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ORIGINAL ARTICLE

The efficacy of ultrasound-guided extracorporeal shockwave therapy in patients with cervical spondylosis and nuchal ligament calcification

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Abstract We investigated the effects of extracorporeal shockwave therapy (ESWT) on the rehabilitation of cervical spondylosis with nuchal ligament (NL) calcification under X-ray and ultrasound guidance. Sixty patients with cervical spondylosis and calcification of NL were selected and randomly assigned to three groups: A, B, and C. Patients in Group A received rehabilitation with 20 minutes of hot packs and underwent 15 minutes of intermittent cervical traction three times/week for 6 weeks. Patients in Group B received the same rehabilitation as those in Group A and ESWT (2000 impulses, 0.27 mJ/mm^2) over the calcified NL guided by X-ray image. Patients in Group C received the same treatment as those in Group B, but the ESWT was guided by musculoskeletal sonography. The therapeutic effects were evaluated by: changes in range of motion (ROM) of the cervical spine including flexion, extension, lateral bending, and rotation; visual analog pain scale; and Neck Disability Index before and after treatment and at follow up 3 months later. We found a significant reduction in pain in each treated group after treatment and at follow up. However, patients in Groups B and C showed more improvements in ROM and neck pain relief after treatment and a decrease in Neck Disability Index. Furthermore, patients in Group C showed better cervical ROM at follow up than Group B. ESWT is an

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adjuvant treatment in the management of cervical spondylosis with calcification of NL and ultrasound-guided ESWT results in more functional improvements.

Introduction

The nuchal ligament (NL) is an intervertebral syndesmosis which spans the median nuchal line to the cervical spinous process; it is firmly attached to the external occipital protuberance and extends to the spinous process of C7. It is typically described as a bilaminar fibroelastic intermuscular septum interposed between the paired groups of four muscles (rhomboideus minor, serratus posterior superior, splenius capitis, and trapezius) of the cerviconuchal region [1—3]. The NL is a reliable landmark and widely used as a means to assure a midline orientation. Some reports have demonstrated that NL is important for maintaining the lordotic alignment of the cervical spine and stabilizing the head during movement of the cervical spine [4—6]. Furthermore, dysfunction of the NL may be one of the factors that predisposes a patient to progressive kyphosis or localized junctional deformity [7,8] and may worsen cervical spine stability and alignment [9].

Ossification of the NL (ONL) is a radio-opaque formation in the soft tissue behind the spinous processes of the cervical spine. It is usually clinically asymptomatic, but is often observed in patients, especially of Asian descent, who are older than 40 years. ONL is usually discovered by radiography taken for other clinical reasons, such as pain or stiffness in the neck, head, upper arms, or upper back [10,11].

Not all reported cases of cyamella are associated with knee arthritis. Scapinelli [12] reported that ONL is a true sesamoid bone resulting from a slow, gradual substitution of normal ligamentous tissues by calcified fibrocartilage, and is similar to those commonly found in the tendons of limb muscles, such as cyamella of the popliteus. Others reported that the formation of ONL may be a result of NL trauma or, more often it may be related to chronic overload in the NL [13—15]. Some authors articulated that ONL may be one of the spinal ligament ossification syndromes such as ossification of the ligamentum flavum, ossification of the anterior longitudinal ligament, and ossification of the posterior longitudinal ligament [11,16,17]. Therefore, similar to the ossification of other spinal ligaments, ONL may be a coexisting disorder or may be a risk factor of other cervical degenerated diseases.

In a prior report, we demonstrated a relationship between the size of ONL and the severity of cervical disorder including decreased range of motion (ROM), radiculopathy, spinal degeneration, and malalignment [18]. Our results showed that more than half of all patients with chronic neck pain and stiffness were positive in cervical root signs and prone to having larger ONL, and that the neck ROM of all participants was significantly below the normal average in all directions. Most patients had moderate loss of cervical lordotic curve, which made them prone to changes in cervical spondylosis.

After introduction of extracorporeal shockwave therapy (ESWT) for the treatment of nephrolithiasis, the indication of ESWT has been extended. In orthopedics, ESWT is indicated in pseudarthrosis and enthesopathies, such as epicondylitis, calcifying tendonitis, and plantar fasciitis [19]. Clinical reports revealed that good to very good clinical success was established for tennis elbow as well as for plantar fasciitis [20]. However, there are still few reports focusing on the effects of ESWT on the calcification of NL. Therefore, in the present study, we investigated the effects of ESWT on the rehabilitation of patients with cervical spondylosis with NL calcification. While performing ESWT, the patient was kept in a sitting position with neck flexion to fix the ONL, which may affect the distance between the probe and ONL. Therefore, our hypothesis is that ESWT is an effective adjuvant management for ONL and ultrasound-guided ESWT may be more practical for ONL treatment than X-ray guided.

