İstanbul Med J 2025; 26(1): 16-21
DOI: 10.4274/imj.galenos.2024.90236

Comparison of the Effectiveness of Blinded Versus Ultrasound-Guided Trigger Point Injections into the Trapezius Muscle in Patients with Fibromyalgia

Muhammet Şahin Elbastı[1], Songül Bağlan Yentür[2]

[1]Elazığ Medical Hospital, Clinic of Physical Medicine and Rehabilitation, Elazığ, Türkiye
[2]Fırat University Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Elazığ, Türkiye

ABSTRACT

Introduction: The primary objectives of treating fibromyalgia syndrome (FMS), which frequently coexists with myofascial pain syndrome (MPS), are to deactivate trigger points, alleviate pain, and remove factors that exacerbate the condition. Recently, the use of ultrasound (US) has been advocated to reduce potential complications during trigger point injections (TPI) and to ensure a more effective treatment administration. This study aimed to compare the effectiveness of blinded versus US-guided TPI into the trapezius muscle in patients with FMS and associated MPS.

Methods: A total of 75 patients with FMS and trapezius muscle trigger points indicative of MPS participated in this study. They were randomly assigned to one of two groups: the US-guided trigger point group and the blinded trigger point group. Both groups followed the same home exercise regimen, which included stretching and posture exercises targeting the trapezius and pectoral muscles. The effectiveness of the treatments was evaluated one month after treatment. The assessment tools included the Fibromyalgia Impact Questionnaire for function, the visual analog scale for pain, the Beck Anxiety Inventory for anxiety, and the Neck Disability Questionnaire for neck disability.

Results: Data from 60 patients were included in the final analysis. No statistically significant differences were found between the demographic variables of the two groups ($p>0.05$). A comparison of US-guided and blinded TPI revealed a significant difference in neck disability ($p=0.041$). Both groups showed significant improvements in all evaluated parameters from pre-treatment to post-treatment ($p<0.05$).

Conclusion: US-guided TPI positively impacted pain, function, anxiety, and neck pain in patients with FMS and associated MPS. This method can be recommended in clinical settings to help alleviate the symptoms of both conditions.

Keywords: Fibromyalgia, injection, myofascial pain syndrome, trigger point

Introduction

Fibromyalgia syndrome (FMS) is characterized by chronic, widespread musculoskeletal pain that is often accompanied by other symptoms, such as fatigue, sleep disturbances, and mood disorders. It is estimated that 2-8% of the world population will be affected by FMS (1). Although FMS can be observed in all races at any age and sex, it is most commonly observed in patients aged 40-60 years and female patients (2). The pathogenesis of FMS is still not fully explained (3). Central sensitization plays a role in FMS, chronic fatigue syndrome, functional dyspepsia, interstitial cystitis, irritable bowel syndrome, temporomandibular joint dysfunction, myofascial pain syndrome (MPS), posttraumatic stress disorder, and restless legs syndrome (3,4). Pain is associated with disease severity, decreased functional level, and FMS in individuals with FMS. Therefore, it is an important symptom that may affect physical functionality (5).

MAS is a regional pain disorder that affects all age groups and manifests itself with symptoms and signs, such as pain, spasm, and limitation of movement, characterized by hypersensitive points in muscles or fascia called trigger points (6). Although the exact prevalence of MAS in the general population is not clearly stated in the available literature, some studies have revealed that MAS accounts for 30-85% of musculoskeletal pain cases (7).

Neck and upper back pain is the most common complaint of MAS because the trapezius muscle is affected. The main goal of this approach is to

Address for Correspondence: Songül Bağlan Yentür MD, Fırat University Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation, Elazığ, Türkiye
E-mail: songulbaglan23@hotmail.com **ORCID ID:** orcid.org/0000-0001-9394-4817

Cite this article as: Elbastı MŞ, Bağlan Yentür S. Comparison of the effectiveness of blinded versus ultrasound-guided trigger point injections into the trapezius muscle in patients with fibromyalgia. İstanbul Med J. 2025; 26(1): 16-21

Received: 05.06.2024
Accepted: 02.12.2024
Publication Date: 19.02.2025

achieve normal muscle length, function, and strength by eliminating muscle tension and alleviating chronic pain (8). Chronic pain causes insomnia, anxiety, and depression and may be a multidimensional problem by causing a comorbid or secondary decrease in activity (9).

