


Effect of transcutaneous irradiation under the radial artery on hemodynamic variables in hypertensive patients: Double-blind clinical study

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ABSTRACT

Systemic Arterial Hypertension (SAH) is a multifactorial clinical condition, with a high rate of morbidity and mortality and low control rates. Although photobiomodulation (FBM) is capable of inducing a photobiological interaction inside cells and modifying the micro and macrovascular response *in situ*, there is a lack of studies that evidence its systemic effect, especially clinical and placebo controlled. Thus, this study aimed to evaluate the modulatory effects on blood pressure control in hypertensive patients after transcutaneous photobiomodulation of the radial artery. To this end, 44 participants were randomly divided into 4 groups, one group irradiated for 60 minutes a day, for 5 days, being repeated after 20 days with a total of 3 cycles (Group A), and their respective placebo (Group B); the third group was irradiated for 30 minutes a day, for 10 days, and repeated after 20 days, also totaling 3 cycles (Group C), and their respective placebo (Group D). All participants remained with previously instituted conventional drug treatment. Before the interventions, after each cycle and at the end of the interventions, blood pressure and heart rate were measured. Before and at the end of the interventions, blood samples were collected to measure interleukins 6 and 1beta. Statistical analysis was performed to compare the groups in each phase of treatment, with $\alpha=0.05$. Modulatory effects were evidenced in the control of blood pressure in hypertensive patients after photobiomodulation. Group A showed a better response to the reduction of hemodynamic variables than group C. Multidisciplinary care may have increased the adherence to treatment of all participants, including the placebo groups, which also showed a decrease in the values of hemodynamic variables.

Keywords: Photobiomodulation, Systemic arterial hypertension, Hemodynamic variables, Low-level laser.



INTRODUCTION

Systemic Arterial Hypertension (SAH) is currently a risk factor for the development of cardiovascular diseases (CVD) and associated with the aging process, because as we age the risk of developing SAH increases alarmingly. SAH is a chronic non-communicable disease (NCD) of multifactorial origin, with high prevalence and low control rates, characterized by high and sustained levels of systolic and/or diastolic blood pressure (BP), ≥ 140 mmHg and/or 90 mmHg, respectively, and by metabolic alterations leading to the risk of cardiovascular complications, which may be aggravated if accompanied by other risk factors for cardiovascular disease, such as diabetes and hypercholesterolemia. Hypertension is characterized by high and sustained levels of systolic and/or diastolic blood pressure (BP), ≥ 140 mmHg and/or 90 mmHg, respectively, and by metabolic alterations leading to the risk of cardiovascular complications, which is aggravated by the association of other risk factors (RF) for cardiovascular disease (Nobre, 2013 *et al*, 2013); (Bernardi *et al*, 2023); (Amaral Moreira-Mota, 2023).

According to studies by the Global Burden of Diseases (GBD) there is a forecast of about 10.8 million annual deaths and 235 million years of disability-adjusted lives lost related to high blood pressure, unfortunately a silent disease. (DALYs – *Disability Adjusted Life Years* (Liu *et al*, 2023); (Buso *et al*, 2024).

Considered a global public health problem, this disease affects more than 1.2 billion people worldwide, 70 million people in the United States, causing 9.4 million deaths each year worldwide (Lim *et al*, 20122). According to the VII Brazilian Guidelines on Hypertension (2016), it is a chronic non-communicable disease, representing high levels of mortality in the world and can account for up to 75% of deaths in countries in the Americas and the Caribbean (Barroso *et al*, 2021)

The presence of SAH is a condition resulting from genetic/epigenetic, environmental, social, cultural and lifestyle factors³. Among the modifiable risk factors for hypertension are unhealthy diets, characterized by excessive salt consumption, diet rich in saturated fat and trans fats, low consumption of fruits and vegetables; Sedentary lifestyle; tobacco and alcohol consumption and overweight or obesity³. Non-modifiable risk factors include a family history of hypertension, age over 65 years, and coexisting diseases such as diabetes mellitus or kidney disease ((WHO< 2013); (Weber *et al*, 2014); (Oigman, 1987); (Miranda, 2023)

Hypertension has a significant impact on health and socioeconomic costs worldwide, especially in developed countries, where the use of processed foods is common. Regarding the complications of SAH can occur in the target organs, such as the heart (coronary artery disease), heart failure, atrial fibrillation and sudden death; brain (ischemic or hemorrhagic stroke), dementia; kidneys (chronic kidney disease) and arterial system (peripheral arterial obstructive disease) (Siqueira, 2023); (Malta *et al*, 2023).

