Factors Associated with Underutilization of Inhalation Corticosteroids among Asthmatic Patients Attending Tikur Anbessa Specialized Hospital

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This is to certify that the thesis prepared by Yohanes Ayele entitled: *Factors Associated with Underutilization of Inhalation Corticosteroids among Asthmatic Patients Attending Tikur Anbessa specialized Hospital*, and submitted in partial fulfillment of the requirements for the degree of Master of Pharmacy in Pharmacy Practice complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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Abstract

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Addis Ababa University, 2015

Inhalation Corticosteroids (ICS) is a cornerstone medicine for preventive therapy of persistence asthma. However, underutilization of ICS is common and little is known about factors contributing to this underutilization. The objective of this study was to assess factors associated with underutilization of ICS in asthmatic patients. A cross-sectional study involving interview was conducted among asthmatic patients attending chest clinic of Tikur Anbessa Specilized Hospital (TASH) from 1 May to 31 July, 2014. A total of 131 patients were included in the study. In addition, physicians working at the chest clinic of TASH were also requested to fill out a self-administered questionnaire. A multivariate logistic regression was employed to examine the association between variables. Overall, underutilization of ICS from patients' perspective was found to be 64.7%. Monthly income, comorbidity and manners of ICS use were found to be significantly associated with underutilization of ICS. Patients' reported reasons for underutilization of ICS include; unaffordability, using only when symptoms appear, inaccessibility, side effects and recommendation by physicians. Similarly, physicians reported unaffordability, fear of side effects and dependency, and inaccessibility as reasons for underutilization of ICS. In this setting, prevalence of underutilization of ICS was high, and is associated with unaffordability and inaccessibility of ICS, patients' poor knowledge of asthma and ICS, negative attitude toward ICS, and absence of local guideline for asthma management.

Thus, concerned authorities need to take measures that ensure availability of ICS at an affordable price and increase awareness of patients on ICS and asthma.

Key words: - Inhalation corticosteroids, Underutilization, Asthma

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List of Abbreviations and Acronyms

AAU	Addis Ababa University
AOR	Adjusted Odds Ratio
CI	Confidence Interval
COR	Crude Odds Ratio
COPD	Chronic Obstructive Pulmonary Disease
ETB	Ethiopian Birr
GINA	Global Initiative for Asthma
ICS	Inhalation Corticosteroids
ISAAC	International Study of Asthma and Allergies in Childhood
ILD	Interstitial Lung Disease
LABA	Long Acting Beta Agonist
LM	Leukotriene Modifiers
NHLBI	National Heart, Lung, and Blood Institute
OR	Odds Ratio
SPSS	Statistical Package for Social Science
SD	Standard Deviation
TASH	Tikur Anbessa Specialized Hospital
WHO	World Health Organization

1. Introduction

1.1 Background

"Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role, in particular, mast cells, eosinophils, T lymphocytes, neutrophils, and epithelial cells. In susceptible persons, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough, particularly at night and in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment."[1]

Approximately, 250 million people worldwide have asthma.[2] The disease is more prevalent in developed countries with highest rate seen in Australia (21.5%), Sweden (20.2%), the United Kingdom (18.2%), Canada (14.1%), and the United States of America (10.9%).[3,4]

Although not comparable with high income countries, many low and middle income countries are showing an increase in prevalence, increasing the overall world burden of asthma.[5]According to World Health Organization (WHO) survey report, the mean prevalence of asthma was 8.2% and 5.2% in poorest countries and middle income countries, respectively.[6] In Africa estimate suggested that greater than 50 million individuals have asthma.[3] Some of African countries are shown to have high asthma prevalence, for example, South Africa (8.1%),[7] Nigeria (7-18%),[8] and Egypt (9.4%).[9]

With respect to asthma prevalence in Ethiopia nationwide data addressing adult population is lacking. Community based studies done in Jimma reported 3.6 % prevalence of asthma.[10] Other studies indicated 10.7 % and 16.2% of 12 months self-reported prevalence of wheezing in school children in Addis Ababa and Gonder, respectively.[11,12] Similarly, International Study of Asthma

and Allergies in Childhood (ISAAC) phase three study estimated asthma symptom (wheeze in the past 12 months) prevalence of 9.9% in pediatric population of Ethiopia.[5]

The expression of asthma is a complex interactive process between; host factors, particularly genetics, and environmental exposures that occur at a crucial time in the development of the immune system.[1,13] Multiple interacting genes are involved in the process, some having a protective effect and others contributing to the disease pathogenesis.[14] Genetic factors account for 35% to 70% of the susceptibility.[15] Environmental risk factors for the development of asthma include socioeconomic status, family size, exposure to second hand tobacco smoke in infancy and in utero, allergen exposure, urbanization, and decreased exposure to common childhood infectious agents.[16]

Asthma can often be diagnosed on the basis of a patient's symptoms and medical history.[1] Measurements of lung function such as peak expiratory flow rate and forced expiratory volume in the first second provide an assessment of severity and help confirm the diagnosis of asthma.[17]

Assessment of severity is essential to guide initial doses of medications and the frequency of subsequent medical review.[17,18] The severity of asthma varies within and between individuals and is judged according to symptoms and medication requirement. Chronic bronchial asthma is classified as intermittent or persistent asthma. The latter is again divided into mild, moderate and severe persistent asthma.[1,17- 19]

Airway inflammations are a major factor in the pathophysiology of asthma and remain as a primary target of treatment. Although asthma cannot be cured, appropriate management can ensure adequate control of the disease, reverse and even prevent disease process and enable people to enjoy good quality of life. The successful management of patients with asthma includes four essential components: routine assessment and monitoring, patient education to create a

partnership between clinician and patient, controlling environmental factors and comorbid conditions that contribute to asthma severity and pharmacologic therapy.[1,16]

Pharmacological therapy is key part of asthma management. Generally, asthma drugs can be classified as relievers (short acting bronchodilators with rapid onset) and controller. There are two groups of controllers; those with anti-inflammatory action including corticosteroids and leukotriene modifiers (LM), and those with a sustained bronchodilator action including long acting β-agonists (LABA) and slow-release theophyllines.[1,17-120]

Medications with anti-inflammatory activity are recommended for all patients with persistent asthma and ICS are the first line drugs for maintenance therapy.[19] ICS available alone as inhaled formulations include: beclometasone, budesonide, fluticasone, mometasone, ciclesonide, flusinolide and triamcinolone.[13] Currently, there are also five ICS and LABA combination products available on the market: budesonide and formoterol, fluticasone and salmeterol, mometasone and formoterol, beclomethasone and formoterol, and fluticasone and vilanterol.[21]

Guidelines recommend a stepwise approach for treatment of asthma.[1,16] Treatment is started at the step most appropriate to the initial severity of the asthma, with the aim of achieving early control of symptoms and optimizing respiratory function. Control is maintained by stepping up treatment as necessary and stepping down when control is good.[1,17-20]

For adult patients, mild intermittent asthma is treated with inhaled short acting beta two agonists as required, otherwise called Step1. Persistent asthma treatment starts from Step 2 and goes up to step 5. Step 2 is dedicated for treatment of mild persistence asthma with regular low dose (100-250 µg) of beclometasone or its equivalent daily. Alternatively, LM can be used. Moderate persistence should be treated with low dose ICS and LABA. Alternatives include medium dose of ICS (250-500 µg) or high dose (>500-1000 µg) beclometasone or low dose ICS and orally

administered LM or sustained release theophylline. Two (Step 4 and 5) options are available for management of severe persistent asthma depending up on the response of the patients. At step 4, medium or high doses of ICS and LABA daily could be sufficient. Alternative include medium or high doses of ICS and LM or sustained release theophylline. At Step 5, continuous or frequent courses of oral corticosteroids (lowest possible dose) are introduced to Step 4 regimen.[17,22]

1.2 Statement of the Problem

The burden of asthma is significant and its impact include reduced quality of life, lost productivity, increased health care costs, the risk of hospitalization and even death.[23] Worldwide 180,000 deaths are attributed to asthma each year, most of this coming from low and low to middle income countries.[2]

Not only the human burden but also economic burden of asthma is also considerable. For example, in the United State alone, the annual economic cost of asthma was estimated at $19.7 billion.[24] In Europe, the total cost of asthma was estimated to be $21.65 billion per year.[7] In developing countries, annual asthma cost was estimated at $20 billion.[25] These deaths and costs are usually attributed to poor asthma control and management.[24]

While the disease has substantial impact on health care costs and patients morbidity and mortality, there are effective treatments.[26] ICS are the most effective medications for long-term control of persistent asthma across all age groups and in most of the therapy care steps.[27,28,29] However, studies done in different part of the world indicate low utilization of these key medications.[14,24,30] Underutilization of ICS leads to poor asthma control, frequent emergency room visit, hospitalizations, and an reduction in quality.[6] The problem is significant in developing countries where asthma is mostly under treated, leading to high morbidity and mortality.[30]

In this respect, Ethiopia is not an exception. A Study done in Jimma reported only 3.8 % use of ICS among all asthmatic patients attending Jimma University Specialized Hospital.[31] Another study done in TASH [32] also reported underutilization of ICS (24%) being a significant predictor of uncontrolled asthma and asthmatic attacks. However, the studies did not indicate factors that are contributing for the problem. Therefore, the aim of this study was to identify the factors associated with underutilization of ICS.

