

Laser therapy and topical drug treatment for onychomycosis in people with diabetes: A case-series study*

Laserterapia e tratamento medicamentoso tópico na onicomicose em pessoas com diabetes: série de casos

Terapia láser y tratamiento con medicamento tópico para onicomicosis en personas con diabetes: serie de casos

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Abstract

Objective: to describe the effects of low-level laser therapy and of topical drug treatment for onychomycosis in people with diabetes. **Method:** a qualitative study of the case-series type. The participants were 21 individuals with diabetes divided into two groups, the first treated with laser and the second with topical medication from October 2020 to August 2021. The data were collected in a clinical history and examination of the nail plates and organized in a database, whose analysis took place through descriptive statistics. **Results:** it was identified that 30% and 26% of the nail plates attained clinical cure in groups I and II, respectively. When assessing the

satisfactory response, groups I and II presented 63% and 53%, respectively. **Conclusion:** the onychomycosis treatment with laser therapy presented higher prevalence of satisfactory response and clinical cure than the topical drug treatment.

Descriptors: Nursing; Low-Level Light Therapy; Photochemotherapy; Onychomycosis; Diabetes Mellitus

Resumo

Objetivo: descrever os efeitos da laserterapia de baixa intensidade e do tratamento medicamentoso tópico da onicomicose em pessoas com diabetes. **Método:** estudo quantitativo, do tipo série de casos. Os participantes foram 21 pessoas com diabetes divididas em dois grupos, sendo o primeiro tratado com laser e o segundo com medicamento tópico no período de outubro de 2020 a agosto de 2021. Os dados foram coletados em histórico e exame clínico das lâminas ungueais e organizados em banco de dados, cuja análise ocorreu por meio de estatística descritiva. **Resultados:** identificou-se que no grupo I 30% das lâminas ungueais obtiveram cura clínica e no II 26%. Ao avaliar a resposta satisfatória o grupo I apresentou 63% e o II 53%. **Conclusão:** o tratamento da onicomicose com laserterapia apresentou maior prevalência de resposta satisfatória e cura clínica do que o tratamento medicamento tópico.

Descritores: Enfermagem; Terapia com Luz de Baixa Intensidade; Fotoquimioterapia; Onicomicose; Diabetes Mellitus

Resumen

Objetivo: describir los efectos de la Terapia Láser de Baja Intensidad y del tratamiento con medicamento tópico para la onicomicosis en personas con diabetes. **Método:** estudio cuantitativo del tipo serie de casos. Los participantes fueron 21 personas con diabetes divididas en dos grupos: el primero tratado con láser y el segundo con un medicamento tópico entre octubre de 2020 y agosto de 2021. Los datos se recolectaron de las historias y los exámenes clínicos de las placas ungueales y se los organizó en una base de datos, cuyo análisis se realizó por medio de estadística descriptiva. **Resultados:** se identificó que el 30% y el 26% de las placas ungueales alcanzaron cura clínica en los grupos I y II, respectivamente. Al evaluar la respuesta satisfactoria, los grupos I y II presentaron 63% y 53%. **Conclusión:** el tratamiento de la onicomicosis con terapia láser presentó mayor prevalencia de respuestas satisfactoria y cura clínica que el tratamiento con medicamento tópico.

Descriptor: Enfermería; Terapia por Luz de Baja Intensidad; Fotoquimioterapia; Onicomicosis; Diabetes Mellitus

Introduction

Diabetes *Mellitus* (DM) is a chronic metabolic disease of diverse etiology characterized by hyperglycemia and associated with an absolute or relative deficiency in insulin production, secretion or action. Thus, it can interfere in the metabolism of carbohydrates, lipids and proteins.¹

Currently, Diabetes is considered a global public health problem and its complications are becoming the leading cause of morbidity and mortality in the world.² When not properly treated (mainly evidenced by high blood glucose levels for extended periods of time), DM can affect the entire body, consequently favoring the development of a series of acute and chronic complications.³

Therefore, a multiprofessional approach in the treatment of people with diabetes is fundamental to achieve favorable results. Hypoglycemia, diabetic ketoacidosis and hyperglycemic hyperosmolar syndrome are among the main acute complications. In addition, chronic complications include the following: stroke, myocardial infarction, chronic kidney disease, blindness caused by diabetic retinopathy, peripheral arterial disease, peripheral neuropathy and diabetic foot.³

