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## Impact of different instructional interventions in training on inhalers amongst Asthma and COPD patients

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### ABSTRACT

The aim of this study is to assess the impact of different instructional interventions in training on inhalers amongst asthma and COPD patients. A randomized, prospective interventional study was conducted. Different instructional methods were prepared based on guidelines review and expert's opinion. A total of 210 study participants were included and randomized to different intervention groups such as A. patient information leaflets B. video demonstration C. Direct pharmacist instruction. The inhaler use competency was measured at baseline and after intervention with checklist. Of the 210 subjects, statistically significant differences were observed when compared with the direct pharmacist intervention with other two interventions, for MDI (P-value < 0.005), MDI with spacer (P-value < 0.001) and Lupihaler (P-value < 0.001). For the Rotahaler (P-value 0.3), Revoliser (P-value 0.5) a significant improvement was observed with Direct pharmacist intervention when compared with other two interventions. Different critical steps that were more frequently inappropriately performed are shaking before actuation, breath-out before inhalation, pressing the canister once, hold breath for at least 5-10 seconds, exhaling away from DPI, fast & deep inhalation for DPI. Direct pharmacist instruction has more impact on study participants compared to other interventions in improvement of before and after counselling mean checklist scores, lesser inhaler technique errors were observed when compared with other interventions provided. Other materials can be used along with direct pharmacist intervention for a better understanding of the patients.

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### INTRODUCTION

According to Global initiative for Asthma (GINA) guidelines, Asthma is a heterogenous disease, usually characterized by chronic airway inflammation (WHO, 2005). According to Global initiative for chronic Obstructive Lung Disease (GOLD), 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 (bronchitis) and /or alveolar abnormalities (Emphysema) usually caused by significant exposure to noxious par-

ticles or gases (Soriano *et al.*, 2015).

Globally, 235 million people suffer from asthma and 65 million people suffer from moderate to severe COPD. The prevalence of asthma has been estimated to range 3-38% in children and 2-12% in adults, being the commonest chronic disorder among children (Koul and Patel, 2015).

In India the prevalence of asthma is estimated to be 2.05% among those aged >15 years and the total number of COPD cases had been increased to 28.1 million (3.3% prevalence) in 1990 to 55.3 million (4.2% prevalence) in 2016 (GINA, 2018). The number of cases for chronic respiratory diseases, the total Disability adjusted life year (DALY) in 1990 is increased from 4.5% to 6.4% in 2016. India contributes 32% of total DALY globally due to respiratory diseases. Chronic respiratory diseases are a global health problem affecting all age groups, with increasing prevalence in many developing countries (GOLD, 2019).

Asthma and COPD results in significant morbidity, mortality and economic burden of the patients Globally. Health care professionals are trained to manage asthma/COPD exacerbations in hospital-based settings.

Inhalation medications are the corner stone treatment for the management of Obstructive lung diseases (Asthma and COPD). Inhalational bronchodilators (beta-2 agonists, anti-muscarinic agents) and anti-inflammatory drugs (corticosteroids) are recommended at any stage of the disease (Bonini and Usmani, 2015). Oral treatments such as theophylline, phosphodiesterase-4 inhibitors and corticosteroids are intermittently used. Certainly, inhaled treatment has more benefits than oral treatment, as inhalation allows effective delivery of active molecules directly to the target site of action there by it allow high deposition of medication in lungs and minimize the systemic side effects. Inhalers are mediator devices for the effective delivery of inhalation medication to the airways. Different types of inhaler devices are available in market, some of those are Metered dose inhalers (MDI), Dry powdered inhalers (DPI) and small volume nebulizers (SVNs) (Leiva-Fernández *et al.*, 2012). Pressurized MDIs and DPIs are the devices most commonly used for drug delivery in the treatment of asthma and COPD. Every device has it's own specific technique to use, which delivers the medication directly into the airways. Different types of DPI inhaler devices are Rotahaler, Revoliser, Lupihaler etc. With the correct use of MDI, the quantity of active drug that reaches into airways site of action is 5- 15 % and with the DPI

9-30% (National asthma council Australia, 2018).

