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Original Article

Comparison of extracorporeal shock wave therapy and manual therapy on active trigger points of the sternocleidomastoid muscle in cervicogenic headache: A randomized controlled trial

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ABSTRACT

Objectives: This study aims to investigate the effect of extracorporeal shock wave therapy (ESWT) and manual therapy (MT) on active trigger points of the sternocleidomastoid muscle (SCM) in patients with cervicogenic headache (CEH).

Patients and methods: A total of 42 patients were included (27 females, 15 males; mean age: 33.2±7.7 years; range, 18 to 45 years) in the randomized controlled trial between March 2022 and December 2022. The patients were randomly divided into the ESWT group (n=21) and the MT group (n=21). Each group received therapy once a week for four weeks. The primary outcome measure was the Visual Analog Scale (VAS), and secondary outcome measures were pressure pain threshold (PPT), Neck Disability Index (NDI), and stiffness (shear elastic modulus) of the SCM measured at baseline, postintervention, and four weeks after treatment.

Results: One patient from the ESWT group was lost to follow-up. The missing data were imputed for intention-to-treat analysis. Significant decreases of VAS, NDI, and shear elastic modulus of SCM were found at postintervention and four weeks after treatment in both groups ($p<0.01$). The PPT scores markedly increased over time compared to baseline in both groups ($p<0.01$). The repeated measures of analysis of variance revealed a significant time effect ($p<0.001$) in each outcome variable for both groups. There were no significant differences between the two groups in VAS, PPT, NDI, and the stiffness of SCM at each time point.

Conclusion: Extracorporeal shock wave therapy and MT were equally effective in pain relief, functional recovery, and reduction of muscle stiffness. Extracorporeal shock wave therapy may be used as an alternative treatment method for CEH patients with active myofascial trigger points of the SCM.

Keywords: Cervicogenic headache, extracorporeal shock wave therapy, manual therapy, trigger points.

Headache is a common complaint encountered by neurologists and physiotherapists, which severely influences the patients' quality of life and normal work.[1] Cervicogenic headache (CEH) is characterized by unilateral, referred head pain triggered by neck movement and sustained or awkward neck postures and restricted cervical range of motion and is significantly relieved in parallel with the improvement in the cervical disorder or lesion.[2,3] It has been reported that the prevalence of CEH was 4.1% in the general population,[2] accounting for about 15 to 20% of headache patients, with a female/male ratio of 0.97.[4]

Various pathological changes in the neck, such as joint dysfunction, disc and ligament injury, and muscle stiffness, can lead to CEH.[2,5] Currently, myofascial trigger points (MTPs) deriving from the upper cervical musculature are becoming a research hotspot.[6] They are the main cause of myofascial pain syndrome (MPS) and may explain about half of chronic pain in the head and neck.[7] An MTP is identified as a hypersensitive taut band in a muscle tissue characterized by the presence of referred pain by palpation and is divided into active MTP and latent MTP.[8] Both active MTP and latent MTP can cause

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muscle dysfunction, such as pain, weakness, stiffness, and imbalance.[9] The MTPs are common in the neck muscles, such as sternocleidomastoid muscle (SCM), upper trapezius muscle, suboccipital muscles, and temporalis muscles.[10] Some studies suggested that MTPs originating from SCM may have a vital role in the pathogenesis of CEH.[11,12]

There are many therapeutic methods for MTPs in clinical practice, but currently no clinically acceptable guidelines are available. Clinicians need to integrate various factors to develop treatment plans, such as level of treatment evidence, patient preferences, and clinical experience. Manual therapy (MT) is a series of noninvasive techniques, including ischemic compression, MTP pressure release, passive stretching, and muscle energy techniques.[13] There is moderately strong evidence supporting MT for immediate pain relief in the treatment of MPS and MTPs.[14] Previous studies reported the effectiveness of MT techniques in treating CEH patients, and they found that MT might relieve pain and improve neck functions in the short term.[15,16] However, the use of MT also has risks due to its reported adverse events and side effects.[17] The safety and efficacy of MT for the treatment of head and neck pain still need to be proven.[18,19]

