1.0 INTRODUCTION

1.1 DEFINITION OF COPD

Chronic Obstructive Pulmonary Disease (COPD) is not one single disease but an umbrella term used to describe progressive lung diseases including chronic bronchitis, emphysema, refractory (non-reversible) asthma, and some forms of bronchiectasis (WHO, 2014). Several diverse definitions exist for COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD) defined COPD as “a preventable and treatable disease characterized by airflow limitation that is not fully reversible. The airflow limitation is usually both progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases” (Vestbo et al., 2013). The American Thoracic Society (ATS) has defined COPD as “a disease state characterized by the presence of airflow limitation due to chronic bronchitis or emphysema; the airflow obstruction is generally progressive, may be accompanied by airway hyperreactivity, and may be partially reversible” (Rabe et al., 2007). The European Respiratory Society (ERS) defined COPD as “reduced maximum expiratory flow and slow forced emptying of the lungs, which is slowly progressive and mostly irreversible to present medical treatment” (Siafakas et al., 1995). For these three different definitions, however, the specific categorization of airflow obstruction, reversibility, and severity of disease varies. COPD can develop for years without obvious shortness of breath. It is a diverse condition from asthma, but it can be hard to make a distinction between COPD and chronic asthma. The more recognizable terms 'chronic bronchitis' and 'emphysema' are no longer used, but are now incorporated within the COPD diagnosis (Petty, 2006).

1.2 BURDEN OF COPD

1.2.1 Global prevalence

According to Burden of Obstructive Lung Disease (BOLD) study, the average prevalence of COPD is 10.1%, with wide variations (Buist, Vollmer, & McBurnie, 2008). It is higher for male (14%) than for female patients (8%) (WHO, 2012). The prevalence of physiologically defined COPD in adults aged ≥ 40 yrs is 9 – 10%, smokers (15.4%), males (9.8%) and person with urban residence (10.2%) (Halbert et al., 2006). The prevalence of COPD (FEV1/FVC < lower limits of normal) in never-smokers was 6.4%, constituting 27% of all COPD subjects (Tan et al., 2015).

1.2.2 Indian prevalence

India suffers a significant, growing percentage of COPD mortality, one of the highest in the world. A systematic review of four studies identified general prevalence of chronic bronchitis in rural areas between 6.5% and 7.7% (McKay, Mahesh, Fordham, & Majeed, 2012). Bhome (2012) reported COPD prevalence between 3 and 8% among Indian males, and 2.5 to 4.5% for Indian females.

1.2.3 Economic burden of COPD

COPD causes a heavy health and economic burden around the world thus generates high healthcare costs. The total cost effectiveness of COPD morbidity and mortality in the United States were approximated at $23.9 billion in 1993 (Sullivan, Ramsey, & Lee, 2000). Direct treatments for COPD-related illness reported for $14.7 billion, and the remaining $9.2 billion were accounted for indirect morbidity and premature mortality as lost future earnings. According to the National Heart, Lung, and Blood Institute (NHLBI) the total annual

expenditure of COPD to the U.S., was $38.8 billion in 2005. Similar data from another US study propose that 10% of persons with COPD account for > 70% of all medical care costs (Au & Sullivan, 2008). Currently, COPD is a more costly disease than asthma and, depending on country, 50–75% of the costs are for services associated with exacerbations (Celli et al., 2004). In India, the economic burden of COPD was estimated at INR 35,331 crores (Murthy & Sastry, 2005). It is linked to comorbid diseases, such as depression, anxiety and cardiovascular disease, which add to the large financial burden associated with this disorder (Mannino & Braman, 2007).

1.2.4 COPD as Social burden

According to WHO, 62 million people had moderate to severe COPD in 2002 (WHO, 2004) with the total number of COPD cases predicted to raise to about 200 million in 2010 (WHO, 2014). More than 3 million died of it in 2005, which corresponds to 5% of all deaths globally, about 90% in low- and middle-income countries. Total COPD deaths are projected to increase by over 30% in the next 10 years unless urgent action is taken to reduce underlying risk factors, especially tobacco use (WHO, 2011). As a consequence of its high incidence and chronicity, COPD causes elevated resource utilization with frequent clinician visits, recurrent hospitalizations due to acute exacerbations, and the need for chronic therapy (eg, supplemental oxygen therapy, medication (Buist et al., 2007).

