

The Effectiveness of Fluidotherapy in Poststroke Complex Regional Pain Syndrome: A Randomized Controlled Study

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Objective: To evaluate whether combining fluidotherapy to conventional rehabilitation program provides additional improvements on pain severity, upper extremity functions, and edema volume in patients with poststroke complex regional pain syndrome (CRPS). **Design:** Randomized controlled trial. **Setting:** Training and research hospital. **Participants:** Thirty hemiplegic patients with subacute stage CRPS type-1 of the upper extremity. **Interventions:** The patients randomly divided into 2 groups. Both groups received a 3 week conventional rehabilitation program (5 days/week, 2-4 hours/day). Experimental group received 15 sessions additional fluidotherapy application to the affected upper extremity (40 °C, 20 minutes in continuous mode, 5 sessions/week). **Main Outcome Measures:** We evaluated the distal upper arm edema with a volumeter. Other used clinical assessment scales were Brunnstrom recovery stages of the arm and hand for motor recovery, motor items of the functional independence measure for functional status, visual analog scale for pain severity, and the painDETECT questionnaire for presence and the severity of neuropathic pain. **Results:** The mean age of the participants was 64.3 ± 11.66 (28-84). At the post-treatment evaluation, significant improvements were revealed regarding to the edema volume, pain visual analog scale, painDETECT and functional independence measure scores, and the Brunnstrom stages of upper extremity and hand in both groups ($P < .05$). But among the parameters mentioned above, only the decrease in edema volume and the painDETECT scores were greater in fluidotherapy group than the control group ($P < .05$). **Conclusions:** Addition of the fluidotherapy to the conventional rehabilitation program provides better improvements on neuropathic pain and edema volume in subacute stage poststroke CRPS.

Key Words: Complex regional pain syndrome—fluidotherapy—hand volume—hemiplegia—neuropathic pain—physical agents—rehabilitation

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Introduction

Complex regional pain syndrome (CRPS) is a painful condition characterized by spontaneous or stimulus-induced pain which is disproportionate to the initiating event and accompanied by various autonomic, sensory, and motor abnormalities. There are 2 types of CRPS: CRPS type I occurs following an illness or injury without nerve damage, while CRPS II occurs after a significant

nerve injury. Independent from the type, both have the same signs and symptoms. CRPS is a clinical diagnosis made based on the history, and the clinical examination findings.¹⁻⁴ The underlying pathophysiology is still unclear but peripheral and central neurogenic inflammation, autonomic dysfunction and maladaptive neuroplasticity are the some of the explanatory models.⁵ There are various precipitating factors involved in the aetiology of

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this condition. Trauma is considered to be the most common precipitating factor. Other known factors include heart attacks, inflammatory diseases, smoking, hereditary factors and stroke.^{3,6}

Poststroke CRPS is an important disabling complication in stroke survivors and the incidence was reported ranging between 21% and 31%. Biomechanical factors leading mechanical instability of the shoulder joint and micro-trauma are considered to be the risk factors.⁷⁻⁹ In post-stroke CRPS, simultaneous shoulder and wrist pain occurs with the relatively spared elbow joint. Some other signs and symptoms can be counted as edema, warmth, and redness of the hand, limited range of motion (ROM) of the upper extremity joints except wrist; tenderness of the metacarpophalangeal joints, subsequent joint contractions, and functional limitation of the extremity.^{7,10}

In the treatment of CRPS, physical and occupational therapy are playing the key roles. But the treatment also includes medication, interventions to the sympathetic system, surgery, and psychotherapy when it is necessary. Physical therapy includes elevation, massage, ROM and graded strengthening exercises, stress loading, and sensory re-education.^{2,6,11,12} Electrotherapy (diadynamic and, interferential current, transcutaneous electrical nerve stimulation [TENS]) and several heat modalities such as ultrasound, hot/cold packs, paraffin wax, whirlpool, contrast baths, and fluidotherapy also can be used due to the stage of the CRPS to relieve the symptoms of pain, edema, stiffness and hypersensitivity.¹³⁻¹⁵

