**A Dissertation On**

# EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA


Submitted by

**Dr. R. ARTHI, B.N.Y.S (Reg. No. 461611001)**

Under the guidance of

**Prof. Dr. N. MANAVALAN, N.D. (OSM), M.A (G.T), M.Sc (Y&N), M.Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H**


Submitted to

**The Tamil Nadu Dr. M.G.R. Medical University, Chennai**

In partial fulfillment of the requirements for the award of degree of

**DOCTOR OF MEDICINE**
**BRANCH – I: NATUROPATHY**


**POST GRADUATE DEPARTMENT OF NATUROPATHY**

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL,**

**CHENNAI – 600 106.**


**OCTOBER 2019**

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMILNADU**

## CERTIFICATE BY THE GUIDE

This is to certify that **"EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA"** is a bonafide work done by the Postgraduate **Dr. R. ARTHI**, Department of Naturopathy, Government Yoga Medical College and Hospital , Chennai - 600106, under my guidance and supervision in partial fulfillment of regulations of **The Tamil Nadu Dr.M.G.R. Medical University, Chennai** for the award of degree of DOCTOR OF MEDICINE **(**M.D) – Naturopathy, BRANCH – I during the academic period 2016 to 2019.

Place: Chennai.

Date :

**SIGNATURE OF THE GUIDE**

**Dr. N. MANAVALAN,**
N.D. (OSM), M.A (G.T), M.Sc (Y&N),
M.Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H
Head of the Department – Department of Naturopathy,
Government Yoga and Naturopathy Medical College
and Hospital, Chennai – 106.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMILNADU**

**ENDORSEMENT BY THE HEAD OF THE DEPARTMENT**

I certify that the dissertation entitled **"EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA"** is the record of original research work carried out by **Dr. R. ARTHI,** Department of Naturopathy, Government Yoga and Naturopathy Medical College and Hospital**,** Chennai– 600 106, submitted for the degree of **DOCTOR OF MEDICINE M.D–Branch–I (Naturopathy)** under my guidance and supervision, and that this work has not formed the basis for the award of any degree, diploma, associate ship, fellowship or other titles in this University or any other University or Institution of higher learning.

Place : Chennai.

Date :

**SIGNATURE OF THE H.O.D**

**Dr. N. MANAVALAN,**

N.D. (OSM), M.A (G.T), M.Sc (Y&N),
M.Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H
Department of Naturopathy,
Government Yoga and Naturopathy Medical College
and Hospital, Chennai – 106.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMILNADU**

**ENDORSEMENT BY THE PRINCIPAL**

I certify that the dissertation entitled **"EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA"** is the record of original research work carried out by **Dr. R. ARTHI,** Department of Naturopathy, Government Yoga and Naturopathy Medical College and Hospital**,** Chennai– 600 106 submitted for the award of degree of **DOCTOR OF MEDICINE (M.D) Branch – I (Naturopathy)** under my guidance and supervision, and that this work has not formed the basis for the award of any degree, diploma, associate ship, fellowship or other titles in this University or any other University or Institution of higher learning.

Place : Chennai.

Date :

**SIGNATURE OF THE PRINCIPAL**

**Dr. N. MANAVALAN,**
N.D. (OSM), M.A (G.T), M.Sc (Y&N),
M.Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H
Head of the Department – Department of Naturopathy,
Government Yoga and Naturopathy Medical College
and Hospital, Chennai – 106.

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI, TAMILNADU**

## DECLARATION BY THE CANDIDATE

I, **Dr. R. ARTHI** solemnly declare that this dissertation entitled **"EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA"** is a bonafide and genuine research work carried out by me at Government Yoga and Naturopathy Medical College and Hospital, Chennai from May 2018 - March 2019 under the guidance and supervision of **Dr. N. MANAVALAN**, Head of the Department - Department of Naturopathy. This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of requirements for the award of M.D. Degree (Branch – I – Naturopathy) in Yoga and Naturopathy.

**Place:** Chennai **Signature of the Candidate**

**Date:**

(Dr. R. Arthi)

**INSTITUTIONAL ETHICAL COMMITTEE**

**GOVERNMENT YOGA AND NATUROPATHY MEDICAL COLLEGE AND HOSPITAL, CHENNAI – 600 106.**

## CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Government Yoga & Naturopathy Medical College and Hospital, Chennai reviewed and discussed the application for approval of "**EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA**", project work submitted by Dr. R. ARTHI, 2nd year M. D. Naturopathy, Post graduate, Government Yoga and Naturopathy Medical College and Hospital, Chennai.

The proposal is **Approved**.

The Institutional Ethical Committee expects to be informed about the progress of the study and adverse drug reactions during the course of the study and any change in the protocol and patient information sheet / informed consent and asks to be provided a copy of the final report.

## COPYRIGHT

I hereby declare that the Tamil Nadu Dr. M.G.R. Medical University, Chennai, TamilNadu shall have the rights to preserve, use and disseminate this Dissertation / Thesis in print or electronic format for academic / research purpose.

Place: Chennai

Date:

Signature of the candidate,

(Dr . R. Arthi)

## ACKNOWLEDGEMENT

First and foremost, praises and thanks to the God, the almighty for his showers of blessings, good health and well-being throughout my research work to complete the research successfully.

I wish to express my sincere thanks to Professor Dr. N. Manavalan Principal of Faculty, Govt Yoga & Naturopathy medical college and hospital, H.O.D Naturopathy for being my mentor and guide throughout my project and helpful in completing my dissertation.

I am grateful to Professor Dr. S.T. Venkateswaran H.O.D of Yoga., for his constant support and encouragement. I also thank Professor Late. Dr. Himeshwari, H.O.D of Acupuncture and Energy Medicine for her support.

I am grateful thankful for the tremendous sacrifices that my parents Mr. K. Ranganathan and Mrs. R. Tamilselvi made for my education and their support to complete this research work.

I have been fortunate to get help from Dr. Magesh kumar AMO, Govt Yoga & Naturopathy medical college and hospital and I extend my thanks to him for his constant guidance throughout the study especially in choosing equipment and statistical work.

I would like to extend my thanks to all lecturers / medical officers who offered collegial guidance and support over the years. I am deeply obliged to all my PG Colleagues and Undergraduate friends who have been there at all phases of this study.

I would like to thank the therapeutic assistants for extending their full cooperation on administration of Cold Chest Pack. With sincere gratitude I thank all the participants who contributed so much to this study, without them this study could not have been possible.

I would like to thank the participants who accepted, regularly attended and co-operated in this study.

Finally my thanks to the all people who have supported me to complete my research work directly or indirectly.

**Dr. R. ARTHI**

## LIST OF ABBREVIATIONS

| | |
|---|---|
| **CHPK** | Chest Pack |
| **PEFR** | Peak Expiratory Flow Rate |
| **Ig E** | Immunoglobulin E |
| **PGs** | Prostaglandins |
| **Th2** | T-helper type-2 |
| **LTs** | Leukotrienes |
| **TXA2** | Thromboxane A2 |
| **ILs** | Interleukins |
| **ROAD** | Reversible Obstructive Airway Disease |
| **BHR** | Bronchial Hyper- Responsiveness |
| **GERD** | Gastro Esophageal Reflux Disease, |
| **WRA** | Work-related asthma |
| **FEV1** | Forced Expiratory Volume 1 |
| **FVC** | Forced Vital Capacity |
| **NCV** | Nerve Conduction Velocity |
| **VC** | Vital Capacity |
| **MBC** | Maximum Breathing Capacity |
| **AHR** | Airway Hyper Reactivity |
| **RSV** | Respiratory Syncytial Virus |
| **EIB** | Exercise-Induced Bronchoconstriction |
| **VT** | Tidal Volume |
| **MVV** | Maximum Voluntary Ventilation |
| **SDIA** | Steroid-Dependent Intractable Asthma |

## ABSTRACT

**Introduction:** Many studies reported that the practice of Naturopathy, especially with hydrotherapy treatment, influences in improving pulmonary function. The current study was conducted to determine the effect of using Cold Chest Pack for improving pulmonary functions.

**Objective:** The intended research work aims at assessing the efficacy of Cold Chest Pack in improving the Pulmonary functions of Bronchial Asthma patients

**Study Design:** Randomized Control Trial.

**Method:** A total of 71 study subjects belonging within the age group of 20-44 years, participated in the study. The study participants were randomized into intervention and control group. The intervention group participants will be given cold chest pack for 30 minutes for 25 days (5 days/week for 5 weeks) along with conventional medicine. Control group will be only under conventional medicine. After 5 weeks again PEFR will be recorded for both groups.

**Result:** The study showed significant improvement in the PEFR values of the study participants. The pulmonary function observed to be significantly improved with cold chest pack among study participants.

**Conclusion:** The practice of hydrotherapy mediated Cold Chest Pack facilitates in improving the PEFR and strengthening the pulmonary function significantly.



**Keywords:** Peak Expiratory Flow Rate, Cold Chest Pack, Pulmonary Function, Hydrotherapy

## Table of contents


| Sl. No. | INDEX | Page No. |
|---|---|---|
| 1 | INTRODUCTION | 1 |
| 2 | AIMS AND OBJECTIVES | 14 |
| 3 | REVIEW OF LITERATURE | 15 |
| 4 | MATERIALS AND METHODOLOGY | 48 |
| 5 | RESULTS | 60 |
| 6 | DISCUSSIONS | 68 |
| 7 | CONCLUSION | 72 |
| 8 | SUMMARY | 75 |
| | References | 77 |
| 9 | ANNEXURE | 88 |

## LIST OF TABLES


| Table No. | Topic | Page No. |
|---|---|---|
| 3.1 | List of agents responsible as triggers in asthma (Chauhan et ah, 1996) | 21 |
| 5.1 | Anthropometric variables between the groups | 61 |
| 5.2 | Effect of Cold Chest Pack on PEFR in both CHPK group and control group | 62 |
| 5.3 | Effect of Cold Chest Pack on PEFR among the male subjects between CHPK group and control group | 64 |
| 5.4 | Effect of Cold Chest Pack on PEFR among the female subjects between CHPK group and control group | 66 |

## LIST OF FIGURES


| Fig No. | CONTENTS | Page No. |
|---|---|---|
| 1.1 | Changes in airway wall, muscle and lumen of Bronchus and Alveoli in Bronchial Asthma | 2 |
| 1.2 | Manifestations of Asthma | 4 |
| 1.3 | Triggering factors of Asthma | 5 |
| 1.4 | Factors responsible for Asthma | 6 |
| 1.5 | Normal and Asthmatic Lung and Airway | 7 |
| 1.6 | Diagram of Pulmonary Ventilation and Volumes | 9 |
| 3.1 | Illustrated manifestation of Asthmatic Airway | 16 |
| 3.2 | Global Asthma Report and its prevalence | 18 |
| 3.3 | Prevalence of Bronchial Asthma in India | 19 |
| 3.4 | Mechanism of Asthmatic attacks by triggering factors | 20 |
| 3.5 | Risk Factors in Asthma | 23 |
| 3.6 | Symptoms of Asthmatic Attack | 25 |
| 3.7 | Illustration of Bronchial Asthma | 26 |
| 3.8 | Pathology of Asthma | 27 |
| 3.9 | Mechanism behind Asthma | 28 |
| 3.10 | Mechanism and Pathophysiology behind Asthma | 30 |
| 3.11 | Subtype classification based on age of onset | 32 |
| 3.12 | Subtype classification based on location of exposure | 33 |
| 3.13 | Subtype classification based on response to inflammation | 34 |
| 3.14 | Exercise-induced bronchoconstriction (EIB) | 35 |

| | | |
|---|---|---|
| 3.15 | Common Environmental Triggers responsible for Bronchial Asthma | 37 |
| 3.16 | Massage Therapy | 41 |
| 3.17 | General Hydrotherapy mediated approach involving water exercise | 44 |
| 4.1 | Getting Informed Consent from the patient | 49 |
| 4.2 | Flowchart representation of Research Methodology | 52 |
| 4.3 | Chest pack types (Square Chest Pack, Roller Chest Pack and Abdominal Bandage) | 54 |
| 4.4 | Illustrative representation of application of Cold Chest pack to patients in sitting position | 55 |
| 4.5 | Illustrative representation of application of Cold Chest pack to patients in supine position | 56 |
| 4.6 | PEFR (Airmed Clement Clarkes International, England) | 57 |
| 4.7 | Representation of parts of PEF Meter | 58 |
| 4.8 | Illustrative representation of using PEFR by patients | 58 |
| 5.1 | Effect of Cold Chest Pack on PEFR in both CHPK group and control group | 63 |
| 5.2 | Effect of Cold Chest Pack on PEFR among the male subjects | 65 |
| 5.3 | Effect of Cold Chest Pack on PEFR among the female subjects | 67 |

# 1.0 INTRODUCTION

The prime objective of the project is to establish the significance and efficacy of the medical system involving Naturopathy, over the Conventional Medical System, especially with reference to cold compression.

There is a noticeable increase in health care burden from asthma in several areas of the world. There is also a global concern on the change in asthma epidemiology and clinical spectrum. There is not only an apparent increase in general prevalence in several geographic areas, but also in the number of cases of difficult, refractory and fatal (or near fatal) asthma. Moreover, there are complex and confounding associations and relationships with infections and infestations, air pollution, tobacco smoking and environmental tobacco smoke exposure[1, 2].

## 1.1 Definition of Asthma

The word asthma originates from an ancient Greek word meaning panting[3]. The global strategy for asthma management and prevention guidelines define as a chronic inflammatory disorder of the airways associated with increased airway hyper responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness and coughing particularly at night or early morning. Airway inflammation produces airflow limitation through acute broncho-constriction, chronic mucus plug formation and airway wall swelling or remodeling[4]. Asthma is a Reversible Obstructive Airway Disease (ROAD) coupled with bronchial hyper- responsiveness (BHR) and airway inflammation. ASTHMA = ROAD (reversible obstructive airway disease) + BHR (bronchial hyper responsiveness).

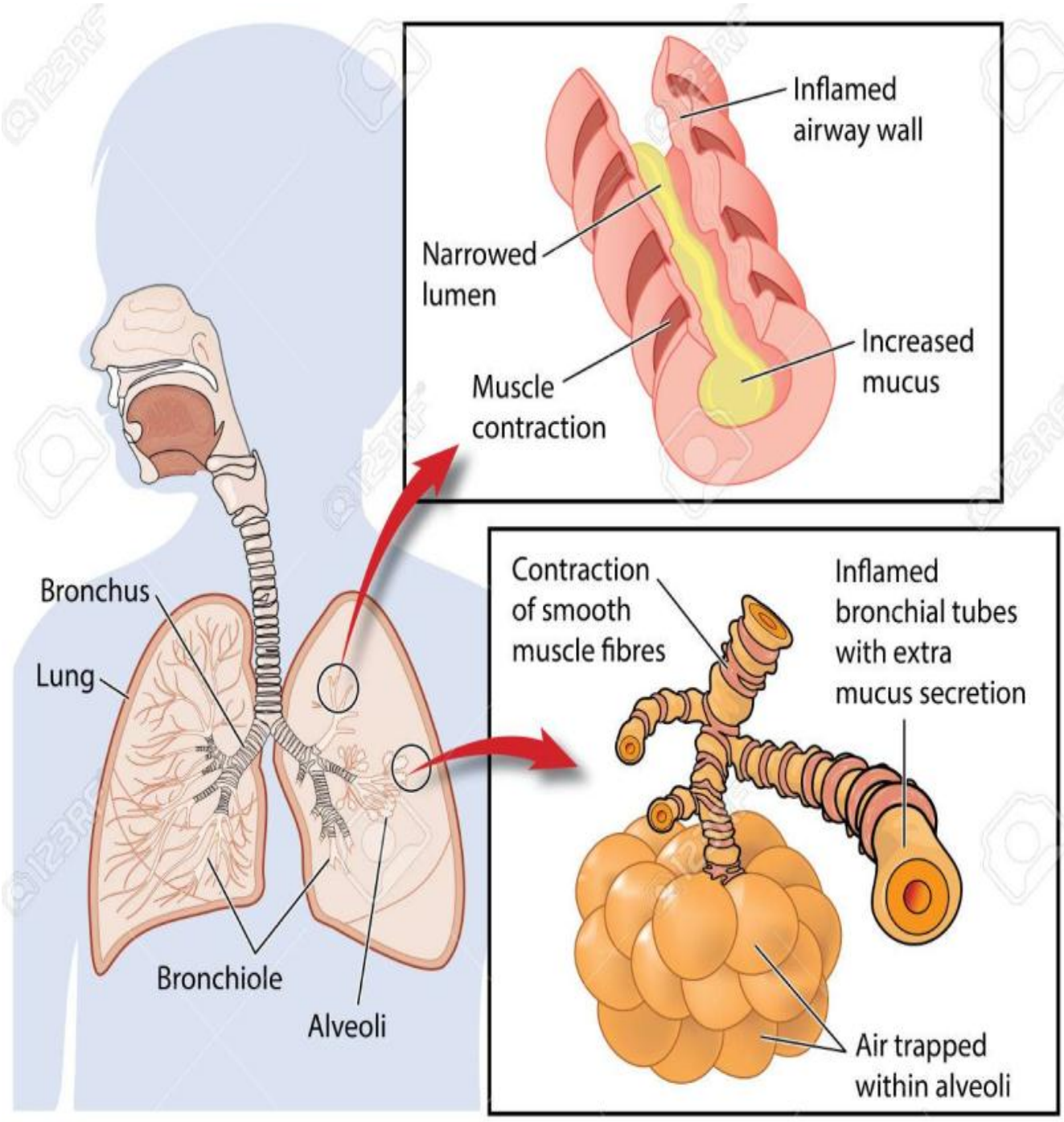


**Figure 1.1: Changes in airway wall, muscle and lumen of Bronchus and Alveoli in Bronchial Asthma**

Asthma is a heterogenous disorder that is characterized by variable airflow obstruction, airway inflammation and hyper responsiveness, and reversibility either spontaneously or as a result of treatment[5]. Chronic inflammation is related with

airway hyper responsiveness leading to wheezing, shortness of breath, chest tightness and coughing, particularly during night or early in the morning. Asthma is a global problem estimated to affect 300 million people around the world[4].

Depending on the severity of bronchial asthma in the individual patient, there may be phases of partial or total freedom from symptoms, alternating with periods of variably severe illness. This fact has been integrated into the definition of bronchial asthma, which is now defined as a chronic inflammatory disease of the airways characterized by bronchial hyper-reactivity and a variable degree of airway obstruction.

Airway obstruction in bronchial asthma is mainly caused by the following four mechanisms:

- Contraction of bronchial smooth muscle
- Edema of the airway walls
- Mucous plugging of the bronchioles
- Irreversible changes in the lungs ("remodeling").

### 1.2 Manifestations of asthma

Bronchial asthma[6] is a medical condition which causes the airway path of the lungs to swell and narrow. Due to this swelling, the air path produces excess mucus making it hard to breathe, which results in coughing, short breath, and wheezing. The disease is chronic and interferes with daily working.

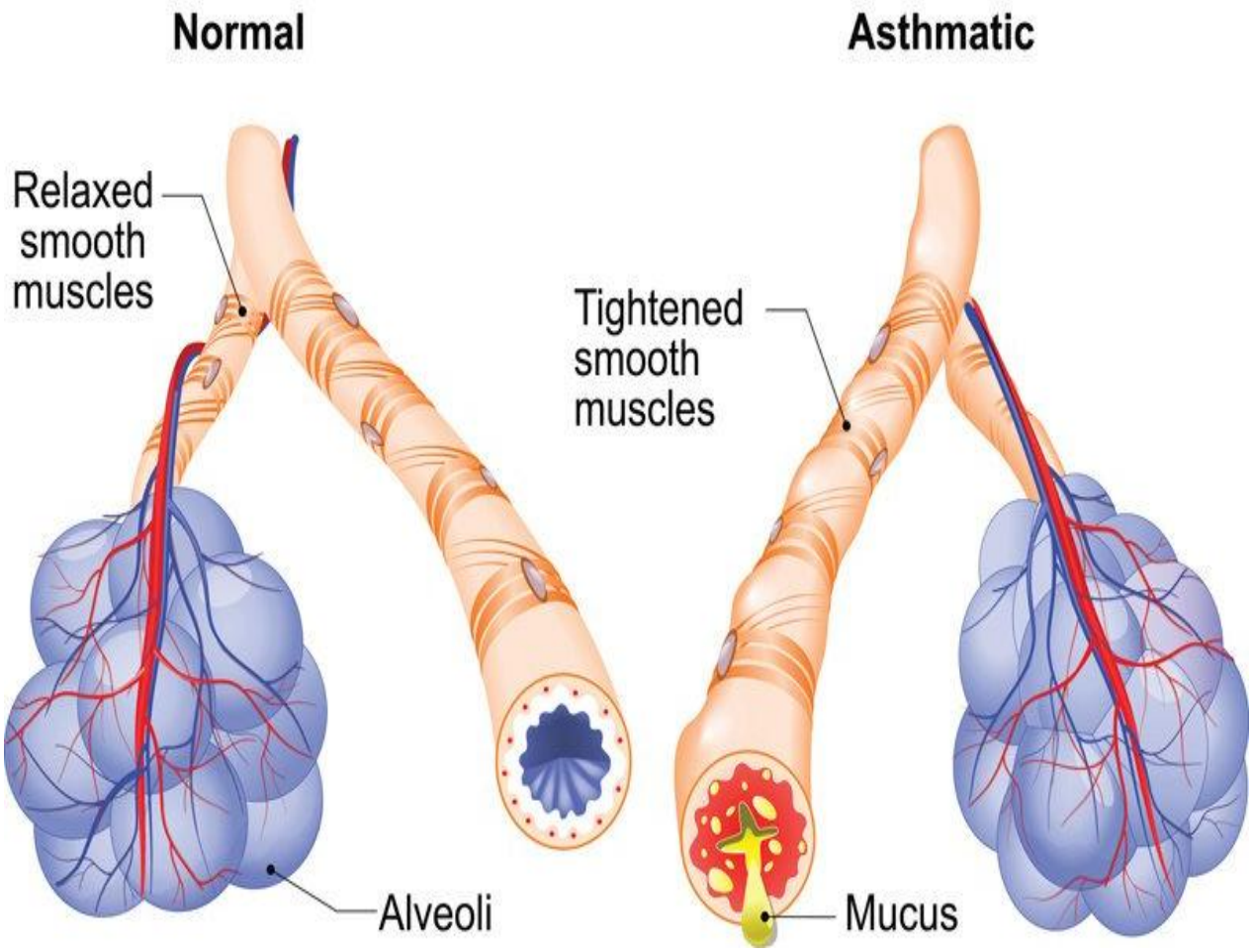


**Figure 1.2: Manifestations of Asthma**

## 1.3 Causes and Risk factors

Though the root cause of bronchial asthma is unclear, it occurs largely due to environmental or genetic factors. The factors that trigger an asthma reaction are:

Exposure to substances such as pollen, dust, animal fur, sand, and bacteria, which triggers allergic reactions[7].

