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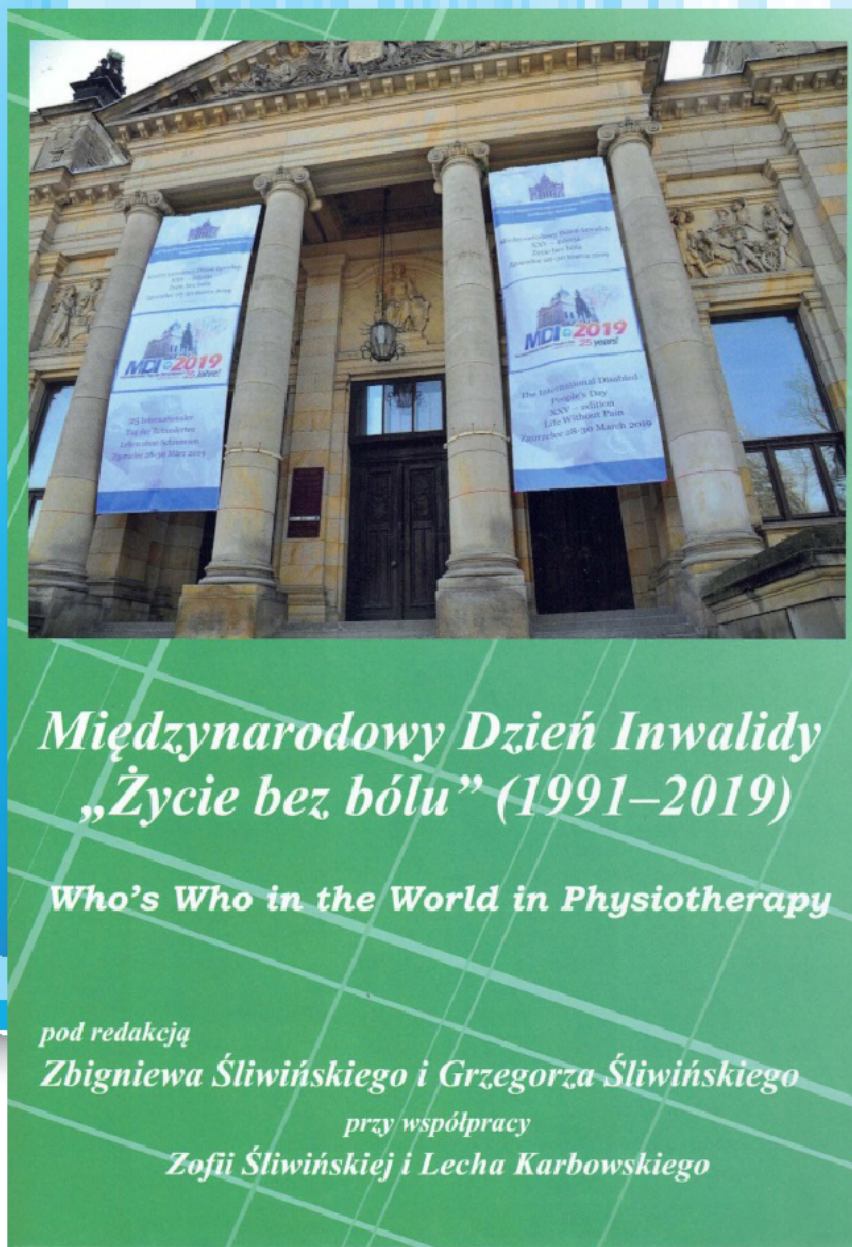
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Effect of cold and ultrasonic therapy on postural kyphosis in pre and post-menopausal women: A randomized controlled trial

Wpływ terapii zimnem i ultradźwiękami na kifozę posturalną u kobiet przed i po menopauzie: randomizowane badanie kontrolowane

