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박사학위논문

근막동통 증후군에 의한  
만성요통 환자에서 체외충격파  
치료의 효과

조선대학교 대학원  
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The Effect of Extracorporeal Shock Wave Therapy on  
Chronic Low Back Pain Patients due to Myofascial  
Pain Syndrome

2015년 8월 25일

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이 논문을 의학박사학위신청 논문으로 제출함.

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## 강정훈의 박사학위논문을 인준함

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## 초록

### 근막동통 증후군에 의한 만성요통 환자에서 체외충격과 치료의 효과

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**목적** : 이 논문은 근막동통 증후군에 의한 만성 요통 환자에서 체외충격과 치료의 효과를 알아보려고 연구되었다.

**방법** : 총 43명의 만성 요통 환자가 연구에 참여하였고, 두 그룹으로 분류되었다. 연구를 시작하기 전 두 그룹 간 나이, 키, 몸무게와 시각 통증 강도 및 일상생활 medical outcomes study short form-36(SF-36)과 요통의 기능 장애 척도인 Oswestry disability index는 유의한 차이가 없었다. 대조군은 열 치료, 전기 치료 및 운동 치료를 포함한 일반적인 재활 치료를 시행 하였고, 연구군은 추가로 총 8차례 체외충격과 치료(0.10 - 0.15mJ/mm<sup>2</sup> FED, 1000 impulse, 4Hz, weekly)를 시행하였다. 8주후 모든 환자에서 시각 통증 척도, 일상생활 medical outcomes study short form-36(SF-36)과 요통의 기능 장애 척도인 Oswestry disability index가 호전되었다.

**결과** : 연구를 시작하기 전 두 그룹의 차이는 없었지만 8주간의 치료 이후 연구군에서 시각 통증 척도, 일상생활 medical outcomes study short form-36(SF-36)과 요통의 기능 장애 척도인 Oswestry disability index가 유의할 만한 호전이 관찰되었다.

**결론** : 근막동통 증후군에 의한 만성 요통 환자에서 체외충격과 치료가 효과적



인 재활 치료가 될 수 있을 것으로 고려된다.

Key Words : Ultrasonography, Extracorporeal shock wave therapy, Chronic low back pain

## I. INTRODUCTION

Back pain is a symptom, which is originated only from the musculoskeletal system, except lumbar pain derived from pregnancy, menstruation, urinary tract infection, and etc. The waist pain below 10th thoracic vertebra lasts more than 3 days, regardless of the presence of radiating pain. Low back pain is the most common pain experienced by humans, and it is widely known that more than 80 percent of humans experience the pain at least once in a lifetime.<sup>1</sup> Most acute low back pain can be cured within 8-10 weeks irrespective of treatment, but many people, who recovered from the acute low back pain, have a relapse, and some develop chronic low back pain lasting more than 6 months.<sup>2,3</sup> While acute low back pain resulting from sprain of muscle and ligament can easily cured and the prognosis is good, chronic low back pain not only shows a bad prognosis but also has a great influence on patients' social and mental stability due to persistent pain.<sup>4</sup> Chronic low back pain is induced by abnormality of the vertebral structure, and nerves are distributed in the structure. Mechanical and chemical changes of the structure have the pain transferred to the brain through the lateral spinothalamic tract and the laminar tract, and response to the pain is expressed.<sup>5</sup>

Treatment of chronic low back pain is various and determined by the degree of disease and other conditions, and it is largely divided into three types. Most chronic low back pain patients undergo medical treatment at first, which includes medication, physical therapy, posture education, therapeutic exercise, manipulation, and traction. As invasive treatment, selective nerve root block, epidural steroid injection, and radiofrequency ablation are performed. When there is no response to the treatment and otherwise serious disease conditions are shown, operations are conducted at last.

Recently, new conservative treatments are performed, one of which is extracorporeal shock wave therapy(ESWT). An extracorporeal shock wave is defined as a pressure wave induced by explosion, and spark, high-speed eruption, which make strong pressure variations in elastic materials of gas, liquid, and solid, and it is transferred at the speed of ultrasound. In addition, it crushes deposits in the body and increases blood flow in tissue, and triggers a healing process with inflammatory reaction, and can reduce pain by decreasing neurotransmitters. After it was demonstrated that the shock wave is effective for delayed union of pseudarthrosis or fracture, it was firstly applied to connective tissue disease.<sup>6</sup> Then, after it was proved that it has an effect on tenosynovitis, calcific tendinitis, and plantar fasciitis, it is utilized in musculoskeletal disorders.<sup>7,8</sup>

ESWT, which is applied to the treatment for inflammation and fibrosis of various connective tissue, is widely carried out in musculoskeletal disease, but it is difficult to find the study about the therapy as an initial treatment option because the study for chronic low back pain due to myofascial syndrome was carried out with patients who failed to respond to conservative therapy. Therefore, this study purposed to investigate the effectiveness of initial treatment effect of ESWT on chronic low back pain resulting from myofascial pain syndrome.

