



Original article

Using a laser based program in patients diagnosed with fibromyalgia

Rubén Fernández García,^{a,*} José Damián Suárez Holgado,^b Israel Formieles Ortiz,^c Félix Zurita Ortega,^a Matías Valverde Cepeda,^d Manuel Fernández Sánchez^e

^aPsicología y Fisioterapia, Departamento de Enfermería y Fisioterapia, Escuela de Ciencias de la Salud, Universidad de Almería, Almería, Spain

^bFisioterapia, Hospital USP de Marbella, Málaga, Spain

^cFisioterapia, Centro Aquae, Almería, Spain

^dReumatología, Departamento de Neurociencia y ciencias de la Salud, Universidad de Almería, Almería, Spain

^eDepartamento de Enfermería y Fisioterapia, Escuela de Ciencias de la Salud, Universidad de Almería, Almería, Spain

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ABSTRACT

In this study, the benefits of a program of treatment by laser were evaluated on the improvement of symptoms associated with fibromyalgia. A total of 31 participants took part in the study, all of them women, randomized into two groups: intervention with laser and placebo. The intervention with girdase E11010 consisted of the individual application of six frequencies on seven anatomical zones of the body. The results were statistically significant differences for "weariness" and "difficulty sleeping" variables. In the rest of the variables, we did not find any statistical significance. One of the conclusions from the present study is the need for development of new research to verify the influence of girdase E1.1010 in the improvement of symptoms associated with fibromyalgia

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Utilización de un programa con láser en pacientes diagnosticados de fibromialgia

RESUMEN

En esta investigación se evaluaron los efectos de un programa con láser en pacientes diagnosticados con fibromialgia (FM). Participaron en el estudio un total de 31 mujeres, las cuales fueron distribuidas de forma aleatoria a 2 grupos experimentales: intervención con láser y placebo. Las sesiones de intervención en el grupo experimental consistieron en la aplicación con el girdase E1.1010, de 6 frecuencias en 7 puntos anatómicos del cuerpo. En el grupo placebo, se utilizó el mismo procedimiento, con la excepción que el láser permanecía apagado.

Los resultados indicaron diferencias estadísticamente significativas en las variables «cansancio» y «dificultades en el sueño». En el resto de las variables, no se encontró significación estadística alguna. Una de las conclusiones más destacadas del presente estudio es la necesidad y desarrollo de nuevas investigaciones para comprobar la influencia del girdase E1.1010, en la mejora de la sintomatología asociada a la fibromialgia.

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Palabras clave:

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Introduction

Several population studies have estimated the prevalence of fibromyalgia (FM) at 4.2% in females and 0.2% in males.¹ The percentages vary depending on the diagnostic criteria employed. However, recent data from the American College of Rheumatology

allow this prevalence to be set at between 2%-4% of the general population.²

The most common form is described in young adults, between 25-50 years of age, although the clinical syndrome has also been diagnosed in people over 60 years, with mild manifestations and generally associated with arthrosis.³

It is understood that pain is the main symptom in FM.^{4,5} Another symptom to be taken into account is stiffness, which is observed in 76% of patients.⁶ Symptoms not related to the musculoskeletal apparatus include a sense of fatigue,⁷ psychological manifestations such as anxiety and depression,⁸ sleeping disorders⁹ and so on.

* Corresponding author.

E-mail address: rubenfer@ual.es (R. Fernández García).

The cause of this disorder is not known, but physical and emotional trauma seem to play an important role in the emergence of the disease.¹⁰ Other causes that have been considered and associated with FM syndrome are abnormal pain transmission responses,¹¹ hereditary tendency,¹² biochemical abnormalities of the central nervous system,¹³ etc.

