Impact of Inhalers in the Management of Asthma/Chronic Obstructive Pulmonary Disease in General Public

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Abstract

Background- Appropriate selection and adherence to inhalers is essential in the management of Asthma/ Chronic Obstructive Pulmonary Disease. Even though there are some benefits pertaining to the use of inhalers,the drawbacks have led to poor lung capacity among the patients and therefore poorer management and control of disease conditions. **Objective**s- the objectives are to monitor adherence and satisfaction to the inhalers, counsel the patients about right inhaler technique and consequences of incorrect use and to evaluate lung function. **Methods-** This prospective observational study was conducted in three phases namely Evaluation of Test for the Adherence to Inhalers (TAI-10 questionnaire); Health Education Program; Evaluation of Feeling of Satisfaction with inhaler questionnaire (FSI-10). **Results-** The study included 404 subjects where the inspiratory and expiratory lung capacities were measured using three ball incentive spirometer and peak floor meter respectively. After health education program, the lung capacities of the subjects gradually increased which was initially deprived. The p-value for peak flow meter and spirometer which was interpreted using two-tailed t test indicated that the results were statistically significant. Furthermore, scores for TAI-10 and FSI-10 were assessed and results were analysed. **Conclusions-**Poor adherence to the use of inhalers is a major challenge in the management of asthma/COPD, which occurs due to lack of awareness about the right use of inhalers. Hence, the clinical pharmacist should educate the asthma/ COPD patients on the appropriate use of inhaler for the better management of the disorders.

Key words *- test for adherence to inhalers, feeling of satisfaction with inhaler, lung functions, right inhaler technique.*

Introduction

Bronchial asthma and COPD (Chronic Obstructive Pulmonary Disease) are the two major respiratory disorders contributing to the increased mortality and morbidity across the world. According to 2016, global statistics 235 million people affected by asthma worldwide, of which 15 to 20 million people are from India.[1] On the other hand, 90 percents of death associated with COPD occur in low to middle-income countries. It is also estimated that by 2030 COPD becomes the third leading cause of death worldwide.[2]

In countries like India people consider asthma as a stigma and fail to seek health care services, as a result, there is no conclusive evidence about the prevalence of asthma. Besides respiratory inhalers are considered to be the best treatment in the management of bronchial asthma and COPD. There are different types of inhalers that are available and are utilized in the management of asthma. People believe that inhalers are strong medications and are also habit-forming because of

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which they fail to adhere to the therapy. The increased mortality and morbidity rates associated with these disorders occur mainly either due to poor compliance or due to inappropriate use of inhalers. It was also found that there is a dearth of health education pertaining to the need for the use of inhalers in the management of these respiratory illnesses, among the public. The lack of knowledge to incorporate correct techniques may cause depressive episodes due to limitations in the daily activities, poor management of disease condition, and frequent exacerbations leading to poor quality of life.[3]

One of the most common concerns is the feeling of satisfaction with inhaler use. If the patient is satisfied and has a better understanding why the inhaler is used in their case will help us obtain a good control in their condition. Age, disease control, and training in inhalation technique all play a compelling role than a diagnosis in understanding and explaining satisfaction with the device in patients with asthma and COPD. Hence better training and more active monitoring of inhalation techniques will help improve patient satisfaction and outcomes.[4]

Another aspect with inhaler use is adherence. Most of our population are rarely adherent to inhaler use than oral therapies and this nonadherence leads to poor control of lung function, which in turn causes poor management of the underlying condition. Nonadherence is extremely common across all severities of asthma and also a common reason for "difficult asthma" in adults and youngsters. Also, poor adherence to inhalers may be associated with suboptimal outcomes and disease exacerbation. Studies have shown that adherence to inhaled therapy for asthma and COPD probably reduces the risk of exacerbation by improving both symptoms control and disease outcomes.[5]

Precise use of inhalers in administering the drugs has a direct relationship with the delivery and efficacy of these medications. When the technique of inhalation is poor, the drugs are often not delivered appropriately to the lungs leading to poor treatment outcomes. Poor inhalation technique leads to poor efficacy of medications; the prescription of more or additional medication with a higher probability of side-effects; increased costs; frequent hospitalizations and emergent department visits.[6]

Once the proper inhalational technique is incorporated, the patients' satisfaction with their inhaler use and the level of adherence to the inhalers may yield a positive prognosis and good quality of life.