As a noninvasive and safe technique, extracorporeal shock wave therapy (ESWT) has been applied to treat MTP-related pain in MPS.[20,21] Recent studies have reported that ESWT was effective in pain relief and functional recovery in MPS of the trapezius muscle.[22,23] The possible mechanisms for the benefits of ESWT in MPS included the direct effects on tissue and indirect mechanotransduction effects by increasing perfusion, promoting angiogenesis, and altering pain signaling.[24] Based on this information, ESWT may be effective in treating MTP-related pain. To the best of our knowledge, the effects of ESWT on CEH patients with active MTPs in the SCM have not been evaluated. In light of current data, this study aimed to examine the efficacy of ESWT applied to the trigger point in the SCM in the treatment of CEH and compare the effectiveness of ESWT versus MT on pain, neck disability, and stiffness of SCM in CEH patients.

PATIENTS AND METHODS

This randomized controlled trial was conducted at the rehabilitation clinic of Weifang People's Hospital between March 2022 and December 2022. This study recruited 42 CEH patients (27 females, 15 males; mean age: 33.2±7.7 years; range, 18 to 45 years). The diagnosis of CEH was made by an experienced neurologist according to the third edition of the International Classification of Headache Disorders criteria determined by International Headache Society (IHS).[25] The palpation of active MTPs in SCM was performed by a physiotherapist with more than eight years of experience in MPS. The diagnostic criteria for an MTP were as follows:[26] a hypersensitive spot in a taut band, local twitch experienced by patients on manual palpation, and reproduction of the patient's painful symptoms by palpating the spot. Before the beginning of the trial, a detailed physical examination, imaging, and ultrasound examination were conducted. Subjects enrolled in the study had active triggers on one side of the SCM and had suffered from unilateral headache for at least three months. They had not received any treatment during the past three months, such as massage, physiotherapy, and analgesic medicines, and they could not receive any other treatment interventions during the treatment period, except for intragroup treatment; otherwise, they were excluded from the trial. Exclusion criteria included active trigger points in bilateral SCM, neck, shoulder, and facial muscles, the diagnoses of other types of headaches, neurological symptoms, fracture of cervical vertebra, a history of cervical surgery or trauma, combination with cervical deformity or fibromyalgia, patients who cannot complete the experiment, pregnant women, patients with large unstable carotid plaque or carotid stenosis or occlusion, and patients with bleeding disease or bleeding tendency. A written informed consent was obtained from each patient. The study protocol was approved by the Weifang People's Hospital Ethics Committee (date: 25.03.2021, no: KYLL2021-03-25). The study was conducted in accordance with the principles of the Declaration of Helsinki.

We used the sealed envelope method to randomize allocation of subjects in this study. Once the patients were enrolled, they would select one of 42 sealed envelopes from an outpatient nurse who was not aware of the treatment assignments. There were the names of the grouping and instructions to find that group in the envelopes. Ultimately, a total of 42 patients met the inclusion criteria and were randomly allocated to two groups: the ESWT group (n=21) and the MT group (n=21). Figure 1 shows the flowchart of the study.

