Winter 1-3-2020

To study Drug Utilization and QoL in patients with Bronchial Asthma

Kanav Khera Dr
Manipal College of Pharmaceutical Sciences, kanav.khera@manipal.edu

To study Drug Utilization and QoL in patients with Bronchial Asthma

A Project Report Submitted to

MANIPAL ACADEMY OF HIGHER EDUCATION

In partial fulfilment for the degree of Doctor of Pharmacy (Pharm D)

Submitted By:

Ananya A Nayak
Reg. No: 150614046

M. Srivalli Soumya
Reg. No: 150614024

Pharm D 5th year
Department of Pharmacy Practice,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education,
Manipal.

MARCH 2020

Under the Guidance of

Guide:
Dr. Kanav Khera
Assistant Professor (senior grade)
Department of Pharmacy Practice,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education,
Manipal-576104,
Karnataka, India

Co-Guide:
Dr. Aswini Kumar Mohapatra
Professor and Unit Head
Department of Respiratory Medicine,
Kasturba Hospital,
Manipal Academy of Higher Education,
Manipal-576104,
Karnataka, India

Co-Guide:
Dr. Basavaraj S Hadapad
Professor and Head
Division of Ayurveda, CIMR,
Manipal Academy of Higher Education,
Manipal-576104,
Karnataka, India

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Certificate

This is to certify that this project report entitled **"To study Drug Utilization and QoL in patients with Bronchial Asthma"**, by Ms. Ananya A Nayak, and Ms. M.Srivalli Soumya for the completion of 5th year PharmD comprises of the bonafide work done by them in the Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE, Manipal, Department of Respiratory Medicine, Kasturba Hospital, Manipal and Division of Ayurveda, CIMR, MAHE, Manipal, under the guidance of Dr. Kanav Khera, Assistant Professor (senior grade), Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE, Manipal, Co-guides Dr. Aswini Kumar Mohapatra Professor and Unit Head, Department of Respiratory Medicine, Kasturba Hospital, MAHE, Manipal and Dr. Basavaraj S Hadapad, Professor and Head, Division of Ayurveda, CIMR, MAHE, Manipal.

I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2019-2020.

Dr. Kanav Khera
Assistant Professor (senior grade)
Department of Pharmacy Practice,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education,
Manipal – 576104.
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Dr. Basavaraj S Hadapad
Professor and Head
Division of Ayurveda, CIMR,
Manipal Academy of Higher Education,
Manipal-576104,
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I recommend this piece of work for acceptance for the partial fulfilment of the completion of the 5th year Pharm D program of the Manipal Academy of Higher Education, Manipal for the Academic year 2019-2020.

Dr. C. Mallikarjuna Rao
Principal,
Manipal College of Pharmaceutical Sciences,
Manipal Academy of Higher Education,
Manipal – 576104.
Karnataka, India.

Place: Manipal
Date:

MANIPAL COLLEGE
OF PHARMACEUTICAL SCIENCES
MANIPAL
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Declaration

We hereby declare that the project entitled "To study Drug Utilization and QoL in patients with Bronchial Asthma", was carried out under the guidance of Dr. Kanav Khera, Assistant Professor (Senior grade), Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, MAHE, Manipal, Dr. Aswini Kumar Mohapatra, Professor and Unit Head, Department of Respiratory Medicine, Kasturba Hospital, MAHE, Manipal and Dr. Basavaraj S Hadapad, Professor and Head, Division of Ayurveda, CIMR, MAHE, Manipal. The extent and source of information derived from the existing literature have been indicated throughout the project work at appropriate places. The work is original and has not been submitted in part or full for any diploma or degree purpose for this or any other university.

Ananya A Nayak

Reg. No: 150614046

M. Srivalli Soumya

Reg. No: 150614024

Place: Manipal

Date:

Acknowledgement

"In the name of God, the Almighty, the most Generous and Merciful".
We express our utmost gratefulness to the almighty for the blessing throughout this study. We are extremely thankful to our family and friends for giving us the opportunity to carry ourselves forward in the path of dream and for their unflagging love, care, attention, concern and support throughout our lives.

We humbly owe gratitude and sincere regards to our respected teacher and guide **Dr. Kanav Khera,** Associate Professor, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, for his valuable guidance, encouragement, untiring patience and support laid by him during all stages of our study. His encouragement and fruitful suggestions have enabled to make our work worthy of presentation.

We extend our sincere and heartfelt thanks to **Dr. Aswini Kumar Mohapatra** Professor and Unit Head, Department of Respiratory Medicine, Kasturba Hospital, MAHE, Manipal and **Dr. Basavaraj S Hadapad,** Professor and Head, Division of Ayurveda, CIMR, MAHE, Manipal for their endless support and cooperation.

We would also like to express our sincere gratitude to **Prof. Emeritus Elizabeth F Juniper**, Department of Clinical Epidemiology and Biostatistics, McMaster University, Ontario, Canada for providing us with the AQLQ(S) questionnaires in English and Kannada for free of cost.

Special thanks to Dr. Shivraj Kumar, nursing staff of Department of Respiratory Medicine and Division of Ayurveda who have directly or indirectly supported us during the completion of the project.

Lastly, we offer our regards and blessings to all of those who supported us in any respect during completion of the project.

LIST OF ABBREVIATIONS

BA	Bronchial Asthma
QOL	Quality of Life
AQLQ(S)	Case Report Form
ICF	Informed Consent Form
PIS	Participation Information Sheets
CRF	Case Report Form
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
GINA	Global Initiative for Asthma
NAEPP	National Asthma Education and Prevention Program
WHO	World Health Organization
ICS	Inhaled Corticosteroids
SABA	Short-Acting β_2-Agonists
LABA	Long-Acting Inhaled β_2-Agonists
LTRA	Leukotriene Receptor Antagonist
HDM SLIT	House Dust Mite Sublingual Immunotherapy
TXA2RA	Thromboxane A2 Receptor Antagonists
FEV1	Forced Expiratory Volume
FVC	Forced Vital Capacity
BHR	Bronchial Hyperresponsiveness
ACT	Asthma Control Test
cACT	Childhood Asthma Control Test
ACQ	Asthma Control Questionnaire
ATAQ	Asthma Therapy Assessment Questionnaire
LASS	Lara Asthma Symptom Scale
LWAQ	Living with Asthma Questionnaire
AQLQ	Asthma Quality Life Questionnaire
SGRQ	St. George's Respiratory Questionnaire
ABP	Asthma Bother Profile
ABG	Arterial Blood Gas
PFT	Pulmonary Function Test
miniPEFR	Mini Peak Expiratory Flow Rate

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ABSTRACT

Background: Bronchial Asthma (BA) is a chronic inflammatory of the airways.[1] It is generally known that asthma can cause an impact on a patient's Quality of Life (QoL), mostly in a negative manner. To perceive the impact it has on the population, 'Questionnaires on Quality of Life' in asthmatic patients were made. Improving the QoL of patients with asthma mainly aims at reducing the risk of exacerbation and preventing morbidity related to asthma. Drug Utilization studies are important in order to assess the current prescription patterns against standard guidelines and can help in rationalizing the management. The economic burden of asthma has increased drastically across the globe over several decades. Patients' knowledge, awareness of the disease, and low cost of therapy are key factors in improving quality of life. [2]

Objectives: To study the Drug Utilization, direct costs and the QoL of asthmatic patients.

Methods: A prospective study was conducted among 46 Bronchial asthma patients with and without comorbidities who visited the Respiratory Out-patient department in Kasturba Hospital after obtaining the ethical clearance. The study aimed at assessing the QoL, drug utilization patterns, and direct cost of therapy. Quality of Life was measured using the Asthma Quality of Life Questionnaire (AQLQ) and the direct cost of therapy was analyzed using the medications prescribed by the physicians, consultation fee and lab charges. [3] Patient were given an AQLQ along with an informed consent form (ICF), taking the proper consent of the patient, Participation Information Sheets (PIS) was provided regarding the information on the project being conducted. Each patient was given 10-15 minutes to sign the ICF and complete the AQLQ. The information obtained from the patient was transferred from hard copies of Case Report Forms (CRFs) to SPSS 20 and analyzed.

Results: 57 patient files were collected out of which 11 files came under exclusion criteria, thus 46 patients' data was collected. Mean age of the study population (N = 46) was 40.85 ± 10.02 years. It was found that 67% of the study population were females and 33% were males. 56.5% of patients had comorbidities whereas 43.5% did not. FEV1 (post) values taken show that 45.6% of patients have an obstruction. The mean Overall AQLQ score was 4.99 ± 1.24, mean Activity Limitation score was 4.83 ± 1.33, mean Symptoms score was 5.11 ± 1.41, mean Emotional Function score was 5.22 ± 1.31 and mean Environmental Stimuli score was 4.66 ± 1.55. These values along with FEV1 (post) values show that moderate impairment is seen among the patients. Patients without comorbidities had a better QoL (5.17 ± 1.38) than in patients with comorbidities (4.86 ± 1.12). Patients who were literate had a higher QoL than the illiterate patients. The average total cost of treatment, drug cost and lab charges in 46 patients were found to be 2252±1057, 1142.15 ± 484.35 and 920.33 ± 902.31 respectively. The average cost of therapy was found to be high in the case of patients with co-morbidities.

Conclusion: The results of the study suggest that more studies need to be conducted on QoL of patients and educate the patients further on the disease knowledge and medication knowledge thus improving their quality of life and reducing the average cost of therapy.

INTRODUCTION

1. INTRODUCTION

1.1 Definition

BA 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, macrophages, neutrophils, and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or early morning [4].

1.2 Epidemiology

Around 339 million people across the globe, suffer from asthma and this number will rise to around 100 million more people being affected by 2025. According to GINA 2018 report, out of 1.31 billion people in India, 6% of children and 2% of adults have asthma. Globally, asthma has been ranked 16th and 28th among years lived with disability and a leading cause of the burden of disease respectively. Worldwide, deaths from this condition have reached over 420,000 in 2016 with more than 1000 per day. About 80% of deaths occur mainly in low and lower-middle-income countries. The rate of asthma is increasing as communities adopt western lifestyles and become urbanized [5]. Global prevalence (%) of Clinical Asthma includes mainly the countries of Africa, the Americas, Eastern Mediterranean, Europe, South East Asia, Western Pacific, and a total global percentage [6].

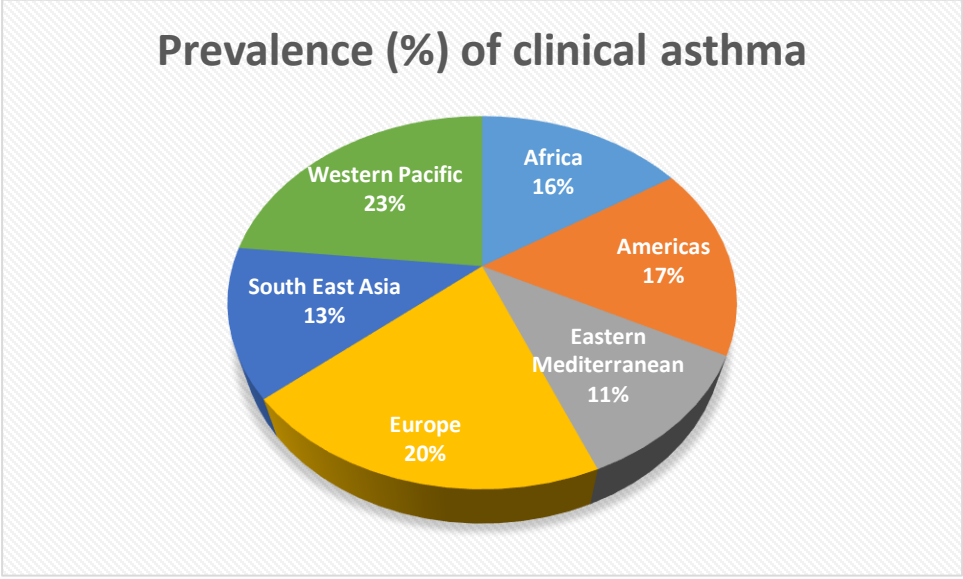

Figure 1. Global prevalence (%) of Clinical Asthma

1.3 Burden of Asthma

A rising burden of Asthma is observed in countries of all financial levels. It is considered both in terms of direct medical cost (i.e. hospital admissions, cost of pharmaceuticals, etc.) and indirect medical cost (i.e. time lost from work, premature death, etc.)[7]. Both social and economic perspectives are required in terms of evaluation of cost for optimal treatment and patient care. Economic evaluations of asthma have been done in many countries. In the U.S., a study was published in the American Journal of Respiratory and Critical Care Medicine which showed a 20-year cost of uncontrolled asthma which estimated to exceed $963 billion. But there are only limited population-based studies. In South India, a study was published in Lung India where the annual cost of asthma treatment was found to be 18,737 INR [8]. The majority of the cost would be out of their own pockets as there is no proper insurance system developed in India.

2. NEED FOR STUDY

Even with the progressing rise in asthma, there are only a few studies done on Drug Utilization patterns, QoL, and cost in India. In order to understand the effect of medications, a questionnaire was administered to assess QoL and the objective data generated determined their functional, emotional, environmental, and activity limitation on a daily basis.

Drug Utilization study aims at assessing the QoL in asthma patients, to determine their functional problems, and to find the association it shared with patient demographics as there are only a few studies done on QoL on asthma patients in India.

The cost of therapy is a key factor in low socio-economic patients for obtaining medications planned out by physicians and the subsequent visits. There is a need for patients, doctors, administrators, pharmacists, nurses to be provided with an estimate of the direct cost of therapy which could be used to determine a cheaper and affordable drug regimen to poor patients without compromising on the quality. The economic data obtained can be utilized to determine the burden on patients on a day to day basis that may have a direct effect on the patient's QoL.

Hence, there is a need for more studies to be done to emphasize the importance of drug utilization, QoL, and cost to find out the probable causes of a low QoL which can help health care professionals to intervene in a patient-specific approach to improve the outcome.

AIMS & OBJECTIVES

3.0 AIMS AND OBJECTIVES:

Primary objectives:

1. To study drug utilization patterns in patients with Bronchial Asthma.

Secondary objective:

1. To study the quality of life among bronchial asthma patients.
2. To determine the cost of therapy for bronchial asthma patients.

LITERATURE REVIEW

4. REVIEW OF LITERATURE

Bronchial Asthma is defined as a chronic inflammatory disorder of the airways where many cells and cellular elements have an important role especially mast cells, eosinophils, T-lymphocytes, macrophages, neutrophils, and epithelial cells [4]. It is associated with hyper-responsive reaction due to exposure to various risk factors resulting in the obstruction and airflow limitation of the airways. The most common risk factors include exposure to allergens (includes allergy to certain animals with fur, insects, dust, pollen, food, etc.), irritants in the air (such as occupational irritants, tobacco smoke, strong odors, chemical irritants) respiratory (viral) infections, extreme weather conditions, extreme exercise, strong emotional factors and drugs including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)[9]. Asthma presents with symptoms of breathlessness, wheezing, chest tightness, and coughing, particularly at night or early morning [10].

According to Global Initiative for Asthma (GINA) and National Asthma Education and Prevention Program (NAEPP) guidelines, asthma is classified into 4 groups based on severity: intermittent asthma, and mild, moderate, and severe persistent asthma [11].

	INTERMITTENT	MILD PERSISTENT	MODERATE PERSISTENT	SEVERE PERSISTENT
SYMPTOMS	≤ 2 days/week	>2 days/ week but not daily	Daily	Throughout the day
NIGHTTIME AWAKENINGS	≤ 2 x month	3-4 x month	>1 x week, but not nightly	Often 7 x week
RESCUE MEDICATION USE	≤ 2 days/ week	>2 days/ week	Daily	Several times per day
INTERFERENCE WITH NORMAL ACTIVITY	None	Minor	Some	Extreme
LUNG FUNCTION ***Normal FEV_1/FVC:** **8-19 Y (85%)** **20-39 Y (80%)** **40-59 Y (75%)** **60-80 Y (70%)**	FEV_1 > 80% FEV_1/FVC normal	FEV_1 > 80% FEV_1/FVC normal	FEV_1 60-80% FEV_1/FVC reduced 5%	FEV_1 < 60% FEV_1/FVC reduced > 5%
EXACERBATIONS	Brief	May affect activity and sleep	May affect activity and sleep	Frequent

Table 1: Severity of Asthma

Asthma is generally considered to be a costly illness, the total costs to society, whether direct, indirect or intangible costs, are difficult to estimate, because of different disease characterizations [7]. Use of bronchodilators and anti-inflammatory drugs as current pharmacotherapy helps primarily in leading to symptomatic improvement and suppression of airway inflammation along with a decrease of bronchial hyper responsiveness [12].

It is generally characterized by airflow obstruction, hyper-responsiveness, and airway inflammation: these problems generally lead to episodes of cough, breathlessness, and chest tightness, particularly at night or early morning. It is triggered due to the consequence of complex gene-environment interactions [13].

BA is a common airway disease in children and adults, and affects around 339 million people worldwide. According to GINA, asthma affects about 1 – 18% of the population in different countries. GINA defines asthma as a heterogeneous disease that is usually characterized by chronic airway inflammation which includes symptoms such as wheezing, shortness of breath, chest tightness, and cough with different intensities and timing.

GINA was initiated in 1989 to raise awareness among the public healthcare sectors and the general public about asthma and its effects.

GINA has assessed asthma which involves the control, assessment of asthma along with its treatment techniques, compliance of medications, and other comorbidities along with asthma which can make way for a poor quality of life [5].

The prevalence of asthma is increasing due to the rapid industrialization of cities [14]. With the development of India from an agricultural society into an industrializing country, the dense population, the air pollution challenges, changing lifestyle, and the other environmental factors very much affect the prevalence and incidence of asthma for everyone [15]. Due to the difference in methodology of studies and wide geographical and environmental variations which include air pollution, smoking, and other occupational exposures (factory, farming, or other occupational exposures) in India, the estimated prevalence rate ranges from 2% to 23% [14]. Due to living in an area with meagre medical facilities and inadequate financial resources, proper treatment of asthma is lacking.

In India, there are vast economic, religious, racial and socio-political differences which affect the treatment and its outcome. The reasons for poor prognosis are poor adherence, poor compliance, inadequate education and poverty along with other secondary reasons. Due to the

Cultural diversity along with their lay beliefs of people can determine their disease acceptance and therapy. Many people can be afraid of the current health care system or do not trust the medications being prescribed. Poverty and inner-city living play an important role along with income in terms of adherence and compliance to medications. Factors affecting adherence include financially unstable populations who lack proper transport, are unable to pay for their medications, have family problems, etc. thus leading to a decrease in patient QoL [16].

