

Japanese Acupuncture - Current Research

Japanese Traditional Medicine Text (10) – Gynecology

Yoji Shimizu

Department of Acupuncture and Moxibustion

Chuwa Professional Training College of Medical Care

1. Introduction

Here we introduce studies on the effects of acupuncture treatment for gynecological disorders. The main subjects' dysmenorrhea, menstrual cycle abnormalities, infertility, and menopause are subject mainly. We found that most of the studies from abroad were high level, evidence based research based on RCTs (randomized controlled trials), and however, Japanese studies were primarily case studies with essentially no RCTs presented. One similarity between foreign research and that from Japan is that, compared to reports on acupuncture, is the relative dearth of research on moxibustion. A large number of the studies from abroad are based on traditional Chinese medicine (traditional Chinese medicine TCM) theory as a standard treatment. In contrast, the various reports from Japan are based on the classical theories from Classical Text and TCM, such as the somatic – visceral reflex. Because recent Acupuncture research examines therapeutic effects on the endocrine system, it is becoming more important worldwide. In the future, I hope that beyond TCM, clinical research based on classical theory and texts contributes to Japan's own research development.

Now we will proceed with our discussion of research on Infertility [6.Obstetrics].

2. The current state of Clinical Research Abroad

a) Dysmenorrhea

Many RCTs on Acupuncture treatment for dysmenorrhea have been performed, these trials often involve a study of women with primary dysmenorrhea. Additionally, there have been numerous “systematic reviews” published.

1) Systematic review

Yang H et al.¹⁾ reported that among the reviews of acupuncture research on primary dysmenorrhea, most of the reported research (32 published reports) had been ranked at a low level. Relevant research included 18 studies comparing analgesics and acupuncture. Acupuncture was found to be significantly effective. However, it was reported that 9 of these studies did not show significant effectiveness. These reports focused on traditional Chinese medicine, pain medication, psychotherapy with placebo acupuncture used as the control group.

2) Randomized Controlled Trials

Helms JM et al reported the results of RCTs. The subjects for these trials included 43 women complaining of dysmenorrhea. Subjects were randomly assigned to an acupuncture group, placebo acupuncture group and a standard control group. Results following a pre-determined course of treatment were compared between the groups. Improvement rates (that is, reports of reduced pain) within the acupuncture group were the highest. It was also reported that the frequency of analgesic treatment decreased the most within acupuncture group.

Also, Caroline A. et al. investigated 92 women with primary dysmenorrhea. The acupuncture treatment group and the placebo acupuncture treatment control group were compared. Following the treatment series, the acupuncture treatment group tended to have fewer days of menstrual pain compared to the control group. Three months after the treatment series, compared to the placebo acupuncture group, the acupuncture treatment group had significantly fewer days of menstrual pain. Additionally, the required amount of additional analgesics was also significantly reduced among the acupuncture treatment subjects. However, it was reported that 6 months following the trials, the effects of the acupuncture treatments were no longer reported by the subjects.

b) Irregular Menstruation

The causes of irregular menstruation are manifold including but not limited to anovulation various disorders associated with the corpus luteum. Clinical studies on menstrual cycle abnormalities are often intricately related to infertility research. Clinical studies on polycystic ovary syndrome (PCOS) have been carried out in efforts to clarify the causes of irregular menstruation.

1) Systematic Review

Lim CE et al.²⁾ reviewed acupuncture research on PCOS. They found that acupuncture treatment for PCOS patients led to increased blood flow to the ovaries, reduced in the number of ovarian cysts and overall size of the ovaries, and, seemed to influence blood sugar levels and insulin sensitivity by reducing circulating blood insulin levels.