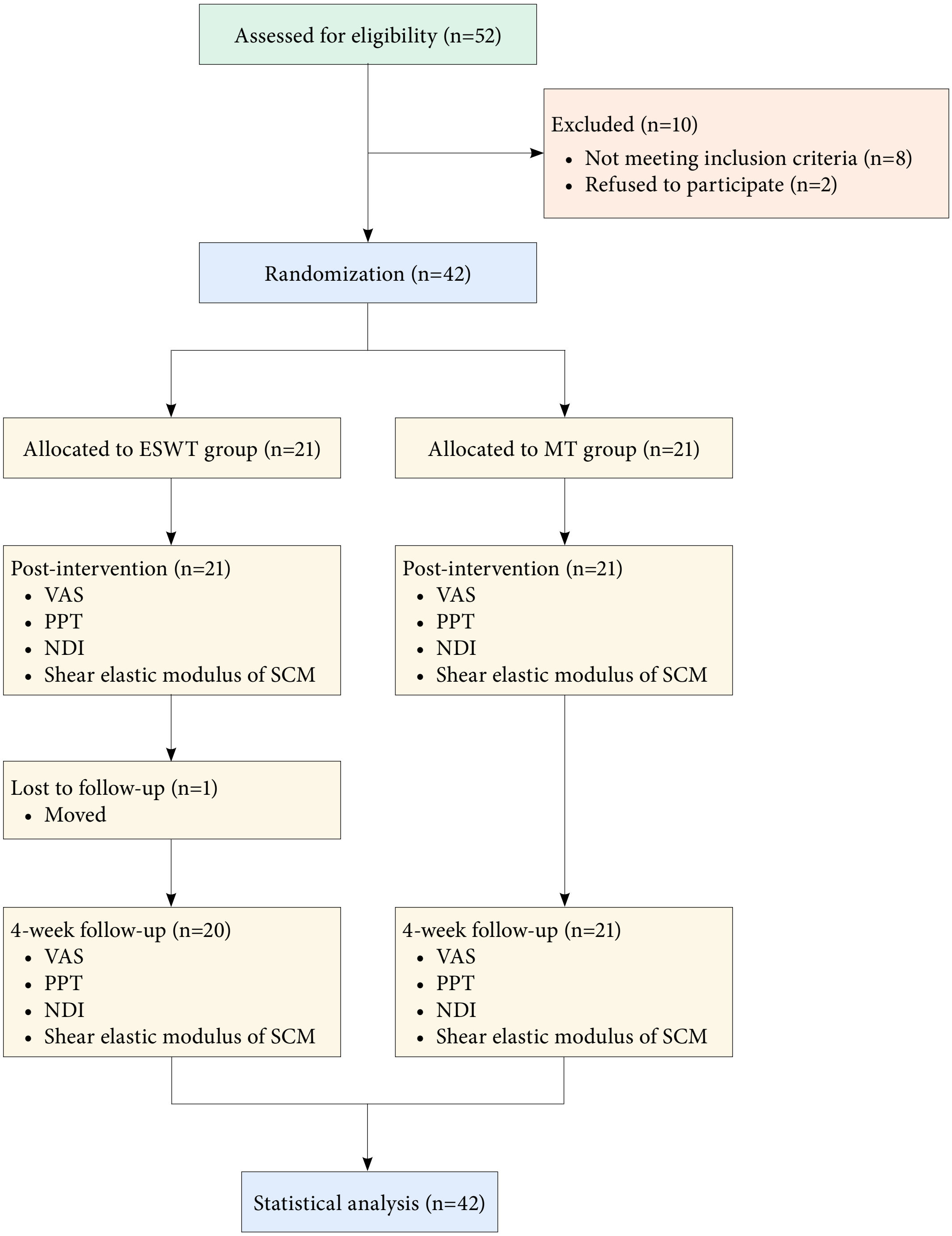

Figure 1. Flowchart of the study.

ESWT: Extracorporeal shock wave therapy; MT: Manual therapy; VAS: Visual Analog Scale; PPT: Pressure pain threshold; NDI: Neck Disability Index; SCM: Sternocleidomastoid muscle. Forty-two patients were included in the statistical analysis.

Due to lack of unified clinical guidelines on the treatment sessions of MTP therapy in individuals with CEH, we designed the experimental scheme based on clinical experience and previous studies.[11,27-29] A positive outcome was expected after all treatments were completed. Both groups received four treatment sessions with a one-week interval between each session for four weeks. First, we collected baseline data of patients and then performed ESWT and MT treatments, respectively.

Postintervention outcomes were assessed one day after the end of four weeks of treatment. Finally, patients returned for a follow-up evaluation four weeks after the last treatment.

We implemented treatment on active trigger points of the SCM at the symptomatic side of the headache. Each group was conducted by a designated physiotherapist with eight years of clinical experience. All patients were instructed to lie in supine position with their head in neutral position. Before starting therapy, the existence of MTPs was confirmed by palpation and marked with a permanent marker. The examiners who performed the assessments and the statistician were unaware of the treatment assignments.