Diabetic foot is related to sensory-motor and peripheral autonomic neuropathy associated with various degrees of peripheral arterial disease in the lower limbs of individuals with DM. It is characterized by the presence of tissue infection, ulceration and/or destruction.⁴

It is noted that, among the complications arising from diabetes, foot ulcers stand out as one of the main problems and challenges to be faced by health systems. In Brazil, the costs related to amputations associated with diabetes corresponded to R\$ 17.27 millions. During this same period, the hospitalization due to diabetic foot deterioration represented 17.83million dollars. This accounts for a total cost of around 48.4million reais, corresponding to between 40% and 70% of all non-traumatic lower limb amputations.⁵⁻⁶

Among the infections related to diabetic foot, fungal infections in nail plates and feet have 45.9% incidence and affect the unilateral areas of the feet. In turn, the bilateral areas are affected in around 20% of the cases.⁷ The nail plate is one of the cutaneous annexes consisting of three horizontal layers: a thin dorsal plate, an intermediate plate and a ventral layer. As for the function, the act of protecting the fingers from traumas (defense) and revealing systemic diseases stands out, mainly to preserve touch.⁸

Onychomycosis is defined as a fungal infection that affects the nails, having fungi from

genus *Trichophyton* and *Epidermophyton* and exceptionally *Microsporum* as main agents. They are more easily installed in people with peripheral circulatory disorders, decreased resistance, trauma, and maintenance factors such as profession, climate and hormonal dysfunction.⁸

It is known that the treatment route for onychomycosis is oftentimes difficult to choose. This is because a significant percentage of people with diabetes may not present favorable health conditions for the implementation of care measures through classic therapy with systemic medications (antifungal drugs). The conventional drug treatment can be divided into two: the first one is systemic via the oral route, using Terbinafine, Itraconazole and Fluconazole. In turn, the second option refers to topical administration, mainly of the Amorolfine and Ciclopirox drugs.⁹

Another non-pharmacological way to eliminate onychomycosis is Low-Level Laser Therapy (LLLT). It offers important advantages when compared to drug treatments, such as lower cost and no adverse effects.⁷

LLLT is a therapeutic instrument that consists in emitting low-power and non-ionizing electromagnetic radiation capable of acting as a biomodulator in cells and tissues. Therefore, it greatly favors the tissue repair process.¹⁰ Laser therapy has been employed as a care technology and used in the assistant practice of different health areas, including Nursing, in the care of people with diabetic foot.¹⁰

It is worth noting that the radiation emitted by low-power lasers has shown analgesic, anti-inflammatory and healing effects. Thus, it is also currently used in the tissue repair process due to the low energy density employed and its wavelength capable of penetrating the tissues.¹¹

In addition, the properties related to the control of disordered tumor cell growth and antimicrobial action are also highlighted, both achieved through Photodynamic Therapy (PDT).¹² This therapy consists of a combination of three elements: a photosensitizer, a light source and oxygen. When associated, they produce localized photo-oxidative injuries capable of acting in various pathological processes. Thus, the photosensitizers are activated by action of the light, transferring energy to molecular oxygen and promoting immediate cell death as a result of this combination.¹²⁻¹³

Bacteria and fungi are destructed due to the transfer of electrons or hydrogen, thus leading to the production of Type I free radicals. But it can also occur by energy transfer to oxygen (Type II reaction), generating *singlet* oxygen, a free radical that promotes death of the microorganism.¹⁴ Consequently, this study has the following research problem: Which is the outcome of using LLLT and topical drug treatment to eliminate onychomycosis in people with

diabetes? Therefore, the objective of this study was to describe the effects of LLLT and of topical drug treatment for onychomycosis in people with diabetes.

Method

This is a quantitative research study of the case-series type, with evaluation before and after the intervention and developed from October 2020 to August 2021 in the Clinical Podiatry Nursing Service from an outpatient complex located in a public health unit in Rio de Janeiro. It is noted that case-series studies include a description of the characteristics and outcomes among individuals in a group subjected to an intervention during a given period of time and without a Control Group.

