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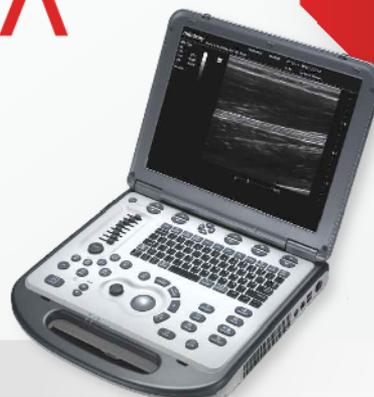
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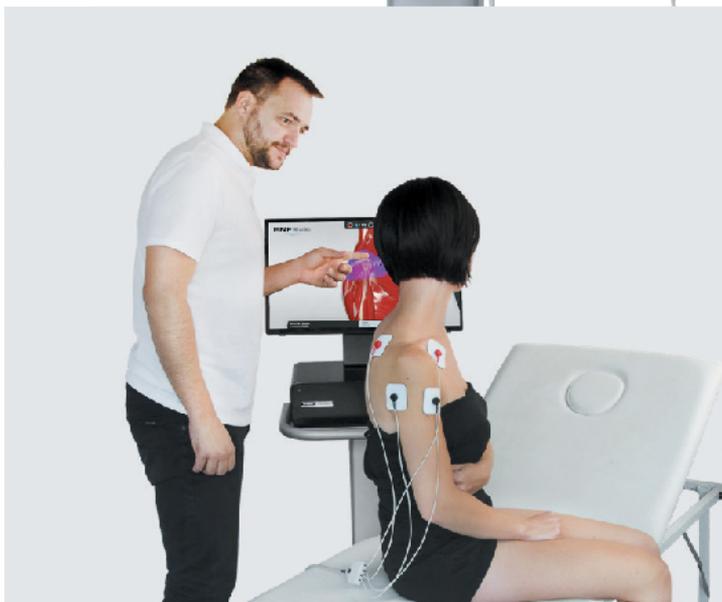
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# Effect of Siwa sand baths versus sulphurous water bath on inflammatory biomarkers, pain, and physical function in patients with rheumatoid arthritis: A randomized, single-blind controlled trial

*Wpływ kąpeli piaskowych Siwa i kąpeli siarkowych na biomarkery stanu zapalnego, ból i sprawność fizyczną u pacjentów z reumatoidalnym zapaleniem stawów: randomizowane badanie z pojedynczą ślełą próbą*

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## Abstract

Background. Sand baths and sulphurous water bath has been approved as alternative modalities for treating various musculoskeletal diseases. Although that, current evidence is not clear enough to support naturotherapy modalities as an effective method to treat Rheumatoid Arthritis (RA). Objectives. This study aimed to compare the effect of Siwa sand baths and Sulphurous water bath on inflammatory biomarkers (ESR, CRP, RF), pain intensity, physical function, and wrist Range of Motion (ROM) in patients with RA.

Methods. A randomized single-blind controlled clinical trial was designed to treat 30 patients with chronic RA. These patients were randomly assigned into two groups of 15 patients each: Group A (n = 15) received Siwa sand baths, and group B (n = 15) received sulphurous water bath (each bath lasting 20 minutes, for 7 successive days). Inflammatory biomarkers, physical function, pain intensity, and wrist joint ROM were measured for all patients at three intervals (before treatment, after 7 days of treatment, and after 1-month follow-up).

Results. The results showed that after 7 days of treatment there were significant differences between both groups in all measured variables in favor of group B, ESR (p = 0.0001), CRP (p = 0.001), RF (p = 0.0001), HAQ (p = 0.0001), pain (p = 0.001), wrist extension (p = 0.001), wrist flexion (p = 0.0001). While at 1-month follow-up, the analysis showed significant differences between both groups in all measured variables in favor of group A (p < 0.05).

Conclusion. Both Siwa sand baths and sulphurous water bath have an improvement effect on inflammatory biomarkers, pain, daily activities, and wrist ROM but Siwa sand baths has more effect in the long term better than sulphurous water bath.

## Key words:

Siwa sand baths, Sulphurous water bath, Rheumatoid arthritis, Inflammatory biomarkers

## Streszczenie

Informacje wprowadzające. Kąpiele piaskowe i kąpiele siarkowe zostały zatwierdzone jako alternatywne metody leczenia różnych dolegliwości układu mięśniowo-szkieletowego. Mimo to obecne dowody nie są wystarczające, by potwierdzić skuteczność naturoterapii jako metody leczenia reumatoidalnego zapalenia stawów (RZS).

