International Journal of General Medicine & Surgery

Available Online: http://ijgms.edwiserinternational.com

The Influence of Extracorporeal Shockwave Therapy and Kinesiotherapy on Health Status in Females with Knee Osteoarthritis: A Randomized Controlled Trial

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Article info

Received 01 June 2017
Revised 17 July 2017
Published 01 August 2017

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Abstract

Objective: *Evaluation the effectiveness of two conservative treatments on quality of life in females with knee osteoarthritis (OA).*
Methods: *60 females (age 40–75) were randomized to a five-week treatment of extracorporeal shockwave therapy group (ESWT, n=30) or a kinesiotherapy group (KIN, n=30). At baseline and after the 5-weeks' treatment, quality of life (WOMAC), pain (VAS), movement of the knees in extension and flexion (ROM), and a walked distance (6-MWT) were recorded.*
Results: *Post-intervention both groups reached improvement of health status, but the significant differences favoring the ESWT were found with regard to WOMAC, MD (mean difference)=20 points, 95% CI (confidence interval) [-25 to -4], p=0.006 for total scores, VAS in the right and left knees, MD=2 cm, 95% CI [-2 to -1], p <0.001, and MD=1 cm, 95% CI [-2 to -1], p=0.007 respectively, ROM (extension) in both knees, MD=3 degrees, 95% CI [-4 to -1], p=0.028 and p=0.014 respectively, ROM (flexion) in both knees, MD=7 degrees, 95% CI [3 to 10, and 4 to 11], p=0.007 and p < 0.001 respectively, and 6-MWT, MD=44 m, 95% CI [26 to 62], p<0.001.*
Conclusion: *Among the females, treated for OA of the knee, ESWT led to greater health benefits than KIN protocol.*

Keywords: Shockwave; Kinesiotherapy; Knee; Osteoarthritis

Introduction

Modern people are increasingly exposed for knee osteoarthritis (OA), which leads to the limitation of daily activities, and, thus worsens of the life quality [1-3]. Current several pharmacologic strategies and surgical interventions are used in patients suffering from OA of the knee [4,5]. Physiotherapy is an alternative method; however, it is frequently used together with pharmacology before as well as after a surgery. Several studies have shown that physiotherapy treatment improves muscle strength, flexibility of the knee, gait speed, reduces pain and as a result the quality of life improves [6-10]. Currently, extracorporeal shockwaves therapy (ESWT) is recommended, because it shows high efficiency in improving quality of life in patients with knee OA [11].

A systematic review shows that conservative treatments are useful for knee OA. ESWT has not previously been compared with kinesiotherapy (KIN) for patients with knee OA. Having noticed the lack of that kind of research, the current research team decided to carry out the present study. Consequently, the team conducted a randomized controlled trial to compare the effects of ESWT and KIN on pain, quality of life, range of motion

of the knee and the functional capacity in patients with knee OA.

Methods

Participants

The participants were assessed for eligibility by an independent physician not involved into the study. The study was conducted between July 18, 2016, and October 24, 2016 at the Physiotherapy Outpatient Department of the Regional Hospital (Zywiec, Poland). The participants were the patients in the department at the hospital. Seventy-two prospective participants were screened for inclusion. Twelve of them were excluded based on the eligibility criteria.

The inclusion criteria were: females 40-75 years old (our patients were females, because at the time of our research the Regional Hospital in Zywiec organized the specialized examinations directed to females with diagnosed knee OA, so we united our efforts); lack of receiving any other physical therapy treatments than ESWT or KIN on the knee OA; radiological evidence of osteophytes, reported by a radiologist; the diagnosis of bilateral knee OA according to the American College of Rheumatology criteria [12]. The exclusion criteria were: unilateral knee OA; previous knee joint surgery; uncontrolled hypertension or cardiovascular, pulmonary diseases; inability to perform physical exercises; insufficient communication ability to comprehend or comply with the treatment protocol.

A randomized, controlled trial with a blinded assessor was prospectively registered in Chinese Clinical Trial Registry [ID: ChiCTR-IIR-16008783 (registered on: 07/06/2016)]. This study was performed in accordance with Declaration of Helsinki, and also the Consolidated Standards of Reporting Trials (CONSORT) [13]. The Ethics Committee of the Holycross College accepted the study (approval No. 11/152014KB on 03/04/2016). All the patients gave their written informed consent to participate in the study.

