Low level laser therapy in oral mucositis: a pilot study

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Abstract

Aim: The goal of this pilot study was to investigate the capacity of pain relief and wound healing of low level laser therapy (LLLT) in chemotherapy-induced oral mucositis (OM) in a paediatric oncology population group.

Study design and methods: 16 children (mean age 9.4 years) from the Gent University Hospital - Department Paediatric Oncology/haematology, suffering from chemotherapy-induced OM were selected. During clinical investigations, the OM grade was assessed using the WHO classification. All children were treated using a GaAlAs diode laser with 830 nm wavelength and a potency of 150 mW. The energy released was adapted according to the severity of the OM lesions. The same protocol was repeated every 48 hrs until healing of each lesion occurred. Subjective pain was monitored before and immediately after treatment by an appropriate pain scale and functional impairment was recorded. At each visit, related blood cell counts were recorded.

Results: After 12 mths, records were evaluated and information about treatment sequence, treatment sessions and frequencies related to the pain sensation and comfort were registered. Immediately after beaming the OM, pain relief was noticed. Depending on the severity of OM, on average, 2.5 treatments per lesion in a period of 1 week were sufficient to heal a mucositis lesion.

Conclusions: LLLT, one of the most recent and promising treatment therapies, has been shown to reduce the severity and duration of mucositis and to relieve pain significantly. In the present study similar effects were obtained with the GaAlAs 830nm diode laser. It became clear that using the latter diode device, new guidelines could be developed as a function of the WHO-OM grades i.e. the lower the grade, the less energy needed. Immediate pain relief and improved wound healing resolved functional impairment that was obtained in all cases.

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Efficacy of low-level laser for treatment of cancer oral mucositis: a systematic review and meta-analysis

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Abstract

Review effectiveness of low-level laser therapy (LLLT) in the curative treatment of oral mucositis (OM) in patients receiving cancer therapy. A systematic review with meta-analysis was performed using Medline, Embase, and Cochrane Library databases according to PRISMA guidelines, to identify randomized controlled trials (RCT) on OM in patients during and/or after cancer therapy and in which the therapeutic approach was LLLT, with wavelengths between 632 and 970 nm. We considered grade of OM as a dichotomous variable (such as an improvement or not in severe OM on the seventh day of therapy), with the analysis of subgroups of adult patients or children and adolescents and as a continuous variable with determination of the time for the complete resolution and the subgroup analysis occurred with the strata of the samples by treatment only with chemotherapy or chemotherapy and radiotherapy. This paper's protocol was registered a priori at https://www.crd.york.ac.uk/PROSPERO . We found five RCT (total of 315 patients) with adequate methodology. LLLT was effective, presenting a 62% risk reduction of severe mucositis on the seventh day of evaluation (RR = 0.38 [95% CI, 0.19-0.75]). When we analyzed subgroups, RR was 0.28 (95% CI 0.17-0.46) in the adult studies and 0.90 (95% CI, 0.46-1.78) in the studies with children and adolescents. We demonstrated a mean reduction of 4.21 days in the time of complete resolution of OM (CI - 5.65 to - 2.76) in favor of LLLT. There is moderate evidence that LLLT is effective in resolving OM lesions in adult patients undergoing cancer therapy. LLLT demonstrates potential for decreasing the resolution time of OM lesions by approximately 4.21 days.

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Effectiveness of low-level laser therapy for oral mucositis prevention in patients undergoing chemoradiotherapy for the treatment of head and neck cancer: A systematic review and meta-analysis

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Abstract

Oral Mucositis is a frequent and debilitating inflammatory complication in patients with head and neck malignancies and may lead to unplanned treatment interruptions due to intense pain and dysphagia. This systematic review with meta-analysis was performed to determine the effectiveness of low-level laser therapy in preventing oral mucositis in this context. The following databases were searched through September 2018, with last search performed on May 2019, for clinical trials: MEDLINE via PubMed, Cochrane Central, Scopus, Lilacs, ISI Web of Science and SIGLE via Open Grey. From 14,525 records, 4 studies were included in the review and 3 studies were included in meta-analysis. Data from 500 patients (mean age of 53.595 and 54.14 for intervention and control groups, respectively) were analysed. Meta-analysis showed that laser therapy prevents oral mucositis incidence in 28% and 23% of cases during the third and fourth follow-up week, respectively, in comparison to a placebo-treated control group. There was no statistically significant difference the prevention of pain; dysphagia and quality of life were not analysed due to missing. Laser therapy was effective in preventing oral mucositis from the 15th to the 45th days of chemoradiotherapy. However, new primary studies with low risk of bias are needed so a higher scientific evidence can be obtained.

