

Takagi award-winning paper

A comparison of the effectiveness between acupuncture and local injection for neck pain: a randomized controlled clinical trial

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Abstract

[Objective] The purpose of this study was to compare the effectiveness of acupuncture and local injection for neck pain.

[Methods] A randomized controlled clinical trial was conducted in which 33 patients with neck pain were randomly allocated to either an acupuncture group or a local injection group. For the acupuncture group (n = 16), a stainless steel needle was inserted to depths from 10 to 20 mm and manually stimulated (sparrow pecking method) for 20 seconds. While a 25 gauge needle was inserted to depths from 10 to 20 mm, neovitacain (dibucaine hydrochloride 0.1 percent, sodium salicylate 0.3 percent, calcium bromide 0.2 percent) and neurotropin (a non protein component extracted from the skin of rabbits treated with vaccinia virus) were injected for the local injection groups (n = 17). Both groups received each treatment at the most painful points weekly during four weeks. Primary outcome measurement was intensity of the pain evaluated with a visual analogue scale (VAS). Secondary outcomes were Neck Disability Index (NDI) and a standardized questionnaire of cervical root disease (developed by Tanaka et al. at Tohoku Univ.). The evaluations were independent from the therapists.

[Results] The acupuncture group showed better results in all the outcome measurements than those in the local injection group for the effect immediately after the treatment, the effect of sequential treatment and the sustained effect after completion of treatment.

[Discussion] The result of this study suggested that acupuncture can become a more useful treatment method compared with local injection. The difference of the effects between two treatment methods may be due to the difference of the mechanism to suppress pain.

Key words: randomized controlled trial, neck pain, acupuncture, local injection

I. Introduction

At present, in the number of patients by complaints in orthopedic outpatient clinics, patients who visit with neck pain as a chief complaint constitute a substantial percentage¹⁾. Many of them suffer from neck pain based on cervical vertebra degeneration due to a cervical spondylosis and cervical disc herniation²⁾. As a conservative treatment for such neck pain, orthopedists of-

ten use local injection to a painful point^{3,4)}. In recent years, they often call an injection of a local anesthetic to the maximum tender site a trigger point injection⁵⁾, and the trigger point injection is made in the same way as the local injection. It is also clinically well known that acupuncture and moxibustion therapy has an effect in neck pain. Acupuncture to local areas such as a pain site and a tender site take a certain effect^{6,7)}. Thus, in spite that both acupuncture and local injection are considered as

effective for neck pain, there are very few reports that compare their effects⁸). Particularly, there is no comparative study with the same treated site at present. To clarify the effectiveness of acupuncture, we allocated the sites to be treated to the patients' subjective pain sites, and examined the effect of acupuncture or local injection treatment in a randomized controlled clinical trial.

II. Methods

The participants were patients with neck pain due to cervical spondylosis, cervical disc herniation, etc. who consulted the Meiji University of Oriental Medicine Hospital, Department of Orthopedic Surgery from May 2005 to September 2006. A doctor explained the study and obtained written consent from each of them at the time of their medical examination. In addition, patients who participated were taken as those who had not received the allocated treatment in the past. Those who had a related disease in their neck or upper extremity or had received other treatments on their neck or upper extremity within one month before starting this study were excepted from the study. Participants, 33 patients (18 male, 15 female) who had neck pain were randomly allocated to two groups of acupuncture (16) and local injection (17) using a computer program (Sample Size 2.0, Blackwell Science, Inc.).

The patients' diseases were cervical spondylosis (25) cervical disc lesion (4), cervical disc herniation (2), cervical myelopathy (1), and ossification of the posterior longitudinal ligament (1). Among the 33 patients, 13 developed upper extremity symptoms, and none had lower extremity symptoms. We directed the participants not to undergo any other treatments during this study, and not take any other drugs except those taken since one month or more before starting this study and change the drug. This study obtained approval from the Ethics Committee, Meiji University of Oriental Medicine (Approval No. 17-34).

