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Original Article

The Effect of Balneotherapy at the Dead Sea on the Quality of Life of Patients with Fibromyalgia Syndrome

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Abstract: Fibromyalgia (FS) is an idiopathic chronic pain syndrome defined by widespread non-articular musculoskeletal pain and generalised tender points. As there is no effective treatment, patients with this condition have impaired quality of life (QoL). The aim of this study was to assess the possible effect of balneotherapy at the Dead Sea area on the QoL of patients with FS. Forty-eight subjects participated in the study; half of them received balneotherapy, and half did not. Their QoL (using SF-36), psychological well-being and FS-related symptoms were assessed prior to arrival at the spa hotel in the Dead Sea area, at the end of the 10-day stay, and 1 and 3 months later. A significant improvement was reported on most subscales of the SF-36 and on most symptoms. The improvement in physical aspects of QoL lasted usually 3 months, but on psychological measures the improvement was shorter. Subjects in the balneotherapy group reported higher and longer-lasting improvement than subjects in the control group. In conclusion, staying at the Dead Sea spa, in addition to balneotherapy, can transiently improve the QoL of patients with FS. Other studies with longer follow-up are needed to support our findings.

Keywords: Balneotherapy; Dead Sea; Fibromyalgia; Health related quality of life; SF-36

Introduction

Fibromyalgia syndrome (FS) is a chronic disorder of widespread pain or stiffness in the muscles or joints, accompanied by tenderness on examination at specific, predictable anatomic sites known as tender points [1–3]. The prevalence of FS in the general population is estimated as 2% [4], and it affects mainly women. A constellation of ancillary symptoms may be present, including headache, fatigue, sleep disturbance, paresthesias, irritable bowel syndrome, subjective joint swelling and other manifestations [3]. The currently accepted criteria for the diagnosis of FS are the 1990 American College of Rheumatology (ACR) criteria [5], and they include the presence of widespread pain in combination with tenderness at 11 or more of 18 specific tender point sites.

As in other disabling conditions, FS influences working capacity, family life, social functioning and quality of life [6–8]. Furthermore, we have shown that the quality of life (QoL) of relatives of FS patients is also impaired [9].

The long-term treatment of FS remains problematic because the natural history of this condition appears to be one of continuous and unremitting pain. There is no one treatment strategy that is effective in all patients. It is not surprising, then, that patients with FS frequently seek alternatives to traditional medical therapies, such as physiotherapy, massage therapy and acupuncture.

Spas and balneotherapy are used in health-related tourism throughout the world. These may be regarded as a special form of physiotherapy that favourably affects muscle tone, joint mobility and pain intensity [10]. The Dead Sea region in Israel is a major area for patients with various types of arthritis and other diseases. The

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unique climatic conditions in this area and the balneologic therapy, which is based primarily on mudpacks and bathing in sulphur baths and in Dead Sea water, combine to alleviate the symptoms of arthritis. Controlled studies conducted over the past 10 years have demonstrated that treatments provided at the Dead Sea have a positive effect on patients with inflammatory arthritides, such as rheumatoid and psoriatic arthritis, and on non-inflammatory arthritides such as osteoarthritis. In previous studies we have shown that balneotherapy (sulphur baths or mudpacks) in the Dead Sea area was effective in the treatment of patients with rheumatoid arthritis and psoriatic arthritis [11,12].

The aim of the present study was to assess the possible effects of balneotherapy at the Dead Sea on the QoL of patients with FS.

Patients and Methods

The subjects were 48 women chosen at random from a list of female patients with FS attending the rheumatology outpatient clinic in the Soroka University Hospital, Beer Sheva, Israel. The clinic serves as a tertiary referral center for the southern part of Israel. All subjects fulfilled the 1990 ACR criteria for the classification of FS [5], and had no other accompanying disease.

The patients were randomly allocated into two groups, treatment and control, with 24 subjects in each. Balneotherapy in the treatment group was based on bathing in a sulphur pool heated at 37 °C for 20 min, but the control group did not receive this treatment. All participants stayed at the Dead Sea for 10 days. Patients in both groups had similar degrees of activity, food and rest, and were asked to continue their regular medications for FS.

The quality of life, psychological well-being and FS-related symptoms were assessed by a researcher, who was blinded to the mode of treatment. The patients were first evaluated at the rheumatic disease clinic of the Soroka Medical Center, 2–3 days before arriving at the Spa Hotel (time 1); then, at the Spa Hotel clinic (time 2), at the end of the study (10 days); and finally, 1 month (time 3) and 3 months (time 4) after completion of the study, at the rheumatic disease clinic.

The study was approved by the Helsinki Ethics Committee of the Soroka Medical Center; all participants gave their written informed consent.

