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Non-Invasive Laser Therapy Effect on Lipid Profile and Renal Function in Metabolic Syndrome: Randomized Control Trial

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ABSTRACT

INTRODUCTION. Metabolic syndrome (MetS) represents an assortment of interconnected metabolic risk factors, particularly central obesity, dyslipidemia, and hyperglycemia. These variables have a detrimental impact on renal function and contribute to increased mortality. This timeline necessitates a prompt approach that enables the deployment of safe and non-intrusive therapeutic equipment in conjunction with therapy for MetS patients. Accordingly, we aim to investigate whether using a low-level laser (LLL) watch device as a non-invasive instrument enhances multiple metabolic parameters, so it may be a practical therapeutic approach for managing metabolic disorders.

AIM. To investigate the effect of non-invasive laser therapy on parameters of lipid profile and renal function in patients with metabolic syndrome.

MATERIALS AND METHODS. This study enrolled 40 MetS patients of both genders aged 45–65 years. The study group received a 12-week treatment consisting of oral hypoglycemic medication and LLL therapy (LLLT), which involved three weekly sessions performed in the morning, targeting the wrist area using a continual output diode laser (skin contact mode, maximum power: 0.005 W, beam spot area: 0.03 cm^2, energy density: 288 J/cm^3, and radiation time: 1800 s). The control group only received hypoglycemia medications. Laboratory lipid profile and renal function measurements were conducted prior to and following the trial.

RESULTS. Following a 12-week laser watch therapy, the results revealed a significant decline in total cholesterol (TC), triglycerides (TG), and low-density lipoprotein (LDL) levels and an increase in high-density lipoprotein (HDL) levels, which was slightly improved in the control ($p < 0.00$). Moreover, glomerular filtration rate (GFR) and creatinine levels were significantly improved, while the control group did not experience any significant improvement ($p > 0.5$).

DISCUSSION. Combining non-invasive laser therapy with hypoglycemic medications significantly improved the lipid profile in patients with MetS; however, kidney function, like GFR and creatinine levels, was enhanced. Furthermore, lower TC and TG levels might be due to the reduction of glycation and promoted LDL receptors which increased LDL catabolism.

CONCLUSION. Non-invasive laser therapy enhances lipid profile and renal function in MetS patients. Furthermore, the control group had a minimal effect on the lipid profile and no effect on renal function.

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KEYWORDS: laser watch, mets, dyslipidemia, hyperglycemia, renal function.

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Влияние неинвазивной лазерной терапии на липидный профиль и функцию почек при метаболическом синдроме: рандомизированное контрольное исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Метаболический синдром (MetS) представляет собой совокупность взаимосвязанных метаболических факторов риска, в частности, центрального ожирения, дислипидемии и гипергликемии. Эти факторы оказывают пагубное влияние на функцию почек и способствуют повышению смертности, что требует оперативного подхода, позволяющего использование безопасного и неинтрузивного медицинского оборудования в сочетании с терапией для пациентов с MetS. Соответственно, мы поставили перед собой цель изучить, влияет ли использование низкочастотных лазерных терапевтических часов в качестве неинвазивного инструмента на улучшение многочисленных метаболических параметров.

ЦЕЛЬ. Изучить влияние неинвазивной лазерной терапии на показатели липидного профиля и функции почек у пациентов с метаболическим синдромом.

МАТЕРИАЛЫ И МЕТОДЫ. В исследовании приняли участие 40 пациентов с метаболическим синдромом обоих полов в возрасте 45–65 лет. Исследуемая группа получала 12-недельный курс лечения, состоящий из пероральных сахароснижающих препаратов и низкочастотной лазерной терапии (НЛТ), который включал три еженедельных утренних сеанса путем воздействия на область запястья с помощью диодного лазера непрерывного действия (режим контакта с кожей, максимальная мощность: 0,005 Вт, площадь пятна луча: 0,03 см^2, энергия плотность: 288 Дж/см^3, время облучения: 1800 с). Контрольная группа получала только препараты для лечения гипогликемии. Лабораторные исследования липидного профиля и функции почек проводились до и после исследования.