Regarding hemodynamic variables, hemodynamics can be defined as the area of pathophysiology that is dedicated to the study of circulatory movements and the forces involved in blood circulation. Generally, blood pressure values depend on its fundamental hemodynamic variables: total systemic blood flow (cardiac output) and the resistance offered by blood vessels (Oigman, 1987); (Silva *et al*, 2020).

Blood pressure is determined by the product of cardiac output (CO) by peripheral vascular resistance (PVR). The manifestation of SAH is necessarily related to changes in these parameters (Matozinhos, 2011 *et al*); (Junior *et al*, 2006); (Winlansky *et al*, 2006).

Cardiac output is determined by the product between heart rate (HR) and stroke volume (SV). The increase or decrease of these factors can directly influence the blood pressure value. Circulating blood volume is a determining factor in stroke volume, which depends directly on sodium concentrations. Heart rate control can be influenced by neurological, endocrine and cardiac factors (Matozinhos, 2011 *et al*); (Winlansky *et al*, 2006).

When it comes to the treatment of SAH, it is done through a combination of non-pharmacological and pharmacological treatment, where the first includes the risk of SAH and CVD and the implementation of strategies that can reverse or prevent the progression of these factors, implying mainly in the change of the patient's lifestyle, regardless of blood pressure levels (Batista, et as, 2022); (Barrosos *et al*, 2021).

Adherence to treatment consists of accepting adherence to treatment by following the guidelines of the health professional who attended him. Such guidelines include the prescription or not of drugs, dietary measures, lifestyle changes, such as smoking and alcohol cessation, weight control, and encouragement of regular physical activity (Batista, et as, 2022); (Silva *et al*, 2022); (Haynes *et al*, 2021).

As non-adherence is identified as the main cause of uncontrolled arterial hypertension, which is a significant risk factor for cardiovascular events according to Araújo and Garcia, (2026), it is necessary to seek therapies that facilitate this process in order to promote improvement in the quality of life of hypertensive patients (Silva *et al*, 2022).

Low Intensity Laser (LLLT), or photobiomodulation (FBM) is a current treatment in the control of SAH, as it is capable of inducing a photobiological response inside cells, activating the production of adenosine triphosphate (ATP), nitric oxide (NO) and reactive oxygen species (ROS), also altering sodium-potassium pumps and calcium channels in cell membranes. Being a light that does not emit heat, LED (Light-Emitting Diode) and LASER (Light Amplification by Stimulated Emission of Radiation), have been the most used light sources for these experiments (Dos Santos *et al*, 2023); Koru *et at*, 1988).



Considering that blood pressure control and adherence to treatment is extremely important in the treatment of hypertension in order to minimize the aggravations and mortality rates due to cardiovascular diseases, it is necessary to seek methods that facilitate the control of this chronic disease.

The use of laser has been shown to be effective in the treatment of inflammatory diseases, however there is much to be explored about photobiomodulation so that this therapy can benefit several areas of health. There is evidence that photobiomodulation compensates for the degeneration of capillaries, in addition, it has been reported that photobiomodulation induces the release of nitric oxide from cells, which triggers vasodilation of nearby blood vessels, increasing blood and lymphatic flow (Dos Santos *et al*, 2023); (Valverde and Mitrofanis, 2022)

Recent evidence in several experimental animal models that photobiomodulation reduces hypertension. In one model, involving constriction of the renal artery, photobiomodulation generates a long-lasting hypotensive effect after a device has been implanted in the abdominal aorta. This effect is thought to be incited by a photobiomodulation-induced vasodilation following a release of nitric oxide. In another model of hypertension, involving the implantation of a cannula in the femoral artery, photobiomodulation applied externally to the abdomen considerably reduced blood pressure, together increasing serum nitric oxide levels (Colombo *et al*, 2021); (Kovalenko *et al*, 2018); (Maksimovich, 2019).

