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ORIGINAL ARTICLE

Treatment of fibromyalgia among patients with mastalgia and fibromyalgia improved mastalgia

Mastaljisi olan fibromiyalji ve mastalji hastalarında tedavi ile mastalji düzeliyor

Tonguç Utku YILMAZ,[1] Murat İNANIR,[2] Saffet ÇINAR,[3] Sertaç Ata GÜLER,[3] Nihat Zafer UTKAN[3]

Summary

Objectives: The aim of this study is to examine the effect of fibromyalgia (FM) treatment on mastalgia by performing fibromyalgia screening in patients who applied for mastalgia and whose underlying cause could not be found.

Methods: Patients who applied to Kocaeli University General Surgery Outpatient Clinic between November 2017 and November 2020 with breast pain were included (n=120). Patients without cancer, systemic disease, previous breast surgery, and breast mass larger than 3 cm (n=30) were referred to the Physical Therapy and Rehabilitation Outpatient Clinic. A total of 13 patients (43%) were diagnosed with FMS. Twelve of them were given selective serotonin-noradrenaline reuptake inhibitor (duloxetine) treatment for 3 months. Turkish version of the Short Form – 36 (SF-36) quality of life scores, Visual Analog Scale (VAS), Cardiff breast pain score before and after treatment were compared. The remaining 17 patients were followed as only mastalgia.

Results: Patients with fibromyalgia and mastalgia had similar demographic results. At the end of the 3rd month, the complaints of breast pain completely regressed in all of the patients. Statistically significant changes were detected in VAS score, the number of trigger points, and SF-36 quality of life scores, Cardiff breast pain score after duloxetine treatment.

Conclusion: In the presence of unexplained mastalgia, fibromyalgia should be kept in mind. Duloxetine treatment improved the breast pain and quality of life in patients with mastalgia and fibromyalgia.

Keywords: Breast Pain Score; duloxetine; fibromyalgia; mastalgia.

Özet

Amaç: Bu çalışmanın amacı, altta yatan herhangi bir sebep bulunamayan mastalji hastalarında fibromiyalji taramasının yapılmasının önemi ve fibromiyalji tedavisinin mastalji üzerine etkisinin araştırılması.

Gereç ve Yöntem: Bu çalışma, Kasım 2017 ile Kasım 2020 tarihleri arasında Kocaeli Üniversitesi Genel Cerrahi Anabilim Dalı Polikliniğine meme ağrısı ile başvuran (n=120) hastalar üzerinde yapılmıştır. Bilinen kanser, sistemik romatolojik hastalık, geçirilmiş meme ameliyatı ve memesinde 3 cm'den büyük kitle olan hastalar çalışma dışı bırakılmıştır. Çalışmaya dahil edilen (n=30) hasta Fizik Tedavi ve Rehabilitasyon bölümüne yönlendirilmiştir. Toplam 13 hasta fibromiyalji tanısı almıştır. On iki hasta 3 aylık selektif serotonin noradrenalin reuptake inhibitörü (Duloksetin) tedavisi almıştır. Hastaların tedavi öncesi ve sonrası hayat kaliteleri, Cardiff meme ağrı skorları, VAS skorları değerlendirilmiştir. Kalan 17 hasta mastalji nedeniyle takip edilmiştir.

Bulgular: Fibromiyalji ve sadece mastalji olan hastaların karşılaştırılmasında benzer demografik bulgular saptanmıştır. Üç ayın sonunda, meme ağrıları tamamen düzelmiştir. Duloksetin tedavisi sonrası hastaların VAS, ağrı noktaları, SF-36 skorları ve Cardiff meme skorlarında belirgin düzelme gözlenmiştir.

Sonuç: Sebebi açıklanamayan meme ağrılarında fibromiyalji akılda tutulmalıdır. Duloksetin tedavisi, mastalji ve fibromiyalji olan hastaların meme ağrısı ve hayat kalitesinde düzelme sağlamaktadır.

Anahtar sözcükler: Duloksetin; fibromiyalji; mastalji; Meme Ağrı Skoru.

