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Clinical trial

Balneotherapy is an alternative treatment for mastalgia; a randomized controlled trial☆,☆☆

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ABSTRACT

Introduction: Mastalgia is the most common breast related complaint. Balneotherapy is widely used as a non-pharmacological treatment modality in many European countries. The objective of this study was to determine the efficacy of balneotherapy in patients with mastalgia.

Methods: A randomized controlled clinical trial was conducted with forty women with mastalgia. Patients were randomly assigned to the control and balneotherapy groups. Conventional therapy was recommended for both groups for 6 weeks. The balneotherapy group was also given a total of ten sessions of balneotherapy during the last two weeks. Breast pain level, serum cytokine levels including interleukin-1β and tumor necrosis factor (TNF)-α and quality of life were evaluated in both groups before and 6-weeks after study. The Breast pain questionnaire was used for the assessment of mastalgia. This questionnaire includes sensorial and affective data, visual analog scale (VAS) and present pain intensity (PPI). Quality of life was measured by using Short Form (SF)-36.

Results: Baseline total breast pain scores (BPS) and cytokine levels were similar between the groups. Total BPS ($p = 0.001$), VAS ($p = 0.039$) and PPI ($p = 0.004$) in the balneotherapy group significantly improved after therapy. TNF-α level in the balneotherapy group also significantly decreased after therapy ($p = 0.003$). The results of SF-36 showed that five subscales were significantly improved in the balneotherapy group however only social functioning was significantly improved in the control group after treatment.

Conclusion: The results of the study revealed that balneotherapy may be an effective method in the treatment of mastalgia and it can be recommended by clinicians.

1. Introduction

Mastalgia or breast pain is the most common breast related complaint, occurring in up to 69% of women at some time in their life [1,2]. Mastalgia can be severe enough to prevent usual daily living activities and it diminishes quality of life. Although many factors including hormonal, nutritional, and psychological factors were considered in the etiopathogenesis, literature related to this topic is not clear. Furthermore, there is no breast-related disease cause to explain breast pain in many patients with mastalgia. The hypothalamic-pituitary adrenal (HPA) axis dysfunction, abnormal hormonal response to stimuli, hormonal medications, disorders of lipid metabolism, and psychological factors has been discussed in the etiopathogenesis of mastalgia [3]. The lack of clarity in etiopathogenesis is also reflected in the treatment. Current treatments are unsatisfactory for many patients and there is no single ideal treatment for mastalgia.

Frequent mastalgia (weekly, daily or almost daily) is strongly associated with posttraumatic stress disorder, depression and panic disorder, or unexplained pain syndromes such as irritable bowel syndrome, chronic pelvic pain and fibromyalgia (FM) [4]. In 2011, we also detected two distinctive entities mastalgia and FM which seem to frequently coexist in approximately 40% of patients [5]. The HPA axis

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plays a major role in the regulation of stress responses in FM similar to mastalgia [6]. Treatment is difficult and there is no consensus on ideal treatment in both of the diseases. A combination of pharmacological and non-pharmacological treatment modalities are usually required for optimal management of musculoskeletal diseases. Previously balneotherapy suggested as a non-pharmacological treatment for the management of musculoskeletal disorders such as FM and osteoarthritis [7–9].

Mastalgia is similar to FM in terms of etiological uncertainty and treatment approaches. Effective treatment modalities are required to improve quality of life in patients with mastalgia. We aimed to analyze the effects of balneotherapy on pain and quality of life in patients with mastalgia.

2. Patients and methods

This was an assessor-blinded randomized controlled clinical study. Our Ethical Committee approved the study, and informed consent was obtained from all individual participants included in the study.

2.1. Inclusiıon/exclusion criteria

Forty women with mastalgia took part in the study between June 2015 and February 2017. Diseases that may cause additional pain in the chest area (history of previous breast surgery; inflammatory and/or tumoral breast or chest disorders such as mastitis, fibrocystic breasts, breast cancer or chest malignancies etc.) or might have hindered balneotherapy (ischemic heart disease, uncontrolled hypertension, chronic venous insufficiency, etc.) were excluded from the study.

All patients had a detailed breast examination performed by the same surgeon and were evaluated using breast imaging techniques including mammography and/or ultrasonography by the same radiologist before study.

