

International Journal of Medical Science and Applied Research (IJMSAR)

Available Online at: https://www.ijmsar.com Volume – 4, Issue –2, March – 2021, Page No. : 09 – 35

Comparison Of Patient Knowledge On Safe And Effective Use Of MDI Before And After Counseling With The Help Of ACT Score

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Citation of this Article: Mrs. Gopika B, Ms. Anu Anna Varghese, Ms. Krupa Saji, Dr. Luke Mathew, Mr. Philip Jacob, Dr. Abel Abraham Thomas, Dr. Elessy Abraham, Dr. Reshma Elsa Tom, "Comparison Of Patient Knowledge On Safe And Effective Use Of MDI Before And After Counseling With The Help Of ACT Score", IJMSAR – March – 2021, Vol. – 4, Issue - 3, P. No. 09-35.

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Type of Publication: Original Research Article **Conflicts of Interest:** Nil

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. The objective of the study was to evaluate the effectiveness of patient and care giver training in the use of metered dose inhaler devices using Asthma Control Test score (**ACT**).A Quasi-Experimental study was carried out in 126 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. The study showed that, asthma was more prevalent in the age group of 60-80 years (38%) and most of them having poor inhalation technique during before counselling session. Thus counselling of the subjects regarding the proper use of MDI is very important and it made a huge impact on the disease process in asthmatic patients. Also a large variation in ACT score in the after counselling sessions compared to before counselling was observed ACT scoring is a validated scoring method used for assessment of asthma severity.

MDI- METEREDDOSE INHALER , ACT- ASTHMA CONTROL TEST.

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 [1]. 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 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 [34]. 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 [37]. Adequate patient education helps the patient to have a better adherence with the therapy and thus helps in gaining better disease control as well. The effect on patient education can be assessed with the help of ACT score established by America Thoracic society. This is a patient self- administered tool for identifying those with poorly controlled asthma. ACT assesses the frequency of shortness of breath and general asthma symptoms, use of rescue medications, the effect of asthma on daily functioning, and overall self-assessment of asthma control. The scores range from 5 (poor control of asthma) to 25 (complete control of asthma), with higher scores reflecting greater asthma control. An ACT score >19 indicates well-controlled asthma.

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

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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

- 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. Pediatric 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.
- 1. In the past 4weeks, how much of the time did your asthma keep you from getting as much done at work, school, or at a home?
 - All of time
 - Most of the time
 - Some of the time
 - A little of time
 - None of the time
- 2. During the past 4weeks, how often have you had shortness of breath?
 - More than once daily
 - Once a day
 - 3-6 times a week
 - Once or twice a week
 - Not at all
- 3. During the past 4 weeks, how often did you asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
 - 4 or more nights a week
 - 2-3 nights a week
 - once a week
 - once a twice a week
 - not at all

4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication?

- 3 or more times per day
- 1-2 times per day
- 2-3 times per week
- Once a week or less
- Not at all
- 5. How would you rate your asthma control during the past 4 weeks?
 - Not controlled at all
 - poorly controlled
 - somewhat controlled
 - well controlled
 - completely controlled

Score

Score: 25-asthma appear under control

Score: 20-24-reasonably well controlled

Score: less than 20-Off target

20. If not controlled (ACT score) why do you think it was not under control on inhalers?

- Patient symptoms not resolved
- Side effects
- Device not patient friendly
- 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.
- 1. 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 analyzed by using descriptive statistical method.

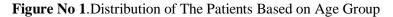
Statistical Analysis

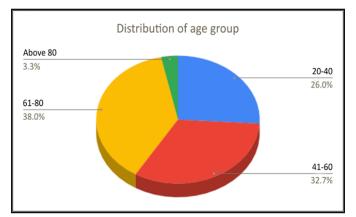
The study was analyzed by using Microsoft Excel 2007.

Result

S.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

Table No 1. Distribution of Age Group



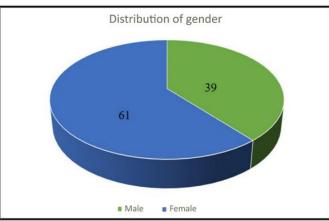


Among 150 study population enrolled in the study, the majority of the subjects belongs to the age

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.

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

Table No 2. Distribution of Gender



Among 150 study population enrolled in the study, the majority of subjects were females which were about 61%

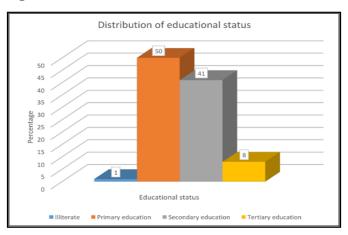
(92 subjects) and 39% were males (58 subjects).

