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COST EFFECTIVE ANALYSIS OF INHALERS USED FOR ASTHMA MANAGEMENT: AN INTERVENTIONAL APPROACH

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Keywords:

Asthma, Corticosteroids, Inhalers, Adherence, Patient satisfaction, Prospective Interventional sampling

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ABSTRACT: Background and Objectives: The aim of the study is to evaluate the comparison based on cost effectiveness of inhalers used for asthma managements. The study utilized prospective interventional sampling approach and included Patient above 18 years and below 60 years, outpatients and In-patients, Asthma patients with comorbid conditions and excluded Pregnant and lactating women, unwilling patients, Subjects with communication problem, terminally ill/ ICU patients, Patient having insurance. **Results:** The incidence of asthma was seen mostly in the patients of age category 48 years and older (30.6%). Most of the patients were from the upper middle category (59%). After giving proper counselling to the patients, it was clearly evident that there will be improvement in adherence (76.4%). The subjects (47.2%, n=68) were found to be highly satisfied with the treatment provided to them by the physician. The PFT values after adherence were found to be 84.118±12.647. The most common inhaler device was found to be (61.1%, n=88). The mean drug cost for Budesonide/Formoterol was found to be less compared to other Rupees 476.095±119.717. **Interpretation and Conclusions:** When considering the mean cost of corticosteroid inhaler, Fluticasone/ Formoterol was considered as cost effective followed by other alternatives. The corticosteroid inhaler with high effective but consider to be high cost when compared with Budesonide/ Formoterol, Fluticasone, but least cost when compared with Mometasone containing inhaler.

INTRODUCTION: Asthma is a condition in which the airways become narrow and swollen and may produce extra mucus. This can cause difficulty breathing, coughing, wheezing (wheezing) and shortness of breath [1]. For some people, asthma is a minor concern. For others, it can be a major problem that interferes with daily activities and can lead to life-threatening asthma attacks.

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Asthma cannot be cured, but the symptoms can be controlled. Because asthma often changes over time, it's important to work with the doctor to track the signs and symptoms and adjust the treatment as needed. Asthma is the primary physiological event that causes clinical symptoms, airway narrowing and subsequent airflow obstruction.

In acute asthma exacerbations, bronchial smooth muscles contract (bronchoconstriction) to narrow the airways in response to various stimuli, such as allergens or irritants. Allergen-induced acute bronchoconstriction is caused by the release of Ig E-dependent mediators from mast cells, including histamine, tryptase, leukotrienes, and prostaglandins.

Aspirin and other nonsteroidal anti-inflammatory drugs can cause acute airflow obstruction in some patients, and evidence suggests that this non-Ig E-mediated response involves the release of mediators from airway cells. In addition, other stimuli (including exercise, cold weather, and stimulants) can cause acute airflow obstruction [3]. Steroid medications, also known as corticosteroids, are often prescribed to treat asthma [4]. Steroids are effective in reducing asthma symptoms in many people, but they do not work for everyone. Additionally, some steroid prescriptions can cause serious side effects [5].

Inhaled steroids reduce swelling in the lungs and allow to breathe better. In some cases, they also reduce mucus production. It takes several weeks to see results from inhaled steroids. It cannot be used to treat asthma attacks when they occur but can prevent future attacks [6]. In most cases, the longer the steroids are being used, the more likely there is a need to rely on a rescue inhaler [7]. An inhaler is a hand-held portable device that delivers medicine into the lungs. There are a variety of asthma inhalers available to control asthma symptoms [8]. To find the best inhaler its needed to find a balance between the right medication and the type of inhaler that suits the needs and the ability to use the inhaler properly [9].

