

## **Randomized, double-blind, placebo-controlled trial of oral aloe vera gel for active ulcerative colitis**

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**BACKGROUND:** The herbal preparation, aloe vera, has been claimed to have anti-inflammatory effects and, despite a lack of evidence of its therapeutic efficacy, is widely used by patients with inflammatory bowel disease.

**Aim:** To perform a double-blind, randomized, placebo-controlled trial of the efficacy and safety of aloe vera gel for the treatment of mildly to moderately active ulcerative colitis.

**METHODS:** Forty-four evaluable hospital out-patients were randomly given oral aloe vera gel or placebo, 100 mL twice daily for 4 weeks, in a 2 : 1 ratio. The primary outcome measures were clinical remission (Simple Clinical Colitis Activity Index  $\leq 2$ ), sigmoidoscopic remission (Baron score  $\leq 1$ ) and histological remission (Saverymuttu score  $\leq 1$ ). Secondary outcome measures included changes in the Simple Clinical Colitis Activity Index (improvement was defined as a decrease of  $\geq 3$  points; response was defined as remission or improvement), Baron score, histology score, haemoglobin, platelet count, erythrocyte sedimentation rate, C-reactive protein and albumin.

**RESULTS:** Clinical remission, improvement and response occurred in nine (30%), 11 (37%) and 14 (47%), respectively, of 30 patients given aloe vera, compared with one (7%) [ $P = 0.09$ ; odds ratio, 5.6 (0.6–49)], one (7%) [ $P = 0.06$ ; odds ratio, 7.5 (0.9–66)] and two (14%) [ $P < 0.05$ ; odds ratio, 5.3 (1.0–27)], respectively, of 14 patients taking placebo. The Simple Clinical Colitis Activity Index and histological scores decreased significantly during treatment with aloe vera ( $P = 0.01$  and  $P = 0.03$ , respectively), but not with placebo. Sigmoidoscopic scores and laboratory variables showed no significant differences between aloe vera and placebo. Adverse events were minor and similar in both groups of patients.

**CONCLUSION:** Oral aloe vera taken for 4 weeks produced a clinical response more often than placebo; it also reduced the histological disease activity and appeared to be safe. Further evaluation of the therapeutic potential of aloe vera gel in inflammatory bowel disease is needed