According to previous research, ESWT with an energy flux density (EFD) range of 0.10 to 0.25 mJ/mm^2 is effective in managing MTPs in MPS.[22,27] In this study, participants in the ESWT group received 1,000 shock waves with EFD=0.18 mJ/mm^2 and a frequency of 3.5 Hz using an American DJO 2074 device (DJO Medical Device Trading Co., Ltd., California, USA). During the treatment, the patient indicated to stop at any time if they felt any pain or discomfort. During the treatment process, the therapist grasped the marked MTPs with the thumb, middle finger, and index finger of the left hand, applied clean coupling gel to the marked area, and vertically placed the probe (R15 mm) with the right hand at the marked MTPs (Figure 2).

For the MT group, different manual approaches, including MTP compression and passive stretching, were applied in treating the MTPs based on previous research.[11,26] In those studies, patients who received MT experienced great improvements in pain relief and cervical range of motion. Therefore, different manual approaches over the MTP in SCM were applied for this study. After identifying the MTPs, the therapist first applied a little pressure to the marked MTP taut band with the thumb, index, and middle fingers, gradually increased the pressure to maximum tolerable level, and maintained the pressure until the therapist felt the taut band disappeared or the headache pattern was reproduced (Figure 3). This process was repeated three to five times, with a 30-sec interval between each repetition. Participants in the MT group were also given the taut band fibers passive stretching. Briefly, the therapist placed his thumbs over the taut band, then slowly stretched with appropriate strength, and slid the fingers in opposite directions. The strength of the manipulation was based on the principle of not causing obvious pain.

The Visual Analog Scale (VAS) was used to assess the intensity of headache. The VAS is a subjective measure that requires patients to indicate the degree of pain on a scale. The scale ranges from 0 (no pain) to 10 (the worst imaginable pain).

A portable algometer (SY-JL100A; Jiangsu Suyun Medical Materials Co., Ltd., Lianyungang, China) was used to measure the pressure pain threshold (PPT) on the trigger points of the SCM. An amount of pressure was applied to the MTP by placing the pressure algometer vertically on the patient's skin surface with the patient in the supine position. The pressure was stopped once the patient began to feel pain, and the degree of pain at that moment was

Figure 2. Extracorporeal shock wave therapy was applied to an active trigger point of the right sternocleidomastoid muscle in cervicogenic headache.

Figure 3. The compression of manual therapy was applied to myofascial trigger point of the right sternocleidomastoid muscle in cervicogenic headache.

measured in Newtons. Each value was measured three times at an interval of 30 sec, and the mean value was calculated for the following analysis.

Neck function was evaluated using the Persian version of the Neck Disability Index (NDI). This is a highly valid and reliable instrument for assessing neck function,[30] including a 10-item scaled questionnaire, such as neck pain, headache, sleeping, reading, and driving. The minimum score for each item is 0, and the maximum score is 5. Higher scores represent more severe pain and disability.[31]

Shear wave ultrasound elastography (Supersonic Imagine, Aix-en-Provence, France) was used to measure the stiffness of SCM via an SL10-2 MHz linear array transducer, with a maximum elastic modulus of 600 kPa. Elastography examinations were manipulated by a well-experienced sonologist who was blinded to the groups.

To ensure that each measurement was taken in the same location, we conducted examinations at four different sites of each SCM, which were near the mastoid process, at the mandibular angle level, at the thyroid cartilage level, and near the sternoclavicular joint. All subjects lay in the supine position without pillows and kept their heads in neutral position. First, the transducer was targeted at one of the above sites using B-mode ultrasound until the muscle shape was clear. Afterward, shear

