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RESEARCH ARTICLE

EFFECT OF INSTRUMENT ASSISTED SOFT TISSUE MOBILIZATION IN PATIENTS WITH CERVICAL DISC HERNIATION: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Purpose: The effects of Instrument Assisted Soft Tissue Mobilization (IASTM) on cervical disc herniation (CDH) have not been extensively studied. The study aimed to investigate the effect of the IASTM technique on pain, functionality and psychology in CDH.
Methods: A two-armed randomized controlled trial was carried out with 24 patients with CDH. Participants were randomized into two groups: conventional physiotherapy (n=12) and IASTM plus conventional physiotherapy (n=12). A conventional rehabilitation consists of a hot pack, electrotherapy, and exercises five days a week for four weeks. IASTM technique has been used for two sessions per week for four weeks. Patients were assessed with Visual Analogue Scale (VAS), Neck Disability Index (NDI), Copenhagen Neck Functional Disability Scale (CNFDS), Hospital Anxiety and Depression Scale (HADS).
Results: Both groups had improvements in VAS scores ($p<0.05$). IASTM group yielded more reduction in resting and activity pains ($p_{resting}=0.001$, $p_{activity}=0.001$). Disability scores of both groups improved ($p<0.05$). However, no difference was encountered between the groups regarding function and disability ($p>0.05$). Both the intervention and control groups showed a decrease in anxiety and depression symptoms ($p<0.05$). The anxiety and depression score of the intervention group yielded better results than the control group ($p<0.05$).
Conclusion: IASTM improved patients' rest and activity pain, anxiety and depression symptoms. On the other hand, IASTM provided advancement on function and disability scores simply as effective as conventional physiotherapy.

Keywords: Anxiety, cervical pain, disability, instrument-assisted soft tissue mobilization

INTRODUCTION

Neck pain is a significant public health problem (1). Approximately 48.5% of people experience neck pain at some point in lifespan (2). Cervical disc pathologies are the most common factor triggering neck pain (3). Therefore, patients with neck pain should be handled

in terms of biomechanical features of the anatomical region (4). The cervical region has less stability and greater mobility than other spinal cord segments. This specific condition causes an increase in both compression and rotational forces on the intervertebral discs. Increased compression and rotational forces protrude the nucleus pulposus to the contralateral side, promoting degeneration (5, 6). In addition, external mechanical factors such as overuse of spinal cord segments, posture disorders, and repetitive traumas directly affect disc mechanics and cause disc degeneration (7). Cadaver studies determined the existence of free nerve endings in the annular part of degenerated discs. This anatomical finding helps to further understand the mechanism of pain formation due to cervical disc degeneration (8).

There is a direct relationship between chronic pain and the functional status of individuals with cervical disc herniation (9). Long-term neck pain causes inhibition in deep flexor and extensor muscle groups, resulting in decreased functional capacity (10). Depending on the decreased function, basic and instrumental activities of daily living of individuals might be affected (11). Correspondingly, possible secondary psychosocial disorders, including anxiety and depression, could entail more ominous actual clinical results (12).

Various treatment modalities, including medication, invasive techniques, and conventional physiotherapy, are commonly applied to heal these frequent symptoms in patients with cervical disc herniation (13, 14). In recent years, "Instrument-Assisted Soft Tissue Mobilization (IASTM)" has become a trending technique with a positive effect on soft tissue pathologies (15). Recent studies have been demonstrated the effect of IASTM on cervical symptoms, including cervicogenic pain, pain threshold, disability muscle tone (16-18). IASTM is a highly applicable and cost-effective technique in low back and neck pain (15, 19). However, studies on the effect of the IASTM in neck pathologies are limited. The physical and psychosocial effects of IASTM on cervical disc herniation have not been extensively studied. A holistic consideration of the psychological state with the basic physical clinical parameters (e.g., pain, function) would provide essential clinical practical output. The aim of the study was to investigate the effectiveness of the IASTM technique on pain, functionality and psychosocial status in patients with cervical disc herniation.