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S. 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

Table No 3. Distribution of Educational Status

Figure No 3. Distribution of Patient's Educational Status

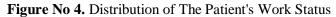


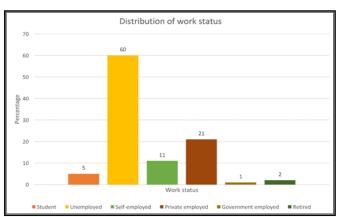
Among 150 study population enrolled in the study, the majority of study population had primaryeducation (50%), followed by 61 subjects had secondary education (41%), followed by 12 subjects had tertiary education (8%) and 1% of the subjects were illiterate.

Page .

 Table No 4. Distribution of Work Status

S. 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





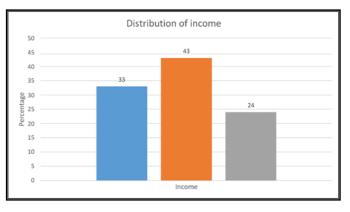
Among 150 subjects enrolled in the study, the majority of study population (60%) were unemployed, followed by 32 subjects were private employed (21%),

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%).

S. 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
		150	100

Table No 5. Distribution of Income

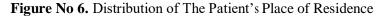
Figure No 5. Monthly Income of The Subjects

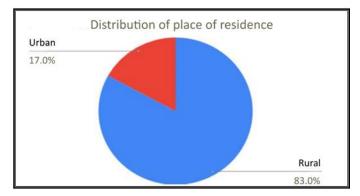


Among 150 subjects enrolled in the study, the majority of the subject's monthly income was 10,000-20,000 (43%) followed by 33% of subjects had monthly income of < 10,000 and 24% of subject's monthly income is > 20,000.

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

Table No 6. Distribution of Place of Residence



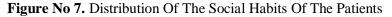


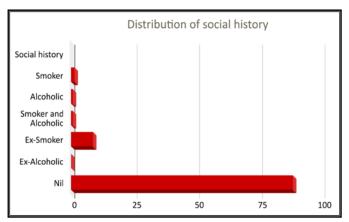
Among 150 study population enrolled in the study, majority of the population were from rural areas

which was about 125 subjects (83%) and rest of the population were from urban areas (25 subjects).

S. 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

Table No 7. Distribution of Social History





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

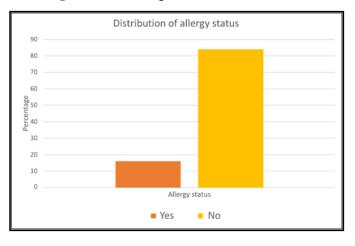
subjects had smoking as their social habit followed by 1 subject had alcoholism and 1 subject with both alcoholism and smoking as their social habits.

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Table No 8. Distribution of Allergy Status

S. 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

(84%) did not have any allergic status and 24 subjects

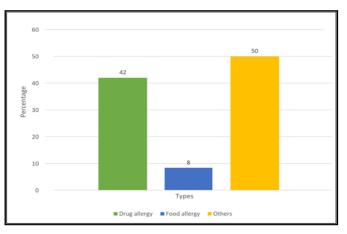
(16%) showed some sort of allergies.

study, majority of the study population, 126 subjects

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

Table No 9. Type of Allergies of Patients

Figure No 9. Distribution of Type of Allergy



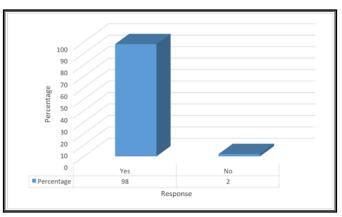
Among the 24 subjects who had allergy, 12grains,subjects had other types of allergy such as dust, pollendrug al

grains, animal fur etc. (50%) followed by 10 subjects had drug allergy (42%) and 8 subjects had food allergy (8%).

Table No 10. Habbit of Regular Exercise

S. No.	Response	Frequency	Percentage
1	Yes	147	98
2	No	3	2
	Total	150	100

Figure No 10. Regular Exercise



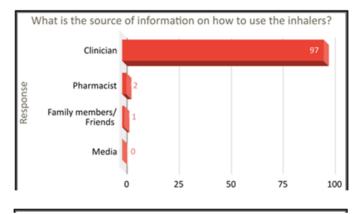
Among the 150-study population enrolled in the

study, 98% of subjects exercised on regular basis.

S. 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

Table No 11. Source Of Information On Use Of Inhalers

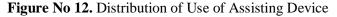
Figure No 11. Source of Information Of Inhaler Use

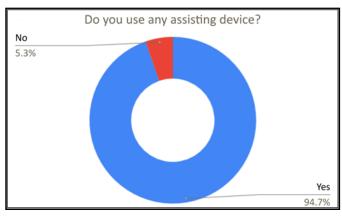


Among 150 study population enrolled in the study, majority of the subjects obtained knowledge regarding the use of inhaler from clinician (97%), followed by 2 subjects gained knowledge from pharmacist and 1 subject from family member.

