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Original Scientific Article

Effectiveness of balneotherapy in knee osteoarthritis

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ABSTRACT

***Aim**:* We aimed to investigate the effects of balneotherapy on knee osteoarthritis in present randomized controlled single blind clinical trial.

Methods: Patients with knee osteoarthritis according to ACR criteria whom admitted to our institute were randomly assigned to two groups, 22 patients in each.

Balneotherapy group received a total of 24 mixed thermo mineral baths at 37-38 ° C for 20 minutes in a schedule of 2 weeks, 6 days a week, 2 times a day in Gönen Spas. Patients in the control group were received medical treatment and monitored as outpatients.

Study population were administered to pain (VAS), The Western Ontario and McMaster Universities Arthritis Index (WOMAC) and The Health Assessment Questionnaire (HAQ) evaluation before treatment, post treatment and on 4th week after treatment. In addition, 10 step ladder-up and 15 meter walking time was calculated.

Results: Significant improvement in Pain (VAS), Pain (WOMAC-A), joint stiffness (WOMAC-B), joint function (WOMAC-C), The Health Assessment Questionnaire (HAQ) and in 10 steps ladder up and down tests achieved in balneotherapy group compared to pretreatment values. 15 meter walking time was improved at 4 week compared to baseline measurements. In control group, there was no significant improvement in the evaluated parameters at 4th week compared to pretreatment evaluation.

Conclusion: We conclude that balneotherapy may be effective in improving pain and functional status in patients with knee osteoarthritis.

Keywords: Knee osteoarthritis; balneotherapy; Spa therapy.

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Introduction

Osteoarthritis (OA), the most common joint disorder worldwide, is the leading cause of joint pain in clinical practice [1]. The most common affected joint is knee in primary OA. Disability is usually caused by knee OA and more common in women. The rate of

symptomatic knee OA in population older than 55 years of age is 13% [2]. Guidelines suggest pharmacologic and non-pharmacologic therapies in combination in treatment of OA [3,4]. Spa treatment and balneotherapy attracted great attention as non-pharmacologic treatment methods in OA treatment, recently.

Spa therapy is a non-pharmacologic method that used in musculoskeletal disorders [5]. In addition to balneotherapy, Spa therapy may include a various types of therapeutic options that improve general health, including exercise, massage and regulation of daily physical activities. However, balneotherapy is the mainstay of Spa therapy. Although it has not been fully understood yet, thermomineral waters have positive effects in pain, physical functions and quality of life via mechanical, thermal and chemical pathways [6]. It has long lasting effects when the applications used by cures. Pharmacologic treatment of OA includes non-steroidal anti-inflammatory drugs, paracetamol and opioids. Serious gastrointestinal, cardiologic and renal side effects are related to these medications.

In sake of avoidance from such side effects, we aimed to observe the effectiveness of balneotherapy as a non-pharmacologic approach in treatment of knee OA.

Methods

Study Design

This prospective, randomized-controlled, mono-blind study conducted in Istanbul University Medical School, Department of Medical Ecology and Hydro-climatology after approval of local ethics committee.

Participants

Patients presented to outpatient clinics of our institution with knee pain were enrolled to the study. Inclusion criteria were as follows: age between 50 to 75 years, primary knee OA according to the ACR criteria, bilateral grade 2-3 radiologic findings of OA according to Kellgreen& Lawrence scale, symptomatic knee pain for at least 3 months. Exclusion criteria were as follows: secondary OA due to other causes, significant pathologies in lumbar, hip and ankle joints which could affect study results, decompensated organ failure, malignancy, hemorrhagic diathesis, active infection, knee trauma or surgery within previous 6 months, intra articular steroid or hyaluronic acid injection into knee joint within previous 6 months and subjects received balneotherapy or peloidotherapy within last 1 year. According to exclusion criteria, 49 subjects (9 balneotherapy within last 1 year, 6 secondary OA, 7 with significant joint pathologies, 8 with history of knee trauma or surgery, 5 received intra-articular(steroid or hyaluronic acid) injection, 2 with malignant diseases and 12 not given consent to be participated) were not included to the study.