1.3 DIAGNOSIS OF COPD

1.3.1 Clinical feature

COPD describes a group of lung conditions that make it hard to empty the air out of the lungs. This difficulty is characterized by increasing breathlessness or the feeling of being tired with related symptoms such as chronic cough or sputum production, exertion dyspnoea,

expectoration, wheeze. A clinical diagnosis of COPD should be considered in any patient who has the above symptoms and a history of exposure to risk factors for the disease (Celli et al., 2004). Clinical diagnosis needs to be confirmed by standardised spirometric tests in the presence of not-fully-reversible airflow limitation. Although COPD affects the lungs, it also produces significant systemic consequences also.

1.3.2 Spirometric diagnosis

Spirometry is required to make a clinical diagnosis of COPD; the presence of a post-bronchodilator forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ≤0.70 confirms the presence of persistent airflow limitation that is not fully reversible and thus of COPD. In 1986, ATS first recommended a fixed ratio of forced expiratory volume in one second (FEV1) to forced vital capacity (FVC), 0.75 to define airflow obstruction (Renzetti et al., 2015). Subsequent ATS documents generically defined airflow obstruction as a decline of FEV1/FVC, without recommending any numerical cut-off point (ATS, 1991). By contrast, ERS guidelines (Quanjer et al., 1993) proposed the diagnosis of airflow obstruction be based on a ratio of FEV1 to slow vital capacity (VC), 88 and 89% of predicted in males and females, respectively. Since 2001, GOLD took a step back, defining COPD by a fixed FEV1/FVC, 0.70 (Pauwels et al., 2001), even if it was already apparent that it may be a source of falsely positive cases in the general population (Viegi et al., 2000). This was confirmed in a study in the USA (Celli, Halbert, Isonaka, & Schau, 2003) evaluating the impact of different definitions of airflow obstruction on the epidemiology of COPD. At variance with the GOLD guidelines, the recent ATS/ERS guidelines on lung function testing stressed the use of lower limits of normality (LLN), *i.e.* the lower fifth percentile of the frequency distribution of a healthy population, to define pulmonary function abnormalities (Pellegrino et al., 2005).

1.3.3 Differential diagnosis

A major differential diagnosis is asthma. Other potential diagnoses are usually easier to distinguish from COPD, and include: congestive heart failure, bronchiectasis, tuberculosis, obliterative bronchiolitis, diffuse panbronchiolitis (Price & Brusselle, 2013).

1.4 CLASSIFICATION OF COPD

1.4.1 Four stage classification

The GOLD has introduced a four-stage classification of COPD [Table 1] severity based on their degree of airflow limitation measured during pulmonary function tests (PFTs) (Huijsmans, de Haan, ten Hacken, Straver, & van't Hul, 2008). Spirometric classification has proved useful in predicting health status (Ferrer et al., 1997) utilisation of healthcare resources (Dewan et al., 2000), development of exacerbation (Burge et al., 2000) and mortality (Anthonisen, Wright, & Hodgkin, 1986) in COPD.

Table 1: Four-stage classification of COPD based on PFT

Severity	**Postbronchodilator FEV1/FVC**	**FEV1 % predicted**
Atrisk Patients who: • smoke or have exposure to pollutants • have cough, sputum or dyspnea • have family history of respiratory disease	>0.7	≥80

Severity	Postbronchodilator FEV1/FVC	FEV1 % predicted
Mild COPD	≤0.7	≥80
Moderate COPD	≤0.7	50-80
Severe COPD	≤0.7	30-50
Very severe COPD	≤0.7	<30

Legends: FEV1: forced expiratory volume in one second; FVC: forced vital capacity.

