Effects of extracorporeal shock wave therapy in patients with knee osteoarthritis
A cohort study protocol

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Abstract

Background: Osteoarthritis is the most common form of arthritis, and is a major cause of disability and chronic pain in adults. However, there is very limited evidence in the scientific literature to support the effectiveness of extracorporeal shockwave therapy (ESWT) in human knee osteoarthritis. This retrospective study aimed to compare the efficacy of ESWT treatment with sham-ESWT on pain, walking speed, physical function, and adverse effects in knee osteoarthritis.

Methods: This study will be performed and reported in accordance with the Strengthening the Reporting of Observational studies in Epidemiology checklist. We reviewed patients diagnosed with knee osteoarthritis at our academic center from 2016 to 2017. This retrospective cohort study was approved by the institutional review board in Ruijin Hospital. The primary outcome measure was pain on movement measured by a 100-cm visual analog scale. The secondary outcome measures included the Western Ontario and McMaster University Osteoarthritis Index, range of motion, and adverse effects. Statistical analysis was performed using Statistical Package for Social Sciences version 20.0 (IBM Corporation, Armonk, NY). A P-value of <.05 was defined as statistical significance.

Results: The hypothesis was that ESWT would be an effective treatment for improving pain and physical function in knee osteoarthritis to control symptoms.

Trial registration: This study protocol was registered in Research Registry (researchregistry5801).

Abbreviations: ACR = American College of Rheumatology, ESWT = extracorporeal shockwave therapy, VAS = visual analog scale, WOMAC = Western Ontario and McMaster University Osteoarthritis Index.

Keywords: extracorporeal shockwave therapy, knee osteoarthritis, pain control; protocol, retrospective

1. Introduction

Osteoarthritis is the most common form of arthritis, and is a major cause of disability and chronic pain in adults\textsuperscript{[1,2]} Even though osteoarthritis can involve single and/or multiple peripheral joints, including the knee, hip, and hand, the knee is the most common joint localization of symptomatic osteoarthritis.\textsuperscript{[3,4]} Knee osteoarthritis is the most common cause of disability and joint pain in adults\textsuperscript{[3,4]} and is primarily characterized by chronic pain which is exacerbated by central sensitization\textsuperscript{[5,6]}, and reduced physical functioning. In addition, patients with osteoarthritis often suffer from comorbid depression\textsuperscript{[7]} and anxiety, and significantly worse quality of life\textsuperscript{[8,9]}

Conservative treatment has been regarded as the first-line therapy for knee osteoarthritis, including rest, nonsteroidal anti-inflammatory drugs, physiotherapy, corticosteroid injection, or dry needling.\textsuperscript{[10–12]} However, the effectiveness of these treatments is still not well-established. Extracorporeal shock wave therapy (ESWT) appears to be a promising alternative and has been proven to be beneficial in several musculoskeletal diseases and especially enthesopathies, including plantar fasciitis, elbow epicondylitis, patella tendinitis, and achilles tendinitis.\textsuperscript{[13,14]} ESWT is a pulsed sound wave, characterized by short duration, high pressure amplitude, and relatively low tensile wave component.\textsuperscript{[15]} The mechanism of ESWT is not completely clear. However, it is speculated that ESWT may produce a reflexive analgesic effect by inducing excitability of the axon and destroying unmyelinated sensory fibers.\textsuperscript{[16]}

Although there are many studies about ESWT on musculoskeletal disorders as well as on chondroprotective effect on animal have been published,\textsuperscript{[17–19]} there is very limited evidence in the scientific literature to support the effectiveness of ESWT in human knee osteoarthritis.\textsuperscript{[20]} Thus, more studies are still needed to explore the effect and safety of ESWT on the treatment of knee
osteoarthritis. This retrospective study aimed to compare the
efficacy of ESWT treatment with sham-ESWT on pain, walking
speed, physical function, and adverse effects in knee osteoarthri-
tis. The hypothesis was that ESWT would be an effective
treatment for improving pain and physical function in knee
osteoarthritis to control symptoms.

2. Materials and methods

This study will be performed and reported in accordance with the
Strengthening the Reporting of Observational studies in
Epidemiology checklist. We reviewed patients diagnosed with
knee osteoarthritis at our academic center from 2016 to 2017.
This retrospective cohort study was approved by the institutional
review board in Ruijin Hospital (SHRJ00127) and was registered
in the research registry (researchregistry5801).