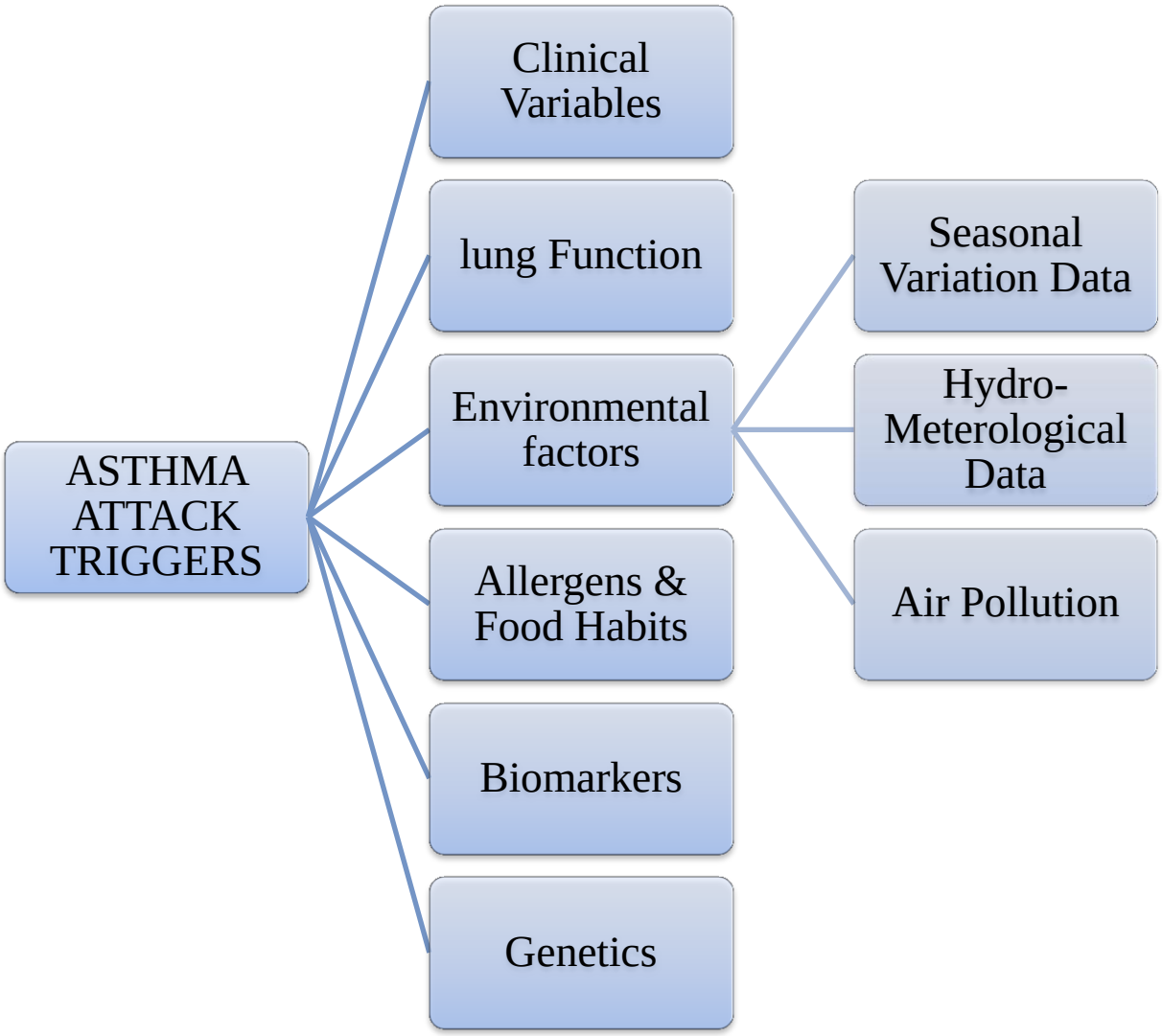


**Figure 1.3: Triggering factors of Asthma**

Other includes,

- Viral Infection like cold and flu, or pneumonia.
- Air Pollution, smoke, fumes from vehicles, etc.
- Stress and anxiety.
- Physical activity or exercise induced asthma.
- Medications like aspirin, Ibuprofen, beta-blockers, etc.

- Acid reflux or gastroesophageal reflux disease (GERD).
- Perfumes and fragrances.
- Weather, especially extreme changes in temperature.

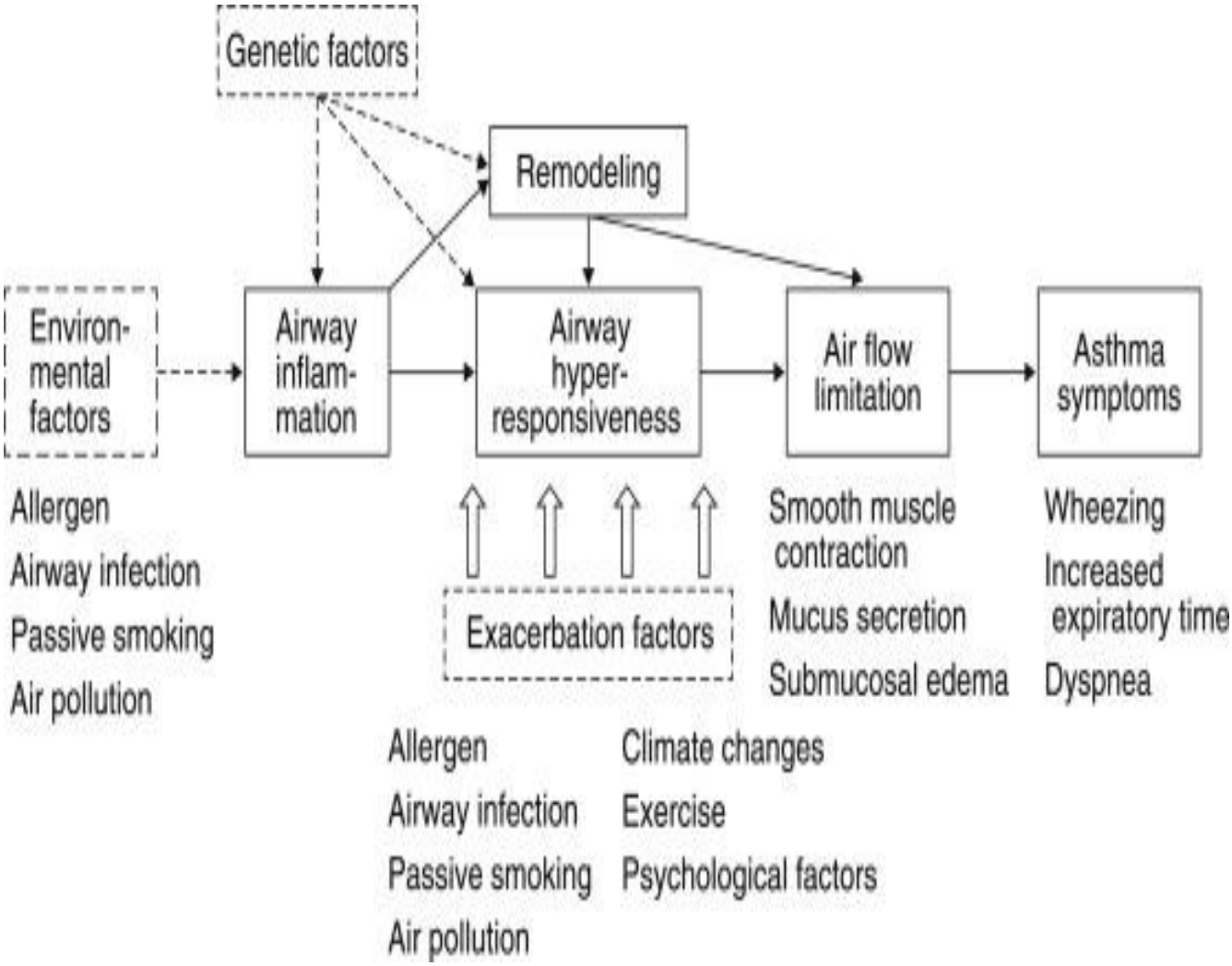


**Figure 1.4: Factors responsible for Asthma**

Risk factors of asthma can be outlined under personal and environmental factors. Heredity, gender and obesity are the main subtitles of personal factors. Environmental factors comprise of allergens, infections (especially viruses), occupational sensitisers, smoking (active and also passive), air pollution (inner and outer) and lifestyle (rural life, diet, consumption of antibiotics etc.).

## 1.4 The Abnormalities of Pulmonary Function in Asthma

The primary functional disturbance in asthma[8] is bronchial narrowing or obstruction. This may be due to spasm of the bronchial muscles, swelling of the bronchial walls or obstruction of the lumen by mucus. Bronchial obstruction makes the flow of air in and out of the lungs more difficult. In particular, the time required to expel the inspired air is increased. If the expiratory forces are insufficient to expel all of the inspired tidal volume then air will be trapped in the lungs and pulmonary ventilation will be impaired. This hypoventilation may be associated with hypoxia and carbon dioxide retention. Pulmonary emphysema[9] and other structural damage to the lung which sometimes complicates asthma leads to increased insufficiency of pulmonary function and may be associated with pulmonary heart disease.

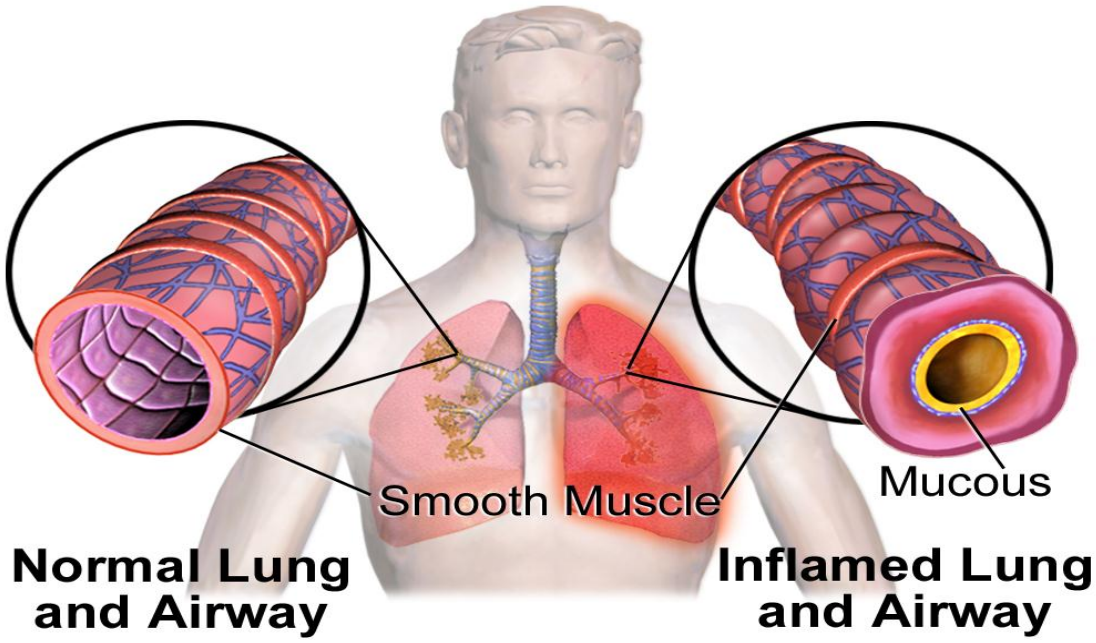


**Figure 1.5: Normal and Asthmatic Lung and Airway**

## 1.5 Pulmonary Function Tests in Asthma

Pulmonary function[10] tests can, broadly speaking, be divided into four varieties according to whether they test pulmonary ventilation, lung volumes, gas exchange (including diffusion across the alveolar walls and ventilation-perfusion relationships), or the mechanical properties of the lung.

### 1.5.1 Pulmonary Ventilation

Dynamic measurements of pulmonary ventilation[11] are convenient and also very sensitive indicators of the severity of asthma and need no more elaborate apparatus than a recording spirometer. The forced expiratory volume in one second (FEV1) is the volume of air expired in one second in a forced expiration after a maximum inspiration. It is a measure of the expiratory flow rate and is a simple repeatable and sensitive test of expiratory obstruction. The FEV1 is low in asthma and is increased by effective broncho-dilators. The vital capacity (VC) is the maximal volume of air that can be expired following a maximum inspiration. It is a poor index of the severity of asthma since it is not a dynamic (timed) measurement. Thus, given enough time, an asthmatic may be able to empty the lungs of air satisfactorily so that the VC may be little impaired in asthma and influenced little by effective bronchodilators[12]. The ratio is a valuable index of expiratory VC obstruction. It is normally 80 per cent or more, but is low where asthmatic bronchial obstruction or air trapping due to emphysema is present. Patients with uncomplicated asthma attain a normal ratio when fully recovered, but where asthma is complicated by chronic

emphysema the ratio remains low in spite of effective treatment of asthmatic bronchial obstruction[13].

**CITRON: Pulmonary Function in Bronchial Asthma**

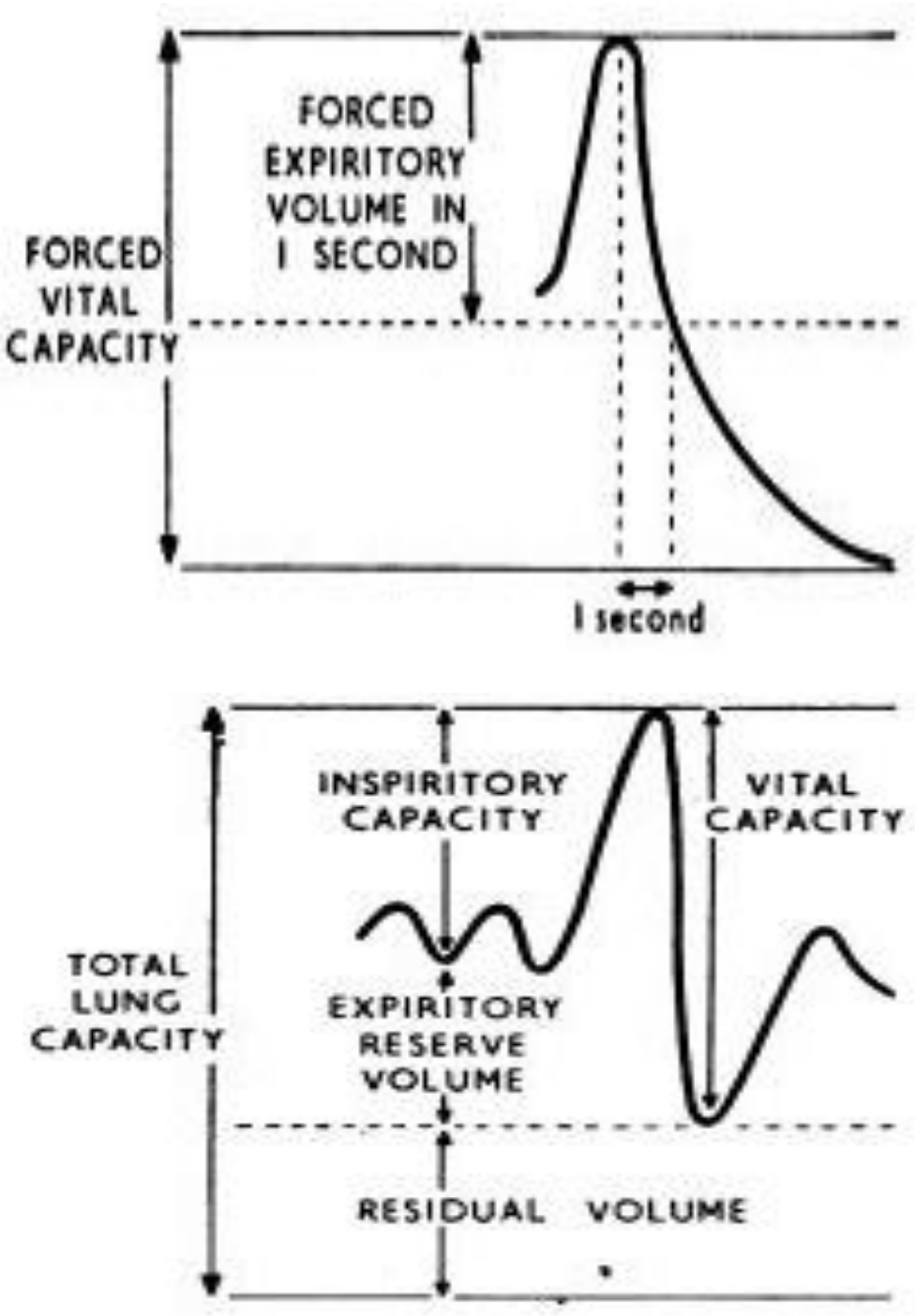


**Figure 1.6: Diagram of Pulmonary Ventilation and Volumes**

The maximum breathing capacity (MBC) is the maximal volume of air that can be breathed per minute. This is reduced in asthma. It is a more difficult and exhausting test for the patient and needs more co-operation than the FEV test, and in any case its value can be reliably predicted by multiplying the value of the FEV, in litres by 35[14]. Progressive elevation of respiratory level at the beginning of inspiration in the MBC spirogram tracing to hyperinflation levels is found when air trapping occurs in asthma or emphysema. The peak expiratory flow rate is reduced in asthma and may be simply measured by a specially designed peak flow meter.

### 1.5.2 The Mechanical Properties of the Lung

**Measurements of intrathoracic pressures**[15] by means of intraoesophageal pressure recorders show that during asthma respiratory pressure swings are much increased, becoming very low on inspiration and high on expiration.

**The work of breathing**, which is measured by the product of the pressure change and the volume change, is greatly increased so causing the patient the sensation of dyspnoea and increasing the oxygen demands of the body.

**Lung compliance** defines lung stiffness or elasticity and is expressed as volume change per unit of pressure change. Increased lung stiffness, that is low compliance, is usually found in asthma[16].

Lung resistance, which is expressed as pressure change per unit of gas flow, is increased in asthma in association with the bronchial obstruction.

## 1.6 Diagnosing Bronchial Asthma

Because asthma symptoms[17] don't always happen during your doctor's appointment, it's important for you to describe yours, or your child's, asthma signs and symptoms to your health care provider. You might also notice when the symptoms occur such as during exercise, with a cold, or after smelling smoke.

Asthma tests[18] may include:

- Spirometry: A lung function test to measure breathing capacity and how well you breathe. You will breathe into a device called a spirometer.
- Peak Expiratory Flow (PEF): Using a device called a peak flow meter, you forcefully exhale into the tube to measure the force of air you can expend out of your lungs. Peak flow monitoring can allow you to monitor how well your asthma is doing at home.
- Chest X-ray: Your doctor may do a chest X-ray to rule out any other diseases that may be causing similar symptoms.

## 1.7 Naturopathy

Naturopathy is a science of disease elimination without drugs. It is based on the principle of cooperation with the natural laws of life which are forever working within, as well as outside the body and it makes use of only the natural elements like water, air, light, heat, food, etc., for the purpose of curing disease[19].

Naturopathy can be defined as a drugless, non-invasive, rational and evidence-based system of medicine imparting treatments with natural elements based on the

theories of vitality, toxemia and the self-healing capacity of the body and the principles of healthy living. Naturopathic life- style is a form of holistic mind-body medicine, developed thousands of years ago, is simple and can be practiced by all[20].

### 1.8 Hydrotherapy in treatment of Bronchial Asthma

Hydrotherapy treatment[21] is a part of naturopathy process that involves using water as an effective treatment as it promotes healing. It serves as a treatment of various disorders via utilizing different states of waters. Their application using all states of water has been in practice since age-old days. Hydrothermal therapy additionally uses temperature effects, as in hot & cold baths, saunas, wraps, etc., and in all its forms-solid, fluid, vapour, ice and steam, internally and externally. Water is without doubt the most ancient of all remedial agents for disease. Healing[22] could be achieved via steam inhalation, warm/ cold compresses nasal irrigation. Such techniques tend to loosen the secretion of nasal airway as well as cleanse the mucosal linings of the nasal passage. Besides they facilitate in improving the breathing and drainage as well. In case of aromatic steam involves with numerous herbal remedies which in turn soothes the inflamed nasal mucosa and sinus membrane. However for the present study, we incorporate cold chest pack as an effective hydrotherapy mediated approach for treating bronchial asthma.

#### 1.8.1 Cold chest pack

It is a part of hydrotherapy treatment[23] facilitating in an increased peak expiratory flow rate with exhibiting an immediate effect on bronchial asthma patients. Temperature of the chest's cavity is diminished considerably within ten minutes of

application of the thoracic compress. Chest's blood-vessels are made to instantly contract upon its contact with where the cold compress has been made. And on reaction phase (after ten minutes) there will be dilation of bronchial vessels and tract which enhances free expiration where asthmatic patients getting trouble. The tidal air also increased more than 1/3$^{rd}$ in volume.

The immediate effect of a cold chest pack application has been related to different factors, viz, (i) Circulatory effects, since the application is believed to cause vasoconstriction of blood vessels in the skin over the chest and (ii) the cold stimulation may also increase overall sympathetic tone, hence bringing about bronchodilation[24]. This is especially important as it is generally understood that there is sympathetic beta receptor hyposensitivity in bronchial asthma, along with a adrenoreceptor hypersensitivity and parasympathetic hypersensitivity[25].

**1.9 RATIONALE:**

Cold chest pack is being widely used as a therapy in naturopathic system of medicine. The previous study on this was done without control group and done along with other naturopathy, yoga and acupuncture treatments. So the rationale is to observe the changes in PEFR among asthmatic patients with cold chest pack with a control group under conventional medicine.

# 2.0 AIMS AND OBJECTIVES

**Aim:**

To evaluate the effect of Cold Chest pack on pulmonary changes in patients with Bronchial asthma.

