

The Therapeutic Effects of Acupuncture on Patients with Chronic Neck Myofascial Pain Syndrome: A Single-Blind Randomized Controlled Trial

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Abstract: Chronic neck myofascial pain syndrome (MPS) is a common disorder seen in clinics. There is no gold standard method to treat myofascial pain. We investigated the effects of acupuncture on patients with chronic neck MPS by a single-blind randomized controlled trial. A total of 35 patients were randomly allocated to an acupuncture group (AG) or a sham acupuncture group (SG). Each subject received acupuncture treatment twice per week for three consecutive weeks. The primary outcome measure was quality of life as assessed with Short Form-36, and secondary outcome measures were neck range of motion (ROM), motion-related pain, and Short-Form McGill Pain Questionnaire (SF-MPQ), as determined by a blinded investigator. The clinical assessments were made before treatment (BT) and after six acupuncture treatments (AT), as well as four weeks (F1) and 12 weeks (F2) after the end of the treatment. A total of 34 patients completed the trial. The results indicated that there is no significant difference in the ROM, motion-related pain, and SF-MPQ scores between AG and SG at AT, F1 and F2 (all $p > 0.05$). However, AG has greater improvement in

physical functioning and role emotional of Short Form-36 quality of life at F2. The results indicate that acupuncture may be used to improve the quality of life in patients with chronic neck MPS.

Keywords: Myofascial Pain Syndrome; Acupuncture; McGill Pain Questionnaire; Short Form-36; Visual Analogue Scale (VAS).

Introduction

Myofascial pain syndrome (MPS) is a form of muscle pain arising from myofascial trigger points that commonly manifests as sensory, motor, and autonomic dysfunction. The myofascial trigger points are hyperirritable spots in a taut band of skeletal muscle that cause referred pain, local tenderness under compression, and local twitch response (LTR) within the band on plucking palpation across the fibers (Borg-Stein and Simons, 2002). Patients may experience regional pain, dizziness, balance problems, and fatigue, and may also suffer from an inability to work, mood changes, and reduced quality of life (Borg-Stein and Simons, 2002). The prevalence of MPS has been reported to range from 30% of patients with regional pain in an internal medicine group practice (Skootsky *et al.*, 1989) to 74% to 85% of patients presenting to a comprehensive pain center (Fishbain *et al.*, 1986; Cummings and Baldry, 2007). Treatments include pharmacologic modalities such as non-steroidal anti-inflammatory drugs, tramadol, and tricyclic antidepressants, as well as non-pharmacologic treatment such as massage and physical therapies. However, no “gold standard” of management has been suggested until now.

Acupuncture, one of the most popular complementary treatment modalities, is often used to treat patients with pain. Birch and Jamison (1998) assessed specific and nonspecific effects of Japanese acupuncture for chronic neck MPS. They found greater pain improvement in the relevant acupuncture group than in the irrelevant acupuncture group and the control group, but no significant differences in the perceived effectiveness of treatment were observed. The manual acupuncture was not superior to physical therapy in reducing pain intensity in patients with MPS affecting the neck and shoulders (White and Ernst, 1999). The purpose of the present study was to investigate the effect of acupuncture on patients with neck MPS. Therefore, we designed a single-blind randomized controlled trial. The primary outcome measure was quality of life as assessed with the Medical Outcomes 36-Item Short Form Health Survey (SF-36), and secondary outcome measures were neck range of motion (ROM), motion-related pain intensity as indicated on a visual analogue scale (VAS, 0–100 mm), and the Short-Form McGill Pain Questionnaire (SF-MPQ).

Material and Methods

Subjects

Thirty-eight patients with chronic neck MPS were recruited from the Department of Neurology at Nantou Hospital, Department of Health, from December 2007 to December

2008. Three patients were excluded from the study before signing the informed consent form, one with chronic MPS due to cervical root compression, one who took anticoagulant agents, and one who refused acupuncture after we explained the protocol. We defined MPS according to four common criteria (Tough *et al.*, 2007): (1) tender spots in a taut band; (2) patient-perceived pain on tender spot palpation; (3) predicted pain referral pattern; and (4) local twitch response. Inclusion criteria were as follows: (1) age from 18 to 85 years; and (2) neck MPS affecting the trapezius, sternocleidomastoideus, and splenius capitis muscles for more than one month, with no related treatment including acupuncture within the two weeks before the study. Exclusion criteria were presentation with fracture or surgery of the cervical spine, cervical radiculopathy and/or myelopathy, any rheumatic disorder, systemic disorders, major psychiatric disorder, alcoholism, substance abuse, coagulation dysfunction, pregnancy, any contraindications to acupuncture, or refusal to sign the informed consent form after receiving detailed information about the study purpose and procedures. The study protocol was approved by the institutional review board of Nantou Hospital, Department of Health prior to the study.

