Original Article

A Prospective Interventional Study On Clinical Pharmacist Assisted Counselling Towards Usage Of Inhaler Devices And Its Impact On Copd And Asthma Patients

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Abstract

Background: Asthma and COPD are the respiratory diseases. Asthma is a persistent lung disease presented with chronic cough, SOB that occurs from bronchial hyper responsiveness and inflammation. COPD is also known as COAD (Chronic obstructive airway disease) is the airway obstructive disease which leads to obstruction of the airflow that is either partially or completely and results in dysfunction of the lungs disease. The purpose of the study is to provide the clinical pharmacist assisted counselling towards usage of inhaler devices and assessing its impact by using inhaler specific checklist for both MDI,DPI and nebulizer assessment. Inhaler devices such as nebulizer, metered dose inhaler (MDI), dry powder inhaler(DPI) have an advantageous impact in control of asthma and COPD.

Materials and Methods: A prospective interventional study was held for half of the year. All the data were collected, documented and analyzed based on standard protocol. The collected data were statistically analysed by using paired T –test.

Results: In this study we observed that patients had improved the correct usage of inhaler devices after counselling than before and also helps to relieve from symptoms.

Conclusion: We conclude that patients had improved their performance on usage of inhaler devices in post counselling than to pre counselling. The involvement of clinical pharmacist in counselling shows improvement on correct usage of inhalation technique in COPD and asthma patients.

Keywords: Asthma, COPD, Inhaler devices, SOB, Counselling.

INTRODUCTION:

Asthma:

Asthma is a persistent lung disease mainly presented with recurrent gasp, cough and SOB occurs as a result of swelling and hyper responsiveness of the airways. As per epidemiological data united states has the higher disease rate of asthma that is it affects about 20million individuals.[1]

Classification of Asthma:

Patients with asthma are categorized in to:
Extrinsic asthma Intrinsic, asthma Occupational asthma Potentially fatal asthma Exercise induced asthmaCough variant asthma[2]. The goal of therapy is the control of symptoms. Such control of symptoms can be obtained through proper patient education about medication, life style modifications, avoidance of exposure to triggering factors, individualized, pharmacotherapy and regular follow up.[3]

COPD:

COPD is a persistent pathological condition in which airway limitation is seen due toover production of phlegm, severe cough and inflammation of airways. One of the strongest cause behind the COPD is cigarette smoking. Depending on production of phlegm and age, COPD is categorized in to chronic bronchitis and emphysema.
Patients with COPD are more prone to lung infections caused by bacteria or virus.[4] Triggering factors of Asthma and

COPD includes tobacco, alcohol consumption , respiratory tract infections, smoke ,perfumes , laughter , a dirty surroundings , air conditioning, rain, traffic fumes, citrus fruits, esophageal reflux, house hold animals, flowers or pollen grains , medication , psychiatric factors.[5]

Epidemiology:

In world wide the third most leading disease that results in death is COPD, according to epidemiological data over 80% of deaths are occurred due to COPD .[6]

In 2016, WHO reported that asthma affected 235 million people around the world, in which India had affected rate of 15-20 million people.[7,8]

In India, the prevalence of asthma in women of age group 15-49 years is 2% and asthma in men of age group 15-49 years and women of age group 15-19 years is 1% were reported in developing countries.[9]

Inhaler devices:

Inhaler devices are the first choice of treatment in the management of asthmaand COPD. These devices directly delivers the drug in to the airways. The most commonly used four types of inhalers were:

Nebulizers:

Nebulizers or inhalators.Dry powder inhalers.

Metered dose inhalers.Soft mist inhalers.

These devices are highly preferred devices by gediatric patients with physical and psychological impairment and for pediatric patients because of its ease of use. The only requirement of nebulizer is to take quick inhalations.[10]Although usage of MDI and DPI has been increased but still the nebulizers are continuing in selected patients.[11]The performance of nebulizers can be analyzed by using two main parameters. They are: the droplet size distributionof the aerosol and the drug output rate. These two parameters are usually determined by the design of the device and the user conditions of the nebulizer. Based on laboratory evaluation the type of nebulizer is selected for individual patient[12].

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Dry powder inhalers (DPI):

In this type of devices, the drug powder is scattered by the energy that is produced by inhalation. This scattered drug is delivered to the lungs[13].