The inability to use an inhaler properly is most commonly associated with various factors that include poor knowledge about asthma, a lack of inhaler usage technique, advanced age, and lack of education. Effective inhaler education is unquestionably a critical component. All patients should be effectively counselled about the proper technique when they receive an inhaler, although the findings of several studies provide contrary results. Where the reports suggest that 33% to 94% of patients do not receive training on proper technique, when they are first given an inhaler. The widespread use of inhalers, combined with the well documented prevalence of improper technique among patient populations with asthma and COPD, suggests that new strategies are warranted to improve the techniques in the use of inhaler of patients for who rely on inhaler therapy.

For the management of asthma and COPD, it requires a correct inhalation technique that should be performed by the patient to obtain optimal efficacy of medication. So, it is necessary to educate the patient regarding correct techniques in the use of inhalers by providing educational interventions. These include Patient Information Leaflets (PIL) in the form of a package insert pamphlets, videos by the Centre for disease control and prevention (CDC), online videos, Multimedia Training, Inhaler based remainder labels and direct pharmacist or HCP provided educational intervention (Donald, 2017). Different patients have different level of perception depending on their literacy status, age etc. It's necessary to intervene the patient with appropriate ideal educational method for better outcomes.

Patient education is an important parameter in promoting health outcome of patient. This may be provided by any healthcare professional who had taken proper training. There are different ways of resources to provide patient education which includes Brochures or other printed materials, Podcasts, Videos, PowerPoint Presentations, Posters or charts, Models or props, Group classes, Trained peer educators. Each resource has its own advantages and disadvantages. The response from person to person is different, mixed media method frequently works well.

Pharmacist being well trained and skilled healthcare professional plays a critical role (Basheti *et al.*, 2019), both in achieving initial correct inhaler technique and also in maintaining the correct inhaler use over time. Inhaler technique demonstrated by the pharmacist is significant in explaining the nature, frequency and skill level. Repeating the provision of

intervention by pharmacist over time, increases the proportion of patients returning to follow-up visits, who maintain the correct technique.

The need for this nature of Research study is due to lack of pharmacist education intervention, severity of disease, lack of inhalation adherence due to lack of knowledge on the use of inhaler technique and complexity of technique in the use of inhaler. Hence study was aimed to design, develop and compare the impact of different instructional interventions in training on inhalers among asthma and COPD patients.

## METHODOLOGY

### *Study subjects*

A randomized prospective interventional study was conducted in Pulmonology, Paediatrics, General Medicine departments of tertiary care teaching hospital located in southern part of India over a period of nine months. Study was approved by Institutional Human Ethics Committee of JSS college of pharmacy, Mysuru. Patients age with 6 years and above of any gender who are on inhaler treatment among asthma and COPD were included. Patients having visual and hearing difficulties, major psychiatric problems and who are not willing to participate were excluded in the study.

### *Study design*

A total of 210 subjects who met the study criteria were enrolled. Patient socio-demographics includes age, diagnosis, education qualification, social history, present and past medical & medication history, type of inhaler being used were documented. Patients were randomly assigned by using envelope method into one of three interventions:

1. Direct pharmacist instruction of inhaler technique,
2. Watching a video demonstrated by HCP in local language
3. Reading a Patient information leaflets prepared and validated in local language.