РЕЗУЛЬТАТЫ. После 12-недельной терапии с использованием лазерных терапевтических часов результаты показали значительное снижение уровня общего холестерина, триглицеридов и липопротеидов низкой плотности, а также повышение уровня липопротеидов высокой плотности, который был незначительно был лучше в группе контроля ($p < 0,00$). Кроме того, уровень гломерулярной фильтрации и уровень креатинина были значительно снижены, в то время как в контрольной группе не наблюдалось какого-либо существенного улучшения ($p > 0,5$).

ОБСУЖДЕНИЕ. Сочетание неинвазивной лазерной терапии с гипогликемическими препаратами значительно улучшило липидный профиль у пациентов с метастазами, однако показатели функции почек, такие как уровень гломерулярной фильтрации и уровень креатинина, были улучшены. Кроме того, снижение уровней холестерина и триглицеридов может быть связано со снижением активности рецепторов липопротеидов низкой плотности, способствующих гликированию, что усиливает катаболизм липопротеидов низкой плотности.

ЗАКЛЮЧЕНИЕ. Неинвазивная лазерная терапия улучшает липидный профиль и функцию почек у пациентов с MetS. Кроме того, в контрольной группе наблюдалось минимальное влияние на липидный профиль и отсутствие влияния на функцию почек.

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КЛЮЧЕВЫЕ СЛОВА: низкоуровневые лазерные часы, MetS, дислипидемия, гипергликемия, функция почек.

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INTRODUCTION

Metabolic syndrome (MetS), often known as X syndrome, refers to a grouping of different metabolic risk factors rather than a pathological condition. These risk factors have the potential to significantly elevate the occurrence of dyslipidemia and chronic kidney disease (CKD). The documented occurrence of MetS differs based on the study group's age, gender, ethnic background, and socioeconomic status. Moreover, MetS has been unequivocally shown in clinical and epidemiological research to originate from central obesity. Due to a substantial worldwide rise in obesity rates throughout the past three decades, MetS prevalence has bee considerably increased [1]

Among the Egyptian population, different rates of MetS prevalence in adults have been observed when using different definitions. These rates were as follows: 43.8 % according to the American Heart Association definition, 42.5 % in accordance with the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III definition, 44.3 % according to the International Diabetes Federation (IDF) definition, 33.8 % according to the IDF definition with Egyptian cutoffs, and 41.5 % according to the Joint Interim Statement (JIS) definition with Egyptian cutoffs. Significantly, there is a lack of uniformity in the precision of distinct definitions used for MetS diagnosis. For instance, the JIS definition, which incorporates an Egyptian cutoff, has been suggested as the most appropriate method for identifying MetS in Egyptians. This recommendation is due to the outdated nature of the IDF definition, dating back to 2005, which employs European cutoffs for MetS characteristics. Consequently, the IDF definition is impractical for use in clinical practice [2]. The global MetS prevalence is 12.5–31.4 % depending on the criterion used. The Americas and the Eastern Mediterranean region had far higher prevalence rates, which rose with national affluence [3]. The ATP III criteria of the NCEP considered MetS as the second major target for cardiovascular disease) CVD (prevention, as it was discovered that patients with MetS have a higher risk of developing CVD in the next 5–10 years than those without Mets and patients with CVD and MetS had an increased risk of all-cause death. Accordingly, MetS will decline physical health and quality of life, besides negatively impacting psychological health [4].

