A Dissertation on

"EFFECT OF PRANAYAMA ON SERUM IgE, EOSINOPHILIA AND PULMONARY FUNCTION ON CHILDHOOD ASTHMA"

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In partial fulfillment of the requirements for the degree of

DOCTOR OF MEDICINE IN YOGA

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The Institutional Ethics Committee of Government Yoga and Naturopathy Medical College, reviewed and discussed the application for approval of the proposal "**EFFECT OF PRANAYAMA ON SERUM IgE, EOSINOPHILIA AND PULMONARY FUNCTION ON CHILDHOOD ASTHMA"** for project work submitted by **Dr.T.KAVITHA** 2nd year **M.D. YOGA**, Post Graduate of Government Yoga and Naturopathy Medical College, Chennai – 600 106

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Date: Chennai **Dr.T.Kavitha**

LIST OF ABBREVIATIONS

AHR	Airway Hyper Responsiveness
ABGs	Arterial Blood Gases
ACT	Asthma Control Test
ANB	Alternate Nostril Breathing
ANYB	Alternate Nostril Yogic Breathing
API	Asthma Predictive Index
AQLQ	Asthma Quality Of Life Questionnaire
BA	Bronchial Asthma
BHR	Bronchial Hyper Responsiveness
BMI	Body Mass Index
CHA	Childhood Asthma
DBP	Diastolic Blood Pressure
EIB	Exercise Induced Broncho Constriction
EPR	Expert Panel Recommends
FEV1	Forced Expiratory Volume one
FVC	Forced Vital Capacity
GINA	Global Imitative For Asthma
GIT	Gastro Intestinal Tract
GM-CSF	Granulocyte Macrophage -Colony Stimulating Factor
ICAM	Intercellular Cell Adhesion Molecules
ICS	Inhaled Corticosteroid

IgE	Immunoglobulin E
IL	Interleukins
ISAAC	International Society For Augmentative And Alternative Communication (ISAAC
LABA	Long-Acting Beta Agonists
LNYB	Left Nostril Yogic Breathing
LTRIs	Lower Respiratory Tract Infections
MCP	Monocyte Chemotactic Protein
MEP	Maximum Expiratory Pressure
MIP	Macrophage Inflammatory Protein
MIP	Maximum Inspiratory Pressure
MMEFR	Maximum Mid Expiratory Flow Rate
NACA	National Advisory Council On Aging
NAEPP	National Asthma Education And Prevention Program's
PAQLQ	Pediatric Asthma Quality of Life Questionnaire
PEFR	Peak Expiratory Flow Rate
PFT	Pulmonary Function Test
PR	Pulse Rate
QOL	Quality Of Life
R1	Reagent 1
R2	Reagent 2
RNYB	Right Nostril Yogic Breathing

ROAD	Reversible Obstructive Airway Disease
RSV	Respiratory Infection With Syncytial Viruses
SABA	Inhaled Short-Acting Beta-2 Agonist
SBP	Systolic Blood Pressure
T1	T Helper Cell 1
T2	T Helper Cell 2
Th	T Helper Cell
TLC	Total Leukocytes
TNF-ß	Tumour Necrosis Factor Beta
URTIs	Upper Respiratory Tract Infections
VC	Vital Capacity
VCAM	Vascular Cell Adhesion Molecules

ABSTRACT

Background: Asthma is one of the most chronic childhood illnesses, characterized by chronic inflammation of the airways. This inflammation causes narrowing of the airways and an increased sensitivity to inhaled irritants and allergens. Asthma is a leading cause of school absences. From 1980-1994, the rate of asthma in children under the age of five increased more than 150%. The root cause of asthma is still unknown. Asthma can begin at any age. With proper management and education, children's with asthma can lead normal, active lives. Thus, the present study was conducted to evaluate the effect of pranayama on serum IgE, eosinophilia and pulmonary function on childhood asthma

Methods: A total of 74 subjects with childhood asthma were included in the study. SC subjects were asked to undergo a single session (20 minutes) of pranayama and CG (rest in sitting pose) with conventional medication .Baseline and post-test assessments of Serum IgE, Eosinophil's, PEFR and PAQLQ levels were measured on Day1 and Day 28 of intervention. Statistical analysis was performed using statistical package for the social sciences, version 16. P value <0.05 was considered as significant.

Results: Pranayama showed statistically significant improvement, however no significant difference in IgE and Eosinophil between group participants on childhood asthma was observed.

Conclusion: The present study suggests that, pranayama practice was effective in improving childhood asthma by improving the pulmonary functions and quality of life.

Keywords: Childhood asthma, Eosinophilia, Pranayama, Serum IgE

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1.0. INTRODUCTION

Asthma could be a serious global pathological state affecting all age groups. Its prevalence is increasing in many countries, especially among children. Although some countries have seen a decline in hospitalizations and deaths from asthma, asthma still imposes an unacceptable burden on health care systems, and society through loss of productivity within the workplace and, especially for pediatric asthma, disruption to the family(1)

Asthma in childhood could be a significant reason for morbidity, leading to numerous days of altered activity and school absence.(2). Moreover, there are complex and confounding associations and relationships with infections and infestations, noise pollution, tobacco smoking and environmental tobacco smoke exposure.

Kaufman (2011) describes the pathophysiology of asthma as a condition which affects the lower respiratory tract by narrowing the airways as results of epithelial damage, excessive mucus production, and edema, bronchoconstriction and muscle damage. In asthma the cells within the epithelium layer is also destroyed and peel away, making the tract more in danger of allergens and infections, thereby contributing to airway hyper-responsiveness (AHR)

Asthma also triggers the event of mucus cells and mucus glands. This increases

mucus production, thus forming mucous plugs which could obstruct the airways (Monahan et al. 2007). Airway edema is another change that happens within the tract. It involves the dilation and leaking of capillaries within the airway walls which limits airflow (Kaufman 2011).

Monahan et al. (2007) also adds that increased capillary permeability and leakage can obstruct the airways to swelling. They also explain that the inflammatory agents like histamine, tryptase, leukotriences and prostaglandins act on smooth muscles of airway walls and cause bronchoconstriction which restricts the airflow to alveoli.

Brown and Edwards (2012) says that wheezing, breathlessness, chest tightness and cough are the foremost common clinical manifestations of asthma. They occur especially in the dark and in the early morning and might vary from person to person.

According to NACA (2006) frequent cough, feeling weak, wheezing after exercise, shortness of breath and sleeping difficulties is early signs of asthma while severe wheezing, continuous cough, rapid breathing, anxiety, chest pain, blue lips and fingernails are the symptoms of severe asthma attacks.

In preschool children one third of all children have these symptoms before the age of six, but only 40% of this wheezing kindergartener will continue to have asthma. In older school- aged children the majority of the children have asthma. Quality of life is affected by asthma control. Sleep disruption and exercised induced airflow limitation have a negative impact on participation in sports and group action, and may also influence family life.

Diagnosing asthma are often done by obtaining a detailed history, performing physical examinations, pulmonary function testing, and various laboratory investigation .pulmonary function tests (PFTs),done using spirometry, are the foremost accurate tests that may be performed to diagnose. Additionally, arterial blood gases testing (ABGs) and sputum for culture testing, serum IgE may also be accustomed diagnose asthma further. The results of ABGs are used to assess the oxygen and carbon dioxide levels within the blood during asthma, while the presence of eosinophils is assessed in sputum testing (Monahan et al. 2007). Finally, chest X-rays can even be used to find any changes in chest structure like hyperinflation, mucous build up and lung collapse (Brown & Edwards 2012)

On the idea of handling part the Childhood asthma (CHA) attack are often managed by pharmacological in addition as by non-pharmacological treatment. . Regarding pharmacological management international rule of thumb like such as the GINA guideline and the British Guideline on the Management of Asthma are leading. The medications used to manage asthma long term are symptom preventers and symptom controllers. Symptom reliever medications are used for the immediate control of its symptoms. Leukotriene modifiers are used for the treatment of chronic asthma. Symptom relievers are used for the immediate treatment and relief of symptoms in an acute asthma attack which include short-acting beta-2 agonists (Salbutamol, terbutaline), oral or IV corticosteroids and epinephrine.

Non-pharmacological measures aim at avoiding tobacco smoke, triggers, and proper self-asthma care along with this yoga therapy which includes breathing practices (pranayama) also aims to improve the respiratory routine. Pranayama (Breathing

exercises) are a non-drug treatment that can be routinely used in the treatment of people with asthma. Breathing exercises aim to manage the hyperventilation (over breathing) and symptoms of asthma in children's.

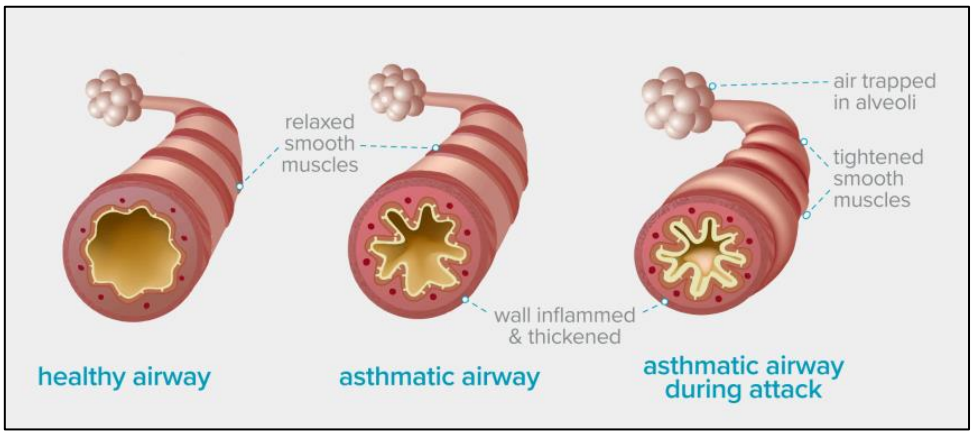
Many research studies show effects of yoga in adults. Since childhood health forms a foundation for adult health, present work was planned to study the effects of pranayama (breathing exercise) in children on serum IgE, eosinophilia, peak expiratory flow rate and quality of life in childhood asthma

2.0. LITERATURE REVIEW

2.1. Definition of Asthma:

Global Strategy for Asthma Management and Prevention Guidelines define asthma as "a chronic inflammatory disorder of airways associated with increased airway hyper responsiveness (AHR), recurrent episodes of wheezing, breathlessness, chest tightness, and coughing."(1)**.** Bronchial asthma (BA) is a serious global health problem. 5% to 10% of persons of all ages suffer from this chronic airway disorder (3). BA is a Reversible Obstructive Airway Disease (ROAD) coupled with bronchial hyper- responsiveness (BHR) and airway inflammation. BA = ROAD (reversible obstructive airway disease) + BHR (bronchial hyper responsiveness)

Figure 1: Asthma and your airway (Top row) Location of the lungs and airways in the body. (Second row) At left cross section of a normal airway. Middle and right images show a cross-section of an airway during asthma symptoms and attack(4)



Source:http://www.nlm.nih.gov/medlineplus/magazine/issues/fall11/articles/fall11pg4.html

2.2. Epidemiology:

Globally, asthma is ranked 16th among the leading causes of years lived with disability and 28th among the leading causes of burden of disease, as measured by disability-adjusted life years. Around 300 million people have asthma worldwide, and it is likely that by 2025 a further 100 million may be affected.(5)

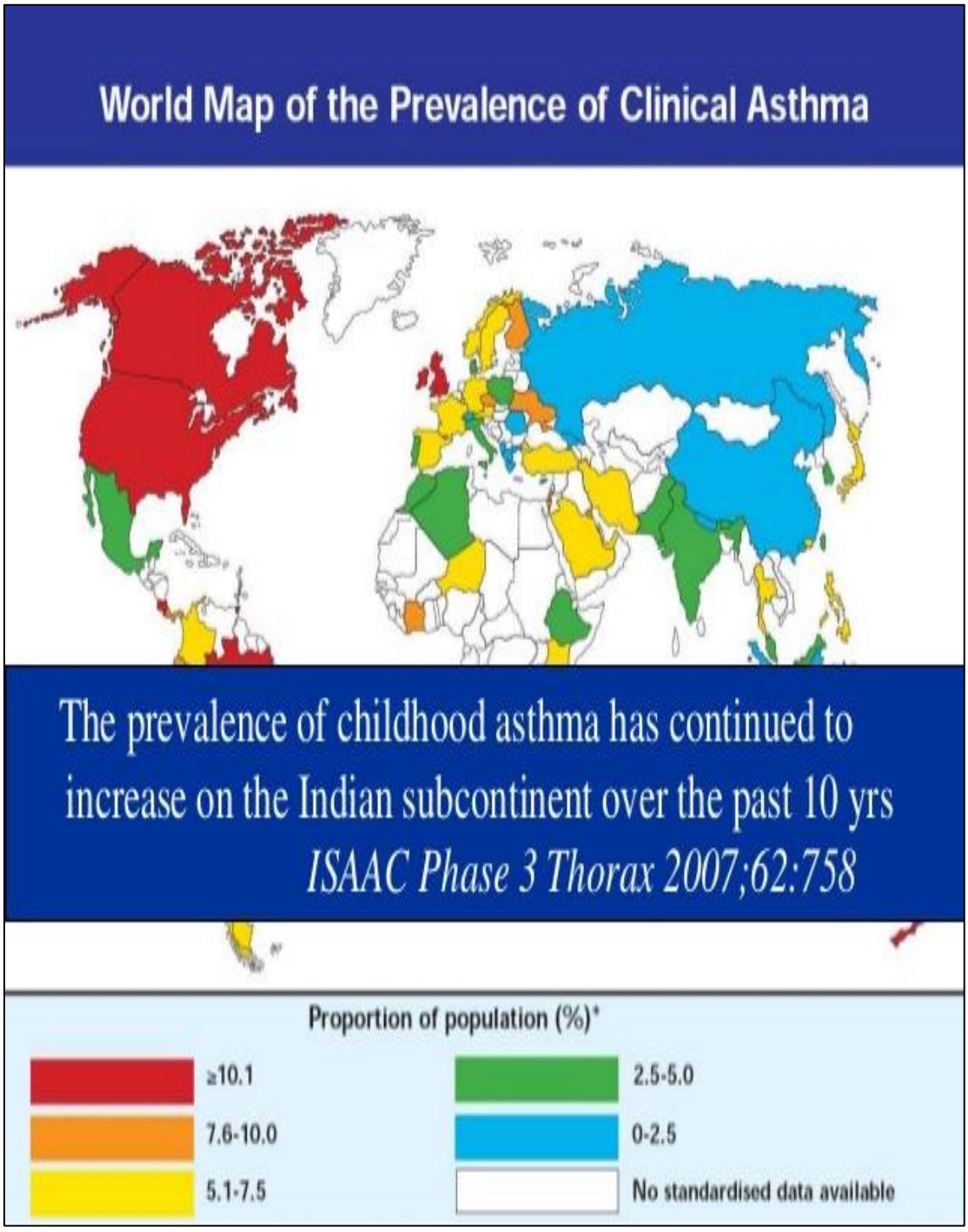
Asthma prevalence and severity are increasing among Indian children. There is a paucity of data on paediatric asthma in rural India and treatment received by asthmatics is not up-to-standard treatment guidelines.

Masoli et al (2014) reported that the prevalence of asthma is approximately 300 million cases all over the world and India alone has 30 million asthma patients (10% of the global burden). Asthma is increasing 50% per decade. Out of every 250 deaths, one is due to asthma worldwide.

Male gender and living in poverty are demographic risk factors for having childhood asthma (CHA). CHA is among the most common causes of childhood emergency department visits, hospitalizations, and missed school days.

Approximately, 80% of all asthmatic patients report disease onset prior to 6 years of age. However, of all young children who experience recurrent wheezing, only a minority go on to have persistent asthma in later childhood. Diagnosed asthma in adults is generally reported as 2.7 to 4.0% in most European countries, 12.0% in England and 9 5 to 17 9% in Australia. The overall burden of asthma in India is estimated at more than 15 million patients.

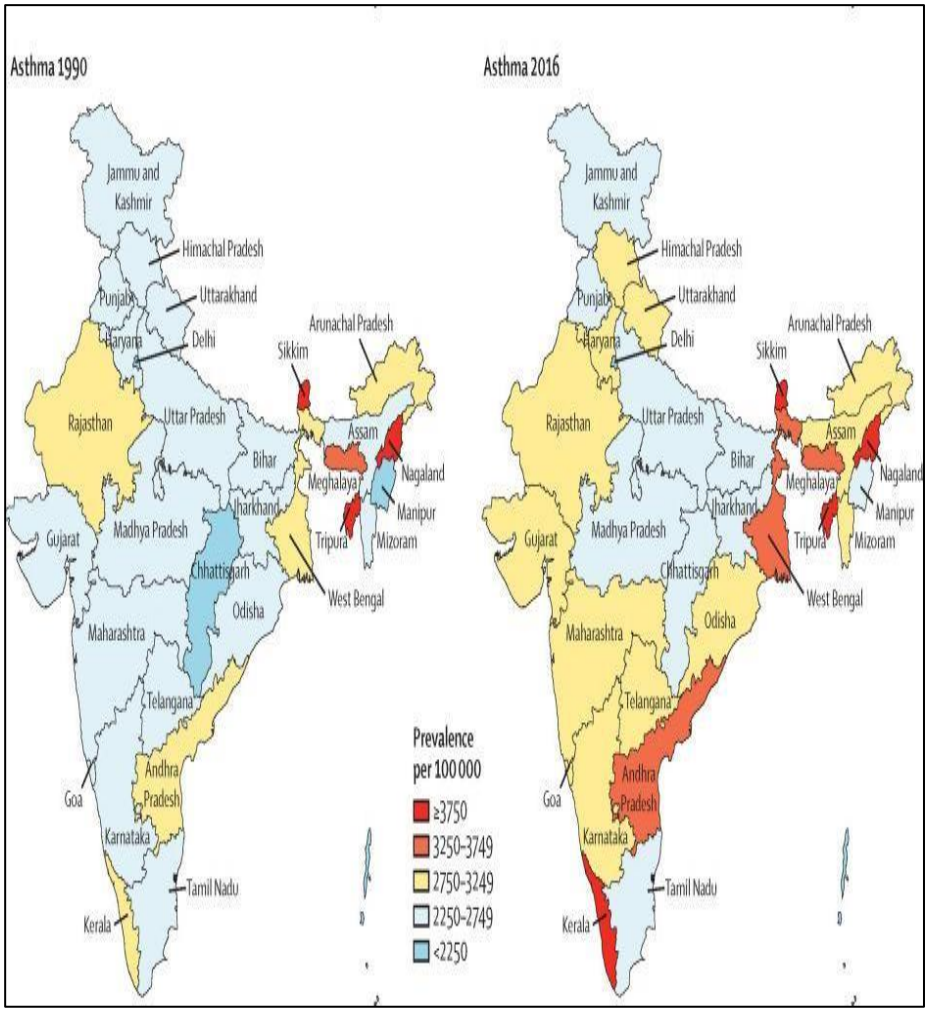
Figure 2: Global Asthma Report and its prevalence



Source: ISAAC phase 3 Thorax 2007;62:758

The following illustration represents the prevalence of Bronchial asthma in India comparing 1990 and 2016 (6)

Figure 3: Prevalence of Bronchial Asthma in India (1990 and 2016)