The cost-effective method suggest that such program is mainly used to reduce economic burden, improve knowledge, decreasing exposure to asthma triggers, enhancing the outcome of the disease, improve the quality of life [10]. The cost-effective ratio will compare both the cost and effectiveness of the treatment by calculating with the use of incremental cost effectiveness ratio (ICER).

$$ICER = C_1 - C_0 / E1 - E0$$

(C_1 represent the cost of intervention, C_0 represent the cost of pre-program, E_1 represents the outcome after the intervention, and E_2 represent the outcomes before the intervention). The specific objectives are to:

1. Find out the cost effectiveness of corticosteroid inhalers.
2. To compute patient counseling on administration technique of inhaler use.
3. To assess the factors influencing prescribing pattern of inhalers.
4. To evaluate the patient contendness and elements influencing the medication adherence.
5. To evaluate the prescribing criterion of inhalers.

MATERIALS AND METHODS: The study was carried out under Pulmonology Department at NIMS Medicity, Neyyantinkara, Tertiary care Teaching hospital in Trivandrum, Kerala. The inpatients and outpatients from the Pulmonology Department of NIMS Medicity, Neyyantinkara, Trivandrum, Kerala. The sample size at 95% confidence interval was 160 with a level of significance of 0.05. The study was sanctioned by Institutional ethical committee with approval number: ECR/218/Inst/Ker/2013/RR-20. The P-Value was determined by using Z-Test and Student T-Test. After the collection of the data, it was recorded and analyzed using MS Excel spreadsheet and SPSS version R.

Experimental Design: The study was a prospective interventional approach which was carried out over a period of 6 months commencing from September 2023 to February 2024. The study included the Patient above 18years and below 60years, Outpatients and In-patients, Asthma patients with comorbid conditions and excluded those patients who are Pregnant and lactating women, unwilling patients, Subjects with communication problem, terminally ill/ ICU patients, Patient having an Insurance.

Study Variables: Patient socio demographic factors such as age, gender, education, employment, social habits, sedentary lifestyle, comorbidities, mental and physical discomfort, perceptions towards disease.

Socio – economic factors determine health include occupational, education, monthly income using modified Kuppuswamy socio-economic scale. Direct cost includes visits to emergency services, hospital admissions, medications, including all types of medications, such as over-the-counter and alternative medicines, outpatient visits. Indirect costs include work-related losses e.g. temporary

disability in terms of partial or total lost-days, early disability, permanent disability.

Data Collection and Analysis: The data collection form include patient demographics, reason for admission, education, occupation, income, PFT values, prescribed medication cost, laboratory values include ESR, CRP values and expenses related to medical condition and other expenses. The modified Kuppuswamy Socio- economic scale was used to assess socioeconomic status.

Tools and Questionnaires used:

Modified Kuppuswamy Scale: The modified Kuppuswamy scale is commonly used to measure SES in urban and rural areas. This scale was developed by Kuppuswamy in 1976 and consists of a multi-point scale of 3-29 that assesses the education and occupation of the head of the household, and the household's monthly income. This scale divides the study population into five SESs. The occupation and education of the head of the household is mostly unchanged over time. The scale must be updated according to changes in the Consumer Price Index (CPI), so that the socio-economic scale is applicable to the population being studied [11].

The economic burden can be evaluated from Kuppuswamy scale. It should describe the individual background status. Based on patient need's the physician should prescribe the medication for better clinical outcome [12].

Medication Adherence Reasons Scale (Mar-Scale): The Medication Adherence Reasons Scale (MAR-Scale) is a comprehensive 20-item scale developed to measure medication adherence. The scale has 1 item assessing the overall level or frequency of non-adherence and 19 items frequently cited by patients as a common reason for non-adherence. The scale was developed with the goal of developing a specific measure based on the items in the scale [13, 14, 15].

The patient counselling which involves the healthy interaction between the pharmacist and patients. The objective of the patient counselling is to bring the intervention after the therapeutic outcome, the resulting with comparison of pre-treatment and posttreatment [16, 17].

Lung Function Biomarker: PFT was used to measure the condition of movement of air in and out of the lungs FEV1 was considered the main PFT biomarker for assessing severity of asthma in the subjects and it's divided into five levels based on % predicted value.