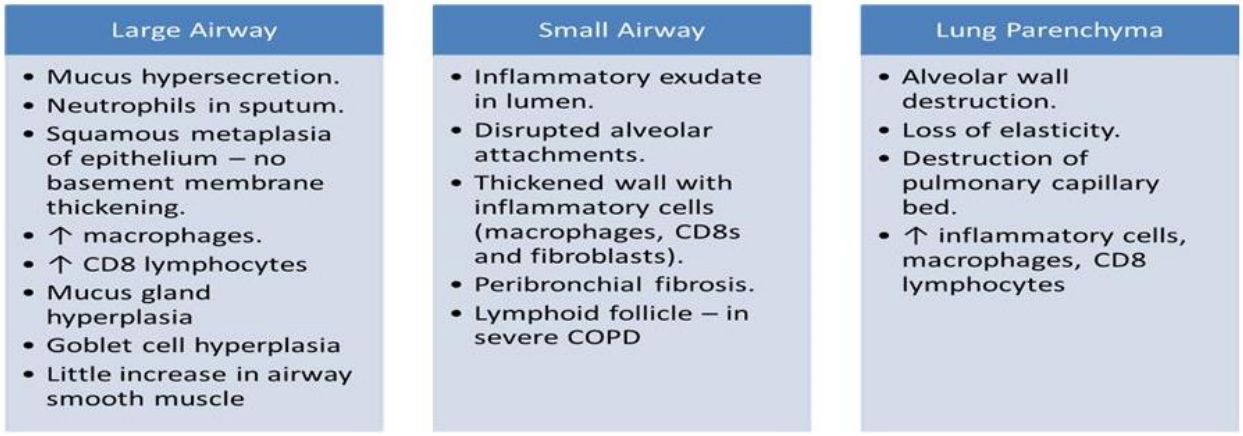
PFT alone does not explain the heterogeneous features of COPD. Therefore, the GOLD 2011 document proposed a new multidimensional grading system that assessed the respiratory and systemic expressions of COPD would better classify, predict outcome and exacerbation risk in these patients (Vestbo, Hurd, & Rodriguez-Roisin, 2012).

1.4.2 BODE index

The BODE index, a simple multidimensional 10-point scale in which higher scores indicate a higher risk of death, The BODE index is a multidimensional scale comprising the body-mass index (B), the degree of airflow obstruction (O), functional dyspnea (D), and exercise capacity (E) as assessed by the 6 minute walk test (6 MWT). The scale ranges from 0 to 10 points, with higher scores indicating a greater risk of death. It can be divided in four quartiles, quartile 1 is a score of 0–2, quartile 2 is a score of 3–4, quartile 3 a score of 5–6, and quartile 4 a score of 7–10 (Celli et al., 2004). It is better than the FEV1 at predicting the risk of death from any cause and from respiratory causes among patients with COPD.

1.5 PATHOPHYSIOLOGY OF COPD

As COPD advances, pathologic changes cause physiologic changes that result progressively worsening dyspnoea, initially during exercise, and over time, even at rest (Vestbo et al., 2013). Mucus hypersecretion and ciliary dysfunction are combined with cough productive of mucoid sputum. The physiologic changes that occur as the disease worsens include mucus hypersecretion, ciliary dysfunction, airflow limitation, pulmonary hyperinflation, abnormal gas exchange, pulmonary hypertension and cor pulmonale (Barnes, 2004).



Hyperinflation occurs when air is trapped within the lungs after each breath because of an imbalance in the volume of air being inhaled and exhaled. That is, air is inhaled before complete exhalation has occurred. In patients with COPD, the time to exhale is prolonged because of hyperinflation (Ferguson, 2006). Hyperinflation appears to be a central mechanism that directly links the pathophysiology of COPD to important patient-reported outcomes, such as exercise performance, dyspnoea and quality of life (QoL).Oxidative stress has a role in many of the pathogenic processes of COPD and may be one mechanism that boosts the inflammatory response. The development of emphysema may involve alveolar cell loss through apoptosis. This mechanism may connect the vascular endothelial growth factor pathway and oxidative stress (MacNee, 2012).