The goal of treating MAS is to deactivate trigger points, alleviate pain, and eliminate factors that exacerbate the condition. Several treatment modalities are available for managing MAS. Trigger point injections (TPI), which have been used for years to treat musculoskeletal pain, are the most common treatment for refractory MAS (10,11). Trigger points are usually palpated during physical examination before injection. In obese patients, palpation of trigger points is challenging and sometimes impossible. It is difficult to know whether the needle is properly inserted into the muscle tissue in these patients. This may lead to an increase in complications, such as pneumothorax or injection into adipose tissue, when performing TPI in the posterolateral neck and thoracic spine muscles (12). Recently, some authors have recommended the use of diagnostic ultrasound (US) to reduce potential complications during TPI and to enhance injection effectiveness (12-14).

This study aimed to compare the effectiveness of blinded versus US-guided TPI into the trapezius muscle in individuals with FMS.

Methods

The sample size and power calculation for the study were determined using G*Power version 3.1.9.4. In the power analysis based on the results of the comparison of the difference between the visual analog scale (VAS) score averages in the study of Ateş and Çoğalgil (15) with the risk of α=0.05, 1-α=0.80 accuracy rate condition, and the effect size 0.75 actualpower: 0.80, it was concluded that a minimum of 30 people should participate in each group. Randomization was performed in 75 patients to reduce possible sample loss.

The study included 75 patients aged 20-60 years who were admitted to the Physical Medicine and Rehabilitation Outpatient Clinic of Elazığ Medical Hospital with FMS meeting the 2013 ACR criteria and cervical chronic MAS meeting the diagnostic criteria of Travell and Simons. Fifteen patients who met the exclusion criteria were excluded from the study. The study was continued for 60 patients. The randomization of the groups was performed by simple randomization using the website www.random.org. Participants were included in the groups according to the randomization list. Participants were explained that they would receive one of two different forms of TPI, but they were blinded to the study hypotheses. The first group (n=30) received MAS injection under US-guidance. The second group (n=30) received a blinded MAS injection. Both groups followed an identical home exercise regimen, which included stretching and posture exercises for the upper trapezius and pectoral muscles, administered simultaneously. Patients were reassessed 1 month after treatment to evaluate the effectiveness of the intervention.

Patients aged 20-60 years who met the 2013 ACR criteria, were diagnosed with FMS and cervical chronic MAS according to Travel and Simons criteria, had a palpated tense band in the upper trapezius muscle, and at least 1 active trigger point were included in the study. Patients with a diagnosis of cervical radiculopathy, myelopathy, local or systemic infection, treatment for MAS in the last 3 months, symptom duration less than 3 months, pregnancy status, acute or chronic disease that would cause clinical confusion at the time of the study (malignancy, fracture, organ failure vs.), uncompensated cardiovascular disease, history of inflammatory disease, history of bleeding diathesis, anticoagulant use, and cognitive inability to communicate were excluded.

Approval for our study was obtained from the Fırat University Non-Interventional Research Ethics Committee (approval number: 2024/03-10, date: 13.02.2024), and all patients were informed verbally and in writing about the study, and a consent form was signed.

Outcome Measurements

All patients were evaluated by the same investigator before treatment, and demographic information was obtained. Post-treatment controls were evaluated by an expert investigator who was blinded to the study.

The pain levels of the patients in the last week were questioned using a 0-10 cm long VAS. “0” indicated that the patient had no pain, and “10” indicated that the patient’s pain was unbearably severe (16).

Functional evaluation of the patients was performed using the Fibromyalgia Impact Questionnaire (FIQ). The FIQ is a 10-item scale that evaluates the health status and physical function of patients with FMS. A Turkish validity and reliability study was conducted by Sarmer et al. (17). High scores indicate low functionality.