Introduction

Mastalgia, or breast pain, is the most common breast-related discomfort in women. Its prevalence reaches up to 70% in studies.[1,2] Breast pain often brings thoughts of malignancy to women's minds, but breast cancer is seen in only 2.9% of patients whose major symptom is mastalgia.[3,4] The main reason is usually benign or unexplained conditions. Although hormonal status, nutrition, and psychological factors are shown in the etiology of mastal-

[1]Department of Organ Transplantation, Acıbadem University Atakent Hospital, İstanbul, Türkiye
[2]Department of Physical Medicine and Rehabilitation, Kocaeli University Faculty of Medicine, Kocaeli, Türkiye
[3]Department of General Surgery, Kocaeli University Faculty of Medicine, Kocaeli, Türkiye

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Correspondence: Dr. Tonguç Utku Yılmaz. Acıbadem Üniversitesi, Atakent Hastanesi, Organ Nakli Birimi, İstanbul, Türkiye.
Phone: +90 - 212 - 404 40 20 **e-mail:** drutkuyilmaz@yahoo.com

gia, the exact reason is not clear.[5,6] Therefore, inadequate, delayed, and inappropriate approaches cause physical, financial, and emotional losses.[7] Success of different treatments vary between 45–90%.[6,8] For this reason, selection of the best treatment for appropriate patients is important.

Fibromyalgia (FM) is a chronic pain condition characterized by fatigue, sleep disturbances, and functional symptoms.[9] The prevalence of fibromyalgia is reported to be between 2–8% and increases in the 40–60 age groups.[10] Prevalence of FM among women in Türkiye is 3.6%, but highest (10.1%) among women between 50–59 years of age.[11] Studies showed that FM is more common in the female gender, among people with low educational and socioeconomic levels, and in the 40–60 age group.[10] Treatment of FM consists of patient education, pharmacological treatment, and psychotherapy, but the satisfaction rate might be as low as 50%.[9,12] Coexistence of mastalgia and fibromyalgia has been presented in previous studies at about 30–40%.[13–15] For this reason, a significant percentage of patients with mastalgia might be undertreated if not definitively diagnosed.

Here in this study, we aimed to find the ratio of fibromyalgia among patients with mastalgia and to see the efficacy of fibromyalgia treatment on mastalgia.

Material and Methods

Ethical approval for this study was obtained from the Clinical Research Ethics Committee of Kocaeli University (Date: 02 March 2015; decision number: KOÜ KAEK 2015/50). The study was conducted in Kocaeli University General Surgery Outpatient Clinic between November 2017 and November 2020 among patients (n=120) with breast pain for at least 3 months. All patients with breast pain (cyclic or non-cyclic) were examined by the same surgeon. Detailed anamnesis was taken. Age, BMI, educational status, menopausal status, employment status, smoking consumption, and educational status of the patients were recorded. All patients were evaluated with ultrasound, but patients older than 40 years old also underwent mammography examination. Patients with cancer, rheumatological disease, cervical arthritis, Tietze syndrome, previous breast surgeries, and breast mass or cyst larger than 2 cm were excluded (n=90) from the study. Remaining patients (n=30) were referred to the Physical Therapy and Rehabilitation Outpatient Clinic for fibromyalgia (FM) evaluation. The diagnosis of FM is based on the 2010 preliminary American College of Rheumatology classification criteria.[16] Thirteen patients were diagnosed with FM. One patient was excluded from the study because she had started in vitro fertilization (IVF) treatment during the follow-up. Turkish version of the SF-36 quality of life scores, VAS scores during examination, number of pain trigger points, and durations of pain of the patients were recorded.[17] The patients diagnosed with FM were given duloxetine (Cymbalta, Eli Lilly and Company, IN, USA) 30mg b.i.d. per oral for 3 months. After treatment; VAS scores during examination, SF-36 scores, number of pain trigger points were questioned after the duloxetine treatment. The breast pain was scored by the Cardiff pain chart, which includes 31 columns for each day of a month. The patients were asked to fill out the chart every day for menstrual cycles during treatment. VAS was also applied and recorded for scoring breast pain.[18]

Remaining 17 patients with only mastalgia were informed about suitable bra wearing and also underwent evening primrose oil (EPO) (30mg/day, Solgar, USA) treatment. Patients without relief underwent non-steroid anti-inflammatory drugs (Naproxen 550 mg, b.i.d.) (Apranax, 550 mg, Abdi İbrahim İlaç, İstanbul, Turkey). Patients were followed up for six months. After treatment, mean VAS scores during examination, and Cardiff breast pain scores were evaluated before and after treatment. This research met the Ethical Principles for Medical Research Involving Human Subjects, outlined in the Helsinki Declaration of 1975 (revised 2013).