Biological structures undergo photochemical reactions when exposed to light. Photoreceptors convert light into electrical impulses, which are transmitted to the parts of the brain responsible for processing visual information. Near-infrared light transillumination (NILT) is a form of phototherapy that has demonstrated advantageous effects. Photobiomodulation (PBM), often referred to as low-level laser treatment (LLLT), is proposed as a safe, non-invasive, and devoid-of-adverse effects technique, particularly suitable for vulnerable groups. Additionally, it mitigates inflammation, pain, and edema while facilitating wound, deep tissue, and nerve healing and preventing tissue damage [5]. Monochromaticity, directionality, spatial and temporal coherence, and brightness are the defining features of a laser, an energy-emitting device with a power output of 0.00–0.1 W. Some mammalian cells, such as cytochrome c oxidase, are positively affected by visible light owing to its Near Infrared (NIR) absorption peaks. This light reduces tissue hypoxia, enhances oxygenation, and promotes improved tissue metabolism. The mitochondria are regarded to be a possible location for the fundamental effects of light, resulting in heightened ATP synthesis. Consequently, these effects result in heightened cellular proliferation and migration, mainly exhibited by fibroblasts [6]. Additionally, LLLT has the potential to effectively treat renal fibrosis, lower blood pressure, enhance glomerular filtration rate, and reduce the buildup of collagen fibers in individuals with type 2 diabetes (T2DM), dyslipidemia, and hypertension. The LLLT can enhance sodium-potassium activity, catalysis, and sodium-potassium ATPase activity. Moreover, LLLT can be utilized to facilitate the recovery and restoration of musculoskeletal injuries through diminishing inflammation, enhancing proangiogenic activity, and promoting epithelial cell migration and proliferation [7].

Accordingly, we reinforce this concept in our study by utilizing the laser watch, the latest innovation in laser therapy. This treatment involves the application of laser beams directly on the wrist, which allows for continuous transcutaneous blood irradiation. As a result, it has emerged as a novel therapeutic approach for treating a wide range of disorders.

AIM

To investigate the effect of non-invasive laser therapy on parameters of lipid profile and renal function in patients with metabolic syndrome.

MATERIALS AND METHODS

This double-blinded, randomized-controlled trial was performed from April 2023 to October 2023, with a register number of NCT06193746 on clinicaltrials.gov. Before participation, participants received an explanation of the purpose, potential risks, and expected advantages of the study and signed an informed contest. The Faculty of Physical Therapy Cairo University's Ethical Committee approved this study (No: P.T.REC/012/004441). The study included 40 patients aged 45–65 years who were clinically stable and had been diagnosed with Mets accompanied by dyslipidemia and renal dysfunction and hadn't been receiving statins but they taked hypoglycemic medication for over a year and not receiving. Participants were recruited from Berket El Haj Medical Center and had a comprehensive checkup before the research started. Herein, we randomly and equally (n = 20) divided the patients into the study group that received LLLT on the wrist for 3 sessions/week/12 weeks in addition to hypoglycemic medications, as well as that the control group only had hypoglycemic medications. To conduct the randomization process, an impartial colleague, who was unaware of the study and had no participation in it, extracted opaque, sealed envelopes from a container and randomly assigned each envelope with a group description.

Participants who do not meet any of the following exclusion criteria were excluded: using specific medications (corticosteroids or diuretics) that could potentially affect the accuracy of the test results or have an impact on blood cholesterol and weight; having CVD (congestive heart failure, unstable angina, severe hypotension or hypertension, myocardial infarction, and arrhythmias), severe autonomic neuropathy, and liver or renal failure, as these conditions could influence the photosensitivity reaction; experiencing an active response to treatment; having an infection in the laser treatment area, such as a wound, burn, allergy, or another external injury; being a smoker or alcoholic; having hypothyroidism; having hemorrhagic diseases, anemia, or a cancer history; being pregnant, breastfeeding, or planning to become pregnant prior to the study completion; having mental disorders including dementia or schizophrenia.

Evaluation of Eligibility

The trial enrolled 45 patients; during the evaluation, 5 individuals were excluded: 3 did not meet the inclusion criteria, and the remaining 2 voluntarily withdrew their participation from the study.

Outcome Measurement

After obtaining initial measures of body weight, height, and waist circumference (WC), we calculated the body mass index (BMI) as follows:

BMI = Weight (kg) / Height (m^2).

Laboratory Measurements

The renal function and lipid profiles of both groups were assessed using the Devia 1800 chemistry system (siemens-healthineers, Germany) before and after the 12-week trial. The assessments were conducted at ROYAL LABS laboratories.