2.1. Patients

Inclusion criteria: patients diagnosed with knee osteoarthritis
according to the diagnostic criteria of American College of
Rheumatology (ACR) who wanted to receive shock wave
therapy. ACR criteria included that of knee pain, osteophytes,
and 1 of the following: age >50 years, morning stiffness <30
minutes duration, or crepitus on active motion of the knee. The
enrolled patients were over 45 years old, with unilateral knee
joint symptoms, knee pain in the past 3 months, K-L classification
of grade 2 or 3, and cartilage magnetic resonance imaging
diagnosis of Recht grade II or III. Exclusion criteria: patients with
bilateral knee joint symptoms; patients with a history of spinal
stenosis; patients with a history of nervous system disease or
secondary arthritis (inflammatory or metabolic); patients receiving
surgery in the involved knee joint or intra-articular injection
within the past 6 months; and patients with any contraindication
of magnetic resonance imaging or radioscopy.

2.2. Interventions

Participants in the experimental group received ESWT. All
ESWTs were given by a single experienced physical therapist.
ESWT was conducted using an Electro Medical Systems
instrument once a week for 4 consecutive weeks (4 sessions in
total). The parameters of therapy included a total of 2000 pulses
of 8 Hz frequency at 2.5 bar of pneumatic pressure. The first 1000
pulses were evenly distributed to pain points (the maximum
number of pain points is 4). The remaining pulses were slid back
and forth on the patellofemoral and tibiofemoral borders. No
local anesthesia or other injections was used. Participants
assigned to the placebo group were managed by the same
physical therapist with the same ESWT protocol, but the air
pressure was set at 0.2 bar.

2.3. Home exercise

As part of the treatment program, all participants, regardless of the
group, were educated on a simple home exercise program for the
first visit. The program was comprised of a single knee extensor
muscle strengthening. The patient sat in a chair, straightened his/
her knee as far as possible, kept it for 10 seconds, repeated 10 times,
and did 3 groups per day. Therapist-applied manual forces were
not permitted in the exercise program. The home exercise was
supervised by a physiotherapist once every 3 days over the phone.

### Table 1
Postoperative outcomes.

| Outcome | ESWT group | Control group | P value |
|---------|------------|---------------|---------|
| VAS score |            |               |         |
| WOMAC   |            |               |         |
| Range of motion |        |               |         |
| Adverse effects |      |               |         |

ESWT = extracorporeal shock wave therapy, VAS = visual analog scale, WOMAC = Western Ontario and McMaster University Osteoarthritis Index.

2.4. Outcome evaluation

The patient demographics were recorded retrospectively from
their electronic patient notes. The primary outcome measure
was pain on movement measured by a 100-cm visual analog
scale (VAS). Pain was evaluated on a VAS with 0 = no pain, and
100 = worst imaginable pain. The secondary outcome measures
included the Western Ontario and McMaster University
Osteoarthritis Index (WOMAC), range of motion, and adverse
effects. The WOMAC assesses symptoms of osteoarthritis and is
a validated disease-specific self-reporting questionnaire referring
to the 48 hours before assessment. The index consists of 5
questions for severity of knee pain, 2 for stiffness, and 17 for
limitations in physical function. The WOMAC score ranges from
0 (best) to 96 (worst), with high score representing worse
symptom severity (Table 1).

2.5. Statistical analysis

Statistical analysis was performed using Statistical Package for
Social Sciences version 20.0 (IBM Corporation, Armonk, NY).
Parametric and non-parametric tests were used as appropriate to
assess continuous variables for significant differences between
groups. A Student t test was used to compare linear variables
between groups. Dichotomous variables were assessed using a chi
square test. Multivariate linear and regression analyses were used
to identify independent predictors of outcome. A P-value of <.05
was defined as statistical significance.

3. Discussion

Knee osteoarthritis is the most common chronic degenerative
joint disorder in the clinical, which causes arthritic symptoms,
such as joint pain, stiffness, limitations in movement, and loss of
functions. Worldwide estimates are that 9.6% of men and 18.0%
of women aged over 60 years have symptomatic osteoarthritis.
Recently, ESWT was reported to have good results for treating
knee osteoarthritis. It provided another alternative for the
treatment of knee osteoarthritis. This retrospective study aimed
to compare the efficacy of ESWT treatment with sham-ESWT on
pain, walking speed, physical function, and adverse effects in
knee osteoarthritis. The hypothesis was that ESWT would be an
effective treatment for improving pain and physical function in
knee osteoarthritis to control symptoms.

Author contributions

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