Procedures

The participants were randomly assigned either to an intervention group that received ESWT, the ESWT group, or to a control group that received kinesiotherapy, the KIN group. The participants were assigned to the groups in a 1:1 ratio using a simple-computerized random-number generator [14]. The randomization was achieved by having the participants select one of 60 sealed, opaque envelopes enclosing the information about the group allocation. The envelopes had been prepared and shuffled by an independent investigator not involved in the study. The researchers were blinded as the type of the treatment procedure. To keep the assessors blinded, the participants were reminded before each measurement not to reveal the nature of their treatments. They were unaware of their group allocations and were informed only about the existence of 2 groups and not about the study's objectives.

Intervention

The whole treatment was performed at the Physiotherapy Outpatient Department of the Regional Hospital in Zywiec, Poland. The same physiotherapist supervised the ESWT and KIN interventions. He remained blind to the primary and the secondary outcome measures throughout the trial.

1. In the ESWT group, 30 females underwent 5 shockwave sessions, one weekly for 5 weeks. They received 1.000 pulses during the first session, 1.500 during the second and the third sessions, 2.000 during the fourth and the fifth sessions (pressure, 2.5 bar; frequency, 8 Hz; energy density, 0.4 mJ/mm2). The treatments were performed using a Rosetta ESWT (CR Technology, Korea). Each treatment session did not exceed 10 minutes [15].

2. In the KIN group, 30 females received 10 kinesiotherapy session, two per week for 5 weeks. The KIN protocol consisted:

Warm-up: 1. Global flexion-extension of the lower limb [sets of 10 repeats on each leg, 10 seconds intervals between the sets].

2. Alternated dorsal plantar flexion of the ankles in a supine position [3 sets of 10 repeats on each leg, 10 seconds intervals between the sets].

Stretching: 1. Stretching of the hamstrings in a supine position [1 set of 10 repeats of the affected leg, 10 seconds resistance of each stretch, 10 seconds relaxation between the stretches].

Strengthening: 1. Isometric knee extensors in a supine position: knee flex 0 degrees [1 set of 10 repeats of the affected leg, 10 seconds resistance of each contraction, 10 seconds intervals between the contractions].

2. Isometric knee extensors in a supine position: knee flex 60 degrees [1 set of 10 repeats of the affected leg, 10 seconds resistance of each contraction, 10 seconds intervals between the contractions].

3. Isometric hamstrings in a supine position: knee flex 60 degrees 1 set of 10 repeats of the affected leg, 10 seconds resistance of each contraction, 10 seconds intervals between the contractions].

4. Concentric-eccentric hip abductors and adductors in a side lying position [2 sets of 10 repeats of the affected leg, 10 seconds intervals between the sets].

Functional task-oriented training:

1. Get up and sit down [2 sets of 10 repeats, 10 seconds intervals between the sets].

2. Resistive knee extensor strengthening against Thera-Band while patient's sitting [3 sets of 10 repeats of the affected leg, 10 seconds intervals between the sets].

3. Controlled bilateral knee flexion-extension while patient's standing [2 sets of 10 repeats, 10 seconds intervals between the sets].

4. Alternated knee flexion to 90 degrees while patient's standing [2 sets of 10 repeats of each leg, 10 seconds intervals between the sets].

5. Step-ups using a step [2 sets of 10 repeats, 10 seconds intervals between the sets].

6. Walking forward, backward and/or laterally while crossing the lower limbs [10 meters].

Endurance:1. Stationary cycling [5 minutes]. Each treatment session did not exceed 1 hour [16].

Outcome measures

An investigator blind to the allocation of the patients performed all the evaluations at baseline (Week 0), as well as two days after the last treatment session (Week 5). The following parameters were assessed:

Primary parameter was:

1. Quality of life – WOMAC, it consists of 24 questions and probes clinically important symptoms in the areas of pain (5 questions), stiffness (2 questions), and physical function (17 questions) for patients with osteoarthritis of the knee. The higher score was achieved, the worse perceived health was. The patients answered the questions to describe their symptoms and difficulties from the past 3 days [17].

The secondary parameters were:

1. Pain-10-cm VAS, for which 0 represents the absence of pain and 10 represents the unbearable pain [18]. The patients indicated their current level of pain for both knees by marking a point on the scale.

2. Knee ROM of the extension and the flexion – measured bilaterally using goniometer (MSD Europe bvba, Londerzeel, Belgium) according to Sagital-Frontal-Transverse-Rotation (SFTR) Method of Recording [19]. Each knee (extension and flexion) was measured twice with the accuracy of 1 degree, and the biggest angle from the two measurements was recorded for the statistical analysis.

3. Functional capacity–6-MWT, the patients walked in a 100 m-long indoor hallway free of obstacles. The length of the corridor was marked every 1 meter. The distance covered (in meters during 6 min) was recorded for the statistical analysis [20].