Randomization and Blinding

The 35 subjects were randomly divided into an acupuncture group (AG) and a sham acupuncture group (SG). A randomly ordered list of the subjects was generated by a computer. If the number was odd, the patient was allocated to AG. If the number was even, the patient was allocated to SG. This study was designed as a single-blind study.

Acupuncture Treatment

Acupuncture treatment was performed by a Chinese medicine doctor with more than five years of acupuncture experience. The treatment was administered in a quiet room with the patient in a prone position.

In the AG, the subjects were treated with stainless steel acupuncture needles (32-gauge, Helio Medical Supplies, USA) inserted bilaterally into the Fenhchi (GB20) and Jianliao (TE14) acupoints with 1.5 cun length disposal needles, and the Houxi (SI3) acupoints with 1.0 cun length disposable needles. These acupoints were chosen according to the selection of local points, and according to meridian theory of Traditional Chinese Medicine, which states that the midline of the neck belongs to the governor vessel (GV) and the Houxi acupoints connect to the GV. The acupuncture needles were inserted into the acupoints and manually twisted to obtain a “Qi” sensation. The needles were then left in place for 20 min. The acupuncture treatment was performed twice a week for three consecutive weeks, for a total of six acupuncture treatment sessions. In the SG, the methods were identical to those in the AG, except that the acupuncture needles were inserted into the subcutaneous tissue to a depth of about 2 mm without manual twisting.

Outcome Measures

The primary outcome measure was quality of life as assessed using the SF-36, including eight multi-item scales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and mental health (MH). Possible scores range from 0 (maximal symptoms or limitations, poor health status) to 100 (no symptoms or limitations, good health status) after conversion. The integration of the first four scales is the physical health component summary (PCS), and the integration of the remaining four scales is the mental health component summary (MCS).

Secondary outcome measures were ROM and, motion-related pain with VAS, and the SF-MPQ. A custom-made inclinometer was used to measure ROM for six cervical spine movements (flexion, extension, lateral incline to right/left, rotation to right/left). The VAS score was used to evaluate the intensity of motion-related pain with the six types of neck movements, with the highest pain score chosen as the goal of improvement. The SF-MPQ was used to estimate the pain intensity. It provides a list of words that describe the different characteristics of the experience of pain, with descriptors 1 through 11 pertaining to the sensory dimension (SD) and descriptors 12 through 15 pertaining to the affective dimension (AD); their intensity is indicated as none (0), mild (1), moderate (2), or severe (3). The VAS, the second part of SF-MPQ, was used to measure the average current pain intensity of patients. The last part of the questionnaire assesses present pain intensity (PPI) using a numerical scale of 0 to 5, with verbal descriptors to represent perceived pain from least to worst. The total score is the sum of the SD, AD, and PPI scores. Clinical assessments of acupuncture treatment were performed by an evaluator who was blinded to the group allocation before treatment (BT), after six acupuncture treatment sessions (AT), and at 4 (follow-up 1, F1) and 12 (follow-up 2, F2) weeks after the treatment.

Statistical Analysis

Statistical analyses of all study variables were performed according to intention-to-treat analysis. Analysis of the basic background data was performed using the chi-square test for qualitative data and the Mann-Whitney U test for quantitative information. We calculated the mean ROM in the six movement directions, and nonparametric variance measured with the Mann-Whitney U test was used to compare mean ROM, motion-related pain, SF-MPQ scores, and SF-36 scores between the two groups. Intra-group comparisons were made between BT and AT, between BT and F1, and between BT and F2 and analyzed using the Friedman test as the overall test and the Wilcoxon signed rank test and Bonferroni correction test for multiple comparisons. For sample size calculations, we used a 2-tailed significance level of $\alpha = 0.05$ for all assessments. Based on an expected SD of 10 for the changes of SF-36 scale scores during study period, the effective expected sample size of 16 patients per group provided 90% statistical power for detecting a 12-point or greater difference between treatment and control groups with the assumption that the changes from the baseline score for control group was 12.