Fluidotherapy, is a dry heat modality using a unit which creates a convection-formed vortex with the combination of heated air and sawdust-type substances in a chamber. It has positive effects on hypersensitivity because of the tactile stimulation effect. Another utility of this unit is allowing the active ROM exercises of the hand.^{14,16,17} Although, fluidotherapy is accepted as a useful treatment for CRPS providing decrease in pain severity, stiffness and hypersensitivity, there is paucity of studies supporting this effectiveness.¹⁸ To our knowledge only 1 study evaluated the efficacy of fluidotherapy on pain severity and disability in patients with post stroke CRPS.¹¹ In the mentioned study fluidotherapy was combined with stress loading exercises. In another study by Han et al., the fluidotherapy was applied to the stroke patients with hand edema, and they investigated the effects on edema volume and hand dexterity.¹⁹ In our study, we aimed to evaluate whether combining fluidotherapy to conventional rehabilitation program provides additional improvements on pain severity, upper extremity functions and edema volume in hemiplegic patients accompanied with CRPS type 1.

Materials and Methods

Participants

A total of 200 patients with hemiplegia evaluated between April 2014 and March 2015 in our inpatient rehabilitation center. By the clinical and radiological evaluation,

42 patients were found to have unilateral CRPS type 1 at the hemiplegic upper extremity according to Budapest clinical diagnostic criteria.¹ The inclusion criteria of the study were having stroke less than 12 months; presence of sub-acute stage CRPS type I due to the cerebrovascular accident and mini-mental state examination score at least 23 points. The exclusion criteria were presence of neglect, sensory or motor aphasia, presence of shoulder subluxation, unstable medical condition, other causes of CRPS (postfracture, postsurgery, and peripheral nerve injury), bilateral CRPS-1, having psychotic disorders, presence of neuropathic pain syndromes such as diabetic neuropathy and having open wounds in the treatment area. Considered the inclusion and exclusion criteria only 32 patients were eligible for study and they were randomly assigned to control and experimental group. During the rehabilitation program 1 patient from each group had to remove from the study because of the new onset unstable medical conditions. At last 15 patients in control group and 15 patients in experimental group completed the rehabilitation program and were included the final analysis (Fig 1). All subjects provided written informed consent before the participation to the study. Ethical approval was obtained from the local Ethical Committee.

Sample Size

A total sample size of 28 subjects (14 controls and 14 study participants) were necessary to test the statistical significance of a difference of at least 2 units due to the change of the painDETECT scores after the treatment between the groups with .80 power and .05 error. Sample size calculations were performed using G*Power Software Package (version 3.1.4).

Study Design

This study was designed as a single blind randomized controlled trial. A computer-generated randomization program was used to randomly assign the patients to the control group or experimental group. Same investigator (U.H.T) who was blinded to group allocation performed the pre and post-treatment evaluations.

At the pretreatment evaluation, all patients were questioned about the sociodemographic (age, gender, body mass index, income, educational, marital, and working status), and the clinical characteristics (affected side, localization of the lesion, etiology, comorbidities, use of cigarette, and disease duration). Presence of spasticity by Modified Ashworth Scale (MAS), sensory (pinprick, light touch, allodynia, hyperalgesia, and heat-pain) and motor deficits were also evaluated with physical examination. Volumetric measurements and the clinical assessment scales such as the functional independence measure (FIM), Brunnstrom motor recovery stages (BMRS), visual analog scale (VAS), and PainDETECT questionnaire were also performed before and after the 3-week treatment duration.

