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Influence of Non-pharmacological Treatment on Pain, Morning Stiffness, Fatigue, and Physical Function in Patients with Psoriatic Arthritis

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ABSTRACT Naphthalanotherapy (NT) is a therapeutic procedure that uses mineral oil obtained from petroleum. The aim of this study was to investigate the influence of the duration of NT combined with an individually adjusted rehabilitation program (IARP) on pain, morning stiffness (MS), fatigue, and physical function in patients with psoriatic arthritis (PsA). A total of 29 consecutive patients with PsA were divided into two groups. Group 1 (n=17) participated in a two-week and Group 2 (n=12) in a three-week intervention program. Pain (using the Visual Analogue Scale – VAS), fatigue (VAS and Functional Assessment of Chronic Illness Therapy-Fatigue – FACIT-F), duration of MS (minutes), and physical function (Health Assessment Questionnaire – HAQ) were assessed before and after therapy. Statistical analysis was performed using SPSS version 20, with $P<0.05$. There was a significant improvement in VAS-pain, VAS-fatigue, MS, HAQ, and FACIT-F before vs after therapy: Group 1:5.88±1.62 vs 3.94±1.25, $P=0.001$; 6.59±1.73 vs 4.35±1.73, $P=0.001$; 35.47±31.64 vs 23.71±29.30, $P=0.001$; 1.43±0.78 vs 1.23±0.74, $P=0.001$; 25.88±10.89 vs 30.71±10.65, $P=0.009$; Group 2: 6.17±1.27 vs 3.92±1.44, $P=0.001$; 6.50±1.93 vs 3.75±1.71, $P=0.001$; 38.42±32.00 vs 21.25±17.31, $P=0.006$; 1.47±0.79 vs 0.93±0.54, $P=0.008$; 25.00±9.87 vs 36.83±7.20, $P=0.001$, respectively. Regarding the length of the therapy, significant difference was reached only in FACIT-F ($P=0.009$). Two-week and three-week NT combined with IARP are equally efficient in reduction of pain and MS, as well as in improving physical function in patients with PsA. The three-week program showed an additional effect on reducing fatigue assessed by the FACIT-F score.

KEY WORDS: psoriatic arthritis, rehabilitation, pain, physical functional performance, fatigue, naphtalanotherapy

INTRODUCTION

Naphthalan is dark-brown mineral oil of high viscosity and a specific aromatic odor, obtained from petroleum in the superficial layers of the earth. Naphthalanotherapy (NT) is a therapeutic procedure that uses naphthalan in the treatment and rehabilitation of psoriasis (PsO) and psoriatic arthritis (PsA) at the Special Hospital for Medical Rehabilitation – Naftalan in Ivanić-Grad, Croatia. Naphthalan can

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be applied as a naphthalan bath, iontophoresis with naphthalan, sonophoresis, mastic therapy, and occlusive naphthalan dressing. Naphthalan contains a high percentage (55%) of naphthene carbohydrates, 15% of aromatic carbohydrates, no methane carbohydrates, and a negligible concentration of light benzine, and ligroin and kerosine fractions. It is characterized by high polycyclicity of naphthene carbohydrates: isoprenanes, steranes, and triterpanes, which a chemical structure that closely resembles hormones, vitamins, and bioactive substances and to which medical properties have been ascribed (1-3). Studies have confirmed that naphthalan is neither a skin irritant nor carcinogenic (1,2). One of the first descriptions regarding the medical effects of naphthalan oil was published in 1894, with a focus on the skin and joint disease (4). Different studies have demonstrated the healing and anti-inflammatory properties of naphthalan in the treatment of PsO and PsA (1,5-6).

PsA is a heterogeneous form of inflammatory, seronegative arthritis that occurs in around 30% of patients with PsO and is presented as peripheral and/or axial disease. The estimated prevalence of PsA is 0.3-1.0% in the general population. There is still a high prevalence of undiagnosed PsA in patients with PsO (up to 30%). Usually, PsO predates the appearance of arthritis, but in 5% arthritis may occur before PsO, and the onset of PsO and PsA occurs simultaneously, i.e. within the same year, in 15% to 20% of patients (7-9). Patients with severe psoriasis and nail changes are at greater risk of developing PsA. PsA is very heterogenic disease, and the clinical picture may change over the disease course in individual patients. Inflammatory seronegative disease of the joints and spine with dactylitis and/or enthesitis in patients with current psoriasis or a personal and/or a family history of psoriasis strongly indicate PsA (10,11). Epidemiological data have shown that PsA is a potentially severe joint disease associated with joint damage and loss of joint function, resulting in increased disability, morbidity, and mortality (12). Despite the presence of new medications (conventional and targeted synthetic disease-modifying anti-rheumatic drugs and biologics), severe disease with significant functional impairment develops in at least 20% of patients, especially in polyarticular disease. Late diagnosis and late-onset of treatment contribute to poor prognosis (13,14). More recent research has shown that PsO and PsA are often associated with depression, metabolic syndrome (central obesity, dyslipidemia, hypertension, and insulin resistance), non-alcoholic fat liver disease (NAFLD), cardiovascular diseases, and osteoporosis (15).