2) Randomized Controlled Trials

Stener and Victorin E et al.³⁾ recruited 20 women with PCOS and divided them into three trial groups: the electro-acupuncture stimulation (EA) group, the exercise group and the no treatment group. Many of the common features of PCOS, such as central obesity, hyper-insulinemia and obstructive sleep apnea (OSA), are associated with chronic sympathetic over activity, suggesting that sympathetic—excitation may be involved in the pathogenesis of this condition. PCOS patients are known to have accelerated sympathetic nerve activity within muscle. Stener and Victorin reported that the exercise and EA groups experienced inhibition of this phenomenon of the muscle sympathetic nerve activity.

3) Comparative Clinical Research比

Stener and Victorin E et al. recruited a group of 24 PCOS women with non-ovulatory menstrual cycles or oligomenorrhea. Their reported results for the women who underwent EA, ovulatory cycles increased significantly. EA pretreatment average was 0.15 compared to a treatment and post-treatment average of 0.66.

c) Menopause

Among the research on the effects of acupuncture treatment for gynecological diseases, studies on menopause have been particularly frequent. There are numerous symptoms associated with Menopause, but many of the RCTs are conducted to verify the effect of acupuncture treatment for hot flashes.

1) Randomized Controlled Trials

Cohen SM et al. used 18 women who complained of hot flashes. The subjects were randomly divided into two groups. The first group received acupuncture treatments using points appropriate for menopausal symptoms and the second group received acupuncture treatments designed for general strength and vitality. For the acupuncture treatment trial group, comparing the frequency and intensity of the hot flashes prior to the treatment series it was reported that, during and following the treatments, hot flash frequency and intensity was significantly reduced. Similarly, for the general strength and vitality trial group, hot flashes were significantly reduced following the treatments. Further, both groups reported significantly improved sleep following the treatments.

Borud EK et al.⁴⁾ investigated the effects of acupuncture treatment combined with education about self-care compared to only education about self-care in 267 menopausal women. The trial groups were randomly selected and following the treatment series hot flash frequency and intensity were compared. It was reported that the acupuncture treatment group had significantly reduced hot flash frequency and intensity. However, at the 6 and 12 month follow-up sessions, there were no significant differences between the groups.

Also, in recent years there have been numerous of reported studies examining the effect of acupuncture treatment for menopausal symptoms caused by the side effects of hormone therapy in breast cancer patients in recent years.

Walker EM et al. randomly assigned 50 breast cancer patients with depression to acupuncture

treatments or venlafaxine (anti-depressant) protocol. Comparing results, both groups reported significant improvements in hot flashes, depression and other QOL indexes. However, it was reported that the acupuncture group's reports indicated that acupuncture was more effective than the pharmaceutical alternative.

3. Currents Status and Prospects for Clinical Research in Japan

a) Dysmenorrhea

1) Research on Dysmenorrhea

Clinical studies from Japan on Dysmenorrhea focus mainly on painful menstruation and various pain symptoms experienced during menstruation. There are fewer reports on the cause of the pain and other symptom sequela or on classification of common primary or secondary symptoms. Comparative studies on study design, case series and case reports make up the majority of published literature.

a. Comparative Clinical Research

Yoshimoto et al.⁵⁾, conducted research on 51 women with dysmenorrhea (painful menstruation). They established a treatment a treatment free period prior to and following the determined treatment series. They reported the results of their examination on the effect of embedded needles at Sp6 on menstrual pain. During the treatment period, pain assessments showed the subject's pain improved in about half of the participants. The amount of medication taken by the subjects also decreased significantly.

Tanaka et al. divided 22 women subjects with dysmenorrhea into 2 groups. The first group received acupuncture that included retention method with dispersing stimulation. The second group received retention method acupuncture without dispersing stimulation. The treatment protocol began with 2 weeks of treatment, followed by a week without treatment. After menstruation had continued from between 1-3 days, the subjects received a 10 minute

retention method acupuncture treatment. The researchers used a visual analogue scale (VAS) with both trial groups and reported that both groups felt their lower abdominal pain was relieved immediately following the treatments but that there were no significant differences between the groups.