The purpose of the current study was to monitor the vital steps in the inhaler use so as to avoid treatment failure, interruption of daily activities due to poor management, non-adherence, and recurrent hospital admissions. Hence the current study was designed to assess the compliance of patients with inhaler use by checking the subjects' adherence, counseling the patient about the right use of inhalers, evaluate lung functions, educate the consequences of incorrect inhaler use and estimate satisfaction with inhaler use.

Materials and Methods

A prospective observational, community-based study was carried out for a period of six months in south Bengaluru. The subjects with a self-reported medical history of asthma/COPD and belonging to the age range between 15 and 85 years were recruited into the study. The need for the study was explained and oral consent was obtained from the subjects willing to participate in the study. The data on subject demographics were obtained. The satisfaction and adherence to the inhaler use was assessed using questionnaires such as Feeling of Satisfaction with Inhalers (FSI), and Test for Adherence to Inhalers (TAI) respectively. While the lung functions were measured using a peak flow meter and three ball incentive spirometer. Additionally, Lupihaler, Rotahaler, Metered-dose inhaler, Accuhaler and Zerostat Spacer were used to demonstrate the correct technique of inhaler use.

The study was conducted in three phases:

Phase 1:- Evaluation of Test for the Adherence to Inhalers (TAI-10 questionnaire);

In this phase, the study subjects were interviewed face-to-face, and information regarding their demographic details and current therapy was captured in

the data collection form. In addition, study subjects were asked to answer the TAI questionnaire to assess the level of adherence. Later, the subjects underwent screening for their lung function by performing spirometer and peak expiratory flow meter for 3 consecutive times, and the average of the readings was documented.

Phase 2: Health Education Program by demonstrating the steps to use inhalers

In this phase, the study subjects were asked to demonstrate the steps they followed usually while using an inhaler. If an incorrect technique was observed, the corrections were explained (Health Education Program) and ensured proper use before closing the session by asking the patients to explain the corrections and demonstrate (without giving themselves another dose) how they would now administer their medications. During the Health Education program, the subjects were instructed about the steps to be used while inhaling and importance of each step was discussed along with the consequences of incorrect inhaler use and their impact on the severity of Asthma/COPD.

Phase 3: Assessing the satisfaction with the current inhaler using Feeling of Satisfaction with inhaler questionnaire

This phase was conducted after an interval of one week where Patient satisfaction with his or her current inhaler was assessed with the specific Feeling of Satisfaction with Inhaler (FSI-10) questionnaire. At the end of this phase, the subjects' lung function was screened similar to that of Phase 1.

Statistical Analysis

The obtained data were analyzed using SPSS Software version 17. The percentage and numbers were used to summarize categorical variables. A two-Tailed t-test was used to analyze the values of the lung function tests that are 3-ball incentive Spirometer and Peak flow meter, keeping the significance as 0.05%.

