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Original Article

Randomized Controlled Trial of East-West Collaborate Medical Treatment on Female Chronic Shoulder Pain Patients

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국문초록

여성 만성견비통 환자에 대한 동서 협진 치료의 무작위 대조군 연구

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목적 : 만성 견비통 환자에 대한 침 치료와 신경 차단술 병행 치료의 효과를 검증하고자 함.

방법 : 만성 견비통 환자 60명을 대상으로 동서병행치료군(EW group, n=20), 한방 침치료군(E group, n=20), 무처치 대조군(C group, n=20)으로 무작위 배정한 후 연구를 시작했다. 동서병행치료군은 먼저 견갑상 신경차단술, 견봉하 주사 및 압통점 국소 마취제를 맞은 후 5분간 휴식을 취한 후 肩髃(LI_{15}), 肩髎(TE_{14}), 肩井(GB_{21}) 및 동씨침의 肩中穴과 腎關穴에 침치료를 주 2회 4주간 받았다. 한방 침치료군은 주 2회, 4주간 肩髃(LI_{15}), 肩髎(TE_{14}), 肩井(GB_{21}) 및 동씨침의 肩中穴과 腎關穴에 침치료를 받았으며, 무처치 대조군은 4주간

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특별한 처치를 받지 않았다. 모든 환자들은 일상생활에서 자가 운동을 실시하도록 지시 받았다. 치료 시작 전과 치료 4주 후 Constant Shoulder Assessment(CSA), Shoulder Pain and Disability Index(SPADI), 및 환자의 주관적 통증 평가를 Visual Analogue Scale(VAS)로 측정하여 모인 데이터 통계를 분석하였다.

결과 : 동서병행치료군 및 한방 침치료군 모두 CSA, SPADI 및 VAS상에서 유의한($p<0.05$) 호전을 보였다. 동서병행치료군의 CSA, SPADI, VAS는 무처치 대조군과 비교하여 유의한 우의를 나타냈으며, 한방 침치료군과 비교하여 VAS에서 유의한 차이를 나타냈다.

결론 : 침치료와 신경차단술 병행 치료방법은 만성 견비통을 유의하게 호전시켰다. 무처치 대조군과의 차이는 3개의 측정 도구 모두에서 유의한 차이가 있었으며, 침치료만 받은 환자들과도 주관적 통증 척도에서 유의한 차이를 보였다.

핵심단어 : 침, 신경차단술, 만성견비통, Constant Shoulder Assessment, Shoulder Pain and Disability Index, Visual Analogue Scale

I. Introduction

Shoulder pain is a very common condition. It is the third most common cause of musculoskeletal consultation in primary care[1,2].

There are various causes for shoulder pain. The most common are postural disorder, fibrositis, sprain, strain, subacromial bursitis, subdeltoid bursitis, suprapinatus tendinitis, calcareous supraspinatus tendinitis, supraspinatus tendinitis with calcification, rupture of rotator cuff, bicipital tenosynovitis, glenohumeral instability and frozen shoulder[3].

There are many commonly used treatments for shoulder disorders, including physiotherapy modalities, non-steroidal anti-inflammatory drugs, glucocorticosteroid injections, oral glucocorticosteroids, manipulation under anaesthesia, hydrodilatation(distension arthrography), acupuncture and surgery[4].

In terms of Oriental Medicine, shoulder pain is caused due to wind, coldness, dampness, phlegm and retained fluid, bruise, blood stagnation, and stagnation of Qi and blood. Acupuncture treatment according to the cause of shoulder pain is being widely practiced[5].

Recent studies on acupuncture for shoulder pain consist of acupuncture compared with ultrasound and NSAID, placebo acupuncture, placebo ultrasound, ear acupuncture and physical treatment, and random treatment[6]. Documents concerning deep acupuncture compared with shallow acupuncture[7], electroacupuncture compared with stellate ganglion block and suprascapular nerve block[8], and acupuncture combined with exercise compared with exercise alone were also found[9].

As for collaborate medicine where eastern and western treatment are combined, Lin[8] reported electroacupuncture combined with regional nerve block showed statistically significant improvement compared to single treatments.

As for domestic studies, clinical studies on nerve block treatment[10,11], acupuncture treatment[12] and herb medicine injection acupuncture[13] applied on shoulder pain were found. But, studies comparing acupuncture with western medicine or combining acupuncture with western medicine for shoulder pain were not found.

This study aims to observe the effect of acupuncture collaborated with nerve block treatment on chronic shoulder patients and evaluate the treatment effectiveness by comparing with acupuncture treatment and no treatment. By doing so, we hope to provide essential data for future studies on East-West Collaborate medicine.

