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Radial Extracorporeal Shock Wave Versus Diclofenac Phonophoresis on Myofascial Trigger Points of Upper Fibers of Trapezius

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> Abstract --- Patients with myofascial pain not only suffer from decreased functional status as a result of the musculoskeletal pain but, also they suffer from impaired mood and decreased quality of life. The purpose of this study was to compare between the effect of radial extracorporeal shock wave therapy (rESWT) and diclofenac phonophoresis (PH) on pain intensity, threshold and neck functional abilities in patients with myofascial trigger points (MTrps) of upper fibers of trapezius. Methodology: Forty five patients of both genders aged from 18- 30 years old with MTrps of upper fibers of trapezius, were assigned randomly and equally into 3 groups: Group A: consisted of 15 patients received rESWT on upper fibers of trapezius in addition to conventional physical therapy treatment. Group B: consisted of 15 patients received PH of diclofenac sodium, in addition to conventional physical therapy treatment. Group C: consisted of 15 patients received the conventional physical therapy treatment only. Results: There was no significance difference between groups pretreatment in all measured variables; while post-treatment measured values revealed that there was significance improvement in all measured variables in shockwave group at the expense of Diclofenac PH and control groups.

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022. **Corresponding author**: Kasem, R. M. A. A. E.-L.; Email: Dr.ramykasem88@hotmail.com Manuscript submitted: 18 Nov 2021, Manuscript revised: 27 Feb 2022, Accepted for publication: 09 March 2022 *Keywords*---diclofenac phonophoresis, extracorporeal shock wave, fibers trapezius, myofascial trigger point.

Introduction

Myofascial pain is a notable health problem and it is estimated that about 85% of general population complain from myofascial pain. It includes a collection of the sensory, motor, and autonomic symptoms such as local and referred pain, decreased Range of Motion (ROM), and weakness. The effect of myofascial pain can be quite severe causing not only decreased functional status as a result of the musculoskeletal pain, but also impaired mood and decreased quality of life (Khalil & Abdulla, 2018).

Upper fibers of trapezius muscle appear to be commonly affected by MTrps, and it's the most sensitive to the pressure of an algom¬eter and cause pain attacks in about 85% of the population (Ji et al., 2012). Active-MTrps contained in the upper trapezius frequently induce tension headache, neck pain, vertigo, muscle dysfunction, and limited neck and shoulder ROM (Sarrafzadeh et al., 2012).

Several studies have demonstrated the efficacy of rESWT for pain relief and clinical improvement in patients with MPS (Király et al., 2018). The principle of rESWT is the production of mechanical energy by high air pressure. This energy is propagated in the tissues as the primary therapeutic effect, and the secondary effects refer to the biological effects which may lead to tissue repair and regeneration by causing micro-functional and micro-structural changes (Király et al., 2018).

Also, Phonophoresis (PH) is another treatment method which frequently used along with anti-inflammatory topical drugs for the management of pain and inflammation in musculoskeletal conditions (Unlu et al., 2008). It's the use of ultrasound (US) to increase in skin absorption and penetration topically applied drugs. It's a noninvasive, painless method that has fewer side effects and well tolerated (Ustun et al., 2014). So this study was conducted to compare between the effect of rESWT and diclofenac PH on pain intensity, pain threshold and neck functional abilities in patients with MTrps of upper fibers of trapezius.

Subjects, Materials and Methods

This study was conducted in the Out-patient clinic of Modern University for Science and Technology, to compare the effect of rESWT and diclofenac PH on treatment of MTrps of upper fibers of trapezius through March 2021 to September 2021. The study was ethically approved by the research Ethical Committee of the Faculty of Physical Therapy, Cairo University, Egypt (P.T.RE/009/002037).

Design of the study

Simple randomized control study (pre and posttest experimental study).