Statistical Analysis

Statistical analysis was performed with SPSS 18.0 software (SPSS, Inc, Chicago, IL, USA). All values are expressed as the mean±standard deviation for metric variables and as frequency (percentage) for categorical variables. The Mann-Whitney U test was used to compare the two groups in terms of metric variables, and the chi-square test was used for categorical variables. p-values<0.05 were considered statistically significant for all tests.

Table 1. Characteristics of the study population

	Mastalgia + Fibromiyalgia (n=12)	Mastalgia (n=17)	p
Mean age (years) mean±SD	41.3±9.3	39.7±7.9	NS
Mean BMI (kg/m^2)	34.3±4.2	30.2±5.7	NS
Education			NS
Primary scholl	8 (66.6%)	11 (65%)	
High scholl	4 (33.3%)	5 (35%)	
Employment status			NS
Housewife	11 (91.6%)	12 (70.5%)	
Employed	1 (8.4%)	5 (29.5%)	
Breast pain distribution			NS
Left breast upper outer quadrant	4 (33%)	6 (35%)	
Upper outer quadrant of both breasts	4 (33%)	6 (35%)	
Widespread	4 (33%)	5 (30%)	
Type of breast pain			NS
Cyclic	4 (33.3%)	10 (58.8%)	
Non - cylic	8 (66.6%)	7 (41.2%)	
Mean duration of breast pain (month)±SD	14.4±9.8	12.9±6.9	NS
Menapausal status			NS
Pre - menopausal	10 (83.3%)	11 (65%)	
Post - menopausal	2 (16.6%)	5 (35%)	
Smoking	5 (41%)	6 (%35)	NS

SD: Standard deviation; BMI: Body mass index; NS: Not significant.

Table 2. Before / after treatment VAS scores during examination, pain trigger point scores of patients with fibromyalgia. After treatment Cardiff breast pain score of patients with fibromyalgia

	Before treatment	After treatment	p
Mean VAS±SD	7.5±0.56	2.4±0.49	<0.01
Mean number of pain trigger joint±SD	12.8±1.3	4.25±0.64	<0.01
Mean Cardiff breast pain (score)	–	1.8±1.3	–

SD: Standart deviation; VAS: Visual Analog Score.

Results

The characteristics of the population are presented in Table 1. There was no significant difference between patients with FM+mastalgia and patients with mastalgia only.

Among patients, 25% had no possible pathology related to mastalgia. To avoid any potential bias, we excluded 75% of the patients with possible factors related to mastalgia. Fibromyalgia was seen in 43% of the patients (n=13). If all patients were included in the study, 10.8% of the patients who had admitted to the outpatient clinic with mastalgia had fibromyalgia. The study was completed with 12 patients without any loss of follow-up.

The treatment response of the patients diagnosed with FM and mastalgia and treated with 30 mg/day duloxetine for 3 months is shown in Table 2. The response to the treatment was monitored every month. The mean CBS was 5.2±1.4, 3.1±0.9, and 1.8±1.3 at the end of the 1st, 2nd, and 3rd months of treatment, respectively. All patients with fibromyalgia got rid of breast pain after the treatment. The mean VAS score, mean Cardiff breast pain score, and mean number of trigger points of the patients with

Table 3. SF-36 score of the patient with FM+mastalgia before and after the treatment

SF-36 Quality of life Scale subdimensions	Before treatment Mean±SD	After treatment Mean±SD	p
Physical functioning*	70.1±15.4	89.3±11.2	0.001
Social functioning*	73.3±12.3	86.7±15.9	0.01
Bodily pain*	69.2±18.5	78.5±18.3	0.02
Vitality*	49.7±15.3	60.3±11.7	0.02
Emotional role limitation*	64.1±13.2	74.7±15.2	0.03
Physical role limitation*	63.3±12.2	76.7±10.3	0.01
Mental health**	63.7±12.6	72.9±9.7	0.02
General health perception*	48.3±9.1	62.9±12.1	0.02

SD: Standart deviation; *: Mann-Whitney U test; **: t-test.

