High-energy Flux Density Extracorporeal Shock-wave Therapy Versus Therapeutic Steroid Injection in Costochondritis: A Single-Blind, Randomised Controlled Study

Extrakorporale Stoßwellentherapie mit hoher Energieflussdichte im Vergleich zur therapeutischen Steroidinjektion bei Costochondritis: Eine einfach blinde, randomisierte, kontrollierte Studie

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Keywords

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ABSTRACT

Background This study aims to investigate the effects of extracorporeal shock-wave therapy (ESWT) and intra-articular steroid injection (IASI) on pain, depression, quality of life and pressure pain threshold (PPT) in patients with costochondritis. **Methods** A total of 67 patients diagnosed with costochondritis were included. Patients were divided into 2 groups. Group 1 (n=34) received high-energy flux density (H-ESWT) (>0.28 mJ/mm²) for a total of 7 sessions at 3-day intervals. Group 2 (n=33) received IASI twice at 2-week intervals. At baseline and one month after treatment, Visual Analog Scale (VAS), Short Form-36 (SF-36), Pittsburgh Sleep Quality Index (PSQI), Beck Depression Inventory (BDI) scores and PPT values were compared.

Results There was a statistically significant decrease in VAS scores after treatment compared with baseline scores in both groups. The PPT and SF-36 subscale scores were also statistically significantly higher (p < 0.05). After treatment, VAS and PPT showed a significantly better improvement in Group 1 compared to Group 2. There was a significant correlation between VAS and SF-36 physical functioning as well as pain subscales in Group 1 and a significant correlation between VAS and SF-36 physical functioning to Group 2.

Conclusions Our data suggest that both treatments H-ESWT and IASI are effective in costochondritis patients. Of note, H-ESWT has a stronger effect on pain and PPT scores.

ZUSAMMENFASSUNG

Hintergrund Ziel dieser Studie ist es, die Auswirkungen der extrakorporalen Stoßwellentherapie (ESWT) und der intraartikulären Steroidinjektion (IASI) auf Schmerzen, Depressionen, Lebensqualität und Druckschmerzschwelle (PPT) bei Patienten mit Costochondritis zu untersuchen.

Methoden Insgesamt wurden 67 Patienten mit der Diagnose einer Costochondritis eingeschlossen. Die Patienten wurden in 2 Gruppen eingeteilt. Gruppe 1 (n = 34) erhielt für insgesamt 7 Sitzungen in 3-tägigen Intervallen eine hochenergetische Flussdichte (H-ESWT) (> 0,28 mJ/mm²). Gruppe 2 (n = 33) erhielt 2-mal im Abstand von 2 Wochen IASI. Zu Studienbeginn und einen Monat nach der Behandlung wurden die Werte für Visual Analog Scale (VAS), Short Form-36 (SF-36), Pittsburgh Sleep Quality Index (PSQI), Beck Depression Inventory (BDI) und PPT-Werte verglichen. **Ergebnisse** Es gab eine statistisch signifikante Abnahme der VAS-Werte nach der Behandlung im Vergleich zu den Ausgangswerten in beiden Gruppen. Die Subskalenwerte für PPT und SF-36 waren ebenfalls statistisch signifikant höher (p<0,05). Nach der Behandlung zeigten VAS und PPT eine signifikant größere Verbesserung in Gruppe 1 im Vergleich zu Gruppe 2. Es bestand ein signifikanter Zusammenhang zwischen der VAS und der körperlichen Funktionsfähigkeit nach SF-36, sowie

Schmerz-Subskalen in Gruppe 1 und eine signifikante Korrelation zwischen der VAS und der körperlichen Funktionsfähigkeit nach SF-36 in Gruppe 2.

Schlussfolgerungen Unsere Daten deuten darauf hin, dass sowohl die H-ESWT als auch die IASI-Behandlung bei Patienten mit Costochondritis wirksam sind. Die H-ESWT hat dabei eine stärkere Wirkung auf Schmerzen und PPT-Scores.