METHODS

Study Design

A randomized controlled trial was conducted in *"blinded for peer review"*. The study was reported regarding the "Consolidated Standards of Reporting Trials (CONSORT) stages and SPIRIT (Statement of Recommendations for Interventional Trials)" guidelines (20). The study protocol was approved by the Marmara University Faculty of Medicine Clinical Research Ethics Committee (Decision Date: 03.05.2019, No: 09.2019.491). The study was carried out in accordance with the ethical principles and the Helsinki Declaration. This research was also registered to the "clinicaltrials.gov" (Registration No: NCT04803669)

Participants

Twenty-eight patients who applied to the physical therapy outpatient clinic with cervical disc herniation diagnosis were enrolled in the study. Inclusion criteria of the study were; (1) a radiological diagnosis of bulging or protrusion, (2) pain score >2 regarding the visual analog scale, and (3) neck pain >3 months. The exclusion criteria of the study were; (1) a history of neck-shoulder surgery/injury, (2) cortisone usage, (3) extrude/sequestered disc, (4) a history of fibromyalgia. After the eligibility procedure, 24 patients were randomized into two groups: conventional physiotherapy (n=12) and conventional physiotherapy plus IASTM group (n=12). All included patients completed the follow-up process and enrolled in the statistical analysis stage. The CONSORT flow chart of the study is given in Figure 1.

Recruitment process

The steps of the recruitment procedure are as follows: All individuals are informed about the objectives of the program (e.g., intervention, duration, assessments, potential risks). Documented, and a verbal statement was given. After the consent was obtained from the individuals, the voluntary consent form was signed. The study started after diagnosing individuals with cervical disc herniation via radiological evaluations by a specialist physician. The patients were directed to a physiotherapist from the physical therapy outpatient clinic.

Randomization and blinding

A simple randomization method was used in this trial.