Lipid Profile Blood Test

Participants must undergo a fasting period of 9–12 hours before the test, during which they are only allowed to consume water. After the needle was inserted, a small amount of blood was collected in a sterile vial or syringe. A lipid panel was used to examine four lipid types in a blood sample: high-density lipoprotein (HDL; < 50 mg/dL), low-density lipoprotein (LDL; > 130 mg/dL), triglycerides (TG; > 150 mg/dL), and total cholesterol (TC; > 200 mg/dL).

Kidney Function Test

This test was conducted to assess renal function directly by measuring the glomerular filtration rate (GFR), ideally between 90 mL/min/1.73m^2. The creatinine levels should also be within the range of 0.60–1.4. Fasting was unnecessary for the test, and blood samples were obtained using a hollow needle implanted into the arm vein. The blood was collected and transferred into a test tube for analysis.

LLLT

The laser watch device utilizes a semiconductor LLL equipment (model: BS-W11, Hubei Boshi Co. Ltd., China), which provides ten separate laser beams utilized to target the radial and ulnar arteries at the wrist site using transcutaneous means (extra-vascular blood irradiation). The LLLT was administered for 30 min every session, 3 times a week, for 12 weeks [8]. This precautionary measure was taken based on previous studies that have shown that laser irradiation can enhance the process of intestinal absorption. Experts in medical devices from Cairo University's National Institute of Laser Enhanced Sciences (Egypt) evaluated and inspected the collimation, coherence, and monochromatic gadget. Table 1 summarizes the specifications and features of the used laser equipment [8].

Statistical Analysis

The statistical analysis was conducted through SPSS version 25 for Windows (IBM SPSS, Chicago, IL, USA). Unpaired t-test and chi-squared test were performed to compare subject characteristics as well as sex distribution between groups, respectively. The data was assessed for normal distribution using the Shapiro-Wilk test while deploying Levene's test to assess variance homogeneity among the groups. A Mixed MANOVA was used for determining the treatment effect on TC, TG, HDL, LDL, GFR, and creatinine levels. Post-hoc tests were conducted to compare multiple groups, using the Bonferroni correction for subsequent multiple comparisons. $p < 0.05$ indicated a significant difference.

Table 1. The application parameters and characteristics of laser watch radiation [8]

Parameters	Value
Site of applications	At wrist of the non-dominant hand to prevent interference with daily activities of the patients
Monochromatic wavelength, nm	650
Maximum power produced by a single laser output, W	0.005
A spot's diameter, cm	0.2
A spot's size, cm²	0.03
Power density, w/cm²	0.16
Radiation time, s	1800
Energy density, J/cm²	288
Energy, J	8.64
Mode for terminal laser output	Continuous
Session Duration	Thirty minutes
Laser beams numbers	Ten
Time	Patients need to fast four hours in the morning prior to the session to prevent rise in blood sugar levels
Total duration of treatment	Three times a week for 12 consecutive weeks
Type of beam	(Red) infrared laser light
Instability of the terminal laser output	± Ten percentage
Mode of display	Liquid crystal display
Safety class	3R-class laser product, internally powered supply Apparatus

RESULTS

Data was obtained from 40 MetS patients with dyslipidemia and renal impairment who had finished the research. Figure 1 illustrates recruitment, exclusion, assessment, and intervention.

Subject Characteristics

The results revealed a non-significant difference between groups in age, BMI, and sex distribution ($p > 0.05$; Table 2).

