

Title: AN OPEN LABELLED, RANDOMISED, PROSPECTIVE STUDY COMPARING THE EFFICACY AND SAFETY OF DOXOFYLLINE WITH THEOPHYLLINE IN COPD PATIENTS

Background: Chronic pulmonary obstructive disease (COPD) is an important public health problem which is preventable as well as treatable. It is one of the major cause of chronic morbidity and mortality throughout the world. There is a need to address the well known safety issues in using theophylline. We need a better drug with greater efficacy and safety profile to treat COPD. Therefore, the present study is designed to compare the clinical efficacy and safety of oral theophylline and doxofylline in patients with Grade 1-2 COPD (Based on GOLD Criteria) attending the outpatient department of Chest Medicine in Tirunelveli Medical College Hospital.

Methods: A total of 60 patients were enrolled for the study and were randomized to two groups of 30 patients with one group receiving Theophylline and the other, Doxofylline in addition to standard therapy, for a period of 12 weeks. Each patient was followed up at 6 weeks and 12 weeks for the assessment of efficacy parameters using a pulmonary function test (PFT), COPD Assessment questionnaire (CAT) and safety was assessed by recording adverse drug reactions.

Results: Both theophylline and doxofylline produced significant improvements in PFT and CAT Score at 6 weeks and 12 weeks within their respective groups. But when compared between the two groups, there was no significant improvement.

The number of ADR in theophylline group is higher compared with doxofylline group patients. The most common adverse effect observed in both groups was dyspepsia

Conclusions: Doxofylline is equally efficacious and has a better safety profile when compared to theophylline thus becomes a safer alternative in the treatment of Grade 1-2 COPD(GOLD Criteria).

Keywords: Chronic pulmonary obstructive disease, Doxofylline, Theophylline, Pulmonary function test, COPD Assessment test questionnaire