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Comparing Efficiencies of Local Anesthetic Injection and Photobiomodulation in the Treatment of Fibromyalgia Syndrome

Fibromyalji Sendromunun Tedavisinde Lokal Anestetik Enjeksiyonu ve Fotobiyomodülasyon Tekniklerinin Etkinliklerinin Karşılaştırılması

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ÖZET

AMAÇ: Bu çalışmada fibromiyalji tanılı hastaların tedavisinde lokal anestetik enjeksiyon yöntemi ile fotobiyomodülasyon yönteminin etkinliklerinin karşılaştırılması amaçlanmıştır.

GEREÇ VE YÖNTEM: Amerikan Romatoloji Cemiyeti tanısal kriterlerine göre fibromiyalji sendromu tanısı konmuş olan 20 ila 60 yaş arasındaki 40 kadın hasta çalışmaya dâhil edilmiştir. Hastalar randomize olarak iki çalışma koluna ayrılmış, bir gruba omuz kuşağındaki hassas noktalara prilokain enjeksiyonu yapılırken, diğer gruba ise fotobiyomodülasyon tekniği ile düşük doz lazer uygulaması yapılmıştır. Ayrıca, her iki çalışma kolundaki hastalara uygun postüral ve germe egzersizlerinin yer aldığı bir eğitim programı uygulanmıştır. Hassas nokta sayısı, sabah sertliği, uyku kalitesi, kas spazmları ve kısıtlılık parametreleri likert ölçeği ile, ağrı seviyeleri görsel analog skala ile, hastaların genel durumları Fibromiyalji Etki Anketi ile ve hastaların psikososyal durumları ise Beck Depresyon Ölçeği ile değerlendirilmiştir..

BULGULAR: Her iki çalışma kolunda uygulanan tedavi yöntemlerinin hastalarda istatistiksel olarak anlamlı iyileşme sağladığı tespit edilmiş, ancak iki tedavi modalitesinin arasında istatistiksel olarak anlamlı fark bulunmadığı tespit edilmiştir. Lokal anestetik enjeksiyonu ile hassas nokta sayısındaki azalmanın, kas spazmlarındaki düzelmenin ve kısıtlılık seviyesindeki düşüşün daha fazla olduğu, fotobiyomodülasyon kolunda ise sabah sertliğinin, uyku kalitesinin ve Beck depresyon skalası skorlarının daha fazla düzelme gösterdiği belirlenmiştir..

SONUÇ: Bulgularımıza göre her iki yöntemin de fibromiyalji sendromunun tedavisinde etkin şekilde kullanılabileceği görülmüştür. Ancak, hastaların klinik özellikleri göz önünde tutularak en uygun tedavi yönteminin seçilmesi hastaların tedavi başarısını artıracaktır.

Anahtar Kelimeler: fibromiyalji, lokal anestetik, fotobiyomodülasyon

ABSTRACT

OBJECTIVE: This study aimed to evaluate the efficiencies of local anesthetic injection and photobiomodulation methods in the treatment of fibromyalgia syndrome.

MATERIALS AND METHODS: A total of 40 patients between 20 to 60 years-of-age and diagnosed with fibromyalgia syndrome according to the diagnostic criteria of the American College of Rheumatology were included in the study. Patients were randomized into two study arms, of which the first group received prilocaine injection to the tender points on the shoulder girdle, and the second group of patients received photobiomodulation by low-dose laser application. Also, both study groups received an education program that included postural and stretching exercises. The number of tender points, morning stiffness, sleep quality, muscle spasms, and disability parameters were compared using likert scale, pain levels were compared using visual analog scale (VAS), general status was compared using Fibromyalgia Impact Questionnaire (FIQ), and psychological status were compared using Beck Depression Inventory (BDI).

RESULTS: Both methods showed statistically significant improvements. Additionally, regarding the improvement levels, local anesthetic injection decreased the number of trigger points, and improved muscle spasm and disability levels more. On the other hand, low-dose laser therapy improved the morning stiffness, sleep quality, and Beck depression scale scores more.

