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Difference between therapeutic effects of deep and superficial acupuncture needle insertion for low back pain: A randomized controlled clinical trial

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Abstract

[Objective] The purpose of this study was to compare the effects of superficial and deep insertion of acupuncture needles in the treatment of patients with low back pain and to search for more effective acupuncture methods.

[Methods] A randomized controlled clinical trial was conducted in which 32 patients with low back pain for more than three months of duration were randomly allocated either to a superficial acupuncture group (n = 16) or a deep acupuncture group (n = 16). Treatment was done for the most painful points of the patients. In the superficial insertion group, the needle was only inserted to a depth of 5 mm, whereas in the deep insertion group, the needle was inserted to a depth of about 20 mm, and was manually stimulated (sparrow pecking method) for 20 seconds. Both groups were treated weekly for four weeks. The visual analog scale (VAS) of pain, Roland-Morris Disability Questionnaire (RDQ), and Pain Disability Assessment Scale (PDAS) were used for outcome measurement.

[Result] VAS, RDQ and PDAS scores showed significant differences between groups (VAS: $p < 0.05$, RDQ: $p < 0.001$, PDAS: $p < 0.05$) in change over time with the deep insertion group having more favorable results than the superficial insertion group. The degree of change from the baseline at the time of each evaluation was calculated and results for the two groups were compared. The deep insertion group was significantly better in tendency to improve directly after the first treatment ($p < 0.01$), in cumulative effect after repeated treatment (VAS: $p = 0.13$, RDQ: $p < 0.05$, PDAS: $p < 0.01$), and in sustained effect after completion of treatment (VAS: $p < 0.05$, RDQ: $p < 0.01$, PDAS: $p < 0.05$).

[Discussion and Conclusion] The study showed that deep stimulation is a more effective treatment than superficial stimulation. It is thought that the differences of the effects are due to different influences of the treatments on the pain threshold, muscle blood flow, and muscle tones..

Key words: *randomized controlled trial, low back pain, acupuncture, depth of insertion*

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Ⅰ. Introduction

The rate of people complaining of low back pain, which is one of the complaints in a broad age group, is very high in Japan[1]. There are many people who get outpatient treatment for prolonged low back pain. In recent years, an increasing number of people have gone to see practitioners of acupuncture, moxibustion, and massage[2]. It can be observed that acupuncture and moxibustion therapies are recognized as useful treatments for low back pain. Moreover, in literature surveys, the therapeutic effects of acupuncture have been extensively verified by systematic review, meta-analysis, etc. Studies with Western medicine treatment as the control achieved good results[3-6]. There are, however, a variety of acupuncture procedures and techniques, and although their individual usefulness is indicated, there is no fixed view on more effective acupuncture at present. When needling into the same region, there are various reports on depth of insertion. Some of them describe that therapeutic effects differ depending on depth of insertion[7-9]. Thus, this study focuses on insertion depth of the needle. Needle stimulation used was either superficial or deep insertion in the same region with the subjective pain site of the patients frequently used in acupuncture treatment as the acupuncture points, and the effects were examined by a randomized controlled trial.

II. Materials and Methods

1. Materials

The subjects were patients who were seen at the Meiji University of Integrative Medicine, Department of Orthopedic Surgery Clinic, with only low back pain prolonged more than three months or with severe low back pain prolonged more than three months other than leg symptoms. The leg symptoms were caused by low back disorders. Patients with no experience with acupuncture treatment were chosen among those who had the applicable above symptoms. Further, in order to evaluate pain and Quality of Life (QOL) to judge the effects of acupuncture treatment, we excluded patients with minor symptoms with pain below 30 mm in the Visual Analogue Scale (VAS) before treatment, in which it was thought to be hard to detect the change, from the subjects. The patients who had started another treatment for low back pain or changed the treatment within one month before starting the study were also excluded. In addition, the cases suited to these exclusion criteria also received acupuncture treatment during the same period as this study period.