1. Intervention

Both groups of acupuncture and local injection received each treatment once a week for four weeks at the most painful 3-5 points. For the acupuncture group, a stainless steel needle (length: 40 mm, diameter: 0.18 mm, Seirin) was inserted to depths from 10 to 20 mm, manually stimulated (sparrow pecking method) after confirming there was acupuncture sensation (hibiki), and then

pulled out. For the local injection group, a 25 gauge needle (length: 25 mm, diameter: 0.50 mm, Terumo) was inserted to depths from 10 to 20 mm, injected with a drug solution, and then pulled out. They were injected with neovitacain (dibucaine hydrochloride 0.1 percent, sodium salicylate 0.3 percent, calcium bromide 0.2 percent) and neurotrophin (a non protein component extracted from the skin of rabbits treated with vaccinia virus), which is generally used as a trigger point injection in orthopedic surgery clinics. Acupuncture was done by one acupuncturist with over three years experience, and local injection was by three orthopedists with over 10 years clinical experience. Acupuncture and local injection were carried out in the outpatient clinic of Meiji University of Oriental Medicine Hospital Department of Orthopedic Surgery.

2. Evaluation method

Evaluations were performed before the 1st treatment, before and after each treatment, and two and four weeks after completion of treatment for both groups by evaluators blinded to the patient's groups allocation. The Visual Analogue Scale (VAS) was used for subjective evaluation on neck pain. It was recorded as no pain at the left end (0 mm), maximum pain the participant experienced in the past at the right end (100 mm) on a linear scale of 100 mm. In addition, we used the Japanese translation of the Neck Disability Index (NDI)⁹ that evaluates neck pain, headache, and concentration plus the seven items on the interfere level in daily life according to the six grade system. We also used a standardized questionnaire of cervical root disease (developed by Tanaka et al. at Tohoku Univ.)¹⁰ to understand the severity of symptoms. VAS for pain was employed at before the 1st treatment, before and after each treatment, and two and four weeks after completion of treatment. NDI and a standardized questionnaire of cervical root disease were carried out before the 1st treatment, at the completion of treatment, two and four weeks after completion of treatment.

3. Statistical analysis

The t-test was performed for the comparison between the two groups on the reference data before treatment, the observed VAS score and the VAS change (the value subtracted of the VAS score before treatment from the VAS score after treatment) on the effect immediately after the 1st treatment. Also, the t-test was performed for the observed VAS score and the VAS change on the

effect by sequential treatment (comparison between before the 1 st treatment and the 4 th treatment; the VAS score before the 4 th treatment subtracted from the VAS score before the 1 st treatment), NDI and a standardized questionnaire of cervical root disease (both are comparisons before the 1 st treatment and at the completion of treatment), as well as the observed VAS score on the sustained effect after completion of treatment and the VAS change (the value subtracted of the VAS score before the 1 st treatment from the VAS score two or four weeks after completion of treatment), and NDI and a standardized questionnaire of cervical root disease (both are comparisons before the 1 st treatment and two and four weeks after completion of treatment). A Bonferroni correction was used for this. Regarding the difference in the change pattern between both groups, we used Repeated-Measure Analysis of Variance (ANOVA). We used StatView 4.5 (SAS Institute, Japan) for all the statistics. We defined a risk rate below 5% as significant.

III. Results

To clarify the effectiveness of this study, we compared the two groups on the reference data before treatment. There was no significant difference in age, sex,

and disease duration between both groups. Also, in VAS, NDI and a standardized questionnaire of cervical root disease, there was no significant difference between both groups (Table 1). Neither group had a case of worsening symptoms nor any adverse event by treatment. Further, there was no dropout during the period of this study.

1. Temporal change pattern by treatment

There was a significant difference between both groups in temporal VAS change by treatment. The acupuncture group showed a clear improvement ($p < 0.0001$). Similarly, for NDI and a standardized questionnaire of cervical root disease, the acupuncture group showed a clear improvement (NDI: $p < 0.0001$ and a standardized questionnaire of cervical root disease: $p < 0.0001$) (Fig. 1).

2. Effect at immediately after treatment

For the effect immediately after treatment, it was judged that the comparison before and after the 1 st treatment would be the most suitable, since the effect by sequential treatment may be included. For the effect immediately after the 1 st treatment, there was a significant change in the observed VAS scores in both groups (acupuncture group $p < 0.0001$, local injection group $p =$

Table 1 Comparison between the two groups before treatment
There was no significant difference between the two groups in the reference data.

