642 Combination Therapy with Montelukast and Antihistamines (desloratadine or Levocetirizine) Improves Quality of Life in Patients with Persistent Allergic Rhinitis: a Double Blind Placebo Controlled Study

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RATIONALE: We investigated the effects of 6 weeks of treatment of persistent allergic rhinitis with either montelukast alone, desloratadine alone, levocetirizine alone or the combination of montelukast and either desloratadine or levocetirizine on patient quality of life (HRQL).

METHODS: A 32 week randomized, double blind, placebo controlled, cross-over study was performed on 40 adult patients with persistent allergic rhinitis. 20 subjects received montelukast (10mg) and/or desloratadine (5 mg) or placebo. 20 patients received montelukast (10mg) and/or levocetirizine (5 mg) or placebo. The sequence of the treatment options was assigned randomly. Quality of life was assessed on the day before and on the last day of each treatment period according to HRQL. The mean value for each health dimension was calculated and the HRQL was presented as a mean of 7 dimension scores.

RESULTS: Mean quality of life score in the desloratadine/montelukast arm before treatment was 3.1±0.41; after placebo was 2.16±0.43; after desloratadine was1.79±0.38; after montelukast was 1.48±0.37; and after concomitant montelukast and desloratadine was 1.59±0.37. Mean quality of life score in the montelukast/ desloratadine arm before treatment was 2.58±0.49; after placebo was 1.78±0.46; after levocetirizine was 1.38±0.42; after montelukast was 1.36±0.37; and after concomitant montelukast and levocetirizine was 1.26±0.39.

CONCLUSIONS: Treatment with montelukast alone, desloratadine alone, levocetirizine alone and the combination of montelukast plus antihistamine significantly improved quality of life when compared to both baseline and placebo therapy. Concomitant treatment with montelukast plus antihistamine gave additional, sometimes significant, improvement of quality of life when compared with each agent alone.

Funding: Medical University of Lodz

643 Prescription Medication Use Following Rhinitis Diagnosis: An Examination of Pharmacy Claims in the Integrated Healthcare Information Services (IHCIS) Database

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RATIONALE: We examined patterns of intranasal steroid (INS), nonsedating antihistamine (NSA) and leukotriene modifier (LM) use after rhinitis diagnosis.

METHODS: A retrospective, observational cohort study of 717,353 rhinitis patients was conducted using IHCIS, a large medical claims database. Patients met the following criteria: rhinitis diagnosis between January 1, 2000 and December 31, 2004, aged 4 years or older at diagnosis and at least 12 months of plan eligibility prior to diagnosis. No restrictions were placed on medication use prior to diagnosis. Rates of INS, NSA and LM dispensings were calculated using linked pharmacy claims.

RESULTS: Forty-six percent of patients filled at least one prescription for INS, NSA or LM within 3 months of rhinitis diagnosis. Six months after diagnosis, half of the patients (49.6%) had not filled any prescriptions for the medications. Among treated patients, 49.7% filled at least one INS prescription and 73.4% filled at least one NSA within 6 months of diagnosis. One-quarter (24.7%) of treated patients filled prescriptions for INS and NSA within 30 days of one another. For treated patients with at least 12 months of pharmacy eligibility post-diagnosis, the average number of dispensings in the first year was 2.9 for NSA users and 2.2 for INS users.

CONCLUSIONS: While half of patients did not receive any dispensings within 6 months of diagnosis, a NSA was most commonly dispensed among those treated with prescription medicines. Among patients with rhinitis, concomitant use of INS and NSA was common, suggesting incomplete symptom relief with one medication alone.

Funding: GlaxoSmithKline

644 Allergic Responses Induced by Grass Pollen in an Environmental Challenge Chamber (ECC) Reflect Changes During Seasonal High Pollen Counts in Allergic Rhinitis Patients

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RATIONALE: This study compared the allergic responses induced in an ECC to those under natural exposure during the grass pollen season in allergic and healthy individuals.

METHODS: Sixty patients with seasonal allergic rhinitis and sixty age-matched healthy controls were included. Subjects were exposed to grass pollen in an ECC for 4h at two visits during wintertime. At these visits and at two visits during the grass pollen season nasal symptoms (TNSS, VAS), nasal flow, FEV1 and exhaled NO were determined.

RESULTS: Healthy individuals showed no allergic responses in all parameters at any timepoint. Allergic patients demonstrated highly reproducible changes during ECC challenges (TNSS: +3.8 and +4.1; VAS: +2.3 and +2.3; nasal flow: -117 and -96 mm/s; eNO: +9.0 and +9.5 ppb). During pollen season, values were significantly increased at the first visit with high pollen counts (TNSS: +2.3; VAS: +1.4; nasal flow: -26 mm/s; eNO: +8.9 ppb). These values were comparable to the changes induced in the ECC. At the second visit with low pollen counts, changes were minor (TNSS: +0.8; VAS: +0.4; nasal flow: -0.5mm/s; eNO: +7.5ppb). FEV1 did not change at all visits.

CONCLUSIONS: Induction of allergic symptoms in the ECC is highly reproducible and reflects changes during high pollen counts in the pollen season.

Funding: University of Bochum

645 Safety and Efficacy of Olopatadine Hydrochloride Nasal Spray 665 mcg (Patanase® Nasal Spray) in Patients with Perennial Allergic Rhinitis

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RATIONALE: To demonstrate the long-term safety and efficacy of olopatadine hydrochloride (OLO) nasal spray 665 mcg (Patanase® Nasal Spray) in patients with perennial allergic rhinitis (PAR).

METHODS: This was a randomized, placebo-controlled, double-masked, parallel group study in patients > 12 years of age with a history of PAR verified by skin prick or intradermal testing. Patients received OLO or placebo (vehicle spray), 2 sprays in each nostril twice daily, for up to 1 year. An efficacy questionnaire was completed by the patient at monthly visits and adverse events, nasal, cardiovascular, and physical examination parameters were monitored throughout the study.

RESULTS: Nine hundred twenty-four patients were evaluable for intent to treat analysis, including 648 patients treated for 1 year. OLO was superior to placebo in mean response to patient rated relief across all visits (2.4 versus 2.6, respectively, $p<0.0001$). OLO provided more than a 50% increase in symptoms-free days compared to placebo (14.9% versus 9.5%, $p<0.0001$).

Epistaxis and bad/bitter taste were more common in patients receiving OLO. These events were mild and transient in nature. A similar incidence of nasal ulceration, infection and anatomic abnormalities compared to placebo and no adverse cardiovascular effects (including QT interval) were observed with OLO.

CONCLUSIONS: Patanase® Nasal Spray administered twice daily for up to 1 year is effective in treating PAR and is associated with greater patient rated relief of symptoms and more symptom-free days than placebo. Side effects were mild and similar to those observed with other intranasal allergy products. No adverse cardiovascular effects were observed with treatment.