Table No 12. Usage of Assisting Device

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





Among 150 study population enrolled in the study, majority of the study population used spacer along

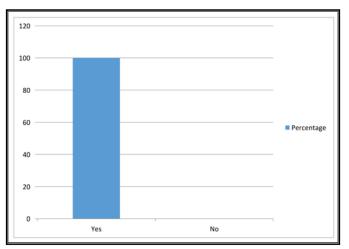
with MDI (95%) and rest of the population used MDI without spacer (5%).

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

Table No 13. Regular Use Spacer Along With MDI?

Figure No 13. Regular Use Of Spacer With MDI

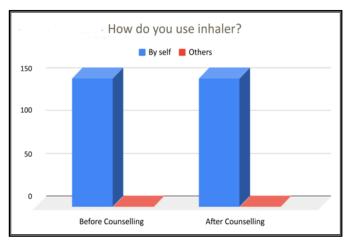


The above figure reveals that all of the 126 study

subjects regularly used spacer along with inhaler

Table No 14. Use of Inhaler

S. No.	Response	Before Counselling	After Counselling
1	By self	150	150
2	Others	0	0



Among 150 study population, all the subjects

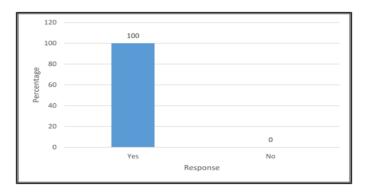
used inhaler by self in before counselling and after counselling.

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Table No 15. Patient's Knowledge about the	of Inhalers
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S. No.	Response	Frequency	Percentage
1	Yes	150	100
2	No	0	0
	Total	150	100

Figure No 15. Knowledge about the Use of MDI



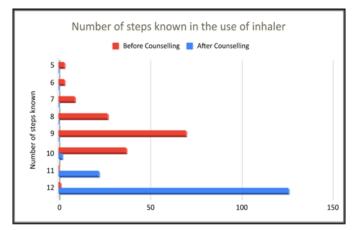
Among the 150 study population enrolled in the study,

100 % of subjects had proper knowledge about the use of MDI device.

Table No 16. Knowledge on method of use of inhaler before and after counselling

S. 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 No16. 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

N

12, 3 subjects knew 5 out of 12 and 1 subject knew 12

(126 subjects) followed by 22 subjects knew 11 out of 12

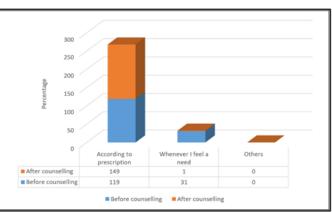
and 2 subjects knew 10 out of 12.

out of 12 in before counselling. But after counselling, majority of subjects were able to demonstrate 12 steps

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

Table No 17. Pattern of inhaler use

Figure No 17	. Time when	inhaler used
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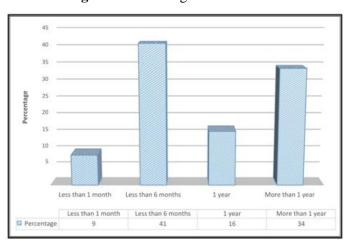


Among the 150 study population enrolled in the study, in before counselling, 119 subjects took inhaler according to the prescription and 31 subjects took inhaler whenever they felt a need. But after counselling, 149 subjects took inhaler according to prescription and 1 subject took inhaler whenever the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

S. 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

Table No 18. Length of inhaler use

Figure No 18. Length of inhaler use

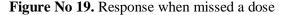


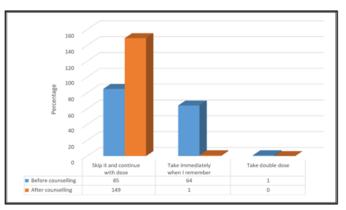
Among 150 study population enrolled in the study, majority of the subjects used the inhaler for less than 6 months (41%), followed by 51 subjects used the

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%).

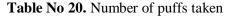
Table No 19. Pattern of use of drug when a dose is missed

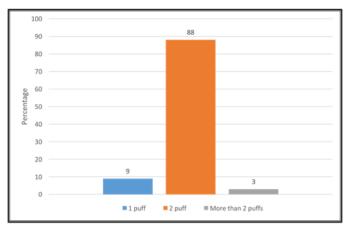
S. No.	Response	Before counselling	After counselling
1	Skip it and continue with dose	85	149
2	Take immediately when I remember	64	1
3	Take double dose	1	0





Among the 150 cases evaluated in the study, in before counselling 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 aftercounselling, 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.



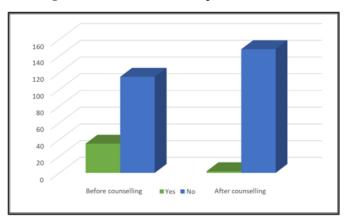


Among 150 study population enrolled in the study, majority of the subjects took 2 puff (88%), followed by 14 subjects (9%) took 1 puff at a time (9%) and the rest 4 subjects (3%) took more than 2 puffs at a time.