CONCLUSION: According to our results, both methods were efficient for the treatment of fibromyalgia syndrome. Individual patient assessment, and selecting the method that most fits the patient needs is crucial for successful outcomes.

Key Words: fibromyalgia, local anesthetic, photobiomodulation, laser therapy

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INTRODUCTION

Fibromyalgia is the second most common rheumatologic disease following osteoarthritis [1]. This disease can also be defined as a chronic pain disorder without an exactly known etiology and physiopathology [2, 3]. Its prevalence may vary between 2% to 8% based on the diagnostic criteria used [4]. It is characterized with prevalent musculoskeletal pain and fatigue, and these may be accompanied frequently with cognitive and mood disorders [5, 6]. This disease may present in both sexes and in all age groups, but is mostly affects females between 40 to 60 years of age [6].

The current treatment of fibromyalgia syndrome includes an integrated approach of pharmacological and non-pharmacological methods, and active participation of patients to treatment course. Current guidelines emphasize the importance of including the specialists who are experienced in patient education, exercise therapists, and cognitive behavioral therapists in a team for the treatment of fibromyalgia [1]. The exercise therapies, physical treatments, and psychotherapies will both increase the functional capacities, as well as their quality of life [7, 8].

One of the methods for the treatment of fibromyalgia is local anesthetic injection. This method enables both local pain control, as well as stimulation of blood flow to ischemic tissues. Prilocaine injections may also provide a 2 weeks to 3 months of symptom-free periods [9]. Another non-pharmacological treatment modality of fibromyalgia is laser applications, and these applications have been reported to decrease the number of sensitive points and improve the physical examination findings [10]. Laser treatment is a phototherapy method and it is based on the principle that monochromatic rays have a biomodulatory effect in biological tissues. In this application, low energy doses are applied to the tissues to stimulate cellular processes and to accelerate biochemical reactions. Currently, infrared, Gallium-Arsenide (Ga-Ar) and Helium-Neon lasers are among the methods that can be used for this purpose. With these methods, low-power energy applications are performed to prevent thermal changes while stimulating neuronal activity [11, 12]. While these applications are generally referred to as “low-dose laser therapy” in the literature, this terminology was revised as “photobiomodulation” in 2014 at the nomenclature consensus meeting of the North American Phototherapy Association and the World Laser Therapy Association [13].

In the light of the available information in the literature, we aimed to compare the efficacy of local anesthetic injection and photobiomodulation techniques for decreasing the number of tender points, pain, and other symptoms in patients with fibromyalgia.

METHODS

The protocol of this randomized, single-blind, prospective study was approved by the Ethics Committee of Abant Izzet Baysal University, and the study was conducted at the Department of Physical Therapy and Rehabilitation of Abant Izzet Baysal University Medical Faculty. We included female patients between 20 to 60 years of age, whom were diagnosed with fibromyalgia according to the American College of Rheumatology (ACR) criteria and had pain in the shoulder girdle for at least 3 months. Patients with secondary fibromyalgia, psychiatric disease, immunodeficiency, clinically significant neurological, endocrinological or inflammatory disease, local infection at the shoulder joint and pregnancy status were excluded.

