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MANUEL LENF DRENAJI SAĞLIKLI KADINLARDA OTONOMİK FONKSİYONLARI ETKİLER Mİ?: BİR RANDOMİZE KONTROLLÜ ÇALIŞMA

ARAŞTIRMA MAKALESİ

ÖZ

Amaç: Bu çalışma, sağlıklı kadınlarda manuel lenf drenajının (MLD) otonomik fonksiyonlar üzerindeki etkilerini incelemeyi amaçlamaktadır.

Yöntem: 40 sağlıklı kadın çalışmaya dahil edildi. Tek kör randomize kontrollü çalışmada katılımcılar MLD, sham MLD ve kontrol grubu olarak 3 gruba ayrıldı. Katılımcıların demografik bilgileri, kan basıncı ve kalp hızı değişkenliği (KHD) değerlendirildikten sonra soğuk basınç testi uygulandı. Testin hemen ardından kan basıncı ve KHD yeniden değerlendirildi. MLD grubuna MLD uygulamaları yapıldı. Sham MLD grubuna sham protokolü uygulandı. Kontrol grubundan 10 dakika sırt üstü yatmaları istendi. Uygulama sonrası katılımcılar tekrar değerlendirildi.

Sonuçlar: Sistolik kan basıncı soğuk basınç testi ile her 3 grupta da düşerken, sham MLD grubunda uygulama sonrası düşmeye devam etti (p<0,05). Soğuk basınç testi sonrası MLD, sham MLD ve kontrol gruplarında kalp atım hızında anlamlı azalma olurken, uygulama sonrası sadece MLD grubunda anlamlı düşüş devam etti (p<0,05). KHD'nin RMSSD parametresi uygulama sonrası sadece MLD grubunda anlamlı olarak arttı (p<0,05). RR aralığı değeri hem soğuk basınç testi hem de uygulama sonrası MLD ve kontrol gruplarında arttı (p<0,05).

Tartışma: MLD, KHD parametrelerindeki değişiklik nedeniyle parasempatik sinir sisteminin aktivasyonunda kullanılabilir. Parasempatik sinir sistemi aktivasyonu özellikle otonomik etkilenim olan bazı hastalıkların tedavisinde önemli bir tedavi yaklaşımı olabilir.

Anahtar Kelimeler: Kalp hızı değişkenliği, Manuel lenf drenajı, Otonomik fonksiyon, Soğuk basınç testi

DOES MANUAL LYMPH DRAINAGE AFFECT AUTONOMIC FUNCTIONS IN HEALTHY WOMEN?: A RANDOMIZED CONTROLLED STUDY

ORIGINAL ARTICLE

ABSTRACT

Purpose: This study aimed to examine the effects of manual lymph drainage (MLD) on autonomic functions in healthy women.

Methods: 40 women were included in the study. In the single-blind randomized controlled study, the participants were divided into 3 groups MLD, sham MLD, and control group. After evaluating the demographic information, blood pressure (BP), and heart rate variability (HRV) of the participants, the cold pressure test was applied. Immediately after the test, BP and HRV were re-evaluated. The MLD group received MLD applications. A sham protocol was applied to the sham MLD group. The control group was asked to lie on their back for 10 minutes. After the application, participants were re-evaluated.

Results: While systolic BP decreased in all 3 groups with the cold pressure test, it continued to decrease after the application in the sham MLD group (p<0.05). While there was a significant decrease in heart rate in the MLD, sham MLD, and control groups after the cold pressure test, a significant decrease continued only in the MLD group after the application (p<0.05). The RMSSD parameter of HRV increased significantly only in the MLD group after the application (p<0.05). The RR interval value increased both after the cold pressure test and after the application in MLD and control groups (p<0.05).

Conclusion: MLD can be used in the activation of parasympathetic nervous system (PNS) due to the change in HRV parameters. PNS activation can be an important therapeutic approach in the treatment of some diseases, especially those with autonomic involvement.