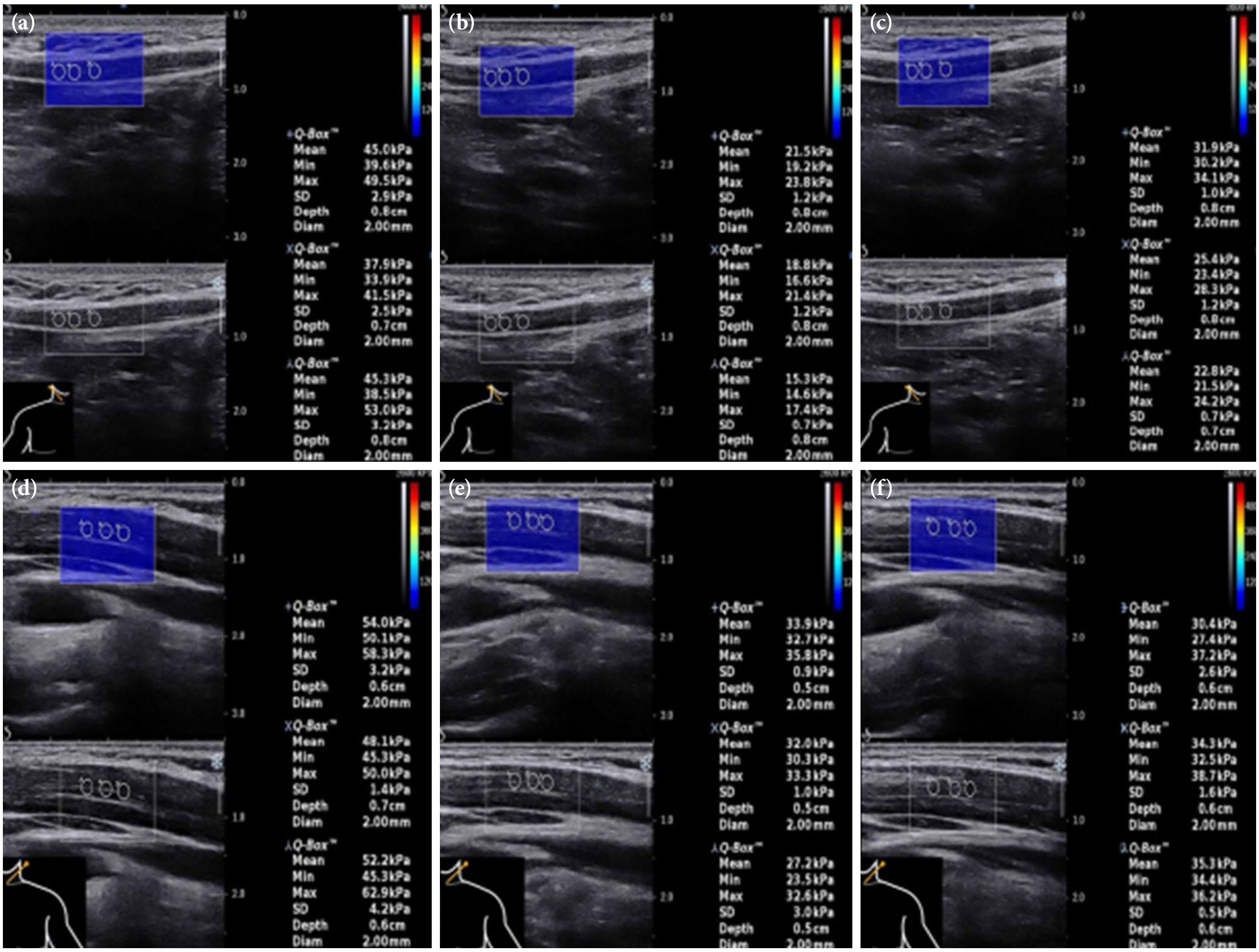

Figure 4. Measurement of the stiffness of the SCM with shear elastic modulus using shear wave elastography. Each image shows three regions of interest (the three white circles) at one of the four sites measured. **(a-c)** Images demonstrate the elastic modulus of the right SCM at the first site in the ESWT group before ESWT treatment, postintervention, and at the four-week follow-up, respectively. **(d-f)** Images display the elastic modulus of the left SCM at the third site in the MT group before MT treatment, postintervention, and at the four-week follow-up, respectively.

SCM: Sternocleidomastoid muscle; ESWT: Extracorporeal shockwave therapy; MT: Manual therapy.

elastic modulus mode was applied to get elastic modulus value. For each site, three elastic modulus values were taken in the elastic frame using a region of interest 2 mm in diameter (Figure 4). According to the aforementioned method, regions of interest were measured at each site and the mean values of elastic modulus were calculated. Each site was measured three times and the mean value of four regions of interest was used for further analysis.