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Abstract

Background. Thoracic kyphosis is one of the manifestations of post-menopausal spinal osteoporosis so it is preferable to prevent incidence of kyphosis related to estrogen deficiency especially for premenopausal whose kyphosis start to be developed. **Purpose.** The aim of this study was to detect the effect of cold and ultrasonic therapy on postural kyphosis with middle back pain in pre and post-menopausal women. **Materials and Methods.** Sixty non-osteoporotic pre and post-menopausal women between the ages of 40 and 60 years, assigned randomly into 3 groups equal in numbers; each group consisted of 10 pre and 10 post-menopausal women; Group (A) received physiotherapy program followed by cold therapy, Group (B) received ultrasonic therapy followed by physiotherapy program, and Group (C) received ultrasonic then the physiotherapy program followed by cold therapy. The three groups followed the same physiotherapy program in form of strengthening, stretching and postural reeducation, three sessions per week for three months. The kyphotic index and pain were assessed by flexicurve ruler and visual analogue scale (VAS) respectively pre- and post-interventions. **Results.** Within the three groups (A, B & C) the kyphotic index and pain showed significant decrease ($P < 0.0001$) post treatment in both pre- and post-menopausal conditions, while they showed clinical improvement and non-significant difference ($P > 0.05$) when compared pre to post-menopause conditions in the pre- and post-treatment. The clinical improvement in the kyphotic index in group (A), (B) & (C) at pre as well as post-menopausal conditions were equal [(↓8.44% & ↓7.1%), (↓7.7% & ↓8.12%) & (↓9.68% & ↓11.08%)] and VAS were [(↓32% & ↓35%), (↓40% & 30%) & (↓37.55%, ↓31.57%)] respectively post treatment. **Conclusion.** Adding cold and ultrasound therapy to physiotherapy program have a clinical impact in reducing kyphosis and pain in pre- and post-menopausal women.

Key words:

Cold, Ultrasonic, Menopause, Kyphosis, Flexicurve ruler

Streszczenie

Informacje wprowadzające. Kifoza piersiowa jest jednym z objawów pomenopauzalnej osteoporozy kręgosłupa, dlatego zaleca się zapobieganie występowaniu kifozy związanej z niedoborem estrogenów, zwłaszcza u kobiet przed menopauzą, u których kifoza zaczyna się rozwijać. Cel. Celem pracy było wykrycie wpływu terapii zimnem i ultradźwiękami na kifozę posturalną z bólem środkowej części pleców u kobiet przed i po menopauzie. Materiały i metody. Sześćdziesiąt kobiet, u których nie stwierdzono osteoporozy, przed i po menopauzie w wieku od 40 do 60 lat, przydzielonych losowo do 3 równych liczebnie grup; każda grupa składała się z 10 kobiet przed i 10 po menopauzie; Grupa (A) była poddawana programowi fizjoterapii, a następnie terapii zimnem, Grupa (B) była poddawana terapii ultradźwiękowej, a następnie programowi fizjoterapii, zaś Grupa (C) była poddawana działaniu ultradźwięków, a następnie programowi fizjoterapii i terapii zimnem. Trzy grupy realizowały ten sam program fizjoterapii w formie wzmacniania, rozciągania i reedukacji postawy, trzy sesje tygodniowo przez trzy miesiące. Wskaźnik kifotyczny i ból oceniano za pomocą linijki flexicurve i wizualnej skali analogowej (VAS) odpowiednio przed i po zastosowanej terapii. Wyniki. W trzech grupach (A, B i C) wskaźnik kifotyczny i ból wykazały znaczny spadek ($P < 0,0001$) po leczeniu zarówno w przypadku kobiet przed, jak i po menopauzie. Wykazano poprawę kliniczną i nieistotną różnicę ($P > 0,05$) porównując stan pacjentek przed i po menopauzie w okresie przed i po leczeniu. Kliniczna poprawa wskaźnika kifotycznego w grupie (A), (B) i (C) przed i po menopauzie była równa [(↓8,44% i ↓7,1%) (↓7,7% i ↓8,12%) i (↓9,68% i ↓11,08%)], natomiast wyniki VAS wynosiły odpowiednio [(↓32% i ↓35%) (↓40% i 30%) i (↓37,55%, ↓31,57%)] po leczeniu. Wniosek. Wprowadzenie terapii zimnem i ultradźwiękami do programu fizjoterapii ma kliniczny wpływ na zmniejszenie kifozy i bólu u kobiet przed i po menopauzie.