b. Case Studies

Yamashita et al., reported their results from a comparative case review of 7 women with dysmenorrhea. With each passing week of their cycle, these women tended to have lower dysmenorrhea symptom scores. Significantly lower discomfort scores were reported prior to the treatments and during the second and third weeks of their cycles. Treatment results for the seven subjects included one remarkably effective case, 3 significantly effective cases. The remaining 3 subjects did not find the treatments effective. Notably, significant decreases were observed in lethargy and lower abdominal pain. It was reported that, in all 7 subjects, symptoms that had previously interfered with life style enjoyment and daily activities improved.

c. Case Reports

Taguchi et al.,⁶⁾ investigated the effects of tack needles on Sp6 in 2 patients with functional dysmenorrhea. After 2 weeks of treatment, subject 1 reported a Menstrual Disorders Index of 96.5 but after 6 and 10 weeks of treatment her Menstrual Disorders index had decreased to 49 and then 40. VAS scores and amounts of medications decreased until the 6th week but were then found to be increasing again following the 10th week. The second subjects started treatment with a Menstrual Disorders Index of 59. Her score was 49.5 after one month of treatment and 21.5 after 5 months. Both her VAS scores and necessary amount of pain relievers also decreased over the course of the treatment series.

Among the case reports of acupuncture treatment for organic dysmenorrhea, Yamashita et al, reported on the results of acupuncture treatment for a 29-

year-old woman with dysmenorrhea whose symptoms resulted from bilateral chocolate ovarian cysts. Following a series of 42 acupuncture treatments, it was reported that her Menstrual Disorders Index had decreased from 37 to 23 and she reported that her menstrual pain was “no longer interfering with her daily activities” and has improved to a level that “no longer bothered her”.

2) Prospects for Future Research

Among gynecologic clinical studies in Japan, I suspect the number of reports on dysmenorrhea is relatively large. Pain symptoms, such as menstrual pains associated with dysmenorrhea, are suitable for short-term observation and represent the main reason for the prevalence of such studies. In the future, reports of studies designed with follow-up periods and appropriate control groups would add significantly to the value of this research. Also standardized classification of the cause of symptoms, such as primary or secondary would also be desirable.

b) Irregular Menstruation

1) Research on Irregular Menstruation

Studies of menstrual cycle abnormalities make up the majority of reported cases and comparative studies. Research often focuses on amenorrhea and disorders associated with ovulation. Most research aims to clarify evaluation methods and observations of physical changes experienced during the menstrual cycle. Specifically, many research reports include easily obtainable data comparing of the time course of basal body temperature and menstrual cycle dates.

a. Comparative Clinical Research

Shimizu et al.^{7, 8)}, targeting six women who were suspected of anovulatory cycle disease by tracking their basal body temperature. They observed changes in basal body temperature following Stick Moxa treatments on the feet and Electro-acupuncture at Sp6 combined with infra-red irradiation. They reported that, after 6 months of treatment, 2 subjects experienced high-temperature

phases of 4 days. Additionally, after one year of treatment, 5 subjects were confirmed to have high-temperature phases as well.

Further, 33 adult women were asked to measure their basal temperature for 3 months. Six subjects were found to have normal basal body temperature changes and regular menstruation, they made up the control group. The trial group was made up of 7 women who were not found to have normal basal body temperature fluctuations throughout their cycle. After conducting a 75 g glucose tolerance test, both groups were compared. Blood glucose levels and blood insulin levels were significantly higher in the abnormal group. Blood glucose was abnormally high at 30, 60, and 120 minute intervals. Abnormally high blood insulin levels were confirmed at 120 minutes. For the abnormal trial group, ear acupuncture, needling at Sp6 combined with infra-red light was continued for one year. Blood sugar and insulin levels prior to and following the treatment series were compared and found to be significantly reduced at 30- and 120-minute intervals following the treatment series. It was reported, following the course of treatment, that the menstrual cycle duration (number of days) was reduced and the high temperature phase was significantly lengthened.