The Beck Anxiety Scale (Beck-A) was used to determine the anxiety level of the patients (18). The Likert scale comprises 21 items describing anxiety symptoms. Each item was graded as none-mild-moderate-severe or scored between 0 and 3. Total score <10 indicates minimal or none, 10-18 mild-moderate, 19-29 moderate-severe, 30-63 severe anxiety (18).

The Neck Disability Questionnaire (NDQ) was used to assess the effect of neck pain on daily life (19). The questionnaire comprises 10 questions probing the effect of neck pain on pain sensitivity, personal care, weight lifting, reading, headaches, concentration, work/study, driving, sleep, and social activities. Patients were asked to choose only one of the 6 answer options for each question, considering the last month. Scoring was performed between 0 and 5 for each question. For the 10 questions, a score between 0 and 50 was obtained by summing the scores of the 10 selected options. The classification of limitations according to the NDQ score was as follows: 0-4: no limitation, 5-14: mild limitation, 15-24: moderate limitation, 25-34: severe limitation, >34: totally limited.

Intervention

The trigger points of all cases were determined and marked with a pencil at the beginning of the procedure. The skin was then cleaned with a suitable antiseptic solution, and a sterile, 25 G, 1.5-inch dental-tip needle was used. All patients were injected with 5 mL of 2% lidocaine + 5 mL of 0.9% NaCl. During injection in the first group; the linear probe (PLT-704SBT, 7.5 MHz) of the US device (Toshiba Aplio 300, Japan) was kept parallel to the trapezoidal fibers on the marked trigger point, and the dental-tipped needle was directed to the targeted point in the plane with real-time imaging (12). While injecting the second group; the needle was directed to the most sensitive point and advanced until it reached the trigger point. When the trigger point was touched, it was confirmed

that we were within the trigger point by feeling tenderness and pain not only in the local area but also in the reflection area and by observing the local twitch response or contraction of the band containing the trigger point. After negative aspiration, 0.5 cc of the solution prepared at each trigger point was injected intramuscularly.

Statistical Analysis

All statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 22.0 for Microsoft Windows. To assess whether the data followed a normal distribution, the Kolmogorov-Smirnov and Shapiro-Wilk tests were used. The data were then analyzed using either parametric or non-parametric statistical methods, as appropriate. Descriptive statistics are reported as numbers, percentages, and as minimum, maximum, mean ± standard deviation. Categorical variables were examined using the Pearson's chi-squared test, whereas continuous variables were assessed using the Independent t-test and Mann-Whitney U test. For dependent group comparisons, the Wilcoxon test was used to non-parametric data, and the Paired Sample t-test was used for parametric data. A p-value 0.05 was considered statistically significant.

Results

The demographic characteristics of the patients are presented in Table 1. There were no statistically significant differences in demographic variables among the three groups concerning demographic variables ($p>0.05$). Figure 1 illustrates the study design and flow chart. The study included 60 female patients. Group 1 consisted of patients receiving US-guided injections, while group 2 consisted of those receiving blinded injections. The mean number of active trigger points detected and injected in group 1 was 3.30±1.20, while the mean number of active trigger points detected and injected in group 2 was 3±1.28. There was no significant difference in the number of injections between the two groups ($p=0.348$). A summary of the pre- and posttreatment comparisons between the two groups is presented in Table 2, revealing a significant difference only in the NDQ ($p=0.041$). Table 3 presents a comparison of the groups before and after treatment, showing statistically significant differences in the parameters assessed post-treatment in both groups ($p<0.05$). Table 4 summarizes the subgroup ratios for VAS, NDQ, and Beck-A in both groups, where no significant differences were observed in the analyzed parameters.

Discussion

This study aimed to compare US-guided and blinded TPIs. The results of the study demonstrated that there was no significant difference between US-guided and blinded applications in pain, anxiety, and FIQ; a significant difference was obtained only in the NDQ. Although no statistically significant difference was observed, the US-guided application was found to provide more improvement in pain, anxiety, and FIQ. In addition, significant differences in the evaluated parameters were observed between both groups. These results suggest that US-guided injection is important in clinics because it can provide better clinical outcomes.