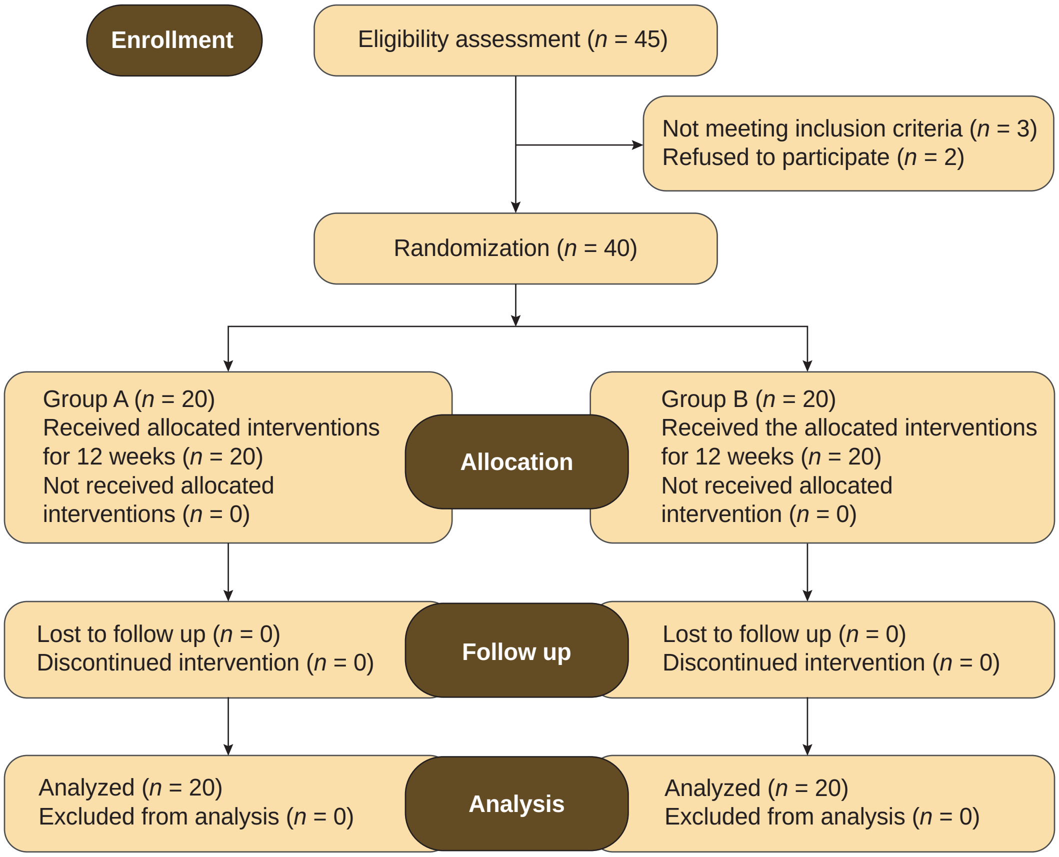

Fig. 1. Flow chart of the study

Table 2. Subject characteristics of both groups

Parameter	Study group Mean ± SD	Control group Mean ± SD	MD	*t*-value	*p*-value
Age, years	53.80 ± 4.82	54.55 ± 5.29	−0.75	−0.46	0.64
BMI, kg/m²	32.95 ± 1.17	32.45 ± 1.21	0.5	1.35	0.18
Sex, *n* (%)					
Females	18 (90 %)	16 (80 %)		(χ^2 = 0.78)	0.37
Males	2 (10 %)	4 (20 %)			

Note: *SD — standard deviation; MD — mean difference; p-value — probability value; χ^2 — Chi squared value.*

Effect of Treatment on TC, TG, HDL, LDL, GFR and Creatinine

The results of the Mixed MANOVA indicated a significant interaction between treatment and time (F = 24.31, p = 0.001). The treatment had a non-significant main impact (F = 2.26, p = 0.06). The finding demonstrated a significant main impact of time (F = 193.56, p = 0.001).

Within Group Comparison

Both groups experienced significantly reduced TC, TG, and LDL levels and increased HDL levels post-treatment compared with their pre-treatment levels ($p > 0.001$, Table 3). The study group exhibited significantly lower GFR and creatinine levels post-treatment than pre-treatment ($p > 0.001$). In contrast, the control group showed a non-significant change ($p > 0.05$, Table 4).