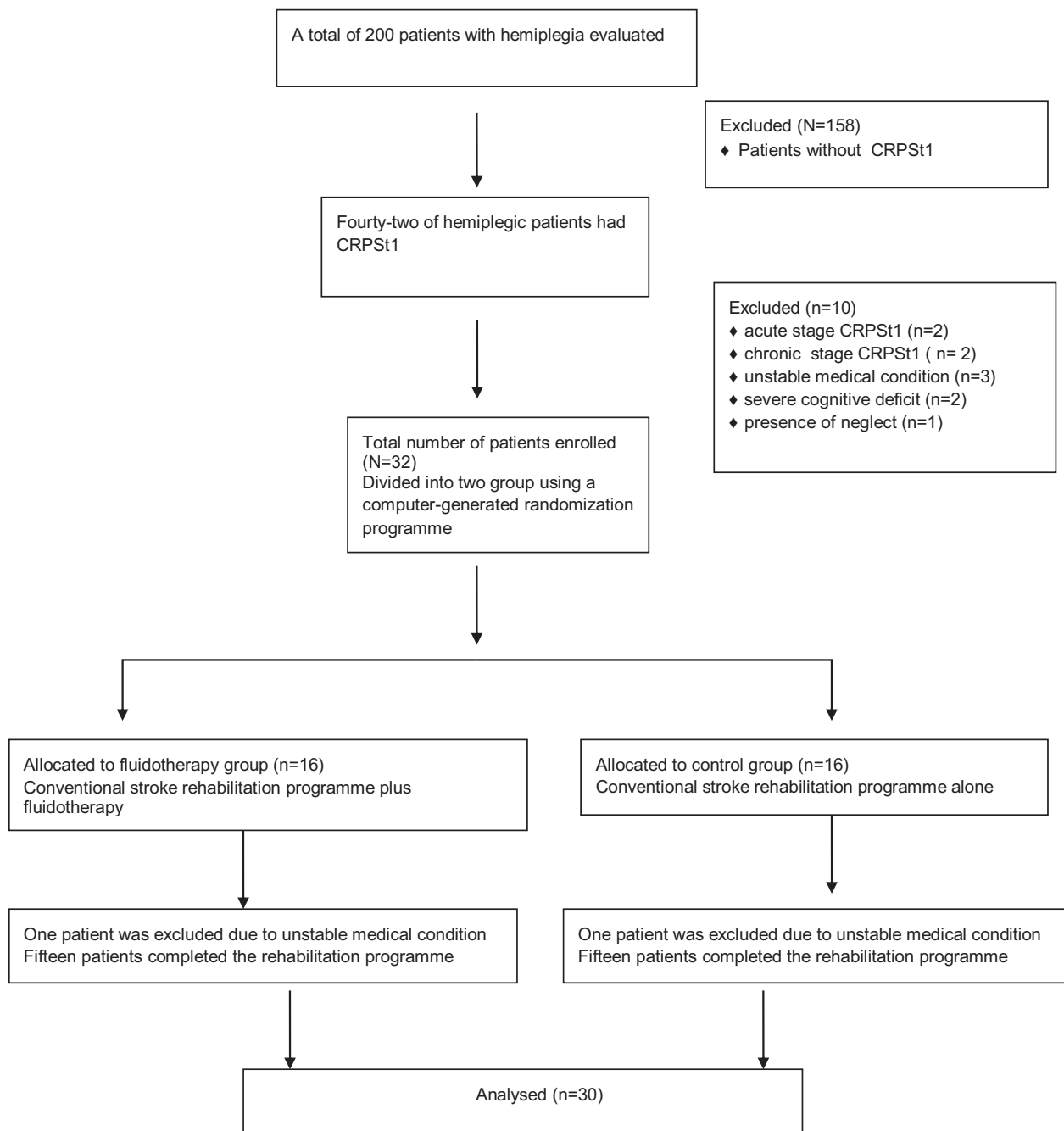


Figure 1. Flow diagram for randomized subject enrollment in this study.

Intervention

Both groups received 5 days a week and 2-4 hours a day conventional stroke rehabilitation program during 3 weeks. The rehabilitation program included neurophysiological treatment approaches, occupational therapy, and physiotherapy (positioning, ROM, stretching, strengthening exercises, postural control, weight-shifting, gait training, endurance training, orthosis [if required], and education), and speech therapy (if required). Both groups also received conventional TENS (Everyway branded,

EV-603M) to the hemiplegic upper extremity at a frequency of 100 hertz with 10-30 mA and 50-100 ms pulse duration.

Application of Fluidotherapy

Only the subjects in the experimental group received a total of 15 sessions (5 sessions per week) application of fluidotherapy device (Fizyoflug 2000 branded) at a temperature of 40 °C for 20 minutes in continuous mode

addition to conventional rehabilitation program. Before the application, the patient washed the affected upper extremity and removed all the jewelries. Then, the patient was positioned as the area to be treated would be relaxed and comfortable. The affected extremity inserted into the sleeve and closed snugly around the proximal arm. The patient was encouraged to do active ROM exercises with the wrist, metacarpophalangeal, and interphalangeal joints if available.

