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CLINICAL STUDY

Efficacy and safety of Aloe vera syrup for the treatment of gastro-esophageal reflux disease: a pilot randomized positive-controlled trial

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Abstract

OBJECTIVE: To investigate the use of Aloe vera (A. vera) for the treatment of gastroesophageal reflux disease (GERD) symptoms and compare its effects with those of omeprazole and ranitidine.

METHODS: In this pilot, randomized controlled trial, 79 subjects were allocated to A. vera syrup (standardized to 5.0 mg polysaccharide per mL of syrup) at a dose of 10 mL/d, omeprazole capsule (20 g/d) or ranitidine tablet (150 mg in a fasted state in the morning and 150 mg 30 min before sleep at night) for a period of 4 weeks. The frequencies of eight main symptoms of GERD (heartburn, food regurgitation, flatulence, belching, dysphagia, nausea, vomiting and acid regurgitation) were assessed at weeks 2 and 4 of the trial.

RESULTS: A. vera was safe and well tolerated and reduced the frequencies of all the assessed GERD symptoms, with no adverse events requiring withdrawal.

CONCLUSION: A. vera may provide a safe and effective treatment for reducing the symptoms of GERD.

Key words: Aloe vera; Gastroesophageal reflux disease; Complementary therapies; Treatment outcome; Randomized controlled trial

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a chronic, recurrent and progressive disease associated with a wide range of esophageal (e.g. esophageal ulcer, esophageal cancer, Barrett's disease) as well as non-esophageal (e.g. respiratory problems, chest pain, angina) complications. Mucosal damage caused by gastric refluxate means that GERD occasionally shows similar symptoms to functional dyspepsia and irritable bowel syndrome.[1]

Official statistics suggest that 44% of the population of the United States experience GERD symptoms at least once a month, and 20% at least once a week.[2,3] The overall prevalence of GERD in the Western world has been reported to be about 10%-20%, making it one of the most common gastrointestinal diseases.[4] However,

despite the high prevalence of GERD, its definitive diagnosis and clinical differentiation from other morbidities is difficult, at least partly because of the presence of atypical manifestations such as laryngopharngeal reflux, chronic cough, asthma and dental erosions.[1] Notably, GERD symptoms have been reported to adversely affect patients' daily activities and quality of life, and impose a substantial cost on healthcare systems.[5,6]

Regarding the recurrent nature of GERD, most patients require continuous and long-term medication. Proton pump inhibitors and H_2 receptor blockers are the most commonly prescribed drug classes for GERD. However, despite their proven effect and widespread use, adverse events such as hypochlorhydria, cardiac events and increased risk of hip fractures have led to concerns over the safety of these drugs,[7,8] resulting in a surge of interest in identifying natural remedies that can effectively control GERD symptoms and prevent its complications.

Aloe vera (A. vera) is a medicinal plant with wide applications in the pharmaceutical industry for both systemic[9,10] and dermatologic disorders.[11-14] A. vera gel has been demonstrated to possess several pharmacological actions including antioxidant, anti-inflammatory, analgesic, anti-proliferative, and anti-diabetic properties.[15] Furthermore, A. vera has also shown anti-ulcer,[16,17] wound-healing,[18] and antimicrobial[19] effects, all of which may be relevant to the treatment of GERD and its comorbidities. However, despite these promising mechanisms of action and positive findings in preclinical models of GERD and peptic ulcers,[16,17] clinical evaluations of A. vera gel as a treatment for GERD have been scarce. The present trial aimed to explore the clinical efficacy of A. vera syrup compared with the standard medications omeprazole and ranitidine in patients suffering from GERD symptoms.

METHODS

Subjects

This randomized, open-label, positive-controlled clinical trial enrolled patients aged 18-65 years who were diagnosed with GERD and referred to the endoscopy ward at the Baqiyatallah Hospital (Tehran, Iran). The study protocol was approved by the institutional Ethics Committee and written informed consent was obtained from all participants. Exclusion criteria were pregnancy, breastfeeding, and presence of hematemesis, odynophagia, treatment-resistant GERD, other gastrointestinal disorders (e.g. peptic ulcer, irritable bowel syndrome, obstructive diseases), hepatic diseases, malnutrition syndrome, hematologic diseases, use of muscle relaxant drugs (e.g. anticholinergic agents, calcium channel blockers), or history of hypersensitivity to A. vera preparations.

Treatments

Seventy-nine eligible subjects were randomly allocated to A. vera syrup (10 mL once a day), omeprazole capsule (20 mg once a day) or ranitidine tablet (150 mg in a fasted state in the morning and 150 mg 30 min before sleep at night) for a period of 4 weeks. Randomization was performed using a random-number table controlled by the pharmacy. A. vera syrup was formulated by the Barij Essence Pharmaceutical Co., (Mashade Ardehal, Kashan, Iran), and was standardized to 5.0 mg polysaccharide per mL of syrup.

Efficacy measures

Assessment of treatment efficacy was symptom-based.[20,21] Improvements in common GERD symptoms were measured according to a modified Reflux Disease Questionnaire,[22] which is a validated, self-administered scale that is widely used for the assessment of anti-reflux treatment effects.[23] The frequencies of eight main symptoms of GERD, namely heartburn, food regurgitation, flatulence, belching, dysphagia, nausea, vomiting and acid regurgitation, were assessed at weeks 2 and 4 of the trial and were compared between the different treatment arms.

Statistical analysis

Statistical analyses were performed using SPSS software version 16.0 (SPSS Inc., Chicago, IL, USA). Within-group comparisons of the frequencies of GERD symptoms were carried out using the binomial sign test. Between-group comparisons were made using Pearson's χ^2 or Fisher's exact test. Quantitative data are expressed as the mean ± standard deviation ($\bar{x} \pm s$). In all analyses, a two-sided P value < 0.05 was considered to be statistically significant.

RESULTS

The demographic characteristics of the study groups including age, sex, body mass index, educational level and smoking habit are shown in Table 1. There were no significant differences in any of these parameters between the groups.

The severities of GERD symptoms were assessed after 2 and 4 weeks of treatment. The baseline frequencies of all the evaluated GERD symptoms were similar in the A. vera, ranitidine and omeprazole groups (P > 0.05). The frequencies of all GERD symptoms were reduced at both 2 and 4 weeks of treatment in the A. vera group compared with baseline, with a trend towards further improvement in the frequencies of heartburn, flatulence and belching from weeks 2-4 of the trial (Table 2).

In the omeprazole group, the frequencies of all assessed symptoms were significantly reduced compared with baseline at both time points (weeks 2 and 4) and the frequencies of heartburn, flatulence, belching and acid regurgitation showed further reductions at week 4 compared with week 2 (Table 2).

In the ranitidine group, the frequencies of heartburn,