Keywords: Autonomic function, Cold pressure test, Heart rate variability, Manual lymph drainage

INTRODUCTION

The autonomic nervous system (ANS) is a complex system that includes many areas of both the central and peripheral nervous system and is associated with many organs (1). It is responsible for regulating visceral functions and maintaining homeostasis in the body. Two important parts of the peripheral autonomic nervous system; while the sympathetic nervous system sends 'fight or flight' signals to the body, the parasympathetic nervous system sends the 'rest or digest' signal (2). ANS is evaluated clinically through maneuvers that trigger the autonomic nervous system such as blood pressure, heart rate variability (HRV), valsalva maneuver, or sudomotor autonomic tests (3). HRV is a physiological signal consisting of oscillations in successive intervals of heartbeats controlled by the autonomic nervous system. It is an effective method in the non-invasive evaluation of both the sympathetic and parasympathetic nervous systems (4). Electrocardiography (ECG), a noninvasive method, is used to evaluate cardiovascular autonomic functions. ECG recordings are made in two different ways. The first is the short-term measurements before/after that are made under control in a laboratory environment. Short-term measurements over 5 minutes are standard. The other is the holter measurement made for 24 hours (5). Short-term measurements reflect the relationship between the sympathetic and parasympathetic nervous systems. Long-term measurements reflect change in heart rate with involvement of circadian rhythm, core body temperature, sleep, metabolism, and renin-angiotensin systems (6).

Manual lymph drainage (MLD) is a manual therapy method consisting of low-pressure, slow, repetitive movements that allow the skin to return to its starting position to accelerate and direct lymphatic flow (7). MLD, which is used as a component of complex decongestive therapy in the treatment of lymphedema; can be used in the treatment of many diseases and symptoms such as traumatic injuries, muscle fiber tears, complex regional pain syndrome, scar treatment, rheumatological diseases, headache, migraine, fibromyalgia (8). The mechanism underlying the use of MLD in diseases other than lymphedema treatment; is explained as the effects on the autonomic nervous system, cardiovascular system, and pain (9).

Experimental stress was taken from the field of engineering by Hans Selye in 1936 and defined as a phenomenon that produces a series of interrelated symptoms with various stimuli in biological systems. Stress sources can be physical, psychological, or mixed. The stress-related changes occur at the psychological (emotional and cognitive), behavioral (fight or flight), and physiological (altered autonomic and neuroendocrine function) levels (10). The cold pressure test is frequently used in the evaluation of the autonomic nervous system by creating experimental acute stress. There are different studies in the literature that the cold pressure test, which is a simple, reliable, reproducible, and well-designed test, activates the autonomic nervous system sympathetically or parasympathetically (11).

The results regarding the effects of MLD on ANS are controversial and limited in the literature (9,12–15). The methodological deficiencies and differences in the current studies, the lack of consensus in the results, and the absence of the sham MLD protocol necessitate the need for new studies.

The study aimed to evaluate the effect of experimental stress on the autonomic functions with the cold pressure test applied for 2 minutes and to determine the effects of MLD applied afterward.

METHODS

Study Design

The study was approved by the Ethics Committee of Kutahya Health Sciences University (Protocol No. 2021/03-06) and was conducted at Kutahya Health Sciences University, Department of Physiotherapy and Rehabilitation from June 7, 2021, to July 2, 2022. The manuscript was reported according to CONSORT guideline. 46 participants were included in the study. But 6 participants were excluded from the study because of unwillingness to continue the study and unable to complete the cold pressure test (Figure 1.) . The inclusion criteria for the study were being over 18 years of age and being voluntary to participate in the study. The exclusion criteria were having advanced cardiorespiratory diseases, orthopedic and neurological problems, using medication related to pain and cardiovascular system, having skin disorders that prevent skin contact, and having cold urticaria. All study procedures were conducted according to the principles of Good Clinical Practice and the Helsinki Declaration. Written informed consent was obtained from all individual participants.

