



### **Study Of Adverse Drug Reactions Associated With Metered Dose Inhaler**

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#### **Abstract**

Asthma is a common chronic respiratory disease affecting 1-18% of population in different countries. It can be treated mainly with inhaled medications in several forms, including pressurized metered-dose inhaler (MDI). Incorrect use of inhalers is very common and subsequently leads to poor control of asthma. So pharmacists have a crucial role in educating patients about the correct use of inhaler devices. This

study aims at providing adequate knowledge on MDI use to help the patients to attain the target of asthma control. The objective of the study was to evaluate the common drug related problems associated with the use of MDI. A Quasi-Experimental study was carried out in 150 patients diagnosed with asthma and undergoing inhaler therapy in the Pulmonology department of Believers Church Medical College Hospital, Thiruvalla

from November 2019 to April 2020. Inhalation technique of MDI was obtained using a standard checklist of steps recommended in American Thoracic Society guidelines. This study focused on the effectiveness of individualized mentoring of patients as well as their care givers on proper use of MDI through demonstration and face-to-face training by using WHO guidelines. The study showed that most of the study subjects having poor inhalation technique during before counselling session and also experienced some adverse drug event associated with inhalational drugs. Adverse effects are less daunting when their possibility has been discussed and they are not totally unexpected, and the patient can associate the effect with a specific new intervention.

### **Keywords**

Adverse Drug Event; American Thoracic Society; Metered Dose Inhaler

### **Introduction**

Metered-dose inhaler is an inhaler device with specified doses that provides a certain dose of the active agent in each puff. MDIs consist of a suspension or dispersion of one or more active ingredient in propellant or a mixture of propellants or a mixture of solvent and propellants. The role of propellant in an MDI system is to provide the required pressure to atomize drug formulation into micron-scaled droplets. Pressurized metered-dose inhalers (MDI) are a type of MDIs that works based on the pressurized propellant in the aerosol chamber. The advantage of MDIs is the accurate and repeatable dosing, which minimizes the errors.<sup>(1)</sup> The basic advantage of aerosol therapy lies in the delivery of high local concentration of drug directly into the site of action which minimizes the systemic side effects. This is achieved with a much lower dose compared to what may be required for systemic administration for

equivalent therapeutic response. The commonest aerosolized drugs are the bronchodilators and anti-inflammatory agents used for obstructive airway disease such as asthma and chronic obstructive pulmonary disease (COPD), their efficiency results from local effects in the airway<sup>(3)</sup>. High local concentration of these agents in the lung maximizes their intended effects and minimizes systemic absorption and potential local adverse drug reactions. Another advantage of this mode of drug delivery is the rapidity of onset of action after the drug is inhaled as compared to other modes of delivery.<sup>(1)</sup> Pressurized metered dose inhalers are the most common drug delivery system for aerosolized therapy, providing a cost effective and safe method of drug delivery to the lungs. Therapeutic success depends on adequate lung deposition of drug and this factor is influenced by the technique used by the patient to inhale the aerosol most of the patients do not use their inhaler in the correct fashion and studies have shown that a large percentage of patients have a faulty technique when using the MDI<sup>(33)</sup>.

Nowadays, MDIs are commonly used along with spacers. A Spacer device is a tube extension to an MDI or a holding chamber with a port at one end to which an MDI is attached, a mask or mouthpiece is attached to the other end. Patients dispense drugs into the spacer and inhale by breathing normally through the mouthpiece. The use of a spacer reduces both the velocity and size of the aerosol particles and dispenses with the need for patient coordination between actuation of the MDI and inhalation of the aerosol. Also, it reduces the deposition of drugs on the oropharynx and thus reduces the associated side effects.<sup>(12)</sup> The use of an inhaler device involves a complex series of steps, which need to be performed correctly. Failing to perform one or more steps correctly can

reduce delivery and hence effectiveness, and safety of medication. Several studies have demonstrated that 50-80% of patients fail to use their inhaler devices correctly. Patients are often not aware that they use their inhaled medication inadequately, and overestimate their own abilities. Incorrect use of inhalation devices may lead to uncontrolled disease state, unwanted side effects and can also cause higher treatment cost<sup>(34)</sup>. Clinical response to inhaled medication depends on the inhalation technique of the patient. Incorrect technique prevents patient from getting maximal benefit from their medication. As a result, patient education about inhaler technique is very important in the management of airway disease.<sup>(37)</sup> Also, there are some common drug related problems associated with MDIs use, which are, oral thrush, cough, nausea, dysphonia etc., but these adverse effects are less daunting when their possibility has been discussed and they are not totally unexpected, and the patient can associate the effect with a specific new intervention. Those side effects are usually neglected and underestimated by the patients. These effects are also poorly studied, and the information regarding the rates of these side effects are limited.<sup>(41)</sup> Oral thrush is a common side effects of inhaled steroids, it occurs when a yeast infection grows in your mouth or throat, result in a white film appear on your tongue. An increased concentration of glucose in saliva resulting from the deposited oropharyngeal corticosteroids may be responsible for the candidiasis. Dysphonia is the difficulty in speaking due to physical disorder of the mouth, tongue, throat or vocal cords. Use of medications containing corticosteroids can cause dysphonia most likely via a myopathy of the laryngopharynx (particularly responsible for voice production).<sup>(43)</sup> Tremor is one of the major side effects of medication containing salbutamol, it occurs due to

the imbalance between fast and slow twitch muscle group of the extremities.<sup>(44)</sup> Nausea or vomiting may occur due to the development of bad taste in the mouth due to inhaled drugs. Cough occurs due to increased pressure in the vocal cords when it is closed, an explosive release of air when the vocal cords open giving a cough. Inhaler may leave small amount of medicine in vocal cords can change the sound of the voice or may lead to hoarseness.<sup>(41)</sup> The degree of any complication will vary with each drug, its dose, and dosing frequency as well as with the type of device being used. Oropharyngeal deposition of ICS, due to inadequate inhaler use or failure to rinse the mouth after administration, can result in oral candidiasis or dysphonia Nasal corticosteroids can penetrate the pharynx and larynx, consequently they have the potential to cause symptoms in the oral cavity and pharynx. This high frequency of local symptoms might be associated with use of medium or high doses of drugs. Assessment of patient's perception of adverse effects could provide a greater understanding the extent and severity of these effects and could aid in determining the risk-benefit ratio of the use of particular drug. Some patients may stop the usage of MDI on encounter of ADRs. They will strongly believe that the problems that they are facing are due to MDIs. Many of these patients will not let their doctor know about these adverse effects, which may lead to the abrupt stoppage of drug use. Most of these side effects may subside on decrease of drug dosage or switching on to another drug. But without letting the doctor know, nothing could be done. This may also lead to delayed clinical recovery. This study aims at providing adequate knowledge on MDI use to help the patients to attain the target of asthma control. The objective of the study was

to evaluate the common drug related problems associated with the use of MDI.

## **Materials and Methods**

### **Study Site**

Study was conducted in Pulmonology Department at BCMCH, Thiruvalla.

### **Study Design**

This study is a Quasi Experimental study.

### **Study Period**

This study was conducted for a period of six months from November 2019- April 2020.

### **Study Approval**

The study was conducted after obtaining the approval from Institutional Ethical Committee, BCMCH Thiruvalla.

