

Complementary Therapies in Clinical Practice

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Efficacy of *Plantago major* seed in management of ulcerative colitis symptoms: A randomized, placebo controlled, clinical trial

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Abstract

Objective

Evaluation of the effect of <u>Plantago</u> major (P. major) seed on <u>ulcerative colitis</u> (UC) symptoms.

Methods

In this randomized double-blind clinical trial, 61 subjects received $3600 \,\mathrm{mg/day}$ roasted *P. major* seed in intervention group (n=31) and roasted wheat flour in control group (n=30), for 8 weeks, as a complementary to standard medications. Variables were assessed using the Lichtiger <u>Colitis</u> Activity Index (LCAI) at baseline, week 4, and week 8.

Results

51 patients completed the trial (n=28 in *Plantago* and n=23 in <u>placebo</u> groups). Abdominal tenderness (p=0.011), gastroesophageal reflux and gastric pain (p=0.049 for both), were significantly less severe in *P. major* group. Visible <u>blood in stool</u> (p=0.001), distension (p=0.001), and anal pain (p=0.051), decreased significantly in *P. major* group, although no significant difference was observed between the two groups: (p=0.224), (p=0.283), and (p=0.455) respectively.

Conclusion

P. major seems to be effective in complementary management of UC.

Introduction

The most common inflammatory bowel disease worldwide, ulcerative colitis (UC), is an idiopathic inflammatory condition of the colon, associated with superficial erosions on the colonic wall, diffuse friability, and bleeding [1]. The main onset, peaks between the ages of 15 and 30 years [2]. UC is

characterized by persistent mucosal inflammation that begins in the rectum and spreads to proximal parts [1]. Definitive diagnosis is based on endoscopy and biopsy of intestinal mucosa, which is indicative of chronic colitis. Symptoms include dysentery, abdominal pain, fever (in severe cases), anemia, extreme fatigue, weight loss, and anorexia, as well as developmental disorders in children [3]. The continuous rise in healthcare costs associated with this disease, is in part due to costly therapies [4]. The most widely used drugs for inducing remission in these patients include aminosalicylates and corticosteroids [5]. However, none of the treatment options are effective enough, with 90% of patients still experiencing a relapsing course 25 years after diagnosis [6]. Furthermore, these medications have some important and serious side effects such as acute kidney injury, hemolytic anemia (Heinz bodies), hepatitis, male infertility (with sulfasalazine), pancreatitis, and hyperglycemia (secondary diabetes mellitus) [6]. The importance of paying attention to this disease is clear considering: 1) the increasing rate of colitis (incidence: 1.2 to 20.3 cases per 100,000 persons per year, and prevalence: 7.6 to 245 cases per 100,000 per year) [7], 2) lack of complete remission, which leads to a huge economic burden and is associated with serious complications such as toxic megacolon, stenosis, dysplasia, and colorectal cancer [6], and 3) the side effects of common medications [8]. Therefore, we decided to study a natural medicine that is safe, cheap and accessible, and selected the herb according to Persian Medicine (PM) resources. Plantago major L. (P. major) (large plantain) is a pharmacological plant, which belongs to the family Plantoginacae. This plant is useful for the treatment of intestinal ulcers and cessation of intestinal diarrhea and bleeding [9]. It contains tannins, coumarins, flavonoids, polyphenols and gluten, which have been shown to have anti-inflammatory, anti-ulcerative, anti-fever, anti-diarrhea, antimicrobial and wound healing properties [10]. The aim of this study was to investigate the effect of *P. major* on clinical symptoms of UC.

Section snippets

Participants and study setting

This randomized clinical trial was conducted in the gastroenterology clinic of Imam Khomeini Hospital in Urmia city (Iran) between December of 2018 and June 2019. Inclusion criteria comprised men and women aged 15–70 years, and colitis symptoms that were diagnosed as UC and confirmed with colonoscopy. Patients with the following criteria were not included in the trial: massive bleeding, or the need for hospitalization or emergency surgery, symptoms of fulminant colitis, peritonitis, megacolon...

Participants characteristics

A total of 75 patients with mild, moderate and severe ulcerative colitis were recruited, of which 14 had one of the exclusion criteria and thus, 61 were included and randomized in two groups. During the 8 weeks of study, 10 patients dropped-out (three in *P. major* group and seven in placebo group). Ultimately, 51 patients completed the study and were analysed (28 patients in *P. major* group and 23 patients in the placebo group) (Fig. 1). The baseline variables did not significantly differ between ...

Discussion

The aim of this study was to compare the efficacy of P. major seed with placebo for UC symptom management. Our results showed that abdominal tenderness improved significantly in Plantago group compared with placebo (p=0.011). Visible blood in stool decreased significantly in Plantago group at the 8th week (p=0.001), although no significant difference was observed between the two groups (p=0.224). Secondary outcomes including gastroesophageal reflux and gastric pain improved significantly...

Conclusion

P. major seeds effectively improve abdominal tenderness, gastroesophageal reflux, and gastric pain in UC compared with placebo, and may be considered for complementary management of UC. Further studies with larger sample size, longer intervention, follow-up, and inclusion of more cases of severe disease is suggested....

Author contribution

AB generated the study idea and participated in designing the study, acquisition of data, analysis and interpretation of data, and drafting the article. As the statistical consultant, AD participated in study design, and analysis and interpretation of data. AJH participated in clinical assessment and acquisition of data. FE and JA participated in designing the study and drafting the article. All authors participated in writing parts of the manuscript draft, revised the whole manuscript...

Declaration of competing interest

The authors have no conflict of interests to declare....

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Evaluation of anti-inflammatory effects of leaf and seed extracts of Plantago major on acetic acid-induced ulcerative colitis in rats

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Citation Excerpt:

...For example, Turel et al. showed the anti-inflammatory and hepatoprotective effects of the P. major seed extract in rats (Türel et al., 2009). A study on 61 patients with UC revealed that the ingestion of the roasted P. major seeds reduced abdominal pain in those patients (Baghizadeh et al., 2021); however, the histopathological changes or mucosal damage were not addressed in this study. In the present study, however, treatment with the P. major seed extract did cause a modest decrease in the histopathological damages and ulcer index in the experimental groups compared to the group receiving no treatment....

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