Significant differences were observed in pain, neck disability, FIQ, and anxiety after the interventions in both groups. Chronic widespread pain is the main symptom of FMS. Chronic and recurrent pain can cause loss of function and become a socioeconomic problem with its financial burden, as well as affecting the whole life of the individual (20). Among diseases that cause chronic widespread pain and disability, MAS is an important pain syndrome that is generally ignored by physicians. Timely detection and treatment of trigger points can prevent the progression of MAS (21). One treatment method is local anesthetic injection. This method provides both local pain control and blood flow stimulation

Table 1. Demographic characteristics of participants in groups 1 and 2

Parameters (mean ± SD)		Group 1, (n=30)	Group 2, (n=30)	p
Age (years)		44.03±11.14	45.40±9.72	0.609*
Weight (kg)		67.70±10.59	70.50±11.23	0.325**
Height (cm)		160.70±5.52	160.80±6.39	0.949**
BMI (kg/cm^2)		26.33±4.70	27.38±4.89	0.145**
Education level	Primary school	7 (23.3%)	1 (3.3%)	0.145***
	Middle school	13 (43.3%)	18 (60%)	
	High school	5 (8.3%)	6 (20%)	
	University	5 (16.7%)	5 (16.7%)	
Marital status	Married	23 (76.7%)	21 (70%)	0.559***
	Single	7 (23.3%)	9 (30%)	
Menopause	Yes	10 (33.3%)	12 (40%)	0.592***
	No	20 (66.7%)	18 (60%)	
Smoking	No	6 (20%)	7 (23.3%)	0.754***
	Former smoker	24 (80%)	23 (76.7%)	
Working status	No	24 (80%)	27 (90%)	0.278***
	Yes	6 (20%)	3 (10%)	
Number of trigger points		3.30±1.20	3±1.28	0.348*

SD: Standard deviation, BMI: Body mass index, *: Mann-Whitney U test, **: Independent t-test, ***: Pearson's chi-squared test

to ischemic tissues. Prilocaine injections can also provide symptom-free periods of 2 weeks to 3 months (15). TPI is considered the gold standard in trigger point treatment because it is a rapid and effective method for pain relief. The results of this study demonstrated that TPI was effective in terms of clinical parameters. Therefore, TPI, with or without US guidance, should be applied together with other physical therapy methods, as described in this study (22). It is known that neck pain is effective in reducing the psychological, social, and physical status of patients with FMS (23). Improvements in the levels of neck disability, functional level, and anxiety may stem from the decrease in pain observed in this study.