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Low-level laser therapy in treatment of chemoradiotherapy-induced mucositis in head and neck cancer: results of a randomised, triple blind, multicentre phase III trial

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Background

Low-level laser therapy (LLLT) also called Photobiomodulation therapy (PBMT) could reduce oral mucositis (OM) incidence and severity in head and neck cancer patients treated by chemoradiotherapy, however randomised data about efficacy and safety are missing with curative dose 4 J/cm2.

Methods

This phase III trial was conducted in patients with oral cavity, or oro/hypopharyngeal cancers (stage III or IV). Patients were treated by lasertherapy on OM lesions grade ≥ 2 (4 J/cm2 or placebo), during chemoradiotherapy and until recovery. Severity of OM (incidence and duration of grades ≥3) was used as primary endpoint and blindly assessed.

Results

Among 97 randomised patients, 83 patients (85.6%) could be assessed finally (erroneous inclusions, chemoradiotherapy interruptions) and 32 patients had no lasertherapy because of unreachable OM lesions. Randomisation and population characteristics (sex ratio, age, chemoradiotherapy procedures, toxicities incidence) were still comparable between the two LLLT/PBMT groups. An acute OM (grade ≥ 3) was observed in 41 patients (49.4%): 23 patients (54.8%) of the active laser group versus 18 (43.9%) in the control group (modified intend to treat, p = 0.32). Median time before occurrence of OM ≥ grade 3 in half of the patients was 8 weeks in active laser group (vs. 9 weeks in control group). However, 95% of patients exhibited a very good tolerance of LLLT/PBMT.

Conclusions

This study assessed LLLT/PBMT according to the Multinational Association of Supportive care in Cancer recommendations but lacked power. LLLT/PBMT was well tolerated with a good safety profile, which promotes its use in clinical routine for severe OM treatment.

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Long-term survival of a randomized phase III trial of head and neck cancer patients receiving concurrent chemoradiation therapy with or without low-level laser therapy (LLLT) to prevent oral mucositis.

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BACKGROUND: The impact of low-level laser therapy (LLLT) to prevent oral mucositis in patients treated with exclusive chemoradiation therapy remains unknown. This study evaluated the overall, disease-free and progression-free survival of these patients. METHODS: Overall, disease-free and progression-free survival of 94 patients diagnosed with oropharynx, nasopharynx, and hypopharynx cancer, who participated on a phase III study, was evaluated from 2007 to 2015. The patients were subjected to conventional radiotherapy plus cisplatin every 3weeks. LLLT was applied with an InGaAlP diode (660nm-100mW-1J-4J/cm(2)). RESULTS: With a median followup of 41.3months (range 0.7-101.9), patients receiving LLLT had a statistically significant better complete response to treatment than those in the placebo group (LG=89.1%; PG=67.4%; p=0.013). Patients subjected to LLLT also displayed increase in progression-free survival than those in the placebo group (61.7% vs. 40.4%; p=0.030; HR:1:93; CI 95%: 1.07-3.5) and had a tendency for better overall survival (57.4% vs. 40.4%; p=0.90; HR:1.64; CI 95%: 0.92-2.91). CONCLUSION: This is the first study to suggest that LLLT may improve survival of head and neck cancer patients treated with chemoradiotherapy. Further studies, with a larger sample, are necessary to confirm our findings.

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Effect of low-level laser therapy on chemoradiotherapy-induced oral mucositis and salivary inflammatory mediators in head and neck cancer patients.

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BACKGROUND AND OBJECTIVE: Oral mucositis (OM) is considered a painful and debilitating side effect in patients receiving head and neck cancer treatment. Low-level laser therapy (LLLT) proved to be effective to prevent and treat chemoradiotherapy-induced OM. The aim of this study was to evaluate the effect of LLLT in the severity of OM in patients with head and neck cancer and on the release of salivary inflammatory mediators. Clinical (score of OM severity) and biochemical parameters (concentration of inflammatory mediators, growth factors, and enzymes in saliva) were used. MATERIALS AND METHODS: Thirty patients were randomized into two groups: control and laser. LLLT was performed three times a week in the laser group, while control group received sham irradiation. OM severity was assessed according to the World Health Organization (WHO) and National Cancer Institute (NCI) scales. Pro-inflammatory and anti-inflammatory cytokines (TNF-alpha, IL-6, IL-1beta, IL-10, TGFbeta), growth factors (EGF, FGF, VEGF), and metalloproteinases (MMP2/TIMP2, MMP9/TIMP2) concentrations were assessed using ELISA test. Saliva samples were collected on admission, and at the 7th, 21st, and 35th sessions of radiotherapy. RESULTS: The laser group showed a reduction in the severity of OM, which coursed with significantly diminished salivary concentration of EGF and VEGF in the 7th radiotherapy session and of IL-6 and FGF in the 35th. There was a trend for reduced levels of IL-1beta, TNF-alpha, IL-10, TGF-beta, MMP2/TIMP2, MMP9/TIMP2 in the laser group compared to the control, however, no statistically significant differences were found. CONCLUSIONS: These findings demonstrated that LLLT was effective in reducing the severity of chemoradiotherapy-induced OM and was associated with the reduction of inflammation and repair. Lasers Surg. Med. 47:296-305, 2015. (c) 2015 Wiley Periodicals, Inc.

