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Vascular Systemic Photobiomodulation on Blood Pressure, Capillary Glucose, Pain Level and Oxygen Saturation in Individuals with Diabetic Foot

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Abstract: *Diabetic foot is one of the complications caused by Diabetes Mellitus, which leads to severe damage to the patient, such as chronic wounds, infections, and in some cases, even foot amputation. Among complementary treatment modalities, vascular systemic photobiomodulation of the Intravascular Laser Irradiation of Blood (ILIB) type stands out, which has systemic effects that may contribute to improvements in cases of diabetic foot. Thus, the objective of this study was to evaluate the effects of ILIB on blood pressure, capillary blood glucose, pain level, and oxygen saturation in individuals with diabetic foot. This is a longitudinal study with a quantitative approach, approved by the Human Research Ethics Committee of the Federal University of Maranhão, under opinion number 5.219.607. The study was conducted at the Vascular Clinic of the Municipal Hospital of Imperatriz. Initially, the sociodemographic and clinical questionnaire was applied, and data related to blood pressure, capillary blood glucose, pain level, and oxygen saturation were collected before and after the ten sessions of vascular systemic photobiomodulation, using 660 nm wavelength, 100 mW output power, and 30-minute application time. Results: The results showed that after ten ILIB sessions, there was a significant improvement in systolic blood pressure and heart rate, but no significant changes were observed in the other parameters. Final considerations: It is concluded that the modified ILIB applied to individuals with diabetic foot is effective in reducing systolic pressure and heart rate.*

Key Word*: Diabetes Mellitus. Diabetic Foot. Low Intensity Light Therapy.*

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I. Introduction

Diabetes Mellitus (DM) is characterized by a chronic metabolic disorder whose main characteristic is high levels of capillary glucose for long periods of time. DM originates from the impairment of insulin production by pancreatic beta cells present in the liver or from defects in insulin receptors that prevent the use of the insulin produced. This metabolic syndrome is divided into subgroups: type 1 DM, type 2 DM and gestational DM (ARRIGOTTI *et al*., 2022).

Brazil is the fourth country in the world with the highest number of people with DM, and according to recent estimates, 14.3 million people currently have the disease. In addition to chronic hyperglycemia, the accumulation of harmful behaviors such as smoking, alcoholism, inadequate diet and sedentary lifestyle corroborate increasingly worrying projections about DM (SENTEIO*et al*., 2018). In 2015, 5 million deaths in the world were caused by DM, which corresponds to 1 death every 6 seconds. By the year 2040, it is estimated that 642 million people will develop the disease (SILVA *et al.,* 2023).

Among the complications resulting from DM, diabetic foot is among those that deserve greater attention. This is because complications from diabetic foot are responsible for up to 70% of all lower limb amputations. Such a complication is an alarming factor, since the mortality rate increases and impairs the individual's quality of life, both physical and mental (SILVA *et al.,* 2023).

Complications in DM result from uncontrolled blood glucose levels in the bloodstream. Chronic hyperglycemia leads to endothelial inflammation that results in an increase in advanced glycation end products, which promotes oxidative stress, triggering vascular complications and the appearance of specific lesions, in diabetic individuals (CASTRO et al., 2021).

The complications of DM are divided into vascular complications. In microvascular complications, diabetic nephropathy, diabetic retinopathy, diabetic neuropathy and vascular complications in the lower limbs are noted. Macrovascular complications, in turn, are associated with hyperglycemia and risk factors such as obesity, smoking, and hypertension that lead to stroke, acute myocardial infarction, and peripheral arterial obstructive disease (PAD) (SBD, 2019).

Diabetic foot comes as a consequence of Diabetic Neuropathy (DN), which causes the loss of painful and thermal sensitivity. Therefore, this condition favors the occurrence of trauma and ulcerations that result in diabetic foot. The diabetic foot is caused, in addition to DN, by peripheral arterial obstructive disease and infections that form the triad of the diabetic foot (MOREIRA, 2020).

