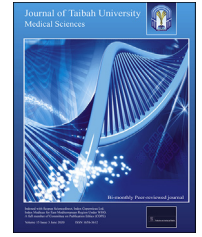




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Original Article

Comparison of the effects between low- versus medium-energy radial extracorporeal shock wave therapy on knee osteoarthritis: A randomised controlled trial

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المخلص

أهداف البحث: تهدف هذه الدراسة لمقارنة تأثير الموجات الصدمية الشعاعية ذات الطاقة المنخفضة والمتوسطة خارج الجسم على خشونة مفصل الركبة.

طرق البحث: تم تقسيم ٤٥ مريضا (٢٦ من الإناث و١٩ من الذكور)، يتراوح أعمارهم من ٤٥ إلى ٥٥ عاما، يعانون من خشونة مفصل الركبة المرحلة ٢ بشكل عشوائي إلى ثلاث مجموعات متساوية. أخذت المجموعة أ العلاج بالموجات الصدمية الشعاعية ذات طاقة منخفضة (٢٠٠٠ صدمة/جلسة، ١٠ هرتز وطاقة ٠.٠٢ مم^٢/مجمول) وتمارين التقوية مرة في الأسبوع لمدة أربعة أسابيع؛ أخذت المجموعة ب العلاج بالموجات الصدمية الشعاعية ذات طاقة متوسطة (٢٠٠٠ صدمة/جلسة، ١٠ هرتز وطاقة ٠.١٧٨ مم^٢/مجمول) وتمارين التقوية مرة في الأسبوع لمدة أربعة أسابيع، وأخذت المجموعة ج (مجموعة التحكم) العلاج بالموجات الصدمية الزائفة بالإضافة إلى تمارين التقوية مرة في الأسبوع لمدة أربعة أسابيع. تم تحديد شدة الألم بواسطة مقياس التناظرية البصرية، الوظيفة البدنية للركبة بواسطة النسخة العربية من النموذج القصير لمقياس الوظيفة البدنية نتيجة إصابة وخشونة الركبة. تم قياس الدعم في الركبة بواسطة الديناموميتر الحركي قبل وبعد نهاية برنامج العلاج.

النتائج: أظهر التحليل داخل المجموعة اختلافا كبيرا في الألم، ووظيفة الركبة ومنع الحركة في المجموعة أ والمجموعة ب قبل وبعد برنامج العلاج. كما أظهر التحليل بين المجموعة اختلافا كبيرا في جميع المتغيرات بعد العلاج لصالح المجموعة ب.

الاستنتاجات: يعتبر العلاج بالموجات الصدمية الشعاعية ذات الطاقة المنخفضة والمتوسطة طريقة فاعلة لعلاج خشونة مفصل الركبة مع تأثير أعلى للعلاج بالموجات الصدمية الشعاعية متوسطة الطاقة.

الكلمات المفتاحية: الديناموميتر الحركي؛ خشونة الركبة؛ الحس الحركي للركبة؛ العلاج بالموجات الصدمية الشعاعية خارج الجسم

Abstract

Objective: This study aimed to compare the effects between low- versus medium-energy radial extracorporeal shock wave therapy on knee osteoarthritis (KOA).

Method: Forty-five patients (26 women and 19 men) aged 45–55 years with grade 2 KOA were randomly assigned into the following three groups (all n = 15): Group A received low-energy radial shock wave therapy (2000 shock/session [10 Hz], energy flux density [EFD] 0.02 mJ/mm²) with strengthening exercises once per week for 4 weeks; Group B received medium-energy radial shock wave therapy (2000 shock/session [10 Hz], EFD 0.178 mJ/mm²) with strengthening exercises once per week for 4 weeks; and Group C (control group) received sham shock wave therapy with strengthening exercises once per week for 4 weeks. Severity of pain was determined using the visual analogue scale, and knee physical function was assessed using the Arabic version of the knee injury and osteoarthritis outcome score physical function short form. Knee proprioception was measured before and after the treatment programme using an isokinetic dynamometer.