Outcome Measures

Volumetric Measurements

A water displacement method with a volumeter was used to measure the composite volume of the hand and the lower arm. This method is accepted as the gold standard for the measurement of limb swelling.²⁰ The container was filled with enough water and then the patient immersed the arm into the volumeter with the web between the third and fourth finger resting on a plastic bar. The water flowing from the spout was collected into a beaker and then measured with a graduated cylinder. The patients were advised not to move the extremity until the end of the water displacement. The measurements (in millilitres) were taken bilaterally at the seated position and at the same time of the day.

Motor Recovery

BMRS for hand and upper extremity were used to assess the patients' neurological recovery. It includes 6 stages and higher stages demonstrate better recovery. Stage I: presence of flaccidity, incapability of voluntary movement; Stage II, spasticity appears; Stage III, increased spasticity, gaining minimal voluntary movement control in synergy patterns; Stage IV, decreased spasticity, capability of voluntary movements out of synergy patterns; Stage V, more decrease in spasticity, capability of more complex combinations of movements; and Stage VI, disappearance of spasticity, capability of movement of individual joints, and almost normal coordination.^{21,22}

Functional Status

The FIM was used to evaluate the functional status of the participants.²³ This universal assessment tool contains a total of 18 items (13 items for physical/motor functions and 5 items for cognitive functions). The FIM-motor items comprises of the subscales of self-care, sphincter control, transfer, and locomotion, while the FIM-cognitive items related to communication and social cognition subscales. Each item is scored with a 7-point ordinal scale ranged from complete independence (score = 7) to total assistance requirement (complete dependence) (score = 1). Higher FIM scores show higher level of independence. In this

study, we used only FIM-motor items total score. The reliability and validity study of the Turkish version of the FIM was conducted by Kucukdeveci et al.²⁴

Assessment of the Pain

Visual analog scale

The VAS was used to assess the severity of pain on upper extremity while resting and performing active ROM exercises. This tool consists of a 10 cm line and the extreme left "0" indicates no pain while extreme right "10" indicates unbearable pain. The patients were asked to mark the position which reflects the severity of their pain.

The painDETECT questionnaire

The painDETECT questionnaire (PDQ) was used to evaluate the potential presence and the severity of neuropathic pain.²⁵ PDQ is a self-reported questionnaire which is comprised of 7 sensory symptom items for pain graded from 0 to 5, one item on pain course pattern, and the other on pain radiation. The total scores of the questionnaire ranges from 0 to 38. A score of 19-38 indicates likely NP, 13-18 indicates being unclear or possible NP, and ≤ 12 indicates the characterization of pain is more likely to be nociceptive. The validity and reliability study of the Turkish version of the PDQ was conducted by Alkan et al.²⁶

Statistical Analysis

Analysis was performed by using SPSS 20.0 (SPSS Inc., Chicago, IL). Distribution of continuous variables was assessed by Shapiro-Wilk test. Descriptive statistics were expressed as mean \pm standard deviation (SD) for continuous variables; median (minimum-maximum) for discrete variables, and number and percentage (%) for categorical variables. Comparisons between the groups in terms of sociodemographic and clinical characteristics were assessed by Kruskal-Wallis test for mean values, Mann-Whitney *U* test for median values and chi-square test for categorical variables. The Wilcoxon Signed-Ranks test was used to determine statically significant changes in volumetric measurements, BMRS, PDQ, and VAS scores after the treatment period within each group and the Mann-Whitney *U* test was used to compare the difference between the groups. The mixed analysis of variance was applied to test for the interaction effect between group and time for edema volume. The statistical significance level was set at *P* less than .05.