### *Tools for the study*

Data collection form, Informed consent form, feedback form. Checklist was prepared for MDI, MDI with spacer, Rotahaler, Revoliser, Lupihaler in English and the checklist scores were 11,12,9,10,11 respectively. Both pre counselling score and post counselling score were assessed with the checklist. Five pictogram-based patient information leaflets

were designed by considering literature search using Inhaler technique use for different inhalers (MDI, MDI with spacer, Rotahaler, Revoliser, Lupihaler) as key words for better understanding of illiterate patients too. Baker Able Leaflet Design (BALD) method (Adepu and Swamy, 2012) was applied to evaluate the layout and design characteristics of the PIL, the resulted layout and design was above standard. Pictogram based patient information leaflet was prepared in English and applied for Flesch Reading Ease Readability Formula as readability tool (Lawshe, 1975) was applied to the designed leaflets, leaflets were found to be fairly easy to read. By using Lawshe content validity index formula (Adepu and Swamy, 2012) content validity of leaflet was done for all the points individually to assess whether the points are essential and useful or inessential, in order to check the quality of information provided. Content validity Index is the mean of the CVR values of the retained item and the content of leaflets, it was highly significant (P value < 0.001). Videos were face validated with expert.

$$\text{Content validity ratio } CvR = \frac{ne - N/2}{N/2}$$

Patient was administered with any one type of instructional intervention (counselling method) as per randomisation. The randomised group under patient information leaflet (PIL), the patients were provided with a specific inhaler device technique PIL and given time to read and understand the PIL. The randomised group under video demonstration, Clinical Pharmacist demonstrated teaching video was shown to the patients and asked them to watch and understand the steps and techniques involved in the use of their specific inhaler. In the randomised group under direct pharmacist intervention, the patients were directly counselled by the clinical pharmacist about the using technique of their specific inhaler. After the intervention/counselling given, patients were again asked to perform their inhaler technique use and correctness are checked against the checklist, sum of the correct steps done was calculated and documented as post-counselling score. After the session was completed feedback was taken from the patient to understand the comfort of the patient with the intervention provided. The study subjects were counselled on correct use of the inhaler device again at the end of the study.

In this study we compared the mean checklist scores of different inhalers with in the different instructional group as primary outcome and secondary outcome was to compare the checklist means of different interventions of different inhalers. Different inhaler checklist errors were compared among

3 interventions. Results of inhaler errors are correlated with age, education status and risk factors are correlated with social and family history.

### **Statistical analysis**

Data analysis was conducted by using IBM SPSS 21.0 software. Paired t- test was used to determine the difference between before and after intervention and within the intervention group separately. One-way ANOVA post Hoc test was used to determine the checklist mean scores of before and after counselling of different inhalers among the different intervention groups. P value < 0.005 was considered as statistically significant.

## **RESULTS AND DISCUSSION**

### **Demographic details**

Most of the Asthma and COPD study participants were in the age group of 41-60 (13.3%) and 61-80 (37.2%) respectively. Majority of COPD study participants were male (49.5%) and however, in asthma group male and female population were equal in number. The number of illiterate participants were more in COPD group (33.33%) than in asthma group (10%). Most of the COPD study participants were domicile in rural area (37.7%) whereas, the study participants having asthma were residing in urban area (17.6%). Majority of the COPD study participants were smokers (16.2%) followed by reformed smokers (59%) and Non- alcoholics (31%). Whereas in asthma most of the study participants were Non-smokers (26.2%) and Non-alcoholics (56.6%). Among 210 study participants 18 participants had family history of Asthma or respiratory symptoms. In our study we observed risk factors among 139 study participants who were smoking (79.13%), family history (12.9%), biogas (6.47%), occupation (1.4%). Number of study participants using different inhaler devices as shown in Graph 1.

### **Randomisation**

The instructional intervention method was assigned to the participants accordingly by using envelope randomisation method. Majority of study participants were intervened with direct pharmacist instruction (39%) followed by patient information leaflet (34%) and video demonstration (27%). Due to envelope randomisation method used the number of study participants in each intervention group were not equally distributed as shown in the below Graph 2.

### **Comparison of impact of instructional interventions**

The impact of instructional intervention was

assessed using the inhalation device check list, as it was a direct indication, how patients have understood the method of using inhaler which was instructed using different techniques.

