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File: ■ *Pelargonium sidoides*
■ Children
■ Tonsillopharyngitis

HC 090694-394

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RE: *Pelargonium sidoides* Extract Provides Rapid, Safe, Symptomatic Relief for Sore Throats in Children Not Caused by Group A Beta Strep

Bereznoy VV, Riley DS, Wassmer G, Heger M. Efficacy of extract of *Pelargonium sidoides* in children with acute non-group a beta-hemolytic streptococcus tonsillopharyngitis: a randomized, double-blind, placebo-controlled trial. *Altern Ther Health Med*. Sep-Oct 2003;9(5):68-79.

Acute tonsillopharyngitis is an inflammation of the tonsils and throat that can be caused by a viral infection or an infection of group A beta-hemolytic streptococcus (GABHS) or other bacteria. Non-GABHS tonsillopharyngitis should not be treated with antibiotics, but doctors often prescribe them due to historical practice and patient expectation. Clinical studies have shown the EPs 7630 extract of *Pelargonium sidoides* (Dr. Willmar Schwabe Pharmaceuticals; Karlsruhe, Germany; identical to Umckaloabo®; ISO Pharmaceuticals; Ettlingen, Germany) is effective in the treatment of acute tonsillopharyngitis and acute bronchitis.[1] The authors of this study write that it was the first confirmatory placebo-controlled clinical trial on EPs 7630 in the treatment of acute non-GABHS tonsillopharyngitis in children in a primary care setting.

The study enrolled 144 patients in 6 study sites at 4 pediatric and ENT primary care outpatient clinics across the Ukraine. The patients were aged 6-10 years and had acute exudative tonsillopharyngitis for 48 hours or less with a negative rapid test for GABHS and Tonsillopharyngitis Severity Score (TSS) of 8 points or less. The TSS measures sore throat pain, difficulty in swallowing, local inflammation (pharyngeal erythema), fever, and salivation. Each symptom is assessed by a clinical investigator on a 4-point scale from 0 (absent) to 3 (severe). Fever is measured using an infrared ear thermometer and scored from 0 (<37.5°C) to 3 (≥39.5°C). The patients were randomized into the placebo or treatment group in sequence at each study site. There was 1 placebo withdrawal on the first day, leaving 143 patients in the final analysis, including 73 patients in the EPs 7630 group and 70 in the placebo group.

The patients took a daily dose of 3 mL (60 drops) of the placebo or of a liquid preparation of EPs 7630 per day in 3 doses (20 drops [1 mL] each) 30 minutes before or after meals for 7 days (day 0 to day 6). One hundred grams of the EPs 7630 preparation

contained 20 g of glycerol and 80 g of an aqueous ethanolic extract of *P. sidoides* roots (EPs 7630) corresponding to 8 g of plant material. The placebo was similar in color, taste, smell, and viscosity to EPs 7630. In cases of fever, the patients were allowed acetaminophen suppositories 3 times daily. The primary outcome measure was the change in TSS from day 0 to day 4. In addition, the Integrative Medicine Outcome Score (IMOS) was used to measure the treatment outcome from "deterioration" to "complete recovery." Safety was assessed using a verbal rating scale from "bad" to "very good" and by monitoring adverse events. Treatment outcome and tolerability were rated separately by the patients and/or their legal guardians and by the clinical investigator.

In the EPs 7630 group, 4 out of 73 patients withdrew early without a complete recovery, while 44 out of 70 patients in the placebo group did so. The most frequent reason for withdrawal was lack of compliance in the EPs 7630 group (n=2) and lack of efficacy in the placebo group (n=29). The TSS decreased from day 0 to day 4 by 7.1 ± 2.1 points for EPs 7630 and 2.5 ± 3.6 points in the placebo group. The covariate adjusted decrease was 7.0 ± 2.4 points in the EPs 7630 group and 2.9 ± 2.4 points in the placebo group ($P<0.0001$, 95% Repeated Confidence Interval 2.7; 4.9). On day 2, the TSS had decreased from 10.3 ± 1.2 points to 6.8 ± 2.2 points in the EPs 7630 group and from 9.7 ± 1.4 points to 8.2 ± 2.8 points in the placebo group ($P<0.0001$). On day 4, a TSS of less than 5 points was observed in 56 patients (76.7%) in the EPs 7630 group and 24 patients (34.3%) in the placebo group ($P<0.0001$). On day 4, a TSS decrease of at least 5 points was observed in 67 patients (91.8%) in the EPs 7630 group and 25 patients (35.7%) of the placebo group. Rapid recovery (TSS<5 points and TSS decrease>5 points on day 4) was observed in 55 patients (75.3%) of the EPs 7630 group and 23 patients (32.9%) of the placebo group ($P<0.0001$). Clinical investigators, patients, and/or their guardians rated the treatment outcome as superior in the EPs 7630 group compared to the placebo group. There was less acetaminophen use in the EPs 7630 group compared to the placebo group. No serious adverse events related to EPs 7630 were observed. More patients experienced adverse events in the placebo group than in the EPs 7630 group (placebo: n=14, EPs 7630: n=1, $P<0.0003$). The authors write that all adverse events were complications of the illness.

More research is needed to confirm the effects observed in this study and to determine their mechanism of action. The inhibition of bacterial and viral adhesion to the tonsil surface may play a role. Clinical trials with longer follow-up period are warranted. The authors conclude that EPs 7630 is more effective than a placebo in the initial treatment of non-GABHS tonsillopharyngitis in children. They write that it decreased the severity of symptoms, shortened the duration of the illness, and protected the patients from complications.

—Marissa Oppel-Sutter, MS

Reference

1. Brown D. Extract of *Pelargonium sidoides*: South African herbal remedy successfully treats acute bronchitis and tonsillopharyngitis. *HerbalGram*. 2004; 63:17-19.

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