Lasers Surg Med 2015 Apr 47(4) 296-305

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Low level laser therapy against radiation induced oral mucositis in elderly head and neck cancer patients-a randomized placebo controlled trial.

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OBJECTIVES: Radiotherapy (RT) is treatment of choice for Elderly Head and Neck Cancer (HNC) patients. Oral mucositis (OM) during RT affects patient's routine oral activities and overall health. Low Level Laser Therapy (LLLT) provided some promising results against cancer therapy induced OM in children and adults. No study specifically evaluated effects of LLLT against RT induced OM in elderly HNC patients until date, hence we did this study. MATERIAL AND METHODS: This double blinded study randomized 46 elderly HNC patients scheduled for RT [Dosage=66 Gray (2 Gy/fraction), 5 fractions/week, total 33 fractions for 6.5 weeks], into laser (22) and placebo (24) groups. Laser group patients received LLLT [Helium-Neon, lambda=632.8 nm, power density=0.024 W/cm(2), dosage=3.0 J/point at six anatomical sites bilaterally i.e. 12 locations, total dose/session=36 J, beam aperture diameter=0.6 mm, beam spot size=1 cm(2), irradiated area diameter=1 cm(2), irradiation time/point=125 s, 5 sessions/week, non-contact method-distance between probe and irradiated tissues <1 cm, whereas placebo group did not receive laser. OM grades (RTOG/EORTC Scale), oral pain, weight loss, need for morphine analgesics and tube feeding, and RT break were recorded by a blinded assessor. Descriptive statistics and repeated measures ANOVA were used for analysis keeping $p<0.05$. RESULTS: Significant reduction in the incidence and duration of severe OM ($p=0.016$) and severe pain ($p=0.023$) and weight loss ($p=0.004$) was observed in laser than placebo group. No difference was found for enteral feeding use ($p=0.667$) between two groups. CONCLUSIONS: LLLT decreased the severity of OM and oral pain in elderly HNC patients. Also, lesser weight loss, morphine analgesic use and radiation break happened in laser group.

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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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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, doubleblind, placebo-controlled phase III trial. Chemoradiotherapy consisted of conventional radiotherapy plus concurrent cisplatin every 3weeks. 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.

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Effect of low-level laser therapy on patient reported measures of oral mucositis and quality of life in head and neck cancer patients receiving chemoradiotherapy-a randomized controlled trial.

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PURPOSE: Chemoradiotherapy (CRT)-induced oral mucositis (OM) adversely affects a patient's oral functions and quality of life (QOL). Low-level laser therapy (LLLT) showed some preventive and curative effects against clinically reported objective measures of OM in few trials including our recently published study. There is dearth of evidence regarding the effects of LLLT on patient's subjective experience of OM and QOL. Hence, we did this study to evaluate the effects of LLLT on a patient's reported measures of OM and QOL in head and neck cancer (HNC) patients receiving CRT. METHODS: This triple blinded study randomized 220 HNC patients scheduled for CRT (three weekly Cisplatin + RT = 66 Gray (2 Gy/session), five fractions/week for 6.5 weeks, total 33 fractions) into laser (110) and placebo (110) groups. The laser group received LLLT (Technomed Electronics Advanced Laser Therapy 1000, He-Ne, lambda = 632.8 nm, power density = 24 mW/cm(2), dosage = 3.0 J at each point, total dose/session = 36-40 J, spot size 1 cm(2), irradiation time/point 125 s) before each radiation session, while the placebo group did not receive laser therapy. Methodology was similar to our recently published study (Gautam et al. Radiother Oncol 104:349-354, 2012). In this part of our study, a blinded assessor collected subjective outcomes of the patient's reported measures of OM using Oral Mucositis Weekly Questionnaire-Head and Neck (OMWQ-HN) and QOL using Functional Assessment of Cancer Treatment-Head and Neck (FACT-HN) Questionnaire. Data were analyzed using repeated measure ANOVA through general linear model. Statistical significance was kept at $p < 0.05$. RESULTS: Results analysis revealed that OMWQ-HN ($F = 12.199$, $df = 6,1314$, $p < 0.001$) and FACT-HN ($p < 0.05$) scores were significantly lower in LLLT than placebo group patients. Also, a significant reduction ($p < 0.001$) in incidence of severe OM, need for opioid analgesics, and total parenteral nutrition was observed. CONCLUSIONS: LLLT was effective in improving the patient's subjective experience of OM and QOL in HNC patients receiving CRT.