Vascular systemic photobiomodulation by *Intravascular Laser Irradiation of Blood* (ILIB) It is a photobiomodulation modality that radiates laser into the blood through an optical fiber positioned under a blood vessel, usually a vein in the forearm. Irradiation lasts approximately 30 minutes, which is believed to be sufficient to expose whole blood to light, producing systemic effects. Due to its systemic effects, modified ILIB improves body functioning, through a modulation of venous blood, decreases the glucose levels in the bloodstream, better irrigation to the tissues, maintenance of the homeostasis of pressure levels and thus helps in tissue repair and pain control (MENEGUZZO*et al.*, 2016).

Based on the above, this study aimed to evaluate the effects of ILIB blood pressure, capillary glucose, pain level and oxygen saturation in individuals with diabetic foot.

II. Material And Methods

This is a longitudinal study, with a quantitative approach, which is part of an umbrella project approved by the Human Research Ethics Committee of the Federal University of Maranhão, through opinion no.: 5.219.607 and CAAE: 54895021.1.0000.5086.

The study population consisted of all diabetic patients with diabetic foot ulcers treated at the Vascular Clinic of the Municipal Hospital of Imperatriz. The sample consisted of 07 (seven), by non-probabilistic inclusion, by convenience, by

Those aged 18 years or older were included; clinical diagnosis of type II diabetes; being followed up at the study site; presence of ulcer in the foot region; preserved cognitive capacity, assessed with the aid of the mini mental state examination (MEEN). Smokers; Alcoholic; Neuromuscular or musculoskeletal diseases; PAOD, determined by measuring the ankle-brachial index (ABI) less than 0.90; conditions that contraindicate photobiomodulation, such as: pregnancy, sensitivity, cancer, glaucoma, undiagnosed lesions, sepsis, infection at the application site, use of pacemaker, electronic and/or metallic implant at the application site, and use of corticosteroids and antibiotics.

Data collection took place from April 2022 to January 2023. The participants were recruited through a verbal invitation, where they received all the information of the study. Including the need to fast from food for 12 hours. Upon acceptance, they were instructed to sign the Free and Informed Consent Form, after this act, the questionnaires were applied and later the intervention.

A sociodemographic and clinical questionnaire was used to investigate information such as: age, gender, years of schooling, skin color, marital status, socioeconomic level and occupation. In addition, we sought to evaluate the clinical condition such as: presence of comorbidities, medications in use, social, medical and surgical history, time of diagnosis of diabetes, time of ulceration, weight, height and Body Mass Index (BMI) and as well as lifestyle habits. With a 10-minute rest, the variables described below were collected over the ten sessions, always before and after the intervention.

The level of pain was assessed using the Numerical Estimation Scale, which has numerical ranges from 0 to 10, where zero represents no pain and 10 represents unbearable pain. To measure blood pressure, the auscultatory method with a sphygmomanometer (BD,® Brazil) and stethoscope (BD,® Brazil) was used to measure systolic (SBP) and diastolic (DBP) blood pressure.

Oxygen saturation and heart rate were obtained using an oximeter. The oximeter sensor was placed on the participant's middle finger or thumb, it is important to note that the finger chosen for measurement with the oximeter did not contain nail polish. The value was recorded after 3 minutes of positioning the oximeter on the participant's finger.

Capillary glucose was monitored in the fasting state, with a digital glucometer (ACCU – CHEK®), ACCU - CHEK® lancing device and respective lancets, graded from 1 to 5 in increasing degrees of skin penetration depth. Grade 5 was standardized for the study.

To carry out the study intervention, the Therapy EC laser model of DMC® Equipamentos Ltda, registered with Anvisa under No. 80030810156, with a red spectrum with a semiconductor diode that emits a wavelength of 660 nm, useful power of 100 mW, cross-sectional area of the beam of 0.0434cm², with continuous emission mode, was used. In a period of ten days, lasting 30 minutes.

