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[Intervention Review]

# Interventions for treating collagenous colitis

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## ABSTRACT

### Background

Collagenous colitis is a disorder that is recognized as a cause of chronic diarrhea. Treatment has been based mainly on anecdotal evidence. This review was performed to identify therapies for collagenous colitis that have been proven in randomized trials.

### Objectives

To determine effective treatments for patients with clinically active collagenous colitis.

### Search methods

Relevant papers published between 1970 and June 2006 were identified via the MEDLINE and PUBMED databases. Manual searches from the references of identified papers, as well as review papers on collagenous or microscopic colitis were performed to identify additional studies. Abstracts from major gastroenterological meetings were searched to identify research submitted in abstract form only. Finally, the Cochrane Controlled Trials Register and the Cochrane Inflammatory Bowel Disease and Functional Bowel Disorders Group Specialized Trials Register were searched for other studies.

### Selection criteria

Seven randomized trials were identified. One trial studied bismuth subsalicylate (published in abstract form only), one trial studied *Boswellia serrata* extract (published in abstract form only), one trial studied probiotics, one trial studied prednisolone, and 3 trials studied budesonide for the therapy of collagenous colitis.

### Data collection and analysis

Data were extracted independently by each author onto 2x2 tables (treatment versus placebo and response versus no response). For therapies assessed in one trial only, p-values were derived using the chi-square test. For therapies assessed in more than one trial, summary test statistics were derived using the Peto odds ratio and 95% confidence intervals. Data were combined for analysis only if the outcomes were sufficiently similar in definition.

### Main results

There were 9 patients with collagenous colitis in the trial studying bismuth subsalicylate (nine 262 mg tablets daily for 8 weeks). Those randomized to active drug were more likely to have clinical ( $p = 0.003$ ) and histological ( $p = 0.003$ ) improvement than those assigned to placebo. Eleven patients were enrolled in the trial studying prednisolone (50 mg daily for 2 weeks). There was a trend towards clinical response in patients on active medication compared to placebo ( $p = 0.064$ ). The effect of prednisolone on histologic improvement was not studied. Thirty-one patients were enrolled in the *Boswellia serrata* extract trial. Clinical improvement was noted in 44% of patients who received active treatment compared to 27% of patients who received placebo ( $p = 0.32$ ). Twenty-nine patients were enrolled in the

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probiotics trial. Clinical improvement was noted in 29% of patients who received probiotics compared to 13% of patients who received placebo ( $p = 0.635$ ). A total of 94 patients were enrolled in 3 trials studying budesonide (9 mg daily or in a tapering schedule for 6 to 8 weeks). The pooled odds ratio for clinical response to treatment with budesonide was 12.32 (95% CI 5.53 - 27.46), with a number needed to treat of 2 patients. There was significant histological improvement with treatment in all 3 trials studying budesonide therapy. Budesonide also appears to improve patients' quality of life.

### Authors' conclusions

Budesonide is effective for the treatment of collagenous colitis. The evidence for benefit with bismuth subsalicylate is weaker. The effectiveness of prednisolone, *Boswellia serrata* extract, probiotics and other therapies for induction or maintenance of remission of collagenous colitis is unknown and requires further study.

### PLAIN LANGUAGE SUMMARY

#### **Budesonide is effective for treating collagenous colitis.**

Budesonide is a corticosteroid drug that is rapidly metabolized by the liver thereby reducing corticosteroid related side effects. This review shows that budesonide is effective for treating chronic diarrhea associated with collagenous colitis over a 6-8 week period. Budesonide also appears to improve patients' quality of life. There is also weaker evidence that bismuth subsalicylate (Pepto Bismol), a non-steroid therapy, may be effective for treating collagenous colitis over an 8 week period. Treatments such as prednisolone, *Boswellia serrata* extract, and probiotics require further study. The long term effects of these treatments for collagenous colitis and their usefulness in preventing disease recurrence have not been studied.