It contains a blend which consists of both active drug and larger carrier molecules. Active drug is carried by larger carrier molecules. Active drug particles enters the airways to show the therapeutic effect while carrier molecules deposit in the mouth. [14]

Steps to use dry powder inhaler:

1. To load the medication dose device instructions should be followed.
2. Breathe off completely while standing or sit up straight.
3. Hold the mouth piece in to mouth and breathe in quickly and energetically with lipsclosed tightly around the inhaler while breathing.
4. Remove the device from your mouth and hold the breathe for 5-10 sec then expirateslowly.
5. While using a capsule device, open and check the device whether the drug is completely inhaled or not .If not inhale again or if completely inhaled discard the capsule.
6. Use a dry cloth to clean the mouth piece and do not rinse with water.
7. Close the device and store it in a dry place. [15]

Metered dose inhalers (MDI'S):

A key components of PMDI consists of: Propellants, Formulation, A metering valve, Actuator, all these key components helps in the spray formation and helps in the determination of transport of drug to the lungs.[16]

Steps to use MDI:

1. Remove sputum completely before inhalation.
2. Shake well the inhaler before use.
3. Hold the lips tightly around the mouth piece.
4. Uplift the head slightly.
5. Breathe out deliberately, while emptying the air in the lungs.
6. Activate the aerosol by breathing intensely and keeping the tongue down.
7. Wait for 10-15 sec and then exhale slowly.
8. Use warm water for cleansing your mouth.[17]

AIM AND OBJECTIVES:

The aim of this study is to provide the clinical pharmacist assisted counseling towards usage of inhaler devices and its impact on asthma and COPD patients. The objectives of this study is to educate the patients regarding the usage of inhaler devices, to estimate the patient adherence by using inhaler devices, to assess the impact of inhaler device regimen in patients with asthma and COPD, to ensure the efficacy of inhaler devices.

METHODOLOGY:

This prospective hospital based interventional study is carried out at Santhiram medical college and general hospital, Nandyal, Andhra Pradesh, India. This study included a total of 152 subjects attending the pulmonology department. Informed consent was obtained from all subjects. Patients who are diagnosed with asthma and COPD, patients with all age groups, patients with informed consent forms are included in the study. Participants who are unwilling to join the study, pregnant and breast feeding women are excluded from the study. The study involves the counseling of asthma and COPD patients towards usage of inhaler devices by clinicalpharmacist and assessing the impact of counseling at the time of follow up by using item score check list. The statistical tool used for this study is paired T- test.
The study protocol was approved by institutional ethics committee.

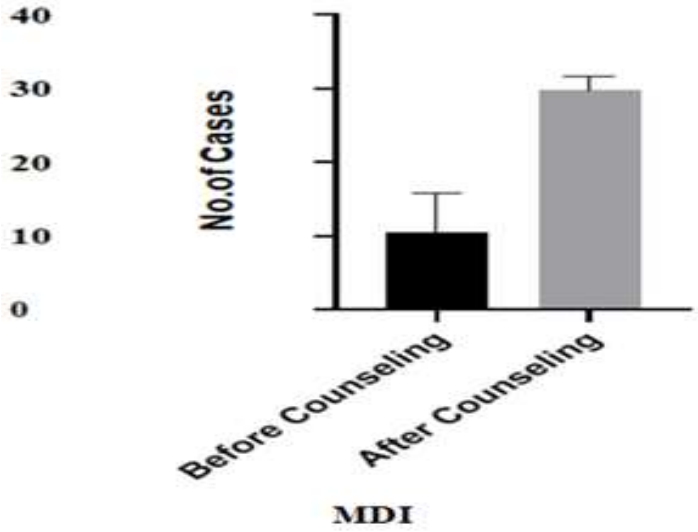
Statistical Test for MDI usage before and after counseling:

Normality and Log-normality test

Test for normal distribution	BeforeCounselling	AfterCounselling
Anderson-Darling test		
A2*	0.7930	0.4238
P value	0.0257	0.2539
Passed normality test (alpha=0.05)?	No	Yes
P value summary	*	Ns
D'Agostino & Pearson test		
K2	3.232	1.110
P value	0.1986	0.5742
Passed normality test (alpha=0.05)?	Yes	Yes
P value summary	ns	Ns
Shapiro-Wilk test		
W	0.8142	0.9011
P value	0.0216	0.2254
Passed normality test (alpha=0.05)?	No	Yes
P value summary	*	Ns
Kolmogorov-Smirnov test		
KS distance	0.2292	0.1875
P value	>0.1000	>0.1000
Passed normality test (alpha=0.05)?	Yes	Yes
P value summary	ns	Ns