Cele. Niniejsze badanie miało na celu porównanie wpływu kąpeli piaskowych Siwa i kąpeli siarkowej na biomarkery stanu zapalnego (OB, CRP, RF), intensywność bólu, sprawność fizyczną i zakres ruchu nadgarstka (ROM) u pacjentów z RZS.

Metody. Randomizowane, kontrolowane badanie kliniczne z pojedynczą ślełą próbą zostało przeprowadzone na 30 pacjentach z przewlekłym RZS. Pacjenci ci zostali losowo przydzieleni do dwóch grup po 15 pacjentów każda: Grupa A (n = 15) była poddawana kąpielom piaskowym Siwa, a grupa B (n = 15) kąpielom siarkowym (każda kąpiel trwająca 20 minut, przez 7 kolejnych dni). U wszystkich pacjentów mierzono biomarkery stanu zapalnego, sprawność fizyczną, intensywność bólu i ROM nadgarstka w trzech odstępach czasu (przed leczeniem, po 7 dniach leczenia i po 1 miesiącu obserwacji).

Wyniki. Wyniki wykazały, że po 7 dniach leczenia wystąpiły istotne różnice między obiema grupami we wszystkich mierzonych zmiennych na korzyść grupy B: ESR (p = 0,0001), CRP (p = 0,001), RF (p = 0,0001), HAQ (p = 0,0001), ból (p = 0,001), wyprost nadgarstka (p = 0,001), zgięcie nadgarstka (p = 0,0001). Podczas gdy po 1 miesiącu obserwacji analiza wykazała istotne różnice między obiema grupami we wszystkich mierzonych zmiennych na korzyść grupy A (p < 0,05).

Wniosek. Zarówno kąpiele piaskowe Siwa, jak i kąpiele siarkowe mają korzystny wpływ na biomarkery stanu zapalnego, ból, codzienne czynności i ROM nadgarstka, jednak kąpiele piaskowe Siwa mają większy efekt długoterminowy niż kąpiele siarkowe.

## Słowa kluczowe

kąpiele piaskowe Siwa, kąpiele siarkowe, Reumatoidalne zapalenie stawów, Biomarkery stanu zapalnego

## Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease characterized by morning stiffness and persistent symmetrical polyarthritis of large and small joints that typically affects the lining of the synovial joints. It affects 0.5 to 1% of the world's general population, and leads to musculoskeletal and functional impairment [1, 2]. It is also associated with socioeconomic costs derived from medical costs as well as from social and functional disability [3, 4]

The main objectives of RA treatment are an early stop of inflammation within the course of the disease, slow the rate of joint damage, and relieve symptoms [5]. Other treatment objectives include improvement of physical function, pain management, and maintenance of function for basic ADL activities [6, 7]. Pharmacological intervention has been used in the treatment of RA, including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Disease-Modifying Anti-Rheumatoid Drugs (DMARDs), and corticosteroids, but some of them can cause side effects [8]. Therefore, non-pharmacological intervention by physiotherapy and naturotherapy has been approved as alternative modalities for treating RA with fewer side effects.

Naturotherapy such as sand baths and sulphurous water bath is a type of alternative medicine, which is believed to have an improvement effect on symptoms of RA [9]. Some special sands under the form of sand-bath are being used worldwide in a therapeutic application called psammotherapy, especially for the treatment of musculoskeletal diseases. The essential characteristics of sand bathing are its cheapness, its effectiveness in the treatment of a variety of diseases, and few side effects. Also, when it is used as a therapeutic agent, it provides tonicity for both muscular and locomotor systems [10, 11].

Sulphurous mineral water is also another form of naturotherapy that helps to manage many chronic inflammatory diseases and age-related disorders with its anti-inflammatory and antioxidant properties [12]. Many clinical studies confirm the positive effect of this approach in prevention and treatment as well as in the rehabilitation of many different rheumatic disorders [13, 14]. Also, recent results showed that spa treatment has an effective role in reducing pain, improving function and quality of life [15, 16].

