Double-Blind Study Comparing Ketotifen and DSCG in Adolescent Asthmatics

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Ketotifen is a new orally active drug with anti-allergic properties [1]. It prevents 48/80-induced histamine release from isolated rat peritoneal mast cells and inhibits the release of both histamine and SRS-A from human basophils. It has been shown to protect against histamine and specific allergens in bronchial challenge tests [2].

In order to compare the clinical efficacy and tolerance of ketotifen and disodium cromoglycate (DSCG), a 12-week double-blind, double-dummy study was carried out involving adolescents aged 15–18 years with allergic asthma, randomly assigned to each treatment group. The groups were comparable as regards asthma symptoms and pulmonary function. All patients satisfied the following criteria for inclusion: a well-documented history of asthma, a positive skin test to common allergens, a forced expiratory volume in 1 sec of less than 70% of the predicted value and a response of 20% or more to the inhalation of orciprena-line. The number and dosage of anti-asthmatic drugs used was recorded and a comprehensive laboratory analysis including full

1 Extended abstract

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blood count, urinalysis, transaminases etc. was carried out. A 2-week placebo period preceded the study. 16 children, 8 in each group, completed the trial. They were given oral ketotifen 1 mg b.i.d. and DSCG 20 mg q.i.d. by inhalation as active drugs. The evaluation, made every 2 weeks for the first month and then at 4-week intervals, comprised asthma symptoms, current medication and spirometry. In addition each patient recorded the medication used, the frequency and severity of wheezing and peak flow measurements daily.

The results show ketotifen to be as effective as DSCG in the prevention of asthma symptoms. The improvement in wheezing during the day between the initial and the last period of observation was statistically significant ($p < 0.05$) within each group. The pulmonary function tests (MMEFR, FEV₁) showed a transient tendency for improvement in the ketotifen but not in the DSCG group. However, differences within and between groups were not statistically significant. Anti-asthmatic drug use could be discontinued in 7 patients and remained unchanged in 3 patients in both groups. 2 patients with ketotifen and 3 with DSCG were able to decrease it, whereas 3 asthmatics on ketotifen and 4 on DSCG had to in-

crease their amount of β_2 -stimulators. Ketotifen was extremely well tolerated, as no side-effects were reported. There were no changes during the study in blood chemistries, urinalyses or haematologic analyses.

In conclusion ketotifen as a prophylactic agent in adolescent asthmatics is as effective as DSCG and has the advantage of a twice daily oral administration which facilitates compliance to therapy. Ketotifen is also a safe medication and no side-effects were observed. Further studies are needed to demonstrate the superiority of one drug over the other.

References

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