Results: The within-group analysis showed significant differences in severity of pain, knee physical function, and

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knee proprioception in Groups A and B before and after the treatment programme ($p < 0.05$). The between-group analysis showed significant differences in all variables after treatment, with more significant differences observed in Group B than in Groups A and C ($p < 0.05$).

Conclusion: Low- and medium-energy radial shock wave therapies are effective modalities for the treatment of KOA, with medium-energy radial shock wave therapy being superior to low-energy radial shock wave therapy.

Keywords: Isokinetic dynamometer; Knee osteoarthritis; Knee proprioception; Radial extracorporeal shock wave

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Introduction

Osteoarthritis (OA) is the most common form of arthritis that leads to disability. This degenerative disease affects approximately 302 million people worldwide.¹ Clinical symptoms of knee OA (KOA) include the following: progressive knee joint pain, rigidity, and swelling. End-stage KOA results in joint deformity and loss of quality of life.² In severe KOA, joint replacement remains the treatment of choice, but considering its economic cost and surgical risk, other treatment strategies are required to immediately treat KOA and to prevent its progression.³ Patient's physical characteristics such as age, activities of daily living, disease aetiologies, and disease grades are factors affecting the treatment of KOA.⁴

Nowadays, extracorporeal shock wave therapy (ESWT), which is a non-surgical conservative treatment procedure, has been introduced for the treatment of KOA. Shock wave is used for the treatment of several musculoskeletal disorders.⁵ Shock wave therapy has the following advantages: it is non-invasive, does not require hospitalisation, is cheap, and has low adverse effects. Shock wave is an effective treatment at certain stage when surgical intervention was selected for various musculoskeletal diseases.⁶

Shock wave therapy suppresses pain, increases range of motion, and prevents vascular disease progression.⁷ To the best of our knowledge, studies determining the effective dose of shock wave therapy for the improvement of proprioception on KOA have not yet been conducted. Hence, the current study aimed to compare the effects between low- versus medium-energy radial ESWT on severity of pain, knee proprioception, and knee physical function.

Materials and Methods

Study design

This study was a randomised controlled trial conducted at the outpatient clinic of the Faculty of Physical Therapy, Modern University for Technology and Information from

June 2018 to October 2018. This study followed the Consolidated Standards Of Reporting Trials guidelines.

Calculations to determine the sample size were performed for pain scores measured by the visual analogue scale (VAS) as a primary outcome measure using G power 3.1 software. The calculations were based on an effect size of 0.291, an alpha level of 0.05, a desired power of 80%, and a numerator degree of freedom of 1 and 2 experimental groups. The estimated desired total sample size in the study was 42 patients. To achieve the expected dropout before the study's completion, a total of 45 patients were included in the study (Figure 1).

Patient characteristics

Forty-five patients (26 women and 19 men) were randomly assigned into three equal groups after they provided informed consent. Randomisation was performed using a sealed envelope. Before the study started, a therapist gathered the 55 patients who met the inclusion criteria, and each patient was instructed to select one of the sealed envelopes. There were 45 sealed envelopes, and 15 of these enveloped contained letter (A), 15 contained letter (B), and 15 contained letter (C). Hence, the total number for each group was obtained.