### **With-in intervention group**

MDI checklist mean score was compared in baseline/before counselling (BC) and after counselling (AC) with-in the intervention group, the difference was statistically significant with Direct pharmacist instruction (P-value < 0.001), Patient information leaflet (P-value 0.01) and Video demonstration (P-value 0.003) at 95% confidence interval as mentioned in Table 1.

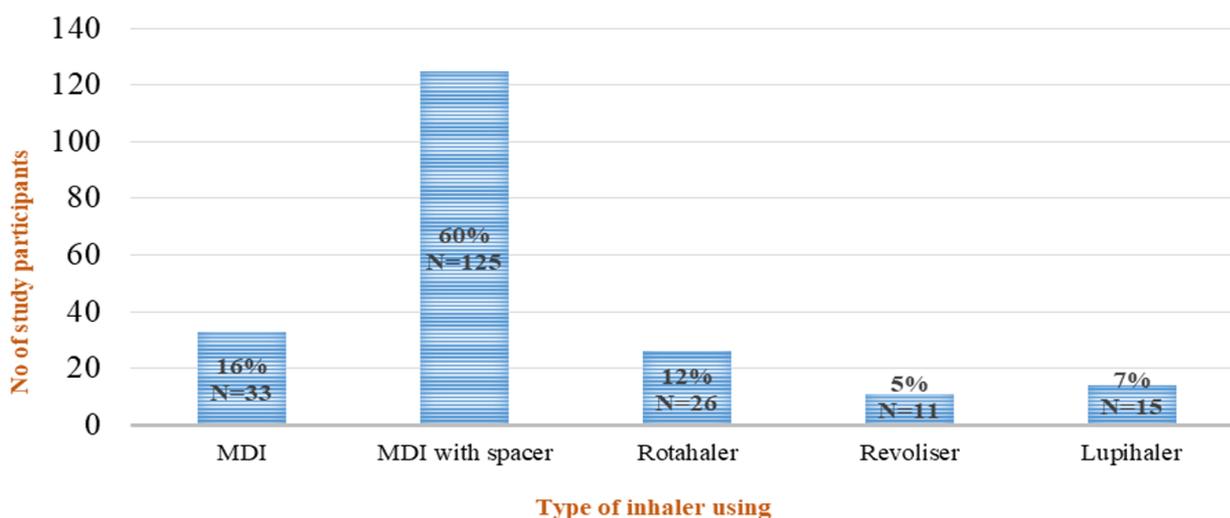
Similarly, checklist mean score of participants using MDI with spacer was compared from BC to AC with-in the intervention group, statistically significant difference was observed with Direct pharmacist instruction (P-value < 0.001), Patient information leaflet (P-value < 0.001) and Video demonstration (P-value < 0.001) at 95% confidence interval as mentioned in Table 2.

When Rotahaler checklist mean score was compared in BC and AC with-in the intervention group, the difference was statistically significant with Direct pharmacist instruction (P-value < 0.001), Patient information leaflet (P-value 0.02) and Video demonstration (P-value 0.04) at 95% confidence interval