## Materials and Methods

Thirty patients (19 women, 11 men) with RA according to the criteria of the 2010 American Rheumatism Association [17], were recruited from the Outpatient Rheumatology Clinic of Siwa Central Hospital, Marsa Matrouh. The patients were recruited from June 2018 to August 2019 for a 7-day treatment investigation with a 1-month follow-up. They were eligible to participate in the study if they had: Age ranged from 20 and 50 years [11], stable medication for the last three months. While, patients were excluded if they exhibited any of the following criteria: high disease activity, such that changing or starting a slow acting antirheumatic drug was considered necessary by the rheumatologist; presence of one or more arthroplasties of weight bearing joints, active ischaemic heart disease, severe hypertension, uncontrolled diabetes mellitus, peripheral vascular disease, or central nervous system dis-

ases, such as epilepsy. Also, pregnant women and patients who received physiotherapy treatment six months before the study were excluded.

## Study design

The study was designed as a prospective pre–post-test, single-blind, randomized controlled trial. The procedure of the study was clarified in details for each patient before initial evaluation and study enrollment, and each patient signed an informed consent form before participating in the study, and that form is institutionally approved and accepted by the Institutional Ethics Committee (NO: P.T. REC/012/001627). The study has followed the Guidelines of the Declaration of Helsinki on the conduct of human research, and the study was registered at the Pan African Clinical Trial Registry database and the registration number was PACTR201912834190028.

## Methods of assessment

The primary outcome measure included measurement of inflammatory biomarkers [(Erythrocyte Sedimentation Rate (ESR), C-reactive protein (CRP), and rheumatoid factor (RF)]. Laboratory investigation was carried out in the clinical pathology department by taking a 5 cm blood sample from an antecubital vein into anticoagulated tubes, after that these samples were analyzed, and the results were considered.

Physical function, pain severity, and wrist joint ROM were recognized as the secondary outcomes. The physical function of the patient was evaluated using the Health Assessment Questionnaire (HAQ), which evaluates functional disability in eight categories such as in walking, dressing, hygiene, reaching, gripping, rising, eating, and in the regular daily activities [18]. With four response categories were 3, unable to do any physical activity; 2, able with great difficulty; 1, able with less difficulty; and 0, able to do the function easily. In each section, the highest response was used as points for that function. To determine the total score of HAQ, the total highest responses in all sections were divided by 8 to form a score with a range of 0 to 3 [19]. In the current study, we use the Arabic version of HAQ which has been found to show good validity [20].

Severity of pain was evaluated by the Visual Analogue Scale (VAS). Each patient was asked to mark and score on a line at the point that represents his/her intensity of pain on a 10 cm line anchored with “0” at one end representing “no pain” and “10” at the other end representing “the worst pain”. Using VAS for pain assessment has some advantages in clinical trials as it is the most common and reliable type of pain scale [21].

To assess active ROM of wrist flexion and extension of the dominant hand, Digital Absolute + Axis TM Goniometer (Baseline 12-1027) was used. The digital goniometer was found to show good reliability, validity, and clinical usability for the measurement of joint ROM [22]. The fulcrum of the goniometer was placed at the ulnar styloid process, the movable arm of the goniometer was placed along the fifth metacarpal and the stationary goniometer arm was placed along the lateral aspect of the distal forearm. Then, the patient was asked to perform the movements and the degrees of ROM for flexion and extension were recorded in the patient sheet.

