Immediate Effects of Simultaneous Application of Transcutaneous Electrical Nerve Stimulation and Ultrasound Phonophoresis on Active Myofascial Trigger Points

A Randomized Controlled Trial

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Objective: The aim of the study was to investigate the efficacy of phonophoresis with combined therapy on active myofascial trigger points.

Participants: One hundred participants with acute mechanical neck pain and at least one active myofascial trigger point in the upper trapezius were randomly assigned into four equal groups.

Intervention: Groups consisted of diclofenac phonophoresis with combined therapy, diclofenac phonophoresis, ultrasound (US) with coupling gel, and sham US and applied for 10 mins over myofascial trigger points.

Measurements: Measurements included pressure pain threshold and active cervical lateral flexion.

Results: There were statistically significant improvements in postintervention pressure pain threshold and range of motion values in treatment groups ($P < 0.0001$). As for the sham US, no significant difference was found between the preintervention and postintervention values ($P > 0.05$). Bonferroni correction test revealed that there was a significant difference between all the four groups in pressure pain threshold values ($P < 0.0001$); however, it was nonsignificant ($P > 0.05$) for range of motion.

Conclusions: Diclofenac phonophoresis with combined therapy, phonophoresis, and US were all effective in increasing pressure pain threshold values and range of motion. In addition, phonophoresis with combined therapy was shown to be superior over phonophoresis, and phonophoresis was superior over US in terms of reducing pain sensitivity. However, none of the treatment groups were found to be superior over the other in increasing range of motion.

Key Words: Myofascial Trigger Points, Combined Therapy, Phonophoresis, Ultrasound

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Myofascial pain syndrome (MPS) is a common regional painful condition that affects the musculoskeletal system.[1] It is characterized by chronically shortened muscle fibers that harbor hyperirritable nodules, myofascial trigger points (MTrPs), within taut bands of skeletal muscle.[2,3] It is the single most common source of musculoskeletal pain that is encountered in clinical practice, with a prevalence of 37% in men and 65% in women before the age of 30 to 60 yrs.[3,4] Common precipitating factors of MPS may include direct or indirect trauma, spinal pathology, cumulative and repetitive strain, postural impairment and imbalance, and physical deconditioning.[5]

Myofascial trigger points can be active, producing spontaneous pain, or latent, painful only on deep palpation.[2] The upper trapezius (UT) muscle seems to be commonly affected by MTrPs, providing its significant role in cervical mobility and stability.[6,7] Active MTrPs contained in the UT frequently induce tension headache, neck pain vertigo, muscle dysfunction, and limited neck and shoulder range of motion (ROM).[8] Inactivating active MTrPs and releasing taut bands are currently the most generally recognized strategies for MPS therapy.[2,9] Multifaceted approach, such as patients' education, ergonomic training, nonsteroidal anti-inflammatory drugs, and physical therapy, is often required in the treatment of myofascial pain.[9] Physical therapy modalities, including thermal, cryotherapy, electrotherapy (TENS), ultrasound (US), manual therapy, and stretching exercises, are considered the most commonly encountered treatment approaches that have been proven effective.[9–13]

Through its mechanical and/or thermal effects, US can provide deep tissue heating,[14] enhance vascular and cell membrane permeability,[4,15] improve angiogenesis,[16] and increase microcirculation[17] consequently promoting muscular relaxation, increasing connective tissue extensibility, and reducing myofascial pain.[18] Phonophoresis (PH), also referred to as sonophoresis or ultrasonophoresis, is a method of enhancing diffusion of topically applied medication through increasing skin absorption to

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The Board Council of Higher Education of the School of Physical Therapy, the Institutional Review Board of Higher Education and Research of Cairo University, and the Supreme Council of Universities at Egypt approved this study. The study is prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001677493). All participants gave written informed consent before data collection began.

