Population-based open-label clinical effectiveness assessment of the cysteinyl leukotriene receptor antagonist pranlukast

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Although the efficacy of cysteinyl leukotriene receptor antagonists in asthma therapy has been established through controlled clinical trials, there are no data concerning the effectiveness of their use in clinical practice, in which there is no rigid selection based on specific inclusion and exclusion criteria. The aim of the present study was to evaluate the effectiveness of pranlukast in clinical practice. More than 2500 outpatients with mild to severe persistent asthma answered an input questionnaire, which consisted of 33 items assessing asthma symptoms in terms of six activities of daily living during the previous 2 weeks. Of these patients, 1138 received treatment with pranlukast and answered the same questionnaire 4-6 weeks after the start of treatment. In 923 of these 1138 patients, we examined the impact of concomitantly used inhaled steroids, β2-adrenergic agonists or sustained-release theophylline on the effectiveness of pranlukast treatment. One hundred and sixty-seven control patients completed the questionnaire twice but did not receive pranlukast treatment. We found a significant decrease in the number of asthma symptoms reported among both the 1138 patients treated with pranlukast and the 167 control patients. However, the magnitude of the decrease in symptoms was significantly ($P < 0.001$) greater with pranlukast treatment. Moreover, pranlukast was equally efficacious in the presence and absence of concomitantly used inhaled steroids, β2-adrenergic agonists or sustained-release theophylline. In conclusion, pranlukast was shown to have clinical effective- ness in the treatment of mild to severe persistent asthma symptoms.

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