The participants were selected by convenience among people with Type II DM treated at the Clinical Podiatry service and referred with a clinical diagnosis of onychomycosis. The eligible subjects were those that had not made use of systemic/topical antibiotics in the last 48 hours prior to entering the research protocol. People with peripheral arterial disease were excluded from the study, as well as those who were not able to perform self-care on their feet, nails and shoes due to cognitive and/or physical difficulties, and pregnant women.

The convenience sample selection technique was used for allocation to the groups. After each interview, the researchers allocated to Group I the participants who were available to attend the service for LLLT application and, to Group II, the other participants who, for displacement reasons, could not attend the locus with the necessary frequency to apply LLLT. Subsequently, they self-applied the topical medication at their homes. The people included in the study were all the users referred to this service during the research period, and there were no withdrawals or refusals regarding participation.

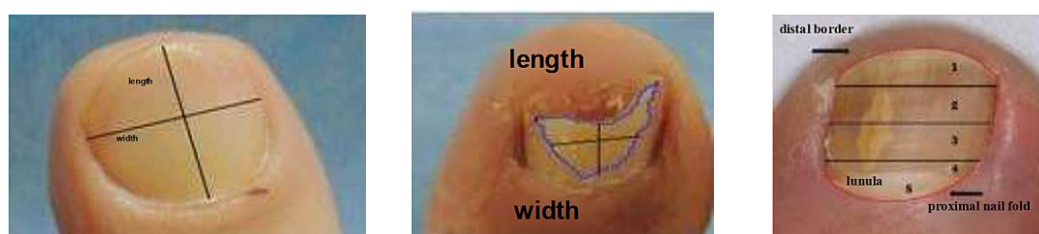
Group I consisted of 9 users who had a total of 27 nail plates with onychomycosis. They were subjected to the LLLT treatment for onychomycosis. The individuals allocated to Group II were those with diabetes who underwent onychomycosis treatment with self-application of topical medication (Ciclopirox 2% in drops), each one at their respective home. Group I consisted of 12 users who had a total of 38 nail plates with onychomycosis.

The protocol adopted was a Nursing consultation with a general clinical evaluation and recording of the following variables: age; gender; glycated hemoglobin dosage in the last 90 days; foot hygiene condition; previous treatments; and footwear care. The nail plates were evaluated

using an instrument called Onychomycosis Severity Index (OSI).¹⁵ OSI is a clinical assessment tool that is non-invasive and easy to apply to establish onychomycosis severity. Furthermore, it generates the severity index obtained by the scores corresponding to the clinical variables related to severity of the nail plate lesion produced by the fungal infection.

The first score obtained refers to the nail area affected by onychomycosis. For due determination, the total nail area was measured with the aid of a caliper and, subsequently, by measuring the affected nail area. With the results, the affected area percentage was calculated using simple rule of three. The following scoring was subsequently applied:¹⁵ from 1% to 10% of the affected area was assigned 1 point; from 11% to 25%, 2 points; from 26% to 50%, 3 points; from 51% to 75%, 4 points; and, if greater than 76%, 5 points (Figure 1).

Figure 1 - Determination of the area affected by Onychomycosis and proximity of the matrix



Source: Printed material from the Clinical Podiatry Nursing Service (2021)

The second score¹⁵ is obtained by determining the fungal lesion proximity to the nail matrix. Thus, the closer to the matrix, the more severe the onychomycosis and the higher the score. 1 point would also be assigned if onychomycosis was located in the distal $\frac{1}{4}$ of the nail, 2 points in the distal $\frac{1}{2}$, 3 points in the distal $\frac{3}{4}$, 4 points in the proximal $\frac{1}{4}$, and 5 points if it reached the matrix, as shown in Figure 1.

The third score¹⁵ is obtained by adding 10 points for presence of a longitudinal band, a spot (dermatophytoma) or for presence of subungual hyperkeratosis greater than 2 mm. After evaluating all scores, the area score value is multiplied by the matrix proximity score value to the result of this operation. Subsequently, another 10 points are assigned regarding presence of dermatophytoma and/or subungual hyperkeratosis. The result is the OSI index, which can vary between mild, with a total score of 1 to 5, moderate from 6 to 15, and severe from 16 to 35.¹⁵

After the initial evaluation, all the participants were subjected to podoprophyllaxis (podiatric technique consisting in nail plate cleaning, thinning and sanding). Its objective is to remove the parts affected by the fungal infection and provide equal conditions for penetration of the treatments proposed.