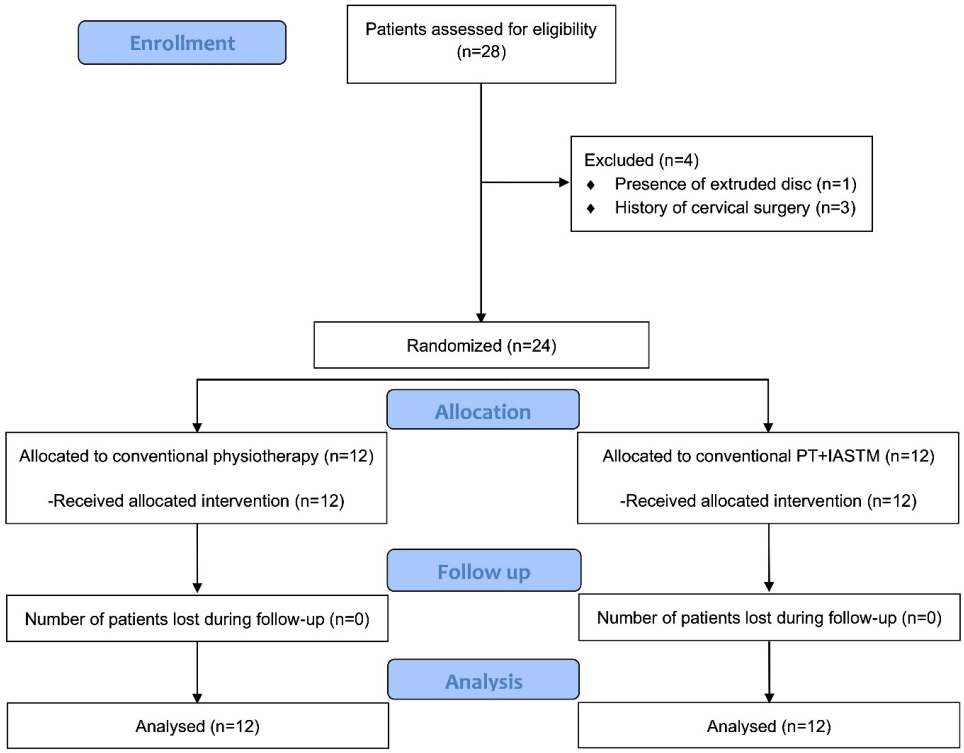

Figure 1. CONSORT FLOW CHART OF THE TRIAL

Participants were randomized using the sealed envelope method and divided into two groups. The blinding of the therapist was not possible due to the essence of the study. On the other hand, evaluator blinding was not possible due to the existing facilities of the setting.

Sample size

G-Power 3 was used to calculate the required minimum sample size of the study (21). Regarding the visual analog scale based difference values of the mean and standard deviation score of the referenced similar study (17), the effect size was determined as 1.09. Consequently, a total of 24 patients (minimum 12 individuals in each group) were calculated with a power of 0.80 and a confidence interval of 0.05.

Interventions

Conventional physiotherapy group (control group):

"The conventional treatment program consisted of a hot pack, electrotherapy agents, and an exercise program (22). The heat application was applied to the neck and upper back area by wrapping hot water bags and a towel for 25 minutes. The electrotherapy program consisted of transcutaneous electrical stimulation (TENS) and ultrasound (US). Conventional TENS (Acu Tens, 100 Hz, 200 ms, 1-100 mA) was applied for 25 minutes with two channels and four electrodes on the neck and upper trapezius muscle. The current intensity was adjusted not to cause disturbance in the patient. The US technique was applied (1-2.5 W/cm2, 1 MHz) for 5 minutes. The exercise program was applied after every electrotherapy session for 25 minutes under the supervision of a physiotherapist. This exercise program consisted of deep flexor and extensor strengthening, posture, stretching, and mobilization exercises with iso-flex bands."

Conventional physiotherapy plus IASTM group (intervention group):

"The identical conventional physiotherapy protocol was applied to the intervention group. IASTM was performed with a stainless-steel instrument (PTR medical, Turkey) using the brushing technique (short brushing made at an angle of 30°) to the superficial and deep fascia and muscle fibers between the C1-T1 neck-shoulder segments (23). A water-based gel was used to prevent the adverse effects that may occur due to friction in the tissue. This technique was applied in two weekly sessions and 5 minutes each for four weeks, totaling eight sessions (16)."

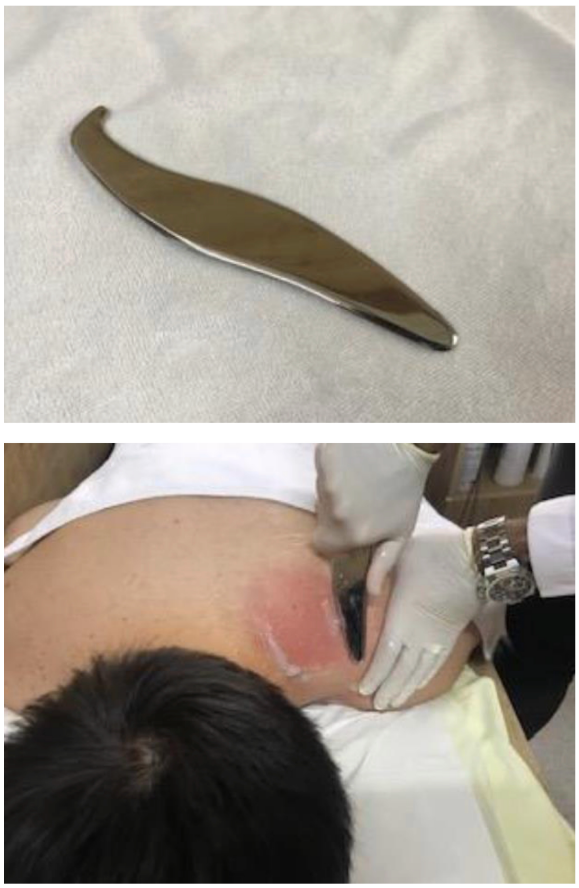

Figure 2. IASTM intervention illustration: the application material and technique

Assessments

"All patients were evaluated at baseline and four weeks after the intervention. Sociodemographic data form was used to record the patient's gender, age, body mass index, onset of pain, and herniation types.