**Objectives:**

To observe the changes in PEFR while applying Cold chest pack in Bronchial asthmatic patients.

# 3.0 REVIEW OF LITERATURE

## 3.1 BRONCHIAL ASTHMA

Asthma is a chronic inflammatory disease characterized by symptoms (dyspnoea wheezing, chest tightness and coughing), airway inflammation, reversible airflow obstruction, bronchoconstriction, airway hyper reactivity (AHR), influx and activation of inflammatory cells, plasma exudation, increased mucus production and airway remodeling[26]. This disease triggered by mast cells activated via immunoglobulin E (IgE)-mediated allergic challenge.

Studies of allergic lung inflammation have identified a number of effector cells and their mediators. It involves the activation of many cells like mast cells, macrophages/monocytes, eosinophils, T-helper type-2 lymphocytes (Th2), dendritic cells, basophils, neutrophils and platelets (inflammatory) and epithelial cells, smooth muscle cells, endothelial cells and fibroblasts (structural) are all capable of synthesizing and releasing inflammatory mediators[27]. Activation of these cells by allergen leads to release of inflammatory mediators like cytokines, prostaglandins (PGs), leukotrienes (LTs), interleukins (ILs) and thromboxane (TXA2)[28]. Several previous studies have emphasized the role of these mediators in the pathogenesis of allergic inflammation and asthma. In addition, there is increasing clinical and experimental evidences suggest that excess production of reactive oxygen species and defective endogenous antioxidant defense mechanisms may be present in asthma[29, 30]. It is a multifactorial disease process associated with genetic, allergic, environmental, infectious, emotional, and nutritional components.

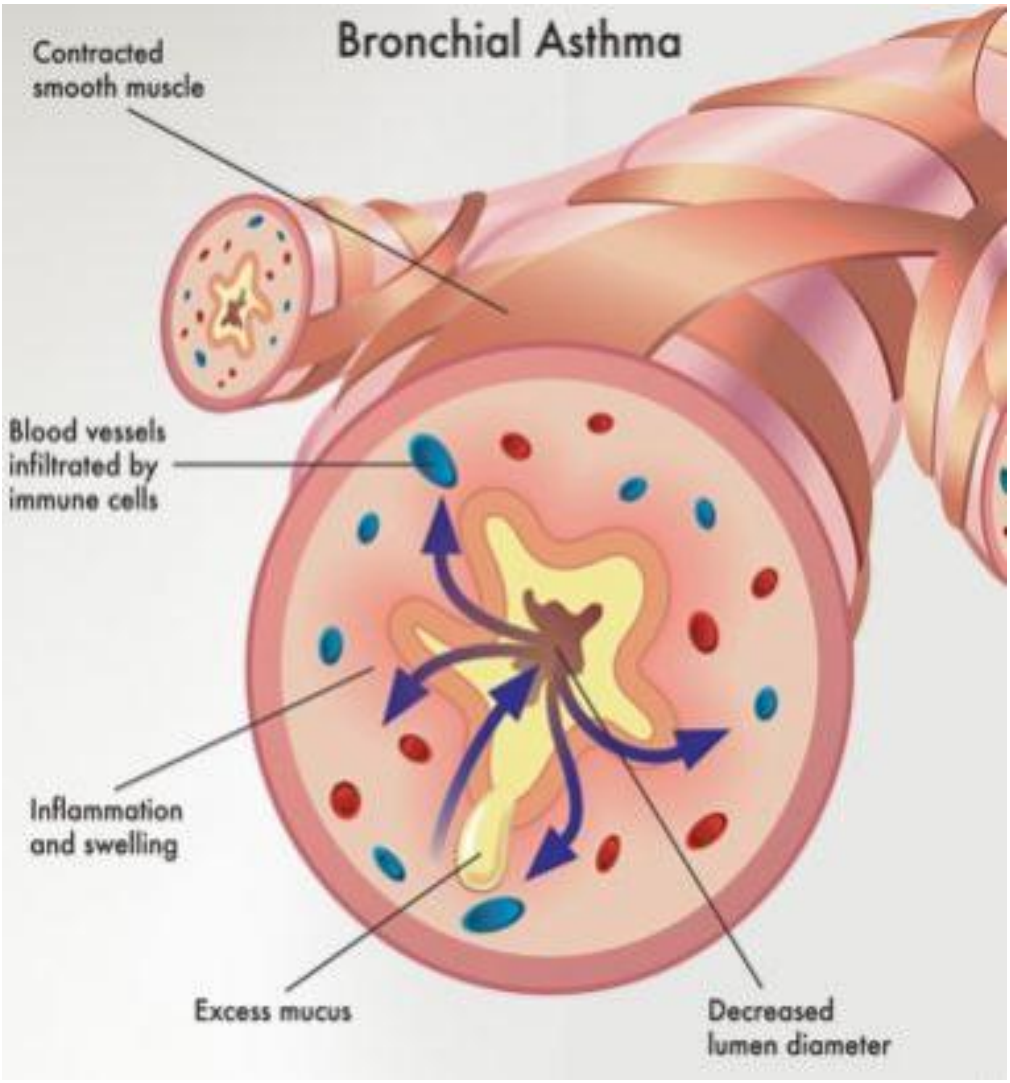


**Figure 3.1: Illustrated manifestation of Asthmatic Airway**

## 3.2 PREVELANCE OF BRONCHIAL ASTHMA

Millions of people have allergic diseases. It is estimated that 20% of all Americans have either rhinitis, asthma, or other allergic diseases[31]. Bronchial asthma is one of the most common illnesses in the western world. Asthma affects approximately 8% of the world's population[32]. In United States the prevalence is 71%.

Approximately 5,000 people die each year due to asthma. Across racial and socioeconomic groups, the death rate from asthma mirrors the incidence, with African-Americans having the highest mortality from this disease. The death rates for asthma are higher in the inner city and in lower socioeconomic groups.

The exact cause of this difference might be due to genetic, socioeconomic, and/or access to the health care issues. Direct costs (doctors' visits, hospitalization, drugs, etc.) and indirect costs (work and school absenteeism, etc.) of asthma vary, depending on the reference, but are estimated to be approximately $6 billion per year[33]. The incidence of asthma and the morbidity and mortality caused by asthma have increased during the last 30 years in developed countries despite the advent of new drug treatments and increasing awareness of the need for better disease management[34]. Prevalence varies from region to region depending upon the definition used for diagnosis of asthma[35].

In 2012, approximately 8% or 18.7 million US adults were diagnosed with asthma[36]. The prevalence of intermittent asthma ranged from 23.6% in Alabama to 43.5% in Utah between 2006 and 2010; no specific geographic pattern was identified. The prevalence of asthma is higher among younger adults (18–24 years of age). The prevalence of asthma was 10.3% in the 18–24 year age group, 8.7% in the 25–34 year age group, 8.1% in the 35–44 year age group, 8.5% in the 45–54 year age group, 9.4% in the 55–64 year age group, and 8.1% in the 65 and older age group in 2010[37].

A cross-sectional survey[38] demonstrated that the prevalence of childhood asthma in the cities of Beijing, Chongqing, and Guangzhou was 3.15%, 7.45%, and 2.09%, pointing toward rising prevalence. Behavioral and environmental factors also

play a role. The genetics involved in the eventual development of asthma is complex and incompletely understood[39].

Diagnosed asthma in adults is generally reported as 2.7 to 4.0% in most European countries, 12.0% in England[40] and 9 5 to 17 9% in Australia[41]. The overall burden of asthma in India is estimated at more than 15 million patients[42].

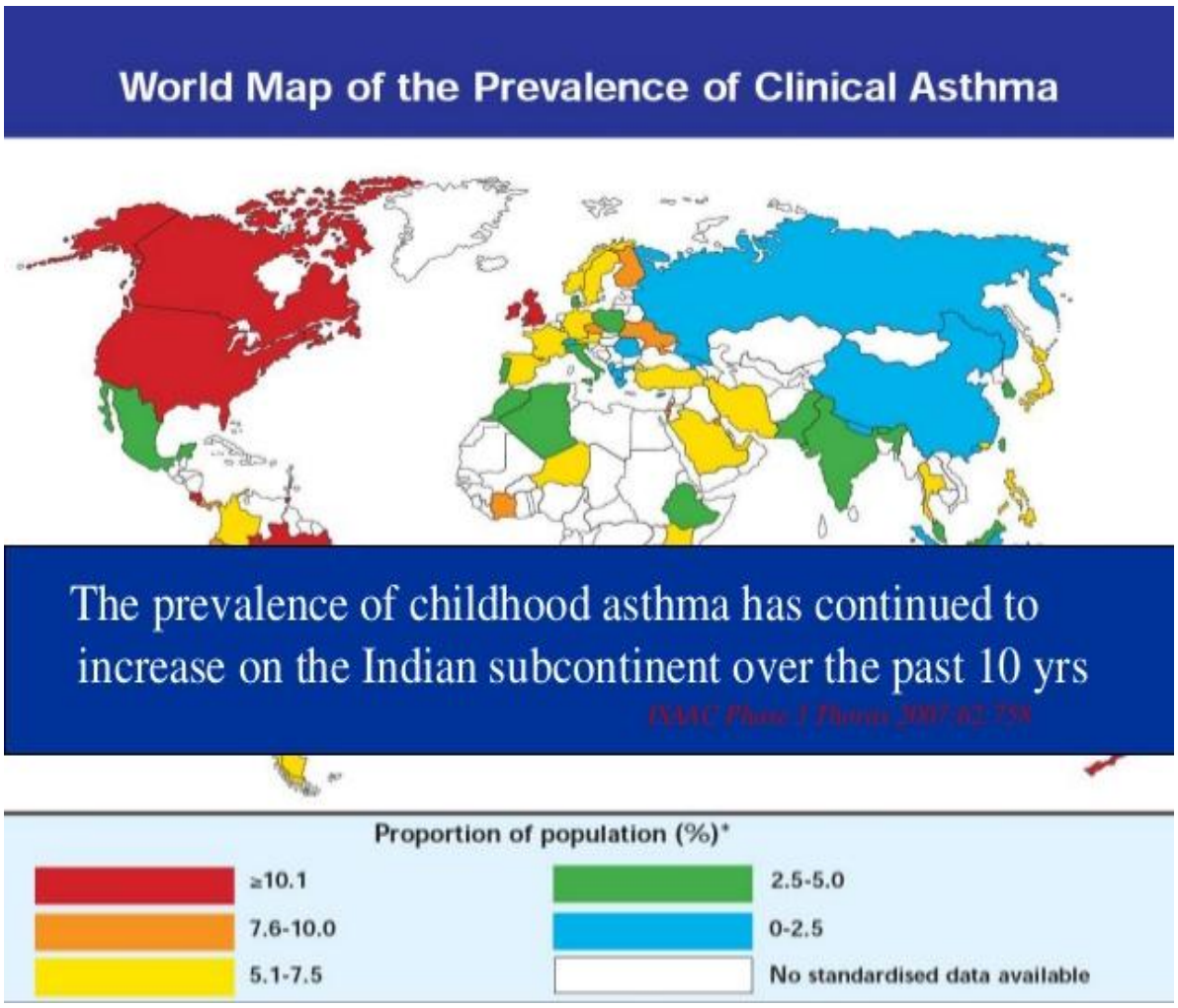


**Figure 3.2: Global Asthma Report and its prevalence**

The following illustration represents the prevalence of Bronchial asthma in India comparing 1990 and 2016

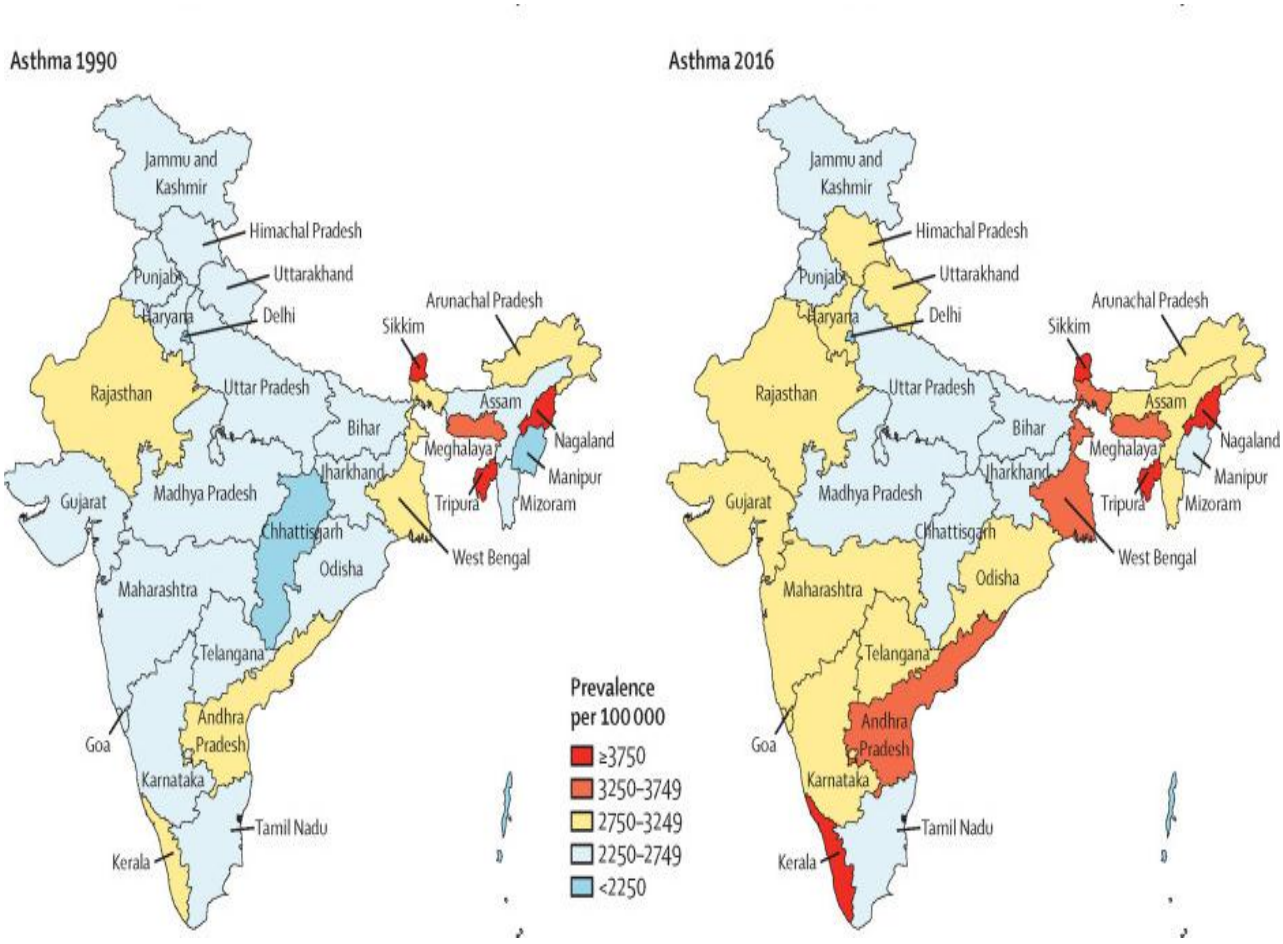


**Figure 3.3: Prevalence of Bronchial Asthma in India (1990 and 2016)**

## 3.3 ETIOLOGY OF BRONCHIAL ASTHMA

Increasing evidence from case control surveys, population studies and allergen avoidance studies suggests inhalant allergy plays an important role in the etiology of asthma[43]. Although an association between inhalant allergy and asthma has been recognized for over 100 years, in many cases it has been difficult to demonstrate cause and effect. This is because in part some asthmatic patients are non-allergic, and even in allergic patients many other factors are known to trigger asthma attacks[44].

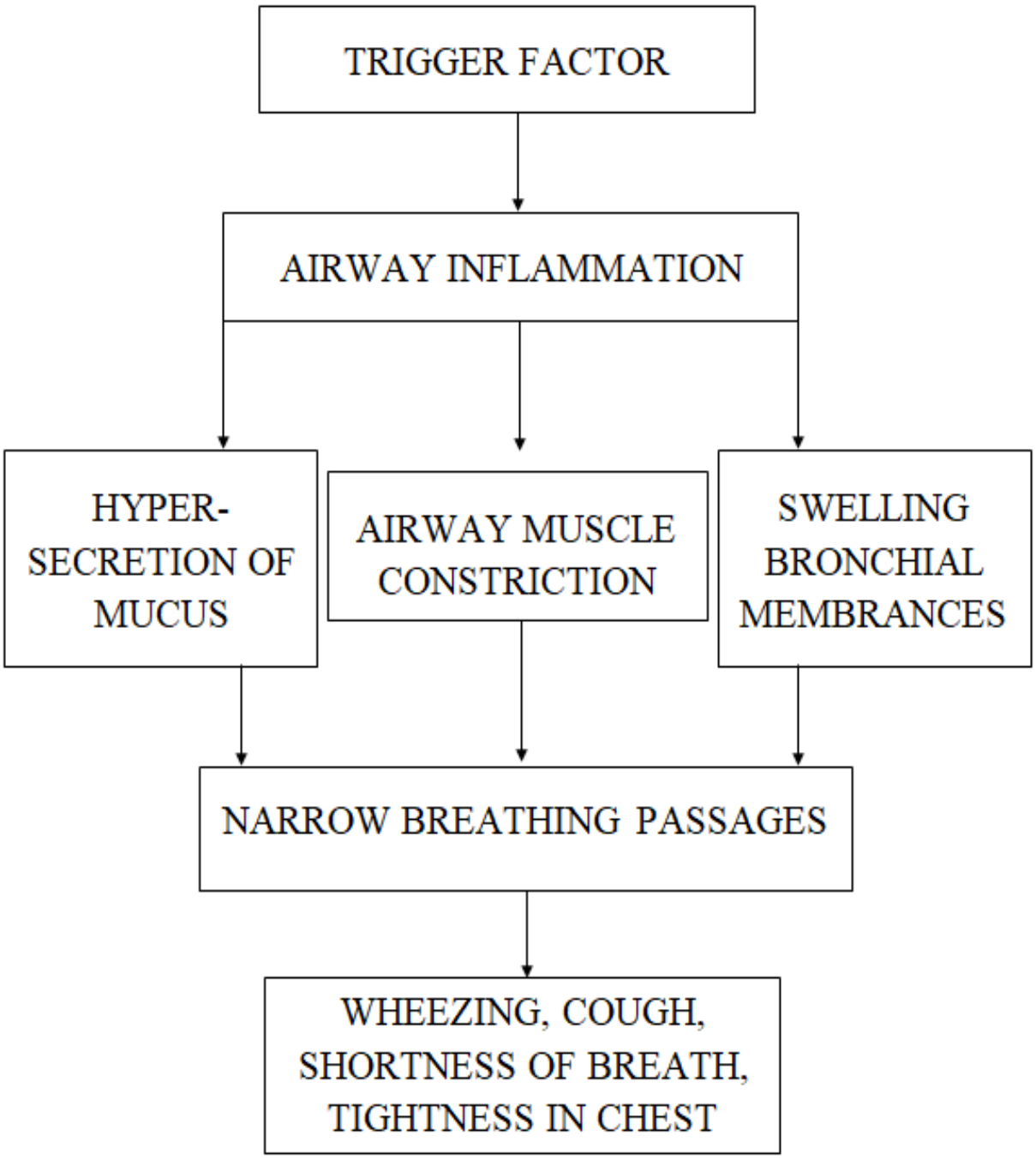


**Figure 3.4: Mechanism of Asthmatic attacks by triggering factors**

Exposure to certain stimuli initiates inflammation and structural changes in airway hyper responsiveness and variable airflow obstruction, which in turn cause most asthma symptoms. There are large numbers of such stimuli; the more important includes environmental, chemical exposure, occupational sensitizing agents, respiratory viral infections and nonspecific irritant inhalation[45].

**Table 3.1: List of agents responsible as triggers in asthma (Chauhan et ah, 1996)**

| LIST OF AGENTS | EVENTS TRIGGERING ASTHMA |
|---|---|
| **ACUTE AIRWAY** | Bacterial: H influenza, S. pneumonia, M Cattarhalis |
| **INFECTION** | Viral Rhinoviruses, Picorna viruses, Respiratory syncytial virus (RSV), influenza A, B, Coronaviruses, Atypical' C Pneumonia |
| **ALLERGENS** | Air born pollens (grass, trees, weeds), house-dust mites (Dermatophagoides pteronyssinus), animal dander, cockroaches and fungal spores |
| **ENVIRONMENT** | Cold air, fog, ozone, sulfur dioxide, nitrogen, tobacco smoke and wood smoke |
| **EMOTIONS** | Anxiety, stress, laughter |
| **EXERCISE** | Particularly in a cold, dry climate |
| **DRUGS/PRESERVATIVES** | Aspirin, NSAIDs, sulfites, benzalkonium chloride, p-blockers |
| **OCCUPATIONAL STIMULI** | Bakers (flour dust), farmers (hay mold); spice and enzyme workers, printers (arabic gum); chemical workers (azodyes, anthraquinone, ethylenediamme, toluene, diisocyanates, PVC); Q plastics, rubber and wood workers (formaldehyde, western cedar, dimethylethanolamine, anhydrides |

## 3.4 RISK FACTORS OF ASTHMA

- Exposure to tobacco smoke
- Previous allergic reactions, including skin reactions, food allergies or hay fever (allergic rhinitis)
- A family history of asthma, allergic rhinitis, hives or eczema
- Living in an urban area with increased exposure to air pollution
- Low birth weight, Obesity
- A chronic runny or stuffy nose (rhinitis)
- Severe lower respiratory tract infection, such as pneumonia
- Inflamed sinuses (sinusitis)
- Heartburn (gastroesophageal reflux disease, or GERD)
- Being a male[46].