The participants allocated to Group I underwent 10 LLLT sessions with PDT therapy with a 7-day interval between each session, totaling 10 weeks of treatment. This technique consisted in applying methylene blue solution at a 0.5% concentration on the nail plate. After applying the blue dye, 5 minutes were allowed for the photosensitizing solution to be impregnated throughout the nail and LLLT was subsequently applied. An Easy Laser model laser equipment was used, patented by the Ricardo Trajano Institute in 2009 and registered at the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) under number 80030819009.

The Easy Laser equipment has 100 mw power, with simultaneous emission of red and infrared lasers. It offers red laser beam and low-power infrared laser emission and has a wavelength of 808nm and 660nm (nanometers), respectively, in continuous mode. Transmission of the lasers by means of optical fiber allows emitting a collimated and highly-directed light beam to the tissue.

Nail plate irradiation was used to perform PDT. Simultaneously, the low-power red laser beam with 660nm wavelength and 12 Joules per square centimeter dosimetry was used.

The participants allocated to Group II received 1 vial of 2% Ciclopirox olamine in drops and were instructed to apply one drop every 12h on the affected nail plate for 10 weeks. Thus, all participants were re-evaluated 6 months after performing the interventions through the OSI.¹⁵ Such period was necessary because of the slow growth of the foot nail plates of the individuals involved. The OSI assessment was performed on all study participants in both groups (pre- and post-treatment), and its score used to verify the outcome. As a result, it was possible to verify that onychomycosis can be cured with $OSI = 0$, that onychomycosis improves when $Pre-OSI > Post-OSI$, that onychomycosis is maintained when $Pre-OSI = Post-OSI$, and that onychomycosis worsens when $Pre-OSI < Post-OSI$.¹⁵

Once data collection was concluded, the results were organized in a *Microsoft Excel* 2010 database and subsequently analyzed by means of descriptive statistics. A simple data survey in the SPSS software was made to investigate the variables.

The OSI¹⁵ scores were compared before and after the treatment in each group and, subsequently, their clinical cure rates were compared. For being a descriptive research study, no statistical or significance tests were applied to compare the samples.

The study follows the recommendations set forth in Resolution No. 466/2012 of the National Health Council, which regulates research studies involving human beings. In addition, it

was submitted to the institution's Research Ethics Committee via *Plataforma Brasil*, obtaining positive opinion on April 29th, 2022, with number 5,379,029.¹⁶

Results

In groups I and II, respectively, the highest distribution by age group corresponded to individuals over 60 years old and with a frequency of 89% (n=8) and 58% (n=7). The others belonged to the adult age group from 19 to 59years old: 11% (n=1) and 42% (n=5). It is worth noting that the mean age was 66/67 years old.

It was observed that, in Group I, no individual had HbA1c > 6.5%, normality/pre-diabetes range; that 55% (n=5) had HbA1c between 6.6% to 7.5%, glycemic control range; and that 45% (n=4) had HbA1c between 7.6% to 20%, where there is no therapeutic glycemic control.⁶

In Group II, 16% (n=2) of the subjects presented HbA1c > 6.5% (normal/pre-diabetes range), 9% (n=1) had HbA1c between 6.6% to 7.5% (glycemic control range) and 75% (n=9) had HbA1c between 7.6% to 20%, where there is also no therapeutic glycemic control.

In Group II, it was verified that more than 70% of the participants presented uncontrolled glycaemia. However, it should be noted that the population included in this group is greater than that of the first one, as can be seen in Table 1, which shows the characteristics related to the nail changes presented by the individuals in both groups:

Table 1- Characteristics related to the nail lesions presented by the individuals – 2022.