- FEV1 > 70% of mild prediction.
- FEV1 - 60-69% is average.
- FEV1 -50-59% is moderate to severe.
- FEV1 -35-49% is worse.
- FEV1 <35% is considered very severe.

Method of cost Calculation: Costs were divided into two categories: direct costs and indirect costs. Direct costs consisted of direct medical costs and direct non-medical costs. Direct medical cost comprised self-reported clinical and hospital charges including prescription, consultation, diagnostic and procedure charges from different types of healthcare facilities.

Other costs in the category included were the costs of transportation, meals, accommodation, and other related expenditures. Indirect costs consisted of the opportunity cost of the time of the respondents during the course the treatment. Informal care costs by the caregivers were not included for this study due to unavailability of data [18]. The corresponding unit cost for each component of inpatient and outpatient care services; information on time spent in the facility; the length of stay; number of absent days from work after discharge.

RESULTS AND DISCUSSION:

Dropouts:

- Total number of samples: 160
- Total number of dropouts: 16

With respect to **Table 1** The drop out category are considered to be high in age group of 18-27, due to the reason for medical distrust in physicians and hospitals, due to high cost of medication, lack of communication between physician and patient, due to belief in chance of productivity loss.

TABLE 1: BASELINE PARAMETERS OF DROPOUTS

Age (Years)	18-27	28-37		38-47	≥48
	5	4		3	4
Gender	Male (9)			Female (7)	
Socio Economic Status	Lower (0)	Upper Lower (0)	Lower Middle (6)	Upper Middle (10)	Upper (0)
Total Cost of Inhalers (Rupees)			817.375		
Total Cost (Rupees)			3714.76		

Subject Demographic Details: The most prominent age category was found to be 48-60 years. The mean age of the patients was found to be 39 yrs. This is because of multiple underlying diseases and have prominent exposure to the outside world therefore there is a higher chance of incidence [19, 20]. The gender wise distribution was found to be equal (50%, n=72) for both the categories [21, 22, 23] based on study of gender difference, the mechanism driving was more common towards female when compared to the men due to the role of sex hormone in regulating asthma condition. It was clearly evident that the middle class are often more included and the treatment options for asthma such as inhalers and steroids are more likely accessible to affluent families [24, 25]. The study has shown that the increased risk of asthma condition is severe in low social class groups. Based on **Fig. 1** female patients belonging to the category of 28-38 years was considered to be potentially affected with asthma condition.

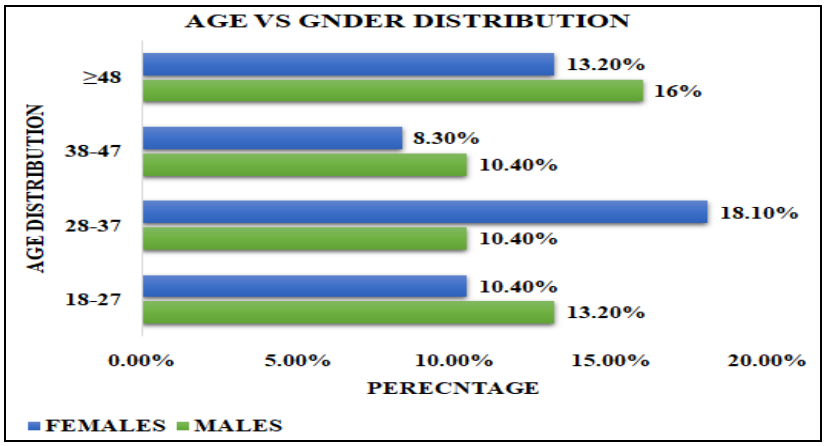

FIG. 1: BAR DIAGRAM REPRESENTING PERCENTAGE DISTRIBUTION OF AGE AND GENDER

Women are supposed to regulate with sex hormone during puberty, menstruation period and pregnancy [26, 27]. The study clearly define the socioeconomic status relation with asthma condition. The age group from 20-60 year from the lower social class group considered as more prone towards the risk of asthma and they are more potential to increase the condition. The patients belonging to the age group of 18-27 of the category lower middle are mostly presented with asthma condition Since, the middle-class accounts for a sizable portion of the Indian population [28]. Majority of the patients are from the lower middle and upper lower class. The males (n=46, 31.9%) are more, followed by the females from the lower middle group (n=43, 29.9%).

