

A Comparative Study on the Effect of PTN on Improving Upper Back Muscle Stiffness

YAMAGUCHI Shogo

Tokyo Therapeutic Institute

ABSTRACT

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 it was reported that the origin of the tender point has not been sufficiently studied. 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 abovementioned 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.

KEYWORDS

Upper back muscle stiffness; Acupuncture; Press tack needle; Sham; CCT.

1. Introduction

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.

2. Methods

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.

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 Fatigue³) 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.

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.

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.

Confirmation and ways of handling the generation of adverse events:

2.1 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.

2.2 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.

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 abovementioned 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.

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.

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) χ^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%.

3. Results

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.

3.1 Background Factors

The subjects in the sham group included: 7 males and 18 females who were 31.8 ± 9.0 years old (mean \pm 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 diagnosed 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).

3.2 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.

3.3 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.

3.4 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.

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).

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.

4. Considerations

4.1 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 group⁴), or a single blind method⁵), 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 into the body would be different. In addition, since the needle insertion method for the PTN is a simple method in which the entire sticker 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 study⁶), 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.

4.2 Occurrence Factors of Upper Back Muscle Stiffness and the Improvement Effects Associated with the PTN

Although Ishida⁷⁾ 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, Sasaki⁸⁾ 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 investigation³⁾ 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 analytically tracked. Studying the level of the feeling of fatigue accompanied with acute fatigue or subacute fatigue has important meaning⁹⁾. The group III of “localized dysphoria” in the Questionnaire on Subjective Symptoms 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 dysfunction in the cerebral limbic system and hypothalamus¹⁰⁾.

The effect¹¹⁾ 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 so-called “treatment before the onset of disease”, has been suggested.

On the other hand, there is a possibility that the occurrence of upper back muscle stiffness may originate in cervicobrachial impairment¹²⁾. 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 treatment method for treating upper back muscle stiffness originating from cervicobrachial disorders.

4.3 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.

5. Conclusion

The following results were obtained in the comparative study about the short term effects of the PTN treatment 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.

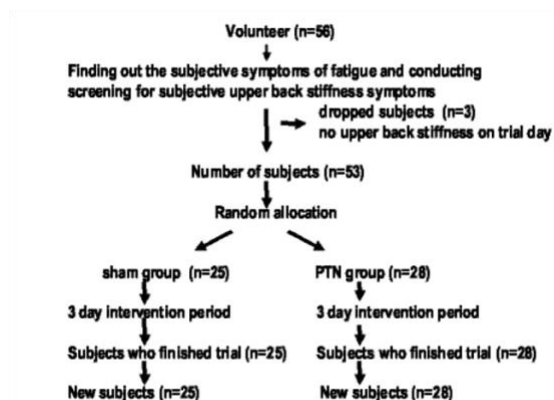


Figure 1 Flow Diagram illustrating the flow and follow-up of subjects in the clinical trial

Table 1 Background of Subjects

		sham	PTN	Unit
No. of Dialysis patients		25	28	case
Gender	Male	7	8	case
	Female	18	20	case
Height		161.0 ± 6.9	162.0 ± 6.5	cm
Weight		57.1 ± 10.4	57.4 ± 11.3	kg
Period of Continual Upper Back Stiffness		7.7 ± 5.3	9.7 ± 7.8	years
Acupuncture Treatment Experience	Yes	25	28	case
	No	0	0	case
Diagnosis	Yes	2	3	case
	No	23	23	case
Positive Findings upon Manual Examination	Yes	6	9	case
	No	19	19	case

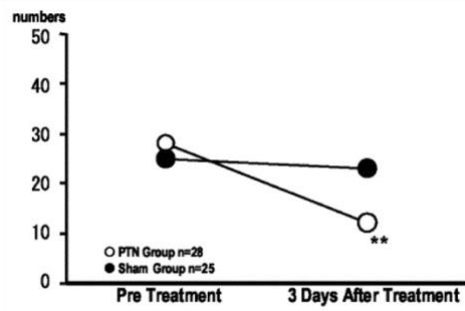


Figure 2 Changes in "existing upper back muscle stiffness"