The 1990 classification criteria of the American College of Rheumatology are widely accepted for the diagnosis of FM. These focus on the presence of diffuse pain, absence of systemic disease and at least 11 positive painful points out of 18 recommended in exploration.¹⁴

Medical treatment for FM may include prescription of NSAIDs or analgesics that may partly alleviate the pain.¹⁵ Drugs that facilitate deep sleep and relax muscles, as well as antidepressants, may also prove useful.¹⁶ Among other things, the practice of physical exercise¹⁷ and the use of laser therapy¹⁸ may also be recommended for treatment of FM-associated symptoms.

Taking into account the type of laser used in this study, it is interesting to address the phenomenon of cutaneous photoperception, that is, the skin acts like a radar that serves the nervous system in regulating neuromediator secretion.¹⁹ Each wavelength of light emitted by the Girlase machine favours the production of a specific series of neurotransmitters, which may help to regulate the biochemical abnormalities that occur at central nervous system level in patients with FM.¹³

Authors such as Paul Nogier found that photoperception was not uniform throughout the entire surface of the skin. This scientist noted that the skin system was divided into 7 zones or “plates”. Each plate had a specific cutaneous photoperception for recurrent frequencies of infrared radiation. Based on the practical guidelines derived from Nogier’s discovery, it would be appropriate to refer to 7 areas that photoperceive a specific type of frequency, so that each frequency would produce a characteristic therapeutic effect in the body. In this regard, frequency A would have a therapeutic effect on inflammatory processes, frequency B on nutrition and metabolism problems, frequency C on locomotive problems, frequency D on problems of laterality, frequency E on pain problems, frequency F on subcortical problems and frequency G on cortical problems.¹⁹

Objective

The main objective considered in the study was to assess the effect of the Girlase E1.1010 apparatus on fatigue, sleep difficulties, neck pain, vaginal pain during intercourse and general pain in a sample of patients diagnosed with FM.

Subjects and methods

The sample consisted of 31 women with a mean age of 50 years (range, 36–61 years) and an average of 4.1 years from diagnosis of FM (range, 3–10 years).

All subjects were born in the province of Almería (Spain) and were grouped according to a normal distribution.

Design

The experimental design included pre-test and post-test measurements as well as a placebo group. Each participant was blindly and randomly assigned to one of the 2 experimental conditions, that is, laser or placebo group. It should be clarified that both groups believed they would receive laser treatment.

We conducted two pre-test measurements of the dependent variables before administering treatment.

Variables

The descriptive variables used were:

- (1) Age.
- (2) Gender.
- (3) Time since diagnosis of FM.

The laser procedure (see procedure) was the independent variable.

The dependent variables used in the study were:

- (1) Impact of FM (FIQ).
- (2) Fatigue.
- (3) Sleeping difficulties. In this case, the degree of fatigue experienced upon awakening was the main assessment.
- (4) General pain.
- (5) Neck pain.
- (6) Vaginal pain during intercourse.

Instruments

- (1) Portable Laser Girlase E1.1010. The technical characteristics of this instrument were:
 - Wavelength: 905 nm +10 nm.
 - Mode: pulsed.
 - Duration of pulses: 70 ns.
 - Energy per pulse: nominal = 0.70 mJ.
 - Peak power of pulses: 1000 mW nominal.
 - Frequency of pulses:
 - Position:
 - A 292 Hz; B 594 Hz; C 1.168 Hz; D 2.336 Hz; E 4.672 Hz; F 73 Hz; G 146 Hz
- (2) CRD Clinical FM Survey.

This survey recorded the following variables: (1) age; (2) gender; (3) time to FM diagnosis; (4) impact of FM.

In addition to the variables described above, the CRD also included the Fibromyalgia Impact Questionnaire (FIQ) by Esteve and Battle.²⁰ This instrument is designed to quantify the overall impact of FM on several dimensions (functionality, perception of pain, stiffness and fatigue, sleep difficulties, depression, anxiety and ability to carry out paid and domestic work).

- (3) VAS Scale.

The visual analogue scale (VAS) is a Likert scale with numbers from 1 (minimal pain) to 10 (severe pain), which evaluated the intensity of the pain experienced by each participant.²¹ This scale enabled the following variables to be recorded: “general pain”, “sore throat” and “vaginal pain during intercourse.”