Based on Patient Contentedness, Adherence and Effect of Counselling on Inhalers and corticosteroids: The percentage of adherence to the prescribed medication and proper use of inhalers after the counselling given (76.4%, n=110) are considered to be more than those patients non-adherent (23.6%, n=34) to the medication [29]. From here we know good adherence results with lower risk of severe asthma exacerbation that would reduce the impact of economic burden in the population. From the above study people belonging to upper middle and upper lower are found to be highly adherent to the prescribed medication when compared with other categories. The reason for which, the people belonging to the upper middle class has more concern regarding the health status among family, society when compared to other commodities. From **Fig. 2** (p value=0.051: *Significant)* the patients' administrating Fluticasone/ Formoterol was found to be highly adherent to the medication prescribed by physician

when compared to the other three alternatives. Whereas 9.7% (n=14) of the patients taking Fluticasone alone was found to be non-adherence. In case of Mometasone even though 9.7% (n=14) patients were found to be adherent, the satisfaction score was very less. More adherence is seen in the case of Budesonide+ Formoterol group. It reveals that (47.2%, n=68) was highly satisfied with the intervention provided followed by (36.8%, n=53) was moderately satisfied and finally (16%, n=23) was less satisfied with the interventions provided to them when compared to the other two. The dissatisfaction was higher among the patients with high number of asthma control problems, with physician communication problems, belief in medication problems, belief in religion. From the study patients were found to be highly satisfied with the treatment regimen when treated with Fluticasone+ Formoterol (31.9%, n=46), whereas the satisfaction was less with Mometasone (9.7%, n=14).

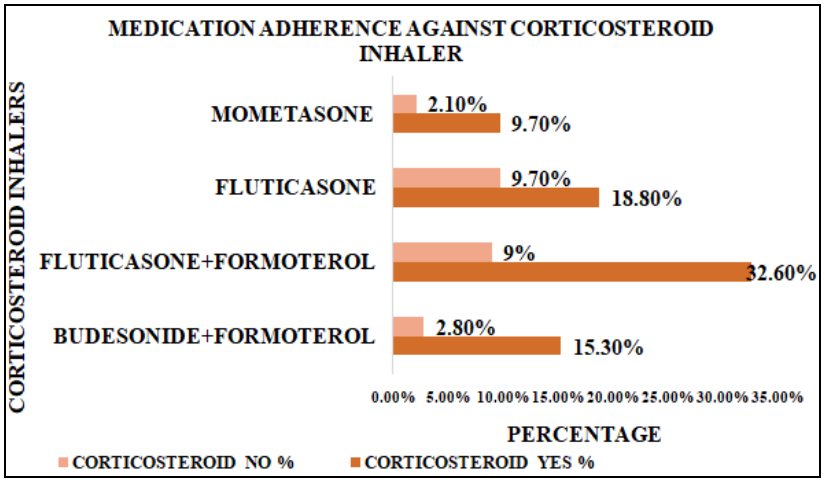

FIG. 2: BAR DIAGRAM REPRESENTING PERCENTAGE DISTRIBUTION OF MEDICATION ADHERENCE AGAINST CORTICOSTEROID INHALERS

It was due to high individual drug cost of Mometasone when compared with Fluticasone+ Formoterol the Fluticasone containing corticosteroid significantly reduce the asthmatic symptoms associated with comorbidities and improve quality of life. From **Fig. 3** (p value = 0.02: *Significant)* it was evident that the patients are highly satisfied with a satisfaction score of two while using MDIs. The least satisfaction score of Four was noted in patients using Revolizer. Initially, PFT value measured with decreased level lung function, the PFT values was F_1VC (22.9), $FEF_{25-75\%}$ (22.29), FEV_1 (23.81), FVC (25.58). The asthma condition, in which it should be gradually reversible and diagnosed with given Bronchodilator.