During the irradiations, procedure gloves, protective goggles for the participant and the researcher were used, and the participant's forearm was wrapped in transparent and disposable polyvinyl chloride (PVC) film, to avoid direct contact with the laser pen and the application bracelet. After each application, the pen and bracelet were cleaned with 70% alcohol.

The data collected through questionnaires were organized in the Microsoft Excel program. For statistical analysis, the BioEstat 5.0 program was used with the t-test and ANOVA, with a significance level of 0.05.

III. Result

Table 1. Characterization of the participants according to socioeconomic variables (n=7). Imperatriz, Brazil, 2023.

Variables		n	%
Sex	Male	5	71,4
	Female	2	28,6
Race	White	1	14,3
	Black	0	0,0
	Brown	5	71,4
	Yellow	0	0,0
	Indigenous	1	14,3
Schooling	Illiterate	3	42,9
	Complete elementary school	2	28,6
	Incomplete elementary school	1	14,3
	Incomplete high school	1	14,3
Marital status	With partner	3	42,9
	No companion	4	57,1
Profession	Retired	0	0,0
	Autonomous	3	42,9
	Housewife	2	28,6
	Watchful	1	14,3
	Unemployed	1	14,3
	Taxi driver	0	0,0
Income	No income	3	42,9
	Up to 1 salary	2	28,6
	Between 1 and 2 salaries	2	28,6
City	Other cities	0	0,0
	Empress	7	100,0
Variable	**Medium (±SD)**		
Age (years)	56 (±11)		

Among the participants, 5 were male and 2 female, the mean age of the participants was 56 years and all were from the city of Imperatriz, MA. About the level of education, 3 of the participants were illiterate, 1 had incomplete elementary school, 2 had completed elementary school, and finally, 1 had incomplete high school. Regarding marital status, 3 of the participants stated that they had a stable union/were married, while 4 of the participants reported being single. Regarding income, in the study period the current minimum wage was R$ 1212.00 (one thousand two hundred and twelve reais) and 2 of the participants had an income of up to one minimum wage, 2 had an income of one to two minimum wages and 3 had no income. That said, 3 reported being self-employed, 2 are housewives, 1 is a security guard and 1 was unemployed.

Table 2. Characterization of the participants according to clinical variables and lifestyle habits (n=7). Imperatriz/Brazil, 2023.

Variables		n	%
Drug treatment	Oral hypoglycaemic	6	85,7
	Insulin	0	0,0
	Both	1	14,3
Presence of SAH	No	4	57,1
	Yes	3	42,9
Presence of hypercholesterolemia	No	5	71,4
	Yes	2	28,6
BMI	Normal (18.6 to 24.9)	4	57,1
	Overweight (25 to 29.9)	1	14,3
	Obesity (>30)	2	28,6
Ambulation	No ambulation	3	42,9
	With help	0	0,0
	Wheelchair	0	0,0
	Lameness	4	57,1
Former smoker	No	4	57,1
	Yes	3	42,9
Former drinker	No	4	57,1

Daily water intake	Yes	3	42,9
	3 to 5 glasses	1	14,3
	More than 5 cups	6	85,7
Hypoglycemic diet	No	4	57,1
	Yes	3	42,9
Physical activity	No	6	85,7
	Yes	1	14,3
Complications of diabetes	No	1	14,3
	Yes	6	85,7

In Table 2, regarding the treatment of diabetes mellitus, 6 of the participants reported using only oral hypoglycemic agents, while 1 reported using both oral hypoglycemic agents and insulin. With regard to comorbidities, 5 of the participants reported that they did not have systemic arterial hypertension, while 3 reported that they were hypertensive. Furthermore, more than half of the sample 5 participants did not have hypercholesterolemia, while only 2 had this metabolic condition. Regarding the Body Mass Index (BMI), 4 of the participants were normal weight, 1 was overweight and 2 were obese. Regarding ambulation, 3 of the participants were not walking, however, 4 were presenting a limping gait.