Group A received low-energy radial shock wave therapy (2000 shock/session [10 Hz]; energy flux density [EFD], 0.02 mJ/mm^2) with strengthening exercises. **Group B** received medium-energy radial shock wave therapy (2000 shock/session [10 Hz]; EFD, 0.178 mJ/mm^2) with strengthening exercises. **Group C** received sham shock wave therapy with strengthening exercises. The inclusion criteria were as follows: (1) patients aged 45–55 years; (2) patients with symptomatic unilateral KOA, which lasted for 3 months, based on the clinical criteria of the American College of Rheumatology as diagnosed by a physician⁸; (3) patients with grade 2 KOA based on X-ray results according to Kellgren and Lawrence classification⁸; (4) patients experiencing pain on the medial tibial plateau⁸; and (5) patients with grade 5 or higher pain intensity based on VAS.⁹ The exclusion criteria were as follows: (1) patients with vestibular and neurological system diseases and systematic inflammatory disorders; (2) patients receiving steroid injection therapy in the last 6 months¹⁰; (3) patients with knee haematoma; and (4) patients contraindicated to undergo X-ray.⁸

Procedures

Assessments

All assessments were performed by a therapist before and after the treatment programme.

Pain level was measured using the VAS, which comprises a 10-cm-long line with two ends, with one end having no pain or discomfort and the other end having worst pain. The VAS is considered a valid and reliable tool in the assessment of pain intensity.¹¹ In this study, each patient was instructed to mark the part of the line that indicated his/her pain intensity.¹²

Knee physical function was assessed using the Arabic version of the knee injury and osteoarthritis outcome score physical function (KOOS-PS) short form, which is a valid and reliable tool for the assessment of KOA. It comprises seven items, and the measure was calculated by summing the ranks of seven items (or calculating the mean percentage) of

the KOOS-PS. It is considered that patients with 0–7 (0%–20%), 7–14 (20%–40%), 14–21 (40%–60%), 21–28 (60%–80%), and 28–35 (80%–100%) scores have no physical functional disability, mild physical functional disability, moderate physical functional disability, severe physical functional disability, and very severe physical functional disability, respectively.¹³ Each item was explained in detail, and patients were instructed to select one sentence out of the five that best describes their function, with higher scores indicating great loss of function. Finally, proprioception was assessed as follows.

First, each patient sat on the Biodex system III (Shirley, NY, 11967, USA) chair with a reclined backrest; the centre of the osteoarthritic knee was in similar alignment with that of the dynamometer axis, the starting position was 90° flexion, and special straps secured the patient trunk, pelvis, and thigh with a special tibial pad fixed 3 cm above the lateral malleolus. A blind fold was used to prevent any visual input. The patient performed three repetitions of the predetermined test (active reposition accuracy with a speed of 15°/s and a target angle of 45°),¹⁴ as shown in Figure 2.

For standard test situation, the patient moved the tested limb to the target angle (45°) with a hold for 10 s so he/she could remember the position and subsequently returned to the starting position.¹⁵

After resting for 5 s, the patient actively moved the tested limb to the target position and pressed the Hold/Release button to stop the apparatus once he/she felt it.¹⁴

The patient performed three trials with 30-second rest between each trial. Subsequently, the mean angular difference of all trials, which was represented in degrees as the difference between the end position (45°) and the patient's perceived end position, was used for statistical analysis as the patient's reposition accuracy deficit as shown in Figure 2.¹⁶

Interventions

Radial shock wave therapy. The patient lay in 90° knee flexion in a supine position, with the therapist standing beside the

limb and the patient holding the probe of the radial extracorporeal shock wave apparatus (EME S.r.l. via Degli Abeti 88/161122 Pesaro [serial number: EM12681015], Italy) firmly on the most tender points at the level of the medial tibial plateau in a continuous movement. Group A received low-energy radial shock wave therapy (2000 shock/session [10 Hz]; EFD, 0.02 mJ/mm²), Group B received medium-energy radial shock wave therapy (2000 shock/session [10 Hz]; EFD, 0.178 mJ/mm²), and Group C received sham shock wave therapy (2000 shock/session [10 Hz]; EFD, 0 mJ/mm²) once per week for 4 weeks,⁸ as shown in Figure 3.