Results

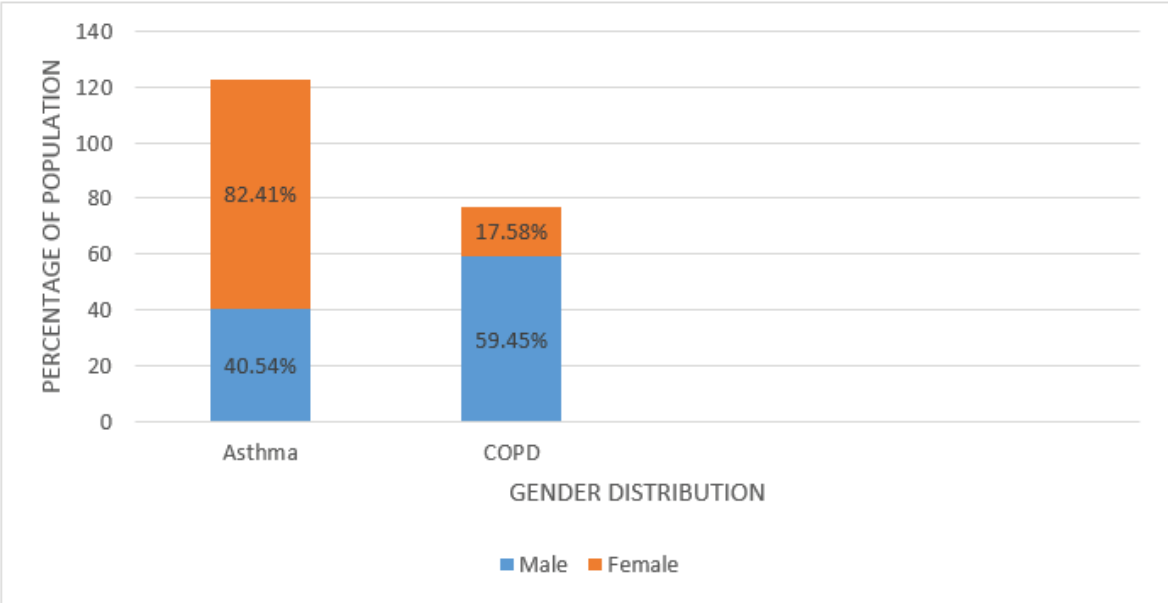

Figure 1: Gender distribution based on asthma and COPD

Figure 1: In the current study, a total of 404 patients with asthma or COPD were enrolled and followed up with an interval of one week. Among the 404 subjects, 182 (45.05%) were females and 222 (54.95%) were males. Also, 240 (59.40%) subjects had asthma and 164 (40.59%) subjects had COPD. The prevalence of asthma was more in females while the prevalence of COPD was more in males.

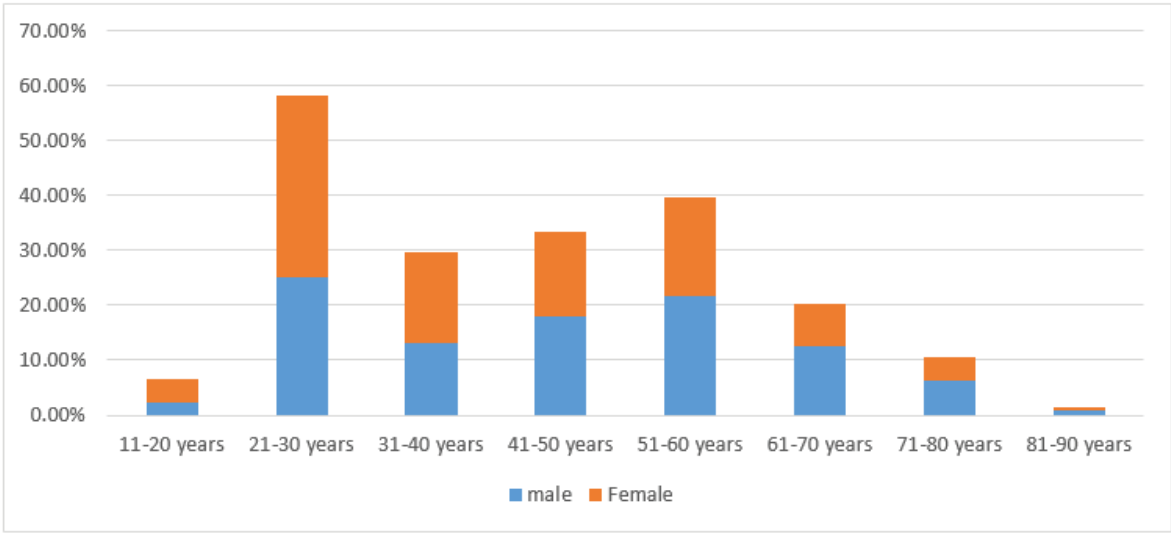

Figure 2: Distribution of patients based on age group:

Figure 2: The overall age group of the subjects ranged from 15 years to 85 years. The maximum number of asthma or COPD patients were in the age group ranging from 21-30 years

Table 1: depicts that 64(15.8%) subjects had poor expiratory lung capacity and 340(84.15%) subjects had average expiratory lung capacity during Phase 1. After one week interval, it was observed that 22(5.44%) subjects had poor expiratory lung capacity, 361(89.35%) subjects had average expiratory lung capacity and 21(5.19%) subjects had good expiratory lung capacity at Phase 3 of the study.

