Oral Prophylaxis of Bronchial Asthma in Children

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In a controlled, double-blind study of 12 weeks duration the protective action of ketotifen in young children was compared with the effect of placebo and it was also determined whether concomitant therapy (steroids and/or bronchodilators) could be reduced.

50 children aged between 1 and 9 years with confirmed allergic bronchial asthma of 6 months to 6 years duration and with reversible bronchospasm were randomly divided into two comparable groups. In 34 children (15 on placebo, 19 on ketotifen) desensitization had previously been tried. No child was receiving other prophylactic treatment but all were taking β_2 -stimulators and/or steroids. According to their body weight they received daily doses of 1, 1.5 or 2 mg of ketotifen. This was given in the form of scored tablets twice or three times a day, the same regimen applying to placebo tablets. At the beginning of the study the medical history was recorded and a general examination including full blood count and liver function tests (SGOT, SGPT, alkaline phosphatase) carried out. At weeks 2, 4, 8 and 12, the patients were assessed clinically, Extended abstract

Full paper to be published elsewhere.

and daily use of concurrent medication was recorded. At weeks 4, 8 and 12, blood was taken for laboratory tests. At the end of the study an overall assessment of efficacy and safety was made by the investigator. The definitions used were: very effective (symptoms hardly present, no more wheezing or asthma attacks and concomitant medication no longer required), effective (marked improvement, number of asthma episodes reduced by more than 50%, concomitant therapy reduced), weakly effective (slight improvement, number of asthma episodes hardly changed, concomitant medication unaltered), and ineffective (no improvement in symptoms, a change in therapy necessary). All 50 patients completed the study. In both groups there was a comparable improvement in dyspnoea and asthmatic complaints. The incidence of asthmatic attacks was significantly lower in the ketotifen group (mean 1.65 ± 2.1) as compared with the placebo group (mean 3.73 ± 3.6 ; $p < 0.01$) from week 8 onwards. 5 of the 6 children taking corticosteroids were in the ketotifen group and 4 were able to reduce their daily dosage, 3 ultimately discontinuing corticosteroids altogether. All the children were receiving β_2 -stimulants and whilst on ketotifen 17 reduced their daily

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dose and 14 of them were able to discontinue their β_2 -stimulants. The figures for the placebo group were 4 and 3, respectively. This is statistically significant ($p < 0.005$). In 19 patients taking placebo it was necessary to increase the bronchodilator dose as compared with only 6 patients taking ketoti-fen. No statistically significant or clinically relevant changes occurred in blood

pressure and pulse rate, with the exception of 1 patient on ketotifen who inexplicably had a pulse rate of 140/min and a blood pressure of 170/120 at the last visit. No side-effects related to ketotifen treatment were recorded. Laboratory investigations showed no pathological trends in either group. In this study ketotifen has proved to be effective and safe in the prophylaxis of bronchial asthma and the tablets were well accepted even by the young children involved in the study.