Interventions

Study population grouped into 2; balneotherapy group (group 1) whom received balneotherapy and control group (group 2) whom received medical treatment. Group 1 received a total of 24 mixed thermo mineral baths at 37-38 ° C for 20 minutes in a schedule of 2 weeks, 6 days a week, 2 times a day in Gönen Spas. Patients in group 1 received 2 baths a day for six days a week (excluding Sundays) for 2 weeks, first session at between 8 to 9 am and second session at between 4 to 5 pm, each day. Each bath was lasted for 20 minutes and they had rest for 30 minutes after each bath. Blood pressure and heart rate was measured before and after bath for each participant in group 1. Group 2 subjects were

followed up as outpatients and prescribed for paracetamol if necessary. All patients in group 2 were allowed to take oral paracetamol in proportion to severity of pain (maximum 2 g/day). No thermal crisis or other situation occurred during balneotherapy sessions and all subjects fulfilled the schedule.

Randomization and Blinding

Subjects whom given consent for participating in the study and whom met the inclusion criteria were randomized in to two groups by simple randomization with computerized random numbers formula. Patients were not aware of the group that they have been enlisted. Physician that performed evaluation results were not aware of the study groups, either. Statistical analysis were performed by statisticians not aware of the study.

Evaluation

Evaluation of the participants performed before treatment (T0), after treatment at 2nd week (T1), and at 4th week (T2). Study population were administered to pain Visual Analog Scales (VAS), Western Ontario and Mc-Master Universities Osteoarthritis Index (WOMAC) and The Health Assessment Questionnaire (HAQ) evaluation before treatment, post treatment and on 4th week after treatment. In addition, 10 step ladder-up and 15 meter walking time was calculated.

VAS is a commonly used method of determining the degree of pain. It consists of a line 10 cm (or 100 mm) long drawn horizontally or vertically. The distance from the lowest VAS to the patient's mark was measured in mm (0-100) to quantify the patient's pain severity [7].

WOMAC is a commonly used health status measure in knee or hip OA patients. It consists of three parts: pain (5 items), stiffness (2 items) and physical function (17 items). It contains 24 items in total. The scoring of the items is based on the Likert scale. In the Likert scale, patients indicate pain and difficulty levels by giving scores between 0 and 4 which correspond to: None (0), Mild (1), Moderate (2), Severe (3), and Extreme (4). Turkish validity and reliability studies were performed [8].

HAQ is especially used in adult patients with arthritis. It can evaluate all dimensions of health outcomes such as disability and discomfort. There are a total of 20 questions in the health evaluation questionnaire covering eight areas related to dressing, straightening, eating, walking, hygiene, reaching, understanding and daily work. The score is between 0 and 3 points. (0: Do not make the activity without difficulty, 1: Do it with difficulty, 2: Do it with difficulty, 3: Do not do it at all) [9].

Statistical Analysis

Statistical analysis was performed with the IBM SPSS 10.0 statistical package program on the basis of modified intention-to-treat. Descriptive statistical methods were used in the analysis of demographic data. The normality test of the data was evaluated by the Shapiro-Wilk test. The data were observed to be normally distributed. The intra-group comparisons were made using the paired sample test, and the inter-group comparisons were made using the independent sample test. A p value <0.05 was considered statistically significant.

