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Original article

EARLY RESULTS OF TREATMENT WITH RADIAL EXTRACORPOREAL SHOCK WAVE THERAPY COMPARED TO CONVENTIONAL PHYSICAL THERAPY IN PATIENTS WITH KNEE OSTEOARTHRITIS

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Abstract

Knee osteoarthritis is a common musculoskeletal disorder. Radial extracorporeal shock wave therapy (RECTUB) is as a new effective conservative method.

This was a prospective, monocentric, interventional, non-randomized, controlled, clinical study that included a total of 50 patients divided into two groups. The study group was treated with RECTUB and kinesitherapy, and the control group was treated with conventional physical therapy and kinesitherapy. The patients' progress was monitored on the Numeric scale of pain and the WOMAC Index of functional ability before the treatment started; then immediately after its completion, and finally 3 months afterwards.

It was shown that patients from the study and control groups did not differ significantly in terms of pain intensity at the treatment beginning and at their first control, while the difference in pain intensity between the two groups at their second control was significantly different in favor of the study group. The total value and the values of the three subscales on the WOMAC index were insignificantly different between the two groups before the treatment from a statistical point of view, with significantly lower values thereof obtained in patients in the study group at the first and second control.

The results of this study demonstrate the benefits of using RECTUB as a safe, non-invasive, conservative treatment for knee osteoarthritis with better and longer-lasting effect on reducing pain and improving the functional ability of patients with knee osteoarthritis in contrast to patients treated with conventional physical therapy.

Keywords: knee osteoarthritis, radial extracorporeal shock wave therapy

Introduction

Osteoarthritis (OA) is the most common musculoskeletal disorder characterized by gradual loss of articular cartilage. This leads to a gradual thinning of the cartilage which results

in bones rubbing together, creating stiffness, pain, and impaired movement[1]. It is a major cause of disability in the elderly population around the globe, especially in developing countries. The prevalence is increasing and will continue to do so with the increase in population, its aging and the epidemic increase of weight gain. This type of musculoskeletal disorder places a heavy burden on individuals, communities, health and social care systems[1].

Osteoarthritis has been found to be the fifth highest cause of years lost to disability in the whole population in high-income countries, and the ninth highest cause in low- and middle-income countries. Worldwide estimates are that 9.6% of men and 18.0% of women over the age of 60 have symptomatic osteoarthritis. Radiographic evidence of knee osteoarthritis is present in approximately 30% of men and women over the age of 65.2 years[2]. Approximately 80% of those with osteoarthritis will have limitations in movement, and 25% cannot perform their major activities of daily life[3].

In the process of osteoarthritis, in addition to cartilage degeneration, the synovial membrane and the subchondral bone also play an important role. The changes that occur in the cartilage lead to processes of fibrillation and cracks, as well as to the appearance of the so-called ulcerations that lead to complete destruction of the thickness of the joint surfaces. This is accompanied by bone changes and the appearance of osteophytes as well as thinning of the subchondral plateau[3].

Osteoarthritis has a multifactorial etiology consisting of both systemic and local risk factors. Systemic risk factors include: age – the most important factor in the development of osteoarthritis[4]; gender – where women have a higher degree of pain and disability than men; genetic factors – it has been proven that between 39% and 65% of osteoarthritis in the general population is due to genetic factors[4]. Local risk factors include: injury or trauma to the joint where articular cartilage joint loses its flexibility, destroys cells, and reduces the load on the subchondral bone; obesity; occupational or workplace risks involving recurrent injuries, and physical injuries[5]; physical activity/sports activities also play an important role in the development of knee osteoarthritis[4]. Professional athletes who participate in sports with high physical impact have an increased risk of knee osteoarthritis[5]. Knee osteoarthritis is most often manifested by pain which is the earliest and dominant symptom. Other symptoms include stiffness in the knee, especially in the morning or after prolonged sitting; swelling; a feeling of warmth in the joint; decreased mobility in the knee joint, and crepitations when the knee moves[4]. The diagnosis of knee osteoarthritis is made on the basis of clinical examination which can confirm many of the symptoms including crepitations, swelling in the knee, limited range of motion and pain during normal knee movements. Confirmation of the disease can be done with conventional radiography, which is the simplest and most cost-effective method[6]. The Kellgren and Lawrence Scale is considered as gold standard for diagnosing knee osteoarthritis and consists of four degrees of radiological diagnosis of knee osteoarthritis[7].

Treatment of knee osteoarthritis can be conservative and surgical. Conservative treatment consists of non-pharmacological and pharmacological treatment. Non-pharmacological treatment primarily consists of educating patients, self-managing the condition, applying kinesitherapy, and weight loss. This treatment also includes the application of physical modalities as well as the application of orthoses.