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deeper tissues by means of the US.[14] Phonophoresis may be possibly advantageous if effective, considering that it encourages drugs to be delivered unaffected, in contrast to ingestion of drugs.[19] Phonophoresis is frequently used along with anti-inflammatory topical drugs for the management of pain and inflammation in musculoskeletal conditions.[20] However, numerous studies have reported conflicting results with regard to its efficacy.[19–23]

Recently, few studies have reported the efficacy of combined therapy (CT) in limited conditions. Combined therapy uses the combination of US and bipolar electrotherapeutical current concurrently at the same site and is used as a single modality.[24] Combined therapy enabled healing of chronic ulcerations.[25] In addition, CT with interferential therapy improved pain, ROM, and function in knee osteoarthritis.[26] It also facilitated sleep and decreased pain in fibromyalgia patients.[24,27] Combined therapy with conventional TENS was considered to be more beneficial in resolving active-MTrP pain and increasing ROM when compared with ischemic compression.[28]

The use of CT has generated much interest, and literature around this modality is stated with paucity. Nonetheless, numerous studies have demonstrated a diversity of results regarding PH with an anti-inflammatory drug in the management of MPS.[19–23] To our knowledge, no studies have been found in literature, on CT with PH. In this single-blinded, randomized controlled study, we aimed to compare the immediate effects of diclofenac PH-CT (US with conventional TENS), PH with diclofenac gel alone, conventional US, and sham US on pressure pain threshold (PPT) and cervical lateral-flexion ROM in patients with acute mechanical neck pain harboring active MTrPs.

METHODS

Trial Design and Sample

A single-blinded randomized controlled trial design was carried out at a private orthopedic outpatient clinic in Heliopolis, Cairo, Egypt, from January 2017 to February 2017. This study conforms to all CONSORT guidelines and reports the required information accordingly (see Checklist, Supplemental Digital Content, http://links.lww.com/PHM/A536). One hundred participants, 46 men and 54 women, with ages ranging from 25 to 45 yrs were selected from the outpatient clinic of the School of Physical Therapy at Cairo University. Participants were included if they had the following: (1) at least one UT active MTrP; (2) consistent neck pain within the preceding 3 mos; (3) acute mechanical neck dysfunction, particularly, muscular strain due to faulty posture, which was clinically diagnosed by an orthopedic physician; (4) received no physical therapy for the past 3 mos; and (5) inability to move through full ROM with pain at the end of the range. An x-ray and magnetic resonance imaging scan were performed, and participants were ruled out if they had the following conditions: (1) any spinal involvement, as herniated or prolapsed disc, and spondylolisthesis; (2) whiplash injury, previous cervical surgery, cervical radiculopathy, or myelopathy; and (3) undertaken physical therapy interventions for the cervical spine in the last 3 mos.

Then, participants were randomly assigned to one of the following four groups: the PH-CT group, the PH group, the conventional US group, or the sham-US control group. Each group had 25 participants. In addition, all groups received passive stretch for the UT muscle immediately after intervention. Pressure pain threshold and active cervical lateral-flexion ROM were assessed before and after intervention. All participants provided written informed consent to participate in our study (see Checklist, Supplemental Digital Content, http://links.lww.com/PHM/A536). A flowchart (Fig. 1) demonstrates the assignment of participants into groups. The Board Council of Higher Education of the School of Physical Therapy, the Institutional Review Board of Higher Education and Research of Cairo University, and the Supreme Council of Universities at Egypt approved our study. The study is prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12616001677493).

Myofascial Trigger Points Identification and Clinical Examination

A physical examination was performed to ascertain the presence or absence of active MTrPs within the UT. Active MTrPs were identified per allocations and standard clinical criteria defined by Simons et al.[2] This included a palpable taut band containing an exquisite tender nodule through which digital compression of the nodule produced a referred pain pattern. Moreover, snapping palpation across the taut band triggered a local twitch response.[2]

Flat and pincer palpation were used having the participant in prone position and the UT muscle placed in a considerable stretched-up position (lateral flexion and rotation to the opposite side) to lengthen and widen the area within which active MTrPs were found with ease. Figure 2 shows sites of MTrP1 that were located in the mid portion of the anterior border of the UT and comprises mostly vertical fibers that attach anteriorly to the clavicle. MTrP2 was found caudal and lateral to MTrP1 in the center of the more nearly horizontal fibers of the UT.[2] Palpation was executed three times on the identified sites, every time in the identical spot, assuring intrarater consistency in finding the same active MTrP. The examiner then marked the most tender, active MTrP and documented them.