Table No 21. Habbit of taking more puffs than advice

S. No.	Response	Before counselling	After counselling
1	Yes	35	2
2	No	115	148

Figure No-21: Use of more puff than advised

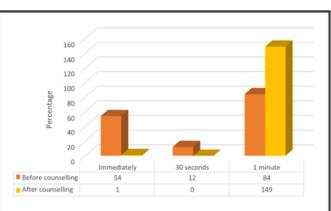


Among 150 study population enrolled in the study, majority of the subjects did not take more puff than advice (115 subjects) in the before counselling and 35 subjects took more puff than advice. But after counselling, 148 subjects followed the correct use, that is taking 2 puff and 2 subjects took more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

Table No 22. Time gap between each puff

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

Figure No 22. Time gap between each puff



Among the 150 study population enrolled in the study, in before counselling 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

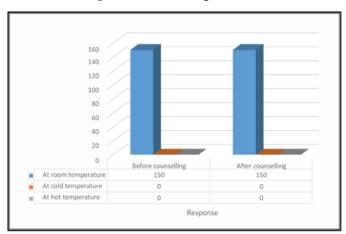
of the 12 subjects had taken the drug within 30 seconds time gap. But after patient counselling, 149 subjects followed the correct method of taking each puff 1 minute

apart and only the remaining 1 subject had taken each

puff immediately one after the other.

S. No.	Response	Before counselling	After counselling
1	At room temperature	150	150
2	At cold temperature	0	0
3	At hot temperature	0	0

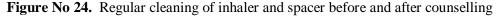
Figure No 23. Storage of MDI

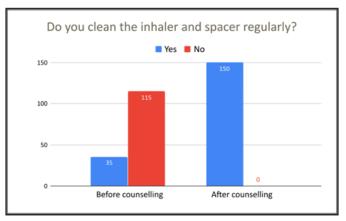


Among the 150 cases evaluated in the study, in both before and after counselling, all the 150 subjects followed the correct technique of storing the MDI at room temperature.

Table No 24. Regular cleaning of inhaler and spacer

S. No.	Response	Before counselling	After counselling
1	Yes	35	150
2	No	115	0





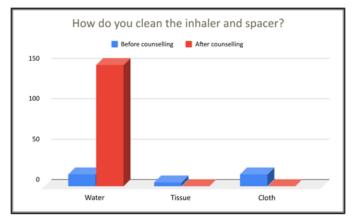
Among 150 study population, 35 subjects cleaned their inhaler and spacer regularly before attending the counselling. But after- counselling, all

subjects followed the instruction of regular cleaning their inhalers and spacers.

Table No 25. Cleaning techniques of inhaler and spacer

S. No.	Response	Before counselling	After counselling
1	Water	15	150
2	Tissue	5	0
3	Cloth	15	0

Figure No 25. Method of cleaning of inhaler and spacer



Among the 35 subjects who cleaned their inhaler and spacer regularly before attending the counselling, 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- counselling, all the subjects were using water to clean their inhaler and spacer.

Table No 26. Method of drying of inhaler and spacer after cleaning it

S. No.	Response	Before counselling	After counselling
1	By cloth	22	0
2	Air dry	13	150
3	Sun dry	0	0



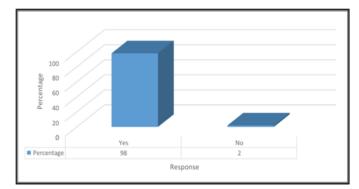
Figure No 26. Drying technique after cleaning the inhaler and spacer

Among 35 subjects who cleaned their inhaler and spacer before counselling, 22 subjects dried their inhaler after cleaning using cloth and 13 subjects used air dry. But after counselling, 150 subjects who cleaned their inhaler and spacer, dried it using air.

Table No 27. Method of the use of inhaler before instruction as per patient knowledge (act score)

S. No.	ACT SCORE	Interpretation	Before counselling	After counselling
1	25	Well controlled	0	0
2	20-24	On target	1	150
3	Less than 20	Off target	149	0

Figure No 27. Proper use of inhaler and control of asthma using act score

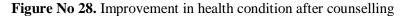


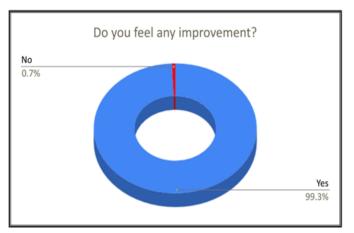
Among the 150 subjects enrolled in the study, a large variation experienced in ACT score both in before and after counselling sessions i.e,149 subjects who were

in off –target (less than 20) during before counselling, were brought to on- target (20-24) after counselling.

Table No 28. Evidence of improvement

S. No.	Response	Frequency	Percentage
1	Yes	149	100
2	No	1	0
	Total	147	100





Among the 150-study population enrolled in the study, 98% of the study subjects had improvement in their health condition.

Discussion

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

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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 counselling 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 counselling on MDI use and assessing the patient's recovery from the disease using ACT score through the phases of before and after counselling sessions.

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 ongoing 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 make more mucus then 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.