Of thirty-two patients who had low back pain and from whom informed consent was obtained, 16 were randomly assigned to the superficial insertion group (Group A), and 16 to the deep insertion group (Group B), using a computer program (Sample Size 2.0: Blackwell Science Ltd.). The subjects were directed not to take other medical treatments during this experiment for low back pain, and not to administer/use medicine other than those they had used more than one month before this study started. This study was conducted under the approval of the Ethics Committee of Meiji University of Integrative Medicine (Approval No. 20-42).

2. Intervention

The stimulation points for both Groups A and B were 3-12 subjective pain sites. As a way to determine subjective pain sites, we asked them to show a posture to feel pain or to indicate the region of feeling pain with movement with their fingers within the lower back (high lumber levels L 1-S 1, including buttocks). Group A only had the skin cut (about 5 mm) and in Group B the needle was inserted about 20 mm. After that we stimulated using a sparrow pecking method during 20 seconds, and then removed the needle for both groups. The needle used was a disposable filiform (40 mm, No. 18, stainless steel needle, SEIRIN). The study period was seven weeks; four treatments once a week, and then a non-treatment term of four weeks after the final treatment day, followed by re-evaluation. All medical treatments were done in the clinic of the Meiji University of Integrative Medicine, Department of Orthopedic Surgery Clinic by a practitioner in acupuncture and moxibustion with one year clinical experience.

3. Evaluation methods

VAS was used for a subjective evaluation of low back pain, recording the pain on a 100 mm straight line; from the left end (0 mm) as "With no pain" to the right end (100 mm) as "The worst pain imaginable". Moreover, for the purpose of grasping the grade of disability in daily life due to low back pain, the Roland-Morris Disability Questionnaire for Japanese Patients with Low Back Pain,10 which is a Quality of Life Scale (QOLS) specific to low back pain, and the Pain Disability Assessment Scale (PDAS), 11 which measures grades of

the disability in daily life for patients with severe chronic pain, were used. RDQ is a 24-item (on a scale of 24) questionnaire, PDAS is a 20-item evaluation form (four grade evaluation of 0-3 scores in each item, on a scale of 60). Both of them indicate that the higher the score, the more severe the disability. VAS was recorded before and after the first treatment, before each treatment, and four weeks after the last treatment. RDQ and PDAS were evaluated before the first treatment, at the time of the end of the last treatment, and four weeks after the last treatment. At the time of the first treatment, we asked the subjects about the feeling when inserting the needle and the presence of pain when cutting the skin, taking the possibility that needle insertion influences the curative effect. One practitioner in acupuncture and moxibustion who did not know the details of the experiment evaluated in the clinic. The diagram of this study is shown in Fig. 1.

4. Statistical analysis

All the results are indicated as mean value ± standard deviation (mean ± S.D.).

Baseline data (age, disease duration, presence of leg symptoms, and initial scores of VAS, RDQ, and PDAS) before treatment, comparison between groups on the number of the needle used by each group, and within-group comparison of VAS scores observed before and after the first treatment in each group were analyzed by t-test, and for male-female ratio, presence of leg pain, needle insertion feeling, and skin cutting pain, P value was obtained using Fisher's exact test. Repeated-measure analysis of variance (ANOVA) was used for the pattern of change over time of each group, and its difference. Further, a t-test with the Bonferroni correction for amount of change (observed value before the first treatment - observed value at the time of each evaluation) was used for within-group comparison on effects immediately after treatment, effects from continuous treatment, and sustained effects after treatment regarding each evaluation item. StatView 4.5 (SAS Institute, Japan) was used for all the statistical analyses. The significance level was set at $P < 0.05$.