Materials and methods

Patients

Sixty patients with cervical spondylosis and NL calcification (Figure 1) were selected and randomly assigned to three groups: A, B, and C (20 patients in each group, as shown in Figure 2). Patients in Group A received 20 minutes of hot packs and underwent 15 minutes of intermittent cervical traction three times/week for 6 weeks, with a traction force of 15—25% of their body weight. Patients in Group B received the same rehabilitation as those in Group A and ESWT (2000 impulses, 0.27 mJ/mm^2) over the calcified NL guided by X-ray image. Patients in Group C received the same treatment as Group B but the ESWT was guided by musculoskeletal sonography. The therapeutic effects were evaluated by: changes in ROM of cervical spine including flexion, extension, lateral bending, and rotation; visual analog pain scale (VAS); and Neck Disability Index (NDI) [21] before and after treatment and at follow up 3 months later.

All participants gave informed consent for the study, and the study protocol was approved by the Ethical Review Committee of Kaohsiung Medical University.

Radiographic assessments of the cervical spine

All patients underwent serial cervical radiographic images at anterior-posterior view, lateral view, and bilaterally oblique view. These images were optimized for evaluation of cervical bony structures and were digitally acquired through a

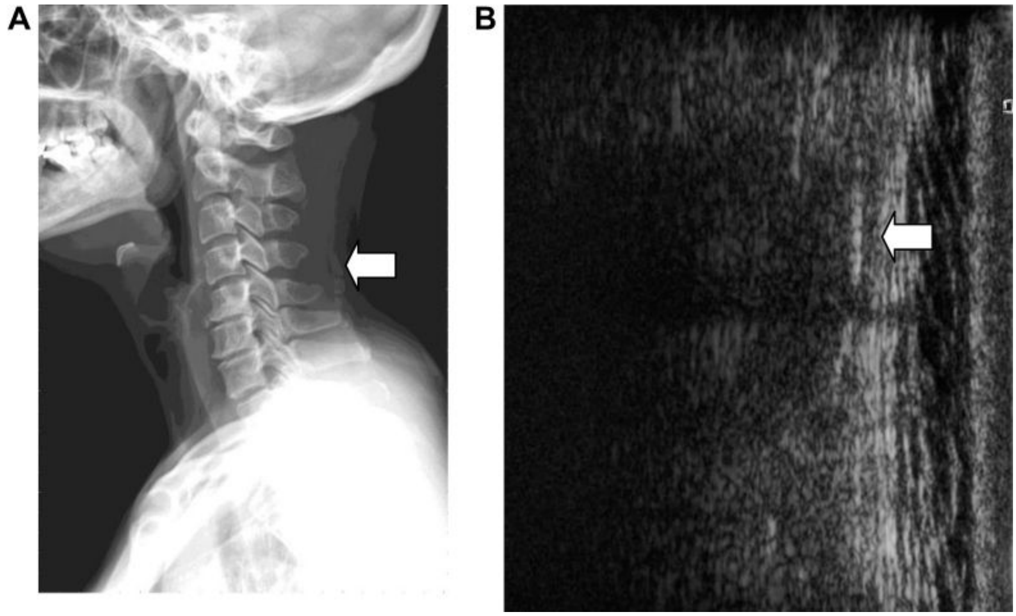

Figure 1. (A) X-ray and (B) ultrasound image of calcification of nuchal ligament (arrows).

picture archiving and communication system (PACS). All assessments were performed subsequently using PACS software. Cross-sectional areas (CSA) of ONL were measured by one of the authors (another rehabilitation physician) who knew nothing about the patient's information.

Neck ROM measurement

A goniometer was used to measure the cervical active ROM (AROM); the patients were seated in a chair in an upright position and did some neck warm-up exercises before measurement. Using a universal goniometer, the examiner measured cervical AROM in flexion-extension, bilateral lateral bending, and bilateral lateral rotation three times. Then, the mean values of the three measurements of total flexion-extension, lateral bending, and lateral rotation were calculated and recorded. All these clinical measurements were done by one of the authors, a rehabilitation physician, without any information from the patients' radiographs.