1.3 Literature Review

1.3.1 Prevalence of Inhalation Corticosteroids Use

Despite proven benefit of ICS for persistence asthma, studies done in different parts of the world have failed to show their adequate utilization owing to different factors, both patients and care providers related.[8,25,30]

A retrospective chart review study was conducted to assess the prevalence of specific factors considered causative or contributive to asthma.[33] In this study, it was reported that 65% of the patients had been using a dose of ICS below that recommended in the National Heart, Lung, and Blood Institute (NHLBI) guideline. Similarly, a retrospective study done in France on asthma management practices of general practitioners using a computerized database reported about 38.4% of ICS underuse.[34]

A study carried out by prescription monitoring in order to establish drug-prescribing trend of anti-asthmatic drugs in two hospitals of India and reported only 30.9% ICS use.[35] Similarly, A survey conducted in the general population of asthma in North Africa (Tunisia, Algeria and Morocco) by structured telephone interview to evaluate asthma control using sample of 624.[36] In

this study, it was reported that only 163 subjects (26.1%) had been receiving ICS alone or in combination with LABA.

In Ethiopia, studies focusing on ICS use have rarely been done, A cross-sectional study done in Jimma [31] to assess asthma control on asthmatic patients attending chest clinic of Jimma Uinversity Specialized Hospital, reported only 9 subjects (3.8%) using ICS while similar study done in TASH indicated about 76% [32] ICS use.

1.3.2 Factors Related to Underutilization of Inhaled Corticosteroids

Studies done previously have indicated that socio-demographic characteristics like age, sex, educational status, and monthly income to contribute to underutilization of ICS.[26,37,38]

Regarding age of patients, contradicting findings have been reported. A study was conducted to assess factors associated with underuse of ICS and over use of inhaled beta agonists in adult patients.[26] In this study, it was reported that younger population (18-34) had more probability of underutilization of ICS compared to older population. By contrast, Sin and Tu,[39] on their study of pattern of ICS use among elderly patients(≥65), reported age as an important barriers to ICS therapy in this population.

A number of studies have failed to show association between sex and ICS underutilization.[40,41] However, high risk of underutilization of ICS among female patients was reported.[26] Similarly, other study reported underuse of ICS among female population compared to the male gender.[39]

Although, most of the studies done in the area failed to demonstrate significant association between educational background and ICS underutilization,[40] a few studies have reported significant relation between these two variables. For example, study done in the United State found significant association between less than 12 years formal education and ICS underuse.[37]

Similarly, a Saud Arabian study reported significant association between irregular use of ICS and less than high school education (p=0.03).[42] =

Other important socio-demographic factor often mentioned in relation to ICS use, including in developed countries is income of patients. A study reported significant association between less than $20,000 (P=0.002) household income a year and underutilization of ICS.[37] A Canadian study done to assess factors associated with the appropriate use of asthma drugs also highlighted the negative impact of low level income of patients' on ICS use.[43]

A related concern to income of patients is the issue of affordability of ICS. Generally, it is well understood that cost of medications affects utilization pattern of patients adversely. The problem is critical when it comes to asthma drugs, particularly ICS, which is the mainstay therapy of asthma. Studies done in different corners of the world have indicated low affordability of ICS including in developed countries. For instance, a study done in four states of the USA (Alabama, California, Illinois, and Texas) suggested affordability of ICS as one of the factor predicting patients-reported use of ICS.[41] The finding showed that insured patients had significantly higher odds for the use of ICS [Crude Odds Ratio (COR) = 2.38;CI,1.06–5.11] compared with uninsured patients.

Unaffordability is not the only problem related to ICS use but unavailability also a huge concern, particularly in developing countries. Studies reported that many asthma patients in developing countries was not receiving adequate treatment because ICS was either excessively expensive or not available.[6,25,44] Similarly, a literature review done in Nigeria on challenges of asthma management also indicated a high cost and unavailability of ICS as a major obstacle for adequate asthma management.[7] Similar findings were reported from Uganda [45] and Ethiopia.[6,31]

Other than socio-demographic characteristics, disease characteristics like severity and duration of asthma and comorbidity have been suggested in association with low ICS use.

Because of increased burden of disease among severe asthma patients, one may expect increased use of ICS in this population. A study supports this idea reporting that patients with moderate or severe asthma were more likely to use ICS than mild asthma.[26] Similarly, other studies also showed greater compliance among patients with severe persistent asthma than moderate persistent asthma.[36,46] On the other hand, a study conducted to evaluate the effect of severity on compliance to four times a day dosing of beclomethasone did not find significant relationship between the change in asthma severity and compliance with the beclomethasone regimen.[50]

There is a popular belief that compliance to medication increases with duration of disease. However, studies that are discordant to this notion can be found in the literature. For example, a study done in France found that the odds for taking medication as prescribed decreased as duration of asthma increased.[51] Similarly, longitudinal study [52] done on asthma and allergy patients reported patients tending to "distance" themselves from medical therapy and adapting in their own ways to the illness.

It would not be incorrect to speculate association between comorbidity and medication adherence. Studies have reported poor medication adherence among patients with comorbidity.[46,53] Studies done on ICS utilization have also reported similar finding. For example, according to study done in Canada,[39] patients with comorbidity were at an increased risk of not receiving ICS therapy compared to those having no comorbidities [Adjusted odds ratio(AOR) =3.45, 95% CI:1.56 - 7.69].

Other factors worth mentioning in relation to underutilization of ICS include patients' understanding of the disease process, medications and their attitude toward the disease and the medications, particularly ICS.

Patients understanding of the disease and their attitude are very important part of the medications use. It has been reported that patients fail to understand underlining pathophysiology of the disease, which is an inflammatory nature of asthma. Some patients also believe that asthma is an episodic rather than a chronic.[37] These misunderstandings could directly influence ICS utilization pattern of the patients. For example, studies have indicated that asthma patients discontinue or reduce the dose of ICS when they become symptom free.[37,42,46,54] A cross-sectional survey was done on 394 patients in Philadelphia to determine factors associated with regular use of ICS.[54] In this study, the most frequently cited reasons for inconsistent use of ICS was a belief that it was unnecessary during asymptomatic periods.

Similarly, knowledge of ICS and attitude toward it could affects compliance. Studies have indicated that patients discontinue or reduce the dose of the ICS due to misunderstanding the role of ICS,[55] fear of perceived side-effects [56] and fear of addiction to ICS.[37] For example, a Canadian survey of 603 asthmatic patients, aimed at determining the perception of the role and potential side effects of ICS, reported side effects as a major reason for reduced ICS use (59%).[55] Similarly, a study assessed asthma patients' self-reported behaviors towards ICS.[57] In this study, discontinuation and reducing of ICS dose, mentioning continuous use could be harmful, was found to be common practice. A prospective study of 334 adult asthmatic patients who were prescribed with ICS in Saudi Arabia also reported fear of addiction (60%) and side effects (40%) affecting regular uses of ICS.[42]

Apart from patients' related factors, care providers' related factors have been suggested to contribute to low ICS use. For example, a study reported prescribers failing to increase the dose of ICS for treatment of uncontrolled asthma.[58] Similarly, study done in Latin America, reported lack of trend toward increased use of ICS as severity of the disease changes from mild to severe persistent asthma.[59]

In addition, lack of awareness and failure to adhere to asthma management guidelines have been related to underutilization of ICS.[33,45] In connection, evidence also suggest that physicians under prescribe ICS.[60,61] A study was done to assess the cause of suboptimal ICS use among Canadian children with persistent asthma.[60] This study had identified that ICS are often not prescribed for long term daily uses as recommended by Canadian asthma consensus guideline for patient with persistent asthma. Another study done in Uganda also reported under prescribing practice of ICS.[45]

2. Objectives

2.1 General objective

To asses factors associated with underutilization of ICS in asthmatic patients attending at the chest clinic of Tikur Anbessa Specialized Hospital.