Randomization

This study was planned as a single-blind randomized controlled trial. Randomization was performed using the online computer program (http://www.randomizer.org). The randomization method based on a single sequence of random assignments is known as simple randomization. The participants included in the study were randomly divided into 3 groups; manual lymph drainage, sham manual lymph drainage, and a control group in the computer program. Participants were assigned to groups in a 1:1 ratio. Assignment and randomization were made by the researcher (M.I.A.). The participants were blinded. The content and name of the treatment approach applied to the participants have not been detailed; however, it has been stated that sham MLD and MLD groups will receive a manual treatment approach. Each participant has been individually treated without observing the treatment approach applied to other participants.

Study Protocol

Participants rested for 5 minutes before the first evaluation. The first evaluation was made after the demographic information of the participant was obtained. Within the scope of this evaluation, blood pressure, heart rate, and heart rate variability were evaluated. All assessments were performed on the patient's dominant upper extremity. After the evaluation, cold pressure test was applied to the dominant extremity. A second assessment was made immediately after the test. All of the parameters examined within the scope of the first evaluation were examined for the second time. Appropriate treatment was applied to the group to which the participant belonged. After the treatment, the third evaluation was made and the study was terminat-

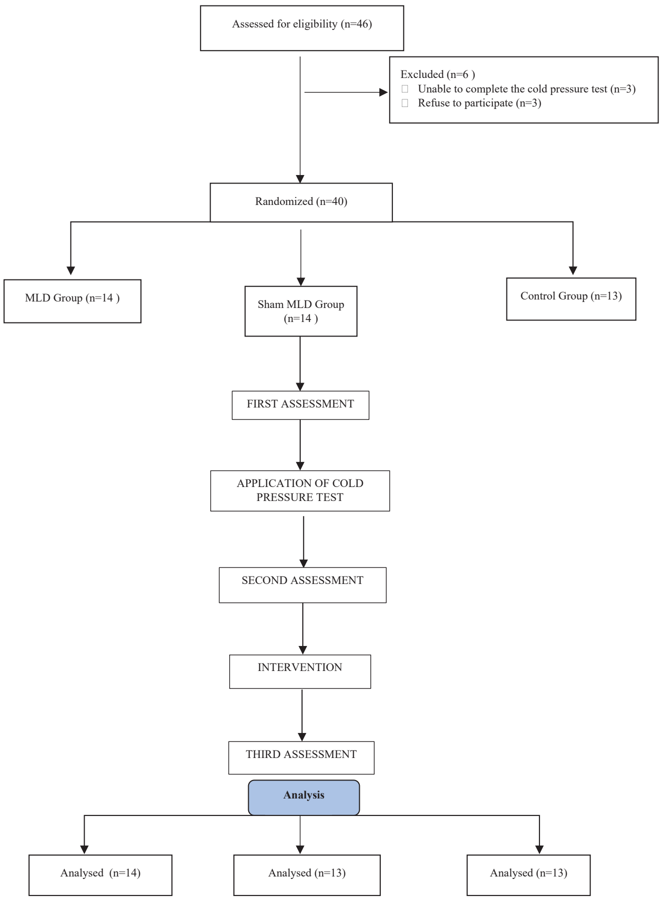

Figure 1. Flow Chart

ed. All participants were asked to avoid exercise, caffeine, energy drinks, and heavy meals at least 1 hour before the test. Environmental noise, light, and temperature were controlled during the test.

Outcome Measures

Demographic information

First, a form prepared by the research physiotherapist was filled out to define the participant's height, body weight, body mass index, age, occupation, smoking, and alcohol use.

Evaluation of Blood Pressure

Blood pressure was evaluated with the Omron® M2 Basic (Omron Healthcare, Kyoto, Japan) brand measuring device (16). A single measurement was made on the dominant arm while the participants were in the sitting position. Systolic blood pressure (SBP) (mmHg) and diastolic blood pressure (DBP) (mmHg) were evaluated.