Strengthening exercise. For each session, every patient performed three sets of straight leg raising exercise, and each set comprised ten repetitions. The patient lay in the crock lying position with the other limb held in a flexed position. Subsequently, the patient was allowed to raise his/her limb to 45° by quadriceps contraction with a hold for 6 s, slowly bringing down the limb to the starting position followed by 6-second relaxation.¹⁷

Finally, the patient performed 20 repetitions of isometric quadriceps exercise, where the patient held the limb in extension for 5 s and subsequently relaxed for 5 other seconds.¹⁸

Statistical analyses. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) for Windows version 20 (SPSS, Inc., Chicago, IL). Analysis of variance (ANOVA) and the chi-squared test were used to analyse patient characteristics. The Shapiro–Wilk test for normality showed that measured variables were normally distributed; thus, mixed multivariate ANOVA was used for statistical analysis. Significance was set at $p \leq 0.05$.

Results

Patient characteristics

As shown in Table 1, ANOVA showed no statistically significant difference between the three groups in age,

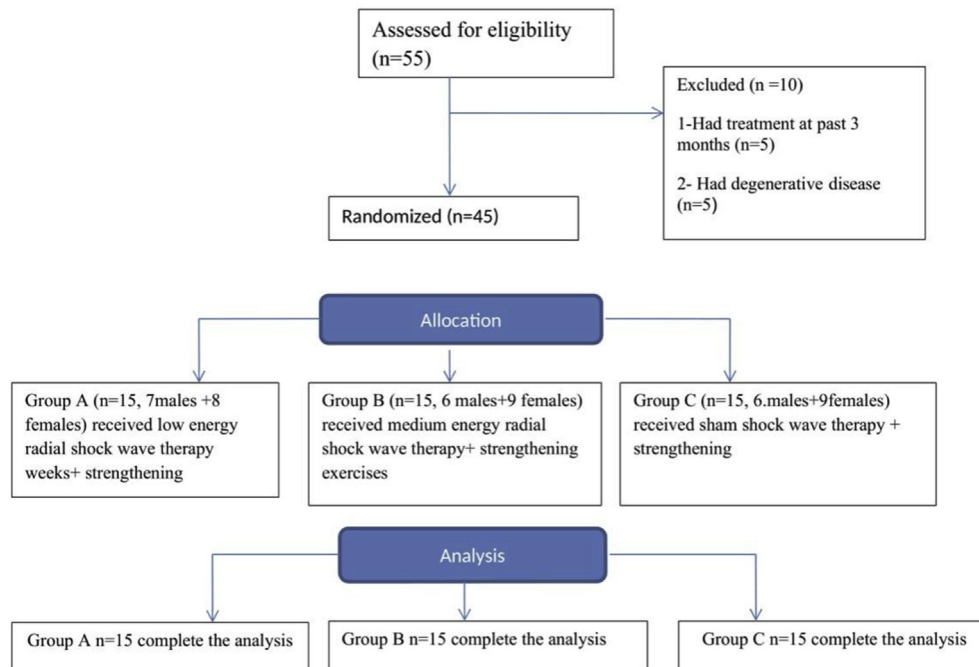


Figure 1: CONSORT Flow chart for patients in the study.