FM+mastalgia before and after the treatment were given in Table 2. The mean SF-36 score of patients with FM+mastalgia is presented in Table 3. No side effects of treatment were seen.

The mean follow-up of patients with mastalgia was 5.3±1.2 months. The mean VAS score of patients with mastalgia before treatment was 7.9±0.9. Among the patients with mastalgia, 13 patients (76.5%) got rid of breast pain after 2 months of EPO treatment. After quitting the treatment, 10 of them suffered from breast pain again, and EPO treatment was restarted. At the end of 6 months, the mean VAS score during examination was 4.1±2.3. Remaining 4 patients whose pain did not improve with EPO underwent NSAID treatment. It was learned that they had used the drugs when needed instead of routinely. At the end of six months, the mean VAS score was 4.9±1.2. The overall mean VAS score among patients with mastalgia after treatment was 4.5±1.8. When compared with the mean VAS scores of patients with FM+mastalgia and patients with mastalgia only, the difference was statistically significant (p=0.01).

Discussion

Mastalgia is a common and painful experience among women. Mastalgia can disturb the quality of life, sleep quality, sexual life, social life, and work life.[19,20] Besides the underlying pathologies, the etiologies of unexplained mastalgia can be hormonal factors, life habits, stress. Imbalance between estrogen and progesterone might lead to mastalgia; for this reason, in some cases, Danazol can be an option for mastalgia.[8] Here in our study, we did not prefer Danazol for our patients, because of the side effects. Alcohol, smoking, obesity, caffeine consumption, and bra size are factors that have been investigated for mastalgia.[21,22] For this reason, we recommended lifestyle changes, especially suitable bra usage, to our patients. In the systematic review about mastalgia, it was shown that suitable bra usage is a first-line management for mastalgia.[6] Although some dietary advice has been pointed out in the literature, there's no consensus for dietary changes in mastalgia.[6] There's a focus on the psychogenic properties of mastalgia. Although mastalgia seems to be a problem mainly related to the breast; nowadays, psychological factors play an important role in the approach to mastalgia.[23] In recent studies, it was seen that patients with mastalgia are experiencing more depression, anxiety, and social dysfunction.[24] In the study of Jenkins et al.,[23] it was found that 67% of patients with mastalgia were resistant to mastalgia treatment including Danazol and EPO; and most of them were diagnosed with anxiety and depression. In the study of Colegrave et al.,[19] psychiatric diagnosis (84%) was very high among patients with mastalgia. In our study, 25% of patients had unexplained mastalgia.

Unexplained pain syndromes such as FM, functional gastrointestinal disorders, irritable bowel disease, dyspepsia are all called stress-based diseases. The relationship between FM and gastrointestinal disorders and irritable bowel diseases has been investigated before.[14,25] In our study, the prevalence of FM in patients with mastalgia is 10%, which is similar to the Turkish prevalence.[11] However, the prevalence

of FM among unexplained mastalgia is 43%. This is an important finding, suggesting mastalgia might be a subset of FM symptoms. Here in our study, in order to find unexplained mastalgia, we excluded several pathologies. By this way, we were able to obtain a more homogenous group (25% of all mastalgia patients).

Fibromyalgia is an unexplained chronic pain syndrome characterized by widespread musculoskeletal pain with mood disorders, anxiety symptoms, and sleep disturbances, and has a prevalence of 1–5%.[9] The failure of the regulation of the stress system and dysfunction in central pain mechanisms may play a role in the pathophysiology of the illness, leading to a loss of capacity to adapt to all kinds of stressors. Although there are several studies reporting that low socioeconomic level, female gender, emotional abuse, and stress are risk factors for both mastalgia and fibromyalgia,[23,26] there is only one study in the literature about the coexistence of Mastalgia and FM.[13] Studies about mastalgia point to unexplained pain syndromes or several psychosocial needs.[24,27] These results might be due to undiagnosed FM patients among mastalgia cases. As seen in Table 1, there's no significant difference in demographics or pain style between patients with FM+mastalgia and mastalgia only. For this reason, it's important to suspect the existence of FM in unexplained mastalgia. These patients form 43% of all unexplained mastalgia patients. This ratio is similar to the study of Genç et al.[13] (42%). Also, the prevalence of mastalgia in FM patients was found to be 36% in the study of Genç et al.[13] In a study conducted by Sen et al.[15] in 2015, it was stated that 38% of the mastalgia group and 47% of the fibromyalgia group had mastalgia+fibromyalgia symptoms. The mean age, BMI, and education levels of patients in our study were similar to previous studies.[2,8,13,15] This is because mastalgia is more common in menopausal women. The ratio of smoking in our study is less than in previous studies. As mentioned in the systematic review by Hafız et al.,[6] smoking, methylxanthines, essential fatty acids, and vitamins have not been proved to be associated with mastalgia.