There is very little evidence available to assess the efficacy of non-pharmacological treatment in PsA.

This study aimed to evaluate the influence of the duration of NT combined with an individually adjusted rehabilitation program (IARP) on pain, morning stiffness, fatigue, and physical function in patients with PsA.

PATIENTS AND METHODS

Patients

This study was conducted in 2017 at the Special Hospital for Medical Rehabilitation – Naftalan, Ivanic Grad, Croatia. This study was approved by the local Ethics Committee under the number 238/10-111-616-2/17. Each patient signed informed consent before being included in the study. The study has been performed following the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

A total of 29 consecutive patients, 10 (34.5%) women and 19 (65.5%) men, diagnosed with PsA with peripheral joint involvement (oligoarticular or polyarticular) were included in the study. All patients were diagnosed with PsO as well. The age median was 59 years (range 35-76 years). At baseline, the groups were homogeneous regarding clinical and demographic characteristics. There was no statistically significant difference between the groups at the beginning of the study regarding age, sex, duration of the disease, pain intensity, fatigue, and functional status (Table 1). Patients were divided into two groups. In the first group of 17 patients, NT and IARP were conducted for two weeks (5 days per week), and the same program was conducted for three weeks in the second group of 12 patients (5 days per week). NT was applied in the form of naphthalan baths. IARP consisted of kinesiotherapy (range of motion exercises and strengthening exercises), hydrotherapy (pool exercises in thermal water), and electrophysical therapy. No change in analgesic therapy (nonsteroidal anti-inflammatory drugs – NSAIDs, paracetamol/acetaminophen, and tramadol) and glucocorticoid dose was allowed during the study. All patients were instructed on how to fulfill specific self-administered patient questionnaires at the beginning and the end of the rehabilitation.

Assessment of pain, fatigue, morning stiffness, and functional status

The Visual Analogue Scale (VAS, score 0-10) was used for the measurement of patient perception of pain and fatigue. It was presented as a straight, 10 cm

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horizontal line, with the left end marked as "no pain" or "no fatigue" and a higher score indicating a higher level of pain or fatigue. Additionally, the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F version 4, score 0-52) questionnaire was used to assess patient fatigue, with a higher score indicating lower fatigue and a better quality of life (16). The Health Assessment Questionnaire (HAQ) was used to assess patient functional ability in everyday life, where a HAQ score bellow 1 was considered a mild disability, HAQ score from 1 to 2 was considered moderate disability, and score above 2 was considered a severe disability (17). Morning stiffness was assessed using the estimated duration of morning stiffness by the patient and was expressed in minutes.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) version 20. Continuous and categorical variables were described using descriptive statistics. The Kolmogorov- Smirnov test was run to examine whether the data are normally distributed. Median, range, mean, and SD were calculated for continuous variables, while relative frequencies were computed for all variables. The T-test and X^2 tests were used, where applicable, for the analysis of difference between the groups. A value of $P<0.05$ was used to determine statistical significance.

RESULTS

The results showed statistically significant alleviation of pain and fatigue (VAS), as well as shortening of morning stiffness and improvement of HAQ and FACIT-F scores after two weeks of NT combined with IARP: 5.88±1.62 vs 3.94±1.25 (*P*=0.001), 6.59±1.73 vs 4.35±1.73 (*P*=0.001), 35.47±31.64 vs 23.71±29.30 (*P*=0.001), 1.43±0.78 vs 1.23±0.74 (*P*=0.001), 25.88±10.89 vs 30.71±10.65 (*P*=0.009), respectively. There was also a statistically significant alleviation of pain and fatigue as well as shortening of morning stiffness and improvement in HAQ score and FACIT-F score after three weeks of NT combined with IARP: 6.17±1.27 vs 3.92±1.44 (*P*=0.001), 6.50±1.93 vs 3.75±1.71 (*P*=0.001), 38.42±32.00 vs 21.25±17.31 (*P*=0.006), 1.47±0.79 vs 0.93±0.54 (*P*=0.008), 25.00±9.87 vs 36.83±7.20 (*P*=0.001), respectively. The results are shown in Table 2. There was no statistically significant difference between the groups in analyzed rehabilitation outcomes regarding the length of therapy, except in the improvement of FACIT-F score (*P*=0.009). Figure 1 shows improvement in pain, fatigue, morning stiffness, and in HAQ and FACIT-F scores after two (light gray bars) and three weeks of therapy (dark gray bars). The biggest difference in results is precisely in FACIT-F, which improved significantly more after the three-week therapy program compared with the two-week therapy program.