2.2 Specific objectives

- ✓ To describe the disease characteristics of the study participants
- ✓ To determine prevalence of ICS use
- ✓ To determine knowledge and attitude of the participants towards asthma and ICS
- ✓ To identify factors that influence ICS use

3. Methods

3.1 Study Setting and Period

The study was conducted at the chest clinic of TASH from 1 May to 31 July, 2014. TASH is located in Addis Ababa, the capital of Ethiopia, and it is the largest hospital in the country and provides a tertiary level care. Affiliated with the Addis Ababa University (AAU), College of Health Sciences, TASH is training center for medical and other health sciences students. The hospital has 800 beds and offers treatment for approximately 370,000- 400,000 patients per year both at inpatient and outpatient levels.[62] The hospital has different specialized clinics like Oncology, Cardiology, Chest, Renal, and Gastroenterology among others.

In the study clinic, patients with various respiratory disorders including asthma, Chronic Obstructive Pulmonary Disease (COPD), and Interstitial Lung Disease (ILD) are followed and treated. The unit has around 600 asthmatic patients registered for follow up care. At the time of data collection, the clinic had nine physicians (one senior pulmonologist, five fellow pulmonologists and three residents) and four nurses.

3.2 Study Design

Facility based prospective cross-sectional study involving patient interview and chart review was conducted in TASH to assess factors associated with underutilization of ICS.

3.3 Source and Study Population

The source populations were all patients attending the chest clinic of TASH with confirmed asthma and the study population consisted of patients with persistent asthma attending chest clinic of TASH during the study period.

3.4 Inclusion and Exclusion Criteria

3.4.1 Inclusion Criteria

Patients with persistent asthma of duration greater than one year and age greater or equal to eighteen were included in the study.

3.4.2 Exclusion Criteria

Patients with one or more of the following comorbidities: Congestive heart failure, COPD, Pulmonary hypertension and ILD were excluded from the study because these diseases have similar symptoms such as cough and shortness of breath with asthma making assessment of asthma severity difficult. Patients who had less than three months of follow up at the chest clinic were also excluded from the study.

3.5 Sample Size and Sampling Procedure

3.5.1 Sample Size of Study Population

The sample size of the patients was determined based on single population proportion formula. Since there were no similar studies previously done in the setting, the proportion (p) of underutilization of ICS was taken as 50%. With 95% confidence interval (CI) and marginal error (d) of 5%, the calculated sample size (n) was 384.

$$n = \frac{Z^2_{\alpha/2} p(1-p)}{d^2}$$

Since the study population was less than 10,000, the sample size was adjusted by using the following formula to get minimum sample size required for the study.

$$\text{Corrected sample size} = \frac{n \times N}{n + N}$$

The estimated total population of asthma patients attending the chest clinic during the study period (three months) was 192 (N). Substituting the values in the above formula produced an adjusted sample size of 128. Taking 10% for contingency (13), the final sample size was 141.

Regarding sample size of physicians involved in the study, eight physicians (four fellows and four residents) working in the chest clinic was included in the study.

3.5.2 Sampling Procedure

All asthmatic patients attending the chest clinic of TASH during the study period and fulfilling the inclusion criteria were included in the study. To avoid double counting of cases, patients who had undergone the interview were documented each day and any patient coming to the clinic at specific day was counterchecked with the document prior to conducting the interview.

3.6 Study Variables

3.6.1 Independent Variables

Independent variables of the study were socio-demographic characteristics, disease characteristics (severity and duration of asthma, comorbidity, use of other medications than asthma medications), manners of ICS use (whether ICS were used alone or in combination with LABA), asthma knowledge and attitude, and ICS knowledge and attitude.

3.6.2 Dependent Variable

The dependent variable of the study was ICS underutilization.

3.7 Data Collection and Management

3.7.1 Data Collection Tools

For data collection, a structured questionnaire (Annex I) was adopted from previous studies[63-65] and appropriate modifications were made to serve our purpose. The questionnaire was translated into Amharic (Annex II) and back into English to check the consistency of meaning. The questionnaire had four parts: socio-demographic characteristics, disease characteristics, prevalence of ICS use, and knowledge and attitude towards asthma and ICS.

Severity of asthma was assessed and classified by using Global Initiative for Asthma (GINA) criteria.

Data from physicians was also collected using a self-administered semi-structured questionnaire focusing on ICS use practice of physicians and associated factors (Annex III).

3.7.2 Recruitment of Data Collectors and Training

Data from patients was collected by a nurse who works at the chest unit of TASH and a pharmacist. Training was given to data collectors on how to administer the questionnaire, content and pattern of questionnaire.

3.7.3 Data Quality Assurance

Pre-test of the questionnaire was performed on 5% of the sample size prior to study period. Patients who participated in the pre-test were not included in the final sample of the study. In addition to providing training for the data collectors on how best to extract information from the patients, the questionnaires were reviewed and checked every day for completeness and the necessary feedback was provided to the data collectors.

3.7.4 Data Processing and Analysis

Each completed questionnaire was assigned a unique code. The data entry was made by using Epi info version 3.5.4. The data generated was analyzed using Statistical Package for Social Science (SPSS) for windows version 20. Descriptive statistics such as mean, median and standard deviations (SD) were used to summarize the result. The data was presented by using tables and charts.

To determine knowledge of the respondents, for each question on asthma and ICS, one point was given for 'Yes' responses and zero for 'No' and "I don't know" responses. Sum of the points was computed for each patient from a total score of five. Four points which is the median score was used as cut-off point for knowledge of asthma and ICS.

Similarly, attitude toward asthma and ICS were dichotomized into positive and negative attitude by computing sum of the attitude questions from thirteen and twenty-five, respectively. Largest point (five) was assigned for positive response and smallest point (one) for negative response on five point likert scale. The median score was selected as cut-off point and it was found to be twenty-five and seventeen for asthma and ICS attitude, respectively.[66]

Each variable was evaluated independently in a bivariate analysis and association was determined using cross tabulation and COR with 95% CI. All variables associated with the underutilization of ICS at a probability level of less than or equal to 0.25 on the bivariate analysis were entered into a multivariate logistic regression analysis to control for confounders. The final model was selected by using Wald criterion and Hosmer and Lemeshow test to determine variables that were independently associated with the underutilization of ICS at a probability level of less than 0.05.

3.8 Ethical Consideration

Before collection of the data, ethical clearance was obtained from research review committee of the School of Pharmacy and Department of Internal Medicine of AAU. During data collection, brief explanation about the objective and significance of the study was given to each participant in order to obtain verbal consent and avoid misunderstanding. Participants were communicated in respectful way during an interview and their name was not used in any of the documents. Those who had been taking ICS were shown appropriate inhalation technique. In addition, the participants were advised on potential side effects and their management.

3.9 Operational Definitions

Inhalation corticosteroids: Inhalation steroids used alone or in combination with LABA

Underutilization of ICS: Recommendation of suboptimal regimen from physicians' side or primary non-adherence or discontinuation at all or use of suboptimal regimen from the patients' side.

Suboptimal regimen: The dose and frequency of ICS below recommended by GINA guideline for the specific step of asthma management.

Primary non-adherence: Never filling the prescription

Good knowledge: When participants scored points greater or equal to four as the median score for asthma and ICS.

Poor knowledge: When participants scored points less than four as the median score for asthma and ICS.

Positive attitude: When participants scored points greater or equal to twenty-five as the median score for asthma and greater or equal to seventeen as the median score for ICS.

Negative attitude: When participants scored points less than twenty-five as the median score for asthma and less than seventeen as the median score for ICS.

4. Results

4.1 Socio-demographic Characteristics of Asthmatic Patients

A total of 141asthmatic patients fulfilling the criteria were interviewed and ten questionnaires were rejected because of their incompleteness. As it is shown below in table 1, mean age of the patients was 52.29 (SD $\pm$14.58) with a range of 19 and 80. Women comprised of about 64% of study population and about 65% of the participants were married. With regard to educational status, a sizable proportion of the patients (34.4%) had college diploma and above, while 25.2% of the participants did not have formal education. The median monthly income level of the participants was 900 ETB with a range of 100 to 6000 ETB.

Table 1: Socio-demographic characteristics of asthmatic patients

Socio-demographic characteristics	Frequency (n)	Percent (%)
Age*		
18-34	16	12.2
35-64	82	62.6
≥65	33	25.2
Mean ± SD		52.29 ± 14.58
Sex		
Male	47	35.9
Female	84	64.1
Marital status		
Single	46	35.1
Married	85	64.9
Education		
No formal education	33	25.2
Primary education	33	25.2
High school	20	15.3
College diploma and above	45	34.4
Monthly income**		
≤1200	73	60.8
1201-2500	28	23.3
>2500	19	15.8

** Based on previous studies[26]; **Based on the Ethiopian civil servant monthly salary scale*

4.2 Disease Characteristics of the Asthmatic Patients

As it is shown below in a table 2, the mean duration of asthma for this study group was 20.9 years (SD ±11.38). About 59% of the patients had one or more comorbidity. Figure 1 shows distribution of severity of asthma. According to the classification of GINA, forty five (34.4%) and 44 (33.6%) participants had mild persistent asthma and moderate persistent asthma, respectively.

