Randomised cross-over comparison of five inhaler systems for bronchodilator therapy. Br J Clin Pract, 1992; 46: 249–251.
17. van der Palen J, Klein JJ, Kerkhoff AH, van Herwaarden CL. Evaluation of the effectiveness of four different inhalers in patients with chronic obstructive pulmonary disease. Thorax, 1995; 50: 1183–1187.
18. Baverstock M et al Do healthcare professionals have sufficient knowledge of inhaler technique in order to educate their patients effectively in their use? Thorax, 2010; 65: (suppl.4): A119.
19. Crompton G et al The need to improve inhalation technique in Europe: a report from the Aerosol Drug Management Improvement Team. Respiratory Medicine, 2006; 100: 1479-94.
20. Lavorini F et al The ADMIT series – Issues in inhalation therapy. Training tools for inhalation devices. Primary Care Respiratory Journal, 2010; 19: 4, 335-41.
21. GINA guidelines 2017:ginaasthma.org.
22. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017:goldcopd.org.