- (4) Digital Electronic Timer Clock - LG brand.
- (5) Laser Eyewear - Enraf Nonius brand.
- (6) Manumed Optimal 3-section trolley - Enraf Nonius brand.

Procedure

The research took place at the University of Almería (UAL). Both groups followed the same action sequence; however, it should be noted that one of the groups received a placebo. The study followed the ethical requirements needed in research with humans, according to relevant regulations.

This study lasted 8 weeks. During that time, a total of 2 pre-tests (2 weeks) and 6 post-tests (6 weeks) were conducted in both experimental groups (on the same day of the week and at the same time).

The pre-test consisted of the application of the CRD surveys. In the post-tests, the CRDs were applied during the first 10 minutes of each session in both experimental groups, and the laser intervention was carried out immediately after that, for approximately 42 min. The difference between both experimental groups was that, in the placebo group, the laser was turned off and at a distance of 15 cm from the body of the patient during the intervention.

Table 1
Action procedure in the Experimental Group (EG) and the Control Group (GC)

	EG	CG
Pre-test	Application of CRD survey	Application of CRD survey
Pos-test	1st step: CRD Application (10 min) 2nd step: Intervention with laser (42 min)	1st step: CRD Application (10 min) 2nd step: Intervention with laser switched off (42 min) under the same conditions as the EG group

Table 2
Site of application of the laser frequencies

Number of anatomical areas	Site of application
First anatomical area	Anal region
Second anatomical area	Hypogastrium
Third anatomical area	Epigastric region
Fourth anatomical area	Left chest region
Fifth anatomical area	Anterior vertical region
Sixth anatomical area	Crista galli
Seventh anatomical area	Between bregma and vertex

Specifically, laser intervention in the experimental group during each of the post-tests consisted of the individual application of 6 frequencies (one minute per frequency) (G-10: counter-clockwise clockwise; D+30 counter-clockwise; G+30 counter-clockwise; D+10 clockwise; D+30 counter-clockwise; A+30 counter-clockwise) at each of the 7 anatomical points selected.^{22,23} The order of application of the frequencies in the different areas was as follows (Table 1):

In each of the post-tests, the application frequency was 2 cycles per second at a distance of 1 cm from the skin of the subject and with the laser describing a circle of 10 cm in diameter.

In both groups, the subjects were in their underwear, in the supine position, with their head towards the ceiling and eyes closed, arms supinated close to the body and lower limbs spaced at 30 cm.

Table 3
Mean and SD per group/total

	Mean and SD per group			Total mean and SD	
	Mean	SD		Mean	SD
Age	51.6	6.18		52.0	5.95
Time with fibromyalgia diagnosis	52.4	5.88		4.09	1.39
	4.37	1.41			
	3.80	1.37			

CG indicates control group; EG, experimental group; SD, standard deviation.

Table 4
Descriptive statistics and analysis of variance in the Experimental (EG) and Control (CG) Groups

	Pre-test	Post-test	F, P value		
	Mean and SD EG	Mean and SD CG	Mean	SD	F, P value
Impact of fibromyalgia	71.45	60.89	11.80	52.30	15.22
			15.28	50.37	24.18
Fatigue	8.25	7.93	1.48	3.93	1.76
			1.79	5.92	3.38
Sleeping difficulties	7.53	5.72	2.09	5.23	2.56
			3.13	7.14	2.44
General pain	8.43	8.43	1.75	6.12	2.91
			2.44	6.73	2.25
Neck pain	8.29	7.36	1.64	6.33	2.82
			2.29	6.81	3.02
Vaginal pain during intercourse	6.87	6.87	4.34	4.75	2.35
			2.65	5.73	3.21

The study protocol was approved by the corresponding local ethics committees and followed the guidelines of the Declaration of Helsinki.

All patients included in the study received sufficient information and gave their written informed consent to participate in it.