WHO (World Health Organization) has defined adherence to long-term therapy as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".[17]

Many advances have been seen in the clinical treatment of asthma over the past years. Even with all the advances, the frequency and morbidity of asthma is continuously increasing. In general, scientific evidence found on asthma along with its continuous negative effects seen in this society has a key role in both the doctor's and the patient's performance [18]. The main reasons for this have been proved to be due to inadequate education about the seriousness of their illness along with poor compliance with their medications. Every patient should be thoroughly educated about their disease by health professionals and should self-motivate to adhere to their medications thus providing better health. This concept is referred to as self-efficacy according to WHO [17].

According to GINA guidelines 2019

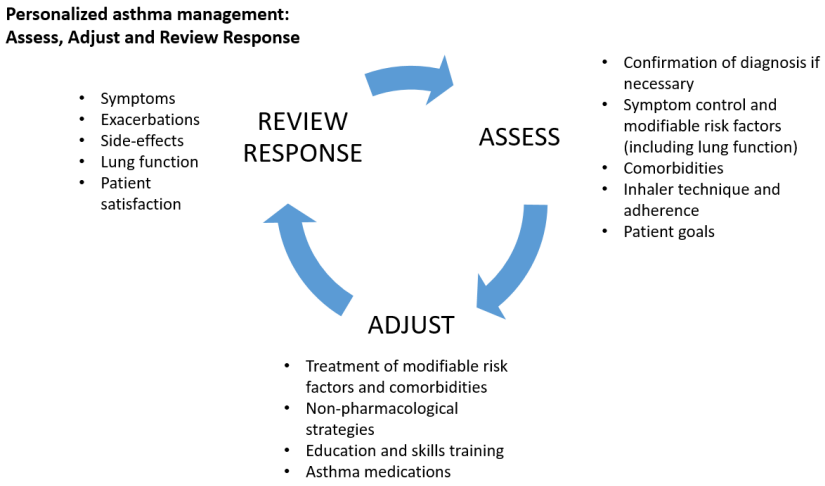

Figure 2: GINA Personalized asthma management [5]

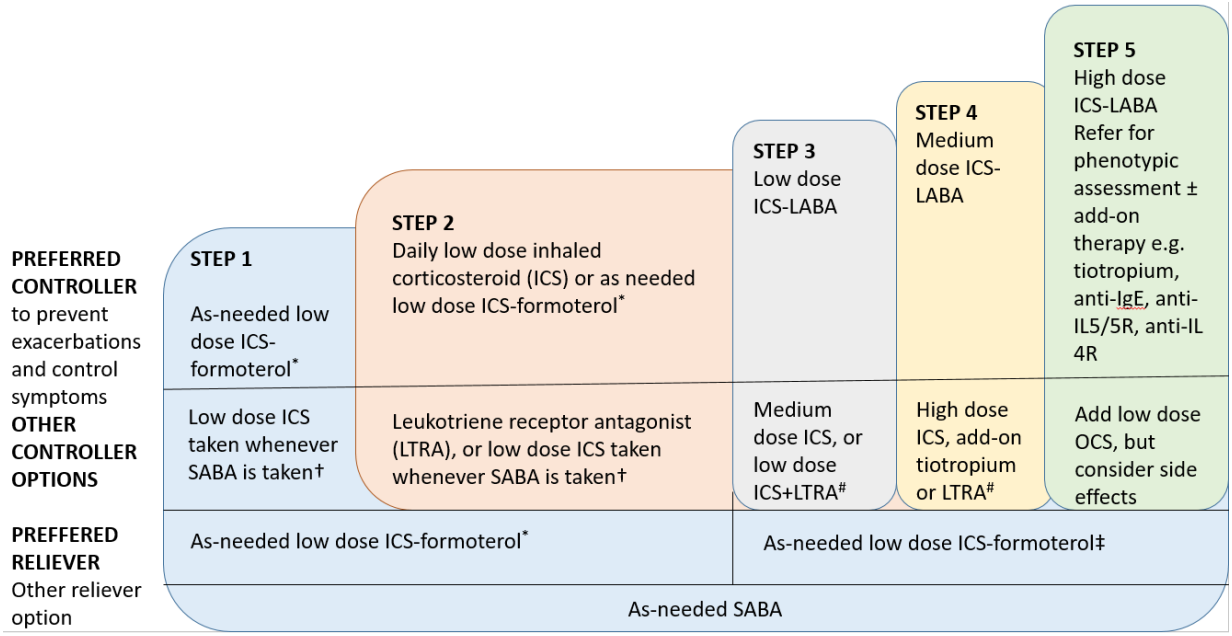

Figure 3: Treatment of Bronchial Asthma [5]

*Off-label; data only with budesonide-formoterol (bud-form)

†Off-label; separate or combination ICS and SABA inhalers

‡Low-dose ICS-form is the reliever for patients prescribed bud-form or BDP-form maintenance and reliever therapy

#Consider adding HDM SLIT for sensitized patients with allergic rhinitis and FEV1 > 70% predicted

Treatment of asthma consists of many classifications such as Short-acting β_2-agonists (SABA), Long-acting inhaled β_2-agonists (LABA), Inhaled corticosteroids (ICS), Leukotriene receptor antagonist (LTRA), Methyl-xanthines, Oral corticosteroids, anti-histamines, expectorants, mucolytic agents and Thromboxane A2 receptor antagonists (TXA2RA). The first-line therapy for exacerbation of asthma includes SABA, corticosteroids, inhaled ipratropium bromide, and Oxygen supplement. The most widely prescribed class is inhaled corticosteroids which are considered to be most beneficial for the treatment of asthma as their direct mode of action is to the airways. The reduction of unwanted systemic effects is seen as they reduce systemic exposure.

Actions useful in treating asthma include:

- Increasing the number of β_2-adrenergic receptors and improving the receptor responsiveness to β_2-adrenergic stimulation

- Reducing mucus production and hypersecretion
- Reducing BHR (Bronchial Hyper responsiveness), and
- Reducing airway edema and exudation.

Lifestyle modifications for asthma include:

- To quit smoking as the smoke irritates the airways
- Drinking plenty of water especially during exercise to ensure hydration, keeping body cells functioning and keeping the mucus of the airways loose
- Avoiding environmental stimuli and allergens that might provoke an exacerbation
- Use of air mask in case of dust exposure and
- Taking plenty of rest in case of tiredness or shortness of breath[4]

Every patient must understand and follow the basic principles of self-management to prevent exacerbation of their condition. The principles include:

- Assessing the severity of asthma by interpreting key symptoms and peak flow meter readings.
- Regular use of ICS and SABA on an as-needed basis for long term treatment.
- In the case of severe asthma, systemic corticosteroids, long-acting β-agonists, and medical review are suggested.
- Unification of self-assessment and self-management with written guidelines for long-term treatment as well as for acute treatment of asthma [19].

The economic cost of asthma is considered in terms of both direct (hospital admissions and cost of medicines) and indirect costs (time lost from work, traveling cost and premature death, etc.)[20] Direct medical costs contribute as the largest component of asthma medicines especially in North America and Europe. Although in the Middle East and South Asia, costs such as outpatient costs, doctor visits, and visits to Emergency Departments contributed to the larger proportion of total costs. Indirect costs are often ignored in the cost estimates but studies report that these costs of asthma contribute as a significant aspect of the economic burden [21].

Numerous studies have confirmed the inadequacy of asthma control. The severity of airway diseases can be assessed using Health-related quality of life Questionnaire. Asthma can reduce the quality of a life due to its physical and psychosocial complications.

QUESTIONNAIRES	NUMBER OF ITEMS	TARGET AGE (IN YEARS)	RECALL WINDOW (WEEKS)	SCORING SYSTEM	VALIDATED METHODS (OR) SETTING OF ADMINISTRATION	QUESTIONNAIRE CONTENT						
						SYMPTOM FREQUENCY	RELIEVER USE	ACTIVITY LIMITATIONS	NOCTURNAL SYMPTOMS	EXACERBATION	EMOTIONAL FUNTION	ENVIRONMENTAL STIMULI
ACT	5	>12	4	Range is from: 5-25: >19 = controlled 16-19 = not well controlled <16 = very poorly controlled Minimum clinically important difference = 3 points	Clinical setting, home, phone, mail, internet	Yes	Yes	Yes	Yes	No	No	No
cACT	7	4-11	4	Range is from: 0-27: >22 = well controlled <19 = uncontrolled Minimum clinically important difference = 2 points	Clinical settings, home	Yes	No	Yes	Yes	No	No	No
ACQ	6	>12 OR 16-17	1	Score ranges from 0 to 6 <0.5 = partially controlled >1 = uncontrolled Minimum clinically important difference = 0.5 points for adults or 0.4 points for children	Clinical settings, home, phone, mail	Yes	Yes	Yes	Yes	No	No	No

ATAQ	4	≥18	4	Number of control problems: 0 = controlled 1-2 = not well controlled 3-4 = very poorly controlled Minimum clinically important difference not identified	Clinical settings, mail, home	No	Yes	Yes	Yes	No	No	No
LASS	8	>3	4	Score ranges from 8 to 40, with higher scores representing more severe asthma symptoms, Minimum clinically important difference = 7 points	Clinical settings	Yes	No	No	Yes	Yes	No	No
AQLQ (S)	32	≥12	2 weeks	7-point scale for each domain. Overall score is mean of all 32 items (range 1–7). Domain scores are mean of specific domain items (range 1–7).	Clinical settings, Self-administered	Yes	No	Yes	Yes	Yes	Yes	Yes

LWAQ	68		None	Three point Likert scale. A mixture of positive and negative items compensates for acquiescence bias	Clinical settings, Self-administered	Yes	Yes	Yes	Yes	No	Yes	No
AQLQ	32	17-70	2 weeks	7-point scale for each domain. Overall score is mean of all 32 items (range 1–7). Domain scores are mean of specific domain items (range 1–7).	Interviewer administered, self-administered	Yes	No	Yes	Yes	Yes	Yes	Yes
SGRQ	50	Any	1, 3 or 12 months	Scores range from 0 to 100, with higher scores indicating more limitations	Self, phone interview, online, computer-based	Yes	No	Yes	No	No	Yes	No
ABP	22	Adults	None	Total score and scores for 2 domains: distress,	Self	Yes	No	Yes	No	No	Yes	No

Table 2: Different type of Asthma Questionnaires compared [22] [23] [24] [25]

Out of all the available questionnaires, AQLQ (S) was chosen as it is widely used and validated for use in multiple countries. It has also been adapted to create versions for use in pediatric asthma and rhinitis. Quicker and easier to use than original AQLQ.

Thus studies on AQLQ (S) were done which have shown how a treatment affects the patient's life either in a positive or negative. It includes a disease-specific 32 questions which include 4 domains: Symptoms, emotions, exposure to environmental stimuli, and activity limitations. Patients rate each question according to what they experienced during the previous 14 days and answer each question based on a 7 point scale system. The scoring was done by dividing the 32 items in the questionnaire into 4 domains where: Questions 1-5, 11, 19, 25, 28, 31, 32 was included under the Activity limitation domain. Questions 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30 was included for calculating Symptoms domain. Questions 7, 13, 15, 21 and 27 for Emotional function domain. Questions 9, 17, 23, and 26 for the Environmental stimuli domain. A mean score was taken for all the 32 questions on their responses by finding their mean: adding all the 32 values and diving the value by 32. Thus the scores for each domain and overall mean would range from 1 to 7 where 1 indicates very poor QoL with severe impairments due to their asthma, whereas 7 indicates better QoL and no impairments due to asthma. The score 4 in the middle of the range indicates a moderate degree of impairment.

METHODOLOGY

5. METHODOLOGY

5.1 Study Site: The study was conducted at Kasturba Hospital in the Department of Respiratory Medicine.

5.2 Study design: Prospective observational study

5.3 Study period: 6 months (October 2019 to March 2020)

5.4 Sample Size: 46 patient files were collected

5.5 Ethical Approval:

The protocol for this study was approved by the Institutional Ethical Committee of Kasturba Hospital, Manipal. (IEC: 544/2019)

5.6 Study criteria: The study group comprised of patients who came to the Out-Patient Department in the Department of Respiratory Medicine who met the following criteria during the study period:

5.6.1 Inclusion criteria:

- Patients (age $\geq$ 18 years to $\leq$55 years) diagnosed with BA.
- Patients of both genders.
- Out-patients visiting to the Respiratory Department.

5.6.2 Exclusion criteria:

- Patients with cardiovascular disease (Cardiac arrest, Arrhythmia, Congenital heart disease, stroke)
- Patient's with hepatic and renal impairment.
- Pregnant and lactating women.
- Patients with neurological impairment.

5.7 Data source:

The study population broadly represents the South Indian population. All the necessary and relevant data were obtained from the medical records, finance department and interviews of patients diagnosed with BA.

5.8 Study materials

- ✓ Participant Information Sheet (PIS) - Used to provide necessary details (purpose, benefits/risks, procedure) regarding the study.
- ✓ Informed Consent Form (ICF) – An Informed consent form in Kannada or English was obtained from each participant before study initiation.
- ✓ Case Report Form (CRF) – To collect the necessary data from the patient records, an individual data collection form was designed, which included: demographics, complaints on admission, date of consultation, patient history (personal, family, social, medical and medication), diagnosis, Arterial Blood Gas (ABG) reports, Pulmonary Function Test (PFT) reports, Mini Peak Expiratory Flow Rate (PEFR) readings, allergy tests, laboratory findings, drug treatment chart, cost per drug and cost of total therapy and follow up.
- ✓ Asthma Quality of Life Questionnaire Standardized (AQLQ -S) – A questionnaire was requested from the Juniper QoL network and their permission was obtained for administration of the questionnaire to patients at first encounter. After the permission was granted, the original copy of questionnaires was obtained from the Juniper QoL network including English and Kannada versions of the questionnaire.

5.9 Operation modality

The study was carried out in 6 main stages:

Stage 1: Designing data collection form

Stage 2: Evaluation of CRF design

Stage 3: Data collection

Stage 4: Administration of AQLQ (S)

Stage 5: Data entry

Stage 6: Evaluation & Analysis

STAGE 1: **Designing a data collection form**

Patient demographics, laboratory data, treatment chart, follow up and cost of therapy were taken into consideration while designing a CRF.

STAGE 2: Evaluation of CRF design

The designed form was then evaluated by one internal and two external experts to ensure its applicability, relevance, and accuracy according to the Head of Unit of Respiratory Department and Head of Ayurveda Department.

STAGE 3: Data collection

1. Data of 46 patients was collected using the designed form.
2. After the informed consent was taken, the participant informant sheet was given.
3. The patient and/or patient party was asked a set of questions regarding their demographics and relevant histories like social, medical, familial, etc.
4. Data were simultaneously recorded on printed copies of CRFs.

STAGE 4: Administration of AQLQ (S)

1. The questionnaire was administered to the patient at the first encounter.
2. The patient was asked to fill the questionnaire provided according to their symptoms, activity limitation, emotional function, and environmental stimuli for the past two weeks.
3. According to their preferred language, English or Kannada questionnaires were given.

STAGE 5: Data entry

1. The collected data was checked for aberrancies and collated thereafter.
2. It was then entered into SPSS and re-checked for duplications.
3. This provides a platform through which the demographics and follow-up of the patient can be assessed.

STAGE 6: Evaluation & analysis

1. The data entered was analyzed based on the demographic information, ABG reports, PFT reports, Mini PEFR readings, risk factors like social history, familial history, co-morbidities, cost, and AQLQ (S).
2. Asthma Quality of Life Questionnaire (S) includes a disease-specific 32 questions which include 4 domains: Symptoms, emotions, exposure to environmental stimuli, and activity limitations. Patients rate each question according to what they experienced during the previous 14 days and answer each question based on a 7 point scale system. The scoring was done by dividing the 32 items in the questionnaire into 4 domains where:

DOMAINS	QUESTION NUMBERS	NUMBER OF QUESTIONS
Activity limitation	1-5, 11, 19, 25, 28, 31, 32	11
Symptoms	6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30	12
Emotional function	7, 13, 15, 21, 27	5
Environmental stimuli	9, 17, 23, 26	4

Table 3: Classification of AQLQ (S)

A mean score was taken for all the 32 questions on their responses by finding their mean: adding all the 32 values and diving the value by 32. Thus the scores for each domain and overall mean would range from 1 to 7 where 1 indicates very poor QoL with severe impairments due to their asthma, whereas 7 indicates better QoL and no impairments due to asthma. The score 4 in the middle of the range indicates a moderate degree of impairment.

3. The cost of therapy was taken from the finance department. The costs include cost per drug, physician's consultation fee, allergy test, PFT, or any other tests done for the patient.
4. Data analysis was carried out at the end of data collection by using SPSS version 20.

RESULTS

6.RESULTS

A prospective observational study was conducted where 57 files were collected out of which 11 files came under exclusion criteria, thus 46 patients' data was collected. comprising of n=46 patients to evaluate the demographic parameters, comorbidities, drug utilization patterns, cost of direct therapy and quality of life of each patient conducted in Department of Respiratory Medicine, KMC, MAHE, Manipal

6.1 Demographic Overview

Sex {n (%)}	Male: 15 (32.6%)	Female: 31 (67.4%)
Age in years (mean ± S.D.)	40.85 ± 10.02 years	
Co-morbidities {n (%)}	Present: 26 (56.5%)	Absent: 20 (43.5%)
Educational status {n (%)}	Literate: 43 (93.5%)	Illiterate: 3 (6.5%)
Allergy {n (%)}	Present: 13 (28.3%)	Absent: 33 (71.7%)
SPO_2 {n (%)}	97.63 ± 0.96	
MiniPEFR {n (%)}	304.47 ± 104.59	
Pulmonary Function Tests	**(mean ± SD)**	
FVC (pre)	77.77 ± 18.17	
FVC (post)	74.23 ± 19.64	
FEV_1 (pre)	71.19 ± 19.42	
FEV_1 (post)	74.39 ± 19.33	
FEV_1/FVC (pre)	90.94 ± 11.03	
FEV_1/FVC (post)	93.52 ± 10.22	
Overall AQLQ score	4.99 ± 1.24	
Activity Limitation	4.83 ± 1.33	
Symptoms	5.11 ± 1.41	
Emotional Function	5.22 ± 1.31	
Environmental Stimuli	4.66 ± 1.55	

Table 4: Demographic Overview

6.1.1 Sex

Out of n=46 patients enrolled in the study, 15 (32.6%) were male and 31 (67.4%) were female. This shows a majority of subjects in the study were female.