In view of the above, verifying the effects of systemic photobiomodulation on blood pressure control in hypertensive patients is promising and relevant in the current scenario, mainly with the aim of preventing health problems for patients and the consequent high cost to public health, minimizing the gaps in the literature in this area.

This study aimed to describe hemodynamic changes in hypertensive patients when treated with systemic photobiomodulation, and to evaluate whether patients diagnosed as hypertensive were affected by any comorbidity/complication due to post-photobiomodulation SAH.

METHOD

This is a single-center, controlled, randomized, double-blind clinical trial. The number of participants was determined using the G*Power software (version 3.1.9.2, Franz Faul, Universität Kiel, Germany), in which the mean and standard deviation values of the primary outcome variable (systolic or diastolic blood pressure) were inserted. The calculation was performed using ANOVA for independent samples, with a significance of 5% and a test power of 95%. The sample consisted of 44 participants under medical follow-up at the Integrated Health Outpatient Clinic of Universidade Nove de Julho, located in the city of São Paulo, Brazil, from March 2019 to January 2020.



Recruitment was carried out through nursing consultations with hypertensive patients treated at the outpatient clinic.

For the study, the following exclusion criteria were used:

INCLUSION CRITERIA

Hypertensive patients aged between 30 and 80 years who agreed to participate in the study accepted below and signed the ICF (Informed Consent Form). Diagnosis of SAH declared by stage I or II medical certificate.

EXCLUSION CRITERIA

Hypotension prior to photobiomodulation; pregnant women, patients with Glaucoma, patients with electronic implants, such as cardiac pacemakers, epilepsy, seizures, history of neoplasms or photosensitivity.

The project was approved by the Research Ethics Committee of Universidade Nove de Julho under registration CAAE 85714318.3.0000.5511 (Annex A). The protocol of this study was registered in the REBEC (Brazilian Registry of Clinical Trials), with identification RBR-7n55nz, received in February 2019, available in <http://www.ensaiosclinicos.gov.br/rg/?q=RBR-7n55nz>.

This study presented minimal risks since, according to the literature found, they include the decrease in blood pressure by photobiomodulation.

At first, an analysis of the multiprofessional medical records was carried out with a search for hypertensive patients, finding a population of 284 patients with hypertension. However, the sample that accepted participation in the study and met the inclusion criteria resulted in 44 individuals.

The objective of this study was to evaluate the effects of transcutaneous photobiomodulation under two protocols: exposure time of 60 minutes per day, Group A (**Laser 60**), and 30 minutes per day, Group C (**Laser 30**), with the respective placebo groups Groups B and D (**Placebo 60 and Placebo 30**, respectively):

- **Group A (Laser 60):** individuals using antihypertensive drug therapy and transcutaneous FBM sessions for 60 minutes daily, for 5 days, with repetition after 20 days with a total of 3 cycles.
- **Group B (Placebo 60):** subjects on antihypertensive drug therapy and placebo sessions of transcutaneous FBM for 60 minutes daily, for 5 days, with repetition after 20 days totaling 3 cycles. Placebo was performed by placing a beam shutter at the laser output, but no radiation was delivered to the target.



- **Group C (Laser 30):** subjects using antihypertensive drug therapy and transcutaneous FBM sessions for 30 minutes daily, for 10 days, with repetition after 20 days for a total of 3 cycles.
- **Group D (Placebo 30):** subjects on antihypertensive drug therapy and transcutaneous FBM sessions for 30 minutes daily, for 10 days, being repeated after 20 days with a total of 3 cycles. The placebo was performed by placing a beam shutter on the laser output, however no radiation was delivered to the target.

Blood pressure (primary variable) and heart rate measurements were performed before, during, and at the end of each session. The Mean Arterial Pressure (MAP) was obtained by the formula below:

$$PAM = \frac{\text{FORMULA 1} \text{ systolic} + (\text{diastolic} \times 2)}{3}$$

The data were analyzed using descriptive and inferential statistics and compiled in tables and graphs, with the help of the statistical program Origin 2017.