Evaluation of Heart Rate and Heart Rate Variability

Polar H10 (Polar Electro Oy, Kempele, Finland) heart rate sensor was used to evaluate heart rate and heart rate variability (17). Polar H10 is a heart rate sensor that is placed under the chest with an elastic electrode strap. RR intervals were recorded for 5 minutes with the smartphone app (Elite HRV) (18). The measurement was made with the participant in a sitting position, without any clothing in the area where the device was placed. Heart rate variability was investigated in both time and frequency domains that are heart rate (beats/minute), the standard deviation of NN intervals (SDNN) (ms), the root mean square of successive differences between normal heartbeats (RMSSD) (ms), the proportion of NN50 divided by the total number of NN (PNN50) (%), mean RR interval, total power, LF/HF ratio (Hz), low frequency (LF) (Hz), high frequency (HF) (Hz).

Cold Pressure Test

The test is used to induce experimental stress, induce systemic stress, and evaluate the autonomic nervous system (20–22). In the test protocol; The participant was asked to immerse his dominant hand in water at 4 °C and hold it for 2 minutes. The temperature of the water was monitored with the help of an in-water thermometer. By adding ice cubes, the water temperature was kept constant at 4 °C for 2 minutes. After 2 minutes, he took his hands out of the water and the test was terminated (23,24).

Manual Lymph Drainage

MLD was administered by a certified and experienced physiotherapist (H.K.) trained in the Vodder technique. MLD; neck drainage, abdominal drainage, stimulation of axillary lymph nodes, and right arm drainage were performed by following a special technique and sequence (7). MLD was applied in a comfortable position while the patient was lying in the supine position. It took an average of 20 minutes.

Sham manual lymph drainage

Sham MLD was planned by the same physical therapist as the opposite of MLD techniques. For the Sham MLD protocol, opinions were obtained from 3 physiotherapists who are experts and experienced in the field of complex unloading physiotherapy and 3 physiotherapists working in different fields. Deep pressure was applied from distal to proximal with rapid movements to the right extremity to which the cold pressure test was applied. Fingers, dorsal and palmar surfaces of the hand, forearm, elbow, and upper arm were applied in order. The application was performed while the patient was lying in the supine position and lasted an average of 20 minutes.

Participants in the control group were asked to lie on their backs for 10 minutes without speaking in a quiet, calm environment. At the end of 10 minutes, the patient was placed in a sitting position again and the third evaluation was performed.

Statistical Analysis

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS for Windows Version 25.0, USA). Continuous variables were expressed in mean±standard deviation (SD), while categorical variables were stated as numbers and percentages. All variables were assessed for normal distribution using the Kolmogorov–Smirnov. Repeated measures ANOVA was used to evaluate the differences in the mean values of the normally distributed quantitative data. In the absence of

Table 1. The Demographic Comparison in the Groups

		n	Mean±SD	Med	Min	Max	F/KW	p
Age (years)	**MLD**	14	24.14±5.32	22.00	19.00	38.00	KW=1.205	0.547
	Sham MLD	13	25.23±4.71	23.00	20.00	37.00		
	Control	13	24.85±6.11	22.00	19.00	41.00		
Menstrual Cycle Day	**MLD**	14	18.07±7.24	163.50	158.00	170.00	F=1.046	0.361
	Sham MLD	13	13.85±8.48	163.00	150.00	173.00		
	Control	13	15.00±7.91	164.00	154.00	173.00		
Height (cm)	**MLD**	14	163.00±3.90	57.00	49.00	77.00	F=0.033	0.967
	Sham MLD	13	163.54±6.36	62.50	49.00	92.00		
	Control	13	163.23±5.82	65.00	47.00	82.00		
Weight (kg)	**MLD**	14	58.15±7.37	22.30	17.60	30.80	F=1.625	0.212
	Sham MLD	13	64.54±14.04	22.45	18.20	34.70		
	Control	13	65.5±11.59	25.50	16.70	32.50		
Body Mass Index (kg/m2)	**MLD**	14	22.03±3.41	23.20	15.00	36.10	F=1.294	0.287
	Sham MLD	13	24.03±5.00	27.65	15.60	40.90		
	Control	13	24.68±4.6	30.60	11.10	41.50		