Results

Subject Characteristics and Basic Data

Thirty-five patients with chronic neck MPS participated in this trial. One patient in the AG withdrew because of simultaneous Chinese herbal treatment, and the other 34 subjects completed the trial (Fig. 1). No significant differences were found between the AG and SG in subject characteristics and basic data, including age, gender, and acupuncture history (Table 1). Three patients, two in the AG and one in the SG, were lost to follow-up and did not receive outcome measurements at F2. Therefore, they were analyzed according to the last observation carry-forward rule.

One patient in the AG developed ecchymosed over the left Fenhchi acupoint region after finishing the third acupuncture treatment, which was treated with ice packing and disappeared completely one week later. One patient in the SG experienced slight dizziness after finishing the second acupuncture treatment; this symptom quickly disappeared after the patient took a short rest and drank some hot water. All 34 patients were asked at F1 to

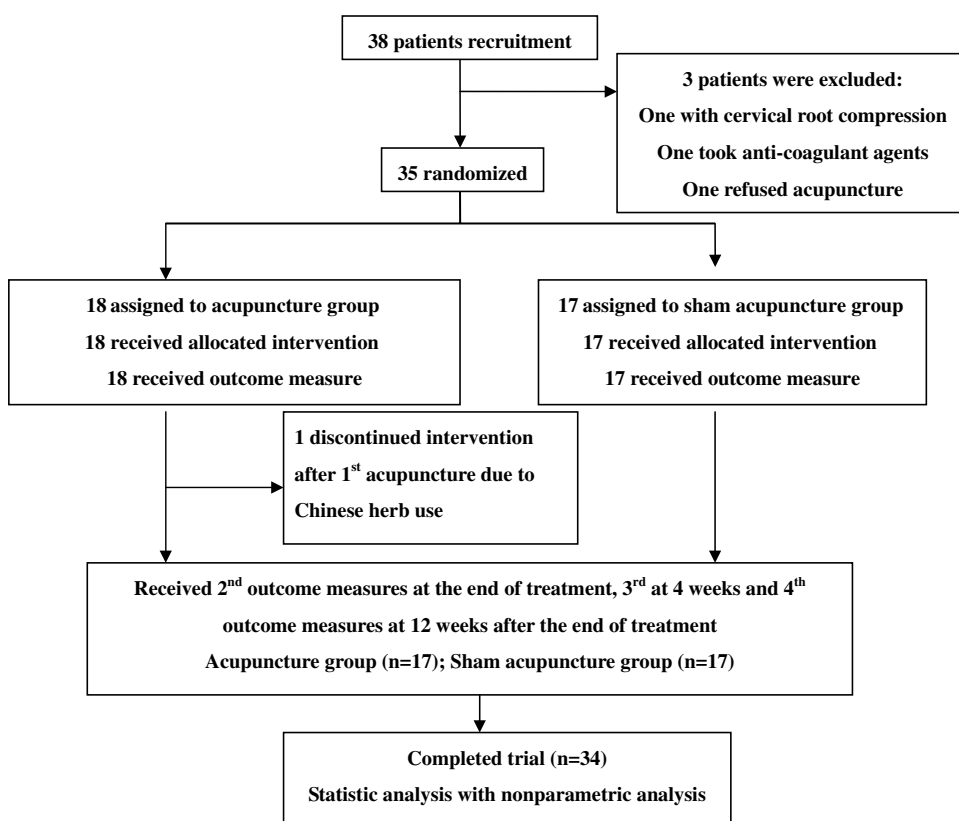


Figure 1. Flow chart.

Table 1. Characteristics and Basic Data of 34 Patients with Chronic Neck Myofascial Pain Syndrome

Characteristics	AG	SG
Number	17	17
Gender (female/male)	11/6	13/4
Mean age (years, range)	47.2 (31–66)	45.9 (33–56)
Acupuncture history (yes/no)	4/13	5/12
Answer for group (right/wrong)	11/6	9/8

AG: Acupuncture group; SG: sham acupuncture group.

which group they thought they had been allocated. No difference was found between the two groups in the rate of correct response to this question (Table 1).

Main Outcome Measure

The PF, RP, BP, GH, and PCS scores of SF-36 were greater at AT, F1 and F2 than that at BT in AG and SG groups (all $p < 0.05$, Table 2). The RE scores of SF-36 were greater at AT, F1, and F2 than at BT in AG ($p < 0.05$, Table 2). The VT and MH scores of SF-36 were greater at F1 than at BT in SG ($p < 0.05$, Table 2). The SF and MCS scores of SF-36 were greater at AT and F2 than at BT in AG ($p < 0.05$, Table 2).