Introduction

Costochondritis is a painful condition caused by inflammation of sternocostal joints without swelling. The causes of costochondritis are unknown, but genetic, viruses, and injury are possible causes. Inflammation can occur in bilateral sternocostal junction, but is usually only on one side. There is no specific diagnostic test for costocontritis. The diagnosis of costochondritis is made on the physical examination with tenderness and pain. Pain is typically reproducible by palpation and radiates to chest [1]. It affects as many as 30% of patients presenting to emergency departments with chest pain [2]. The pain may occur during physical activity or inspiration [3].

Although no consensus has been established upon the treatment of costochondritis, treatment usually focuses on pain relief with acetaminophen, non-steroidal anti-inflammatory drugs, physical therapy modalities, and intra-articular steroid injections (IASI) [4, 5].

Extracorporeal shock wave therapy (ESWT) is a non-invasive procedure which has been proven to be effective in treating musculoskeletal system diseases including PF, calcific tendinopathies, lateral and medial epicondylitis, and myofascial pain syndrome (MPS) [6–8]. Although the mechanism of action of ESWT in costochondritis is still unclear, the energy crisis hypothesis may explain how ESWT affects other conditions [9, 10]. The mechanisms through which ESWT exerts its therapeutic effects are thought to be increased tissue perfusion, increased vascularization, and altered pain stimuli in ischemic tissues by an increased intake of calcium.

In the literature, there are some reports investigating the efficacy of ESWT in costochondritis; however, there is a very limited number of studies comparing ESWT and IASI in this patient population. In the present study, we, therefore, aimed to compare the effects of ESWT vs. IASI on pain, depression, quality of life, and pressure pain threshold (PPT) in patients with costochondritis.

Methods

Study population

This single-blind, prospective, randomized-controlled clinical study was conducted at the University of Health Sciences, Umraniye Training and Research Hospital, Musculoskeletal Outpatient Clinic between September 2019 and February 2020. A total of 67 patients (10 males, 57 females; mean age: 43.4 ± 13.2 years; range, 19–67 years) with the diagnosis of costochondritis were included in the study. Inclusion criteria were as follows: having a clinical diagnosis of costochondritis; reproducible pain by palpation of costal cartilages and sternocostal ribs radiating to the chest wall; and having

persistent pain at least for six months as assessed by a Visual Analog Scale (VAS) [11]. Exclusion criteria were as follows: no prior treatment including ESWT and steroid injection within the past 6 months; having a diagnosis of other cardiovascular and lung diseases; having a malignancy, vitamin D deficiency, other inflammatory disease, pregnancy, cardiac pacemaker, local infections, or severe cardiac and renal diseases. To rule out other cardiovascular and lung diseases, all patients underwent a detailed physical examination and laboratory testing. In addition, posterioanterior (PA) and lateral plain chest radiographs, electrocardiography and thoracic computed tomography (CT) scans were obtained. A written informed consent was obtained from each patient. The study protocol was approved by the University of Health Sciences, Umraniye Training and Research Hospital Ethics Committee (06/09/2019 54132726-000-18027). The study was conducted in accordance with the principles of the Declaration of Helsinki.