Habit of Exercising

About 98% of the study population had the habit of regular exercise especially breathing exercises such as pranayama, diaphragmatic breathing etc. According to Kang.J et.al, breathing exercises improve the lung function as it enhances the respiratory muscles resulting in easy breathing. The study subjects were counselled about the importance of breathing exercises and made sure that they are following it regularly.

Patient's Knowledge on Use of Inhalers/Spacers

While assessing the knowledge of study subjects on the use of inhalers, in the before counselling 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 counselling 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 counselling 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 counselling sessions, only 119 patients took their medication according to the prescription and 31 patients took their medication whenever they needed. But after the counselling sessions, 149 patients followed the instruction of taking the medication only according to the prescription.

During the before counselling 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 counselling 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 counselling 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 counselling 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 counselling 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 counselling session. But after the counselling, 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 counselling 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 counselled 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 counselling sessions, only 35 subjects cleaned their inhaler/spacer regularly but after the counselling 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 counselling, all subjects used water to clean their inhaler/spacer. Those subjects who cleaned their inhaler/spacer in the before counselling, majority of them used clothes (22 subjects) followed by 13 subjects used air to dry their inhaler/spacer. But after attending the counselling, 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.

Act Score

Based on ACT score, 149 patients in the study population was under the category "off-target" as they had poor control over asthma. But after the counselling sessions, all of the 150 samples reached "on-target" as their symptoms were subsiding and they got a better control over their disease. This was achieved as a result of the appropriate treatment and correct method of administration of drugs. Patient counselling helped the study population to understand the inhaler technique properly and also encouraged them to follow the instructions regularly. This helped them to get a control over their disease. According to Nguyen.T.S et.al, patient counselling helps to improve patient's inhaler technique aiming at better disease control.

Status of Improvement

All of the study population (100%) had improvement after the treatment and patient counselling sessions. On face-to-face interview with the patients, they responded that they have been highly benefited from the patient counselling sessions on MDI use. The sessions included demonstration of techniques, teach back method, explaining the techniques with the help of pictures and videos, counselling the care givers, telephonic conversations with the patients etc. All these techniques benefited as the patients were able to follow and reproduce the instructions. Counselling the care givers was a new approach which helped especially the elderly on the correct use of inhalers.

Conclusion

This Quasi-Experimental study was conducted among 150 subjects on the topic "Effectiveness of patient counselling in the use of metered dose inhaler" at Believers Church Medical College Hospital, Thiruvalla. The study was primarily focused on to the improvement of inhaler use in all the study subjects through proper counselling. Main strategies adopted were assessing the patient's knowledge about safe and effective use of MDI with the help of questionnaire, followed by patient spacer, importance of the assisting device, cleaning of inhaler device, storage of inhaler devices, drug related problems associated with MDI use etc. Upon patient's revisit, their knowledge about safe and effective use of MDI was assessed with the help of the same questionnaire. By comparing these two sessions, level of improvement of each subject on inhaler use after proper counselling session was analysed. In this study, an additional approach was used, that is validated ACT scoring method (Asthma Control Test) that helped the study to get a valuable result. ACT assesses the frequency of shortness of breath and general asthma symptoms, use of rescue medications, the effect of asthma on daily functioning, and overall self-assessment of asthma control etc. ACT score is divided into three categories "off target",

counselling. It includes, proper use of MDI along with

"on target" and the third one is "well done." ACT scoring provides a numerical score that help the health care providers to determine how well asthma has been controlled over the last 4 weeks, giving a score out of 25. If the score is 25 it belongs to the category, "well done" that means asthma appears to have been under control over the last 4 weeks. If the score is in between 20 to 24, it belongs to the category, "on target" that means asthma appears to have been reasonably well controlled during the past 4 weeks. If the score is less than 20, it belongs to the category, "off target" that means asthma may not have been controlled during the past 4 weeks. In the study conducted by Molimard. M et.al, inhalation technique of MDI by patients is inappropriate so proper patient counselling is needed. Taking more puff than advised, non-adherence in the technique of MDI use etc. lead to precipitation of ADR thus it complicates the management of asthma so proper counselling regarding the use of MDI is important in

patients with asthma in order to improve their disease condition and reduce the risk of adverse drug reaction. This study focuses on mentoring the patients as well as their caregivers on proper use of MDI.

From the study, majority of the study population (38%) were in the age group of 60-80 years, 33% of subjects were in 40-60 age group and 26% were in the age of 20-40 years. Majority of study population (61%) were females. That means, majority of our study subjects were elderly and females too. As majority of the population is elderly, they may experience physical challenges, impairment in hearing, loss of memory etc. which may impede device instruction and they may be unable to learn or retain techniques necessary for effective administration of MDI. So, it is necessary to counsel the caregivers too. Among 150 subjects enrolled in the study, 50% had primary education and majority of our study population (60%) were unemployed. About 43% had a monthly income of Rupees 10000-20000.About 83% of study subjects were from rural areas.