Słowa kluczowe

zimno, ultradźwięki, menopauza, kifoza, linijka flexicurve

Introduction

Hyperkyphosis is an excessive anterior concavity of the thoracic spine [1], appeared in female in the menopausal time [2] due to deficient of estrogen in menopausal and postmenopausal women, that is associated with osteoporosis in many cases [3].

After 40 years old, the kyphotic angle begins to increase usually more rapidly in women than men. However, a curve of more than 40° is considered excessive exaggerated thoracic kyphosis. 70% of those patients do not suffer from decreased bone mineral density [1-4]. These cases have progressive postural changes [5], height loss, upper and middle back pain, that can increase risk of osteoporotic fracture, respiratory complications [1] and deteriorated activities of daily living [4]. The hormonal changes of menopause lead to bone density decreasing, that there is impaired renewal process of external rough surface of each vertebral body, this weakens the outside of the vertebra leading to compression of the inner centrum soft part [6]. Also, spinal degenerative changes with subsequent weakness [2], habitual poor posture, and decreased extensor strength of spine in addition to dryness of the inter-vertebral disks, difficulty in rising from chair are possible risk factors in other menopausal-related hyper kyphosis [5-7], especially when associated with impaired muscle mass as in Sarcopenia which is characterized by atrophy of fast muscle fibers, type II fibers in women with age of 50 or above [3].

The flexicurve ruler tool has the accuracy, reliability, and practicality making it ideal for clinical assessment [1] as being small in size, suitable performance for periodic evaluation, easy usage and being inexpensive [8] as well as it prevents person exposure to radiation as in radiographs [2]. A kyphosis index value greater than 13 is defined as hyperkyphotic [9].

The aims of therapeutic exercises for kyphosis are to increase back extensor strength, spinal flexibility, change hyperkyphosis toward the normal, alleviate pain leading to improve the posture physically and functionally that resulted in reduced falls risk, fractures rates, and increased daily activities [6] and if the exercises combined with postural training, it helps to maintain a more upright posture [7]. So the proper exercise program should include breathing exercise [10], postural exercise, passive stretching of anterior thoracic muscles and hamstrings [1], classical segmented range of motion, massage, stretching for shortened anterior muscular chain, training of flexor muscles [1]; as spinal extension mobility leads to improve postural awareness which is necessary for kyphotic cases [7].

Ultrasonic with a 1MHz; has deep mechanical waves penetrate of about 3–5 cm below the skin, results in natural mechanical stimulation via piezoelectric phenomenon promoting local bone micro-deformations improving the bone strength [10]. Pulsed ultrasound with its non-thermal effect increases cellular activity which is due to combine of stable cavitation and acoustic streaming [11], in addition micro massage effect, facilitating tissue fluid interchange and tissue mobility [12]; other advantage; the production of prostaglandin E2, an important bone-healing mediator that inhibits mature osteoclasts from resorbing bone and stimulating osteoblasts for bone formation [10] resulted in decreasing pain, improve muscular and ligamentous elasticity with subsequent muscle strength, spasm and blood circulation [11].

Cold therapy promotes decrease in local metabolism to reduce symptoms, aids the healing process, promotes survival of tissue

subjected to an environment with low oxygen supply, decreases oxidative damages, a decrease in blood flow secondary to local vasoconstriction that reduces pro-inflammatory substances of blood circulation of the treated area, decrease of nerve conduction velocity and muscle spasm, which accelerate the healing process and pain threshold [13]. Gel packs can be used for more effective cooling [13]. So, the aim of this study was to detect the effect of cold and ultrasonic therapy on postural kyphosis with middle back pain in pre and post-menopausal women.

Materials and methods

Study Design

This study was designed as a prospective, randomized, single-blind, pre-post-test, controlled trial. Ethical approval was obtained from the institutional review board at Faculty of Physical Therapy, Cairo University before study commencement [No: P.T.REC/012/002463]. Informed consent was obtained from each participant after explaining the study's nature, purpose and benefits, informing them of their right to refuse or withdraw at any time, and about the confidentiality of any obtained information. Anonymity was assured through coding of all data. The study was conducted between August 2019 till October 2020.