Radial extracorporeal shock wave therapy (RECTUB) is a treatment with high-intensity acoustic radiation that is used for therapeutic purposes. The extracorporeal shock wave is an acoustic wave characterized by high positive pressures of more than 1000 bar (100 MPa), which can be developed within an extremely short rise time (10^{-9} seconds) and followed by a low-

pressure phase of tensile stress equivalent to 100 bar (10 MPa). As the pulse duration of the shock wave is extremely short (3 to 5μs) and is generated at low frequencies, it is minimally absorbed by the tissues; therefore no thermal effect is generated[8].

Materials and Methods

This was a prospective, monocentric, interventional, non-randomized, controlled, clinical study that took place at the PHI University Clinic for Physical Medicine and Rehabilitation in Skopje, R. North Macedonia. A total of 50 patients with knee osteoarthritis diagnosed radiologically according to the Kellgren and Lawrence scale were included. Patients were of both genders, aged 40 to 65 years, who underwent rehabilitation treatment on an outpatient or inpatient basis in this Clinic. All respondents included in the study were informed about the research, about the type and method of implementing the therapy. Each of the included patients signed an informed consent for voluntary participation in the study before the start of the rehabilitation treatment.

Inclusion criteria were: patient's age between 40 to 65 years, and a physical examination done confirming the presence of at least one of the following clinical criteria: knee pain, morning stiffness not longer than 30 minutes and presence of crepitations during active movement of the knee, whereas knee osteoarthritis was radiographically diagnosed according to the Kellgren and Lawrence scale. Exclusion criteria were: patient’s age (under 40 and over 65), pregnancy, presence of acute and chronic diseases: neurological, infectious, malignant diseases, ulcers of the skin of the knee joint, secondary arthritis, information on any surgical treatment in the examined knee, data on the application of physical therapy less than 3 months from the treatment with RECTUB and data on intra-articular injections with corticosteroids and hyaluronic acid less than 6 months before the RECTUB treatment.

Patients were divided into two groups: Group 1 – study group (SG) comprising 25 patients treated with RECTUB and kinesitherapy (isotonic and isometric exercises to strengthen the knee muscles and active exercises to increase the range of motion in the knees), and Group 2 – control group (CG) that included 25 patients treated with conventional physical therapy (ultrasound and interference currents) and kinesitherapy (isotonic and isometric exercises to strengthen the knee muscles and active exercises to increase the range of motion in the knees).

Application of radial extracorporeal shock wave therapy was performed with the Impactis M Shockwave Therapy Unit (Astar ABR, Bielsko-Biala, Poland). A total of 5 treatments were applied once a week, upon prior recommendation to do them on the same day of the week. Therapy was applied according to the manufacturer's recommendations: 2000 strokes in the area of painful points of the knee at 2 bar pressure, 10 Hz frequency and 5-minute application duration.

Patients included in the control group were treated with ultrasound therapy and interference current therapy. Ultrasound therapy was performed using a gel to obtain an efficient transfer of ultrasound waves with an intensity of 0.7W on area of 1 cm of the knee for a duration of 5 minutes. The therapy with interference currents was applied with a rhythmic frequency of 60-100Hz, for a duration of 15 minutes. For both physical modalities, the device model PhysioGo 300A/301A (Astar, Bielsko-Biala, Poland) was used. A total of 10 treatments were applied with a weekend break.

Patients from both groups performed kinesitherapy treatment consisting of isotonic and isometric exercises to strengthen the knee muscles, as well as active exercises to increase the range of motion of the knee joint. At the same time, patients from the study group underwent

kinesitherapy treatment for a duration of 10 consecutive days with weekend breaks, whereas in the control group, the kinesitherapy treatment was carried out during the days of application of the physical procedures.

Clinical Scales made in the study: The 11-point Numerical Pain Scale was used to assess knee pain intensity level. Western Ontario and Mcmaster University (WOMAC) OA index was used for evaluation of functional capacity in patients. This index is divided into three subscales, namely for pain, for stiffness and for functional ability of patients with osteoarthritis of the knee. The total score was determined as well as the score individually on the three subscales. Clinical scales were evaluated and points were assigned to patients from both groups: before the treatment started; immediately after its completion (after 5 weeks in the study group and after 2 weeks in the control group), as well as 3 months after physical and rehabilitation treatment.

Results

The statistical data analysis was done with the statistical package SPSS for Windows 26.0. The Shapiro-Wilk's W test was used to test the normality of the data.