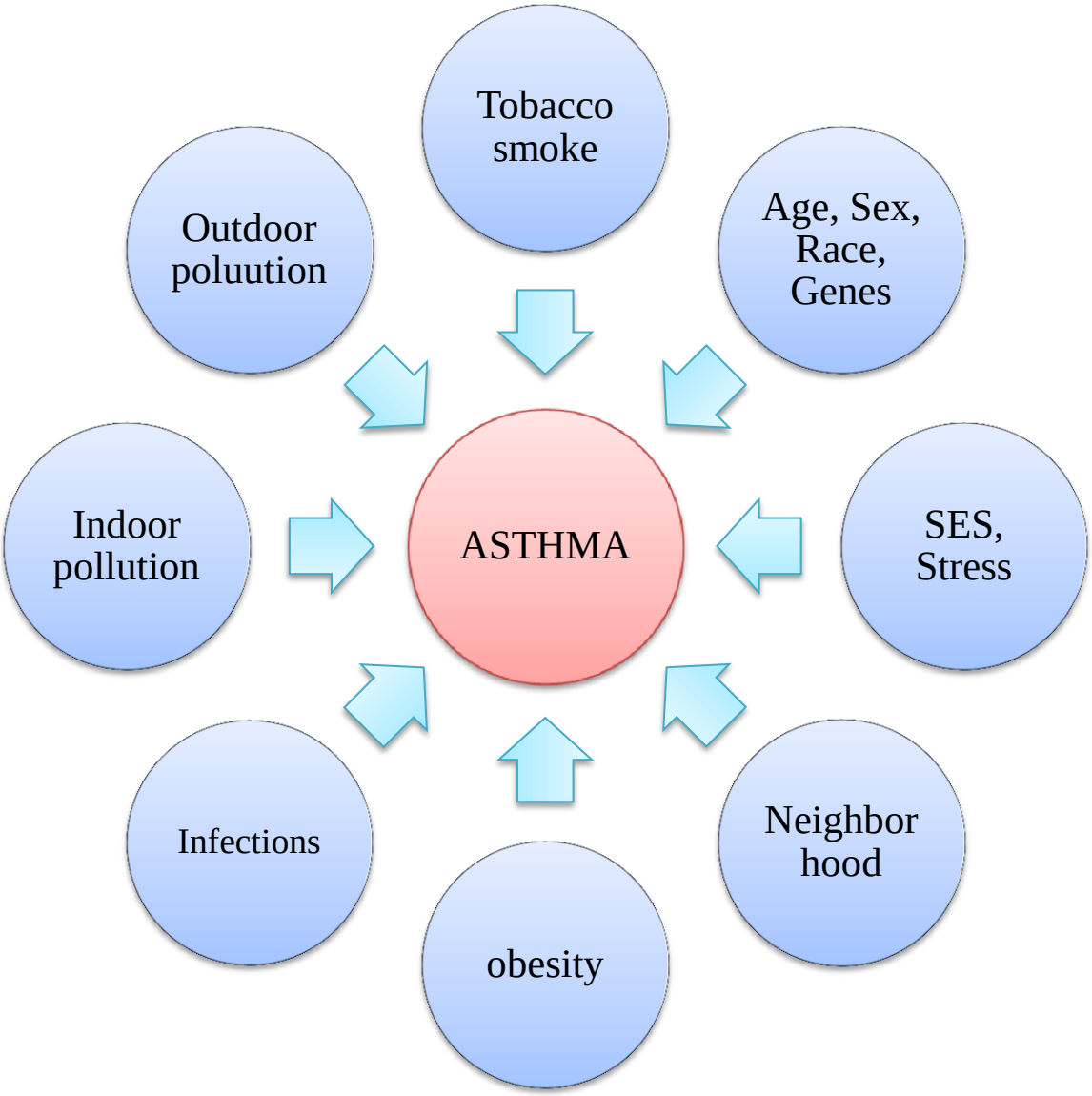


**Figure 3.5: Risk Factors in Asthma**

## 3.5 SYMPTOMS OF ASTHMA

- Shortness of breath
- Rapid breathing
- Spasmodic  cough
- Severe wheezing
- Anxiousness
- Difficulty in talking
- chocking sensation
- Tightness in neck muscles
- Blue lips and / fingernails
- Tightness in chest
- Pale and sweaty face

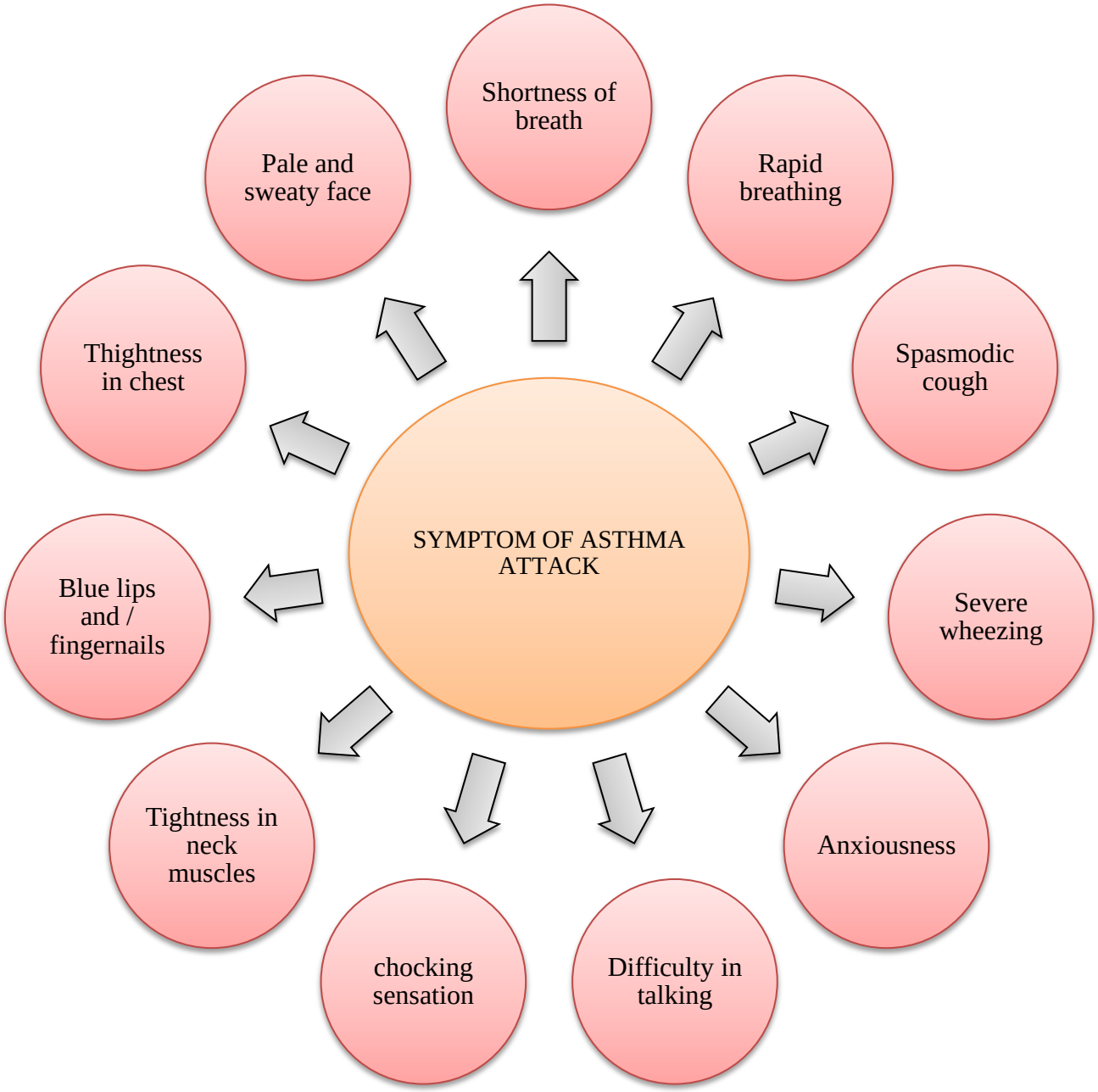


**Figure 3.6: Symptoms of Asthmatic Attack**

## 3.6 MECHANISM AND PATHOLOGICAL COMPLICATIONS BEHIND ASTHMA

The respiratory system[47] plays a major role in exchanging gases in the body. It brings oxygen to the lungs and disposes of carbon dioxide. With every breath, air enters the body via the mouth or nose and moves down towards the lungs through the airway. The airway leads to the chest, where it splits into two – the bronchiole. Each of the bronchiole splits into smaller tubes until they reach the nodes in the lungs. If the bronchioles are blocked, less oxygen reaches the lungs, resulting in respiratory problems. The lining of the bronchiole has a number of glands which secrete mucus. During an asthma attack the bronchiole contracts (bronchospasm) while the lining expands and fluids build up, further constricting the airway. In many cases, the asthma attack occurs after exposure to stimuli. These stimuli are called allergens. Sometimes, the attack is the result of exercise or other agents that are not directly connected to an allergic reaction. Viral infections also cause asthma attacks.

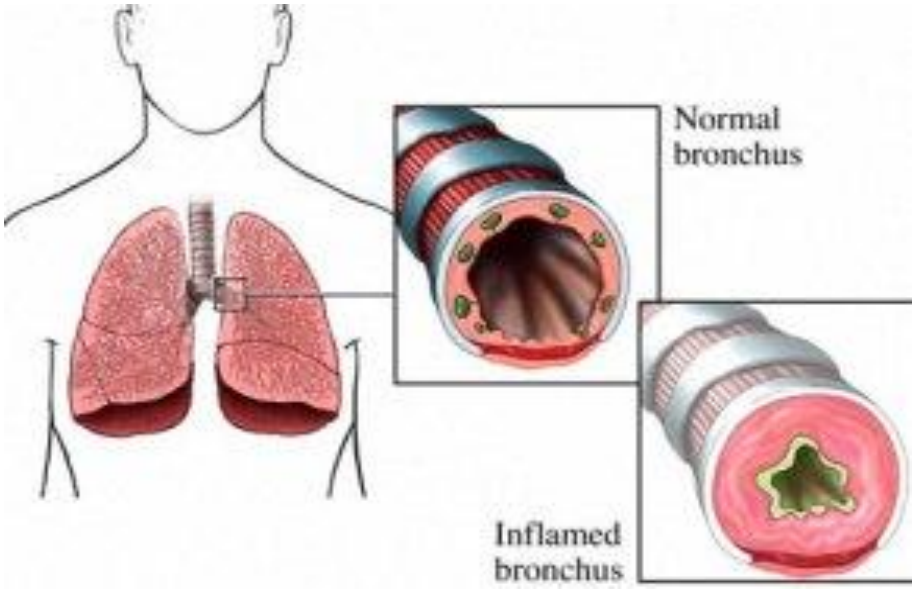


**Figure 3.7: Illustration of Bronchial Asthma**

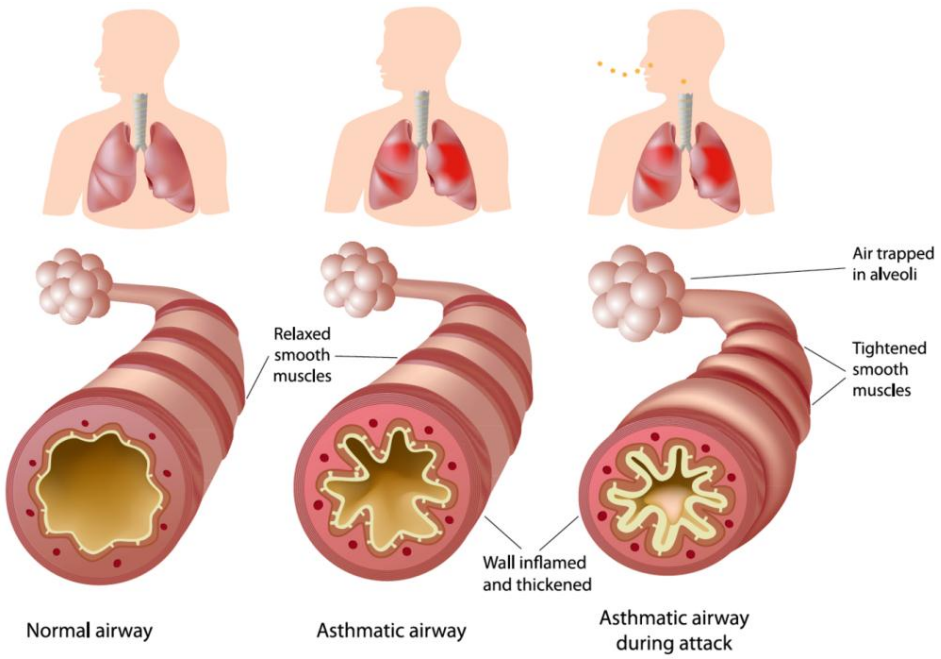


**Figure 3.8: Pathology of Asthma**

When a person with asthma suffers from an asthma attack[48], the attack happens in two stages. During the first stage, the muscles surrounding the airways contract and mast 34 cells are released. Afterwards, the second stage of inflammation begins. A large number of inflamed cells build up in the airway and release substances which worsen the constriction of the surrounding muscle and cause a build-up of fluid in the lining of the bronchiole. The inflammation worsens over a period of time and if left untreated, can become chronic and cause irreparable damage to the airways. Asthma is an overreaction to various stimuli. This overreaction can happen extremely quickly. The asthma attack causes three reactions: constriction of the airways, thickening of the inner lining and secretion of sputum into the airways. Together, these three reactions block the airways, making it difficult to breathe and it results in shortness of breath. Children's airways are smaller than adults, which makes their asthma attacks more severe[49].

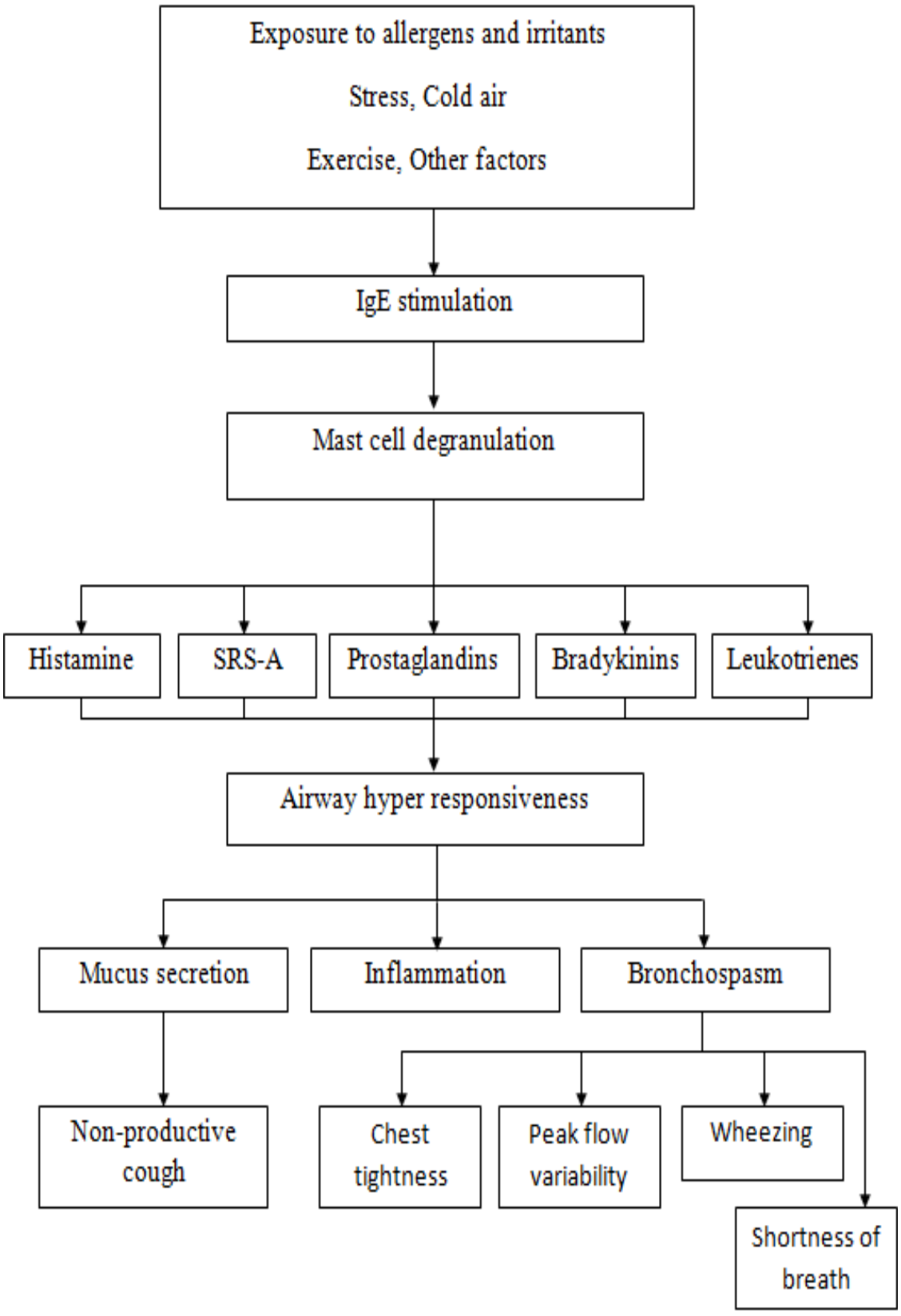


**Figure 3.9: Mechanism behind Asthma**

The pathophysiologic basis of asthma is not clearly understood. It appears to have complex, multifactorial etiology which results from an interplay of many hereditary factors and more number of environmental factors. Bronchial biopsies from patients with even mild asthma have marked evidence of chronic inflammation, and cytokines and other mediators of inflammation are well found in bronchial washings from asthma patients. Some families are more prone to development of allergies, and there is a well-known co-relation between allergies and asthma.

This suggests a genetic predisposition, but it appears that a number of genes are involved in this mechanism. Allergic reactions are mediated by antibodies of IgE class. People who are prone to IgE-mediated allergic reactions are said to be "atopic" meaning, they have a genetic predisposition to make IgE antibodies in response to certain allergens. While allergic reactions are mediated by IgE antibodies, T and B lymphocytes play an important role in production of IgE. There are two different types of T helper cells (Th lymphocytes) designated Th1 and Th2.

Th1 cells tend to promote cell-mediated immune responses by producing cytokines like interferon-gamma, interleukin-2 (IL-2), and TNF-β. In contrast, Th2 cells promote the production of IgE antibodies by producing IL-4 and IL-13, which are interleukins that act on B lymphocytes (B cells) to promote the production of IgE antibodies to a specific antigen. People who are prone to develop allergies, i.e., atopic people, believed to have a higher ratio of Th2/Th1 cells, and this is believed to be an important factor in the tendency to produce allergy-mediating IgE antibodies. These observations are evidently relevant to asthma, since biopsies of the bronchial mucosa of patients with asthma have surplus of activated Th2 cells. These observations

indicate that an imbalance in Th2/Th1 plays an important role in the development of allergies and, specifically, of asthma.

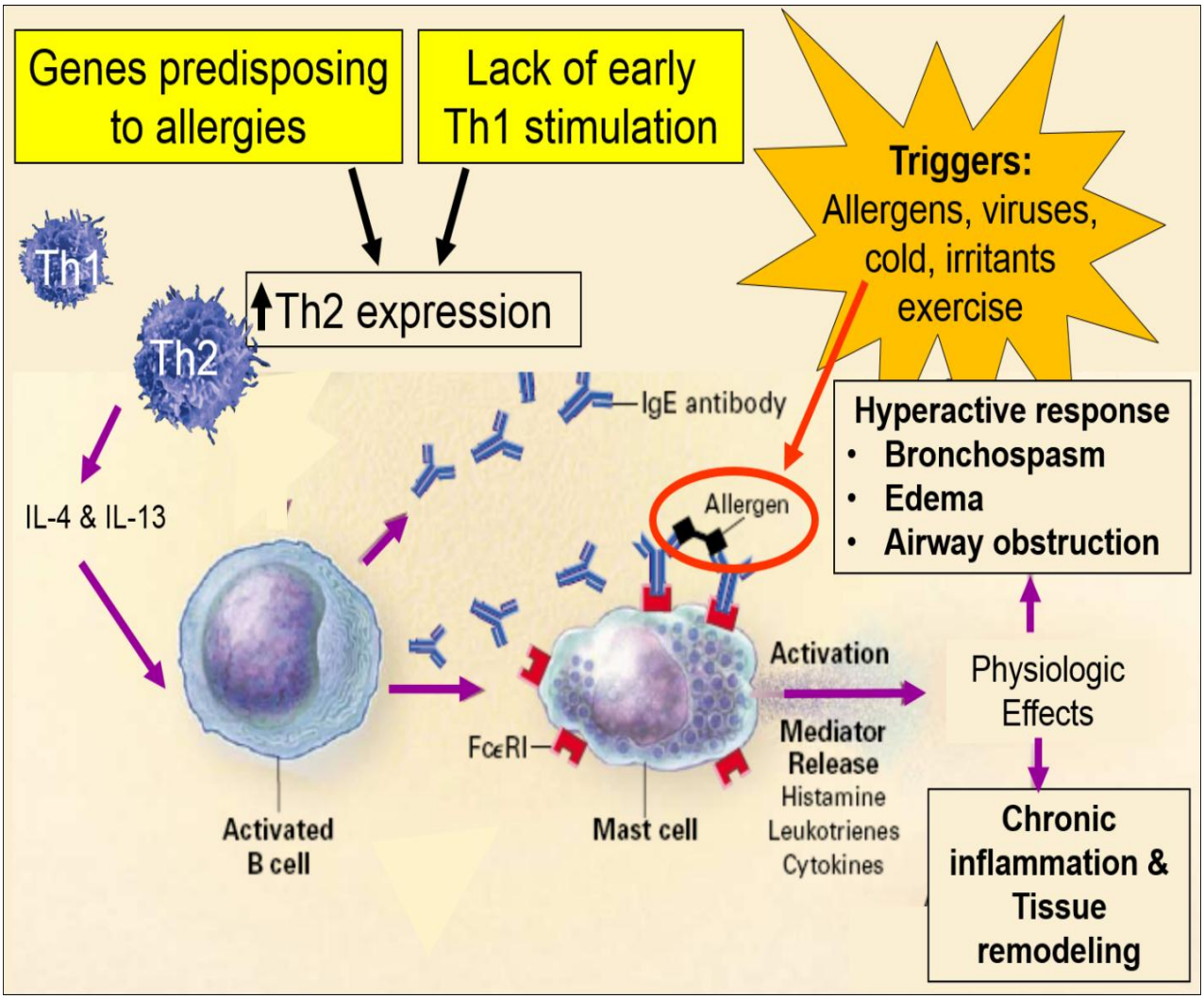


**Figure 3.10: Mechanism and Pathophysiology behind Asthma**

Cold chest pack[50] along with hot foot and arm bath for bronchial asthma is clinically used in naturopathy to relieve pulmonary congestion, decrease pulmonary mucous membrane irritation and increase the depth of respiration. Cold chest pack increased peak expiratory flow rate as an immediate effect in bronchial asthma

patients. Cold chest pack along with hot foot and arm bath in bronchial asthma patients is believed to reduce pulmonary congestion, decrease pulmonary mucous membrane irritation and increase depth of respiration.

