

Phase II double-blind randomized study comparing oral aloe vera versus placebo to prevent radiation-related mucositis in patients with head-and-neck neoplasms.

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Abstract:

PURPOSE: In a single-institution, double-blind, prospective, randomized trial, we determined whether oral aloe vera gel can reduce radiation-induced mucositis in head-and-neck cancer patients. **METHODS AND MATERIALS:** We randomized 58 head-and-neck cancer patients between oral aloe vera and placebo. To be included in this Phase II protocol, patients had to be treated with radiotherapy with curative intent at Stanford University between February 1999 and March 2002. We examined patients biweekly for mucositis at 15 head-and-neck subsites and administered quality-of-life questionnaires. **RESULTS:** Patients in the aloe and placebo groups were statistically identical in baseline characteristics. By the end of treatment, the two groups were also statistically identical in maximal grade of toxicity, duration of Grade 2 or worse mucositis, quality-of-life scores, percentage of weight loss, use of pain medications, hydration requirement, oral infections, and prolonged radiation breaks.

CONCLUSION: In our randomized study, oral aloe vera was not a beneficial adjunct to head-and-neck radiotherapy. The mean quality-of-life scores were greater in the aloe vera group, but the differences were not statistically significant. Oral aloe vera did not improve tolerance to head-and-neck radiotherapy, decrease mucositis, reduce soreness, or otherwise improve patient well-being.