RESULTS

A single examiner was responsible for the randomization and initial interview. A second examiner was trained to perform anthropometric assessments, measurement of hemodynamic variables, and blood collection. A third examiner was trained to perform the FBM. As this was a double-blind study, the sample did not know the type of intervention that was being submitted and the statistical analysis of the results was performed by a fifth person, without knowledge of the groups.

In the table below, the dosimetry used in this study.

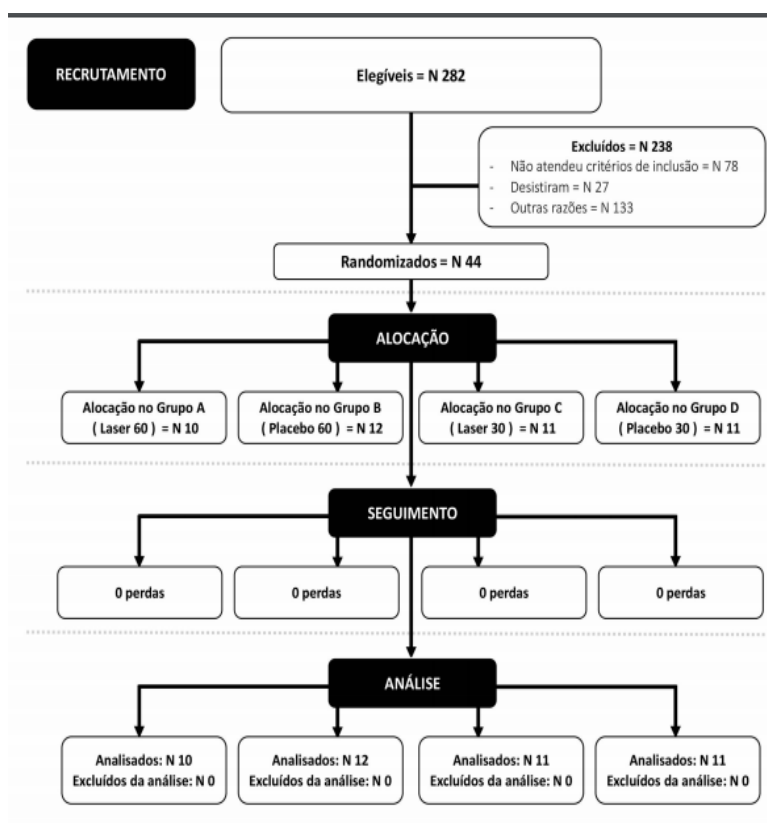
Table 1: Dosimetric parameters proposed for the study.

Protocols	Irradiation 30'	Irradiation 60'
Wavelength (nm)	660	
Mode of operation	Continuous	
Average radiant power (mW)	100	
Polarization	Random	
Opening diameter (cm)	0,06	
Irradiated Area (cm ²)	0,003	
Irradiância (W/cm ²)	35,386	
Exposure time per stop(s)	1800	3600
Radiant Exposure (J/cm ²)	63694,26	127388,53
Radiant energy per session (J)	180	360
Number of irradiated points	1	
Application technique	Contact	
Number of sessions during therapy	30 (3 cycles of 10 sessions)	15 (3 cycles of 5 sessions)

Source: Authors

Figure 1 shows the recruitment and distribution of the participants in the study.

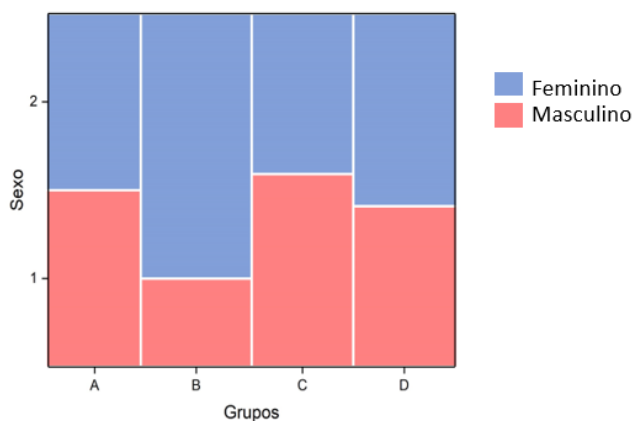
Figure 1: Flowchart of the procedures for inclusion, allocation, follow-up and analysis of participants, according to CONSORT.



