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> **FILE: Butterbur** (*Petasites hybridus*) Seasonal Allergic Rhinitis Adenosine Monophosphate

> > HC 040143-263

Date: August 31, 2004

RE: Butterbur Extract Improves Symptoms of Seasonal Allergic Rhinitis

Lee DKC, Carstairs IJ, Haggart K, Jackson CM, Currie GP, Lipworth BJ. Butterbur, a herbal remedy, attenuates adenosine monophosphate induced nasal responsiveness in seasonal allergic rhinitis. Clin Exp Allergy. 2003;33:882-886.

Butterbur (BB; *Petasites hybridus*) was shown in a recent randomized controlled trial to be as effective as H₁-antihistamine therapy with cetirizine in alleviating the symptoms of seasonal allergic rhinitis.¹ The mechanism of action appears to be the inhibition of the biosynthesis of cysteinyl leukotrienes by petasin, the active ingredient in BB. Moreover, this herb has been shown to decrease nasal concentrations of histamine and cysteinyl leukotrienes. Since no placebo-controlled studies to evaluate the effectiveness of BB on objective outcome measures of seasonal allergic rhinitis have been conducted, the authors assessed the effects of BB on adenosine monophosphate (AMP) nasal provocation testing in patients with seasonal allergic rhinitis.

Twenty patients [10 men and 10 women with a mean (\pm SEM) age of 35 \pm 3 y] with seasonal allergic rhinitis were enrolled during the grass pollen season (July and August 2002) according to a randomized, double-blind, placebo-controlled, crossover design. The subjects' usual allergy treatments were stopped for a 1-week run-in period before the study began. The subjects were then randomly assigned to receive either 50 mg BB (Petaforce®; Bioforce Ltd., Irvine, United Kingdom) or placebo twice daily for 2 weeks sequentially. The subjects were required to measure their peak nasal inspiratory flow (PINF), and they received a single dose of 400 mg AMP/mL. Spontaneous recovery after this nasal AMP challenge was monitored with PNIF measurements at 1.5, 5, 10, 15, 20, 30, 40, and 60 minutes. In addition, blood samples were drawn to evaluate liver function.

Recovery from the nasal AMP challenge was significantly attenuated (P = 0.028) in the BB group (mean \pm SEM: 584 \pm 289 area under the curve %.minute) compared with that in the placebo group (1438 \pm 240 area under the curve %.minute). The maximum decrease in PNIF from baseline was significantly lower (P = 0.036) in the BB group ($30 \pm 4\%$) than in

the placebo group $(43 \pm 5\%)$. Liver function - based on concentrations of alanine aminotransferase, bilirubin, albumin, and alkaline phosphatase - indicated no significant differences between groups.

The results indicated that the consumption of BB for 2 weeks attenuated the nasal response to AMP challenge relative to placebo, both in terms of recovery and in the maximum decrease in PNIF. BB protected against the action of AMP on the nasal mucosa by both lessening the acute decrease in PNIF after a single dose of AMP and by hastening recovery. Unpurified BB contains pyrrolizidine alkaloids, which are hepatotoxic and carcinogenic; however, these toxic substances had been removed from the BB used in this study. The authors acknowledge that this study was limited since the safety of BB was not evaluated adequately, which would have required a much larger sample size and a longer study period.

In conclusion, BB was superior to placebo "in attenuating the response to AMP." This finding suggests protective effects on allergen-sensitized mast cell priming. The authors recommend that dose-response studies and long-term safety studies be conducted to further evaluate the effects of BB in patients with allergic rhinitis as well as in those with asthma. Of related interest are the findings of two recent clinical trials that successfully demonstrated the ability of a standardized extract of the rhizome of purple butterbur to safely and effectively reduce the frequency and intensity of migraine headaches.²

—Brenda Milot, ELS

References

¹Schapowal A. Randomised controlled trial of butterbur and cetirizine for treating seasonal allergic rhinitis. *BMJ*. 2000;324:144.
²Brown DJ. Standardized butterbur extract for migraine treatment: A clinical overview. *HerbalGram*. 2003;58:18-19.

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