Taguchi et al. investigated 16 women complaining of irregular menstruation by comparing a no-treatment period followed by electro-acupuncture group following a pre-determined protocol. Results showed that 6 subjects improved, 5 had no change and 2 became worse following the treatments. Five of the subjects became bi-phasic following the protocol. The author reported that there was no significant change in the cycle duration or basal body temperature (taken at the eardrum).

b. Case Study Reports

Shimizu et al. reported on a 23 year old diagnosed with hypothalamic amenorrhea. She had seen no change following a course of Kaumann Therapy and fertility drugs. These researchers treated her with EA (Electro acupuncture). After 45 days her period

started and after 8 menstrual cycles a high temperature phase was confirmed. E2 values were taken prior to the treatment series (14th day of her cycle, 57.2pg/ml) and again after 19 weeks of treatment (day 17 of her cycle, 278.9pg/ml). Samples were taken while the basal body temperature was in its low temperature phase. The subjects also reported that her facial skin was less dry and the edema she had experienced on her lower legs was much improved.

2) Prospects for Future Research

Clinically, many women with menstrual abnormalities tend to also have or develop infertility. Because treatment periods for these types of patients tend to be protracted and patients may not feel the results of the treatments, it has been difficult to attract new patients to participate in these types of treatments.

Studies using the basal body temperature as an evaluation method are very common. Basal body temperature is a simple and effective objective evaluation method to determine whether or not the woman's cycle is bi-phasic, but cannot be relied on to confirm the presence or absence of ovulation.

In the future, studies should be carried out within a relatively short period of time and it is necessary to carry out verification using objective evaluation methods, such as ultrasound and blood tests in collaboration with medical institutions.

c) Menopause

Research on menopause in Japan, as well as abroad, can be divided into reporting that focuses on one symptom of menopause and reporting that evaluates patients with menopausal symptoms as a whole using an index table. Most research designs include comparative studies of case reports or systematic review of a series of specific cases.

1) Research Studies on Menopause

a. Comparative Research

Yaegashi et al.⁹⁾ divided their treatment subjects into two groups. All subjects were on hormone

replacement therapy for menopausal symptoms and also complained of retractable shoulder pain. The first group (23 women) received acupuncture treatments, the second group (24 women) received a muscle relaxant. Results were obtained by interview and responses were divided into a 4-tier evaluation scheme. The researchers found that the acupuncture group reported significantly improved symptoms compared with the muscle relaxant treatment group.

b. Case Study Reviews

Miki et al. attempted to differentiate between psychogenic and autonomic complaints among 150 menopausal women with indefinite complaints. They used a CMI survey and autonomic function testing to better clarify these difficult complaints. Acupuncture was performed at appropriate neck, shoulder and/ or upper back, with retention method. Moxibustion was performed at the low abdomen, low back and around the sacrum. Five small cones were burned on each of the chosen points. The researchers found that more than 72% of the patients responded positively to the treatments, reporting their autonomic symptoms had improved.

c. Case Report

Sawada et al. performed two case reports. The first case involves the case of a 48 year-old post-menopausal woman who received acupuncture treatments at a pace of twice in a two week interval for 6 months. Her Kupperman index decreased, but her hot flashes and her blood hormone levels remained unchanged. Following these results she started hormone replacement therapy. The second case focused on a 47 year-old woman who complained of urinary incontinence following a left ovariectomy. It was recommended that she perform pelvic floor exercises at home and receive acupuncture two times every two weeks. Quantitative urinary incontinence tests were used to evaluate her progress and suggested that a great degree of improvement had occurred.

2) Prospects for Future Research

Compared to research on menopause from abroad, the number of Japanese reports are relatively few.

It cannot be said that many symptoms of menopause are necessarily specific because they are often the result of other hidden underlying conditions such as conditions arising from poor circulation that might include chilliness, aches and pains etc. And then there are the usual complaints of hot flashes and stiff shoulders. It is difficult to classify Menopause as a gynecological disorder. Since menopause can reduce the QOL of menopausal women over a long period of time, it may be beneficial to maintain on-going follow-up and review of treatments and patient changes.

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