Column B	After Counselling
vs.	vs.
Column A	Before Counselling
Paired t test	
P value	<0.0001
P value summary	****
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=12.75, df=9
Number of pairs	10
How big is the difference?	
Mean of differences (B - A)	19.40
SD of differences	4.812
SEM of differences	1.522
95% confidence interval	15.96 to 22.84
R squared (partial eta squared)	0.9475
How effective was the pairing?	
Correlation coefficient (r)	0.5026
P value (one tailed)	0.0694

P value summary	Ns
Was the pairing significantly effective?	No



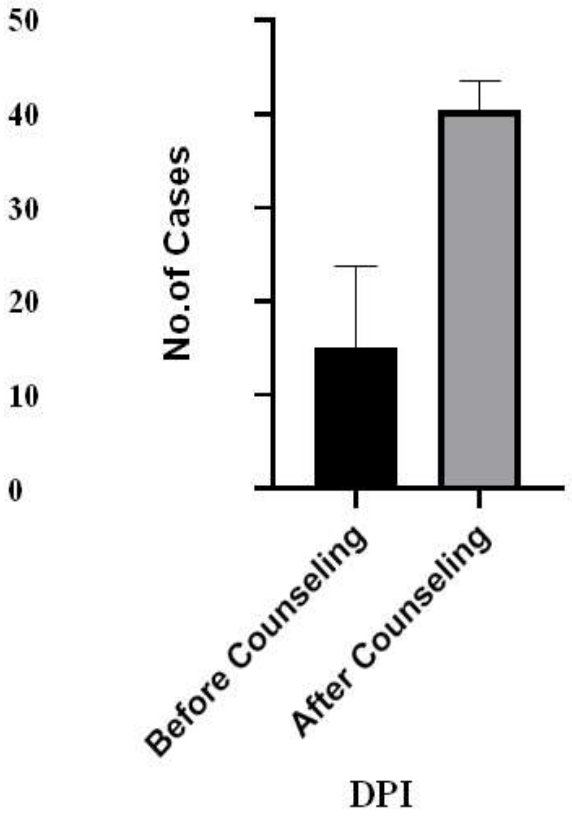
Statistical test for DPI usage before and after counseling:

Test for normal distribution	BeforeCounselling	AfterCounselling
Anderson-Darling test		
A2*	N too small	N too small
P value		
Passed normality test (alpha=0.05)?		
P value summary		
D'Agostino & Pearson test		
K2	N too small	N too small
P value		
Passed normality test (alpha=0.05)?		
P value summary		
Shapiro-Wilk test		
W	0.7617	0.9518
P value	0.0259	0.7547
Passed normality test (alpha=0.05)?	No	Yes
P value summary	*	Ns
Kolmogorov-Smirnov test		
KS distance	0.3333	0.1868

P value	0.0359	>0.1000
Passed normality test (alpha=0.05)?	No	Yes
P value summary	*	Ns
Number of values	6	6

Table Analyzed	Data 1
Column B	After Counselling
vs.	vs.
Column A	Before Counselling
Wilcoxon matched-pairs signed rank test	
P value	0.0313
Exact or approximate P value?	Exact
P value summary	*
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
Sum of positive, negative ranks	21.00 , 0.000
Sum of signed ranks (W)	21.00
Number of pairs	6
Number of ties (ignored)	0

Median of differences	
Median	27.50
How effective was the pairing?	
rs (Spearman)	0.8286
P value (one tailed)	0.0292
P value summary	*
Was the pairing significantly effective?	Yes



RESULTS:

In our study we observed that scores on usage of MDI, DPI are improved after counseling, patients relieved from SOB and other symptoms after using inhalerdevices. This indicates that counselling is effective in the management of asthma and COPD patients who are using inhaler devices. The results are shown in the following tables:

Table.No:1 Inhaler specific checklist with item score-MDITotal no. of patients using MDI are 32

MDI steps that are followed by patients	Before counselling	After counselling
1) Have you cough as much as sputum as possible?	9(28.1%)	32(100%)
2) Have you shake the aerosol before use?	20(62.5%)	32(100%)
3) Did you placed your lips tightly aroundthe mouth piece	10(31.25%)	30(93.75%)
4) Did you tilt your head backwardslightly?	6(18.75%)	29(90.6%)
5) Have you breathed out deliberately,while emptying the air in the lungs?	12(37.5%)	27(84.3%)
6) Did you activate the aerosol by breathing intensely and keeping thetongue down?	5(15.6%)	30(93.75%)
7) Have you hold your breath for 10-15sec?	6(18.75%)	30(93.75%)
8) Have you rinse your mouth with warm water?	8(25%)	28(87.5%)

Figure.No:1 Bar diagram of MDI usage before and after counseling.

