The Effects of Press Tack Needle Treatment on Upper Back Muscle Stiffness -Comparative Study Using Sham Needle-

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Abstract

[Purpose] A controlled Clinical Trial (CCT) was conducted using the Press Tack Needle (PTN) as the control for studying the effects of the PTN on upper back muscle stiffness.

[Subjects and Method] The subjects were male and female volunteers (total 53) who had experienced upper back muscle stiffness. The areas treated with the PTN or sham were tender points in the posterior cervical region, the upper back region, and the interscapular region. The needles were continuously indwelt for three days. An evaluation was performed on the awareness of upper back muscle stiffness 3 days after treatment, utilizing the VAS values for the degree of upper back muscle stiffness before treatment, immediately after treatment, and 3 days after treatment.

[Results] The number of subjects reporting the "existence of upper back shoulder stiffness" decreased to 12 of 28 persons in the PTN group, and to 23 of 25 in the sham group, with a significant difference between the 2 groups (p<0.01).

Regarding VAS values for upper back muscle stiffness, the sham group demonstrated 55.2 ± 17.5 mm before treatment, 46.5 ± 19.7 mm immediately after treatment, and 45.9 ± 21.7 mm 3 days after treatment, and the PTN group demonstrated 52.5 ± 20.7 mm before treatment, 40.5 ± 22.4 immediately after treatment, and 34.2 ± 19.7 mm 3 days after treatment. The PTN group showed a decrease immediately after treatment (p<0.05) and 3 days after treatment (p<0.01).

[Conclusion] It was suggested that the continuous indwelling of the PTN improves upper back muscle stiffness.

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Key words: upper back muscle stiffness, acupuncture, Press Tack Needle, sham, CCT

I . Introduction

Acupuncture-and-moxibustion treatment is one of the treatment methods widely used for upper back muscle stiffness, along with warm or cold therapy, phototherapy, electrotherapy, and massage therapy. These therapies are widely used in daily life despite the few large scale randomized controlled trials. This is thought to be because a certain sensitization can be expected and also because there are few complications.
associated with these therapies, so they can continued for a long period\(^2\). Although the Press Tack Needle (PTN) is frequently used with the objective of prolonging the duration of response to general acupuncture and moxibustion treatment and for alleviation of chronic symptoms, such as upper back muscle stiffness, there are still few reports verifying the efficacy of PTN treatment, performed independently of regular (non-patch style) needling in clinical trials.

Since treatment using PTNs is comparatively simple and it can be easily performed without sophisticated technology, it certainly has potential as a self-care tool. If the efficacy of press tack needling can be proved on a scientific basis, this treatment system may also contribute to the marketing development of acupuncture and moxibustion therapy.

This study was conducted in order to verify the treatment effects of the PTN, using volunteers who suffered upper back muscle stiffness, by comparing the changes in subjective symptoms before and after treatment with PTN or sham, so that the clinical merit of PTN treatment could be assessed.

II. Methods

1. Informed consent

The trial was conducted by obtaining signatures of consent after having orally explained the meaning of the study and the possibility of the occurrence of adverse events associated with participation in the study. The main points of this study are: (1) there haven't been any reports that have examined the effects of a single treatment using PTNs for upper back muscle stiffness; (2) the goal of this study is to grasp the changes in upper back muscle stiffness by leaving a needle of 0.6 mm in length continuously indwelled on the surface of the stiff muscle for 3 days; (3) In this clinical trial, the treatment effects are compared by randomly assigning the patients complaining of upper back muscle stiffness to either a sham group or a PTN group; (4) there is a possibility that subjects may be assigned to a sham group, and; (5) this clinical trial will be an important reference, which scientifically bears out the clinical effects of acupuncture treatment.

2. Subjects

There were a total of 53 male and female subjects, who were described as "having upper back muscle stiffness" and who were experiencing (III) dysphoria, according to the Questionnaire on Subjective Symptoms of Fatigue\(^3\) by the Working Group for Occupational Fatigue, Japan Society for Occupational Health, out of 56 staff members and students in our college with subjective upper back muscle stiffness who were recruited as volunteers. Furthermore, the target of this trial was "upper back muscle stiffness" presenting with chronic subjective symptoms, while excluding temporary upper back muscle stiffness, such as acute muscle pain or delayed onset muscle soreness caused by exercise or work activity. As a matter of course, subjects were asked to refrain from receiving acupuncture and moxibustion treatment, massage, applying poultices, and taking drugs for the treatment of upper back muscle stiffness during the trial period.