Table 2: Disease characteristics of the asthmatic patients

Variables	Frequency (n)	Percent (%)
Duration of asthma		
≤21	68	51.9
>21	63	48.1
Mean ± SD		20.09 ± 11.38
Comorbidity		
Yes	77	58.8
No	54	41.2
Use of other medications		
Yes	57	43.5
No	74	56.5

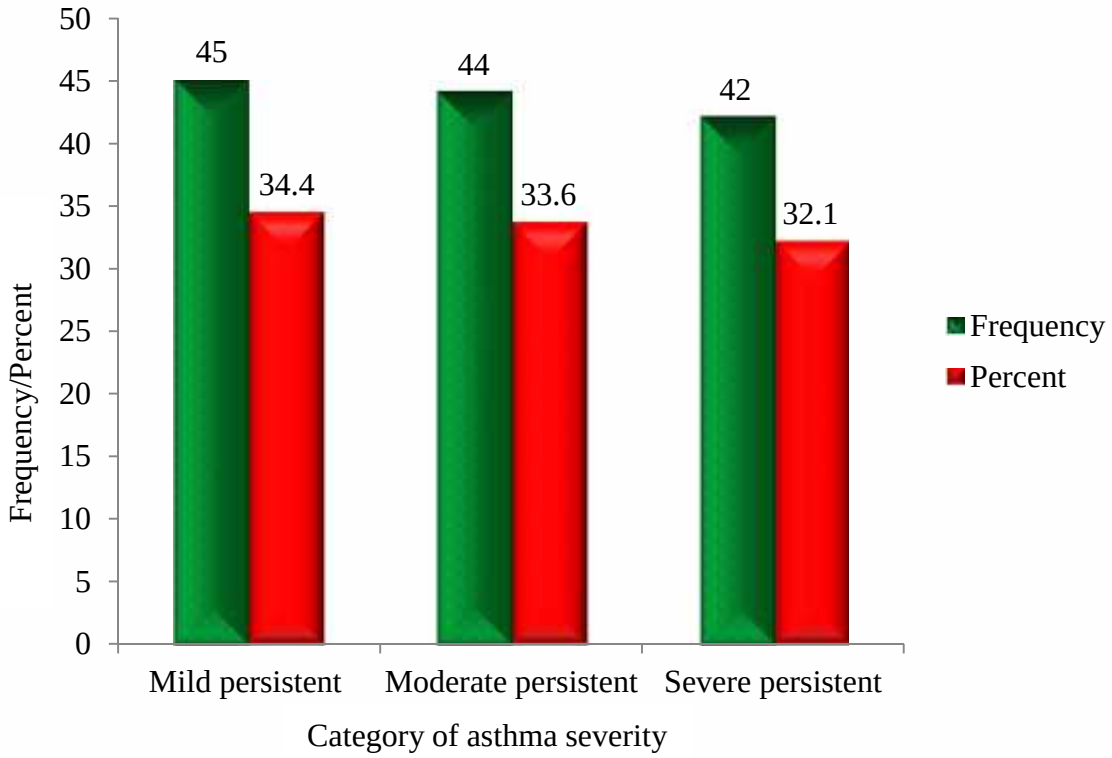


Figure 1: Severity of asthma according to Global Initiative for Asthma classification

4.3 Prevalence of Inhalation Corticosteroids Use

As it is shown in table 3, ICS were prescribed in 90.8% of the cases; out of which ICS alone was accounted for 73.9% of the cases. The remaining received ICS + LABA. Among the patients prescribed with ICS, 61.3% had been taking ICS, 23.5% discontinued, and 15.1% were primary non-adherent. From those who had been taking ICS, about 42% of the patients were on suboptimal regimen. Overall, from patients' perspective, underutilization of ICS was found to be 64.7%.

Table 3: Prevalence of Inhalation corticosteroids use

Prevalence of ICS use	Frequency (n)	Percent (%)
ICS prescribed		
Yes	119	90.8
No	12	9.2
Manners of ICS use		
ICS alone	88	73.9
ICS with LABA	31	26.1
From ICS prescribed patients		
On ICS then	73	61.3
Discontinued	28	23.5
Primary non-adherence	18	15.1
From on ICS then patients		
Optimal regimen	42	57.5
Suboptimal regimen	31	42.5
Underutilization of ICS		
Yes	77	64.7
No	42	32.1

4.4 Patients' knowledge and Attitude toward Asthma and Inhalation Corticosteroids

The study also assessed patients' knowledge and attitude towards asthma and anti-asthmatics, particularly ICS.As it is seen in table 4, more than half (61.4%) of the ICS users had good asthma knowledge, while most of them (90.1%) had positive attitude towards asthma. Less than half

(45.5%) of the ICS users had good knowledge of ICS while only 54.5% of the ICS users shown positive attitude toward ICS.

Table 4: Patients' knowledge and attitude toward asthma and Inhalation corticosteroids

Pattern of ICS use	Frequency (n)	Percent (%)
Asthma knowledge		
Good	62	61.4
Poor	39	38.6
Attitude towards asthma		
Positive	91	90.1
Negative	10	9.9
ICS knowledge		
Good	46	45.5
Poor	55	54.5
Attitude toward ICS		
Positive	55	54.5
Negative	46	45.5

4.5 Factors Associated with Underutilization of Inhalation Corticosteroids

Statistical analysis was performed to see the crude associations between proposed independent variables and underutilization of ICS.As it is seen in table 5, from the socio-demographic factors, monthly income of the participants was significantly associated with underutilization of ICS indicating that those who had monthly income of less than or equal to 1200 ETB were about 8 times more likely to underutilize ICS than those who had more than 2500 ETB [95% CI: 2.18-30.00]. The remaining socio-demographic factors did not demonstrate significant association with underutilization of ICS except education. In this study, it was found that patients who did not have formal education were about 3 times more likely to underutilize ICS than those who had college Diploma or above [95% CI: 1.07-8.73].

Table 5: Association between socio-demographic characteristics and underutilization of Inhalation corticosteroids

Socio-demographic characteristics	Underutilization of ICS		COR (95% CI)
	Yes n (%)	No n (%)	
Age			
18-34	6 (66.7)	3 (33.3)	1.00
35-64	51 (63.8)	29 (36.2)	0.879 (0.20-3.78)
≥65	20 (66.7)	10 (33.3)	1.000 (0.20-4.86)
Sex			
Male	28 (63.6)	16 (36.4)	1.00
Female	49 (65.3)	26 (34.7)	1.077 (0.49- 2.32)
Marital status			
Single	25 (64.1)	14 (35.9)	0.962 (0.43 - 2.14)
Married	52 (65)	28 (35)	1.00
Education			
No formal education	25 (78.1)	7 (21.9)	**3.061 (1.07-8.73)***
Primary education	20 (64.5)	11 (35.5)	1.558 (0.59-4.10)
High school	11 (64.7)	6 (35.3)	1.571 (0.48- 5.10)
College Diploma and above	21 (53.8)	18 (46.2)	1.00
Monthly income			
≤1200	54 (78.3)	15 (21.7)	**8.100 (2.18- 30.00)***
1201-2500	14 (51.9)	13 (48.1)	2.423 (0.59- 9.82)
>2500	4 (30.8)	9 (69.2)	1.00

**** Significant association (p<0.05)***

Another variable that showed significant association on binary regression was manners of ICS use. As it is shown in table 6, in this study patients who had been prescribed ICS alone were about 4.5 times more likely to underutilize than those had been prescribed with the combination of ICS and LABA [95% CI: 1.88-10.62]. Comorbidity also found to have significant association with underutilization of ICS. Patients with comorbidity had about 2 times more chance of underutilizing ICS compared to patients with no comorbidity [95% CI:1.001- 4.65].