	Acupuncture group	Local injection group		
Patient (number)	16 (male: 10, female: 6)	17 (male: 8, female: 9)		
Age (age, mean \pm SD)	63 \pm 13	69 \pm 11		
Disease duration (day, mean \pm SD)	321 \pm 585	334 \pm 498		
Diagnosis (number)	Cervical spondylosis	11		
	Cervical herniated disc	2	Cervical spondylosis	14
	Cervical disc lesion	2	Cervical disc lesion	2
	Cervical ossification of the posterior longitudinal ligament	1	Cervical spondylosis	1
VAS score (mm, mean \pm SD)	75.6 \pm 24.8	62.6 \pm 23.5		
NDI (point, mean \pm SD)	11.3 \pm 8.5	11.6 \pm 5.6		
Standardized questionnaire of cervical root disease (point, mean \pm SD)	14.1 \pm 3.2	15.7 \pm 3.3		
Medicine used (number)	Antiinflammatory analgesic plaster	3	Antiinflammatory analgesic plaster	4
	Antiphlogistic analgetic	2	Antiphlogistic analgetic	3
	Vitamin preparation	2	Vitamin preparation	1

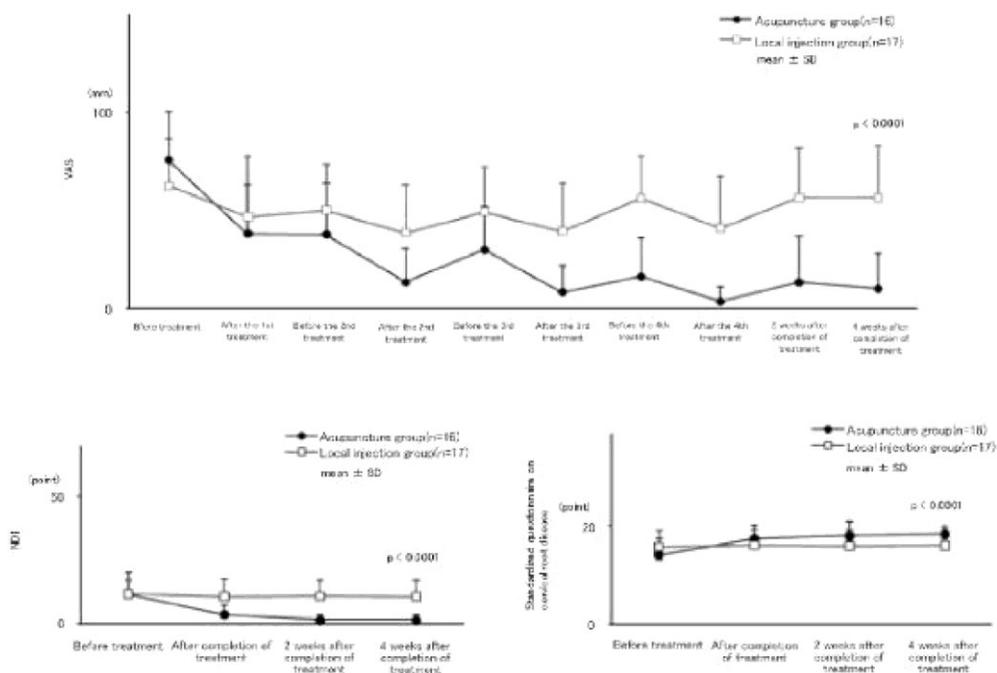


Figure 1 Temporal change by treatment

In all the outcome measurements, VAS, NDI and a standardized questionnaire of cervical root disease, there was a significant difference between both groups, and the acupuncture group showed a clear improving tendency.

0.001). For the VAS change, comparing with the local injection group, the acupuncture group significantly improved ($p = 0.01$) (Fig. 2).

3. Effect from sequential treatment

For the effect from sequential treatment, we compared the VAS scores before the 1st treatment and the 4th treatment that do not include the effect immediately after treatment. In the observed VAS scores, the acupuncture group showed a significant improvement ($p < 0.001$), and the local injection group did not ($p = 0.1996$). Also, in the VAS change, the acupuncture group showed a significant improvement compared with the local injection group ($p < 0.0001$) (Fig. 3). For NDI and a standardized questionnaire of cervical root disease, we compared the values before the 1st treatment and at the completion of treatment. While both evaluations indicated no significant change in the local injection group (NDI: $p = 0.1391$, a standardized questionnaire of cervical root disease: $p = 0.1357$), the acupuncture group

improved significantly (NDI: $p < 0.01$, a standardized questionnaire of cervical root disease: $p < 0.0001$) (Fig. 4).