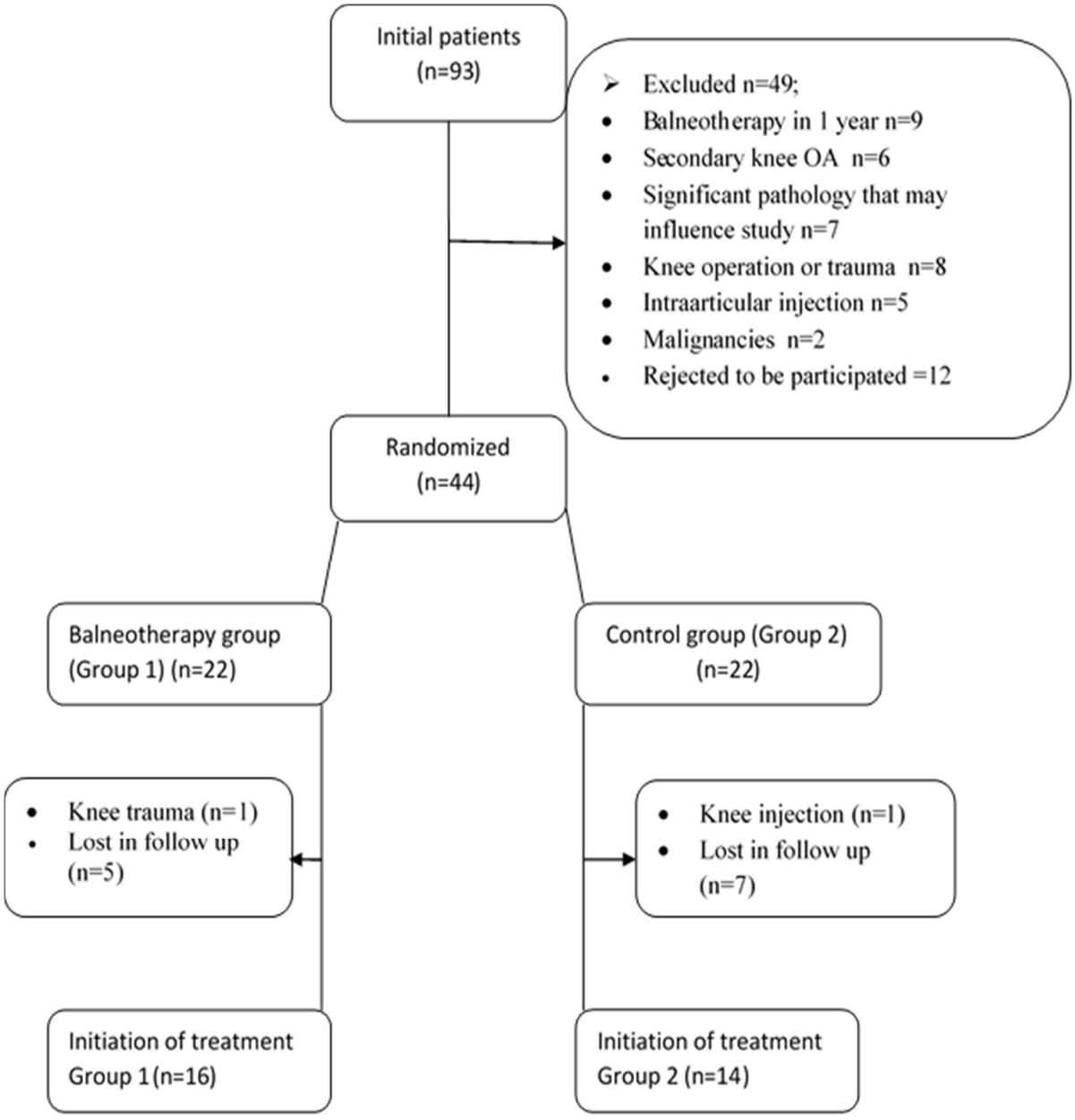
Results

Forty-four patients with primary knee OA who met the criteria for inclusion and given consent were randomly assigned into two groups, 22 patients in each group. During treatment and follow-up, 6 patients (knee trauma n = 1, n =

5) in group 1, 8 patients in group 2 (n = 7 in follow-up, n = 1 in knee injection due to effusion) could not complete the treatment. 16 in group 1 and 14 in group 2 completed the study. The flow diagram of the work is shown in figure 1.

When the demographic characteristics of the patients were analyzed, there was no statistically significant difference between the groups in terms of gender distribution and age averages (Table 1).