Table 6: Association between disease characteristics of the patients and underutilization of Inhalation corticosteroids

Variables	Underutilization of ICS		COR (95% CI)
	Yes n (%)	No n (%)	
Duration of asthma			
≤21	33 (56.9)	25 (43.1)	1.00
>21	44 (72.1)	17 (27.9)	1.96 (0.92-4.21)
Comorbidity			
Yes	51 (71.8)	20 (28.2)	**2.15 (1.001- 4.65)***
No	26 (54.2)	22 (45.2)	1.00
Use of other medication			
Yes	36 (67.9)	17 (32.1)	1.29 (0.60-2.76)
No	41 (62.1)	25 (37.9)	1.00
Manners of ICS use			
ICS alone	65 (73.9)	23 (26.1)	**4.45 (1.88-10.62)***
ICS with LABA	12 (38.7)	19 (61.3)	1.00
Severity of Asthma			
Mild	26 (61.9)	16 (38.1)	1.00
Moderate	21 (52.5)	19 (47.5)	0.68 (0.28-1.64)
Severe	30 (81.1)	7 (18.9)	2.64 (0.94-7.40)

**** Significant association (p<0.05)***

Table 7 shows patients' knowledge and attitude towards asthma and ICS and no significant association was found with underutilization of ICS. However, binary regression showed increased odds of underutilization of ICS among patients with poor knowledge of asthma [COR=1.23, 95% CI: 0.54-2.79] and poor attitude toward asthma [COR= 3.14, 95 % CI: 0.63-15.59] (Table 7).

Table 7: Association between patient knowledge and attitude towards asthma and underutilization of Inhalation corticosteroids

Variables	Underutilization of ICS		COR (95% CI)
	Yes n (%)	No n (%)	
Asthma knowledge			
Good	35 (59.3)	24 (40.7)	1.00
Poor	27 (64.3)	15 (35.7)	1.23 (0.54-2.79)
Attitude toward asthma			
Positive	51(56)	40 (44)	1.00
Negative	8 (80.0)	2 (20.0)	3.13 (0.63-15.59)
ICS knowledge			
Good	27 (58.7)	19 (41.3)	1.00
Poor	32 (58.2)	23 (41.8)	1.02 (0.46-2.26)
Attitude toward ICS			
Positive	30 (54.5)	25 (45.5)	1.00
Negative	29 (63)	17 (37)	1.42 (0.64-3.16)

A multiple logistic regression analysis was conducted to predict underutilization of ICS using monthly income, duration of asthma, co-morbidity, manners of ICS use and severity of asthma as predictors. After adjusting for other variables, monthly income, comorbidity and manners of ICS use remained significant predictors of underutilization of ICS.

As it is shown in table 8, patients who earned monthly income less than or equal to 1200 ETB were about 5 times more likely to underutilize ICS than those earned greater than 2500 ETB [95% CI: 1.10-22.14]. Patients with comorbidity were about 3 times more likely to underutilize ICS than those with no comorbidity [95% CI:1.11-8.688].The model also indicated 4.4 times increased odds of underutilization among patients who had been prescribed with ICS alone compared to patients who had been filled with ICS and LABA combination [(95% CI: 1.49-12.92].

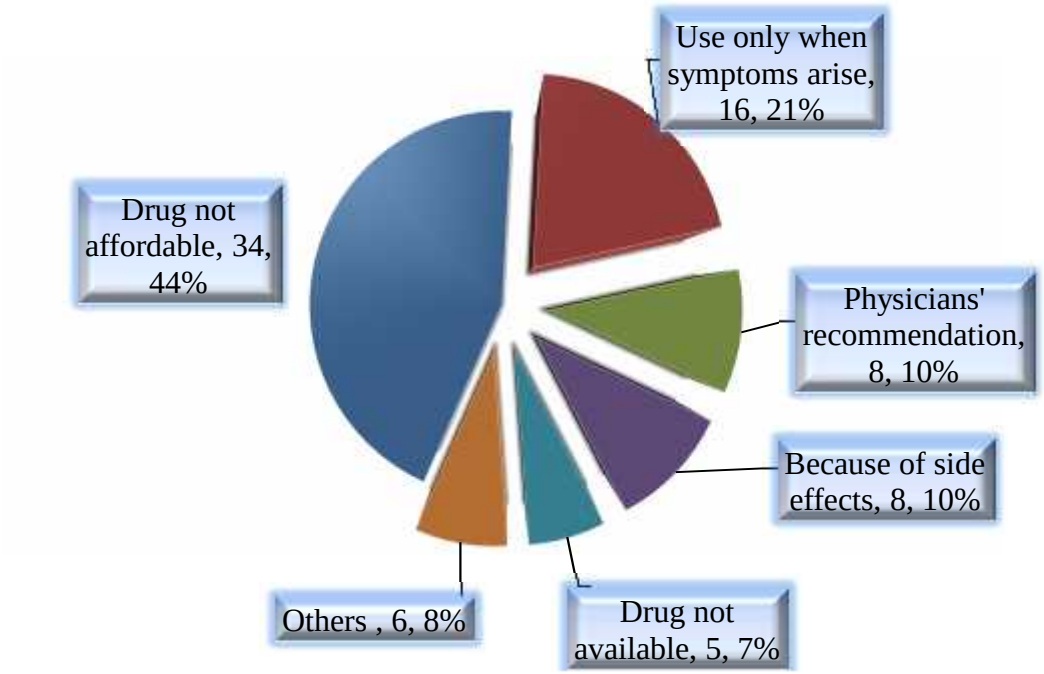
Table 8: Multivariate analysis of factors associated with underutilization of Inhalation corticosteroids

Variables	Underutilization of ICS		COR (95% CI)	AOR
	Yes n (%)	No n (%)		
Monthly income				
≤1200	54 (78.3)	15 (21.7)	**8.10 (2.19- 30.00)***	**5.35 (1.10-22.16)**
1201-2500	14 (51.9)	13 (48.1)	2.42 (0.59- 9.82)	1.46 (0.29-7.22)
>2500	4 (30.8)	9 (69.2)	1.00	1.00
Duration of asthma				
≤21	33 (56.9)	25 (43.1)	1.00	1.00
>21	44 (72.1)	17 (27.9)	1.96 (0.91-4.21)	1.49 (0.54-4.15)
Comorbidity				
Yes	51 (71.8)	20 (28.2)	**2.15 (1.001- 4.65)***	**3.10 (1.11-8.69)***
No	26 (54.2)	22 (45.2)	1.00	1.00
Manners of ICS use				
ICS alone	65 (73.9)	23 (26.1)	**4.44 (1.88-10.62)***	**4.39 (1.49-12.92)***
ICS with LABA	12 (38.7)	19 (61.3)	1.00	1.00
Severity of Asthma				
Mild	26 (61.9)	16 (38.1)	1.00	1.00
Moderate	21 (52.5)	19 (47.5)	0.68 (0.28-1.64)	0.545 (0.16-1.87)
Severe	30 (81.1)	7 (18.9)	2.63 (0.94-7.40)	3.17 (0.86- 11.75)

**** Significant association (p<0.05)***

4.6 Patients' Reported Reasons for Underutilization

Patients were also asked about the reason relates to underutilization of ICS and as it seen in figure 2 most commonly mentioned reason was unaffordability (44%). In addition, about 21% of the patients tended to decrease the dose or change the dose frequency of the drug when they felt symptom free, while 10% claimed that they had been taking the regimen as recommended.



***Others**: forgetfulness, lack of effect, not liking the drug, and fear of dependence*

Figure 2: Patients' reported reasons for underutilization

4.7 Physicians' Reported Reasons for Patients' Underutilization

Physicians were asked about their preferred drug for management of persistent asthma and all of them responded that their first choices of drug are ICS either alone or in combination with LABA. Asked if there were any circumstances in which they prescribe other drugs than ICS, all of them said 'yes'. Physicians also responded that there were circumstances that forced them to use other drugs than ICS, mentioning the use of either oral steroids or Theophedrine for uncontrolled asthma (4 physicians) and severe asthma (2 physicians). Some of them (4 physicians) also pointed out other reason like unavailability and patients' inability to afford ICS as a driving force to prescribe other drugs.

In respect to continuous use of ICS, most of the physicians (6) replied that they would recommend continuous use of ICS even if the patients remained symptom free. Asked if they

would make any modification on initial regimen, most of them responded that they would consider decreasing the dose to the least possible dose (5) and maintain initial regimen (1). Concerning their choice of regimen for different severity category of asthma, variation among physicians' response was seen as described in Table 9.