4. Effect from sustained effect after treatment

Sustained effect after treatment was compared before the 1st treatment and two and four weeks after completion of treatment in VAS, NDI, and a standardized questionnaire of cervical root disease,

In the comparison of the values before treatment and two weeks after treatment, the observed VAS scores significantly improved only in the acupuncture group (acupuncture group $p < 0.001$, local injection group $p = 0.388$). In addition, in the comparison of the VAS change, the acupuncture group significantly improved ($p < 0.0001$). While NDI and a standardized questionnaire of cervical root disease indicated a significant change in the acupuncture group (NDI: $p = 0.01$, a standardized questionnaire of cervical root disease: $p = 0.0001$), the local injection group did not improve significantly (NDI:

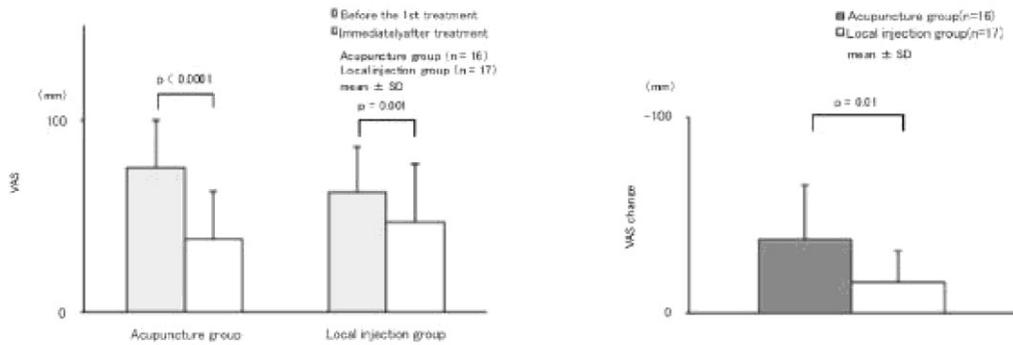


Figure 2 Effect at immediately after treatment

Immediately after the 1st treatment, both groups showed a significant change. Acupuncture had a higher curative effect. The left graph shows the observed value and the right graph is its change

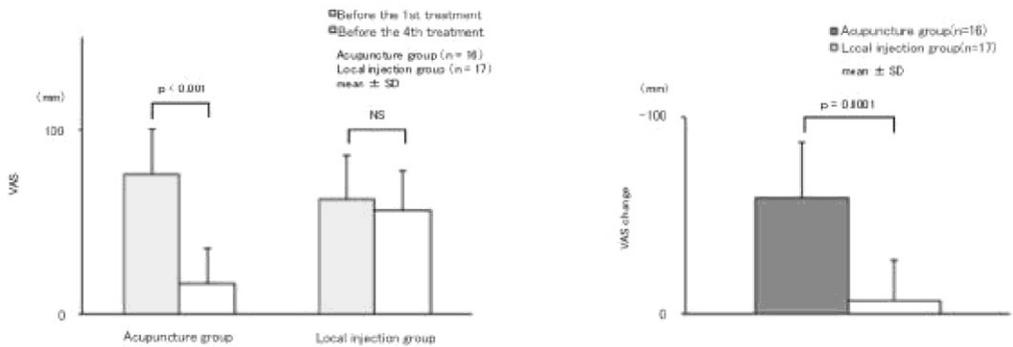


Figure 3 Effect from sequential treatment (Comparison between before the 1st treatment and the 4th treatment)

For VAS, the acupuncture group showed a significant improvement, and the local injection group did not. The left graph shows the observed value and the right graph is its change.