### **Sample Size**

Assuming that the proportion of people with partially or completely controlled asthma before counseling was 48% and 68% after, the minimum sample was 126. The assumed type 1 error was 0.05 and power was 90%. The formula used was SLOVIN'S FORMULA,

$$n = \frac{N}{1 + Ne^2}$$
 where, n= number of samples, N- total population, e = margin of error

### **Study Criteria**

#### **Inclusion Criteria**

1. Patients (above 18 years) on treatment with Metered dose inhaler device
2. New patients in Pulmonology OPD who were diagnosed with Asthma

#### **Exclusion Criteria**

1. Paediatric Patients
2. Patients who were not willing to participate

#### **Source of Data and Materials**

1. Patients case sheets
2. Patients prescriptions

### **3. Pulmonary Function Test Report**

#### **Method of Collection of Data**

- All patients satisfying the study criteria were enrolled in the study after obtaining a written informed consent printed in patient's understandable language from the patient or care-giver, in case of the patient being unable to give the consent.
- Collected demographics of the patient (name, age, sex, socio-economic status, medical, medication, family and social history etc.)
- Collected data regarding the disease, type of MDI used, mode of administration, dose and frequency.
- Assessed the patient's knowledge about safe and effective use of MDI with the help of questionnaire.
- Estimated of ACT score in patients diagnosed with Asthma.
- Counseled the patients on safe and effective use of MDI with the help of 12 steps used as per guidelines.
  - a. Remove the cap from the mouthpiece of both the MDI and the spacer.
  - b. Insert the MDI mouthpiece in the soft opening of the spacer. The MDI canister needs to be in an upright position.
  - c. Shake the MDI with attached spacer several times.
  - d. Breathe out, away from the spacer, to the end of your normal breath.
  - e. Place the mouthpiece of the spacer into your mouth, past your teeth and above your tongue. Close your lips around the mouthpiece. If you are using a spacer with a mask, place the mask over your nose and mouth. Be sure the mask has a good seal against your cheeks and chin.

There should be no space between the mask and your skin.

- f. Press down on the top of the metal canister once, to release the medicine into the spacer.
- g. Breathe in deeply and slowly through your mouth. If the spacer makes a “whistling” sound, you are breathing in too fast. You should NOT hear a whistle.
- h. Hold your breath for 5 to 10 seconds.
- i. Breathe out slowly.
- j. If you are instructed to take more than one puff (spray), wait about 15 to 30 seconds (or as directed by the package insert) before taking the next puff. Then repeat steps 4-10.

k. Replace the cap on the mouthpiece of the MDI inhaler and spacer after you have finished.

- l. If you are inhaling a steroid, rinse your mouth out with water, swish, gargle and spit.
- Upon the patient’s revisit, their knowledge about safe and effective use of MDI was accessed with the help of a questionnaire or telephonic interview with the patient would be conducted in case of the patient being unable to visit the OPD.
- The collected data was analysed by using descriptive statistical method.

### Statistical Analysis

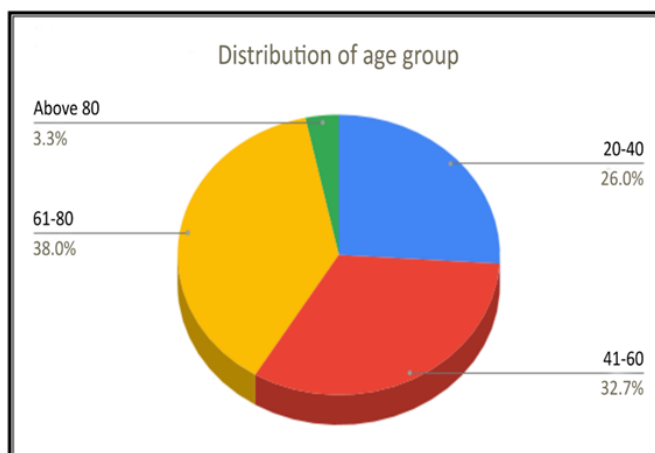
The study was analysed by using Microsoft Excel 2007.

### Result and Discussion

Table No 1: Distribution of Age Group

Sl. No.	Age group	Frequency	Percentage
1	20-40	39	26
2	41-60	49	33
3	61-80	57	38
4	Above 80	5	3
	Total	150	100

Figure No 1: Distribution of the Patients Based on Age Group

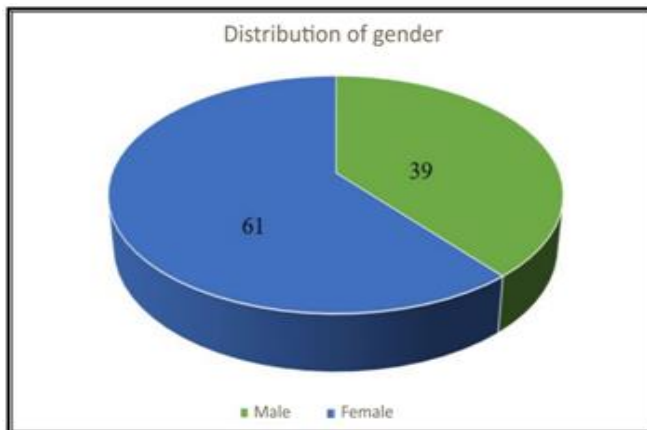


Among 150 study population enrolled in the study, the majority of the subjects belongs to the age group of 60-80 years (38%) followed by 40-60 years (33%), 20-40 (26%) and 3% of the subjects belongs to the age group >80 years.

**Table No 2: Distribution of Gender**

Sl. No.	Gender	Frequency	Percentage
1	Male	58	39
2	Female	92	61
	Total	150	100

**Figure No 2: Gender wise distribution**

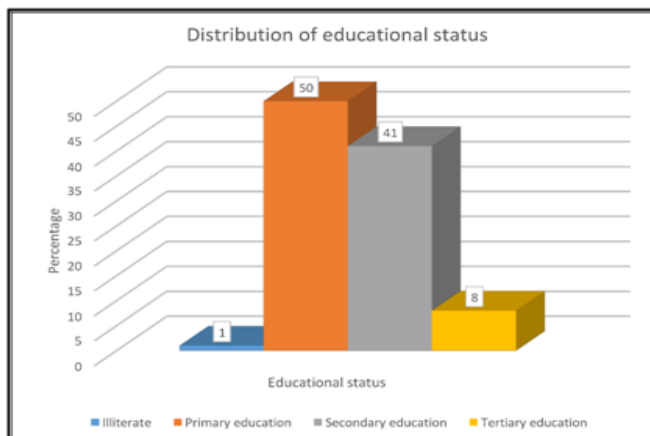


Among 150 study population enrolled in the study, the majority of subjects were females which were about 61% (92 subjects) and 39% were males (58subjects).

**Table No 3: Distribution of educational status**

Sl. No.	Educational Status	Frequency	Percentage
1	Illiterate	1	1
2	Primary education	76	50
3	Secondary education	61	41
4	Tertiary education	12	8
	Total	150	100

**Figure No 3: Distribution of patient’s educational status**

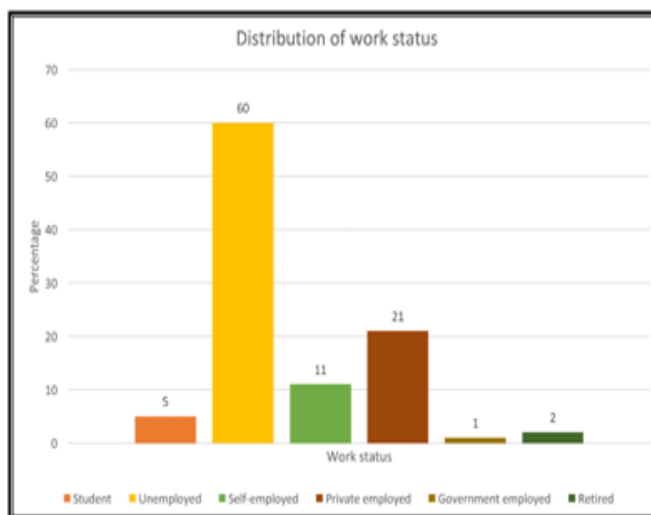


Among 150 study population enrolled in the study, the majority of study population had primary education (50%), followed by 61 subjects had secondary education (41%), followed by 12 subjects had tertiary education (8%) and 1% of the subjects were illiterate.