## II. MATERIALS AND METHODS

### 1. Subjects

Among patients who have suffered from chronic low back pain for more than 6 months and did not undergo systematic rehabilitative therapy, those whose illness was diagnosed as the myofascial pain syndrome are objects. Detailed medical examinations by interview and

physical examination were performed for diagnosis of musculoskeletal system pain, and simple x-ray, electromyography, computed tomography, and magnetic resonance imaging were carried out for diagnosis and thorough examinations of low back pain. Those, whose illness was diagnosed as spinal stenosis, spinal tumor, herniated nucleus pulposus, spondylolisthesis, spinal instability, and spinal anomaly under medical imaging inspection, and lumbosacral radiculopathy, and myelopathy under EMG examination, were excluded from the objects. Myofascial pain syndrome was distinguished, based on Simons' criteria.<sup>9</sup> The number of objects was 43, and they were randomly divided as the experimental group of 22 people with shockwave therapy and the control group of 21 people without it. During the treatment, all patients underwent both conservative treatment including resting, medication, and physical therapy, and therapeutic exercise including spine stabilization exercise. Medicine, which might have an influence on pain, was not changed during the medical care. Additional criteria for inclusion in this study were never having undergone surgery for the relief of low back pain, having no mental or cognitive problem that would have affected the study.

## **2. Method**

### 1) Low back pain treatment

#### A. Physical therapy

##### a) Heat therapy

Among heat therapy, superficial heat therapy used hot packs, and deep heat therapy utilized ultrasound. Hot packs and ultrasound increase blood flow and relax muscles by expanding blood vessels. Hot packs were dip in the water tank maintaining 70~75° C water

temperature. During treatment, they were taken out of it and were wrapped up in 6-ply towels, and then they were put to the lumbar area for 20~30 minutes. The ultrasound was a 3MHz continuous wave of  $0.5\sim 2.5\text{W}/\text{cm}^2$  and it was applied by stroking for 5 minutes.

#### b) Electrical therapy

Electrical therapy increases the amount of dopamine, epinephrine, and serotonin and reduces the action potential of A-delta nerves transferring pain. Transcutaneous Electrical Nerve Stimulation(TENS) was performed using a 2~4Hz low frequency wave for 20 minutes.

#### B. Therapeutic exercise

Lumbar exercise was performed for pain relief, abdominal/psoas/hip joint muscle strengthening, endurance enhancement of the trunk and the lower extremity muscles, flexibility recovery of the trunk and lower extremity joints, and enhancement of general physical fitness. Spine stabilization exercise was performed using sling and Swiss ball, and the exercise period was 8 weeks, and it was carried out 3 times per week, and each exercise time was about 1 hour.

#### C. Medication

Medication relieves pain and improves activity. In the treatment, the analgesic anti-inflammatory drug was acetaminophen, and the muscle relaxant was eperisone HCl.

#### 2) Extracorporeal shock wave therapy

Extracorporeal shockwave therapy used the equipment of the electro-hydraulic type(Evotron®), Switech Medical, Kreuzlingen, Switzerland). According to how well patients in the experimental group endured pain, 4-Hz shock waves of 1,000 times in energy flux

density(EFD) of  $0.10\text{--}0.15\text{mJ}/\text{mm}^2$  were applied once a week totally for 8 weeks. In order to transfer accurate shock wave energy to a targeting area, after it was decided through the physical examination, the settings of the shock wave therapy equipment were adjusted, and treatment was performed. Most of the targeting areas were mainly Quadratus lumborum, Gluteus maximus, and Gluteus medius. When evidence of acute inflammation such as rubefaction, swelling, and heat sensation was observed in treatment areas, the examine was excluded from the experimental group.

### 3) Evaluation method

In order to evaluate the degree of pain, function, and disability, visual analogue scale(VAS), medical outcomes study short form-36(SF-36), and Oswestry disability index(ODI) were utilized. In the experimental group, the evaluation was carried out using a questionnaire with an outpatient follow-up, just before the treatment and 8 weeks after the treatment. The control group was appraised in the same way at the same time.