Between-Group Comparison

The study group had a significant reduction in TC, TG, and LDL levels, as well as a significant increase in HDL levels, compared to the control group post-treatment ($p < 0.01$). The results revealed no significant disparity in GFR and creatinine levels between the groups post-treatment ($p > 0.05$, Table 3 and Table 4)

DISCUSSION

This study suggests that using non-invasive laser therapy for 36 sessions (3 sessions/week/12 weeks), combined with hypoglycemic medications, significantly affects total cholesterol, TG, and LDL cholesterol by reducing them and increasing HDL in MetS patients. However, kidney function, including GFR and creatinine levels, had an elevation in the study group, while the control group showed a non-

Table 3. Mean TC, TG, HDL, and LDL pre- and post-treatment of study and control groups

Parameter	Pre-treatment Mean ± SD	Post-treatment Mean ± SD	MD	% of change	*p*-value
TC, mg/dL					
Study group	200.70 ± 24.11	173.15 ± 21.24	27.55	13.73	0.001
Control group	206.60 ± 18.68	192.45 ± 19.58	14.15	6.85	0.001
MD	–5.9	–19.3			
	***p* = 0.39**	***p* = 0.005**			
TG, mg/dL					
Study group	168.50 ± 31.88	134.15 ± 26.44	34.35	20.39	0.001
Control group	172.15 ± 28.16	155.70 ± 24.68	16.45	9.56	0.001
MD	–3.65	–21.55			
	***p* = 0.70**	***p* = 0.01**			
HDL, mg/dL					
Study group	45.25 ± 5.91	50.20 ± 6.87	–4.95	10.94	0.001
Control group	44.25 ± 6.13	45.55 ± 6.41	–1.5	3.41	0.001
MD	1.2	4.65			
	***p* = 0.53**	***p* = 0.03**			
LDL, mg/dL					
Study group	122.65 ± 22.65	101.57 ± 12.08	21.08	17.19	0.001
Control group	124.50 ± 19.81	114.15 ± 16.63	10.35	8.31	0.001
MD	–1.85	–12.58			
	***p* = 0.78**	***p* = 0.009**			

Note: *SD — standard deviation; MD — mean difference; p-value — probability value.*

Table 4. Mean GFR and creatinine pre- and post-treatment of study and control groups

Parameter	Pre-treatment Mean ± SD	Post-treatment Mean ± SD	MD	% of change	*p*-value
GFR, mL/min					
Study group	99.45 ± 17.89	95.45 ± 14.27	4	4.02	0.004
Control group	98 ± 21.97	97.60 ± 18.79	0.4	0.41	0.76
MD	1.45	–2.15			
	***p* = 0.82**	***p* = 0.68**			
Creatinine, mg/dL					
Study group	0.69 ± 0.19	0.64 ± 0.21	0.05	7.25	0.001
Control group	0.67 ± 0.21	0.66 ± 0.24	0.01	1.49	0.25
MD	0.02	–0.02			
	***p* = 0.82**	***p* = 0.74**			

Note: *SD — standard deviation; MD — mean difference; p-value — probability value.*

significant difference. This agreed with Fares H.M et al. [9], who has found that a laser watch and hypoglycemic medications significantly reduce blood glucose levels and lipid profile measurement in T2DM patients, suggesting that it is safe and efficient to treat patients with T2DM and dyslipidemia by using a laser watch as an extra therapy in addition to the usual care. Our results corroborate the findings of Serry Z.M.H. et al. [10] that extra-vascular laser blood irradiation by laser watch reduces blood glucose levels, improving metabolic parameters by improving dyslipidemia.

Additionally, a meta-analysis [11] have indicated that intravenous laser treatment significantly decreases blood glucose levels in T2DM and may be used as an additional therapy, which is supported by our data. Improved blood glucose regulation has been shown to alleviate diabetes-related dyslipidemia partially [12]. Lower levels of TC and TG resulted from decreased glycation and enhanced LDL receptors, which increased LDL catabolism and decreased VLDL levels in diabetes mellitus. This might account for the improved lipid profile of the control group. Our results align with Melekhovets O. et al. [13], who has stated that ILIB lowers TG, TC, and LDL levels in individuals with hypothyroidism or dyslipidemia alone. Nevertheless, unlike in our study, where the laser watch was worn for 12 weeks, ILIB was only used for one month. Laser acupuncture and diet-exercise intervention have a modest positive effect on dyslipidemia in individuals with metabolic disorders [14]. This effect was achieved by reducing TG, LDL-C, and HDL-C levels. Nevertheless, laser acupuncture was more efficient than the diet-exercise intervention in reducing TC levels. Furthermore, Liu T.C.-Y. et al. [15] has observed that individuals with coronary heart disease or cerebral infarction who get intranasal laser treatment had better blood lipid profiles.

