

Extracorporeal shockwave therapy for the treatment of knee osteoarthritis

A retrospective study

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Abstract

This retrospective study investigated the effect and safety of extracorporeal shockwave therapy (ESWT) for treatment of knee osteoarthritis (KOA).

In this retrospective study, 105 patients with KOA were included. Of those, 60 patients underwent ESWT, whereas 45 patients received laser therapy. Effect was measured by the Numeric Rating Scale (NRS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). In addition, adverse events (AEs) were also recorded in this study. All outcome measurements were evaluated at the end of weeks 1, 6, and 12.

Compared with the laser therapy, ESWT showed greater effect in KOA symptoms relief with regard to NRS, WOMAC total, and its subscores at week 6 ($P < .05$) and week 12 ($P < .01$) after treatment. No AE, however, occurred in both groups.

The results of this retrospective study found that ESWT may be efficacious and safe for the treatment of patients with KOA. It, however, had an intrinsic limitation as a retrospective study. Prospective study with larger sample size is still needed to warrant the result of this study in the future.

Abbreviations: AE = adverse events, ESWT = extracorporeal shockwave therapy, KOA = knee osteoarthritis, NO = nitric oxide, NRS = Numeric Rating Scale, rESWT = radial ESWT, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

Keywords: effect, extracorporeal shockwave therapy, knee osteoarthritis, safety

1. Introduction

Knee osteoarthritis (KOA) is one of the disabling joint disease of advanced age.^[1–3] It often results in the knee pain, stiffness, restricted movement, sleep disturbance, and even poor quality of life and psychological disability.^[4–6] The progressive aging of the population has also caused to the increase in the incidence and

prevalence of KOA, and such condition has become a major public health issue.^[7,8] It has been reported that 9.6% of men and 18% of women have symptomatic KOA at the age of 60 years and above.^[9] In addition, approximately 25% population older than 55 years have reported at least 1 attack of knee pain each year,^[10] and approximately 13% of older population have diagnosed as having KOA over the 7 years.^[11]

As for treatment, pharmacological therapy often has limited benefit for KOA pain relief.^[12] Furthermore, the use of pharmacological drugs is often associated with serious adverse events (AEs), including bleeding and gastrointestinal ulcers.^[13] Complementary therapies, such as local injection,^[14,15] acupuncture,^[16,17] moxibustion,^[18] cupping therapy,^[19] exercise,^[20] and laser therapy^[21] are also used to treat KOA. They are, however, not sufficient to control chronic, severe KOA pain. Although surgery is generally effective for the treatment of patients with advanced KOA,^[22] some older patients with limiting comorbidities may not be able to undergo such intervention appropriately. In such conditions, extracorporeal shockwave therapy (ESWT) might be a successful alternative treatment in patients with KOA with few complications.^[23] ESWT is a nonsurgical and noninvasive intervention by using shock waves outside the body, especially for patients who cannot be treated by anti-inflammatory or immobilization devices. This quick effective intervention is often used to treat many chronic painful orthopedic conditions.

It has been reported that ESWT can be used to treat patients with KOA.^[23] Limited data on the ESWT for the treatment of KOA are, however, available. Thus, more studies are still needed to explore the effect and safety of ESWT on the treatment of KOA. In this retrospective study, we investigated the effect and safety of ESWT for the treatment in patients with KOA, compared with laser therapy.

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WL and YP contributed equally to this work.

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2. Materials and methods

2.1. Ethics

This study was formally approved by the ethics committee of The First Hospital of Harbin City, The First Affiliated Hospital of Harbin Medical University, and The Fourth Affiliated Hospital of Harbin Medical University. All patients provided the informed consent.

2.2. Design

This retrospective study included 105 patients with KOA. They were assigned to an ESWT therapy group and a laser therapy group according to the different interventions they received. Sixty patients underwent ESWT and were assigned to the ESWT therapy group, whereas 45 patients received laser therapy and were assigned to the laser therapy group. Patients in both groups were treated for 12 weeks. All outcomes were measured at the end of 1-, 6-, and 12-week treatment.

2.3. Eligibility criteria

This retrospective study was also conducted at these 3 hospitals between January 2015 and December 2016. All 105 patients were diagnosed with KOA. In addition, the inclusion criteria included the following: patients had >6 months history of KOA and pain intensity was >4, measured by Numeric Rating Scale (NRS). The exclusion criteria included patients had history of knee surgery, tumors, or they received ESWT or laser therapy 1 month before this study.