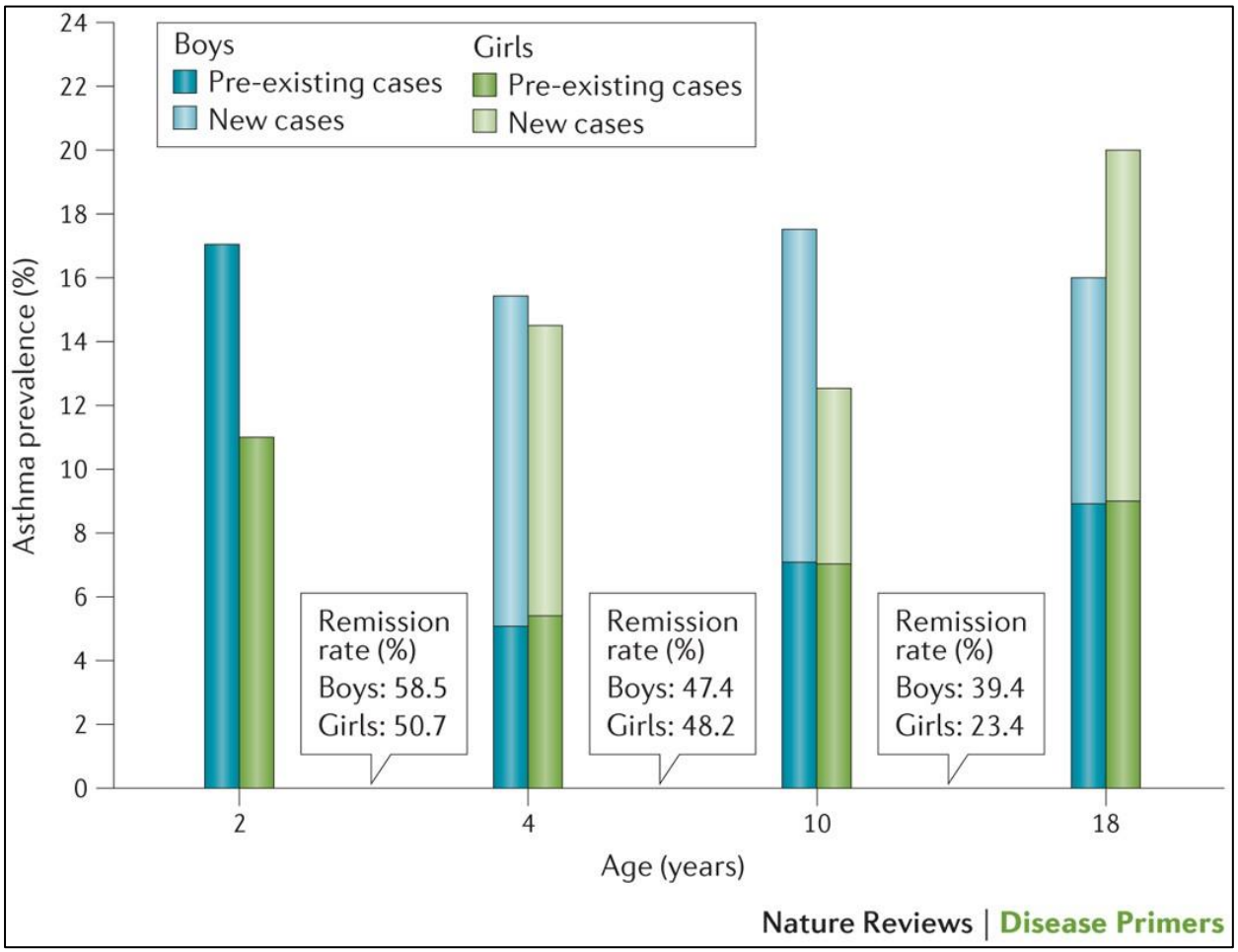


Source: https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(18)30409-1/fulltext#%2

Asthma is more common in boys than girls in early childhood, throughout puberty and early adulthood, boys experience asthma remission at a higher rate than in girls. In

addition, girls acquire asthma more often than boys after puberty. Consequently, the sex ratio of asthma during childhood reverses in adolescence and in young adulthood(7)

Figure 4: Proportions of children and adolescents with asthma in the Isle of Wight birth cohort

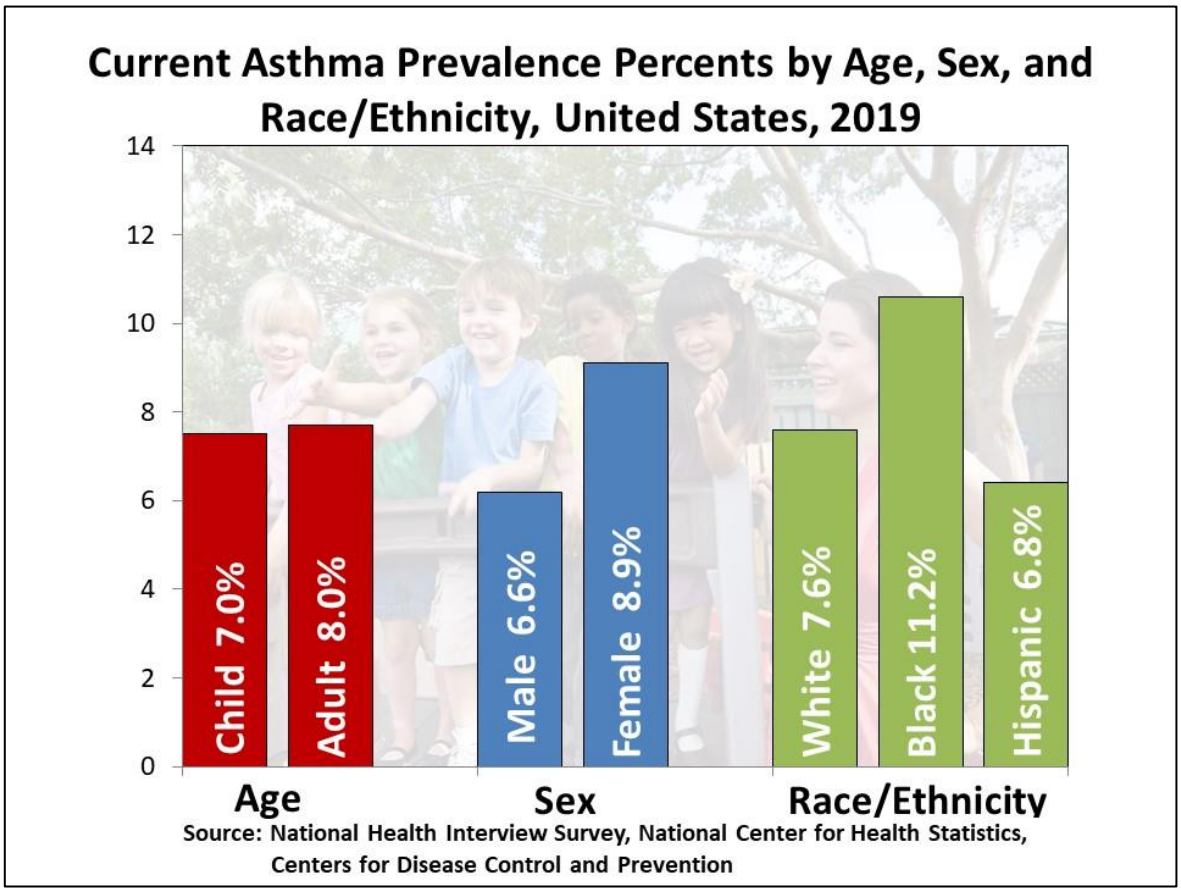


Source: Arshad, S. H. et al. Pathophysiological characterization of asthma transitions across adolescence. Respir. Res. 15, 153 (2014)

Bars represent the proportion of either boys or girls at particular ages who have asthma, with light-shaded sections representing the proportion of new cases that did

not carry over from the previous age group (positive transition); the boxes between bars indicate the percentage of children who grew out of asthma in the intervening years (negative transition or remission).

Figure 5: The latest national and state statistics on the burden of asthma among children and adults.

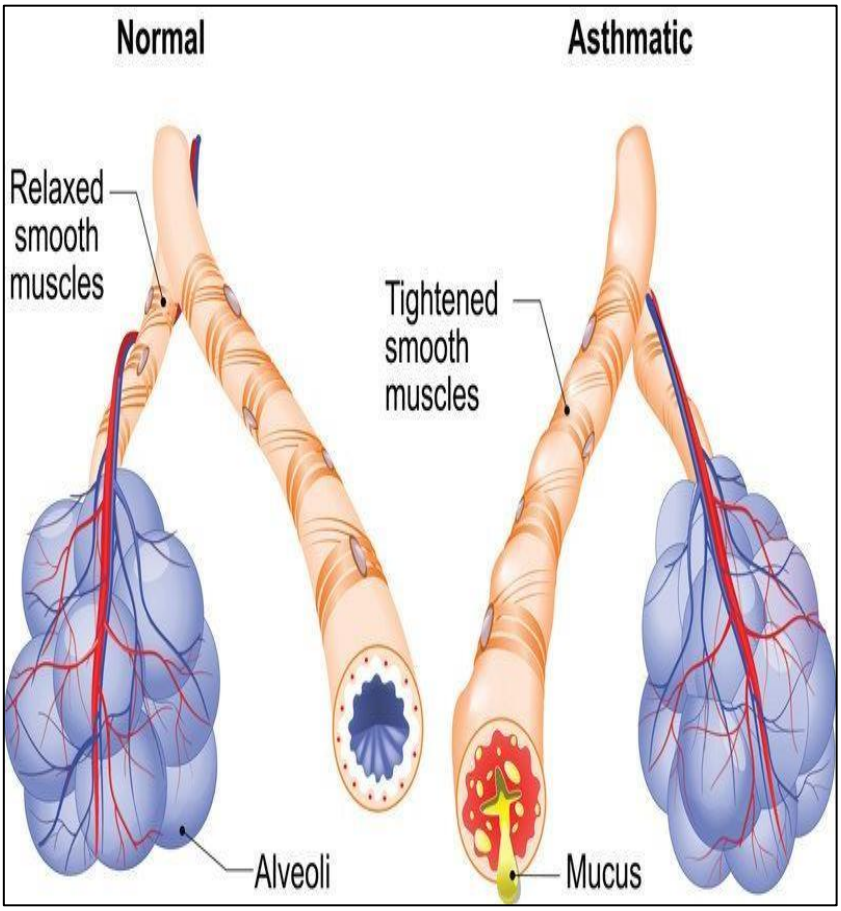


Source: National Health interview survey, National centre for Health statistics, centre for disease control and prevention

2.3. Manifestation of Asthma

Bronchial asthma 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 6: Manifestation of asthma

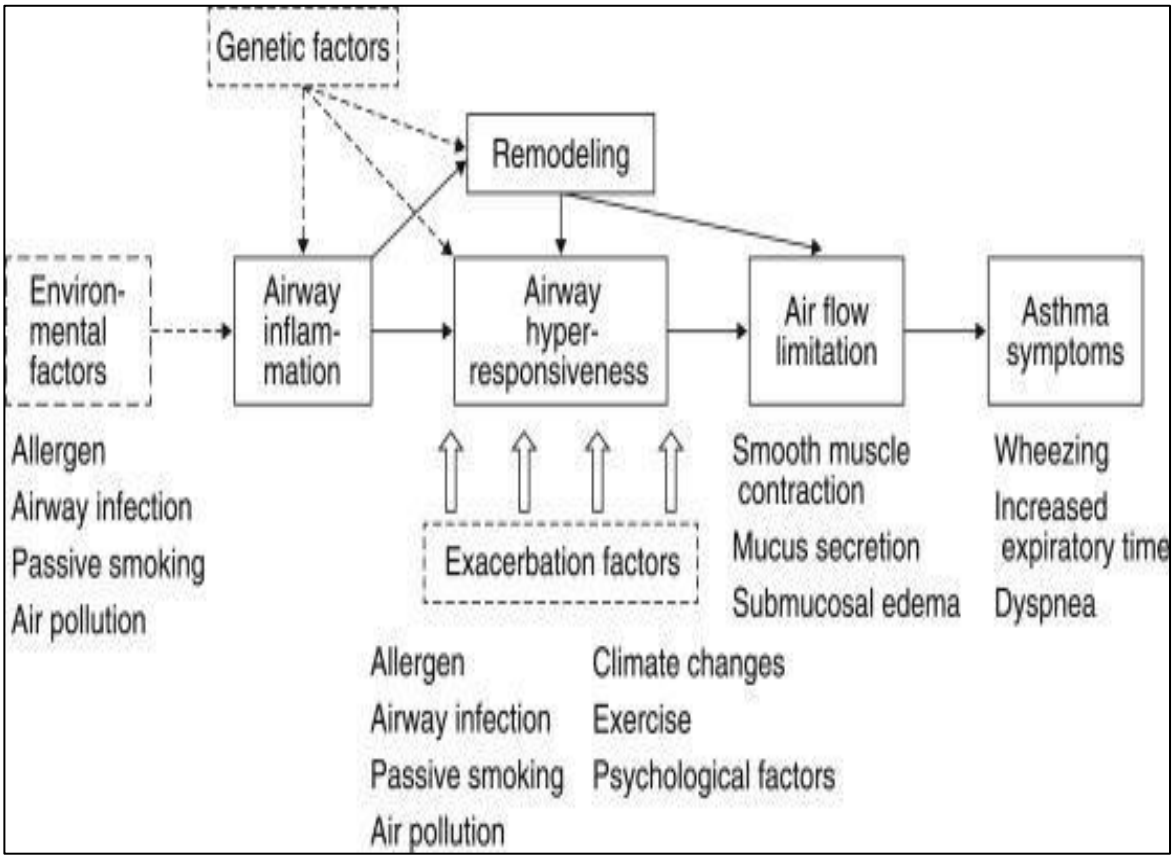


Source: https://www.everydayhealth.com/hs/asthma/complications-uncontrolled-asthma/

2.4. Risk factors:

Childhood risk factors for asthma may include allergic by-environment interaction probably explains much of the sensitization, environmental tobacco smoke, exposure to animals, breastfeeding, decreased lung function in infancy, International variation in prevalence rates for Allergy and family size and structure, socio-economic status, antibiotics asthma. Environmental factors such as infections and expo-and infections and sex and gender(8)

Figure 7: Factors Responsible for asthma

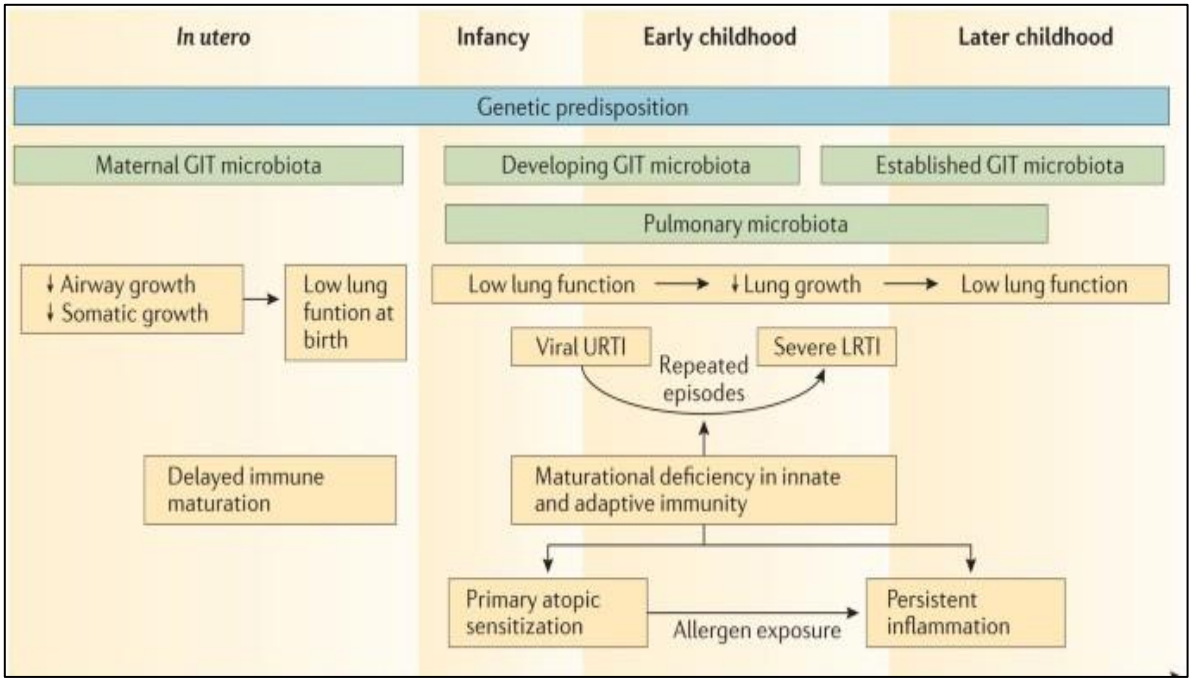


Source: https://1library.net/document/dzxk4dqr-effect-cold-chest-pulmonary-functions-patients-bronchial-asthma.html

2.5. Disease onset:

A key trigger for the onset of asthma in children is severe wheezing in early life in response to viral infections, especially respiratory infection with syncytial virus (RSV) or rhinovirus. A second trigger is the emergence and then persistence of a T2-type allergic immune response in the airways. In the first 2 years of life, all children become infected with RSV and rhinovirus, so the question is not whether infection is a causal factor in the onset of asthma, but whether there is an underlying developmental defect of the lungs and/or the innate immune system that confers asthma susceptibility.

Figure 8: Asthma as a developmental disease.



Source: Holgate, S., Wenzel, S., Postma, D. *et al.* Asthma. *Nat Rev Dis Primers* 1, 15025 (2015). https://doi.org/10.1038/nrdp.2015.25

Asthma is caused by failure of the respiratory and immune systems to develop normally. This schematic (**Figure 8**) represents asthma risk factors that operate at different stages of life. (7)

Asthma risk at birth is influence by genetic predispositions, impaired lung function and delayed immune maturation. Postnatal risk factors that increase asthma risk include reduced lung growth resulting in low lung function, the timing of acquisition of specific components of the pulmonary micro biota, repeated episodes of viral upper respiratory tract infections (URTIs) that spread to the lower airway and result in severe lower respiratory tract infections (LRTIs), maturational deficiencies in the innate and adaptive immune systems that increase the risk of severe LRTIs and favour primary allergic sensitization and repeated allergen exposure, resulting in persistent airway inflammation.