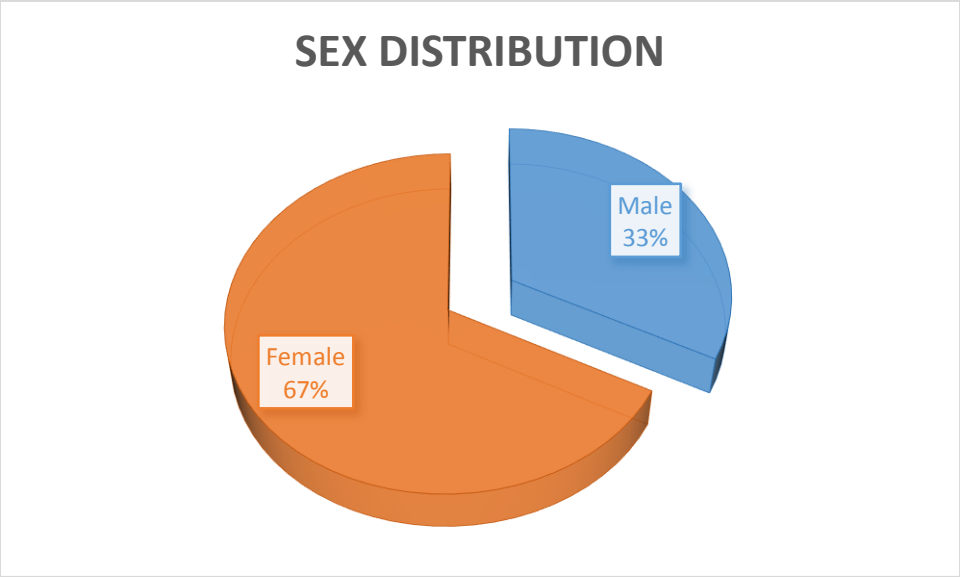

Figure 4: Sex Distribution

6.1.2 Age

Among the 46 patients, the majority of the patients fell under the age group of 31-40 years (30.4%), followed by age groups 41-50 years (28.3%), 51-55 years (21.7%), and 18-30 (19.6%).

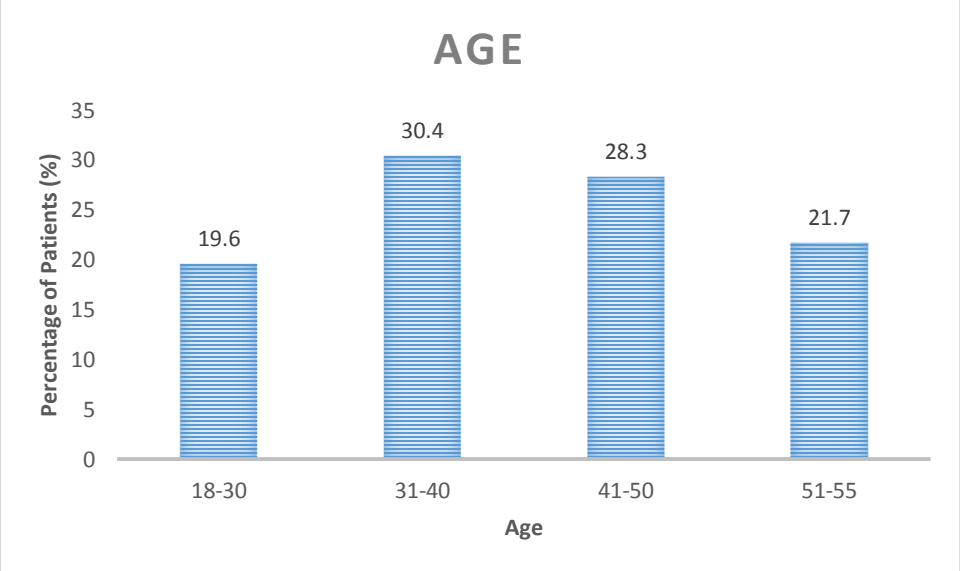

Figure 5: Range of age of all patients

Out of 46 patients, number of females below age 40 were 13 and number of females above 40 years of age were 18.

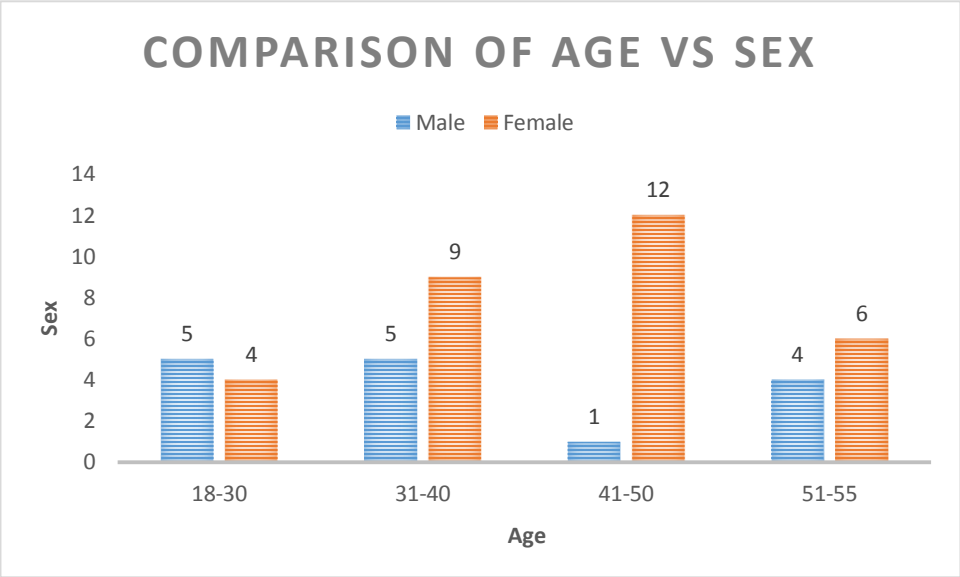

Figure 6: Age vs Sex

6.1.3 Co-morbidities:

Out of 46 patients, 26 (56.5%) had Bronchial Asthma with other co-morbidities and 20 (43.5%) had only Bronchial Asthma.

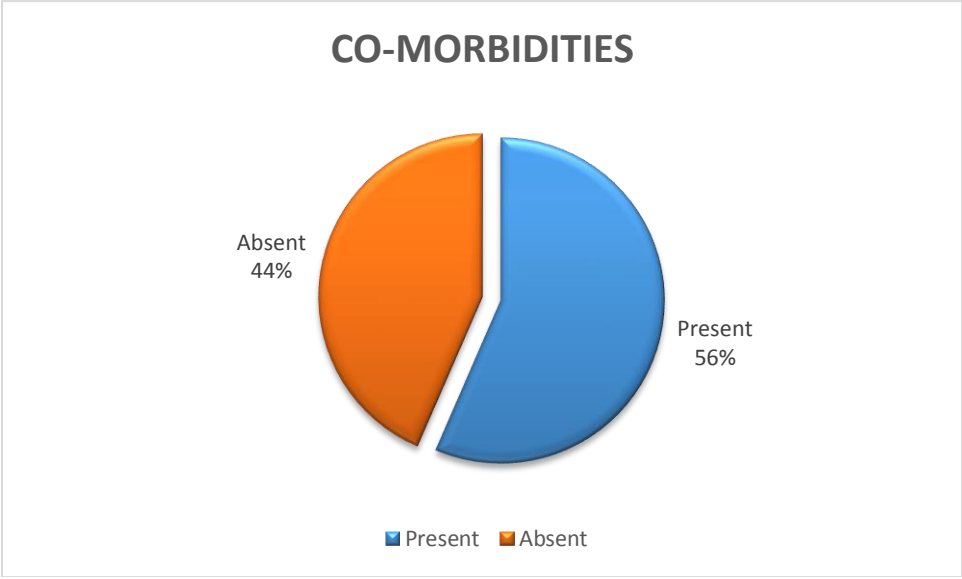

Figure 7: Co-morbidities

Among 46 patients, the co-morbidity which was mostly recorded was Allergic Rhinitis (26.1%) followed by Others which include Post TB, Antral Ulcers, Bronchiectasis, Eczema, GERD, Iron Deficiency Anaemia, Obstructive Airway Disease, Pulmonary Artery Hypertension, Post Nasal Drip and Sinonasal polyposis (22%).

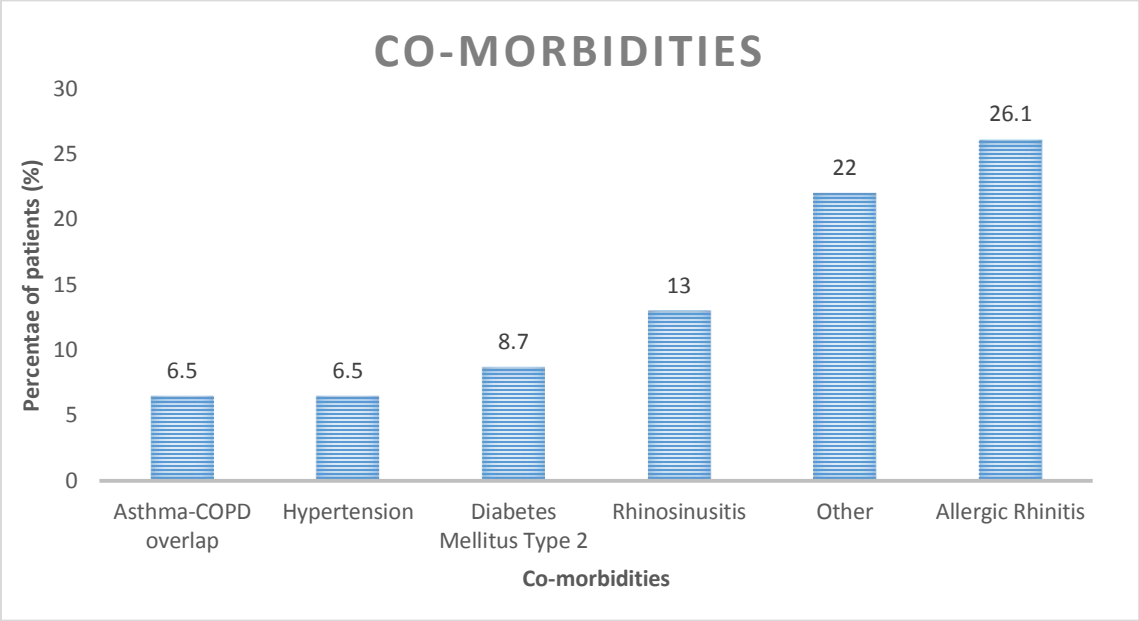

Figure 8: Different comorbidities

6.1.4 Educational status

Among n=46 patients, 43 (93%) were literate whereas 3 (7%) were illiterate.

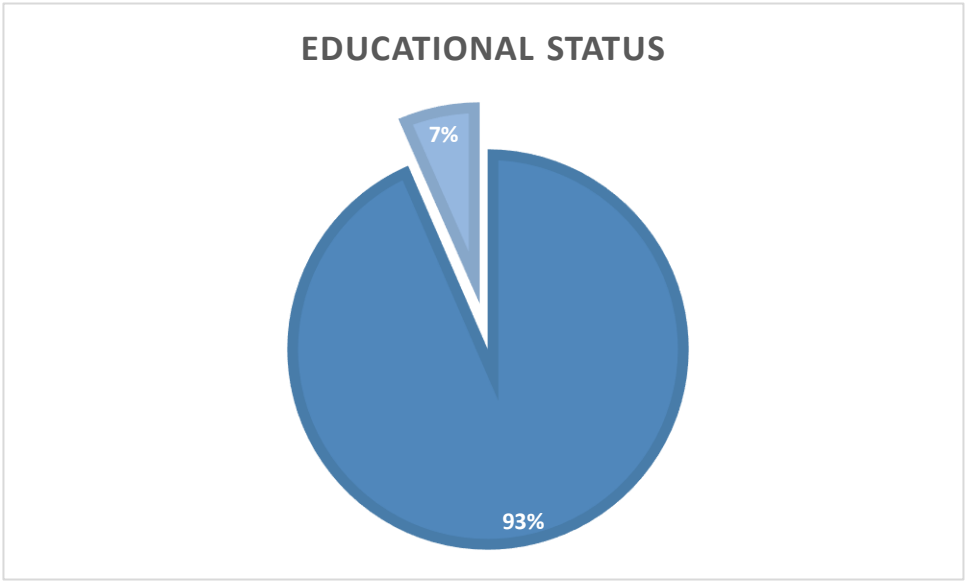

Figure 9: Educational status

6.1.5 Allergy

Out of n=46 patients, 13 (28%) had other allergies whereas 33 (72%) did not have any allergies.

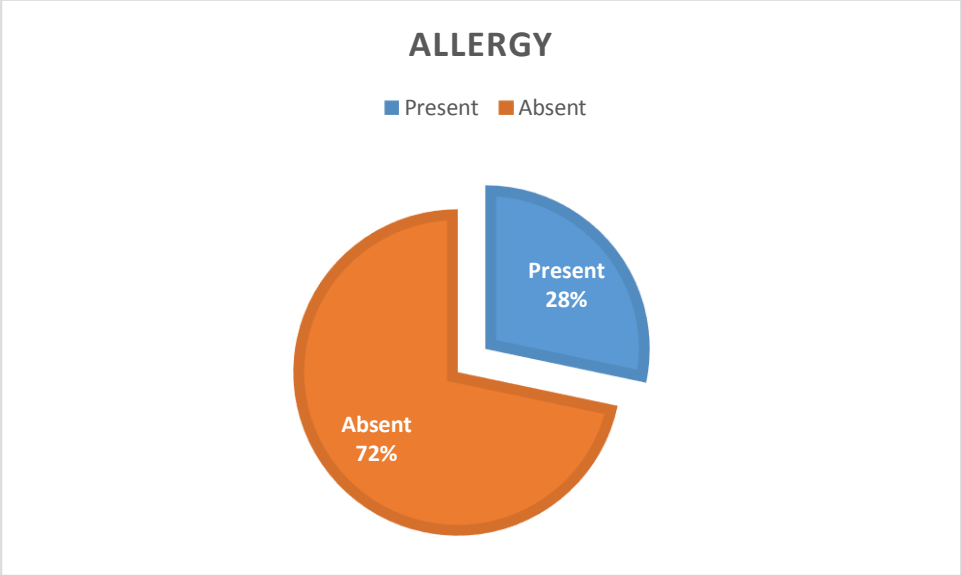

Figure 10: Allergy

Among 46 patients, dust allergy (21.7%) was found to be present more than other allergies.

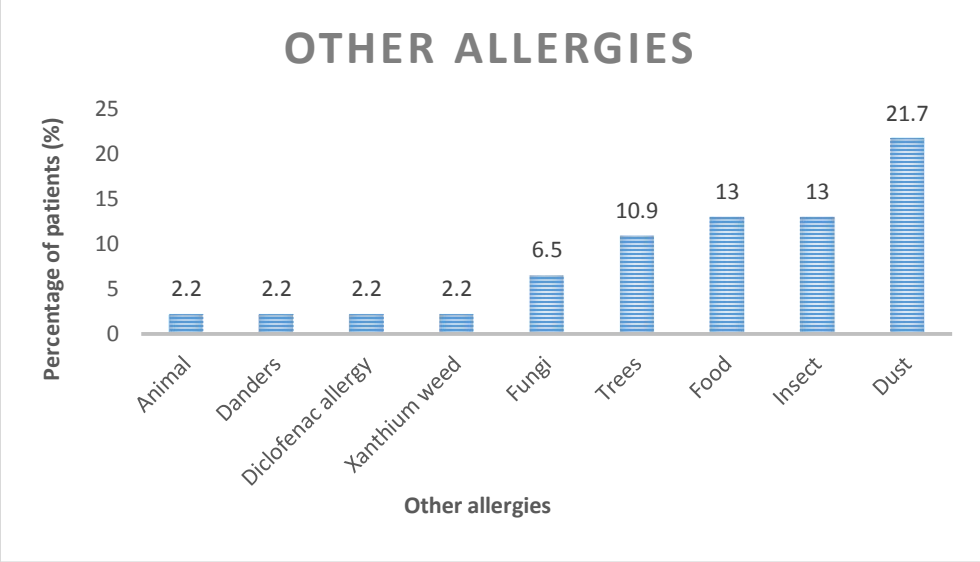

Figure 11: Other Allergies

6.1.6 ABG (Arterial Blood Gas) – SPO_2 (% on RA)

Among 46 patients, 30 values (65.2%) were missing, hence out of 16 patients, 9 patients (19.6%) had an SPO_2 of 98% followed by 3 patients (6.5%) had 96%.

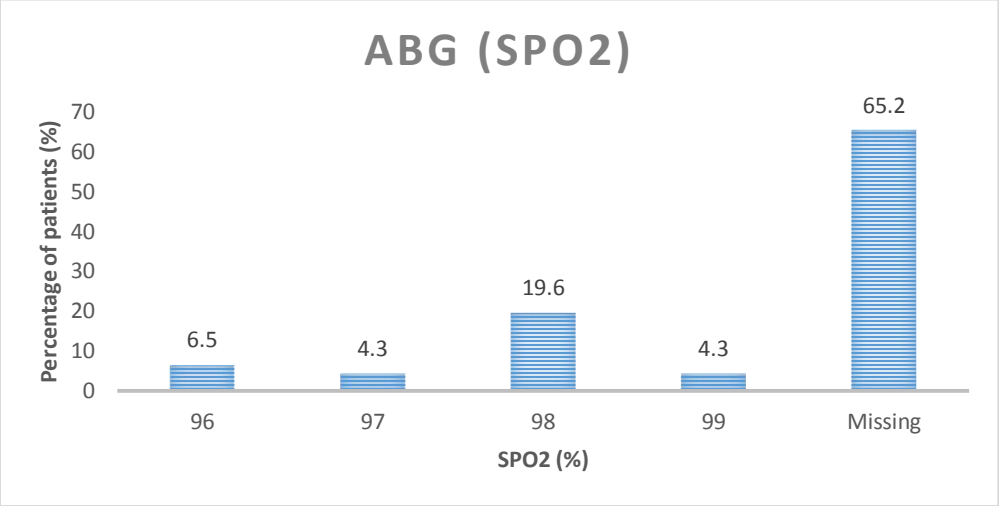

Figure 12: Arterial Blood Gas (SPO_2)

6.1.7 Symptoms

Among n=46 patients, the most common symptoms were found to be Breathing problems (63%), Coughing (60.9%), Wheezing (41.3%) and Nasal symptoms (21.7%). Others (37.2%) include Aspergilloma surgery, Bloating, Chest pain, Chest paint, anxiety, Dyspnea, Exacerbation, Fever, Headache, Joint pain, Left foot swelling, Sinus complaints, Sputum mucoid, Throat irritation and Weakness.