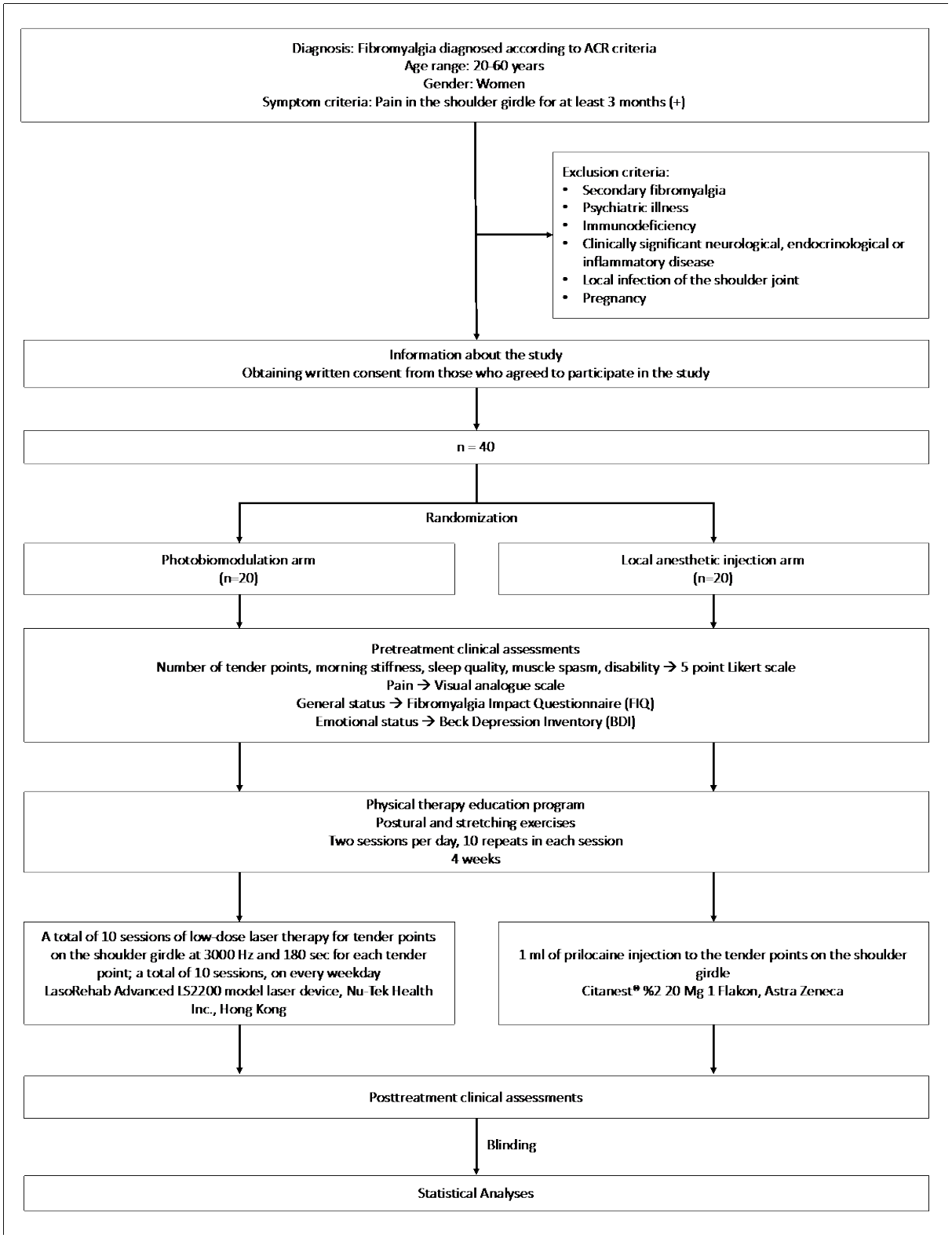
The sample size estimations revealed 35 patients were needed to determine the study findings with 80% power under the two-tailed hypothesis design and 5% type I error assumptions when the effect size (d) of the improvement in the clinical status of the patients for both local anesthetic injection and photobiomodulation techniques was considered as 0.5. With inclusion of the 10% non-response rate, a total of 40 patients were included in the study.

The participants were randomized into two groups (local anesthetic injection (LAI) and photobiomodulation (PBM)) through a block randomization using a digital random number generator. There are 20 patients in each group. A training program including postural and stretching exercises was administered to both study groups for two times a day, and 10 repeats in each session for 4 weeks. In addition to this program, 1 ml prilocaine (Citanest® 2% 20 Mg 1 Vial, Astra Zeneca) was injected daily to the tender points in the shoulder girdle of the patients in the local anesthetic injection group. And, in the photobiomodulation group, a total of 10 sessions of low-dose laser therapy (LasoRehab Advanced LS2200 model laser device, Nu-Tek

Health Inc., Hong Kong) was administered at 3000 Hz and 180 seconds.