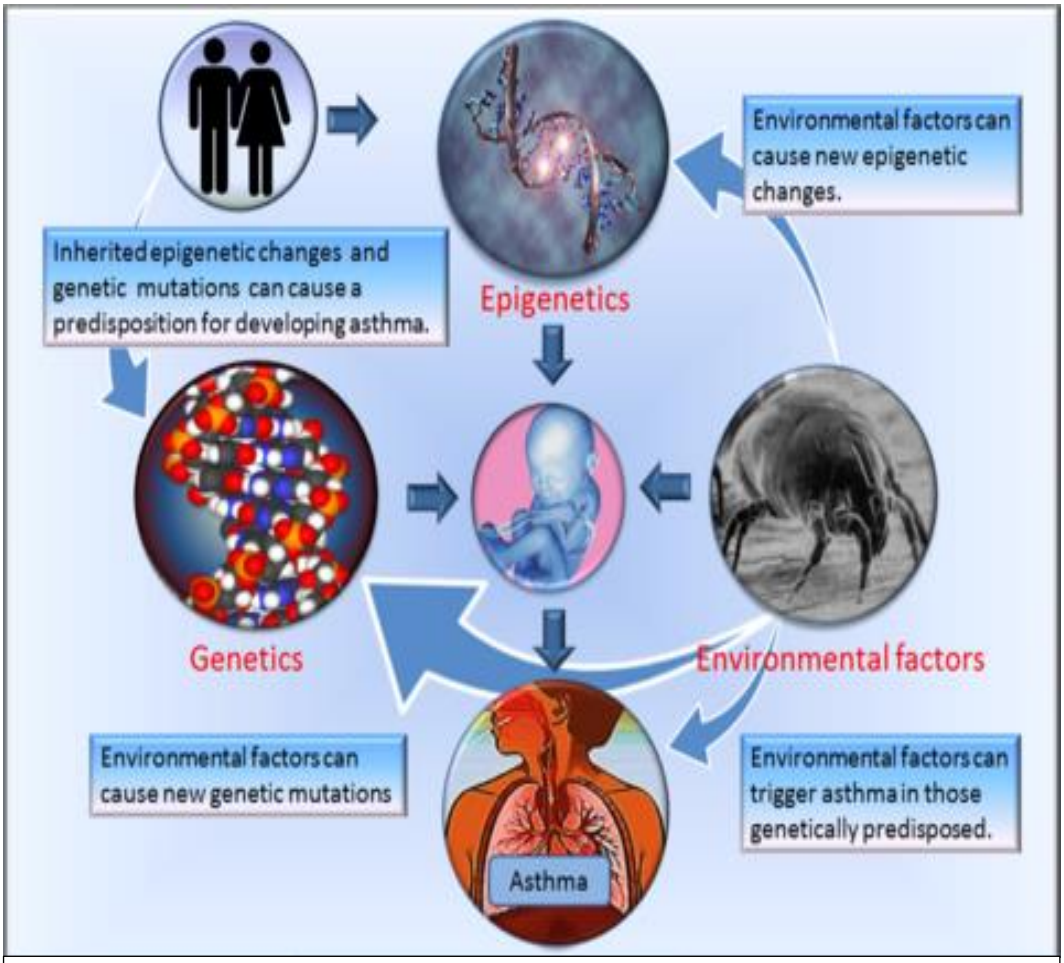
The maternal gastrointestinal tract (GIT) micro biota is thought to influence priming of the fetal immune system and the postnatal development of the infant GIT micro biota is influenced by early-life exposures. Although each individual pathway increases the risk of asthma, the major risk is produced when a child progresses through multiple risk pathways simultaneously.(7)

2.6. Etiology of CHA:

A combination of environmental exposures and inherent biological and genetic susceptibilities can trigger AHR

- **Genetics:** To date, more than 100 genetic loci have been linked to asthma, although relatively few have consistently been linked to asthma
- **Environment:**
    - Common viral infections of the respiratory tract
    - animal dander
    - Indoor allergens (Dust mites, Cockroaches)
    - Seasonal aeroallergens (trees, grasses, weeds)
    - Air pollutants (dust, Wood- or coal-burning smoke)
    - Strong or noxious odours or fumes
    - Cold air, dry air
    - Exercise and psychological factors

Figure 9: Asthma cause



It is believed that a person gets asthma for different reasons, including the genes they get from their parents (genetics), changes in the way some of their genes work (epigenetics) and things in their life that are not healthy (unhealthy or negative environmental factors).

Source: https://simple.wikipedia.org/wiki/Asthma

Asthma is often seen in children. It is a leading cause of missed school days and hospital visits for children. An allergic reaction is a key part of asthma in children. Asthma and allergies often occur together.

Figure 10: Summaries of Factors that correlate with childhood asthma

Source: https://asthmaallergyclinic.in/asthma/childhood-asthma/

2.7. Types of Asthma

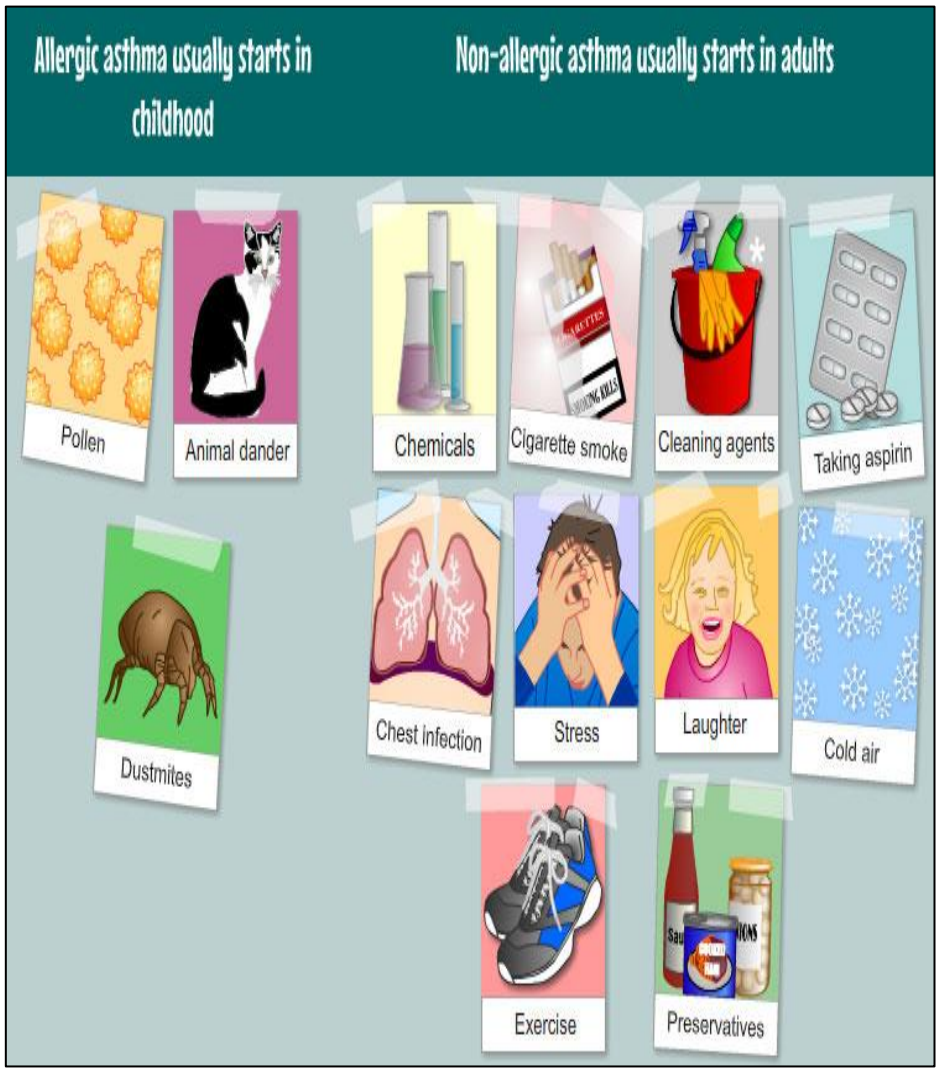
There are several types of asthma with different symptoms and triggers. Some common types of asthma and asthma-related illnesses diagnosed in children include:

- **Allergic asthma**: Classic asthma symptoms are brought on by something your child is allergic to, such as pollen, dust, mold, pet dander, or certain foods. The allergy may also cause sneezing, itchy and watery eyes, runny nose, or hives.
- **Exercise-induced bronchoconstriction (EIB):** Symptoms are caused by dehydration of the air passages due to changes in breathing during exertion, especially in cold air. Symptoms may be classic or also include sore throat, upset stomach, and decreased endurance.
- **Cough-variant asthma:** Some children's only asthma symptom is a dry cough that may wake them up, come on after exercise, get worse in cold and/or dry weather, or worsen after exposure to allergens. In some cases, this may be a sign of early asthma, although only about 30% of people diagnosed with this condition go on to develop classic asthma symptoms.

Less common Types:

- **Non-allergic asthma:** Classic asthma symptoms may be triggered by things that irritate the airways, including airborne irritants (pollution, smoke, fumes), acid reflux, cold weather, humidity stress, and respiratory infections.
- **Nocturnal asthma:** Classic symptoms frequently interrupt sleep and may be triggered by allergens or non-allergen irritants in the bedroom, especially when sleeping with a window open. Some children fall back to sleep too quickly to remember waking up, so the telltale symptom is daytime sleepiness.

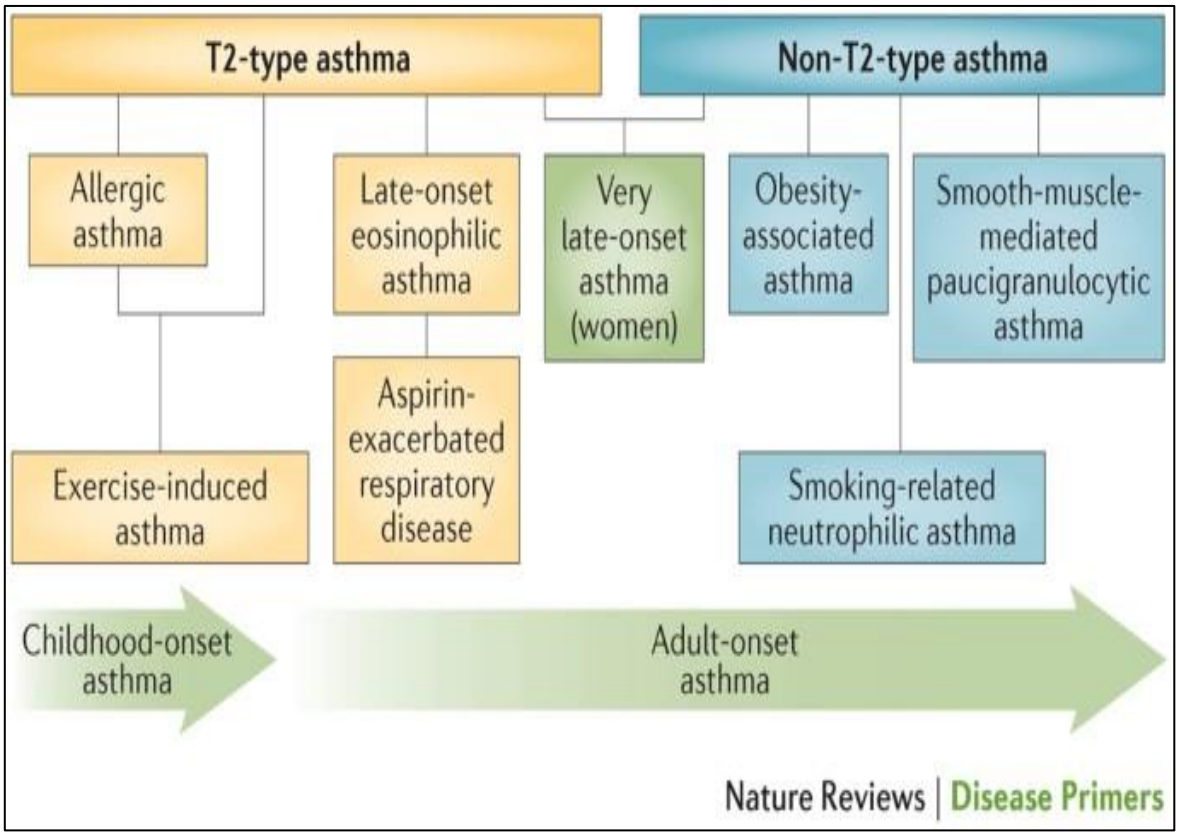
Figure 11: Types of asthma



Source: https://mylungsmylife.org/topics/group-3/a-parents-guide-to-asthma/types-of-asthma-2/

Cluster and other non-hierarchical analyses have identified subtypes of asthma associated with differing causal pathways, natural histories and responses to interventions (7)

Figure 12: Selected asthma sub phenotypes



Source: Holgate, S., Wenzel, S., Postma, D. et al. Asthma. Nat Rev Dis Primers **1,** 15025 (2015). https://doi.org/10.1038/nrdp.2015.25

New sub phenotypes and associated causal pathways, or endotypes, of asthma are being discovered through the application of non-hierarchical statistical analyses of clinical, physiological and laboratory characteristics.

2.7.1. Specific types in childhood asthma

- **Early onset (<12years)**
  - Childhood-onset asthma a relatively homogeneous group

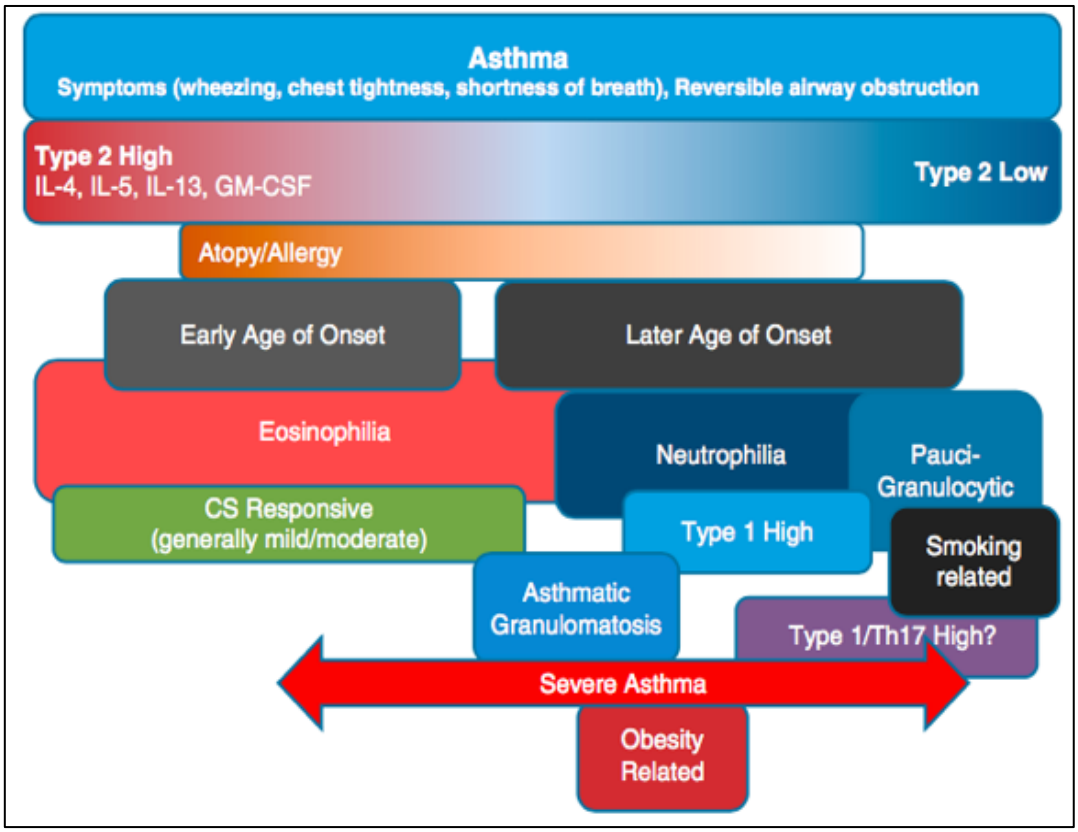
- Allergic Asthma (Atopic) Usually a strong allergic History.
- Family history of asthma.

- **Late onset (>12years)**
  - Adult-onset asthmatics are a very mixed group

    Heterogeneous
  - Late onset – Atopic (34%) have less severe disease. Those

    with severe disease are less likely to be atopic
  - Non Atopic (52%) have mild-to-moderate persistent asthma
  - Late onset eosinophilic asthma
  - AERD Aspirin Exacerbated Respiratory Disease

Figure 13: Overview of asthma



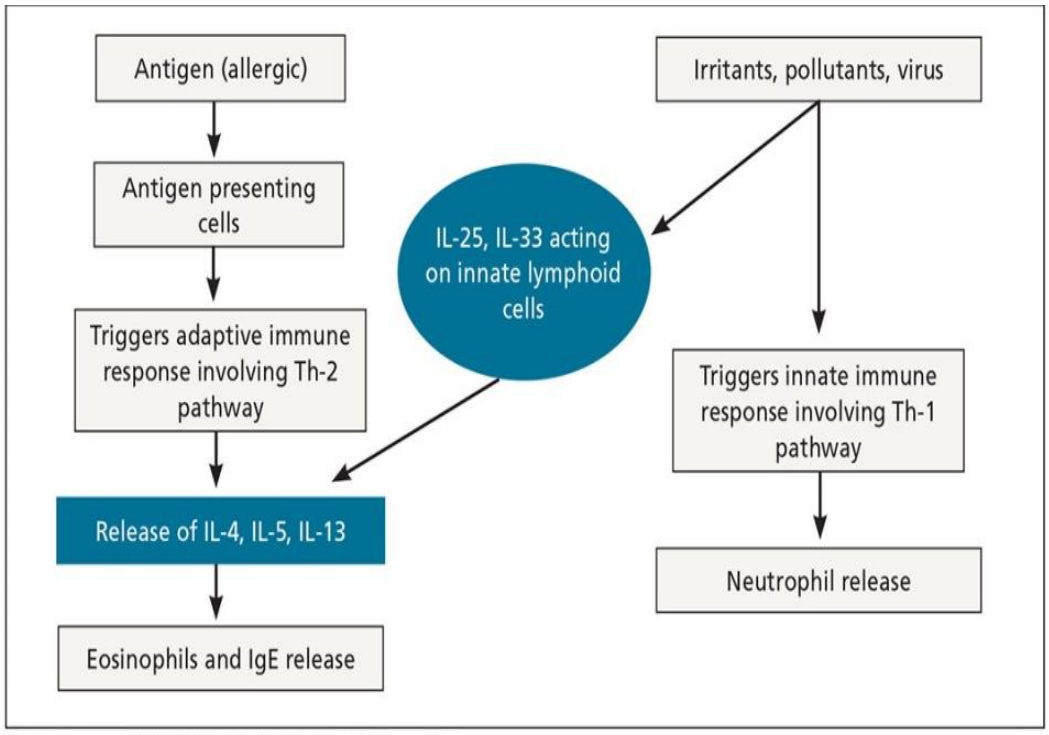
Source: https://slidetodoc.com/bronchial-asthma-3-rd-year-medical-students-dr/

2.8.Pathophysiology of asthma:

There are 2 basic phenotypes of asthma—Neutrophil pre- dominant and Eosinophilic predominant—and 3 key components to its pathophysiology

- Airway inflammation
- Airway obstruction
- Bronchial hyper responsiveness (BHR**)**(9)

Figure 14: Pathophysiology of asthma



IgE, immunoglobulin E; IL, interleukin; Th, T-helper cell.