Naturopathy along with other treatment modalities uses cold chest pack as the first line of treatment in the management of various disorders. The chest pack is used in pulmonary congestion, pulmonary tuberculosis, chronic bronchitis, chronic pneumonia, chronic pleuritis, pulmonary hemorrhage and threatened cardiac failure [51]. Quinlan[52] et al., (2002) study showed spa therapy improved ventilator function in steroid dependent intractable asthma. Sathyaprabha[53] et al., (2001) made a study on naturopathic intervention (included massage, hydrotherapy, colour therapy, fasting and diet therapy, mud and yoga therapy) in bronchial asthma patients showed significant improvement PEFR, vital capacity, forced vital capacity, forced expiratory volume1, FEV/FEC%, Maximum voluntary ventilation and absolute eosinophil count.

Though cold chest pack has been extensively used in clinical scenario both for rejuvenation as well as therapy, its underlying mechanisms are less understood. There are no previous studies on the effect of cold chest pack on heart rate variability specifically as such. It is essential to understand the underlying mechanisms of cold chest pack on autonomic nervous system before applying them as therapeutic agents.

### 3.7 ASTHMA SUBTYPES

Asthma is triggered and aggravated by many different sources. Subtypes of the condition can be described demographically by age of onset, type and place of exposure, and in terms of the pathophysiology of the underlying inflammation.

Asthma has been classified according to age (childhood-onset and adult onset asthma). Childhood-onset asthma begins during childhood with a peak prevalence of 10% among children 5–9 years of age[37]. The "allergic triad" includes asthma, atopic dermatitis, and allergic rhinitis, and there seems to be some progression from atopic dermatitis and food allergy during infancy to asthma and/or allergic rhinitis during childhood[38]. Approximately 58% of all children with asthma are expected to have complete resolution of symptoms by adulthood, and 11% will continue to have infrequent episodic asthma[39]. Male gender was a significant predictor of asthma remission[54]. Adult-onset asthma refers to persons older than 20 years of age. Asthma diagnosed among young adults is associated with cold-air bronchial hyper-responsiveness at 6 years of age, late-onset and persistent wheezing by 6 years of age, and female gender[54].

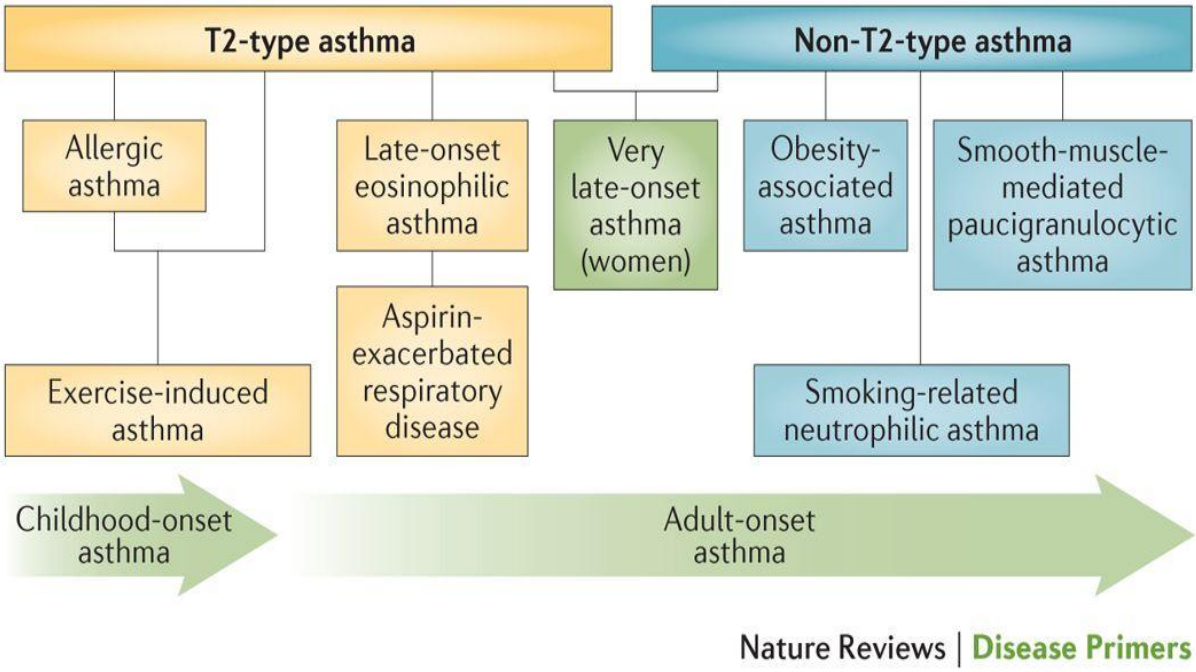


**Figure 3.11: Subtype classification based on age of onset**

Asthma may also be classified based on the location of the exposure. Work-related asthma (WRA) includes work-exacerbated asthma (pre-existing or concurrent asthma worsened by factors related to the workplace environment) and occupational asthma (new-onset asthma attributed to the workplace environment) [55]. The route of inflammatory response also defines asthma. Allergic asthma is mediated by immunoglobulin E (IgE) reactions to airborne allergens. Common IgE-mediated allergens have been identified from dust mites, pet dander, cockroaches, molds, and grass pollens[56]. Symptoms usually begin before the 20th birthday and are usually not severe and do not progress; however, heavy exposure can cause acute severe or even fatal reactions[57].

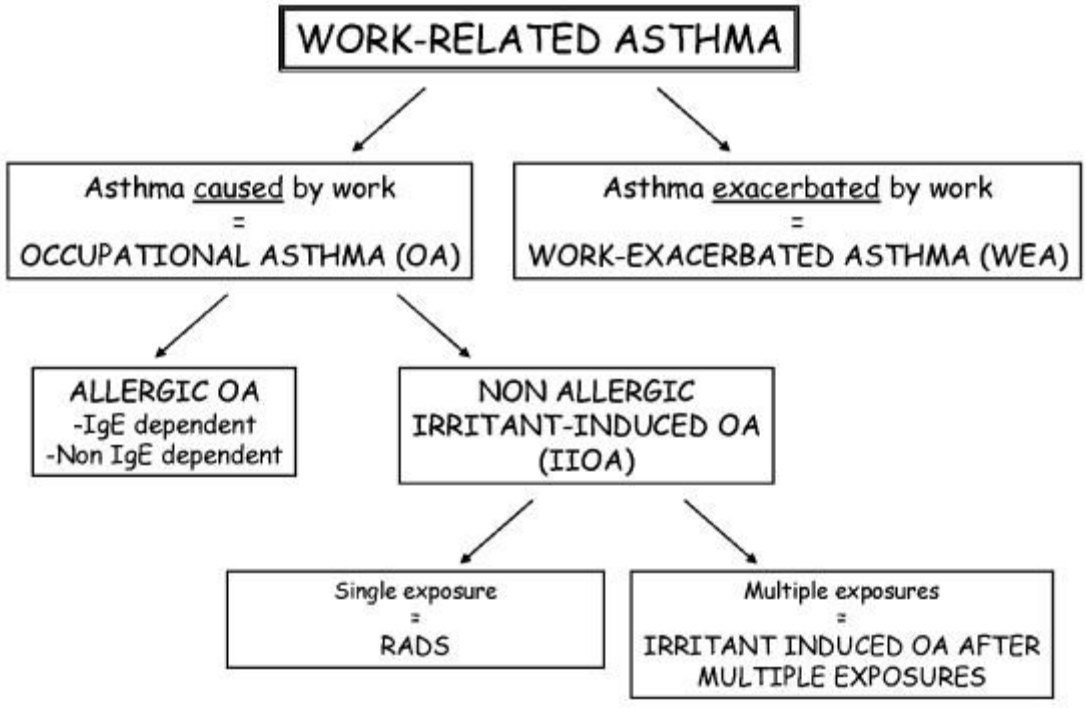


**Figure 3.12: Subtype classification based on location of exposure**

Intrinsic or non-allergic asthma is defined as that which does not involve an identified IgE response[58]. This type is more common in middle-aged and older adults. Compared with allergic asthma, intrinsic asthma is more persistent, and it is more likely to progress in severity and to become irreversible Irritant asthma is caused by a non-corrosive chemical that directly causes inflammation of both the upper and lower respiratory epithelium[59].

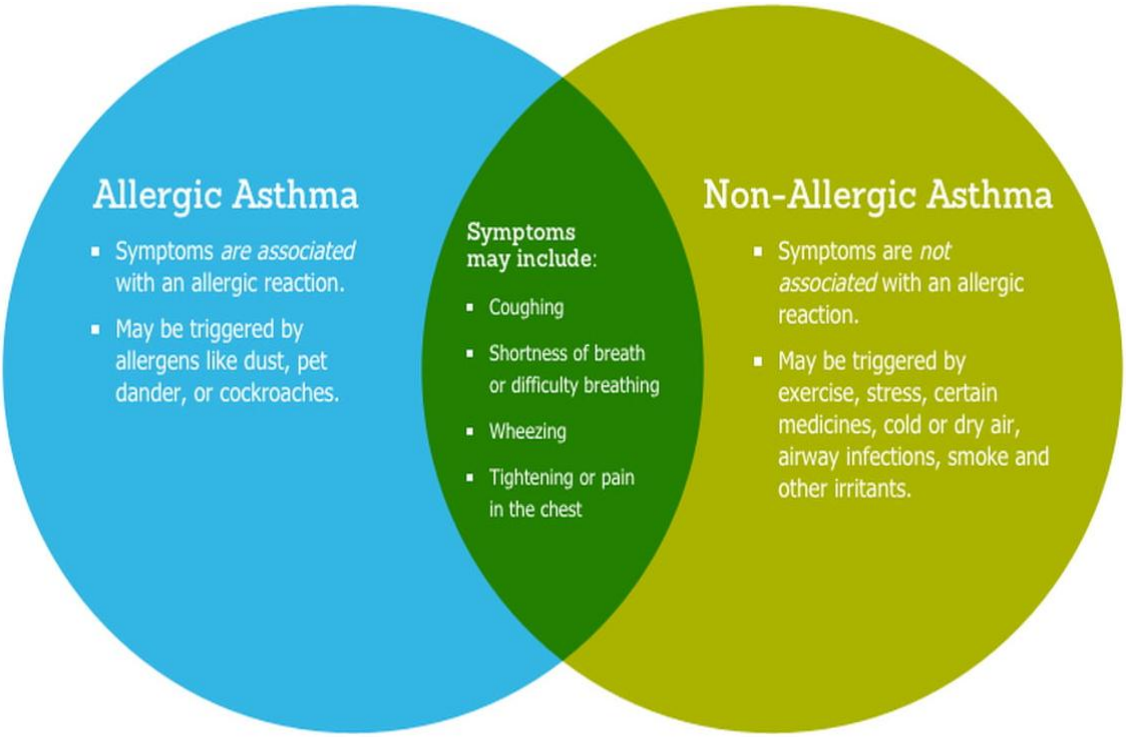


**Figure 3.13: Subtype classification based on response to inflammation**

Irritants include a wide variety of chemicals that are found in the home, workplace, and outdoor environment. Examples of irritants include solvents found in paints and glues, chlorine, bleach, and ammonia in household cleaners, hydrochloric and sulfuric acid, floor sealants, formaldehyde, capsaicin found in hot peppers, and metal-working fluids[59]. Common outdoor air pollutants are byproducts of fuel

combustion and include ozone, fine particulate matter, nitrogen dioxide, and sulfur dioxide[60].

Asthma can also be exacerbated by other extrinsic physical factors. Exercise-induced bronchoconstriction (EIB) is defined as the transient narrowing of the lower airways that occurs after vigorous exercise. EIB may occur in persons with or without the diagnosis of chronic asthma. The diagnosis of EIB usually requires a 10%–15% decrease in post-exercise forced expiratory volume in 1 s (FEV1) (pulmonary function test) compared to pre-exercise value[61].

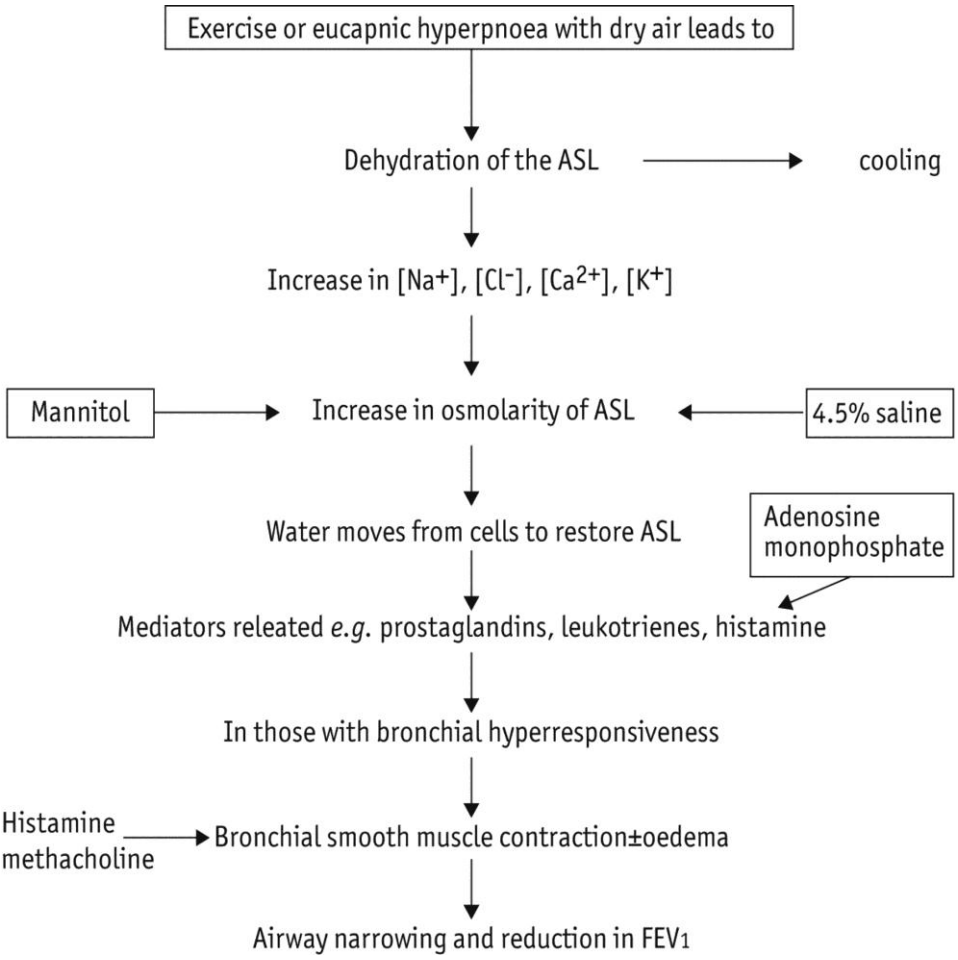


**Figure 3.14: Exercise-induced bronchoconstriction (EIB)**

## 3.8 CONTROL OF ENVIRONMENTAL TRIGGERS

Patients with asthma symptoms should be assessed for triggers that affect their condition. Skin testing or serum analysis of the IgE response to panels of common allergens can help to identify specific causes. If a single source of allergen reactivity is identified from testing, then one should consider allergen immunotherapy[62]. Potential environmental triggers to asthma are identified with the use of questionnaires.

A review of the literature has not identified any specific environmental questionnaires available that have been validated in controlled studies. Home intervention programs are focused on instructing patients how to reduce exposure to indoor allergens and respiratory irritants[62]. Home investigators can also be trained to identify sources of triggers and implement low cost ways to decrease exposure. Evidence-Based Review reducing home allergen content from house dust mites, cockroaches, animal dander, and mold have been developed[56].

Other common home irritants include exposure to paint, glue solvents, household cleaners, pesticides, and tobacco smoke. Use of a gas stove with poor ventilation and wood burning stoves can also be a large contributor of particulate irritants in home[56].

The following Figure illustrates the common environmental triggers responsible for bronchial asthma.

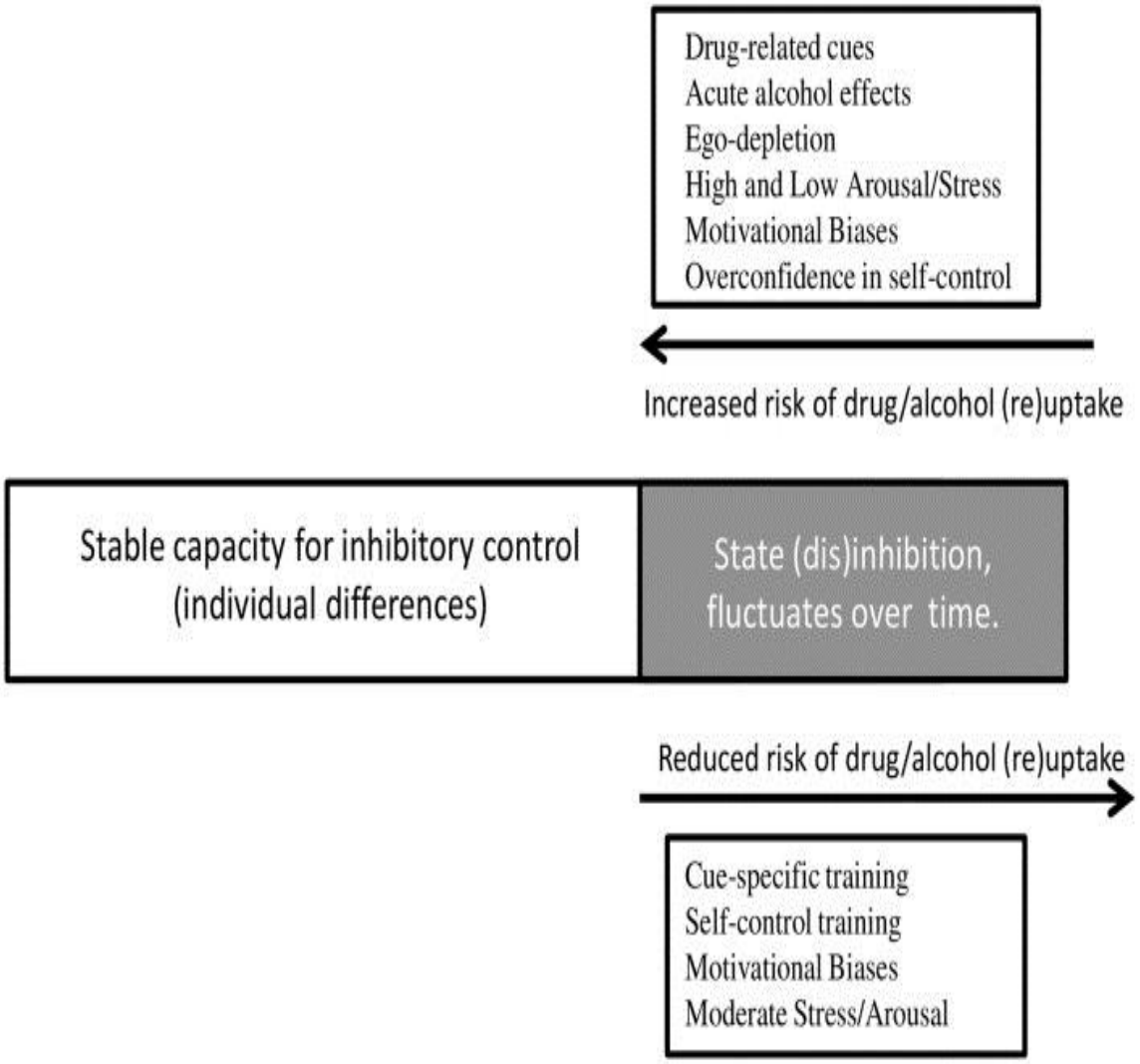


**Figure 3.15: Common Environmental Triggers responsible for Bronchial Asthma**

## 3.9 ALTERNATIVE TREATMENT OPTIONS FOR TREATING ASTHMA

### Yoga

One of the fundamental philosophical tenets of Yoga[63], which means "union" (of body and spirit) and is an ancient Indian meditative exercise technique, is that the breath is the most important bodily function that needs to be controlled. The Sanskrit word for breath is "prana" which also means life force or spirit. Thus, control of the

breath is crucial for optimal health and wellbeing, and a good place to start when life or health is out of balance. Breathing exercises are extremely helpful for asthmatics because they strengthen respiratory muscles, eliminate inefficient use of accessory muscles of respiration (such as abdominal or neck muscles), replace forceful breathing, which compresses airways, with relaxed breathing it can reduce hyperventilation, by increasing expiration it can reduce the sensation of breathlessness, by increasing the functioning of the diaphragm it can enhance clearing of airways and it can give the confidence to withstand breathlessness.

To help control an acute asthma attack, the patient should be asked to sit leaning forward with their head on their arms that should rest on a table. Alternatively, the patient can try lying semi-prone, with arms and legs slightly bent and relaxed, body and limbs well supported by pillows.

**Light Therapy**

Light therapy stated by Dr. Richard Brouse, a chiropractic physician, biochemist, certified clinical nutritionist, teacher, and author, says, 'The gentle heat of far-infrared helps to detoxify the body, promotes relaxation, and improves circulation[64]. It can also help ease the pain and symptoms of problems such as arthritis, allergies, asthma, injuries, and diabetes. In almost every instance, it seems to reduce pain and speed the healing process. Again, thousands of people have reported wonderful benefits from the use of the Hot house and many after using it the very first time. Trying to describe what this complete therapy feels like is comparable to trying to describe your most wonderful vacation you were on to your best friend. Words can't describe it, and you need to experience it.

