

The possible side effects of High Intensity Laser Efectele adverse posibile ale laserului de înaltă intensitate

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Abstract

Background. High Intensity Laser Therapy (HILT) is a recent rehabilitation therapy, which is successfully used at present in posttraumatic diseases of the locomotor system including sport injuries, due to its fast efficacy and its non-invasive mode of action. HILT has not been studied until recently in clinical studies and not studied at all yet in terms of possible side effects.

Aims. 1) To select a program on a HILT device with standard parameters, in a standard application area; in this case it was a knee application; 2) to select the possible side effects or unpleasant reactions of HIL; 3) to evaluate the impact of HIL on the specific area, from the point of view of side effects or unpleasant reactions; 4) to analyze the data and to make an interpretation of the reached results.

Methods. The study comprised 20 volunteers, aged between 20-65, with no major recent surgeries or trauma, no major organ illnesses, skin type I, II, III or IV, with an apparently healthy knee joint, in the Rehabilitation Department of the Colentina Clinical Hospital of Bucharest. A Czech device: BTL-6000 High Intensity Laser, 12w, 1064 nm, in standard parameters was used to identify the side effects. We selected a group of parameters that were chosen to demonstrate, from the point of view of side effects or unpleasant reactions of heating, the impact of each application during 6 sessions: presence/absence of side effects such as: erythema, hyposensitivity, hypersensitivity, petechiae or the unpleasant sensation of heating, using the same scale: 0=absent; 1=present.

Results. No side effects of any applications were identified. An unpleasant sensation of heating was encountered in 5% of applications.

Conclusions. 1) The results do not identify any side effects of HIL applications. Only an unpleasant sensation of heating was encountered in 5% of cases, which is rather an individual intolerance to the duration of application and it is necessary to adapt the therapy time, in order to avoid it. 2) Further studies should be realized on a larger group, trying to evaluate the side effects of all the most used protocols existing in the machine manual.

Key words: High Intensity Laser, side effects, unpleasant sensation of heating.

Rezumat

Premize. Terapia cu laser de înaltă intensitate (High Intensity Laser Therapy-HILT) este un mijloc de reabilitare recent introdus în arsenalul terapeutic de recuperare. HILT este folosit în prezent cu succes în patologia post traumatică a aparatului locomotor, inclusiv după traumatismele sportive, datorită efectelor benefice instalate rapid și a modului de acțiune non-invaziv, fiind încă puțin studiat în studii clinice și deloc studiat din punctul de vedere al efectelor adverse.

Obiective. 1) Selectarea unui program de aplicație a laserului de înaltă intensitate, cu parametrii standard, precum și selectarea unei zone de aplicație bine definite, în acest caz la nivelul genunchiului; 2) selectarea posibilelor efecte adverse sau reacții neplăcute ale aplicațiilor de HIL; 3) evaluarea impactului aplicațiilor de HIL din punctul de vedere al efectelor adverse sau al reacțiilor neplăcute; 4) analizarea datelor și interpretarea rezultatelor.

Metode. Studiul a fost realizat pe un grup de 20 de voluntari, cu vârste cuprinse între 20-65 de ani, care nu au avut intervenții chirurgicale sau traumatisme recente, cu fototipul de piele din clasele de tip I, II, III sau IV conform scalei Fitzpatrick (pielea neagră sau brun închis a fost exclusă), cu articulația genunchiului aparent sănătoasă, din punct de vedere clinic, în cadrul Secției de Recuperare Medicală a Spitalului Clinic Colentina din București, folosind un dispozitiv BTL-6000 High Intensity Laser, 12w, 1064nm, și un protocol specific al aplicațiilor în vederea identificării posibilelor reacții adverse. Am înregistrat un grup de parametri care să arate, din punctul de vedere al efectelor adverse sau al reacțiilor neplăcute, impactul HIL, după fiecare aplicație, timp de 6 ședințe: prezența/absența efectelor secundare care pot apărea: eritem, hipoestezie, hiperestezie, peteșii sau senzație neplăcută de căldură, folosind aceeași scală pentru toți acești parametri: 0 = absent; 1 = prezent.

Concluzii. 1) Rezultatele nu au identificat efecte secundare ale aplicației HIL. Doar senzația neplăcută de căldură a fost găsită în 5% din cazuri, dar aceasta este, de fapt, un efect de intoleranță al aplicației HIL-faza II “biostimularea”, fiind necesară reducerea timpului aplicației, în funcție de toleranța individuală, în vederea evitării senzației neplăcute de căldură. 2) Efectuarea unui studiu pe un grup mai mare, cu încercarea de a evalua efectele secundare a celor mai folosite protocoale existente în manualul de utilizare.

Cuvinte cheie: laser de înaltă intensitate, efecte secundare, senzație neplăcută de căldură.