Table No 4: Distribution of work status

Sl. No.	Work Status	Frequency	Percentage
1	Student	8	5
2	Unemployed	91	60
3	Self-employed	16	11
4	Private employed	32	21
5	Government employed	1	1
6	Retired	2	2
	Total	150	100

Figure No 4: Distribution of the patient's work status

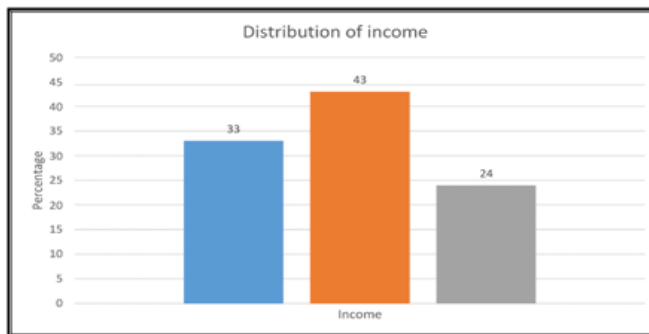


Among 150 subjects enrolled in the study, the majority of study population (60%) was unemployed, followed by 32 subjects were private employed (21%), followed by 16 subjects were self- employed (11%), followed by 8 subjects were students (5%). The least observed in our study was government employed (1%).

Table No 5: Distribution of income

Sl. No.	Income	Frequency	Percentage
1	Less than 10,000	50	33
2	10,000-20,000	64	43
3	Greater than 20,000	36	24
	Total	150	100

Figure No 5: Monthly income of the subjects

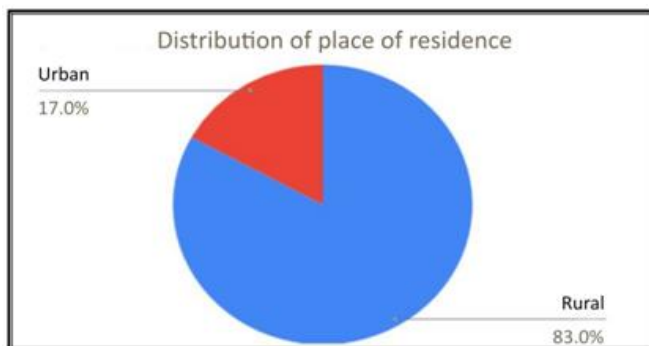


Among 150 subjects enrolled in the study, the majority of the subject’s monthly income was 10,000-20,000 (43%) followed by 33% of subjects had monthly income of <10,000 and 24% of subject’s monthly income is >20,000.

Table No 6: Distribution of place of residence

Sl. No.	Place of residence	Frequency	Percentage
1	Rural	125	83
2	Urban	25	17
	Total	150	100

Figure No 6: Distribution of the patient’s place of residence



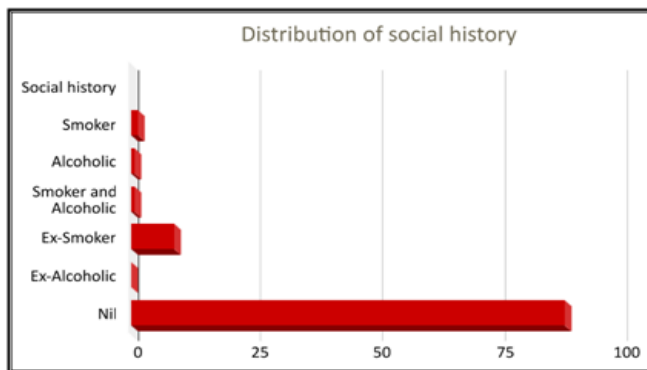
Among 150 study population enrolled in the study, majority of the population were from rural areas which was about 125 subjects (83%) and rest of the population were from urban areas (25 subjects).

Table No 7: Distribution of social history

Sl. No.	Social history	Frequency	Percentage
1	Smoker	2	1
2	Alcoholic	1	1
3	Smoker and Alcoholic	1	1
4	Ex-Smoker	13	9
5	Ex-Alcoholic	0	0
6	Nil	133	89
	Total	150	100



Figure No 7: Distribution of the social habits of the patients

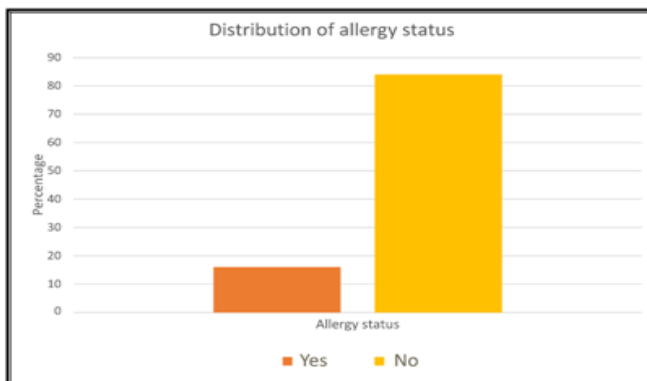


Among the 150 study population enrolled in the study, 133 subjects did not have any social habits (89%) followed by 13 subjects were ex-smokers (9%), 2 subjects had smoking as their social habit followed by 1 subject had alcoholism and 1 subject with both alcoholism and smoking as their social habits.

Table No 8: Distribution of allergy status

Sl. No.	Allergy Status	Frequency	Percentage
1	Yes	24	16
2	No	126	84
	Total	150	100

Figure No 8: Allergic status of the patients

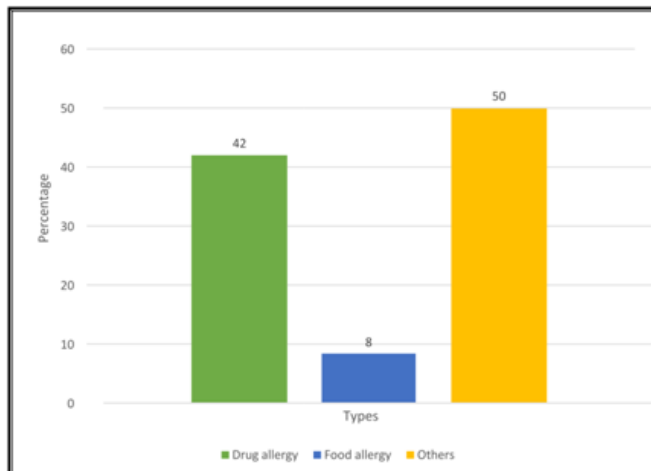


Among 150 study population enrolled in the study, majority of the study population, 126 subjects (84%) did not have any allergic status and 24 subjects (16%) showed some sort of allergies.

Table No 9: If yes, what type of allergy do you have?

Sl. No.	Types	Frequency	Percentage
1	Drug allergy	10	42
2	Food allergy	2	8
3	Others	12	50
	Total	24	100

Figure No 9: Distribution of type of allergy

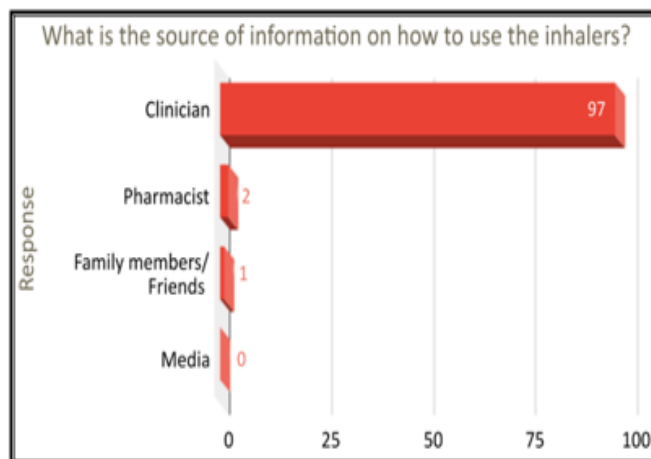


Among the 24 subjects who had allergy, 12 subjects had other types of allergy such as dust, pollen grains, animal fur etc. (50%) followed by 10 subjects had drug allergy (42%) and 8 subjects had food allergy (8%).