Social history such as smoking and alcoholism are some of the contributory factors for asthma symptoms but in our study, majority did not have such social history (89%) but 9 % were ex-smokers, followed by smoking, alcoholic and smoking+alcoholic to 3%. These could be the contributing factors to developed asthma. While assessing the allergic status, 16% of the study population presented with allergies in which 50% of allergens were dust, pollen grain and animal fur which are some of the common risk factor in asthmatics. About 42% had drug allergy and 8% had food allergy. During the counselling session, impact of exercise in controlling asthma were discussed, thus 98% of subjects exercised on a regular basis. About 97% gained information from clinician regarding the proper use of MDI and only few relatives etc. Majority of the study subjects (90%) used inhaler with the help of spacer devices and used it in a regular basis. While assessing the knowledge of study subjects on the 12 steps to be followed regarding the use of inhaler device, in the before counselling session, out of 12 steps, 70 subjects knew 9 steps, 37 subjects knew10 steps and 27 subjects knew 8 steps correctly and 1 subject knew all 12 steps. But after counselling session,126 subjects knew all 12 steps. This 12 steps instruction are very essential part of the study because majority of our subjects were elders and so there is increased chances for these subjects to forget on the ways to use inhaler and so mentoring the patients and caregivers would help to attain optimum therapeutic outcome and thereby achieve the prime goal of the present study. Most of the subjects were already aware of the problems while sharing an inhaler device such as infection, not all inhaler works in the same way for all person. Thus, all subjects did not share their inhaler with anyone. In the before counselling session, only 119 patients took their medication according to the prescription and 31 patients took their medication whenever they needed. But after the counselling session, 149 subjects followed the instruction of taking the medication only according to prescription. Taking medication according to the prescription is one of the crucial factors to avoid the deterioration of disease and occurrence of side effects. About 41% of the study population was taking the medication for less than 6 months and 34% of the study subjects were on therapy for more than 1 year. During the before counselling session, when a dose was missed ,85 patients skipped that dose and continued with the next dose and 64 patients took the medication immediately as they remembered, but after the counselling session, 149

gathered information from other sources such as friends,

patients followed the instruction of taking the missed dose by maintaining a gap of 12 hours. It is important to maintain a gap of 12 hours between 2 doses.

Among 150 study population enrolled in the study, majority of the subjects (88%) took 2 puff at a time and in before counselling session, about 35 subjects took more puff than advised and the number of subjects taking more puff than advised reduced to 2 in the aftercounselling session. In before counselling session, only 84 subjects among the 150 maintained the gap between 2 puffs as 1 minute, but after counselling,149 subjects followed the instruction of maintaining a gap of 1 minute. Temperature fluctuations can affect the medications in MDI so it should be kept at room temperature. All subjects followed the instruction and stored it only at room temperature. Cleaning the inhaler is another major concern, cleaning the spacer /inhaler with clean water and air to dry their inhaler will drive to the success of the treatment. In the before counselling session, only 35 subjects cleaned their inhaler or spacer regularly but after the counselling session all the subjects started cleaning their inhaler/spacer on regular intervals. Out of 35 subjects who cleaned their inhaler, 15 subjects each used water and cloth respectively and 5 subject used tissue for cleaning the inhaler and only 13 subjects followed air to dry their inhaler. But after the counselling session, all subjects followed the instruction of using water for cleaning their inhaler and air to dry their inhaler/spacer.

Based on the ACT scoring, 149 subjects in the study population were under the category "off- target" as they had poor control of asthma. But after the counselling session, all of the 150 subjects reached "ontarget" that is, they acquired a better knowledge that improved their adherence to treatment and also reducing their disease symptoms.

References

- Jabadzadh.Y,Yaqoubi.S.Therapeutic nanostructure for pulmonary drug delivery.Micro and nanotechnology2017; 619-638
- KhilaniG.C ,Banga.A . Aerosol therapy.The Indian Journal of Chest Disease and Allied Science 2008; 50:209-220
- 3. Ari.A. Patient education and adherence to aerosol therapy. Respiratory care 2015; 60(6): 941-957
- Kebede.B,Mamo G, Molla.A. Association of Asthma control and MDI use technique among adult asthmatic patients attending outpatient clinic,in research limited country: prospective study. Canadian respiratory journal2019:1-6
- Fink.J.B, Rubin.B.K. Problems with inhaler use : A call for improved clinician and patient education. Respiratorycare 2005; 50 (10) :1360-1375
- Mahon.J et al.Misuse and /or treatment delivery failure of inhalers among patients with asthma or COPD: A review and recommendations for the conduct of future research. Respiratory medicine 2017; 129:98-116
- Myers.T.R.The science guiding selection of an aerosol delivery device .Respiratory care 2013; 58 (11):1963-1973
- Frost.G.D,Penrose.A, Hall.J ,Mackenzie.D.I.Asthma related prescribing patterns with four different corticosteroids inhaler device. Respiratory medicine 1998; 92:135-1356
- Dubus.J.C.Marguet.C,Deschildre.A.Local side effects of Inhaled corticosteroid in asthmatic children: influence of drug ,age, dose and device .European journal of Allergy and immunology 2001;56(10): 944-948
- 10. I.JWilliamson,S.P.Matusiewecz,P.H.Brown,A.P.Gre ning,G.K.Crompton.Frequency of voice problems