III. Results

For the purpose of checking the validity of this study, we performed a comparison between two groups with the baseline data before treatment. There were no signif-

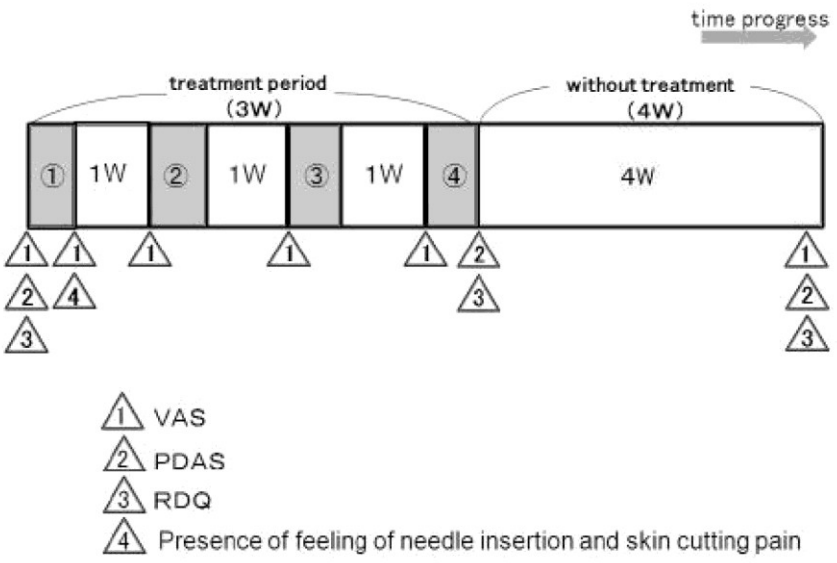

Figure 1. The diagram of this study

VAS, RDQ,and PDAS were evaluated before and after the first treatment, before each treatment, at the time of the end of the last treatment and four weeks after the last treatment.

①～④ indicate the points when acupuncture was performed. ⚠～⚠ indicate the points when each evaluation was carried

icant differences in age, male-female ratio, decease duration, presence of leg symptoms, or the initial scores of VAS, RDQ, and PDAS between two groups. The number of patients by disease was 22 for degenerative lumbar spine disease, 4 for lumbar spinal stenosis, 5 for degenerative lumbar spondylolisthesis, and 1 for lumbar disc disease (Table 1). Neither group showed that the treatment resulted in worsening of symptoms, or having adverse events, and there was no incomplete case during the study period.

1. Number of needles used (Number of acupuncture points)

In this study, although 3-12 subjective pain sites of the patients were determined as the acupuncture points, based on the sites checked at the time of the first treatment, subsequent treatments were performed at almost the same points. The number of needles used in one treatment (number of acupuncture points) was 7.1 ± 2.4 needles for Group A and 6.6 ± 2.3 needles for Group B. There was no significant difference between both groups ($p = 0.4984$).

2. Presence of feeling of needle insertion and skin cutting pain

For the presence of feeling of needle insertion we asked the subjects at the time of the first treatment, 4 subjects answered yes and 12 subjects no in Group A, and 10 subjects yes and 6 subjects no in Group B, which indicated there was no significant difference ($p = 0.0732$). Similarly, about the presence of skin cutting pain, 6 subjects answered yes and 10 subjects no in Group A, and 3 subjects yes and 13 subjects no in Group B, which indicated there was no significant difference ($p = 0.0732$).

3. Effects immediately after treatment (Fig. 2)

For the effects immediately after the treatment, we compared the scores before and after the first treatment since there may be the possibility of including the effect by continuation of treatment for the comparison between before and after the second or later treatments. The observed VAS scores improved from 57.8 ± 17.3 mm before the treatment to 39.6 ± 14.3 mm immediately after the treatment for Group A, and from 58.4 ± 14.0 to 24.3 ± 8.5 for Group B. Both groups showed a significant change (Group A: $p < 0.001$, Group B: $p < 0.0001$).

Table 1. Comparison between two groups with the baseline data before treatment
There were no significant differences between two groups with the baseline data before treatment.