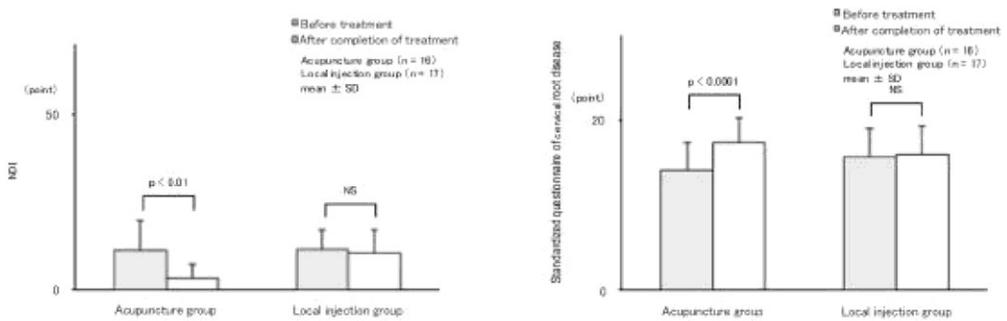


Figure 4 Effect of sequential treatment (Comparison between before the 1st treatment and after completion of treatment)

The acupuncture group indicated a significant improvement in NDI and a standardized questionnaire of cervical root disease, but the local injection group did not.

$p < 0.1603$, a standardized questionnaire of cervical root disease: $p < 0.3818$) (Fig. 5).

In the comparison of the values before treatment and four weeks after completion of treatment, the same as in the comparison two weeks after completion of treatment, the observed VAS scores significantly improved only in the acupuncture group (acupuncture group $p < 0.001$, local injection group $p = 0.3293$). In the comparison of the VAS change, the same as in the comparison two weeks after treatment, the acupuncture group significantly improved ($p < 0.0001$). While NDI and a standardized questionnaire of cervical root disease similarly indicated a significant change in the acupuncture group (NDI: $p = 0.01$, a standardized questionnaire of cervical root disease: $p < 0.0001$), the local injection group did not improve significantly (NDI: $p < 0.1325$, a standardized questionnaire of cervical root disease: $p < 0.2603$) (Fig. 6).

IV. Discussion

To date, there is no report that compares acupuncture with local injection on the same treatment site to ease pain. In similar reports that compare the effect of a local analgesic with physiological saline or the effect of a local analgesic with dry needle, the results indicate an equivalent effect or that a physiological saline was more effective¹¹⁻¹³.

Based on these researches, to clarify the effectiveness of acupuncture, we studied patients who suffered from neck pain in two groups of acupuncture and local injection treatment (a control) that is generally considered to be effective. We limited the points to be treated as their subjective maximum painful points.

Table 1 shows the comparison of the reference data between both groups of participants in this study. There was no significant difference in age, sex, disease dura-

