Original article

Usefulness of radial extracorporeal shock wave therapy for the spasticity of the subscapularis in patients with stroke: a pilot study

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Keywords: *spasticity; extracorporeal shock wave therapy; stroke; shoulder*

Background There are not many studies about treatment of shoulder spasticity. Although botulinum toxin injection has been reported to be effective for shoulder spasticity, the effectiveness was judged by pain and limited motion change, but not the spasticity itself. Shoulder spasticity is considered to play an important role in hemiplegic frozen shoulder. However, the subscapularis muscle, unlike the pectoralis major muscle, is located deep beneath scapula, where conventional injection is difficult to perform. As extracorporeal shock wave therapy (ESWT) has been reported to be effective for spasticity relief, and we thought spasticity of subscapularis muscle located deep beneath the scapula would be a good candidate for ESWT treatment. This study was to evaluate the beneficial effects of radial ESWT (rESWT) on spastic subscapularis muscle in stroke patients.

Methods This is an uncontrolled, prospective, unicenter, clinical pilot study. Stroke patients (*n*=57; mean age 55.4 years) with spastic shoulders were recruited between June 2011 and February 2012 at the University Rehabilitation Hospital. rESWT was administered to each patient every two or three days for two weeks (five total treatments). Evaluation consisted of 11 measurements for each patient; at the start of each of the five treatments and once per week during the following six weeks. Spasticity was measured at external rotator muscles of the shoulder using the modified Ashworth scale (MAS), and passive range of motion (ROM) of the shoulder in external rotation was recorded. Pain was measured using a visual analogue scale (VAS) during passive ROM of the shoulder in external rotation, and was additionally recorded for patients who preserved cognitive and communicative ability (Pain group).

Results Reduction in MAS and VAS and improvement of ROM during and after rESWT treatments were prominent compared to baseline. The reduction in MAS and VAS and improvement of ROM continued four weeks after the last treatment and the effects of the treatment decreased afterward.

Conclusion rESWT will be able to provide stroke patients with an effective and safe procedure for the reduction of spasticity and pain as well as for the improvement of ROM of spastic shoulders.

Chin Med J 2013;126 (24): 4638-4643

Spasticity is defined as a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks due to hyperexcitability of the stretch reflex.[1] The sustained contraction of a group of spastic muscles may result in permanent contracture and skeletal deformities.[2]

Specific treatments for spastic shoulder muscles are still a topic of research interest. Muscles involved with internal rotation of the shoulder, the subscapularis and the pectoralis major, play a pivotal role in the painful, contracted shoulder.[3] Although spasticity treatment for the subscapularis muscle is more effective to increase the range of motion of the spastic shoulder compared to treatment of the pectoralis muscle,[4] the muscles that should be targeted for a more effective treatment have not been studied. Studies of botulinum toxin injections into the internal rotator of the spastic shoulder reported that individual injections into the pectoralis major[5-7] or the subscapularis[8] decreased pain severity but had little effect on spasticity. It would be ideal to treat both the pectoralis major and subscapularis muscles to decrease spasticity in the shoulder. However, the subscapularis is located too deep inside the scapula to treat accurately and safely, while the pectoralis major is superficial. The efficacy of botulinum toxin is maximized by injecting the toxin close to the site of action (motor endplates),[9] and the deep location of the subscapularis makes this injection difficult. Most studies failed to confirm that botulinum toxin injection into the subscapularis was appropriately placed at the site of action. With regard to the upper and lower subscapular nerve block, accuracy and safety are similar to that of the intramuscular botulinum toxin injection. Furthermore, most research on botulinum toxin injection into spastic shoulders has focused on shoulder pain, not spasticity, as the main outcome.[5-8,10] Such research should recruit patients

DOI: 10.3760/cma.j.issn.0366-6999.20131129
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This study was supported by the Basic Science Research Program through the National Research Foundationof Korea, funded by the Ministry of Education, Science and Technology (No. 2011-0005611).

with enough cognition to score the pain severity; but the sample size of these studies were small. This would be a limitation when evaluating the efficacy of these treatments on spasticity.