Figure 1. Flow diagram.



There was no statistically significant difference between study groups before treatment period in terms of evaluation parameters (Table 2).

Pain (VAS), pain (WOMAC-A), joint stiffness (WOMAC-B), physical function (WOMAC-C), HAQ and ten steps up and down test results were significantly improved in post treatment

Table 1. Characteristics of the study population

Parameters		Group 1	Group 2	*p*
Gender	Men (n)	5	2	0.399*
	Women(n)	11	12	
Age		62,3 ± 6,7	57,9 ±7,4	0,272**
Disease Duration (months)		5,3 ±1,1	5,9 ±1,5	0,464**

Mean±SD, * *Chi-Square test* ** *t-test*

Table 2. Comparison of values within the groups and between the groups

Parameters	Time period	Mean ±SD	Mean ±SD	İnter-group p*	İntra-group p**(T1-T0)		İntra-group P**(T2-T0)	
		Group1	Group2		Group1	Group2	Group1	Group2
VAS (pain)	T0	77,25±20,61	62,92±18,93	0.057	0.0003	0.298	0.00004	0.423
	T1	46±31,01	56,07±21,86					
	T2	38,43±30,33	59,28±20,02					
WOMAC-A (pain)	T0	2,05±0,840	2,0±0,970	0.882	0.0006	0.782	0.00003	0.938
	T1	1,237±0,938	1,9±0,843					
	T2	0,962±1,035	1,885±0,563					
WOMAC-B (stiffness)	T0	1,843±0,831	1,75±0,727	0.744	0.001	0.744	0.00002	0.611
	T1	1,25±0,875	1,821±0,868					
	T2	0,875±0,903	1,928±0,916					
WOMAC-C (function)	T0	1,781±0.840	1,47±0,830	0.565	0.0002	0.884	0.00003	0.565
	T1	1,02±0,811	1,622±0,916					
	T2	0,984±0,811	1,730±1,065					
HAQ	T0	44,57±17,495	42,52±15,156	0.137	0.0003	0.813	0.0001	0.320
	T1	25,96±15,304	24,52±16,102					
	T2	33,00±18,148	6,27±15,648					
10 steps up and down	T0	21,187±7,467	16,642±4,516	0.055	0.001	0.903	0.01	0.806
	T1	16,25±6,668	16,50±4,433					
	T2	17,00±5,656	17,428±3,715					
15 meters walking	T0	15,81±3,93	14,78±2,48	0.390	0.390	0.730	0.02	0.110
	T1	14,18±3,10	14,50±1,91					
	T2	13,56±2,87	15,00±1,88					

T0: Before treatment, T1: After treatment at 2nd week, T2: After treatment at 4th week. VAS: Visual Analog Scales, WOMAC: Western Ontario and Mc-Master Universities Osteoarthritis Index, HAQ: The Health Assessment Questionnaire. *Independent samples t test (between the groups). **Paired sample test (within the groups). Group1: balneotherapy, Group 2: control group

(at 2nd week) values compared to pretreatment values in group 1. 15 meters walking time was also improved in Group 1 at 4th week post treatment period compared to basal values. In the group 2, the time dependent change of intra-group values was not statistically significant (Table 2).

Comparison between groups performed by taking the differences of each variable depending on the time. There was a statistically significant difference between the two groups. A statistically significant difference was found in favor of the group 1 when compared with the control subjects in terms of differences in the measurements of pain (VAS), pain (WOMAC-A), joint stiffness (WOMAC-B) and physical function (WOMAC-C). Although the 15-meter walking time difference scores did not show any significant difference statistically between the two groups at the end of treatment (2nd week), the treatment results were statistically significant in favor of the group 1 in all evaluation parameters at 4th week in post treatment period. Values of study parameters of the cohort are summarized in table 3.

