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File: ■ French Maritime Pine (*Pinus pinaster*)
■ Pycnogenol®
■ Allergic Rhinitis

HC 071021-406

Date: August 13, 2010

RE: Standardized Bark Extract of French Maritime Pine (Pycnogenol®) Decreases Nasal and Ocular Symptoms in Allergic Rhinitis Patients in Pilot Study

Wilson D, Evans M, Guthrie N, et al. A randomized, double-blind, placebo-controlled exploratory study to evaluate the potential of Pycnogenol® for improving allergic rhinitis symptoms. *Phytother Res*. June 14, 2010; [epub ahead of print]. doi:10.1002/ptr.3232.

Allergic rhinitis is one of the most frequent diseases encountered in clinical practice and, although not life-threatening, it represents a dramatic impairment on quality of life. To avoid adverse side effects related to continuous or on-demand medications for seasonal allergic rhinitis, subjects are now seeking complementary and alternative treatments. Pycnogenol® (Horphag Research; Geneva, Switzerland), a standardized bark extract of the French maritime pine (*Pinus pinaster*) anecdotally considered beneficial in treating hay fever, has been proven clinically effective in improving respiratory distress and lowering leukotriene levels in asthma patients.[1-3] This single-center, randomized, double-blind, placebo-controlled pilot study evaluated its effectiveness in improving the symptoms of allergic rhinitis in adults allergic to birch pollen.

Otherwise healthy subjects (18-65 years old) with a positive skin prick test response to birch pollen and not affected by asthma, sinusitis, or conditions other than allergies known to cause rhinitis were enrolled in the study. Skin prick test results for other airborne allergens from trees such as oak and grass pollens were also documented. Patients were randomized to Pycnogenol (Manhattan Drug Company; Hillside, New Jersey) or placebo and instructed to take a 50 mg tablet in the morning and evening with meals. Nineteen eligible subjects were randomized at baseline, beginning treatment 3-4 weeks before the start of the birch pollen season in 2008, and 41 subjects began treatment 5-6 weeks before the start of the season in 2009, as well as at trial completion. Blood was collected at each of 5 screenings 2-4 weeks apart for the measurement of total IgE and birch allergen specific IgE determination.

Subjects completed a daily self-administered questionnaire to rate nasal (sneezing, stuffy nose, runny nose, itchy nose) and eye (burning or itchy, watering or tearing eyes, redness) symptoms. The local pollen forecast was checked daily and recorded for the duration of the study. Changes of nasal and eye symptoms scores between groups were compared using analysis of variance and unpaired t-tests. Comparisons of frequencies were made using the Chi-square test. Birch allergen IgE comparisons between groups were made with unpaired t-tests and analysis of covariance. Results are presented as mean values and standard

deviation. $P < 0.05$ was considered statistically significant.

In 2008, no significant difference was noted between groups for total eye (0.50 ± 0.58 versus 0.23 ± 0.29) and total nasal symptom (0.62 ± 0.48 versus 0.54 ± 0.40) scores, Pycnogenol versus placebo, respectively. During the pollen season, a more pronounced but non-statistically significant increase in birch allergen IgE titer was recorded in the placebo group (n = 9; 7.8 ± 15.0 KU/L) compared to the Pycnogenol group (n = 10; 5.0 ± 13.1 KU/L). In 2009, subjects were instructed to begin treatment at least 5 weeks prior to the predicted birch allergy season, but its onset was then delayed several weeks. Eight subjects started 6-7 weeks prior, and another 18 subjects 7-8 weeks prior to the start of the birch pollen season. The total average nasal symptom score for the allergy season was lower in the Pycnogenol group (n = 20; 0.31 ± 0.30) than in the placebo group (n = 21; 0.39 ± 0.33). A trend toward lower average total eye symptom scores was registered in the Pycnogenol group (0.13 ± 0.18) versus placebo (0.20 ± 0.21). Comparison between trial start and end of the allergy season showed an increase of 31.9% of birch specific IgE titer in the placebo group compared to 19.4% in the Pycnogenol group. In spite of a much higher birch pollen count in the 2009 season compared with 2008, the symptoms scores of groups in 2009 were significantly lower than in 2008 ($P = 0.028$). There was no significant difference between groups in the number of adverse events.

The proportion of subjects making use of non-prescription antihistamines as rescue medication at least once during the study was slightly lower in the Pycnogenol group (11/30; 36.7%) compared to placebo (15/30; 50%), while a sub-analysis showed that the group starting Pycnogenol over 7 weeks prior to the birch pollen appearance required very little rescue medication (1/8; 12.5%) compared to placebo (5/10; 50%). The limited number of subjects in this sub-analysis did not allow for statistical evaluation, but it seems likely that the immune-modulating effect of Pycnogenol may require the more extended time to manifest in noticeable symptom reduction.

This study indicates that Pycnogenol may represent a promising therapeutic modality for subjects with allergic rhinitis when taken in a timely manner: subjects treated with Pycnogenol had better nasal and ocular symptoms and required less rescue medication when treatment was started more than 5 weeks prior to the onset of the allergy season. The interpretation of these results were made more difficult by the concurrent seasonal exposure to birch and oak pollens, since in 2009 75% of placebo users tested allergic to oak compared to 68% of Pycnogenol users. The authors recommend additional studies with a bigger sample size and/or higher dosages to provide statistical significance and clarify optimum dosage and mechanisms of action.

—Silvia Giovanelli Ris

References

[1]Rohdewald P. A review of the French maritime pine bark extract (Pycnogenol), a herbal medication with a diverse clinical pharmacology. *Int J Clin Pharmacol Ther*. 2002;40:158-168.
[2]Hosseini S, Pishnamazi S, Sadrzadeh SM, Farid F, Farid R, Watson RR. Pycnogenol® in the management of asthma. *J Med Food*. 2001;4:201-209.
[3]Lau BH, Riesen SK, Truong KP, Lau EW, Rohdewald P, Barreta RA. Pycnogenol as an adjunct in the management of childhood asthma. *J Asthma.* 2004;41:825-832.

The American Botanical Council has chosen not to reprint the original article. The article can be found at http://www.kgksynergize.com/_lib/img/Pycnogenol.pdf.