2.4. Interventions

Sixty patients with KOA underwent ESWT with 3000 pulses of 0.11 mJ/mm² at a frequency of 15 Hz by using the Pain Treatment System of Radial Shockwave Device (SonoThera, Hanil TM Co. Ltd, Wonju-si, Gangwon-do, Korea). All patients presented in a supine position with affected knee unbent. The shockwave probe was applied to the trigger point around the attacked knee. All patients were treated for 5 sessions with an interval of 3 days for a total of 12 weeks. Forty-five patients received laser therapy. The calibrated laser device (Standard Class 3B; Stockholm, Sweden) was used to treat patients with KOA. It applied over the joint line with 5 points of synovial region of the medial side. In addition, 4 points at the lateral side were also applied. The measurement output energy was 0.2 J/point for a total dose of 20 J each treatment per knee.

2.5. Outcome measurements

The outcomes measured by the 11-point NRS^[24] and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).^[25] The NRS tool ranges from 0 to 10, with 0 as no pain, and 10 as the worst pain. The WOMAC tool includes 24 items, and it is divided into 3 subscales to evaluate the pain, stiffness, and physical function. The subscale of pain with 5 items ranges from 0 to 20, with 0 as no pain, and 20 as the worst pain. The subscale of stiffness with 2 items varies from 0 to 8, with 0 as no pain, and 20 as the worst pain. The subscale of physical function with 17 items ranges from 0 to 68. In addition, AEs were also recorded in this study. We assessed and analyzed the outcome data of NRS and WOMAC at the end of 1, 6, and 12 weeks. In addition, we analyzed the data of AEs at the end of 12-week treatment.

Table 1

Characteristics of included patients.

Characteristics	ESWT therapy (n=60)	Laser therapy (n=45)	P
Mean age, y	60.1 (10.1)	58.7 (11.2)	.51
Sex			
Male	38 (63.3)	27 (60.0)	.73
Female	22 (36.7)	18 (40.0)	.73
BMI, kg/m ²	25.1 (2.4)	25.5 (2.5)	.41
Duration of KOA, y	5.7 (2.3)	5.6 (2.8)	.85
NRS score	7.5 (1.3)	7.4 (1.1)	.67
WOMAC score			
Total	32.3 (11.0)	30.9 (11.6)	.53
Pain	7.7 (2.2)	7.6 (2.3)	.37
Stiffness	2.3 (1.0)	2.2 (1.0)	.61
Function	21.5 (9.0)	21.2 (8.9)	.86

Data are present as mean ± standard deviation or number (%).

BMI = body mass index, ESWT = extracorporeal shockwave therapy, KOA = knee osteoarthritis, NRS = Numeric Rating Scale, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

2.6. Statistical analysis

All data were analyzed using the Statistical Package for the Social Sciences software v.19.0 (SPSS Inc, Chicago, IL). The continuous variable data at baseline, and NRS and WOMAC scores were analyzed by *t* test (normally distributed data) or Mann-Whitney rank sum test (not normally distributed data) at the end of 1-, 6-, and 12-week treatment. The categorical data at baseline were analyzed by Pearson chi-square test. Two-sided *P* values of <.05 were regarded as the statistical significance.

3. Results

The characteristics of 105 included patients with KOA are summarized in Table 1. No significant differences of characteristic values were found at baseline between 2 groups (Table 1). These characteristics consisted of age, sex, body mass index, duration of KOA, NRS score, WOMAC total, and its subscores.

At baseline, the NRS scores by ESWT therapy and laser therapy were 7.5 ± 1.3 and 7.4 ± 1.1, respectively (Table 1). After 1 week, the NRS scores by each therapy were 6.9 ± 1.5 and 7.0 ± 1.4, respectively (Fig. 1). After 6 weeks, they were 5.0 ± 1.7 and 6.7 ± 1.8, and after 12 weeks, they were 2.8 ± 1.4 and 6.4 ± 1.6, respectively (Fig. 1). There were significant differences between

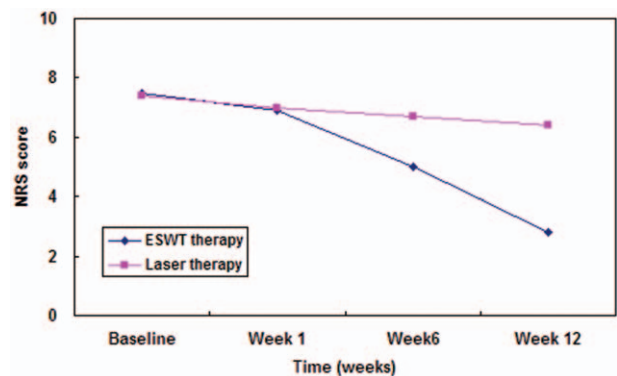


Figure 1. Comparison of NRS scores between 2 therapies. ESWT = extracorporeal shockwave therapy, NRS = Numeric Rating Scale.