**Siddha medicine**

The leaves of the Justicia adhatoda[65] plant contain the alkaloid, vasicine (C11H12N2O), which is responsible for low-level, persistent bronchodilatation, and an essential oil which is chiefly responsible for expectorant action. The leaves and roots contain other alkaloids vasicinone, vasicinolone, and vasicol which may contribute to the bronchodilatory effect through anticholinergic action on the vagal innervations of the bronchi. The bronchodilation effect is considerably increased after atropine administration. Studies have also shown Vasa to be effective in the treatment of amlapitta (dyspepsia) and pyorrhea. In vitro growth of several strains of Mycoplasma tuberculosis was inhibited by the essential oil at concentrations in the range of 220 g/mL. There has also been a report of thrombopoetic (platelet-increasing) activity with vasicine. Traditional Uses: The juice expressed from the leaves and the decoction of the leaves and roots are useful in asthma, bronchitis, and other chronic coughs. Dried leaves are used in dhoomapana (smoking) in the treatment of bronchial asthma. The leaf decoction is an excellent expectorant when decocted with punarnava (Boerhaavia diffusa) and then combined with ginger juice and black pepper. Another effective preparation for the treatment of asthma is the decoction of vasa, guduchi (Tinospora cordifolia), and kantakari (Solanum surratense) mixed with honey. Vasa have also been used to treat skin conditions by combining it with triphala and using the decoction both internally and externally. Vasa is also indicated in the treatment of internal hemorrhage, and is used for this indication as a decoction with haritaki, made into a ghrita, or taken alone as the leaf juice.

## Homeopathy

Homeopathy[66], major tenet of homeopathy is the law of similar or like cures like (i.e., a substance can cure in a patient the same set of symptoms it can induce in a healthy individual). A plant, mineral, or other product is chosen on the basis that it would, if given to a healthy volunteer, cause the presenting symptoms of the patient. When given in a much diluted form, the chosen homeopathic remedy should alleviate these symptoms. Currently, there are over 2000 substances known as remedies in the homeopathic Materia Medica. For example, a homeopathic preparation derived from cockroaches may be used to treat a form of asthma characterized by suffocation with an accumulation of mucus. Another manifestation of asthma might be treated with a different preparation. Choosing remedies based on the symptoms rather than the disease itself is an integral part of the holistic approach to treatment by homeopathic practitioners. As the remedy in its pure form would likely have some degree of toxicity, it is diluted and shaken (succussed) in a 1:10 (X or D for decimal) or 1:100 (C for centesimal) dilution in a water-alcohol solution. The higher the dilution is, the more potent is the medicine. Insoluble substances are pulverized and formed into pellets with sucrose and/or lactose. Highly diluted preparations are greater than Avogadro's number and no longer contain the original molecule. The precise mechanism of action of homeopathic medicines on biological symptoms is still unexplained. For many, the lack of a scientific explanation for homeopathic treatments raises questions about its legitimacy. Some believe that complex interactions occur during dilutions that impart a memory of the original substance to the water molecule.

**Massage Therapy**

**Figure 3.16**: **Massage Therapy**

There are many different types of massage[67] as they all have one aspect in common, They are a holistic, alternative treatment. They bring about an effect on all the systems of the body - digestive, detoxification, respiratory, circulatory, lymphatic, endocrine, and nervous systems. It is thought that many of today's health problems arise from stress. However, most people underestimate the effects of a poor diet which leaves the body less able to cope with stress. Stress upsets the delicate balance and homeostasis of all bodily functions; re-establishing this balance requires a holistic approach. Regular massages can be an effective way of calming the whole system, which can be enhanced with certain essential oils added to the massage oil or cream. Hot Stone Massage Therapy has been used for centuries to relax and treat breathing problems. Ancient Ayurvedic therapy with hot river bed stones melts away stress and tension and draws out impurities from the body. Several studies show positive effects when parents massage their asthmatic children; there is less anxiety and a reduction in the stress.

## 3.10 HYDROTHERAPY APPROACHES FOR BRONCHIAL ASTHMA

Hydrotherapy[68] is the use of water for recuperative and healing purposes. Hydrotherapy treatment is largely considered to be the oldest form of medical treatment known to man. Hydrotherapy tubs and other items of hydrotherapy equipment are still used in modern times for a vast range of therapeutic measures. Along with treating diseases and improving wound healing, circulation, relaxation, digestion, and the immune system, hydrotherapy has been proven to be beneficial for people with acne, anxiety, arthritis, asthma, back pain, burns, chronic fatigue syndrome, constipation, depression, and varicose veins etc. The reviewer suggests that the application of water to treat disease has been used throughout history. It is known that Hippocrates (460-375 BC) used hot and cold water in the treatment of multiple disease states

Hydrotherapy is the external or internal use of water in any of its forms (water, ice, steam) for health promotion or treatment of various diseases with various temperatures, pressure, duration, and site. It is one of the naturopathic treatment modality used widely in ancient cultures including India, Egypt, China, etc[69].

Superficial cold application may cause physiologic reactions such as decrease in local metabolic function, local edema, nerve conduction velocity (NCV), muscle spasm, and increase in local anesthetic effects.

At present, hydrotherapy is applied[70] to treat a myriad of diseases including musculoskeletal problems. The majority of the evidence on the effectiveness of

hydrotherapy to treat the described disease states and conditions comes from small case series/reports and subsequent low level evidence

The higher level evidence that was reviewed does not suggest hydrotherapy is effective in treating osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, chronic low back pain, and fibromyalgia or pressure ulcers. There were two papers that did suggest that post ACL reconstructive surgery patients may have better outcomes than those undertaking land-based exercises alone.

The application of hydrotherapy is not always without risk. There are reports in the literature regarding legionella infections, burn, folliculitis and hypersensitivity pneumonitis which were directly related to the hydrotherapy.

Also the major factors affecting $O_2$ transport during immersion at the time of hydrotherapy are temperature and hydrostatic pressure. $O_2$ transport was improved above neutral temperature, because of increase in cardiac output resulting from the combined actions of hydrostatic counter pressure and body heating. Below neutral temperature, $O_2$ transport is altered. At any of the temperatures tested, the pulmonary tissue volume and arterial blood gases were not significantly affected.

Significant decrease in vital capacity (VC) with bath temperature was observed (i.e., VC at 40°C >34°C >25°C). Significant increase in tidal volume (VT) in cold or hot water compared with thermo neutral water (i.e., VT 40°C >34°C< 25°C). Alterations in respiratory muscles functioning might produce variations of the pulmonary volumes as a function of water temperature.

Asthma is a common condition in which inflammation and narrowing of the air conducting tubes may cause intermittent symptoms, possibly limiting activities of daily life. Some adults believe that exercise could trigger an asthma attack. However, research has shown that the adults who exercise may have less chance of having an asthma attack, and taking exercise in water may be more beneficial than taking exercise on land. In this review, we aimed to evaluate the effect and safety of water-based exercise for adults with asthma.

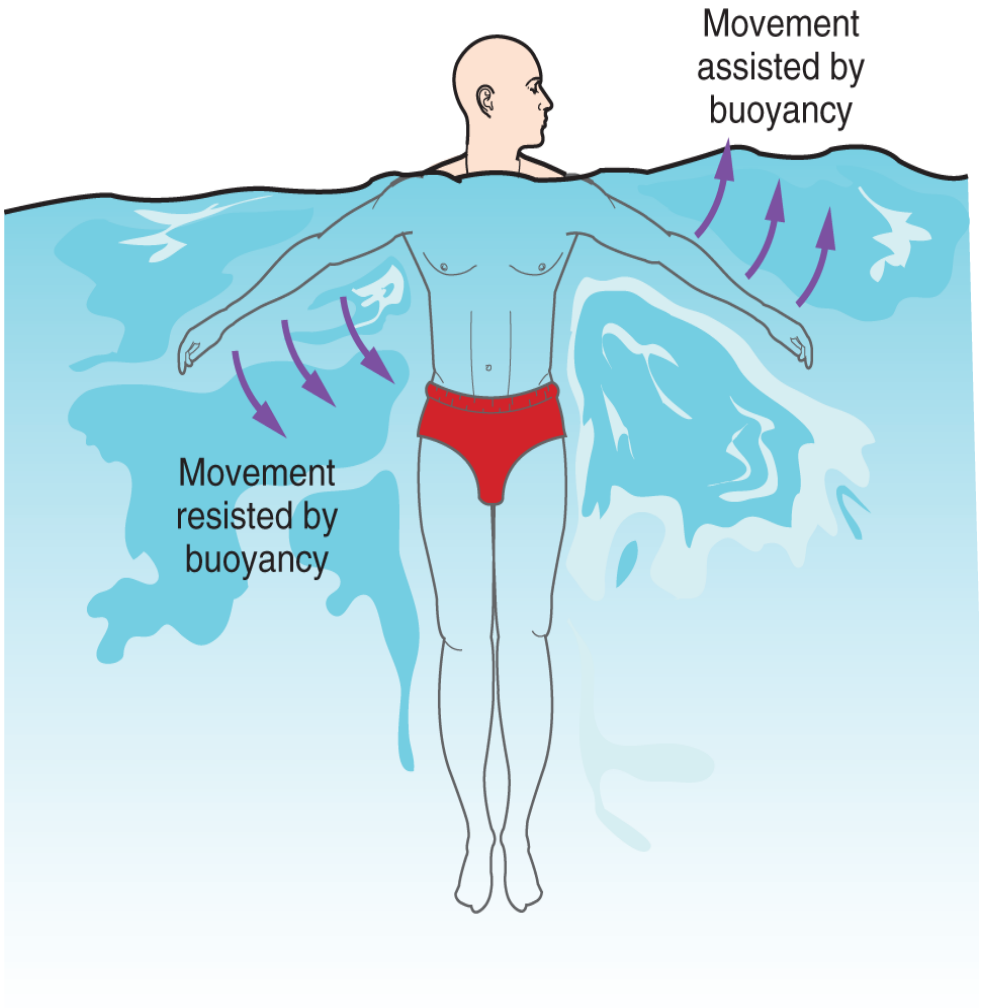


**Figure 3.17: General Hydrotherapy mediated approach involving water exercise**

## 3.11 EFFECT OF COLD CHEST PACK ON PULMONARY FUNCTIONS OF PATIENTS WITH BRONCHIAL ASTHMA

The reversible bronchoconstriction which is characteristic in PEFR, VC, FVC, FEV1, FEV/FEC%, MVV (Maximum Voluntary Ventilation) and absolute eosinophil count. The changes in diet[71], yoga practices[72] and to other patients reported a feeling of well-being, freshness and non-pharmacological externally applied treatments[73].

Hence it was concluded that earliest study on yoga suggested that Transcendental Meditation, Naturopathy and yoga helps in inducing positive health, was a useful adjunct in treating bronchial asthma. A later alleviating the symptoms of disease by acting at physical controlled trial with fifty three patients each in yoga and control and mental levels. A cold chest pack which is used as a treatment of choice in flow rate and decreased weekly attacks of asthma following two weeks of yoga[74].

Singh V[75] et al (1990) evaluated the effect of a single yoga technique (kunjal) and showed definite subjective and objective improvements during the week they practiced yoga well as improved symptoms after three weeks. Apart from yoga, several non-pharmacological treatments have been shown to be beneficial in the treatment of bronchial asthma. The changes in ventilatory function were examined in 37 patients with steroid-dependent intractable asthma (SDIA) following spa therapy[73].

There were significant improvements in Forced Vital Capacity (FVC), Peak Expiratory Flow Rate (PEFR), which suggested that the spa therapy improves the condition of small airways disorder in patients with SDIA. Sathyaprabha[53] et al., (2001) evaluated the usefulness of Naturopathy intervention (a combination treatments including massage, hydrotherapy, color therapy, fasting and diet therapy,

mud application and yoga therapy) in bronchial asthma patients. The results suggested that there was a significant improvement in PEFR, VC, FVC, FEV1, FEV/FEC%, MVV (Maximum Voluntary Ventilation) and absolute eosinophil count. The patients reported a feeling of well-being, freshness and comfortable breathing. Hence it was concluded that Naturopathy and yoga helps in inducing positive health, alleviating the symptoms of disease by acting at physical and mental levels.

A cold chest pack which is used as a treatment of choice in naturopathy along with hot foot and arm bath for bronchial asthma is believed to reduce pulmonary congestion, decrease pulmonary mucus membrane irritation and increase the depth of respiration[76]. Since there are no studies conducted to evaluated the effects of a cold chest pack in isolation on pulmonary functions in bronchial asthma patients, the present study was conducted to evaluate the immediate effect of a cold chest pack on the Peak Expiratory Flow Rate (PEFR) and whether the immediate effect would change after 21 days of treatment with other natural remedies and yogic practices in bronchial asthma patients.

The immediate effect of a cold chest pack application has been related to different factors, viz, (i) Circulatory effects, since the application is believed to cause vasoconstriction of blood vessels in the skin over the chest and (ii) the cold stimulation may also increase overall sympathetic tone, hence bringing about bronchodilation[24]. This is especially important as it is generally understood that there is sympathetic beta receptor hyposensitivity in bronchial asthma, along with a adrenoreceptor hypersensitivity and parasympathetic hypersensitivity[25].

Crapo (1994)[77] had discussed the guidelines for interpretation of pulmonary function tests and suggested that such interpretations depend on the equipment used and patient's performance. Nihlén[78] et al (1999) had explained the need for pulmonary function analysis for three different sets of smoking adults. The author has discussed the clinical importance of lung function analysis for detecting the pulmonary emphysema.

Feyrouz[79] et al (2003) had described how PFTs are used to identify the patterns and severities of abnormality. The authors have analyzed pulmonary function test with some typical examples and concluded that interpretation of PFT has to be towards recognizing the pattern of 11 physiological impairment. Blieden[80] et al (2004) had statistically explained the lung function during exercise. It is shown that obtaining useful information from pulmonary function tests requires both adequate equipment and reproducible performance. A guideline for mechanical lung function measurement was suggested by Miller[81] et al (2005). Lung function measures have been investigated in relation to traffic indices such as proximity to main roads or modeled traffic related pollutants, but again findings in adults are inconclusive and evidence of longitudinal effects lacking[82].

# 4.0 MATERIALS AND METHODOLOGY:

The methodology involved in the following research is described in detail in the above chapter.

## 4.1 STUDY DESIGN:

The study employed Randomized Control Trial study. This intended study is entailed on evaluating the efficacy of 'Cold Chest Pack' in improving the pulmonary functions of patients with bronchial asthma via monitoring PEFR.

## 4.2. ETHICAL CONSIDERATIONS

### 4.2.1 ETHICAL CLEARANCE

Ethical clearance was sought from the Institutional Ethics Committee prior to the start of the study and the approval for the same was granted.

### 4.2.2 WRITTEN INFORMED CONSENT

Subjects who fulfilled inclusion criteria were apprised about the purpose of the study and their rights as research subjects. Informed consent form was administered in English.

As all the subjects understood spoke English, there was no requirement of translating the signed informed consent form into native language i.e., Tamil. Adequate time was given to each patient to go through the information sheet and their queries were answered.

Their right to withdraw anytime from the study and the need for willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent. (A sample information sheet and consent form is enclosed as Annexure 1).

**Figure 4.1: Getting Informed Consent from the patient**

## 4.3 DURATION OF INTERVENTION AND STUDY PERIOD:

The entire duration of Intervention was carried out over a period of 5 days/week for 5 weeks (Therefore a net total of 25 days) and the complete duration of study was observed for a total period of 10 months.

## 4.4 SAMPLE SIZE:

The study comprised a total of 71 study participants. The sample size is categorized under two groups. First group (n=37) represents intervention groups and the remaining 34 belongs under the control group.

## 4.5 SELECTION CRITERIA:

The following intervention study was carried out, by carrying out certain inclusion and exclusion criteria, which is given below.

### 4.5.1. Inclusion Criteria:

- Age **:** 20 to 44 years,
- Gender: Both male and female subjects
- Patients with history of asthma or other typical clinical symptoms associated with respiratory issues
- Willingness to participate in the study.

### 4.5.2. Exclusion Criteria:

While selecting the study participants, there are certain factors that must be observed beforehand. These exclusion factors are:

- Subjects who had participated in another clinical trial in the previous months
- Have received systemic corticosteroids in the previous 2 weeks

- With systemic infection, respiratory infection, pulmonary tuberculosis and fungal infection in the previous 1 month.
- Hospitalization due to acute exacerbation of asthma in the previous 3 months or in the baseline period
- With other severe primary diseases including hypertension, cancer, hyperthyroidism, bronchiectasis, cardiac insufficiency and conditions.

## 4.6 METHODOLOGY:

The methodology involves two groups in this study. A total of 71 patients who were fulfilling inclusion criteria participated in the study. Prior to the retrieval of the informed consent, the PEFR was recorded with base-line measurement and randomizing under 2 groups as stated below with ’37 individuals’ in intervention group and the remaining 34 under the Control group.

Intervention group were given Cold Chest pack for the duration of 30 minutes for 25 days (5 days/week for 5 weeks) along with conventional medicine. Control group will be only under conventional medicine. After 5 weeks, again PEFR was recorded for both groups. Assessments based on the pulmonary function before and after the intervention period determines the efficacy of cold chest pack in treating bronchial asthma.

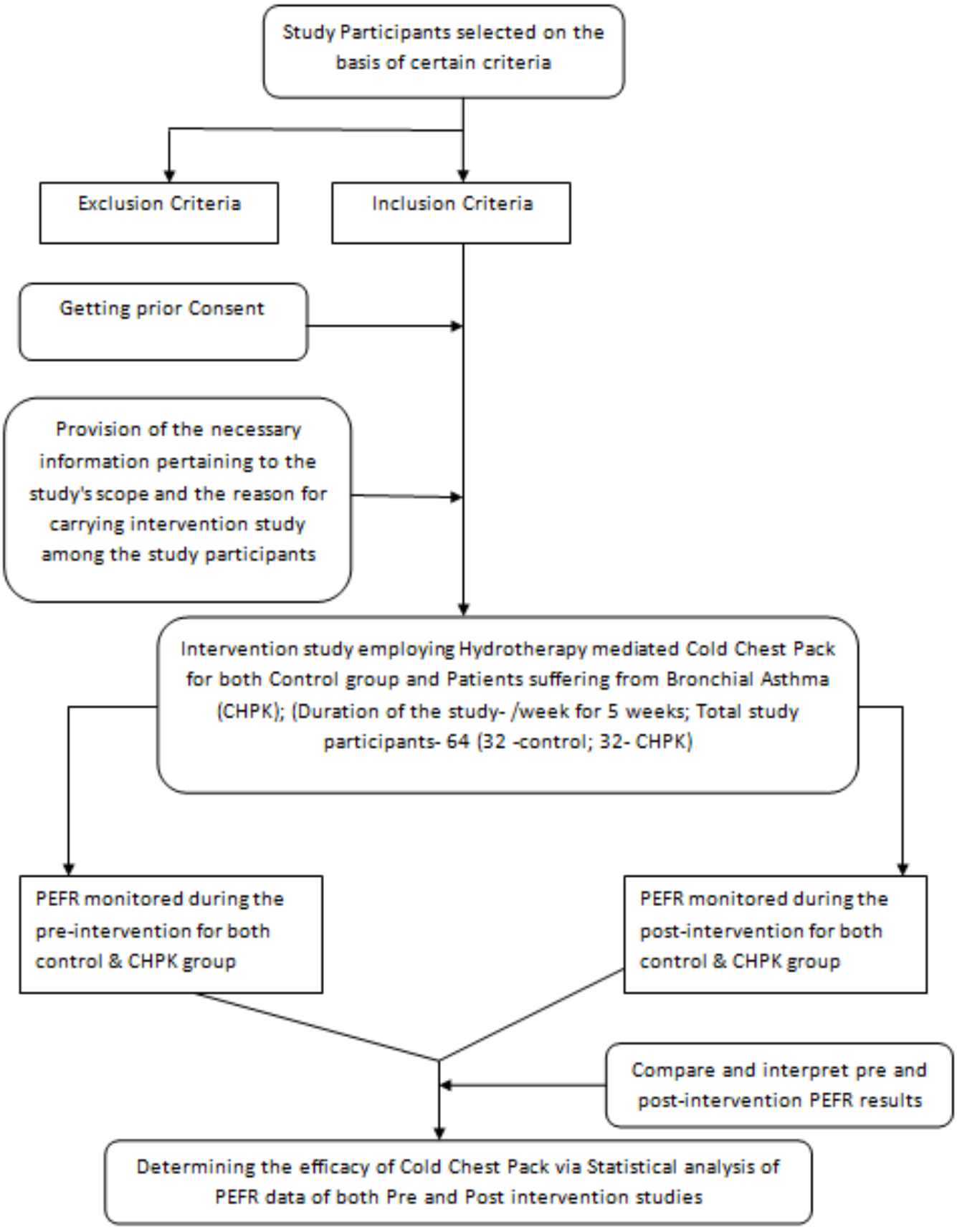


**Figure 4.2: Flowchart representation of Research Methodology**

Out of 71 subjects, 7 subjects discontinued with the practice during different time of the study. All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further treatment. Subjects who are withdrawn from the study were not being replaced.

## 4.7 INTERVENTION PROCEDURE:

Cold Chest back was performed among the study participants in the sessions with a total duration of 30 minutes.

- Patients are made to be in sitting/supine position during the intervention.
- The chest pack, comprised cotton cloth which is approximately 8-10 inches in width, 6-8 feet in length, should be loosely rolled up, dipped into water at $58^{o}F$ - $62^{o}F$, and wrung out without unrolling.
- The bandage is applied in a sort of "figure 8" fashion. ( ***bandage*** applied alternately to two parts, usually two segments of a limb above and below the joint, in such a way that the turns describe the ***figure 8***)
- A flannel bandage of the same width and a little greater length is applied over the moist bandage precisely the same manner to make it fit snugly at every point so as exclude the air.
- The pack was removed after 30 min.