Results

A total of 35 patients (15 patients for each fluidotherapy and control group) mean age 64.3 ± 11.66 (28-84) were enrolled to the study. There were no statically significant differences between the groups in terms of sociodemographic

Table 1. Sociodemographic and clinical characteristics of the patients and intergroup comparisons

Variables	Fluidotherapy	Control	P
Age, years	62.61 ± 9.23	63.46 ± 14.63	.70
Sex, male/female	5/10 (33.3/66.7)	7/8 (46.7/53.3)	.71
BMI, kg/m ²	28.74 ± 4.40	29.3 ± 3.69	.31
Educational status			
Illiterate	4 (26.7)	5 (33.3)	.76
Low	8 (53.3)	6 (40)	
high	3 (20)	4 (26.7)	
Marital status, married/unmarried	10/5 (66.7/33.3)	10/5 (66.7/33.3)	.65
Working status, working/not working	8/42 (16/84)	11/39 (22/78)	.28
Income, low/medium	10/5 (66.7/33.3)	12/3 (80/20)	.08
Time after stroke onset, days	127.8 ± 54.1	151.4 ± 48.1	.85
Effected side Dominant/nondominant	5/10 (33.3/66.7)	7/8 (46.7/53.3)	.45
Localization of lesion			.61
MCA	10 (66.7)	7 (46.7)	
ACA	2 (13.3)	2 (13.3)	
PCA	2 (13.3)	5 (33.3)	
Other	1 (6.7)	1 (6.7)	
Etiology, trombo-embolia/hemorrhage	11/4 (73.3/26.7)	13/2 (86.7/13.3)	.36
Comorbidities			
Diabetes mellitus	8 (53.3)	10 (66.6)	.81
Hypertension	45 (90)	47 (94)	.82
Dyslipidemia	5 (33.3)	6 (40)	.70
CAD	6 (40)	6 (40)	1
Use of cigarette	1 (6.7)	0 (0)	.31
Disease duration, days	82.53 ± 68.51	120.73 ± 79.32	.20
Edema volume	72.33 ± 21.35	65.33 ± 25.79	.09
BMRS-upper extremity	2.46 ± 1.35	1.8 ± 1.14	.14
BMRS-hand	2.6 ± 1.59	2 ± 1.36	.24
MAS	1.4 ± 1.29	1.46 ± 1.18	.84
FIM	15.33 ± 7.54	12.93 ± 7.21	.22
Pain VAS			
With activity	7.93 ± .88	7.6 ± 1.12	.58
At rest	6.4 ± .82	6.2 ± 1.08	.40
PDQ	15.66 ± 6.29	14.8 ± 4.84	.70

NOTE. Scores are mean ± SD, or n (%). Significance at $P < .05$.

Abbreviations: ACA, anterior cerebral artery; BMI, body mass index; BMRS, Brunnstrom motor recovery stages; CAD, coronary artery disease; FIM, functional independence measure; MAS, modified Ashworth scale; MCA, middle cerebral artery; PCA, posterior cerebral artery; PDQ, PainDETECT questionnaire; VAS, visual analog scale.

and clinical properties demonstrated in Table 1. The pre-treatment evaluations of the edema volume of the affected upper extremity and the clinical assessment tools such as BMRS, MAS, FIM, VAS, and PDQ also revealed no significant difference between the groups.

The rehabilitation time between fluidotherapy and control groups revealed no significant difference (148.3 ± 30.8 , 160.6 ± 25.1 , minutes respectively $P = .17$). At the post-treatment evaluation, significant improvements were revealed regarding to the edema volume, BMRS of upper extremity and hand, FIM scores, pain VAS, and painDETECT scores in both groups ($P < .05$). But among the parameters mentioned above, only the decrease in edema volume and the painDETECT scores were greater in fluidotherapy group than the control group ($P < .05$) (Table 2). As mentioned in Table 1, edema volume in fluidotherapy group tended to be higher than that in control group.

Therefore, we analyzed Group \times Time interaction by a mixed analysis of variance for edema volume and the results showed a significant interaction ($F(1,28) = 8.9$ $P = .006$) between the groups.

The rates of the presence of the sensory deficits (pin-prick, light touch, allodynia, hyperalgesia, and heat pain) were also evaluated before and after the treatment in both groups. Only the rates of hyperalgesia and allodynia significantly decreased in fluidotherapy group (Table 3).