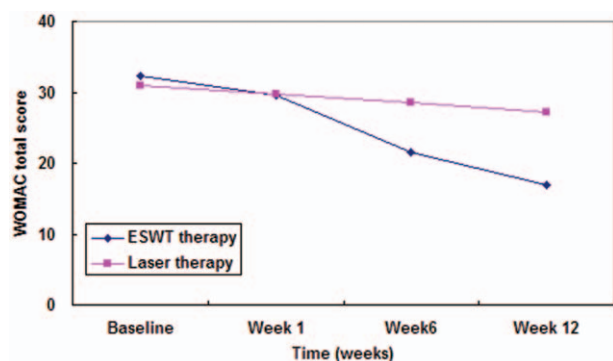


Figure 2. Comparison of WOMAC total scores between 2 therapies. ESWT = extracorporeal shockwave therapy, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

the 2 therapies at weeks 6 ($P < .01$) and weeks 12 ($P < .01$) (Fig. 1).

At baseline, the WOMAC total scores by ESWT therapy and laser therapy were 32.3 ± 11.0 and 30.9 ± 11.6 , respectively (Table 1). After 1 week, the total WOMAC scores by the 2 therapies were 29.5 ± 11.3 and 29.7 ± 11.8 , respectively; after 6 weeks, they were 21.5 ± 10.5 and 28.6 ± 12.1 , respectively; and after 12 weeks, they were 16.9 ± 9.1 and 27.2 ± 10.9 , respectively (Fig. 2). There were also significant differences between the 2 therapies at week 6 ($P < .01$) and week 12 ($P < .01$) (Fig. 2).

The WOMAC subscores of pain, stiffness, and function by 2 therapies were 7.7 ± 2.2 , 2.3 ± 1.0 , 21.5 ± 9.0 and 7.6 ± 2.3 , 2.2 ± 1.0 , 21.2 ± 8.9 , respectively (Table 1). After 1 week, WOMAC subscores for the 2 therapies were 7.1 ± 2.3 , 2.1 ± 0.9 , 20.3 ± 9.4 and 7.2 ± 2.3 , 2.1 ± 1.0 , 20.6 ± 9.1 , respectively (Figs. 3–5). After 6 weeks, they were 1.4 ± 0.8 , 2.3 ± 1.0 , 15.1 ± 8.3 and 6.8 ± 2.5 , 2.0 ± 0.9 , 19.9 ± 9.4 , respectively (Figs. 3–5); after 12 weeks, they were 3.0 ± 2.1 , 1.0 ± 0.7 , 12.8 ± 6.9 and 6.5 ± 2.4 , 1.8 ± 0.8 , 19.6 ± 8.0 , respectively (Figs. 3–5).

As for safety, no AE was recorded by any of the therapies during the study period.

4. Discussion

Several animal studies and clinical studies investigated the mechanism, efficacy, and safety of ESWT for the KOA. Ochiai et al^[26] explored the effect ESWT on KOA in a rat knee model. The results showed that the enhancement in walking ability and

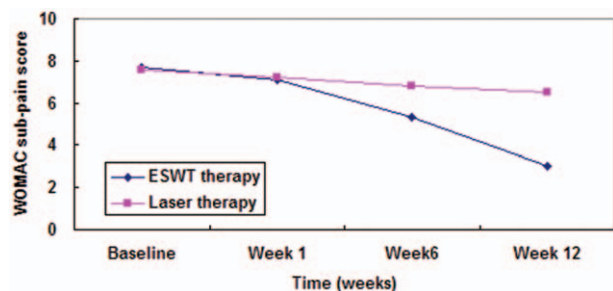


Figure 3. Comparison of WOMAC subpain scores between 2 therapies. ESWT = extracorporeal shockwave therapy, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