Table No 10: What is the source of information on how to use the inhalers?

Sl. No.	Response	Frequency	Percentage
1	Clinician	147	97
2	Pharmacist	2	2
3	Family members/Friends	1	1
4	Media	0	0
	Total	150	100

Figure No 10: Source of information of inhaler use

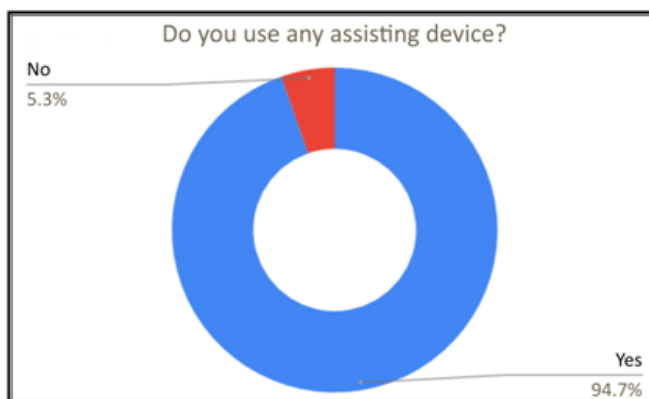


Among 150 study population enrolled in the study, majority of the subjects obtained knowledge regarding the use of inhaler from clinician (97%), followed by 2 subjects gained knowledge from pharmacist and 1 subject from family member.

**Table No 11:** Do you use any assisting device?

Sl. No.	Response	Frequency	Percentage
1	Yes	142	95
2	No	8	5
	Total	150	100

**Figure No 11:** Distribution of use of assisting device

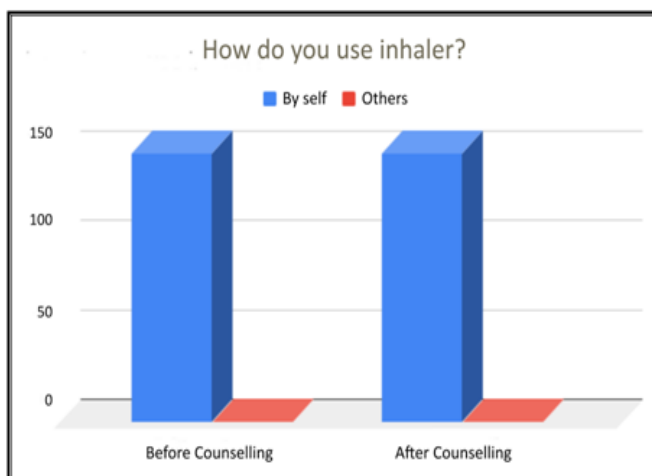


Among 150 study population enrolled in the study, majority of the study population used spacer along with MDI (95%) and rest of the population used MDI without spacer (5%).

**Table No 12:** If yes, did you regularly use spacer along with MDI?

Sl. No.	Response	Frequency	Percentage
1	Yes	150	100
2	No	0	0
	Total	150	100

**Figure No 13:** Way of using inhaler

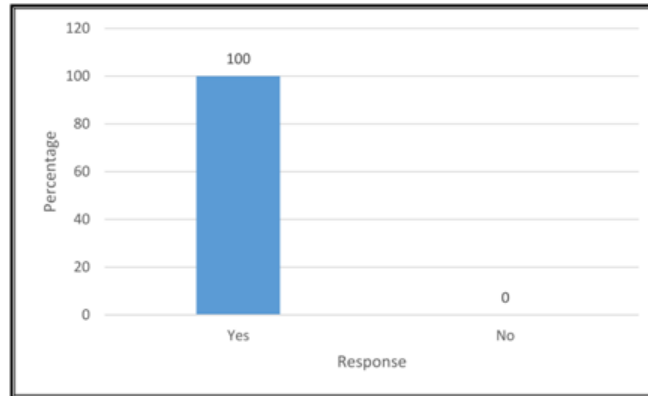


Among 150 study population, all the subjects used inhaler by self in before counseling and after counseling.

**Table No 14: Do you know how to use MDI?**

Sl. No.	Response	Frequency	Percentage
1	Yes	150	100
2	No	0	0
	Total	150	100

**Figure No 14: Knowledge about the use of MDI**

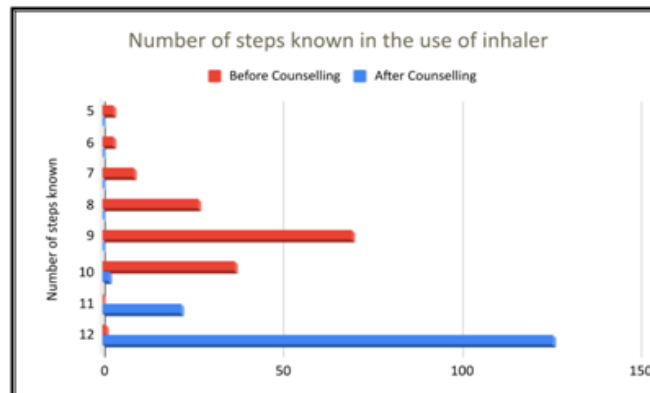


Among the 150 study population enrolled in the study, 100 % of subjects had proper knowledge about the use of MDI device.

**Table no 15: Knowledge on method of use of inhaler before and after counseling**

Sl. No.	Number Of Steps Known	Before Counselling	After Counselling
1	5	3	0
2	6	3	0
3	7	9	0
4	8	27	0
5	9	70	0
6	10	37	2
7	11	0	22
8	12	1	126

**Figure No 15: Number of steps known in the use of inhaler**

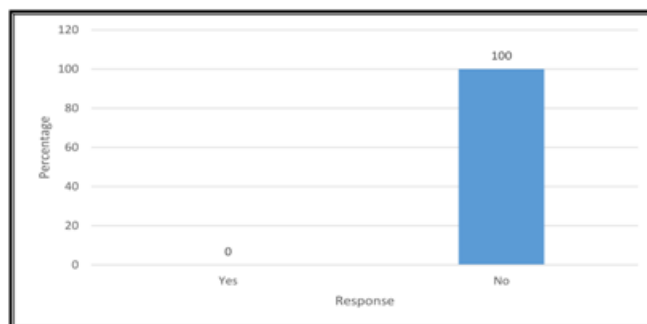


When all subjects enrolled in the study were asked to demonstrate 12 steps of use of MDI, majority of the subjects (70subjects) knew 9 steps out of 12 in the proper use of MDI followed by 37 subjects knew 10 steps out of 12, 27 subjects knew 8 step out of 12, 9 subjects knew 7 steps out of 12, 3 subjects knew 6 out of 12, 3 subjects knew 5 out of 12 and 1 subject knew 12 out of 12 in before counseling. But after counseling, majority of subjects were able to demonstrate 12 steps (126 subjects) followed by 22 subjects knew 11 out of 12 and 2 subjects knew 10 out of 12.