Table 2: revealed 228(56.43%) subjects had poor inspiratory lung capacity and 176(43.56%) subjects had average lung capacity at Phase 1 of the study. After an interval of one week, it was observed that 57(14.10%) subjects had poor inspiratory lung capacity and 347(85.89%) subjects had average inspiratory lung capacity at Phase 3 of the study

Table 3: shows that 13(3.21%) subjects had good adherence to inhalers having the score =50, 44(10.89%) subjects had intermediate adherence with the score ranging from 46-49 and 347(85.89%) subjects had poor adherence with the score ≤45 indicating that more subjects were seen with poor adherence.

Table 4: represents that FSI-10 scores by group and for the whole study population. The asthma group was more satisfied overall having the mean percentage of 94.23% v/s 93.26% and the highest rated item in both the groups was item 1(easy to learn to use an inhaler) which had a positive rate of 98.16% and 97.68% in both Asthma and COPD subjects respectively. Again the second highest item in both subjects was item 10 (overall satisfaction) with a positive rate of 98.12% and 96.34%. In contrast the 2 lowest rated items were the same for both that is item 4(easy to clean inhaler) with a rate of 82.66% and 85.36% and item 5(normal activities) with a rate of 88.5% and 88.17% respectively.

Table 1: Grouping subjects based on peak flow meter before and after follow up:

PFER (L/min)	Before follow up	After follow up
Poor	64 (15.8%)	22 (5.44%)
Average	340 (84.15%)	361 (89.35%)
Good	-	21(5.19%)
Total (N)	404 (100%)	404 (100%)

Table 2: Grouping subjects based on spirometer before and after follow up:

Spirometer (three ball test)	Before follow up	After follow up
Poor	228 (56.43%)	57 (14.10%)
Average	176 (43.56%)	347 (85.89%)
Good	-	-
Total (N)	404 (100%)	404 (100%)

Table 3: TAI adherence level

TAI- 10 item question scores	No. Of responses (N)	Percentage of responses (%)	Interpretation
=50	13	3.21	Good Adherence
46-49	44	10.89	Intermediate Adherence
≤45	347	85.89	Poor Adherence

Table 4: Feeling of Satisfaction with Inhalers

Item (Q.No.) In questionnaire	Asthma total score	Percentage of item the score for asthma(%)	COPD total score	Percentage of item score for COPD (%)
1	1178	98.17	801	97.68
2	1140	95	785	95.73
3	1169	97.42	782	95.36
4	992	82.67	700	85.36
5	1062	88.5	723	88.17
6	1168	97.34	784	95.60
7	1163	96.92	773	94.26
8	1114	92.84	737	89.88
9	1144	95.34	773	94.27
10	1181	98.12	790	96.34

Discussion

Control of the disease is not established in practice even though there are several inhalational therapies to assist in the control of Asthma/COPD. One of the significant reasons is poor inhalational techniques whereas lack of education among the patients and lack of time for the physicians to counsel the appropriate measures to use the inhalers have also contributed to the failure of disease control.

Out of 404 subjects enrolled, 222(54.95%) were males and 182(45.05%) were females. Among 404 subjects enrolled, 240(59.40%) subjects had asthma and 164(40.59%) subjects had COPD. Out of 240 subjects having Asthma 90(37.5%) subjects were male and 150(52.5%) subjects were females. Out of 164 subjects having COPD, 132(80.48%) subjects were males, and 32(19.51%) subjects were females (Figure 1). Most of the Asthma and COPD subjects had ages ranging from 21-30 years (Figure 2).

Out of 404 subjects, it was observed that 64 (15.8%) subjects had poor expiratory lung capacity and 340(84.15%) subjects had average expiratory lung capacity during Phase 1. After one week of health education, it was observed that 22 (5.44%) subjects had poor expiratory lung capacity, 361(89.35%) subjects had average expiratory lung capacity and 21(5.19%) subjects had good expiratory lung capacity at Phase 3 of the study. The health education program on the right use of inhalers showed an improvement in lung function (Table 1). It was found that there was a statistically significant association between the right use of inhalers and improvement in lung capacity at $p<0.00001$. Therefore, there is an association between good inhaler technique and lung capacity. Similar findings were observed in a study by Bassam Mahboub et al, where PEFR, with or without questionnaire could be used as a simple tool in the primary health care setting to determine the airflow limitation compatible with COPD.[7]