Extracorporeal shock wave therapy (ESWT) has been suggested as a non-invasive, alternative treatment for spasticity. ESWT involves a sequence of single sonic pulses characterized by high peak pressure (100 MPa), fast pressure rise (<10 ns), and short duration (10 μs). ESWT is conveyed by an appropriate generator to a specific target area with an energy flux density in the range of 0.003 to 0.890 mJ/mm^2. The waves of radial extracorporeal shock wave therapy (rESWT), compared with that of conventional focused ESWT, disperse eccentrically from the applicator tip without concentrating the shock wave field in the targeted tissue.[11] The therapeutic effect of rESWT occurs a few centimeters deep within the skin surface (0 to 3.5 cm).[12,13] Some studies have demonstrated a reduction in spasticity after applying ESWT (including rESWT) without significant side effects.[12,14-16]

Because injection of botulinum toxin into the subscapularis at the motor endplate is technically difficult, our study focused on assessing the beneficial effects of rESWT on the spastic subscapularis muscle but not on the pectoralis muscles in stroke patients. In this study, the effectiveness of treatment was evaluated by observing spasticity itself rather than functional measurements. We hypothesized that rESWT would be effective and safe for the reduction of spasticity of the shoulder in external rotation because it would successfully treat the spastic subscapularis.

METHODS

Subjects

Patients were recruited for this study from among hospitalized patients at a university hospital between June 2011 and February 2012. The inclusion criteria included: (1) duration of stroke ≥9 months; (2) hemiplegia or quadriplegia (in cases of quadriplegia, the more affected shoulder with respect to spasticity and limitation of range of motion (ROM)); (3) limitation of passive external rotation of the spastic shoulder ≥20°; and (4) modified Ashworth scale (MAS) ≥1. For pain assessment, patients who preserved cognitive and communicative ability, all subjects who scored above 24 on the Mini-Mental Status Examination,[17] and whose visual analogue scale (VAS) for shoulder pain was more than 4/10 were included (Group II). The exclusion criteria included: (1) intra-articular injection into the affected shoulder during the previous six months or use of systemic corticosteroids during the previous four months; (2) presence of another explanation for the pain (e.g. fracture, complex regional pain syndrome, or radiculopathy); (3) prior surgery to either the affected shoulder or neck region; (4) presence of an unstable medical condition or uncontrolled systemic disease; (5) prior treatment with botulinum toxin in the affected shoulder within nine months; and (6) prior treatment with ESWT to the shoulder. Approval from the Institutional Review Board was obtained before conducting the study. Written informed consent was obtained from all participants or main care givers after an explanation about the nature of the study and examination.

rESWT

Masterplus MP200® (Storz Medical AG, Tagerwillen, Switzerland) was as the rESWT machine used and was provided by a physiatrist. The treatment was administered every two or three days for two weeks (five times total) according to the manufacturer's recommendations. The patient was positioned lying on their side with the affected side up. The shoulder was placed in flexion, with external rotation and abduction to facilitate access to the subscapularis muscle with the probe (Figure 1). In this position, we found that only the teres major muscle is located above the subscapularis and the pectoralis major is not placed in the treatment window.[18] The skin overlying the tip of the acromion and the inferior angle of the scapula was marked with a pen. The target area for the subscapularis was medial to the midpoint between the tip of the acromion and the inferior angle of the scapula. The target area for rESWT was arbitrary because no guideline has been established. The frequency applied was 8 Hz. There were 3000 pulses per session with an energy flux density 0.63 mJ/mm^2 (1.6 bar). Deep impact (diameter 15 mm) with the depth of 0–60 mm was used for the head of the rESWT machine. One session took about 15 minutes. During the study period, all patients were allowed to take previously prescribed oral anti-spastic medications and/or analgesics and received a standard course of physiotherapy including ROM exercise, massage, passive stretching, and physiotherapy with active movement. However, no additional analgesics or anti-spastic medications for shoulder conditions were permitted.

This pilot study was a non-controlled, prospective, clinical trial. The patients were examined by another physiatrist who was not blinded to the study. The primary outcome measures were spasticity during the external rotation of the shoulder using the MAS while in a seated position. For convenience of statistical analysis, MAS grade 1+ was matched to point 2; grades 2, 3 and 4 were matched to

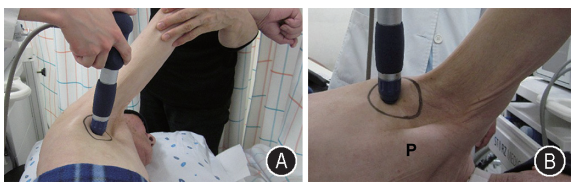

Figure 1. Patient's position for treatment. **A:** during the rESWT procedure, the patient was lying on their lateral side with the treatment side up. The shoulder was placed in a position of flexion, external rotation, and abduction so the rESWT probe was able to access the posterior axillary fold. **B:** in this position, only the teres major muscle is located above the subscapularis and the pectoralis major is not placed in the treatment window (circle). rESWT: radial extracorporeal shock wave therapy. P: pectoralis major.