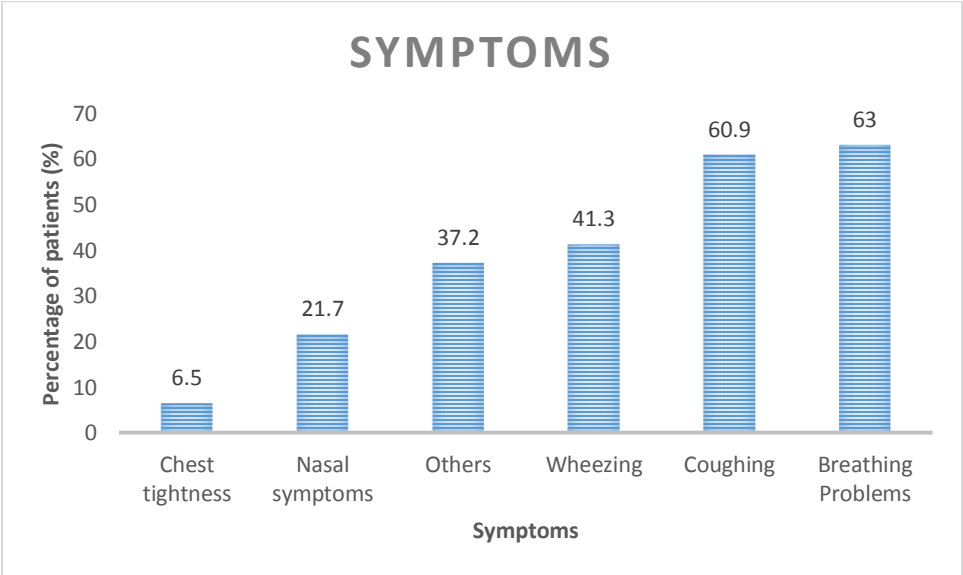

Figure 13: Symptoms

6.1.8 Patient occupation

Out of n=46 patients, 20 (43.5%) were homemakers, 4 (8.7%) were laborers, 4(8.7%) were farmers, 2(4.3%) were carpenters, 2 (4.3%) were lecturers, 2 (4.3%) were teachers and the rest had other jobs. Other occupations include Bank employee, Cook, Coolie, Flower seller, Housemaid, Mechanic, Mill worker, Nurse, Parlour, Railway employee, Service and Village accountant.

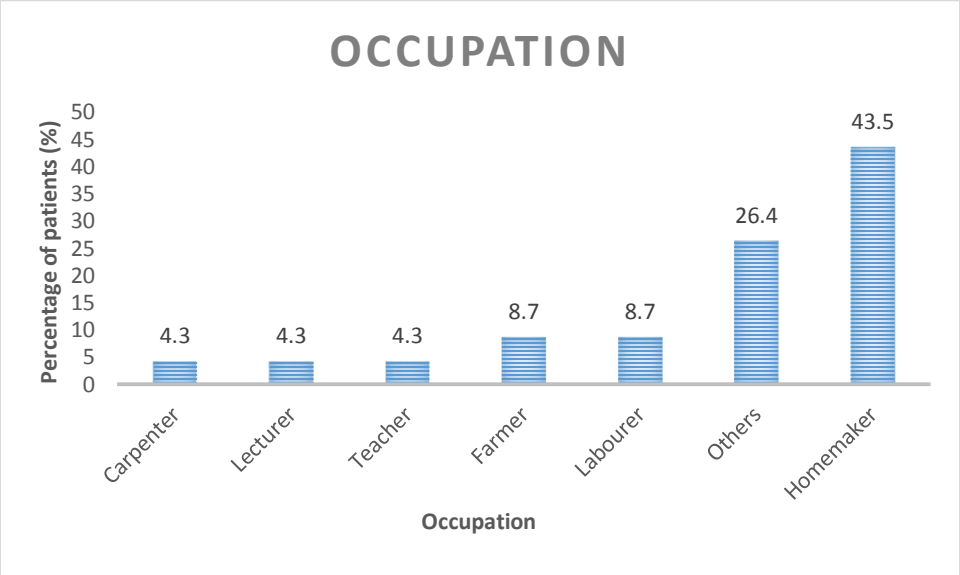

Figure 14: Occupation

6.1.9 miniPEFR (Pulmonary Expiratory Flow Rate)

Among n = 46 patients, the mean miniPEFR was found to be 304.47 ± 104.59.

6.1.10 Pulmonary Function Tests:

FEV_1/FVC (post) values show that mean ± SD is 93.53 ± 10.22 which indications the minimum value is 83.3 and the maximum value is 103.74. As the ratio is not less than 70%, there is no obstruction.

Tests	Mean ± SD (%)
FVC (pre)	77.77 ± 18.17
FVC (post)	74.23 ± 19.64
FEV_1 (pre)	71.19 ± 19.42
FEV_1 (post)	74.39 ± 19.33
FEV_1/FVC (pre)	90.94 ± 11.03
FEV_1/FVC (post)	93.52 ± 10.22

Table 5: Pulmonary Function Tests (Mean ± SD)

Among n = 46 patients, FEV_1 pre values show that 45.6% of patients have a value less than 80%, hence for these patients, an obstruction is seen whereas 21.7% had values above 80% and 32.6% values were missing.

	FVC (pre)	FVC (post)	FEV1 (pre)	FEV1 (post)	FEV1/FVC (pre)	FEV1/FVC (post)
<60% (Severe Persistent)	10.9	8.7	13	17.4		
60-80% (Moderate Persistent)	28.3	32.6	32.6	32.6	15.2	8.7
>80% (Mild Persistent (or) Intermittent)	28.3	26.1	21.7	17.4	52.2	58.7
Missing	32.6	32.6	32.6	32.6	32.6	32.6

Table 6: Pulmonary Function Tests (Percentages)

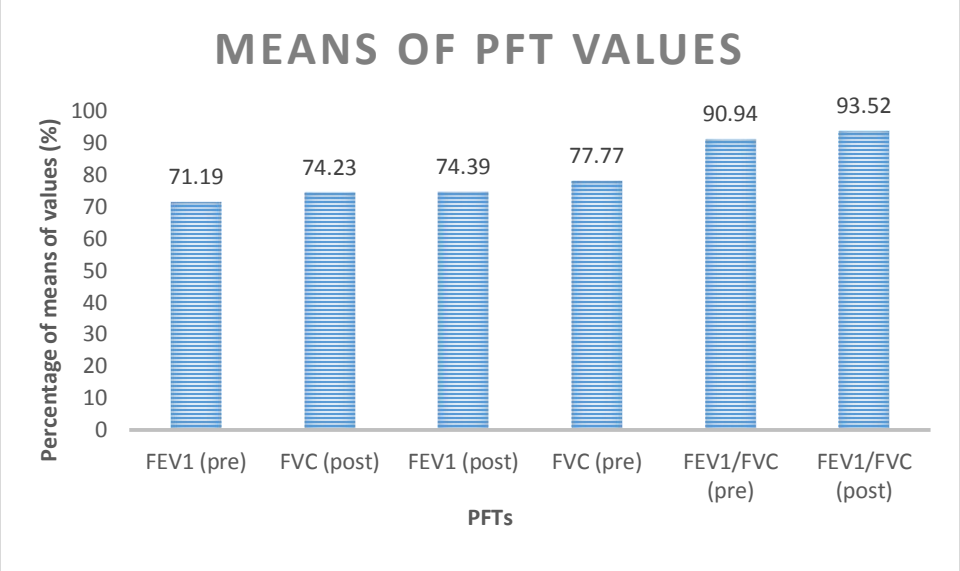

Figure 15: PFT values

6.2 Drug Utilization Evaluation

This table shows different therapies given to the patients, among which 23 patients (50%) were given a five-drug therapy, 7 patients (15.2%) were given a four-drug therapy, 6 patients (13%) were given three-drug therapy, 4 patients (8.7%) were given six-drug therapy, 4 patietns (8.7%) were given a two-drug therapy, 1 patient (2.2%) was given seven-drug therapy and 1 patient (2.2%) was given a single-drug therapy.

Single Therapy	Dual Therapy	Triple therapy	Quadruple therapy	Quintuple therapy	Sextuple therapy	Septuple therapy
1	4	6	7	23	4	1

Table 7: Different drug therapies

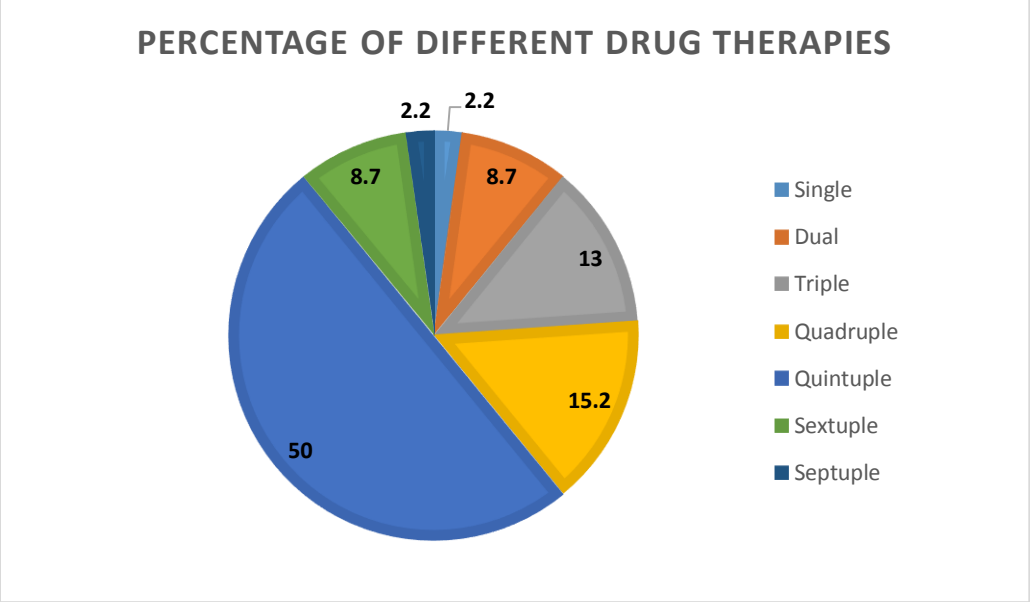

Figure 16: Different drug therapies

6.2.1 Medications

Among 46 patients, 43 patients (93.5%) were given LABA + ICS combination, 37 patients (80.4%) were given LTRA + Anti-histamine combination, 27 patients (58.7%) were given Corticosteroids. These three were the main drugs given to patients for the treatment of Asthma. The combination of LABA + ICS which was prescribed to the patients consisted of Formoterol + Budesonide for almost all patients. According to FDA, using LABAs alone to treat asthma without an ICS to treat lung inflammation is associated with an increased risk of asthma-related death. ICS alone helps in decreasing the inflammation in the lungs and LABAs help the muscles around the airways to stay relaxed to prevent symptoms such as wheezing, coughing, chest tightness, and shortness of breath. In four trials conducted by the FDA, it showed that LABA+ICS combination medicines were more effective in decreasing asthma attacks compared to ICS alone.[26]

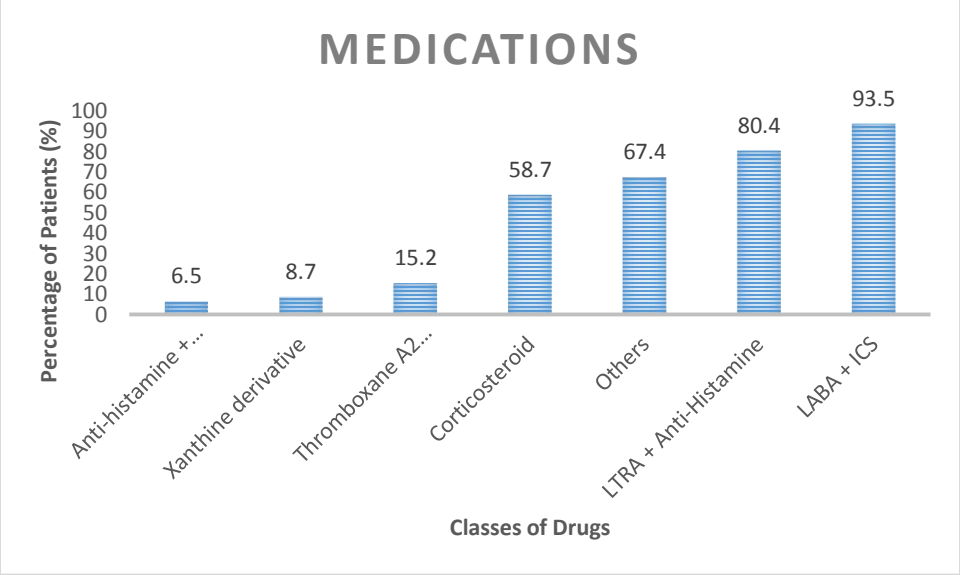

Figure 17: Medications

6.2.2 Types of therapy compared with different aspects of QoL

This table shows the overall AQLQ score and other domains of QoL compared with different therapies. This shows that patients receiving Triple therapy had the highest QoL as compared to other therapies.

	OVERALL AQLQ SCORE	ACTIVITY LIMITATION	SYMPTOMS	EMOTIONAL FUNCTION	ENVIRONMENTAL STIMULI
SINGLE	5.87	5.82	6.17	5.8	5.25
DUAL	4.58 ± 0.94	4.27 ± 1.40	4.39 ± 1.26	4.59 ± 0.92	5.56 ± 1.42
TRIPLE	5.50 ± 1.44	5.30 ± 1.44	5.61 ± 1.64	5.83 ± 1.90	5.27 ± 1.93
QUADRUPLE	5.24 ± 1.65	4.9 ± 1.76	5.49 ± 1.90	5.40 ± 1.96	4.78 ± 2.00
QUINTUPLE	5.01 ± 1.04	4.96 ± 1.36	5.13 ± 1.16	5.23 ± 1.71	4.38 ± 1.39
SEXTUPLE	4.66 ± 0.86	4.32 ± 0.62	4.94 ± 0.74	4.95 ± 1.43	4.31 ± 1.57
SEPTUPLE	1.94	1.64	1.66	3.2	3.75

Table 8: Comparison of therapies and QoL

6.2.3 Comparison of age groups with different aspects of QoL

Among 46 patients, patients in the age group of 31 – 40 had the highest QoL as compared to others.

AGE	OVERALL AQLQ SCORE	ACTIVITY LIMITATION	SYMPTOMS	EMOTIONAL FUNCTION	ENVIRONMENTAL STIMULI
18 – 30	4.97 ± 0.90	4.95 ± 0.93	5.16 ± 0.97	4.93 ± 1.33	4.28 ± 1.25
31 – 40	5.53 ± 1.41	5.45 ± 1.37	5.56 ± 1.68	5.44 ± 1.69	5.32 ± 1.42
41 – 50	4.34 ± 1.16	4.08 ± 1.42	4.48 ± 1.31	4.97 ± 1.15	4.03 ± 1.50
51 – 55	5.09 ± 1.07	4.82 ± 1.12	5.27 ± 1.34	5.45 ± 0.94	4.9 ± 1.80

Table 9: Comparison of age groups and QoL

6.2.4 Comparison of comorbidities with overall AQLQ score

Among 46 patients, 26 patients had comorbidities whereas 22 did not. Patients without comorbidities had a better QoL (5.17 ± 1.38) than in patients with comorbidities.

	Comorbidities	N	Mean ± SD
Overall AQLQ score	**With**	26	4.86 ± 1.12
Overall AQLQ score	**Without**	20	5.17 ± 1.38

Table 10: Comparison of comorbidities and Overall AQLQ score

6.2.5 Comparison of gender and different aspects of QoL

Among 46 patients, 15 were male and 31 were female. This table shows the mean ± SD for the overall AQLQ score and other domains of QoL. This shows that females had a better QoL than males.

Sex	Overall AQLQ score	Activity Limitation	Symptoms	Emotional Function	Environmental Stimuli
Male	4.89 ± 1.21	4.47 ± 1.22	5.03 ± 1.31	5.29 ± 1.48	4.75 ± 1.72
Female	5.04 ± 4.99	4.99 ± 1.36	5.15 ± 1.47	5.19 ± 1.25	4.62 ± 1.49

Table 11: Comparison of gender and QoL

Comparison of mean scores of overall AQLQ score and other domains of QoL with gender

This graph shows that in all domains except environmental stimuli, females have a higher QoL than males.

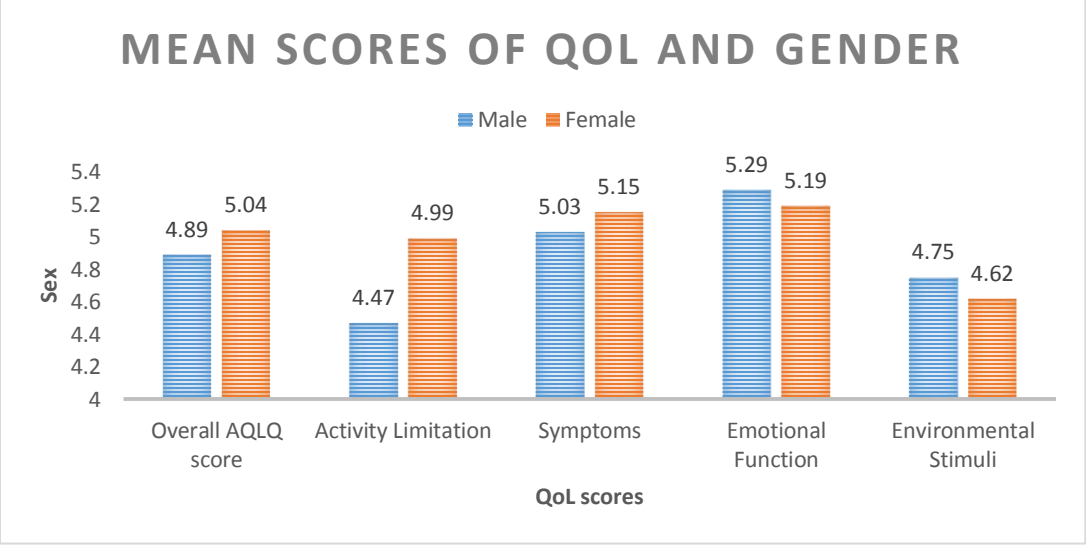

Figure 18: Comparison of mean scores of QoL and Gender

6.2.6 Comparison of educational status and various aspects of Quality of Life

Among 46 patients, mean scores of Literate patients had a better Quality of Life than Illiterate patients in Overall AQLQ score (5.02), Activity Limitation (4.84), Symptoms (5.14), Emotional function (5.26) and Environmental stimuli (4.68).