While using the spirometer, it was observed that out of 404 subjects 228(56.43%) subjects had poor inspiratory lung capacity and 176 (43.56%) subjects had average lung capacity at 1st Phase of the study. After an interval of one week, it was observed that 57(14.10%) subjects had poor inspiratory lung capacity and 347(85.89%) subjects had average inspiratory lung capacity at the 3rd Phase of the study (Table 2). This was similar to the study conducted by Tatiana Zacarias Rondinel et al which concluded that Incentive Spirometer provides an improvement in asthma control and quality of life for patients with severe asthma.[8]

Out of 404 subjects, it was observed that 13(3.21%) subjects had good adherence to inhalers having the score =50, 44(10.89%) subjects had intermediate adherence with the score ranging from 46-49 and 347(85.89%) subjects had poor adherence with a score ≤45 (Table 3). Our study concluded that a high proportion of participants had poor lung function before counselling using TAI(Test for Adherence to Inhalers)[9], where similar outcomes were observed in the study conducted by Vincent Plaza et al which inferred that TAI is a reliable and homogenous questionnaire to identify easily non-adherence and to classify from a clinical perspective the barriers related to the use of inhalers in asthma and COPD. [10]

The health Education given in Phase 2 was found to be beneficial as a significant increase was observed in lung function. It was noticed that proper inhaler use/technique also improved lung function. Thereby a reduction was seen in clinical manifestations of Asthma/ COPD.

The FSI-10[11] is a self-completed 10-item questionnaire to assess patient opinions regarding ease or difficulty of use, portability, and usability of devices for delivery of inhaled medications. We grouped the patient responses on 5-point scale into positive ("yes "and "frequently") and negative responses ("rarely" and "no"), the highest-rated item in both the groups was item 1(easy to learn to use an inhaler) which had a positive rate of 98.16% and 97.68% in both Asthma and COPD subjects respectively. Again the second highest item in both subjects was item 10 (overall satisfaction) with a positive rate of 98.12% and 96.34%. In contrast, the 2 lowest rated items were the same for both is item 4(easy to clean inhaler) with a rate of 82.66% and 85.36%, and item 5(normal activities) with a rate of 88.5% and 88.17% (Table 4). It is easy to understand, complete and infer the difference in patients' satisfaction with different inhalers. This was similar to the study conducted by Miguel Perpina Tordera et al which concluded that FSI-10 is a useful instrument for assessing the degree of satisfaction of asthmatic patients regarding available inhalation devices which were easy to understand and complete, and was able to identify differences in patient

satisfaction with the different inhalers.[12]

In the current study, poor adherence to the inhaler use (poor adherence value) was identified before the health education session, which was clinically evident with the low lung function (Table 1 & Table 2). During the health education session, the right steps involved in the use of inhalers were demonstrated personally. In the follow-up visit, the lung function values of the study subjects showed an improvement (Table 1 & Table 2), which may indicate an improvement in the adherence to inhaler use. However, the study subjects were found to be satisfied with the use of inhalers (Table 4). The health care team should work to improve patient satisfaction with the use of inhalers because improved satisfaction may increase the adherence rate, which helps in better management of asthma or COPD. This decreases the morbidity and mortality rate, health care costs, and emergency admission to the hospital.

Limitations of The Study

The limitations of our study were the follow-up interval for the lung function tests were of a short period, medications used by the patients were not taken into consideration, the steps missed by the subjects during inhalation was not documented, however, the incorrect steps were corrected by oral communication. Limitations inherent to the FSI-10 scale may also have influenced our results, as no minimum score have been established to determine clinically relevant differences and the cut-off level to distinguish between high and low-level satisfactions was arbitrary.

Future Directions:-

Pharmacist intervention to patients about inhaler technique and medication adherence had improved outcomes in disease control. Hence pharmacists taking part in therapy and management of asthma and COPD can help the patients be more educated about their disease and medications; and improve disease control and therapy outcomes.

Conclusion

Poor adherence to the use of inhalers is a major challenge in the management of asthma/COPD, which occurs due to lack of awareness about the right use of inhalers. Hence, the clinical pharmacist should educate asthma/ COPD patients on the appropriate use of an inhaler for the better management of the disorders.

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Conflict of Interest- None

Ethical Clearance: ethical clearance was taken from Institutional Ethics Committee of PES College of Pharmacy, Bangalore.

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