Interventions

TENS and US were delivered via a calibrated Intelect Advanced Combo therapy system (2752CC; Chattanooga DJO France SAS Industries; Mexico) device. It features a CT built-in software system that is composed of a two-channel electrotherapy and US. The selected US parameters were applied for all four groups. It consisted of 1-MHz continuous mode with an intensity set at 1.5 W/cm^2 and with 100-Hz repetition rate.[17,18] A 5-cm^2 crystal head with an effective radiating area of 4.0(1.0) cm^2 was used. For the PH-CT group, conventional-TENS parameters were set at high modulated frequency pulses (120–200 pulses per second), phase duration of 200 microsecs, and an asymmetric biphasic waveform with a continuous pattern.[29]

With the participant in a prone position and the head slightly flexed and rotated to the opposite side, the skin was sterilized with 70% isopropyl alcohol. For the CT-PH group, the dispersive negative electrode of channel two was placed distal to the active MTrPs, on the deltoid muscle, whereas the US head acted as the positive electrode. Here,

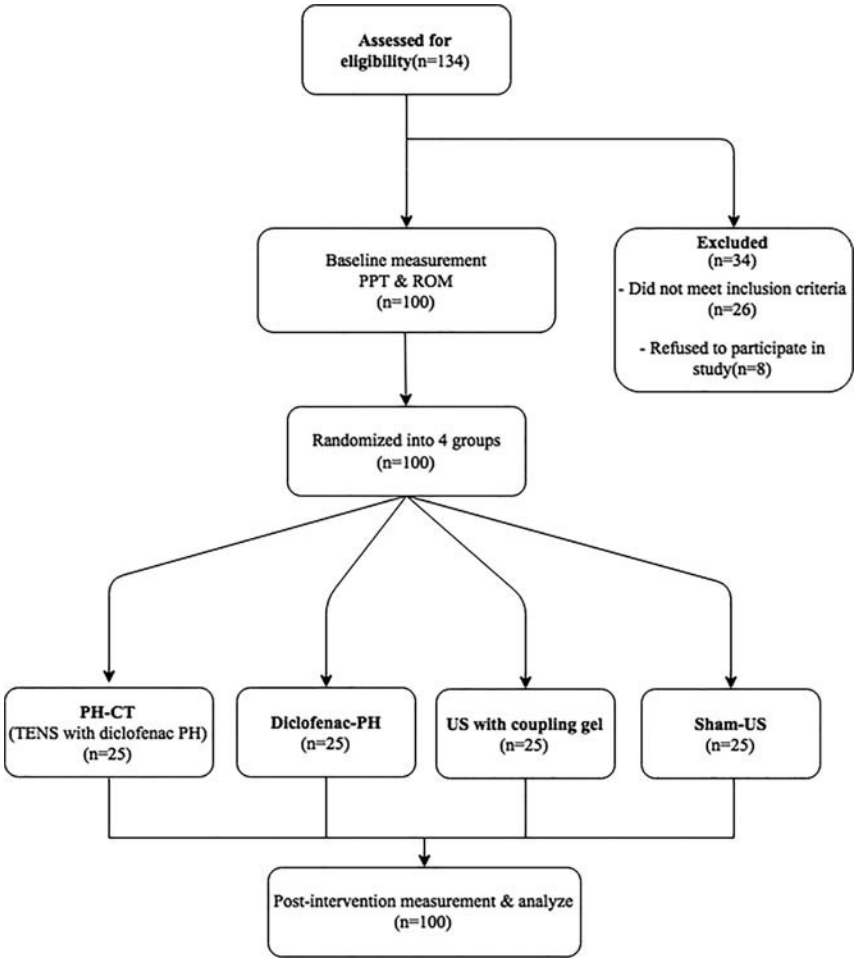

FIGURE 1. Methodology flowchart.

