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FILE: ▪ *Pelargonium sidoides*
▪ Common Cold

HC 040384-361

Date: September 30, 2008

RE: *Pelargonium sidoides* Root Liquid Extract Recommended for Common Cold

Patrick G, Hickner J. This obscure herb works for the common cold. *J Fam Pract*. March 2008;57(3):157-161.

The term "common cold" refers to a collection of symptoms, including sore throat, rhinorrhea, nasal congestion, cough, low-grade fever, and malaise, usually self-limited and lasting 10 to 14 days, caused by a number of viruses, most commonly by a rhinovirus.[1] Although Americans spend about $2.9 billion annually on over-the-counter (OTC) cold preparations and $1.1 billion on unnecessary antibiotics,[2] evidence for the efficacy of the various cold remedies is inconclusive and contradictory.

The authors report on a previously published multicenter, prospective, double-blind, placebo-controlled randomized trial to evaluate the effectiveness of a liquid herbal preparation from the roots of *Pelargonium sidoides* for decreasing the duration and severity of symptoms of the common cold.[3]

Between December 2003 and May 2004, 207 patients were recruited from 8 outpatient departments in Ukraine. The patients (two-thirds were women) were aged 18 to 55 years, with 2 major cold symptoms (nasal discharge and sore throat) and at least 1 minor cold symptom (nasal congestion, sneezing, scratchy throat, hoarseness, cough, headache, muscle aches, or fever) or with 1 major cold symptom and at least 3 minor symptoms. Duration of their symptoms ranged from 24 to 48 hours.

Exclusion criteria included any acute ear, nose, throat, and respiratory tract disease other than the common cold; positive rapid strep test; 6 or more episodes of recurrent tonsillitis, sinusitis, or otitis within the past 12 months, or any chronic ear, nose, throat, or respiratory tract disease; treatment with antibiotics, glucocorticoids, or antihistaminic drugs during the 4 weeks before the trial; treatment with cold medications that might impair the trial results; and use of cough or pain relief medications or any other treatment for the common cold within seven days before the trial.

The patients were randomized into 1 of 4 groups: 52 received 30 drops of the investigational medication 3 times daily vs. 51 who received placebo; and 52 patients received 60 drops of the medication 3 times daily vs. 52 patients who received a higher-dose placebo. The drops were taken at least 30 minutes before or after a meal, from day 1 through day 10.

The authors reported that the investigational medication was a preparation of the roots of *P. sidoides*, extraction solution: ethanol 11% (1:8-10) (wt/wt). The placebo was matched for color, smell, taste, and viscosity. Both treatments were supplied by Dr. Willmar Schwabe GmbH & Co. (Karlsruhe, Germany).

The study report gives the outcomes of the low-dose arm only.

The severity of cold symptoms was evaluated by using the validated Cold Intensity Score (CIS), derived from the sum of scores for 10 cold-related symptoms (sore throat, nasal congestion, nasal drainage, sneezing, hoarseness, scratchy throat, cough, muscle aches, headaches, fever) on a scale of 0 to 4 (0 = not present and 4 = very severe). At baseline, the mean total CIS was comparable in both treatment and placebo groups. From baseline to day 5, the mean total CIS decreased by 10.4 ± 3.0 in the treatment group vs. 5.6 ± 4.3 in the placebo group ($P<0.0001$).

The number of patients achieving clinical cure by day 10 was significantly higher in the treatment group (78.8% vs. 31.4%, $P<0.0001$). The average number of days absent from work was significantly lower in the treatment group than in the placebo group (6.9 ± 1.8 vs. 8.2 ± 2.1, $P<0.0003$), as were the days with less than 100% of usual activity (7.1 ± 1.5 in the treatment group vs. 8.7 ± 1.3 in the placebo group, $P<0.0001$).

Patients in the low-dose arm experienced 3 nonserious adverse events, and 1 experienced mild epistaxis. Tolerability was rated slightly better in the treatment than placebo group on day 5: of the 52 patients in the treatment group, 49 (94%) rated the tolerability of the preparation as good or very good vs. 42 of 51 patients (82%) in the placebo group.

"We recognize that this is only 1 clinical trial, and the results may not be replicated in future trials," write the authors. However, they were impressed by the effect size of the study. Of concern are the facts that one of the study authors is an employee of the pharmaceutical company that manufactures the *P. sidoides* preparation and that the results of the high-dose arm were not reported. However, "in the final analysis, we think that these findings justify recommending this…to our patients," write the authors.

One of the challenges in doing so, however, is that the efficacy of *Pelargonium* may be less when started later in the course of the illness (and not within 48 hours of the onset of symptoms as reported in this trial). "Our conclusion is that patients could be advised to purchase the medication to have on hand at home at the start of the cold season," write the authors.

The authors report that their Internet search failed to yield a distributor of the German preparation used in the study that would be available in the United States. However, *P. sidoides* root liquid extract is available in the United States under the brand name Umcka™ Cold Care (Nature's Way, Springville, Utah).

—Shari Henson

References

[1]Heikkinen T, Jarvinen A. The common cold. *Lancet*. 2003;361:51-59.
[2]Fendrick AM, Monto AS, Nightengale B, Sarnes M. The economic burden of non-influenza related viral respiratory tract infection in the United States. *Arch Intern Med*. 2003;163:487-494.
[3]Lizogub VG, Riley DS, Heger M. Efficacy of a *Pelargonium sidoides* preparation in patients with the common cold: a randomized, double blind, placebo-controlled clinical trial. *Explore (NY)*. 2007;3:573-584.

The American Botanical Council has chosen not to reprint the original article due to lack of response from the publisher.