Participants

Sixty pre and post-menopausal women between 40–60 years, body mass index (BMI) ranged from 29–40 kg/m² and they were suffering from postural kyphosis with subsequent thoracic back pain were selected from Out Patient Clinic at Faculty of Physical Therapy, Cairo University, to engage in this study. Women having cardiovascular, asthma, chest disease, brain tumor, vertebral as well as lower limbs deformities, osteoporosis and who received hormonal replacement therapy as well as pain killer drugs were excluded from the study.

The pre and post-menopausal women were randomly divided into three groups equal in numbers, each group consisted of 10 pre and 10 post-menopausal women: Group (A) received physiotherapy program followed by cold therapy, Group (B) received ultrasonic therapy followed by physiotherapy program, and Group (C) received ultrasonic then the physiotherapy program followed by cold therapy. The three groups followed the same physiotherapy program in form of strengthening training, stretching and postural reeducation; three sessions per week for 3 months.

Outcome measures

The following evaluation was done for the three groups before and after treatment.

- Thoracic kyphosis was measured by 50 cm flexicurve ruler. The woman was instructed to stand up straight, then the spinous process of C₇ and T₁₂ are marked on the woman's skin with a grease marker. The ruler was placed on the dorsal spine that its superior end at C₇ and the inferior end at T₁₂, hence the ruler was firmly pushed to be molded to the thoracic curve, carefully molded ruler was transferred to the paper, then its outline was traced on the paper, straight line was drawn from the ruler position at C₇ to ruler position at T₁₂, corresponding to the length of thoracic kyphosis (L), which was measured in centimeters, the width of the thoracic kyphosis (TW) in centimeters was determined by drawing a perpendicular, horizontal line

from the apex of the thoracic curve which is the highest point in the thoracic curve to the point at which it intersected the straight line drawn from C₇ to T₁₂ (TW). Thoracic width (TW) and thoracic length (TL) were measured, then kyphosis index was Calculated: $(TW/TL) \times 100$ [9].

- Pain was assessed using visual analogue scale (VAS) which is straight horizontal line of fixed length, 100 mm classified to equal centimeters from 0: 10, patients were asked to record pain scores via VAS to measure the intensity and the amount of pain that the woman felt, ranged from none to an extreme amount of pain [9].

- Body mass index (BMI) measurement, the weight and height of each woman in the three groups were measured, each woman stood on the scale wearing light clothes and bare feet, then, BMI for each woman was calculated according to the equation: $BMI = \text{Weight (kg)} / \text{Height squared (m}^2\text{)}$, obesity over 30 kg/m² [5].

- Waist/Hip ratio (WHR) measurement: from standing position with both feet together, waist circumference was measured around the midpoint between the iliac crests and lowest rib margins, while the hip circumference was measured at the level of greater trochanter. Then, WHR was calculated for each woman by dividing waist circumference by hip circumference; measurements > 0.85 for women used as a measure of central obesity [5].

Treatment program

Each woman in the three groups (A, B & C) engaged in a supervised therapeutic exercise from prone, supine and sitting position, 3times/week for 3 months. Each exercise was performed 3 sets of 8 repetitions with 10 second hold, and then relaxes for 10 second [1]. From prone: stretching of pectorals major, strengthening of back muscles, massage of back muscles in the form of steady movement, kneading and stroking, on the muscles for 60 second, myofascial release in the form of light, manual, sustained pressure to stretch and lengthen the fascia for 60 second. From supine: Breathing exercises was applied 3 times in the form of lateral costal breathing in addition

tion to postural education, strengthening of abdominals, stretching of hamstrings, and mobilization by lying supine on a foam roller for 60 second. From sitting: stretching of trapezius, passive stretching of anterior thoracic muscles, strengthening of arm muscles, and massage of back muscles.