#### A. Pain evaluation

Visual analogue scale(VAS) is an indication of the degree of pain patients themselves feel by dividing 10cm table into 10 parts. When there is no interference with one's daily life and no symptom, VAS is 0, and when a patient cannot lead his or her everyday life at all and severe pain he or she cannot stand lasts, VAS is 10. This test is easily and frequently used to assess the degree of pain, and it is utilized for pain evaluation and control of adults and recently as an index of acute pain. In a certain research, VAS was proved to be predominant over fixed interval scale, and relative pain scale, and relative pain scale, and verbal rating scale.<sup>10-12</sup> In addition, because

VAS needs no special apparatus, it can be easily and frequently used in a variety of environments, and it takes less time necessary for application, and moreover, variables of measured data can be statistically processed.

#### B. Function evaluation

Medical outcomes study short form-36(SF-36) consists of 3 areas(functional status, well-being, and overall evaluation of health) and 36 items of health level about 8 domains. The contents are divided into 8 parts:physical function(PF), social function(SF), role limitation due to physical emotional problems(RE), mental health(MH), vitality(VT), bodily pain(BP), and general health perception(GH). They covers general parts which have an influence on health including physical and mental status. A lot of researches have demonstrated its feasibility and reliability, and various clinical results can be extracted, and it was proved that researches on large populations can be conducted, and it is reported that it is also relevant to the measure of the health level of relatively homogeneous populations. Scores of the eight items evaluating the level of health were summed up based on research Likert scale. Each item has the worst score, 1, and the best score, 2~6, according to the questions. The scores of all questions were summed up, and the total score was converted into a 100-point scale. As a result, those who receive the highest score in each item are healthy people, and get 100 points. It means that the higher the score is, the higher the quality of life in the corresponding area is.<sup>13</sup>

#### C. Disability evaluation

Oswestry Disability Index(ODI) can be easily determined, and the examinee needs to record the degree of achievement of 12 tasks in person. The assessment area in ODI includes pain degree, personal

management, lifting, walking, sitting, standing, sleeping, sex, travel, work,(housework), and changes in pain. The total score is 60, and each item has a 6-point scale(0~5), and 0 represents no disability, and 5 means severe disability, and the lower the score is, the less the disability is.<sup>14</sup>

#### D. Sonographic evaluation

All patients were tested with ultrasonography and color Doppler examination every two weeks. The quadratus lumborum was evaluated by ACUVIX V10(Medison, JMEDIATECH, Korea) with a linear transducer at 5-13MHz frequencies. Patients were in prone position during examination and both sides were evaluated and compared with each other.

#### 3) Statistical method

Statistical analysis utilizes SPSS version 16.0. In order to compare the status between before and after treatment of the experimental group and the control group, a paired t-test was performed, and Mann-Whitney test was used to compare the degree of improvement between two groups. In the judgement of statistical significance in the results of analysis, p-value smaller than 0.05 was considered to be statistically significant.

### III. RESULTS

#### 1. The patients' characteristics

The average age of all people who participated in the experiment was 43.1 years old, and their average height was 165.3cm, and their average weight was 58.72kg, and there was not a significant difference between the experimental group and the control groups. (p>0.05)



## 2. Pain evaluation

VAS reduced from  $5.4 \pm 1.6$  before treatment to  $2.2 \pm 0.8$  after treatment in the experimental group, and it showed significant decrease from  $5.3 \pm 1.8$  before treatment to  $3.1 \pm 0.6$  after treatment also in the control group. ( $p < 0.05$ ) After treatment, in comparison of the degree of changes in VAS between two groups, VAS was  $3.1 \pm 0.7$  in the experimental group and  $2.0 \pm 0.8$  in the control group, and there was a statistically significant difference between two groups. ( $p < 0.05$ )

## 3. Function evaluation

SF-36 showed significant increase between before and after treatment from  $36.7 \pm 7.8$  to  $52.3 \pm 8.5$  in the experimental group and from  $37.2 \pm 8.2$  to  $45.6 \pm 8.4$  in the control group. ( $p < 0.05$ ) After treatment, in comparison of the degree of changes in SF-36 between two groups, SF-36 was  $18.4 \pm 5.3$  in the experimental group and  $10.2 \pm 3.4$  in the control group, and there was a statistically significant difference between two groups. ( $p < 0.05$ )