Measurement of pain severity

The severity of neck pain was evaluated by the VAS after patients had remained in a sitting upright posture with back support. The instrument consisted of horizontal lines 10 cm long, with anchor points of 0 (no pain) and 10 (maximum pain).

Measurement of NDI

NDI questionnaires are commonly used for neck disability evaluation, which includes neck pain intensity, personal care, lifting, reading headaches, concentration, work, driving, sleeping, and recreation. Each item is graded from 0 to 5; the maximum score is 50. The higher the score is, the more severe the neck disability is.

The treatment of ESWT

The patient was kept in a sitting position with neck flexion position to fix the NL. ESWT was performed with a piezoelectric shockwave generator (F10G4 Richard Wolf GmbH, Knittlingen, Germany). The dose of ESWT applied was according to the general therapeutic dose for calcific tendinopathy [22], and the level of density depended on the size of the ONL. In our study, ultrasound gel was applied to the skin and the applicator couple was put into place with an impulse energy flux density of 0.27 mJ/mm^2 (ranging from 15 to 18/20), with a frequency range of 1–8 Hz and a pressure range of 11–82 MPa, 2000 impulses for calcified NL weekly from the 1st week for 6 weeks. Patients in Group B received ESWT (2000 impulses, 0.27 mJ/mm^2) over the calcified NL. In patients in Group B, the location and the depth of the probe of shock wave applied were guided by X-ray image. Patients in Group C received the same treatment as in Group B, but the location and the depth of the probe of shock wave applied were guided by musculoskeletal sonography.

Statistical analysis

A paired Student t test was used to study the changes in ROM, VAS, NDI, and CSA in each group immediately after treatment and at follow up 3 months later. A one-way ANOVA with the Tukey test was used to compare the differences in ROM, VAS, NDI, and CSA between treated groups. A statistically significant difference was defined as $p < 0.05$.

Results

Changes in cervical ROM

ROM of the cervical spine improved after treatment and follow up in all groups; the improvement in patients in