3. Study Procedures and Method of Allocation

(1) Screening and allocation of subjective upper back muscle stiffness

The Questionnaire on Subjective Symptoms of Fatigue was used prior to starting the trial, on the actual day of the trial, in order to screen subjects being recruited as volunteers for the existence of upper back stiffness. The coordinator carried out the informed consent related procedures for the subjects who became trial candidates, and after that allocation was performed by dividing the candidates into 2 groups, the sham group and the PTN group. This was conducted according to the cast draw method by the subject him/herself, a method by which the subject does not know his/her own assignment. The coordinator prepared the shams and PTNs, which could not be differentiated before the start of the trial by package appearance, and once the allocation was completed one or the other of these packages was handed to the subject according to the results of the assignment.

(2) Evaluation, cervicobrachial manual test, and implementation of treatment procedures

The subject went to a practitioner that used PTN treatment in order to determine the area to be treated. The practitioner conducted an inquiry and a manual test on the cervicobrachial areas, and then detected specific pressure sensitive areas on the subject by palpating the posterior aspect of the cervical region, the upper part of the back, and the interscapular area. At this point, the subject wrote down "the level of the upper back muscle stiffness experienced before the treatment" on a VAS (visual analog scale). The practitioner then performed
treatment by applying shams or PTNs on the subject, depending on what s/he had been assigned and then the subject marked the "the level of upper back muscle stiffness experienced immediately after treatment" on the VAS.

The subject visited the clinic again after the continuous application of indwelled sham(s) or the PTN(s) for three days, and filled out the Questionnaire on Subjective Symptoms of Fatigue by his/herself.

The sham or the PTN were then removed by a different practitioner than the one who had inserted the needle, and the subject immediately marked "the level of upper back muscle stiffness after 3 days" on the VAS.

(3) Confirmation and ways of handling the generation of adverse events

1) Response at the time of treatment

The coordinator indicated that the PTN should be withdrawn immediately if pain were experienced from the skin puncture or if discomfort occurred and that the subject should report the circumstances associated with the pain caused by the skin puncture or the discomfort felt immediately after the skin puncture.

2) Response under continuous indwelling

When adverse events, such as discomfort, pain, or itchiness were generated during the continuous indwelling of the sham or the PTN, the subject was instructed to contact the coordinator promptly about the situation. We decided that, as a general rule, when an adverse event occurred, the subject would visit our clinic to have the sham or PTN removed and thereafter the subject's progress would be observed.


The manual tests for cervicobrachial pain are performed in the orthopedics field, and are used for the screening of thoracic outlet syndrome. In this study, the Jackson Test, Spurling Test, biceps brachii muscle tendon reflex, brachioradial muscle tendon reflex, triceps brachii muscle tendon reflex, and the dysesthesia test were conducted for detecting radiculopathy; the Morrie's Test, Adson's Test, and the Allen Test were conducted for the scalenus syndrome as part of the thoracic outlet syndrome; the Wright Text was conducted for the minor pectoralis muscle syndrome; and the Eden Test was performed for the costoclavicular syndrome.

5. Intervention

The PTN used was a Pyonex acupuncture needle, 0.6 mm in length and 0.2 mm in diameter, made by Seirin Co., Ltd. The sham was created by taking the same type of needle as the PTN and removing the tip during the manufacturing process so it would cause tactile pressure stimulation, without puncturing the body. These PTNs were packed individually and provided by the above-mentioned company in such a way that the PTNs and the shams were indistinguishable.

The treatment points consisted of less than four marked parts of induration in the posterior cervical region, upper back region, and interscapular region detected by the practitioner during palpation, and were not limited to Meridian Points. Treatment using either the PTNs or the shams was performed in the sitting position.