The differences in the PF score and the RE score of SF-36 between F2 and BT were greater in the AG than that in SG (both $p < 0.05$, Table 3). The differences in the RP, BP, GH, VT, SF, MH, PCS, and MCS scores of SF-36 between AT and BT and between F1 and BT were not significantly different between AG and SG (all $p > 0.05$, Table 3).

Secondary Outcome Measures

The neck ROM scores were greater at AT, F1 and F2 than that at BT in AG and SG groups (all $p < 0.05$, Table 4). The VAS scores of motion-related pain were greater at BT than at AT, F1 and F2 in the AG (all $p < 0.05$, Table 4), and were greater at BT than at AT in the SG ($p < 0.05$, Table 4).

The differences in the ROM scores and VAS scores of motion-related pain between AT and BT, between F1 and BT, and between F2 and BT were not significantly different between AG and SG.

The SD, AD, VAS, PPI, and total scores of SF-MPQ were greater at BT than at AT, F1 and F2 in AG and SG (all $p < 0.05$, Table 5).

The results of SD, AD, VAS, PPI, and total scores of SF-MPQ between AT and BT, between F1 and BT, and between F2 and BT showed no significant differences between AG and SG.

Discussion

Our results indicated that the differences in the PF score and the RE score of SF-36 between F2 and BT were greater in the AG than in the SG, suggesting that acupuncture

Table 2. Effect of Acupuncture on Quality Of Life (SF-36) in Patients with Chronic Neck Myofascial Pain Syndrome

	BT	AT	F1	F2
Physical Functioning (PF)				
AG	75 (65,82.5)	90 (90,100)***	100 (95,100)***	100 (97.5,100)***
SG	75 (72.5,85)	95 (90,100)***	100 (87.5,100)***	95 (82.5,100)**
Role Physical (RP)				
AG	25 (0,50)	100 (50,100)***	100 (75,100)***	100 (100,100)***
SG	25 (0,37.5)	100 (62.5,100)***	100 (100,100)***	100 (25,100)**
Bodily Pain (BP)				
AG	41 (22,56.5)	62 (51,74)***	62 (31,84)**	51 (51,62)***
SG	41 (32,46)	72 (62,72)***	72 (57,84)***	62 (41,78)**
General Health (GH)				
AG	45 (35,48.5)	60 (55,66)***	65 (55,77)***	65 (55,70)**
SG	35 (32.5,47)	62 (35,72)***	65 (51,72)***	65 (65,71)***
Vitality (VT)				
AG	45 (37.5,60)	50 (50,70)	70 (32.5,80)**	70 (65,80)***
SG	45 (32.5,57.5)	50 (40,80)	70 (50,77.5)**	70 (37.5,70)
Social Functioning (SF)				
AG	62.5 (50,68.75)	75 (68.75,87.5)**	62.5 (43.75,87.5)	87.5 (75,87.5)**
SG	62.5 (37.5,68.75)	75 (62.5,87.5)	75 (62.5,87.5)	62.5 (50,87.5)
Role Emotional (RE)				
AG	66.67 (0,100)	100 (100,100)**	100 (66.67,100)**	100 (100,100)**
SG	33.33 (0,100)	100 (16.67,100)	100 (66.67,100)	100 (0,100)
Mental Health (MH)				
AG	64 (34,68)	68 (62,74)	72 (56,82)	72 (60,82)**
SG	56 (52,64)	68 (54,76)**	68 (64,80)***	68 (58,74)
Physical Health Component Summary (PCS)				
AG	39.3 (35.05,42.07)	48.9 (44.92,50.82)***	51.5 (48.44,53.37)***	49.6 (49,51.40)***
SG	38.2 (35.27,40.98)	51.9 (46.60,53.51)***	51.6 (48.47,55.93)***	47.7 (43.54,54.06)***
Mental Health Component Summary (MCS)				
AG	40.5 (29.93,48.13)	50.6 (49.98,52.71)**	46.3 (37.48,52.77)	49.2 (48.35,53.41)**
SG	39.4 (33.66,46.08)	47.0 (38.44,50.06)	46.8 (41.59,51.59)	46.8 (39.61,50.83)

Median (25th, 75th); AG: acupuncture group; SG: sham acupuncture group; BT: before acupuncture; AT: at finishing six acupuncture treatment; F1: at four weeks after the acupuncture treatment; F2: at 12 weeks after the acupuncture treatment. **p < 0.05, ***p < 0.01 compared to BT.