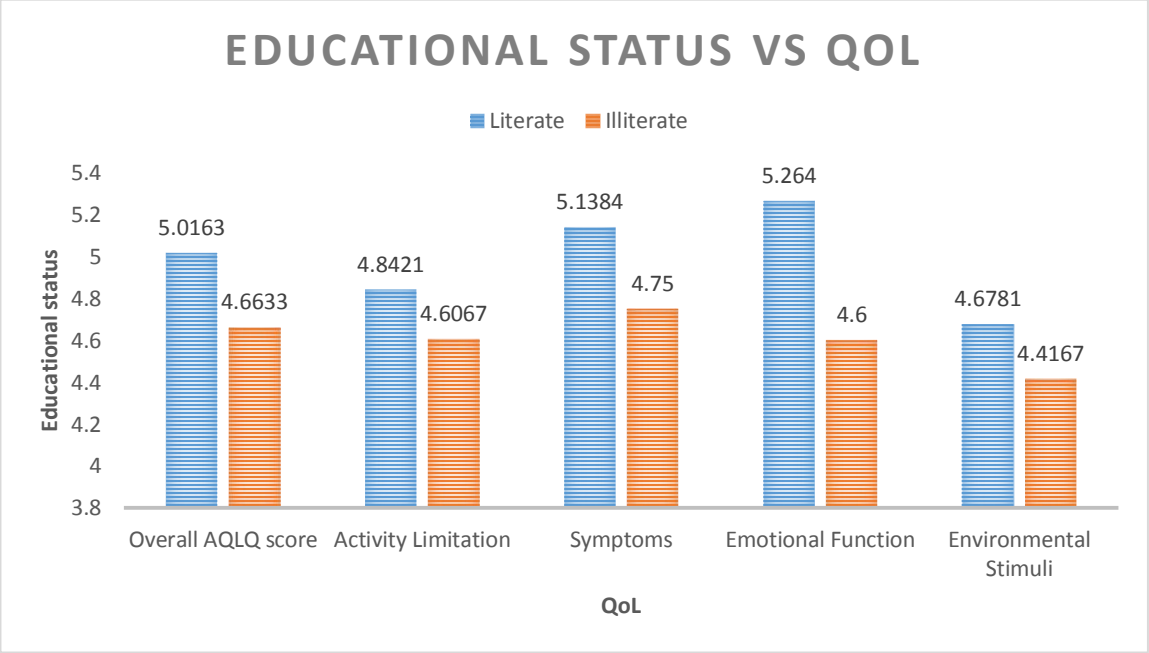

Figure 19: Comparison of Educational status and QoL

6.3 Individual drug cost, lab charges and total cost

Among 46 patients, the average total cost was found to be ₹2252.24 ± 1056.56, average drug cost was found to be ₹1142.15 ± 484.35 and average lab charges were found to be ₹920.33 ± 902.31.

	Total cost	Drug cost	Lab charges
Mean ± SD	2252.24 ± 1056.56	1142.15 ± 484.35	920.33 ± 902.31

Table 12: Mean ± SD of different costs

6.3.1 Comparing costs of patients with and without allergic rhinitis

Among 46 patients, 12 patients had allergic rhinitis whereas 34 did not. This graph shows that patients with allergic rhinitis had drug costs, lab charges, and total cost higher than in patients without allergic rhinitis.

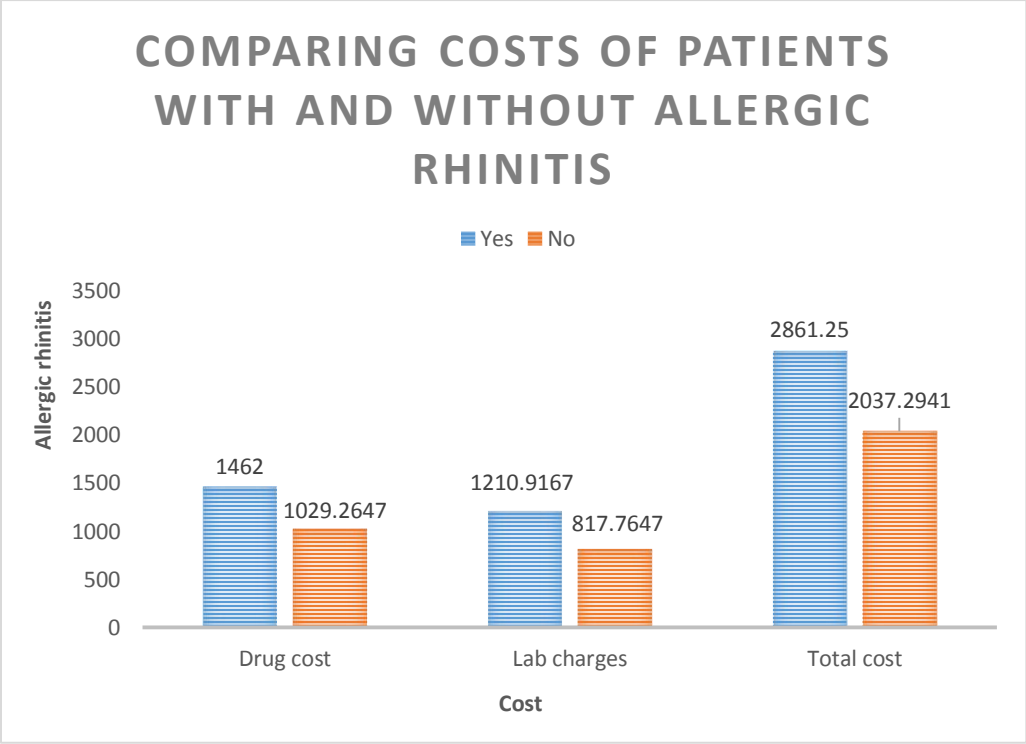

Figure 20: Comparison of costs of patients with and without allergic rhinitis

6.3.2 Comparison of costs of patients with and without comorbidities

Among 46 patients, 26 patients had comorbidities whereas 22 did not. This graph shows that the drug costs and total cost in patients with comorbidities were higher than in patients without comorbidities. But lab charges were slightly higher in patients without comorbidities.

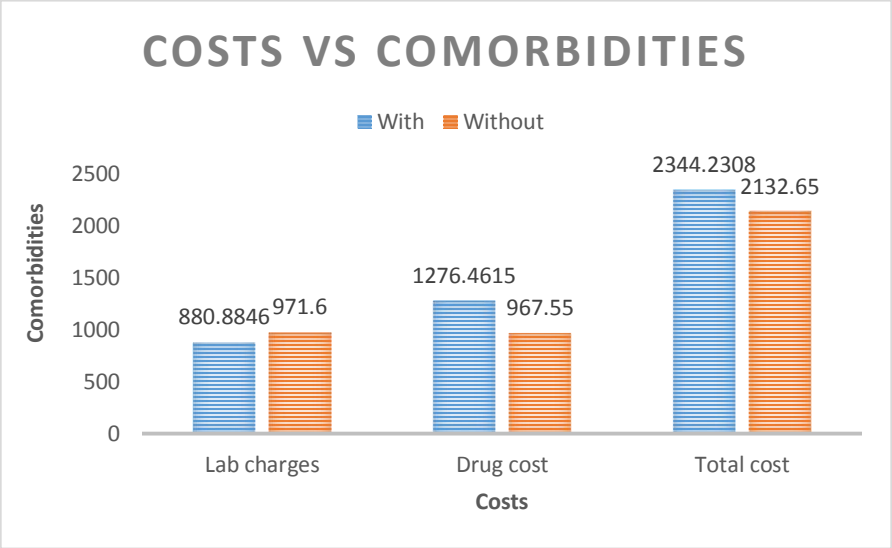

Figure 21: Comparison of costs of patients with and without comorbidities

6.3.3 Comparison of costs of patients with and without allergies

Among 46 patients, 13 patients had allergies whereas 33 did not. This graph shows that patients with allergies had lab charges, drug costs and total costs higher than patients without allergies.

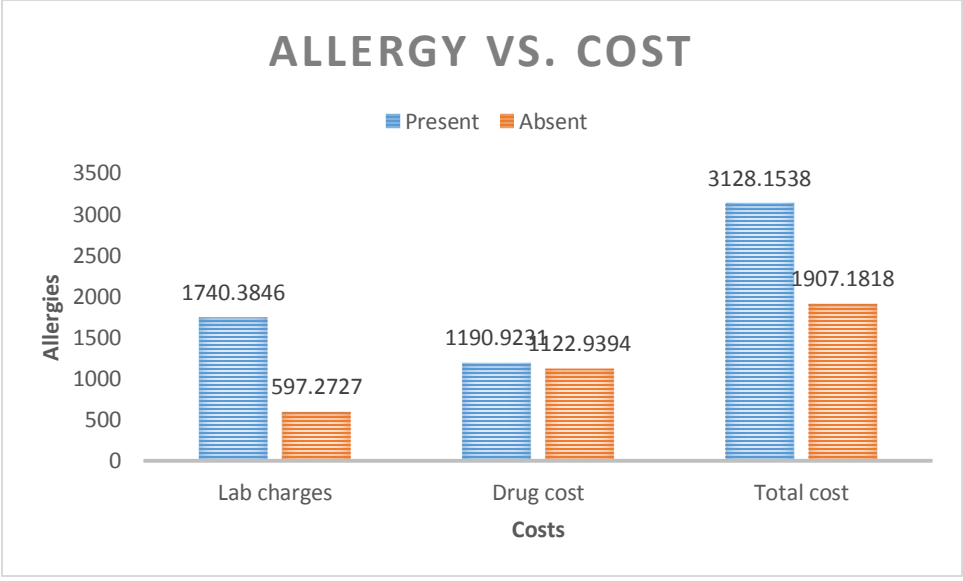

Figure 22: Comparison of costs of patients with and without allergies

DISCUSSION

7. DISCUSSION

7.1 Demographics details of the patients

The aim of our study was to synthesize the evidence that can influence QoL in adults with asthma. Symptoms such as breathlessness, coughing, wheezing and chest tightness can influence an individual's life, resulting in activity limitation, emotional, financial and medication related burden that can negatively impact QoL.

The incidence and prevalence of asthma in India is affected because of its immense geographical and environmental diversities. According to different studies most patients experience uncontrolled symptoms. Our study evaluated the common problems affecting the QoL of BA, with stratification for several possible factors of impairment (age, sex, education status, occupation, allergy, respiratory rate, oxygen saturation, and presence of co-morbidities).

A total of 46 patients were enrolled in the study. It was found that 67% of the study population were females and 33% were males. Number of females below 40 years of age were 13 and number of females above 40 years of age were 18.

Our study showed that the incidence of asthma was predominant in females than in males. Similar findings were seen in the study conducted by Morris M.J. in 2019 which stated that the majority of adult-onset cases in persons older than 40 years of age occurred in females [27].

The mean age in our study was found to be 40.85 ± 10.02, which was different from the other studies carried across the country. This could be due to the fact that our study has only 46 patients.

7.2 Quality of Life of patients

Patients diagnosed with asthma experience several problems concerning everyday activities and functions, which adversely affects their AQLQ. Patient's problems relating to their therapy cannot be credited to the lack of their knowledge on the disease and/or lack of adherence alone. The decision-making process of adults and caregivers is based on their population, experiences, and preferences and therefore patients should be viewed as active participants in care.

The purpose of our study was to find out the QoL (using AQLQ) of BA patients at baseline. The study patients visited the respiratory department, who had confirmed diagnosis of BA and sometimes with co-morbid conditions like hypertension, diabetes mellitus, allergies, post-TB, antral ulcers, etc.

The sample size in our study was 46 and AQLQ was administered to all patients meeting the inclusion criteria.

The symptoms of asthma showed a distressing level (5.11 ± 1.41) which mainly included Breathing problems (63%), Coughing (60.9%), Wheezing (41.3%), and Nasal symptoms (21.7%).

A study from Italy found that QOL (as evaluated by AQLQ) is significantly impaired in the group

of patients with dyspnea, chest tightness, and asthmatic crisis. [28]

As a part of the TENOR study conducted in the US, including adolescents and adults, Luskin et al. showed that asthma exacerbation frequency and severity and the number of triggers at baseline were strongly associated with patients' asthma-related QOL. They also identified specific asthma triggers that were strongly associated with QOL and risk of future exacerbations. [29]

In a study from England, a mini Asthma Quality of Life Questionnaire (mAQLQ), and Asthma Symptom Utility (ASUI) measures were significantly worse for patients suffering exacerbations compared to those without, however, no data about the domains were measured in this work. [30]

The study showed that there was a moderate activity limitation (4.83 ± 1.33), where the population had difficulties in performing activities such as climbing stairs, walking, sleeping, hurrying, exercising, shopping, housework, talking, exposure to environmental dust/smoke.

When measuring the emotional function of the patients 5.22 ± 1.31, the troubling factors were found to be frustration, concerned about having asthma and the use of medications, afraid of gasping for breath, and afraid of not having medication available.

Environmental stimuli affecting BA patients (4.66 ± 1.55) was the lowest score through all the categories, and thus affecting the patient's QoL. The presence of stimuli like exposure to cigarette smoke, dust, seasonal pollens, air pollution, exposure to strong smell or perfume were found to be the contributing factors. This could be improved by giving proper awareness among patients about stimulating factors by the nurses, pharmacists, and physicians.

In a study done by Uchmanowicz B., et al, results showed that QoL scores can be impaired by Frequency of the symptoms like chest tightness and shortness of breath. Among the domains measured, the most affected were activity limitation and environmental stimuli thereby reducing overall QoL. [31]

In a study done by Kotwani A. et al, Overall AQLQ score was found to be 3.68 ± 0.78, Activity Limitation was 3.7 ± 1.04, Symptoms was 3.84 ± 0.81, Emotion function was 3.9 ± 0.68 and Environmental stimuli was found to be 2.95 ± 0.28. This study showed a moderate to severe impairment as the values were closer to 1 which indicates severe impairment whereas our study results can be classified as moderate impairment as the values are closer to 4 which indicates moderate impairment [32].

The baseline activity limitation in males was found to be high than in females. This may be due to the measurement of activity limitation set by the AQLQ, other than measuring the type of work each gender does.

There is a difference in the type of work done by males and females from the demographics of the study population.

The emotional function in males was higher than in females, this could be because females might perceive the same level of airflow obstruction differently than males and its impact on their daily living. Another possible reason can be due to differences in their psychological, biological, or cultural distinction between the two. The environmental stimuli and symptoms were higher in males than in females. This could be because of a higher number of females in the study group

and also due to repeated exposure to the same stimuli like kitchen smoke and house dust.

The overall AQLQ score was high in the 31-40 age group patients. This could have been due to a proper understanding of the severity of the disease, proper use of medications and avoidance of allergens. Most of the patients above 40 years didn't understand the proper use of inhalers and avoidance of allergens. Patients without comorbidities had better QoL. No previous studies were done comparing various aspects of QoL between males and females.

7.3 Drug Utilization Evaluation

Overall DUE showed that ICS+LABA, was the drug of choice for asthmatic patients, probably due to convenience, safety, and effectiveness. The main three drugs given to patients for the treatment of Asthma were LTRA+ICS combination (93.5%), LTRA+Anti-Histamine combination (80.4%), and Corticosteroids (58.7%). From 2019, for safety, GINA no longer recommends starting treatment with SABA and recommends all adults and adolescents with asthma to receive ICS containing controller treatment to reduce the risk of serious exacerbations and to control symptoms. The new ICS controller options include low dose ICS-LABA, regular ICS or ICS-LABA every day and maintenance and reliever treatment with ICS-LABA [33].

7.4 Cost of therapy

BA is found to be the commonest inflammatory condition in developed and developing countries and it creates a substantial burden on individuals and families and thereby results in under-diagnosis and under-treatment in low-income developing countries like India. The average total cost of treatment, drug cost and lab charges in 46 patients were found to be 2252±1057, 1142.15 ± 484.35 and 920.33 ± 902.31 respectively. In a study done by Aneeshkumar S. et al, mean annual costs were taken for medication cost and lab charges which were found to be 7427/year and 1103/year [34]. This disparity in cost could be because physicians prescribed the drugs according to the severity of diseases, co-morbidities, patient affordability, the need of preventive medications, different types of medical devices, and different medical tests.

The average cost of therapy was found to be higher in the case of patients with co-morbidities. In a study conducted by Chen W. et al, 13% of patient costs were attributable to asthma and 65% were attributable to comorbidities [35]. This could be due to the additional burden from medications that were needed for the treatment, prevention, and control of comorbid conditions.

Patients with allergies and allergic rhinitis had drug costs, lab charges, and total cost higher than in patients without allergies and allergic rhinitis.

LIMITATIONS

8. LIMITATIONS

- The cost of medicines was not uniform, varied depending on pharmacies.
- Duration of medicines not prescribed for some patients.
- Our prospective study was limited by the lack of lab values (LFTs, peak flow measurement) that would have helped stage asthma as per GINA guidelines.
- Patients don't come for review thereby adherence is not well understood
- Small sample size
- The study included patients that had BA and other co-morbid conditions. The presence of other co-morbid conditions may impact the
- Patients QoL and cost of therapy.

CONCLUSION

9. CONCLUSION

- BA affects the physical, emotional, and social aspects of the life of a patient. Therefore, maintenance of a good QoL is required to prevent the risk of exacerbation and mortality associated with the disease.
- This study showed that sociodemographic factors such as age, gender, co-morbidities, education level and occupation status of the patients has an impact on all the domains of QoL.
- The QoL assessment with domains like symptoms, emotional function, and activity limitations were found to be severe and environmental stimuli were found to be moderate. This is an important tool in perceiving the impact of the BA on the day to day life of patients suffering from this condition.
- The study found that the total cost of therapy was higher in patients with co-morbid conditions. The knowledge obtained from the present study can further help to plan interventions needed to improve the effective management of bronchial asthma.
- Along with conventional strategies and guideline-based treatments, other non-pharmacological therapies can be implemented to achieve better outcomes.

FUTURE DIRECTIONS

10. FUTURE DIRECTIONS

- Proper therapeutic interventions and patient education can improve QoL.
- Having a national dashboard for asthma and allergies can be beneficial to track asthma progress.

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APPENDICES

APPENDIX I: CTRI REGISTRATION NO. & IEC CERTIFICATE

CTRI REGISTRATION NUMBER: CTRI/2019/10/021481

Kasturba Medical College and Kasturba Hospital
Institutional Ethics Committee
(Registration No. ECR/146/Inst/KA/2013/RR-16)

Communication of the decision of the Institutional Ethics Committee

Wednesday 14th August 2019 **IEC : 544/2019**

Project title	:	Comparative study of Drug Utilization and effects in Ayurveda and Conventional treatment in Bronchial Asthma.
Principal Investigator	:	Miss. Ananya A Nayak
Guide/ Co Guide/ Co Investigators	:	Dr. Kanav Khera, M. Srivalli Soumya, Dr. Basavaraj S Hadapad, Dr. Aswini Kumar Mohapatra
Name & Address of Institution	:	Department of Pharmacy Practice, MCOPS, MAHE, Manipal, Division of Ayurveda, CIMR, MAHE, Manipal, Department of Respiratory Medicine, KMC, Manipal
Status of review	:	New
Date of review	:	13.08.2019
Decision of the IEC	:	Approved for the study period from 13.08.2019 to 30.01.2021.
Endorsement of continuation of approval : (due date 12.08.2020)	:	Signature and Seal

- The PI and all members of the project shall ensure compliance to current regulatory provisions (as per Schedule Y of Drugs and Cosmetics Act and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the SOP of IEC including timely submission of Interim Annual Report and Final Closure Report
- Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant
- Inform IEC in case of any proposed amendments (change in protocol / procedure, site / Investigator etc)
- Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.
- Members of IEC have the right to monitor any project with prior intimation.
- Ensure registration of this study at Clinical Trials Registry - India (CTRI) before the enrollment of the first participant (The registration number is to be forwarded to the IEC within 7 days of your successful registration).