Cryo gel pack was applied on the upper back (Thoracic) of each woman in group (A&C) from prone position after applying paraffin oil as lubricant, the total duration of cold application was 45 minutes divided into 3 time of application each time of 10 minutes followed by 5 minutes of rest [14]. With checking the skin after 30 seconds, for color changes or blistering. Participants were advised to apply cold application for 10 minutes if she feels any pain due to prolonged effort at any other time of the session.

Ultrasound therapy was applied for 10 minutes using pulsed mode to deliver low-intensity ultrasound, with parameters of 1 MHz frequency with transducer having radiating area of 5.0 cm², intensity up to 1.5 W/cm², gel was used as a coupling media. Ultrasound therapy was applied to the upper back on para spinal muscles at the thoracic region of each woman in group (B & C).

Statistical analysis

Results are expressed as mean $\pm$ standard deviation (SD). Comparison of different variables among and within three groups was performed using 3x2x2 mixed design MANOVA for normally distributed data. Statistical Package for Social Sciences (SPSS) computer program (version 23 windows) was used for data analysis. With the initial alpha level set at 0.05.

Results

The demographic characteristics of pre, post-menopausal women are shown in (Table 1), there were no significant effects of the tested group on all tested general characteristics ($P = 0.309$). In addition, there were significant effects of the condition on the tested general characteristics ($P = 0.0001^*$). Also, the interaction between the two independent variables was insignificant ($P = 0.7$), Table 1.

Table 1. Descriptive statistics and two-way MANOVA for general characteristics between Pre Menopause and post Menopause at among different groups

Variables	Group A		Group B		Group C	
	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause
Age [years]	43.7 $\pm$ 3.71	56.6 $\pm$ 3.62	46.1 $\pm$ 5.74	56.6 $\pm$ 3.33	43.9 $\pm$ 5.06	56.5 $\pm$ 2.12
BMI [kg/m ²]	32.79 $\pm$ 2.19	34.39 $\pm$ 2.98	31.84 $\pm$ 3.17	36.16 $\pm$ 2.48	32.79 $\pm$ 2.85	35.34 $\pm$ 2.53
Waist/hip ratio	0.81 $\pm$ 0.03	0.82 $\pm$ 0.04	0.8 $\pm$ 0.08	0.8 $\pm$ 0.07	0.77 $\pm$ 0.05	0.76 $\pm$ 0.07
Pre Menopause Vs. post Menopause	Group A		Group B		Group C	
	F-value	p-value	F-value	p-value	F-value	p-value
Age [years]	49.309	0.0001*	32.668	0.0001*	47.043	0.0001*
BMI [kg/m ²]	1.725	0.195	12.521	0.001*	4.365	0.041*
Waist/hip ratio	0.147	0.703	0.019	0.89	0.03	0.862

*Significant at alpha level < 0.05

There was significant reduction (p -value = 0.0001*) in the thoracic kyphotic index measured with flexicurve ruler and in pain intensity measured by VAS at post treatment in comparison to pre-treatment in both pre-menopause and post-meno-

pause conditions in the three groups and non-significant difference ($p > 0.05$) at post-menopause compared to pre-menopause conditions in the pre and post treatment tests among groups. (Table 2 & 3).

Table 2. Descriptive statistics and 3×2×2 mixed design MANOVA for Thoracic kyphotic index by Flexicurve ruler between pre Menopause and post Menopause at different measuring periods among three groups