Visual Analog Scale (VAS): VAS is a practical and reliable assessment used to determine patients' pain severity. Scoring is accomplished between 0-10 points. "0" represents the absence of pain, and "10" represents the maximum pain. The time of neck pain onset, resting, and activity pain was questioned using the VAS (24).

Neck Disability Index (NDI): NDI has been prepared in 10 main sections as pain intensity, self-care, lifting, reading, headache, attention, working, driving, sleeping and recreation. The patients included in the study are asked to give a score between 0 (no disability) and 5 (disability) for each item. The total score varies between 0 (no disability) and 50 (disability). Telci-Aslan et al. Turkish validity and reliability was performed by (25).

Copenhagen Neck Functional Disability Scale (CNFDS): CNFDS evaluates the disability of patients due to neck pain (26). The scale consists of 15 items. Items are answered as "Yes, No, Sometimes" and scored between 0 to 2 points. Those who answer "Yes" to the first five questions of the scale receive "0", those who answer "sometimes" get "1 point," and those who answer "no" get "2 points". For the other ten questions, scoring is done in reverse. The total score is between 0 and 30 points. If the total score is "0", it means "no neck pain and disability," and "30" means "maximum neck pain and disability" (27).

Hospital Anxiety and Depression Scale (HADS): HADS includes anxiety and depression subscales. The scale consists of 14 items in total. Even-numbered items assess depression, and odd-numbered items assess anxiety. The answers are in a four-point Likert format and are scored between 0 to 3. The cut-off point for the anxiety subscale of the scale is 10, and 7 points for the depression subscale (28)."

Statistical Analysis

In classifying the data obtained in the study, qualitative and quantitative statistical methods were evaluated with the "Statistical Package for the Social Sciences (SPSS) 11.0 statistical program", and significance was assessed at $p<0.05$ level. The normality distributions of the data were analyzed with the "Kolmogorov-Smirnov test". "The Mann-Whitney U" test was used because the data between groups did not show normal distribution. The "Wilcoxon Signed Rank Test" was used for in-group comparison. "Fisher's exact chi-square test" was used to analyses non-quantitative data.

Whether the results were clinically significant or not was determined according to Cohen's effect size calculation. The effect size for each variable was calculated based on the average changes in the results obtained before and after treatment. This calculation suggests the effect size as small 0.2, medium 0.5, and large 0.8.

RESULTS

The median age of the individuals in the control and intervention groups were 34.50 and 40 years, respectively. Body Mass Index (BMI), gender, pain

Table 1. Baseline characteristics of the patients

	Control	Intervention	p
Age	34.50	40.00	0.285
BMI	25.34	28.51	0.028
Pain Onset	5.50	18.00	0.087
Gender (n,			
Female	5 (41.70)	6 (50.00)	0.500
Male	7 (58.30)	6 (50.00)	
Herniation			
Bulging	2 (16.66)	1 (8.33)	0.381
Protrusion	10 (83.33)	11 (91.66)	

n: number of individuals, BMI: body mass index

onset and clinical features of herniation are presented in Table 1. There was no difference between groups regarding baseline characteristics ($p>0.05$), except BMI ($p=0.028$).