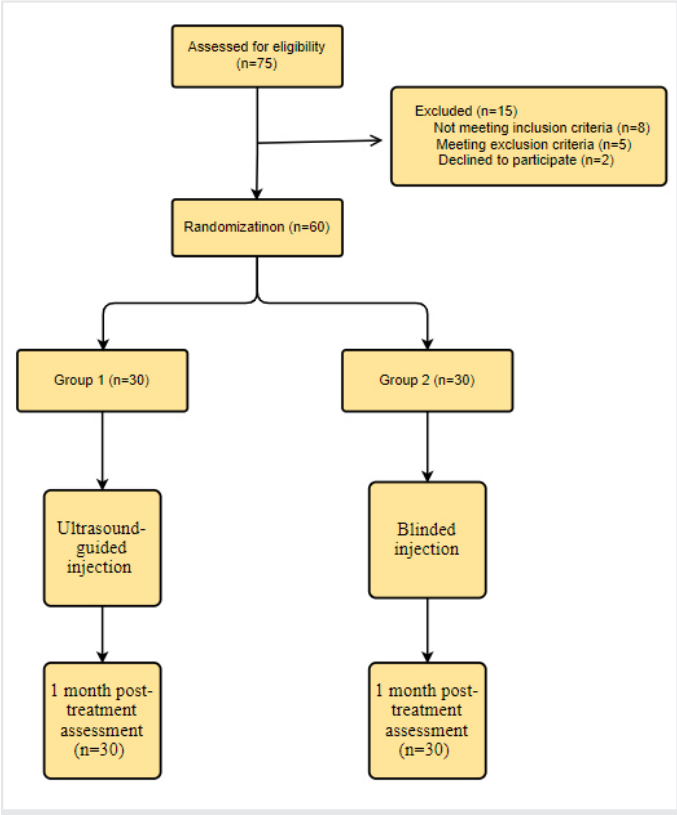

Figure 1. Study flow chart

Although there was no significant difference between US-guided and blinded injection in many parameters, it was observed that US-guided injection provided more improvement when the changes in the groups were analyzed in our study. The small sample size may be a reason for not obtaining a statistically significant differences. A significant difference could be observed with a larger sample. Injections into the upper trapezius muscle, which is only a superficial muscle, may be effective for similar improvement in both groups. Deep injections are recognized as more effective than superficial injections, and using US guidance can help reduce the risk of complications associated with blind injections, such as pneumothorax, air embolism, accidental intrathecal injection, peripheral nerve injuries, and muscle injuries (24). In a review study including US-guided applications, it was reported that all applications resulted in zero or minimal side effects. Therefore, US provides a significant advantage for deep injections (25). However, similar side effects are less common in superficial applications. Therefore, the results of this study suggest that the use of US in superficial injections may provide more successful results in terms of clinical parameters. However, blinded treatment is also effective. In a study conducted by Kang et al. (26), similar to our study, US-guided TPI was demonstrated to be a more useful method than blind injection. Kang et al. (26) evaluated the effects of 4 weeks of treatment in this study; we evaluated the acute effects in this study. The lack of long-term results in our study may be a deficiency, but according to the authors' knowledge, no study has evaluated the acute effects of TPI application in the literature. The proposed method is important in terms of evaluating the gains obtained immediately after application. Ultrasonography has the potential to be a diagnostic aid at the bedside to help clinicians make an accurate diagnosis, improve patient experience during examination, and avoid unnecessary treatments that may reduce the risk of iatrogenic damage.

Table 2. Comparison of the pre- and posttreatment values of pain, function, disability, and anxiety between groups 1 and 2

Parameters	Pre-treatment			Post-treatment		
	Group 1, (n=30)	Group 2, (n=30)	p	Group 1, (n=30)	Group 2, (n=30)	p
VAS	8.00±1.55	7.40±1.56	0.136*	6.40±1.69	6.76±1.56	0.474*
FIQ	64.38±6.99	62.18±8.88	0.292**	58.81±6.43	59.85±7.09	0.555**
NDQ	31.23±11.30	28.43±10.54	0.325**	20.33±8.20	26.20±10.47	**0.041***
Beck-A	27.60±12.38	28.80±12.44	0.709**	24.86±10.66	26.36±11.33	0.610*

VAS: Visual analog scale, FIQ: Fibromyalgia Impact Questionnaire, NDQ: Neck Disability Questionnaire, Beck- A: Beck Anxiety Scale, *: Mann-Whitney U test, **: Independent t-test

Table 3. Comparison of parameters before and after treatment in groups 1 and 2

Parameters	Group 1			Group 2		
	Pre-treatment	Post-treatment	p	Pre-treatment	Post-treatment	p
VAS	8.00±1.55	6.40±1.69	**<0.001***	7.40±1.56	6.76±1.56	**0.014***
FIQ	64.38±6.99	58.81±6.43	**<0.001****	62.18±8.88	59.85±7.09	**0.006***
NDQ	31.23±11.30	20.33±8.20	**<0.001***	28.43±10.54	26.20±10.47	**0.010***
Beck-A	27.60±12.38	24.86±10.66	**0.001***	28.80±12.44	26.36±11.33	**0.002***

VAS: Visual analog scale, FIQ: Fibromyalgia Impact Questionnaire, NDQ: Neck Disability Questionnaire, Beck-A: Beck Anxiety Scale, *: Wilcoxon test, **: Paired sample t-test

Table 4. Subgroup comparison of pain, neck disability, and anxiety in the two groups