Thoracic kyphotic index	Group A		Group B		Group C	
	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause
Pre treatment	14.57 ± 0.85	14.77 ± 1.26	14.93 ± 0.68	15.01 ± 1.21	15.28 ± 0.69	14.62 ± 0.94
Post treatment	13.34 ± 0.74	13.72 ± 1.37	13.78 ± 0.66	13.79 ± 1.26	13.8 ± 0.75	13 ± 0.72
MD	1.23	1.05	1.15	1.22	1.48	1.62
% of change	8.44%	7.1%	7.7%	8.12%	9.68%	11.08%
Multiple pairwise comparisons between pre and post treatment values for Thoracic kyphotic index by Flexicurve ruler at three groups						
Pre Menopause Vs. post Menopause	Group A		Group B		Group C	
	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause
p-value	0.0001*	0.0001*	0.0001*	0.0001*	0.0001*	0.0001*
Multiple pairwise comparisons between pre menopause and post menopause values for Thoracic kyphotic index by Flexicurve ruler at different measuring periods at three groups						
Pre Menopause Vs. post Menopause	Group A		Group B		Group C	
	Pre treatment	Post treatment	Pre treatment	Post treatment	Pre treatment	Post treatment
p-value	0.661	0.395	0.851	0.994	0.131	0.069
Multiple pairwise comparison tests (Post hoc tests) for Thoracic kyphotic index by Flexicurve ruler among three groups at different measuring periods with different conditions (Pre Menopause and post Menopause)						
p-value	Pre Menopause			Post Menopause		
	Group (A) Vs. group (B)	Group (A) Vs. group (C)	Group(B) Vs. group (C)	Group (A) Vs. group (B)	Group (A) Vs. group (C)	Group(B) Vs. group (C)
Pre treatment	0.99	0.345	0.99	0.99	0.99	0.99
Post treatment	0.966	0.913	0.99	0.99	0.301	0.221

Table 3. Descriptive statistics and 3×2×2 mixed design MANOVA for pain intensity by VAS between pre Menopause and post Menopause at different measuring periods among three groups

VAS (Scores)	Group A		Group B		Group C	
	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause
Pre treatment	8 ± 1.65	8 ± 1.24	8.1 ± 0.87	8.3 ± 1.15	8.6 ± 1.07	7.6 ± 0.96
Post treatment	5.44 ± 1.74	5.2 ± 1.31	4.8 ± 1.13	5.8 ± 1.54	5.37 ± 1.47	5.2 ± 1.27
MD	2.56	2.8	3.3	2.5	3.23	2.4
% of change	32%	35%	40%	30%	37.55%	31.57%
Multiple pairwise comparisons between pre and post treatment values for VAS at three groups						
Pre Menopause Vs. post Menopause	Group A		Group B		Group C	
	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause	Pre Menopause	Post Menopause
p-value	0.0001*	0.0001*	0.0001*	0.0001*	0.0001*	0.0001*

Multiple pairwise comparisons between Pre Menopause and post Menopause values for VAS at different measuring periods at three groups						
Pre Menopause Vs. post Menopause	Group A		Group B		Group C	
	Pre treatment	Post treatment	Pre treatment	Post treatment	Pre treatment	Post treatment
p-value	0.99	0.692	0.706	0.1	0.064	0.051

Multiple pairwise comparison tests (Post hoc tests) for VAS among three groups at different measuring periods with different conditions (Pre Menopause and post Menopause)						
p-value	Pre Menopause			Post Menopause		
	Group (A) Vs. group (B)	Group (A) Vs. group (C)	Group(B) Vs. group (C)	Group (A) Vs. group (B)	Group (A) Vs. group (C)	Group(B) Vs. group (C)
Pre treatment	0.99	0.82	0.99	0.99	0.99	0.571
Post treatment	0.894	0.99	0.212	0.957	0.957	0.148

*Significant at alpha level < 0.05; p-value: Probability value

Discussion

The use of ultrasound as well as cold therapy are effective modalities for the treatment of musculoskeletal disorders [14 & 15] but not be used before specifically for pre and post-menopausal cases with kyphosis; so it is too limited to be reviewed. Therefore, this study was the first to investigate the effect of cold, ultrasonic therapy and both on pre and postmenopausal women having postural kyphosis and thoracic back pain.

Within the three groups (A, B & C) the kyphotic index and thoracic back pain showed significant decrease ($P < 0.0001$) post treatment in both pre- and post-menopausal conditions, while they showed clinical improvement and non-significant difference ($P > 0.05$) when compared pre to post-menopause conditions in the pre- and post-treatment. Post treatment, the kyphotic index became below 13 in 6 cases representing 30% of cases in group (A) and (C) and 3 cases representing 15% in group (B) and thoracic pain became less than 5 measured by VAS in 5 cases representing 25% in group (B) and 6 cases representing 30% in group (C).