The numbers of tender points, morning stiffness, sleep quality, muscle spasm and disability were evaluated with a 5-point Likert-type scale, and pain was evaluated using visual analog scale. Fibromyalgia Impact Questionnaire (FIQ) was used to evaluate the general status of the patients and Beck Depression Inventory (BDI) was used to evaluate the emotional status of the patients. The flowchart of the study is summarized in Figure 1.

Figure 1. *Study flow-chart*



Fibromyalgia Impact Questionnaire

Turkish validity and reliability of this questionnaire was shown by Ediz et al. [14], and the questionnaire evaluates the "Function", "General Impact" and "Symptom" status of the patients on a scale of 0-10 (0: best, 10: worst). The total score of the questionnaire is calculated by summing 1/3 of the "Function" total score, the "General Impact" total score, and 1/2 of the "Symptom" total score.

Beck Depression Scale

The validity and reliability of the Turkish version of this scale was shown by Hisli [15]. The depression status of the patients is evaluated on a 21 question scale. The total score of 0-13 from the 0-3 point questions means no depression, 14-24 means moderate depression, and 25 points and above is interpreted in favor of the presence of severe depression.

Statistical Analysis

Descriptive statistics of the study are presented with mean and standard deviation for numerical data, and frequency and percentage for categorical data. Comparisons of the numerical data between the independent groups of the study were performed by Mann-Whitney U test, and before and after the treatment of the dependent groups by Wilcoxon test. In all analyzes, 5% Type-I error was accepted for statistical significance. G * Power for Mac software was used for sample size calculations, and SPSS 21 software (IBM Inc., Armonk, NY, USA) was used for statistical analysis.

RESULTS

All patients in the LAI and PBM groups have completed the treatment and included in the analyses. The mean ages (SD) of the women in LAI and PBM groups were 39.4 (13.9) and 39.6 (12.4) years, respectively (p=0.96). For the marital status, more patients were married in LAI group (85% vs. 70%), but the difference was not significant (p=0.46). Likewise, the occupation (p=1.00) and education status (p=0.95) were also similar between two groups. The general demographics of the patients were summarized in Table 1.

The comparisons of clinical parameters between study groups, and between pre- and post-treatment periods were presented in Table 2. Improvements in each clinical assessment parameter after treatment in both groups were found to be statistically significant.

Table 1. *General demographics of the patients*

	PBM (n=20) Mean±SD	LAI (n=20) Mean±SD	Z	p
Age (years)	39.6 ± 12.4	39.4 ± 13.9	-0.048	0.96
	n (%)	**n (%)**	χ^2	**p**
Marital status			1.73	0.46
Single/divorced	6 (30)	3 (15)		
Married	14 (70)	17 (85)		
Occupation			0	1.00
Housewife	13 (65)	13 (65)		
Working	7 (35)	7 (35)		
Education			1.71	0.95
Primary	6 (31.6)	6 (30)		
Secondary	2 (10.5)	3 (15)		
High school	6 (31.6)	8 (40)		
University	4 (21.1)	3 (15)		

Table 2. *Comparisons of clinical parameters between study groups, and between pre- and post-treatment measurements*