points 3, 4 and 5.[19] Secondary outcome measures were the passive ROM of the shoulder for external rotation using goniometry while in a seated position and VAS only in the Group II. In Group II, pain was measured using a VAS on a scale of 0–10 during passive ROM of the shoulder in external rotation. Adverse events and rESWT-related pain were monitored throughout. Evaluation consisted of 11 measurements for each patient: at the start of each treatment (five times) and once per week in the following six weeks (six times).

Sample size was determined a priori, assuming a paired *t* test with α equal to 0.05 and power at 80% and the Bonferroni correction. The sample size was calculated based on ability to detect differences (δ) of 1.1 on the MAS at 1-week follow-up (primary outcome measure), with standard deviations of 1.2 calculated from results of a recent article using the Lehr's formula ($16/(2\times\delta/\sigma)$) and a 20% drop-out rate.[10,16,20] According to these calculations, more than 57 subjects were needed.

A linear mixed model was used to evaluate changes in range of motion, MAS, and visual analogue scale over time. Time was considered a categorical value. The fixed time effect model was used. A possible difference in sequence across the baseline to 6-week follow-up was analyzed. The multiple comparisons with the Bonferroni correction as the post-hoc analysis were used to compare any point of the rate change that was significantly different from baseline. Time was considered a continuous value. The estimates of change in the slope between the baseline and 4-week follow-up and the 4-week to 6-week follow-up were analyzed. Time by indicator variable (before and after the 4-week follow-up interaction) was considered a fixed effect. The data were presented as the mean ± standard deviation (SD) and 95% confidence intervals (95% *CI*). Statistical calculations and analyses were performed with SAS version 9.1.3 (SAS Institute Inc., USA), and null hypotheses of no difference were rejected if *P*-values were less than 0.05.

RESULTS

Overall, 57 patients with a mean age of 55.4 years (range, 20–70 years) were enrolled. General characteristics of the patients are shown in the Table 1. All but two patients in the study were receiving anti-spastic medication. None of the patients were lost to follow-up. No serious side effects were observed over the 6-week follow-up period. Post-treatment pain rated <4 on VAS was reported by seven patients in Group II, and one patient experienced petechiae that disappeared spontaneously.

Table 2 shows the passive ROM and MAS of the shoulder in external rotation and VAS (only in Group II) at baseline and at specific time points. Figure 2 shows the mean profile graphs of these same parameters. Post-hoc analysis revealed that the reduction of MAS and VAS, and the improvement of ROM during and after rESWT were significantly different than those same measurements at baseline (Table 3). Table 4 shows the changes of the slope and interaction before and after the 4-week follow-up, the time point at which the values changed significantly. All parameters showed a time effect. The reduction of MAS and VAS, and the improvement in ROM continued four weeks after treatment. However, the effects of the treatment decreased after four weeks.

Table 1. Patient characteristics

Items	Total (*n*=57)	Group II (*n*=18)
Patient characteristics		
Age (years, mean±SD)	55.4±13.2	53.4±16.8
Gender (female, (*n* (%))	24 (42.1)	7 (38.9)
Past medical history (*n* (%))		
Ischemic stroke	22 (38.6)	7 (38.9)
Hemorrhagic stroke	35 (61.4)	11 (61.1)
Hemiplegia	46 (80.7)	17 (94.4)
Quadriplegia	11 (19.3)	1 (5.6)
Anti-spastic medication	55 (96.5)	16 (88.9)
Analgesics	20 (35.1)	15 (83.3)
Stroke onset (month, mean±SD)	24.6±11.7	22.2±8.2
Modified Rankin scale (mean±SD)	3.8±0.8	2.8±0.4

Group II: patients who rated their shoulder pain; SD: standard deviation.