	Group A	Group B
number (sex)	16(male:8,female:8)	16(male:9,female:7)
age (mean±SD)	69.8±11.3	68.8±11.0
Duratiion of low back pain (years、mean±SD)	6.6±6.3	7.4±4.5
Diagnosis	spondylosis deformans 11 degenerative spondylolisthesis 3 spinal canal stenosis 1 lumber discopathy 1	spondylosis deformans 11 spinal canal stenosis 3 degenerative spondylolisthesis 2
VAS(mm、mean±SD)	57.8±17.3	58.4±14.0
RDQ(points、mean±SD)	7.6±3.2	9.4±2.4
PDAS(points、mean±SD)	16.6±8.2	17.3±6.7
presence of leg symptoms	existence:5 nothing:11	existence:6 nothing:10
Other treatment	Compress 11	compress 12 antiphlogistic analgetic 1

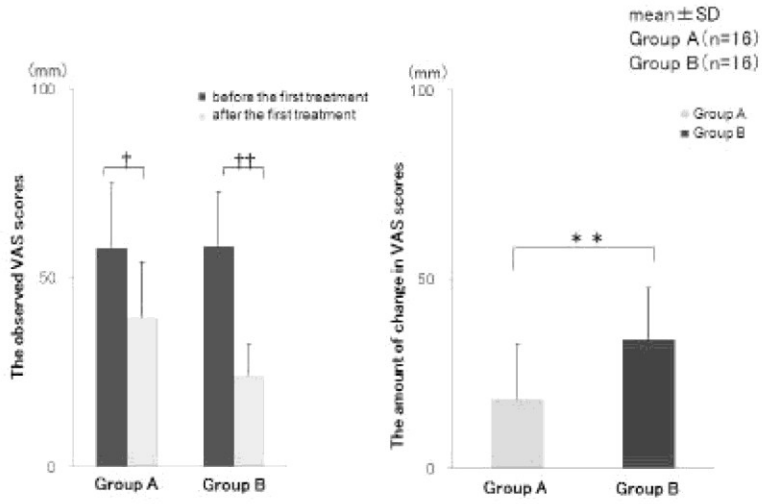

Figure 2. Effects immediately after treatment

Left side shows the observed VAS scores, right side shows the amount of change in VAS scores (scores before the first treatment - scores after the first treatment).

As to the effects immediately after the first treatment, both groups showed a significant improvement in the observed scores of VAS. In the amount of change, a significant difference was found between both groups, and Group B had good results.

＊＊p<0.01　　†p＜0.001　　††p＜0.0001

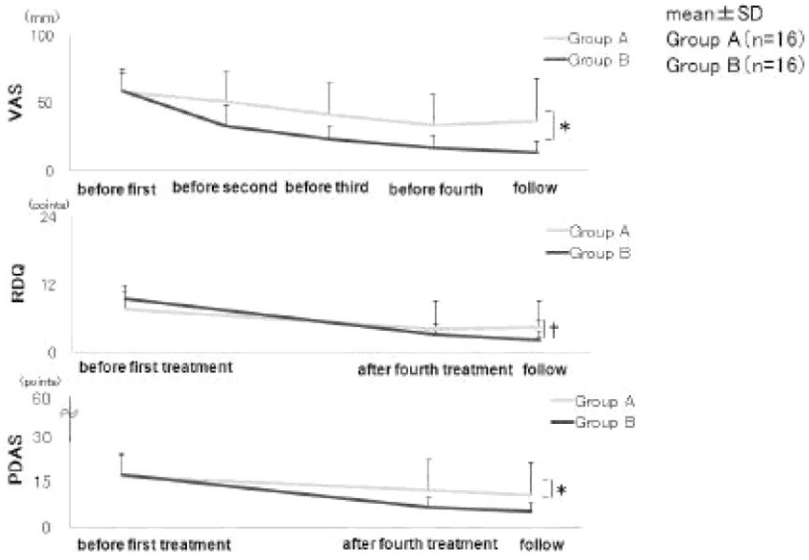

Figure 3. Pattern of change over time by treatment

Both groups showed significant improvement on VAS, RDQ, and PDAS assessment. There was integration between both groups.