Quality of Life Assessment

QoL was assessed by SF-36 [13,14]. This is a health-related profile of QoL that contains 36 items and measures health status across three domains: functional status, well-being and overall evaluation of health. Its psychometric properties are well characterised, and it has been documented to have high reliability and validity in a wide variety of patient populations [15], including rheumatologic conditions [16,17] and FS [18].

The Hebrew translation of the SF-36 was validated in an adult general population [19], and we have used it on patients with widespread pain, with and without FS [20]. The SF-36 contains eight scales: physical functioning, social functioning, role limitations attributable to physical and emotional problems, mental health, vitality, bodily pain, and general health. Each scale generates a score from 0 to 100, with a high score indicating better health and less body pain [14]. These scales are also scored to produce two summary measures of physical and mental health, PCS and MCS, respectively [21].

Psychological Status

Psychological status was assessed by the anxiety and depression subscales of the Arthritis Impact Measurement Scales [22]; each consisted of six questions, on a 6-point scale. The final indices are the average scores normalised to range from 0 to 10, with 0 reflecting the best condition. A helplessness scale was adopted from the Health Assessment Questionnaire (HAQ) [23,24]. The scale includes five questions, such as ‘my condition is controlling my life’, on a 1–5 scale, with 5 referring to worst outcome. The five scores are summed, resulting in the Rheumatology Attitudes Index.

FS Symptoms

Five visual analogue scales (VAS) from HAQ [23,24] were used to assess pain, fatigue, sleep disturbance, gastroenterological problems and global severity. These scales are 15 cm lines, anchored at each end with descriptors such as ‘no pain’/‘severe pain’. The time-frame of the assessment is ‘in the past week’. The 15 cm line was converted to a 0–3 scale, with 3 corresponding to the worst condition, and then normalised into a 0–100 scale (100 = worst possible score).

Statistical Analysis

T-tests for independent samples were used to compare means of quantitative variables in the treatment and control groups, and proportions were compared by χ^2 tests. Time and group effects were assessed by two-way repeated measurement analysis of variance, using the STATA statistical software [25].

Results

The demographic characteristics of the 48 FS patients are summarised in Table 1. No significant differences were observed between the treatment and control groups. The mean age of the subjects was 54 years; most of them were married with low education levels; half of them were employed, and their mean reported disease duration was approximately 10 years.

Table 1. Demographic and clinical background of treatment group and control group

Variable	Treatment Group <i>n</i> = 24	Control Group <i>n</i> = 24
Age, years, mean (SD)	54.6 (8.4)	54.3 (8.0)
Married, %	70.8	83.3
Employed, %	50.0	41.7
Education, years, mean (SD)	10.3 (5.0)	9.3 (4.3)
Disease duration, years, mean (SD)	11.1 (12.2)	9.4 (8.9)

Note: All the differences are statistically not significant ($p > 0.05$).

Table 2 gives the results of the QoL (as measured by SF-36); severity of FS-related symptoms and psychological well-being in the study group across four time periods. After 10 days in the Dead Sea area (time 2) a significant improvement was observed on five out of eight subscales of SF-36 (Table 2a). Only a few of the measures (physical functioning and body pain) maintained the level of improvement, whereas after 1–3 months the others returned to their baseline levels.

A similar pattern was observed in the reported severity of symptoms and psychological well-being (Table 2b). Pain, fatigue and general well-being were reported to significantly improve following the stay in the spa, and the improvement lasted for as long as 3 months. In contrast, the anxiety and depression levels, despite being considerably improved after 10 days, gradually returned to the baseline levels after 3 months (Table 2c).

Furthermore, we were specifically interested in whether the QoL of FS subjects treated by balneotherapy differed from that of FS subjects who did not receive such treatment. Therefore, as described in the Methods

Table 2. Quality of life, severity of symptoms and psychological variables by time ($n = 48$)

Variable (range)	Time 1	Time 2	Time 3	Time 4	Significance [#]
a. SF-36 (0-100*):					
Physical functioning	34	41	41	45	0.055
Role physical	19	31	44	30	0.097
Role emotional	48	54	56	56	1.000
Social functioning	42	56	42	42	0.032
Body pain	19	39	30	31	0.001
Mental health	51	70	56	54	0.001
Vitality	39	59	45	43	0.001
General health	27	32	33	35	0.140
b. Severity of symptoms (0*100):					
Pain	66	45	45	41	0.002
Fatigue	65	43	44	41	0.046
Sleep problems	51	41	40	38	1.000
Stomach problems	25	20	18	19	1.000
General well-being	66	48	44	41	0.007
c. Psychological well-being:					
Anxiety (0*-10)	5.8	3.7	5.0	5.4	0.001
Depression (0*10)	3.9	2.3	3.7	3.8	0.001
Helplessness (5*25)	18	17	17	17	1.000

*Best possible score.

