

Original Studies

Japanese-Style Acupuncture for Endometriosis-Related Pelvic Pain in Adolescents and Young Women: Results of a Randomized Sham-Controlled Trial

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Abstract. *Study Objective:* To assess feasibility, and collect preliminary data for a subsequent randomized, sham-controlled trial to evaluate Japanese-style acupuncture for reducing chronic pelvic pain and improving health-related quality of life (HRQOL) in adolescents with endometriosis.

Design: Randomized, sham-controlled trial.

Settings: Tertiary-referral hospital.

Participants: Eighteen young women (13–22y) with laparoscopically-diagnosed endometriosis-related chronic pelvic pain.

Interventions: A Japanese style of acupuncture and a sham acupuncture control. Sixteen treatments were administered over 8 weeks.

Main Outcome Measures: Protocol feasibility, recruitment numbers, pain not associated with menses or intercourse, and multiple HRQOL instruments including Endometriosis Health Profile, Pediatric Quality of Life, Perceived Stress, and Activity Limitation.

Results: Fourteen participants (out of 18 randomized) completed the study per protocol. Participants in the active acupuncture group ($n = 9$) experienced an average 4.8 (SD = 2.4) point reduction on a 11 point scale (62%) in pain after 4 weeks, which differed significantly from the control group's ($n = 5$) average reduction of 1.4 (SD = 2.1) points ($P = 0.004$). Reduction in pain in the active group persisted through a 6-month assessment; however, after 4 weeks, differences between the active and control group decreased and were not statistically significant. All HRQOL measures indicated greater improvements in the active acupuncture group compared to the control; however, the majority of these trends were not statistically significant. No serious adverse events were reported.

Conclusion: Preliminary estimates indicate that Japanese-style acupuncture may be an effective, safe, and well-tolerated adjunct therapy for endometriosis-related pelvic pain in adolescents. A more definitive trial evaluating Japanese-style acupuncture in this population is both feasible and warranted.

Key Words. Acupuncture—Endometriosis—Pelvic pain—Sham acupuncture—Inflammatory cytokines

Introduction

Chronic pelvic pain in adolescent girls is the cause of nearly 10% of their outpatient gynecology visits.¹ It is believed that 25–38% of adolescents with chronic pelvic pain (i.e. 3 to 6 months of pain) have endometriosis.² In addition to an increased risk of infertility associated with endometriosis, endometriosis-related chronic pelvic pain in adolescent girls is associated with significant functional morbidity including anxiety, depression, absence from school, and decreases in psychosocial functioning.^{3,4}

Although much research has focused on treatments for women with pelvic pain between the reproductive ages of 25 and 40,⁵ far less attention has been paid to adolescents with this disease. Consequently, treatment options for adolescents are more limited than for adults. Current recommendations as outlined by the American College of Obstetricians and Gynecologists include surgical diagnosis and destruction of visible lesions followed by medical therapy with suppression of ovulation and menses.⁶ These therapies are not

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always effective and a multidisciplinary approach to endometriosis associated chronic pelvic pain may be needed.^{7,8} Moreover, certain hormonal options for adults such as Depo-Lupron are generally not offered to adolescents younger than 16 years of age because of concerns of a potential adverse impact on bone density and development.^{2,6} Therefore there is a pressing need for additional therapies for adolescents with endometriosis-related pelvic pain.

In the West, acupuncture is commonly used as an adjunct therapy in the treatment of both pain^{9–12} and gynecological conditions.^{9,13,14} Recent studies indicate that complementary and alternative therapies, including acupuncture, are increasingly being used and are well received by adolescent patients.^{15–18} However, little research has evaluated acupuncture's efficacy in the treatment of gynecological pain,^{19,20} particularly in adolescent women.²¹

To better evaluate the potential application of acupuncture for endometriosis-related chronic pelvic pain in young women, and to inform the design of a future, more definitive study, we conducted a pilot randomized, sham-controlled trial with the following primary aims: (1) To determine the feasibility of recruiting and retaining adolescents and young women with endometriosis-related chronic pelvic pain into a randomized controlled trial of acupuncture; and (2) To collect preliminary data to evaluate the efficacy of Japanese-style acupuncture in reducing endometriosis-related pelvic pain and improving health-related quality of life in adolescents. A secondary aim of this study was to collect preliminary data to evaluate hypotheses regarding the relationship between endometriosis-related pelvic pain and inflammatory cytokines,²² and the impact of acupuncture on inflammatory cytokine levels.^{23,24}

Materials and Methods

Study Design and Population

This study was a prospective, randomized sham-controlled trial with blinding of patients and outcome assessors; but because acupuncture was manually administered, blinding of acupuncturists was not possible. The trial protocol was approved by applicable institutional review boards and was monitored by an independent data safety and monitoring board. All participants provided written informed consent. Participants less than 18 years old signed an assent form and a legal guardian signed a consent form.

Potential study participants were identified and recruited through a combination of efforts including: direct recruitment of current patients from a senior physician (M.R.L.) at Children's Hospital Boston (CHB), Division of Gynecology; sending letters to former CHB patients with endometriosis identified

through a hospital database; mailings and personal deliveries of study brochures and posters to gynecology, pediatric, and acupuncture clinics in the Boston area; presentations at local medical facilities; advertisements in Boston area public and college-specific newspapers and magazines; and internet listings.

Eligibility criteria for study participants included: 13–22 years old; diagnosis of Stage I, II, or III endometriosis determined by laparoscopic surgery within past 5 years; persisting pelvic pain with an intensity between 2 and 8 on a 10-point numerical scale; post menarchal; intact uterus and at least one ovary; a candidate for, or already using, combination hormonal therapy (oral contraceptive pill, contraceptive patch, or contraceptive vaginal ring); no prior experience with acupuncture; and living within 2 hours of the Boston metropolitan area. Study candidates were excluded from consideration if they: were pregnant or lactating; had a history of drug or alcohol abuse; had used a GnRH analogue such as Depo-Lupron® or Synarel® within the 6 months prior to their participation in the study; or had a co-existing disabling physical or psychiatric condition that the study physician believed might interfere with participation in the study.

Study Procedures

Recruitment, screening, enrollment, and general study procedures are described in Figure 1.

All active and sham acupuncture treatments and study visits were provided to participants enrolled in the study at no cost. Participants were informed that at the end of the study, those randomized to receive sham treatments would be offered a free course of active acupuncture. All parking costs for hospital visits were covered, and participants were reimbursed up to \$200 for study-related transportation costs including taxicab and non-hospital parking fees. Over the course of the study, participants were also remunerated with three \$20 gift certificates to the GAP® clothing store.

Interventions

This study employed a style of Japanese acupuncture developed by Shima and Chace²⁵ and Manaka et al,²⁶ and follows the Japanese acupuncture training curriculum at the New England School of Acupuncture. In comparison to typical traditional Chinese medicine (TCM) acupuncture, Japanese acupuncture uses smaller needles and inserts needles less deeply and with less manipulation.²⁷ For these reasons, we believed Japanese acupuncture would be less invasive than TCM, and thus better received by our adolescent population. Japanese acupuncture has been shown to be effective in treating certain pain conditions.²⁸ The specific acupuncture protocols employed in this

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