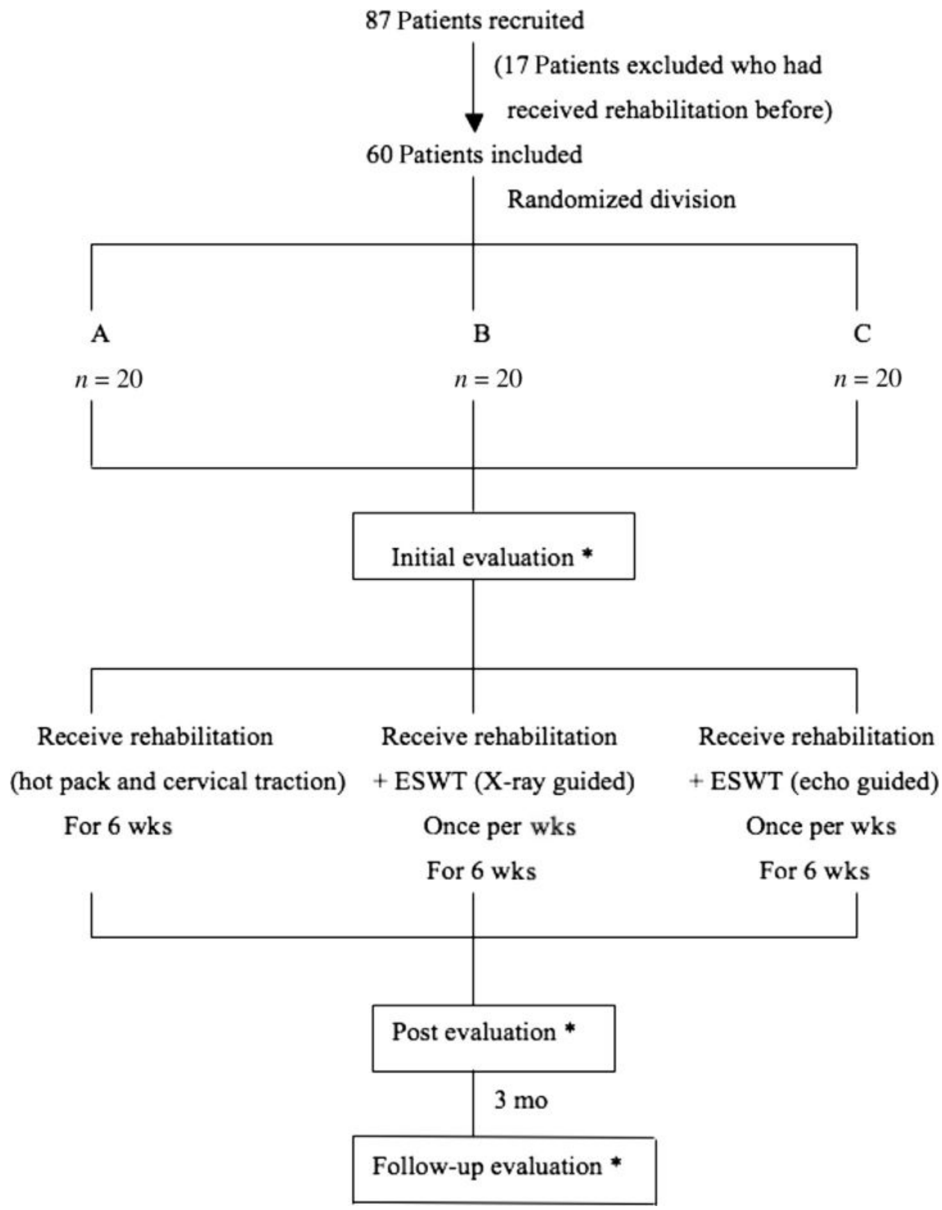

Figure 2. A flowchart of the study. * Evaluation included: range of motion of neck, pain severity, Neck Disability Index, and cross-sectional areas of ossification of the nuchal ligament. ESWT = extracorporeal shockwave therapy.

Groups B and C were better than those in Group A as shown in Tables 1–3.

Changes in neck pain

Each treated group had a reduction in pain after treatment and at follow up as shown in Table 4. However, patients in Groups B and C showed more improvement in neck pain relief after treatment than those in Group A, and patients in Group C had the best improvement.

Changes in NDI

Each treated group had a significant reduction in NDI scores after treatment and at follow up as shown in Table 5. Groups B and C showed more improvement in NDI than Group A. There was no significant difference between NDI in Groups B and C after treatment and follow up.

Changes in CSA of ONL

Groups B and C had a reduction in CSA after treatment and at follow up as shown in Table 6. However, there was no significant difference between the change of CSA in Groups B and C after treatment and follow up.

Discussion

The NL is an important structure for cervical spine stability because it may affect the flexibility and muscular activities of the neck region [1–6,9]. Clinically, ONL may cause

Table 1 Changes in range of motion (ROM) of neck flexion (flex) and extension (ext) after treatment and follow up (degrees; mean $\pm$ standard deviation).

		A (n = 20)	B (n = 20)	C (n = 20)
Initial	Flex	25.4 ± 6.6	24.4 ± 7.0	26.6 ± 5.4
	Ext	20.5 ± 7.2	22.5 ± 6.3	20.3 ± 6.2
	ROM	45.3 ± 7.6	46.4 ± 8.3	46.3 ± 5.1
Post-treatment	Flex	27.3 ± 5.7	34.3 ± 4.6[a]	36.3 ± 7.5[a]
	Ext	20.1 ± 6.1	28.3 ± 5.3[a]	30.2 ± 5.5[a]
	ROM	47.5 ± 7.0[b]	62.1 ± 6.2[a]	66.3 ± 8.1[a]
Follow up	Flex	28.3 ± 6.7	34.7 ± 3.6[a]	37.2 ± 4.5[a]
	Ext	21.6 ± 8.2	27.6 ± 4.8[a]	32.4 ± 5.2[a]
	ROM	51.5 ± 7.9[b]	63.2 ± 7.4[a]	70.3 ± 6.4[a,c]

[a] Significant difference compared with initial status.
[b] Significant difference compared with extracorporeal shockwave therapy groups.
[c] Significant difference between X-ray-guided and echo-guided groups.

chronic pain, tightness, and ROM limitation of the neck and upper back, cervical spondylosis, and upper limb numbness [10,11]. Scapinelli [12] reported that the formation of NL calcification is secondary to some mechanical factors. During neck flexion, a tight NL can cause greater compressive force on the vertebral bodies and facet joints transmitted through the spinous processes and pedicles of the cervical spine. The locations of ONL were reported to be correlated with cervical spur formation and foramen narrowing and to occur most frequently at the lower spinal segments [15]. Its size is variable and correlated with the severity of clinical signs and symptoms, as shown in our previous study [18].