The trial period was scheduled from October 10 to November 27, 2000 and the subjects participated for 3 continuous days.

The practitioners in charge consisted of five full-time instructors, who worked in the school affiliated acupuncture clinic, and seven acupuncture and moxibustion clinical training students. The coordinator and the practitioners had no contact with each other; and moreover, the practitioners applied the PTNs that the subjects had brought in without knowing whether they were shams or PTNs.

6. Endpoints

The VAS values for: before practice, immediately after practice, and 3 days later, and the III group "having upper back muscle stiffness" on the Questionnaire for Subjective Symptoms of Fatigue before the treatment, and the values for 3 days after practice were used for evaluating the effects of treatment for upper back muscle stiffness. The VAS method utilized a 100 mm length black line, on which the current degree of upper back muscle stiffness was marked on a continuum extending from the left end which represented "no upper back muscle stiffness" and the right end that represented "the strongest upper back muscle stiffness in one's life".

In the processing of the VAS value, the measured distance from the left end to the marked point was expressed numerically in 1 mm units. Therefore, as the VAS values would become larger, the stronger the upper back muscle stiffness would be.
7. Statistical Work
The test of significance was conducted on the sham group and the PTN as follows: (1) t-test for the height, weight, and period of continuation of the upper back muscle stiffness from the subject's background, and (2) \( \chi^2 \) test for comparing the change before practice and 3 days after among the subjects "having upper back muscle stiffness" in (III) dysphorias(4). The two-way ANOVA was used to evaluate successive change of the VAS values for the "before treatment", "immediately after treatment", and "3 days after" periods; the difference was evaluated using (Fisher's PLSD test); and a multiple comparison and determination of the statistically significant difference was evaluated with a significance level of 5%.

III. Results
1. Subject's Progress and Follow-up
The subject's progress and follow-up are shown in Fig. 1 by the trial flow chart. Although there were 56 people who applied for this trial and from whom consent was obtained in writing, 3 of these people were excluded because they were deemed inappropriate as trial subjects due to the fact that they did not fall under the category of "having upper back muscle stiffness" in the Questionnaire on Subjective Symptoms of Fatigue performed on the trial day.
A random allocation of 53 trial subjects was conducted by assigning subjects to the sham group (n=25) or to the PTN group (n=28). Since no one dropped out during the three days of the intervention, all subjects in each of the groups were used as analysis subjects at the completion of the trial.

2. Subject Backgrounds
(1) Background factors
The subjects in the sham group included: 7 males and 18 females who were 31.8 ± 9.0 years old (mean ± S.D., hereinafter described as same); 161.0±6.9 cm in height; and 57.1 ± 10.4 kg in weight. The subjects in the PTN group included: 8 males and 20 females who were 35.1 ± 11.9 years old; 162.0 ± 9.5 cm in height; and 57.4 ± 11.3 kg in weight. The duration of upper back muscle stiffness was: 7.7 ± 5.3 years for the sham group and 9.7 ± 7.8 years for the PTN group. In addition, a significant difference was not recognized between these groups.
Two out of twenty-five in the sham group had been diagnosed in a medical institution as having cervicobrachial syndrome or cervical spondylosis. When the manual tests were performed, 6 out of 25 subjects, including the 2 who had been diagnosed, were recognized to have at least one positive finding. Three out of twenty-eight subjects in the PTN group had been diag-
nosed in a medical institute, each with a diagnosis of cervical spondylosis, upper back muscle stiffness, or muscle pain, respectively. When the manual tests for cervicobrachial pain were performed, nine out of twenty-eight subjects were recognized to have at least one positive finding; however, the positive findings found in the manual test were not found in the subjects who had been diagnosed with upper back muscle stiffness or muscle pain (Table 1).

(2) Number of PTNs or a shams used

The number of PTN insertions was 3.50 per person on the average, and the number of sham insertions was 3.96 per person on the average.

(3) Conditions for generation of skin puncture pain and the discomfort derived from the skin immediately after puncture

The skin puncture pain and the discomfort generated immediately after skin puncture were studied in the sham group and the PTN group.

Skin puncture pain and generation of discomfort were not recognized in either of the groups.