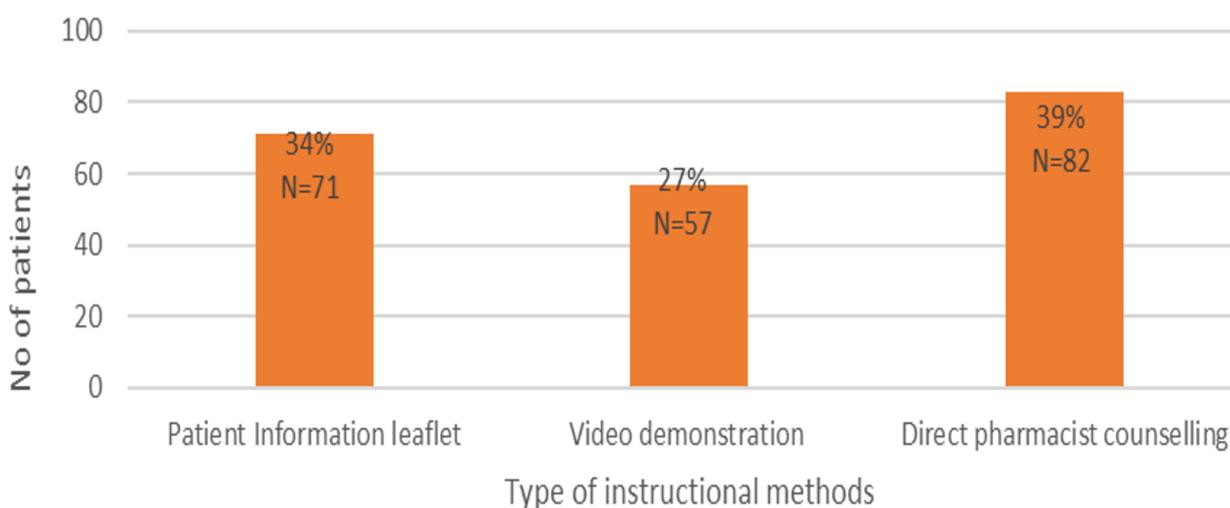
When Revoliser checklist mean score was compared in BC and AC with-in the intervention group, statistically significant differences were observed with video demonstration (P-value 0.03) whereas, in patients randomized with PIL (P-value 0.07) and Direct pharmacist instruction (P-value 0.29) no statistical significance was observed with-in groups.

When Lupihaler checklist mean score was compared in baseline/before counselling and after counselling with-in the intervention group, statistically significant difference was not observed with Direct pharmacist instruction (P-value 0.07) and Video demonstration (P-value 0.06) and statistical difference was observed with Patient information leaflet (P-value 0.02).

Overall, a statistically significant differences were observed among 3 intervention groups, when post counselling mean-checklist score of MDI, MDI with spacer and Lupihaler was compared (P < 0.005). But for Rotahaler and Revoliser statistically significant difference was not observed among 3 intervention groups (P>0.05). Feedback was obtained about the comfort with instructional intervention method used from study participants, 100% and 95% satisfactory rate observed with direct phar-



Graph 1: Number of study participants using different types of inhaler



Graph 2: number of patients randomized to different instructional groups

**Table 1: With-in intervention group checklist score is participants using MDI**

Intervention	Before/ After counselling	N	Mean ± SD	P-value
1. Direct pharmacist instruction	BC	13	8.1 ± 1.6	< 0.001
	AC	13	10.8 ± 0.4	
2. PIL	BC	10	6.8 ± 2.7	0.01
	AC	10	9.0 ± 1.7	
3. Video demonstration	BC	10	7.4 ± 2.0	0.003
	AC	10	9.7 ± 1.3	

**Table 2: With-in intervention group checklist score in participants using MDI with spacer**

Intervention	Before/ After counselling	N	Mean $\pm$ SD	P-value
1. Direct pharmacist instruction	BC	51	7.7 $\pm$ 2.2	< 0.001
	AC	51	11.6 $\pm$ .72	
2. PIL	BC	42	7.8 $\pm$ 1.9	< 0.001
	AC	42	9.1 $\pm$ 2.5	
3. Video demonstration	BC	32	7.3 $\pm$ 2.1	< 0.001
	AC	32	10.2 $\pm$ 1.5	

macist instruction and video demonstration respectively, whereas, only 28% of the patients were comfortable with patient information leaflets.