**Table No 16:** Did you share your inhaler with anyone?

Sl. No.	Response	Frequency	Percentage
1	Yes	0	0
2	No	150	100
	Total	150	100

**Figure No16:** Sharing of inhaler with anyone

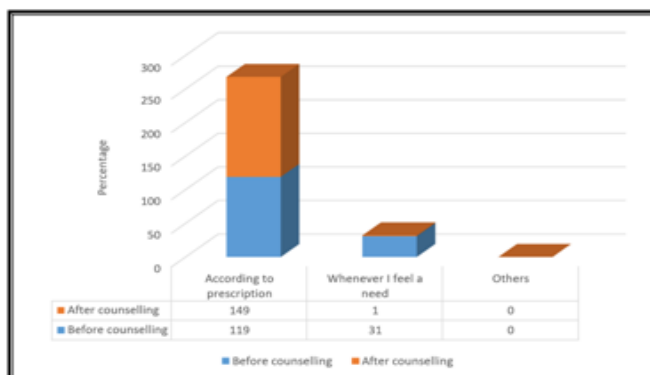


Among the 150 study population enrolled in the study, 100 % of subjects did not share their inhalers with others.

**Table No17:** When did you take inhalers?

Sl. No.	Response	Before Counselling	After Counselling
1	According to prescription	119	149
2	Whenever I feel a need	31	1
3	Others	0	0

**Figure No 18:** Time when inhaler used

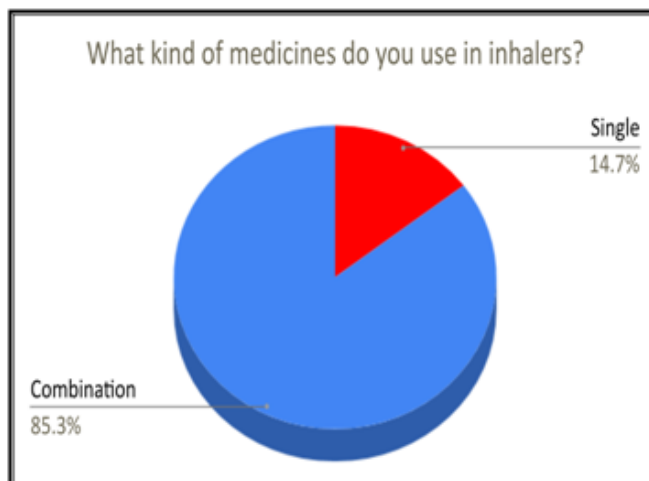


Among the 150 study population enrolled in the study, in before counseling, 119 subjects took inhaler according to the prescription and 31 subjects took inhaler whenever they felt a need. But after counselling, 149 subjects took inhaler according to prescription and 1 subject took inhaler whenever the subject felt a need.

**Table No 18:** What Kind of medicines do you use in inhalers?

Sl.No.	Response	Frequency	Percentage
1	Single	22	15
2	Combination	128	85
	Total	150	100

**Figure No18:** Types of medicines used

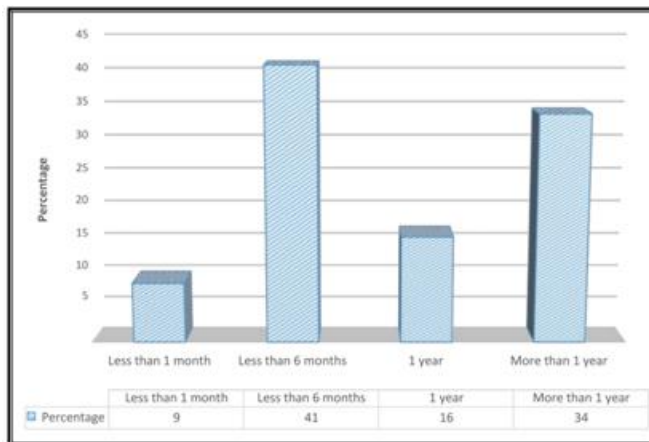


Among 150 study population enrolled in the study, majority of the subjects took combination drugs (85%) and 22 subjects took single drugs (15%).

**Table No 19:** How long you have been taking this medication?

Sl.No.	Response	Frequency	Percentage
1	Less than 1 month	13	9
2	Less than 6 months	62	41
3	1 year	24	16
4	More than 1 year	51	34
	Total	150	100

Figure No 19: Duration of inhaler used

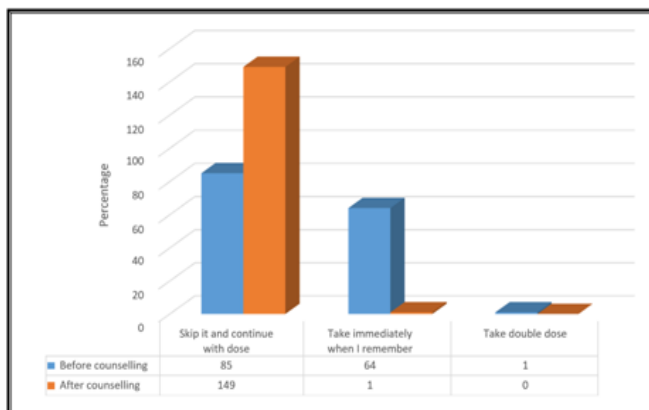


Among 150 study population enrolled in the study, majority of the subjects used the inhaler for less than 6 months (41%), followed by 51 subjects used the inhaler for more than 1 year (34%), followed by 24 subjects used the inhaler for about 1 year (16%) and 13 subjects used the inhaler for less than 1 month (9%).

Table No 20: What have you done when you missed a dose?

Sl. No.	Response	Before Counselling	After Counselling
1	Skip it and continue with dose	85	149
2	Take immediately when I remember	64	1
3	Take double dose	1	0

Figure No 20: Response when missed a dose

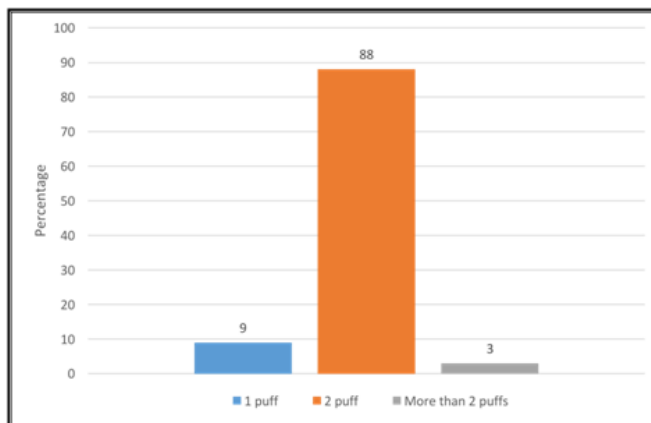


Among the 150 cases evaluated in the study, in before counseling session, 85 subjects skipped the dose of inhaler and continued with the next dose, followed by 64 subjects took the inhaler when they remembered and only 1 subject took double the dose. But after- counseling, 149 subjects followed the correct method, that is to skip and continue with next dose when they missed a dose of inhaler and only the remaining 1 subject took inhaler immediately when the subjects remembered.

**Table No 21:** How much puff do you take at a time?

Sl. No.	Response	Frequency	Percentage
1	1 puff	14	9
2	2 puff	132	88
3	More than 2 puffs	4	3
	Total	150	100

**Figure No 21:** Number of puffs taken

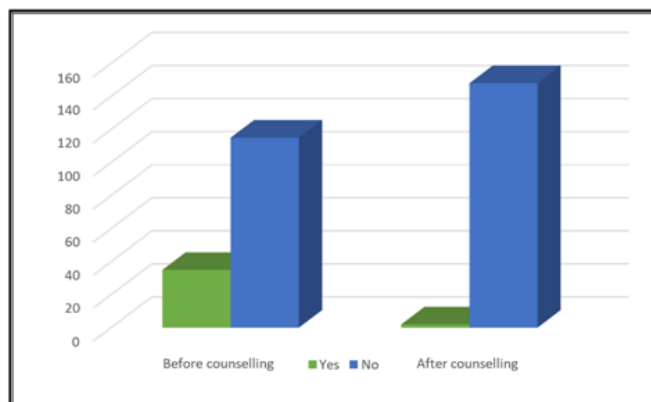


Among 150 study population enrolled in the study, majority of the subjects took 2 puffs (88%), followed by 14 subjects (9%) took 1 puff at a time (9%) and the rest 4 subjects (3%) took more than 2 puffs at a time.