## 4. Disability evaluation

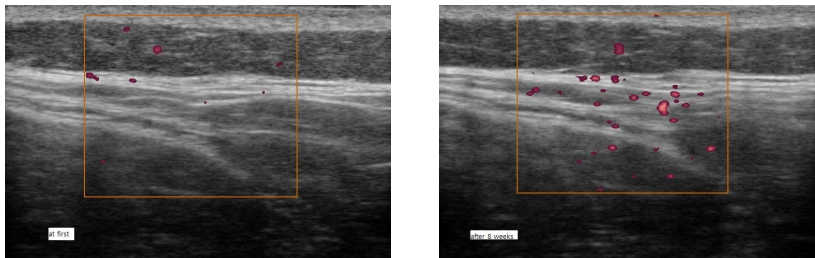
ODI showed significant decrease between before and after treatment from  $28.4 \pm 11.2$  to  $13.4 \pm 5.7$  in the experimental group and from  $28.9 \pm 10.3$  to  $18.6 \pm 8.9$  in the control group. ( $p < 0.05$ ) After treatment, in comparison of the degree of changes in ODI between two groups, ODI was  $14.8 \pm 4.2$  in the experimental group and  $9.8 \pm 3.1$  in the control group, and there was a statistically significant difference between two groups. ( $p < 0.05$ )

## 5. Color Doppler examination

In the ESWT group, a significant increase of neo-vessels was noted

in 6 weeks, whereas no increase of neo-vessels was noted in the control group. (Fig. 1.)

Fig. 1 Longitudinal color Doppler ultrasound images demonstrate neovascularization in quadratus lumborum muscle of ESWT group.



The difference in the number of neo-vessels were statistically significant.

#### IV. DISCUSSION

Low back pain patients within the last 6 months account for 40% of the total population, and it is reported that 84% of the entire population suffers from the low back pain. The low back pain is a common symptom in clinical examinations, which limits patients' daily life. Additionally, medical expenses spent on the examination and the management reach a significant level in society.<sup>14</sup> According to the survey data from Ministry of Health and Welfare in 2002, the number of low back pain patients is increasing also in South Korea, and the number of restricted activity days per 100 people is 105.19, and lying sick in bed is annually for 22.04 days on average, and losses due to the low back pain area 360.2 billion won, 0.07% of GDP. That is because chronic low back pain patients do not receive proper treatment and have their works, daily life, and leisure, and it becomes a main factor of economic loss and labor loss.<sup>15</sup>

The main cause of chronic low back pain is a generalized/localized disease and a primary spine disorder. For example, there are lumbosacral muscles, ligament injury, lumbar facet arthropathy, sacroiliac joint arthropathy, and discogenic disease by degenerative change. A cause of chronic low back pain is myofascial pain syndrome, which has a high prevalence rate, 30% of patients.<sup>16</sup>

Myofascial pain syndrome(MPS) is a state, in which a trigger point resulting in referred pain arises in muscles. It is accompanied by deep pain, which occurs in a fascia area connecting to various muscle groups and bone. It does not remain in a certain muscle for a long time, but it is chronic and highly recurrent. As a pathophysiologic feature of MPS trigger points, acute onset, injury or bad posture cause chronic shock, and it brings the sarcoplasmic reticulum injury, and therefore, as calcium releases and functions with ATP, continuous local contraction of muscle fiber happens and metabolism increases. Capillary between contracted muscles is pressed out, and accordingly, the amount of microcirculation decreases and the energy supply necessary for metabolism diminishes. Through this vicious cycle, a certain process is blocked or exceeds, and more contraction makes a trigger point induce continuous pain. Moreover, changes in vasomotornerve in or around the trigger point increase vascular permeability by blood vessel dilatation, releasing bradykinin, prostaglandin, and etc. By changing osmosis and hydrogen ion concentration, nociceptor stimulus and hypersensitivity around the area increase, leading to the pain.<sup>17</sup>

After treatment with an extracorporeal shock wave was used to remove stones from kidney and gallbladder in 1976, it has been tried as a novel treatment of various orthopedic diseases in German since the early 1990s. In 1995, German Shock Wave Institute announced that the extracorporeal shock wave could be utilized for treatment of calcific tendinitis of the shoulder, painful heel syndrome, lateral

epicondylitis, and pseudarthrosis in the orthopedic department. In 2000, United States Food and Drug Administration(US FDA) approved the extracorporeal shock wave as a means for treatment of chronic plantar fasciitis. Also, in South Korea, Ministry of Health and Welfare approved the use of the extracorporeal shock wave for treatment of musculoskeletal disorders in 2005. The extracorporeal shock wave enables treatment to be undergone without operation, and it is being applied to a variety of muscular tissues. Therefore, the extracorporeal shock wave therapy was applied to back pain patients due to myofascial pain syndrome.

Physician use the parameter of Energy Flux Density(EFD) to illustrate the fact that shock wave energy flows through an area with perpendicular orientation to the direction of propagation and its unit is  $\text{mJ}/\text{mm}^2$ .