- Dr. I. Hmimidi, et al. International Journal of Medical Science and Applied Research (IJMSAR)
 - and cough in patients using pressurized aerosol inhaled steroid preparation.EurRespir J 1995;8:590-592
- 11. Pinto.R.C. et.al,Local adverse effects associated with use of inhaled corticosteroids in patients with moderate or severe asthma. Journal Brasileirodepneumologia 2013;39(4): 409-19
- C.Terzano.Metered dose inhalers and spacer devices. European Review for Medical and Pharmacological Sciences 1999; 3:159-169
- Magroni.M.S. et.al.Asthma control in primary care: The results of an observational cross- sectional study in Italy and Spain. World Allergy Organization Journal 2017;10(13): 1-7
- Schatz.Met.al.Asthma control test:Reliabity, Validity, and Responsiveness in patients not previously followed by asthma specialists Journal of Allergy and Clinical immunology 2006:549-555
- 15. Purohit.N.A, Patel.P.P, Desai .K.M.An evaluation of impact of educational interventions on the technique of use of metered dose inhalers by patient. Indian Journal of Pharmacology 2017;49(2):194-200.
- Kakkanattu.T.J. et.al,Impact of MDI technique education in medical outpatient department. Journal of clinical and diagnostic research 2018:12(8):5-7
- 17. Chauhan. et al.An evaluation of metered dose inhaler administration technique in patients of Asthma and Chronic Obstructive Pulmonary Disease. Journal of Applied Pharmaceutical Science 2016;6(2):115-118.
- Ganguly.A. et.al.Study of proper use of inhalation devices by bronchial asthma or COPD patients attended in a tertiary care hospital. Journal of Clinical and Diagnostic Research 2014;8(10):4-7.
- 19. Normansell. R, Kew. K.M, Mathioudakis. A.G, Interventions to improve inhaler technique for people

with Asthma .Cochrane Database of systematic review.2017;3:1-121.

- 20. Nguyen.T.S. et.al,Pharmacists training to improve inhaler technique of patients with COPD in Vietnam.International journal of COPD 2018;13:1863-187
- 21. Price.D. et.al.Factors associated with appropriate inhaler use in patients with COPD .International journal of COPD 2018;13:695-702
- 22. E.Nadi,F.Zeraati,Evaluation of Metered Dose Inhaler technique among healthcare providers. ActaMedicaIranica 2005;43(4):268-272
- 23. Sharma.S,Chhabra.G,Luhadia.S.K,Knowledge,attitu de,practicesof inhalational therapy among nursing staff posted at tertiary care hospital. International Journal of Research Medical Services 2017;5(10):4285-4288
- 24. Shastay.A,CorrectUse Of Inhalers: Help Patient Breathe Easier, Home health care;36(4):262-263.
- 25. Sanchis.J,Gich.I,Pedersen.S,Systematic Review of Errors In Inhaler Use. Has Patient Technique Improved Over Time? Respiratory care2016;150(2):394-406
- 26. Job.F.M. et al.Enhancing Respiratory Medicine Adherence: The Role of Health care Professionals And Cost –Effectiveness Considerations. Journal of allergy And Immunology 2016;4(5):835-846
- 27. Klijin.S.L. et.al.Effectiveness and success factors of educational inhaler technique interventions in asthma and COPD patients : a systematic review. Primary Care Respiratory Medicine2017;24;1-10
- 28. Al-Moamary.M.S,Al-Karodi.A,Al-Gobain.M.O,Tamin.H.M,Utilization and responsiveness of ACT at the initiation of therapy for patients with asthma : a randomized controlled trial. BCMC Pulmonology Medicine 2012;12(14):2-7

.

- Axtell.S,Haines.S,Fairclough.J. ,Effectiveness of Various Methods of Teaching Proper Inhaler Technique:The importance of Pharmacist Counselling.Journal of pharmacy practice2017;30(2):195-201
- Press.G.V. et al. Effectiveness of intervention to Teach Metered-Dose and Discuss Inhaler Techniques.AnnalsATS journal2016;13(6):816-824
- Abegaz.M.T,Shegena.A.E,Gessie.F.N,Gebreyohanns
 .A.E,Seid.A.M.Barriers to and competency with the use of metered dose inhaler and its impact on disease control among adult asthmatic patients in Ethiopia.BMC pulmonary Medicine2020;20(48):1-13
- 32. Basheti.A.I,Salhi.B.Y,Basheti.M.M,Hamadi.A.S,Alqerem.W.Role of pharmacist I improving inhaler technique and asthma management in rural areas in Jordan.Clinicalpharmacology:Advances and Applications2019;(11):103-116
- 33. Pereira.P.L,Clement.Y,Simeon.D.Educationalinterve ntionfor correct pressurised metered dose inhaler technique in Trinidadian patients with asthma.Patient Education counselling2001;42(1):91-97
- 34. Hammerlein.A,Muller.U,Schulz.M.Pharmacist-led intervention study to improve inhalation technique in asthma and COPD patients.Journal of Evaluation in Clinical Practice2011;17:61-70
- 35. Ansari.M,Rao.S.B,Koju.R,Shakya.R.Impact of pharmaceutical intervention on inhalation technique.Journal of Science ,Enginearing and Technology2005;1(1):1-10
- 36. Molimard.M. et al.Assessment of Hanling of Inhaler Devices in Real Life: An Observational Study in 3811 Patients in Primary Care.Journal of aerosol medicine2003;16(3):249-254