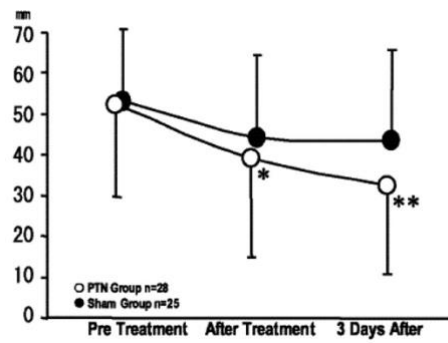


Figure 3 Effects of the PTN for upper back muscle stiffness

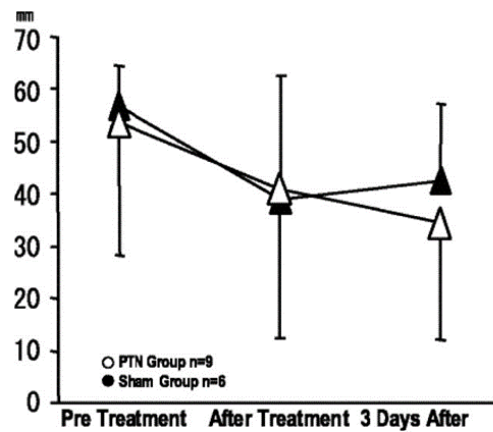


Figure 4a Effects of the PTN for upper back muscle stiffness
-Positive findings exist in the manual test-

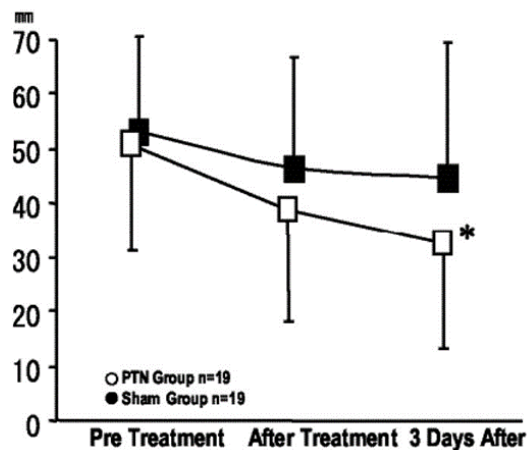


Figure 4b Effects of the PTN for upper back muscle stiffness
-Positive findings did not exist in the manual test-

References

- Kagamimori Sadanobu; Michikazu Sekine, Etsuko Kajita, Isamu Matsubara, Sakae Ohmura. "Demand and Supply of Manipulative Therapies for Musculoskeletal Complaints in Japan." *J Jap Asso Physical Med Balneol Climatol.* 2001, 64(2):103-112.
- Kazutoshi Yokogushi, Hiroshi Narita. "Physical Therapy for Muscle pain, Upper Back Muscle Pain, and Low Back Pain." *Japan Medical Journal.* 2001, 4045:94-5.
- Kazutaka. "Modern People and Fatigue," expanded edition. Kinokuniya Book Store. Tokyo, 1994, pp. 93-137.
- Ernst E. & White A. (translators: Hitoshi Yamashita, Hiroshi Tsukayama). "Evidence based Acupuncture. Western Medical Acupuncture". Ido-no-Nippon Sha, Inc. 2001, pp. 53-94.
- "WHO Regional Office for the Western Pacific Guidelines for Clinical Research on Acupuncture." *Journal of the Japan Society of Acupuncture and Moxibustion.* 1995, 45(2):154-166.
- Yasuhisa Kaneko, Hiroko Nishizuka, Masako Inoue, Michikata Lida, Kazuo Nomoto, et al. "Preventive Effects of PTNs on Muscle Fatigue Caused by Total Body Endurance Training." *The Showa University Journal of Medical Sciences.* 2000, 24:38-44.
- Hajime Ishida. "Upper Back Muscle Pain, Diagnosis and Therapy." 1989, pp. 201-204.
- Kazuro Sasaki. "Study on Upper Back Muscle Pain and Acupuncture and Moxibustion Treatment." Isshi.
- Nishijo, Takao Kumazawa (Supervising Editors), "Science of Clinical Acupuncture and Moxibustion," Tokyo, Ishiyaku Publishers, Inc. 2000, pp. 109-32.
- Yoshio Saito. Survey Methods for Subjective Symptoms of Fatigue and Respective Applications. Survey of Work Load. Labor Science Institute. 1984; 161-73.

- Nomura T, Ohsawa A. "Mental Fatigue." *PT Journal*. 1996, 30(10):721-7.
- Nishijo K, Mori H, Tsukayama H. Yamashita H. "Scientific Approach to Acupuncture." *Journal of the Japan Society of Acupuncture and Moxibustion*. 1995, 45(3):177-191.
- Kazuo Terayama, Teruo Tsuji, "Standard Orthopaedic Surgery Version 7." Tokyo Igaku-Shoin, Ltd. 2000, pp. 388-423.
- Kawakita K., Miura T. "Deep Pain Measurement at Tender Points by Pulse Algometry with Insulated Needle Electrodes." *Pain*. 1991, 44:235-239.
- Kenji Kawakita. "Acupuncture and Moxibustion Stimulation as Noxious Stimuli – Hypothesis of Polymodal Receptor". Isshi Nishijo, Takao.
- Kumazawa (Supervising Editors), "Science of Clinical Acupuncture and Moxibustion." Tokyo: Ishiyaku Publishers, Inc. 2000, pp. 395-408.

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