	PBM (n=20) Mean±SD	LAI (n=20) Mean±SD	U	p
Number of tender points				
Pre-treatment	13.7±1.92	13±1.62	-1.161	0.245
Post-treatment	9.95±1.7	9.15±1.53	-1.653	0.098
Z	-3.985	-3.975		
p	<0.001	<0.001		
Morning stiffness				
Pre-treatment	2.65±1.39	2.05±1.05	-1.305	0.192
Post-treatment	2.15±0.99	1.8±0.77	-1.144	0.252
Z	-2.714	-2.236		
p	0.007	0.025		
Sleep quality				
Pre-treatment	3.75±0.64	3.35±0.75	-1.781	0.075
Post-treatment	2.8±0.62	2.65±0.67	-0.591	0.555
Z	-4.146	-3.276		
p	<0.001	0.001		
Muscle spasm				
Pre-treatment	3.6±0.82	3.65±0.59	-0.097	0.923
Post-treatment	2.8±0.62	2.5±0.61	-2.255	0.024
Z	-3.557	-3.508		
p	<0.001	<0.001		
Disability				
Pre-treatment	3.15±0.67	3.15±0.81	-0.119	0.905
Post-treatment	2.6±0.5	2.35±0.49	-1.563	0.118
Z	-3.051	-3.358		
p	0.002	0.001		
VAS				
Pre-treatment	6.8±1.32	7.8±1.32	-2.677	0.007
Post-treatment	3.15±1.35	3.95±1.19	-1.925	0.054
Z	-3.984	-3.95		
p	<0.001	<0.001		
BDS				
Pre-treatment	17.05±6.07	16.15±5.46	-0.475	0.635
Post-treatment	14.4±6.17	13.4±4.48	-0.217	0.828
Z	-2.871	-3.182		
p	0.004	0.001		
FIQ				
Pre-treatment	55.91±8.44	59.05±10.98	-1.082	0.279
Post-treatment	34.15±8.18	35.24±10.68	-0.298	0.766
Z	-3.92	-3.823		
p	<0.001	<0.001		

The comparisons in each study group revealed that the pretreatment pain score was significantly high in LAI group (7.81.3 vs. 6.81.3; p=0,007), and this was still marginally

significant after the treatment (3.95□1.2 vs. 3.2□1.4; p=0.054). All other clinical parameters were similar between the study groups.

Table 3.*Percent improvement in clinical parameters*

	PBM (n=20) % IMP*	LAI (n=20) % IMP*	U	p
Number of tender points	27.5	29.7	-1.042	0.297
Morning stiffness	12.6	7.9	-0.965	0.335
Sleep quality	25.2	19.6	-1.056	0.291
Muscle spasm	20.3	29.6	-1.802	0.072
Disability	15.4	22.4	-1.416	0.157
Pain	55.0	48.8	-1.345	0.179
BDS***	15.2	14.6	-0.789	0.430
FIQ**	39.1	39.4	-0.243	0.808

** **IMP** improvement* *****FIQ** Fibromyalgia Impact Questionnaire*
**** **BDS** Beck Depression Scale*

The percent improvements in clinical parameters were presented in Table 3. Accordingly, none of the improvement levels were significantly different between study groups. Nevertheless, the decreases in the number of tender points (29.7% vs. 27.5%), muscle spasm (29.6% vs. 20.3%), and disability scores (22.4% vs. 15.4%) were more in LAI group. On the other hand, improvements in morning stiffness (12.6% vs. 7.9%), sleep quality (25.2% vs. 19.6%), and pain (55% vs. 48.8%) were found to be higher in PBM group.

DISCUSSION

Fibromyalgia is a disease characterized by widespread muscle pain and fatigue and is often associated with some other cognitive and mood disorders. In this study, we compared the efficacy of photobiomodulation and local anesthetic injection methods in the treatment of this condition, which negatively affects the quality of life of the patients, and found that both methods may provide clinical benefit for the patients. In addition, although it did not reach the statistical significance, the two methods were found to improve different clinical parameters with different proportions.

The primary aim in the treatment of fibromyalgia is to achieve pain control as well as to improve the functional capacity. Various pharmacological and non-pharmacological methods are being used for this goal. Nevertheless, alternative treatment methods are also investigated since some patients may be refractory to treatment, or cannot tolerate or loss the adherence to the treatment [16]. According to the currently available literature, patient education, physical therapies, exercise applications, pharmacotherapy, and low-dose laser therapies are among the most commonly applied methods in the treatment of fibromyalgia [17, 18].