This study was designed to compare the effectiveness of different instructional interventions by comparing its mean checklist scores. This is first of its kind to compare multiple instructional interventions (PIL, direct pharmacist instruction, video demonstration) with the different inhalers (MDI, MDI with spacer, Rotahaler, Revoliser, Lupihaler). One-way ANOVA statistical method was used to compare the different instructional methods with different inhalers. Comparison of mean checklist score of MDI with 1. Direct pharmacist instruction 2. Patient Information Leaflet 3. Video demonstration was done, statistically significant difference (P-value < 0.005) was observed with direct pharmacist instructional intervention. This was mainly attributed to face to face demonstration. Literacy, age of patients was some barriers for Patient information leaflets, that may have led to not understanding of PIL, that could have impacted on incorrect use of inhalers. A statistically significant difference was found when comparing with 3 interventions for MDI with spacer (P-value < 0.005) and Lupihaler (P-value < 0.005) with direct pharmacist instruction intervention. There is no statistically significant difference was observed for mean checklist score of Rotahaler (P-value 0.3) and Revoliser (P-value 0.5) with 3 interventions. However, overall there was significant difference observed between before and after counselling in all the 3-intervention group. When scores were compared between the intervention group, group provided with direct pharmacist instruction had better results, this may be because our study population also has illiterate group, who may not be comfortable and understand as counselling points were provided in leaflet form and video demonstration only. But there is improvement in before and after counselling points as PIL's also have pictogram that would have helped them but not to the extent of direct pharmacist intervention method. In our study we observed no statisti-

cally significant difference, before and after counselling of Revoliser inhaler with PIL group and within the direct pharmacist instruction group as only 2 patients were randomised in to group, they were also demonstrating their inhaler technique correctly and had higher checklist scores before counselling and hence no much difference was seen after the educational intervention. Patients randomised into this were well educated hence their understanding was better compared to the patients randomized into other groups. Similar findings were observed in to the studies conducted by Francisca Leiva-Fernández et. al. (Leiva-Fernández *et al.*, 2012) conducted a study that explained the intervention which provided with patient information leaflet plus training by instructor had better impact and increased correct inhalation technique when compared with intervention which provided with only patient information leaflet. A similar study was conducted by Abdallah *et al.* (1996) explains that pictogram medals plus verbal counsel group improved 7-8 times than only verbal counsel group. Axtell *et al.* (2017) and Shrestha *et al.* (1996) also demonstrated direct counselling by a health care professional had a better success rate in improvising the inhaler technique skills.

Educational interventions are more important to educate the patient's use of inhalers with correct technique (Lavorini *et al.*, 2008). Different interventions are available and each having its own limitation specific to patient. To overcome the limitations, different instructional interventions like Patient information leaflet, video demonstration were prepared in English and translated to regional language (Kannada) and the impact of each type of instructional method is different in different patient population.

In our study we observed that the patients with low literacy and elder age were not able to read and understand the provided information leaflets, with this post counselling scores were didn't improved as greater as seen in direct pharmacist instruc-

tion. This is one of the major barriers of study participants with patient information leaflets. Video demonstration had good impact when compared with PIL but videos and multimedia are not very useful in poor economic and aged patients as the reach to these media may be limited. For all patients irrespective of their age, gender, literacy and economic status, pharmacist's back counselling has more impact on study participants and improves the therapeutic outcome.

### Limitations

All the patients who visited pulmonology OPD, Medicine and paediatrics could not be included in the study because of the time constraint. Patients lacked interest and lack of time for participation in the study were observed.

### CONCLUSIONS

In this study, we have observed that the patients who received direct pharmacist instruction intervention has better impact and overall checklist errors were minimal when compared with other two interventions which was measurable. It is necessary to understand the patient related factors and comfort for providing intervention. As direct pharmacist counselling provides the best platform to interact with patients, understand their difficulties which indirectly help them to perform each step correctly, it will benefit in improving the technique of using inhalers. With the direct pharmacist instruction, we can minimize the patient related barriers and improve the understanding of technical use of inhaler with a revising method. So, based on the observation from the study, we can conclude that direct pharmacist instruction has a greater impact on patients in improving correct technical use and better treatment outcomes. We can use other materials along with direct pharmacist intervention for better understanding of the patients. So, there is high need of providing best instructional intervention while giving first advice of inhalers to patients.

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