The significant decrease in kyphotic index and thoracic pain within group (B & C) post treatment may be related to the effect of ultrasonic on improving ligament extensibility and bone remodeling due to its mechanical effect and piezoelectric phenomenon as mentioned by Sheng et al., [16] who investigated the beneficial effect of ultrasound on bone healing condition [16], and on pain and muscle spasm by deactivating trigger points, so reducing muscle tension, restoring muscle length and relaxation in tight bands [15].

Another explanation; for reducing the pain after ultrasound application in cases of myofascial pain syndrome is the calming of the trigger point by short-term antinociceptive evoking effects on trigger points that resulting in loosening the tightness of the muscle which leads to restore normal muscle length, function, strength and improvements in range of motion [15]. Furthermore, the increased blood flow after ultrasound aiding the removal of pain-causing mediators and inflammation from the painful area in both periarticular calcific tendinitis [17]. Also, Rutten et al. [19] reported the effect of ultrasound in collagen production in vitro study [18]. As, ultrasound stimulated the molecular processes of fibroblasts responsible for collagen

synthesis that it caused an increase in intracellular calcium in fibroblasts, suggesting that the mechanical effects disrupt the membrane, permitting diffusion of calcium into the cell [19].

The significant decrease in kyphotic index and thoracic pain within group (A&C) post treatment may be related to the effect of ice application by increasing capillary density in muscle tissue, the vaso constriction of blood vessels, which restricts the blood flow in the skin so decreases tissue temperatures, the sensory nerves in the skin are provoked to fire continuously until physiologically exhausted and energy consumption improvement in the cell [20–21].

Also, the significant effect of using cryogel application in group (A & C) could be confirmed by many studies as using cryogel pack has effective results in different diseases via its effect at reducing skin surface temperature and at maintaining these lower due to accumulative effect of its application, so it affects nerve conduction velocity [13–22].

The significant improvement in the three groups (A, B & C) post treatment come in agreement with the study of Katzman et al., [1], Spencer et al. [6] and Bansal et al. [7]. As in postmenopausal women with symptomatic upper back pain who performing exercise training became better by increasing upper back extensor muscle endurance which was assessed using the isometric chest raise test and thoracic kyphosis which was assessed by using the vertebral centroid angle on a lateral radiograph [6]. Also, trunk extension exercises including stretching of shoulder flexors, and spinal extensor strengthening in the form of quadreped alternate arm/leg lift, and prone trunk extension in 60 postmenopausal women, reduced the hyperkyphosis angle (5% improvement in kyphosis index and 4.4% improvement in kyphosis angle measured by the flexicurve) due to dilatation of the blood vessels and improving heart pump for more blood giving way which results in gaining of muscular strength and kyphotic spine posture [1].

In addition, back muscle exercise for strengthening of extensors for one hour, twice a week for 4 months, showed a significant improvement in the back muscle extensor strength without a corresponding improvement in posture [23], whereas another study reported that posture improved after back muscle extensor strength exercise only among participants with weak back musc-

les and kyphosis of at least $\geq 34^\circ$ through increasing spinal extension mobility and postural awareness [24–25]. Also, 8 weeks of an exercise program is very effective in reducing pain and postural thoracic kyphosis in endometriosis women [26]. Other explanation for the effect of exercise on the muscular structure, could be attributed to the improvement of muscle protein synthesis and muscle quality. It also reduced intramuscular fat, as it improves muscle mass and strength and attenuates the development of sarcopenia which is the most common muscular complication in menopausal women [3]. So, this study adding a new knowledge about the effect of cold and ultrasound on treating pre and post-menopausal women having thoracic kyphosis, which needed to start early the proper management to reduce their pain which hinder the already weakened, spasmed dehydrated muscles to avoid muscular fatigue which hinder the good effect of exercise training.

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The limitation of the present study is its short duration. Thus, longitudinal studies are necessary to explore the prolonged effect of cold and ultrasound therapy on kyphotic angle and a greater number of patients are necessary to explore their extended effects in pre and post-menopausal women.

Conclusion

Cold and ultrasound therapy and both of them combined with exercise have a clinical improvement on thoracic kyphosis and pain in pre and post-menopausal women.

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