Dr. Rajeshkrishna Bhandary P
MEMBER SECRETARY - IEC

IEC Secretariat, Room No. 22, Ground Floor, Faculty Room Complex, Kasturba Medical College Premises,
asturba Medical College, Manipal - 576104, Karnataka, India. Phone : +91 - 0820 - 2933522,Fax : +91 - 0820 - 2571927. Email : iec.kmc@manipal.e

APPENDIX ll a: ADULT PIS (ENGLISH)

PARTICIPANT INFORMATION SHEET

Project title: Comparative study of Drug Utilization and effects in Ayurveda and Conventional treatment in Bronchial Asthma.
IEC No.:
Sponsor Name: NA
Language: English

Principal Investigator: Ananya A Nayak
Designation: Student
Hospital: Kasturba Hospital, Manipal
Mobile number: 7975827672

Please read this form carefully. If you don't understand the language or any information in this document, please discuss with study doctor. Your participation in this study is voluntary, and you can enquire about all details before giving your written consent to participate in this study.

1. Introduction to the research study:

You are invited to participate in this study because you have Bronchial Asthma. This study involves the use of a drug as prescribed by your treating physician. This is an observational study.

2. Purpose of the study:

1. To look at the safety/efficacy of drugs as prescribed by your treating physician in treatment of Bronchial Asthma.
2. To study the quality of life among Bronchial Asthma patients.

3. Who can take part?

- Inclusion criteria: Those patients who are diagnosed as Bronchial Asthma who are above 18 years of age group up to 55 years of age, patients of both genders and out-patients visiting the Respiratory and Ayurveda departments.
- Exclusion criteria: Patients with CV disorders, hepatic and renal impairment, those who are pregnant, lactating and patients with neurological disorders.

4. Information about the study (as a whole):

- Sample size: Minimum of 125 patients individually in Ayurveda and Conventional treatment in Bronchial Asthma. (Total: Minimum 250)

5. What will happen to you (the individual participant) during the study?

- Please provide information as enquired by the clinical pharmacist/physician. Your identity will

remain confidential.

- A questionnaire will be provided to assess the quality of life.

6. <u>You're (the individual participant) role/responsibility in the study</u>:

- Provide accurate information whenever asked.
- Inform the study doctor about any problem/side effects experienced during the treatment.
- Follow the investigators instruction.
- If you want to discontinue from the study, study doctor to be informed.

7. <u>What are the risks?</u>

Minimal risks

8. <u>What are the potential benefits of participating in the study?</u>

There is no direct or indirect benefit to the participant. However, if you take part in this study you may help other patients with Bronchial Asthma by contributing to the knowledge.

9. <u>What are the alternative treatments available?</u>

The study does not involve or influence any treatment, hence this section is not applicable.

10. <u>Cost of participating in the study:</u>

No additional cost for being a part of this study. But you have to pay for your own drugs, tests and procedures required to be done during the study period as this is an observational study.

11. <u>Compensation for injury:</u>

If a problem arises as a direct result of the study procedure (administering questionnaire and data from the file), the researcher will ensure that adequate care is provided to you.

12. <u>Confidentiality of information:</u>

Information from the study records including your name, address, medical records, results of tests, study results will be kept confidential and will be reviewed only by authorized personnel from the sponsor or their representative, Ethics Committee or regulatory bodies. The data will not be made available to another individual unless you specifically give permission in writing. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications.

13. New information about the study:

Any new information available during the course of the study will be informed to you if it has relevance to your decision regarding continuing in the study. Results of your participation will be disclosed to you if you indicate your desire for it.

14. Voluntary participation:

Your participation in this study is voluntary; you may decline to participate at any time and you need not give any reason for the same, and such withdrawal shall be without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician.

If you withdraw from the study before data collection is completed, your data collected until you indicated withdrawal will be used in the study report. Sponsor or the investigator may stop the research or your participation in it at any time for some or other reason without your permission.

15. Whom to contact in case of any questions:

If you experience adverse effects as a result of participating in this study, you may contact the Principal Investigator (Ananya A Nayak) as detailed above.

If you have any questions about the informed consent process or your rights as a participant, you may contact the Member Secretary of the Kasturba Medical College and Kasturba Hospital - Institutional Ethics Committee at Room 22, Ground floor, KMC Faculty Rooms, adjacent to KMC Administrative Block, Kasturba Medical College, Manipal - 576104. Phone: 0820 29 33522. Timings: 9:00 AM to 5:00 PM.

If you have any questions about this form or any study related issue, you may also contact the following person.

Name: Dr. Girish Thunga
Address: Department of Pharmacy Practice, MCOPS, MAHE, Manipal

Telephone No: +919880151127

APPENDIX ll b: ADULT PIS (KANNADA)

ಭಾಗೀದಾರರ ಮಾಹಿತಿ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾಕ್ಕೆ ಆಯುರ್ವೇದ ಮತ್ತು ಸಾಂಪ್ರದಾಯಿಕ ಚಿಕಿತ್ಸೆಗಳಲ್ಲಿ ಔಷಧ ಬಳಕೆಯ ಪರಿಣಾಮಗಳ ಪರಸ್ಪರ ತುಲನಾ ಅಧ್ಯಯನ.

ಅಧ್ಯಯನದ ಸಂಖ್ಯೆ:

ಪ್ರಾಯೋಜಕರು: ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

ಭಾಷೆ: ಕನ್ನಡ

ಮುಖ್ಯ ಸಂಶೋಧಕರು: ಅನನ್ಯ ಎ ನಾಯಕ್.

ಹುದ್ದೆ: ವಿದ್ಯಾರ್ಥಿನಿ.

ಆಸ್ಪತ್ರೆ: ಕಸ್ತೂರ್ಬಾ ಆಸ್ಪತ್ರೆ, ಮಣಿಪಾಲ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 7975827672

ದಯವಿಟ್ಟು ಈ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಜಾಗರೂಕತೆಯಿಂದ ಓದಿರಿ. ನಿಮಗೆ ಇದರಲ್ಲಿನ ಭಾಷೆ ಅಥವಾ ಯಾವುದೇ ಮಾಹಿತಿಗಳು ಅರ್ಥವಾಗದೇ ಇದ್ದಲ್ಲಿ, ದಯವಿಟ್ಟು ಅಧ್ಯಯನಕಾರ ವೈದ್ಯರುಗಳ ಜೊತೆಯಲ್ಲಿ ಚರ್ಚಿಸಿರಿ. ಈ ಅಧ್ಯಯನಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ನೀಡುವ ಮೊದಲು ಅಧ್ಯಯನದ ವಿವರಗಳ ಬಗ್ಗೆ ವಿಚಾರಣೆ ಮಾಡಬಹುದು.

1.ಅಧ್ಯಯನದ ಪ್ರಸ್ತಾವನೆ:

ನಿಮ್ಮನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಹ್ವಾಹಿಸುತ್ತಿದ್ದೇವೆ ಏಕೆಂದರೆ, ನಿಮಗೆ ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾ ಇರುತ್ತದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಚಿಕಿತ್ಸಾ ವೈದ್ಯರು ಸೂಚಿಸಿರುವ ಔಷಧಿ ಉಪಯೋಗಿಸುವಿಕೆಯು ಒಳಗೊಂಡಿರುತ್ತದೆ. ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ.

2. ಅಧ್ಯಯನದ ಉದ್ದೇಶ:

1.ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾಕ್ಕೆ ನಿಮ್ಮ ಚಿಕಿತ್ಸಾ ವೈದ್ಯರು ಸೂಚಿಸಿರುವ ಔಷಧಿಯ ರಕ್ಷಣೆ/ಪರಿಣಾಮಕಾರಿತ್ವತೆಯನ್ನು ನೋಡಲಾಗುವುದು.

2. ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾ ಇರುವ ರೋಗಿಗ ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ಅಧ್ಯಯನ ಮಾಡಲಾಗುವುದು.

3. ಅಧ್ಯಯನದಲ್ಲಿ ಯಾರು ಭಾಗವಹಿಸುವರು:

ಒಳಗಿಡುವ ಮಾನದಂಡ:

- 18 ರಿಂದ 55 ವರ್ಷ ವಯಸ್ಸಿನೊಳಗಿರುವ, ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾ ಇರುವಿಕೆಯ ರೋಗನಿರ್ಣಯವಾಗಿರುವ, ಎಲ್ಲಾ ಲಿಂಗದವರು. ಮತ್ತು ಉಸಿರಾಟ ಮತ್ತು ಆಯುರ್ವೇದ ವಿಭಾಗಕ್ಕೆ ಹೊರರೋಗಿಗಳಾಗಿ ಭೇಟಿ ನೀಡಿರುವ ರೋಗಿಗಳು ಪಾಲ್ಗೊಳ್ಳುವರು.

ಹೊರಗಿಡುವ ಮಾನದಂಡ:

- ಯಾವ ರೋಗಿಗೆ ಸಿವಿ ಅಸ್ವಸ್ಥತೆ, ಹೆಪಟಿಕ್ ಮತ್ತು ಮೂತ್ರಪಿಂಡದ ದುರ್ಬಲತೆ ಇರುವ ರೋಗಿಗಳು, ಗರ್ಭಿಣಿಯರು, ಹಾಲುಣಿಸುವ ತಾಯಂದಿರು, ಒಳರೋಗಿಗಳಾಗಿರುವವರ ಡಾಟಾಗಳು ಹಾಗೂ ನರರೋಗದ ಅಸ್ವಸ್ಥತೆ ಇರುವ ರೋಗಿಗಳು ಪಾಲ್ಗೊಳ್ಳುವಂತಿಲ್ಲ.

4.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಮಾಹಿತಿ (ಸಂಪೂರ್ಣ):

- ಮಾದರಿ ಅಳತೆ: ವೈಯಕ್ತಿಕವಾಗಿ ಆಯುರ್ವೇದ ಮತ್ತು ಸಾಂಪ್ರದಾಯಿಕ ಚಿಕಿತ್ಸೆಗಾಗಿ ಬರುವ ಕನಿಷ್ಟ 125 ಜನ ರೋಗಿಗಳು.

5. ಅಧ್ಯಯನದ ಸಂದರ್ಭದಲ್ಲಿ ನಿಮಗೆ ವಿವಾಗಬಹುದು:

- ದಯವಿಟ್ಟು, ಚಿಕಿತ್ಸಾಲಯ ಔಷಧಿಕಾರರ/ವೈದ್ಯರುಗಳ ಅವಶ್ಯಕ ಮಾಹಿತಿಗಳನ್ನು ಒದಗಿಸಬೇಕಾಗುವುದು. ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಗುರುತುಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುವುದು.
- ಪ್ರಶ್ನಾವಳಿಗಳನ್ನು ನೀಡಲಾಗುವುದು, ಆ ಮೂಲಕ ಜೀವನದ ಗುಣಮಟ್ಟವನ್ನು ನಿರ್ಣಯಿಸಲಾಗುವುದು.

6. ನಿಮ್ಮ ಜವಾಬ್ದಾರಿ/ಪಾತ್ರ:

- ಕೇಳಲಾದ ವಿಷಯಕ್ಕೆ ಸರಿಯಾದ ಉತ್ತರವನ್ನು ಕೊಡಬೇಕಾಗುವುದು.
- ನಿಮಗೇನಾದರೂ ತೊಂದರೆ/ವ್ಯತಿರಿಕ್ತ ಪರಿಣಾಮದ ಅನುಭವವಾದಲ್ಲಿ ಅಧ್ಯಯನಕಾರ ವೈದ್ಯರಲ್ಲಿ ತಿಳಿಸಬೇಕಾಗುವುದು.
- ಸಂಶೋಧನಾಕಾರ ಸಲಹೆ ಸೂಚನೆಯನ್ನು ಪಾಲಿಸಬೇಕಾಗುವುದು.
- ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಿಲ್ಲಿಸುವುದಿದ್ದಲ್ಲಿ ಸಂಶೋಧನಾಕಾರರಲ್ಲಿ ತಿಳಿಸಬೇಕಾಗುವುದು.

7. ಅಪಾಯಗಳಾವುವು?.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಕನಿಷ್ಠ ಪ್ರಮಾಣದ ಅಪಾಯಗಳಿರುತ್ತದೆ.

8. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದರಿಂದ ಆಗಬಹುದಾದ ಸಂಭಾವ್ಯ ಪ್ರಯೋಜನಗಳು:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ನಿಮಗೆ ನೇರವಾಗಿ ಯಾವುದೇ ಪ್ರಯೋಜನಗಳು ಸಿಗುವುದಿಲ್ಲ. ಆದಾಗ್ಯೂ, ನೀವು ಭಾಗವಹಿಸಿದ್ದಲ್ಲಿ, ನೀವು ಇತರೇ ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾ ರೋಗಿಗಳಿಗೆ ತಿಳುವಳಿಕೆ ಪಡೆಯಲು ಸಹಾಯ ಮಾಡಿದಂತಾಗುತ್ತದೆ.

9. ಯಾವ ಯಾವ ಪರ್ಯಾಯ ಚಿಕಿತ್ಸೆಗಳು ಲಭ್ಯ ಇವೆ?.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ರೀತಿಯ ಚಿಕಿತ್ಸಾ ಹಸ್ತಕ್ಷೇಪಗಳಿರುವುದಿಲ್ಲ. ಆದ್ದರಿಂದ ಈ ವಿಭಾಗವು ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

10. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗಿಯಾಗುವುದರಿಂದ ತಗಲುವ ವೆಚ್ಚ:

ಈ ಅಧ್ಯಯನದ ಸಲುವಾಗಿ ಹೆಚ್ಚುವರಿಯಾಗಿ ಹಣ ಪಾವತಿಸಬೇಕಾಗಿಲ್ಲ. ಆದರೆ, ನಿಮ್ಮ ಸ್ವಂತ ಔಷಧಿ, ಪರೀಕ್ಷೆ ಮತ್ತು ಅವಶ್ಯಕ ಚಿಕಿತ್ಸಾ ವಿಧಾನಗಳಿಗೆ ನೀವು ಹಣ ಖರ್ಚು ಮಾಡಬೇಕಾಗುವುದು. ಇದು ಒಂದು ವೀಕ್ಷಣಾ ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ.

11. ಗಾಯ/ತೊಂದರೆಗೆ ಪರಿಹಾರ.

ಈ ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನದ ಸಂಶೋದನಾ ಕಾರಣದಿಂದಾಗಿ ನೇರವಾಗಿ ಯಾವುದೇ ತೊಂದರೆಗಳಾದಲ್ಲಿ (ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಸಮಯದಲ್ಲಿ ಮತ್ತು ಕಡತಗಳಿಂದ ಡಾಟಾಗಳನ್ನು ಪಡೆಯುವಾಗ) ಅಧ್ಯಯನಕಾರರರು ಜವಾಬ್ದಾರರಾಗಿರುತ್ತಾರೆ, ಅವರು ನಿಮಗೆ ಸೂಕ್ತವಾದ ಆರೈಕೆಯನ್ನು ಒದಗಿಸುತ್ತಾರೆ.

12. ಮಾಹಿತಿಯ ಗೌಪ್ಯತೆ:

ಈ ಅಧ್ಯಯನದ ಮಾಹಿತಿ ಪ್ರತಿಯಲ್ಲಿ ನಿಮ್ಮ ಹೆಸರು, ವಿಳಾಸ, ವೈದ್ಯಕೀಯ ಸಂಗತಿ, ತಪಾಸಣೆಯ ಫಲಿತಾಂಶಗಳಿರುತ್ತವೆ. ಇವುಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುವುದು. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟ ಸಂಶೋಧಕರು, ಸಂಘದ ನೈತಿಕ ಸಮಿತಿ ಪ್ರಮುಖರು ಅಥವಾ ನಿಯಂತ್ರಕ ಸಂಸ್ಥೆಯವರು ಪರಿಶೀಲಿಸುವರು ಇದರಲ್ಲಿನ ವೈಯಕ್ತಿಕ ಡಾಟಾಗಳನ್ನು ನಿಮ್ಮ ಲಿಖಿತ ಅನುಮತಿ ಇಲ್ಲದೇ ಅನ್ಯ ವ್ಯಕ್ತಿಗಳಿಗೆ ನೀಡಲಾಗುವುದಿಲ್ಲ. ಅದರ ಫಲಿತಾಂಶ ಹಾಗು ಮಾಹಿತಿಗಳನ್ನು ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಗುರುತು, ಹೆಸರು, ವಿಳಾಸಗಳಾವುದನ್ನೂ ತಿಳಿಯಪಡಿಸದೆ ಪ್ರಕಟಿಸಲೂಬಹುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ರೀತಿಯ ಮೌಖಿಕ ಮತ್ತು ಲಿಖಿತ ಬರವಣಿಗೆಯ ವಿವರಣೆಗಳು ಅವಲಂಬನೆಯಾಗಿರುವುದಿಲ್ಲ.

13.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಹೊಸ ಮಾಹಿತಿ.

ಈ ಅಧ್ಯಯನದ ಅಭ್ಯಾಸದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಹೊಸ ಮಾಹಿತಿಗಳು ಕಂಡುಬಂದಲ್ಲಿ ಅಭ್ಯಾಸ ಮುಂದುವರಿಸುವ ಬಗ್ಗೆ ನಿಮಗೆ ನಿರ್ಣಯಗಳನ್ನು ತಿಳಿಸಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಪಡೆಯಲು ನೀವು ಇಚ್ಛಿಸಿದಲ್ಲಿ, ಅದನ್ನು ನಿಮಗೆ ನೀಡಲಾಗುತ್ತದೆ.