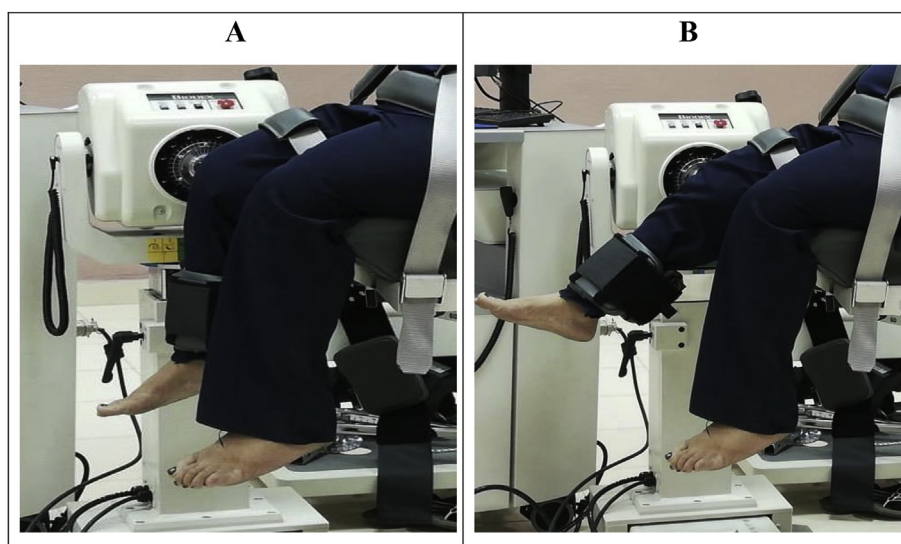


Figure 2: Assessment of knee proprioception at 45°. 'A' starting position, 'B' end position.

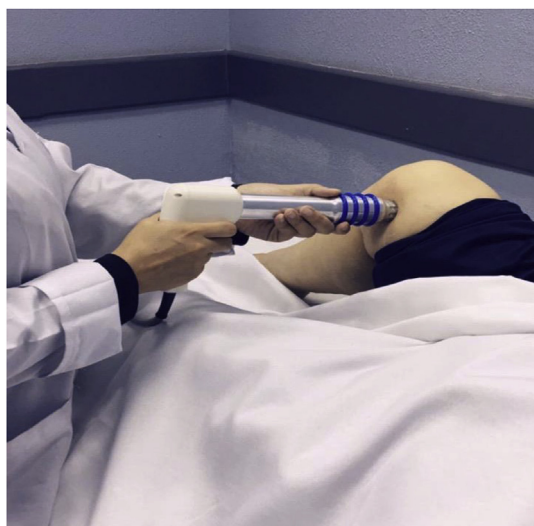


Figure 3: Application of shock wave therapy on the most tender points around the medial tibial plateau.

weight, height, and body mass index ($p = 0.798, 0.895, 0.995,$ and $0.930,$ respectively).

The chi-squared test showed no statistically significant difference between the three groups in sex distribution and affected knee side ($p = 0.528$ and $0.528,$ respectively).

Within-group analysis

As shown in [Table 2](#), Groups A and B showed statistically significant difference between pre- and post-treatment values of severity of pain, knee physical function, and knee proprioception ($p < 0.05$). Group C showed no statistically significant difference between pre- and post-treatment values of severity of pain, knee physical function, and knee proprioception ($p > 0.05$).

Between-group analysis

As shown in [Table 3](#), there were no statistically significant differences between the three groups in all pre-treatment

Table 1: General and baseline characteristics of patients in the three groups.

General characteristics						
Parametric data	Group A	Group B	Group C	F-value	P-value	Sig
Sex (female:male)	9:6	10:5	7:8		0.528	NS
Age (years)	50.4 ± 3.4	49.9 ± 2.6	49.7 ± 3.1	0.227	0.798	NS
Weight (kg)	86.9 ± 10.5	88.6 ± 10	87.3 ± 9.7	0.112	0.895	NS
Height (cm)	168.3 ± 8.9	167.4 ± 9.5	167.6 ± 8.1	0.046	0.995	NS
BMI (kg/m ²)	30.7 ± 3.5	31 ± 2.4	31.1 ± 3	0.073	0.930	NS
VAS	7.46 ± 1.50	7.53 ± 1.84	7.66 ± 1.83	159.58	0.001	NS
Non-parametric data	Group A	Group B	Group C	χ^2 value	P-value	Sig
Sex (female:male)	9:6	10:5	7:8	1.2753	0.528	NS
Dominant	11 (73.3%)	9 (60%)	12 (80%)	1.5144	1.5144	NS
Non-dominant	4 (26.6%)	6 (40%)	3 (20%)			NS

Sig: significant, NS: not significant, SD: standard deviation, P: probability.
 χ^2 : chi-squared value.