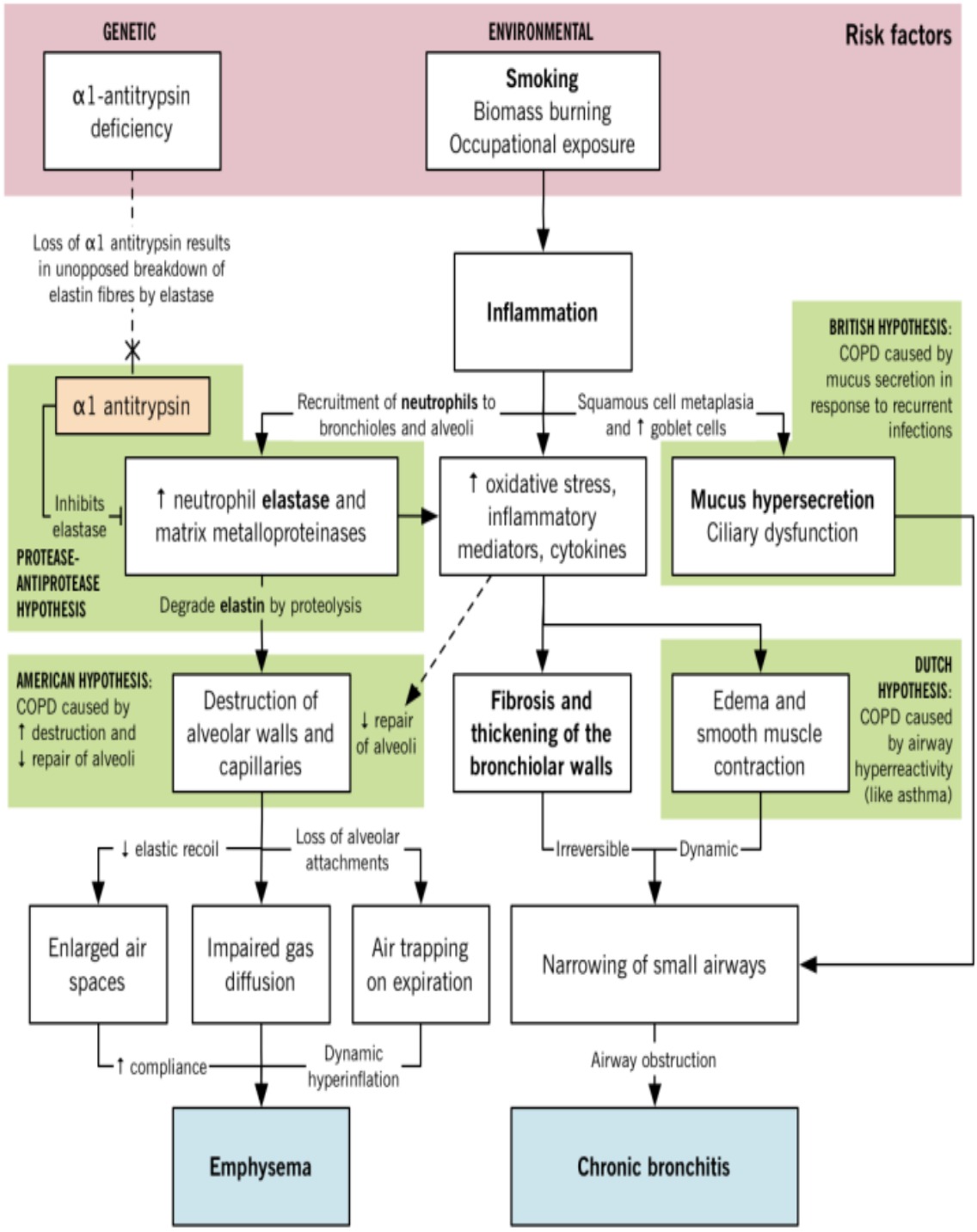


Figure 1: Flow chart of pathogenesis of COPD

1.6 CONVENTIONAL MANAGEMENT OF COPD

The conventional therapeutic strategy in the management of COPD directed mostly at management of the patient's presenting symptoms, such as breathlessness, fatigue, depression, anxiety, pain and insomnia. COPD is incurable, oxygen therapy has been shown to increase survival in selected patients. Smoking cessation may slow the decline (Romain, Pauwels & Rabe, 2004). Medicines are prescribed that widen the breathing tubes (bronchodilators), reduce swelling in the breathing tubes (anti-inflammatory drugs) or treat infection (antibiotics). Medications have been shown to help stabilize the breathing passages and decrease swelling. These medications must be taken every day, probably for the rest of the life in order to provide control of your COPD. Currently, there is no treatment available to restore damaged bronchi from bronchitis or alveoli affected by a large amount of emphysema. Unfortunately, the damage that has been done to the alveoli is permanent. In some cases, surgery (lung volume reduction) can be performed as a way of removing some areas of the lungs with large amounts of emphysema. The goals of effective COPD management are to: prevent disease progression, relieve symptoms, improve exercise tolerance, improve health status, prevent and treat complications and exacerbations, manage stable COPD, assess and monitor disease, trim down risk factors, reduce mortality. Pulmonary rehabilitation program can be helpful in learning to use the lung power more efficiently. It may train the patients to be in control of their breathing, instead of the breathing controlling them (Hill, 2006).