DISCUSSION

NT has been used in the Special Hospital for Medical Rehabilitation – Naftalan in Croatia in the treatment of chronic skin and rheumatic diseases for the last 30 years. The antipsoriatic skin properties of NT have been assessed in multiple studies conducted by

Table 1. Patient characteristics at baseline

	Group 1 (n=12)	Group 2 (n=17)	X^2 test	*P*-value
Sex: number (%)	female: 5 (41.67) male: 7 (58.33)	female: 5 (29.4) male: 12 (70.59)	0.468	0.494
	Group 1 (n=12)	Group 2 (n=17)	t-test	*P*-value
Age (years): mean (range)	59.08 (48-69)	60.0 (35-76)	-0.38	0.710
Duration of the disease (years): mean (±SD)	17.50 (±9.65)	18.26 (±11.18)	0.19	0.849
VAS pain (mm): mean (±SD)	6.17 (±1.27)	5.88 (±1.62)	-0.51	0.615
VAS fatigue (mm): mean (±SD)	6.50 (±1.93)	6.59 (±1.73)	-0.13	0.898
Morning stiffness (minutes): mean (±SD)	38.42 (±32.0)	35.47 (±31.64)	-0.25	0.808
HAQ (0-3): mean (±SD)	1.47 (±0.79)	1.43 (±0.78)	-0.12	0.906
FACIT-F (0-52): mean (±SD)	25.0 (±9.87)	25.88 (±10.89)	0.22	0.825

VAS: visual analogue scale; HAQ: Health Assessment Questionnaire; FACIT-F: Functional Assessment of Chronic Illness Therapy-Fatigue

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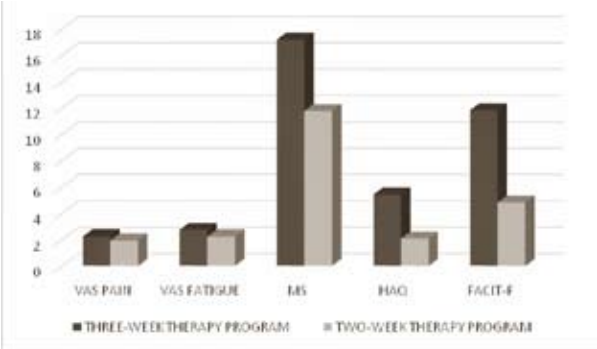
Table 2. Alleviation of pain and fatigue (VAS), shortening of morning stiffness, and improvement of HAQ and FACIT-F scores after two and three weeks of NT combined with IARP

	Group 1 two weeks of therapy				Group 2 three weeks of therapy			
	Before therapy	After therapy	t-test	*P*-value	Before therapy	After therapy	t-test	*P*-value
	Mean (±SD)	Mean (±SD)			Mean (±SD)	Mean (±SD)		
VAS pain (0-10)	5.88 (1.62)	3.94 (1.25)	5.130	0.001*	6.17 (1.27)	3.92 (1.44)	4.294	0.001*
VAS fatigue (0-10)	6.59 (1.73)	4.35 (1.73)	6.226	0.001*	6.50 (1.93)	3.75 (1.71)	6.698	0.001*
Morning stiffness (minutes)	35.47 (31.64)	23.71 (29.30)	4.883	0.001*	38.42 (32.00)	21.25 (17.31)	3.404	0.006*
HAQ (0-3)	1.43 (0.78)	1.23 (0.74)	4.198	0.001*	1.47 (0.79)	0.93 (0.54)	3.264	0.008*
FACIT-F (0-52)	25.88 (10.89)	30.71 (10.65)	-2.980	0.009*	25.00 (9.87)	36.83 (7.20)	-6.411	0.001*

*statistically significant difference
VAS: visual analogue scale; MS: morning stiffness; HAQ: Health Assessment Questionnaire; FACIT-F: Functional Assessment of Chronic Illness Therapy Fatigue