Statistical analysis

The sample size was calculated by PASS version 15 software (NCSS, LLC., Kaysville, UT, USA). Eighteen patients in each group were required on the basis of a difference of 1.2 on VAS and a standard deviation of 1.0 after data collection according to the preliminary experiment, with a two-sided test, an alpha of 0.05, a power of 0.9, as well as including an estimated dropout rate of 10%. The final sample size for each group was 21, with a total of 42 for the whole trial.

In this study, all statistical analyses were performed using the IBM SPSS version 26.0 software (IBM Corp., Armonk, NY, USA). For lost data, we followed the principle of intention-to-treat analysis. Means, standard deviations, and 95% confidence intervals were calculated for numerical data. The Shapiro-Wilk test was used to check the normality of data distribution. The comparisons of VAS, PPT, NDI, and shear elastic modulus between the MT group and ESWT group were analyzed by repeated measures of analysis of variance (ANOVA), and the least significant difference test was performed for within-group comparisons. Fisher exact test was used to analyze sex and affected side (presence of active MTP in SCM). The independent sample t-test was performed to compare age, weight, height, and pain duration between groups. A p-value <0.05 was considered statistically significant. Partial eta-squared values (η^2_p) were used to express the effect sizes between groups. An $\eta^2_p \geq 0.01$ was considered small, $\eta^2_p \geq 0.06$ was considered medium, and $\eta^2_p \geq 0.14$ was considered large.

RESULTS

One patient from the ESWT group was lost to follow-up at the end of the study for moving. Finally, 20 patients in the ESWT group and 21 patients in the MT group completed the study. The missing data were imputed for intention-to-treat analysis (Figure 1). No significant differences were found in baseline demographics for both groups before the intervention ($p>0.05$, Table 1).

Visual Analog Scale scores significantly declined for subjects in both the MT and ESWT groups after treatment, and the effects were maintained until four weeks posttreatment ($p<0.01$, Table 2). According to repeated measures ANOVA, the effect of time was significant ($F=205.884$, $p<0.001$, $\eta^2_p=0.837$), while the interaction effect between time and group had no statistical difference ($F=0.180$, $p=0.816$, $\eta^2_p=0.004$). Both groups had no differences in VAS at each time point (Table 2).

Significant improvement of PPT values were found postintervention and four weeks after treatment compared to baseline ($p<0.01$). The effect of time caused a significant difference in PPT ($F=74.957$, $p<0.001$,

TABLE 1
Baseline demographic data for both groups

	MT group		ESWT group		
	n	Mean±SD	n	Mean±SD	*p*
Age (years)		32.95±7.98		33.48±7.53	0.828#
Sex					0.334*
Female	15		12		
Male	6		9		
Affected side					0.346*
Left	11		14		
Right	10		7		
Weight (kg)		69.37±9.81		68.63±10.53	0.816#
Height (cm)		168.48±7.77		170.00±6.99	0.508#
Pain duration (month)		11.14±5.83		10.95±5.54	0.914#

MT: Manual therapy; ESWT: Extracorporeal shockwave therapy; SD: Standard deviation; * Fisher exact test; # Independent sample t-test; p<0.05 was considered significant.

TABLE 2
Inter- and intragroup comparisons of VAS, PPT, NDI, and SCM stiffness in the MT and ESWT groups

	Baseline	Postintervention	4-week post-treatment				
	Mean±SD	Mean±SD	Mean±SD		F	*p*#	η^2_p
VAS score							
MT group	6.90±1.04	3.29±1.15*	3.29±1.06*	Group	0.538	0.468	0.013
ESWT group	6.81±1.44	2.95±1.02*	3.14±1.15*	Time	205.884	<0.001	0.837
				Group × time	0.180	0.816	0.004
PPT (N)							
MT group	18.03±3.29	25.28±3.06*	23.07±3.17*	Group	1.109	0.299	0.027
ESWT group	17.83±3.76	26.48±3.58*	24.24±3.17*	Time	74.957	<0.001	0.652
				Group × time	0.712	0.490	0.017
NDI score							
MT group	28.52±5.11	16.24±3.05*	18.52±3.44*	Group	2.039	0.161	0.048
ESWT group	26.76±4.17	15.48±3.80*	17.24±4.27*	Time	140.670	<0.001	0.779
				Group × time	0.222	0.788	0.006
Stiffness of SCM (kPa)							
MT group	52.95±9.43	31.84±6.31*	34.05±5.59*	Group	0.304	0.585	0.008
ESWT group	54.37±8.58	29.87±6.82*	31.66±6.99*	Time	137.771	<0.001	0.876
				Group × time	0.925	0.405	0.045