A recent literature search revealed only a limited number of studies that directly compared the low-dose laser therapy and local anesthetic injection methods like in our study. In one of those studies, Tuncay et al.[19] found that both methods decreased the pain and disease symptoms. But, authors have also reported that low-dose laser therapy was more effective in the early treatment period. In our study, we found that clinical parameters that are more associated with early treatment effect like morning stiffness, sleep quality and pain were improved better in the PBM arm, which was considered as a similar finding with those of Tuncay et al. In another study, de Souza et al.[20] compared the low-dose laser therapy and anesthetic injection for the treatment of orofacial pain in patients with fibromyalgia, and reported that 780 nm wavelength diode laser GaAlAs (Gallium-Aluminum-Arsenide) and 2% lidocaine injection methods had equivalent efficacy to control the orofacial pain in these patients. Our patients are in concordance with the findings of de Souza et al.

There are also several other previous studies that compared these two methods per se. One of these studies was conducted by Hong et al. [21], and evaluated the efficacy of 0.5% xylocaine injection to the tender points on trapezius muscle of the patients with myofascial pain syndrome and with/without fibromyalgia syndrome, and found that patients with fibromyalgia were benefited from this treatment more when compared to ones without. In another study, Altindag and Gur [22] compared the dry needling and local anesthetic injection methods on tender points of the patients with fibromyalgia, and reported that both methods were efficient to eliminate the pain and improve the quality of life. A similar study was also conducted by Genc et al.[23], which found that both dry needling and local anesthetic methods increased the pain threshold and tissue compliance, and decreased the pain scores. Another study by Guzel et al. [24] compared the local anesthetic injection and dry needling in the treatment of myofascial pain syndrome, and reported that local anesthetic injection had favorable effects for symptom management and depression. When our result are

compared with the currently available literature data, they were found to be in a general accordance, which suggest that local anesthetic injection was an efficient method for pain control and emotional status improvement.

Another method evaluated in our study is the photobiomodulation method, also defined as low dose laser application, which is reported to be safe and effective in the treatment of musculoskeletal disorders such as fibromyalgia. Studies have reported that low-dose laser treatments are effective in improving fibromyalgia symptoms and quality of life (number of tender points, pain, fatigue, morning stiffness, and depression) [10, 25]. In a study by Simunovic [26], it was reported that low-dose laser therapy applied to sensitive points can be used both alone and in combination with other therapeutic interventions, and analgesic needs of patients can be significantly reduced or even completely eliminated with adequate application. Another study was conducted by Hakguder et al.[27], and reported that the use of low-dose laser with stretching exercises provided significantly higher improvement than stretching alone. And de Carvalho et al.[28] also found that the addition of low-dose laser to exercise training provided better results than the exercise program alone.

Apart from these, several studies reported that low-dose laser applications yield statistically significant results compared to placebo laser [10, 29, 30], but several others reported that low-dose laser applications provided similar results with placebo laser [31, 32].These conflicting outcomes might be associated with patient selection criteria, demographic and clinical characteristics of patient populations, and laser types and dosages used. For better outcomes, it is important to follow the dosage and administration recommendations by professional organizations such as World Association for Laser Therapy (WALT)[33]. Indeed, in a recent systematic review and meta-analysis study evaluating the efficacy of low-dose laser treatments in the treatment of fibromyalgia, this method was reported to be highly effective and provide significant clinical benefit [34] as we found in our study.

LIMITATIONS

The small sample size, the lack of long follow-up period and a placebo-control group are the main limitations of the present study.

CONCLUSION

In conclusion, our results revealed that local anesthetic injection and photobiomodulation / low dose laser therapy are both effective methods in the treatment of fibromyalgia and there is no statistically significant difference between their efficacies. However, when the improvement rates are considered, local anesthetic injection method was found to be more effective on tender points, muscle spasm and limitation, and low dose laser therapy was more effective on morning stiffness, sleep quality, pain and depression. Therefore, both methods can be used effectively in the treatment of fibromyalgia, but considering the clinical features of the patients will be the most appropriate approach in determining the method to be applied in the treatment.

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