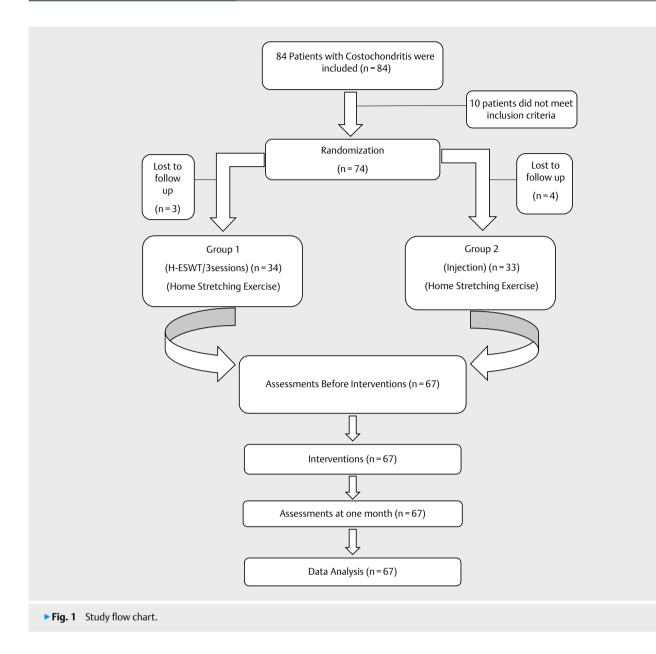
Randomization

Randomization was performed using sequentially numbered, opaque, sealed envelopes. The investigators who assessed pre- and post-treatment measurements were not allowed to attend to the intervention period and were blinded to group allocation. The patients were divided into two groups. Group 1 (n = 34) received high-energy flux density (H-ESWT) (0.26 mJ/mm²) for a total of seven sessions at 3-day intervals. Group 2 (n = 33) received IASI for 2 times at 2-week intervals. Data including baseline demographic characteristics of all patients were recorded. The study flow chart is shown in **Fig. 1**.

Interventions

The ESWT group received ESWT using Modus Inceler Medikal, Ankara, Turkey. A total of 7 sessions of focused ESWT was performed at 3-day intervals. The ESWT was applied at costal cartilages and sternocostal joints at 500 pulses/point, a total of 1,500 to 3,000 pulses/session 1.5 to 3 bars with H-ESWT (>0.28 mJ/mm²) in each session.

The IASI group received IASI for 2 times at 2-week intervals. 2 mL of betamethasone was injected to each painful point by a specialist. After the patient was given the appropriate position, the costosternal joints to be injected were determined and marked with a ballpoint pen. The area to be injected was cleaned without touching it. After wearing a sterile glove, corticosteroid was injected into the joints at a 90 degree angle after negative aspiration before injection. After the injection, pneumothorax was excluded with chest radiograph.



Chest stretching exercises were given to all patients in both groups. All patients were instructed about the exercises by physiotherapists and the first set of exercises were performed under the supervision of clinical physiotherapists. All patients were instructed to do 10 repetitions of each exercise set 3 times a day for 2 weeks.

Primary outcome measures

The PPT was defined as the point at which a sensation of pressure changed into a sensation of pain. The PPT was evaluated using the Baseline[®] Dolorimeter-22 lb Capacity (Fabrication Enterprises, NY, USA). Pressure pain in the upper trapezius was measured using a baseline dolorimeter (Pain Diagnosis and Treatment Inc., CA, USA). The instrument consists of a gauge attached to a hard rubber tip 1 cm in diameter. The dial gauge can be calibrated in kg or pounds (lb), ranging from 1 to 30 kg or from 1 to 60 lb at an interval of 0.25 kg or 0.5 lb. The force recorded is the amount of pressure

which causes pain. Inter-individual reliability is good to excellent (interclass correlation coefficient = 0.75–0.89) [12].

Secondary outcome measures

All pre- (at baseline) and post-treatment (at one month) measurements were evaluated by a single investigator. The VAS was used to evaluate pain severity. The score ranges from 0 to 10, and 0 indicates no pain, while 10 indicates unbearable pain.

The Short Form-36 (SF-36), which consists of 8 subscales and 36 items, was used to evaluate physical and mental health of the patients. It is a valid survey for the evaluation of quality of life and consists of the following subscales: physical functioning (PF), limitations of daily activities by difficulty in physical role (DPR), pain severity by bodily pain (BP), rating of health by general health (GH), energy and fatigue by vitality (VT), limitations of daily activities by social functioning (SF), and limitation of regular daily activities by difficulty in emotional role (DER) and mental health (MH) [13].