Source: Rali PM, Yaa N, Rali G, Rali M, Health N. mean more targeted therapy. 2020;69(3)

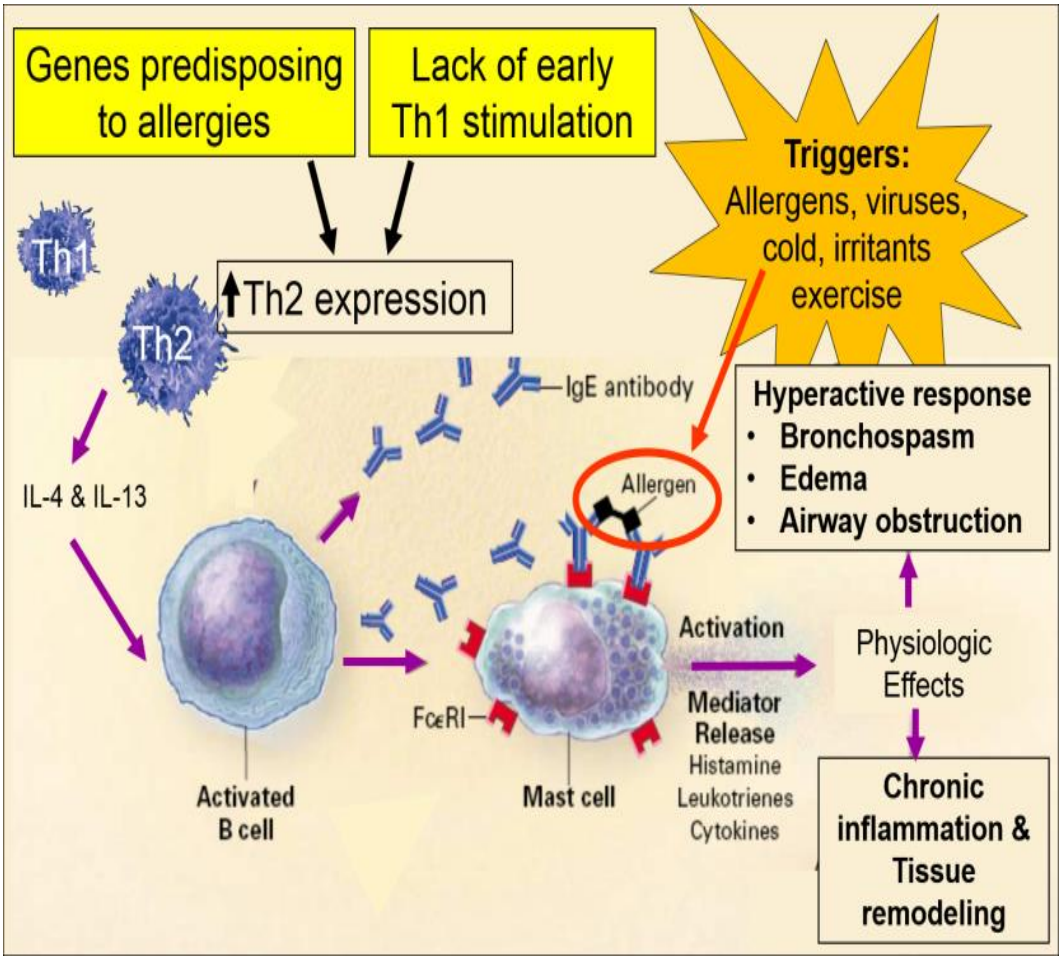
The pathophysiologic basis of asthma is not well understood. It appears to have a complex, multifactorial etiology that results from interplay of many hereditary factors and several environmental factors. Bronchial biopsies from patients with even mild asthma have evidence of chronic inflammation, and cytokines and other mediators of inflammation are found in bronchial washings from asthma patients. Some families are more prone to the development of allergies, and there is a well-known association between allergies and asthma. This suggests a genetic predisposition, but it appears that several genes are involved.

Allergic reactions are mediated by antibodies of the IgE class. People who are prone to IgE-mediated allergic reactions are said to be "atopic meaning that 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 the production of IgE. There are two types of T helper cells (Th lymphocytes) designated Th1 and Th2. Th1 cells tend to promote cell-mediated immune responses by producing 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 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, are believed to have a higher ratio of Th2/Th1 cells, and this is believed to be an important factor in their tendency to produce allergy-mediating IgE antibodies.

These observations are relevant to asthma since biopsies of the bronchial mucosa of patients with asthma have an excess of activated Th2 cells. Many authors take these observations to indicate that an imbalance in Th2/Th1 plays an important role in the development of allergies and, specifically, asthma

Figure 15: Th1 and Th2 interaction

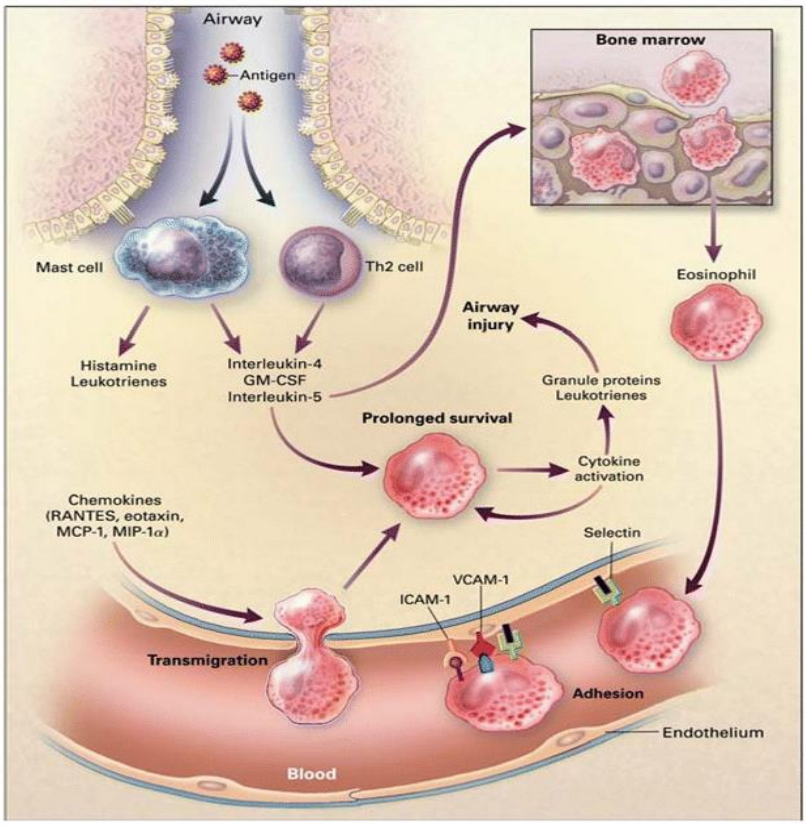


Source: Busse W. & Lemanske R: N. Engl. J. Med. 2001;344(5):350-362

2.8.1. *Airway inflammation:*

Inflammation has a central role in the pathophysiology of asthma. As noted in the definition of asthma, airway inflammation involves an interaction of many cell types and multiple mediators. The cellular profile and the response of the structural cells in asthma are quite consistent.

Figure 16: Airway inflammation



Source: National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2007 Aug.

- Inhaled antigen activates mast cells and Th2 cells in the airway. They in turn induce the production of mediators of inflammation (such as histamine and leukotrienes) and cytokines including interleukin-4 and interleukin-5.Interleukin-5 travels to the bone marrow and causes terminal differentiation of eosinophils.
- Circulating eosinophil enter the area of allergic inflammation and begin migrating to the lung by rolling, through interactions with selectins, and eventually adhering to endothelium through the binding of integrins to members of the immunoglobulin superfamily of adhesion proteins: vascular-cell adhesion molecule 1 (VCAM-1) and intercellular adhesion molecule 1(ICAM-1).
- As the eosinophils enter the matrix of the airway through the influence of various chemokines and cytokines, their survival is prolonged by interleukin-4 and granulocyte-macrophage colony-stimulating factor (GM-CSF). On activation, the eosinophil releases inflammatory mediators, such as leukotrienes and granule proteins, to injure airway tissues.
- In addition, eosinophil's can generate GM-CSF to prolong and potentiate their survival and contribution to persistent airway inflammation. MCP-1, monocyte chemotactic protein; and MIP-1α, macrophage inflammatory protein.

Source: From Busse WW, Lemanske RF. Advances in Immunology N Engl J Med 2001; 344: 350-62.

Table 1: Inflammatory cells and Meditators

Inflammatory cells	**Inflammatory Mediators**
Lymphocytes, Mast cells, Eosinophil, Neutrophils, Dendritic cells, Macrophages, Residential cells of the airway. Epithelial cells	Cytokines, cysteinyl Leukotriene, Nitric oxide, Immunoglobulin E

2.8.2.*Cellular Response in Asthma*:

Lymphocytes:

The activation and regulation of lymphocytes play a central role in asthmatic inflammation. It is increasingly recognized that diverse panels of lymphocyte lineages and cytokine profiles are involved in the asthmatic phenotypes in particular the involvement of T helper type 2 (Th2). Several Th2 cytokines have the potential to modulate airway inflammation, in particular interleukin-13 which induces AHR. Independently of IgE and eosinophilia in animal models. (10).Generation of Th2 cytokines (e.g., interleukin-4 (IL-4), IL-5, and IL-13) could also explain the overproduction of IgE, presence of eosinophils, and development of AHR(11)

Eosinophils:

Increased numbers of eosinophils exist in the airways of most, but not all, persons who have asthma (Chu and Martin 2001; Sampson 2000; Williams 2004). These cells contain inflammatory enzymes, generate leukotrienes, and express a wide variety of

pro-inflammatory cytokines. Increases in eosinophils often correlate with greater asthma severity.(11). Increased numbers of eosinophils have been reported in the peripheral blood of patients with eosinophilic disorders such as asthma.(12)

Immunoglobulin E (IgE):

IgE is the antibody responsible for activation of allergic reactions and is important to the pathogenesis of allergic diseases and the development and persistence of inflammation. IgE attaches to cell surfaces via a specific high-affinity receptor. The mast cell has large numbers of IgE receptors; these, when activated by interaction with antigen, release a wide variety of mediators to initiate acute bronchospasm and also to release pro-inflammatory cytokines to perpetuate underlying airway inflammation (Boyce 2003; Sporik et al. 1995). Other cells, basophils, dendritic cells, and lymphocytes also have high-affinity IgE receptors.(11)

2.9. Classification of asthma severity:

According to the National Asthma Education and Prevention Program's (NAEPP) Guidelines for the Diagnosis and Management of Asthma , divided into four levels of asthma severity: mild intermittent, mild persistent, moderate persistent, and severe persistent. In children older than 5 years, three major features are recommended in determining level of severity:(2)

- Frequency of asthma symptoms during the day,
- Frequency of night time asthma symptoms,
- Measures of pulmonary function

Table 2: Criteria For Classification Of Asthma Severity (2)

Severity	**Daytime symptoms**	**Night-time symptoms**	**Exertional symptoms**
Mild intermittent	≤ 2 days/wk	≤2 nights/mo	≤2 times/mo
Mild persistent	3-6 days/wk	3-4nights/mo	3-4 times/mo
Moderate persistent	Daily	5-9 nights/mo	5-9 times /mo
Severe persistent	continuously	≥10 nights/mo	≥10 times/mo

2.10. Asthma Predictive index

The asthma predictive index (API) is a guide to determining which small children will likely have asthma in later years. Children younger than 3 years who have had 4 or more significant wheezing episodes in the past year are much more likely to have persistent (i.e., lifelong) asthma after 5 years if they have either of the following:

Table 3: Asthma Predictive Index (API) for asthma [a] ascertainment(13)

Major Criteria	Minor criteria
1. Physician diagnosis of asthma for parents	1. Physician diagnosis of allergic rhinitis for patient
2. Physician diagnosis of eczema for patient	2. Wheezing apart from colds
	3. Eosinophilia (≥ 4%)
[a]Asthma is determined by frequent wheezing episodes (two or more wheezing episodes within one year) plus at least one of major criteria or two of minor criteria	

Source:https://www.researchgate.net/figure/Asthma-Predictive-Index-API-for-asthma-a-ascertainment_tbl1_323157499

2.11. Diagnosis of CHA:

A careful medical history, physical examination, pulmonary function tests, and additional tests will provide the information needed to ensure a correct diagnosis of asthma. The Expert Panel recommends that the clinician trying to establish a diagnosis of asthma should determine that (EPR–2 1997)(11)

- Episodic symptoms of airflow obstruction are present.
- Airflow obstruction is at least partially reversible.
- Alternative diagnoses are excluded

Recommended methods to establish the diagnosis are (EPR–2 1997):

- Detailed medical history.
- Physical exam focusing on the upper respiratory tract, chest, and skin.
- Spirometry to demonstrate obstruction and assess reversibility, including in children 5 years of age or older. Reversibility is determined either by an increase in FEV1 of ≥12 percent from baseline or by an increase ≥10 percent of predicted FEV1 after inhalation of a short-acting bronchodilator.
- Additional studies as necessary to exclude alternate diagnoses

2.12. Treatment for CHA:

2.12:1. Pharmacological Intervention

Asthma discourse in children can be successful if regularly monitor asthma symptoms and lung function, educate children on how to avoid asthma triggers, and teach children how and when to use asthma medicinal drugs. In a legal age of children, asthma discourse can control symptoms, allowing them to participate in pattern activities. Medication is an effective intervention for childhood asthma. Finding the right medicament and dose to dominance asthma and prevent side effects is an important process.

Two types of medication are used to command CHA

- Long-Term Controller Medicine
- Quick-Relief Medications for Asthma

A) Long-Term Controller Medications for Asthma

Medications taken daily for asthma are called “long-term controller” medicines and function to decrease inflammation (or swelling) of the small airways over time. Types of long-term control medications include:

- Inhaled corticosteroid (ICS) are anti-inflammatory medications most commonly used for long-term dominance
- Leukotriene modifiers like montelukast (Singulair) are added as a secondary medication when inhaled corticosteroids are not enough to control the asthma alone
- Long-acting bronchodilators (also called long-acting beta agonists, or LABA)
- Combination inhalers combine two medications (an inhaled corticosteroid and a long-acting beta-agonist LABA) in a single inhaler. Combination therapy is used as step-up therapy for children not well controlled on inhaled glucocorticoids or montelukast alone
- Theophylline is a bronchodilator that opens the airways but is not used as often now as in the past

B) Quick-Relief Medications for Asthma:

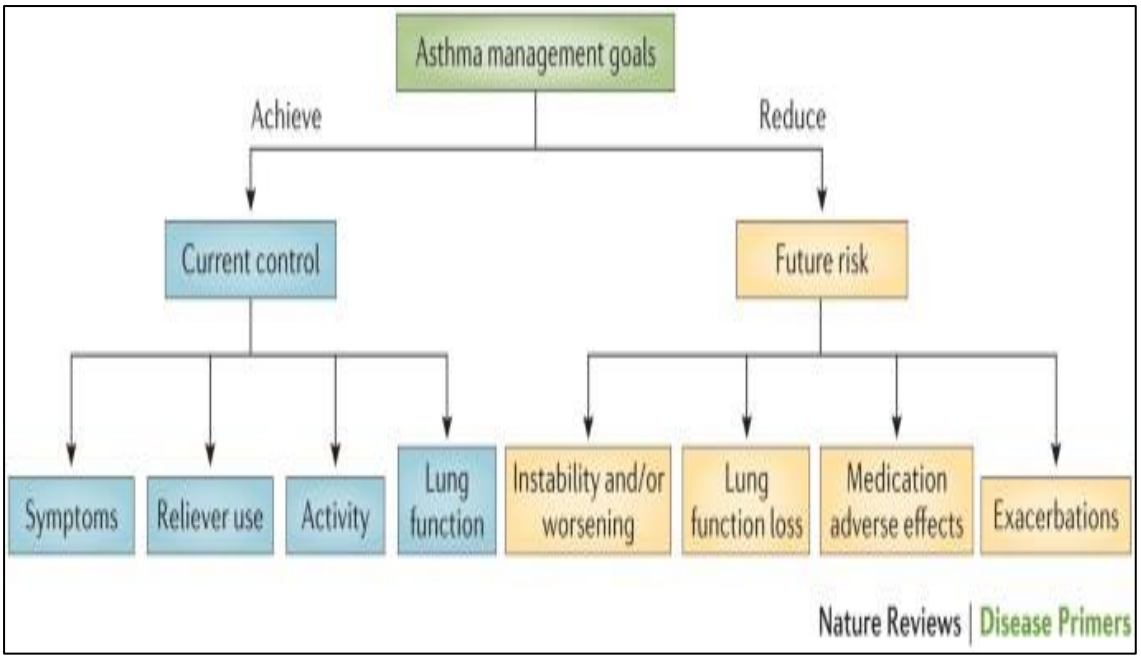
Short-acting bronchodilators (also inhaled short-acting beta-2 agonist or SABA) are highly effective for relieving asthma symptoms by rapidly relaxing the muscles around narrowed airways. However, there is insufficient evidence about the safety of treating asthma with SABA alone. This option should be

reserved for patients with infrequent symptoms (less than twice a month) of short duration, and with no risk divisor for aggravation. Albuterol (Ventolin, Proventil, ProAir, Xopenex) is the most commonly used short-acting bronchodilator.

C) **Overall goals of asthma Management:**

Asthma management should aim to both control the current symptoms of asthma and reduce the risk of future adverse outcomes for patients. Treatment of asthma is primarily focused on improving the day-to-day symptoms of the patient, preventing exacerbations and generally improving their QOL.

Figure17: Overall goals of asthma management



Source: Holgate, S., Wenzel, S., Postma, D. *et al.* Asthma. *Nat Rev Dis Primers* **1,** 15025 (2015). https://doi.org/10.1038/nrdp.2015.25

2.12:2. Non pharmacological intervention

Medication is important in the treatment of asthma, to prevent asthma attacks and keep the condition under control. But many people would like to do more than just take medication. Some of the additional things that can be done have been scientifically proven to help, whereas others have not. Many people with asthma use alternative or complementary medication.

Asthma a chronic disease cannot be cured ,but medicines and lifestyle changes can help to control the symptoms.(14) Yoga is a non-pharmacological adjunct to conventional therapy for asthma.(15)

2: 13. Yoga –conventional Therapy:

The word "yoga" comes from the Sanskrit root "Yuj" which means union, or yoke, to join, and to direct and concentrate one's attention (Lasater 1997 and Raub 2002). Regular practice of yoga promotes durability, endurance, flexibleness and facilitates characteristics of friendliness, compassion, and greater self-control while cultivating a sense of calmness and well-being (Collins 1998). The sustained practice also leads to important outcomes such as changes in life perspective, self-awareness, and an improved sense of energy to live life fully with genuine enjoyment (Atkinson and Permuth-Levine, 2009).

Yoga has been considered as one of the best complementary and alternative medicine by the National Institutes of Health. (14) Similarly, Yoga is also one of the best alternative therapies to control asthma. Yoga is an ancient science that uses postures

and breathing techniques to increase lungs airflow, air capacity, and stamina and reduce stress

Studies say that yoga practices have more effect on various systems of the body. The regular practice of pranayama helps to deflect asthma, reduces the severity of symptoms, strengthens the lungs, and improves breathing capacity.

Pranayama aids in, strengthening of respiratory muscles, release of surfactant & prostaglandins, stimulation of stretch receptors, release of undue tension, adaptation of regulatory mechanisms, and acclimatization of chemoreceptors. It is beneficial for the improvement of lung volumes and capacities in healthy and diseased (of restrictive & obstructive respiratory diseases).

Pranayama is widely used as an alternative therapy in controlling the symptoms of asthma. So the objective of the current study is to observe the changes in the level of serum IgE, eosinophilia, and pulmonary function on childhood asthma by nadishodhana and kapalbhati practice with control group under conventional medicine

The word yoga means 'union': union of mind, body and spirit - the union between us and the intelligent cosmic spirit of creation- 'the oneness of all things'. So pranayama—literally, "control of prana"—isn't just breathing exercises. Through pranayama, you use the breath to affect the constellation of energy that is your body-mind.(16)

Bronchial Asthma is a well-known disease since ancient India and was quoted in charak Samhita as '*Tamasa Swass*' meaning difficulty in ventilation. It is associated

with step-up in airway resistance, hyperinflation of the lung, reduced flow per unit time, and increase work of breathing. Though the modern pharmacological forms have replaced the traditional systems of management, increasing incidence of stress is still posing a great challenge. It is here that yoga shuffling, a vital contribution to the modern medical system(16)

Bronchial Asthma is known to be a functional disorderliness having a psychosomatic component wherein autonomic imbalance may contribute to a possible increment in airway reactivity.

Yoga is one of the methods that can help to increase muscular efficiency, endurance time and aerobic capacity, and can reduce perceived exertion after exercise. Yoga is widely used as a stress reliever. (Miles 1964) was one of the first people to study the respiratory changes during pranayama which could reduce the oxygen consumption and increase working efficiency.(14)Arora S, Bhattacharjee J (2008) states that the practice of yoga produces a physiological state opposite to that of the flight-or-fight emphasis response and with that interruption in the stress response, a sentiency of balance between the mind and torso is achieved.