the US head completed the electric circuit with an electrical wire that was connected to the metal housing of the US head, making it a mobile electrode gliding over the surface of the skin. First, the US parameters were adjusted, followed by adjustment of the TENS parameters. Diclofenac sodium 10-mg gel (Olfen gel; Medical Union Pharmaceuticals, Ismailia, Egypt) was applied instead of coupling US gel used for transmission. The intensity was then raised until a tingling sensation under the US head was achieved, reaching the sensory paresthesia threshold. The intensity was adjusted and increased halfway through the treatment with a mean intensity of 12 mA, if accommodation occurred. Circular stroking with the US head was employed throughout the 10-min treatment period for a single active MTrP (Fig. 3). For the PH group, diclofenac sodium 10 mg gel was used for transmission, while coupling gel was applied for the US group. Same procedures were implemented for the sham-US control group; however, the US intensity was set at zero. Passive stretching of the UT muscle was carried out for 60 secs and repeated 3 times directly after the intervention for all four groups.[2]

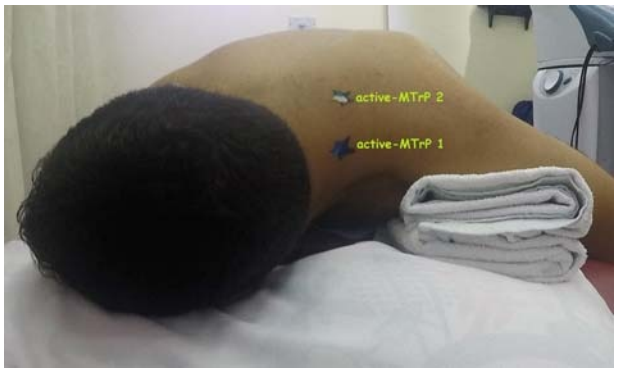

FIGURE 2. Location of UT myofascial trigger points.

Outcome Measure

Primary outcome measure included PPT values. With a handheld digital electronic algometer (Force One gauge-model FDI; Wagner Instruments, Greenwich, CT) placed perpendicular on marked sites, steady downward pressure was applied. Participants were instructed to say "STOP" when the sensation initially shifted from pressure to pain. The digital display denoted the PPT value in kilogram-force. Three successive measurements were taken 20 secs apart, and the mean was considered in the analysis.[30,31] Intraclass correlation coefficient was used to ensure intrarater reliability of the pressure algometer. On

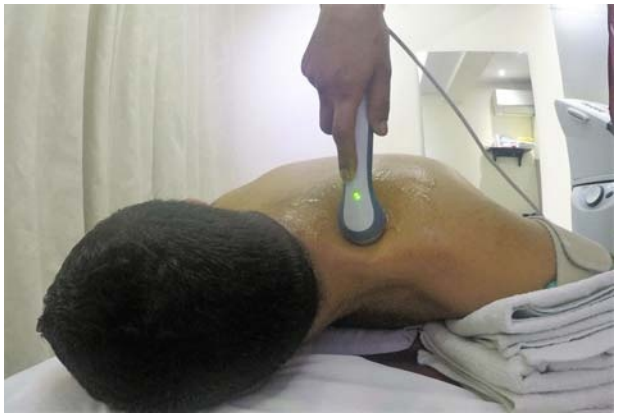

FIGURE 3. Phonophoresis combined therapy application.

three different occasions, the same examiner took three PPT measurements on 15 participants.

Secondary outcome measure included active cervical lateral flexion using an iPhone Clinometer (Peter Breitling, Version 3.3) application. Its validity and reliability were demonstrated in measuring cervical spine flexion, extension, and lateral flexion ROM, however, not rotation.[32–36] This application operates with an internal three axes linear accelerometer used to measure the direction of gravity's pull. With the iPhone placed on the contralateral side of the head and level aligned with the eyes, left and right lateral flexions were measured.[32] Three successive measurements were recorded and the mean was used in the analysis.

Sample Size

The sample size was calculated using PASS 14 (Version 14.0.8) power and sample size software. It was established based on an estimated 45% increase in PPT after US exposure from preceding studies,[9] presuming a mean of 6.9 and 4 with a standard deviation of 2.7, a two-tailed test, an α level of 0.05, and an estimated power (β) of 95%. Grounded on these calculations, an estimated sample size was 25 participants per group.

Randomization

Participants were randomly assigned to receive CT-PH, PH, US, or sham US instantly after baseline measurements. Using SPSS software (IBM), a computer-generated blocked randomized table was created before data collection. Block size was then determined and equal number for all groups within the block was calculated. Blocks where then randomly chosen to determine assignment of participants into the four groups. Individual and sequentially symboled index cards were secured in opaque envelopes. Each participant was given a handpicked envelope and was relocated accordingly to the treatment group. Participants were not aware of which group they were assigned to or which treatment was provided.