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Low-power laser in the prevention of induced oral mucositis in bone marrow transplantation patients: a randomized trial.

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We investigated the clinical effects of low-power laser therapy (LPLT) on prevention and reduction of severity of conditioning-induced oral mucositis (OM) for hematopoietic stem cell transplantation (HSCT). We randomized 38 patients who underwent autologous (AT) or allogeneic (AL) HSCT. A diode InGaAlP was used, emitting light at 660 nm, 50 mW, and 4 J/cm2, measured at the fiberoptic end with 0.196 cm2 of section area. The evaluation of OM was done using the Oral Mucositis Assessment Scale (OMAS) and the World Health Organization (WHO) scale. In the LPLT group, 94.7% of patients had an OM grade (WHO) lower than or equal to grade 2, including 63.2% with grade 0 and 1, whereas in the controls group, 31.5% of patients had an OM grade lower than or equal to grade 2 ($P < .001$). Remarkably, the hazard ratio (HR) for grades 2, 3, and 4 OM was 0.41 (range, 0.22-0.75; $P = .002$) and for grades 3 and 4 it was 0.07 (range, 0.11-0.53; $P < .001$). Using OMAS by the calculation of ulcerous area, 5.3% of the laser group presented with ulcers of 9.1 cm2 to 18 cm2, whereas 73.6% of the control group presented with ulcers from 9.1 cm2 to 18 cm2 ($P = .003$). Our results indicate that the use of upfront LPLT in patients who have undergone HSCT is a powerful instrument in reducing the incidence of OM and is now standard in our center.

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Low energy Helium-Neon laser in the prevention of oral mucositis in patients undergoing bone marrow transplant: results of a double blind randomized trial.

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PURPOSE: To evaluate the efficiency of Helium-Neon (He-Ne) laser in the prevention of oral mucositis induced by high dose chemoradiotherapy before autologous bone marrow transplantation (BMT). METHODS AND MATERIALS: Between 1993 and 1995, 30 consecutive patients receiving an autologous peripheral stem-cell or bone marrow transplant (BMT) after high dose chemoradiotherapy were randomized to possibly receive prophylactic laser to the oral mucosa after giving informed consent. Chemotherapy consisted of cyclophosphamide, 60 mg/kg intravenously (I.V.) on day (d)-5 and d-4 in 27 cases, or melphalan 140 mg/kg I.V. on d-4 in three cases. Total body irradiation (TBI) consisted of 12 Gy midplane dose in six fractions (4 Gy/day for three days). He-Ne laser (632.8 nm wavelength, power 60 mW) applications were performed daily from d-5 to d-1 on five anatomic sites of the oral mucosa. Oral examination was performed daily from d0 to d + 20. Mucositis was scored according to an oral exam guide with a 16 item scale of which four were assessed by the patients themselves. Mean daily self assessment scores for oral pain, ability to swallow and oral dryness were measured. A daily mucositis index (DMI) and a cumulative oral mucositis score (COMS) were established. Requirement for narcotics and parenteral nutrition was recorded. RESULTS: The COMS was significantly reduced among laser treated (L+) patients ($p = 0.04$). The improvement of DMI in L+ patients was also statistically significant ($p < 0.05$) from d + 2 to d + 7. Occurrence and duration of grade III oral mucositis were reduced in L+ patients ($p = 0.01$). Laser applications reduced oral pain as assessed by patients ($p = 0.05$) and L+ patients required less morphine ($p = 0.05$). Xerostomia and ability to swallow were improved among the L+ patients ($p = 0.005$ and $p = 0.01$, respectively). Requirement for parenteral nutrition was not reduced (p = NS). CONCLUSION: Helium-Neon laser treatment was well tolerated, feasible in all cases, and reduced high dose chemoradiotherapy-induced oral mucositis. Optimal laser treatment schedules still needs to be defined.

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http://www.ncbi.nlm.nih.gov/pubmed/?term=9240635