LOW-LEVEL LASER THERAPY AS A PREVENTION AND MANAGEMENT MODALITY OF ORAL MUCOSITIS IN ONCO-HEMATOLOGIC PATIENTS: Clinical study

Mucositis is defined as a mucosal damage that occur secondarily to cancer therapy such as radiotherapy, chemotherapy or bone marrow transplant. It occurs in the oral cavity, pharyngeal, laryngeal, and esophageal regions; and other areas of the gastrointestinal tract. Oral Mucositis (OM) manifestations ranges from a burning sensation to ulcer formation of oral mucosa, which may affect the Quality of Life (QOL) due to the associated malnutrition and dehydration because of pain and discomfort during swallowing.

Over the last 5 years, OM prevalence has been increased because of introduction of aggressive protocols and combined modality regimens. It occurs in approximately 20% to 40% of patients receiving conventional chemotherapy, 80% in patients receiving high-dose chemotherapy as conditioning for hematopoietic stem cell transplantation and in nearly all patients receiving head and neck radiation therapy. Most of studies showed a positive effect of Low-Level Laser Therapy (LLLT) on Radio-chemotherapy induced OM, concluded a presence of unreliable evidence of LLLT efficacy on OM, and suggested carrying out further well designed, placebo-controlled trials to improve this level of evidence.

The aim of the study is to evaluate and to improve the level of evidence of LLLT as a prevention and treatment modality of OM in Onco-Hematologic (OH) patients, and to evaluate its impact on the QOL of these patients. Also, this clinical study will simultaneously try to evaluate and compare two different starting times of LLLT application as a trial to clarify the better starting time of LLLT for the prophylactic purpose, which is still unclear in the literature.

Source of data, this study will be conducted on the attending patients of Oral and Maxillofacial Sciences department and Hematology Unit, Policlinic Umberto I, Sapienza University of Rome.

Collection of data, general information such as name, age, sex and address, medical and dental history, full clinical examination, scoring of OM according to the scale of the Worldwide Organization of Health (WHO), pain grading scale (Visual Analogue Scale), two questionnaires for the evaluation of QOL developed by the European Organization for Research and Treatment of Cancer (EORTC) (QLQ-C30 and QLQ- H&N35), and photographic documentation for each patient will be gathered.

Sample size, it is intended to undertake this study on 60 OH patients. These patients will be divided into four equal groups. The first group and the second group will be for the prevention purpose (before the starting of Chemotherapy); these two groups will differ only in the starting time of application of LLLT. The third group will be for the treatment purpose with LLLT in OH patients with existing Chemotherapy induced OM. The fourth group will be the control group and will be managed with placebo.

Inclusion criteria, the patients of this study should have all the following characteristics: Onco-Hematologic patients (OH), Ongoing or are going to be treated with chemotherapy. Patients in age range of 18 to 80 years.

Exclusion criteria, non cooperative patients, patients with systemic diseases that hinder the wound healing (e.g. uncontrolled diabetes mellitus, etc.) and OH patients with the management of radiotherapy will be excluded from this study.

Keywords: Onco-Hematologic patients (OH), Oral Mucositis (OM), Quality of Life (QOL), Low-Level Laser Therapy (LLLT)

References


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