(4) Site of tender point origin

The tender points in the posterior cervical region, the upper back region, and the interscapular region of the subject were detected by practitioner palpation. 99 sites were detected in the sham group, including 5 sites in the posterior cervical region, 66 sites in the upper back region, and 28 sites in the interscapular region. 98 sites were detected in the PTN group, including 1 site in the posterior cervical region, 73 sites in the upper back region, and 24 sites in the interscapular region.

3. Changes in "having upper back muscle stiffness"

The existence of upper back muscle stiffness was studied, after three days, in the sham group and the PTN group, which was determined as "existing upper back muscle stiffness" according to the Questionnaire on Subjective Symptoms of Fatigue performed before treatment.

The number of subjects who complained of upper back muscle stiffness in three days after treatment was 12 out of 28 subjects in the PTN group in contrast to 23 out of 25 subjects in the sham group. Awareness of upper back muscle stiffness decreased by continual indwelling of the PTNs, and this was significant at less than 1% of percentage of risk (Fig. 2).

4. Effects of the PTN in upper back muscle stiffness

(1) Total calculation using VAS values

The degree of upper back muscle stiffness was expressed by the VAS value, and the successive change for each group was compared. The VAS values of the sham group (n= 25) were 55.2 ± 17.5 mm before treatment, 46.5 ± 19.7 mm immediately after treatment, and 45.9 ± 21.7 mm 3 days after treatment. The PTN group (n= 28) demonstrated 52.5 ± 20.7 mm before treatment, 40.5 ± 22.4 mm immediately after treatment, and 34.2 ± 19.7 mm within 3 days after treatment. A significant change was not recognized in the values for the sham group for immediately after treatment and 3 days after treatment when compared with the values before treatment. The VAS values of the PTN group demonstrated a decrease compared to the values of immediately after treatment.

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(p< 0.05) and the values three days after treatment (p< 0.01) in the PTN group and the sham group (Fig. 3).

(2) Calculation with VAS values -Positive findings exist in the manual test-

The degree of upper back muscle stiffness in subjects recognized to have positive findings by the conduction of manual testing for the cervicobrachial region was expressed with a VAS value as a comparison. The VAS values of the sham group (n= 6) were 56.8 ± 7.1 mm before treatment, 40.7 ± 21.7 mm immediately after treatment, and 43.8 ± 13.6 mm 3 days after the treatment. The VAS values of the PTN group (n= 9) demonstrated 55.6 ± 23.8 mm before treatment, 43.7 ± 26.6 mm immediately after treatment, and 37.4 ± 20.6 mm 3 days after the treatment. There wasn't a recognized significant difference in the VAS values of either group immediately after treatment and the values 3 days after treatment (Fig. 4 a).

(3) Calculation with VAS values -Positive findings did not exist in the manual test-

The degree of upper back muscle stiffness in subjects whom positive findings had not been recognized in the conducting of manual testing for the cervicobrachial region was expressed with VAS values as a comparison. The VAS values of the sham group (n= 19) were 54.6 ± 20. mm before treatment, 48.4 ± 19.3 mm immediately after treatment, and 46.6 ± 23.9 mm within 3 days after treatment. The VAS values of the PTN group (n= 19)
demonstrated 51.5 ± 19.6 mm before treatment, 39.1 ± 20.8 mm immediately after treatment, and became 32.7 ± 19.6 mm 3 days after treatment. A significant change was not recognized in the values for the sham group immediately after treatment and 3 days after treatment.

The VAS values of the PTN group demonstrated a decrease at 3 days after treatment compared to the values before treatment of the PTN group and the sham group (p<0.01) (Fig. 4 b).

5. Generating Circumstances of adverse events

Pain derived from skin puncture during PTN treatment or discomfort generated immediately after needle insertion was not recognized. There weren't any examples of re-insertion of PTNs. When the PTNs or shams were continuously indwelt for 3 days, some adverse events
occurred: in the sham group, itchiness occurred in 3 subjects, and discomfort in 1 subject; in the PTN group: itchiness occurred in 4 subjects and "annoyance resulting from keeping the needles inserted" occurred in 1 subject. Among these symptoms, "annoyance resulting from keeping the needles inserted" disappeared immediately after removing the needles, and other symptoms naturally disappeared in a few days. Moreover, there weren't any subjects who removed the PTNs due to generation of adverse events during the three-day trial period of continuous indwelling.