n: number of participants; SD: standard deviation; kg: kilogram; cm: centimeter; kg/m^2: kilogram/ square meters; F: one-way analysis of variance; KW: Kruskal Wallis H test; MLD: manual lymph drainage; p: significance level; min: minimum; mak: maximum, med: median

normal distribution, it was analyzed performing the Friedman test. In the normal distribution of data, one-way ANOVA was used for within-group comparations. Kruskal Wallis H test was performed in data without normal distribution. If there were any significant differences in the test of within-group or time effects, post hoc comparisons was performed to determine pairwise differences. p<0.05 was accepted statistical signifance for all measurements.

Sample Size

The power of the study was calculated with the analysis program G*Power (G*Power, version 3.1.9.4 for Windows XP, Germany). According to the power analysis of the Heart Rate score of the 40 participants included in the study, the 95% confi-

Table 2. The Changes in the Blood Pressure Values of the Participants Over Time

		n	Before Cold Pressure Test[a]	After Cold Pressure Test[b]	After Treatment Protocol[c]	F^1	p	Post-hoc
			Mean±SD	Mean±SD	Mean±SD			
Systolic Blood Pressure (mmHg)	**MLD**	14	114.79±10.03	108.5±7.53	110.64±10.72	4.724	0.018*	a>b
	Sham MLD	13	110.69±7.27	106.15±12.11	100.38±9.03	7.597	0.003*	a>c
	Control	13	116.85±15.65	106.38±12.98	108.62±14.75	7.872	0.002*	a>b
			F=0.969 p=0.389	F=0.187 p=0.830	F=2.852 p=0.070			
Diastolic Blood Pressure (mmHg)	**MLD**	14	73.86±8.17	71.86±9.68	73.21±6.04	0.342	0.714	-
	Sham MLD	13	70.38±11.91	73.31±15.13	70.38±7.19	1.167	0.558	-
	Control	13	70.62±8.67	70.46±8.33	70.46±7.13	0.007	0.993	-
			F=0.549 p=0.582	KW=0.200 p=0.905	F=0.770 p=0.470			

n: number of participants; SD: standard deviation; MLD: manual lymph drainage; F: one-way analysis of variance; F^1: one way anova for repeated measures; p: significance level; *: p<0,05; min: minimum; mak: maximum, med: median, a: before cold pressure test, b: after cold pressure test, c: after treatment protocol dence level and the power of the study with 1,706 effect sizes were found to be 99.38% (25).

RESULTS

46 participants were included in the study. But 6 participants were excluded from the study because of unwillingness to continue the study and unable to complete the cold pressure test (Figure 1.). The study was completed with 40 women aged 19-41 years. The age, height, body weight, body mass index, and menstrual cycle day of the women participating in the study are given in Table 1, and there was no statistically significant difference between the groups in terms of these data (p<0.05).

In the MLD and control groups, while systolic blood pressure decreased significantly after the cold pressure test (p<0.05), no significant difference was observed after the application (p>0.05). SBP was significantly reduced after sham MLD application (p<0.05). There was no significant change in DBP either after the cold pressure test or after the applications (p>0.05) (Table 2.).