- 37. Bosnic-Anticvevich.Z.S,Sinha.H,So.S,Reddel.K.H.
 Metered dose inhaler technique :The Effect of Two Educational Interventions Delivered in Community Pharmacy Over Time.Journal of Asthma2010;47:251-256
- 38. Harnett. M.C. et. al.A study to assess inhaler technique and its potential impact on asthma control in patients attending an asthma clinic.Journal of Asthma2014;51(4):440-445
- 39. King.L.T,Kho.Y.K.E,Tiong.H.Y,Julaihi.B.N.S.Com parison of effectiveness and time-efficiency between multimedia and conventional counselling on metered-dose inhaler technique education.Journal of Singapore Medicine2015;56(2):103-108
- 40. Rahmati.H,Ansarfard.F,Ghodsbin.F,Ghayumi.A.M,S ayadi.M.The Effect of Training Inhalation Technique with or without Spacer on Maximum Expiratory Flow Rate and Inhaler Usage Skills in Asthmatic Patients:A Randomized Controlled Trial.International Journal of Community Based Nursing and Midwifery2014;2(4)211-219
- 41. Haddad.M.R,Al-

Momani.A.J,Alnadi.M.K,Dbase.F.A.Local side effects of inhalers in patients with COPD in KHMC.Middle East Journal of Internal Medicine2017;10(3):1-4

- 42. Kaplan.A,Price.D.Matching Inhaler Devices with Patients:The Role of the PrimaryCarePhysician.Canadian Respiratory Journal2018;2018:9473051
- 43. Galvan .A.C, Guarderas.C.J.Practical Considerations for Dysphonia Caused by Inhaled Corticosteroids.Mayo Foundation for Medical Education and Research 2012;87(9):901-904
- 44. Nizet.C.A.T,Broeders.C.A.E.M,Folgering.M.Th.H.T remor side effects of salbutamol, quantified by a

laser pointer technique.Journal of Respiratory Medicine2004;98:844-850

- 45. Ali.M.Y.Appropriateness of metered-dose inhaler use in the Yemini community pharmacies.Journal of Taibah University of Medical Science2015;10(3):353-358
- 46. Mebrahtom.M .Mesfin
 N.Gebreyesus.H.Teweldemedhin.M.Status of
 metered dose inhaler technique among patients with
 asthma and its effect on asthma control in Northwest
 Ethiopia.BMCReaearch notes2019;12(15):2-6
- 47. Suthar.J,Patel .A.Z.Shelat.B.Assessment of Inhalation Technique in COPD and Asthma Patients using Metered Dose Inhaler and Rota-haler.Indian Journal of Pharmacy Practice2019;12(4):217-224
- Melani.S.A. et.al.Inhaler mishandling remains common in real life and is associated with reduced disease control.Journal of Respiratory Medicine2011;105(6):930-938
- Mathur.S.K, Vishvanathan.R.K.Relevance of Allergy in Adult.Curr Allergy Asthma Rep2014;14(5):437-346
- 50. Vincken.Wet.al,Spacer devises for inhaler therapy:why use them, and how?ERJ open research 2018;4:1-10
- 51. Ho.S.F et.al, Inhaler technique in old people in the community.Age and Aging 2004;33(2):185-188
- 52. D.Price. et.al, Inhaler competence in asthma: Common barriers to use and recommended solutions.Respiratory Medicine 2013;107:37-46
- 53. Singh.D, The benefits of combined treatment with corticosteroids and long- acting beta agonists.International Journal of COPD 2006;1(3):207-208

- 54. Godara.N, Godara.R, Khullur.M, Impact of Inhalation Therapy and Oral Health.Lung India2011;28(4):272-275
- 55. Lewis.D.A et.al, Exploring the impact of formulation and temperature shock on metered dose inhaler priming.Aerosol Science And Technology 2017;51(1):84-90
- 56. Kang.J, Jeong.D, Choi.H, The effects of breathing exercise types on respiratory muscle activity and body function in patients with mild chronic obstructive pulmonary disease.The Journal of Physical Therapy Science2016;28:500-505