14. ಐಚ್ಛಿಕ ಭಾಗವಹಿಸುವಿಕೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿದ್ದು, ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೂ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಸಮ್ಮತಿಯನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ಹಾಗು ಇದಕ್ಕೆ ಯಾವುದೇ ಕಾರಣ ನೀಡಬೇಕಾಗಿಲ್ಲ. ಇದಕ್ಕಾಗಿ ನಿಮಗೆ ಯಾವುದೇ ದಂಡವಿಲ್ಲ ಮತ್ತು ಸಿಗಬಹುದಾದ ಪ್ರಯೋಜನ/ನಷ್ಟವಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೊದಲು ಹೊರಬಂದರೆ ನಿಮಗೆ ಯಾವುದೇ ಚಿಕಿತ್ಸೆಗೆ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮುಂದಿನ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಯಾವ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಅಥವಾ ನಿಮ್ಮ ವೈದ್ಯರೊಂದಿಗಿನ ಸಂಬಂಧಕ್ಕೆ ಯಾವುದೇ ತೊಂದರೆ ಇರುವುದಿಲ್ಲ.

ಅಧ್ಯಯನ ಪೂರ್ಣಗೊಳಿಸುವ ಮೊದಲು ನೀವು ಹಿಂದೆ ಸರಿದರೆ ನೀವು ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಮೊದಲು ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನದ ವರದಿಯಲ್ಲಿ ಉಪಯೋಗಿಸಲಾಗುವುದು. ಪ್ರಾಯೋಜಕರು ಅಥವಾ ಅಧ್ಯಯನಕಾರರು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅವರ ಅಧ್ಯಯನವನ್ನು ಅಥವಾ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಒಂದಲ್ಲ ಒಂದು ಕಾರಣಕ್ಕಾಗಿ ನಿಮ್ಮ ಅನುಮತಿ ಇಲ್ಲದೆಯೇ ನಿಲ್ಲಿಸಬಹುದು.

15.ಒಂದು ವೇಳೆ ಪ್ರಶ್ನೆಗಳೇನಾದರೂ ಇದ್ದಲ್ಲಿ, ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ನಿಮಗೆ ಏನಾದರೂ ಪ್ರತಿಕೂಲ ತೊಂದರೆಗಳು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕಂಡುಬಂದಲ್ಲಿ ಕೂಡಲೇ ಮುಖ್ಯ ಸಂಶೋಧನಾಕಾರ ಅನನ್ಯ ಎ ನಾಯಕ್‌ರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಿಹಿಸುವಿಕೆಯ ಒಟ್ಟಿಗೆ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನಕಾರರಲ್ಲಿ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಹಕ್ಕಿರುತ್ತದೆ. ಹಾಗಿದ್ದಲ್ಲಿ,ನಿಮಗೆ ಸದಸ್ಯ ಕಾರ್ಯದರ್ಶಿಗಳು, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲದ ನೈತಿಕ ಸಮಿತಿ ಸಂಸ್ಥೆಯ ಕೊಠಡಿ ಸಂಖ್ಯೆ 22, ನೆಲಮಹಡಿ, ಕೆ.ಎಮ್.ಸಿ. ಸಿಬ್ಬಂದಿಗಳ ಕೊಠಡಿ, ಕೆ.ಎಮ್.ಸಿ ಆಡಳಿತ ವಿಭಾಗ ಕಛೇರಿಯ ಪಕ್ಕ, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲ–576 104 ಇವರು ವಿವರಗಳನ್ನು ನೀಡುತ್ತಾರೆ.
ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 0820 2933522 ಸಮಯ: 9:00ಬೆಳಿಗ್ಗೆ. 5:00ಸಂಜೆ.

ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದಾದರೂ ಪ್ರಶ್ನೆ ಅಥವಾ ಸಂಬಂಧಿಸಿದ ವಿಷಯಗಳಿದ್ದಲ್ಲಿ ಈ ಕೆಳಗೆ ತಿಳಿಸಿದ ವ್ಯಕ್ತಿಗಳನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಹೆಸರು: ಡಾ: ಗಿರೀಶ್ ತುಂಗಾ.

ವಿಳಾಸ: ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್ ವಿಭಾಗ, ಎಂಸಿಓಪಿಎಸ್, ಮಾಹೆ, ಮಣಿಪಾಲ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: +91 9880151127

APPENDIX III a: ICF ADULT (ENGLISH)

Project title: Comparative study of Drug Utilization and effects in Ayurveda and Conventional treatment in Bronchial Asthma

I confirm I have read the Participant Information Sheet for the above study and its contents were explained and I have had the opportunity to ask questions and received satisfactory answers.

I understand that my participation in the study is voluntary and that I have the right to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I agree to take part in the above study. I confirm that I have received a copy of the Participant Information Sheet along with this signed and dated informed consent form.

Name of the Research Participant:

Age of the Research Participant:

Address of the Research Participant:

Occupation:

Annual Income of the Participant:

Name & address of the nominee(s) and his relation to the Participant:

_____
_____

_____ _____
Signature of the research subject Date

_____ _____
Name & Signature of the witness Date

_____ _____
Name & Signature of the person explaining the consent Date

APPENDIX lll b: ICF ADULT (KANNADA)

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ಶ್ವಾಸನಾಳದ ಅಸ್ತಮಾಕ್ಕೆ ಆಯುರ್ವೇದ ಮತ್ತು ಸಾಂಪ್ರದಾಯಿಕ ಚಿಕಿತ್ಸೆಗಳಲ್ಲಿ ವಿಷಧ ಬಳಕೆಯ ಪರಿಣಾಮಗಳ ಪರಸ್ಪರ ತುಲನಾ ಅಧ್ಯಯನ.

ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗೀದಾರರ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಓದಿ ತಿಳಿದುಕೊಂಡಿರುತ್ತೇನೆ. ಮತ್ತು ಅದರಲ್ಲಿನ ಮಾಹಿತಿಗಳನ್ನು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ನನಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶ ನೀಡಲಾಗಿದ್ದು, ಅವುಗಳಿಗೆ ಸಮಾಧಾನಕರವಾದ ಉತ್ತರಗಳು ಲಭಿಸಿವೆ ಎಂದು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿದ್ದು, ನನಗೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ, ಯಾವುದೇ ಕಾರಣವಿಲ್ಲದೆ ವೈಯಕ್ತಿಕವಾಗಿ ಭಾಗವಹಿಸುವಿಕೆಯಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಹಕ್ಕಿದೆ. ಈ ನಿರ್ಣಯವು ಮುಂದಿನ ವೈದ್ಯಕೀಯ ತಪಾಸಣೆಗೆ, ಕಾನೂನು ಹಕ್ಕಿಗೆ ಯಾವುದೇ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲವೆಂದು ತಿಳಿದಿರುತ್ತೇನೆ.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿದ್ದು ಹಾಗೂ ನಾನು ಸಹಿ ಮಾಡಿದ ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪ್ರತಿಯನ್ನು ಈ ಕೆಳಗಿನ ದಿನಾಂಕದಂದು ಸ್ವೀಕರಿಸಿರುವೆನೆಂದು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಭಾಗವಹಿಸುವವರ ವಯಸ್ಸು:

ಭಾಗವಹಿಸುವವರ ವಿಳಾಸ:

ಉದ್ಯೋಗ:

ಭಾಗವಹಿಸುವವರ ವಾರ್ಷಿಕ ಆದಾಯ:

ನೊಮಿನಿಯ(ರ) ಹೆಸರು ಮತ್ತು ವಿಳಾಸ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ಜೊತೆಗೆ ಇರುವ ಸಂಬಂಧ :

_____	_____
ಭಾಗವಹಿಸುವವರ ಸಹಿ	ದಿನಾಂಕ
_____	_____
ಸಾಕ್ಷಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ	ದಿನಾಂಕ
_____	_____
ಒಪ್ಪಿಗೆ ವಿವರಿಸುವ ವ್ಯಕ್ತಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ	ದಿನಾಂಕ

APPENDIX IV: ADULT CRF

STUDY: Comparative study of Drug utilization and effects in Ayurveda and Conventional treatment in Bronchial Asthma

DEPARTMENT OF PHARMACY PRACTICE, KASTURBA HOSPITAL, MANIPAL

HOSP. NO: **SEX: M/F :** **AGE:** **WEIGHT:** **HEIGHT:** **BMI:**	**DOA:** **DOD:**

COMPLAINTS ON ADMISSION:
SYMPTOMS:

Wheezing	
Coughing	
Breathing problems	
Chest tightness	

OTHERS:

MEDICAL HISTORY:
MEDICATION HISTORY:
PERSONAL HISTORY:
FAMILY HISTORY:
EDUCATIONAL STATUS:
PREVIOUS ALLERGIES:

PHYSICAL EXAMINATION:

GENERAL -
VITAL SIGNS -
HEENT -
CVS -
RS -
GIT -
GU -
EXT -
CNS -

ROUTINE BIOCHEMICAL INVESTIGATIONS

Urea:	RBS:	Alb:	RBC : Retics:
S.Cr :	Tch :	Glob:	WBC: Hb:
Na:	TGs :	AST:	N: PCV:
K:	T Bili:	ALT:	L: MCV:
FBS:	D Bili:	ALP:	M: MCH:
PPBS:	T. Prot:		E: MCHC:
			B: ESR:

ABG REPORTS	PFT REPORTS	Mini PEFR readings

ALLERGY TEST:

OTHERS:
FINAL DIAGNOSIS:

DRUG TREATMENT CHART:

DRUG WITH DOSE & ROUTE					COST PER DRUG
GENERIC NAME	BRAND NAME	1	2	3	
Follow up:		**COST OF TOTAL THERAPY**			
Mobile no.:					

APPENDIX V a: Asthma Quality of Life Questionnaire Standardized (12 years and above) English

ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (AQLQ(S))

SELF-ADMINISTERED ENGLISH VERSION FOR INDIA

(12 years and above)

For further information:

Elizabeth Juniper, MCSP, MSc
Professor
20 Marcuse Fields
Bosham, West Sussex
PO18 8NA, England
Telephone: +44 1243 572124
Fax: +44 1243 573680
E-mail: juniper@qoltech.co.uk
Web: http://www.qoltech.co.uk

This translation has been made possible through a grant from MUNDIPHARMA RESEARCH Ltd
Translated by MAPI INSTITUTE
Senior Translator: Thangaraj Nagasamy

JANUARY 2010

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
ID7334 / AQLQ(S)-12-SA_AL2.0_eng-IN.doc

ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S)
(ENGLISH VERSION FOR INDIA)
SELF-ADMINISTERED

PATIENT ID: _____

DATE: _____

Please complete **all** the questions by circling the number that best describes how you have been during the **last 14 days as a result of your asthma.**

HOW **LIMITED** HAVE YOU BEEN **DURING THE LAST 14 DAYS** IN THESE ACTIVITIES **AS A RESULT OF YOUR ASTHMA**?

	Totally Limited	Extremely Limited	Very Limited	Moderate Limitation	Some Limitation	A Little Limitation	Not at all Limited
1. STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports)	1	2	3	4	5	6	7
2. MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)	1	2	3	4	5	6	7
3. SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends/relatives)	1	2	3	4	5	6	7
4. WORK/SCHOOL-RELATED ACTIVITIES* (tasks you have to do at work/in school)	1	2	3	4	5	6	7
5. SLEEPING	1	2	3	4	5	6	7

**If you are not employed or self-employed, these should be tasks you have to do most days.*

HOW MUCH **DISCOMFORT OR DISTRESS** HAVE YOU FELT **OVER THE LAST 14 DAYS?**

	A Very Great Deal	A Great Deal	A Good Deal	Moderate Amount	Some	Very Little	None
6. How much discomfort or distress have you felt over the last 14 days as a result of CHEST TIGHTNESS?	1	2	3	4	5	6	7

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
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ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S)
(ENGLISH VERSION FOR INDIA)
SELF-ADMINISTERED

PATIENT ID: _____

DATE: _____

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 14 DAYS** DID YOU:

	All of the Time	Most of the Time	A Lot of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
7. Feel CONCERNED ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
8. Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
9. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO CIGARETTE SMOKE?	1	2	3	4	5	6	7
10. Experience WHEEZING in your chest?	1	2	3	4	5	6	7
11. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF CIGARETTE SMOKE?	1	2	3	4	5	6	7

HOW MUCH **DISCOMFORT OR DISTRESS** HAVE YOU FELT **OVER THE LAST 14 DAYS?**

	A Very Great Deal	A Great Deal	A Good Deal	Moderate Amount	Some	Very Little	None
12. How much discomfort or distress have you felt over the last 14 days as a result of COUGHING?	1	2	3	4	5	6	7

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 14 DAYS** DID YOU:

	All of the Time	Most of the Time	A Lot of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
13. Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
14. Experience a feeling of CHEST HEAVINESS?	1	2	3	4	5	6	7

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
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ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S) PATIENT ID: _____
(ENGLISH VERSION FOR INDIA)
SELF-ADMINISTERED DATE: _____

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 14 DAYS** DID YOU:

	All of the Time	Most of the Time	A Lot of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
15. Feel CONCERNED ABOUT THE NEED TO USE MEDICATION for your asthma?	1	2	3	4	5	6	7
16. Feel the need to CLEAR YOUR THROAT?	1	2	3	4	5	6	7
17. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO DUST?	1	2	3	4	5	6	7
18. Experience DIFFICULTY BREATHING OUT as a result of your asthma?	1	2	3	4	5	6	7
19. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF DUST?	1	2	3	4	5	6	7
20. WAKE UP IN THE MORNING WITH ASTHMA SYMPTOMS?	1	2	3	4	5	6	7
21. Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	1	2	3	4	5	6	7
22. Feel bothered by HEAVY BREATHING?	1	2	3	4	5	6	7
23. Experience asthma symptoms as a RESULT OF THE WEATHER OR AIR POLLUTION OUTSIDE?	1	2	3	4	5	6	7
24. Were you WOKEN AT NIGHT by your asthma?	1	2	3	4	5	6	7
25. AVOID OR LIMIT GOING OUTSIDE BECAUSE OF THE WEATHER OR AIR POLLUTION?	1	2	3	4	5	6	7

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
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ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S)
(ENGLISH VERSION FOR INDIA)
SELF-ADMINISTERED

PATIENT ID: _____

DATE: _____

IN GENERAL, **HOW MUCH OF THE TIME DURING THE LAST 14 DAYS** DID YOU:

	All of the Time	Most of the Time	A Lot of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
26. Experience asthma symptoms as a RESULT OF BEING EXPOSED TO STRONG SMELL OR PERFUME?	1	2	3	4	5	6	7
27. Feel AFRAID OF GASPING FOR BREATH?	1	2	3	4	5	6	7
28. Feel you had to AVOID A SITUATION OR ENVIRONMENT BECAUSE OF STRONG SMELL OR PERFUME?	1	2	3	4	5	6	7
29. Has your asthma INTERFERED WITH GETTING A GOOD NIGHT'S SLEEP?	1	2	3	4	5	6	7
30. Have a feeling of STRUGGLING TO BREATHE?	1	2	3	4	5	6	7

HOW LIMITED HAVE YOU BEEN **DURING THE LAST 14 DAYS**?

	Severely Limited Most Not Done	Very Limited	Moderately Limited Several Not Done	Slightly Limited	Very Slightly Limited Very Few Not Done	Hardly Limited At All	Not Limited Have Done All Activities
31. Think of the OVERALL RANGE OF ACTIVITIES that you would have liked to have done during the last 14 days. How much has your range of activities been limited by your asthma?	1	2	3	4	5	6	7

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
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ASTHMA QUALITY OF LIFE QUESTIONNAIRE (S)
(ENGLISH VERSION FOR INDIA)
SELF-ADMINISTERED

PATIENT ID: _____

DATE: _____

HOW LIMITED HAVE YOU BEEN **DURING THE LAST 14 DAYS**?

	Totally Limited	Extremely Limited	Very Limited	Moderate Limitation	Some Limitation	A Little Limitation	Not at all Limited
32. Overall, in ALL THE ACTIVITIES that you have done during the last 14 days, how limited have you been by your asthma?	1	2	3	4	5	6	7

DOMAIN CODE:

Symptoms: 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30
Activity Limitation: 1, 2, 3, 4, 5, 11, 19, 25, 28, 31, 32
Emotional Function: 7, 13, 15, 21, 27
Environmental Stimuli: 9, 17, 23, 26

Modified on 09 July 2013
AQLQ(S)-12-SA - India/English - Version of 09 Jul 13 - Mapi.
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APPENDIX V b: Asthma Quality of Life Questionnaire Standardized (12 years and above) Kannada

ಉಬ್ಬಸ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ, ಪ್ರಮಾಣಿತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (AQLQ(S))

ರೋಗಿಯ ಬಳಕೆಗಾಗಿ

(SELF-ADMINISTERED)
KANNADA VERSION FOR INDIA

(≥12 ವರ್ಷಗಳು)

ಹೆಚ್ಚಿನ ಮಾಹಿತಿಗಾಗಿ ಸಂಪರ್ಕಿಸಿ:

Elizabeth Juniper, MCSP, MSc
Professor
20 Marcuse Fields
Bosham, West Sussex
PO18 8NA, England
Telephone: +44 1243 572124
Fax: +44 1243 573680
E-mail: juniper@qoltech.co.uk
Web: http://www.qoltech.co.uk

This translation has been made possible through a grant from MUNDIPHARMA RESEARCH Ltd
Translated by MAPI INSTITUTE
Senior Translator: Rajaram Tallur

ಜನವರಿ **2010**

Revised on 07 March 2013
AQLQ(S)-SA12 - India/Kannada - Version of 07 Mar 13 - MAPI Institute.
ID7279 / AQLQ(S)-12-SA_AU2.0_kan-IN.doc

ಎಚ್ಐವಿ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ,
ಪ್ರಮಾಣಿತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (S)
(KANNADA VERSION FOR INDIA)
ರೋಗಿಯ ಬಳಕೆಗಾಗಿ

ರೋಗಿ ಸಂಖ್ಯೆ: _____

ದಿನಾಂಕ: _____

ಪುಟ: 1, 5ರಲ್ಲಿ

ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ಕಳೆದ **2** ವಾರಗಳ ಅವಧಿಯಲ್ಲಿ, ನೀವು ಹೇಗಿದ್ದಿರೆಂದು ಸೂಚಿಸಲು ನಿಮ್ಮ ಸ್ಥಿತಿಯನ್ನು ಸರಿಯಾಗಿ ಬಿಂಬಿಸುವ ಅಂಕೆಗಳಿಗೆ ಉರುಟು ಗುರುತು ಮಾಡುವ ಮೂಲಕ ಎಲ್ಲ ಪ್ರಶ್ನೆಗಳಿಗೆ ಉತ್ತರಿಸಿ.

ಕಳೆದ 2 ವಾರಗಳ ಅವಧಿಯಲ್ಲಿ, ಈ ಚಟುವಟಿಕೆಗಳ ಬೇಳೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ಎಷ್ಟು ಅಡ್ಡಿಯಾಗಿದೆ?