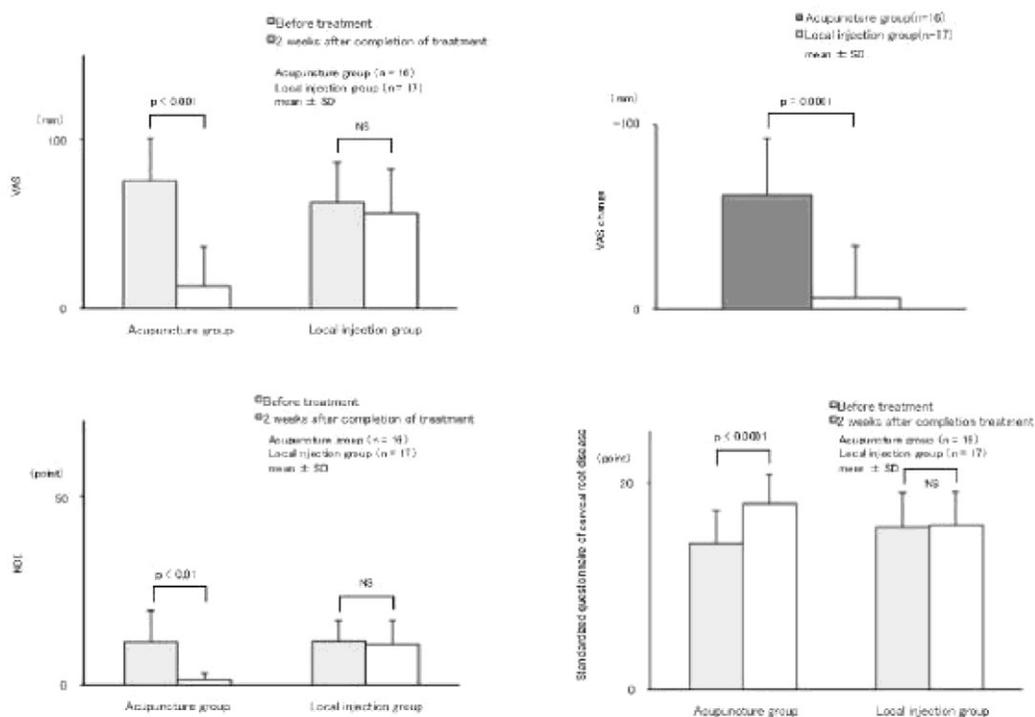


Figure 5 Sustained effect after treatment (Comparison between before the 1st treatment and two weeks after completion of treatment)

In all the outcome measurements, the acupuncture group showed a significant improvement, and the local injection group did not. The upper left graph shows the observed VAS scores, and the right graph is its change. The lower left graph shows the observed NDI, and the right graph is a standardized questionnaire of cervical root disease.

tion, and reference values of other evaluation items between both groups (Table 1). Therefore it is considered that standardization could be attained in the baseline of two groups by randomizing.

In the change pattern by treatment in both groups, there was a significant difference between both groups, and the acupuncture group showed a clear improvement. For the effect immediately after the 1st treatment, there was a significant improvement in the observed VAS scores in both groups. For the VAS change, compared with the local injection group, the acupuncture group has a more significant improvement. Further, the acupuncture group showed a significant improvement in VAS scores in sequential treatment (comparison between before the 1st treatment and the 4th treatment) and the sustained effect after treatment (comparison between before treatment and two and four weeks after comple-

tion of treatment).

In NDI and a standardized questionnaire of cervical root disease, for the effects from sequential treatment (comparison between before the 1st treatment and at the completion of treatment) and sustained effect after treatment (comparison between before treatment and two and four weeks after completion of treatment), the same as in VAS, the acupuncture group had a significant improvement. In these evaluations, NDI indicated a tendency to improve several grades in the six grade system in all the questions. A standardized questionnaire of cervical root disease improved mainly for the items on subjective symptoms.

In this study, the acupuncture group showed a significant improvement in the effect at immediately after the 1st treatment, the effect from sequential treatment, and sustained effect after treatment. The difference in the