**Table No 22:** Did you take more puffs than advice?

Sl. No.	Response	Before Counselling	After Counselling
1	Yes	35	2
2	No	115	148

**Figure No 22:** Use of more puff than advised



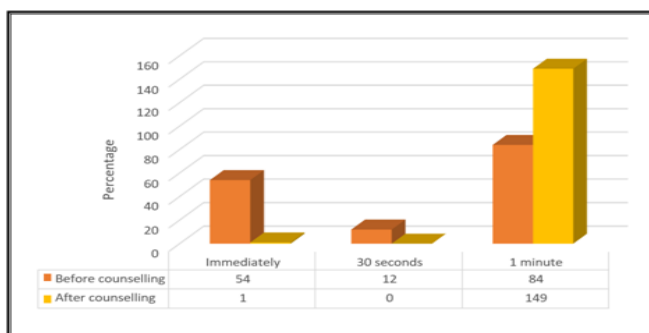


Among 150 study population enrolled in the study, majority of the subjects did not take more puff than advice (115 subjects) in the before counseling and 35 subjects took more puff than advice. But after counseling, 148 subjects followed the correct use, that is taking 2 puff and 2 subjects took more than advice.

**Table No 23:** What was the time gap between each puff?

Sl. No.	Response	Before Counselling	After Counselling
1	Immediately	54	1
2	30 seconds	12	0
3	1 minute	84	149

**Figure No 23:** Time gap between each puff

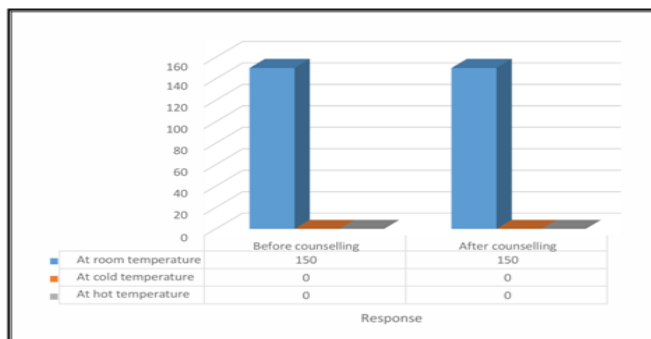


Among the 150 study population enrolled in the study, in before counseling session, 84 subjects had taken the puff within 1-minute time gap, 54 subjects had taken each puff immediately one after the other and rest of the 12 subjects had taken the drug within 30 seconds time gap. But after patient counseling, 149 subjects followed the correct method of taking each puff 1 minute apart and only the remaining 1 subject had taken each puff immediately one after the other.

**Table No 24:** How did you store MDI?

Sl. No.	Response	Before Counselling	After Counselling
1	At room temperature	150	150
2	At cold temperature	0	0
3	At hot temperature	0	0

**Figure No 24:** Types of storage condition

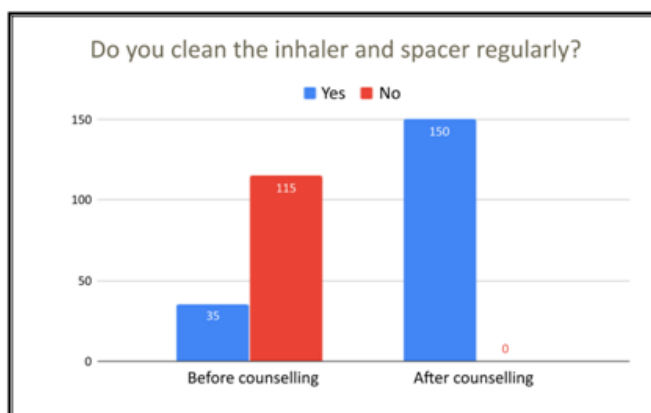


Among the 150 cases evaluated in the study, in both before and after counseling, all the 150 subjects followed the correct technique of storing the MDI at room temperature.

**Table No 25:** Do you clean the inhaler and spacer regularly?

Sl. No.	Response	Before Counselling	After Counselling
1	Yes	35	150
2	No	115	0

**Figure No 25:** Regular cleaning of inhaler and spacer before and after counseling

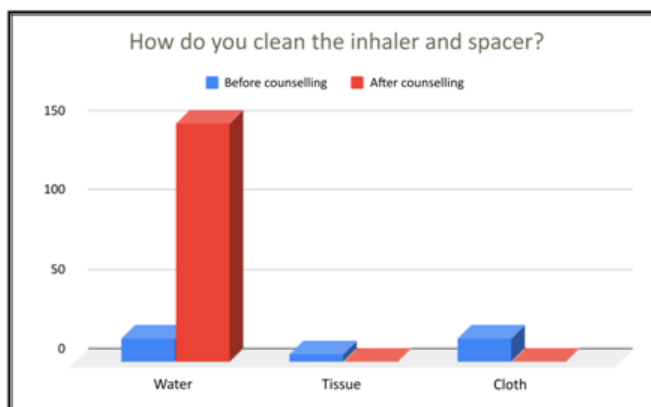


Among 150 study population, 35 subjects cleaned their inhaler and spacer regularly before attending the counseling. But after- counseling, all subjects followed the instruction of regular cleaning their inhalers and spacers.

**Table No 26:** If yes, how do you clean the inhaler and spacer

Sl. No.	Response	Before Counselling	After Counselling
1	Water	15	150
2	Tissue	5	0
3	Cloth	15	0

**Figure No 26:** Method of cleaning of inhaler and spacer

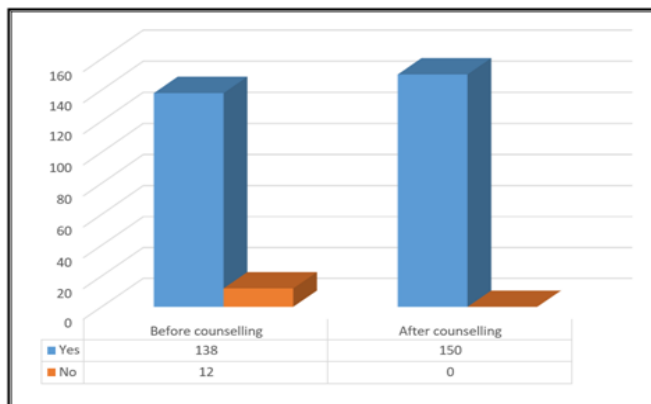


Among the 35 subjects who cleaned their inhaler and spacer regularly before attending the counseling, majority of them cleaned their inhaler and spacer using water and cloth (15 subjects each) and 5 subjects used tissue cleaned their inhaler. But after- counseling, all the subjects were using water to clean their inhaler and spacer.