The Beck Depression Inventory (BDI) was used to evaluate depressive symptomatology. It is a 21-item, self-reporting questionnaire which measures characteristic attitudes and symptoms of depression. The maximum total score is 63, and higher scores indicate greater symptom severity. The validity and reliability studies of the Turkish version of the BDI have been shown [14].

Statistical analysis

A power analysis was performed using the G * Power version 3.1.0 software (Heinrich Heine University, Düsseldorf, Germany) and the sample size was calculated. Based on an alpha value of 0.05 for statistical significance, 33 patients in each group could achieve 80% statistical power. Finally, a total of 66 patients were planned to be recruited in both groups. Assuming a dropout of 15%, 75 patients were expected to be included.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 25.0 software (IBM Corp., Armonk, NY, USA). Descriptive data were expressed in mean ± standard deviation (SD), or number and frequency. The Kolmogorov-Smirnov test was used for normality test of data. The Mann-Whitney U test was performed to analyze non-parametric data. The Wilcoxon signed-rank test was used to compare non-normally distributed data. The Pearson correlation analysis was done to analyze possible correlations between the variables. A *p* value of < 0.05 was considered statistically significant.

Results

Of a total of 67 patients, 57 were females and 10 were males with a mean age of 43.4 ± 13.2 (range, 19-67) years. Totally, there were 34 (50.74%) patients in Group 1 and 33 patients (49.26%) in Group 2. There were no statistically significant differences in the baseline demographic characteristics between the groups (p>0.05). Demographic characteristics of the patients are shown in **Table 1**.

No ESWT-related side effects or tissue damage were seen in any of the patients in the ESWT group. Also, there was no statistically significant difference in the baseline VAS, BDI, PPT, SF-36 subscale scores between the groups (p>0.05). However, there was a statistically significant decrease in the VAS scores at month after the treatment in both groups, compared to baseline scores (p < 0.05), although the decrease was statistically significantly higher in the ESWT group (p<0.05). In addition, there was a statistically significant increase in the SF-36 subscale and PPT scores at one month after the treatment in both groups (p < 0.05) with a statistically significantly higher increase in the ESWT group (p < 0.05). Although there was a statistically significant decrease in the BDI scores at one month after the treatment in both groups, compared to baseline scores (p = 0.854), there was no statically significant difference between the groups. Pre- and post-treatment VAS, BDI, SF-36, and PPT scores in Group 1 and Group 2 are presented in > Table 2.

The correlation analysis revealed a moderate, negative, and statistically significant relationship between the changes in the VAS scores and changes in the SF-36 PF scores (r = -0.541) after the treatment in the ESWT group. In addition, there was a weak, negative, and statistically significant relationship between the changes in the VAS and the changes in the SF-36 BP subscale scores (r = -0.472) after the treatment in the ESWT group. In the IASI group,

		Group 1 (H-ESWT)	Group 2 (IASI)	Total	
		n (%)	n (%)	n (%)	
Age, years, mean ± SD (range)		19-44 (33.6±13.4)	23-47 (33.8±13.2)	19-47 (33.4±13.2)	
Sex, n (%)	Male	5 (14.7)	5 (14.2)	10 (14.9)	
	Female	29 (85.3)	28 (84.8)	57 (85.1)	
Marital status, n (%)	Married	29 (85.3)	25 (75.8)	54 (80.6)	
	Single	5 (14.7)	8 (24.2)	13 (19.4)	
Educational status, n (%)	None	2 (5.9)	1 (3.0)	3 (4.5)	
	Primary	17 (50.0)	15 (45.5)	32 (47.8)	
	Secondary	6 (17.6)	7 (21.2)	13 (19.4)	
	High	2 (5.9)	3 (9.1)	5 (7.5)	
	Graduate/Post graduate	7 (20.6)	7 (21.2)	14 (20.9)	
Income level, n (%)	Low	23 (67.6)	17 (51.5)	40 (59.7)	
	Middle	5 (14.7)	10 (30.3)	15 (22.4)	
	High	6 (17.6)	6 (18.2)	12 (17.9)	

Table 1 Baseline demographic characteristics of the patients.