The study of Olban M. et al. [16] could explain this enhancement, as the lasers increase superoxide production and encourage lipid peroxidation. The heightened generation of reactive oxygen species (ROS) results in the degradation of lipids within the cellular membrane. Temporary holes made in the cell membrane allow lipids and fatty substances to reach the interstitial space, where they are removed by the lymphatic system. It might be explained by the likelihood that NILT alters the potential of the mitochondrial membrane and the intracellular redox state, which would raise the rate of ADP-ATP exchange. These modifications to the mitochondria may reduce cholesterol synthesis by altering the transcription factors required to express important genes involved in the biosynthesis pathway [17]. The study of Ahrabi B. et al. [7] agrees with our study as it has demonstrated that lasers can be useful in lowering ROS levels, fibrosis factors, and inflammatory reactions. Additionally, it can promote glomerular cell proliferation and anti-inflammatory responses.

The study of Ucero A.C. et al. [18] aligns with our study that lower NILT dosages were explored via dose (1.5 J cm^{-2} fs, 3 mW each, for 4.25 min, five diode) applied on the skin (5 times per week for 8 weeks) on a CKD rat model which was indicative of the primary human causes of CKD, MetS-related T2DM. In addition to gradual renal failure, the ZSF1 rat strain exhibits obesity, hyperglycemia, dyslipidemia, and hypertension. A higher overall health level might account for the absence of variations in plasma creatinine between groups. The primary source of creatinine is muscle mass, and maintaining muscular mass is linked to higher creatinine levels. Nonetheless, the study of Astuti S.D. et al. [19] has suggested that a significant impact on the quantity and caliber of granulation tissue was observed after the experiment duration. Administering a 650 nm laser with a dosage of 1 J daily performed on the acupuncture of the mice kidney can increase the effectiveness of treating diabetic rats in the early CKD stages. The findings explain the limited change shown in GFR in study group B, with no significant difference observed between the groups. Although the results were positive, the small number of participating patients limited the experiment. Subsequent investigations will require extended periods of observation and increased participant numbers.

The study of Mikhailov V. et al. [20] observed 205 type 2 diabetic patients with dyslipidemia who approved that the Combination of a visible red laser therapy (630 nm; output power at the fibre tip, 2 mW; exposure period, 15–30 min) in conjunction with antioxidant therapy (about 600 mg daily) for nine months have a positive effect on achieving the lipid normalising effect, there was a significant increase in the level of HDL-c and a decrease in LDL-c levels in the post-treatment Simultaneously a significant decrease in total cholesterol was noted and triglycerides were either normal or within the upper normal limits. The LDL/HDL-c ratio was reduced by two-fold. the combined laser therapy was believed to help in decreasing the intake of hypolipidemic and lipotropic agents and improving MetS symptoms.

Limitation

Our investigation had several limitations. First, the extended follow-up period. Second, the specific inclusion criteria. Last, the small ample size. Therefore, we recommended further investigation utilizing a wide range of inclusion criteria and larger sample size.

CONCLUSION

Non-invasive laser therapy improves lipid profile and renal outcomes, which suggests that MetS with uncontrolled diabetes has improved. Moreover, non-invasive laser therapy can be an alternate treatment approach to be used in conjunction with medications. Additional research with bigger sample sizes must assess the long-term consequences of non-invasive laser therapy and its impact on individuals undergoing renal dialysis.

ADDITIONAL INFORMATION

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Ethical Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the Local Ethics Committee of the Faculty of Physical Therapy Cairo University, Egypt, Protocol No P.T.REC/012/004441 dated February 2, 2023.

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