For further management of the ONL, Smith et al. [23] reported that macroscopic changes in the injured ligament included fibrous scarring with abnormal matrix and resulted in ligamentous thickening; furthermore, under repeated overloading or microtraumatic injury, the thickening ligament will result in fibrosis or calcification formation, which will make it difficult to return its natural structure. Therefore, an effective intervention to change the stiffness of calcification and modulate the repairing process to improve both the structural morphology and the matrix molecular composition of the repairing ligament are indicated.

The underlying mechanism subserving the beneficial effects of shockwave therapy remains unclear. Some potential beneficial mechanisms of ESWT were studied, including direct tissue trauma and cavitation, altered cell membrane permeability, direct effect on nociceptors, and peripheral nerve stimulation [24]. This explained the results of pain reduction immediately after treatment in Groups B and C being better than those in Group A (Table 4). Some studies in animals demonstrated that shockwave therapy enhances angiogenesis-related factors (e.g., endothelial nitric oxide synthase, vascular endothelial growth factor, and proliferating cell nuclear antigen), which could induce neovascularization and tendon healing after injury [25,26]. This was demonstrated by immunohistochemistry, which provided evidence of local tissue regeneration after ESWT and prolonged pain reduction [27,28]; this was compatible with the results of more pain reduction at follow up later in Groups B and C.

Shockwave energy has a mechanical impact force which can destroy and clean the mucoid substance that forms following repeated microtrauma or inflammation, which

Table 2 Changes of range in motion (ROM) of neck rotation after treatment and follow up (degrees; mean $\pm$ standard deviation).

		A (n = 20)	B (n = 20)	C (n = 20)
Initial	Left	40.3 ± 7.1	42.5 ± 7.7	42.1 ± 4.3
	Right	39.5 ± 6.3	44.2 ± 6.5	45.1 ± 5.9
	ROM	80.1 ± 8.0	83.1 ± 8.3	89.2 ± 6.4
Post-treatment	Left	42.5 ± 6.7[b]	48.1 ± 6.3[a]	52.1 ± 5.6
	Right	41.2 ± 9.1	50.6 ± 6.1[a]	54.9 ± 6.8[a]
	ROM	83.6 ± 8.5[b]	97.9 ± 8.1[a]	108.5 ± 8.7[a,c]
Follow up	Left	42.3 ± 8.2	50.1 ± 7.2[a]	54.6 ± 6.1[a]
	Right	40.7 ± 5.7	51.4 ± 7.6[a]	56.3 ± 5.9[a]
	ROM	83.5 ± 9.2[b]	99.7 ± 8.8[a]	111.5 ± 6.3[a,c]

[a] Significant difference compared with initial status.
[b] Significant difference compared with extracorporeal shockwave therapy groups.
[c] Significant difference between X-ray-guided and echo-guided groups.

Table 3 Changes in range of motion (ROM) of neck bending after treatment and follow up (degrees; mean ± standard deviation).

		A (n = 20)	B (n = 20)	C (n = 20)
Initial	Left	25.4 ± 6.6	27.5 ± 5.9	26.7 ± 5.7
	Right	23.7 ± 7.2	23.9 ± 6.9	25.2 ± 6.2
	ROM	49.7 ± 8.9	50.3 ± 7.2	51.4 ± 7.2
Post-treatment	Left	27.1 ± 7.1	35.3 ± 6.2	36.4 ± 6.8
	Right	24.1 ± 6.7	31.3 ± 5.3	36.5 ± 7.1
	ROM	51.3 ± 8.3[b]	67.6 ± 4.9[a]	73.2 ± 8.5[a,c]
Follow up	Left	26.7 ± 4.7	36.3 ± 5.7[a]	37.1.4 ± 4.4[a]
	Right	23.9 ± 4.8	33.1 ± 6.1[a]	38.1 ± 4.9[a]
	ROM	50.3 ± 5.6[b]	71.2 ± 6.8[a]	76.9 ± 5.4[a,c]

[a] Significant difference compared with initial status.
[b] Significant difference compared with extracorporeal shockwave therapy groups.
[c] Significant difference between X-ray-guided and echo-guided groups.

disturbs the healing of a tendon or ligament injury. In addition, the shockwave energy has an impact on disintegration of calcium and relaxes the tightness of fibrous or calcific collagen fibrous. In a previous study, we performed shockwave therapy in patients with knee osteoarthritis and cyamella formation over the popliteal fossa [29]. It demonstrated a significant effect on knee osteoarthritis rehabilitation.