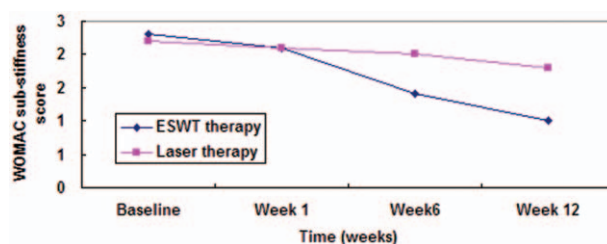


Figure 4. Comparison of WOMAC sub-stiffness scores between 2 therapies. ESWT = extracorporeal shockwave therapy, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

the decreased expression of calcitonin gene-related peptide in dorsal root ganglion neurons indicating that ESWT is an useful intervention for KOA.^[26] Zhao et al^[27] investigated the mechanism of ESWT for KOA in rabbits by reducing nitric oxide (NO) level and chondrocyte apoptosis. Its results demonstrated that ESWT can significantly reduce the level of NO in the synovial cavity of knee joints, and can decrease the chondrocyte apoptosis in rabbits with KOA.^[27] It indicates that ESWT can decrease the progression of KOA in rabbits, and may be used as a useful treatment for KOA.^[27] Zhao et al^[23] also evaluated the efficacy of ESWT for patients with KOA during 12 weeks when compared with placebo. They found that ESWT is efficacious in decreasing pain and enchaining knee function during the 12-week treatment.^[23] Kim et al^[28] investigated the dose-related effects of ESWT in Korean patients with KOA. Their results showed that medium-energy ESWT had greater improvement in pain relief and function restoration than the low-energy ESWT.^[28] Imamura et al^[29] explored the efficacy and safety of radial ESWT (rESWT) for Brazilian patients with disabling pain due to the primary KOA. Its results demonstrated that rESWT is not efficient for the treatment in patients with disabling pain due to the primary KOA.^[29] The data indicate that higher energy of rESWT may be useful for treating patients with such condition.^[29]

Although several previous studies have investigated the efficacy and safety of ESWT for treating patients with KOA, 2 of them focused on the animal studies, and only 1 study included Chinese patients with small sample size. To our best knowledge, this study is the first retrospective research to explore the effect and safety of ESWT in patients with KOA among Chinese population. The results of this study found that ESWT showed promising effect

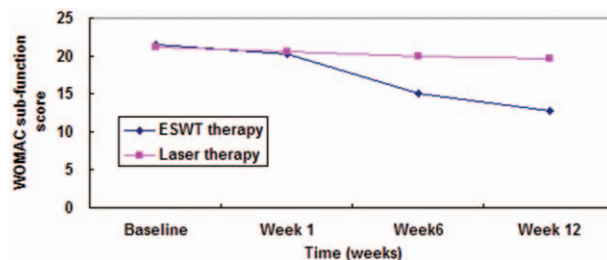


Figure 5. Comparison of WOMAC subfunction scores between 2 therapies. ESWT = extracorporeal shockwave therapy, WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index.

and satisfied safety for the treatment of patients with KOA, compared with the laser therapy.

In this study, the knee pain associated with KOA, measured by the NRS score, and subscale of WOMAC, was significantly relieved by utilizing ESWT, compared with laser therapy. The knee stiffness and function, both measured by the subscales of WOMAC also improved greatly in patients among Chinese population. Moreover, no treatment-related AEs were recorded in both groups in our study.

This study has the following limitations: sample size was relative small in this study, which affected its results; only single dose of ESWT was used in this study; therefore, optimal doses of ESWT should be focused in further study; this study did not evaluate the quality of life in patients with KOA, because it just analyzed the outcome data based on the available completed cases of the included patients; and this study had an intrinsic limitation because it is a retrospective study, which may affect the results of this study. Thus, future studies should include comprehensive outcome measurements, including quality of life measurement.

5. Conclusion

This study found that ESWT may be efficacious and safety for patients with KOA. It, however, suffered from an intrinsic limitation as a retrospective study. Thus, future prospective study with larger sample size should further warrant the results of this study.

Author contributions

Conceptualization: Qinggang Meng, Wei Li, Yu Pan, Zheng-gui Guo, Qi Yue.

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Writing – original draft: Qinggang Meng, Wei Li, Yu Pan, Qi Yang, Zheng-gui Guo, Qi Yue.

Writing – review and editing: Qinggang Meng, Wei Li, Yu Pan, Qi Yang, Zheng-gui Guo, Qi Yue.

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