VAS: Visual analog scale; PPT: Pressure pain threshold; NDI: Neck Disability Index; SCM: Sternocleidomastoid muscle; MT: Manual therapy; ESWT: Extracorporeal shockwave therapy; SD: Standard deviation; * p<0.01, postintervention and four weeks after treatment compared to baseline; p<0.05 was considered significant; # Repeated measures of analysis of variance; * Least significant difference test; The effect sizes between groups were expressed as partial eta-squared values (η^2_p; small ≥0.01, medium ≥0.06, large ≥0.14).

η^2_p=0.652). The repeated measures ANOVA showed no statistical differences between groups (F=1.109, p=0.299, η^2_p=0.027) and in interaction effects of group and time (F=0.712, p=0.490, η^2_p=0.017). Between-group outcome measures showed no significant differences at postintervention and 4-week follow-up (Table 2).

For the NDI, the repeated measures ANOVA revealed no statistical difference between the ESWT and MT groups (F=2.039, p=0.161, η^2_p=0.048). The time-by-group interaction effect (F=0.222, p=0.788, η^2_p=0.006) also had no statistical difference. At the end of treatment and four weeks after treatment, NDI scores in two groups significantly declined compared to before the intervention (p<0.01), and the effect size for the time effect was large (η^2_p=0.779). There were no obvious differences between the two groups at each time point (Table 2).

Compared to baseline, the shear elastic modulus of the SCM markedly decreased from 54.37±8.58 to 29.87±6.82 kPa and from 52.95±9.43 to 31.84±6.31 kPa in the ESWT and MT groups postintervention (p<0.01), respectively. Furthermore, the reductions of the shear elastic modulus were maintained at four weeks posttreatment (p<0.01). According to repeated measures ANOVA, an obvious time effect was observed for the elastic modulus of the SCM in the between-group comparison (F=137.771, p<0.001, η^2_p=0.876). However, no marked statistical differences were found between groups (F=0.304, p=0.585, η^2_p=0.008) or in time-by-group interaction effect (F=0.925, p=0.405, η^2_p=0.045) were found. There were no significant differences between the two groups from baseline to the follow-up period (Table 2).

DISCUSSION

This study was designed to evaluate the effect of ESWT and MT on active trigger points of SCM in patients with CEH. The study found that both methods showed significant reductions in VAS, NDI, and elastic modulus of SCM and obvious improvement in PPT postintervention and were able to maintain the therapeutic effect for four weeks after treatment. There was no significant difference between ESWT and MT groups in each outcome variable. These results suggested that ESWT and MT were equally effective in pain relief, functional recovery, and muscle stiffness reduction in CEH patients with active MTPs of SCM.

In previous studies, strong evidence has been found for the analgesic effect of MT on the management of MTPs.[15,32] The study of Bodes-Pardo et al.[11] showed that MT could significantly reduce pain intensity and obviously improve PPT and cervical function after treatment in CEH patients. Togha et al.[29] demonstrated that ischemic compression decreased headache intensity, frequency, and duration after four sessions of treatment in CEH patients with MTP of SCM. In this study, we observed significant improvement in VAS, NDI, and PPT values both at postintervention and at the four-week follow-up in the MT group, which was in accordance with previous studies. Whether MT can be effective for pain relief and functional recovery in MTPs in CEH patients remains speculative. Manual therapy may reduce MTP activity, restore the length of sarcomeres, induce hyperemia of the taut band, and temporarily elongate connective tissue.[33] Moreover, MT improves parasympathetic nervous activity and reduces the release of acetylcholine.[34]