Karmakar S, *et al* (2015) states that Psychological factors like stress can modulate asthma attack symptoms and influence the management of asthma.

Cohen S *et al* (2005) studies states that increased stress leads to the dysregulation of the hypothalamic-pituitary-adrenal gland and sympathetic-adrenal-medullary axis, disrupting immune and respiratory processes, and producing an increased risk of inflammatory diseases, such as asthma. Thus Yoga offers an effective method of managing and reducing stress.

2.13.1 Yoga on respiratory system:

Yoga integrates an individual's physical, mental and spiritual components and produces a physiological sequence of events in the body reducing this stress response. Yogic exercise enhances muscular intensity and body flexibility, promote and improve respiratory and cardiovascular function and enhance overall well-being and quality of lifespan.(15)

Study conducted by Udupa *et al* (1972) states, the ancient Hindu practice, Hatha yoga have also demonstrated an improvement in respiratory function.

Singh *et al* (2012) concluded in a randomized controlled study of 60 patients that lung function improved significantly in the patients of the yoga group after two months of yoga practice from the baseline. Pranayama and yoga breathing are used to increase respiratory stamina, relax the chest muscles, expand the lungs, raise energy levels, and calm the body.

Mekonnen and Mossie (2010) have shown in a study the effect of yoga on 24 asthma patients for 2 months and they concluded a significant improvement of 10% was found in peak expiratory flow rate (PEFR) in the yoga group and also showed a decreased number of daily attacks per week and night time attacks per month compared to the control group.

A study by Joshi *et al* (1992), also demonstrated improved ventilation function in the

form of lowered respiratory rate, increase FVC, increase FEV1% following six weeks of yoga instruction

R Nagarathna and H R Nagendra(1985) have shown in a controlled study the effect of yoga in long time management of bronchial asthma on 53 patients for two weeks practiced integrated set of yoga exercises, including breathing exercises, suryanamaskar, yogasana (physical postures), pranayama (breath slowing techniques), dhyana (meditation), and a devotional session for 65 minutes daily. They were then compared with a control group of 53 patients with asthma matched for age, sex, and type and severity of asthma, who continued to take their usual drugs. There was a significantly greater improvement in the group who practiced yoga in the weekly number of attacks of asthma, scores for drug treatment, and peak flow rate.(17)

Ramaprabhu et al (2009) reported significant change in FEV1 and PEFR in the yoga group after the regular practice of yoga for 8 week of study period from the baseline, the frequency of rescue medication use significantly decreased over the study period in yoga group and control groups. But, the decrease was achieved relatively earlier and was more marked in the yoga group than in the control group. This study supported the efficacy of yoga in the management of bronchial asthma(18)

2.13.2. Yoga on Childhood asthma:

Studies done by several researchers showed that regular practice of yoga leads to significant improvement in pulmonary function which includes an increase in peak

expiratory flow rate (PEFR), vital capacity (VC), forced vital capacity (FVC), forced expiratory volume one (FEV1) maximum mid expiratory flow rate (MMEFR) (Sathyaprabha et al., 2001; Nagrathna and Nagendra, 1985; Nagendra and Nagrathna, 1986; Gandhi, 1999). Very few studies have also demonstrated the beneficial effects of yoga training on resting pulmonary function, exercise capacity (Jain, 1991)

A study conducted by *Jiwtode Manoj et al* (2015) on 50 school children's of age group 12-15, subjected to training of integrated yoga module for 45 minutes a day for 6 days over a period of 4 months shows statistically significant effect of yoga in pulmonary functions like forced expiratory volumes in first second (FEV1), and peak expiratory floe rate (PEFR) and respiratory pressures like maximum expiratory pressure (MEP), maximum inspiratory pressure (MIP) in study group when compared to control group. This study concludes that yoga training for four months improves lung functions, strength of inspiratory and expiratory muscles in children. Overall if yoga is practiced since childhood, it can be a strong foundation for healthy adult life (19).

It has been used to treat asthma for over 50 years in yoga centers of India. Goyeche et al. (1982) reviewed the work done in this field for about 50 years in various yoga centers of India and Japan. The research showed clearly the benefits of yoga for asthma patients. As an adjunct to conventional therapy, yoga may be effective in managing bronchial asthma.(20).

In the last four-five decades, various yoga techniques have been studied scientifically. They have proved beneficial for lowering cardiovascular risks, blood pressure, respiratory status, and also improve respiration. In addition to psychological well-being,(Khanam et al., 1996). Thus, yoga has been especially effectivein treating and managing psychological disorders, as well as diseases that have a psychosomatic component, such as asthma, hypertension, etc., and has enabled a more holistic approach to the illness of the patient, which often has multiple components.(20)

2.13.3. Pranayama on childhood asthma:

Pranayama methods, which are various kinds of breathing exercises, are utilized by saints living in caves for the prevention of diseases and long-term survival from the traditional period, under natural circumstances. It's been proposed by Patanjali, (600 BCE), the codifier of yoga science that the control of prana (mind) is feasible by regulation of inhalation and exhalation. This is often accomplished by eliminating the pause between inhalation and exhalation or expending it by retention. It regulates the motion of the lungs, resulting into control of heart and nervus vagus.

Regular practice of pranayama may have beneficial effects on nasobronchial disorders like bronchitis, asthma, rhinitis, and customary cold, pharyngitis, obesity, diabetes, hypertension, vascular variability disorders, insulin resistance, heart attacks, allergies, memory dysfunction, and aging.(21)

The nasal tissue is erectile just like sex organs in men and ladies, which is extremely sensitive to breath. Control of breath constitutes a lucid place to

begin toward attainment of control of the autonomic system, and appears to own beneficial effects on the functions of nasal mucosa, pharynx, bronchi, bronchioles, and lungs. These breathing patterns may benefit the omental adipocytes, brain, heart, liver, and kidney functions. The left nostril, diaphragm, and stomach are supplied by the tenth cranial nerve, which can influence pituitary function, the hypothalamus, the epiphysis cerebri, and therefore the supra chiasmatic nucleus.

The science of pranayama is thus intimately connected with the autonomic system and brings its functions under conscious control via breathing patterns and movements of diaphragm and lungs.(21)

Currently, pranayama and other breathing exercises are gaining more prominence because of their role in improving blood oxygenation and utilization of the greater capacity of the lungs, thereby preventing many diseases. The art of pranayama involves methods that increase the movement and expansion of the respiratory organs repeatedly, slowly, and intensely. It involves breathing atmospheric air (inhalation / puraka) into the lungs, and exhaling deoxygenated air from the lungs (Exhalation /Rechaka) and retention of air inside (kumbhaka)(22). Pranayama involves horizontal expansion (dairghya), vertical ascension (aroha), and circular expansion of the lungs and rib cage (thorax) (vishalata). This allows both the front and rear aspects of the lungs to expand in all of their lobes.

Pranayama mode of action towards the development of respiratory system(23)

- Boosts elasticity and strength of collagen fibers thereby facilitates contraction and power of respiration.

- Stimulates secretion of pulmonary surfactant which increases exchange volume of lungs.
- Maintain level of prostaglandins which decreases bronchiolar smooth muscle tonicity resulting in the improved flow of air into lungs.
- Stimulates stretch receptors which affects smooth muscles and improves lung capacities.
- Relaxes skeletal muscles and thoracic cage, it also relaxes smooth muscles of bronchi thus boost pulmonary functions. Extended expiratory period and voluntary breath holding period improves lungs capacity when these techniques of Pranayama performed regularly.

Study conducted by *Erdoğan Yüce, G., & Taşcı, S. (2020)* evaluated the impact of pranayama on asthma control, pulmonary function and quality of life in people with asthma by the practice of pranayama for 20 min once daily for 1 month, and relaxation was applied to the relaxation group similarly in addition to the standard treatment. The study concludes that significant changes seen in ACT Score , overall AQLQ score and subscale score than relaxation group and no significant difference between the groups in terms of PFT parameters(24)

Sabina et al (2005) found that pranayama reduces stress, a common asthma trigger. Breathing techniques and improved control of breathing by yoga in 62 patients of asthma may contribute to the control of asthma symptoms. Breathing exercises emphasized in yoga have the potential to improve lung function and quality of life in asthmatics.(14)

A study assessed the effect of yogic breathing in asthmatics, in which patients were made to breathe through a Pink City Lung exerciser at 1:2 ratio of inhalation: exhalation for 2 weeks, 15 min/day. At the end of 2 weeks, mean forced expiratory volume in 1 s (FEV1), peak expiratory flow rate, symptom score, and inhaler use improved in the experimental group, when compared to controls who were breathing through a placebo device. As an indicator of airway reactivity, the dose of histamine needed to provoke a 20% reduction in FEV 1 (PD 20) was assessed, this increased significantly during Pranayama breathing but not with the placebo device

In healthy individuals pranayama can produce different physiological responses *Upadhyay et al* 2008; and also the responses of alternate nostril breathing (ANB), the Nadi shudhi pranayama on some cardiorespiratory functions were investigated in healthy young adults.

The participants performed ANB exercise (15 minutes every day within the morning) for 4 weeks. Cardiorespiratory parameters were recorded before and after a four-weeks training period. a big increment in PEFR (L/min) and pulse pressure (PP) was noted. Although systolic force per unit area (SBP) decreased insignificantly, the decrease in pulse (PR), rate (RR), diastolic vital sign (DBP) was significant. The results indicated that regular practice of ANB (Nadisudhi) may increase para-sympathetic activity, leading to to decrease in SBP and PP. Alternate nostril breathing (ANB) may modulate cardiorespiratory and autonomic functions. However, the studies are scarce and results highly conflicting.(25)

One study (26) was conducted in healthy young volunteers comprising males (n=20) and females (n=20) in an age range of 17-22 years. In both groups, the RR/min, HR/min, SBP (mm Hg), DBP (mm Hg), PEFR (L/min), and galvanic skin resistance (GSR; microV) were recorded thrice; once as control and then after 15 min (acute exposure) and again following 8 wks of training in ANB (15 min daily). In males the control RR was 16.60 +/- 2.01, HR 75.75 +/- 11.07, SBP-115.9 +/- 7.33, DBP 70.4 +/- 6.28 and PEFR 550.00 +/- 51.50. After 15 min of ANB-RR (14.75 +/- 1.41, P< .001), HR (68.45 +/- 12.41, P< .01) and SBP (113.6 +/- 6.04, P<0.05) fell significantly. After 8 wks of ANB training RR (12.35 +/- 1.35, P< .0001), HR (63.20 +/- 11.11, P< .001), SBP (109.5 +/- 5.61, P< .001), declined to much greater extent and PEFR (571.50 +/- 46.26, P < .01) rose significantly. In females the control RR was 17.25 +/- 1.89, HR-74.90 +/- 12.85, SBP-106.70 +/- 6.91, DBP-68.70 +/- 5.52 and PEFR-394.50 +/- 44.89. After 15 minutes, of ANB RR (15.05 +/- 1.54, P< .001) and HR (64.75 +/- 9.80, P< .001) there was significant decline with concomitant rise in PEFR (407.00 +/- 2.31, P<0.05). Following eight weeks of training the decrement in RR (12.60 +/-1.50, P< .0001) and HR (63.30 +/- 8.65, P< .001) was maintained. SBP (103.10 +/- 4.92, P< .001) and DBP (65.8 +/- 5.54, P< .001) decreased further and PEFR (421.00 +/- 38.51 P< .001) rose, GSR was unaffected by ANB in both males and females. The results suggested that in general, there is a tilt toward parasympathetic dominance by alternate nostril breathing. This breathing may be a useful adjuvant to medical therapy of hypertension and COPD.

The effect of right, left, and alternate nostril yoga breathing (RNYB, LNYB, ANYB, respectively) were compared with breath awareness (BAW) and normal breathing (CTL) (27). Autonomic and respiratory variables were studied in 21 male volunteers with ages between 18 and 45 years and experience in the yoga breathing practices between 3 and 48 months. Subjects were assessed in five experimental sessions on five separate days. The sessions were in fixed possible sequences and subjects were assigned to a sequence randomly. Each session was for 40 min; 30 min for the breathing practice, preceded and followed by 5 min of quiet sitting. Assessments included heart rate variability, skin conductance, finger plethysmogram amplitude, breath rate, and blood pressure. Following RNYB there was a significant increase in systolic, diastolic and mean pressure. In contrast, the systolic and diastolic pressure decreased after ANYB and the systolic and mean pressure were lower after LNYB. Hence, unilateral nostril yoga breathing practices appear to influence the blood pressure in different ways. These effects suggest possible therapeutic applications.

In another study, 53 patients with asthma under-went training for 2 weeks in an integrated set of yoga exercises, including breathing exercises, suryanamaskar, yogasana (physical postures), pranayama (breath slowing techniques), dhyana (meditation), and a devotional session, and were told to practice these exercises for 65 minutes daily (8). They were then compared with a bearing group of 53 patients with asthma matched for age, gender, and sort and severity of asthma, who continued to require their usual drugs. There was a significantly greater improvement within

the group, who practiced yoga within the weekly number of attacks of asthma, scores for drug treatment and peak rate of flow. This study showed the efficacy of yoga within the future management of respiratory disease, but the physiological basis for this beneficial effect has to be examined in additional detail.(17)

Another study shows significant effect in the hematological, biochemical and psychological effects of a yoga training programming conducted in nursing students. 60 healthy nursing students (12 M, 48 F) aged 18.60 ± 0.67 (SD) y were recruited, and 60 min of yoga training was given twice weekly, for 6 months. Selected biochemical and haematological parameters were recorded along with Ferrans and Powers QoL index before and after the training period. QoL was also tested at midterm. The decrease in eosinophils is evidence of a reduction in allergic tendencies. Post intervention statistical analysis (repeated measures of ANOVA) revealed highly significant and beneficial changes in most haematological and biochemical parameters. Major findings are enhanced bone marrow function, reduced allergic tendency, alkalization of urine, metabolic reconditioning (with special emphasis on liver function) and improvement in all QoL indices. This provides a scientific basis for using yoga in allergic conditions where eosinophilia is implicated.(28)

3.0. AIM AND OBJECTIVE

3.1: Aim:

To study the effect of Pranayama on serum IgE, Eosinophilia and pulmonary function of childhood asthma

3.2: Objective:

Primary objective:

- To evaluate the effect of Nadi shodhana and Kapalbhati on serum IgE and eosinophilia of childhood asthma

Secondary objective:

- To evaluate the effect of Nadi shodhana and kapalbhati on pulmonary function and quality of life in children with asthma.

4.0. HYPOTHESIS

4.1. Null Hypothesis (H0): Pranayama practice does not shows any effect on serum IgE, eosinophilia and pulmonary function on childhood asthma

4.2. Alternate Hypothesis (H1): Pranayama practice shows effect on serum IgE, eosinophilia and pulmonary function on childhood asthma

5.0. MATERIALS AND METHODS

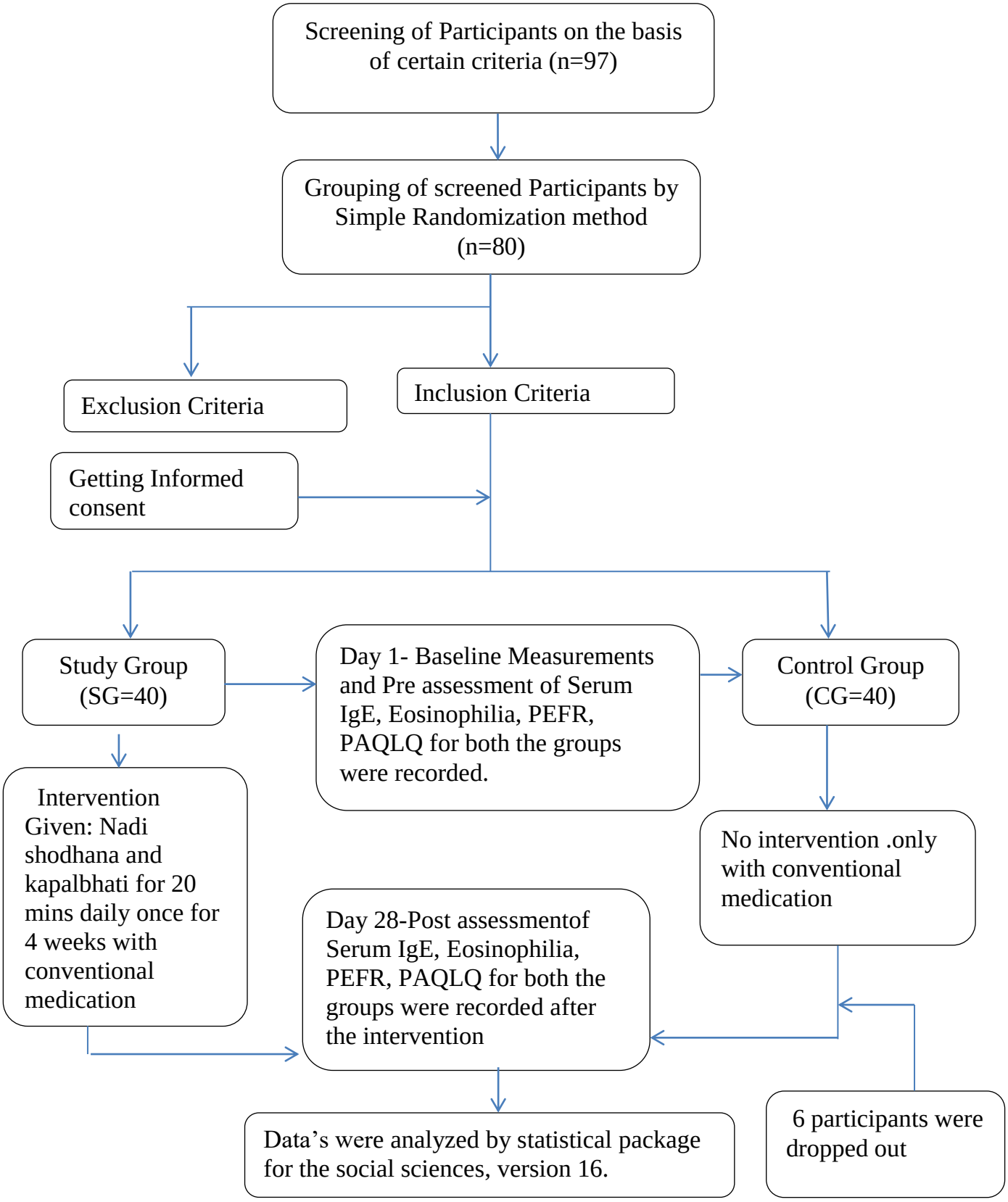
5.1: Study Design

The study employed Randomized Control Trial. Initial screening of the patient was done and allocated into two groups in the field of study, one as a study group (SG) and the other as a Control Group (GC) by simple randomization methods. An aggregate of 80 patients who were fulfilling inclusion criteria participated in the study. After getting the informed consent, the baseline assessment of Serum IgE, Eosinophilia, peak expiratory flow rate (PEFR), and Pediatric asthma quality of life questionnaire with standardized activities (PAQLQ(S)) was recorded with base-line measurement. SG was given pranayama practice (Nadi shodhana and Kapalbhati) for the duration of 20 minutes daily once for 28 days along with conventional medicine. Control group was only under conventional medicine. After 4 weeks, again Serum IgE, Eosinophilia, PEFR, PAQLQ was recorded for both groups.

Out of 80 subjects, 6 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.