[#]Corrected for multiple comparisons between four time points.

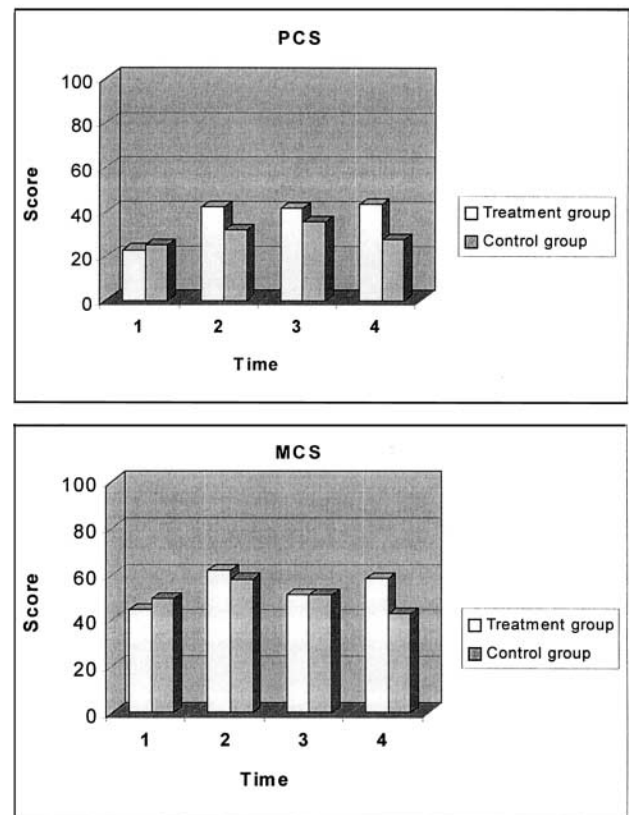
Table 3. Severity of FS-related symptoms in the treatment and control¹ groups by time

Symptoms ²	Time				Significance	
	1	2	3	4	Time effect	Group effect
Pain	64 <i>67</i>	44 <i>46</i>	30 <i>60</i>	43 <i>40</i>	0.0002	0.178
Fatigue	61 <i>68</i>	39 <i>48</i>	28 <i>59</i>	42 <i>41</i>	0.0006	0.034
Sleep problems	53 <i>49</i>	38 <i>34</i>	25 <i>54</i>	36 <i>40</i>	0.184	0.172
Stomach problems	26 <i>24</i>	23 <i>18</i>	14 <i>21</i>	26 <i>13</i>	0.628	0.519
General well-being	68 <i>64</i>	50 <i>45</i>	29 <i>60</i>	45 <i>36</i>	0.0006	0.518

¹Results in the control group are in *italics* (second row)

²The range of the scores is 0–100, 0 = best possible score

section, the 48 FS subjects were divided into two groups, treatment and control. Table 3 and Figs 1 and 2 summarise the effect of balneotherapy on QoL, FS-related symptoms and psychological variables.

**Fig. 1.** Physical (PCS) and mental (MCS) summary measures of quality of life (SF-36) by group and by time (100 = best possible score).