Table 9: Physicians' recommended regimen for different severity category of asthma, Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, 2014

Category of asthma and recommended regimen	No.of physicians
Mild persistent asthma	
Salbutamol PRN	2
Salbutamol PRN +Beclomethasone 200 µg (2 puff bid)	5
Salbutamol PRN + Fluticasone (250 µg) + Salmetrol(50 µg) (1puff bid)	1
Moderate persistent asthma	
Salbutamol PRN +Beclomethasone 200 µg (2 puff bid)	4
Salbutamol PRN +Fluticasone (250 µg) + Salmetrol (50 µg) (1puff bid)	4
Severe persistent asthma	
Salbutamol PRN + Beclomethasone 200 µg (2 puff bid)	1
Salbutamol PRN + Fluticasone (250 µg) + Salmetrol (50 µg) (1puff bid)	2
Salbutamol PRN + Fluticasone (250 µg) + Salmetrol (50 µg) (1puff bid)+ oral steroids	4
Salbutamol PRN + Fluticasone (250µg)+Salmetrol (50µg)(1puff bid)+Theophdrine	1
Salbutamol PRN + Beclomethasone 200 µg (2 puff bid)+ oral steroids	1

PRN: As needed

Asked if there is adequate utilization of ICS from patients' side, all of them responded 'no', and mentioned different reasons for the problem. However, most of them (6) stated cost of ICS as a major barrier. Physicians also pointed out that patients' perceptions such as fear of side effects (2) and dependence (2) as a causes for underutilization. Some of the physicians also mentioned

lack of awareness and failure to advice patients properly about the drug from physicians' side as a causes.

5. Discussions

Although ICS are the cornerstone of asthma therapy, patients tend to underuse these medications. The primary objective of this study was to assess factors associated with underutilization of ICS among persistent asthma patients under regular follow up at the chest unit of TASH.

In the present study, high prevalence of underutilization of ICS was found from patients' perspective. Significant association was found between underutilization of ICS and patients with monthly income of less than 1200 ETB, comorbidity, and manners of ICS use. Most commonly mentioned reasons for underutilization of ICS were increased cost, using only when symptoms arise, recommendation from physicians, side effects, and inaccessibility. Physicians mentioned unaffordability, fear of side effects, and dependence as major reasons for underutilization of ICS.

ICS are the most effective medications currently available to treat patients with persistent asthma. Underutilizations of ICS had been repeatedly mentioned in relation to poor asthma control. Overall, in this study, underutilization of ICS from patients' perspective was found to be 64.7%. The finding is in agreement with a study done in the United States where 65% of the patients were using a dose of ICS below that recommended in the NHLBI guideline for asthma diagnosis and management.[33] However, the major difference between these two studies is that in the later study, most of the underutilization appeared to represent physicians' recommendations. This is not the case in our study where underutilization of ICS was primarily due to primary non-adherence, discontinuation, and suboptimal regimen use. On the other hand, the finding shows much higher underutilization of ICS compared to a French study which reported only about 38% ICS underutilization.[34] The difference seen is probably attributable to disparities between the two study settings.

In a study conducted in India, ICS were used only by 30.9%.[35] Similarly, only 26.1% [36] patients in a study done in North Africa (Tunisia, Morocco and Algeria) were using ICS which is lower than our finding. The disparities seen might be due to the difference in approach used. The prevalence of ICS use was assessed for all asthmatic patients regardless of severity category of asthma in both studies. In the present study, however, patients with only persistent asthma were included and these categories of patients are likely to get ICS prescription. Thus, this might have led to underestimation prevalence of ICS use in those studies.[35,36]

The present finding is higher than a study done in Jimma, in which only 3.8% patients used ICS.[31] This might be partly due to socioeconomic differences between the two cities. The difference between the two settings might also contribute for the discrepancy seen. Underutilization of ICS in the present study, however, is much higher than a study done in the same setting, which reported only about 24% underutilization.[32] This might be due to the fact that appropriateness of the regimen patients had been using was not taken into account in the previous study, which might have led to underestimation of ICS underutilization compared to this study.

Concerning the effects of socio-demographic and disease characteristics of patients on underutilization of ICS, inconsistent findings have been reported from around the globe. In this study; age, gender, marital status, educational level, duration of asthma, severity of asthma, and use of medications other than anti-asthmatics have been seen to have no significant effect on underutilization of ICS.

Generally, out-of-pocket payments for medications affect patients' medications use undesirably. This is considerably problematic in the health care system where patients have no health insurance or any reimbursement mechanism. In the current study, monthly income of participants was significantly associated with underutilization of ICS. Given the increased cost of ICS and

low economic status of the people, particularly patients seen at the study unit, it would not be surprising to find association between level of income of the patients and underutilization of ICS. Although it is difficult to compare this result with studies done in other countries due to discordancy of socioeconomic characteristics, similar finding have been reported in the United States [37] and Canada.[43]

One of the patients' disease characteristics that have been suggested to be associated with underutilization of ICS is comorbidity. The present study also showed significant association between underutilization of ICS and comorbidity. This is in agreement with study done in Canada.[39] Increased odds of underutilization of ICS among patients with one or more comorbidity could be due to different reasons. Patients with comorbidity are more likely to use other medications than ICS which may lead to increased financial burden. Relatedly, taking medications other than asthma medications can result in complicated and burdensome medication regimens often leading to forgetfulness.[46] Finally, physicians might use low dose of ICS due to fear of combined side effects for patients being treated for other comorbidities.[39]

In the present study, manners of ICS use, whether ICS were used alone or in combination with LABA, was significantly associated with ICS underutilization. According to the guideline when ICS alone is used, increasing the dose from low to moderate or high is recommended depending on the steps of management. However, sometimes physicians fail to do so and tend to use similar dose across most steps of asthma management.[58,599] On the other hand, in spite of having prescription for combination therapy, patients tend to use ICS alone mostly due to increased cost of combination therapy which might be inadequate for the given step of management.

With respect to patients' reported reasons for underutilization of ICS, unaffordability of ICS was found to have big influence on ICS use (44%). In this study, both patients and physicians

reported high cost of ICS as a major obstacle for proper use of ICS. This finding is in line with reports from elsewhere.[8,25,31,36,40,41,44] In addition, inaccessibility of ICS in the study setting was reported from both patients and care providers as one of the problems related to ICS underutilization. This might also add to unaffordability of the drug as the patients are forced to buy the drug from private distributors. This finding implies the presence of loophole which needs attention of government as well as other concerned bodies.

In the present study, another reason most frequently mentioned in association with underutilization of ICS next to unaffordability was use of ICS when only symptoms arise (21%). In general, good understanding and perception of the disease and its medications could contribute to patients' compliance positively. Although there was no significant association found between ICS underutilization and knowledge of ICS and asthma, in this study, only 45.5% and 64.1% of the patients had good knowledge of ICS and asthma, respectively. This finding supplements the idea that patients' tendency to use ICS when symptoms arise is because of lack of understanding about the nature of the disease, and exact role ICS in asthma therapy as well as the necessity for their continuous use.[42,54,55]

In this study, a number of patients mentioned side effects of ICS as a reason for underutilization of ICS (10%). The same reason was mentioned by some of the physicians. This is in agreement with other studies.[42,55,57] However, given that the drug is free of serious side effects,[29] it looks like that it was fear or concern about the side effects rather than experiencing side effects that made most of the patients to decrease the dose or discontinue at all.[55] This result underscores the importance of educating asthma patients focusing on their understanding and attitude toward ICS.

Care providers related factors are often mentioned in relation to underutilization of ICS. In the present study, about 10% of ICS underutilization was attributed to recommendation from

physicians. This might be partly due to some physicians underestimate the severity of asthma; as a result using the dose below recommended in the GINA guideline.[33] Physicians may also use lower dose of ICS than recommended in the guideline for special population like elderly due to, for example, fear of side effects.[39]

Another issue worth mentioning as far as care providers are concerned is prescribing pattern of ICS. In this study, about 9% of eligible patients had not received prescription for ICS. This is in consistent with other studies.[60,45] An under prescription could be attributed to different reasons. First, physician may prescribe other drug than ICS intentionally when the patients fail to afford ICS as it was pointed out by some of the physicians. Physicians might also prescribe other drugs like oral steroid or Theophedrine for “uncontrolled asthma”, and in special population like pregnant mothers.

Finally, the health care system itself can affect overall aspect of disease management and drug utilization pattern in general. In this study, absence of local protocol for management of asthma was shown to have negative impact on ICS utilization. Although physicians use international guidelines in situations like this, inconsistent prescribing pattern and failure to adhere to such guidelines might occur.[33] This observation underlines the importance of preparing hospital or national guideline for management of asthma.

6. Limitations of the Study

Since it is a cross-sectional design, it was not possible to find temporal relationship between cause and effect. The present study had also limitation regarding its generalizability. First, the study was not multi-centered, hence did not address different population of asthma. Secondly, due to poor patients flow during study period it was not possible to attain maximum sample size. Therefore, this result should be extrapolated cautiously. In spite of these limitations, the study was able to identify the factors associated to underutilization of ICS from both patients' and physicians' perspective.