Resting and activity pain decreased in both groups at the end of the intervention ($p<0.05$). Also, the pain score of the intervention group improved better than the control group ($p_{rest}=0.001$, $p_{activity}=0.001$). The change occurring during both rest pain and activity pain was clinically in favor of the IASTM group (Cohen's $d_{resting}$: 2.12; Cohen's $d_{activity}$: 1.86). Disability scores of both groups improved ($p<0.05$). However, no difference was encountered between the groups regarding function and disability ($p>0.05$). Both the intervention and control groups showed a decrease in anxiety and depression symptoms ($p<0.05$). The anxiety and depression score of the intervention group yielded better results than the control group ($p=0.015$) and effect sizes were shown at Table 2.

DISCUSSION

The present study examined the effects of IASTM in patients with cervical disc herniation on pain, disability, anxiety, and depression. The literature suggests that IASTM improves pain severity and disability levels in patients with musculoskeletal disorders (29,31). The physical effect of IASTM has been widely demonstrated (15, 29-31). However, its effect on cervical disc herniation-related pain and function is not well-studied. In addition, our study is unique in terms of evaluating the psychosocial effect of IASTM on cervical disc herniation. According to the present study results, IASTM thoroughly improved patients' rest and activity pain, depression and anxiety symptoms. On the other hand, IASTM provide advancement on function and disability scores simply as effective as conventional physiotherapy.

First, the improvement in resting and activity pain in the 4-week follow-up brought along the expectation of also on the functional status. However, the additional pain-related gains of IASTM did not improve functional status and disability. This outcome might be due to our trial's short to medium-term evaluation period. Longer-term monitoring and intervention may be required to observe the intervention's effect on daily living activities. On the other hand, the additional advantage of IASTM was observed in terms of depression and anxiety score. However, more comprehensive psychological screening tests and more detailed analyzes for the evaluation of psychological state can provide precise clinical outcomes (32).

IASTM applications are widely used as an alternative method in musculoskeletal disorders (15-17, 29-31, 33). Lauche et al. and Abdelhamid et al. emphasized the effect of IASTM therapy on pain in individuals with chronic neck pain (29, 34). On the other hand, Mylonas et al. reported the significant positive effect of IASTM on posture and function in patients with neck pain (31). These results provide the further benefits of IASTM on pain, posture and function. However, our study only proved the clinical effectiveness of IASTM in terms of pain and depression. The disability and postural status of Mylonas and colleagues may also have resulted in greater clinical output by performing combined IASTM and neuromuscular exercises. Examining the psychological state in our study provides a unique advantage. In particular, the decrease in pain intensity may have led to improvements in depression and anxiety (35).

Crothers et al. and El-Hafez et al. emphasized no additional advantage of IASTM on pain and disability in individuals with thoracic spinal pain and myofascial pain syndrome, respectively (15, 16). Emshi et al. focused on the positive effect of IASTM on clinical symptoms such as pain severity, range of motion and disability (36). On the other hand, Erden et al. also applied IASTM to the trapezius muscle of patients with myofascial pain syndrome and noted a decrease in trigger point pain (37). This inflammatory process causes the blood supply of the zone and increases fibroblastic activity. Thus, collagen synthesis and maturation in the soft tissue are facilitated, and the

Table 2. Comparison of the results between the groups (median values)

		Control (n=12)	IASTM (n=12)	p[a]	d
VAS-at rest	Baseline	6.50	8.00	0.746	
	6. week	6.00	3.00	0.001	2.12
	p[b]	0.003	0.002	-	
VAS-at activity	Baseline	7.50	7.50	0.500	
	6. week	6.00	3.50	0.001	1.86
	p[b]	0.002	0.003	-	
CNFDS	Baseline	14.00	18.50	0.046	
	6. week	8.00	6.00	0.384	-
	p[b]	0.002	0.002	-	
NDI	Baseline	17.50	21.00	0.418	
	6. week	10.50	7.00	0.258	-
	p[b]	0.002	0.002	-	
HADS-Anxiety	Baseline	10.00	11.00	0.601	
	6. week	7.00	7.00	0.044	0.44
	p[b]	0.003	0.002	-	
HADS-Depression	Baseline	10.50	9.00	0.595	
	6. week	8.00	4.50	0.015	0.30
	p[b]	0.003	0.002	-	

