P.O. Box 144345 Austin, TX 78714-4345 ▪ 512.926.4900 ▪ Fax: 512.926.2345 ▪ www.herbalgram.org

HerbClip™

File: ■ Licorice (*Glycyrrhiza glabra*)
■ Dyspepsia
■ Quality of Life

HC 081171-436

Date: November 15, 2011

RE: Licorice Extract Alleviates Symptoms of Functional Dyspepsia

Raveendra KR, Jayachandra, Srinivasa V, et al. An extract of *Glycyrrhiza glabra* (GutGard) alleviates symptoms of functional dyspepsia: a randomized, double-blind, placebo-controlled study. *Evid Based Complement Alternat Med.* 2012;216970. doi:10.1155/2012/216970.

Licorice (*Glycyrrhiza glabra*), a perennial, temperate zone herb belonging to the family Leguminosae, is reported to possess pharmacological properties such as demulcent, anti-inflammatory, antiulcer activities and clinically, is being used as an alternative medicine for the treatment of peptic ulcer, canker sores, and inflammatory bowel diseases. In traditional Chinese medicine, Chinese licorice (*G. uralensis*) is classified as a Qi tonic, particularly for the spleen, and is commonly used to "harmonize" or buffer herbal formulations. Preclinical studies established the safety and antiulcer activity of GutGard®, an extract of licorice root (Natural Remedies; Bangalore, India). The aim of this randomized, double-blind, placebo-controlled study was to investigate the efficacy and tolerability of GutGard in patients with functional dyspepsia. Symptoms of functional dyspepsia may include "upper abdominal fullness, epigastric pain, belching, bloating, early satiety, nausea, vomiting, regurgitation, heartburn, and loss of appetite."

Investigators enrolled functional dyspepsia subjects, and the trial was conducted in 2 trial centers in Bangalore, India. Researchers assessed functional dyspepsia subjects with validated Rome-III criteria for inclusion. Subjects who were pregnant or nursing or had prior ulcer surgery and those with symptoms of irritable bowel syndrome, previous history of gastroesophageal reflux, ailing from mental illness or chronic illness were excluded.

Functional dyspeptic subjects (n = 50 [placebo, n = 25; GutGard®, n = 25]) were randomized to take placebo or GutGard (75 mg capsules) twice daily for 30 days. GutGard, a flavonoid-rich root extract of licorice has the following phytochemical specifications: glabridin (≥ 3.5% w/w), glabrol (≥ 0.5% w/w), eicosanyl caffeate (≥ 0.1% w/w), docosyl caffeate (≥ 0.1% w/w), total flavonoids (≥ 10% w/w), and glycyrrhizin (≤ 0.5% w/w). Placebo or GutGard was taken after food: 1 capsule in the morning and 1 at night.

Efficacy was evaluated using a validated 7-point Likert scale. This scale is a scoring system ranging from 1 = no problem to 7 = a very severe problem. Subjects rated themselves for the severity of 10 gastrointestinal symptoms with the aid of this scale, including upper abdominal fullness, epigastric pain, belching, bloating, early satiety, nausea, vomiting, regurgitation, heartburn, and loss of appetite. Using the Likert scale, change in the severity of the symptoms was assessed. Assessment of quality of life as a secondary outcome measure was evaluated using the short-form Nepean Dyspepsia Index (NDI). The NDI is a disease-specific health-related quality of life (HRQOL) instrument consisting of a 10-item questionnaire examining the influence of dyspepsia on 5 elements (subscales) in participant's health, such as tension, interference with daily activities, disruption to regular eating/drinking, knowledge/control over disease symptoms, and interference with work/study. It is designed to measure impairment of a subject's ability to engage in relevant aspects of life and also enjoyment of these aspects.

At baseline, subjects were diagnosed with functional dyspepsia. There were no significant differences between the mean demographic characteristics of placebo and treated groups except for age and diastolic blood pressure. GutGard treatment resulted in significant decrease ($P \leq 0.05$) in the total symptom scores on day 15 and day 30, compared to placebo. Each individual symptom, except for early satiety, was notably decreased by GutGard. The treated group showed significant reduction ($P \leq 0.05$) in comparison to placebo in NDI on day 15 and day 30 as well, indicating improved quality of life. There were no treatment-related adverse effects during the study intervention period. Blood sugar had been significantly elevated in the licorice group versus the placebo group on day 0, and it remained so on day 30.

The authors conclude that GutGard efficacy was significant in reducing symptoms in the management of functional dyspepsia. The authors also noted that GutGard use was safe and resulted in significant improvement in quality of life. This study reported no major incidence of adverse side effects and demonstrated that GutGard licorice root extract was well tolerated and effective in patients with functional dyspepsia. The producers of the product were active participants in the study.

Referenced article can be accessed at
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3123991/pdf/ECAM2012-216970.pdf.