Statistical Analysis

A priori the sample size was estimated based on anticipated between group differences 15 points in WOMAC at 5 weeks, assuming a SD of 20 points, an alpha 5%, power of 80%. The calculation showed, that we needed minimum 16 participants in each group. The data analysis provided the mean and SD of the two groups, the mean and SD for the within-groups differences, and a 95% CI for the mean between-groups differences, using inferential techniques. A mean between-groups differences and a 95% CI was calculated for each of the outcomes based on the change scores, ie, week 5 minus week 0 scores. The Shapiro-Wilk test identified the non-normal distribution of the WOMAC, the VAS, the ROM, and the 6-MWT data. To compare the differences between the groups, the Mann-Whitney U test was used. To describe the differences in related treatments, the effect size (Cohen's d) was calculated and classified as small ($d \leq 0.20$), medium ($d \leq 0.50$) and large ($d \geq 0.80$) [21]. The level of statistical significance was set at two-tailed p value of 0.05. Statistica version 12 (StatSoft, Poland) was used for the statistical calculation.

Results

Seventy-two participants with bilateral knee OA were screened and sixty patients who fulfilled the eligibility criteria were selected, 30 in the ESWT group and 30 in the KIN group. Figure 1 displays the flowchart of the study. During the treatments, the participants did not receive any anesthetic or other physical methods. No adverse events were observed. All the participants were analyzed as a part of the group to which they had been randomly allocated. Table 1 displays characteristics of the participants. No significant differences between

groups were found, showing the homogeneity of the sample. After the intervention, the quality of life improved on the WOMAC for both groups. The participants treated with ESWT reached greater improvement on the WOMAC scores for all the domains as presented in Table 2.