Results

Analysis of results

The data were processed through descriptive analysis of variance (single factor ANOVA). The statistical package used was SPSS+ version 15.0.

It should be noted that none of the participants left the study.

Table 2 shows the descriptive statistics (mean and standard deviation per group and total) of the dependent variables "age" and "time with diagnosis of FM" in the experimental group and the control group. In this case, values were distributed evenly for both variables.

Table 3 shows the descriptive data and ANOVA results of the rest of variables selected in the research. Attention should be focused on the variables "fatigue" (F:4.231=0.049) and "sleeping difficulties" (F:0.912=0.044), which both reached statistical significance (Table 4).

Discussion

Within the wide variety and functions that lasers may present,²⁴ in this case we have selected the Grlase E1.1010 to verify its influence on the symptoms associated with FM syndrome.

The patients selected for this study had a mean age of 50 years (SD=5.95) and an average of 4.09 years (SD=1.39) with a diagnosis of FM. In this sense, it is understood that the subjects were within the range in which this disease is usually diagnosed.²⁵

It is very common for patients with FM to present sleep difficulties; that is, they usually have trouble falling asleep and when they wake up in the morning, they report a feeling of not having rested during the night. They also wake up several times

during the night and, apart from this, they may develop restless legs syndrome, further hindering a peaceful sleep.²⁶ Statistically significant differences were found in this study in the variable "sleeping difficulties" through the use of the Grlase ($P=.044$). The results obtained could be due to the intervention, in other words, the application of the selected frequencies (see procedure) favoured the release of neuromediators¹⁹ leading to changes in the sensations that the subjects experienced upon awakening. It would be important to reflect that at present, except for what is presented here, there is no scientific study that has used this type of laser in the treatment of patients with FM.

In general, patients with FM often feel very tired, so that any "burden" can represent a great effort.²⁷ In this research, a $P=.0049$ was obtained for the variable "fatigue". This result could have been influenced by the change achieved in the variable "sleeping difficulties"; that is, it is logical to think that after sleeping better, subjects could also feel less tired. However, the possible effect that the Grlase may have had on the level of significance in this variable should not be forgotten. It is interesting to notice the lack of studies in the scientific literature that have used a laser of this type to reduce physical fatigue in FM.

We now turn our attention to the variables "impact on FM" ($P=.79$), "widespread pain" ($P=.52$) and "neck pain" ($P=.67$). It was noted that, in these 3 variables, the experimental group reported favourable values for the last post-test, compared to the first pre-test. Yet, paradoxically, the placebo group also showed a tendency towards positive values in these variables. This raises the question that the effect of the laser on the experimental group was as effective as the placebo on the control (placebo) group. In this regard, it is appropriate to remember the influence of the placebo effect in patients with FM.²⁸

Finally, regarding the variable "vaginal pain during intercourse", differences were not statistically significant ($P=.33$). However, there was a trend towards improvement in the experimental group (mean=4.75) compared to the placebo group (mean=5.73), in which the values of this variable increased in the last post-test. It could be understood that, on this occasion, it might have been necessary to carry out more intervention sessions to obtain statistical significance.

There are several study limitations to be commented. There should be an attempt to remedy all of them in future studies. Firstly, the number of investigations carried out with the Grlase E1.1010 is negligible. This implies the need to carry out a large number of studies to test the effectiveness of this instrument. It would also be advisable to have a larger sample, as well as male subjects.

It would also have been interesting to compare the use of the Grlase with other types of interventions, such as the use medication, exercise programs, nutritional supplements, psychological therapy, physiotherapy techniques and so on.

Lastly, the number of intervention sessions could have been increased, with a subsequent result assessment.

The main conclusions obtained from this study were:

- Laser therapy can be effective in reducing some symptoms experienced by patients with FM.

- The Grlase E1.1010 was able to help our study subjects in the variables "sleeping difficulties" and "fatigue".
- The Grlase E1.1010 was not effective in reducing the primary symptom associated with FM, namely, pain.

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