Participants' selection

Patients included in the study were assigned randomly and equally into 3 groups, as shown in flow chart of the study (Figure 1):



Figure 1. A flow diagram of the patients' recruitment and retention throughout the study

- Group A: (experimental group) this group consisted of 15 patients from both genders, they received rESWT on upper fibers of trapezius with parameters (1,000 impulses, power of 60 mJ, frequency of 16 Hz) in addition to conventional physical therapy treatment, each patient was subjected to the selected program for 4 sessions through 4 weeks (1 session/week) and was assessed before and after completing the sessions (Ji et al., 2012).
- Group B: (experimental group) this group consisted of 15 patients from both genders, they received PH of diclofenac sodium 10-mg gel (Unlu et al., 2008), with parameters (1 MHz, continuous 1.5 w/cm2 for 5 minutes, 5 cm2 crystal head with an effective radiating area of 4.0 cm2 ±1.0 was utilized) in addition to conventional physical therapy treatment, each patient was subjected to the selected program for 8 sessions through 4 weeks (2 sessions/week) and was assessed before and after completing the sessions (Srbely & Dickey, 2007).
- Group C: (control group) this group consisted of 15 patients from both genders, they received the conventional physical therapy treatment only (manual isometric strengthening exercises for cervical extension, flexion, bilateral side bending and bilateral rotation (moderate resistance from the patient's maximum strength, hold for 10 seconds, for 10 repetitions) passive stretching of the upper fibers of trapezius muscle (stretching will be held for 30 seconds, and repeated 3 times) and deep friction massage, each patient was subjected to the selected program for 8 sessions through 4 weeks (2 sessions/week) and was assessed before and after completing the sessions (Simons et al., 1999).

Inclusion criteria

Patients with ages range from 18 to 30 years old (Esenyel et al., 2000). Patients from both genders. Patients suffering from at least 2 active-MTrps along area of upper fibers of trapezius in both sides (fulfilling the diagnostic criteria of Travell and Simons) with moderate symptoms lasting at least 1 month (Simons et al., 1999). All patients' visual analogue scale before treatment was 6 to 7.

Exclusion criteria

Signs of serious spinal pathology including significant trauma and widespread neurologic changes. Current radiating symptoms (and/or neurological deficit). History of spinal surgery, fracture or malignancy. Specific neck pain, defined as herniated disc, ankylosing spondylitis, spondylolisthesis or other relevant (de Araujo Cazotti et al., 2018).

Instrumentations

Assessment tools

All participants will be assessed before and after treatment process by using:

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Visual analogue scale

The visual analog scale consists of a line, usually 10 cm long, ranging from no pain or discomfort (zero), to the worst pain that could possibly feel (10). The VAS is considered to be one of the best methods available for the estimation of the intensity of pain. It provides a continuous scale for magnitude estimation and consists of a straight line, the ends of which are defined in terms of the extreme limits of pain experience (Boonstra et al., 2008). The VAS is considered valid and reliable for assessment of pain intensity (Breivik et al., 2008).

Pressure algometer

Pressure algometry is a valid and reliable method used for evaluation of sensitivity to pain and the assessment of pressure perception. These results were obtained by a pressure (force) gauge attached to a rubber plunger with an OS-cm diameter consisting of a rubber disk plunger with an 1-cm2 surface (diameter = 1.12 cm) and gauge with a range of 11 kg (Fischer, 1987).

Neck disability index

Neck disability index scores vary from 0 to 50, where 0 is considered "no activity limitation" and 50 is considered "complete disability", consisting of 10 sections (Section 1: Pain Intensity, Section 2: Personal Care, Section 3: Lifting, Section 4: Reading, Section 5: Headaches, Section 6: Concentration, Section 7: Work, Section 8: Driving, Section 9: Sleeping, Section 10: Recreation) (Guyatt et al., 1987). Higher scores represent greater disability and result can expressed as a percentage (score out of 100) by doubling the total score.

Instrumentations for treatment

Shock wave therapy

The shock wave was connected to a handheld or small shock wave applicator device; where in the external housing of the device was hermetically sealed in a non-electrically conductive insulating skin membrane being of a polymer material, preferably a silicone rubber or polyurethane rubber. Shockwave therapy is a multidisciplinary device used in orthopaedics, physiotherapy, sports medicine, urology and veterinary medicine. Its main assets are fast pain relief and mobility restoration. Together with being a non-surgical therapy with no need for painkillers makes it an ideal therapy to speed up recovery and cure various indications causing acute or chronic pain (Haupt, 2002). Shockwave therapy parameters (1,000 impulses, power of 60 mJ, and frequency of 16 Hz)