Ⅱ. Methods

1. Subjects

In order to recruit voluntary chronic shoulder pain patients engaged in computer labor more than 3 hours per day, home-shopping companies, tele-marketing cooperations and costumer service centers were contacted.

Study was conducted between April 17, 2007 and June 8, 2007. The voluntary patients were first interviewed and received medical examinations. Patients diagnosed as chronic pain syndrome were recruited. Thus, among the call center agents working at the costumer center of Korean gas cooperation, 60 female, chronic shoulder pain patients, aged between 20 to 60 were recruited.

Before proceeding, all patients were informed about the objectives and methods of this study. Written consent concerning this clinical study was received from each participant. All factors concerning this clinical study were examined and approved by the Institutional Review Boards(IRB) of Kyung-Hee medical center.

2. Inclusion criteria[9]

After receiving physical examinations, patients with no other pathological conditions which can explain the symptoms, were than evaluated whether or not they matched the following inclusion criteria.

① Shoulder pain for at least 1 month
② Appreciable pain of active or passive motion
③ Pain at night, with inability to lie on the affected side

3. Exclusion criteria[9]

① History of major shoulder injury or surgery ;
② Clinical evidence of other pathology that could possibly account for symptoms ;
③ Patients with evidence of cervical radiculopathy, paresis, or other neurological changes in the upper limb on the involved side ;
④ The presence of underlying fracture, associated inflammatory arthritis, known renal or hepatic disease, haemopoietic disorder, malignancy, any mental disorder likely to interfere with the course or assessment of the disease process ; and
⑤ Painful arc between 40° and 120° abduction indicative of rotator cuff disease

4. randomization & enrollment

Patients fulfilling the criteria were enrolled and randomized according to the randomization code. They were randomly assigned to East-West Collaboration treatment group(EW group, n=20), Eastern acupuncture treatment group(E group, n=20) and Control group(C group, n=20). Patients prescribed with anti-inflammation medications and pain killers were asked to stop the medication and have a 1 week wash out period before they participated in this study.

5. Method of treatment and material

1) East-West collaboration treatment group(EW group)

The EW group first received suprascapular nerve block, subacromial injection and trigger point injection and after 5 minutes of rest received acupuncture treatment on LI_{15}, TE_{14}, GB_{21} and Master Dong's acupuncture points, Shin-gwan and Gyun- joong[14], twice a week for 4 weeks. Patients were instructed to practice self exercise during their daily lives.

In order to perform suprascapular nerve block, the needle was inserted from the Scapula spine towards the supraspinous fossa and steroid mixed with 1% lidocaine 5-8 ml was injected. As for the subacromial injection the patient was asked to sit and relax their shoulder, after distinguishing the acromion, the needle was inserted 1cm below the acromion upward in a 20-30° angle and steroid mixed with 1% lidocaine 5ml was injected. Trigger point injection was performed by searching for tender points and injecting 0.5-2ml topical anesthetic.

2) Eastern acupuncture treatment group(E group)

The E group received acupuncture treatment on LI_{15}, TE_{14}, GB_{21} and Master Dong's acupuncture points, Shin-gwan and Gyun-joong[14], twice a week for 4 weeks. The needles were inserted for 15 minutes after manual stimulation. Patients were instructed to practice self exercise during their daily lives.

Stainless steel acupuncture needles measuring 0.3㎝ in diameter and 4cm in length, manufactured by Dongbang Acupuncture sited in Boryung, South Chungchong province, Korea, was used.

3) Control group(C group)

The C group received no particular treatment for 4 weeks. Only self exercise during daily life was instructed.

6. Assessment

Evaluations were made before study and after 4 weeks from the baseline using Constant Shoulder Assessment(CSA)[15], Shoulder Pain and Disability Index(SPADI)[16] and the patient's subjective pain scale was measured by Visual Analogue Scale(VAS). The obtained data were analyzed and compared.

7. Analysis of data

SPSS 13.0 for windows was used for statistical analysis. The homogeneity of the three groups was verified by one way ANOVA and Chi square test. The significance of change before and after 4 weeks of treatment was analyzed with paired t-test. The significance of difference between the groups were inspected by ANCOVA. The dactum of significance was fixed as $p<0.05$.

Ⅲ. Results

Among the 60 patients enrolled, a total of 6 patients dropped out. 2 patients from each of the three groups dropped out. One patient from EW group and E group failed to receive treatment due to working schedules, one patient of EW group refused treatment due to fear of needle injection, one patient of E group received another treatment without discussion and two patients of C group failed to show up at the final assessment day. These drop out patients were excluded from the final data analysis. The final number of patients who completed the 4 week study was 54.