＊p<0.05　　†p＜0.001

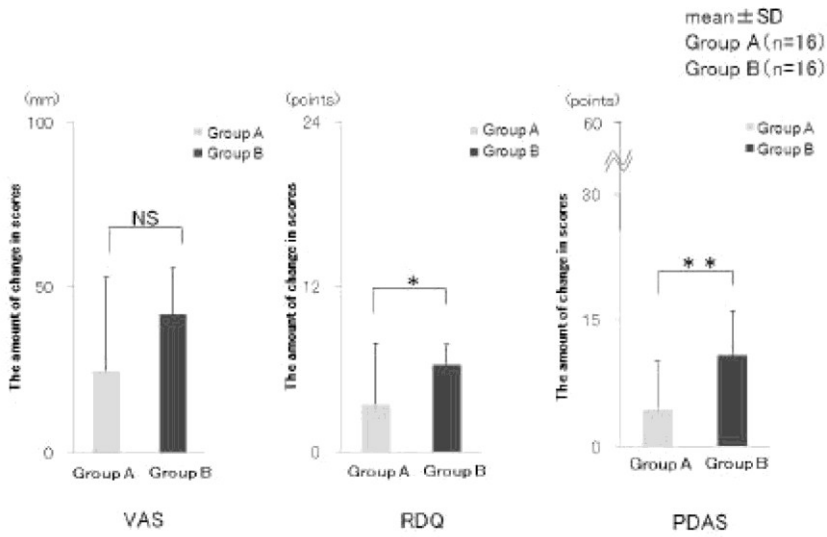

Figure 4. Effects by continuation of treatment
This figure shows the amount of change (scores before first treatment - scores before fourth treatment) in VAS, RDQ and PDAS. Group B showed a significant improvement in RDQ and PDAS.
＊p<0.05　　＊＊p<0.01

The amount of change in VAS scores (scores before the first treatment - scores after the first treatment) were 18.2 ± 14.8 for Group A and 34.2 ± 13.4 for Group B. Group B indicated more significant improvement than Group A ($p < 0.01$).

4. Pattern of change over time by treatment (Fig. 3)

In change over time by treatment, both groups showed significant improvement on VAS, RDQ, and PDAS assessment (VAS: $p < 0.01$ in Group A, $p < 0.0001$ in Group B, RDQ: $p = 0.001$ in Group A, $p < 0.0001$ in Group B, and PDAS: $p < 0.05$ in Group A, $p < 0.0001$ in Group B). There was integration between both groups.

5. Effects by continuation of treatment (Fig. 4)

For the effects by continuation of treatment, we compared the VAS scores before the first and fourth (last) treatments (scores before first treatment - scores before fourth treatment). The results were 24.7 ± 28.7 mm for the superficial insertion group (Group A) and 41.7 ± 14.5 mm for Group B, which did not show a significant difference between the groups ($p = 0.13$). Group B, however, had a better tendency as compared with Group A. For RDQ and PDAS, we compared the amount of change before the first treatment and after the last treatment (scores before the first treatment - scores after the last treatment). RDQ was 3.4 ± 4.4 for Group A, and 6.3 ± 1.5 for Group B. PDAS was 4.4 ± 5.7 for Group A, and 10.8 ± 5.3 for Group B. Group B showed a significant improvement in both evaluations (RDQ: $p < 0.05$, PDAS: $p < 0.01$).

6. Sustained effects after treatment (Fig. 5)

For the sustained effects after treatment, in each evaluation we observed the amount of change before the first treatment and after four weeks of the last treatment (scores before the first treatment scores four weeks after the last treatment). Its VAS was 21.6 ± 33.6 mm for Group A and 45.7 ± 14.2 mm for Group B. Also, RDQ was 3.1 ± 4.1 for Group A, and 12.2 ± 6.1 for Group B. PDAS was 6.0 ± 7.8 for Group A, and 12.2 ± 6.1 for Group B. Group B showed good results in all evaluations (VAS: $p < 0.05$, RDQ: $p < 0.01$, PDAS: $p < 0.05$).