A total of 50 patients were included in this study, 25 patients in the study group and 25 patients in the control group [47 (94%) were females and 3 (6%) males]. Patients' age ranged from 42 to 65 years, with a mean age of 56.9 ±5.9 years. Both groups were homogeneous in terms of gender structure, age and body mass index ($p>0.05$). In both groups female predominance was observed – 92% and 96%, respectively in the study and control group ($p=0.55$); at the age of 51 to 60 years – 64% and 48%, respectively in the study and control group ($p=0.175$); with a non-significantly different mean age (57.2 ± 6.3 *vs*. 58.6 ± 5.2, $p=0.063$) and with a non-significantly different body mass index (31.64 ± 5.9 *vs*. 32.54 ± 6.8, $p=0.62$).

Table 1. Demographic characteristics of the sample

Variables			**groups**		**p-value**
		n	**SG n (%)**	**CG n (%)**	
Gender	female	47	23 (92)	24 (96)	X^2=0.35 p=0.55
	male	3	2 (8)	1 (4)	
Age	41 – 50	6	4 (16)	2 (8)	X^2=3.49 p=0.175
Groups	51 – 60	28	16 (64)	12 (48)	
	61 – 65	16	5 (20)	11 (44)	
Age	mean ±SD		57.2 ± 6.3	58.6 ± 5.2	t=0.08 p=0.063
Years	min- max		42 – 65	47 – 65	
BMI	mean ±SD		31.64 ± 5.9	32.54 ± 6.8	t=0.49 p=0.62
kg/m^2	min- max		23.6 – 45.7	19.8 – 50.6	

X^2 (Chi-square test), t (Student t-test)

Patients from the study and control groups did not differ significantly in terms of pain intensity at the beginning and at their first control ($p>0.05$), while the difference in pain intensity between the two groups at their second control was significantly different ($p=0.0018$), which was due to a significantly stronger pain in CG. The average score of the Numeric scale of pain in SG and CG was 6.52±1.6 and 6.52±1.3 respectively, i.e.: 3.44±1.5 at the beginning; 3.64±1.8 and 1.92±1.4 at the first control, and 3.88±2.3 at the second control, respectively.

Table 2. Numeric scale of pain values

Statistical parameters	At the beginning SG	At the beginning CG	First control SG	First control CG	Second control SG	Second control CG
Numeric scale of pain						
mean ±SD	6.52±1.6	6.52±1.3	3.44±1.5	3.64±1.8	1.92±1.4	3.88±2.3
min- max	3 – 9	3 – 8	0 – 6	0 – 6	0 – 5	0 – 9
median (IQR)	7 (5 – 8)	7 (6 – 8)	4 (2 – 4)	4 (2 – 5)	2 (1 – 3)	3 (2 – 5)
p-value	Z=0.2 p=0.82		Z=0.67 p=0.5		Z=3.1 **p=0.0018	

Z(Mann-Whitney test), **p<0.01

At the beginning, patients from the study and control groups mostly had severe pain – 15 (60%) and 13 (52%) patients, respectively; at the first control they mostly had moderate pain – 15 (60%) and 14 (56%); at the second control, patients in the study group did not have pain more often than patients in the control group – 5 (20%) *versus* 2 (8%), and had weak pain – 17 (68%) versus 11 (44%), whereas less often they had strong pain – 3 (12%)) *versus* 9 (36%), and severe pain – 0 *versus* 3 (12%). The tested difference in the distribution of patients without pain, with mild, moderate and severe pain between the two groups was insignificant at the beginning and at their first control (p>0.05), and significant at their second control (p=0.037).

Table 3. Types of pain according to the numeric scale of pain

Numeric scale of pain	n	At the beginning SG n (%)	At the beginning CG n (%)	n	First control SG n (%)	First control CG n (%)	n	Second control SG n (%)	Second control CG n (%)
without pain				3	1 (4)	2 (8)	7	5 (20)	2 (8)
Mild	2	1 (4)	1 (4)	18	9 (36)	9 (36)	28	17 (68)	11 (44)
Moderate	20	9 (36)	11 (44)	29	15 (60)	14 (56)	12	3 (12)	9 (36)
Severe	28	15 (60)	13 (52)				3	0	3 (12)
p-value	p=0.88			p=1.0			*p=0.037		

p (Fisher's exact); *p<0.05

The initial values of the WOMAC index, its total value and the values of the three subscales were statistically, insignificantly different between the two groups (p>0.05). At the first and second control, the total WOMAC index and its subscales had statistically significantly lower values in SG (p<0.05, p<0.01, p<0.0001), that is, SG patients had less pain, less stiffness in the knee and less restrictions in everyday life. The total WOMAC score was significantly lower in SG compared to CG; at the first control the average and median total values were 19.72±11.1 and 18 in SG, 33.76±18.6 and 37 in CG; at the second control the average and median total values were 11.36±7.5 and 11 in SG, 30.40±17.6 and 29 in CG.