The general character of the patients at baseline is summarized in Table 1. There were no statistically significant differences among the three groups in terms of age, sex, and duration of symptoms ($p>0.05$). There were also no statistically significant differences among the three groups in respect of base line CSA, SPADI and VAS($P>0.05$)(Table 1).

The change of CSA, SPADI and VAS within the EW group is as shown in Table 2. CSA improved from 48.39±5.36 to 61.11±5.80 after the 4 week

Table 1. General characteristics of study population at baseline

	No. of subjects(%)			P value
	EW group (n=18)	E group (n=18)	C group (n=18)	
Age(mean±S.D, years)	40.28±6.31	37.89±6.96	38.39±5.96	0.505*
Duration(months)	34.83±50.83	29.50±34.16	29.50±36.32	0.904*
CSA(before treatment)	48.39±5.36	48.72±6.91	51.94±4.62	0.129*
SPADI	16.28±13.70	14.44±14.16	11.72±9.27	0.554*
VAS	5.72±2.11	5.11±2.30	4.61±2.30	0.337*

* ; using ANOVA, $p<0.05$.

Table 2. The changes of CSA, SPADI and VAS after 1 month eastern treatment in combination with western treatment in chronic shoulder pain patients

Genotype	Before treatment (n=18)	One month treatment (n=18)	P value**
CSA	48.39±5.36	61.11±5.80	0.000*
SPADI	16.28±13.70	7.33±9.86	0.000*
VAS	5.72±2.11	2.33±1.57	0.000*

* paired samples T-test, $p<0.05$.

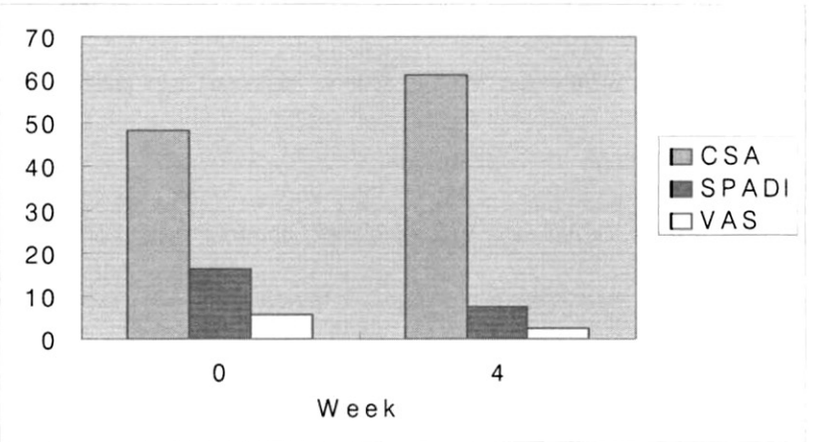

Fig. 1. The changes of CSA, SPADI and VAS in chronic shoulder pain patients before and after one month treatment of eastern treatment in combination with western treatment

Table 3. The changes of CSA, SPADI and VAS after one month eastern treatment in chronic shoulder pain patients

Genotype	Before treatment (n=18)	One month treatment (n=18)	P value**
CSA	48.72±6.90	57.33±6.44	0.000*
SPADI	14.44±14.16	8.67±10.13	0.002*
VAS	5.11±2.30	3.56±2.50	0.011*

* paired samples T-test, $p<0.05$.

treatment. SPADI decreased from 16.28±13.70 to 7.33±9.86 and VAS from 5.72±2.11 to 2.33±1.57. EW group showed significant improvement in CSA, SPADI and VAS after 4 weeks of treatment($p<0.05$) (Table 2, Fig. 1).

The change of CSA, SPADI and VAS within the E group is as shown in Table 3. CSA improved from 48.72±6.90 to 57.33±6.44 after the 4 week treatment. SPADI decreased from 14.44±14.16 to 8.67±10.13 and VAS from 5.11±2.30 to 3.56±2.50. E group showed significant improvement in CSA, SPADI and VAS after 4 weeks of treatment($p<0.05$)(Table 3, Fig. 2).