Discussion

Complex regional pain syndrome is an important complication leading to disability and decreased quality of life in stroke survivors. Physical and occupational therapy are essential for the treatment of CRPS. However, because of the insufficient evidence in the literature, the patients are

Table 2. Pre and post-treatment comparisons of the edema volume and clinical assessment scale scores of the groups

Variables	Pretreatment	Post-treatment	<i>P</i>	Score difference	<i>P</i>
Edema volume					
Fluidotherapy	65 (40-100)	25 (18-80)	<.001	40 (20-70)	.001
Control	60 (35-90)	35 (25-40)	<.001	20 (15-40)	
BMRS-upper extremity					.41
Fluidotherapy	1 (1-5)	2 (1-5)	.02	0 (0-2)	
Control	1 (1-4)	2 (1-5)	.03	0 (0-2)	
BMRS-Hand					.73
Fluidotherapy	1 (1-4)	2 (1-5)	.03	0 (0-3)	
Control	1 (1-5)	2 (1-5)	.04	0 (0-2)	
FIM					
Fluidotherapy	15 (4-33)	18 (7-35)	.002	2 (0-5)	.66
Control	12 (6-36)	14 (8-38)	.003	2 (0-4)	
pain VAS With activity					.11
Fluidotherapy	8 (7-10)	4 (2-6)	.001	3 (1-6)	
Control	8 (5-9)	5 (3-7)	.001	2 (0-5)	
At rest					
Fluidotherapy	6 (5-8)	3 (2-4)	.001	2 (1-4)	.73
Control	6 (5-8)	4 (2-6)	.001	2 (1-4)	
PDQ					
Fluidotherapy	19 (10-30)	15 (6-19)	<.001	4 (0-11)	.03
Control	20 (11-25)	18 (8-20)	.001	2 (0-6)	

NOTE. Scores are median (min-max). Significance at $P < .05$.

Abbreviations: BMRS, Brunnstrom motor recovery stages; FIM, functional independence measure; PDQ, PainDETECT questionnaire; VAS, visual analog scale.

mostly treated with the physical therapy agents and modalities empirically. In our study, we aimed to evaluate the effectiveness of a common use physical therapy agent, fluidotherapy, in CRPS treatment. This study revealed that

combining fluidotherapy to conventional rehabilitation program provides additional improvements in the severity of neuropathic pain and upper limb edema in poststroke CRPS. Although there were significant improvements in other parameters such as FIM, pain VAS, and BMRS scores, no superiorities were found in the fluidotherapy group compared to the control group.

In the clinical practice, electrotherapy and heat modalities are usually added to the rehabilitation program to improve pain, edema, stiffness, and hypersensitivity. In our study, we enrolled patients with subacute phase CRPS. Although less edema volume existed compared with acute stage, it is also required careful patient monitoring when performing thermotherapy in subacute stage. Because, heating causes vasodilatation and increased blood circulation, which may lead to an increase in edema and other signs of inflammation.¹⁷ Heating also provides increase in the tissue extensibility resulting improvement in ROM and joint stiffness. Another important effect is the elevation of the pain threshold which leads to pain reduction. It increases the activity of cutaneous thermoreceptors which has an inhibitory gating effect at the spinal cord level. Other suggested mechanisms contributing pain reduction include reducing ischemia and muscle spasm and facilitating tissue healing due to the increased blood circulation.¹⁷

Fluidotherapy is a heat modality consisting of finely divided solid particles suspended in a heated air providing a dry whirlpool system.²⁷ In this unit, distal arm or

Table 3. Pre and post-treatment comparisons of the rates of the presence of the sensory deficits

Variables	Pretreatment n (%)	Post-treatment n (%)	<i>P</i>
Pinprick sensory deficit			
Fluidotherapy	7 (46)	6 (40)	1
Control	8 (53)	7 (46)	1
Light touch sensory deficit			
Fluidotherapy	9 (60)	9 (60)	1
Control	7 (46)	6 (40)	1
Allodynia			
Fluidotherapy	15 (100)	6 (40)	.02
Control	13 (86)	11 (73)	.5
Hyperalgesia			
Fluidotherapy	14 (93)	7 (46)	.01
Control	14 (93)	10 (66)	.12
Heat-pain sensory deficit			
Fluidotherapy	4 (26)	4 (26)	1
Control	5 (33)	7 (46)	.5

Significance at $P < .05$.