Table 3. The Changes in the HRV Time Domains

			Before Cold Pressure Test[a]	After Cold Pressure Test[b]	After Treatment Protocol[c]	F[1]	p	Post-hoc
		n	**Mean±SD**	**Mean±SD**	**Mean±SD**			
Heart Rate	**MLD**	14	86.43±9.09	84±8.94	82.64±8.61	7.740[1]	**0.002***	**a>b,c**
	Sham MLD	13	83.69±7.34	81.54±7.04	81.00±7.06	7.732[1]	**0.003***	**a>c**
	Control	13	87.85±11.01	84.77±6.69	82.69±6.88	8.167[2]	**0.017***	**a>c**
			F=0.676 p=0.515	KW=1.601 p=0.449	F=0.212 p=0.810			
SDNN (ms)	**MLD**	14	75.9±24.07	74.9±25.79	82.39±24.72	3.431[1]	0.067	----
	Sham MLD	13	93.81±21.33	91.63±24.94	91.2±19.77	0.547[1]	0.586	----
	Control	13	76.49±20.27	81.38±16	78.79±17	3.846[2]	0.146	----
			KW=5.158 p=0.076	F=1.841 p=0.173	F=1.221 p=0.307			
RMSSD (ms)	**MLD**	14	3.76±0.39	3.75±0.47	3.87±0.39	3.441[1]	**0.047***	**c>b**
	Sham MLD	13	4.07±0.28	4.06±0.34	4.07±0.29	0.086[1]	0.918	----
	Control	13	3.76±0.45	3.87±0.34	3.83±0.33	3.231[2]	0.199	----
			F=2.953 p=0.065	F=2.060 p=0.142	KW=3.788 p=0.150			
PNN50 (%)	**MLD**	14	21.79±12.95	24.07±15.50	26.57±15.44	3.084	0.063	----
	Sham MLD	13	33.15±12.16	33.54±14.85	33.38±13.11	0.026	0.974	----
	Control	13	22.46±12.25	26.08±12.04	25.00±11.7	1.299	0.291	----
			F=3.448 p=0.042* Post-hoc: 2>1,3	F=1.630 p=0.210	F=1.413 p=0.256			
Mean RR Interval (ms)	**MLD**	14	711.65±75.19	732.09±78.64	743.71±80.66	**7.334**[1]	**0.011***	**c□a**
	Sham MLD	13	688.02±191.46	754.15±58.29	757.28±61.10	5.922[2]	0.052	----
	Control	13	701.56±84.94	732.17±78.76	739.55±66.1	**6.760**[1]	**0.007***	**c□a**
			KW=0.978 p=0.623	F=0.402 p=0.672	F=0.228 p=0.797			
Total Power (ms²)	**MLD**	14	5153.7±3434.18	5213.88±3481.41	5976.18±3781.67	1.465	0.250	----
	Sham MLD	13	7687.52±4725.37	7999.83±4843.93	8056.39±4177.84	0.111	0.895	----
	Control	13	4648.75±2767.1	5625.71±2881.46	4888.47±2273.13	1.436	0.258	----
			F=2.502 p=0.096	F=2.057 p=0.142	F=2.729 p=0.078			

n: number of participants; SD: standard deviation; MLD: manual lymph drainage; F: one-way analysis of variance; F[1]: one way anova for repeated measures; KW:Kruskal Wallis H test; SDNN:standard deviation of the NN (R-R) intervals; RMSSD;root mean square of successive RR interval differences; PNN50; proportion of NN50 divided by the total number of NN (R-R); p: significance level; *: p<0,05, a: before cold pressure test, b: after cold pressure test, c: after treatment protocol, [1]:MLD, [2]: Sham MLD, [3]: Control, ms: millisecond, ms²: millisecond squared