Regarding lifestyle habits, 3 reported not having alcohol habits or smoking habits. The participants in general, 6 had a good daily water intake, with a parameter of intake of more than 5 glasses of water. However, a worrying data collected is due to the fact that 4 of the participants did not adhere to a hypoglycemic diet, which corroborates the worsening of the diabetes condition. In addition, 6 reported not being adept at physical activity, and this same percentage of participants had micro or macrovascular complications of diabetes. In the population sample of this study, the mean time since diagnosis of diabetes was 11 years.

Table 3. Comparison of pre- and post-intervention variables throughout treatment

Variables	**Day 01**		**Day 05**		**Day 06**		**Day 10**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
[a]HR	**77.28**	**82,85**	**82,57**	**83,85**	**77,00**	**78,42**	**79,85**	**78,57**
p	**0,05**		**0,12**		**0,39**		**0,32**	
[b]O_2S	**98,28**	**98,00**	**98,00**	**98,42**	**97,16**	**98,33**	**98,57**	**97,85**
p	**0,22**		**0,09**		**0,21**		**0,07**	
[c]SP	**132,85**	**127,14**	**125,71**	**125,71**	**126,66**	**126,66**	**127,14**	**118,57**
p	**0,01**		**0,50**		**0,50**		**0,03**	
[d]DP	**84,28**	**78,57**	**85,71**	**84,28**	**85,00**	**86,66**	**77,14**	**82,85**
p	**0,08**		**0,34**		**0,18**		**0,05**	
Glucose	**217,71**	**204,00**	**217,71**	**222,71**	**208,50**	**209,16**	**233,85**	**234,14**
p	**0,04**		**0,25**		**0,35**		**0,48**	
Pain	**1,28**	**0,71**	**3,00**	**2,28**	**1,50**	**3,25**	**1,28**	**1,28**
p	**0,17**		**0,07**		**0,16**		**0,50**	

Legend: [a]Heart Rate. [b]Oxygen Saturation. [c]Systolic Pressure. [d]Diastolic Pressure.

Table 04. Comparison of the pre- and post-intervention variables of day 01 and 05.

Variable	**Day 01 Pre**	**Day 05 Post**	**p**
[a]HR	77,28	83,85	0,01
[b]O_2S	98,28	98,42	0,34
[c]SP	132,85	125,71	0,07
[d]DP	84,28	84,28	0,50
Glucose	217,71	222,71	0,34
Pain	1,28	2,28	0,24

Legend: [a]Heart Rate. [b]Oxygen Saturation. [c]Systolic Pressure. [d]Diastolic Pressure.

In Table 4, the variables of the first day before the ILIB compared with the fifth day after the application of the ILIB, in the heart rate parameter the p-value was 0.01, indicating a statistically significant change. On the other hand, in the variables of oxygen saturation and capillary glucose, the P value was 0.34. Regarding systolic pressure, the P value was 0.07, but the P value in diastolic pressure was 0.50. Regarding the level of pain, the P value was 0.24.

Table 05. Comparison of the pre- and post-intervention variables of day 06 and 10.

Variable	Day 06 Pre	Day 10 Post	p
[a]**HR**	**77,00**	78,57	0,22
[b]**O_2S**	97,16	97,85	0,33
[c]**SP**	126,66	118,57	0,23
[d]**DP**	85,00	82,85	0,50
Glucose	208,50	234,1	0,18
Pain	1,50	1,28	0,50

Legend: [a]Heart Rate. [b]Oxygen Saturation. [c]Systolic Pressure. [d]Diastolic Pressure.

In Table 5, withrespect to the variables analyzed, when we compare the data collected on the sixth day before ILIB (Intravenous Laser Irradiation) with those on the tenth day after ILIB, we observed that there were no significant changes in any of the parameters evaluated. Specifically, the p-value for heart rate was 0.22, indicating that the variations were not statistically significant. Regarding oxygen saturation, the p-value was 0.33, also with no evidence of a relevant change.