[a]: Wilcoxon Signed-Rank Test, [b]: Mann-Whitney U Test, d: Cohen's effect size, IASTM: Instrument-assisted soft tissue mobilization, CNFDS: Copenhagen Neck Functional Disability Scale, NDI: Neck Disability Index, HADS: Hospital Anxiety and Depression Scale, VAS: Visual Analog Scale.

healing process is supported (38-40). This physiological effect may have resulted in positive gains. The application method of the IASTM technique, in which different results were observed in studies on the neck and its circumference, is another issue that should be addressed in clinical effectiveness. The positive effect of the brushing technique we used in our study, especially on pain, should also be considered.

Studies have reported a strong correlation between neck pain and disability (41). Pain intensity is a dimension of disability (42). This technique reduces pain and disability by acting on the active myofascial trigger points of the upper trapezius muscle (36). As a result of our study, it was observed that the disability levels of the patients decreased. The decrease in pain after treatment may have affected disability levels.

IASTM was reported to effectively reduce pain, especially in patients with nonspecific low back pain (43). Zlatkov et al. also emphasized the effectiveness of IASTM on pain and disability in low back pain patients (33). It is noticed that similar results with the neck region are also observed in low back pain. However, there is a lack of results related to evaluating psychological status in chronic low back pain. In this respect, our study is essential in terms of revealing the effect of IASTM on psychosocial status, including diverse spinal conditions.

Chronic pain negatively affects the workforce, social isolation, quality of life, and psychological health (44). Different physiotherapy modalities used in pain treatment aim to improve quality of life, regulate pain, and reduce anxiety and depression complaints (45). In our study, conventional methods and the IASTM protocol, in addition to these methods, caused a decrease in anxiety and depression scores. However, it is proposed that it would be more appropriate to evaluate anxiety and depression with more comprehensive assessment methods in individuals with chronic neck pain in future studies.

Limitations

The limitations of the study should be handled. In this study, the evaluation of the joint range of motion of the cervical region might be appropriate to support

the changes in pain and disability parameters. Also, the HADS scale we used for anxiety and depression included questions about the patient's psychological complaints, preventing the evaluation of physical factors' effects on anxiety and depression. Another limitation concerns the long-term effects of the study. The long-term effects of the IASTM technique on parameters such as pain intensity and disability are unknown. In our study, we evaluated the short-term effectiveness of the technique. Evaluation of the technique's long-term effect will help reveal the actual effect. Long-term follow-up studies can also be a reference for cost-effectiveness analysis studies of treatment. On the other hand, some methodological limitations should be acknowledged. The lack of blinding in the study may suggest measurement-based bias problems. On the other hand, in terms of baseline characteristics, there is a possibility that a significant difference between the groups in BMIs may disrupt the homogeneity. However, we can express that our results provide critical clinical outcomes since BMI does not primarily affect clinical status in cervical disc herniation.

CONCLUSION

According to the results of our study, the IASTM protocol was found to be effective on pain severity and depression in patients with cervical disc hernia. However, the same positive effects were not observed on function and anxiety. It would be beneficial for physiotherapists to add the method to conventional physiotherapy programs as an alternative method since it is low cost, accessible, practical, easily tolerated by the patient, and has high clinical benefits.

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Ethical Approval: The study protocol was approved by the Marmara University Faculty of Medicine Clinical Research Ethics Committee (Decision Date: 03.05.2019, No: 09.2019.491). The study was carried out in accordance with the ethical principles and the Helsinki Declaration. Informed consents of the patients were obtained. This research was also registered to the "clinicaltrials.gov" (Registration No: NCT04803669)
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