Blinding

A statistician blinded to the study approach generated the concealed block randomization and allocation sequence and relocated participants to the four groups. A certified manual physical therapist (blinded to treatment allocations) with more than 12 yrs of experience executed the physical assessment, marked and documented active MTrPs, and collected measurement outcome before and after treatment. Lastly, four certified physical therapists with experience ranging from 3 to 4 yrs managed each group individually. All therapists responsible for carrying out the intervention were blinded to the sequence allocation, physical assessment, and measurement outcome.

Data Analysis

Statistical analysis was computed using SPSS for windows Version 20 (SPSS, Inc, Chicago, IL). Descriptive statistics was used to describe the means and standard deviations of the participants' characteristics. Before data analysis, Shapiro-Wilk test was used to test data normality, and Levene's test was used to test the equality of variances. A 4 × 2-mixed model analysis of variance was used to compare within and between differences in the three treatment groups versus the control group. Moreover, Bonferroni correction test was used to compare between the groups. The P value was set at 0.05.

RESULTS

Table 1 lists the general physical characteristics of the 100 participants in our study. There was no significant difference in the mean values of age, sex, weight, height, and body mass index among the four groups as revealed by the one-way analysis of variance, with a $P > 0.05$. A total of 100 active-MTrP sites were evaluated using the electronic digital algometer and iPhone Clinometer application. The intraclass correlation coefficient for

TABLE 1. General characteristics of the participants

	PH-CT (n = 25)	PH (n = 25)	US (n = 25)	Sham US (n = 25)	F	P
Age, yr	35.04 (4.8)	36.92 (5.1)	35.40 (6.3)	35.64 (6.2)	0.52	0.67 (NS)
Sex					$\chi^2 = 0.805$	0.848 (NS)
Female	14 (56%)	12 (48%)	15 (60%)	13 (52%)		
Male	11 (44%)	13 (52%)	10 (40%)	12 (48%)		
Weight, kg	80.68 (19.34)	83.64 (20.27)	82.56 (19.05)	82.71 (19.16)	0.145	0.933 (NS)
Height, m	1.66 (0.09)	1.64 (0.1)	1.67 (0.14)	1.56 (0.15)	0.242	0.867 (NS)
BMI, kg/m^2	28.89 (4.06)	30.73 (5.3)	30.86 (7.5)	29.94 (4.9)	0.625	0.6 (NS)

Data are expressed as mean (SD) or number (%).

$P > 0.05$ is not significant.

NS, not significant.

TABLE 2. Pair wise comparisons within groups

	PPT			ROM		
	Before	After	*P*	Before	After	*P*
PH-CT	0.858	4.48	0.0001 (S)	35.68	40.16	0.0001 (S)
PH	0.909	3.15	0.0001 (S)	35.68	38.8	0.0001 (S)
US	0.904	1.39	0.0001 (S)	35.8	38.2	0.0001 (S)
Sham US	0.901	0.996	0.145 (NS)	35.8	36.04	0.327 (NS)

Data are expressed as mean.
Significant $P < 0.05$. Not significant $P > 0.05$.
NS, not significant; S, significant.

intrarater reliability of the pressure algometer on UT was 0.96, which indicates high reliability.

Table 2 represents the within group comparison, where multiple pairwise comparison tests revealed that there was a significant increase in postintervention PPT and ROM values for PT-CT, PH, and US when compared with their preintervention values ($P < 0.0001$). However, as for the sham US, there was no significant difference between the preintervention and postintervention PPT and ROM values ($P > 0.05$). Furthermore, the 4 × 2-mixed design model analysis of variance indicated that there were significant overall effects of PH-CT, PH, and US on PPT values as well as active cervical lateral flexion ROM, with *F* values of 641.825 and 77.62, respectively ($P < 0.0001$, Table 3).