Systolic blood pressure showed a p-value of 0.23, while diastolic blood pressure remained at 0.50, demonstrating that there were no changes in both parameters. In addition, capillary glucose presented a p-value of 0.18, and in relation to the pain reported by the patients, the p-value was 0.50, confirming the absence of significant changes after treatment. These results indicate that, under the conditions of the study, the ILIB did not promote measurable changes in these physiological variables.

Table 06. Comparison of the pre- and post-intervention variables of day 01 and 10.

Variable	Day 01 Pre	Day 10 Post	p
[a]**HR**	77,28	78,57	0,35
[b]**O_2S**	98,28	97,85	0,09
[c]**SP**	132,85	118,57	0,04
[d]**DP**	84,28	82,85	0,30
Glucose	217,71	234,1	0,25
Pain	1,28	1,28	0,50

Legend: [a]Heart Rate. [b]Oxygen Saturation. [c]Systolic Pressure. [d]Diastolic Pressure.

In Table 6, in relation to the variables analyzed, when comparing the data from the first day before ILIB (Intravenous Laser Irradiation) with the results obtained on the tenth day after the application of ILIB, we observed the following results: for the heart rate parameter, the p-value was 0.35, indicating that there were no significant changes. Regarding oxygen saturation, the p-value was 0.09, which also does not suggest a significant difference. Notably, systolic blood pressure showed a p-value of 0.04, indicating a statistically significant change. On the other hand, diastolic blood pressure had a p-value of 0.30. Regarding capillary glucose, the p-value was 0.25, with no evidence of alteration. Finally, in relation to the pain reported by the patients, the p-value was 0.50, indicating that there were no relevant changes. These results reinforce that, with the exception of systolic blood pressure, the other variables evaluated did not show statistically significant variations after treatment with ILIB.

IV. Discussion

The findings of this study sought to evaluate the effects of intravascular blood irradiation with laser (modified ILIB) on blood pressure, capillary glucose, pain level and oxygen saturation in individuals with diabetic foot, and to analyze the sociodemographic and clinical profile of 7 participants who were undergoing treatment for diabetic foot ulcer at the study site.

The largest portion of the individuals in this study were men, representing 71.4% of the total participants, and who had a mean age of 56 years. This finding is antagonistic to the report by Arrigoti et al. (2022) who, in their study with 2110 people with a predominance of DM 2 and risk of foot ulcers, had their study composed mainly of women and the mean age was 64 years. In addition, 71.4% of the participants in this research reported being of brown race. On the other hand, Senteio et al. (2018) in their research reported that 71.8% of the participants were white.

Regarding the level of education, 71.4% of the participants were either illiterate or had only incomplete elementary school, characterizing a low level of education for most of the research participants. This data is in line with what Rocha et al. (2022) reported in their research, in which most participants had a low level of education with only complete elementary school. The low level of education is an important fact, since it directly corroborates a higher risk of developing diabetic neuropathy (Arrigotti, 2022).

Regarding comorbidities, 42.9% of the research participants had systemic arterial hypertension (SAH) and were overweight or already obese. In a study conducted by Lira et al. (2021) it was identified that individuals who had these two comorbidities had a higher risk of developing diabetic foot.

Another relevant factor concerns the non-adherence to a hypoglycemic diet by the 57.1% of the individuals participating in the research. This data is worrisome, as non-adherence to a hypoglycemic diet is an aggravating factor for the risk of developing diabetic foot. This factor is usually linked to low economic power that hinders access to adequate food for better glycemic control (Silva, 2017).

With regard to diabetes complications, 85.7% of the research participants had some complication such as retinopathy and paresthesia. Silva (2017) reported in his research that complications such as retinopathy increase the risk of amputations in patients with DM.

Regarding blood glucose control with the use of ILIB-Modified, this study did not find significant improvement in this parameter. Confidence intervals of 95% and a significance level of $p < 0.05$ were used. These findings are in line with those found by Junior (2019), who, in order to evaluate the effectiveness of ILIB-Modified in glycemic control, analyzed the variation in the percentage of glycated hemoglobin. The test group of this study, in addition to the conventional treatment, received ten laser applications using the ILIB-Modified technique. However, the patients did not show improvement, as glycated hemoglobin remained at 8.15%.