At the beginning of the study, only 8 patients did not want to participate in the study due to their intensive work. A total of 40 patients were randomly assigned to receive either a conventional treatment of mastalgia program (the control group, n = 20) or balneotherapy plus conventional treatment of mastalgia program (the balneotherapy group, n = 20) using sequence of random numbers. Four patients from the control group and 6 patients from the balneotherapy group dropped out from study due to several reasons during the study. Finally, 16 patients in the control group and 14 patients in the balneotherapy group completed the study. The flow chart of study is depicted in Fig. 1. Conventional treatment included reassurance regarding the absence of breast cancer, refraining from methylxanthine containing foods and beverages, use of a sports brassiere and paracetamol (maximum daily dose of 1000 mg) were recommended for both groups for 6 weeks. In the balneotherapy group, additional balneotherapy was given in ten sessions under the supervision of a Physical Medicine and Rehabilitation specialist at Haymana natural thermal springs in the last two weeks of the 6 week period. There are many balneotherapy units in Turkey and the properties and temperatures of the natural spring waters differ. Haymana is one of the spa centers and natural spring water contains mostly bicarbonate (610 mg/L), and florid (1.39 mg/L). There is also calcium (124–126 mg/L), magnesium (29–30 mg/L), chrome (0.28–0.34 mg/L), copper (0.33 mg/L), and zinc (0.24 mg/L) present. There are no known toxic effects. The spring thermal heat is 44 °C. The patients received bathing for a total duration of 20 min (10 min in the morning and 10 min in the late afternoon) once a day and five times per week. Patients in both groups continued their daily activities but regular exercise or walking programs were not offered during the treatment program. The use of NSAIDs was prohibited in both groups because they can affect cytokine measurement results.

The Breast pain questionnaire (BPQ) was used for the assessment of mastalgia before and after therapy. It is derived from the McGill Pain Questionnaire and available at “http://apkarianlab.northwestern.edu”. It assesses not only the degree of breast pain, but also the pattern, location, duration and frequency of pain. The calculation of the final BPQ score is simple and classified as mild (0–100), moderate (100–200), and severe (> 200) [10]. BPQ was completed 2 days after the onset of menses in all pre-menopausal patients to ensure the standardization of the study. The questionnaire was repeated at the end of the 6 weeks of treatment. The Turkish version of the Short Form-36 (SF-36) was used to evaluate the quality of life before and after treatment [11]. The SF-36 is a 36 item questionnaire which measures quality of life across eight domains, which are both physically and emotionally based. It is a useful indicator for the change in quality of life over time and treatment. Norm based scoring of the SF-36 was used in this study.

Some inflammatory cytokines such as interleukin (IL)-1β and tumor necrosis factor (TNF)-α are implicated in pain modulation. We analyzed these cytokines, in addition to subjective assessments of pain such as pain questionnaires and scales, to evaluate the pain response to mastalgia treatment in an objective manner before and after the study [12,13]. Enzyme-linked immunosorbent assays (Boster Picokine™ ELISA Kits, USA) were used for the determination of serum levels of these cytokines. Measurements were carried out at baseline and after 6-weeks of treatment.

Shapiro-Wilk test was used to assess normality assumption for continuous variables. The differences in proportions between groups were compared by using Chi-Square or Fisher’s Exact test, where appropriate. Mann-Whitney *U* test was used to evaluate differences between groups in terms of non-normally distributed continuous variables. A Wilcoxon Signed Ranks test was used to evaluate differences between after and before measurements. *p*-value of less than 0.05 was considered statistically significant.

3. Results

The mean ages of the control group and intervention group were 41.4 and 45.9 years, respectively. There were no significant differences with respect to age (p = 0.211), educational background (p = 0.296), body mass index (p = 0.492), marital status (p = 0.657), additional psychiatric disorders (p = 0.105), existence of unexplained pain syndromes (p = 1.000), menopausal status (p = 0.296) and pattern of mastalgia (cyclic or non-cyclic, p = 0.709) between the groups. Daily methylxanthine intake was significantly higher in the balneoterapy group than in the control group (p = 0.001). Prevalence of fibromyalgia among women with mastalgia was determined as 33.3% (n = 10), similar to the figures we found in literature [5]. The demographic and clinical data of the two groups are presented in Table 1.

The total breast pain scores (BPS) were similar at baseline (205.8 in the control group and 215 in the balneotherapy group, p = 0.618). When the baseline subcomponents of BPQ were compared between the groups, p = 0.517 for the sensory component; p = 0.620 for the affective component; p = 0.833 for the visual analogue scale (VAS); and p = 0.423 for present pain intensity (PPI) were detected. There was no significant improvement with respect to total BPS and subcomponents after 6-weeks therapy in the control group. Mean total BPS decreased from 215 to 150.9 (p = 0.001), mean sensory component improved from 13.1 to 6 (p = 0.001), mean VAS decreased from 5.4 to 3.9 (p = 0.039), and mean PPI improved from 3 to 1.7 (p = 0.004) after treatment in the balneotherapy group. When the percentage of change of total BPS and subcomponents from baseline to after treatment were compared between the groups, significant difference was detected for total BPS (p = 0.018), sensory component (p = 0.004), and PPI (p = 0.014) in favor of balneotherapy group. We also compared IL-1β and TNF-α level between the groups. TNF-α values were significantly decreased after treatment in the balneotherapy group (p = 0.003) (Table 2).

The SF-36 norm-based scores are shown in Table 3. While only social functioning significantly improved in the control group, five subscales (role physical, bodily pain, vitality, social functioning, and