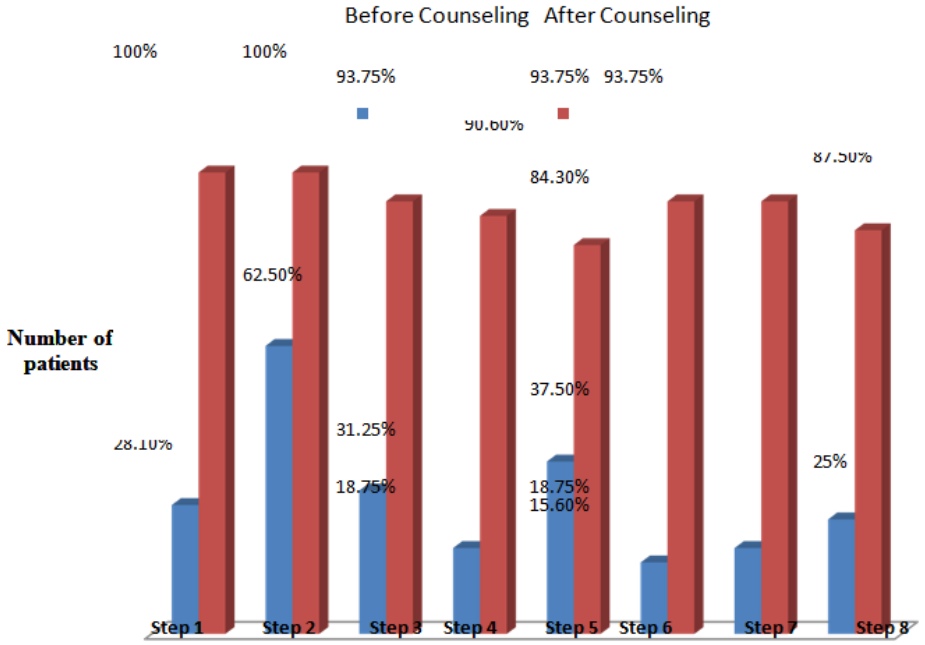
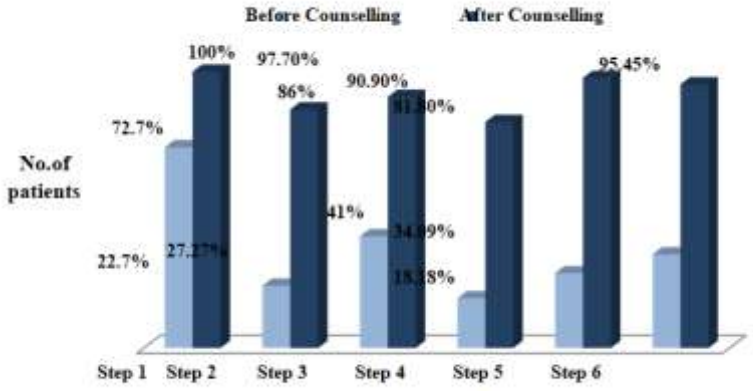


Table.No:2 Inhaler specific checklists with item score- DPI

Total no. of asthma and COPD patients using DPI are 44

DPI steps that are followed by patients	Before counselling	After counselling
1) Did you follow your device instructions toload the medication dose?	32(72.7%)	44(100%)
2) Did you stand or sit up straight and breatheout completely?	10(22.7%)	38(86.36%)
3) Have you put the mouth piece into your mouth, close your lips tightly around it andbreathe in quickly and forcefully?	13(40.6%)	40(90.9%)
4) Did you take DPI out of your mouth, hold your breathe for 5-10 sec, then exhale slowly?	8(18.18%)	36(81.8%)
5) Have you checked your inhaler device whenusing a capsule?	12(27.27%)	43(97.7%)
6) Have you followed the instructions asdescribed in the label?	15(34.09%)	42(95.45%)

