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File: ■ Boswellia (*Boswellia serrata*, Burseraceae) ■ Asthma

HC 031653-553

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RE: Proprietary Boswellia Extract Decreases Use of Corticosteroid Inhalers in Patients with Asthma

Ferrara T, De Vincentiis G, Di Pierro F. Functional study on *Boswellia* phytosome as complementary intervention in asthmatic patients. *Eur Rev Med Pharmacol Sci.* 2015;19(19):3757-3762.

The standard care for asthma, a chronic inflammatory disease, is inhaled corticosteroids plus oral long-acting beta-agonists. Boswellia (*Boswellia serrata*, Burseraceae) resin has demonstrated anti-inflammatory properties and is used to treat asthma. However, the efficacy of boswellia is limited by its low oral bioavailability. Casperome® (Indena SpA; Milan, Italy) is a standardized extract of boswellia that is formulated in a phospholipid delivery system to increase bioavailability. The purpose of this randomized, untreated-control study was to evaluate the efficacy of Casperome in reducing the use of inhaled corticosteroids in patients with asthma.

Patients (n = 32; mean age, 45.8 years) with asthma who were currently being treated with inhaled corticosteroids plus oral long-acting beta-agonists or oral antihistamines or xanthine derivatives participated in this study conducted in centers in Italy. Excluded patients had respiratory diseases other than asthma; kidney or renal diseases; tumor diseases; pregnancy, lactation, or desire for pregnancy; used other anti-leukotriene agents (Lukast[®] class of medications); used supplements; used inhalers other than corticosteroids; or used any other inhalant method (fumigations, etc.). The study began with a 1-week run-in phase to monitor asthma therapy use. Following the run-in, patients received either 500 mg/day Casperome at breakfast along with their regular inhalation/oral asthma therapy or their regular inhalation/oral asthma therapy alone for 4 weeks. The patients were told to decrease the number of inhalations based on their perception of their respiratory function. They recorded in a daily diary the number of inhalations. The primary endpoint was the reduction in the number of inhalations compared with control.

During the run-in phase, all patients used the inhalation therapy 2x/day (14x/week). In the control group, inhalation use was unchanged for the duration of the study. For the Casperome group, the number of inhalations decreased to 13.4x/week at week 1, 11.0x/week at week 2, 9.89x/week at week 3, and 8.00x/week at week 4. This reduction

was statistically decreased compared with baseline (P < 0.0001) and control (P < 0.0001). All adverse events (AEs) were considered mild, and none were serious. The control group had more AEs. Two patients in the Casperome group discontinued due to lack of perceived efficacy.

The authors conclude that Casperome in addition to standard asthma therapy would be beneficial for patients by decreasing the use of corticosteroids. This decrease has the potential to improve quality of life. Boswellia has been shown to inhibit the production of inflammatory prostanoids overexpressed in patients with asthma. Other demonstrated anti-inflammatory activities of boswellia include inhibition of TH1 cytokines and increased production of TH2 cytokines, and regulation of vascular responses to inflammation. The authors suggest that collectively, these effects result in decreased airway inflammation, and hence reduced use of corticosteroids. Limitations of this pilot study include the small number of patients (14-18/group), the lack of blinding, and the lack of a placebo group. These promising results need to be confirmed in a randomized, placebo-controlled, double-blind trial with a larger population. It would be beneficial if future studies also assessed serum levels of boswellic acids and included quality of life as an additional outcome measure.

Indena SpA funded the preparation of the manuscript. One of the authors (Di Pierro) was the main developer of the study product, Casperome.

-Heather S. Oliff, PhD

Referenced article can be accessed at http://www.europeanreview.org/article/9612.