1.7 YOGA AS A SOLUTION

Yoga is a way of life, mainly has four primary components: physical postures to develop strength and flexibility, breathing exercises to enhance respiratory functioning, deep relaxation techniques to cultivate the ability to release anxiety, and meditation/mindfulness

practices to promote emotion and stress regulation skills (Nagarathna & Nagendra, 2013). Psychosomatic ailments arise due to disturbance in the mind (Rajesh, Ilavarasu, Srinivasan, & Nagendra, 2014). The level of documented evidence on Yoga's psychophysiological benefits for different ailments is progressively increasing (Forfylow, 2011; Pascoe & Bauer, 2015; Raub, 2002; Yeung et al., 2014). No drugs could hinder the progress of COPD, but yoga has been shown to reduce disability in many chronic respiratory diseases hence may become valuable means of COPD management.

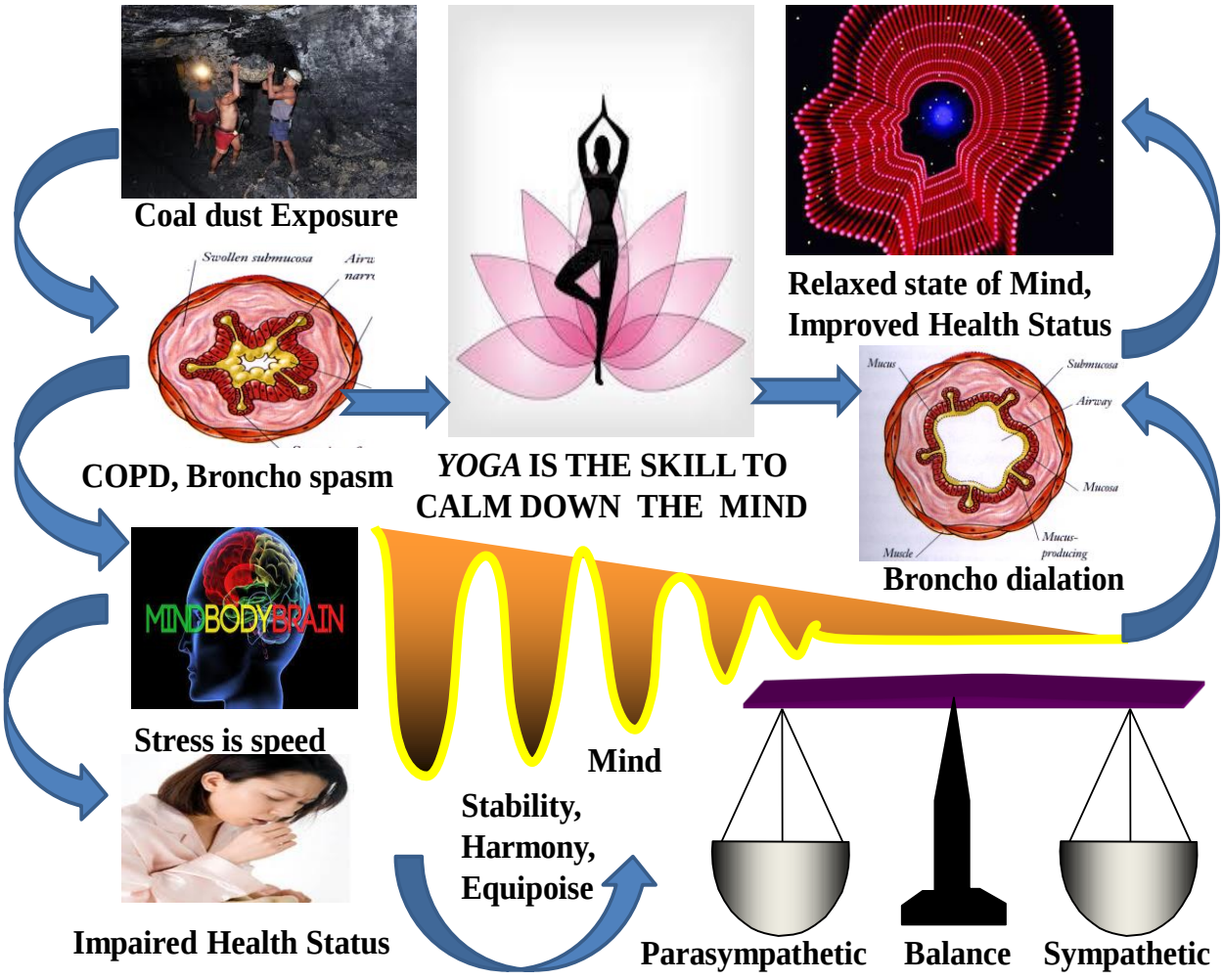


Figure 2: Role of Yoga in the amelioration of COPD

1.8 YOGA FOR COPD

Some research has been conducted on yoga's application to COPD, have reported improved lung function parameters (Fulambarker et al., 2012), increased diffusion capacity (Soni, Munish, Singh, & Singh, 2015), decreased dyspnoea-related distress (Donesky-Cuenco, Nguyen, Paul, & Carrieri-Kohlman, 2009), improved health-related quality of life (Santana et al., 2013). Yoga has been included as a component of exercises prescribed for many pulmonary rehabilitation programs (Hodgkin, Celli, & Connors, 2009). It has also been included as an adjunct to physical therapy treatment in industrial rehabilitation programs and proven to enhance mind-body coordination (Rachiwong, Panasiriwong, Saosomphop, Widjaja, & Ajjimaporn, 2015).

1.9 THE INTEGRATED APPROACH OF YOGA THERAPY (IAYT)

IAYT is a combination of breathing practices, *Āsanas, Prāṇāyāma, Kriyā*, meditation, relaxation techniques, *yogic* counselling for stress management, chanting, and lectures on *Yogic* lifestyle and philosophy (Nagarathna & Nagendra, 2013). Its therapeutic applications as a supplementary therapy for chronic health conditions are well established. It is a program which was first applied to asthma some 30 years ago (Nagarathna & Nagendra, 1985). Other than respiratory problems, benefits have been demonstrated for various disorders such as cancer (Chandwani et al., 2014; Vadiraja et al., 2009), CABG (Raghuram et al., 2014), hypertension (Mashyal, Raghuram, & Bhargav, 