	ವಿಪರೀತ ಅಡ್ಡಿಯಾಗಿದೆ	ಬಹಳ ಅಡ್ಡಿಯಾಗಿದೆ	ಸಾಧಾರಣ ಅಡ್ಡಿಯಾಗಿದೆ	ಸ್ವಲ್ಪ ಅಡ್ಡಿಯಾಗಿದೆ	ಅತಿ ಸ್ವಲ್ಪ ಅಡ್ಡಿಯಾಗಿದೆ	ಕಿಂಚಿತ್ತೂ ಅಡ್ಡಿಯಾಗಿಲ್ಲ	ಅಡ್ಡಿಯಾಗಿಲ್ಲ ಇಲ್ಲ
1. **ಅತಿ ಶ್ರಮದ ಚಟುವಟಿಕೆಗಳು** (ಉದಾ: ಗಡಿಬಿಡಿಯ ಕೆಲಸಗಳು, ವ್ಯಾಯಾಮ ಮಾಡುವುದು, ಮಹಡಿ ಮೆಟ್ಟಿಲುಗಳನ್ನು ಓಡಿ ಹತ್ತುವುದು, ಕ್ರೀಡೆಗಳು)	1	2	3	4	5	6	7
2. **ಸಾಧಾರಣ ಶ್ರಮದ ಚಟುವಟಿಕೆಗಳು** (ಉದಾ: ನಡಿಗೆ, ಮನೆಗೆಲಸ, ತೋಟದ ಕೆಲಸ, ಖರೀದಿ, ಮಹಡಿ ಮೆಟ್ಟಿಲು ಹತ್ತುವುದು)	1	2	3	4	5	6	7
3. **ಸಾಮಾಜಿಕ ಚಟುವಟಿಕೆಗಳು** (ಉದಾ: ಮಾತನಾಡುವುದು, ಸಾಕುಪ್ರಾಣಿಗಳು/ಮಕ್ಕಳೊಂದಿಗೆ ಆಡುವುದು, ಬಂಧು-ಮಿತ್ರರನ್ನು ಭೇಟಿ ಮಾಡುವುದು.)	1	2	3	4	5	6	7.
4. **ಉದ್ಯೋಗ/ಕಾಲೆ ಸಂಬಂಧಿ ಚಟುವಟಿಕೆಗಳು** *(ಉದ್ಯೋಗದ ಸ್ಥಳದಲ್ಲಿ/ಕಾಲೆಯಲ್ಲಿ ಮಾಡುವ ಕೆಲಸಗಳು)	1	2	3	4	5	6	7
5. ನಿದ್ರೆ	1	2	3	4	5	6	7

*ನೀವು ಉದ್ಯೋಗದಲ್ಲಿರದಿದ್ದರೆ ಅಥವಾ ಸ್ವಂತ ಉದ್ಯೋಗಿಗಳಾಗಿದ್ದರೆ, ಹಿಚ್ಕಿನ ದಿನಗಳಲ್ಲಿ, ನೀವು ಮಾಡುವ ಕೆಲಸಗಳೆವು.

ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ನೀವು ಎಷ್ಟು ಕಿರಿಕಿರಿ ಅಥವಾ ಸಂಕಟಗಳನ್ನು ಅನುಭವಿಸಿದ್ದೀರಿ?

	ಬಹಳ ವಿಪರೀತ	ವಿಪರೀತ	ಬಹಳ	ಸಾಧಾರಣ	ಸ್ವಲ್ಪ	ಬಹಳ ಕಡಿಮೆ	ಇಲ್ಲವೇ ಇಲ್ಲ
6. ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, **ಎದೆ ಬಿಗಿತದ** ಕಾರಣದಿಂದಾಗಿ ಎಷ್ಟು ಕಿರಿಕಿರಿ ಅಥವಾ ಸಂಕಟಗಳನ್ನು ಅನುಭವಿಸಿದ್ದೀರಿ?	1	2	3	4	5	6	7

ಬ್ಪಸ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ,
ಪ್ರಮಾಣಿತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (S)
(KANNADA VERSION FOR INDIA)
ರೋಗಿಯ ಬಳಕೆಗಾಗಿ

ರೋಗಿ ಸಂಖ್ಯೆ: _____

ದಿನಾಂಕ: _____

ಪುಟ: 2, 5ರಲ್ಲಿ

ಸಾಮಾನ್ಯವಾಗಿ, **ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ**, ಎಷ್ಟು ಸಮಯ

	ಎಲ್ಲ ಸಮಯಗಳಲ್ಲೂ	ಬಹುತೇಕ ಸಮಯಗಳಲ್ಲಿ	ಬಹಳಷ್ಟು ಸಮಯಗಳಲ್ಲಿ	ಕೆಲವು ಸಮಯಗಳಲ್ಲಿ	ಸ್ವಲ್ಪ ಸಮಯಗಳಲ್ಲಿ	ಆಸ್ಪದ ಸಮಯಗಳಲ್ಲಿ	ಯಾವ ಸಮಯದಲ್ಲೂ ಇಲ್ಲ
7. ನೀವು ಉಬ್ಬಸ ಇರುವುದಕ್ಕಾಗಿ ಗಾಬರಿ ಅನುಭವಿಸಿದ್ದೀರಿ?	1	2	3	4	5	6	7
8. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ಉಸಿರಾಡಲು ಗಾಳಿ ಸಾಲದು ಅನ್ನಿಸಿದೆ?	1	2	3	4	5	6	7
9. ನಿಮಗೆ ಸಿಗರೇಟಿನ ಹೊಗೆಯಿಂದಾಗಿ ಉಬ್ಬಸದ ಲಕ್ಷಣಗಳ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
10. ನಿಮಗೆ ಎದೆಯಲ್ಲಿ ದಮ್ಮಿನ (ಗೂರಲು) ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
11. ನಿಮಗೆ ಸಿಗರೇಟಿನ ಹೊಗೆಯ ಕಾರಣದಿಂದಾಗಿ ಒಂದು ಸನ್ನಿವೇಶ ಅಥವಾ ವಾತಾವರಣದಿಂದ ದೂರವಿರಬೇಕೆಂದು ಅನ್ನಿಸಿದೆ?	1	2	3	4	5	6	7

ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ನಿಮಗೆ ಎಷ್ಟು ಕಿರಿಕಿರಿ ಅಥವಾ ಸಂಕಟದ ಅನುಭವವಾಗಿದೆ?

	ಬಹಳ ವಿಪರೀತ	ವಿಪರೀತ	ಬಹಳ	ಸಾಧಾರಣ	ಸ್ವಲ್ಪ	ಬಹಳ ಕಡಿಮೆ	ಇಲ್ಲವೇ ಇಲ್ಲ
12. ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ಕೆಮ್ಮಿನ ಕಾರಣದಿಂದಾಗಿ ನಿಮಗೆ ಎಷ್ಟು ಕಿರಿಕಿರಿ ಅಥವಾ ಸಂಕಟದ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7

ಸಾಮಾನ್ಯವಾಗಿ, **ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ**, ಎಷ್ಟು ಬಾರಿ

	ಎಲ್ಲ ಸಮಯಗಳಲ್ಲೂ	ಬಹುತೇಕ ಸಮಯಗಳಲ್ಲಿ	ಬಹಳಷ್ಟು ಸಮಯಗಳಲ್ಲಿ	ಕೆಲವು ಸಮಯಗಳಲ್ಲಿ	ಸ್ವಲ್ಪ ಸಮಯಗಳಲ್ಲಿ	ಆಸ್ಪದ ಸಮಯಗಳಲ್ಲಿ	ಯಾವ ಸಮಯದಲ್ಲೂ ಇಲ್ಲ
13. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ನಿರಾಶೆಯಾಗಿದೆ?	1	2	3	4	5	6	7
14. ನಿಮಗೆ ಎದೆ ಭಾರವೆನಿಸುವ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7

...ಸ್ಪ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ,
...ಮಾಣಿತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (S)
(KANNADA VERSION FOR INDIA)
ರೋಗಿಯ ಬಳಕೆಗಾಗಿ

ರೋಗಿ ಸಂಖ್ಯೆ: _____

ದಿನಾಂಕ: _____

ಪುಟ: 3, 5ರಲ್ಲಿ...

ಸಾಮಾನ್ಯವಾಗಿ, ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ... ಎಷ್ಟು ಬಾರಿ

	ಎಂದೂ ಇಲ್ಲ	ಬಹಳ ಕಡಿಮೆ	ಬಹಳಷ್ಟು ಸಮಯಗಳಲ್ಲಿ	ಕೆಲವು ಸಮಯಗಳಲ್ಲಿ	ಸ್ವಲ್ಪ ಸಮಯಗಳಲ್ಲಿ	ಅಪರೂಪ ಸಮಯಗಳಲ್ಲಿ	ಯಾವ ಸಮಯದಲ್ಲೂ ಇಲ್ಲ
15. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸಕ್ಕೆ ಔಷಧಿ ಅಗತ್ಯವಿದೆ ಎಂದು ಆತಂಕದ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
16. ನಿಮಗೆ ಗಂಟಲನ್ನು ಸರಿಪಡಿಸಿಕೊಳ್ಳಬೇಕೆಂದು ಅನ್ನಿಸಿದೆ?	1	2	3	4	5	6	7
17. ನಿಮಗೆ ಧೂಳಿಗೆ ತೆರೆದುಕೊಂಡದ್ದರಿಂದ ಉಬ್ಬಸದ ಲಕ್ಷಣಗಳ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
18. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ಉಸಿರಾಡಲು ಕಷ್ಟವಾಗುವ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
19. ನಿಮಗೆ ಧೂಳಿನ ಕಾರಣದಿಂದಾಗಿ ಒಂದು ಸನ್ನಿವೇಶ ಅಥವಾ ವಾತಾವರಣದಿಂದ ದೂರವಿರಬೇಕೆಂದು ಅನ್ನಿಸಿದೆ?	1	2	3	4	5	6	7
20. ನೀವು ಬೆಳಿಗ್ಗೆ, ಏಳುವಾಗಲೇ ಉಬ್ಬಸದ ಲಕ್ಷಣಗಳು ಕಾಣಿಸಿಕೊಂಡಿದ್ದವು?	1	2	3	4	5	6	7
21. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಔಷಧಿ ನಿಮ್ಮ ಕೈಯಲ್ಲಿ...ಲ್ಲ (ಕೈಯೆಟುಕಿಸಲಿ... ಲಭ್ಯವಿಲ್ಲ...) ಎಂಬ ಭಯದ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
22. ನಿಮಗೆ ಉಸಿರಾಡಲು ತುಂಬಾ ಕಷ್ಟವಾಗುವ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
23. ನಿಮಗೆ ಹವಾಮಾನ ಅಥವಾ ಹೊರಗಿನ ವಾಯು ಮಾಲಿನ್ಯದ ಕಾರಣದಿಂದಾಗಿ ಉಬ್ಬಸದ ಲಕ್ಷಣಗಳು ಕಾಣಿಸಿಕೊಂಡ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
24. ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ರಾತ್ರಿ ನಿದ್ದೆಯಿಂದ ಎಚ್ಚರಿಕೆಯಾಗಿದೆ?	1	2	3	4	5	6	7
25. ನೀವು ಹವಾಮಾನ ಅಥವಾ ಹೊರಗಿನ ವಾಯು ಮಾಲಿನ್ಯದ ಕಾರಣದಿಂದಾಗಿ ಹೊರಗೆ ಹೋಗುವುದರಿಂದ ದೂರ ಇದ್ದಿರಿ ಅಥವಾ ನಿಮಗೆ ಹೊರಗೆ ಹೋಗಲು ಅಡ್ಡಿಯಾಗಿದೆ?	1	2	3	4	5	6	7

ಒಪ್ಪಸ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ,
ಪ್ರಮಾಣಿತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (S) ರೋಗಿ ಸಂಖ್ಯೆ: _____
(KANNADA VERSION FOR INDIA)
ರೋಗಿಯ ಬಳಕೆಗಾಗಿ ದಿನಾಂಕ: _____

ಪುಟ: 4, 5ರಲ್ಲಿ

ಸಾಮಾನ್ಯವಾಗಿ, ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ಎಷ್ಟು ಬಾರಿ

	ಎಲ್ಲ ಸಮಯಗಳಲ್ಲಿ	ಬಹಳಷ್ಟು ಸಮಯಗಳಲ್ಲಿ	ಬಹಳಷ್ಟು ಸಮಯಗಳಲ್ಲಿ	ಕೆಲವು ಸಮಯಗಳಲ್ಲಿ	ಕೆಲವು ಸಮಯಗಳಲ್ಲಿ	ಅಪರೂಪ ಸಮಯಗಳಲ್ಲಿ	ಯಾವ ಸಮಯದಲ್ಲೂ ಇಲ್ಲ
26. ನಿಮಗೆ ಘಾಟು (ಉದಾ: ಮೀನಸು) ಅಥವಾ ಪರಿಮಳ ದ್ರವ್ಯಗಳಿಗೆ (ಉದಾ: ಸೆಂಟು) ತೆರೆದುಕೊಂಡದ್ದರಿಂದ ಉಬ್ಬಸದ ಲಕ್ಷಣಗಳ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
27. ನಿಮಗೆ ಉಸಿರು ಸಿಲುಕುವ ಭಯದ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7
28. ನಿಮಗೆ ಘಾಟು (ಉದಾ: ಮೀನಸು) ಅಥವಾ ಪರಿಮಳ ದ್ರವ್ಯಗಳಿಗೆ (ಉದಾ: ಸೆಂಟು) ತೆರೆದುಕೊಂಡದ್ದರಿಂದ ಒಂದು ಸನ್ನಿವೇಶ ಅಥವಾ ವಾತಾವರಣದಿಂದ ದೂರ ಇರಬೇಕೆನ್ನಿಸಿದೆ?	1	2	3	4	5	6	7
29. ನಿಮಗೆ ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದ ರಾತ್ರಿಯ ಒಳ್ಳೆಯ ನಿದ್ರೆ ಭಂಗವಾಗಿದೆ?	1	2	3	4	5	6	7
30. ನಿಮಗೆ ಉಸಿರಾಡಲು ಗಾಳಿಗಾಗಿ ಒದ್ದಾಡುತ್ತಿರುವ ಅನುಭವವಾಗಿದೆ?	1	2	3	4	5	6	7

ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ಎಷ್ಟು ಬಾರಿ ನಿಮಗೆ ಅಡ್ಡಿಯಾಗಿದೆ

	ವಿಪರೀತ ಅಡ್ಡಿಯಾಗಿದೆ – ಬೇಕಾದ ಚಟುವಟಿಕೆಗಳನ್ನು ಮಾಡಲಾಗಲು	ಬಹಳ ಅಡ್ಡಿಯಾಗಿದೆ	ಸಾಧಾರಣ ಅಡ್ಡಿಯಾಗಿದೆ – ಬಹಳಷ್ಟು ಚಟುವಟಿಕೆಗಳನ್ನು ಮಾಡಲು	ಕೆಲವು ಅಡ್ಡಿಯಾಗಿದೆ	ಅತಿ ಕೆಲವು ಅಡ್ಡಿಯಾಗಿದೆ – ಕೆಲವು ಚಟುವಟಿಕೆಗಳನ್ನು ಮಾಡಲು	ಕೆಲವು ಅಡ್ಡಿಯಾಗಿದೆ	ಅಡ್ಡಿಯಾಗಿಲ್ಲ ಇಲ್ಲ – ನಾನು ಬಯಸಿದ ಎಲ್ಲ ಚಟುವಟಿಕೆಗಳನ್ನೂ ಮಾಡಬಲ್ಲೆ
31. ನೀವು ಸಾಮಾನ್ಯವಾಗಿ ಮಾಡುವ ಎಲ್ಲ ಚಟುವಟಿಕೆಗಳನ್ನು ಒಟ್ಟಾಗಿ ಯೋಚಿಸಿಕೊಳ್ಳಿ. ಆ ಎಲ್ಲ ಚಟುವಟಿಕೆಗಳಲ್ಲಿ, ನಿಮ್ಮ ಉಬ್ಬಸದ ಕಾರಣದಿಂದಾಗಿ ಎಷ್ಟು ಚಟುವಟಿಕೆಗಳನ್ನು ಮಾಡಲು ಸಾಧ್ಯವಾಗಿಲ್ಲ? "	1	2	3	4	5	6	7

ಬ್ರಾಸ ರೋಗಿಗಳ ಜೀವನ ಗುಣಮಟ್ಟದ ಕುರಿತು ಪ್ರಶ್ನಾವಳಿ,
ಪ್ರಮಾಣೀತ ಚಟುವಟಿಕೆಗಳ ಜೊತೆಗೆ (S)
(KANNADA VERSION FOR INDIA)
ರೋಗಿಯ ಬಳಕೆಗಾಗಿ

ರೋಗಿ ಸಂಖ್ಯೆ: _____

ದಿನಾಂಕ: _____

ಪುಟ 5, 5ರಲ್ಲಿ

ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ಎಷ್ಟು ಬಾರಿ ನಿಮಗೆ ಅಡ್ಡಿಯಾಗಿದೆ

	ವಿಪರೀತ ಅಡ್ಡಿಯಾಗಿದೆ	ಬಹಳ ಅಡ್ಡಿಯಾಗಿದೆ	ಸಾಧಾರಣ ಅಡ್ಡಿಯಾಗಿದೆ	ಸ್ವಲ್ಪ ಅಡ್ಡಿಯಾಗಿದೆ	ತೀರ ಸ್ವಲ್ಪ ಅಡ್ಡಿಯಾಗಿದೆ	ಕಿಂಚಿತ್ ಅಡ್ಡಿಯಾಗಿದೆ	ಅಡ್ಡಿಯಾಗಿರಲಿಲ್ಲ
32. ಒಟ್ಟಿನಲ್ಲಿ, ಕಳೆದ ಎರಡು ವಾರಗಳಲ್ಲಿ, ನೀವು ಮಾಡಿದ ಎಲ್ಲ ಚಟುವಟಿಕೆಗಳ ಬೇಳೆ ನಿಮ್ಮ ಉಬ್ಬಸದಿಂದ ನಿಮಗೆ ಎಷ್ಟು ಅಡ್ಡಿಯಾಗಿದೆ?	1	2	3	4	5	6	7

ಪ್ರಭಾವ ಕ್ಷೇತ್ರ ಸೂಚಕ:

ಲಕ್ಷಣಗಳು: **6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 29, 30**
ಚಟುವಟಿಕೆಗಳಿಗೆ ಅಡ್ಡಿ: **1, 2, 3, 4, 5, 11, 19, 25, 28, 31, 32**
ಭಾವನಾತ್ಮಕ ಕೆಲಸಗಳು: **7, 13, 15, 21, 27**
ಪರಿಸರ ಪ್ರೇರಿತ: **9, 17, 23, 26**