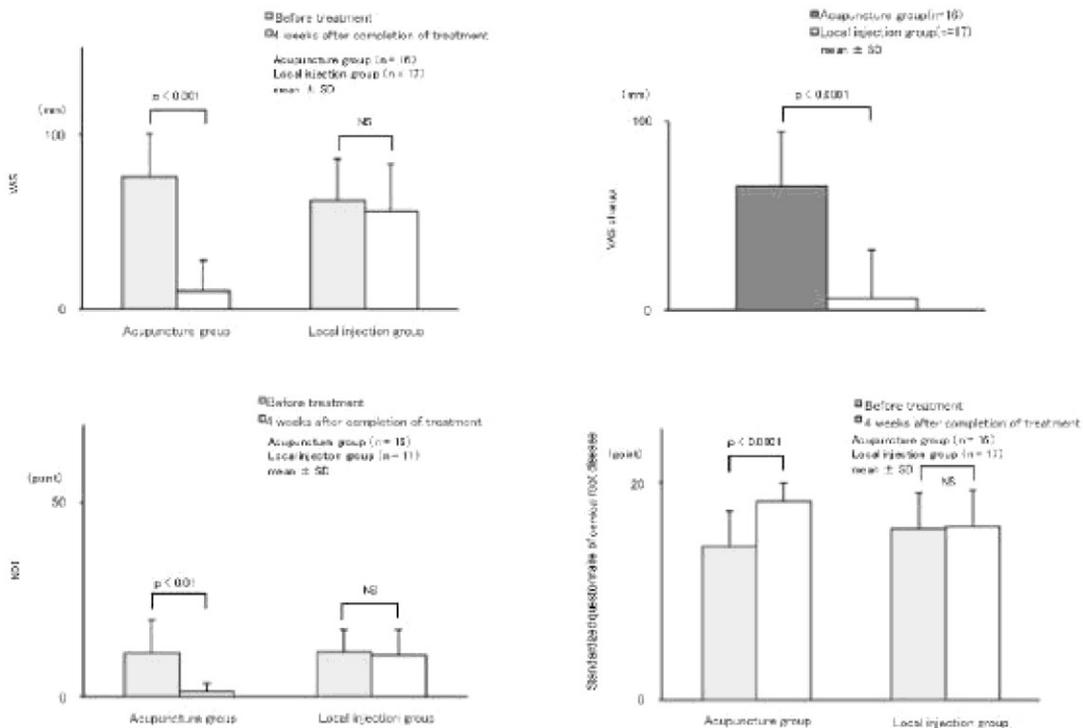


Figure 6 The sustained effect after treatment (Comparison between before the 1st treatment and four weeks after completion of treatment)

There was a significant improvement in the acupuncture group similar to the comparison between before treatment and two weeks after treatment (Fig. 5). The upper left graph shows the observed VAS scores, and the right graph shows its change. The lower left graph shows the observed NDI, and the right graph is a standardized questionnaire of cervical root disease.

treatment effects may be based on the difference in the pain suppression mechanism.

Acupuncture used this time is considered to be physical stimulation treatment by inserting a needle. On the other hand, since local injection involves inserting a needle and injecting local anesthetic, it is thought to be a combined method of stimulation treatment and narcotherapy in which the anesthetic action of the local anesthetic is added to physical stimulation. Acupuncture and local injection are common techniques in terms of inserting a needle. However they are different in whether a narcotic is poured in or not. As a pain suppression mechanism by acupuncture, it is considered that a pain suppression system is activated by the input of nerve is conducted/transmitted¹⁴⁾. As the suppression mechanism of the local anesthetic, it is considered that the conduction of nerve stimulation is blocked by a narcotic acting on a sensory nerve¹⁵⁾. Since this study observed a significant difference in the curative effect between the acupuncture group and the local group, it is conceivable that independent stimulation is more effective concerning the effect immediately after treatment, accumulative effect and sustained effect. Stimulation treatment by needle insertion is effective for pain suppression, and by combining narcotherapy with a different action mechanism with acupuncture, the effect of a stimulation treatment may not act fully.

Frost et al. reported that physiological saline was more effective by comparing a pain suppression effect by mepivacaine and physiological saline by local injection. They gave the reason as the effect of nerve stimulation continuing for a long time because nerve blocking by the narcotic does not occur by injecting only physiological saline.

Also Byrn et al. compared an effect between sterile water and physiological saline, and reported that the sterile water was more effective. They examined the reason that since sterile water is hyposmosis, liquid injection causes C-fiber stimulation and leads to pain relief. In research using acupuncture, Inoue et al. carried out electroacupuncture on a nerve root as a treatment for radicular sciatica to cases that had no effect by nerve-root blocking, and had superior effect. As for the reason why the curative effect differed, they discussed the possibility of the difference in the action mechanism of two treatments^{17,18)}. The same mechanism as in the above could be considered that acupuncture is effective in the result of this study. From the result, clinical acupuncture

treatment on a painful point is thought to be useful as a treatment for neck pain posed by degenerative change, which has a superior effect compared with local injection treatment that is generally effective. It is useful as a treatment when a high effect is acquired. In consideration of a side or harmful effect of drugs, acupuncture has little stress on a human body, and is more useful as a safe and effective treatment.

Although, from the result of this study, it became clear that the curative effects of acupuncture and local injection differ clinically, it is impossible to clarify the difference in the pain suppression mechanism between both groups. As a future subject, it is necessary to clarify the difference in action mechanism in a fundamental comparison between local anesthetic and physiological saline, and between a dry needle, which is only inserting a needle, and physiological saline, as well as doing a clinical study.

V. Conclusion

To make clear the usefulness of acupuncture, we conducted acupuncture and local injection and compared the effectiveness, with 33 patients who had neck pain. In the result, the acupuncture group showed significantly better results for the effect at immediately after treatment and the effect from sequential treatment, and the sustained effect after treatment. From these results, acupuncture considering the subjective pain point is thought to be a more useful treatment, even if compared with local injection that is generally viewed as valid.

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