dermatologists over the past two decades. Vrzogić *et al.* performed immunohistochemical analysis on biopsy specimens from 10 patients with psoriasis vulgaris, obtained before and after 3 weeks of treatment with naphthalan oil, and concluded that NT modifies the expression of the angiogenic factor in psoriatic skin lesions and causes reduction of neovascularization in psoriatic skin lesions (5). In another study, Vrzogić *et al.* reported the possible antiproliferative effect of NT through the decrease of immunocompetent cell count (CD3, CD4, and CD8 lymphocytes) in psoriatic skin lesions (6). Thaci *et al.* demonstrated the antiproliferative effect as well as differentiation-inducing effects of heavy naphthene oil on keratinocytes *in vitro* (18). To the best of our knowledge, there are no recent studies on the therapeutic effect of NT in patients diagnosed with PsA on joint and spine disease. Moreover, there is very little evidence available to assess the efficacy of rehabilitation procedures in PsA (19). Non-pharmacological treatment has mainly been assessed in rheumatoid arthritis and ankylosing spondylitis and in spondyloarthritis as a group. The Physical and Rehabilitation Medicine (PRM) Section of the Union of European Medical Specialists (UEMS) defined the rehabilitation goals in the management of inflammatory arthritis as follows: to control pain and disease activity, prevent joint damage, protect and enhance function, and improve quality of life (QoL). The PRM interventions imply non-pharmacological treatments which include patient education for joint protection, energy conservation and self-management techniques, exercise therapy, physical modalities, orthoses/assistive devices, and balneotherapy (20). The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) published treatment recommendations for management of PsA in 2015 and recommend physiotherapy for axial disease and enthesitis (21). Based on low-quality evidence, the 2018 American College of Rheumatology/National Psoriasis Foundation (ACR/NOF) guideline for the treatment of PsA recommended exercise over no exercise, low-impact exercise (e.g. swimming) over high-impact exercise (e.g. running), physical therapy over no physical therapy, occupational therapy over no occupational therapy, massage therapy over no massage therapy, acupuncture over no acupuncture, smoking cessation over no smoking cessation, and weight loss for patients who are overweight/obese (22). In a study by Roger-Silva *et al.*, a 12-week (twice



Please note that only the results of the HAQ score were multiplied by 10 to improve their visibility.

Figure 1. Improvement in the measured rehabilitation outcomes pre-therapy versus post-therapy.

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a week) resistance exercise training in patients with PsA improved functional capacity, pain, disease activity, and quality of life (QoL). The clinical improvements were not coupled with significant changes in muscular strength (23). Interferential current (IFC) was suggested to improve the skin manifestations of PsO (24). Walker U.A. *et al.* assessed the efficacy of IFC on PsA. They demonstrated that bipolar IFC applied twice daily to the hands, feet, and all affected joints after 16 weeks of IFC therapy improved 36-Item Short Form Health Survey (SF-36)-assessed body pain, but not other SF-36 subscales, as well as morning stiffness, tender joint counts, and physician-assessed disease activity. In contrast, VAS pain, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR) measurements were unchanged. The authors concluded that IFC has analgesic effects in PsA but that it does not have a satisfactory disease modifying effect (25). In a study by Tillet W *et al.*, the highest-ranked outcomes that patients with PsA wished to see from treatment in general were alleviation of pain and fatigue, followed by physical fitness, slowing damage, and QoL/well-being (26). Our study aimed to evaluate the influence of the duration of NT combined with IARP on pain, fatigue, morning stiffness, and physical function in patients with PsA. The domains we included in our research are some of the main components reflecting the QoL in patients diagnosed with PsA. QoL is altered in PsA due to the physical as well as the psychological impact of this disease (27). The impact of PsA appears to be very broad, covering all aspects of life, i.e. activities and participation, physical and emotional aspects, but also domains such as fatigue, coping, or sleep disturbance (27). By measuring the level of pain, fatigue, and function at the beginning and at the end of the treatment, we wanted to demonstrate their change as a mean of improving the QoL in our patients. Primarily, we wanted to see if an additional week of rehabilitation program added significantly to better rehabilitation outcomes. The results showed statistically significant alleviation of pain (VAS pain) and fatigue (VAS and FACIT-F), improvement in physical function (HAQ), and shortening of MS after two as well as after three weeks of NT combined with IARP. A week longer of therapy reached a statistically significant difference only in FACIT-F scores. In other patient-reported outcome measures, there was no statistically significant difference regarding the therapy duration. We found that the additional effect of longer rehabilitation duration on fatigue is important because fatigue represents a major part of the disease burden in patients with PsA, as well as in other inflammatory diseases (28). Moreover, alleviation of pain and fatigue are ranked by patients with PsA as the most important treatment outcomes in PsA (26).

The main limitations of our study are the relatively small sample and the lack of a control group without NT and IARP. Additionally, the severity of skin disease was not assessed, nor was the influence of NT and IARP on skin disease. It is also important to note that because of the diversity of the clinical manifestations of PsA we chose an individually adjusted rehabilitation program rather than a fixed one.

CONSLUSION

We conclude that a two-week rehabilitation program consisting of NT combined with IARP is equally efficient as a three-week rehabilitation program in the alleviation of pain and fatigue measured by VAS, as well as in the reduction of morning stiffness and improvement of physical function in patients with PsA. The three-week rehabilitation program showed an additional effect on reducing fatigue measured by the FACIT-F questionnaire. The results of our study indicate that a longer rehabilitation program is necessary for the reduction of fatigue in patients with PsA but not for the improvement in other important rehabilitation outcomes such as pain, morning stiffness, and physical function.

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