5.2. Trail Profile

Figure 18: Trail profile



5.3: Study settings

Childhood asthma patients from Government Yoga and Naturopathy Medical College and Hospital, and Institute of Child Health Hospital, Egmore under the department of Yoga and Naturopathy has been Recruited for the study.

5.4. Sample Size:

The study comprised a total of 74 study participants. The sample size is categorized under two groups. Study group (n=40) represents intervention groups and the remaining 34(n=34) belongs under the control group.

5.5. Selection Criteria:

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

Inclusion Criteria:

- Age Group -8 to 12 years
- Both sexes
- Children's with conventional medicine
- Children's with asthma history or typical symptoms
- Persons who are ready to give their consent

Exclusion Criteria:

- Systemic diseases like cardiovascular, Digestive, Psychological disorders ,degenerative disorder, renal, neurological diseases
- Participation in another clinical trials in the previous 1 month
- Hospitalized children's

5.6. Withdrawal Criteria

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.

5.7. Ethical Consideration

5.7.1. 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.

5.7.2. Written Informed Consent

Subjects who fulfilled inclusion criteria were apprised about the determination of the study and their rights field as research discipline. The above same was also informed to the subject's parent. An informed consent form was administered in English language. As all the subjects understood spoke English, there was no requisite of translating the signed informed consent form into native language i.e., Tamil. Adequate time was given to each patient to go through the data 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 selective information sheet and consent form is enclosed in Annexure.

5.8. Intervention:

- **Study Group:**

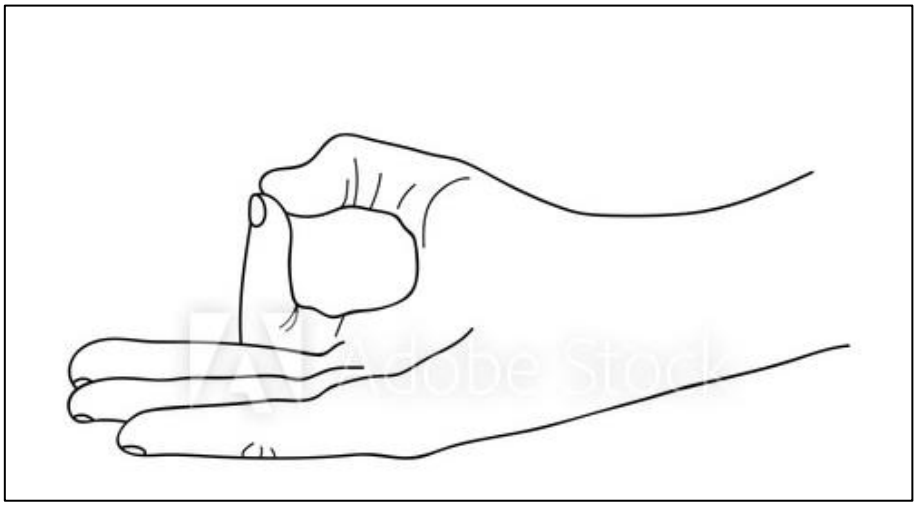
All the subjects were asked to perform specific pranayama for 20 mins daily once for 28 days along with convention medication which includes inhaler salbutamol / foracort 200 mcg, T.Montelukast / T. leukotriene as prescribed.

Specific Pranayama practices like Nadi shodhana and Kapalbhati were given to the study group participants.

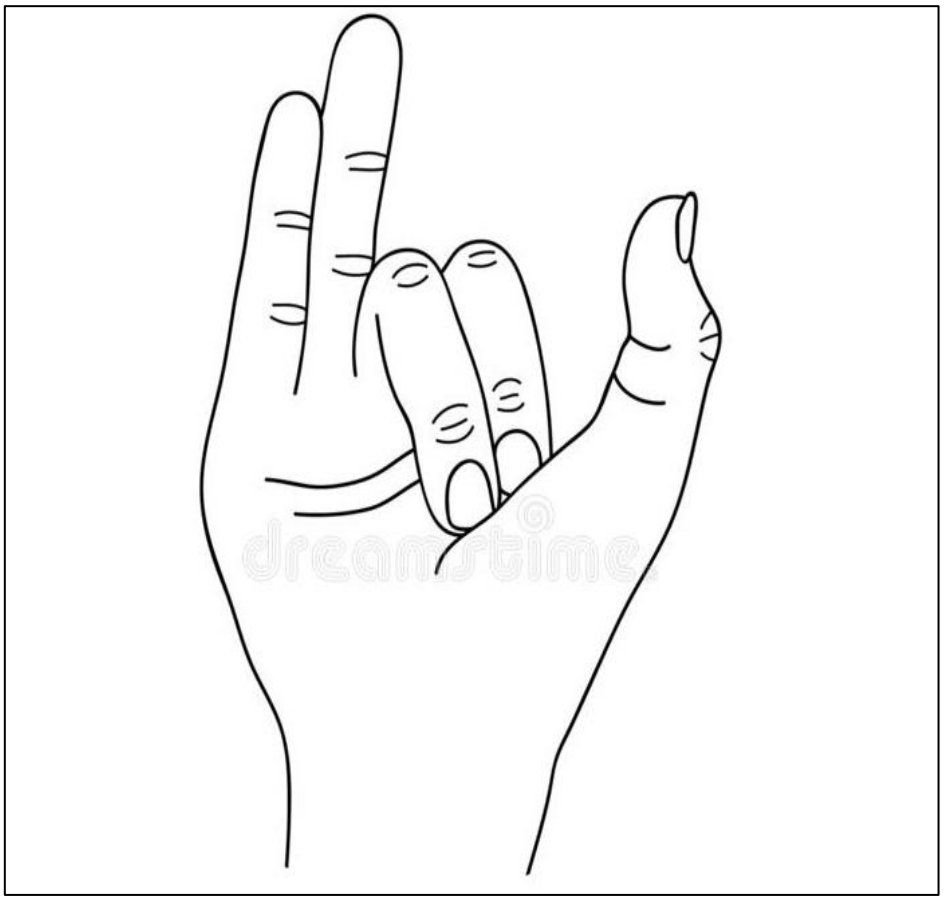
Nadi shodhana pranayama (Psychic Network Purification)

The subject was asked to Sit comfortably with eyes closed and asked to adopt perform Nasagara Mudra in Right Hand and Chin Mudra in Left hand. With closed eyes. Now asked closely to close the right nostril with right thumb and inhale slowly for 5 counts and then asked to close the left nostril with ring finger, releasing the thumb from right nostril and exhale for 5 counts slowly. Again asked to inhale through right nostril for 5 counts slowly and then close the nostril with thumb and exhale slowly for 5 counts by releasing the ring finger from left nostril this is one round and the patient was asked to practice for 10 minutes.

Figure 19: Mudras A) Chin Mudra in Left Hand



B) Nasigara Mudra in Right Hand



Kapalbhati Pranayama (Frontal Brain Cleansing Breath)

- Patient was asked to sit in comfortable position with chin mudra on both the hands, slowly close your eyes and inhale deeply through both the nostrils and exhale forcefully according to their ability. The patient was asked to continue active and forceful exhalation and passive inhalation with maximum speed. After completing one round the patient was asked to take a deep breath and exhale slowly. The practice was done for 10 minutes

- **Control Group**

  All the control group subjects were asked to continue their convention medication which includes inhaler salbutamol / foracort 200 mcg, T.Montelukast / T. leukotriene as prescribed.

5.9. Outcome Variables

5.9.1. Primary Outcome variables:

The primary outcome of the study was the blood hematological examination of serum IgE and Eosinophilia of the participants

Serum IgE Test: Nephchem Immunoglobulins E (Ige) (Nephelometry Method)

- **Specimen Collection:**

The patient skin was cleaned and an elastic band (tourniquet) was applied above the area to get the veins to swell with blood. A needle is inserted into a vein (usually in the arm interior of the elbow) and drawn 5ml of the blood sample into a vial or

syringe. once completed the needle is removed from the vein and the tourniquet is taken off. Standard research laboratory procedures were followed for the solicitation of sampling

The kit utilizes latex enhanced immune turbidimetry to measure the IgE levels in human serum by GB NEPHCHEM (Nephelometry Method). The kit utilizes immune turbidimetry to measure the LgE levels in the human serum. During the test, IgE in the sample binds with the specific anti IgE antibody to cause agglutination. The turbidity caused by agglutination is detected optically by GB NEPHCHEM, analyzer. The change in the absorbance is proportional to the level of IgE in the sample. The actual concentration is obtained by comparing with a calibration curve with the know concentration

Figure 20: Testing Kit Nephchem Immunoglobulin E (IgE) (Nephelometry Method)

Figure 21: Cuvette

- **Kit Contents:**

Reagent Kit Box	
R1- IgE buffer	1x4.1ml
R2- IgE antibody	1x2.05ml
Testing Card	1 no
Accessories Kit Box	
Cuvettes	25 nos
Big Tips	25 nos
Small tips	50 nos

Procedure

- Step 1 insert test card to the card reader slot and display will show promptly add R1 +S (sample)
- Step 2: Pipette out 150 µl of R1 into dedicated cuvette and add 5µl of sample (serum) and place the cuvette in the reading chamber
- Step 3: After the incubation, the display will show promptly add R2

- Step 4: pipette out 75µl of R2 using pipette connected with the machine into the cuvette
- Step 5: once the reaction time got over, the result will show in the display

Eosinophil from stained blood smears:

Measurement of eosinophil's in whole blood for the evaluation of allergic reaction in the body

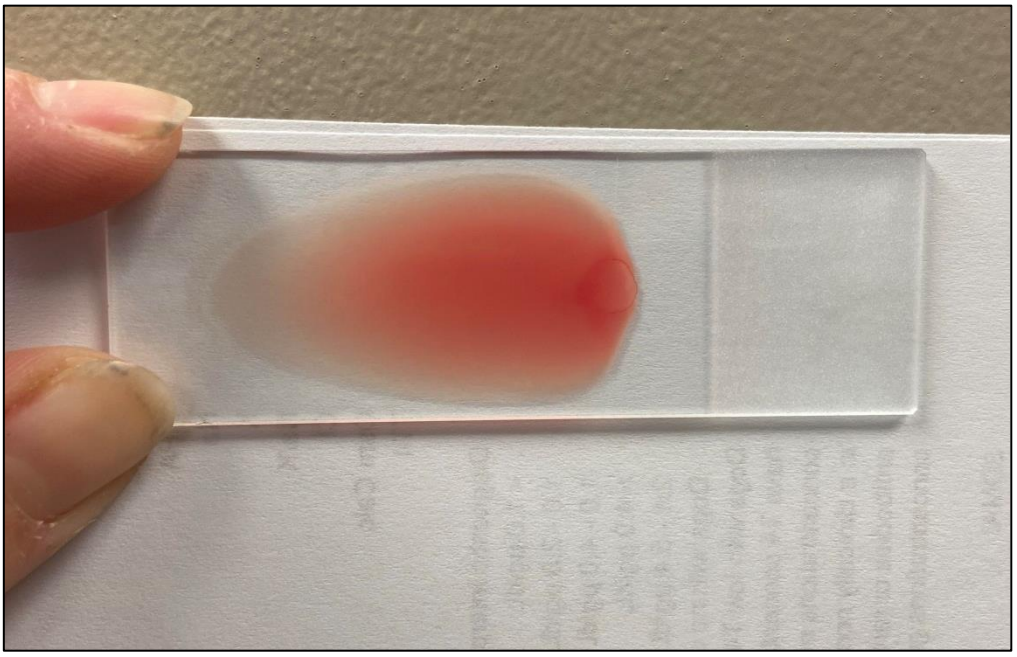
A blood film is stained with Leishman's stain and scanned under oil immersion, from one end to the other. As each WBC is encountered, it is identified until 200 leukocytes have been examined. The percentage distribution of each type of WBC is then calculated. Knowing the TLC and the differential count, it is easy to determine the number of each type of cell per mm3

Specimen collection and procedure:

- The patient's finger was cleaned under aseptic condition and a prick was made on the index finger and placed the drop of blood on 2 clean, grease free dry slides.
- Supporting the left end of the slide between thumb and middle finger of left hand, places the empty slide as spreader in front of the blood drop at an angle of 40°, and draws the spreader back and allows the blood to spread along its width.
- Maintaining a light and even pressure and 40° angle, moved the spreader forward, with a fairly fast and gliding motion, pulling the blood behind it in the form of a thin smear as seen in **figure 22**. Made 3-4 more such smears.

- Now the blood film is placed horizontally over the sink, Poured 8-10 drops of Leishman's stain from a drop -bottle to cover the blood film.
- After 1-2 minutes (or as advised), added equal amount of buffered water, over the stain till the mixture stands from the edges of the slide. Mixed the stain by blowing on it through a glass dropper for 8-10 minutes Watched that no stage the stain is allowed to dry on the blood film. Then drains off the stain under a gentle stream of distilled/tap water and allow it to dry.

Figure 22: Structure of blood smear

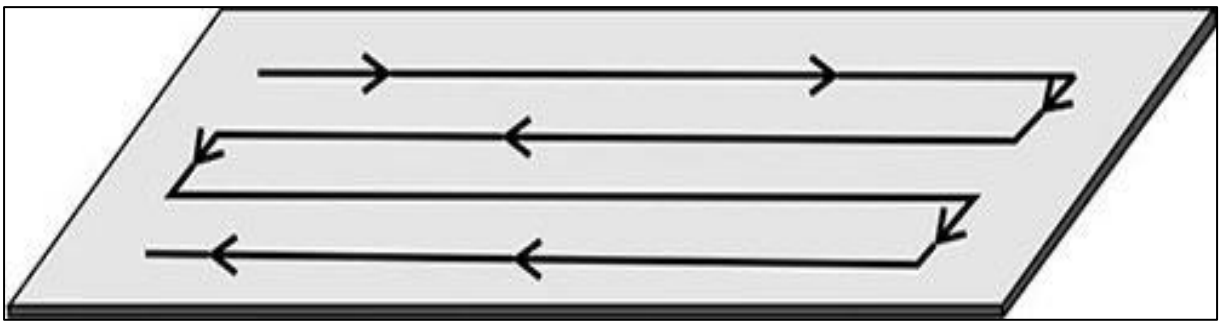


Counting procedure:

Placed the prepared blood smear and stain the smear with leishman stain. Then examined the smear under low power objective for general scanning and assessing the quality of the smear and for studying the distribution pattern of the cells Now Placed a

drop of cedar wood oil on the smear at the feather edge. Brought the oil immersion objective into position, with fine adjustment screw, adjusted the objective and focused the cells. For counting the cells it has been started from one end of the smear and move d the slide in a zig zag manne as seen in **figure 23**. Counted individual white cells and observed the value of eosinophil's particularly

Figure 23: Zigzag manner for counting Leukocytes



Source: Jaypee Digital /e book reader

5.9.2. Secondary Outcome variables:

The Secondary Outcomes of the study was to assess the pulmonary function using PEFR and quality of life of childhood asthma

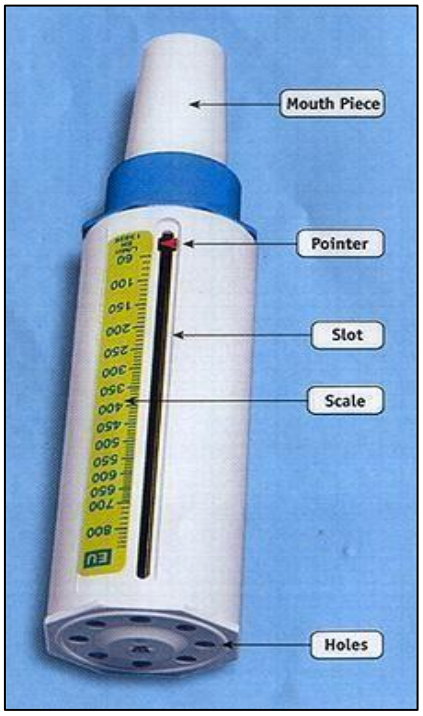
Peak Expiratory Flow Rate:

- The Peak Expiratory Flow Rate (PEFR) will be recorded using the Mini-Wright peak flow meter (Cipla Breath O meter) 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 24: Peak Expiratory Flow Meter (Cipla Breath O meter)

Figure 25: Representation of parts of PEF Meter



Assessment of Quality of Life:

"Quality of Life" is a multidimensional measure encompassing the physical emotional and social functioning of the child. The asthma specific questionnaire contains 23 questions (items) in three areas (domains) of activity, symptoms and emotions.

The pediatric asthma quality of life questionnaire is a Disease-specific questionnaire available in both interviewer and self-administered formats, designed for children aged 7 to 17 years of age. Includes three individualized questions, in which the patient identifies activities which are limited because of asthma.

The patient is asked during his visit how much s/he has been bothered by each of these three activities The questionnaire was administered on Day 1 and day 28 over four weeks and the child's asthma status was assessed for both the group. Categories/domains includes Symptoms (10 items), activity limitations (5 items--3 are individualized), emotional function (8 items).

Scaling of items: 7-point Likert scale. Scoring a of all items are weighted equally. Mean score is calculated across all items within each domain. Overall score is the mean across all items.

5.10: Statistical Analysis

Within group analysis was done using paired samples-t-test and between group analysis was done using independent samples test with the use of statistical package for the social sciences, version 16. P value set as $P<0.05$ significant. The assessments

were done at the baseline and at the post study levels among both the study and control group subjects.

6.0. RESULTS:

The following chapter represents the overall results of the current study "Effect of pranayama on serum IgE, Eosinophilia and pulmonary function of childhood asthma". The resultant outcomes from the interventional studies were monitored from assessing the hematological measurements of serum IgE , eosinophil counts and pulmonary function test using PEFR test as well as quality of life by using PAQLQ which were further subjected to statistical analysis.

Table 4: Baseline Variables between the groups

Variables	Study Group	Control Group	P Value
Age (Years.)	10.25± 1.55	9.44 ±1.48	0.025
Height(m)	1.28± 0.08	1.25± 0.09	0.259
Weight (Kg)	28.14± 6.30	26.28 ±6.59	0.218
BMI(Kg/m^2)	17.12± 2.91	16.56 ±3.09	0.427
SBP mmHg	86.30 ±7.86	85. 35± 10.53	0.660
DBP mmHg	64.23 ±7.46	62.79± 7.83	0.424
PR beats/min	102.80 ±12.55	102.44 ±12.28	0.902
Data expressed as Mean ±SD. within group analysis Paired t test was done to compare the mean difference and between group analysis independent sample t test. P<0.05 set as significant. Note: BMI= Body mass index , SBP= Systolic Blood pressure , DBP=Diastolic blood pressure Pulse rate, PP= Pulse Rate			

Here we can observe the less deviation or variation in the variables Age, Height, Weight, BMI, SBP, DBP and PR in the both the group. At baseline, there was no statistically significant difference between groups.

Thus the pre and post interventional assessment results of both the group are evaluated in the following headings

- Comparison of variables between the study groups
- Comparison of variables between the control group
- Comparison of Serum IgE, Eosinophil's, PEFR, PAQLQ before and after intervention in both study and control group.
- Comparison of Serum IgE before and after intervention in study group
- Comparison of Eosinophilia before and after intervention in study group
- Comparison of PEFR before and after intervention in study group
- Comparison of PAQLQ before and after intervention in study group
- Comparison of Serum IgE before and after intervention in control group
- Comparison of Eosinophilia before and after intervention in control group
- Comparison of PEFR before and after intervention in control group
- Comparison of PAQLQ before and after intervention in control group

Table 5: Comparison of variables between the study groups**.**

Variables	Pre Test	Post Test	P Value
S_ Serum IgE	364.84 ±316.72	358.68± 316.73	0.161
S_Eosinophils	3.05±1.81	2.74 ±1.59	0.002
S_PEFR	98.50 ±28.06	123.25± 31.57	0.000
S_PAQLQ	3.10 ±0.30	4.48 ±0.51	0.000
Data expressed as Mean ±SD. within group analysis Paired t test was done to compare the mean difference P<0.05 set as significant. Note: IgE = Immunoglobulin E, PEFR= Peak Expiratory Flow Rate , PAQLQ= Pediatric Asthma Quality of Life Questionnaire			

There is no statistically significant difference in serum IgE levels before and after intervention. . However, a statistically significant difference was observed with eosinophil count, PEFR and PAQLQ in the study group.