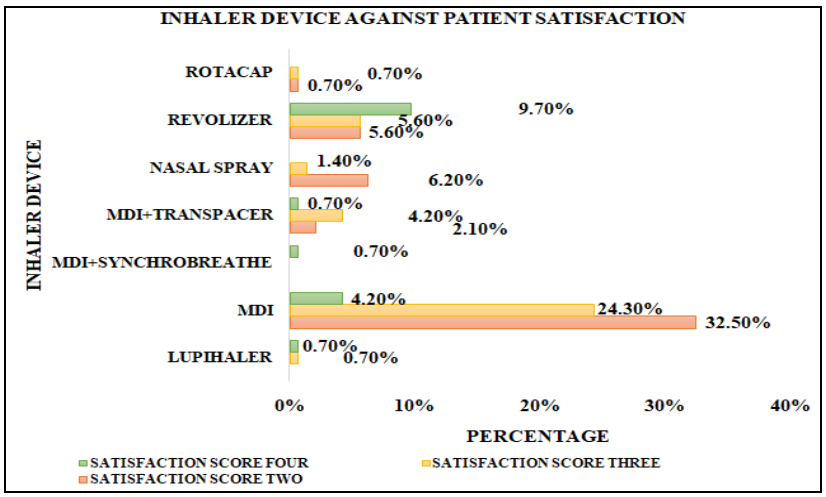

FIG. 3: BAR DIAGRAM REPRESENTING PERCENTAGE DISTRIBUTION OF INHALER DEVICE AGAINST PATIENT SATISFACTION

The effect of patient counselling, medication adherence, proper treatment regimen should be measured after the follow up. Here PFT parameters before and after the follow up was measured, it shows that all the PFT parameters were improved drastically after the initial patient follow up. After the subjects was given adequate counselling techniques regarding the use of Inhaler devices, the importance of medication adherence was examined using the PFT parameters after following up and it's found to be F_1VC (78.02), $FEF_{25-75\%}$ (78.35), FEV_1 (81.03), FVC (81.32). Here PFT value shows the declined level of mean distribution before proper medication adherence. The current study shows the importance of medication adherence in asthma control; the gradual difference should be revealed in subject after following up. The PFT value after following up shows an elevated level of mean distribution after medication adherence. The study used to measure the impact of medication adherence in asthma management, the effective patient counselling used to calculate the level of medication adherence in patients. From **Fig. 4** Medication adherence of the patients was measured before and after following up.