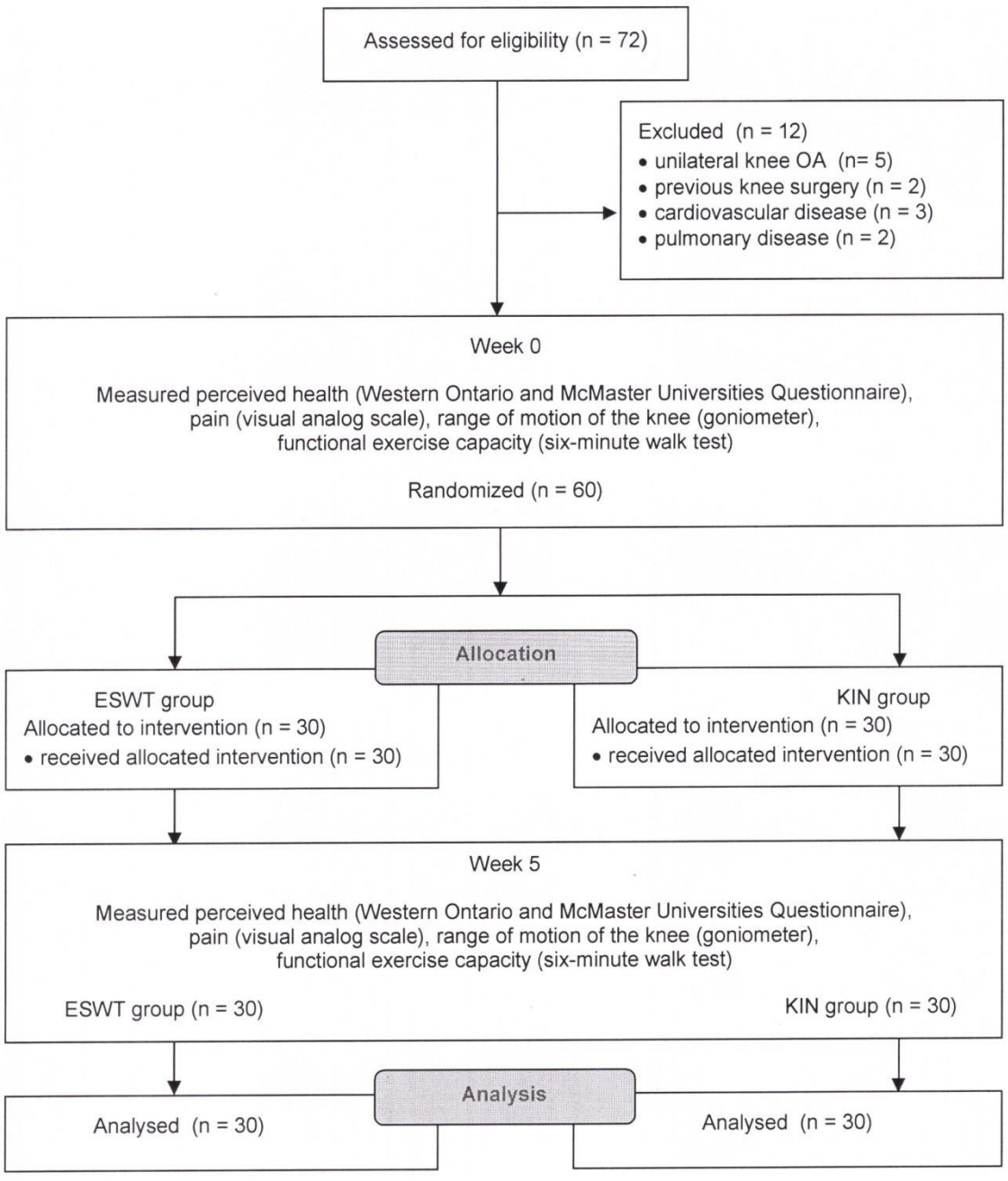

Figure 1: Flowchart of the study.

Regarding the secondary outcomes, after the intervention the research team identified the reduction in pain on the VAS, increasing in range of motion (ROM) in both knees, and functional capacity on the 6-MWT for both groups. The greater improvement in the participants from the ESWT group was identified for all scores. The research team fund the significant differences between the groups with Mann-Whitney U test in favor for the ESWT group. Moreover, the large

effect size between the related treatments confirmed that ESWT was more effective on decreasing symptoms and improving health status in patients with knee OA, as shown in Tables 2 and 3.

Table 1: Characteristics of the participants.

Characteristic	Group ESWT (n=30)	Group KIN (n=30)	P Value[a]
Age (yr) mean (SD)	61.0 (9.0)	59.0 (9.0)	0.376
Height (m) mean (SD)	1.68 (0.03)	1.69 (0.03)	0.144
Mass (kg) mean (SD)	65.8 (4.7)	66.0 (3.6)	0.963
BMI (kg/m^2) mean (SD)	23.2 (1.3)	23.3 (1.3)	0.697
Occupation:			
Physical worker/white-collar worker (n):	21/7	23/9	0.567
Duration of symptoms *(yr)* mean (SD)	8.0 (4.0)	7.0 (4.0)	0.518
ESWT, extracorporeal shockwave therapy; KIN, kinesiotherapy. [a]Calculated using Mann-Whitney *U* estimation.			

Table 2: Mean (SD) of the groups, mean (SD) difference within the groups, and mean (95% CI) difference between the groups for WOMAC (in points) outcomes.

Outcome	Groups				Difference with in groups		Difference between groups		
	Week 0		Week 5		Week 5 minus Week 0		Week 5 minus Week 0		
	ESWT (n=30)	KIN (n=30)	ESWT (n=30)	KIN (n=30)	ESWT	KIN	ESWT minus KIN	P value[a]	Effect size (cohen d)
WOMAC									
P	14(5)	12(5)	6(3)	9(6)	-8(4)	-3(2)	-5(-7 to -4)	0.015	1.58
ST	7(1)	7(2)	2(1)	5(3)	-5(1)	-2(2)	-3(-4 to -2)	<0.001	1.89
PF	52(18)	47(17)	24(14)	33(16)	-28(15)	-14(9)	-14(-20 to -7)	0.016	1.13
TS	71(24)	65(22)	32(16)	46(22)	-39(19)	-19(10)	-20(-25 to -4)	0.006	1.32
ESWT: Extracorporeal Shockwave Therapy; KIN: Kinesiotherapy; WOMAC: Western Ontario and McMaster Universities Questionnaire: P: Pain; ST: Stiffness; PF: Physical Function; TS: Total Score. [a]Calculated using Mann-Whitney *U* estimation.									

Discussion

A number of previous studies demonstrated that therapeutic exercises were effective in the treatment of OA of the knee. Aoki et al. [22] and Ahmed [23] assessed the effects of intervention based on knee stretching exercise versus control maintaining their usual daily physical activity for pain, ROM, and gait speed. The authors concluded, that stretching exercises significantly more effectively improved health status in patients with knee OA. Wang et al. [24] reported that aquatic exercises significantly improved knee ROM, strength of muscles, but had no effect on self-reported physical functioning and pain. Wyatt et al. [25] found that aquatic program, as well as a land-based exercises program increased ROM, prevented thigh muscle atrophy, and decreased pain. Lizis [26] reported that spa physiotherapy combined with local cryotherapy liquid nitrogen vapour and iontophoresis with the drug Olfen-Gel (Diclofenac) improved the ROM and the strength of the muscles acting on the affected knee joint.

