COMPARISON OF INTRanasAL CROMOLYN SODIUM AND ORAL TERFENADINE FOR ALLERgIC RHINITIS. HA Orgel, EO Meltzer, JP Kemp, NE Ostrom and MJ Welch, San Diego, CA.

Topical intranasal cromolyn sodium 42 solution (CS) and oral terfenadine 60 mg tablets (TERF) both relieve symptoms of allergic rhinitis (AR) with few or no adverse effects but no comparison of their relative efficacy has been reported. In this double-blind, double-dummy study, 79 pts, ages 12-56 yrs, with symptoms of AR were randomized to receive either active CS 1 spray in each nostril QID or active TERF BD along with the appropriate placebo spray or tablet for 4 wks following a 1 wk baseline qualification period. Pts' daily symptoms scores were reviewed weekly and constituted the primary efficacy measures; assigned scores were on a 0-5 scale. Changes in nasal cytology, nasal ciliary clearance and rhinomanometry were also assessed. The presence of adverse effects and the overall score of medication given were determined at the end of each week. The CS and TERF groups had comparable baseline scores for severity of AR symptoms and both treatments resulted in significant improvement (p<0.0001) with no statistical difference between them for total symptoms scores at the end of 4 wks. CS pts tended to demonstrate efficacy earlier and TERF pts noted greater improvement in reducing sneezing (p=.04) and duration of nasal itch (p=.05). There were no significant differences in nasal cytology or rhinomanometry. Reports of adverse effects were uncommon and only mild in severity. We conclude that both CS and TERF are comparably effective and well-accepted treatments for AR.

TRIAMCINOLONE ACETONIDE (TA) NASAL AEROSOL IN THE TREATMENT OF SEASONAL ALLERGIC RHINITIS (SAR). D. Tinkelman, M.D., Atlanta, GA; C. Felliers, M.D., Denver, CO; G. Gross, M.D., and A. Segal, M.D., Dallas, TX; L. Sopher, M.D., Princeton, NJ; M. Welch, M.D., San Diego, CA; H. Yeates, M.D., Provo, UT; J. Gorder, M.D., and J. Garcia, Ph.D., Horsham, PA.

TA is effective for the prophylactic treatment of asthma. Recently, the delivery system for this potent medication has been evaluated for use in allergic rhinitis. We studied TA vs. placebo in a 4-week double-blind parallel study in 180 adult patients with symptomatic seasonal allergy. Patients were randomly assigned to either placebo or TA 25 mcg/nostril, qid. Each patient kept a daily diary rating rhinitis symptoms. Both the patient and the physician also gave global evaluations of drug efficacy. In 168 evaluable patients, significant reductions were seen at Week 1, Week 2, and overall in the intensity ratings for rhinitis symptoms (p<0.001) and duration of symptoms in the group given TA (p<0.05). Superiority to placebo was evident by Day 1 and maintained to the end of the study. Both patients and physicians rated the TA as significantly more effective than placebo for the duration of the study (p<0.001). There was a marked reduction in nasal smear eosinophils in the TA group. There was no difference between groups in safety evaluation including no evidence of suppression of the adrenal axis and no evidence of fungal infection. TA in a dose of 25 mcg/nostril, qid, is safe, well tolerated, and effective in reducing symptoms in patients with SAR.

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Fourteen nasal sprays were compared in an open study. 9 pts with seasonal allergic rhinitis were included. In the first week of the study the patients used saline solution as placebo. The remaining 9 weeks were randomized double blind to 1 of 4 sprays, 2 containing nebulized cromolyn sodium and 2 containing montelukast sodium. The sprays were applied in the morning. Both cromolyn preparations (4 mg/ml) were superior to montelukast (10 mg/ml) in reducing symptoms of nasal obstruction, sneezing, and rhinorrhea during the pollen season. No differences were observed between the 2 cromolyn preparations. The nebulized form of cromolyn sodium was significantly more effective than the oral form of montelukast in improving symptoms in patients with seasonal allergic rhinitis. This study indicates that nebulized cromolyn sodium may be a useful treatment modality in patients with seasonal allergic rhinitis. These results support a view that cromolyn sodium is involved in the pathogenesis of allergic rhinitis.

CLINICAL EFFECTIVENESS AND SAFETY OF TRIAMCINOLONE NASAL STEROID SPRAY VS. FLUNISOLIDE NASAL STEROID SPRAY IN THE TREATMENT OF SEASONAL ALLERGIC RHINITIS. L.R. Freidhoff, M.S., P.S. Norman, M.D., P.S. Cricic, M.D., Baltimore, MD.

27 subjects with a typical history of Spring pollenosis as characterized by sneezing, nasal congestion, rhinorhea and verified by positive skin tests to grass pollen extract were entered into a double-blind, randomized, parallel 6 week study to compare the effectiveness of triamcinolone (TRM) nasal steroid spray to flunisolide (FN) nasal steroid spray. The TRM (n=13) and FN (n=14) groups were similar in their entry demographics of age, sex, years of pollinosis (Sex:TRM:SM/FP, FN:SM/FP; age:TRM:med. 33, FN:med. 34; symptoms:TRM:med. 20, FN:med. 20). Symptom Medication Diary (SMD) scores demonstrated similar scores for both the TRM and FN groups during the initial 2 weeks baseline (non-treated) period. Consequently, Both (TRM) and (FN) groups demonstrated efficacy when baseline (weeks 1-2) were compared respectively to peak treatment (weeks 5-6) for both severity and duration of symptoms (P values follow): [FN:severity .001; duration .001/TRM:severity .002; duration .002]. No difference was noted between either nasal steroid preparation when analyzed by SMD for severity or duration of symptoms (P values follow): [Duration: Week (Wk) 1/2:0.24; Wk 3/4: 0.24; Wk 5/6: 0.81; Wk 3-6: 0.42// Severity: Wk 1/2: 0.64; Wk 3/4: 0.51; Wk 5/6: 0.73; Wk 3-6: 0.85]. Analyses of blood cortisol levels likewise showed no differences between pre and treatment phases for either group. We conclude the 2 nasal steroid preparations are equally safe and efficacious by this study.

DRUG EFFECTS ON ANTIGEN-INDUCED RELEASE OF HMW-NCA IN NASAL SECRETION FROM PATIENTS WITH ALLERGIC RHINITIS. T. Onoda, T. Uekusa, N. Nagakura, Y. Ikikura, K. Ohno, Tokyo, Japan.

High molecular weight-neutrophil chemoactivity factor in nasal secretion (HMW-NCA) has been detected in a variety of allergic disorders, mainly on bronchial asthma and urticaria. We have been attempted to determine whether HMW-NCA is playing a role in allergic rhinitis. We have challenged 7 subjects with allergic rhinitis. The disc of house dust mite allergen was placed on nasal membrane and nasal secretion was collected to measure NCA. Then pretreatment of DSCG, Epinephrine and beclomethasone dipropionate (BD) was performed before challenge. NCA was measured by microchemotaxis chamber (Neuro Probe). Molecular weight of NCA was determined by gel filtration using S-400 (Pharmacia). Nasal secretions were applied on the columns of S-400. NCA of each fraction was measured. HMW-NCA was eluted as a single peak with estimated molecular weight of 600K daltons. Pretreatment of DSCG or Epinephrine significantly inhibited clinical symptoms and release of NCA into nasal secretion (P<0.01, P<0.05, respectively). There was no effect of topical administration of BD on clinical signs or NCA release into nasal secretion.

These results support a view that HMW-NCA is involved in the pathogenesis of allergic rhinitis.