leg is immersed into a warming chamber including openings for the extremities. The movements of the solid particles transfer the heat through convection and provide increase in the temperature of immersed extremity.^{17,28} Fluidotherapy is used in clinical practice for pain relief, tissue healing, and desensitization. So it has superiority to other heat modalities especially for CRPS treatment.²⁹ In fluidotherapy, the used solid particles have low affinity for heat and higher heat temperature can be used compared to hydrotherapy. Also the temperature can be kept at a constant value.²⁸

In the literature, there are few studies evaluating the effectiveness of fluidotherapy in poststroke CRPS. In Damayanti et al's study, fluidotherapy combined with stress loading was compared with a control group receiving only conventional occupational therapy. They revealed more improvements in experimental group in terms of pain, arm function, and pain related disability.¹¹ In the mentioned study pain was evaluated only by VAS and assessment scales evaluating the neuropathic pain were not used. In our study we also evaluated neuropathic pain with PDQ and the results showed that combining fluidotherapy to conventional therapy provides better reduction in PDQ scores compared to control group. In fluidotherapy, the movements of the solid particles promote the desensitisation due to the gentle tactile stimulation. So, fluidotherapy seem to be effective in the reduction of neuropathic pain component of CRPS. In addition, we demonstrated that the rates of having hyperalgesia and allodynia are significantly decreased in only fluidotherapy group. In our study, we also revealed significant improvement in pain VAS scores, FIM-motor scale and BMRS in both groups. However no superiorities were found in fluidotherapy group.

In another study, Han et al investigated the effects of fluidotherapy on hand's dexterity and activities of daily living in stroke patients with upper limb edema. After a 3-week fluidotherapy application, they found significant decrease in hand volume evaluated by volumeter, and also significant improvement in Modified Barthel Index assessment scale. But the improvement in Box and Block Test result was not statistically significant. Unlike to our study, the mentioned study did not include control group and the inclusion criteria did not restrict the hand edema to CRPS.¹⁹ In our study, we revealed significant reduction in upper extremity edema volume in both groups but in the fluidotherapy group the improvement was better. As mentioned before, the edema volume might have been increased due to the heat's vasodilatation and blood circulation effect. But to minimize this risk, we did not exceed 40 °C in our fluidotherapy application. We also encouraged the patients to do ROM exercises in the fluidotherapy cabinet. Tactile stimulation and exercises might lead this result due to providing positive effects on lymphatic and venous reflow.

In the literature, there are limited studies about the use of other electrotherapy and heat modalities in the CRPS management.¹⁷ TENS is known as effective in nociceptive and

neuropathic pain management. Several mechanisms including gate control theory, increased opiate release, activation of μ -opioid receptors, local vasodilatation, and stimulation of acupuncture points play role in pain relief.³⁰ Because of the positive effects on neuropathic pain and ease of hand movements, it has widespread use in CRPS management. In our study we aimed to investigate whether fluidotherapy had additional benefit on the treatment and we preferred to apply TENS to both of the groups. But we restricted the start of new medicines which may affect the severity of pain and edema volume such as diuretics, analgesics, NSAID, anticonvulsants (pregabalin, gabapentine), selective serotonin reuptake inhibitors (SSRIs), and serotonin and norepinephrine reuptake inhibitors.

Limitations of the Study

The main limitation of this study was the lack of long-term follow-up. We evaluated the patients before and after a 3-week rehabilitation program. Another important limitation was the restriction of the patient enrolment to subacute stage of CRPS. So we could not generalize the outcome of our study to patients with acute and chronic stage CRPS. We also could not apply sham-fluidotherapy to the control group. We considered holding the hands in the fluidotherapy cabinet without operating the device, but because of the tactile stimulation of the solid particles, the results might also be affected. We did not use sham-fluidotherapy but we encouraged the control group to perform ROM exercises for the same amount of time, in addition to the conventional therapy provided. And another limitation was the lack of objective upper extremity function assessment method like grip strength evaluation.

Conclusion

Adding fluidotherapy to conventional rehabilitation program of poststroke CRPS provides better improvements on neuropathic pain severity and edema volume. However, there is a need for further randomized controlled studies including long-term follow-up.

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