CHAPTER 3

SCOPE AND OBJECTIVES

3.1 STUDY SCOPE

The goals of asthma therapy are to maintain a near normal lung function, absence of asthma symptoms, no activity limitations and no episodes of asthma worsening. The objectives of the asthma treatment are not fulfilled completely with only inhaled corticosteroid (ICS). For this reason, without increasing the dose of ICS, the addition of a second drug with complementary mechanism is preferred.

Patients who are not controlled ideally on low dose ICS alone can be defined as moderate persistent asthmatics. The combination of ICS and long acting β₂ -agonist (LABA) is recommended by the Global Initiative for Asthma (GINA) guideline as the first-line preferred treatment in these patients. The other alternative treatment options recommended are an addition of either leukotriene antagonist (LTA) or Sustained Release Thophylline (SR-T) to a low dose of ICS. Despite the addition of agents like LABA, LTA, SR-T to ICS, many asthma patients still remain both symptomatic and obstructed. One intriguing option as an add-on therapy for patients not responding to ICS is a long acting muscarinic antagonist (LAMA). Though clinical studies have supported the use of LAMA in the treatment of asthma, we could not find many studies in this area.

Measurement of % FEV₁ emphasis only about the pulmonary functions, but do not assess, how the patient feels with asthma. The patient reported outcome measures such as patient perceptions are recognized as an important tool, to give a complete picture of overall asthma control in clinical trials. Measurement of health related quality of life (HRQoL) and asthma symptom scores (day-time and night-time) are few of such outcome measures.
Current treatment guidelines for asthma emphasize the importance of patient education to asthmatics. An education program to improve the awareness of critical diseases like asthma among the affected community would certainly make changes in the disease management.

Globally, studies for head-to-head comparison of various second-line treatment regimens in the form of leukotriene antagonist, sustained release theophylline and long acting muscarinic antagonist co-administered with inhaled corticosteroid are not yet reported with pulmonary function, quality of life and asthma symptom score outcomes.

3.2 AIM

Having the above background information, the aim of the study was:

- To identify the best second-line medication for add-on therapy to a selected inhaled corticosteroid

3.3 STUDY OBJECTIVES

The following objectives helped to achieve the aim of the current study:

- To compare the therapeutic response of second-line treatment regimens (doxofylline, montelukast and tiotropium with inhaled budesonide) with first-line treatment regimen (formoterol with inhaled budesonide) as a control on the pulmonary function using spirometry in patients with mild to moderate persistent asthma

- To compare the Health Related Quality of Life (HRQoL) using Saint George’s Respiratory Questionnaire (SGRQ) among the asthmatic patients receiving second-line treatment regimens with first-line treatment regimen as a control.

- To assess the day-time and night-time symptom scores among the study patients receiving the study drugs.
• To assess the usage of rescue medications among the patients during the study.

• To assess the adverse drug reaction of the study drugs during the study period.