Table 3. Comparison of parameters change values between the groups

Parameters	Groups	T1-T0	*p*	T2-T0	*p*
VAS (pain)	Group 1 Group 2	-28.78±27.23 -4.58±19.87	*0.009*	-38.81±27.11 -3.64±8.10	*0.0001*
WOMAC-A (pain)	Group 1 Group 2	-0.812±0.76 -0.100±0.65	*0.009*	-1.087±0.75 -0.114±0.50	*0.0002*
WOMAC-B (stiffness)	Group 1 Group 2	-0.593±0.58 0.071±0.58	*0.004*	-0.968±0.51 0.178±0.86	0.0003
WOMAC-C (function)	Group 1 Group 2	-0.761±0.63 0.021±0.67	*0.002*	-0.797±0.44 0.130±0.76	*0.0006*
HAQ	Group 1 Group 2	-0.380±0.33 0.025±0.27	*0.0008*	-0.430±0.33 0.125±0.23	*0.0001*
10 steps up and down	Group 1 Group 2	-5.357±5.01 0.230±3.18	*0.003*	-4.187±5.86 0.785±3.92	*0.01*
15 meters walking	Group 1 Group 2	1.62±3.89 0.28±1.72	*0.22*	2.28±3.66 -0.21±1.71	*0.02*

T0: Before treatment, T1: After treatment at 2nd week, T2: After treatment at 4th week. VAS: Visual Analog Scales, WOMAC: Western Ontario and Mc-Master Universities Osteoarthritis Index, HAQ: The Health Assessment Questionnaire. Independent samples t test (between the groups). Group1: balneotherapy, Group 2: control group.

Discussion

Treatment of knee OA is gained great importance since it leads to significant socio-economic loss. However, alternative therapies such as spa treatment gain importance due to the increase in number patients with advanced age who have an active business life.

Karagülle et al.'s[10] have reported that balneotherapy may be effective in musculoskeletal disorders in a systematic review of 15 studies conducted at different spa centers. In Bender et al.'s [11] study conducted in Hungarian thermo mineral waters and Katz et al.'s [12] study conducted in Dead Sea reported that balneotherapy, mud treatment and climatotherapy resulted in pain reduction, joint function and improved quality of life in musculoskeletal disorders.

Although the studies on knee OA therapy are designed in different forms, the treatments are generally applied by staying in the spa facility or by going to the spa facility in daily basis. Forestier et al. [13] investigated the effect of spa therapy on knee OA in a randomized controlled, double-blind study involving 451 multi-centered patients. Balneotherapy, mud pack application and home exercise were applied to the hot spring treatment group and home exercise was applied to the control group. All the patients continued to undergo physical therapy and medical treatment. Although there were significant changes in both groups, VAS and WOMAC values were significantly improved in hot spa group compare to controls at sixth month.

Masiero et al found positive effects of hydro-kinesitherapy on pain, joint function, and gait pattern lasted for 6 months after 2 session of spa cure in obese knee OA patients [14]. Fioravanti et al. [15,16] studied 60 and 103 knee OA patients in two separate studies and found that spa treatment symptomatic relief in subjects resulted in less use of medications and proposed as an alternative therapy for those who could not receive medication. Studies form Turkey, such as, Yurtkuran et al [17], Karagülle et al, [18], Evcik et al [19], Odabasi et al [20] and Sarsan et al [21] all reported beneficial effects of spa treatment on knee OA.

In a meta-analysis of studies conducted with OA patients, Forestier et al reported that therapies in spa centers in Europe and the Middle East were found to be effective on relief of pain and gain of function [22]. In meta-analysis by Matsumato et al, balneotherapy was reported to reduce pain and joint stiffness and improved function in patients with knee OA [23]. In our study, we obtained positive findings in parallel with these studies.

Limitations of present study are small study cohort, short time period of follow-up, and lack of the evaluation of medicine effects.

In conclusion, we suggest that spa therapy could be an effective alternative in treatment of knee OA. Prospective studies with larger population in this topic are still needed.

Compliance with ethical standards

The authors declare that they have no conflicts of interest concerning for this article.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Institutional Research Ethics Committee and with the 1964 helsinki declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

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