treatment can improve quality of life in patients with chronic neck MPS. Several clinical trials of acupuncture for the treatment of neck pain reported that the efficacy of acupuncture was still controversial (NIH consensus development panel on acupuncture, 1998; White and Ernst, 1999; Smith *et al.*, 2000); these studies focused mainly on the relief of pain. The present study was a randomized controlled trial designed to evaluate the effects of acupuncture on chronic neck MPS in terms of both mental and physiological health. Our results

Table 3. Comparison of Effect between Acupuncture and Sham Groups on Quality of Life (SF-36) in Patients with Chronic Neck Myofascial Pain Syndrome

	AT-BT	F1-BT	F2-BT
Physical Functioning (PF)			
AG	15 (10,25)	20 (7.5,35)	25 (12.5,35)#
SG	15 (10,25)	15 (10,25)	15 (7.5,20)
Role Physical (RP)			
AG	25 (0,75)	50 (37.5,75)	75 (50,100)
SG	75 (50,100)	75 (25,100)	25 (0,87.5)
Bodily Pain (BP)			
AG	21 (12,29)	11 (9,46)	11 (5,29)
SG	31 (6,31)	31 (11,52.5)	21 (-5.5,47)
General Health (GH)			
AG	20 (12,24)	25 (20,31)	25 (6,30)
SG	20 (2.5,33.5)	20 (8.5,33.5)	30 (11.5,43.5)
Vitality (VT)			
AG	5 (-5,25)	5 (0,22.5)	25 (15,35)
SG	10 (-7.5,22.5)	15 (0,32.5)	10 (-7.5,30)
Social Functioning (SF)			
AG	12.5 (0,25)	0 (-6.25,12.5)	12.5 (6.25,37.5)
SG	12.5 (-6.25,25)	25 (-12.5,31.25)	12.5 (-18.75,25)
Role Emotional (RE)			
AG	33.33 (0,100)	33.33 (0,83.33)	33.33 (0,100)#
SG	0 (0,66.67)	0 (0,83.33)	0 (0,33.33)
Mental Health (MH)			
AG	8 (-2,28)	8 (-4,26)	8 (2,28)
SG	8 (0,16)	12 (6,18)	8 (0,18)
Physical Health Component Summary (PCS)			
AG	6.9 (4.93,11.39)	13.1 (9.23,15.84)	9.4 (6.79,16.06)
SG	12.8 (6.31,17.17)	13.6 (8.90,17.85)	7.2 (4.58,18.92)
Mental Health Component Summary (MCS)			
AG	8.1 (0.54,17.73)	4.1 (-2.33,10.27)	7.9 (0.13,22.56)
SG	-0.3 (-3.75,12.54)	5.8 (-1.88,11.32)	5.0 (-1.10,9.37)

Median (25th, 75th percentile); AG: acupuncture group; SG: sham acupuncture group; BT: before acupuncture; AT: at finishing six acupuncture treatment; F1: at four weeks after the acupuncture treatment; F2: at 12 weeks after the acupuncture treatment. AT-BT: The difference between AT and BT; F1-BT: the difference between F1 and BT; F2-BT: the difference between F2 and BT; #p < 0.05 compared to SG.

Table 4. Effect of Acupuncture on Neck Range of Motion and Motion-Related Pain in Patients with Chronic Neck Myofascial Pain Syndrome

	BT	AT	F1	F2
Neck Range of Motion				
AG	50.7 (49.00,59.33)	60.0 (55,63.71)***	60.0 (55,65.92)***	60.2 (60.08,63.42)***
SG	54.7 (49.67,59.25)	60.8 (57.33,64.33)***	62.0 (58.33,63.25)***	59.5 (56.33,63.17)**
Motion-Related Pain (Visual analogue score, VAS)				
AG	50 (40,50)	30 (25,40)***	20 (15,45)***	30 (15,50)**
SG	50 (40,50)	40 (20,45)**	30 (20,45)	30 (20,55)

Median (25th, 75th); AG: acupuncture treatment; SG: sham acupuncture treatment; BT: before acupuncture treatment; AT: at finishing six acupuncture treatment; F1: at four weeks after finishing six acupuncture; F2: at 12 weeks after finishing six acupuncture treatment. **p < 0.05, ***p < 0.01 compared to BT.