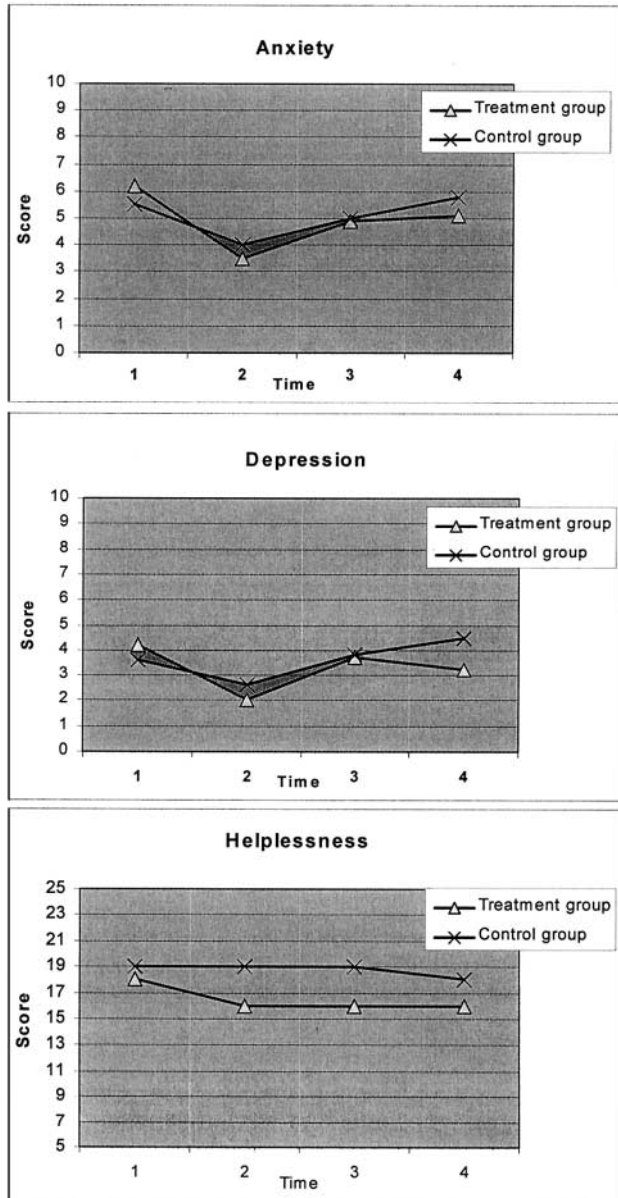


Fig. 2. Measures of psychological well-being by group and by time: anxiety, depression and helplessness.

Figure 1 compares (a) the physical and (b) the mental components of QoL in the treatment and control groups across four periods. Both measures improved significantly after 10 days in the Dead Sea spa, notably in the treatment group, and subsequently (after 3 months) returned to the initial level in both groups. The time effect was significant on both components ($p=0.019$ on physical health; $p=0.036$ on mental health). An effect lasting 3 months was reported on the domain of functioning status in the treatment group only (p of group effect = 0.053).

Pain and fatigue improved significantly for at least 3 months in both groups (Table 3), though the beneficial effect was more pronounced in the treatment group. In sleep and stomach problems no clear trend was observed.

Patients in the treatment group reported lower levels of anxiety ($p<0.001$) and depression ($p<0.001$) following the stay at the Dead Sea resort (Fig. 2). In the control group improvement occurred but did not last. Helplessness remained almost unchanged in both groups (Fig. 2); in the treatment group it decreased slightly ($p=0.069$).

Discussion

Many chronic conditions are associated with lower QoL [26,27]. FS, a syndrome of chronic widespread pain, has been shown to adversely effect the QoL to an extent similar to that of patients with rheumatoid arthritis, chronic obstructive pulmonary disease and insulin-dependent diabetes [7].

This study sought to evaluate the impact of a stay in the Dead Sea area, specifically of balneotherapy, on the QoL of patients with FS. After 10 days at the Dead Sea spa, a significant improvement was reported in most domains of QoL (as measured by SF-36), as well as in FS-related symptoms. Interestingly, the improvement in physical components on QoL lasted usually 3 months, whereas on measures of psychological well-being the improvement was of shorter duration. Subjects in the balneotherapy group reported greater and longer-lasting improvements than subjects in the control group.

The fact that the QoL of all the patients with FS ($n=48$) who stayed at the Dead Sea has improved is not surprising. Because patients with FS live in an atmosphere of stress and anxiety, one might speculate that a change in their usual environment would result in a greater sense of well-being. Indeed, psychological measures (depression and anxiety) had significantly improved after 10 days in the spa, although they returned to their baseline levels after 1 month.

Interestingly, for most of the patients this was the first opportunity to meet others with FS who share similar problems. The patients reported that staying together for 10 days helped them to develop a sense of friendship in solving their common problems. It seems that in many respects the stay for these patients served as a form of group therapy which, according to Yalom [28], promotes healing by normalising symptoms, increases the generalisability of social skills, and improves self-esteem by allowing each member to serve as a helper as well being helped.

Widespread pain is the cardinal symptom in FS. Indeed, pain (measured by SF-36) and fatigue significantly improved following the stay at the Dead Sea, and the change lasted for at least 3 months. Furthermore, this improvement in pain and fatigue was most remarkable in the group that received sulphur baths. Balneotherapy in the Dead Sea has been shown to be effective in different types of inflammatory arthritis, especially rheumatoid [11] and psoriatic [12]. Although FS is not an inflammatory condition, balneotherapy may directly reduce the pain intensity and muscle tone, thereby

explaining the somewhat better outcome of pain in our treatment group.

As FS is a condition of continuous and unremitting pain with no effective treatment, it is clear that our ability to improve the QoL of these patients is limited. In this study we have demonstrated that staying in a Dead Sea spa, especially while receiving balneotherapy, improves some aspects of QoL, at least for 3 months. Since balneotherapy is not known to have adverse side effects, it may be regarded as another possible alternative treatment modality in FS.

In summary, staying at a Dead Sea spa, and especially the addition of balneotherapy, can transiently improve the QoL of patients with FS. Other controlled studies, with longer follow-up periods, are needed to strengthen our findings.

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