Ultrasound

Therapeutic ultrasound unites (ProSound ULS-1000-Medserve Limited. United Kingdom) which had the following criteria: Two transducer sizes, Microprocessor controlled digital screen. Easy to read digital screen offered accurate description of all treatment parameters, over heating temperature sensing monitor and protection (Ay et al., 2011; Ali et al., 2014; Yoo et al., 2020). This sensor was very

important when dealing with experimental animals that couldn't describe the sense of overheating. If the sensor in the transducer head detected a temperature of over 41oC, the word, "Over heat" will flash on the display and the unit would emit three beeps, the unit is inoperable before the heat lowers down to the proper level and the treatment time will be frozen temporarily. When the sensor checks the temperature and finds it has returned to the proper level, the unit will emit two "beeps" and the word "Over heat" will disappear and the display will return to normal. User may press, Start, to continue the treatment with existing parameters. Ultrasound parameters of (1 MHz, continuous 1.5 w/cm2 for 5 minutes, 5 cm2 crystal head with an effective radiating area of 4.0 cm2 ±1.0 was utilized) (Baker et al., 2001).

Procedures

Procedures for assessment

- Assessment of pain intensity The therapist explained to the patients the visual analog scale which consists of a line, usually 10 cm long, ranging from no pain or discomfort (zero), to the worst pain that could possibly feel (10), to determine pain intensity before and after treatment.
- Assessment of pain Threshold During pain threshold assessment the patient sit in a comfortable position and the therapist standing behind him. The tip of the algometer was positioned on TP after allocating it by the therapist through palpation. By pushing the algometer, the force applied to the tibia gradually increased. The participants were not allowed to see the algometer display in any moment, and, as soon as the volunteers experienced a painful sensation, they said "stop", the algometer was immediately released and the force (in Kpa) was read from the display. The technique applied three time successful times and the therapist takes the mean of the three readings for analysis.
- Assessment of neck functional ability The therapist explained to the patients the Neck disability index. The patient was asked to mark each section which most closely described his problem. Each patient considered that two of the statements in any one section may relate to him, but the patient should only mark the box which most closely described his problem.

Procedures for treatment

- Group A (Radial extracorporeal shock wave + conventional therapy) The patient was positioned in a relaxed prone lying position with the head at neutral position in head place in the plinth; the therapist was standing at head level grasping the shockwave probe. Shock wave probe was held stationary in a perpendicular direction on TP in upper fibers of trapezius muscle for 2000 pulses.
- Group B (Diclofenac phonophoresis + conventional therapy) The patient was positioned in a relaxed prone position with the head at neutral position in head place in the plinth; the therapist was standing at head level grasping the US probe. It was held in a perpendicular direction

on TP in upper fibers of trapezius muscle, using diclofenac sodium 10-mg gel as a conducting medium between head of US and patient's skin (Unlu et al., 2008). The application was done in circular movement for 5 minutes on each TP.

- Group c (conventional therapy only):
 - Deep friction massage

The patient was positioned in a relaxed prone lying position with the head at neutral position in head place in the plinth; the therapist was standing at head level grasping the trapezius muscle. The technique was applied at right angles using his thumb to the fibers comprising the tissue containing the lesion in a relaxed and shortened position. Deep transverse friction massage on MTrps of upper fibers of trapezius was done for 5 minutes as shown in figure 3-8 (Kaur & Kapila, 2017).

• Passive stretch

The patient was positioned in a relaxed supine lying position with the head at neutral position; the therapist was standing at head level one hand support shoulder and other one stretch trapezius muscle as shown in figure (3-9). Passive stretching of the upper fibers of trapezius muscle (stretching was held for 30 seconds, and repeated 3 times in each session) (Kay & Blazevich, 2012).

• Isometric strengthening exercises of neck muscles: The patient was positioned in a relaxed sitting position with the head at neutral position; the therapist was standing beside patient grasping the patient's head. Isometric exercise for cervical extension, flexion, bilateral side bending and bilateral rotation (resistance was moderate from the patient's maximum strength, hold for 10 seconds, for 10 repetitions).