The below (figure) represents the different types of cold chest pack:

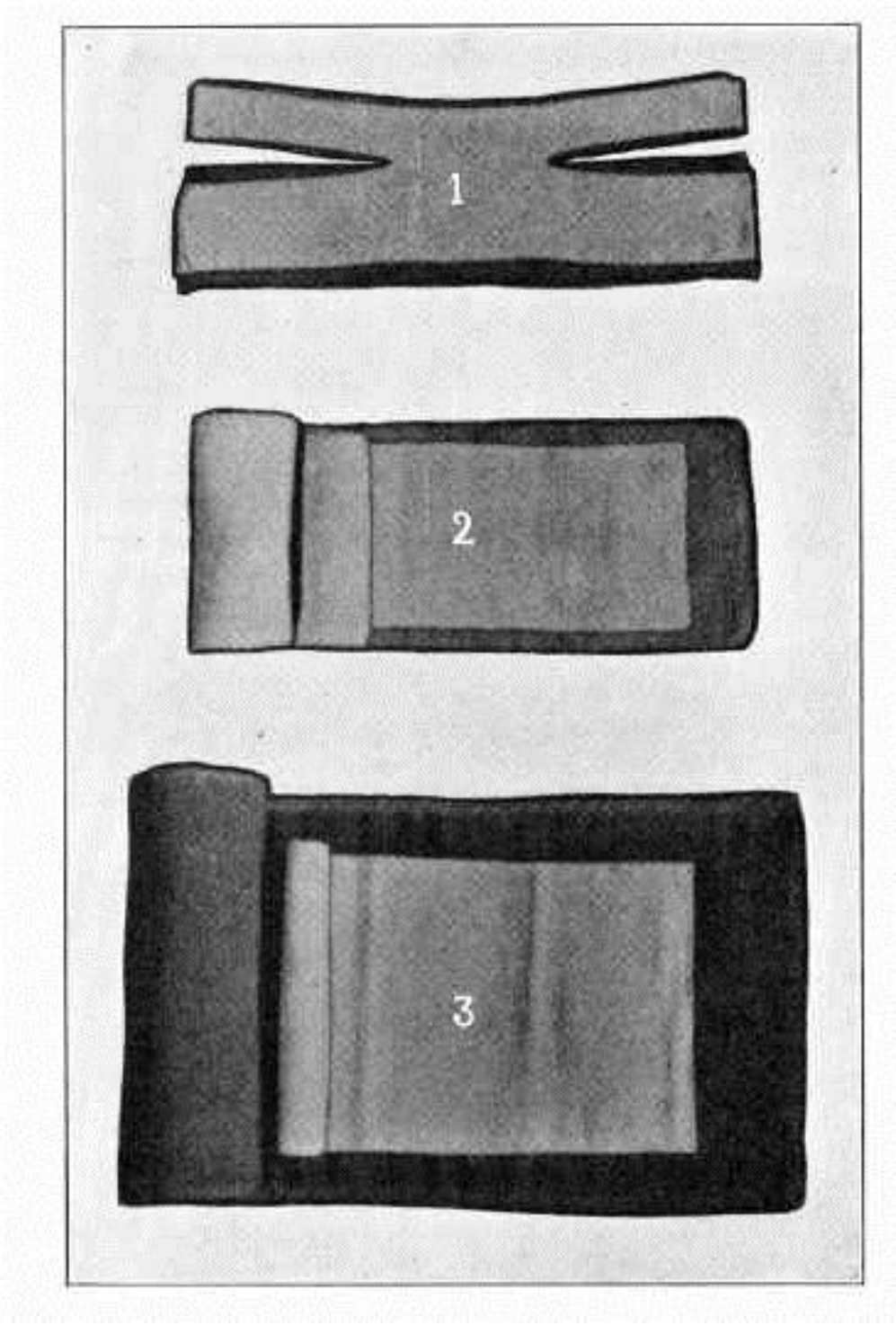


**Figure 4.3: Chest pack types (Square Chest Pack, Roller Chest Pack and Abdominal Bandage)**

**Figure 4.4: Illustrative representation of application of Cold Chest pack to patients in sitting position**

**Figure 4.5: Illustrative representation of application of Cold Chest pack to patients in lying position**

## 4.8 ASSESSMENT OF PULMONARY FUNCTION VIA PEAK EXPIRATORY FLOW RATE (PEFR):

### 4.8.1 Peak Expiratory Flow Rate:

- The Peak Expiratory Flow Rate (PEFR) will be recorded using the Mini-Wright peak flow meter (Airmed Clement Clarkes International, England) as per the standard method of B M Wright.
- The subjects were instructed to take a maximal inspiration and blow into the mouth piece of the device rapidly and forcefully, while standing.
- The values of PEFR achieved in 3 successive attempts were recorded and the highest of 3 values was taken for analysis.


**Figure 4.6: PEFR (Airmed Clement Clarkes International, England)**

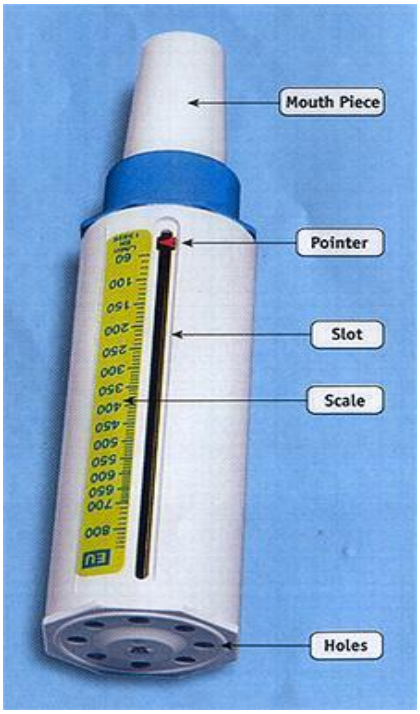


**Figure 4.7: Representation of parts of PEF Meter**

**Figure 4.8: Illustrative representation of using PEFR by patients**

## 4.9. DATA COLLECTION METHODS:

## TOOLS:

All the parameters recorded by Mini-Wright peak flow meter at baseline and 5 weeks after the cold chest pack intervention.

# 5.0 RESULTS

The following chapter represents the overall results of the current study that determines the effectiveness of Cold Chest Pack among the intervention (CHPK) and Control group. The resultant outcomes from the interventional studies were monitored from assessing the pulmonary function test using PEFR test, which were further subjected to statistical analysis.

## 5.1 STATISTICAL ANALYSIS

The following data for each subsets were expressed Mean± SEM. Parametric test had been used since the data fall on normal distribution ($P>0.05$). Comparison of Mean difference for inter group done using unpaired t test and intra group difference done using paired t test. P value set as $P<0.05$ significant. R statistical software version 3.1.1 was used for the statistical analysis and Graph pad version 5 used for the graphical representation.

**The below table represents the anthropometric variables between groups:**

**Table: 5.1 - Anthropometric variables between the groups**

| VARIABLE | CHPK GROUP | CONTROL GROUP |
|---|---|---|
| **Height (cm)** | 160.4±23.90 | 158.8±21.29 |
| **Weight (kg)** | 68.26±8.72 | 70.62±13.45 |
| **BMI (kg/m$^2$)** | 26.70±3.68 | 25.81±4.56 |
| **Male/Female** | 12/20 | 10/22 |

Table 1 shows the anthropometry parameters of participants. All the parameters like height (CHPK group: 160.4±23.90 cm; control group: 158.8±21.29 cm), weight (CHPK group: 68.26±8.72 kg; control group: 70.62±13.45) and BMI (CHPK group: 26.70±3.68; control group: 25.81±4.56) were showed no significant difference in between the group and found normal in range. They are considered as healthy volunteers and were included for this study.

**Overall Effect of Cold Chest Pack among the intervention and control groups**

The following table and illustration depicts the overall effect of pulmonary function via utilizing Cold chest pack among intervention and control groups

**Table. 5.2: Effect of Cold Chest Pack on PEFR in both CHPK group and control group**

| variable | CHPK | | p value | Control | | P value |
|---|---|---|---|---|---|---|
| | Before | After | | Before | After | |
| **PEFR (l/min)** | 181.6±10.67 | 266.7±13.82 ## | 0.0001 | 186.9±10.67 | 198.1±10.96 | 0.4 |

*Data expressed as Mean and SEM. Paired t test was done to compare the mean difference. P<0.05 set as significant. #comparison of after PEFR between CHPK and control group using unpaired t test. ##P<0.0001.*

Table 2 shows the effect of cold chest pack on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant (P<0.01) increase from 181.6±10.67 l/min to 266.7±13.82 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.9±10.67 /min to198.1±10.96 l/min).

**Fig 5.1: Effect of Cold Chest Pack on PEFR in both CHPK group and control group**

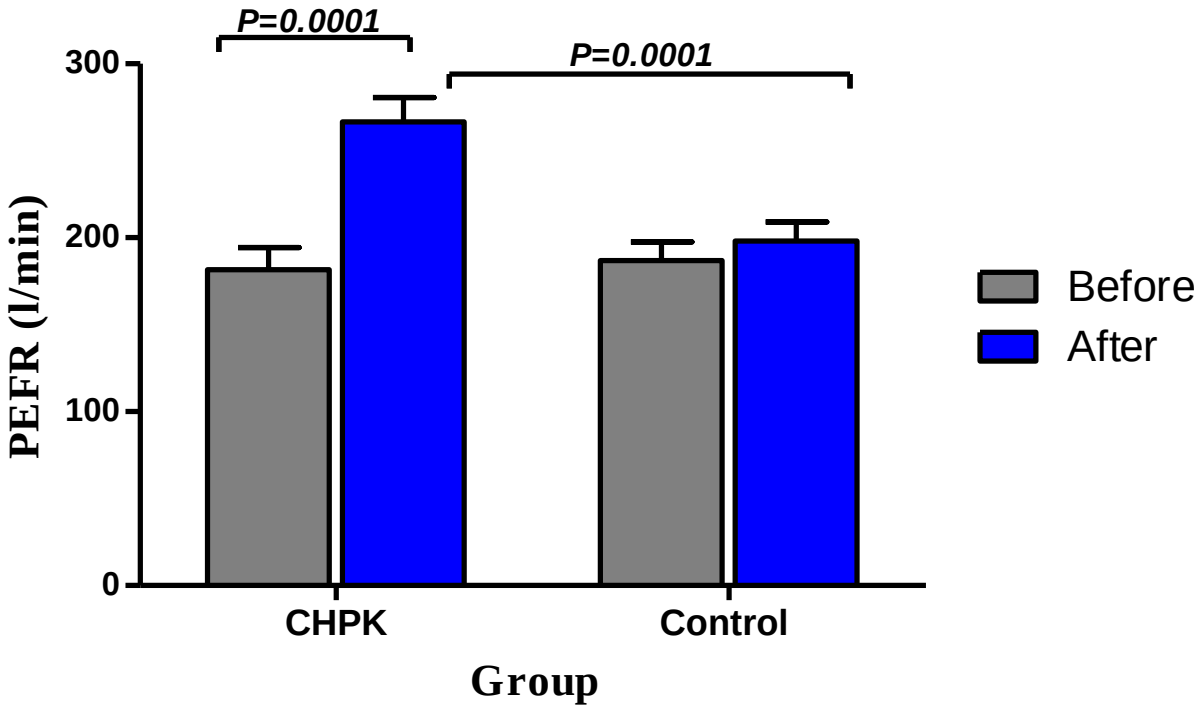


Figure 1 shows the effect of cold chest pack on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 181.6±10.67 l/min to 266.7±13.82 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.9±10.67 /min to198.1±10.96 l/min).

**Gender based investigation on the effect of cold chest pack via determining PEFR between CHPK and Control Group**

The following table and illustration depicts the gender based representation of pulmonary function via utilizing Cold chest pack among intervention and control groups.

**Table. 5.3: Effect of Cold Chest Pack on PEFR among the male subjects between CHPK group and control group**

| variable | CHPK | | p value | Control | | P value |
|---|---|---|---|---|---|---|
| | Before | After | | Before | After | |
| **PEFR (l/min)** | 171.7±12.17 | 285.4±10.80# | 0.001 | 176.2±15.17 | 185.1±11.0 | 0.7 |

*Data expressed as Mean and SEM. Paired t test was done to compare the mean difference. P<0.05 set as significant. #comparison of after PEFR between CHPK and control group using unpaired t test. #P<0.001.*

Table 3 shows the effect of cold chest pack among male subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant (P<0.01) increase from 171.7±12.17 l/min to 285.4±10.80 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (176.2±15.17 /min to 185.1±11.0 l/min).

**Figure 5.2: Effect of Cold Chest Pack on PEFR among the male subjects**

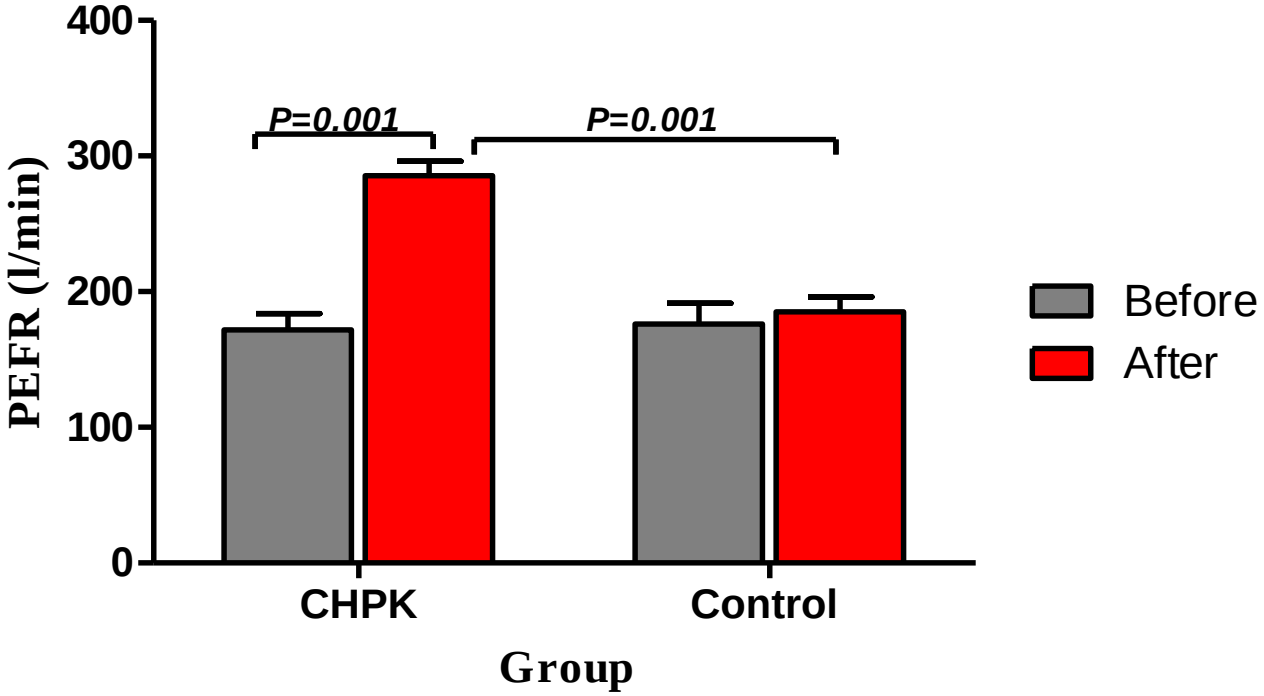


Figure 2 shows the effect of cold chest pack among male subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 171.7±12.17 l/min to 285.4±10.80 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (176.2±15.17 /min to 185.1±11.0 l/min).

**Table.5.4: Effect of Cold Chest Pack on PEFR among the female subjects between CHPK group and control group**

| variable | CHPK | | p value | Control | | P value |
|---|---|---|---|---|---|---|
| | Before | After | | Before | After | |
| **PEFR (l/min)** | 178.7±15.24 | 265.92±17.10[#] | 0.001 | 186.45±12.07 | 195.77±14.09 | 0.8 |

*Data expressed as Mean and SEM. Paired t test was done to compare the mean difference. P<0.05 set as significant. #comparison of after PEFR between CHPK and control group using unpaired t test. #P<0.001.*

Table 4 shows the effect of cold chest pack among female subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant (P<0.01) increase from 178.7±15.24 l/min to 265.92±17.10 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.45±12.07 /min to195.77±14.09 l/min).

**Figure 5.3: Effect of Cold Chest Pack on PEFR among the female subjects**

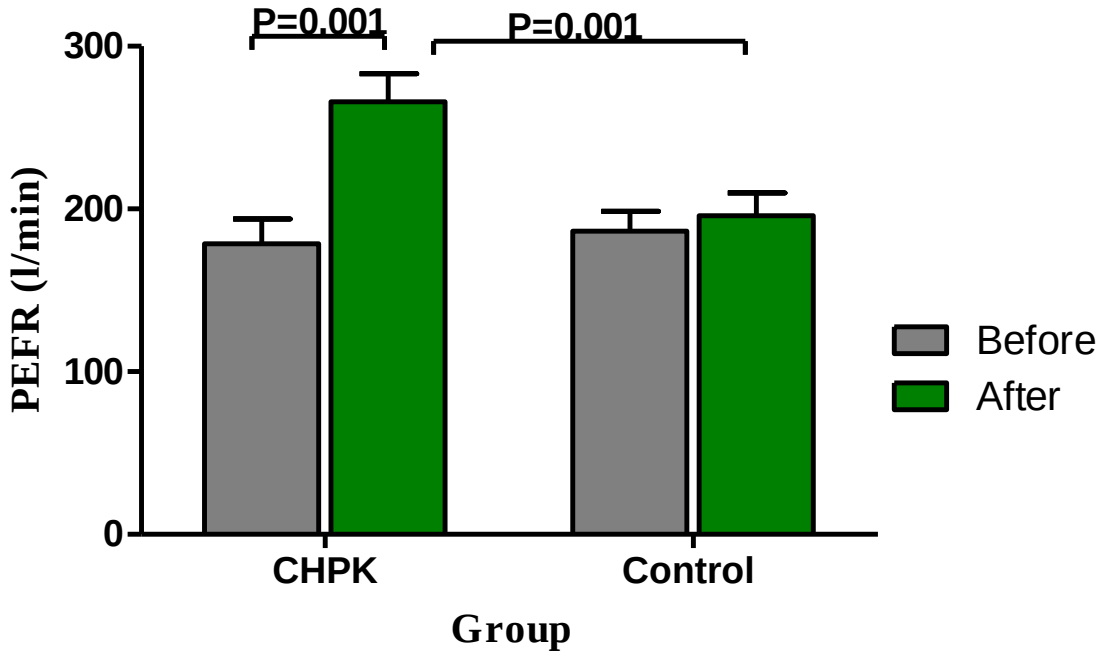


Figure 3 shows the effect of cold chest pack among female subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 178.7±15.24 l/min to 265.92±17.10 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.45±12.07 /min to195.77±14.09 l/min).

# 6.0 DISCUSSIONS

The present study showed that the incorporation of Cold Chest Pack, was carried out over a period of 5 days/week for 5 weeks (net total of 25 days) and the complete duration of study was observed for 10 months. The intervention appeared to have significant impact in the overall PEFR ranges in Pulmonary Function. PEFR acts as major tool for assessing the influence of pulmonary function. Autonomic disturbances could have an adverse impact on pulmonary function.

Bronchial asthma is regarded as the dangerous threat, causing an increase in the mortality, of all age groups. There has been a growing concern with regards to PEFR, which needs necessary interventional approach which is efficacious and impactful on a longer term. Under such situations, many countries rely on naturopathic approaches for treating systemic disorders[83].

The abnormalities observed/monitored in the PEFR and pulmonary functioning directly reflects Bronchial asthma and other associated problems. During its maximal expiratory effort from total lung capacity, the peak expiratory flow occurs in the first 200 milliseconds, which is in the effort dependent portion of expiration. PEF is affected by the fullness of the preceding inspiration, caliber of the large airways, expiratory muscle strength, and voluntary effort. As might be expected, PEF can vary substantially with patient effort and coordination[84].

Peak Expiratory Flow Rate (PEFR) is an important parameter in the management of bronchial asthma. Measurement of PEFR in bronchial asthma is similar to measurement of blood pressure in managing hypertension and measurement

of blood glucose in managing diabetes mellitus. Peak expiratory flow provided a simple quantitative and reproducible measure of resistance and severity of airflow obstruction. Peak expiratory flow can be measured with inexpensive and portable peak expiratory flow meter. Peak flow monitoring can be used for short term monitoring, managing exacerbations and daily long term monitoring[85].

With the application of cold chest pack has been used as treatment for choice in treating the flow rate and also aids in reducing the overall weekly attacks when on combination with following yoga for weeks as well[74].

Another study evaluated the effects of a cold chest pack in isolation on pulmonary functions in bronchial asthma patients, and the studies conducted in evaluating immediate effect of a cold chest pack on the Peak Expiratory Flow Rate (PEFR) and whether the immediate effect would change after treatment with other natural remedies and yogic practices in bronchial asthma patients[5].

These abnormalities and growing illness could be majorly attributed to an individual's poor lifestyle habits, physical stress. However these factors are hopefully modifiable. Utilizing naturopathic standards as an effective approach on long term treatment could assist in a strong and healthy systemic circulation.

The usage of Cold Chest Pack, which is a part of hydrotherapy mediated interventional approach, has been in practice for many centuries. Through incorporation of hydrotherapy mediated with Cold Chest Pack could facilitate in improving the pulmonary functioning, quite effectively. Since there is not enough literature studies have focused on Cold Chest Pack and its impact on. The current

study performed a randomized control study design among 32 Bronchial Asthmatic patients as control and 32 Bronchial Asthmatic Patients as intervention group over a period of 10 months.

As the chest pack has been used as treatment choice in the treatment of bronchial asthma followed by naturopathic treatments in numerous naturopathy hospitals as they are crucial for carrying out investigations on understanding the control group, as it is not possible for ascribing the improved PEFR intractable asthma.

From the observed studies, the PEFR was measured before and after the intervention study for comparative analysis on the overall changes in the PEFR. From the results, the research inferred that with incorporating Cold Chest Pack mediated interventional approach, has drastically improved the PEFR ranges, in both the groups as the Pre interventional assessment with regards as the expiratory flow of the lungs is greater as the bronchial openings were freed/ broadened with incorporating Cold Chest Pack approach.

The interventional approach involving Cold Chest Pack over the period of 10 months has drastically improved the pulmonary Function which is observed on the basis of PEFR. PEFR represents maximum flow rate generated during a forceful exhalation, starting from full lung inflation. PEFR primarily reflects large airway flow and depends on the voluntary effort and muscular strength of the patient.

In our study, there was a demonstrable improvement in the pulmonary function. Through incorporating Cold Chest Pack, among study participant had a

noticeable benefit on general health status of the individual and thus promoting positive health. These beneficial effects were observed within the stipulated duration, exhibiting that the practice of naturopathic treatment over other treatment modes could have a lasting impact, since it rectifies the systemic irregularities, rather than targeting only on the particular illness[5].