Table 2. Outcome measures at each time point

Time	Total ROM (°)	Total MAS	VAS (GII)
ESWT1	50.0±15.3	2.7±0.9	7.9±1.5
ESWT2	49.2±16.0	2.3±0.9	6.9±1.6
ESWT3	54.1±15.9	2.1±0.8	6.1±1.8
ESWT4	59.8±16.4	1.9±0.8	4.8±1.5
ESWT5	63.5±15.0	1.8±0.8	4.4±1.1
Week 1	67.0±14.9	1.7±0.7	3.9±1.3
Week 2	69.0±14.3	1.6±0.7	3.7±1.6
Week 3	70.6±13.1	1.5±0.6	3.5±1.6
Week 4	72.7±12.5	1.4±0.6	3.4±1.5
Week 5	63.9±14.2	1.9±0.8	3.7±1.4
Week 6	56.1±14.8	2.1±0.9	4.5±1.2

Values are estimated means± standard deviations. ROM: range of motion. MAS: modified Ashworth scale. VAS: visual analogue scale. ESWT: extracorporeal shock wave therapy. Total ROM: the passive ROM of the shoulder in external rotation in all patients. Total MAS: MAS during the external rotation of the shoulder. GII: patients who rated their shoulder pain. ESWT1: just before the 1st ESWT(baseline). ESWT2: just before the 2nd ESWT. Week1: one week after the 5th ESWT.

DISCUSSION

This study demonstrates that rESWT treatment of the spastic subscapularis reduced spasticity and pain, and improved the ROM of the shoulder after five sessions of rESWT. The greatest amount of improvement in the measured parameters occurred at week four, but by week six the improvement was decreasing.

Although the effect of ESWT on the spastic shoulder has not been reported, Vidal et al[14] reported a significant decrease in the Ashworth Scale and an increase in the ROM of the upper or lower extremities in 40 spastic muscles of spastic cerebral palsy patients treated with rESWT and that these improvements were maintained for ≥8 weeks after treatment. Manganotti and Amelio[16] reported that after active ESWT, a significant decrease in muscle tonicity was noted on wrist and finger flexor muscles in all patients with

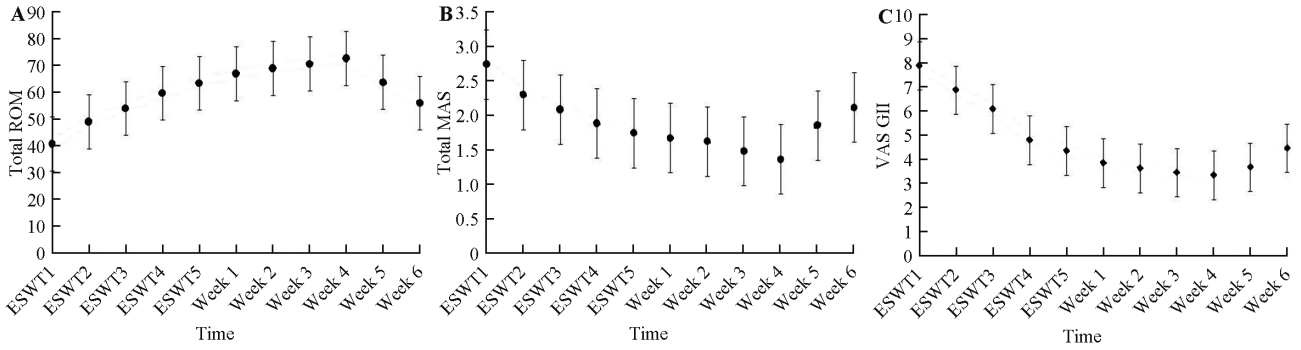

Figure 2. The mean profile graph of the change in the passive ROM of the shoulder in external rotation over time in all patients (**A**). The mean profile graph of the change in MAS during the external rotation of the shoulder over time in all patients (**B**). The mean profile graph of the change in VAS during the passive ROM of the shoulder in external rotation over time in the patients who could rate their shoulder pain (**C**). ROM (°): Range of motion. MAS: modified Ashworth scale.VAS: visual analogue scale. GII: group II, patients who were rated their shoulder pain. ESWT: extracorporeal shock wave therapy. ESWT1: just before the 1st ESWT (baseline). ESWT2: just before the 2nd ESWT. Week 1: one week after the 5th ESWT.

Table 3. Comparison of outcome measures between baseline and each time point

Time	Total ROM		Total MAS		VAS (GII)	
	Raw	Adjusted	Raw	Adjusted	Raw	Adjusted
Baseline–ESWT2	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–ESWT3	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–ESWT4	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–ESWT5	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 1	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 2	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 3	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 4	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 5	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
Baseline–Week 6	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*

Analyzed by using a mixed model with post hoc test.*P <0.05 Raw: raw P-value. Adjust: adjusted P-value (Bonferroni correction) (multiplied by the number of measurements (10)). ROM: range of motion; MAS: modified Ashworth scale; VAS: visual analogue scale; ESWT: extracorporeal shock wave therapy. Total ROM: the passive ROM of the shoulder in external rotation in all patients; Total MAS: MAS during the external rotation of the shoulder; GII: patients who were rated their shoulder pain; ESWT1: just before the 1st ESWT (baseline); ESWT2: just before the 2nd ESWT; Week1: one week after the 5th ESWT.