Table 4. The Changes in the HRV Frequency Domains

		n	Before Cold Pressure Test[a] Mean±SD	After Cold Pressure Test[b] Mean±SD	After Treatment Protocol[c] Mean±SD	F[1]	p	Post-hoc
LF (ms²)	**MLD**	14	4630.64±3272.2	4670.94±3129.8	5385.11±3256.05	1.519	0.241	----
	Sham MLD	13	6866.18±3806.84	6727.56±4418.26	10312.51±13887.07	0.758	0.406	----
	Control	13	4006.3±2430.55	4999.06±2542.43	4363.48±1957.39	6.615	**0.037***	**b>a**
			F=2.846 p=0.071	F=1.363 p=0.268	KW=3.169 p=0.205			
HF (ms²)	**MLD**	14	523.06±309.95	543.01±566.09	538.93±622.67	0.143	0.931	----
	Sham MLD	13	1317.81±959.43	1272.27±1019.18	1316.13±1121.45	0.745	0.689	-----
	Control	13	642.52±471.22	626.65±536.64	525.0±417.61	1.077	0.584	----
			KW=8.632 p=0.013* post hoc: 2>1	**KW=6.046 p=0.049* post hoc: 2>1**	**KW=7.351 p=0.025* post hoc: 2>1**			
LF/HF Ratio	**MLD**	14	10.48±9.01	11.37±9.01	13.25±13.01	2.714	0.257	----
	Sham MLD	13	7.03±3.86	7.75±4.33	7.74±4.80	1.592	0.451	----
	Control	13	9.07±9.41	10.76±5.89	12.58±10.15	8.769	**0.012***	**c>a**
			KW=1.319 p=0.517	F=1.446 P=0.485	KW=2.981 p=0.225			

n: number of participants; SD: standard deviation; MLD: manual lymph drainage; F: one-way analysis of variance; F[1]: one way anova for repeated measures; KW:Kruskal Wallis H test; LF; low frequency, HF; high frequency; p: significance level; *: p<0,05, , a: before cold pressure test, b: after cold pressure test, c: after treatment protocol, [1]:MLD, [2]: Sham MLD, [3]: Control, ms²: millisecond squared

Heart rate decreased significantly in all groups after the application (p<0.05). RMSSD increased significantly after MLD (p<0.05). The mean RR interval increased statistically significantly in both the control group and the MLD group after the application (p<0.05). No significant differences were found in other variables (p>0.05) (Table 3.).

Considering the change in frequency-dependent HRV parameters, it was found that LF and LF/HF ratios increased significantly in the control group (p<0.05). There was no difference in all groups in the other parameters (p>0.05) (Table 4.).

DISCUSSION

This study aimed to evaluate the effect of experimental stress on autonomic functions with the cold pressure test applied for 2 minutes and to determine the effects of MLD applied afterward and compare it with sham MLD and control application. As a result of the study, in the MLD group with the cold pressure test; SBP and heart rate decreased, in the control group; SBP decreased, and LF increased. After MLD application; heart rate decreased, and RMSSD and mean RR interval increased. In the Sham MLD group; heart rate and SBP decreased. In the control group; heart rate decreased, mean RR interval, and LF/HF ratio increased. However, there was no significant difference between the groups after both the cold pressure test and the applications.

In the current literature, some studies found that the cold pressure test changes the ANS in the direction of both the sympathetic and parasympathetic nervous systems. Mechanisms relating to autonomic nervous system response are largely uncertain. Sympathetic activation increases cholinergic reactions by increasing vascular alpha-adrenergic and cardiac beta-adrenergic responses, causing an active coping strategy. Activating ANS in the parasympathetic direction has a passive coping strategy; it may be to decrease beta-adrenergic responses and increase alpha-adrenergic and cholinergic responses or to respond by increasing cortisol levels through the HPA axis (26). In addition, gender, presence of infection, and anxiety levels also affect the response (27,28). As a result of our study, the cold pressure test revealed different effects in all 3 groups. While the cold pressure test revealed activation in the direction of the parasympathetic nervous system in the MLD and control groups, there was no change in the parameters evaluated concerning the autonomic nervous system in the sham MLD group. Some studies have shown that SARS-CoV-2 infection can cause dysautonomia by affecting the autonomic nervous system in the acute, subacute, and chronic periods (29). In a study evaluating the heart rate variability of COVID-19 patients, an increase in the autonomic nervous system towards the parasympathetic system was observed in the patients. The difference between the groups may be because the data of the study were collected during the pandemic and the effects of the SARS-CoV-2 infection on the participants were unknown. The anxiety level of the participants was unknown. It was also unclear whether the results were affected by this difference between groups.