## 7.0 CONCLUSION

The present study confirms that, by incorporating naturopathic treatment involving Cold Chest pack was effective in improving Bronchial asthma and improving the pulmonary functions via monitoring the expiratory flow rate, there by directly improving the sympatho-vagal balance among the study participants. Cold Chest Pack is a simplified procedure and is one of the effective treatments among hydrotherapic treatment, with no side effect in its treatment. From the study, the participants were only administered with Cold Chest pack treatment alone. Within the stipulated time interval, Pulmonary function was observed via monitoring the peak expiratory flow rate (PEFR) was significantly improved among the individuals.

**LIMITATIONS:**

- The current study was a pilot study comprising only of minimal number of subjects.

- The literature sources were limited regarding the therapeutic benefits of Cold Chest Pack.

**RECOMMENDATIONS:**

The same study can be conducted on a larger population with suitable study design and some objective kind of outcome variables could be included to validate the current results.

## 8.0 SUMMARY

- The study's objective was to determine the efficacy of incorporating Cold Chest Pack, in improving the peak expiratory flow rate for patients suffering from bronchial asthma. Peak expiratory flow rate (PEFR) as a result of forced expiration, represents an equivalent over spot measurement retrieved from slope from expiratory spirogram on steepest point. As PEFR relies as much on elastic recoil from lungs and also the caliber of peripheral airways.
- The underlying abnormalities in these parameters in the pulmonary function is quite common and profound among bronchial asthmatic individuals, and also could have a deleterious impact and its related issues.
- The following study was intended majorly towards determining the impact of Cold chest pack in improving the pulmonary functions via PEFR levels. The study was conducted among the bronchial asthmatics and patients who are susceptible as well as exhibit symptoms that attribute to bronchial asthma, over a total period of 10 months. The baseline measurements were monitored initially for evaluating the actual difference in the pulmonary functions via assessing the PEFR ranges. From the observed study, the participants who were administered with hydrotherapic mediated intervention via cold chest pack, exhibited significant improvement in their overall PEFR readings.
- The overall (Mean±SEM) showed significant improvement in the PEFR by the effect of cold chest pack on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 181.6±10.67 l/min to

266.7±13.82 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.9±10.67 l/min to198.1±10.96 l/min).

- Also the overall (Mean±SEM) showed significant improvement in the PEFR by the effect of cold chest pack among male subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 171.7±12.17 l/min to 285.4±10.80 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (176.2±15.17 l/min to 185.1±11.0 l/min).
- The overall (Mean±SEM) showed significant improvement in the PEFR by the effect of cold chest pack among female subjects on pulmonary functioning via assessing the PEFR variables among both control and CHPK group. After CHPK intervention, PEFR showed significant ($P<0.01$) increase from 178.7±15.24 l/min to 265.92±17.10 l/min in CHPK group. Whereas, no such significant changes were found in the control group subjects (186.45±12.07 l/min to195.77±14.09 l/min).

## References


1. Global Initiative for Asthma. National Institute of Health. National Heart, Lung and Blood Institute Publication No. 02- 3659.
2. Burney PGJ. Epidemiology. In: Clark TJH, Godfrey S, Lee TH, Thomson NC, editors. Asthma; 4th edn. London: Arnold. 2000; pp 197-223
3. Asthma In-Depth Report NY times health. 2013 june 23. Available from : http://www.nytimes.com/health/guides/disease/asthma/print.html..
4. Masoli M, Fabian D, Holt S, Beasley R. The global burden of asthma: executive summary of the GINA Dissemination Committee report. Global Initiative for Asthma (GINA) Program. Allergy. 2004 May;59(5) : pp 469- 78
5. N.K Manjunath, Shirley Telles. Therapeutic Applications of a Cold Chest Pack in Bronchial Asthma. W.J Med Sci, 2006,1(1), 18-20.
6. Corrao, William M., Sidney S. Braman, and Richard S. Irwin. "Chronic cough as the sole presenting manifestation of bronchial asthma." *New England Journal of Medicine* 300.12 (1979): 633-637.
7. Gleich, Gerald J. "The eosinophil and bronchial asthma: current understanding." *Journal of Allergy and Clinical Immunology* 85.2 (1990): 422-436.
8. Kattan, Meyer, et al. "Pulmonary function abnormalities in symptom-free children after bronchiolitis." *Pediatrics* 59.5 (1977): 683-688.
9. Snider, Gordon L., et al. "The definition of emphysema: report of a National Heart, Lung, and Blood Institute, Division of Lung Diseases workshop." (1985): 182-185.

10. Nowak, Richard M., et al. "Arterial blood gases and pulmonary function testing in acute bronchial asthma: predicting patient outcomes." *Jama* 249.15 (1983): 2043-2046.
11. Williams, Trevor J., et al. "Risk factors for morbidity in mechanically ventilated patients with acute severe asthma." *American Review of Respiratory Disease* 146.3 (1992): 607-615.
12. Herschfus, J. Aaron, Elliott Bresnick, and Maurice S. Segal. "Pulmonary function studies in bronchial asthma: I. In the control state." *The American journal of medicine* 14.1 (1953): 23-33.
13. Thomson, W. B., and P. Hugh-Jones. "Forced expiratory volume as a test for successful treatment of asthma." *British medical journal* 1.5079 (1958): 1093.
14. Gandevia, Bryan, and P. Hugh-Jones. "Terminology for measurements of ventilatory capacity: a report to the Thoracic Society." *Thorax* 12.4 (1957): 290.
15. Nardell, EDWARD A., and JEROME S. Brody. "Determinants of mechanical properties of rat lung during postnatal development." *Journal of Applied Physiology* 53.1 (1982): 140-148.
16. Segal, M. S., and Attinger, E. 0. (1957). In Clinical Cardiopulmonary Physiology [American College of Chest Physiciansl, ed. B. L. Gordon, p. 283 et seq. Grune and Stratton, New York.
17. Smith, Andrew D., et al. "Diagnosing asthma: comparisons between exhaled nitric oxide measurements and conventional tests." *American journal of respiratory and critical care medicine* 169.4 (2004): 473-478.

18. Pepys, J., and B. J. Hutchcroft. "Bronchial provocation tests in etiologic diagnosis and analysis of asthma." *American Review of Respiratory Disease* 112.6 (1975): 829-859.
19. 5. Dr. Singh.S.J. History and Philosophy of Naturopathy. Lucknow: Nature Cure Printarium; 1980.
20. 6. Joseph B. Definition of Naturopathy and Fasting, National Institute of Naturopathy.Availablefrom: http://www.punenin.org/attach/definitionNaturopathy and Fasting.pdf.
21. Collins, J. V., et al. "Intravenous corticosteroids in treatment of acute bronchial asthma." *The Lancet* 296.7682 (1970): 1047-1050.
22. Bossios, Apostolos, et al. "Rhinovirus infection induces cytotoxicity and delays wound healing in bronchial epithelial cells." *Respiratory research* 6.1 (2005): 114.
23. Hedman, Jouni, et al. "Prevalence of asthma, aspirin intolerance, nasal polyposis and chronic obstructive pulmonary disease in a population-based study." *International journal of epidemiology* 28.4 (1999): 717-722.
24. Manjunath NK, Shirley Telles. Therapeutic Application of a Cold Chest Pack in Bronchial Asthma. W J Med Sci. Jan-Jun, 2006; Volume 1 Number (1): 18-20.
25. Szentivanyi, A., 1968. The beta adrenergic theory of the atopic abnormality in bronchial asthma. J. Allergy, 42: 203-225.
26. Vignola AM, Kips J, Bousquet J. (2000) Tissue remodeling as a feature of persistent asthma. J Allergy ClinImmunol 105(6 pt 1)T041-1053.

27. Saunders MA, Mitchell JA, Seldon PM, Bames PJ, Giembycz MA, Belvisi MG. (1997) Release of granulocyte-macrophage colony-stimulating factor by human cultured airway smooth muscle cells: Suppression by dexamethasone. Br J Pharmacol 120(4):545-546
28. Levine SJ. (1995). Bronchial epithelial cell-cytokine interactions in airway epithelium. J Invest Med 43(3):241-249.
29. Karadag F, Karul AB, Cidag O, Altun C, Eyigor (2005) Is the role of tumor necrosis factoralpha m pathogenesis of asthma mediated by oxidative stress7 Arch lung 6*145-148
30. Kirkham, Paul, and Irfan Rahman. "Oxidative stress in asthma and COPD: antioxidants as a therapeutic strategy." *Pharmacology & therapeutics* 111.2 (2006): 476-494.
31. Du Buske LM. (1996). Introduction: Risk management in asthma and allergic diseases. J Allergy ClinImmunol 98(6 pt 3):S289-S290.
32. Kasserra CE, Harris P, Stenton GR, Abraham W, Langlands JM. (2004). IPL576, 092, a novel anti-inflmmatory compound, inhibits leukocyte infiltration and cha
33. Miller Al. (2001). The etiologies, pathophysiology, and altemative/complementary treatment of asthma. Alter Med Rev 6(1) 20-47
34. Gerstman BB, Bosco LA, Tomita DK, Gross TP, Shaw MM. (1989). Prevalence and treatment of asthma in the Michigan medicaid patient population younger than 45 years, 1980-1986 J Allergy ClinImmunol 83(6): 1032-1039.

35. Aggarwal AN, Chaudhry K, Chhabra SK, D'Souza GA, Gupta D, Jindal SK, Katiyar SK, Kumar R l, Shah B, Vijayan VK for Asthma Epidemiology Study Group. (2006). Prevalence and risk factors for bronchial asthma in Indian adults A multicentre study Indian J Chest Dis Allied Sci 48(l):13-22
36. Blackwell DL, Lucas JW, Clarke TC. Summary health statistics for U.S. adults: national health interview survey, 2012. Vital Health Stat 2014;10(260):1–161.
37. Department of Health and Human Services. [Internet document]. Centers for Disease Control and Prevention. Asthma Facts – CDC's National Asthma Control Program Grantees. Atlanta, GA; 2013
38. Ober C, Yao TC. The genetics of asthma and allergic disease: a 21st century perspective. Immunol Rev 2011;242(1):10–30.
39. Robertson CF. Long-term outcome of childhood asthma. Med J Aust 2002;177 (Suppl):S42–4.
40. Chinn S, Burney P, Jarvis D, Luczynska C (1997) Variation in bronchial responsiveness in the European Community Respiratory Health Survey (ECRHS). EurRespir J 10(11):2495-2501
41. Peat JK, Tovey E, Toelle GB, Haby MM, Gray EJ, Mahmic A, Wool-cock AJ. (1996) House dust mite allergens: a major risk factor for childhood asthma in Australia. Am J RespirCrit Care Med 153(1):141-146.
42. Factsheet: Asthma-a worldwide problem. Document accessed on September 8,2005 at website of International Union Against Tuberculosis and Lung Diseases (IUATLD)

43. Chapman, M. D., Pollart, S. M., Luczynska, C. M., &Platts-Mills, T. A. (1988). Hidden allergic factors in the etiology of asthma. *Chest*, *94*(1), 185-190.
44. Beasley, R., Crane, J., Lai, C. K., & Pearce, N. (2000). Prevalence and etiology of asthma. *Journal of allergy and clinical immunology*, *105*(2), S466-S472.
45. Duff, A. L., &Platts-Mills, T. A. (1992). Allergens and asthma. *Pediatric clinics of North America*, *39*(6), 1277-1291.
46. ML.Kulkarni.Clinical methods in paediatrics –Physical Examination of children-Chapter 25.2nd edition. New Delhi: Jaypee Medical Publishers; 2008. Pp 509-552.].
47. Wenzel, Sally E., et al. "Evidence that severe asthma can be divided pathologically into two inflammatory subtypes with distinct physiologic and clinical characteristics." *American journal of respiratory and critical care medicine* 160.3 (1999): 1001-1008.
48. Sears, Malcolm R., et al. "Regular inhaled beta-agonist treatment in bronchial asthma." *The Lancet* 336.8728 (1990): 1391-1396.
49. June 13, 2013. Available from : http://www.hadaaash-med.com
50. Jeffery, Peter K. "Remodeling in asthma and chronic obstructive lung disease." *American journal of respiratory and critical care medicine* 164.supplement_2 (2001): S28-S38.
51. J H Kellog. The Chest Pack, Techniques of hydrotherapy, Rational Hydrotherapy. (NIN, Pune, 2010)
52. Quinlan, G. J., T. W. Evans, and J. M. C. Gutteridge. "Iron and the redox status of the lungs." *Free Radical Biology and Medicine* 33.10 (2002): 1306-1313.

53. Sathyaprabha, T.N., H. Murthy and B.T.C. Murthy, 2001. Efficacy of Naturopathy and Yoga in Bronchial Asthma-A self-controlled matched scientific study. Indian J. Physiol. Pharmacol., 45: 80-86.
54. Stern DA, Morgan WJ, Halonen M, Wright AL, Martinez FD. Wheezing and bronchial hyper-responsiveness in early childhood as predictors of newly diagnosed asthma in early adulthood: a longitudinal birth-cohort study. Lancet 2008;372(9643):1058–64
55. Friedman-Jiménez G, Beckett WS, Szeinuk J, Petsonk EL. Clinical evaluation, management, and prevention of work-related asthma. Am J Ind Med 2000;37(1):121–41).
56. Crocker DD, Kinyota S, Dumitru GG, Ligon CB, Herman EJ, Ferdinands JM, et al. Effectiveness of home-based, multi-trigger, multicomponent interventions with an environmental focus for reducing asthma morbidity: a community guide systematic review. Am J Prev Med 2011;41(2 Suppl 1):S5–32.].
57. Reed CE. The natural history of asthma. J Allergy ClinImmunol 2006;118(3):543–8; quiz 549–50.
58. Peters SP. Asthma phenotypes: nonallergic (intrinsic) asthma. J allergy ClinImmunolPract 2014;2(6):650–2
59. Brooks SM, Bernstein IL. Irritant-induced airway disorders. Immunol Allergy Clin North Am 2011;31(4):747–68, vi.
60. Guarnieri M, Balmes JR. Outdoor air pollution and asthma. Lancet 2014;383(9928):1581–92

61. Weiler JM, Anderson SD, Randolph C, Bonini S, Craig TJ, Pearlman DS, et al. Pathogenesis, prevalence, diagnosis, and management of exercise-induced bronchoconstriction: a practice parameter. Ann Allergy Asthma Immunol 2010;105(6):S1–47]
62. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma [Internet document]. 2007 Aug
63. Blanc, Paul D., et al. "Alternative therapies among adults with a reported diagnosis of asthma or rhinosinusitis: data from a population-based survey." *Chest* 120.5 (2001): 1461-1467.
64. Martinez, Fernando J., Connie Standiford, and Steven E. Gay. "Is it asthma or COPD? The answer determines proper therapy for chronic airflow obstruction." *Postgraduate medicine* 117.3 (2005): 19-26.
65. Gupta, I., et al. "Effects of Boswellia serrata gum resin in patients with bronchial asthma: results of a double-blind, placebo-controlled, 6-week clinical study." *European journal of medical research* 3.11 (1998): 511-514.
66. Ratcliffe, J., et al. "Assessing patients' preferences for characteristics associated with homeopathic and conventional treatment of asthma: a conjoint analysis study." *Thorax* 57.6 (2002): 503-508.
67. Hondras, Maria A., Klaus Linde, and Arthur P. Jones. "Manual therapy for asthma." *Cochrane Database of Systematic Reviews* 3 (2002).
68. Kurabayashi, Hitoshi, Izumi Machida, and Kazuo Kubota. "Improvement in ejection fraction by hydrotherapy as rehabilitation in patients with chronic

pulmonary emphysema." *Physiotherapy Research International* 3.4 (1998): 284-291.

69. Fleming SA, Gutknecht NC. Gutknecht. Naturopathy and the Primary Care Practice. Prim Care. 2010;37:119–36. [PMC free article] [PubMed]
70. Manjunath, N. K., and Shirley Telles. "Therapeutic application of a cold chest pack in bronchial asthma." (2006).
71. Farrel, K.M., 1985. Gastroesophageal reflex, esophageal disfunction and asthma. In: Weiss, B.E., S.M. Segal and M. Stein (Eds.). Bronchial asthma-mechanisms and therapeutics. Boston: Little, Brown and Company Inc., therapeutics. Boston: Little, Brown and Company Inc.,
72. Wilson, A.F., R. Honsberger, J.T. Chiu and H.S. Novey, 1975. Transcendental Meditation and asthma. Respiration, 32: 74-80,
73. Tanizaki, Y., H. Kitani, M. Okazaki, T. Mifune, F. Mitsunobu, K. Ochi, H. Harada and I. Kimura, 1992. Spa therapy improves ventilatory function in the small airways of patients with steroid-dependent intractable asthma (SDIA). ActaMedica Okayama, 46: 175-178
74. Nagarathna, R. and H.R. Nagendra, 1985. Yoga for bronchial asthma: A controlled study. British Med. J., 291: 1077-1079
75. Singh, V., A. Wisniewski, J. Britton and A. Tattersfield, 1990. Effect of yoga breathing exercises (pranayama) on air way reactivity in subjects with asthma. Lancet, 335: 1381-1383

76. Baer, Hans A. "The potential rejuvenation of American naturopathy as a consequence of the holistic health movement." *Medical Anthropology* 13.4 (1992): 369-383.

77. Crapo, R. O. (1994). Pulmonary-function testing. *New England Journal of Medicine*, *331*(1), 25-30.

78. Nihlén, U., Montnémery, P., Lindholm, L. H., &Löfdahl, C. G. (1999). Detection of chronic obstructive pulmonary disease (COPD) in primary health care: role of spirometry and respiratory symptoms. *Scandinavian journal of primary health care*, *17*(4), 232-237

79. Feyrouz A., Reena M. and Peter J.M. (2003), 'Interpreting pulmonary function tests: Recognize the pattern, and the diagnosis will follow', Cleveland Clinic Journal of Medicine, Vol.70, pp.866-881.

80. Blieden L., Fink G., Algom A., Hardoff R., Hirsch R., Klainman E. and Kramer M.R. (2004), 'Lung function, cardiopulmonary exercise capacity and lung perfusion in patients with corrected tetralogy of fallot', Journal of Clinical and Basic Cardiology, Vol.7, pp.11-14.

81. Miller M.R., Hankinson J., Brusasco V., Burgos F., Casaburi R., Coates A., Crapo R., Enright P., van der Grinten C.P.M., Gustafsson P., Jensen R., Johnson D.C., Maclntyre N., Mckay R., Navajas D., Pedersen O.F., Pellegrino R., Viegi G. and Wanger J. (2005), 'Standardisation of spirometry', European Respiratory Journal, Vol.26, pp.153-161.

82. Rodríguez M.P., McKeever T., Lewis S., Whyatt D., Britton J. and Venn A. (2009), 'Effect of traffic pollution on respiratory and allergic disease in adults:

cross-sectional and longitudinal analyses', BMC Pulmonary Medicine, Vol.9, p.42.

83. Gleich, G. J. (1990). The eosinophil and bronchial asthma: current understanding. *Journal of Allergy and Clinical Immunology*, *85*(2), 422-436.

84. Bousquet, J., Khaltaev, N., Cruz, A. A., Denburg, J., Fokkens, W. J., Togias, A., & Agache, I. (2008). Allergic rhinitis and its impact on asthma (ARIA) 2008. *Allergy*, *63*, 8-160.

85. Balasubramanian, S., Ravikumar, N. R., Chakkarapani, E., &Shivbalan, S. O. (2002). Peak expiratory flow rate in children-A ready reckoner. *Indian pediatrics*, *39*(1), 104-105.

## 9.0 ANNEXURE

### INFORMATION SHEET

We are conducting a study on Bronchial Asthma among patients attending Government Yoga and Naturopathy Medical College Hospital, Chennai and for that your participation may be valuable to us.

The purpose of the study is to evaluate the changes in pulmonary function through Cold Chest pack.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period.

Signature of investigator: Signature of participant:

Date:

## INFORMED CONSENT FORM

**Title of the study: Effects of Cold Chest Pack on Pulmonary functions of Patients with Bronchial Asthma**

**Name of the Participant:**

**Name of the Principal Investigator:** Dr. R. Arthi

**Name of the Institution:** Government Yoga & Naturopathy Medical College,
Chennai – 600 106

**Documentation of the informed consent**

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in "Effect of Cold Chest Pack on Pulmonary functions of Patients with Bronchial Asthma"

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I have not participated in any research study within the past _____month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

11. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

12. I have understood that my identity will be kept confidential if my data are publicly presented.

13. I have had my questions answered to my satisfaction.

14. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form, I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

**For adult participants:**

**Name and signature / thumb impression of the participant (or legal representative if participant incompetent**)

Name _____ Signature_____

Date_____

**Name and Signature of impartial witness (required for illiterate patients):**

Name _____ Signature_____

Date_____

Address and contact number of the impartial witness:

**Name and Signature of the investigator or his representative obtaining consent:**

Name _____ Signature_____

Date_____

## INFORMATION TO PARTICIPANTS

**Investigator: Dr. R. Arthi**

**Name of Participant:**

**Title: Effect of Cold Chest Pack on Pulmonary functions of Patients with Bronchial Asthma**

You are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted in Government Yoga & Naturopathy Medical College, Chennai – 600 106

**What is the Purpose of the Research?**

The purpose of the study to evaluate the effect of Cold Chest pack on pulmonary changes in patients with Bronchial asthma.

**The Study Design**

Randomized controlled Trial

**Study Procedures**

The chest pack, consisted of a cotton cloth, approximately 8-10 inches in width, 6-8 feet in length, should be loosely rolled up, dipped into water at $58^{o}$F - $62^{o}$F, and wrung out without unrolling. The bandage is applied in a sort of "figure 8" fashion. A flannel bandage of the same width and a little greater length is applied over the moist bandage

precisely the same manner to make it fit snugly at every point so as exclude the air. The pack was removed after 30 min. Patients are made to be in supine position during the intervention.

**Possible Risks to you -** Nil

**Possible benefits to you –** Improvement in lung volume and capacity

**Possible benefits to other people**

The result of the research may provide benefits to the society in terms of improving the treatment efficacy for bronchial asthma patients.

**Confidentiality of the information obtained from you**

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

**How will your decision to not participate in the study affect you?**

Your decisions to not to participate in this research study will not affect your medical care or your relationship with investigator or the institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

**Can you decide to stop participating in the study once you start?**

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it is advisable that you talk to the research team prior to stopping the treatment