Table 4. Comparison of outcome measures before and after the 4-week follow-up

Time	Total ROM		Total MAS		GII VAS	
	B (95% *CI*)	*P* values	B (95% *CI*)	*P* values	B (95% *CI*)	*P* values
Before week 4	3.804 (3.577 to 4.030)		–0.150 (–0.164 to –0.136)		–0.567(–0.618 to –0.515)	
After week 4	–7.719 (–10.200 to –5.238)		0.263 (0.109 to 0.417)		0.778(0.211 to 1.345)	
Before vs. after week 4	–11.523 (–14.014 to –9.032)	<0.0001*	0.414 (0.256 to 0.568)	<0.0001*	1.344(0.775 to 1.914)	<0.0001*

The estimates of change in the slope between the baseline and 4-week follow-up and the 4-week to 6-week follow-up were analyzed.*P <0.05. ß: the slope. *CI*: confidence interval. ROM: range of motion. MAS: modified Ashworth scale. VAS: visual analogue scale. Total ROM: the passive ROM of the shoulder in external rotation in all patients. Total MAS: MAS during the external rotation of the shoulder. GII: patients who were rated their shoulder pain. Week 4: four weeks after the 5th extracorporeal shock wave treatment.

stroke at the 1 week and 4-week follow-ups, and that ten of the 20 patients showed persistent reduction in muscle tone 12 weeks after therapy. Furthermore, a significant decrease in the Ashworth Scale, an increase in the ROM, and an increase in the whole plantar surface area of the treated limb were observed in the spastic equinus foot of all cerebral palsy patients following a single active shock wave stimulation; this effect lasted for four weeks in all patients.[15] Different ESWT modalities, radial ESWT[14] vs. focused ESWT,[15,16] and the numbers of treatment sessions, three sessions at intervals of one week[14] vs. one session,[15,16] were used in previous studies that showed the positive effects of ESWT for spasticity. Our study also showed that the anti-spastic effects of rESWT were maintained until the 4-week follow-up.

Previous studies on the effect of botulinum toxin for treating spastic shoulder emphasized the effect on pain more than spasticity. Since the reduction of the spasticity did not directly coincide with pain relief in these studies, the mechanisms of action for botulinum toxin's analgesic effects were theorized to be acting on the neurotransmission afferent pathways and inhibiting substance P production.[21,22] Spasticity creates muscle shortening, which can lead to pain, especially when the muscles are stretched. Muscle shortening and pain also inhibit movement and reduce joint ROM. However, pain and contractures in other soft tissues may have contributed to the overall pain and limitation of motion of the shoulder. To focus on the effect on spasticity, severely spastic patients whose pain level could not be measured were included in this study. The anti-spastic

effect of the rESWT on the shoulder might be clearer if only severely spastic shoulders were evaluated.

ESWT is a safe, non-invasive modality for treating spasticity.[14-16] A study applying rESWT or focused ESWT to spastic muscles did not find side effects during a twelve week follow-up.[16] In addition, when applied to children with cerebral palsy, there were no side effects.[15] We did not observe any serious side effects in this study although some patients complained of post-treatment pain and one patient had petechiae which resolved spontaneously. However, since a patient reported petechiae, further evaluation of the long-term safety for a population taking anticoagulants or platelet inhibitors is needed.

The mechanisms of ESWT on spasticity due to central nervous system injury are still unknown. Variable mechanisms have been proposed, including inducing nitric oxide synthesis,[23] decreasing spinal excitability,[24] and stimulating mechanical vibrations.[24] Additionally, the reduction in spasticity could be caused by improving the stiffness of connective tissue by directly acting on the fibrosis of chronic hypertonic muscles.[16] However, the effect of ESWT on spinal excitability can be excluded as the main mechanism because no significant changes occurred in F wave minimal latency, H-reflex latency, or H-M ratio after ESWT.[12,16] In addition, because the latency and amplitude of the compound muscle action potential and the conduction velocity of the peripheral nerve were not changed after ESWT, the effect of ESWT on the peripheral nerves and a botulinum toxin A-like effect on neuromuscular blockage can be ruled out.