**Table No 27:** Did you rinse your mouth after taking inhalers?

Sl.No.	Response	Before Counselling	After Counselling
1	Yes	138	150
2	No	12	0

**Figure No 27:** Rinsing of mouth after taking inhalers

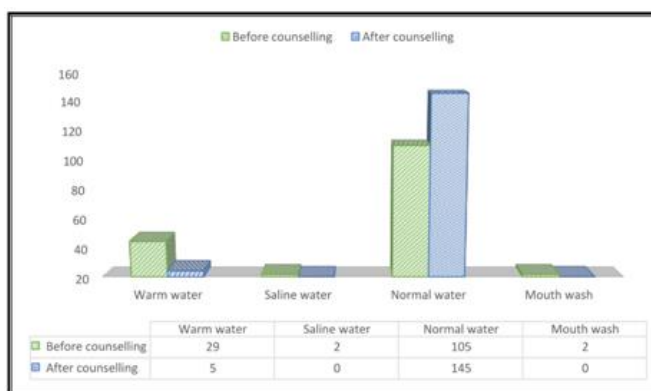


Among the 150 study population enrolled in the study, in before counseling session, 138 subjects were rinsing their mouth after taking inhaler. But, after-counseling all the 150 subjects were rinsing their mouth after taking inhaler.

**Table No 28:** If yes, how did you rinse your mouth?

Sl.No.	Response	Before Counselling	After Counselling
1	Warm water	29	5
2	Saline water	2	0
3	Normal water	105	145
4	Mouth wash	2	0
5	Others	0	0

**Figure No 28:** Mouth washing technique used

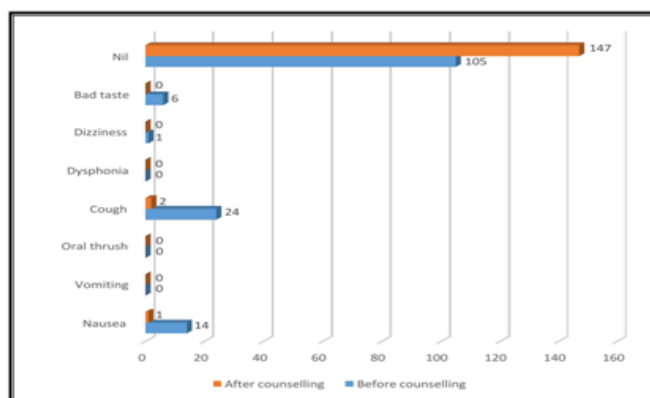


Among 150 study population enrolled in the study, in before counseling session, majority of subjects washed their mouth after using inhaler by using normal water (105 subjects), followed by 29 subjects used warm water, followed by 2 subjects used saline water and 2 subjects used mouth wash. But after counseling, 145 subjects used normal water to rinse their mouth and 5 subjects used warm water.

**Table No 29:** Did you experience any of the following problems when using MDI?

Sl.No.	Response	Before Counselling	After Counselling
1	Nausea	14	1
2	Vomiting	0	0
3	Oral thrush	0	0
4	Cough	24	2
5	Dysphonia	0	0
6	Dizziness	1	0
7	Bad taste	6	0
8	Nil	105	147

**Figure No 29:** ADR due to inhaler use

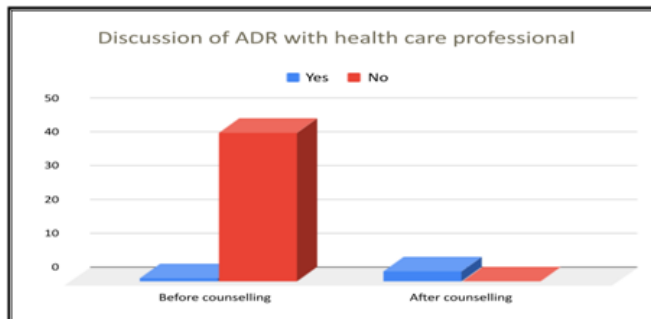


Among the 150 study population enrolled in the study, in before counseling 105 subjects did not experience any side effects as a result of the use of inhalers followed by 24 subjects experienced cough, 14 subjects experienced nausea, and followed by 6 subjects experienced bad taste and 1 subject had dizziness. But after counseling session, majority of the population did not experience any drug related problems (147 subjects) followed by 2 subjects had cough and 1 subject had nausea.

**Table No 30:** If yes, will you bring it to the notice of health care professionals that you had experienced drug related problems?

Sl.No.	Response	Before Counselling	After Counselling
1	Yes	1	3
2	No	44	0

Figure No 30: Discussion of ADR with health care professional

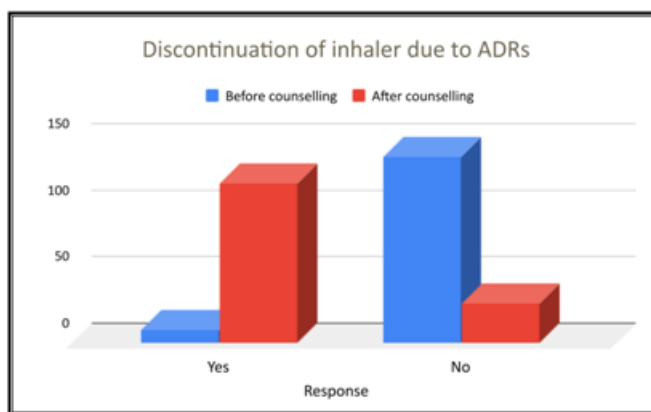


Among 150 study population enrolled in the study, in the before counseling session, 1 subject discussed their issue of ADRs with the health care professionals and in the after- counseling session, only 3 subjects discussed about ADR.

Table No 31: Will you stop using the MDI, if you feel the above stated symptoms in future?

Sl. No.	Response	Before Counselling	After Counselling
1	Yes	10	120
2	No	140	30

Figure No 31: Discontinuation of inhaler due to ADR



When asked about the stopping of MDI if experienced with ADR in future, in the before counseling session, only 10 subjects were willing to stop the use of MDI but after counseling number of subjects willing to stop the use of MDI increased to 120 subjects.

### Discussion

Metered dose inhalers (MDIs) are commonly used these days and this has led to the fast recovery of

disease as well as the decreased incidence of ADRs. The desired effect of the drug is gained only if its use is in the right manner. As explained in the study done by Purohit. A.N et.al, most of the people worldwide are not having the proper knowledge regarding the use of MDIs especially with spacers. If the MDI device is not used properly, the desired therapeutic benefit is not acquired. Many of the patients start to think that the problem lies in the medication and they are not benefited with the

treatment. If the patient is adherent to the therapy and is prescribed with the right drug, the next step is proper administration and handling of medications. Errors in administration and handling of medications can be rectified by proper patient counseling and this study aims at providing adequate patient knowledge on MDI use to help patient to attain the target of asthma control. This study focuses on the effectiveness of patient counseling on MDI use regarding the common side effects associated with inhaled medications.

### **Age and Gender**

Among the 150 study subjects enrolled in the study, 62% were females and were within the age group of 40-80 years, which is contradictory to the study done by Kakkanattu.T.J. et.al, where majority of the study samples were male and were between the age group of 13-40 years. Unlike the olden scenario, women are coming forward to get better treatments. Women seek medical help only, if their physical/mental state is that much worsened. This trend has been changed as women began to break the barriers in all the senses. Increasing age becomes a factor for decreased lung function. So patients under the age group of 40-80 years are more prone to lung diseases.

### **Educational Status and Income**

About 50% of the patients enrolled in the study achieved primary education and about 60% of the study samples were unemployed. This is similar to that of the study done by Chauhan et.al, in which primary education was the educational status of majority of the population under study and most of them were unemployed. Majority of the study population (43%) had a monthly income of 10,000-20,000 rupees.