Table 2: Results of multivariate analysis of variance among the groups for severity of pain, knee physical function, and active repositioning.

Items	Group A		Group B		Group C		F-value (Within group)	P-value
Pain								
Pre-study	7.46 ± 1.50		7.53 ± 1.84		7.66 ± 1.83		159.58	0.001*
Post-study	5.53 ± 1.01		4.06 ± 1.09		7.26 ± 1.62			
P-value	0.0001*		0.0001*		0.139			
% of change	25.8%		46%		5.2%			
Mean difference	1.933		3.467		0.4			
95%confidence interval for difference	Lower bound	Upper bound	Lower bound	Upper bound	Lower bound	Upper bound		
	1.398	2.468	2.93	4.002	-0.135	0.935		
Knee function								
Pre-study	14.133 ± 4.08		14.40 ± 4.11		13.20 ± 3.76		130.279	0.0001*
Post-study	10.20 ± 2.75		7.46 ± 1.55		12.93 ± 3.80			
P-value	0.0001*		0.001*		0.638			
% of change	27.8%		48.1%		2%			
Mean difference	3.933		6.933		0.267			
95%confidence interval for difference	Lower bound	Upper bound	Lower bound	Upper bound	Lower bound	Upper bound		
	2.797	5.070	5.79	8.07	-0.87	1.403		
Active repositioning								
Pre-study	4.4 ± 1.6		4.7 ± 1		4.1 ± 1.3		182.574	0.0001*
Post-study	3 ± 1.6		2.4 ± 0.7		3.8 ± 1.2			
P-value	0.0001*		0.0001*		0.590			
% of change	34.8%		62.9%		2.6%			
Mean difference	1.533		2.96		0.107			
95%confidence interval for difference	Lower bound	Upper bound	Lower bound	Upper bound	Lower bound	Upper bound		
	1.137	1.930	2.563	3.357	-0.290	0.503		

Data are represented as mean ± standard deviation.

*Significant.

Table 3: Pairwise comparison between groups post-study for measured variables.

Dependent variables	Group	Mean difference	Sig	95% confidence interval	
				Lower bound	Upper bound
Pre-treatment					
VAS	A vs. B	-0.67	1.00	-1.649	1.5159
	A vs. C	-0.200	1.00	-1.782	1.382
	B vs. C	-0.133	1.00	-1.715	1.449
KOOS	A vs. B	-0.267	1.00	-3.903	3.369
	A vs. C	0.933	1.00	-2.703	4.569
	B vs. C	1.2	1.00	-2.436	4.836
Active repositioning	A vs. B	-0.273	1.00	-1.452	0.905
	A vs. C	0.300	1.00	-0.878	1.478
	B vs. C	0.573	0.695	-0.605	1.752
Post Treatment					
VAS	A vs. B	1.467	0.010*	0.295	2.639
	A vs. C	-1.733	0.002*	-2.905	-0.561
	B vs. C	-3.200	0.0001*	-4.372	-2.028
KOOS	A vs. B	2.733	0.037*	0.131	5.336
	A vs. C	-2.733	0.037*	-5.336	0.131
	B vs. C	-5.467	0.0001*	-8.069	-2.864
Active repositioning	A vs. B	1.153	0.028*	-0.097	2.209
	A vs. C	-1.127	0.033*	-2.183	-0.071
	B vs. C	-2.280	0.0001*	-3.3336	-1.224

Dependent variables	Within-group comparison (time effect)	P value	Between-group comparison (group effect)	P value	Interaction effect (group* time)	P value
Mixed MANOVA						
VAS	159.58	0.0001*	5.064	0.001*	33.461	0.0001*
KOOS	130.270	0.0001*	1.583	0.217	35.152	0.0001*
Active repositioning	182.574	0.0001*	2.001	0.148	52.685	0.0001*

Asterisk means significant difference between groups.

values ($p > 0.05$), while there were statistically significant differences between all groups in post-treatment values ($p < 0.05$).

