

Herbs and Inflammatory Bowel Disease

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KEYWORDS

- Herbs • Herbal medicines • Ulcerative colitis • Crohn disease
- Inflammatory bowel disease

KEY POINTS

- Herbal products are widely used by patients with inflammatory bowel disease (IBD).
- Mostly small studies of varying quality have suggested that several different herbal preparations may have clinical efficacy in IBD.
- Larger and better designed clinical trials are needed to confirm the efficacy and safety of herbal preparations showing promise in preliminary studies.
- Contrary to widespread belief, herbal products are not necessarily safe.
- Patients and health care workers need to be aware of the limitations and risks associated with the use of herbal products.

INTRODUCTION

Given the common use of herbal products by patients with inflammatory bowel disease (IBD) an understanding of their potential efficacy and safety is essential for clinicians who manage the disease. (See Petros Zazos and Geoffrey C. Nguyen's article, "Use of Complementary and Alternative Medicine in Inflammatory Bowel Disease Around The World," in this issue.)

Many herbal medicine practices are based on ancient ideas or beliefs that ignore modern pathophysiological and pharmacologic concepts, and that historically have placed them outside the realm of scientific evaluation in clinical trials. Although some controlled studies of the effects of herbal preparations have been reported in recent years, much information relating to their possible therapeutic effectiveness remains anecdotal and uncontrolled. However, herbal medicine is readily accessible and is seen by many patients as a potential therapeutic strategy for a

Disclosure Statement: Neither author has any financial or commercial interest to declare.

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Gastroenterol Clin N Am ■ (2017) ■-■
<http://dx.doi.org/10.1016/j.gtc.2017.08.009>

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wide range of reasons, including its use over several centuries, in different cultural and geographic regions; for example, Ayurvedic medicine and Traditional Chinese Medicine (TCM). Furthermore, the lack of clear safety alert signals for herbal products, in part due to the absence of any formal equivalent of drug registries in herbal medicine practice, can lead to lay interpretation of minimal risk being associated with their use.

This article reviews published evidence of the efficacy of herbal preparations in IBD, briefly outline their possible mechanisms of action and highlight the risk of side effects from the herbs used. It ends with a call for better regulation of the manufacture, distribution, and administration of herbal preparations.

EFFICACY OF HERBS IN INFLAMMATORY BOWEL DISEASE

Literature Review

The authors' literature review was compiled using a systematic search of the Medline database from 1966 to 2016. Reports of controlled clinical trials published either in English or with English abstracts were used. Search headings and keywords used were combinations of herbs, herbal therapy, botanic, traditional Chinese medicine, inflammatory bowel disease, colitis, Crohn disease, ulcerative colitis (UC), and proctitis.

Interpreting Trial Results

The difficulties associated with designing, executing, and interpreting trials of new conventional drugs in IBD are numerous¹ and have often been compounded in trials of herbal products. The herbal preparations under testing have often been poorly characterized and/or standardized. Trials have often been small, underpowered, unrandomized, unblinded, and inadequately or totally uncontrolled. Few studies have included subjects whose IBD has been adequately phenotyped. Outcome measures have sometimes been unconventional and unvalidated. Bias may have been introduced by failure to publish trials with negative outcomes. These issues have been emphasized in recent reviews.²⁻⁵

Moreover, rarely has a study in which an herbal preparation has shown an initial indication of efficacy been followed up by a large-scale, well-designed clinical trial to confirm the benefit suggested.⁶ This may in part be a consequence of difficulties in obtaining the necessary funding and regulatory approval for herbal trials. For example, analytical dossiers of the multiple constituents of herbs are difficult and expensive to assemble; without them, however, regulatory approval for a trial may be unobtainable. Furthermore, given the expense entailed, commercial companies may be reluctant to fund clinical trials for a particular indication (in this context, IBD) of preparations that already have a successful market among the general public for other indications.

Review of Trial Outcomes

The authors found nearly 30 controlled clinical studies, as of December 2016, assessing the effects of herbal products in IBD. As shown in **Tables 1** and **2**, we have classified them into 4 subgroups: active UC (induction treatment), inactive UC (remission maintenance), active Crohn disease (induction treatment), and inactive Crohn disease (remission maintenance). For more extensive and detailed tables, readers are referred to other reviews.^{2-5,7}

The overall assessment of the possible efficacy of each herbal product listed in see **Tables 1** and **2** takes into account the quality of the clinical trials investigating each herb, assessed by us and by Cheifetz and colleagues.⁵ Factors considered in rating each trial included trial size, entry criteria, disease definition, concurrent therapies,

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