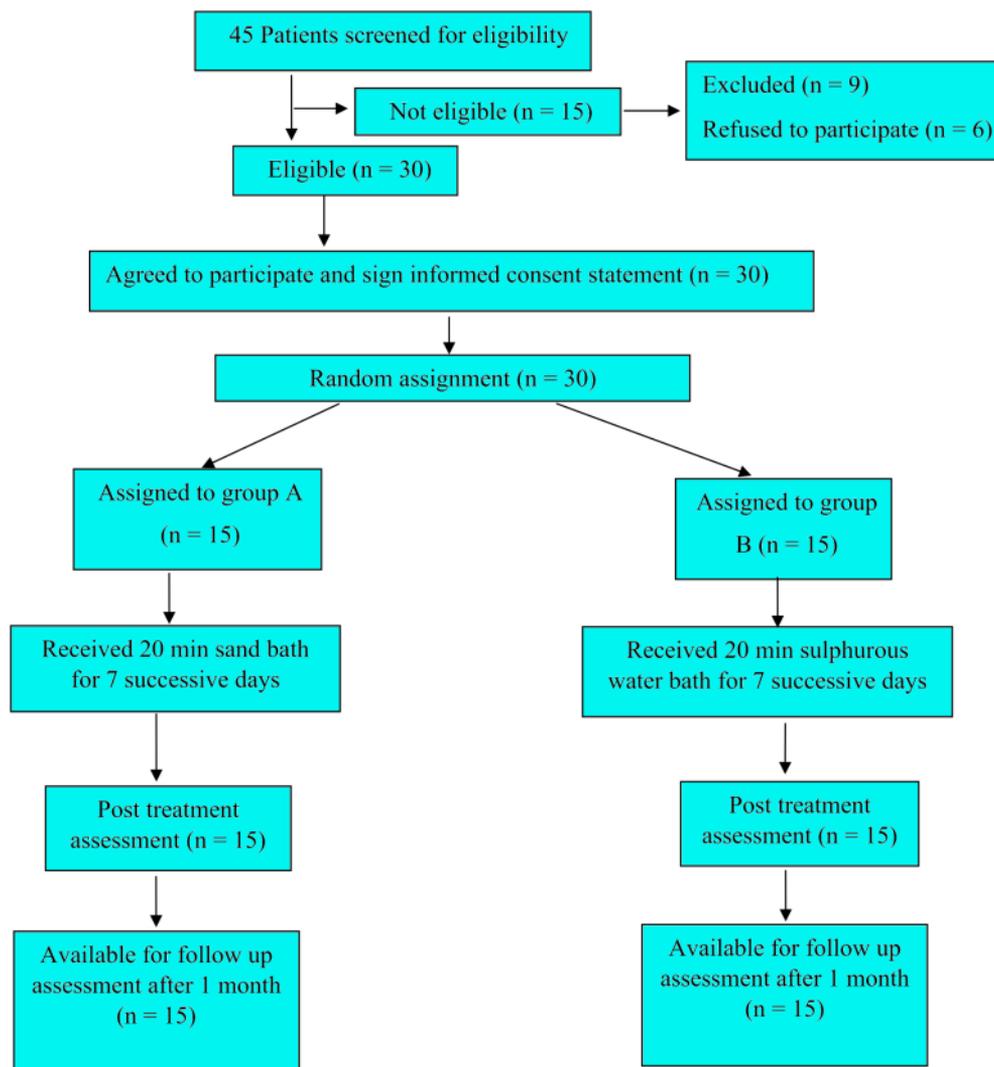


Figure 1. Flow chart of the study

**Interventions**

**Group (A)** received 20 min Siwa sand bath for 7 successive days. The intervention took place at Dakrour Mountain, Siwa Oasis. Sand baths took place between 2 pm and 4 pm in June and August. The temperature of the atmosphere ranged between 40-45 ° C, and the surface sand temperature 75-82°C, while the sand temperature at a depth of 10-20 cm ranged between 50-60°C, measured by an infrared thermometer (Medisana, Made in Germany). A long, shallow hole, 1.0-1.5 m long, 20-40 cm deep, and 80 cm wide, was dug in the early morning to allow sunlight to heat the sand. The patient was lied in the hole for 20 minutes, with his whole body was covered up to his neck with dry hot sand from the desert surface. After the patient finished his sand bath, he was removed from the hole and was wrapped in a towel to prevent exposure to any air draft, which may lead to negative effects such as headaches or muscle stiffness [11]. After that, the patient is kept sitting in an airtight tent near the burial area for 15 minutes until his body returns to its normal temperature and restores its state of rest. Some advice was given to patients after the treatment program: lying on the bed with changing his wet clothes with another dry one every it got wet from sweat, using a towel to shake the sand off his bo-

dy, and drinking plenty of warm fluids (licorice, anise, lemon juice). Patients were also given other advice before and during the treatment program and urged to adhere to it: not to use any creams or lotions before the treatment, not to shower during the treatment period, use hot water when washing face and hands, avoid putting water on any other parts of the body, and not to drink cold fluids or use air conditioners at any time, except after three days of treatment.