7. Conclusion

ICS use has pivotal role in the management of persistent asthma. Many factors can affect prevalence of ICS use. In this study, considerable underutilization of ICS was found. Factors significantly associated with underutilization of ICS include monthly income, comorbidity and manners of ICS use (whether ICS was used either alone or in with combination with LABA). Unaffordability and inaccessibility of ICS, poor knowledge of asthma and ICS, negative attitude toward ICS, and absence of local guideline for asthma management also contributed for underutilization of ICS.

8. Recommendations

Based on the data derived from the present study, the following recommendations can be made:

- ✓ Ministry of Health, Pharmaceutical Fund and Supply Agency, TASH and other concerned bodies should make sure that ICS are available consistently and in an affordable price.
- ✓ TASH and other concerned bodies should prepare educational program on asthma and its medications, particularly ICS for patients on follow up.
- ✓ Ministry of Health and TASH should prepare local guideline for management of asthma.

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Annex

Annex I: Patient Interview Questionnaires

How are you, I am _____. This is an interview to be done with you for a study that is being conducted by Addis Ababa University, School of Pharmacy. This study is prepared to assess factors associated with underutilization of inhalation of corticosteroids. Your participation in the study is very important to identify problems related to inhalation corticosteroids use.

Your name and address will not be written in this form and will never be used in connection with any information you tell us. All the information given by you will be kept strictly confidential and only used for this study. Your participation is voluntary and you are not obligated to answer any question which you do not wish to answer. If you fill uncomfortable to respond to any of the question, please fill free to drop it any time you wish to do so.

Can we proceed? ☐ Yes ☐ No

If "No" Thank the participant and stop an interview

Part 1. Socio-demographic data		
500	Age	
501	Sex	1-Male
		2-Female
502	What is your marital status?	1-Single
		2-Married
		3-Divorced
		4-Widow
503	What is your educational status?	1-No formal education
		2-Primary education
		3-High school
		4-Diploma and above
504	Monthly income in ETB	
Part 2. Disease characteristics		
600	How long is it since you have been diagnosed with asthma?	

601	Severity of asthma based on the GINA criteria	1- Mild persistent
		2- Moderate persistent
		3- Severe persistent
602	Do you have any physician confirmed comorbidity?	1-Yes
		2-No
603	Do you use medication other than asthma medication on regular basis?	1-Yes
		2-No

Part 3. ICS use

700	Did you have prescription for ICS?	1-Yes
		2-No
If yes, specify the drug with dose & frequency:		
701	Are you using ICS currently?	1-Yes
		2-Discontinued
		3-Never used before
If the answer is yes for Qno.701 ask the dose and frequency the patient has been taking		
702	Does the regimen match with severity of the disease	1-Yes
		2-No
703	If the answer is yes for Qno.702, why?	1-It is recommended by physician
		2-Use only when symptomatic
		3-Side effects
		4-Forgetfulness
		5-Drug not affordable
		6-Other (specify)
704	If the patient discontinued use of ICS, why?	1-Drug not affordable
		2-Do not like the drug
		3- Side effects
		4-Lack of effect
		5-Other (specify)
705	If the patient has never used prescribed ICS before, why?	1-Drug not affordable
		2-Drug not available

		3-other(specify)
Part 4. Asthma knowledge		
800	Asthma is a chronic disease.	1-Yes 2-No 3-Don't know
801	The underlying cause of asthma symptoms is airway inflammation and swelling.	1-Yes 2-No 3-Don't know
802	Asthma can kill.	1-Yes 2-No 3-Don't know
803	It is possible to prevent asthma symptoms (wheezing, cough, chest tightness) by appropriate medication.	1-Yes 2-No 3-Don't know
804	It is important to take some asthma medication even though there is no symptom.	1-Yes 2-No 3-Don't know
Attitude toward asthma		
850	Asthma is serious disease and must take treatment.	1-Strongly disagree 2-Disagree 3- Neutral 4- Agree 5-Strongly agree
851	My asthma would be worse if I did not take medication at all.	1-Strongly disagree 2-Disagree 3- Neutral 4-Agree 5-Strongly agree
852	I believe my asthma medication will control my asthma.	1-Strongly disagree 2-Disagree

		3- Neutral
		4- Agree
		5-Strongly agree
853	All my asthma medication is important for me.	1-Strongly disagree
		2-Disagree
		3- Neutral
		4- Agree
		5-Strongly agree
854	I do not feel comfortable when people know that I am asthmatic patient.	1-Strongly disagree
		2-Disagree
		3- Neutral
		4-Agree
		5- Strongly agree
856	I do not fear taking asthma medications in front of peoples.	1-Strongly disagree
		2-Disagree
		3- Neutral
		4- Agree
		5-Strongly agree

Part 5. ICS Knowledge

900	ICS is drug of choice for long term prevention of asthma.	1-Yes
		2-No
		3-Don't know
901	ICS work by fighting inflammation.	1-Yes
		2-No
		3-Don't know
902	The full effect of ICS depends on regular use.	1-Yes
		2-No
		3-Don't know
903	ICS may take days to produce full effect.	1-Yes
		2-No
		3-Don't know
904	When you use ICS, your wheeze or chest tightness gets better immediately.	1-Yes
		2-No
		3-Don't know

Attitude toward ICS		
950	Asthmatic patients should use prophylactic treatment even if they are feeling well.	1-Strongly disagree
		2-Disagree
		3-Neutral
		4-Agree
		5-Strongly agree
951	Regular use of ICS is important to prevent asthma attack and hospitalization.	1-Strongly disagree
		2-Disagree
		3-Neutral
		4-Agree
		5-Strongly agree
952	Since I have been using ICS, my asthma has gotten better.	1-Strongly disagree
		2-Disgree
		3-Neutral
		4-Agree
		5-Strongly agree
953	Regular use of ICS result dependency.	1-Strongly disagree
		2-Disagree
		3-Neutral
		4-Agree
		5-Strongly agree
954	Regular use of ICS can cause side effects	1-Strongly disagree
		2-Disagree
		3-Neutral
		4-Agree
		5-Strongly agree

Thank You!!!

Annex II: Patient Interview Questionnaires (Amharic Version)

ጤና ይስጥልኝ ስሜ_____ እባላለሁ፡፡ የመጣሁት ከአ.አ ዩኒቨርስት ጤና ሳይንስ ኮሌጅ በፈርማስ ት/ት ክፍል ለሚሰራ ጥናት መረጃ ለመሰብሰብ ነው፡፡የጥናቱ ዋና አላማ በsሚነት አስም ለመከላከል የሚወስዱ መዳሃንት (inhalation corticosteroids) ዝቅተኛ አጠቃቀም ጋር የተያያዙ ተግደሮቶች ለማወቅ ሲሆን የርስዎ በዚ ጥናት መሳተፍ የአስም በሽታ ህክምና አግባቡነት ለማሻሻል ጉልህ አስተዋፆ ይኖረዋል፡፡

የሚሰጡት መረጃ በሙሉ በፍፁም አስተማማኝነት ለዚህ ጥናት ብቻ የሚያገለግል ሲሆን በዚህ ቃለ መጠይቅ ስም ይሁን አድራሻ አይገለጽም፡፡መጠይቁ የእርስዎ ፍቃደኝነት ፍጹም ከተረጋገጠ ብቻ የሚካሄድ ይሆናል፡፡በተጨማሪም ለመመለስ የማይፈልጓቸው ጥያቄዎች ካሉ ጥያቄውን ለመመለስ አይገደዱም፡፡እንዲሁም በጥናቱ ላይ በሙሉም ይሁን በከፊል ላለመሳተፍ ከፍለጉ በማንኛውም ሰአት ማቋረጥ ይችላሉ፡፡