Discussion

This study was conducted to determine and compare the effects between low- versus medium-energy shock wave therapy on the treatment of KOA. According to our results, there was a statistically significant difference in severity of pain, knee physical function, and knee proprioception after low- and medium-energy shock wave application, with medium-energy shock wave therapy being superior to low-energy shock wave therapy.

Our results were consistent with the results of Kim et al.'s study,⁸ who revealed that medium-energy shock wave therapy is more effective for pain suppression compared to low-energy shock wave therapy with 1-year follow-up, a result consistent with the result of a previous study, which concluded that higher-energy intensities have greater effect on pain level due to unmyelinated sensory nerve damage.

To the best of our knowledge, this is the first study to assess the effects of shock wave on proprioception. Moreover, according to the current study, pain is directly associated with knee proprioception, and this finding is consistent with that of Shakoore et al.,¹⁹ who confirmed that pain suppression associated with exercise has a direct positive association with muscle strength and proprioception function. Moreover, Felson et al.²⁰ revealed that proprioceptive acuity affects the pain pathway and knee physical function in KOA. Additionally, Akinoglu et al.¹⁰ stated that shock wave therapy has a superior effect compared to ultrasound on the plantar fasciitis, including proprioception improvement, which was assessed using the Biodex III isokinetic device. This finding is consistent with the finding of Zhao et al.,²¹ who stated that ESWT resulted in lower pain levels and better knee functions in patients with KOA compared to placebo at 12-week follow-up after ESWT.

Similarly, Yongming et al.²² revealed the efficacy of ESWT for disabling pain and for the enhancement of knee joint function in patients with KOA and cartilage lesions. Furthermore, Kim et al.⁸ reported that low- and medium-energy ESWT are effective for enhancing knee function and decreasing pain levels, with medium-energy shock wave therapy having superior effect compared to low-energy shock wave therapy.

Additionally, Cho et al.²³ reported that low-energy ESWT reduces pain and enhances physical function and ultrasonic findings in KOA for chronic stroke patients. Moreover, according to this study, ESWT has the following advantages: it

is conservative and highly accessible, does not require hospitalisation, and is a good alternative for intra-articular hyaluronic acid (HA) injections, which have several disadvantages including the following: it results in allergy and pain, with some patients experiencing fear of injection.

Similarly, Lee et al.²⁴ concluded that low-frequency ESWT and intra-articular HA injections are compelling therapies for pain amelioration and physical function improvement, which were measured using the VAS, WOMAC, Lequesne index, 40-m fast-paced walk test, and stair climb test in osteoarthritic patients.

Contrary to our results, Imamura et al.⁹ demonstrated that radial ESWT is considered ineffective in reducing pain in primary KOA.

Study limitation

This study has the following limitation: Blinding was not observed in this study.

Conclusion

Low- and medium-energy radial extracorporeal shock wave therapies are effective modalities in the treatment of KOA, with medium-energy radial extracorporeal shock wave therapy considered superior to low-energy radial extracorporeal shock wave therapy.

Recommendations

We recommend research implementation with the addition of isokinetic proprioceptive exercises.

Source of funding

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Conflict of interest

The authors have no conflict of interest to declare.

Ethical approval

The study was ethically approved by the ethical committee of the Faculty of Physical Therapy, Cairo University, Egypt (NO: NO: P. T.REC/012/001932) and registered at Pan African Clinical Trial Registry (Registry ID PACTR 201805003383422).

Authors contributions

RFH formulated the idea, conducted the study, collected and organised the data. STA was responsible for clinical evaluation and performed the statistical analysis. MHD collected the literature and assisted in writing the original draft. RMK and AAA critically reviewed and approved the final draft. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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