Description	Group I (n=9)		Group II (n=12)	
	n	%	n	%
Foot hygiene condition				
Good	8	85	7	60
Reasonable	1	15	5	40
Bad	-	-	-	-
Shoe hygiene performed				
Yes	7	78	2	26
No	2	22	10	74

When analyzing the characteristics presented in Table 1, which corresponds to the performance of a previous treatment for the injuries, Group II displays a higher percentage of individuals who have already undergone it in relation to Group I. In relation to the hygiene condition and to performing footwear hygiene procedures, the population included in Group I

presents higher rates of foot hygiene and footwear cleaning habit when compared to Group II. Table 2 below evidences the changes in the nail plates before and after the treatments.

Table 2 - Nail plate changes before and after the interventions – 2022.

Changes	Group I (Pre)		Group I (Post)		Group II (Pre)		Group II (Post)	
	n	%	n	%	n	%	n	%
Dystrophy	20	93	10	46	38	100	13	25
Detachment	18	67	6	22	21	55	22	58
Altered Color	27	100	11	41	37	97	28	27

When analyzing the changes found in the nail plates in both groups, before and after the interventions proposed, it was identified that nail dystrophies presented a reduction after applying both interventions. The reduction in groups I and II were 50% and 34%, respectively.

As for nail detachment, it was verified that Group I presented a 66% reduction to the proportion that there was a 4% increase in Group II. Regarding color change, the percentage from Group I had a 60% reduction while a 25% drop was recorded in Group II.

After comparing the data referring to the changes found in the nail plates in the groups (after the interventions), it was possible to identify that the one subjected to laser therapy presented a greater reduction proportion in the changes when compared to the drug treatment.

Table 3 shows the Onychomycosis Severity Index comparison in both groups before and after the interventions proposed.

Table 3 - Onychomycosis Severity Index before and after the interventions – 2022.

Index	OSI (PRE)		OSI (POST)	
	n	%	n	%
Group I (n=27)				
Clinical Cure	-	-	8	30
Mild Severity	2	7	1	4
Moderate Severity	4	15	6	22
Extreme Severity	21	78	12	44
Group II (n=38)				
Clinical Cure	-	-	10	26
Mild Severity	9	24	6	16
Moderate Severity	4	10	6	16
Extreme Severity	25	66	16	42

When analyzing OSI after the interventions, it was identified that groups I and II achieved a cure, according to OSI. In other words, nearly 30% of the nail plates treated in the first group had satisfactory clinical results. Similar success was noticed in the second: nearly 26%. Another relevant data when assessing the post-intervention OSI values in the groups refers to extreme severity. In these cases, the intervention performed in Group I promotes a 34% reduction, whereas the reduction was around 24% in Group II.

To demonstrate the response obtained after performing the interventions in each group, and using the OSI values obtained after the treatment as a metric, the responses to the interventions were grouped. The nail plates that presented OSI = 0 (clinical cure) and/or a score reduction after the intervention were categorized as satisfactory responses to the intervention. Those that maintained the OSI values or presented an increase in the post-intervention scores were categorized as not satisfactory response to the intervention. Table 4 describes the results obtained.

Table4 - Comparison of the response to the intervention between Group I(n=27) and Group II (n=38) – 2022.

Response	Group I		Group II	
	n	%	n	%
Satisfactory	17	63	20	53
Not satisfactory	10	37	18	47

It was evidenced that there was prevalence of satisfactory responses in both groups. In Group I, for example, favorable results were found in 63% of the plates treated. In Group II, which corresponds to 53% of the participants, a higher frequency of beneficial effects was observed in individuals who underwent laser therapy than among those who were subjected to topical drug treatment.

Discussion

The most prevalent age segment in both groups corresponded to elder participants. This is due to the fact that 50% of them have Type 2 DM and are over 60 years old. This fact is important, as physiological debilitations take place as a result of aging.¹⁷⁻¹⁸

Another detail to be added is the occurrence of mycoses. For example: nearly 10% of the general population is affected by onychomycosis. Of them, 20% are aged over 60 years old and 50% of the people affected are at least 70 years old.¹⁹

Regarding adequate control of the glucose levels, absence of glycemic control is related to low adherence to the treatment. A study²⁰ shows that 38% of the patients involved did not adhere to the drug treatment and that 28% were not adherent to the full treatment (drug plus non-drug).