The present results showed that ESWT in Groups B and C resulted in an improvement in neck ROM immediately after the therapy and at follow up 3 months later (Tables 1–3), and that there were significant differences compared with those in Group A. The results may imply that disintegration of the calcification of NL after ESWT resulted in a reduction of stiffness and adjustment of the biomechanics and led to a significant and maintained improvement in ROM.

Furthermore, the improvement in Group C was better than that in Group B both for immediate effects and the follow up in ROM of the neck. This demonstrated that ultrasound-guided ESWT has a better therapeutic effect than ESWT guided by an X-ray image.

In Group B, we localized the depth of ONL by measuring its distance from the cutaneous layer in plain radiography. Plain radiography has its limitations in dynamic application. Ultrasonography is a safe and real time imaging modality for diagnosing musculoskeletal disorders. Ultrasound-guided ESWT has the advantages of not requiring radiation and being in real time to exactly localize the calcification during ESWT.

As shown in Table 5, participants in all groups had immediate and continuous improvement in NDI; there was no significant difference between Group B and Group C. NDI is a commonly used outcome measure for disability in patients with neck pain. The NDI contains 10 items that focus on activities of daily living that are affected by neck pain. Table 4 shows no significant difference in pain reduction between Groups B and C, which explains the same result in NDI.

As shown in Table 6, Groups B and C had a reduction in CSA after treatment and at follow up. However, there was no significant difference between the change of CSA in Groups B and C after treatment and follow up. The results may imply that the absorption of ONL starts with the change of density of the calcified region, but not the size of calcification in our study periods. Follow up for X-ray was only 3 months, therefore the change of ONL size may be measured after a long time follow up.

Although there was some sensation of pain during ESWT application, there were no specific side-effects such as local swelling, erythema, or skin erosion during or after ESWT management, and they will not affect the compliance of patients who receive rehabilitation in our study.

The limitations of our study are the following. Firstly, the sample size was too small to examine other factors that may correlate with incidence or severity of ONL and

Table 4 Changes in neck pain (visual analog scale) before, post-treatment, and follow up (mean ± standard deviation).

	A (n = 20)	B (n = 20)	C (n = 20)
Initial	7.4 ± 1.2	7.8 ± 2.5	7.5 ± 1.8
Post-treatment	6.2 ± 2.7[b]	5.1 ± 1.9[a]	4.2 ± 2.2[a]
Follow up	6.0 ± 3.4[b]	4.9 ± 2.5[a]	4.7 ± 1.9[a]

Significant difference between X-ray-guided and echo-guided extracorporeal shockwave therapy groups.
[a] Significant difference compared with initial status.
[b] Significant difference compared with extracorporeal shockwave therapy groups.

Table 5 Changes in Neck Disability Index in each group (mean ± standard deviation).

	A (n = 20)	B (n = 20)	C (n = 20)
Initial	37.2 ± 11.2	38.2 ± 10.2	38.9 ± 12.3
Post-treatment	33.3 ± 14.2[a,b]	21.7 ± 11.5[a]	22.2 ± 13.2[a]
Follow up	30.2 ± 13.3[a,b]	20.2 ± 11.2[a]	19.2 ± 11.2[a]

[a] Significant difference compared with initial status.
[b] Significant difference compared with extracorporeal shockwave therapy groups.

Table 6 Changes in cross-sectional area (CSA) of ossification of the nuchal ligament in each group after extracorporeal shockwave therapy (mean ± standard deviation).

	B (n = 20)	C (n = 20)
CSA (initial)	97.6 ± 41.2	88.7 ± 44.1
CSA (post-treatment)	98.2 ± 40.5	87.9 ± 45.3
ΔCSA (follow up)	1.0 ± 2.6	0.9 ± 3.6

cervical neural foramen stenosis including sex, age, lifestyle, and the course of associated diseases. However, due to the relatively rare incidence of this condition, larger sample sizes are difficult to achieve. Secondly, the present study lacks comprehensive functional evaluation of ONL-related disorders. Thirdly, we also lack further quantitative measurement of ONL size changes after treatment and at the follow up due to our focus on the functional improvement in the patients' rehabilitation.

The results of the present study suggest that ESWT is an effective adjuvant treatment in improving the cervical ROM and NDI in cervical spondylosis patients with calcification of NL. Ultrasound-guided ESWT results in greater improvement in cervical ROM than that guided by radiography.

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