As per the above analysis:

- Since p-value>0.05, we accept H0 i.e., There is no significant effect between before and after the test in IgE
- Since p-value<0.05, we reject H0 i.e., There is significant effect between before and after the test in eosinophil
- Since p-value<0.05, we reject H0 i.e., There is significant effect between before and after the test in PEFR

- Since p-value<0.05, we reject H0 i.e., There is significant effect between before and after the test in PAQL

Table 6: Comparison of Variables between control groups.

Variables	Pre Test	Post Test	P Value
C_Serum IgE	420.74 ±394.73	416.29 ±386.65	0.198
C_ Eosinophil's	3.23± 1.89	2.81±1.70	0.001
C_PEFR	92.35±25.83	108.82±28.79	0.000
C_PAQLQ	3.12 ±0.33	4.18± 0.67	0.000
Data expressed as Mean ±SD. within group analysis Paired t test was done to compare the mean difference P<0.05 set as significant. Note: IgE = Immunoglobulin E, PEFR= Peak Expiratory Flow Rate , PAQLQ= Pediatric Asthma Quality of Life Questionnaire			

There is no statistically significant difference in serum IgE levels before and after intervention. . However, a statistically significant difference was observed with eosinophil count, PEFR and PAQLQ in the control group.

•Since p-value>0.05, we accept H0 i.e., There is no significant effect between before and after the test in IgE

•Since p-value<0.05, we reject H0 i.e., There is significant effect between before and after the test in Eosinophils

•Since p-value<0.05, we reject H0 i.e., There is significant effect between before and

after the test in PEFR

•Since p-value<0.05, we reject H0 i.e., There is significant effect between before and after the test in PAQL

Table 7: Comparison of Serum IgE, Eosinophil's, PEFR, PAQLQ before and after intervention in both study and control group.

Variables	Study Group		Control Test		P Value	
	Pre Test	**Post Test**	**Pre Test**	**Post Test**	**Pre Test**	**Post Test**
Serum IgE	364.84 ±312.72	358.68 ±316.73	420.74 ±394.73	416.29 ±386.65	0.504	0.486
Eosinophil	3.05± 1.81	2.74± 1.59	3.23± 1.89	2.81± 1.70	0.675	0.854
PEFR	98.50± 28.06	123.25± 31.57	92.35± 25.83	108.82± 28.79	0.333	0.045
PAQLQ	3.10± 0.30	4.48± 0.51	3.12± 0.33	4.18± 0.67	0.811	0.033

Data expressed as Mean ±SD .within group analysis Paired t test was done to compare the mean difference and between group analyses independent sample t test was done. P<0.05 set as significant.Note: IgE= Immunoglobulin E, PEFR= Peak Expiratory Flow Rate , PAQLQ= Pediatric Asthma Quality of Life Questionnaire

There is no statistically significant difference in serum IgE and Eosinophil's between the groups, However, a statistically significant difference was observed with PEFR and PAQLQ in the between group analysis.

- Since p-value>0.05, we accept H0 i.e., There is no significant effect between study and control group in lgE, Eosinophils, and PAQL (Pre-test).
- Since p-value<0.05 we reject H0 i.e., There is significant effect between study and group in PEFR and PAQL (Post-test).

Level of Significance: 0.05 (5%) Confidence level: 0.95 (95%)

Table 8: Comparison of Serum IgE before and after intervention in study group.

Variable	Pre Test	Post Test	P- Value
S_Serum IgE	364.84 ±316.72	358.68± 316.73	0.161
Data expressed as Mean ± SD. Paired sample t test was done to compare the Mean difference. P<0.05 set as significant. Note: IgE = Immunoglobulin E			

The significance of serum IgE in the study group is P = 0.161 which clearly shows that the result is not significant P>0.05. This shows the serum IgE level has not improved considerably after 4 weeks of pranayama intervention in patients with childhood asthma.

Serum IgE:

H0: There is no significant effect between before and after the test in IgE

H1: There is significant effect between before and after the test in IgE

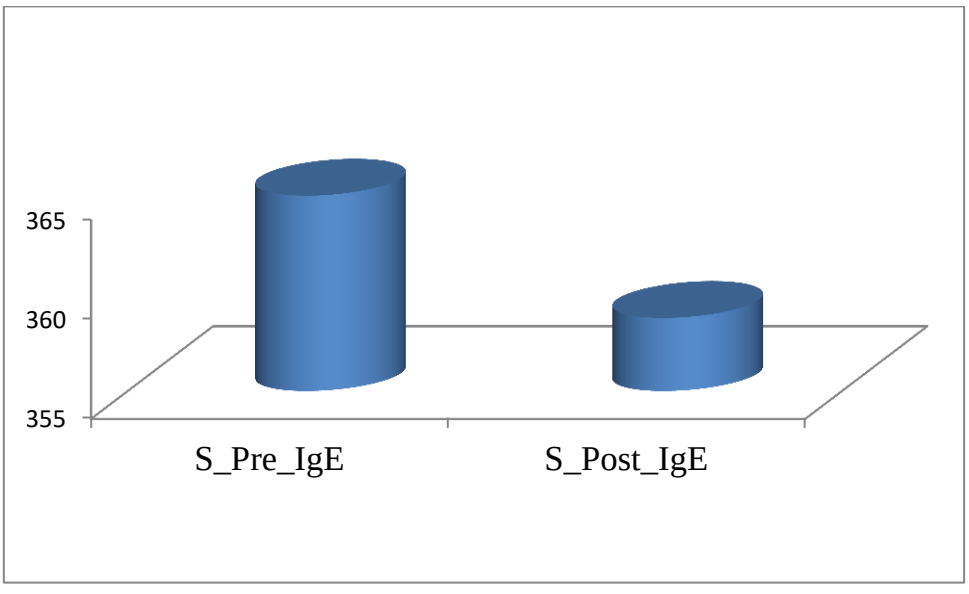


Table 9: Comparison of Eosinophilia before and after intervention in study group

Variable	Pre Test	Post Test	P- Value
S_Eosinophilia	3.05 ±1.81	2.74 ±1.59	0.002
Data expressed as Mean ± SD. Paired sample t test was done to compare the mean Difference .P<0.05 set as significant.			

The significance of Eosinophilia in the study group is P = 0.002 which clearly shows that the result is significant P< 0.05. Thus changes in Eosinophilia level has occurred considerably after 4 weeks of pranayama intervention in patients with childhood asthma.

Eosinophils:

H0: There is no significant effect between before and after the test in eosinophil

H1: There is significant effect between before and after the test in eosinophil

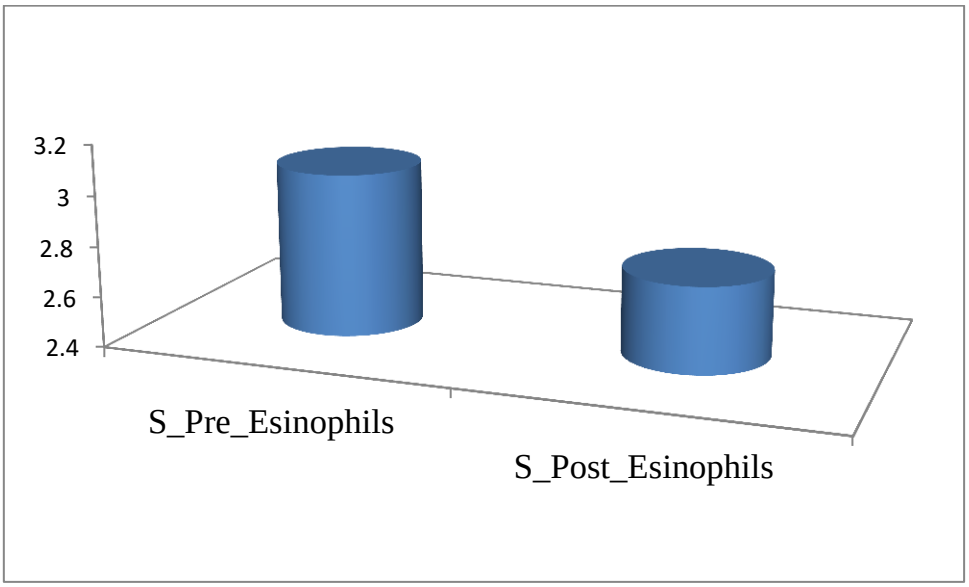


Table 10: Comparison of PEFR before and after intervention in study group

Variable	Pre Test	Post Test	P- Value
PEFR	98.50 ±28.06	123.25 ±31.57	0.000
Data expressed as Mean ± SD. Paired sample t test was done to compare mean Difference .P<0.05 set as significant. Note: PEFR= Peak Expiratory Flow Rate			

The significance of PEFR in the study group is P = 0.000 which clearly shows that the result is significant P<0.05. This shows the PEFR has improved considerably after 4 weeks of pranayama intervention in patients with childhood asthma.

PEFR:

H0: There is no significant effect between before and after the test in PEFR

H1: There is significant effect between before and after the test in PEFR

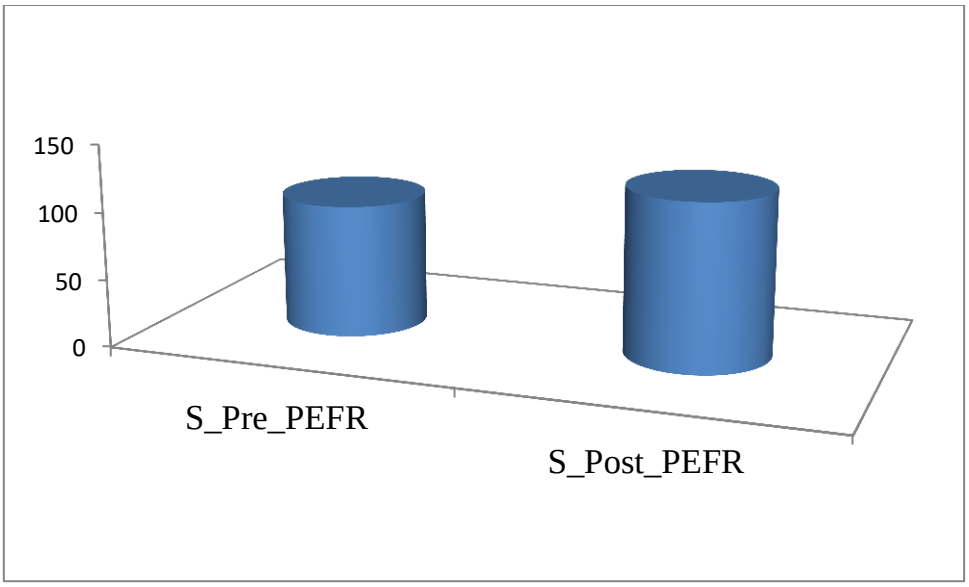


Table 11: Comparison of PAQLQ before and after intervention in study group

Variable	Pre Test	Post Test	P- Value
PAQLQ	3.10 ±0.30	4.48± 0.51	0.000
Data expressed as Mean ± SD. Paired sample t test was done to compare the Mean Difference .P<0.05 set as significant. Note: PAQLQ= Pediatric Asthma Quality of Life Questionnaire			

The significance of PAQLQ in the study group is P = 0.000 which clearly shows that the result is significant P<0.05. This shows the PAQLQ level has improved considerably after 4 weeks of pranayama intervention in patients with childhood asthma.

PAQLQ:

H0: There is no significant effect between before and after the test in PAQLQ

H1: There is significant effect between before and after the test in PAQLQ

Level of Significance: 0.05 (5%) Confidence level: 0.95 (95%

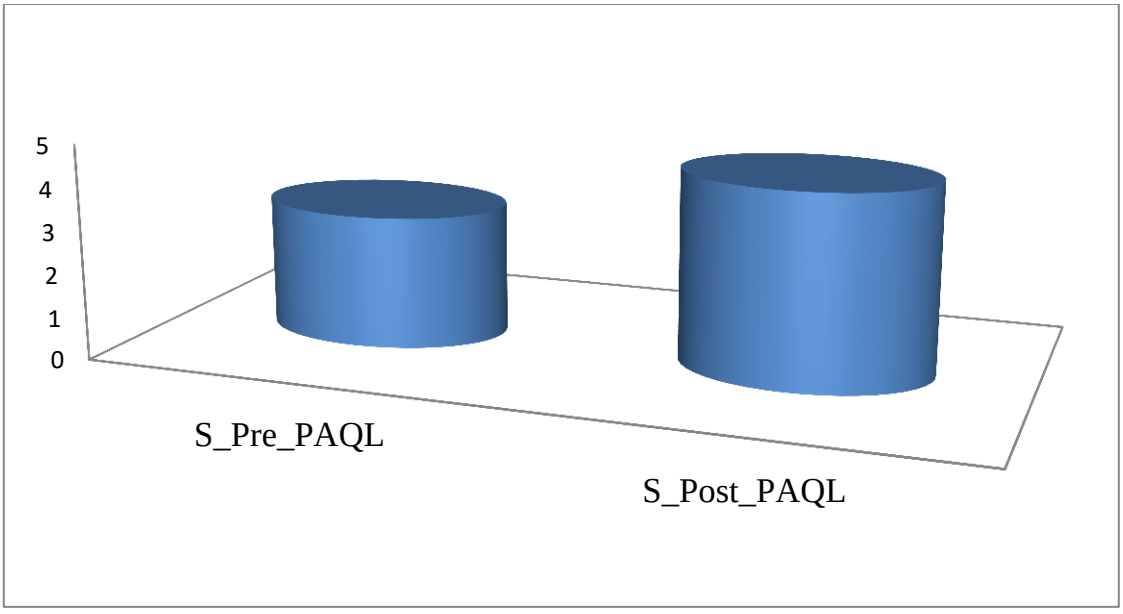


Table 12: Comparison of Serum IgE before and after intervention period in Control group

Variable	Pre Test	Post Test	P- Value
C_Serum IgE	420. 74 ±394.73	416.29 ±386.65	0.198
Data expressed as Mean ± SD. Paired sample t test was done to compare the mean Difference .P<0.05 set as significant. Note: IgE= Immunoglobulin E			

The significance of serum IgE in the control group is P = 0.198 which clearly shows that the result is not significant P>0.05.

Serum IgE:

H0: There is no significant effect between before and after the test in IgE

H1: There is significant effect between before and after the test in IgE

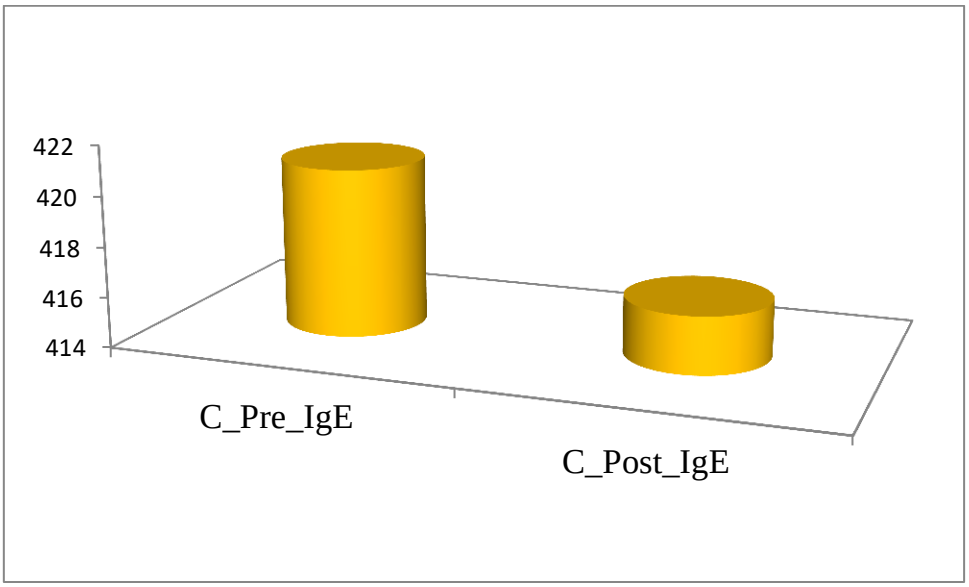


Table 13: Comparison of Eosinophilia before and after intervention period in control group

Variable	Pre Test	Post Test	P- Value
C_Eosinophilia	3.23 ±1.89	2.81 ±1.70	0.001
Data expressed as Mean ± SD. Paired sample t test was done to compare the mean Difference .P<0.05 set as significant.			

The significance of Eosinophilia in the control group is P = 0.001 which clearly shows that the result is significant P< 0.05.

Eosinophil's:

H0: There is no significant effect between before and after the test in Eosinophil's

H1: There is significant effect between before and after the test in Eosinophil's

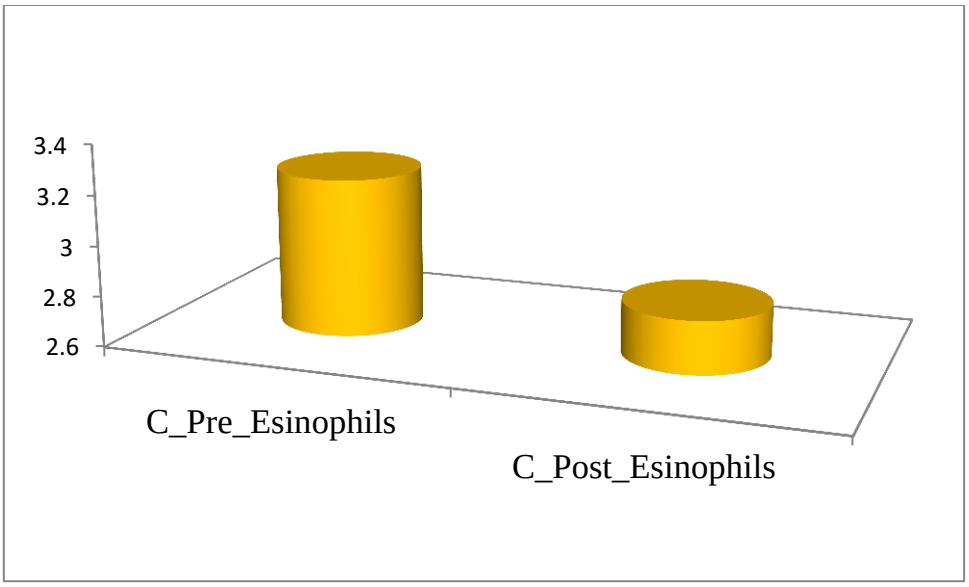


Table 14: Comparison of PEFR before and after intervention period in control group

Variable	Pre Test	Post Test	P- Value
C_PEFR	92.35± 25.83	108.82± 28.79	0.000
Data expressed as Mean ± SD. Paired sample t test was done to compare the mean Difference .P<0.05 set as significant. Note: PEFR= Peak Expiratory Flow Rate			

The significance of PEFR in the control group is P = 0.000 which clearly shows that the result is significant P< 0.05.

