

## A Pilot Randomized Controlled Trial of the Addition of Curcumin Mouthwash in Coconut Oil Solvent Compared with Normal Saline Solution for Preventing and Relieving Oral Mucositis in Locally Advanced Head and Neck Cancer Patients Who Undergoing Concurrent Chemoradiotherapy

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**Background:** Oral mucositis is a common and serious complication in patients receiving concurrent chemoradiotherapy (CCRT) for locally advanced head and neck cancer. We aimed to investigate the feasibility and efficacy of curcumin mouthwash in preventing and relieving CCRT-induced severe oral mucositis.

**Methods:** Within this feasibility study, we conducted a single-center, investigator-blinded, randomized controlled trial in patients with head and neck cancer receiving CCRT with 3-weekly cisplatin (Total RT dose  $\geq$  50 Gy). Eligible patients were randomly assigned to receive curcumin mouthwash (MW) or normal saline solution (NSS) MW. The primary objective of this study is to explore the feasibility and acceptability of the curcumin MW in locally advanced head and neck cancer patients who undergoing CCRT. The secondary objective is to explore the efficacy of the curcumin MW for preventing and relieving oral mucositis in locally advanced head and neck cancer patients who undergoing CCRT.

**Results:** Ten patients in the curcumin MW group and 13 patients in the NSS MW group were analyzed. The study was revealed no significant toxicities or safety concerns of curcumin MW. The incidence of severe oral mucositis (grade 3-4 defined by the WHO grading scale) was reduced in the curcumin MW group compared with the NSS MW group at week 4, 7, and 10. However, it was not statistically different. The severity of oral mucositis was significantly reduced in the curcumin MW group at week 4; the curcumin MW group had a mean of 0.09. In contrast, the NSS MW group had a mean score of 0.32 ( $p=0.016$ ).

**Conclusions:** Results of this pilot study suggest its feasibility and acceptability for the curcumin MW in locally advanced head and neck cancer patients who undergoing CCRT. A large-scale randomized controlled trial seems possible and should be encouraged.

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