As demonstrated in many studies, ESWT has proven effectiveness in the treatment of MTPs in MPS.[23,27,35] However, so far, the efficacy of ESWT has been examined mainly in neck and upper back myofascial pain.[20,22,28] To the best of our knowledge, the evidence for the impact of ESWT on the trigger point of SCM in patients with CEH is still unclear. In this study, we found a significant difference between VAS, PPT, NDI, and shear elastic modulus after treatment and the four-week follow-up in the ESWT group. Analgesic effects were attributed to modulated nitrogen monoxide and vascular growth factor, resulting in vascular hyperplasia, increased blood flow, improved ischemia, and hypoxia.[27] A previous study pointed out that ESWT selectively destroyed unmyelinated fibers and decreased substance P and its synthesis in the dorsal root ganglia.[36] Furthermore, ESWT could induce local microvascular generation and lower muscle tension and spasm, along with alleviating pain by hyperstimulation of nociceptors and blocking the transmission of nerve impulses.[37]

In addition to headache, patients with CEH are often accompanied by pain and stiffness of the neck muscles, and the tension and stiffness of the SCM are often significantly higher than those of healthy people.[10] Recently, shear wave elasticity imaging has been used for measuring muscle stiffness, and its elastic modulus value is proportional to the stiffness,[38] which could be used as a diagnostic tool and a method of evaluation of therapeutic effects in CEH.[39] Jafari et al.[32] observed that the elastic modulus of SCM decreased from 12.33±2.86 to 6.77±1.70 kPa, and muscle stiffness markedly reduced after four sessions of ischemic compression in patients with CEH. Another study also found a reduced elasticity in the SCM after ischemic compression.[29] However, no significant difference in the elasticity was observed compared to the control group. In this study, we found statistically significant reductions of the shear modulus of the SCM both postintervention and in the follow-up period compared to the baseline in both groups. Regardless of the mechanisms, studies found that there might be a correlation between the MTP and headache intensity.[29,35,39] Further studies are required to verify and explore the mechanisms and the link between the muscle stiffness and pain.

Currently, there are no unified standards for ESWT treatment parameters, including EFD, number of shocks, durations of treatment, or treatment course. In the study of Jeon et al.,[36] subjects received 1,500 shocks once a time (EFD=0.10 mJ/mm^2), with a one-week interval between two treatments and three times in total. In another study, Park et al.[40] compared the effectiveness of high-energy ESWT with an EFD of 0.210 mJ/mm^2 and low-energy ESWT with an EFD of 0.068 mJ/mm^2 in patients with MPS of the upper trapezius, with 1,500 shocks once a week for two weeks, and found both groups significantly improved in pain intensity and neck function. In this study, patients received 1,000 shocks with an EFD of 0.18 mJ/mm^2 and frequency of 3.5 Hz once a week for a total of four sessions. We found significant reductions in VAS, NDI, and stiffness of the SCM and improvement in PPT postintervention and at the four-week follow-up. However, the ideal regimen of ESWT for MTPs still needs to be further explored in future studies.

In the present study, both ESWT and MT have similar positive effects in the short-term treatment of CEH patients. As noninvasive techniques, MT may be preferred for superficial muscles, and the effectiveness of MT may rely more on the therapist's experience and skills. However, for deep muscles and when the therapist lacks treatment experience or when MT fails to achieve satisfactory results, ESWT may be used as an alternative treatment for patients.

The current study has some limitations. First, the small sample size we included should be considered, which may influence the repeatability and representativeness of the research results. Second, since our follow-up time was four weeks, we are not sure about the long-term effect of the intervention. Third, the patients' subjective influence cannot be ruled out since patients knew their treatments, and we did not design a pseudotherapy group or a normal group as a control for ethical reasons. Further research with longer follow-up and larger sample size incorporating a control or placebo group to better guide clinical practice is needed.

In conclusion, ESWT and MT were equally effective in pain relief, functional recovery, and reduction of muscle stiffness in CEH patients with active trigger points in SCM. Extracorporeal shock wave therapy may be used as an alternative treatment method for CEH patients with active MTPs.

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Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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