2014), asthma (Rao et al., 2014), diabetes mellitus (McDermott et al., 2014), OA of knee (Ebnezar, Nagarathna, Yogitha, & Nagendra, 2014), Low Back Pain (Tekur, Nagarathna, Chametcha, Hankey, & Nagendra, 2012a), anxiety and depression (Maharana, Nagarathna, Padmalatha, & Nagendra, 2013), autism spectrum disorder (Radhakrishna, Nagarathna, & Nagendra, 2010), Schizophrenia (Duraiswamy, Thirthalli, Nagendra, & Gangadhar, 2007).

1.10 NEED FOR PRESENT STUDY

Earlier studies have reported the positive short-term physiological effects of breathing exercises in people with COPD. Although few studies have concluded that short term yoga practices improved lung function parameters (Behera, 1998), increased diffusion capacity (Soni et al., 2015) decreased dyspnoea related distress (Donesky-Cuenco et al., 2009); independently there are no studies to date that have shown the relation of stress and emotional factors along with COPD. There has been limited study of yoga assessing its adjunctive efficacy in a randomised control trial. Yoga has been shown to be a good preventive therapy for many ailments. However, there are no interventional studies conducted to evaluate the impact of yoga on COPD in coal miners. Limited evidence is available on the effect of mindfulness-based treatments such as yoga for the management of depression and anxiety in COPD patients but no study has been published assessing the effect of yoga on coal miners, for whom the condition is a major work related health hazard. With this background the current study is aimed at throwing light on the possible role of IAYT in prevention and management of COPD. Given the strong theoretical and empirical evidence for the use of IAYT, we hypothesize that it would improve the pulmonary, autonomic, physical and psychological parameters of coal miners with COPD and contribute to their sense of wellbeing compared to controls on conventional care. Hence, the present project is undertaken to evaluate the effects of IAYT on exercise capacity, dyspnoea, fatigue, peripheral capillary oxygen saturation, depression, anxiety, pain and quality of life, as well as its efficacy on pulmonary and autonomic function. We hypothesized that these parameters would improve in yoga group compared to a control group, at least partly for reasons similar to its efficacy to asthma (Nagarathna & Nagendra, 1985; Nagendra & Nagarathna, 1986; Rao et al., 2014).