Table 4. Values of the WOMAC index

WOMAC index						
Statistical parameters	At the beginning SG	At the beginning CG	First control SG	First control CG	Second control SG	Second control CG
Subscale 1 – Intensity of pain						
mean ±SD	10.20±2.5	9.28±2.4	4.36±2.9	7.36±3.8	2.24±1.5	5.72±3.6
min- max	4 – 15	5 – 14	0 – 13	0 – 13	0 – 5	0 – 12
median (IQR)	10(9 – 12)	9(8 – 11)	4(2 – 6)	7(4 – 10)	3(1 – 3)	5(3 – 9)
p-value	t=1.3 p=0.19		t=3.1 **p=0.003		Z=3.5 ***p=0.00048	
Subscale 2 – Knee stiffness						
mean ±SD	3.04±2.1	2.52±2.3	0.60±1.1	1.72±1.9	0.44±0.8	1.88±1.8

min- max	0 – 7	0 – 6	0 – 4	0 – 6	0 – 3	0 – 5
median (IQR)	3(2 – 4)	3(0 – 5)	0(0 – 1)	1(0 – 3)	0(0 – 1)	2(0 – 3)
p-value	Z=0.68 p=0.49		Z=2.0 *p=0.046		Z=2.75 **p=0.0059	
Subscale 3 – Difficulties in performing activities of every day life						
mean ±SD	30.20±11.6	35.84±9.1	14.76±8.3	25.12±14.2	8.68±6.1	22.80±13.4
min- max	3 – 46	7 – 52	4 – 30	0 – 54	0 – 20	1 – 53
median (IQR)	34(22-38)	37(33-42)	14(7 – 22)	27(13 – 38)	8(3 – 13)	21(12 – 34)
p-value	t=1.9 p=0.062		t=3.1 **p=0.0029		Z=3.8 ***p=0.00013	
Total value						
mean ±SD	44.64±12.8	47.64±11.9	19.72±11.1	33.76±18.6	11.36±7.5	30.40±17.6
min- max	8 – 63	14 – 69	4 – 43	0 – 75	0 – 25	1 – 70
median (IQR)	45(36-54)	48(41-54)	18(11 – 28)	37(16 – 46)	11(4 – 18)	29(16 – 45)
p-value	t=0.85 p=0.39		t=3.2 **p=0.0022		Z=3.8 ***p=0.00013	

t (Student t-test), Z (Mann-Whitney test); **p<0.01, ***p<0.0001

Discussion

The results of this study have demonstrated the benefits of using RECTUB as a safe, non-invasive, conservative treatment for knee osteoarthritis. It turned out that the therapeutic effect of its application was maintained for 3 months after its application, especially in pain reduction and improvement of functional ability of patients with knee osteoarthritis. In the systematic review and meta-analysis of Lou *et al*. for the application of extracorporeal shock wave therapy in osteoarthritis and comparison of its use in correlation with other conventional treatments, it has been shown that the application of shock wave therapy resulted in a significant reduction in pain and improvement in functional capacity compared to placebo, intraarticular administration of corticosteroids or hyaluronic acid, analgesics, and ultrasound therapy. Randomized controlled trials were compared the effect of ECTUB with other types of osteoarthritis treatment. Numeric scale of pain and WOMAC index for pain relief and functional fitness were examined. Meta-analysis of the Lu Chen and col. recommend the application of shock wave therapy in the treatment of osteoarthritis as a non-invasive method, safe, secure and effective in the treatment of various forms of osteoarthritis[9]. In the first meta-analysis about the application and efficacy of shock wave therapy in osteoarthritis of the knee conducted by Tengqui *et al*., out of a total of 127 studies, seven comprised a total of 366 patients, of whom 169 were included in the shock wave group; 140 were in the placebo group, and 57 patients belonged to the physical therapy group. The Visual Analogue Scale (VAS), range of motion (ROM), Lequesne index (LI) and WOMAC index were examined. The final results in terms of pain, range of motion, LI and WOMAC index were with a statistically significant difference between ECTUB group and the other two groups. This meta-analysis suggests that shock wave therapy in patients with knee osteoarthritis may achieve a better therapeutic effect than conventional physical therapy[10]. A study by Ji-Hyun Lee *et al*., which reported the effects of shock wave therapy in combination with conventional physical therapy and the effects of conventional physical therapy alone on pain and functional capacity in patients with degenerative osteoarthritis of the knee, found that there was a greater improvement in the measured parameters in the first group. This does not exclude the possibility of considering the combined application of conventional physical therapy with the application of shock wave therapy in the treatment of knee osteoarthritis[11].

Conclusion

Radial extracorporeal shock wave therapy is a non-invasive, safe and effective method of treating patients with knee osteoarthritis. In this study, it has been shown that the effect of the application of this newer conservative physical method gave better and longer lasting results in

reducing pain and improving the functional ability of patients with knee osteoarthritis compared to conservative physical treatment.

Conflict of interest statement. None declared.

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