IV. Considerations

1. Appropriateness of this trial using the sham

In this study design, the sham group, which applies a non-invasive sham needle, was provided as the control group because it is recommended that a method using a non-invasive sham needling group as the control group, or a single blind method, which considers only the influence on the subjects, be set up. Since the idea of a placebo is to "have a psychological influence and to not have a therapeutic effect", apparent differences that may influence the effects must be avoided. In addition, it cannot be overemphasized that the manifestation of pain at the time of skin puncture with the PTN influences whether a sham can become a placebo or not. Therefore, in this survey, the shape of the sham and the PTN and the respective packaging were prepared to be strictly identical in the manufacturing process, so that only the insertion of the needle insertion into the body would be different. In addition, since the needle insertion method for the PTN is a simple method in which the entire stick-er with the needle is applied to the target area, and the needle aspect of the PTN is only 0.6 mm in length and 0.2 mm in diameter, it was considered hard for a difference in needle insertion technique to be produced among the practitioners in charge of performing the needle insertion. However, since the existence of the pain derived from skin puncture at the time of treatment was not checked, and all the subjects were assigned to either the sham or the PTN group, the existence of the psychological influence cannot be denied.

The subjects in this study were a group that did not have any uneasiness about acupuncture treatment at all, and in the preceding study, it was confirmed that selecting subjects who were familiar with the effects of acupuncture was one of the methods for removing the psychological tension associated with the practice of acupuncture itself in order to verify the effect of acupuncture treatment. Nevertheless, in order to handle the bias as a trial control group, it is necessary to take into consideration and study the condition setting according to the study purpose.

2. Occurrence Factors of Upper Back Muscle Stiffness and the Improvement Effects associated with the PTN

Although Ishida based upper back stiffness on the assumption of a subjective feeling of stiffness and reported that it could be objectively confirmed as "extraordinary tonus of muscle, pleasant feeling upon pressure, and lumpiness" in the upper back muscle, Sasaki described that these two do not necessarily go together, and that in addition to physical factors, psychological and social factors are intricately intertwined in the occurrence of upper back muscle stiffness. Furthermore, since there are many people who chronically feel upper back muscle stiffness, it is also important to find the factors that may relate to this occurrence in the individual's living conditions.

An extensive investigation was conducted on the relationship between the occurrence of upper back muscle stiffness and fatigue, and complaints about feelings of fatigue accompanied with work progress were analyti-ally tracked. Studying the level of the feeling of fatigue accompanied with acute fatigue or subacute fatigue has important meaning. The group III of "localized dysphoria" in the Questionnaire on Subjective Sym-toms of Fatigue used in this study expresses a projection of the fatigue to a body part, and it is believed that the occurrence of upper back muscle stiffness is a stress reaction, which means that there are problems in the autonomic nervous system that are caused by depression of the brain-stem reticular activating system and a dys-function in the cerebral limbic system and hypothala-mus.

The effect on the autonomic nerve by acupuncture treatment was studied using the heart rate. Stimulation on the skin/subcutaneous tissue evokes the reaction of the parasympathetic nervous system as the efferent nerve, and it is advocated that three factors of shallow needle insertion, needle insertion during exhalation, and the treatment in sitting position are used in order to evoke this reaction effectively. The PTN treatment of this study includes the two above-mentioned factors because the
inserted depth of the PTN used for this study is shallow due to its 0.6 mm needle length, and consequently, the stimulation is to the skin or subcutaneous tissue, and is performed in the sitting position. Therefore, it is believed that the function of the parasympathetic nervous system was continuously excited immediately after treatment with the PTN, and as a result, this effectively acted to improve the upper back muscle stiffness derived from the stress reaction.

Furthermore, it is considered that a single treatment with the PTN has a self-care aspect in the prevention of fatigue and the acceleration of recovery from fatigue because the treatment can be performed in a comparatively easy manner. Accordingly, the possibility of composing a new avenue for the PTN as one of the acupuncture and moxibustion treatment methods for health enhancement, which correlates in Oriental medicine with traditional treatment with the PTN, and as a result, this effectively acted to improve the upper back muscle stiffness derived from the stress reaction.