In this research, the electrohydraulic low-energy shock wave of  $0.10\text{--}0.12\text{mJ}/\text{mm}^2$  was used for back pain patients due to myofascial pain syndrome. The electrohydraulic system uses the shock wave generation method that shows the typical form of a pressure wave going up steeply and then falling slowly. It is widely known that the electrohydraulic system has few side effects and is the best way, based on laboratory findings.<sup>18</sup> The low-energy extracorporeal shock wave does not need local anesthesia during treatment and can prevent tendinitis, tendon rupture, and blood vessel injury, which might appear in the high-energy extracorporeal shock wave therapy.<sup>19</sup> In addition, because the low energy method keeps patients' compliance from lowering due to pain stemming from the use of high energy and hinders patients from dropping out from the treatment, the electrohydraulic low-energy extrcorporeal shock wave was performed in treatment.

Visual analogue scale is used as a useful tool to evaluate the patient's pain and the treatment status, because it can quantify pain.

The measurement of pain is affected by a diversity of factors, including psychological factors, social factors, and biological factors, such as the subjective nature of pain, the past experience of pain, individuality, cultural background, trust in health care, the stability of finance and family. SF-36 covers not only physical and mental conditions but also overall aspects affecting health, and Oswestry Disability Index is a self-recognition index, which is most sensitive to the change of disability and was used with the health index table to compensate for weakness of VAS.<sup>20</sup>

In this research, both the experimental group and the control group of the extracorporeal shock wave therapy showed improvement in VAS, SF-36, and ODI, and the experimental group had the higher degree of improvement than the control group. After the extracorporeal shock wave therapy was performed for plantar fasciitis and calcific epicondylitis patients, the finding that VAS was improved was shown, similar to the existing research results.<sup>21,22</sup> Therefore, it was verified that when the conservative rehabilitation therapy is used together with ESWT, the treatment of the back pain is more effective.

After ESWT, reduction steps of the low back pain is as follows. At first, after treatment, secretion of powerful pain-causing substances such as prostaglandin E, substance P, and kinin triggers severe pain. concentration of pain-causing substances increases continuously up to 24~28 hours after treatment, and reduces slowly up to 1~8 weeks after treatment, and then is restored to the status before treatment, leading pain to lower.<sup>23</sup> Secondary, the increase of the local growth factor and stem cell recruitment removes inflammation reactions, and it results in reorganization, and variations of cellular metabolism and endothelial cell tissue permeability, leading pain to lower.<sup>24,25</sup> Thirdly, induction of enzymatic and non-enzymatic nitric oxide at rigid muscles has an effect on muscles and ligaments.

Nitric oxide is involved in peripheral neuromuscular junction formation and nerve transmission, memory, and synaptic plasticity of central nervous system, bringing about muscle relaxation.<sup>26</sup> And nitric oxide had been demonstrated as important mediators of angiogenesis. Wang et al. reported that physical shock waves could raise the mechanotransduction of the tissue to convert acoustic shock wave energy into biological signals. The results of their study that shock wave therapy induces the ingrowth of neo-vessels and tissue proliferation associated with the early release of angiogenesis-related factors.<sup>27</sup> The neovascularization may lead to the improvement of blood supply and play a role in tissue regeneration. Fourthly, the extracorporeal shock wave has a direct effect on reduced fibrosis and rheologic components.<sup>28</sup>

In this research, since the back pain was limited to disease resulting from the myofascial pain syndrome, effects of ESWT on the back pain arising due to other factors could not be confirmed. As side effects such as pain during ESWT were observed in some patients, preventive treatment such as the use of creamy matters reducing pain should be considered. Moreover, since evaluation items such as the degree of pain, function, and disability were determined by patients' subjective judgements, blood tests based on lactic acid, prostaglandin E, substance P, kinin, and etc, and objective evaluation like the isokinitic test were not performed. In addition, as the existing research results are insufficient, it is considered that the establishment of standardized protocol and indication through a variety of comparative studies is required in order to maximize the effect of treatment.

## V. CONCLUSION

In this study, after ESWT was applied to patients with back pain

resulting from the myofascial pain syndrome, the effects of treatment intended to be found in terms of the degree of pain, function, and disability change, and the results are as follows:

1) VAS, SF-36, and ODI showed statistically significant differences between experimental groups and control groups after 8 week treatment.

2) Comparing the degree of variation of VAS, SF-36, and ODI before and after treatment, it showed a significant difference between experimental groups and control groups.

As the above results, it is thought that ESWT together with the conservative rehabilitation therapy can have an great influence ESWT treatment of the myofascial pain syndrome.

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