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A Randomized Double-Blind, Placebo-Controlled Trial of Zinc Sulfate Supplementation for Alleviation of Radiation-Induced Oral Mucositis and Pharyngitis in Head and Neck Cancer Patients

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Abstract

Objective: To determine the efficacy of zinc sulfate supplementation in reducing of radiation-induced oral mucositis and pharyngitis in head and neck cancer patients.

Material and Method: One hundred forty four head and neck patients were enrolled in a randomized, double-blind, placebocontrolled trial. Patients who received radiation therapy alone or postoperative radiation therapy were eligible. Radiation therapy used conventional fractionation with 1.8 to 2.0 Gy per fraction, to total doses of 50 to 70 Gy over five to seven weeks. Drug and identically appearing placebo were self-administered 50 mg (10 cc) per meal, three times a day at mealtime. The zinc sulfate and placebo were administered beginning on the first day of radiation, and continued daily including weekends until radiation was completed. Patients were evaluated before radiation, weekly during radiation and at the first month after completion of radiation.

Results: The baseline characteristics of patients, tumor, and treatment were not significantly different between the two groups. There were no statistically significant differences between the two treatment groups in frequency of patients experiencing greater than or equal to grade 2 oral mucositis and pharyngitis at each week during radiation and at the first month after completion of radiation. Six patients (17%) in the zinc sulfate and ten patients (23%) in placebo group developed grade 3 oral mucositis, which was not significantly different. Twenty-two patients (32%) in the zinc sulfate and nineteen patients (27%) in the placebo group developed grade 3 pharyngitis, which was not significantly different. However, there was no observation of grade 4 oral mucositis and pharyngitis in either group. Nausea and vomiting were mostly of mild degree. Adverse events were not statistically significant different between the two groups.

Conclusion: It was concluded that zinc sulfate administered during head and neck radiation therapy produced no significant benefit in relieving radiation-induced oral mucositis and pharyngitis with acceptable side effects.

Keywords: Zinc sulfate, Oral mucositis, Pharyngitis, Radiation therapy, Head and neck cancer

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