The change of CSA, SPADI and VAS within the C group is as shown in Table 4. CSA improved from 51.94±4.62 to 54.89±5.86 after the 4 week study. SPADI scored 11.72±9.27 at baseline and 10.72±8.90 after 4 weeks and VAS scored 4.61±2.30

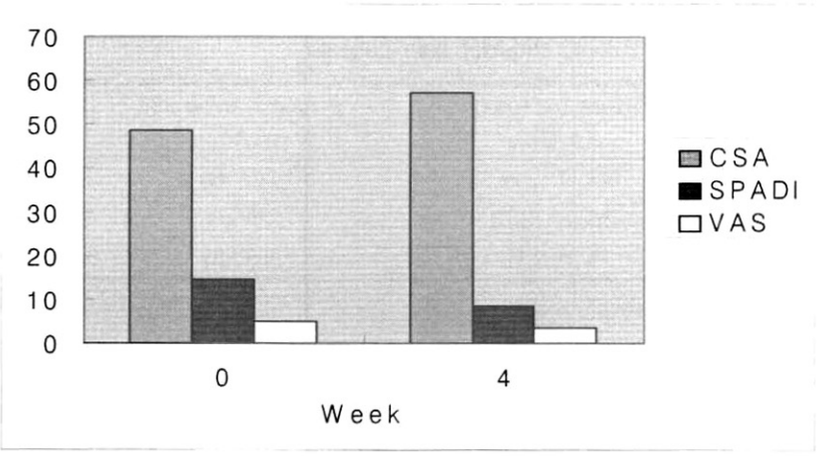

Fig. 2. The changes of CSA, SPADI and VAS in chronic shoulder pain patients before and after one month treatment

Table 4. The changes of CSA, SPADI and VAS of chronic shoulder pain patients in control group after one month

Genotype	Before treatment (n=18)	One month treatment (n=18)	P value*
CSA	51.94±4.62	54.89±5.86	0.034*
SPADI	11.72±9.27	10.72±8.90	0.055
VAS	4.61±2.30	4.33±2.22	0.056

* paired samples T-test, $p<0.05$.

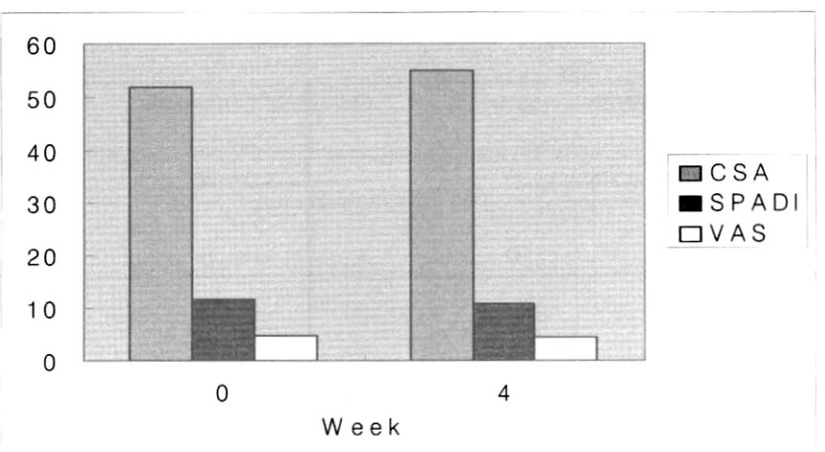

Fig. 3. The changes of CSA, SPADI and VAS in control group of chronic shoulder pain patients

and 4.33±2.22. Only the CSA score improved significantly in C group($p<0.05$). SPADI and VAS of C group showed insignificant difference before and after the 4 week study period($p>0.05$)(Table 4, Fig. 3).

The change of CSA, SPADI and VAS in EW group, E group and C group was compared and analyzed(Table 5).

Table 5. The changes of CSA, SPADI and VAS after one month treatment of each treatments in chronic shoulder pain patients

Genotype	EW group (n=18)	E group (n=18)	C group (n=18)
CSA			
Before treatment	48.39±5.36	48.72±6.90	51.94±4.62
After one month	61.11±5.80	57.33±6.44	54.89±5.86
SPADI			
Before treatment	16.28±13.70	14.44±14.16	11.72±9.27
After one month	7.33±9.86	8.67±10.13	10.72±8.90
VAS			
Before study	5.72±2.11	5.11±2.30	4.61±2.30
After one month	2.33±1.57	3.56±2.50	4.33±2.22

Table 6. The changes of CSA, SPADI and VAS after one month treatment of each treatments in chronic shoulder pain patients

Genotype	EW (n=18), E (n=18) and C (n=18) group	EW group (n=18) and C group (n=18)	E group (n=18) and C group (n=18)	EW group (n=18) and E group (n=18)
CSA				
p-value	0.002*	0.001*	0.011*	0.208
SPADI				
p-value	0.001*	0.000*	0.023*	0.126
VAS				
p-value	0.000*	0.000*	0.065	0.012*

*, ANCOVA, $p<0.05$.