Source: Authors

Most participants were female and this distribution did not vary between the groups ($p=0.49207$) (Figure 2).

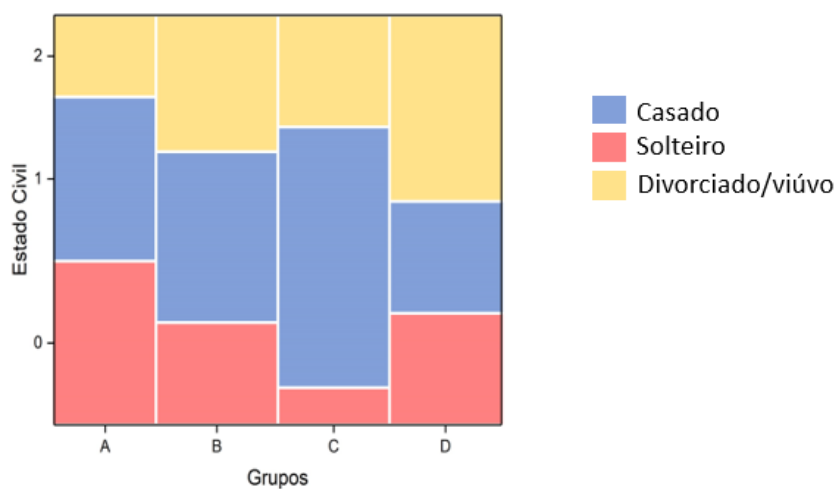
Figure 2: Gender distribution. São Paulo, 2019.



Source: Authors

The mean age of the sample was 62 years, ranging from 39 to 78 years. There was no difference between the groups in terms of age ($p = 0.08335$). Regarding marital status, the majority of the sample declared themselves married, with no significant difference between the groups ($p = 0.55171$), as observed in Figure 3.

Figure 3: Distribution of marital status. São Paulo, 2018.



Source: Authors

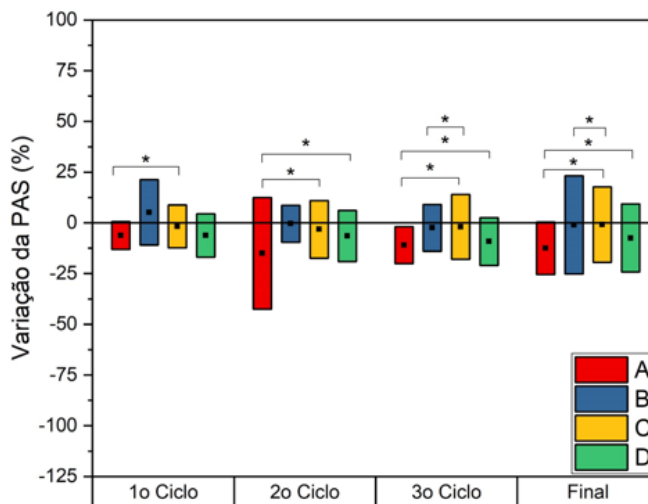
Regarding the hemodynamic data in tables (1, 2, 3 and 4), it is possible to verify the SBP, DBP, MAP, and HR values for each group before the beginning of the interventions (baseline), at the end of the cycles, and after the end of the interventions. Graphs of the variation of these variables in relation to baseline are also shown (Figures 4, 5, 6 and 7).

Table 1: Measured SBP values in each group in the different phases of intervention.

