RATIONALE FOR THE CHOICE OF FLUTICASONE PROPIONATE IN THE CYCLOHALER DEVICE FOR THE BASIC THERAPY OF BRONCIAL ASTHMA

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Abstract. The basis of the treatment of bronchial asthma (BA) is anti-inflammatory therapy with the help of inhaled corticosteroids (ICS). Expectations of high efficacy (small particle size, high receptor affinity, high lipophilicity and lung residence time) and safety (low oral bioavailability, low systemic absorption, high protein binding and rapid systemic clearance) are placed on ICS. According to these characteristics, fluticasone propionate has the optimal therapeutic index.
The aim: to study the possibilities of the use of fluticasone propionate in the cyclohaler device for the basic therapy of BA.
Materials and methods. The study enrolled 376 patients who received fluticasone propionate 125 μg and 250 μg twice daily in a cyclohaler delivery device compared with the original fluticasone propionate 500 μg in patients with moderate asthma. All patients underwent spirometry, peak flowmetry, laboratory studies, registration of asthma symptoms, need in the rescue therapy, vital signs, adverse events.
Results. The clinical and functional efficacy of fluticasone 125 μg twice daily is no inferior than the efficacy of the original fluticasone 500 μg twice daily. There is no clinically significant difference between the effectiveness of the drug in a dose of 125 and 250 μg when taken twice daily with the use of the new generation cyclohaler, which confirms the almost parallel linear dose-effect relationship in the range of medium and high doses of the drug. The incidence of the adverse effects was significantly lower in the group of patients treated with fluticasone 250 μg compared to patients in the other two groups. There were no differences between the groups in laboratory results. There were no differences in cortisol concentrations in blood plasma and 24-hour urine before and after 12 weeks of treatment in the groups using cyclohaler and the reference drug.
Conclusion. Fluticasone propionate administered through a new generation cyclohaler at doses of 125 and 250 μg twice daily is an effective therapy for asthma of moderate severity, and the dose of 250 μg with the use of new generation cyclohaler is clinically equivalent to a twofold higher dose of the reference fluticasone propionate. The safety profile of fluticasone when using of the new generation cyclohaler can be compared with the safety profile of the reference substance.

Key words: bronchial asthma, inhaled corticosteroids, fluticasone propionate, dry powder inhaler, cyclohaler.