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Introduction

High Intensity Laser Therapy (HILT) is a recent rehabilitation therapy successfully used in orthopedic diseases and sports medicine, due to its fast efficacy, with rapid and permanent relief of pain and the resulting reduction of the recovery time (Mondardini, 2002; Valent, 2009; Santamato, 2009). Compared with low level laser therapy (LLLT), whose effects are well studied (Karu, 2005; Hawkins, 2007; Stergioulas, 2008; Ribeiro, 2015), HILT is a new non-invasive laser therapy that has been less studied in clinical studies and not studied at all yet in terms of possible side effects. The properties of laser beam are: absorption, transmission, scattering, and reflection (Fig. 1).

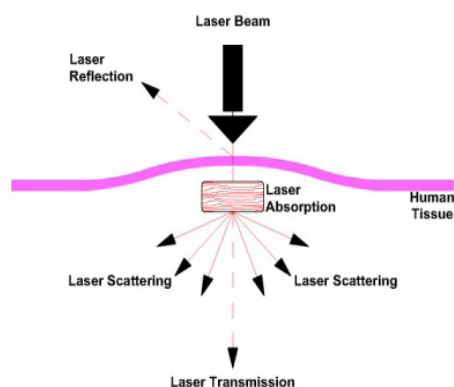


Fig. 1 – Interactions between laser beam and human tissue.

The most important physiological effects of HIL (High Intensity Laser) are (Tuner & Hode, 2010; Prouza et al., 2013; Pryor, 2009): increase in the activity of many intracellular enzymes, specifically in the Krebs cycle, increase of oxygen transportation and also, of glucose utilization, stimulation of DNA synthesis, activation of the Na/K membrane pumps, increase of fibroblast activity, increase of phagocytosis activation, activation of metabolic cellular processes, local changes in some important inflammation mediators (such as histamine and prostaglandins) and in endorphin levels. The most important clinical effects are: analgesia and biostimulation. The analgesic effect is produced by high-power pulsed applications, which create inside the body photomechanical waves that reach the subcutaneous pain receptors, stimulate the A fibers and close the gate for pain transition (according to the gate control theory described by Melzack). The biostimulation effect is the ability to biostimulate cell growth and cell repair (Tuner & Hode, 2010; Prouza et al., 2013; Pryor, 2009). Other effects of HIL are: support for bone formation - migration and proliferation of osteoblasts (Kim et al., 2010; Vescovi et al., 2008; Ninomiya et al., 2003), regenerative processes in cartilaginous tissue such as a high amount of proteoglycans (Zati, 2011), thermal induced effects such as muscular relaxation and pain relief in the trigger points.

In terms of adverse effects, it is commonly accepted that this laser therapy has no known side effects when used by a properly trained professional (Boyraz et al., 2015; Viliani et al., 2010; Viliani et al., 2010).

The contraindications for HIL are: applications in the eye area – possibility of direct eye irradiation and retinal damage, tumor diseases, irradiation of malignancies and

potential precancerous growths, irradiation of patients with cochlear implants, irradiation of endocrine glands, patients with febrile conditions, epilepsy, pregnancy, irradiation of freckles or tattoos, sensory deficit in the treatment area, photosensitive medication, direct application above metallic implants.

Other warnings and precautions are: the therapy parameters have to be adjusted according to the Fitzpatrick scale to avoid heating, scar tissue is associated with poor circulation and reduced cooling through heat transport by blood, sensitive skin may be hypersensitive to heat, redness can be associated with increased temperature and increased absorption properties of the skin, excessive fat tissue is known to transmit heat without much attenuation, no ointments, creams, lotions or heating lotion patches should be used at or in close proximity of the treated area, no therapies that could change body temperature (ultrasound, thermal therapy and electrotherapy) should be used prior to laser treatment.

Objectives

To select a program on a HILT device with standard parameters, in a standard application area; in this case it was a knee application; to select the possible side effects or unpleasant reactions of HIL; to evaluate the impact of HIL on the specific area, from the point of view of side effects or unpleasant reactions; 4) to analyze the data and to make an interpretation of the reached results.

Hypothesis

HIL is a new non-invasive laser therapy that produces no side effects at all. Still, in clinical practice there has been some concern regarding its tolerance and its possible unknown adverse effects because of its deep tissue penetration and maximum power over 50 times higher than in LLLT (low level laser therapy) (Pryor, 2009). Also, because in sport injuries both young and older people are affected, it was interesting to know if there was a difference in the presence/absence of any side effects.

Material and methods

Research protocol

The research was conducted with the approval of the Ethics Commission of the Colentina Clinical Hospital of Bucharest and with the informed consent of the subjects included in the study.

a) Period and place of the research.