Table 3: Mean (SD) of the groups, mean (SD) difference within the groups, and mean (95% CI) difference between the groups for VAS (in points), ROM (in degrees), and 6-MWT (in meters) outcomes.

Outcome	**Groups**				**Difference within groups**		**Difference between groups**		
	Week 0		**Week 5**		**Week 5 minus Week 0**		**Week 5 minus Week 0**		
	ESWT (n=30)	KIN (n=30)	ESWT (n=30)	KIN (n=30)	ESWT	KIN	ESWT minus KIN	P value[a]	Effect size (cohen d)
VAS *(right knee)*	6(2)	6(2)	2(1)	4(2)	-4(1)	-2(1)	-2(-2 to -1)	<0.001	2.00
VAS *(left knee)*	6(2)	6(2)	2(2)	3(2)	-4(1)	-3(1)	-1(-2 to -1)	0.007	1.00
ROM *Extension (right knee)*	15(4)	14(4)	2(2)	4(3)	-13(3)	-10(4)	-3(-4 to -1)	0.028	0.84
ROM *Extension (left knee)*	14(4)	13(3)	2(2)	4(3)	-12(3)	-9(3)	-3(-4 to -1)	0.014	1.33
ROM *Flexion (right knee)*	90(9)	93(6)	110(7)	106(7)	20(7)	13(7)	7(3 to 10)	0.007	0.95
ROM *Flexion (left knee)*	91(7)	93(6)	111(5)	106(5)	20(7)	13(7)	7(4 to 11)	<0.001	0.95
6-MWT	314(82)	297(68)	388(69)	327(73)	74(45)	30(22)	44(26 to 62)	<0.001	1.23

ESWT: Extracorporeal Shockwave Therapy; KIN: Kinesiotherapy; VAS: Visual Analog Scale; ROM: Range of Motion; 6-MWT: Six-Minute Walk Test.
[a]Calculated using Mann-Whitney U estimation.

Some other studies demonstrated positive effects of ESWT in pain and physical functions. Zhao et al. [11] reported, that 4-weeks ESWT of 4000 pulses in total with an impulse energy flux density of 0.25 mJ/mm^2, significantly more improved pain, the Lequesne index, and the WOMAC than ESWT placebo. Kim et al. [27] found that 3-weeks of a medium-energy ESWT with an impulse energy flux density of 0.093 mJ/mm^2, improved the VAS, ROM, WOMAC, and the Lequesne index greater than a low-energy ESWT with an impulse energy flux density of 0.040 mJ/mm^2.

In our study we used an alternative treatment protocol, comparing with other authors, based on 5-weeks ESWT of 8000 pulses in total with an impulse energy flux density of 0.4 mJ/mm^2. Despite on, our findings were in line with the results of other authors, who reported that ESWT or KIN improved the quality of life in patients with knee OA.

Our research team found that patients with knee OA who were treated with ESWT, had statistically significant better score post-intervention in each dimension of the quality of life (WOMAC), pain (VAS), range of motion of the knees (ROM), and functional

capacity (6-MWT). The large therapeutic effect size for all the parameters, in favour for shockwaves confirmed that ESWT was more efficient then KIN for knee OA. Pain is the main symptom associated with knee OA, which decreases daily activity of the patients. Relief of pain improves functional capacity of the musculoskeletal system. Thus, the patients in the ESWT group reached better scores on WOMAC, ROM, and 6-MWT. In addition, the applied energy flux density was friendly to the patients, because our research team did not observe any adverse events during the treatment.

So, the main physiological benefit of ESWT over KIN can be explained by the action mechanisms of ESWT on knee OA, they are likely complex and may include inhibiting afferent pain-receptor function and be influenced by cartilaginous and non-cartilaginous structures in the joint, giving the significant reduction of activity limitations and short duration of the treatment [28].

This study had strengths, including that groups were homogeneous regarding all variables at baseline evaluation, and the interventions were provided by the same experienced physiotherapist, blind to the outcome measures. The major limitation was the short follow-up period. The second limitation was a small sample size. As a result, a future study of long term effects with a larger sample size is needed to confirm our finding.

Conclusion

ESWT is more effective than KIN in improving quality of life, pain, range of motion of the both affected knees, and functional exercise capacity in patients with knee OA.

Acknowledgements

Thanks to all the participants in this study for contributing to the research development in this area.

Conflict of Interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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This manuscript was peer-reviewed
Mode of Review: Single-blinded
Academic Editor: Dr. Ibrahim K Ragab