IV. Discussion

Although modern medical diagnosis and treatment of low back pain have remarkably progressed, there are some cases where the treatment cannot be applied, or sufficient effects cannot be obtained[12]. From the above

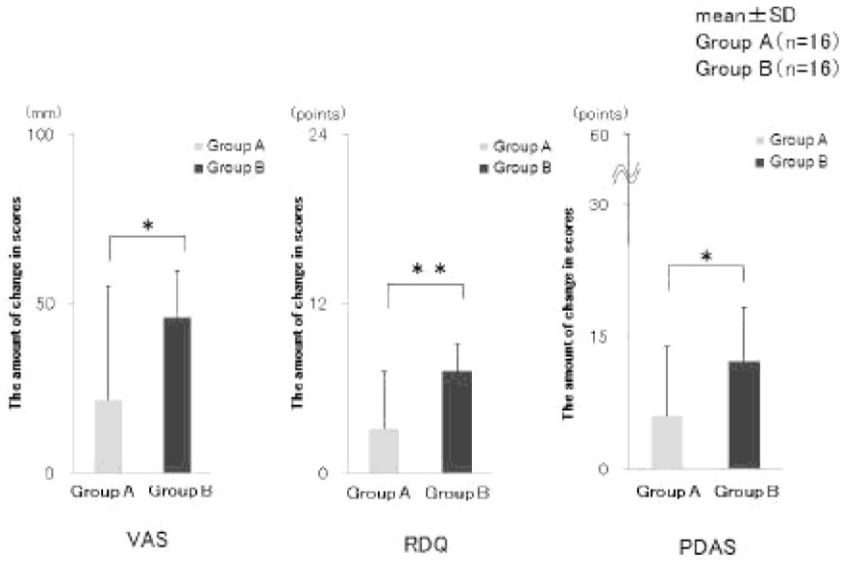

Figure 5. Sustained effects after treatment
This figure shows the amount of change (scores before the first treatment - scores four weeks after the last treatment) in VAS, RDQ and PDAS. Group B showed good results in all evaluations.
＊p<0.05　＊＊p<0.01

and economical aspects, alternative medicine has attracted attention in recent years. Among the alternative medicine treatments, acupuncture is one of the typical cures tried for low back pain[13]. However, there are many opinions regarding procedures and techniques of acupuncture to treat low back pain. As it stands now, we do not have a fixed view about insertion depth of the needle. In order to affirm the position of acupuncture as a useful cure for low back pain, it may be important to establish more effective procedures and techniques. Thus, this study examined insertion depth of the needle for the purpose of searching for more effective acupuncture for low back pain patients.

In comparison between the two groups regarding the baseline data of the patients or subjects before treatment (age, disease duration, presence of leg symptoms, and initial scores of each evaluation), there was not a significant difference between the groups. From the results, it was suggested that there was no particular problem.

As to the effects immediately after the first treatment, both groups showed a significant improvement in the observed scores of VAS. In the amount of change, a significant difference was found between both groups, and Group B had good results.

For the pattern of change over time by treatment of both groups, although the groups showed a significant improvement in each evaluation of VAS, RDQ, and PDAS, there was interaction between them, and Group B showed more significant improvement judging from the graphical tendency. Further, about the contents of change over time of each evaluation, we divided them into cumulative effects by continuation of treatment. Regarding cumulative effects due to continuation of treatment, within-group comparison on the amount of change was made before the first treatment and the fourth (last) treatment for VAS, and before the first treatment and at the time of completing the last treatment. As to VAS, although there was no significant difference between the groups for RDQ and RDAS, there was a significant difference between the groups with good results in Group B.

For the sustained effects after treatment, we compared the groups by the amount of change before treatment and four weeks after treatment for each evaluation of VAS、RDQ, and PDAS. As a result, Group B indicated significant good results in all of the evaluations.