Sample size calculation

The sample size for this study was calculated using the G*power program 3.1.9 (G power program version 3.1, Heinrich-Heine-University, Düsseldorf, Germany). Sample size calculation based on F-tests (MANOVA: Special effects and interactions), Type I error (a) = 0.05, power (1- β error probability) = 0.80, Pillai V = 0. 2497140, and effect size f² (V) = 0. 1426704 with 3 independent groups comparison for pressure algometer as a major variable outcome. The appropriate minimum sample size for this study was 45 patients (15 patients in each group as a minimum).

Data collection and analysis

Data were screened, for normality assumption test and homogeneity of variance. Normality test of data using Shapiro-Wilk test was used, that reflect the data was normally distributed (P>0.05) after removal outliers that detected by box and whiskers plots. Additionally, Levene's test for testing the homogeneity of variance revealed that there was no significant difference (P>0.05). All these findings allowed the researcher to conducted parametric and non-parametric analysis. The data is normally distributed and parametric analysis is done.

The statistical analysis was conducted by using statistical SPSS Package program version 25 for Windows (SPSS, Inc., Chicago, IL). Data are expressed as mean and

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standard deviation for demographic data, VAS, NDI, right pressure algmoeter, and left pressure algmoeter variables. Multivariate analysis of variance (MANOVA) used to compare the tested major variables of interest at different tested groups and measuring periods. Mixed design 3 x 2 MANOVA-test was used, the first independent variable (between subject factors) was the tested group with 3 levels (group A, group B, and group C). The second independent variable (within subject factor) was measuring periods with 2 levels (before and after treatment). Bonferroni correction test was used to compare between pairwise within and between groups of the tested variables which F was significant from MANOVA test. All statistical analyses were significant at probability ($P \le 0.05$).

Results

In the current study, a total of 45 patients participated and they were randomly distributed into 3 groups (15 patients/group). No significant differences in demographic data for age (P=0.103; P>0.05), weight (P=0.423; P>0.05), height (P=0.880; P>0.05), and gender (P=0.734; P>0.05) among groups A, B, and C (Table 1).

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items	Group A	Group A Group B Group C		P-value
	(n=15)	(n=15)	(n=15)	
Age (year)	21.00 ±2.23	23.87 ±3.66	25.20 ±2.51	0.103
Weight (kg)	78.48 ±10.16	78.33 ±8.39	75.67 ±6.64	0.423
Height (cm)	171.07 ±7.61	171.27 ±5.68	170.00 ±4.73	0.880
BMI (kg/m ²)	26.82 ±3.18	26.70 ±2.49	26.18 ±2.27	0.734
Group A: shockwave group: Group B: diclofenac group: Group C: control				

Table 1				
Comparison	of demographic data	among 3 groups		

Group A: shockwave group; Group B: diclofenac group; Group C: control group.

Data are expressed as mean ± standard deviation (SD); P-value: probability value; P-value>0.05: non-significant

The statistical analysis using 3x2 mixed design MANOVA (Table 2) indicated that there were significant differences (F-value=1.996; P=0.044; P<0.05) of the tested groups (the first independent variable) on the all tested dependent variables (VAS, NDI, right pressure algmoeter, and left pressure algmoeter). In addition, there were significant differences (F-value=54.344; P=0.0001; P<0.05) of the measuring periods (the second independent variable) on the tested dependent variables. Moreover, the interaction between the two independent variables (Groups x Periods) was significant (F-value=2.412; P=0.018; P<0.05), which indicates that the effect of the tested group (first independent variable) on the dependent variables was influenced by the measuring periods (second independent variable).

Table 2				
Main effects of independent variables by 3 x 2 MANOVA test for dependent				
measuring variables.				

Source of variation	Wilk's Lambada value	F-value	P-value
Groups effect	0.904	1.996	0.044*
Period effect	0.262	54.344	0.0001*
Groups x period interaction effect	0.790	2.412	0.018*

P-value: probability value * Significant (P-value <0.05)

Multiple pairwise comparison tests (time effect) for outcomes variables within each group (Table 3) showed that there was significantly decreased (P<0.05) in VAS and NDI, however, significantly increased (P<0.05) in right pain threshold and left pain threshold after treatment compared to before-treatment within group A, group B, and group C. This significant decrease in post-treatment of pain intensity and in right and left pain threshold and increase neck functional abilities favor of shockwave group (Group A) than diclofenac group (Group B), and control group (Group C). Multiple pairwise comparison tests (group effect) for outcomes variables among groups A, B, and C (Table 3) indicated no significant differences (P>0.05) before treatment in pain intensity, neck functional abilities, right and left pain threshold. In contrast, there were significant difference (P<0.05) among groups after treatment in pain intensity, neck functional abilities, right and left pain threshold.

