



Boswellia serrata extract for the treatment of collagenous colitis: a randomized, double-blind, placebo-controlled, multicenter trial.

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Background

Collagenous colitis is an idiopathic microscopic colitis characterized by chronic watery diarrhea, a typical subepithelial collagen layer, and lymphoplasmacellular infiltration. Due to their anti-inflammatory properties, Boswellia serrata extract (BSE) have been used in various inflammatory disorders such as bronchial asthma, chronic polyarthritis and inflammatory bowel diseases.

Aim of the Study

We investigated the effect of BSE on symptoms, quality of life and histology in patients with collagenous colitis in a randomized, double-blind, placebo-controlled multicenter trial.

Patients and Methods

Patients with chronic diarrhea (≥ 5 times per day) and histologically proven collagenous colitis were randomized to receive either oral Boswellia serrata extract 400 mg three times daily for 6 weeks or placebo. Complete colonoscopy was performed before and after treatment. Histopathology was assessed by a single pathologist blinded to the patients' treatment. Clinical symptoms were assessed by standardized questionnaires. Patients of the placebo group with persistent diarrhea received cross-over BSE therapy.

Results

31 patients (mean age 59 years, 26 female, 16 verum group) were randomized; 25 patients were available for per protocol analysis.

Six patients (5 verum group) prematurely discontinued treatment due to several reasons: adverse events $n = 3$ (2 verum group), lost of follow-up $n = 1$ (verum group), unwillingness to continue $n = 2$ (verum group).

The rate of clinical remission (frequency of diarrhea ≤ 3 times per day) was higher in the Boswellia serrata extract group than in the placebo group (per protocol 63.3% vs. 26.6%, respectively, Figure 1). Six patients received cross-over BSE therapy, five of them showed complete remission after 6 weeks.

Figure 1: Study Design

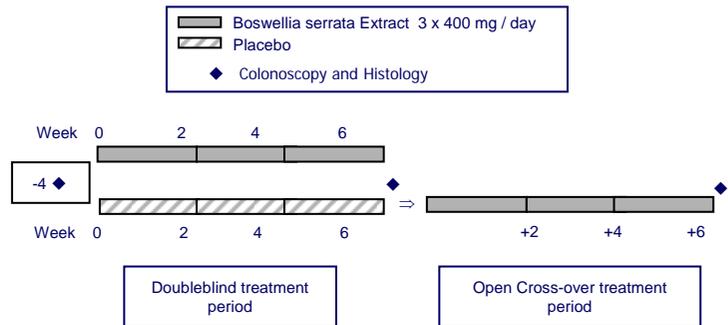
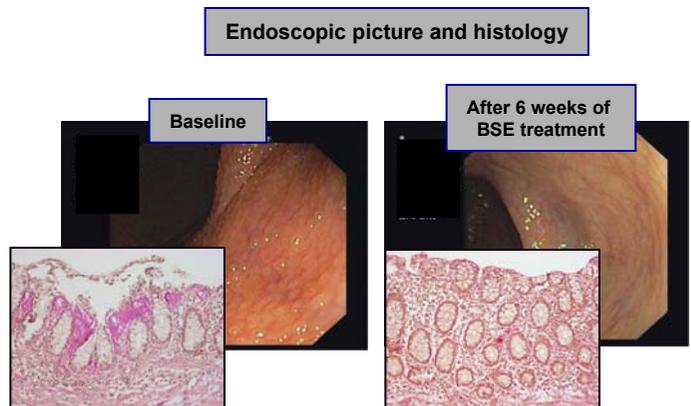
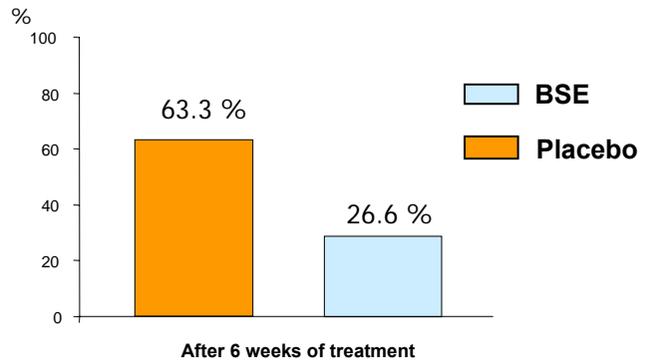


Figure 2: Patients with clinical remission after 6 weeks (per-protocol)



Conclusions

- Oral Boswellia serrata extract is able to induce clinical remission in patients with collagenous colitis.
- The incidence of adverse events was low.