Artichoke Leaf Extract Reduces Symptoms of Irritable Bowel Syndrome and Improves Quality of Life in Otherwise Healthy Volunteers Suffering from Concomitant Dyspepsia: A Subset Analysis

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ABSTRACT

Objectives: Does artichoke leaf extract (ALE) ameliorate symptoms of Irritable bowel syndrome (IBS) in otherwise healthy volunteers suffering concomitant dyspepsia?

Methods: A subset analysis of a previous dose-ranging, open, postal study, in adults suffering dyspepsia. Two hundred and eight (208) adults were identified post hoc as suffering with IBS. IBS incidence, self-reported usual bowel pattern, and the Nepean Dyspepsia Index (NDI) were compared before and after a 2-month intervention period.

Results: There was a significant fall in IBS incidence of 26.4% (p < 0.001) after treatment. A significant shift in self-reported usual bowel pattern away from “alternating constipation/diarrhea” toward “normal” (p < 0.001) was observed. NDI total symptom score significantly decreased by 41% (p < 0.001) after treatment. Similarly, there was a significant 20% improvement in the NDI total quality-of-life (QOL) score in the subset after treatment.

Conclusion: This report supports previous findings that ALE ameliorates symptoms of IBS, plus improves health-related QOL.

INTRODUCTION

Irritable bowel syndrome (IBS) is the most common disorder seen in gastroenterology practice (Olden, 2002). It is a functional disorder characterized by abdominal pain, altered bowel habit, and changes in stool frequency (Camilieri, 2001). There is also evidence that health-related quality of life is significantly reduced in IBS patients compared to healthy controls (Akehurst et al., 2002). The etiology of IBS is unclear. Hypotheses include infection, food sensitivity, antibiotic use, changes in colonic microflora, dietary fiber intake, and genetic factors. There is no accepted cure for IBS and treatments are various. Conventional treatment of symptoms include the elimination of certain foods from the diet, bulk laxatives and stool softeners for constipation, antimotility drugs for diarrhea, and antispasmodics, antimuscarinics, and antidepressants for pain and spasm (Maxwell et al., 1997).

The current standard definition of IBS is through the Rome criteria (Thompson et al., 1999). Although reliable, between 30% and 60% of patients with IBS also meet the criteria for functional dyspepsia, and vice versa (Talley, 1998).

Artichoke leaf extract (ALE: Cynara scolymus L.) has been shown to reduce symptom severity in a subset of patients with dyspepsia identified as suffering from IBS.

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Walker et al., 2001). This paper describes the results of a similar subset analysis from an open dose-ranging study that investigated the efficacy of ALE in ameliorating dyspeptic symptoms and improving quality of life in otherwise healthy adults.

MATERIALS AND METHODS

Analyses were performed on a subset of data collected from a previously reported dose-ranging, open, postal study in otherwise healthy adults suffering dyspepsia (Marakis et al., 2002). Volunteers had been randomly assigned either 320 or 640 mg (1 or 2 capsules) of a standardized (1:5) aqueous full-spectrum extract of artichoke leaves (Cynara™, Lichtwer Pharma [UK] Ltd., Marlow, UK) to be taken daily for 2 months. At baseline and after 2 months, volunteers were asked to complete several questionnaires to assess IBS incidence, self-reported usual bowel pattern (normal, constipation, diarrhea or alternating constipation/diarrhea), and NDI symptom and quality-of-life (QOL) scores (Talley et al., 1999). Although the NDI is validated for symptoms of dyspepsia, the large crossover of symptoms in dyspepsia and IBS meant it was useful as indication of symptom severity within this IBS subset.

The current subset contained data from 208 adults who were selected if they reported abdominal pain for at least 1 to 4 days over a previous 2-week period, accompanied by two of the following symptoms reported over a 2-month period: altered stool frequency (> 3 per day or < 3 per week); altered stool form (loose/watery or hard); altered stool passage (straining, urgency, or feelings of incomplete passage); passage of mucus. These are similar to the Rome criteria.