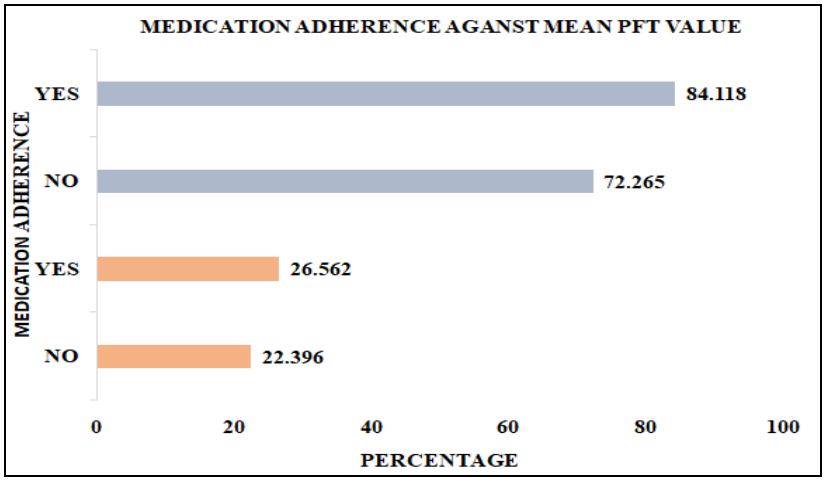

FIG. 4: BAR DIAGRAM REPRESENTING PERCENTAGE DISTRIBUTION OF MEDICATION ADHERENCE AGAINST MEAN PFT VALUES

In which the patients after the initial diagnosing of the condition and persecuting an optimal therapeutic regimen for the condition. In which 22.396±32.543, 26.562±33.507 was the mean PFT values before following up. 72.265±5.754 and 84.118±12.647 were the mean PFT values for non-adherent and adherent patients after the follow up. From the current study it was clearly evident that those patients who are adherent to their therapeutic regimen has an elevated mean PFT values (84.118±12.647).

Cost Effective Analysis of Corticosteroid Inhaler and Devices: The study reveals that the MDIs are considered to be cost effective when compared with other alternative inhaler devices. Here it was evident that the most commonly used Corticosteroid for the management and prevention of asthma is Fluticasone/ Formoterol (41.70%, n=60), Followed by fluticasone alone (28.50%, n=41), Budesonide/ formoterol (18.00%, n=26) and Mometasone (11.80%, n=17).

From **Fig. 5** (p value = 0.04: *Significant)*, the mean cost of the corticosteroid inhalers was found as Budesonide/ Formoterol (476.095 ± 119.717), Fluticasone (848.300 ± 304.897), Fluticasone/ Formoterol (684.512 ± 228.646), Mometasone (1351.000 ± 0.000).

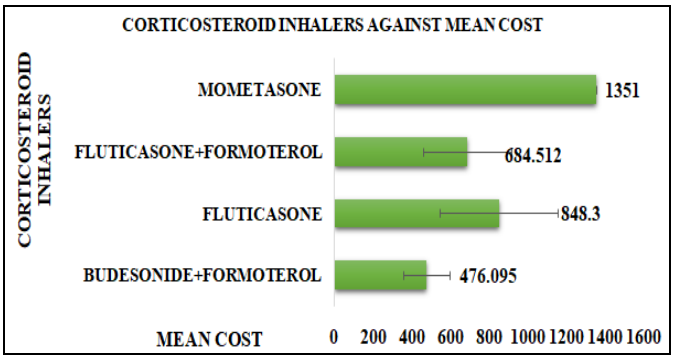

FIG. 5: BAR DIAGRAM REPRESENTING DISTRIBUTION OF CORTICOSTEROID INHALERS AGAINST THEIR MEAN COST

Mometasone has higher Mean cost when compared to other three alternatives, whereas Budesonide/

Formoterol could be considered as a cost-effective alternative to Mometasone. The satisfaction of the treatment received by the patients was classified based on three scoring such as Two (highly satisfied), Three (Moderately Satisfied), Four (Unsatisfied). The total cost of the treatment received by the patient plays an important role in scoring overall patient's satisfaction. From the above study it was examine that the patient satisfaction was less in overall mean total cost. It was expressed as two (5209.958 ± 682.683), three (5316.983 ± 828.759), four (5876.708 ± 1182.828). It says that higher patient satisfaction rate shows less hospital visits and the chance of exacerbation is reduced in asthma patients. The dissatisfaction was higher among the patients with a high number of asthma control problems. Here Fluticasone/ Formoterol is more cost effective than Budesonide. Corticosteroid medications are considered to be effective in asthma management. The better option is to administrate inhaler rather than tablet. The choice of drug should vary upon the patient's need. **Fig. 6** reveals that corticosteroid containing Fluticasone/ Formoterol are better option to treat asthma patient while considering on cost effective management.