A research study²¹ highlights the importance of glycemic control, as decompensated diabetics are more likely to suffer micro- and macro-vascular complications. Thus, they are more susceptible to infections such as onychomycosis, as they can also show deficits in their immune system.²²

In addition, footwear hygiene is highlighted as one of the main preventive measures against onychomycosis reinfections.²³ Foot hygiene is also a strong ally in the treatment of fungal contamination in older adults. In some cases, it is even the only viable treatment since, due to financial problems, topical medications are oftentimes very expensive. In addition to that, there is also each user's clinical issue, something that precludes drug interaction and use of systemic medications.²⁴

This research that investigated onychomycosis showed that the participants from both groups presented clinical signs of the disease before the treatment. Nail dystrophy, onycholysis (separation of the nails from the nail bed), color change, frailty and thickening of the nails are some of these signs.⁸

In conjunction with a compatible photosensitizer and in the presence of oxygen, LLLT

chemically produces by-products. Thus, Reactive Oxygen Species (ROS) acting on cell membranes increase their permeability, penetrate the fungal cells, and cause damage to other intracellular organelles.²⁵

Ciclopirox acts by inhibiting the metal-dependent enzymes. In this way, there is damage to ion transport through the cytoplasmic membrane, to degradation of toxic peroxides, to nutrient intake, and to protein and nucleic acid biosynthesis.²⁶

A research study²⁷ compared the use of high-frequency waves and laser in the onychomycosis treatment. The laser used was Flash Lase III (with 660 nm wave emission) and the photosensitizer was 0.5% methylene blue. It was concluded that users treated with PDT had visible improvements immediately after the second application. Thus, it enhanced efficacy and advantage of the treatment and corroborated this study, as it benefited the nails affected by onychomycosis and treated with LLLT.

It is also worth mentioning that the research used an Nd:YAG 1064 laser, whose result was 63% clinical improvement 3 months after the last session. Therefore, it highlights laser as a safe and effective treatment with no significant adverse effects and well-accepted by the participants.²⁸ Another research study evaluated 40 participants with onychomycosis who were treated with Ciclopirox. It was verified that 22% achieved complete cure (clinical and mycological) after 9 months of treatment. Unfortunately, despite the low cure percentage, the authors indicate the medication as a viable option for participants who cannot tolerate the systemic treatment.²⁹

As limitations, we should emphasize that the participants from Group II were not monitored periodically and weekly as Group I. Therefore, it can be inferred that they would have more clarifications regarding daily foot care than those from Group II. Thus, this may have had repercussions on the study result for Group I with a higher clinical cure rate. Consequently, the comparison of heterogeneous groups can exert an influence on the results. In addition to that, the research does not intend to generalize its results, suggesting other surveys in different settings and contexts.

This study sought to describe the results obtained in the onychomycosis treatment in people with diabetes by means of LLLT and topical drug treatment. The objective was also to enhance care quality for this clientele and to direct, in a scientific way, the assistance provided by nurses specialized in Podiatry. It is noted that Clinical Podiatry emerged in Brazil from 2007 with the leading role of Nursing through the creation of the 1st Specialization Course at *Universidade Federal de São Paulo* (UNIFESP).

Podiatric nurses (specialized in Clinical Podiatry) play an indisputable role in the evaluation of lower limbs, as indicated in the guidelines on diabetic foot prevention and treatment. Additionally, in order to promote health through early diagnosis, analyzing the signs and symptoms with prudence and responsibility is *a sine qua non* condition for success. In other words, it is necessary for professionals to be able to expand the capacity to mobilize and solve complications resulting from diseases (whether acute or chronic); and, thus, minimize the implications that could result in possible amputations.¹⁰

Another benefit of this study is the fact that it generates subsidies for future research on LLLT in the Clinical Nursing practice for people with diabetes. Consequently, it will be possible to show to Nursing professionals the importance of LLLT as a therapeutic instrument, as it provides specialized, effective and economically more viable Nursing assistance when compared to other technologies.

Conclusion

Given the above, when describing the results obtained with LLLT and the use of topical medication in onychomycosis in people with diabetes, it was verified that the laser therapy presented higher prevalence of satisfactory responses and clinical cure than the topical medication treatment in the groups investigated.

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