SBP (mmHg)				
Phases	Group A N= 10	Group B N= 12	Group C N= 11	Group D N= 11
Baseline	141.7±19.3	135.3±21.4	131.0±26.3	125.4±16.7
End 1st Cycle	132.4±16.0	140.6±20.1	126.6±14.3	116.5±11.5
End 2nd Cycle	118.2±39.0	135.3±17.1	123.9±11.9	116.4±12.8
Final 3rd Cycle	123.5±17.8	131.6±10.6	125.4±15.2	112.8±10.0
Final	123.4±20.0	131.0±23.1	126.1±15.1	114.0±12.0

Source: Authors

Figure 4 - SBP variation between the groups. São Paulo, 2019.



*= p< 0,05.

Source: Authors.

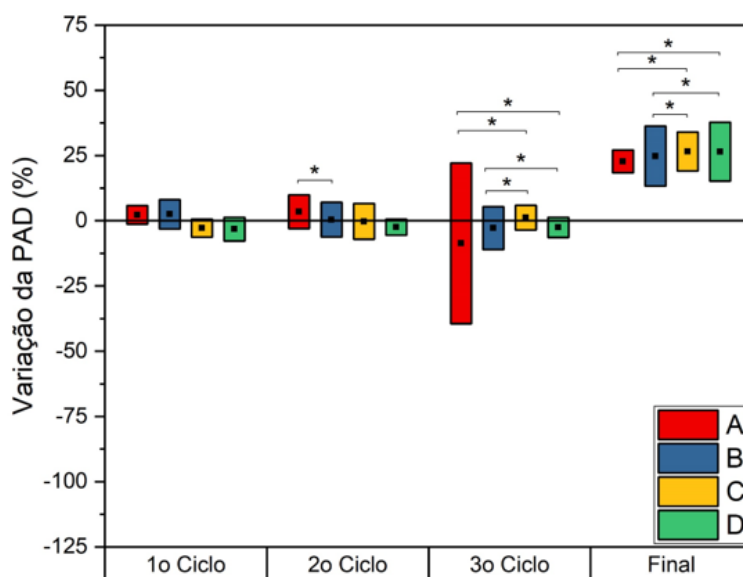
The results show significant differences in all phases analyzed. A decrease in SBP in group A (L60) was observed in all cycles, being in the first cycle in relation to group C (L30), in the second and third cycles in relation to groups C (L30) and D (P30). No significant differences were observed between groups A (L60) and B (P60) or between C (L30) and D (P30), i.e., there was no difference between the groups that received the FBM and their respective placebos when observing the variable PAS.

Table 2: Measured DBP values in each group in the different phases of intervention.

PAD (mmHg)				
Phases	Group A N= 10	Group B N= 12	Group C N= 11	Group D N= 11
Baseline	84.5±11.5	78.5±8.4	74.3±18.8	72.0±15.0
End 1st Cycle	83.5±12.2	81.5±10.9	77.0±11.7	67.7±9.4
End 2nd Cycle	81.1±13.3	78.7±9.1	75.1±10.8	67.0±11.3
Final 3rd Cycle	78.9±15.0	75.9±10.8	75.3±8.3	68.0±11.1
Final	103.6±13.6	97.4±8.8	93.2±20.8	89.8±13.8

Source: Authors

Figure 5 - DBP variation between groups. São Paulo, 2019.



*= p< 0,05.

Source: Authors.

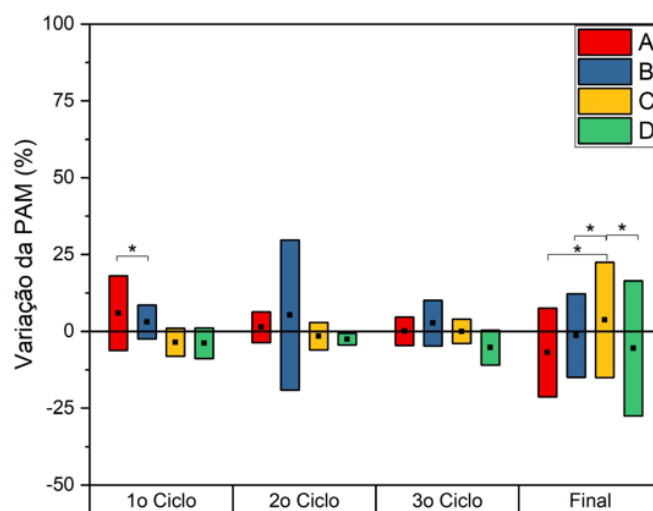
DBP did not show significant variation between the groups during the first cycle. In the second cycle, there was significance between groups A (L60) and B (P60). In the third cycle, there is a greater decline in DBP in group A (L60), but with significance between groups A (L60) and C (L30). That is, again there was no difference between group A and its placebo. It is observed that in the final phase there was an increase in DBP values in all groups, with the same differences observed in the third cycle.