Among group comparison, Bonferroni correction test revealed that there was a significant difference between all four groups in PPT values ($P < 0.0001$, Table 4). Mean differences between groups also showed that the PH-CT yield the highest scores in PPT values. However, as for the active cervical lateral flexion ROM, Bonferroni correction test revealed a significant difference only between the treatment groups versus the sham US ($P < 0.0001$), whereas among treatment groups comparisons were nonsignificant ($P > 0.05$, Table 4).

DISCUSSION

The purpose of the current study was to compare the effects of PH-CT, PH alone, and US on active MTrPs. When comparing within the four groups, all treatment groups yield greater improvements in PPT and ROM values ($P < 0.0001$) than the sham-US group, which received only passive stretch. The key concept in MPS treatment is to eliminate the triggering factor, the MTrP. Physical therapy management methods include ergonomic training, elimination of precipitating factors, superficial and deep heat applications, electrotherapy modalities, dry needling, local injections, passive and active stretch, progressive pressure release, and exercise.[37,38] Through its thermal and nonthermal effects, US is considered a deep heating agent and is known to encourage angiogenesis[16] and to promote muscle relaxation through the increase of cell membrane metabolism and permeability.[4,18] In addition, PH induces active transdermal migration of topical drug molecules via US.[14,39] Under the influence of thermal effects, permeability of the stratum corneum is intensified; hence, drug molecules diffuse from higher to lower concentration of the stratum corneum due to the increased pressure gradient under the transducer of the US head.[40]

TABLE 3. Mean % of change in groups, mean differences within groups, and overall size effect on PPT and lateral cervical flexion ROM

	Scores							Differences Within Groups Baseline (Postintervention)			Differences Between Groups		
	Baseline				Postintervention						Overall Effect[a]		
Outcome	PH-CT	PH	US	Sham US	PH-CT	PH	US	Sham US	PH-CT	PH	US	Sham US	F^b	P^c	Effect Size[d]
PPT	0.85 (0.1)	0.909 (0.1)	0.904 (0.25)	0.9 (0.24)	4.48 (0.39) 427%	3.15 (0.39) 250%	1.39 (0.39) 54%	0.99 (0.25) 10%	3.624 (3.7–3.4)	2.241 (2.36–2.11)	0.488 (0.61–0.36)	0.09 (0.22–0.03)	641.825	0.0001	0.95
Lateral flexion	35.68 (1.7)	35.68 (1.3)	35.8 (1.3)	35.84 (1.6)	40.16 (1.2) 12.64%	38.8 (0.6) 8.9%	38.2 (1.2) 6.7%	36.04 (1.4) 0.37%	4.48 (4.88–4.07)	3.12 (3.52–2.71)	2.4 (2.8–1.99)	0.2 (0.2–0.6)	77.62	0.0001	0.70

Data are expressed as mean(SD) or confidence interval.
[a]4 × 2 analysis of variance.
[b]Mixed-design analysis of variance *F* ratio, representing interaction effect of time by group on dependent variable.
[c]Significant $P < 0.05$.
[d]Partial η: small > 0.01, medium > 0.06, large > 0.14.

TABLE 4. Bonferroni tests and mean difference between the groups

	Mean Difference		Bonferroni Correction Test	
	PPT	Lateral Flexion	PPT	Lateral Flexion
PH-CT vs. PH	0.64 (0.45–0.82)	0.68 (0.3–1.66)	0.0001 (S)	0.3 (NS)
PH-CT vs. US	1.52 (1.33–1.71)	0.92 (0.6–1.9)	0.0001 (S)	0.07 (NS)
PH-CT vs. sham US	1.72 (1.51–1.91)	1.98 (1.004–2.95)	0.0001 (S)	0.0001 (S)
PH vs. US	0.88 (0.69–1.07)	0.24 (0.74–1.22)	0.0001 (S)	1 (NS)
PH vs. sham US	1.08 (0.89–1.27)	1.3 (0.324–2.27)	0.0001 (S)	0.003 (S)
US vs. sham US	0.2 (0.01–0.38)	1.06 (0.084–2.03)	0.03 (S)	0.026 (S)

Data are expressed as mean difference and confidence interval (90% CI).
Significant $P < 0.05$. Not significant $P > 0.05$.
NS, not significant; S, significant.