From September to December 2014, we selected a group of volunteers, with apparently healthy knee joints, in the Rehabilitation Department of the Colentina Clinical Hospital of Bucharest.

b) Subjects and groups

We selected 20 volunteers, with apparently healthy knee joints. Inclusion criteria: age between 20-65, no major recent surgeries or trauma, no major organ illnesses, no pregnancy, no menstruation, skin type I, II, III or IV according to Fitzpatrick phototyping scale (dark brown and black skin was excluded).

c) Tests applied

A Czech device was used: BTL-6000 High Intensity Laser, 12 w, 1064 nm (Fig. 2).



Fig. 2 – BTL-6000 High Intensity Laser device used in the Rehabilitation Department of the Colentina Clinical Hospital, Bucharest (***, 2014a).

The device has a laser unit, a foot switch control and a hand piece which is precisely applied on the knee area in two phases, in every session: phase I - analgesia, and phase II - biostimulation. The group of volunteers followed an individualized medical prescription including 6 sessions of a single application of high intensity laser per day, on the anterior region of one knee, 3 sessions per week. For phase I -analgesia, the application was made by using continuous circular movements (Fig. 3).



Fig. 3 – Phase I - analgesia (***, 2014b).

The device was manually set to the L-7129 program, with a power of 10 W, pulsed application with a frequency of 25 Hz, dose 12 J/cm², total energy 300 J, wave length 1064 nm, area to be treated 25 cm², for 2 minutes.

After the first phase, the device was manually set for phase II - biostimulation. In this case, the application was made by using continuous movements (Fig. 4).



Fig. 4 – Phase II - biostimulation (***, 2014b).

The device manual settings were to the L-7130 program, with a power of 5 W, frequency - density of 120 J/cm², total energy 300 J, wave length 1064 nm, area to be treated 25 cm². The recommended duration was 2-4 minutes and the application lasted for 4 minutes. During the procedure, the patient should feel pleasant warming-up of the skin in the application area.

The possible side effects described in the user's manual of this HIL device are: erythema that can temporarily occur in the treated area, temporary hyposensitivity, temporary hypersensitivity and petechiae. It is also necessary to monitor the unpleasant sensations of heating during phase II -biostimulation.

d) Statistical processing

We recorded a group of parameters that can illustrate, from the point of view of side effects or unpleasant reactions, the impact of HIL after each application during 6 sessions of therapy: presence/absence of local side effects that can temporarily occur, such as erythema, hyposensitivity, hypersensitivity, petechiae or an unpleasant sensation of heating, with the same denotation for all these parameters: 0=absence, 1=presence.

Results

After 6 sessions of daily HIL application, we obtained the following results regarding the number of patients, number of applications, and average values, as shown in Table I.

Table I
Results including the number of patients, number of applications, and average values.

Parameters	Number of patients	Number of applications with denotation	Average %
		1=presence	
Erythema	0	0	0
Hyposensitivity	0	0	0
Hypersensitivity	0	0	0
Petechiae	0	0	0
Unpleasant sensation of heating	1	6	5

The unpleasant sensation of heating was encountered in only 6 applications (on average in 5% of cases) and in those situations it was necessary to interrupt the application. Just 1 patient had an unpleasant sensation of heating, and this sensation appeared at the end of every session of phase II - biostimulation. On the other hand, no side effects - erythema, hyposensitivity, hypersensitivity or petechiae - occurred after the applications.

Discussion

The side effects of HIL were evaluated by using 5 parameters that were monitored for every patient after each session of HIL application. The results are in accordance with those of other studies performed for testing HILT efficacy, which reported the absence of side effects (Boyraz et al., 2015; Viliani, Martini, 2010; Viliani, Ricci, 2010). The results showed that an unpleasant sensation of heating was experienced in only 5% of the cases in the study; however, this effect is not a side effect, but rather

an intolerance to the duration of application of phase II - biostimulation. In this case, it can be recommended to shorten the period of application to a minimum, to avoid the unpleasant effect of heating.

Conclusions

1. The study was performed on a group of 20 volunteers, aged between 20-65, with no major recent surgeries or trauma and skin type I, II, III or IV, with an apparently healthy knee joint, in the Rehabilitation Department of the Colentina Clinical Hospital of Bucharest – CDPC, using a BTL-6000 High Intensity Laser and a specific protocol for applying the therapy, in order to identify possible adverse reactions to HIL therapy.

2. The results showed that no side effects to the HIL applications occurred, and HIL can be safely used in both young and older persons, aged between 20-65 years, a very common age interval for sport injuries.

3. The results evidenced that an unpleasant sensation of heating was encountered in only 5% of cases, which was rather an individual intolerance to the duration of application of phase II - biostimulation.

4. In HIL applications, it is necessary to adapt the therapy time to individual tolerance, in order to avoid the unpleasant sensation of heating.

5. Further studies should be conducted on larger groups, aiming to evaluate the side effects of all the most used protocols existing in the machine manual.

Conflicts of interests

There were no conflicts of interests.

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