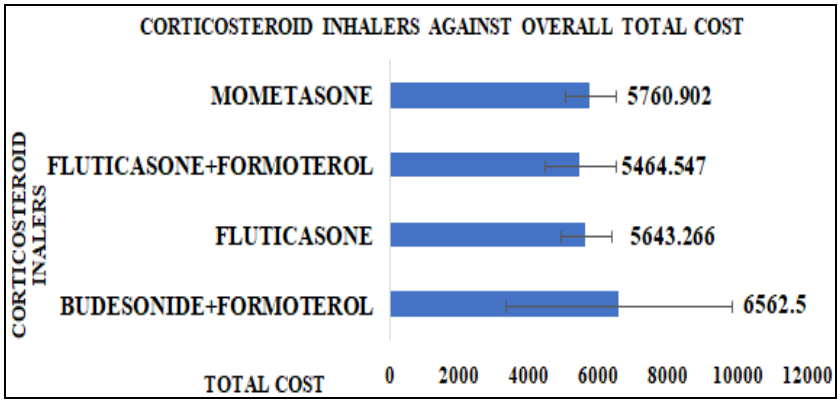

FIG. 6: BAR DIAGRAM REPRESENTING PERCENTAGE DISTRIBUTION OF CORTICOSTEROIDS AGAINST OVERALL TOTAL COST

Four different corticosteroid inhalers were mainly prescribed by the physician Budesonide/ Formoterol (735.000 ± 339.411), Fluticasone (1207.731 ± 331.329), Fluticasone/ Formoterol (1126.292 ± 349.444), Mometasone (1648.374 ± 97.015). The mean drug cost was measured, and it was analysed that the mean drug cost of Mometasone (1648.374 ± 97.015) was compartively higher when compared to Budesonide/ Formoterol (735.000 ± 339.411). The patients recieving Budesonide/ Formoterol experienced 14.1 more SFDs per year, had 69% fewer hospital days and 67% fewer emergency room visits. Medication adherence towards medication was measured. It was then correlated to the total drug cost before and after following up. From **Fig. 7** (p value = 0.013: *Significant)*, The mean total drug cost was found to be (1154.499 ± 369.435) and (1151.144 ± 400.200) before the follow up, then the mean cost was (1325.624 ± 425.919) and (544.042 ± 398.614) after the follow up. Most of the patient shows increased adherence towards medication, resulted with the mean total drug cost (544.042 ± 398.614) after follow up when compared to the non-adherent subjects.

Factors Influencing Prescribing Patterns and Criterion of Inhalers and Corticosteroids: From the study it was able to understand the most commonly used inhaler device is MDI. By considering the age wise distribution the patients of the age group 28-37 years are mostly prescribed MDI followed by 18-27 years. Patients older than 50 yrs are shown to have errors in taking the MDIs. It was evident that the most commonly used and prescribed inhaled corticosteroid is Fluticasone/ Formoterol. It shows that the long-term use of corticosteroid inhaler result with eye disorders, oral candidiasis, dysphonia, hypertension etc. From the study MDI is the most commonly used inhaler device in this hospital setting with the higher prescriptions seen in case of females (32.6%, n=47) when compared to male populations (28.5%, n=41). Here Fluticasone/ Formoterol was most commonly prescribed Corticosteroid inhalers among males (27.1%, n=39) and Fluticasone alone

is the most preferred corticosteroid inhalers used for females (20.8%, n=30).

CONCLUSION: When considering the mean cost of corticosteroid inhaler, Fluticasone/ Formoterol was considered as cost effective followed by other alternatives. The corticosteroid inhaler with high effective but consider to be high cost when compared with Budesonide/ Formoterol, Fluticasone, but least cost when compared with Mometasone containing inhaler. The direct patient/ caregiver interaction is an important factor to implement new system; the proper counselling technique of inhaler use will bring an impact on asthma control. The use of clear, local language and visual aids will be enhancing comprehension in this study. The direct patient counselling will influence the patient medication adherence and bring high degree of patient satisfaction. The elements will be directly measured and cleared based on the individual needs. The prescribing pattern should be changed according to degree of satisfaction and scoring medication adherence.MDI inhaler was mainly used in the individual between the age of 18-60 years.

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CONFLICTS OF INTEREST: The authors declare that they have no conflict of interest.

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