ክፍል አንድ፣ ማህበራዊና የስነሕዝብ መረጃዎችን በተመለከተ		
500	እድሜ	
501	ፆታ	1-ወንድ
		2-ሴት
502	የትዳር ሁኔታ	1-ያላገባ
		2-ያገባ
		3-የፈታ/የፈታች
		4-በል የሞተባት
503	ትምህርት ደረጃ	1-ያልተማሩ
		2-አንደኛ ደረጃ
		3-ሁለተኛ ደረጃ
		4-ድፕሎማና ከዛ በላይ
504	የወር ገቢ በኢቶፒያን ቢሪ	
ክፍል ሁለት፣ የህመሙሁንታዎች		
600	አስም እንዳለቦት ከተነገሮት ስንት ጊዜ ሆነው(በአመት)?	
601	የአስም ህመም ደረጃ (severity)	1-Mild persistent
		2-Moderate persistent
		3-Sever persistent
602	በህክም የተረጋገጠ ለላ በሽታ አለ?	1-አዎን
		2-የለም
603	ከአስም መድሃንት ለላ በቐምነት የምወስዱት መድሃንት አለ?	1-አዎን
		2-የለም
ክፍል ሶስት፣ የ ICS አጠቃቀም ሁነታ		
700	ታካሚዉ የአስም መከላከያ መዳሃንት(ICS)ታዞለታል?	1-አዎን
		2-የለም
ለጥያቀ ቁጥሪ 700-**አዎን** ከሆነ የአዎሳሰዲ ሁነታዉን ይጥቀሱ(regimen)		
701	ታካሚዉ የአስም መከላከያ መዳሃንት (ICS) ታዞለት ከሆነ አሁን ይጠቀማል?	1-አዎን
		2-ይጠቀም ነበር ግን አሁን አይጠቀምም
		3-ምንም ተጠቅሞ አያቅሚ
ለጥያቀ ቁጥሪ 701-**አዎን** ከሆነ አሁን የምዎሲትን የአዎሳሰዲ ሁነታዉን ይጥቀሱ(regimen)		
702	የአወሣሠዲ ሁነታ (regimen) ከበሽታዉ ደረጃ (severity) ጋሪ ይመጣጠናል?	1-አዎን
		2-የለም
703	ለጥያቀ ቁጥሪ 702 መልሱ **የለም** ከሆነ ምክንያት	1-አወሳሰዱ በህክም የታዘዘ ስለሆነ ነዉ

		2-የበሽታ ምልክት ስኖሪ ቢቻ ይወስዳሉ
		3-በተከታተይ መጠቀም የጎንዮሽ ጉዳት ያስከትላል
		4-ስለምረሱ ኑወ
		5-መግዛት ስላቻሉ ነዉ
		6-ልላ:
704	ለጥያቀ ቁጥሪ 701 ታካሚዉ ICS or ICS + LABAን አሁን የማይጠቀም ከሆነ ምክንያት	1-መግዛት ስላቻሉ ነዉ
		2-መዳሃንቱን ስላልወደዱ ነዉ
		3-የጎንዮሽ ጉዳት ስላለዉ ነዉ
		4-ለዉጥ ስላላዩበት ነዉ
		5-ልላ:
705	ታካሚዉ ICS or ICS + LABAን ምንም ተጠቅሞ የማያቅ ከሆነ ምክንያት	1-መግዛት ስላቻሉ ነዉ
		2--መዳሃንቱን ስለማይገኝ ነዉ
		3-ልላ:

ታካሚዉ ICS ያልታዘዘለት ወይም ታዞለት ምንም ተጠቅሞ የማያቅ ከሆነ ቀጥሎ ያሉትን ጥያቀወች ኣይጠየቅም

ክፍል አራት፣ የአስምና ICS እውቀትና አመለካከት

አስምና የአስም እውቀት

800	አስም በህዎት ዘመን ሙሉ የምቆይ በሽታ ነዉ።።	1-አዎን
		2-የለም
		3-አላዉቅም
802	የአስም በሽታ ምልክቶች የምከሰቱት የመተንፈሻ ቱቦ መቆጣት ወይም ማበጥ ስለምኖር ነዉ።።	1-አዎን
		2-የለም
		3-አላዉቅም
803	የአስም በሽታ ለሞት ልዳሪግ ይችላል።።	1-አዎን
		2-የለም
		3-አላዉቅም
804	የአስም በሽታ መንስዔዎች (መተንፈሻ ቱቦ መቆጣት ወይም ማበጥ) በተገቢ መድሃኒት መከላከል ይቻላል።።	1-አዎን
		2-የለም
		3-አላዉቅም
805	የተወሰኑ የአስም መዳሃኒቶችን የበሽታዉ ምልክት ባይኖረ እንኳን መዉሰድ አስፈላግ ነዉ።።	1-አዎን
		2-የለም
		3-አላዉቅም

የአስም አመለካከት

850	አስም አደገኛ በሽታ ስለሆነ መዳሃኒት መዉሰዲ በጣም አስፈላግ ነዉ።።	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
851	የአስም በሽታ ሚንም አይነት መዳሃኒት ካልወሰዱበት ልባባስ ይችላል።።	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
852	አሁን ለአስም የምዎስዳቸዉ መዳሃኒቶች አስሙን እንደምከላከልልኝ አምናለዉ።።	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ

		5-በጣም እስማማለሁ
853	አሁን ለአስም የምዎስዳቸዉ ሁሉም መዳሃኒቶች አስፈላግ ናቸዉ፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
854	ለላ ሰዉ አስም እንዳለብኝ ብያቅ እንኳን ምንም አይመስለኝም፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
855	የአስም መዳሃኒቶችን ሰዉ በተሰባሰበት ቦታ መዉሰዲ አልፈራም፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
የአስም መከላከያ መድሃኒት (ICS) እውቀት		
900	የአስም መከላከያ መድሃኒት (ICS) የአስም በሽታን ለረጅም ጊዜ ለመከላከል ተመራጭ ነው ፡፡	1-አዎን
		2-የለም
		3-አላዉቅም
901	የአስም መከላከያ መድሃኒት(ICS) የመተንፈሻ ቱቦ መቆጣትን ወይም ማበጥ ይከላከላል፡፡	1-አዎን
		2-የለም
		3-አላዉቅም
902	የአስም መከላከያ መድሃኒት(ICS) ሙሉ ውጤት የሚያሳየው ያለማsረጥ ሲጠቀሙ ነዉ፡፡	1-አዎን
		2-የለም
		3-አላዉቅም
903	የአስም መከላከያ መድሃኒት(ICS) ሙሉ ውጤት የሚያሳየው መጠቀም ከጀመሩ ከቀናት ቆይታ በኋላ ነው፡፡	1-አዎን
		2-የለም
		3-አላዉቅም
904	የአስም መከላከያ መድሃኒት(ICS) ሲጠቀሙ የአስም ምልክቶች(ማለትም ማሳል፣ የፉጨት ዲምጽ) ወዲያው ይሻሎታል፡፡	1-አዎን
		2-የለም
		3-አላዉቅም
የአስም መከላከያ መድሃኒት (ICS) አመለካከት		
950	የአስም ምልክቶች በይኖሩ እንኳን የአስም መከላከያ (ICS) መድሃኒት መዉሰዲ አስፈላግ ነዉ፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
951	ያለቐማረጥ የአስም መከላከያ መድሃኒት (ICS) መዉሰዲ በአሰሚ ምክንያት የምከሰቱ ዲንገተኛ ህመምና ሞት ይከላከላል፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በጣም እስማማለሁ
952	የአስም መከላከያ መድሃኒት (ICS) መዉሰዲ ከጀመሪኩኝ አስሙ ተሸሎኛል፡፡	1-በፍጹም አልስማማም
		2-አልስማማም

		3-ገለልተኛ
		4-እስማማለሁ
		5-በፍጹም አልስማማም
953	የአስም መከላከያ መድሃኒት (ICS) አካታትሎ ስዎሥዱት መዉሰዲ የመድሃኒት ጥንኛነትን ያስከትላል፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በፍጹም አልስማማም
954	የአስም መከላከያ መድሃኒትን (ICS) አካታትሎ መዉሰዲ ለብዙ የጎንዮሽ ጉዳት ያጋልጣል፡፡	1-በፍጹም አልስማማም
		2-አልስማማም
		3-ገለልተኛ
		4-እስማማለሁ
		5-በፍጹም አልስማማም

አመሰግናለዉ!!!

Annex III: Physicians Self-administered Questionnaires

This is self-administered questionnaires to be done for a study that is being conducted by Addis Ababa University, School of Pharmacy. This study is prepared to assess factor associated with underutilization of inhalation corticosteroids. Your participation in the study is very important to identify problems related to inhalation corticosteroids use.

All the information given by you will be kept strictly confidential and only used for this study. Your participation is voluntary and you are not obligated to answer any question which you do not wish to answer.

1. What is your choice of drug for treatment of persistent asthma?

    a) ICS or ICS+LABA

    b) Other drugs (specify please) _____

2. If the answer for Q1is ICS or ICS+LABA, is there any circumstance in which you prescribe other drugs than ICS or ICS+LABA?

    ☐ Yes

    ☐ No

3. If the answer is 'yes' for Q2, in what circumstance?

4. Do you recommend patients to take inhalation steroids continuously even if remain symptom free?

    ☐ Yes

    ☐ No

5. If 'yes' for Q 4 do you make any modification on the initial regimen?

    ☐ Yes

    ☐ No

If yes, what will you do?

_____

6. Indicate regimen of your choice for the following category of persistence asthma? (with dose and frequency)

Mild persistent:

Moderate persistent

Sever persistent:

7. Do you think there is adequate utilization of ICS or ICS+LABA by the patients?

☐ Yes

☐ No

8. If the answer for the Q7 is 'No', what do you think is the related factors?

Thank You!!!