FM is a recognized medical condition, defined by diagnostic criteria, and evaluated through severity scales. Among the most important factors that impair prompt diagnosis is the lack of biomarkers: although some salivary (e.g., cortisol, alpha-amylase) or serum (e.g., cytokines) biomarkers have been proposed for FM diagnosis, their validity is still not demonstrated. Accordingly, the prevalence of FM varies depending on the criteria used, samples used, and interpretation of the results, oscillating from 2 to 8% of the general population.[28] Diagnostic complexity is increased by its complex polysymptomatology, which can continuously evolve during the course of the disease in each patient. Therefore, diagnostic criteria are continuously evolving. ACR 2010 criteria were shown to have good specificity (range 91–99%), but highly variable sensitivity (55–82%) compared with either a clinical diagnosis or fulfillment of the ACR 1990 criteria.[29] Here, we used ACR 2010 for the diagnosis of FM. The etiology of mastalgia, after excluding underlying breast pathology, is unclear. Most of the time, they're treated with analgesia. As there's no significant difference between the demographics and pain patterns of mastalgia and mastalgia+FM, it's nearly impossible to differentiate these patients only by general surgery examination.

In this study, we evaluated the pain score of patients at the examination time and scored this with a score. The VAS scores significantly improved after FM treatment. Also, we preferred the Cardiff Breast score for the long-term scores. By this way, we have the ability to follow the changes of pain during treatment time. The success of FM treatment on mastalgia was significantly seen with Cardiff Breast Scoring. It's a good way for long-term follow-up. In the study of Genç et al.,[13] it was stated that both psychosocial and physical needs of patients with severe mastalgia must be addressed as part of an effective and comprehensive management approach. In our study, duloxetine treatment not only improved the mastalgia but also the quality of life scores of patients. The success of duloxetine has been given in previous randomized clinical studies.[30–32] There are several treatment options in FM.[33,34] We preferred duloxetine treatment in FM+mastalgia, that improved all the symptoms of the patients. Duloxetine had been shown to improve the impact of fibromyalgia as measured by the FIQ and the mental component of QOL measures.[35,36] Improvement in pain after duloxetine has been shown in several random-

ized controlled studies, but our study is unique in showing this in mastalgia management.[30,31] As the scope of our study is not the evaluation of general FM findings of patients, we did not evaluate the Mixed-effects model repeated-measures analysis and last observation carried forward analysis. The high success rate of mastalgia in FM patients is not only due to duloxetine. Because these patients were informed about FM in detail by the Department of Physical Medicine and Rehabilitation and closely followed up. They were also informed about daily habits like physical exercise, sleep hours, and diet for FM treatment by the Physical Medicine and Rehabilitation doctor.

Although the treatment results of the mastalgia-only patients are not the focus of this study, it was observed that only 76% of patients got rid of breast pain after EPO treatment, and most of them suffered from recurrence of pain. As the adherence to the treatment in mastalgia-only patients was not optimal, it's difficult to determine the exact success rate. However, it's evident that the selection of patients with FM led to great success after treatment.

Conclusion

In conclusion, fibromyalgia should be considered in patients presenting with mastalgia. Conversely, patients with fibromyalgia complaints may present at the outpatient clinic with mastalgia. We should be particularly vigilant for fibromyalgia, especially in those with noncyclic pain. Nearly 10% of all patients with mastalgia and 43% of patients without any findings can be treated because of fibromyalgia. In cases of concurrent mastalgia and fibromyalgia, treatment improves the quality of life.

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