In this study, Group B indicated better results than Group A on the effects immediately after the first treatment, effects from continuous treatment and sustained

effects after treatment. From the results, concerning effects immediately after treatment, and cumulative effects and sustained effects of treatment for low back pain, it is supposed that a higher effect was obtained by inserting the needle to depths to some extent as compared with superficial insertion to the depth to the level of skin cut.

There appeared to be a difference in two acupuncture treatments with different insertion depth of the needle. When considering the reason in terms of the insertion depth of the needle set in this study, the subjects in Group A were stimulated only to the skin, while on the other hand, Group B subjects were stimulated not only to the skin, subcutaneous tissue and subcutaneous fat, but also to deep tissue such as fascia and muscle layers. It can be inferred that the difference in tissue which receives such stimulation was influenced differently to the control effect of a pain. For the presence of needle insertion feeling and skin cutting pain, there was no significant difference between both groups, and there might be a low possibility that subjective factors influenced the treatment effects. There are reports on the influence that the difference in insertion depth had on acupuncture effects. Chiang et al. reported that there is a high possibility that afferent nerve impulses from acupuncture stimulation are mainly transferred and transmitted via nerves in deep tissue since the effect of acupuncture painkilling in the nerve block region disappeared by blocking afferent nerve in deep tissue, while the effects of acupuncture were not inhibited due to blocking the afferent nerve which governs the skin surface.14 Ceccherelli et al. examined the effects from acupuncture stimulation by deep insertion of the needle using an angioneurotic edema induced model[15]. They reported that deep acupuncture to angioneurotic edema was more effective for mitigating the edema, and suggested the importance of stimulating the muscle at the affected side in signal transfer of acupuncture, as well as the afferent nerves in deep tissues involved. In this study, the reason for which deep stimulation insertion was more effective than superficial insertion, may be the possibility of a similar mechanism as that in the report. In addition, there were reports indicating acupuncture stimulation to muscles raises the pain threshold of the muscle,16 and increases muscle blood flow[17]. Moreover, there was a report that pain and muscle strain have a close relationship[18]. At sites where muscle pain myalgia exists, pain producing substances are produced, and accumulate and receive, transmit and transfer pain. When this state is sustained, C fibers are excited more, which results in excitement of the motor portion of the nervous system and leads to lower muscle tissue circulation and piles up pain producing substances by increased muscle pain. This state is called the "vicious circle of pain" which may be expected to fall into chronic pain conditions[19]. It is important to relieve pain to control this "vicious circle of pain". As mentioned above, needle stimulation to deep tissues may cause an increase in the pain threshold value[16] and influence muscle blood flow[17]. It is inferred that there was a possibility that this behaved in an inhibiting manner, for muscle over strain appeared by the "vicious circle of pain".

From the study results, even when inserting the needle to the same site, treatment effects differed by insertion depth, so that it may more effective to insert the needle to a certain depth where there is a muscle. It, however, remains a matter of speculation on the difference of the pain control mechanism by difference of insertion depth. Also, this study has not clarified the difference in the results by types of low back disorders. Further, some past studies reported that the difference between superficial insertion and deep insertion techniques did not influence treatment effects or superficial insertion showed better results[6,9]. Accordingly, as subjects further to be studied, it should be performed with comparison tests similar to this study, for low back pain with a clearer cause, and basic research on the control mechanism by acupuncture stimulation for pain supposing various low back disorders.

V. Conclusion

For the purpose of searching for more effective acupuncture, we have examined acupuncture treatment of different insertion stimulation to the subjective pain sites for 32 patients with low back pain.

In this study, Group B indicated good results in the effects immediately after treatment, effects from continuous treatment, and sustained effects after treatment. Thus, it is suggested that it would be more efficient to insert the needle to deep tissues when doing acupuncture treatment to subjective pain sites frequently used in acupuncture treatment.

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