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**File: ■ Peppermint (*Mentha x piperita*)  
■ Infantile Colic**

**HC 091261-457**

**Date: September 28, 2012**

**RE: Effectiveness of Peppermint in the Treatment of Infantile Colic**

Alves JGB, Moraes de Brito RdCC, Cavalcanti TS. Effectiveness of *Mentha piperita* [sic] in the treatment of infantile colic: a crossover study. *Evid Based Complement Alternat Med*. July 12, 2012;2012:981352. Doi: 10.1155/2012/981352.

Many newborns suffer from infantile colic, characterized primarily by crying more than 3 hours per day, 3 days a week for at least 3 weeks while hunger or other illness are not factors. There are many theorized causes of this ailment with none more prevalent than gastrointestinal problems, possibly arising from hyperperistalsis, aerophagia, or cow's milk allergy. Peppermint (*Mentha x piperita*) leaves are commonly used for digestive problems and have been found to provide relaxing effects on gastrointestinal muscle.<sup>1,2</sup> This double-blind, crossover study on infantile colic compared the effects of peppermint to simethicone (a mixture of polydimethylsiloxanes), a commonly used pharmaceutical for the alleviation of gas based on reduction of the surface tension of air bubbles.

The study took place at the Instituto de Medicina Integral Professor Fernando Figueira in Recife, Brazil. Infants between the ages of 15-60 days that were breastfed only and had colic were included. Colic was diagnosed by "irritability, restlessness, or crying" for 3 hours per day, 3 days per week for 3 weeks. Enrolled infants were examined throughout the study to rule out other health factors that may cause crying. Infants with illiterate mothers, residing outside of Recife, born premature or with low birth weight (<2,500 g), not thriving, or who had gastrointestinal disorders, an infection, a metabolic disease, or allergies were excluded. Infants on any kind of therapy were also excluded.

Enrolled infants were randomized to either a treatment group consuming 1 liquid drop/kg body weight of a "formulation" of peppermint leaves or liquid drops equivalent to 2.5 mg/kg of simethicone for 7 days. No other information regarding the peppermint liquid drop preparation was provided. After 3 days of washout, infants received the opposite treatment for another 7 days. Infants visited the clinic on the 7<sup>th</sup> and 17<sup>th</sup> days of the study. It is stated that the peppermint and simethicone treatments were identical in "weight, smell, color, taste, and package," and parents filled out a standardized form to document frequency of crying, adherence to treatments, and any adverse side effects. A stopwatch was given to parents to help quantify the length of crying time. The sample size used for this study was determined by a preliminary pilot study.

Of a total of 313 infants, 30 infants had colic and were enrolled in the study, and all infants completed the study. The average age of infants was  $33 \pm 11.1$  days, with an average weight of  $4.650 \pm 415$  g and height of  $54.2 \pm 3.0$  cm. All mothers received prenatal care and 16 (53.3%) had undergone cesarean section. Maternal age ranged from 14 to 32 years ( $22.7 \pm 5.4$ ), and they had 10.4 years ( $\pm 2.5$ ) of schooling. The occurrences of colic at baseline were  $3.9 \pm 1.1$  times per day with an average crying time of  $192 \pm 51.6$  minutes. This was reduced to  $1.6 \pm 0.6$  times per day for a duration of  $111 \pm 28$  minutes at the end of the study. There were no significant differences reported between the changes of either treatment. Also, any significant differences as compared to baseline are not reported. No adverse side effects were observed.

Although parents observed decreases in crying occurrence and duration, this was not significant between the peppermint and simethicone groups. It is mentioned that peppermint oil has been used in children previously to treat other gastrointestinal problems and has been shown to alleviate smooth muscle spasms in vivo. The shortcomings of the study addressed include the issue that colic gets better over time and that this study would not have been able to control for improvement of colic in this manner. There was no control or placebo group used to address this issue. It is also stated that treatment compliance was monitored via parental reporting, and no independent oversight was used to ensure protocol adherence. Other problems with this study include incomplete reporting of data and lack of details concerning the peppermint preparation and source; however, this study does report possible efficacy of peppermint for treating infant colic in the absence of adverse side effects and provides a foundation on which to base future clinical trials.

—Amy C. Keller, PhD

#### References

<sup>1</sup>Blumenthal M, Goldberg A, Brinckmann J, eds. *Herbal Medicine: Expanded Commission E Monographs*. Austin, TX: American Botanical Council; Newton, MA: Integrative Medicine Communications; 2000.

<sup>2</sup>Taylor BA, Luscombe DK, Duthie HL. Inhibitory effect of peppermint oil on gastrointestinal smooth muscle. *Gut*. October 1983;24(10):A992.

Referenced article can be found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3403674/pdf/ECAM2012-981352.pdf>.

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