**Group (B)** received 20 min sulphurous water bath for 7 successive days. The intervention took place at Prezi Spa, Siwas Oasis. The patient gets off his/her clothes and emerged in a thermal sulphurous water pool at 36-37°C for 20 min [23]. The amount of sulphate in water was 820 mg/L. During the bath, patients were not allowed to exercise or swim in the pool and were advised to remain motionless. After the end of the bath, the patient asked to dry himself/herself carefully, wear his/her clothes, and wrapped to avoid air drafts that may have adverse effect.

During the treatment period, all the patients continued to receive their medical treatment regularly without any change in type or dosage.

### Statistical analysis

All statistical tests were performed through the statistical package for social studies (SPSS) version 19 for windows. (IBM SPSS, Chicago, IL, USA). The differences in the baseline data between both groups were analysed using t-test. Mixed MANOVA was conducted to compare the effect of time (pre, post I and post II) and the effect of treatment (between groups), as well as the interaction between treatment and time on mean values of ESR, CRP, RF, physical function, pain intensity, and wrist ROM, Chi squared test were conducted for comparison of sex distribution between groups. The level of significance for all statistical tests was set at  $p < 0.05$ .

### Results

Data obtained from both groups pre, after 7 days of treatment (post I), and at one month after treatment (post II) regarding (ESR), (CRP), (RF), physical function, pain intensity, and wrist ROM were statistically analyzed and compared.

### Participant characteristics

Table 1 showed the demographics characteristics of all patients in both groups. There was no significant difference in age, sex distribution, and all outcomes measures between both groups ( $p > 0.05$ ).

**Table 1. Baseline demographics of participants**

Variable	Group A	Group B
Age [years], mean $\pm$ SD	48 $\pm$ 8.85	49.26 $\pm$ 9.43
<b>Sex, n (%)</b>		
Females	10 (67%)	9 (60%)
Males	5 (33%)	6 (40%)
ESR, mean $\pm$ SD	31.33 $\pm$ 7.88	32.06 $\pm$ 7.02
CRP, mean $\pm$ SD	18.8 $\pm$ 5.68	19.36 $\pm$ 7.24
RF, mean $\pm$ SD	37.43 $\pm$ 7.55	39.41 $\pm$ 9.79
HAQ, mean $\pm$ SD	1.47 $\pm$ 0.52	1.55 $\pm$ 0.36
VAS, mean $\pm$ SD	6.86 $\pm$ 0.63	6.93 $\pm$ 0.74
Wrist extension, mean $\pm$ SD	34.86 $\pm$ 5.42	33.53 $\pm$ 5.66
Wrist flexion, mean $\pm$ SD	43.2 $\pm$ 5.97	42.53 $\pm$ 3.22

ESR, Erythrocyte Sedimentation Rate; CRP, C-reactive Protein; RF, Rheumatoid Factor; HAQ, Health Assessment Questionnaire; VAS, Visual Analogue Scale

### Effect of treatment on ESR, CRP, RF, pain intensity, physical activity, and wrist ROM

Table 2 presents the group means and standard deviations for each of the variables at each evaluation period. Also, the within group differences for each variable are presented for the

7 days vs. baseline evaluations and the 1-month follow-up vs. baseline evaluations. As shown in the table, there were significant differences in all outcome measures within each group after 7 days of treatment and at 1-month follow-up.

**Table 2. Mean  $\pm$  SD for all variables in both study and control groups at each evaluation period, and comparison of changes in outcome measures at pre-treatment, post (I) and post (II) within each treatment group**

Measure	Group	Pre-treatment mean $\pm$ SD	Post (1) mean $\pm$ SD	Post (2) mean $\pm$ SD	P-value	
					Post (I) vs Pre-treatment	Post (II) vs Pre-treatment
ESR	A	31.33 $\pm$ 7.88	38.26 $\pm$ 7.65	22.8 $\pm$ 6.25	0.001	0.001
	B	32.06 $\pm$ 7.02	26.2 $\pm$ 7.78	29 $\pm$ 4.86	0.001	0.02
CRP	A	18.8 $\pm$ 5.68	24.44 $\pm$ 7.26	12.72 $\pm$ 3.71	0.001	0.001
	B	19.36 $\pm$ 7.24	14.78 $\pm$ 6.16	17.7 $\pm$ 5.81	0.001	0.03
RF	A	37.43 $\pm$ 7.55	44.3 $\pm$ 6.85	28.94 $\pm$ 6.14	0.001	0.001
	B	39.41 $\pm$ 9.79	32.57 $\pm$ 8.94	35.93 $\pm$ 6.47	0.001	0.001
HAQ	A	1.47 $\pm$ 0.52	1.98 $\pm$ 0.42	0.86 $\pm$ 0.2	0.001	0.001
	B	1.55 $\pm$ 0.36	0.93 $\pm$ 0.24	1.28 $\pm$ 0.38	0.001	0.002
VAS	A	6.86 $\pm$ 0.63	7.73 $\pm$ 0.88	3.93 $\pm$ 0.79	0.001	0.001
	B	6.93 $\pm$ 0.74	5.6 $\pm$ 0.98	6.26 $\pm$ 0.7	0.001	0.001

