

Phase III trial of low-level laser therapy to prevent oral mucositis in head and neck cancer patients treated with concurrent chemoradiation.

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Source

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Abstract

BACKGROUND:

Oral mucositis (OM) is a complication of chemoradiotherapy treatment of head and neck squamous cell carcinoma (HNSCC) patients with no effective therapy. This study was designed to assess the efficacy of preventive low-level laser therapy (LLLT) in reducing the incidence of grade 3-4 OM.

MATERIAL AND METHODS:

From June 2007 to December 2010, 94 HNSCC patients entered a prospective, randomized, double-blind, placebo-controlled phase III trial. Chemoradiotherapy consisted of conventional radiotherapy plus concurrent cisplatin every 3 weeks. A diode InGaAlP (660nm-100mW-1J-4J/cm²) was used. OM evaluation was performed by WHO and OMAS scales and quality of life by EORTC questionnaires (QLQ).

RESULTS:

A six-fold decrease in the incidence of grades 3-4 OM was detected in the LLLT group compared to the placebo; (6.4% versus 40.5%). LLLT impacted the incidence of grades 3-4 OM to a relative risk ratio of 0.158 (CI 95% 0.050-0.498). After treatment QLQ-C30 showed, differences favoring LLLT in physical, emotional functioning, fatigue, and pain; while the QLQ-H&N35 showed improvements in LLLT arm for pain, swallowing, and trouble with social eating.

CONCLUSION:

Preventive LLLT in HNSCC patients receiving chemoradiotherapy is an effective tool for reducing the incidence of grade 3-4 OM. Efficacy data were corroborated by improvements seen in quality of life.