Figure.No:2 Bar Diagram of DPI Usage Before and After Counseling



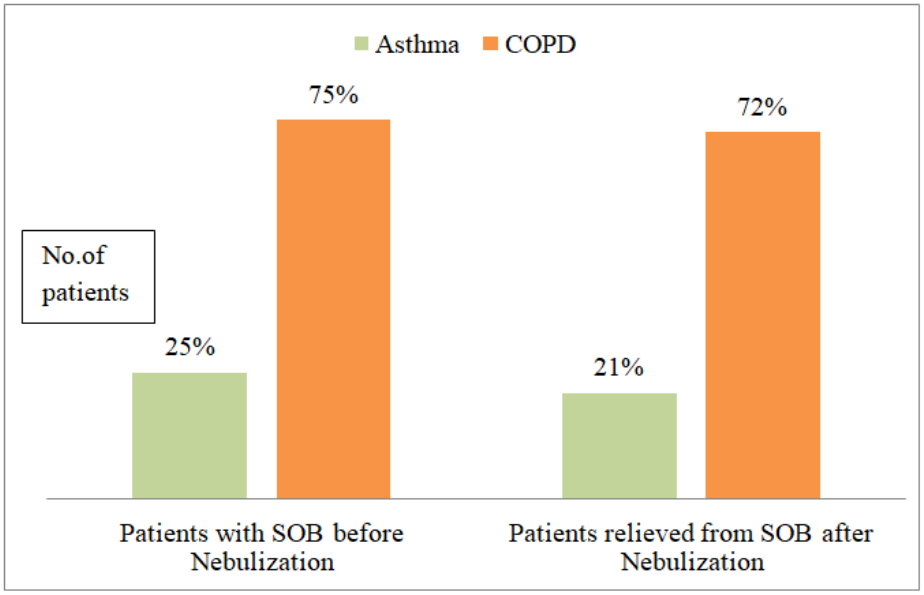
Our study found that patients with correct usage of MDI& DPI had improvedafter counseling

Table.No:3 Nebulizer Assessment

Total number of patients with asthma and COPD using nebulizers are 76.

DISEASE	Patients with SOB before nebulization.	Patients relieved fromSOB after nebulization.
ASTHMA	19(25%)	16(21%)
COPD	57(75%)	55(72%)

Figure.No:3 Bar Diagram of Nebulization Assessment.



This study found that patients relieved from SOB after the usage ofnebulization.

DISCUSSION:

Total no. of asthma and COPD patients using MDI are 32 and Table.no:1 shows that no. of patients followed each MDI step before and after counseling. Most of the patients followed the step-2&step-9 and the least followed step is step-5.*(AlpeshChauhan et al*. suggested that step-3 and step-4 are followed frequently and step-1 is followed rarely. Table no.:1 shows that patients had improved the correct usage of all the essential steps after counseling.)

Total no. of asthma and COPD patients using DPI are 44 and the Table.no:2 shows that no.of patients followed each DPI step before and after counseling. Most commonlyfollowed step is step-1 and the less commonly followed step is step-4 and this table shows that patients had improved correct usage of all the essential steps after counseling. .

The maximum number of patients are relieved from SOB (Table.no:3).

CONCLUSION:

Pharmacist interventions on inhaler techniques were improved patients knowledge about disease and demonstrate different steps of inhalers. Our study concluded that majority of patients in COPD(53%) and asthma(47%) were using inhaler devices inappropriately which reduce the effectiveness of the treatment, decreased drug transport to the lungs, elevated adverse effects and non – compliance.

Most prescribed inhalers among MDI & DPI were DPI.As it was prescribed in new diagnosed patients and has experienced patients. Out of 72 patients with asthma, patients using MDI were 24 and it showed that there is improvement in patient performance on use of inhaler in post counselling than to pre counselling.DPI (29) patients shows improvement on use of inhaler, it shows clinically as well as statistically significance.

Out of 80 patients with COPD, patients using MDI were 8 and showed that there is improvement in patient performance on use if inhaler in post counselling than to pre counselling. DPI(15) patients shows improvement on use of inhaler, it shows clinically as well as statistically significance.

The involvement of clinical pharmacist in counseling the patients shows improvement on correct usage of inhalation technique in COPD and asthma patients. In our study clinical pharmacist role in health care is justified.

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