Several studies dealing with the effects of MLD on HRV have complicated results. A study conducted on healthy men evaluated the effects of MLD on HRV (12). As a result of the study, they found that R-R interval, SDNN, RMSSD, and pNN50 (%) values were higher, and heart rate, LF/HF ratio, and total power were statistically significantly lower in the experimental group. They concluded that MLD changes the autonomic nervous system in the parasympathetic nervous system. In the study, participants were given 2 minutes of psychological stress, but there were no results on how psychological stress changed HRV. In addition, MLD was applied only to the neck and abdomen for 40 minutes. This time is very long only for neck and abdomen MLD applications. Despite these confusing subjects, it was an important study so that we could compare the results of the current study. In a study by Honguten et al., the acute effects of MLD on HRV in healthy volunteers aged 40-65 were evaluated (13). MLD applications were performed by a certified and experienced therapist, in order, to cover the neck, abdomen, and one leg. The control group was only asked to rest. Although there was no difference in HRV parameters as a result of the study, a parasympathetic change was found in the evaluation of the Hoffman reflex in the MLD group.

In our study, MLD parasympathetically activated the autonomic nervous system by decreasing the heart rate and increasing the RMSSD, mean RR interval. The RMSSD means beat-to-beat variance in heart rate and is the primary time measure used to estimate vagal-mediated changes in HRV. An increase in the RMSSD value reflects the activation of the parasympathetic system (6). The mean RR interval is the average of two consecutive R waves in milliseconds. An increase in the mean RR interval indicates activation of the parasympathetic system (5). According to these results, acute MLD can activate the parasympathetic nervous system in healthy women. In addition, there was no significant change in blood pressure after MLD showed that MLD can be used safely in hypertensive individuals. However, considering that our study was conducted in young women, there is a need for studies to be conducted in both different age groups and in men.

This is the first study to compare MLD and sham MLD to the best of our knowledge. We think that testing the sham MLD protocol, which is planned by the researcher as the opposite of MLD principles, will make significant contributions to the literature. A true placebo treatment protocol is not yet available in manual therapy studies. Generally, as a sham protocol, application to a different area or a touch opposite to the application is preferred. It cannot be said that such different touches do not have any effect on health (30). Touch itself can have a positive effect on the body (31). In our study, the sham protocol; affected the autonomic nervous system by causing changes in heart rate and SBP. However, the lack of a study in the literature on which of the parameters evaluating the autonomic nervous system reflects the autonomic activity better and the lack of difference between the groups did not create a clear answer to the superiority of the sham MLD and MLD methods.

In the control group; a decrease in heart rate, mean RR interval, and LF/HF ratio after application suggested parasympathetic system activation. Lying supine may produce a relaxation effect in healthy participants. In future studies, the control group can be applied in a different position.

Limitations

Firstly, the anxiety levels of the participants were not evaluated and their exposure to SARS-CoV-2 infection is unknown. Secondly, this study evaluated the acute effects of a single session of MLD in healthy volunteers. Lastly, this study was conducted as a single-blind study. Especially in studies with sham protocol, the blindness of the evaluator increases the reliability of the study.

CONCLUSION

To the best of our knowledge, this study is the first to implement the sham MLD protocol. MLD can be used in the activation of the parasympathetic nervous system due to the change in HRV parameters. However, there is a need for new studies to be conducted in different patient populations using the sham MLD protocol. Considering the changes that MLD induces in the autonomic nervous system, it can be used not only as a part of complex decongestive physiotherapy but also as a standalone manual treatment approach in conditions where the autonomic nervous system is affected. However, further studies are needed in patient groups and different age groups. In addition, it should be investigated whether HRV parameters are superior to each other in showing the changes in the autonomic nervous system.

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