Moreover, application of two modalities (US and electrical current) simultaneously was suggested to be beneficial because of augmented effects of both modalities that can be attained at the same time. Ultrasound reduces resting potential of the nerve cell membrane resulting in increased permeability to sodium and calcium ions. This reduction takes the nerve membrane closer to the depolarization point; nonetheless, the nerve fails to fire. Simultaneous application of an electrical current to this partially depolarized nerve prompts further depolarization resulting in an action potential.[41] Hence, augmented effects of both therapies can be achieved at the same time.

In the current study, when comparing among all groups, our results revealed that PH-CT (using conventional TENS and diclofenac PH) showed greater reduction in pain sensitivity than diclofenac PH alone, US, and sham US. This can be explained by the triple effect that might have augmented during the application of diclofenac PT-CT concurrently. The purpose of conventional TENS is to activate large diameter Aβ fibers, thus reducing excitability of nociceptors and producing presynaptic or segmental inhibition.[42,43] Concurrently, adding diclofenac gel on active MTPs, which is known because of its nonsteroidal anti-inflammatory effects, and subsequently enhancing its effects by deeper diffusion via US[44] may induce and enhance reduction of inflammation and pain sensitivity, hence the triple effect.

To our knowledge, no pervious trials have explored the effects of CT in conjunction with diclofenac PH. However, CT with TENS was found effective in decreasing active-MTrP pain sensitivity and increasing ROM when compared with ischemic compression technique alone.[28] Moreover, CT with interferential therapy facilitated sleep and quality of life in fibromyalgia patients.[24,27] Furthermore, CT with interferential therapy was shown to be beneficial in osteoarthritis patients, where it improved pain, ROM, and function.[26] These results support our findings, where using diclofenac PH-CT over active MTrPs was shown to be superior to diclofenac PH, US, and sham US in reducing pain sensitivity.

Hasan and Fauzi (2014)[44] investigated the effects of PH and US on De Quervain's tenosynovitis in pregnant and postpartum women. They concluded that PH augments the benefits of US in terms of reducing pain and inflammation and improving functional strength.[44] In addition, Sarrafzadeh et al. (2012)[7] suggested that PH had superior therapeutic effects compared with US in decreasing MTrP pain. These results come in line with our study, where diclofenac PH was found to be superior over the US and sham-US groups in reducing pain. Fundamental to its effectiveness, the efficacy of PH is yet immensely debated. In the current study, the PH-CT, PH, and US groups versus the sham-US group showed a significant difference in increasing active cervical lateral flexion ROM. However, no significant difference was found among treatment groups, indicating that no treatment was superior over the other in terms of increasing ROM.

Lately, Ay et al. (2011)[45] compared the effects of diclofenac PH and US on active MTPs. They found a significant improvement in pain, ROM, and disability in MPS patients, but no significant differences were found between both modalities.[45] In addition, previous studies investigating the effects of PH and US on soft tissue injuries, including tenosynovitis, epicondylitis, tendinitis,[46] and knee osteoarthritis,[21] have also shown that PH was not superior to US. These results, to some extent, come in contrast to our findings, where diclofenac PH was found to have a significant effect on pain sensitivity when compared with US and sham-US effects. However, at the same time, there were no significant differences between PH-CT, PH, and US with regard to ROM. One explanation may be that thermal effects of US included in all treatment groups may have increased tissue temperature, collagen extensibility, blood flow, and enzymatic activity that may have contributed to the increase in ROM.[47,48]

Limitations

Limitations of the present study include the fact that only immediate effects were examined. Therefore, we were unable to examine if our findings were sustained, and thus, conclusions cannot be generalized. Further work needs to focus on short- and long-term effects of PH-CT, measure physiological responses to PH-CT, and identify the mechanisms involved. Future research is also required to investigate the effects of combining different electrical current frequencies and intensity parameters with PH-CT as well as using various anti-inflammatory drugs with PH-CT.

CONCLUSIONS

In conclusion, PH-CT, PH, and US therapies are effective in reducing active MTrP tenderness and increasing ROM. In addition, diclofenac PH-CT had immediate superior effects in

decreasing active MTrPs sensitivity followed by PH and lastly US. However, none of the methods have an immediate advantage when compared with others in terms of increasing ROM.

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