Parameters		Pre-treatment			Post-treatment		
		Group 1, (n=30)	Group 2, (n=30)	p*	Group 1, (n=30)	Group 2, (n=30)	p*
VAS	Mild			0.317	1 (3.3%)		0.559
	Moderate	4 (13.3%)	7 (23.3%)		14 (46.7%)	13 (43.3%)	
	Vigorous	26 (86.7%)	23 (76.7%)		15 (50%)	17 (56.7%)	
NDQ	Mild	1 (3.3%)	3 (10%)	0.433	10 (33.3%)	5 (16.7%)	0.223
	Moderate	8 (26.7%)	8 (26.7%)		10 (33.3%)	10 (33.3%)	
	Vigorous	9 (30%)	12 (40%)		9 (30%)	10 (33.3%)	
	Completely disabled	12 (40%)	7 (23.3%)		1 (3.3%)	5 (16.7%)	
Beck-A	No/minimal	2 (6.7%)	3 (10%)	0.342	2 (6.7%)	4 (13.3%)	0.553
	Mild/moderate	8 (26.7%)	4 (13.3%)		8 (26.7%)	4 (13.3%)	
	Moderate/vigorous	5 (16.7%)	10 (33.3%)		11 (36.7%)	12 (40%)	
	Vigorous	15 (50%)	13 (43.3%)		9 (30%)	10 (33.3%)	

VAS: Visual analog scale, NDQ: Neck Disability Questionnaire, Beck-A: Beck Anxiety Scale, *: Pearson's chi-squared test

Trigger point detection is generally thought to require palpation, but patient tension or startle during palpation may adversely affect the result. Another consideration is the size of the trigger point. For example, trigger points in the upper fibers of the trapezius can be as small as 0.16 ± 0.11 cm^2 and this may cause difficulty in detecting abnormalities in the tissue under the fingers of the palpator (1,27). Therefore, the use of the US may provide more accurate and clear information. This is encouraging because US is a more objective method for diagnosing trigger points. Although visualizing individual trigger points can be challenging because of their small size, some experts recommend using US to ensure accurate needle placement into muscle tissue, avoiding fat or other non-muscle structures during TPI (12).

A significant difference in neck disability between the groups was obtained from this study. Rayalam et al. (28) reported studies on TPI with US guidance and a blinded method. At the end of 4 weeks, no significant difference was observed in manual muscle testing and range of motion, but a significant difference was observed in pain, neck disability, and shoulder disability. In this study, the neck disability level was evaluated using a questionnaire. In this questionnaire, we evaluated neck pain and difficulties in activities of daily living. Although no significant difference was obtained in the pain levels of the patients who participated in our study, the fact that a significant difference was obtained in the level of neck disability may be due to the fact that the patients could use their neck more comfortably in daily life.

Study Limitations

This study has some limitations. The lack of deep tissue injection and not determining possible side effects are limitations for this study. In addition, the small sample size is a limitation of this study.

Conclusion

In our study examining the effects of US-guided and blinded TPI on clinical parameters, we found that both methods were effective for pain, disability, anxiety, and FIQ. Our study is important because it is the first to investigate the acute effects of TPI on clinical symptoms. However, we conclude that US-guided treatment is more effective at the level of neck disability. The development of US technology has significantly improved the quality of soft tissue and muscle scans. The use of US in the TPI technique, real-time imaging of trigger points, and visualization of surrounding tissues or important structures can lead to more successful results. Safety is an important aspect for patients and should not be overlooked. Future research could focus on establishing more objective diagnostic criteria for trigger points through the use of US imaging.

Ethics

Ethics Committee Approval: Approval for our study was obtained from the Fırat University Non-Interventional Research Ethics Committee (approval number: 2024/03-10, date: 13.02.2024).

Informed Consent: All patients were informed verbally and in writing about the study, and a consent form was signed.

Footnotes

Authorship Contributions: Surgical and Medical Practices - M.Ş.E.; Concept - M.Ş.E.; Design - M.Ş.E.; Data Collection or Processing - M.Ş.E.; Analysis or Interpretation - M.Ş.E., S.B.Y.; Literature Search - M.Ş.E., S.B.Y.; Writing - M.Ş.E., S.B.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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