		Groups (Mean ±SD)			
Items	Items	Group A	Group B	Group C	P-value
		(n=15)	(n=15)	(n=15)	
	Before-treatment	6.53 ±1.18	6.14 ±1.09	6.07 ±0.96	0.492
	After-treatment	2.53 ±1.45	2.67 ±1.15	3.40 ±0.91	0.018*
VAS	Mean difference	4.00	3.47	2.67	
	Improvement %	61.26%	56.51%	43.99%	
	P-value	0.0001*	0.0001*	0.0001*	
	Before-treatment	34.24 ±7.50	29.55 ±8.75	27.60 ±6.23	0.072
	After-treatment	11.85 ±6.25	13.64 ±6.40	17.64 ±4.21	0.025*
NDI	Mean difference	22.39	15.91	9.96	
	Improvement %	65.39%	53.84%	36.09%	
	P-value	0.0001*	0.0001*	0.0001*	
	Before-treatment	2.98 ±0.96	3.05 ±0.69	3.28 ±0.61	0.616
Dight processing	After-treatment	5.22 ±1.06	4.50 ±1.22	4.15 ±0.60	0.010*
algometer	Mean difference	2.24	1.45	0.86	
algoinetei	Improvement %	75.17%	47.54%	26.52%	
	P-value	0.0001*	0.0001*	0.009*	
	Before-treatment	3.02 ±0.76	5.67 ±1.03	3.02 ±0.76	0.093
I oft processre	After-treatment	5.67 ±1.03	5.06 ±1.10	5.08 ±0.92	0.040*
algometer	Mean difference	2.65	1.55	1.28	
algometer	Improvement %	87.75%	44.16%	33.68%	
	P-value	0.0001*	0.0001*	0.001*	

Table 3 Inter- and intra-group comparison for outcomes variables

Group A: shockwave group; Group B: diclofenac group; Group C: control group

Data are expressed as mean \pm standard deviation (SD); P-value: probability value * Significant (P<0.05)

Bonferroni test and mean difference for pain intensity, neck functional abilities, right and left pain threshold after-treatment between pairwise of the groups (Table 4). There were significant differences (P<0.05) in pain intensity, neck functional abilities, right and left pain threshold after treatment between group A versus group C and group B versus group C, but no significant difference (P>0.05) between group A versus group B There were significant differences (P<0.05) in left pain threshold after treatment between group B and group A versus group C, but no significant differences (P<0.05) in left pain threshold after treatment between group B and group A versus group C. The mean differences between pairwise groups showed that the pain intensity, neck functional abilities, right and left pain threshold.

 Table 4

 Post-hoc test (Bonferroni test) between pairwise of groups (after treatment)

Variables	Items	Post-hoc (Bonferroni test)			
		Group A vs. Group B	Group A vs. Group C	Group B vs. Group C	
	Mean difference	0.14	0.87	0.73	
VAS	95% CI	-0.94 - 1.21	0.34 - 1.81	0.15 – 1.88	
	P-value	1.000	0.012*	0.030*	
NDI	Mean difference	1.79	5.79	3.99	
	95% CI	4.54 - 8.13	0.54 - 12.13	1.97 – 9.97	
	P-value	1.000	0.035*	0.047*	
Rt. PA	Mean difference	0.71	1.07	0.35	
	95% CI	-0.12 - 1.55	0.22 - 1.90	0.43 – 1.14	
	P-value	0.124	0.008*	0.835	
Lt.PA	Mean difference	0.61	0.59	0.02	
	95% CI	-0.30 - 1.53	-0.32 - 1.51	-0.89 – 0.84	
	P-value	0.032*	0.036*	1.000	

Group A: shockwave group; Group B: diclofenac group; Group C: control group CI: confidence interval; P-value: probability value; * Significant (P<0.05)

Discussion

The main aim of this study was to compare between the effect of rESWT and diclofenac PH on pain intensity, threshold and neck functional abilities in cases of MTrps of upper fibers of trapezius. The present study showed that the statistical analysis using 3x2 mixed design MANOVA indicated that there were significant differences (F-value=1.996; P=0.044; P<0.05) of the tested groups (the first independent variable) on the all tested dependent variables (VAS, NDI, right pressure algmoeter, and left pressure algmoeter). In addition, there were significant differences (F-value=54.344; P=0.0001; P<0.05) of the measuring periods (the second independent variable) on the tested dependent variables. Moreover, the interaction between the two independent variables (Groups x Periods) was significant (F-value=2.412; P=0.018; P<0.05), which indicates that the effect of the tested group (first independent variable) on the dependent variables.