The significance of treatment on the change in IBS incidence was assessed using the McNemar test for dichotomous data. Treatment effect on usual bowel pattern was determined using the Friedman test. An independent samples t test was used to ascertain baseline differences in mean NDI symptom and QOL scores between groups. Analysis of variance (ANOVA) was used to test for differences in mean values within groups. Statistical analyses were performed using SPSS 11.0 for Windows (SPSS Inc., Chicago, IL).

RESULTS

IBS incidence and usual bowel pattern

IBS incidence decreased significantly by 26.4% after treatment with ALE for 2 months, with 55 volunteers falling outside the Rome criteria for IBS (p < 0.001).

More than half of the subset reported a usual bowel pattern that was “alternating constipation/diarrhea” at baseline. However, after treatment, there was a significant shift in usual bowel pattern toward “normal” (p < 0.001), with the percentages in the constipation and diarrhea categories staying approximately the same (Fig. 1). There were no significant differences between the two dose groups.

NDI symptoms and QOL

The NDI symptom index consists of 15 individual domain scores plus a total score. There was a significant decrease in all symptom scores after treatment with the total score decreasing by 41% (p < 0.001). Interestingly, all except two individual baseline scores were significantly worse in the IBS subset compared with the remaining volunteers from the original data set, the “non-IBS” group (p = 0.04 to p < 0.001).

The NDI QOL index consists of four individual domain scores plus a total score. All QOL scores improved after treatment with the total QOL score increasing by 20% (p < 0.001). Similarly, all baseline values were significantly worse in the IBS subset compared with the “non-IBS” group (p < 0.001).

There was no significant effect of dose on NDI symptom or QOL scores.

DISCUSSION

In the current subset analysis, more than one quarter of volunteers fell outside the criteria for IBS after treatment. How-

FIG. 1. Bowel pattern at baseline and after 2 months of treatment with artichoke leaf extract in a subset of otherwise healthy volunteers with dyspepsia suffering irritable bowel syndrome symptoms.
ever, Walker and colleagues (2001) reported a 71% reduction in five IBS symptoms in a subset of dyspeptic patients treated for 6 weeks with a similar extract of ALE. There are a number of explanations for the observed differences.

First, the dosages of ALE taken. Approximately half of the current subset took one capsule daily, the remainder two daily. Walker and colleagues (2001) observed a mean intake of 4.87 capsules daily, on average threefold higher than in the current subset. We did not observe any significant dose-response effects in the current analysis, but it is certainly possible that a dose above two capsules per day would have had a greater effect on IBS symptoms.

Second, the criteria used to identify IBS. Although the percentage of IBS suffers identified from each data set are similar (50% versus 46% in the current analysis), in Walker’s analysis, three of five symptoms (different in definition to those in the current analysis) had to be present. This could have resulting in a different subset profile.

Third, the way in which the data were collected. Walker and colleagues (2001) enrolled IBS patients through a post-marketing surveillance study in which individual symptoms were rated three times throughout the study by a physician. It has been noted that a good and lengthy physician-patient relationship is “as vital as any medication” in the treatment IBS (Maxwell et al., 1997). In the current analysis, there was no personal contact with any of the volunteers. In addition, volunteers knew only that they were being treated for symptoms of dyspepsia, and so had no expectation of resolving any concurrent IBS symptoms. It is therefore postulated that the design of the current study will have minimised the placebo effect that appears to be so strong in the treatment of IBS.

Adverse events in response to ALE administration were not measured in the original study, but other work has shown that adverse drug reactions to ALE are few (Kraft, 1997).

The current subset analysis provides evidence to support the use of ALE in the treatment of IBS symptoms, plus has shown an effect on health-related QOL. Future studies should be designed to compare the therapeutic effects of a wider dose range of ALE against placebo under randomized controlled conditions.

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REFERENCES


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