Measure	Group	Pre-treatment mean ± SD	Post (1) mean ± SD	Post (2) mean ± SD	P-value	
					Post (I) vs Pre-treatment	Post (II) vs Pre-treatment
	A	34.86 ± 5.42	31.33 ± 5.49	41.66 ± 5.49	0.001	0.001
	B	33.53 ± 5.66	38.26 ± 4.5	36.86 ± 5.05	0.001	0.001
	A	43.2 ± 5.97	39.73 ± 5.66	52.66 ± 5.02	0.001	0.001
	B	42.53 ± 3.22	49.2 ± 3.8	47.2 ± 3.62	0.001	0.001

SD, standard deviation; p-value, level of significance; ESR, Erythrocyte Sedimentation Rate; CRP, C-reactive Protein; RF, Rheumatoid Factor; HAQ, Health Assessment Questionnaire; VAS, Visual Analogue Scale

Table 3 presents the between group differences for each variable at the 7 days treatment and the 1-month follow-up. After 7 days of treatment, the analysis showed that there were significant differences between both groups in favor of group B for all measured variables, ESR (p = 0.0001), CRP (p = 0.001), RF (p = 0.0001), HAQ (p = 0.0001), pain (p = 0.001), wrist

extension (p = 0.001), wrist flexion (p = 0.0001). While at 1-month follow-up, the between group analysis showed that there were statistically significant differences between group A compared with that of group B in favor of group A in all measured variables (p < 0.05).

**Table 3. Differences between treatment groups on each outcome measure after 7 days of treatment and at 1-month follow-up**

Measure	Post I (mean ± SD)			Post II (mean ± SD)		
	Group A	Group B	p-value	Group A	Group B	p-value
ESR	38.26 ± 7.65	26.2 ± 7.78	0.001	22.8 ± 6.25	29 ± 4.86	0.008
CRP	24.44 ± 7.26	14.78 ± 6.16	0.001	12.72 ± 3.71	17.7 ± 5.81	0.04
RF	44.3 ± 6.85	32.57 ± 8.94	0.001	28.94 ± 6.14	35.93 ± 6.47	0.03
HAQ	1.98 ± 0.42	0.93 ± 0.24	0.001	0.86 ± 0.2	1.28 ± 0.38	0.002
VAS	7.73 ± 0.88	5.6 ± 0.98	0.001	3.93 ± 0.79	6.26 ± 0.7	0.001
Wrist extension	31.33 ± 5.49	38.26 ± 4.5	0.001	41.66 ± 5.49	36.86 ± 5.05	0.01
Wrist flexion	39.73 ± 5.66	49.2 ± 3.8	0.001	52.66 ± 5.02	47.2 ± 3.62	0.002

SD, standard deviation; p-value, level of significance; ESR, Erythrocyte Sedimentation Rate; CRP, C-reactive Protein; RF, Rheumatoid Factor; HAQ, Health Assessment Questionnaire; VAS, Visual Analogue Scale

## Discussion

Siwa sand bath and sulphurous water bath are old traditional natural therapies used among years to treat musculoskeletal disorders and rheumatic diseases but there are no sufficient studies to demonstrate their effectiveness or to compare between those different naturotherapy modalities. To the best of our knowledge, this was the first study to compare the effect of sand bathing and sulphurous water bath on inflammatory biomarkers, physical function, pain intensity, and wrist joint ROM in patients with RA. So, the discussion of this point is limited in the literature. In the current study, disease activity was evaluated based on inflammatory biomarkers, because it is the most objective and reliable measure and a useful predictive factor for the progression of the disease and for determining the level of joint damage. Also, depending on clinical criteria, the level of C-reactive protein (CRP) was strongly associated with pain, joints morning stiffness, fatigue, articular index, grip strength, and disability [24]. In addition, RF is an auto-antibody found in the blood of RA patients [25].