ESWT, extracorporeal shock wave therapy; IASI, intra-articular steroid injection; SD, standard deviation.

Table 2 Comparison of VAS, BDI, SF-36, and pain threshold scores before and after treatment in ESWT and IASI groups.

		Group 1 (H-ESWT)	Group 2 (IASI)	(inter-group) p ¹	
		Mean±SD (range)	Mean±SD (range)		
VAS	Pre-treatment	6.35±1.04	6.33±0.98	0.984	
	Post-treatment	2.73±0.93	3.66±0.98	< 0.05*	
	Pre-post-treatment p ²	<0.05*	<0.05*		
BDI	Pre-treatment	14.29±8.58	14.45±8.09	0.905	
	Post-treatment	9.82±6.14	10.12±6.30	0.845	
	Pre-post-treatment p ²	<0.05*	<0.05*		
SF-36 PF	Pre-treatment	79.8±13.9	81.6±15.0	0.478	
	Post-treatment	92.7±9.14	90.1±11.4	0.301	
	Pre-post-treatment p ²	<0.05*	<0.05*		
SF-36 DPR	Pre-treatment	44.1±28.9	59.0±32.3	0.049	
	Post-treatment	89.7±19.5	81.0±25.0	0.119	
	Pre-post-treatment p ²	<0.05*	<0.05*		
SF-36 DER	Pre-treatment	41.1±27.2	61.6±29.0 (35)	0.008*	
	Post-treatment	87.2±18.3 (65)	86.8±20.3 (45)	0.935	
	Pre-post-treatment p ²	<0.05*	<0.05*		
SF-36 VT	Pre-treatment	40.1±24.2 (32)	39.5±24.0 (32)	0.920	
	Post-treatment	56.4±21.6 (60)	48.6±23.5 (40)	0.101	
	Pre-post-treatment p ²	<0.05*	<0.05*		
F-36 MH	Pre-treatment	52.4±21.6 (25)	53.2±21.3 (32.5)	2.5) 0.860	
	Post-treatment	65.0±18.6 (62.5)	61.2±20.8 (37.5)	0.428	
	Pre-post-treatment p ²	<0.05*	<0.05*		
F-36 SF	Pre-treatment	66.7±23.9 (32.5)	67.6±25.1 (32.5)	0.888	
	Post-treatment	84.2±13.0 (62.5)	79.3±17.5 (45)	0.194	
	Pre-post-treatment p ²	<0.05*	<0.05*		
SF-36 BP	Pre-treatment	53.7±25.0 (30)	54.2±25.8 (30)	0.929	
	Post-treatment	80.5±14.2 (60)	74.0±20.4 (40)	0.135	
	Pre-post-treatment p ²	<0.05*	<0.05*		
F-36 GH	Pre-treatment	55.1±22.2	54.3±22.1	0.885	
	Post-treatment	65.4±20.8	61.2±20.8	0.410	
	Pre-post-treatment p ²	<0.05*	<0.05*		
PPT	Pre-treatment	3.93±1.04	3.98±1.09	0.793	
	Post-treatment	11.7±1.28	10.8±1.66	< 0.05*	

ESWT, extracorporeal shock wave therapy; IASI, intra-articular steroid injection; SD, standard deviation; VAS, Visual Analog Scale; SF-36 PF, Short Form-36 physical functioning; SF-36 DPR, Short Form-36 difficulty in physical role; SF-36 DER, Short Form-36 difficulty in emotional role; SF-36 VT, Short Form-36 vitality; SF-36 MH, Short Form-36 mental health; SF-36 SF, Short Form-36 social functioning; SF-36 BP, Short Form-36 bodily pain; SF-36 GH, Short Form-36 general health; BDI, Beck Depression Inventory; PPT, pressure pain threshold; 1Mann-Whitney U test; 2Wilcoxon signedrank test * p<0.05.

there was also a weak, negative, and statistically significant relationship between the changes in the SF-36 PF and the changes in the VAS scores (r = -0.419) after the treatment. The results of the correlation analysis of all scales in the ESWT and control groups are summarized in **Table 3**.