PEFR:

H_0: There is no significant effect between before and after the test in PEFR

H_1: There is significant effect between before and after the test in PEFR

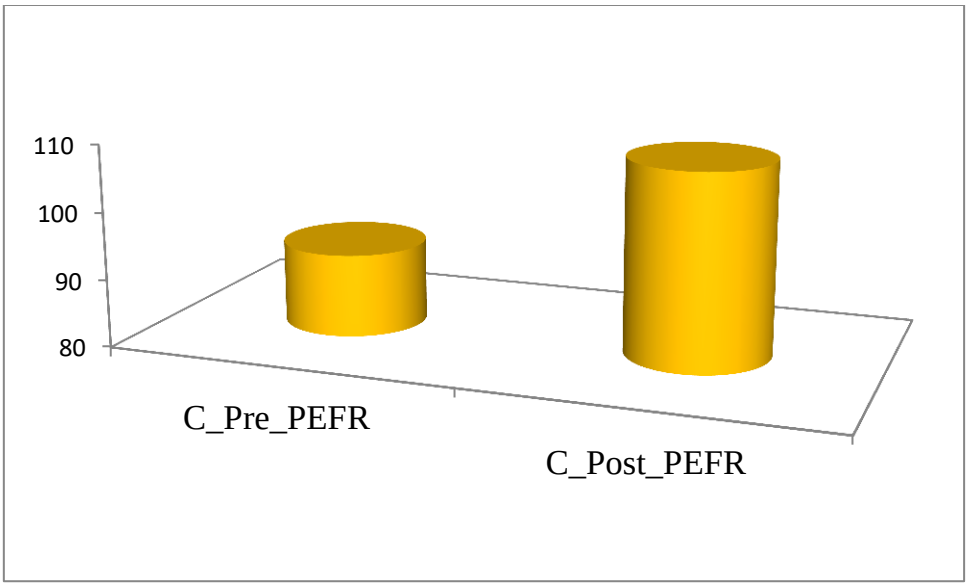


Table 15: Comparison of PAQLQ before and after intervention period in control group

Variable	Pre Test	Post Test	P- Value
C_PAQLQ	3.12 0.33	4.18 0.67	0.000
Data expressed as Mean ± SD. Paired sample t test was done to compare the mean Difference .P<0.05 set as significant. Note: PAQLQ= Pediatric Asthma Quality of Life Questionnaire			

The significance of PEFR in the control group is P = 0.000 which clearly shows that the result is significant P< 0.05.

H_0: There is no significant effect between before and after the test in PAQL

H_1: There is significant effect between before and after the test in PAQL

Level of Significance: 0.05 (5%) Confidence level: 0.95 (95%)

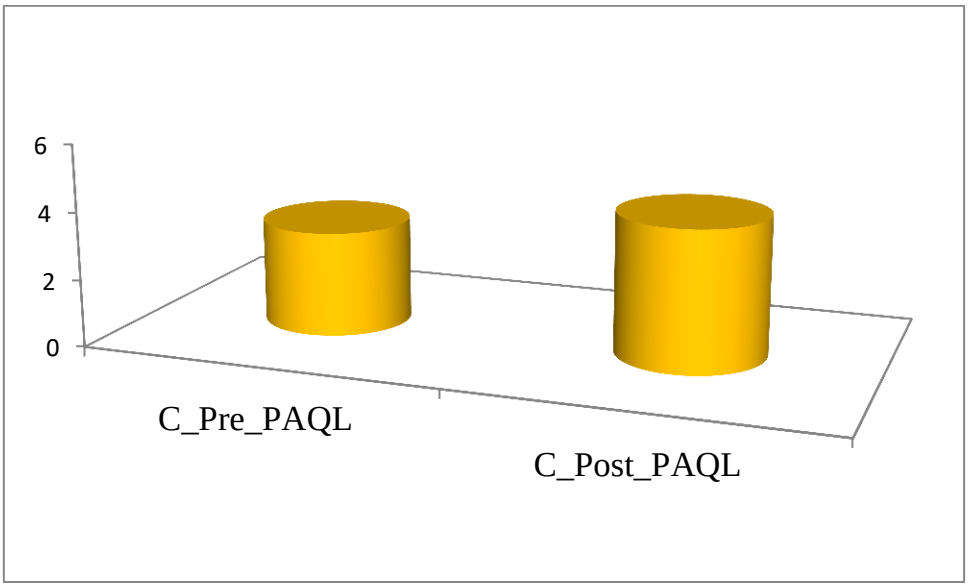


Table 16: Graph of Serum IgE p-value for the Study and Control group:

IgE:

H_0: There is no significant effect between study and control group in IgE

H_1: There is significant effect between study and control group in IgE

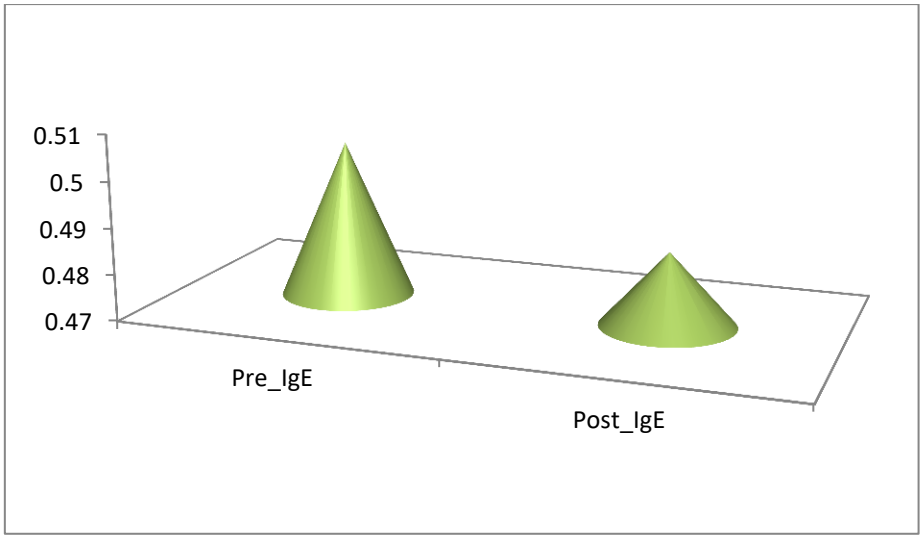
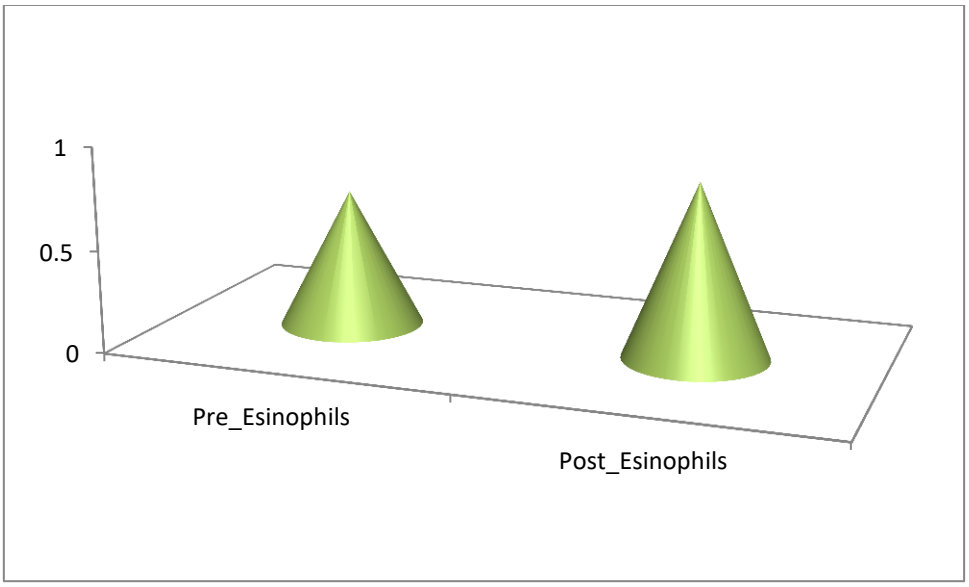


Table 17: Graph of Eosinophil's p-value for the Study and Control group:

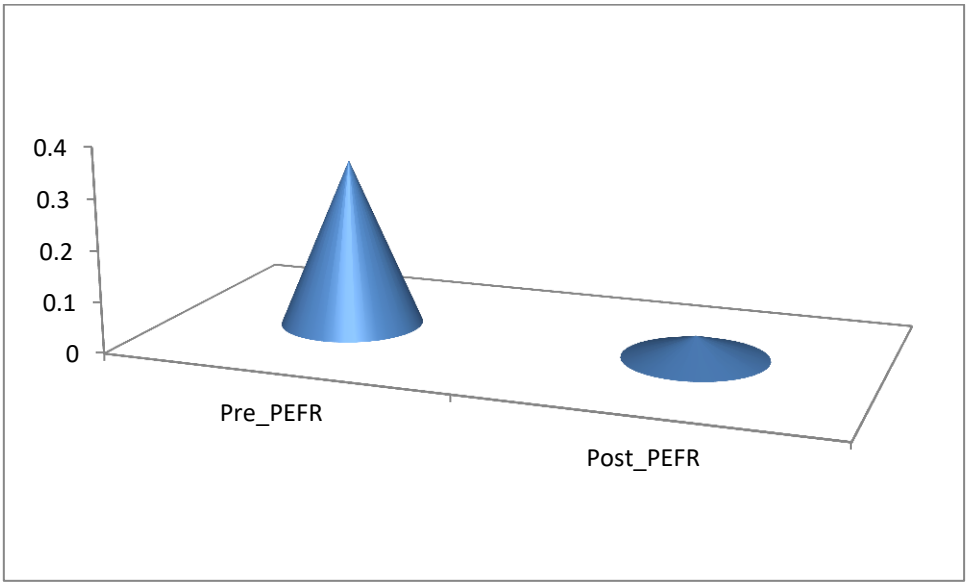


Eosinophils:

H_0: There is no significant effect between study and control group in Eosinophils

H_1: There is significant effect between study and control group in Eosinophils

Table18: Graph of PEFR p-value for the Study and Control group:

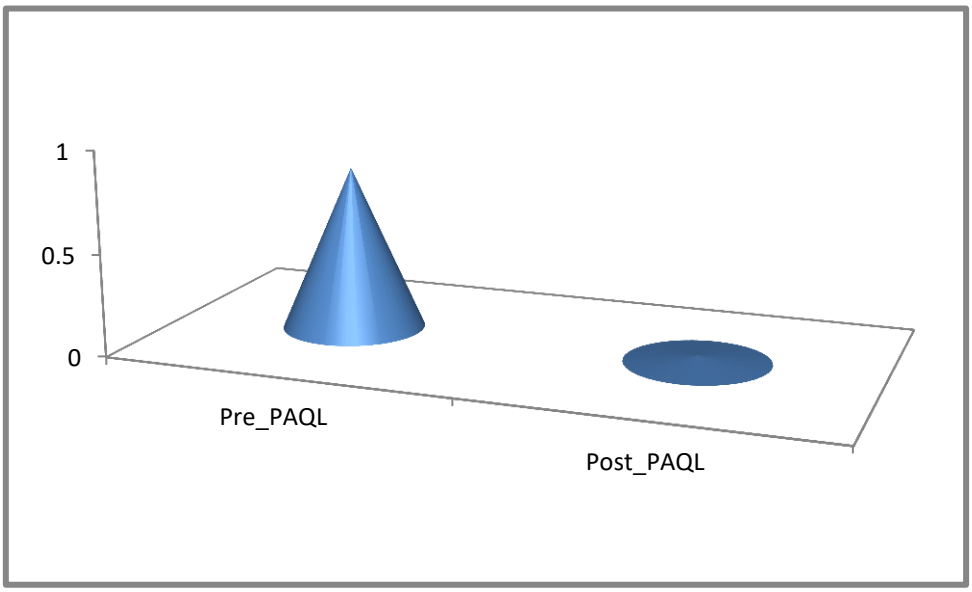


PEFR:

H_0: There is no significant effect between study and control group in PEFR

H_1: There is significant effect between study and control group in PEFR

Table 19: Graph of PAQLQ p-value for the Study and Control group



PAQL:

H_0: There is no significant effect between study and control group in PAQL

H_1: There is significant effect between study and control group in PAQL

7.0. DISCUSSION:

The present study incorporates the effect of pranayama (Nadishudi and Kapalbhati) administrated over a period of 20 mints once daily for 4 weeks and therefore the complete duration of the study was observed for 12 months . Pranayama was found to be beneficial and statistically significant in improving PEFR and PAQLQ, but statistically no significant difference in IgE and Eosinophil between group participants on childhood asthma was observed.

In a study conducted by Gupta 2017 showed significant result in the pulmonary function test (Spirometer) mild to moderate asthmatic children's aged 8-14 years , by practicing integrated yogic lifestyle additionally to medication . The results of the present study also allow a few fairly firm conclusions. Significant, steady and progressive improvement in secondary objective variables such as PEFR and PAQLQ in study group indicates the efficacy of pranayama practice. This is further substantiated by the significantly greater improvement in quality of life in childhood asthma.

Pranayama is traditional techniques practicing from ancient time of Indian civilization; it establishes balances of body, mind and spiritual health. Pranayama used for various purposes such as; maintaining health status & beauty, delaying age and as therapeutic measure against many pathological conditions Pranayama involves three stages of respiratory practice; Puraka (inhalation), Kumbhaka (retention) and Rechaka

(exhalation). These stages when practices with respiratory control then offer several health benefits. Pranayama improves circulatory process of body, boost system and helps in pathological conditions like; asthma and rhinitis.(23)

The practice of Pranayama involves deep inspiration, holding of air followed by deep expiration and relaxation. Pranayama is science of breath that control energy of life, controls emotions and mind.

Pranayama not only pacify biological energy but it also imparts spiritual energy and establishes harmony between body and nature.

Kapalabhati Pranayama may be considered as technique of skull shining breath, clear congestion and improve capacity of lungs. Suppress bloating and supply symptomatic relief within the condition of allergy and bronchitis.

Pranayama significantly helps in respiratory problems since it regulates breathing; detoxify body, improves respiration capacity; maintain rhythm of respiration and purifies air passages. Pranayama maintain harmony of sympathetic and parasympathetic system, causes bronchio-dilatation, reduces respiratory muscles tone and maintain supply of energy thus provide relief in problems associated with respiration.

Since the blood level of Serum IgE and eosinophils is directly related to the allergic reaction and severity of asthma and inversely related to lung functions, we have used

serum IgE and eosinophils as a peripheral marker in understanding the disease progress. In our present study, no significant changes were observed in serum IgE and Eosinophils in either group. The high variability in Serum IgE and Eosinophil's levels suggests the need for a much larger number of subjects and longer intervention period for arriving at definitive conclusions.

7.1. Limitation:

The sample size and duration of pranayama practice were appropriate but larger community study with larger period of follow up should be carried out to establish pranayama as an adjuvant therapy for childhood asthma

7.2. Recommendation for future study:

The same study can be conducted on a larger population and with larger period of follow up with suitable study design and more biochemical and pathological outcome variables could be included to validate the current result

8.0. CONCLUSION

The present study suggests that specific pranayama practice was effective in improving childhood asthma by improving the pulmonary functions and quality of life. The study concludes that pranayama can be added as adjunct therapy for managing childhood asthma

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10.ANNEXURE –I

SCREENING FORM

Screening ID No: **Date:**

Patient Name: **Contact No:**

Gender: **Age (years)**

Address:

Eligibility criteria

Inclusion criteria

Are you willing to give written informed consent?	Yes	No
Does the child 8-12 yrs. of age group?	Yes	No
Does the child have episodes of wheeziness in the chest?	Yes	No
Does the child suffer from the attack of shortness of breath with wheeze?	Yes	No
Does the child cough more than other children?	Yes	No
Does the child ever say his/her chest felt tight or the breathing becomes difficult?	Yes	No
Does the child have ever complained of unexpected breathlessness at rest?	Yes	No
Does the child have missed school for more than one week or more occasions in the last 12 months?	Yes	No
Does the child is under any conventional medication?	Yes	No

Exclusion Criteria

Does the child currently participating in any other clinical trial in the same hospital or other site?	Yes	No
Does the child have any of the following conditions or other medical		

conditions that would prevent the participant completing the trial follow up duration?		
• Neurological	Yes	No
• Digestive	Yes	No
• Cardiovascular	Yes	No
• Psychological Problems	Yes	No

The subject is **eligible/not eligible** for the study

If eligible, subject is allocated **in A (study group)/B (Control group)**

Principal investigator's signature **Date:**

ANNEXURE-II

INFORMED CONSENT FORM

Government Yoga and Naturopathy Medical College, Arumbakkam, Chennai-106

And Institute Of Child Health and Hospital for Children, Egmore, Chennai -008

Title of the study:

Effect of pranayama on serum IgE, Eosinophilia and pulmonary function of childhood asthma

Principal Investigator: Dr.T.Kavitha

Participant's Name: _____

I have been invited to participate in the research study titled "Effect of pranayama on serum IgE ,Eosinophilia and pulmonary function of childhood asthma." I understand that it will involve the practice of pranayama (Nadi shodhana and kapalbhati) which may be useful for my well-being.

- I have been informed that pre and post assessments of serum IgE, Eosinophil counts and peak flow expiratory rate and Paediatric Asthma Quality of Life Questionnaire will be taken using standardized techniques.
- I am aware that there may be no benefit to me personally and that I will not be compensated whatsoever.
- I had given the opportunity to ask questions about the study and the questions what I asked have been answered to my satisfaction.
- I understand that I have the right to withdraw from the research at any time without affecting my medical care or legal rights.

Hereby, I confirm that I have understood the above study. I myself consciously give consent to

Participant in this study.

Date: **Patient's Signature:**

I have accurately read or witnessed the accurate reading of the consent form to the potential participant, and the individual has given opportunity to ask questions. I confirm that the individual has given consent consciously.

Date: **PI's Signature:**

ANNEXURE III

Information to Participants

Investigator: Dr.T.Kavitha

Name of Participant:

Title: "Effect of pranayama on serum IgE ,Esinophilia and pulmonary function of childhood asthma " You are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether 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 and Naturopathy Medical College& Hospital, Chennai.

What is the Purpose of the Research?

The purpose of the research is to study the changes on serum IgE and esinophilia levels, pulmonary function and assess the quality of life of childhood asthma by the practice of pranayama

The Study Design

A prospective randomized control study

Study Procedures

The study involves practice of pranayama intervention (Nadi shudhi and kapalbhati) for 40 selected study subjects for 20 min daily once for 4 weeks The collection of first data is before the practice, second data will be taken at the end of 4 weeks of practice.

Possible Risks to you - Nil

Possible Benefits to you- Serum IgE and eosinophilia will be reduced.

Pulmonary function and quality of life will be improved

Possible benefits to other people

The result of the research may provide benefits to the society in terms of reducing the serum IgE and eosinophilia levels of the affected people and also to reduce the prevalence of childhood asthma in the society.

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.

ANNEXURE –IV

Pediatric Asthma quality of Life Questionnaire

PAEDIATRIC ASTHMA QUALITY OF LIFE QUESTIONNAIRE WITH STANDARDISED ACTIVITIES (PAQLQ(S))

INTERVIEWER-ADMINISTERED (INTERVIEWER-ADMINISTERED) ENGLISH VERSION FOR INDIA

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Senior translator: Thangaraj Nagasamy

JUNE 2011

REMARKS OF THE GUIDE

This work undertaken / to be done by Dr.T.Kavitha titled "**Effect of pranayama on serum IgE ,eosinophilia and pulmonary function on childhood asthma "** at Government Yoga and Naturopathy Medical College & Hospital, done under my supervision and I ensure that the candidate will abide by the rules of the Institutional Ethics Committee.

Dr. S. T. Venkateswaran,
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