Table 3: Measured values of MAP, in each group, in the different phases of intervention. São Paulo, 2019.

PAM (mmHg)				
Phases	Group A N= 10	Group B N= 12	Group C N= 11	Group D N= 11
Baseline	103.6±13.6	97.4±8.8	93.2±20.8	89.8±13.8
End 1st Cycle	100.1±13.2	97.6±12.6	93.0±11.2	83.9±8.7
End 2nd Cycle	97.0±14.4	97.4±9.7	91.3±10.1	83.4±10.3
Final 3rd Cycle	93.8±15.6	94.9±9.2	92.3±9.4	81.2±8.0
Final	96.1±16.9	95.6±12.4	93.4±7.5	82.8±11.6

Source: Authors.

Figure 6 - Variation in MAP between the groups. São Paulo, 2019.



*= p < 0,05.

Source: Authors.

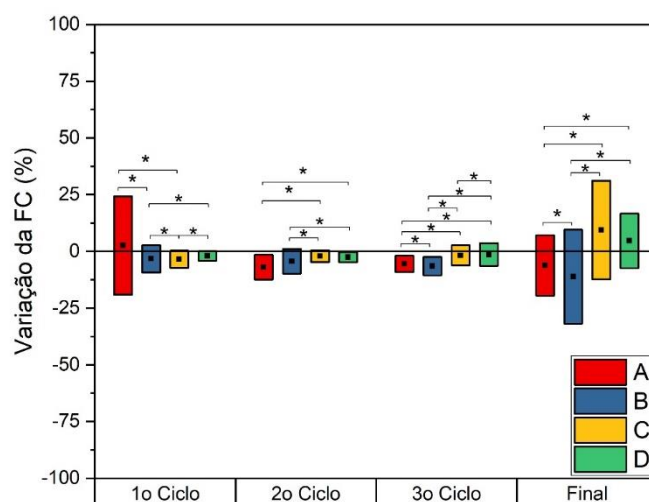
In the first cycle, there was a significant difference in MAP between groups A (L60) and B (P60). In the second and third cycles, there were no significant differences between the groups. In the final phase, group A (L60) had lower MAP than group C (L30), but there was no difference between groups A and D (placebo L30). It can be seen that group C increased MAP in relation to baseline (value above the horizontal line located at zero).

Table 4: Measured HR values in each group in the different phases of intervention.

Phases	FC (bpm)			
	Group A N= 10	Group B N= 12	Group C N= 11	Group D N= 11
Baseline	82±14 AM	82±25 AM	71±7 AM	80±15
End 1st Cycle	82±13 AM	72±12 AM	73±5 AM	77±13 AM
End 2nd Cycle	75±9	75±10	71±6	78±16
Final 3rd Cycle	75±9	71±11 am	74±8	78±14
Final	76±10	68±9	77±11	83±17 am

Source: Authors.

Figure 7 - Variation in MAP between the groups. São Paulo, 2019.



$p^* \geq 5$.

There was a statistical difference in HR in all cycles. In the first, group A had the highest HR in relation to groups B and C. Group C had the lowest HR in relation to the others. In the second cycle, the situation is reversed, with group A being the one with the lowest HR, but with significance only between C and D, that is, once again group A was not different from its placebo. In the third cycle, group A was different from B, C and D, with a decrease in HR. Group C was different from A, B and D, with higher HR. In the final phase, groups A and B had the lowest HR, while C and D had the highest.

DISCUSSION

The hemodynamic variables studied were SBP, DBP, MAP, and HR, which were analyzed during the 3 cycles, in all 4 groups: Group A, with exposure time of 60 minutes per day, and its controlled placebo, Group B; also Group C, 30 minutes a day, and its respective placebo-controlled group, Group D.