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This study revealed that there was significance decreased in pain intensity and NDI in addition to increase in right and left pain threshold at post-treatment compared to pre-treatment, for all three groups. Among groups there were significant decreases in pain intensity and NDI in addition to increase in right and left pain threshold at post-treatment favor of shockwave group (Group A) than diclofenac group (Group B), and control group (Group C).

This result agreed with Taheri et al. (2021), their results indicated significant improvement on pain intensity and neck disability immediately and after four weeks of intervention. After the treatment, the pain score in the rESWT group was significantly lower than in the phonophoresis group. The NDI score was not significantly different between the groups at the end of the treatment. However, after the treatment, the NDI score was significantly lower in the rESWT group than in the phonophoresis group.

The current study come in agreement with the following studies, Müller-Ehrenberg & Licht (2005), showed the positive effect of rESWT on pain relief in the treatment of TPs. In Ramon et al. (2015), study, rESWT was a significant improvement in pain intensity. Moreover, in a randomized pilot study by Park et al. (2018), two different regimens of rESWT were compared, and they showed that both regimens were useful in reducing pain and physical disability in patients with trigger point; however, high-energy was more effective. Similar to these findings, our results indicated that three rESWT treatment sessions were practical in treating MTPs and decreasing pain and physical disability in these patients.

The results of the recent study are comparable with Haghighat & Asl (2016), study results, showing the favorable outcomes after four weeks of treatment with rESWT in patients with MTPs of trapezius muscle. The results of the current study are consistent with the results of a former study by Toghtamesh and colleagues, who found that one session per week of rESWT in patients with MTPs of trapezius muscle significantly, decreased the VAS level and increased ROMs of lateral neck flexion (Toghtamesh et al., 2020).

On the other hand Ustun et al. (2014), performed a study on PH with conventional therapy and demonstrated that PH was more effective than conventional therapy in terms of pain and neck disability in patients with MTPs. Sarrafzadeh et al. (2012), compared the effects of PH of declophenac and conventional therapy in patients with an upper trapezius latent MTPs and detected a significant effect of PH in pain reduction with its superiority to conventional therapy. Similar to the result of these studies, the results of the current study showed a significant effect of PH of declophenac in pain relief and neck disability in patients with MTPs. Myofascial pain reduction in conventional therapy is through its mechanical and thermal effects like providing deep tissue heating, increasing microcirculation, enhancing vascular and cell membrane permeability, and improving angiogenesis. Adding PH gel by increasing skin absorption causes deeper tissues by conventional and, consequently, more relaxation and pain relief (Srbely et al., 2008).

In a study encompassing 60 patients, Aktürk et al. (2018), compared the effectiveness of rESWT and diclofenac PH in MTPs. They used four sessions with three-day intervals of rESWT and 10 sessions of diclofenac PH. They showed a significant effect of both rESWT and diclofenac PH in pain reduction compared to the control group, but they did not observe any significant difference between the two studied treatments.

The result of current study revealed that, post-treatment values compared to pretreatment for all three groups was significantly decreased in VAS and neck functional ability, also there was increase in right and left pain threshold. Among groups there were significant decreases in VAS and NDI; also there was increase in right and left pain threshold at post-treatment in favor of shockwave group than diclofenac group, and control group. The current study concluded that Shockwave group gives the highest value than diclofenac group, and control group.

Limitations

The analysis of the current study has some potential limitations, each of which points toward directions of future study. The limitation for this study was that, no follow up was performed to know the long lasting effect and the recurrence of the symptoms.

Conclusion

Shock wave therapy is more effective in reducing pain and improving neck functional abilities in patients with MTrps than Diclofenac PH.

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