Treatment with rESWT, like botulinum toxin injections, may have a positive effect on pain and limited ROM of the shoulder in addition to a decrease in spasticity. Perhaps because of the effects of ESWT, localized ischemia in the areas of abnormal shortening of the muscles could improve, in turn inhibiting an increase in metabolism, reducing secretion of various pain inducing substances, inhibiting the induction of pain due to excessive stimulation of nociceptors of muscles, and increase the ROM of the shoulder.[25] Further studies are needed to elucidate the mechanism of the effects of ESWT on spasticity.

When botulinum toxin injections are applied to the spastic muscles, the smallest effective dose of botulinum toxin should be injected as close as possible to the motor endplate zone to ensure maximum efficacy with minimum side effects. As previously mentioned, treatment of the subscapularis is technically difficult due to its deep location. In addition, to avoid the formation of antibodies, botulinum toxin injection should not be repeated at the same site within six months.[26] Compared with botulinum toxins, ESWT has several advantages.While needle injections with botulinum toxins can cause tissue damage to adjacent structures, ESWT can be used safely on the subscapularis because it is not necessary to apply it exactly on the motor point. Repetitive or cyclic application of ESWT can also be considered to maintain the reduced spasticity because ESWT might not stimulate the formation of antibodies. In addition, ESWT is non-invasive and relatively inexpensive. However, further study is needed to determine which treatment has a greater anti-spastic effect.

rESWT, compared with conventional focused ESWT, is a low- to medium-energy shock wave generated when a projectile is accelerated by compressed air and hits an applicator.[27] The waves disperse eccentrically from the applicator tip without concentrating the shock wave field in the tissue. Currently, it remains uncertain whether rESWT therapy is superior to focused ESWT in relieving spasticity. A previous study comparing the effectiveness of focused ESWT at different intensity levels and rESWT for treating plantar fasciitis suggested that rESWT was the best treatment, followed by low-, medium-, or high-intensity ESWT, and that the success rates of treatment were not related to the energy levels of ESWT.[28] rESWT was recommended over focused ESWT for treating plantar fasciitis due to its lower cost and better effectiveness in clinical practice.[28] Focused ESWT generates rapidly-rising acoustic waves with high peak-pressure amplitudes, and the majority of energy flux is concentrated on a small focal point. When using ESWT therapy for the treatment of spasticity, it has been applied to the entire muscle belly rather than a small area in the muscle.[15,16] Considering the potential advantages of rESWT, as well as the results of our study and the other aforementioned study,[14] rESWT should be effective for the treatment of spasticity.

The limitations of this study include the lack of a control group and the short observation period. It is not possible to remove all effects of conventional rehabilitation without a control group. However, all patients in the study had strokes at least nine months previous and had not had a change in their performance in spite of their existing physical exercise programs or medical treatments within the month prior to participation. Most patients demonstrated a persistent increase of ROM and decrease in spasticity after rESWT, returning slowly back to baseline values five weeks after the last rESWT. This implies that any gain in ROM and spasticity can be attributed to rESWT, not the conventional rehabilitation programs. Since our follow up period was six weeks after the last rESWT, long term follow up studies are needed to precisely assess effects, especially safety aspects. In addition, a function scale for shoulder assessment should be pursued in future studies. We chose to focus on spasticity as an outcome measure to gauge the effectiveness of rESWT rather than functional measurements. The optimal number of treatments and treatment intervals has yet to be determined. Although a randomized controlled study is needed to conclude the effectiveness of rESWT for shoulder spasticity, we think this pilot study is important and has value for upcoming controlled studies. Future studies should focus on: (1) the effectiveness of rESWT versus focused ESWT; (2) the effectiveness of ESWT on the subscapularis and/or pectoralis major; (3) the effectiveness of ESWT versus botulinum toxin; and (4) the

most effective ESWT protocol.

In conclusion, this study demonstrated that rESWT can reduce spasticity in addition to decreasing pain and limitations in ROM of the shoulder. The results obtained regarding the safety and short-term efficacies of this treatment for the spastic subscapularis suggest that rESWT can provide an effective and safe procedure for spasticity treatment. The reduction in spasticity and pain and improvement of ROM continued four weeks after the last treatment, and then the beneficial effects of the treatment decreased afterward. Further studies are needed to support these results and to understand the mechanism of ESWT for the treatment of spasticity.

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(Received April 27, 2013)
Edited by CUI Yi