After 7 days of treatment, there was a statistically significant improvement in all outcome measures in sulphur bath group

than Siwa sand bath group. There was an increase in inflammatory biomarkers (CRP, ESR, RF) in Siwa sand bath group; the percentage of change was 30% in CRP, 22.11% in ESR, and 18.35% in RF, which lead to an increase in pain intensity, decrease in functional activity, and decrease in ROM of the wrist. This increase in inflammatory biomarkers may be attributed to exposure to excessive heat during the treatment sessions since the temperature of the sand at a depth of 10-20 cm ranges between 50-60 ° C and the sand surface temperature ranges between 75-82 ° C. This explanation is supported by Catherine et al. [26] who reported that excessive heat > 45°C causes stimulation to thermo-nociceptors. One of these thermo-nociceptors which is directly gated by capsaicin and noxious heat and lead to an increase in the production of inflammatory molecules (interleukin-6, interleukin-8, prostaglandin) is the Transient Receptor Potential Vanilloid 1 (TRPV1) [27, 28]. This explanation was confirmed by Hu et al. [29], who reported that TRPV1 plays a central role in the pathology of osteoarthritis and RA, as its activation leads to the release of inflammatory compounds that initiates and potentiate the disease process.

While, after 7 days of treatment, there was a significant decrease in inflammatory biomarkers in sulphur bath group. The percent of change was 18.27% in ESR, 23.65% in CRP, and 18.35% in RF. This decrease in the inflammatory biomarkers leads to a decrease in pain, an increase of ADL, and an increase in wrist ROM. These findings are supported by Prandelli et al. [30], who report that sulfur mineral water and its antioxidant and anti-inflammatory properties help in managing various chronic and age-related inflammatory diseases. This improvement in all outcome measures may be attributed to the effect of the active molecule in sulphurous mineral waters (Hydrogen sulfide), which is attracting scientists' attention due to its different therapeutic applications [31]. It can penetrate the skin and mucous membranes, making it able to work at the cellular level in both skin and internal organs [31, 32]. This explanation can be supported by Burguera et al. [33], who reported that Hydrogen sulfide reduces the signals of interleukin 1 $\beta$  which led to fibroblast-like synoviocytes activation in patients with osteoarthritis.

At a 1-month follow-up with no further intervention, all outcome measures for sulphur bath group continued to improve when compared with baseline values, but this improvement is less than that done after 7-days of treatment. Also, there was a statistically significant improvement in all outcome measures in Siwa sand bath group than sulphur bath group. There was a significant decrease in inflammatory biomarkers in Siwa sand bath group, the percent of change was 27.22% in ESR, 32.34% in CRP, and 22.68% in RF. This decrease in the inflammatory biomarkers leads to a decrease in pain, an increase in ADL, and an increase in wrist ROM. All these positive effects of the sand bath which did not appear previously when assessing after 7 days of treatment may be attributed to the effect of sand bathing which was present at a post I but did not

appear due to the stimulatory effect of noxious heat [34], while after the noxious effect of heat was alleviated and inflammatory processes took its time, all improvements have appeared. It has been reported by Gomes [35] that, sand therapy, as one of the different natural treatment methods, helps tissues get rid of the toxic substances accumulated in them, which helps to strengthen them and their ability to perform their functions with maximum efficiency. In addition to that, we should also consider the Geological studies which showed that Siwa sand represented enriching in Ca, high amounts of magnesium and iron along with high concentrations of silica carbonates [36]. These elements are free to pass through the epidermis and to be absorbed into the cells of the dermis. Also, sand baths and exposure to sunlight helps to provide the body with vitamin D, which aids in calcium metabolism and bone formation and increases their interaction with the function of the immune system [37], and it is well known that vitamin D therapy in combination with Ca therapy increases the absorption capacity of calcium and magnesium which is very necessary for human health [38].

### Conclusion

Both Siwa sand bath and Sulphurous water are effective in controlling inflammatory biomarkers and pain, and in improving functional activity and ROM of the wrist joint, but treatment with Siwa sand bath has a long-term effect than Sulphurous water bath.

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