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FILE: ▪Butterbur (*Petasites hybridus*)
▪Allergic Rhinitis
▪Ze 339

HC 090254-301

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RE: Study Finds Butterbur Extract Effective in Treatment of Allergic Rhinitis

Schapowal, A. Treating intermittent allergic rhinitis: a prospective, randomized, placebo and antihistamine-controlled study of butterbur extract Ze 339. *Phytother Res.* 2005;19:530–537.

Allergic rhinitis (AR) is an inflammation of the nasal mucous membranes caused by environmental allergens such as pollen and dust. It is oftentimes referred to as *hay fever*, which is a misnomer, since the allergen is not necessarily hay, and there is no fever. Symptoms include sneezing, nasal congestion, nasal itching, and watery nasal discharge: some patients also suffer headache, fatigue, and substantially reduced quality of life "with disabling social and work consequences." AR affects an estimated 20% of the population. Commonly, antihistamines are used to treat AR symptoms; however, antihistamines can cause drowsiness. This prospective, randomized, double-blind, parallel group clinical trial compared butterbur (*Petasites hybridus*) carbon dioxide extract Ze 339 (Zeller AG, Switzerland) to fexofenadine (Telfast 180®; Aventis Pharma Limited, New Zealand), a non-sedating antihistamine, and placebo for the treatment of AR.

Volunteers were solicited from 11 outpatient allergy clinics. The study was approved by both German and Swiss ethics committees and registered with both countries' Federal Authorities. Inclusion criteria required that all had moderate or greater severity for seasonal allergic rhinitis for 2 or more years and demonstrated all of the following symptoms: sneezing, rhinorrhoea (runny nose), itchy nose, itchy eyes, and nasal congestion. Excluded were people with a history of mental illness, alcohol or substance abuse, pregnant or nursing women, parasitic infection, bronchial asthma, presence of any "serious concomitant disease," persistent (non-intermittent) AR, corticosteroid use in the 2 months prior to the study, antihistamines in the previous 6 weeks, or anti-inflammatories in the 2 weeks leading up to the trial. Also excluded were people taking α- or β-blocker drugs, clonidine, α-sympathomimetics, azelastine, levocabastine, or antidepressants.

A total of 330 volunteers, 18–80 years old (mean age approximately 38 years) were randomized to receive 1 tablet butterbur extract Ze 339 (standardized to 8 mg petasine) 3 times a day, 1 tablet fexofendadine, or placebo for 2 weeks. Ze 339 is claimed to be free of hepatotoxic pyrrolizidine

alkaloids (PAs). According to the authors, "Blindness was assured by the use of encapsulated 'double-dummies', whereby the daily study medication consisted of three encapsulated tablets containing either active or placebo to match each treatment group." The primary outcome measure was the daytime total symptom score (TSS) for rhinorrhea, sneezing, itchy nose, itchy/red eyes, and nasal congestion. Secondary outcome measures were evening/night TSS, physician's global assessment of efficacy, and responder rates.

Butterbur was equally effective as fexofenadine for treating symptoms of intermittent AR. Mean TSS significantly decreased from baseline to 2 weeks in the butterbur group compared to placebo (3.86 ± 3.6 vs. 0.41 ± 2.9, respectively; $P < 0.0001$), and in the fexofenadine group compared to placebo (3.51 ± 4.1 vs. 0.41 ± 2.9, respectively; $P < 0.0001$). Both treatments were effective at decreasing evening/night TSS ("instantaneous TSS") as well. From baseline to 2 weeks, mean instantaneous TSS decreased 10.4 ± 10.0 in the butterbur group vs. 2.1 ± 7.4 in the placebo group ($P < 0.0001$). Similarly mean instantaneous TSS score significantly decreased in the fexofenadine group compared to placebo (10.4 ± 12.2 vs. 2.1 ± 7.4, respectively; $P < 0.0001$). Significant improvement in physician's assessment of efficacy for both treatment groups compared to placebo was also noted ($P < 0.0001$). Volunteers responded significantly better to butterbur and fexofenadine compared to placebo ($P < 0.0001$). No significant differences were noted in any outcome measured when treatment groups were compared to each other.

Adverse events (AEs) were generally mild in all groups, and included sedation, common cold, and nausea in all groups. Sedation accounted for 6 of 8 AEs (75%) in the fexofenadine group compared to 4 of 10 AEs (40%) in the butterbur group. In the butterbur group, the following AEs were experienced by 1 person each: diarrhea, headache, stomach pain, and limb pain. No changes were detected in liver function tests from baseline to the end of treatment.

This study showed butterbur is as effective as fexofenadine at treating intermittent AR, and both were superior to placebo. Although fexofenadine is considered a non-sedating antihistamine, a large percentage of volunteers in the fexofenadine group experienced sedation, as compared to the butterbur group. Butterbur extract Ze 339 is an effective alternative to fexofenadine in the treatment of intermittent allergic rhinitis.

—John Neustadt, ND

The American Botanical Council has chosen not to reprint the original article.