Table 5. Effect of Acupuncture on the Short-Form McGill Pain Questionnaire (SF-MPQ) in Patients with Chronic Neck Myofascial Pain Syndrome

	BT	AT	F1	F2
Sensory Dimension				
AG	5 (4,5)	3 (2,3)***	2 (2,2.5)***	2 (1,3.5)***
SG	4 (2.5,5)	2 (2,4)**	2 (2,2)***	2 (2,3)***
Affective Dimension				
AG	2 (1,2)	1 (0,1)***	0 (0,1)***	0 (0,0)***
SG	2 (1,2)	0 (0,1)***	0 (0,0)***	0 (0,0)***
Visual Analog Scale				
AG	50 (45,60)	30 (27.5,50)***	30 (10,42.5)***	40 (10,50)***
SG	50 (45,65)	40 (30,50)***	30 (20,37.5)***	30 (20,45)***
Present Pain Intensity				
AG	3 (2,3.5)	1 (1,1.75)***	1 (1,1.5)***	2 (0.5,2)***
SG	3 (2,3)	1 (1,2)***	1 (1,1)***	1 (1,2)***
Total Scores				
AG	9 (7,10)	5 (4,5)***	3 (2,5)***	4 (1.5,6)***
SG	8 (7,10.5)	4 (2.5,6)***	3 (2.5,3)***	3(3,6)***

Median (25th, 75th); AG: acupuncture treatment; SG: sham acupuncture treatment; BT: before acupuncture treatment; AT: at finishing six acupuncture treatment; F1: at four weeks after the acupuncture treatment; F2: at 12 weeks after the acupuncture treatment. **p < 0.05, ***p < 0.01 compared to BT.

indicated that both acupuncture or sham acupuncture treatments improved SF-36 scores, neck ROM, VAS scores of motion-related pain, and SF-MPQ scores at AT, F1 and F2. These results are suggested as follows: (1) patients with chronic neck MPS suffer from not only physiological disability, but also psychological disorders. Therapeutic effects on pain are easily influenced by placebo effects (Cummings and White, 2001); therefore, randomization and blinding are important in good clinical trials. All 34 patients in this study were asked at

F1 whether they belonged to AG or SG, no difference between the two groups was found in the correct rate. Moreover, the subjects could not see the performed acupuncture procedure because of their prone position, thus, the placebo effect can be excluded in the present study; (2) the analgesic effects of acupuncture seem to be mediated by central mechanisms that may involve the ventrolateral spinal cord column, dorsal periaqueductal gray matter, lateral hypothalamus, lateral septum, cingulate bundle, dorsal hippocampus, habenulo-interpeduncular tract, and anterior hypothalamus (Takeshige *et al.*, 1993). Deep acupuncture stimulation produces greater improvement at three months after treatment than superficial acupuncture stimulation in patients with chronic lumbar MPS (Ceccherelli *et al.*, 2002). Because muscles have a receptor connected with group III and group IV nerve fibers, and these fibers are involved in acupuncture analgesia. Another study reports that acupuncture had greater effects on motion-related pain than massage or sham laser acupuncture in patients with chronic neck pain (Irnich *et al.*, 2001). In addition, either deep muscle or superficial subcutaneous stimulation may induce diffuse noxious inhibitory controls to relieve pain (Le Bars *et al.*, 1979). The acupuncture needles were inserted into the muscle layer and manually twisted to obtain Qi in AG, while the needles were inserted only subcutaneously in the SG, which produced the results of the present study.

The present study had some limitations. We recruited patients with chronic neck MPS at a Western neurological clinic who agreed to undergo Chinese acupuncture therapy. Some of the subjects feared possible adverse effects of medication, and others had received inadequate relief from previous medical treatment. They believed in the therapeutic effects of acupuncture. Under these conditions, the possibility of bias cannot be excluded. Moreover, the small numbers of subjects in our trial could result in a lack of statistically significant differences between groups in neck ROM and pain intensity. Adoption of a different study design with a larger number of subjects might have eliminated these two limitations. In terms of complications, one patient developed ecchymosis which was treated with ice packing and disappeared completely one week later. One patient experienced slight dizziness but quickly recovered after taking a short rest and drinking some hot water. Therefore, acupuncture may be widely used in clinic to treat the disease.

In conclusion, AG has greater improvement in physical functioning and role emotional of Short Form-36 quality of life at F2, suggesting that acupuncture may be used to improve the quality of life in patients with chronic neck MPS.

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