Discussion

In the present study, we investigated the effects of ESWT and IASI on quality of life, mental health, and PPT in patients with costochondritis. Our study results showed that that H-ESWT was more effective than IASI on pain, quality of life, and PPT scores in this patient population.

Table 3 Correlation analysis results.							
Group			VAS				
Group 1	BDI	r	0.176				
(H-ESWT)		р	0.319				
	SF-36 PF	r	-0.541**				
		р	0.001				
	SF-36 DPR	r	-0.278				
		р	0.111				
	SF-36 DER	r	-0.064				
		р	0.721				
	SF-36 VT	r	-0.119				
		р	0.501				
	SF-36 MH	r	-0.119				
		р	0.501				
	SF-36 SF	r	-0.267				
		р	0.126				
	BP	r	-0.472**				
		р	0.005				
	GH	r	-0.158				
		р	0.372				
	РРТ	r	-0.161				
		р	0.362				
Group 2 (ISAI)	BDI	r	0.192				
		р	0.286				
	SF-36 PF	r	-0.419**				
		р	0.015				
	SF-36 DPR	r	-0.271				
		р	0.127				
	SF-36 DER	r	0.237				
		р	0.184				
	SF-36 VT	r	0.121				
		р	0.502				
	SF-36 MH	r	0.162				
		р	0.369				
	SF-36 SF	r	-0.171				
		р	0.342				
	BP	r	-0.095				
		р	0.600				
	GH	r	0.129				
		р	0.474				
	PPT	r	-0.137				
		р	0.448				

ESWT, extracorporeal shock wave therapy; IASI, intra-articular steroid injection; SD, standard deviation; VAS, Visual Analog Scale; SF-36 PF, Short Form-36 physical functioning; SF-36 DPR, Short Form-36 difficulty in physical role; SF-36 DER, Short Form-36 difficulty in emotional role; SF-36 VT, Short Form-36 vitality; SF-36 MH, Short Form-36 mental health; SF-36 SF, Short Form-36 social functioning; SF-36 BP, Short Form-36 bodily pain; SF-36 GH, Short Form-36 general health; BDI, Beck Depression Inventory; PPT, pressure pain threshold; Pearson correlation analysis * p < 0.05. Steroids have a broad set of physiological effects in the treatment and prognosis of inflammatory diseases [15]. Ostergaard et al. [16] showed that one or more injections into a joint with aseptic arthritis could significantly alter the joint status as pain decreased and joint mobility increased.

Extracorporeal shock wave therapy is a proven treatment modality in several conditions such as calcific tendinopathies, lateral and medial epicondylitis, and MPS [6–8]. Based on the literature data, in the present study, we used this method vs. IASI in patients with costochondritis which is an inflammatory condition and responds well to anti-inflammatory drugs. In general, ESWT exerts its effects through mechanotransduction which produces pressure and delivers tensile and shearing forces by shock waves to the cells and, therefore, the extracellular matrix messengers are liberated and a varying number and groups of genes in the cell nucleus are activated [17]. Although the working mechanism of ESWT has not been fully demonstrated, several possible mechanisms have been proposed. In a study, ESWT was shown to inhibit overstimulation of the nerves and nociceptors and increased the blood flow, resulting in to pain relief through reduced muscle stiffness and contractions [17] Similarly, ESWT disrupted non-myelinated fibers, decreased the production of substance P level at the dorsal root ganglia, and relieved musculoskeletal pain [18, 19].