The absence of a significant response in improving glycemic control through the application of the ILIB-Modified laser can be explained by some factors, such as limitations in the absorption and reflection of light on the skin, affecting the effectiveness of this technique. The red light beam emitted by the laser can lose part of its properties, such as collimation, which is the ability of the light beam to travel long distances without spreading significantly. In this way, when passing through the skin, the irradiation can both be reflected and spread to neighboring tissues. Therefore, the sum of all these factors corroborates the decrease in the efficacy of ILIB-Modified in glycemic control in patients with type 2 diabetes mellitus.

In this study, ILIB-Modified was shown to be effective in improving blood pressure levels. However, the improvement occurred only in systolic blood pressure, while diastolic blood pressure did not show significant improvement. The results showed a significant improvement in systolic blood pressure, with a p-value of 0.04 in the comparison between the first day before the laser application and the tenth day after the application.

These findings are in line with those found by Lizarelli et al. (2021), in a study composed of 36 women divided into 6 groups, with transcutaneous and transmucosal laser applications. Measurements were taken before treatment, after 30 days, and after 60 days. Among the 6 groups, groups 4 and 6 responded better to the ILIB-Modified technique. In group 4, transmucosal sublingual irradiation was performed, while in group 6, extended transcutaneous irradiation of the radial artery was performed. The efficacy of ILIB-Modified in controlling blood pressure is primarily due to its ability to reduce peripheral vascular resistance. This is because, in this same study, it was shown that ILIB-Modified is able to significantly reduce ($p < 0.05$) cholesterol and triglyceride levels, improving blood flow.

Regarding the improvement of the pain score, this study did not find a significant improvement. In the analyses performed before and after laser application using the ILIB-Modified technique, no p-value was found < 0.05. However, these data are in contrast to those found by Leal et al., (2020), who in their study showed that the Modified ILI was able to bring significant results both in pain score ($p = 0.006$) and in functional capacity ($p = 0.006$) and improvement in the physical limitations that pain caused ($p = 0.005$). ILIB works by blocking cyclooxygenase, an enzyme responsible for breaking down arachidonic acid into prostaglandins, which is mainly responsible for sensitizing nociceptors to pain stimulation.

ILIB-Modified has shown efficacy in improving heart rate. This data is proven by comparing the first day before application with the fifth day after laser application. On the other hand, Filho (2019), in his research with hypertensive obese rats, did not find a significant improvement in heart rate with the use of ILIB-Modified. However, although ILIB-Modified in this study was shown to be effective in lowering blood pressure, it is suggested that this reduction in blood pressure levels was caused by the increase in nitric oxide and the decrease

in inflammatory cytokines. These factors act to reduce peripheral vascular resistance, but did not significantly alter heart rate.

The use of Modified ILIB was not effective in improving saturation, with a $p > 0.05$ in all comparisons analyzed in this study. However, Trindade et al. (2023), in their research with 42 caregivers of the elderly, in which they were divided into 6 groups, one of which received the application of the ILIB-Modified on alternate days for 2 weeks, totaling 8 sessions. In this study, systemic photobiomodulation was able to promote cellular antioxidant action, increasing oxygen uptake and transport by red blood cells.

V. Conclusion

The study evaluated the effects of vascular systemic photobiomodulation of the Intravascular Laser Irradiation of Blood (ILIB) type, on blood pressure, capillary glucose, pain level, oxygen saturation and heart rate in individuals with diabetic foot. The research was carried out with seven participants, predominantly men, with an average age of 56 years. The results showed that ILIB was effective in reducing systolic blood pressure and improving heart rate, but did not show significant improvements in diastolic pressure, capillary glucose, pain level, or oxygen saturation. In conclusion, ILIB demonstrated limited efficacy, being most notable in reducing systolic blood pressure and heart rate, but with no significant impact on the other variables evaluated.

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