On the other hand, there is a possibility that the occurrence of upper back muscle stiffness may originate in cervicobrachial impairment. The existence of such a diagnosis was checked by inquiry and also a manual test for cervicobrachial disorder was performed. The subjects included those who had been diagnosed with cervical spondylosis or cervicobrachial syndrome, or suspected thoracic outlet syndrome according to manual testing performed by the practitioner, or those who had not undergone a diagnosis for such. Although we could not clarify the effects on subjects who had been recognized or suspected to have thoracic outlet syndromes because of the few number of subjects, it is believed that the importance of finding the cause of occurrence of upper back muscle stiffness in order to select the practice method and the stimulus method has become re-clarified.

It is necessary to conduct further studies on determining the method of attaching the PTN and the selection of sealing materials and adhesives are subjects that must be studied in the future. In addition, the sensitivity of the subject should be taken into consideration when determining the length of needle for treatment of upper back muscle stiffness originating from cervicobrachial disorders.

3. Selection of Tender points

It is believed that the tender point is an area where the pain threshold is low and the pain receptor for that area elicits hyperalgesia by sensitization. Although Kawakita reported that the origin of the tender point has not been sufficiently studied yet, he suggested that the decrease in local blood flow and the hypoxic condition due to poor posture forces long time muscle contraction, which triggers the destruction of the cell membrane and injury to the muscle by the production of various active enzymes, and the polymodal receptor is sensitized or results in neurogenic inflammation, which is generated as a result. Consequently, he suggested the possibility that this may cause a localized dot shape, which is the low pain threshold area, in other words, it is the tender point.

In this study, the muscle branches of the 3rd and 4th cervical nerves were distributed on the muscle where tender points accompanied by upper back muscle stiffness were recognized. Moreover, the supraclavicular nerves, which are the cutaneous branches of the above-mentioned nerves, innervate the region of the skin in the proximity of the upper back, which covers these muscles. Therefore, since the PTN treatment on the tactile tender point can be stimulation on the skin, which is innervated by the same nerve as the muscle where the upper back muscle stiffness has occurred, it is thought that the upper back muscle stiffness improved by the change in pain threshold through the receptor of the skin sensory nerve.

4. Response to Adverse Events

When the practitioner in charge was to report the circumstances surrounding the generation of discomfort experienced immediately after needle insertion or upon needle tip insertion, there weren't any reports on the generation of discomfort immediately after skin puncture or pain derived from skin puncture of the needle tip, and there weren't any reports on re-insertion of the PTN.

When the inserted PTN had been indwelled for 3 days, itchiness was the most frequent of adverse events. This phenomenon occurred despite whether the treatment was conducted among the sham group or the PTN group, such that itchiness can be said to be a disadvantage of using the PTN, which is generally left indwelled continuously. The method of attaching the PTN and the selection of sealing materials and adhesives are subjects that must be studied in the future. In addition, the sensitivity of the subject should be taken into consideration when determining the length of needle for treatment of upper back muscle stiffness, because there were subjects who felt discomfort or uneasiness upon needle insertion.

V. Conclusion

The following results were obtained in the comparative study about the short term effects of the PTN treat-
ment with the objective of improving upper back muscle stiffness.

1. Consciousness of the "existence of upper back muscle stiffness" decreased in three days after the PTN treatment (p< 0.01).

2. The VAS values of the subjects who have upper back muscle stiffness (total calculation) decreased immediately after the PTN treatment (p< 0.05) and in three days after the treatment (p< 0.01).

3. The VAS values of the subjects who didn't have positive findings during manual testing, even though they experienced upper back muscle stiffness, decreased in 3 days after the treatment (p< 0.05).

4. The fact that PTN treatment resulted in remarkable improvement in upper back muscle stiffness, suggested that PTN treatment may cause recovery from fatigue at an early stage, and has the possibility of contributing to the maintenance and improvement of health as one of the self-care treatment methods.

References


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