### **Place of Residence and Social Habits**

About 83% of the study population was from rural areas and majority of the study samples (89%) had

no social habits like alcoholism, smoking, ex-alcoholism or smoking. Place of residence and social habits can influence disease like asthma. Alcohol contains substances that known to trigger asthma, like histamine and sulphur dioxide. Also cigarette smoke acts as an airway irritant. When a person inhales tobacco smoke, irritating substances settle in the moist lining of the airways and can set off asthma episodes. Often, the lungs of people with asthma who smoke are in a constant state of poor asthma control. These people often have on-going symptoms of asthma. Tobacco smoke also damages tiny hair-like projections in the airway called cilia. Normally, cilia sweep dust and mucus out of the airways. The cigarette smoke damages cilia so they are unable to work. Cigarette smoke makes more mucus than normal. As a result, when cilia do not work, mucus and other irritating substances build up in the airways. Unlike urban areas, the extend of pollution is less in rural areas. In rural area people depend more on fire wood than other cooking methods. Smoke from burning wood contains small airborne particles that contribute to indoor air pollution. Small particles in the air can pass through your nose or mouth and get into the lungs. This may cause or worsen asthma. As majority of the population is females, their exposure to fire wood may be the reason for their disease even though they had no history of social habits and exposure to urban pollution.

### **Allergic Status**

While assessing the allergic status, only about 16% of the study population presented with allergies in which 50% of the allergies were dust /pollen/animal fur allergies followed by 42% of the study samples had drug allergy and 8% had food allergy. As explained in a study done by Mathur.S.K et.al, the presence of allergic sensitivity is a clear risk for development of respiratory

disorders, especially asthma in childhood or even in adulthood. When people with allergies come in contact with allergens, their immune systems attack the allergens the same way they would a bacteria or virus. This would often leads to watery eyes, runny nose, coughing and also flare-up asthma symptoms.

#### **Patient's Knowledge on Use of Inhalers/Spacers**

While assessing the knowledge of study subjects on the use of inhalers, in the before counseling session, out of 12 steps, 70 subjects followed 9 steps, 37 subjects followed 10 steps and 27 subjects followed 8 steps correctly. Only 1 subject followed the whole 12 steps correctly. After the counseling session, 126 subjects followed the whole steps correctly.

Majority of the study population (about 90%) used spacers along with inhalers and all the study subjects used it regularly. A study done by Vincken. W. et.al explained that the regular use of spacer along with inhalers is essential to deliver the drugs correctly to the lungs with no systemic effects but only the desired local effects. Also healthcare professionals should be empowered and motivated to impart this knowledge in a uniform, systematic way as a part of routine management of airway diseases.

About 41% of the study population was taking the medication for less than 6 months and 34% of the study samples were on therapy for more than one year. This may be because of the selection of those patients who were new in the hospital as the study samples.

All of the 150 patients enrolled in the study used their inhalers by self before and after counseling as they were able to follow the instructions of inhaler use. According to Ho.S.F et.al, patient perception of their own inhaler skills correlates poorly with actual performance, hence their inhaler technique should be checked at every opportunity. If required, in the case of

elderly patients, their care givers can help them in using the inhaler devices.

In the before counseling sessions, only 119 patients took their medication according to the prescription and 31 patients took their medication whenever they needed. But after the counseling sessions, 149 patients followed the instruction of taking the medication only according to the prescription.

During the before counseling session, when a dose was missed, 85 patients skipped that dose and continued with the next one and 64 patients took the medication immediately as they remembered. But after the counseling sessions, 149 patients who skipped their missed dose went for the subsequent dose. The frequency of inhaler medicines is usually twice a day with a time gap of 12 hours. It is very important to take the second dose after 12 hours of the first dose for the dose accuracy. So if a dose is missed, it is better to take the next dose at the right time.

About 88% of the patients took two puffs. Before the counseling session, 54 patients took 2 puffs with no time gap and only 84 patients among the 150 study samples gave a time gap of 1 minute between the two puffs. According to D. Price. et.al, there should be a time gap of 1 minute between the two puffs of an inhaler. After the counseling session, it was observed that 149 patients followed this instruction.

Taking more puffs than instructed may lead to many side effects. Among 150 subjects enrolled in the study, 35 subjects had a tendency to take more puffs than indicated but this attitude was changed after the counseling sessions. About 85% of the study population used combination drugs and the rest of the population used single drug as their type of medication. According to Singh. D, combination inhalers give practical advantages together with increasing compliance as well

as maximizing the chance of synergistic interaction between monocomponents, aiming at optimizing the lung function, symptom relief and exacerbation reduction.

About 93% of the study population depended their clinicians for gaining knowledge on the method of use of inhalers. Rather than pharmacists or other medical professionals, patients trust their clinicians more and are only interested in communicating with them even if other healthcare professionals are ready to help them.

When asked about routine of washing mouth after the use of inhaler, 138 subjects had the habit of washing their mouth in the before counseling session. But after the counseling, all subjects started to wash their mouth after using inhaler. Out of 139 subjects who rinsed their mouth, majority of them used normal water. After the counseling session, the number of patients using normal water to clean their mouth increased from 105-145. According to Godara. N et.al, it is better to use normal water or basic solutions to rinse the mouth after using inhalers. The subjects were counseled to use normal water or basic oral solutions.

Sharing of the inhaler is not a good practice. Nobody among the study subjects shared their inhalers with others as it is not hygienic.

### **Cleaning and Drying of Inhalers/Spacer**

In the before counseling sessions, only 35 subjects cleaned their inhaler/spacer regularly but after the counseling sessions, all the subjects started cleaning inhaler/spacer on regular intervals. Out of 35 subjects who cleaned their inhaler/spacer, 15 study subject each used water and clothes respectively and 5 subjects used tissue. But after attending the counseling, all subjects used water to clean their inhaler/spacer. Those subjects who cleaned their inhaler/spacer in the before

counseling, majority of them used clothes (22 subjects) followed by 13 subjects used air to dry their inhaler/spacer. But after attending the counseling, all subjects started to use air to dry their inhaler/spacer. According to National Asthma Council Australia, cleaning spacers /inhalers using water and allowing parts to air dry without drying with cloth or paper is encouraged. Otherwise, it will result in static building up on the inside of the spacer, which makes the medication stick to the sides.

### **Storage of MDIS**

All the subjects under the study stored their MDI devices in room temperature. Lewis. D.A et.al suggests that transition between warm and cool environment can have a detrimental effect on dose drainage from MDI. So temperature fluctuations have to be avoided and it is better to keep MDIs at room temperatures.

### **Adverse Drug Reactions (ADRS)**

MDI use may cause ADRs in some patients. According to Pinto. R.C et.al, the common side effects associated with MDIs are nausea, oral thrush, cough, bad taste, dysphonia etc. In this study, 45 subjects experienced ADR in which 14 subjects complained about ADRs like nausea, 24 subjects complained about cough, 6 patients complained about bad taste and 1 experienced dizziness. These were first treated by decreasing the dose of the inhaler as reducing 4 puffs a day to 2 puffs a day. This was found to be effective and the ADRs began to subside. In the after counseling session, only 3 subjects experienced ADRs like nausea, cough etc.

Out of 45 subjects who encountered ADRs, only 1 subject informed the clinician about the ADR. Many of them believed that this is not the one to be rectified or to be informed to the clinician. During the



counseling session, they were advised to inform the ADR to clinician and seek the required instructions. After attending the counseling, 3 subjects who encountered with ADR, all of them were willing to inform their clinician about the occurrence of ADR.

In the before counseling session, 140 study subjects responded that they will not stop the use of inhalers if they encounter any ADR in the future. They might be thinking that, stopping the use of inhalers will again worsen their disease condition. They believe that all these side effects are the part of the drug that they are using. In the counseling sessions, the study subjects were counseled about the importance of stopping the inhaler use on occurrence of ADRs and 120 study subjects responded that they will stop the use of inhaler on the very moment they feel any difficulty and will inform their clinician as soon as possible.

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