In general, ESWT can be classified into 3 categories based on its energy levels: low-energy (<0.08 mJ/mm²), medium-energy (0.08– 0.28 mJ/mm²), and high-energy (0.28 mJ/mm²) [20–22]. High-energy ESWT can induce fragmentation and destruction of solid bodies such as kidney stones, gallstones, and body tissues and is often requires sedation or anesthesia, while low-energy ESWT (L-ESWT) exerts its therapeutic effect through neurophysiological mechanisms and does not require the use of sedation or anesthesia and can be applied in the outpatient setting [23]. However, there is no consensus on the optimal therapeutic intensity and dose-response relation [24].

In a study conducted by Müller et al., [25] focused H-ESWT was used in MPS patients and decreased VAS scores at 3 months. Gur et al. [26] used focused H-ESWT and compared 3 sessions vs. a single session of treatment in MPS patients and reported that 3-session treatment improved pain more effectively. In another study, Park et al. [27] examined the efficacy of H-ESWT vs. L-ESWT in MPS patients of the upper trapezius and found improvements in the Verbal Numeric Pain Scale and pressure threshold in both groups, although it was statistically significant in the H-ESWT group. Similarly, Chow et al. [28] divided 57 patients with chronic heel pain into 3 groups to receive either fixed energy density or maximum tolerable energy density or control treatment (30 impulses at a frequency of 3 Hz at the lowest level [0.03 m]/mm²]) once a week for 3 weeks. The maximum tolerable energy density group showed a significant improvement in the FFI and pain scores, while the control group had no improvement after treatment. This finding indicates that the delivery of ESWT with a maximum tolerable energy density is more effective than a fixed energy density. In a meta-analysis of randomized, placebo-controlled trials, the efficacy of different energy levels of ESWT was examined in patients with plantar fasciitis and focused ESWT was found to be more effective than radial ESWT and H-ESWT/medium energy-ESWT were more effective than L-ESWT in the long-term follow-up [29]. In addition, anesthetic premedication was shown to reduce the effectiveness of treatment. Altogether, these findings suggest that an increased number of sessions of ESWT and its use in high-energy density may promote its effectiveness on pain, depression, quality of life, and PPT. Consistent with the previous studies, we used H-ESWT for 7 sessions in our study group. In the current study, we found statistically significant improvements in the SF-36 and BDI scores and pain relief in our patients with costochondritis after the treatment. These findings indicate the importance of H-ESWT for a high number of sessions in pain management in patients with costochondritis. In addition, we found a significant correlation between the VAS and SF-36 PF and BP subscale scores in the ESWT group.

Weak correlation between SF-36 BP and VAS after treatment in the H-ESWT group indicates a faster improvement in ESWT group in patients' pain. However, there was a weak, negative, and statistically significant relationship between the changes in the SF-36 PF and the changes in the VAS scores in the IASI group, suggesting that H-ESWT for a higher number of sessions than a lower number of sessions may be a more effective treatment than IASI.

Nonetheless, there are some limitations to this study. First, relatively small sample size and the presence of a non-treatment group might have affected the results. Second, as the present study included only costochondritis patients, the results cannot be generalized to the general population. Third, the treatment results were only able to be evaluated at one month and, thus, its long-term outcomes are unclear. Further large-scale, long-term studies are needed to confirm these findings.

Conclusions

In conclusion, pain management is of utmost importance in the treatment of costochondritis with reduced pain and improved quality of life, depression, and PPT scores. As data regarding the efficacy of ESWT vs. IASI are scarce, the present study provides valuable implications to guide physicians in the treatment of costochondritis. Based on our study results, we suggest that H-ESWT for a high number of sessions is more effective than IASI in patients with costochondritis.

Competing interest

The authors declare that they have no conflict of interest.

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