group 1 and 5 allergens in a 13 grass extract and to standardise the extraction method.

**Methods:** The grass pollens were extracted in isolation and pooled and also in combination and analysed using a variety of techniques including enzyme-linked immunosorbent assay (ELISA), liquid chromatography-mass spectrometry (LC-MS) and sodium dodecyl sulphate polyacrylamide gel electrophoresis (SDS-PAGE).

**Results:** Gold-staining and IgE immunoblotting revealed a high degree of homology of protein bands between the 13 species and the presence of a densely stained doublet at 25 to 35 kD along with protein bands at approximately 12.5, 17 and 50 kD. The doublet from each grass species demonstrated a high level of group 1 and 5 interspecies homology. However, there were a number of bands unique to specific grasses consistent with evolutionary change and indicative that a grass mix immunotherapeutic could be considered broad spectrum.

**Conclusions:** SDS-PAGE and IgE immunoblotting showed all 13 grasses share a high degree of homology particularly in terms of group 1 and 5 allergens. IgE and IgG ELISA potencies were shown to be independent of extraction method.

10 Seasonal Versus Symptom-based Evaluation of a Depigmented Grass-Birch Allergoid

Oliver Pfarr, MD, Tilo Biedermann, and Angelika Sager, MD. Center for Rhinology and Allergology, Department of Otorhinolaryngology, University Hospital Mannheim, Wiesbaden, Germany; Department of Dermatology, University Hospital, Tübingen, Germany; Medical Department, LETI Pharma GmbH, Witten, Germany.

**Background:** The safety and efficacy of specific immunotherapy (SIT) with depigmented and polymerized allergen extracts of pollen is well documented in several clinical trials. The results of such clinical studies are highly dependent on the quantity and quality of pollen exposure and their measurements. To identify a pollen-independent efficacy assessment we compared the combined symptom and medication score (SMS) measured during the pollen season with the SMS defined by a minimum symptom score of the placebo group in a subcutaneous immunotherapy with a depigmented Grass-Birch allergoid over 2 years.

**Methods:** 269 (ITT) patients with confirmed rhinitis and/or rhinoconjunctivitis were treated during 2009 and 2010 in Germany, Romania, Poland, Lithuania, and Bulgaria. Patients were randomised to the treatment groups on a 2:1 basis (175 verum: 94 placebo). The main parameter in this study was the combined symptom and medication score during the birch and grass pollen season 2010. In addition the SMS of the actively treated patients was analyzed following the placebo treated patients eliciting a considerable symptom burden >2.

**Results:** The clinical results following the seasonal approach are given in the other abstract of our group. Taking all days with mean symptom score >2 in the placebo group as calculation basis, the combined SMS values were considerably lower for actively treated patients than for placebo treated patients. For both seasons, the differences between the treatment groups were highly statistically significant (2009: 5.06 vs 7.97, 2010: 4.26 vs 6.43; ITT set) with P-values of 0.0038 and 0.003.

**Conclusions:** The results show that the efficacy assessment of specific immunotherapy might be better discriminated in relation to the actual symptoms of the placebo group rather than following the days of pollen exposure.

**REFERENCE**

1. Abstract # 3093: Biedermann T, Pfarr O, Sager A. "Comparison of efficacy and safety of a depigmented polymerized allergen extract of grass and birch with placebo in patients with type-I allergic rhinoconjunctivitis."