The wavelength, power, and irradiance remained the same in the irradiated groups. However, by varying the exposure time, the energy delivered and the radiant exposure also varied, as noted in **Table 1**. In group A, the radiant exposure was 127388.53 J/cm², with 360 J per session. In group C, both values were reduced by 50%, due to half the irradiation time. To try to compensate for these differences, group C received twice as many sessions, 30, instead of the 15 sessions in group A. However, according to the results obtained, the irradiated groups behaved differently from each other. Another noteworthy observation was the placebo effect observed in groups B and D, which in some variables was as good as that of the truly irradiated groups.

In the last cycle and at the end of the interventions, SBP decreased in all groups, but when the intervention groups and their respective placebo were analyzed, there was no significant difference between them. There was significance between groups A and C, with lower SBP values in group A. The same results were observed in DBP, however, in the final phase, the values increased in relation to baseline (the means are above the horizontal line at zero). Regarding MAP, there was no significance between the groups in the 3rd cycle. In the final phase, group A was significantly smaller than group C and was not different from its placebo, group B. On the other hand, group C had a significantly higher MAP value than its placebo, group D. HR was also statistically lower in group A in relation to C and there was significance between group A and its placebo, however, HR was even lower in the placebo group (B), both in the last cycle and at the end of the interventions.

In the protocols used here, the wavelength was red (660 nm), unlike Tomimura, but similar to the recent animal study where hypotensive effects were found in rats submitted to FBM, also with a decrease in systolic and diastolic pressure and heart rate (Hudak, 1997)

Another study used transcutaneous FBM to test its efficacy in lowering blood pressure in three groups of patients: normotensive, prehypertensive, and hypertensive. The exposure time was 30 minutes, red laser, 2.5mW of power and 3J of energy. Systolic and diastolic pressure and pulse variables were measured before, during, after and 15 minutes after each treatment. The results showed no significant difference in normotensive individuals. However, there was a difference in pre-hypertensive and hypertensive patients. The authors suggested that FBM can be combined with antihypertensives in patients being treated for SAH (Kaller, 2008).

Thus, as well as the results cited in the literature, FBM decreased the participants' blood pressure levels, especially those submitted to the protocol with 60 minutes of exposure time (group A). In order to understand the behavior of the placebo groups, which also decreased blood pressure levels, although differently from their respective treatments, demographic and anthropometric analyses were performed to verify the homogeneity of the sample.

The groups studied are also similar in terms of pharmacological treatment, using vasodilators, diuretics, beta blockers, and angiotensin-converting enzyme inhibitors, recommended by the guidelines for the treatment of hypertension, in addition to many using hypoglycemic agents for the treatment of DM (Barroso *et al*, 2021).

Regarding the manifestation of complications resulting from SAH, data from the VII Brazilian Guideline on Hypertension state that 30% of deaths are due to CVD (Barroso *et al*, 2021).

Finally, all study participants received a protocol of guidelines for blood pressure control based on the identified risk factors, whose objective was to promote lifestyle change and appropriate use of the medication prescribed by the doctor.



Thus, it is believed that multidisciplinary care may have increased treatment adherence of all participants, including the placebo groups, who did not receive irradiation, but showed a decrease in the values of hemodynamic variables.

CONCLUSIONS

Modulatory effects were evidenced in the control of blood pressure in hypertensive patients after photobiomodulation. In the present study, 30% of the participants had complications resulting from hypertension before photobiomodulation and only one patient had a stroke followed by death after photobiomodulation due to pneumonia. This patient belonged to group C (L30), was severely hypertensive, difficult to control, and was already bedridden due to a previous stroke. The cause of death was pneumonia. It was observed that group A (L 60) had a better response to the reduction of hemodynamic variables than group C (L 30). It can be demonstrated that FBM Therapy has been shown to be an effective alternative in the treatment of several diseases, concluding, new studies are needed to further elucidate the proposed theme and to insert photobiomodulation as an adjuvant protocol in blood pressure control.



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