CSA scores before and after the 4 week study period improved significantly in all three groups. Statistics showed that the improvement of CSA in EW group and E group were both significant compared to C group($p<0.05$) but there was no difference between EW group and E group($p>0.05$).

SPADI scores before and after the 4 week study period improved significantly in EW group and E group. Statistics showed that the improvement of SPADI in EW group and E group were both significant compared to C group($p<0.05$) but there was no difference between EW group and E group ($p>0.05$).

The patients subjective pain scale recorded in the form of VAS showed significant improvement after the 4 week study period in EW group and E group. Statistics showed that the improvement of VAS in EW group was significant compared to bothe E group and C group($p<0.05$) but there was no difference between E group and C group($p>0.05$) (Table 6).

Ⅳ. Discussion

In this study, 60 chronic shoulder pain patients, working as call center agents at Korea Gas Cooperation, were recruited. This was because these call center agents engaged in computer labor more

than 3 hours a day, which raises the possibilities of chronic shoulder pain without severe injuries to occur. Also this makes it possible for us to evaluate the value of treatment methods in terms of occupational medicine in the future.

But, because this study was conducted at a single work site, and on a relatively small sample size, there can be some limitations in generalization of the results. Especially due to disproportion of sex, the results may need reverification with male subjects. Further multi center studies of the same study design will be needed to complement this defect.

Randomization was applied according to the randomization code. And by separating the practitioner from the evaluator, single blind was successfully applied.

When recruiting patients, exclusion criteria eliminated conditions which might need surgical treatment or other treatment modules than acupuncture. Inclusion criteria limited patient selection to those with relatively definite and chronic pain and tender point in the shoulder area.

The western treatment module was selected by professors of anesthesia department and practiced by licensed doctors. It was designed to reflect the most commonly practiced western treatment module in primary care. Acupuncture treatment module was designed based on the Text Book of Acupuncture and Moxibustion. Additional acupuncture points of master Dong were combined based on clinical study of Lee[5].

Assessment tools used were Constant Shoulder Assessment(CSA)[15], Shoulder Pain and Disability Index(SPADI)[16], and Visual Analogue Scale(VAS).

CSA is a simple clinical tool that combines functional assessment of the shoulder with assessment of individual parameters, such as pain and daily activity. It therefore allows evaluation of progress after injury, treatment, or disease with respect to these individual parameters or in terms of overall function. The CSA is easy to use, taking only a few minutes to perform. It is reliable and valid in the overall assessment of shoulder function, with low inter-observer and intra-observer error rates[15,17].

The structure of the SPADI suggests that it would be practical in the clinical setting, particularly the numeric format, which lessens the scoring burden on the clinician when compared to the visual analogue version. Self-report disability measures are key outcomes in orthopaedic clinical trials[16]. SPADI is also appropriate for this study.

By using these measurement tools the following results were obtained.

In treating chronic shoulder pain, 4 weeks of nerve block injection collaborated with acupuncture treatment showed significant improvement in CSA, SPADI and VAS($p<0.05$). 4 weeks of acupuncture treatment showed significant improvement in CSA, SPADI and VAS($p<0.05$).

Chronic shoulder pain patients showed significant improvement in CSA scores even after 4 weeks of no particular treatment($p<0.05$). But, SPADI and VAS showed insignificant differences after 4 weeks of no treatment($p>0.05$).

Collaborate treatment of acupuncture and nerve block injection significantly improves chronic shoulder pain. The difference with untreated patients was significant in CSA, SPADI and VAS, proving the effectiveness of collaborate treatment. The difference with patients who received only acupuncture treatment was significant in VAS showing that collaborate treatment is better in pain control compared to the single treatment.

A conclusion that the combination of acupuncture and nerve block injection may be an effective option in the treatment of chronic shoulder pain can be obtained. Further well-designed clinical trials of larger sample size in this area will be needed.

V. Conclusion

60 chronic shoulder pain patients, working as call center agents at Korea Gas Cooperation, were recruited and studied by Kyung-Hee medical center. Patients were randomly assigned to East-West collaborate treatment group(EW group, n=20), Eastern

treatment group(E group, n=20) and Control group (C group, n=20). Each patient was studied for 4 weeks between April 17, 2007 and June 8, 2007. The next conclusion was obtained based on the study results.

1. In treating chronic shoulder pain, 4 weeks of acupuncture treatment was significantly effective.
2. In treating chronic shoulder pain, 4 weeks of nerve block injection collaborated with acupuncture treatment showed significant effect.
3. Collaborate treatment of acupuncture and nerve block injection was significantly better compared to untreated patients.
4. Collaborate treatment of acupuncture and nerve block injection was significantly better in reducing pain compared to acupuncture treatment.

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