An Innovative Acupuncture Treatment for Primary Dysmenorrhea: A Randomized, Crossover Pilot Study

Maria T. Chao, DrPH, MPA; Christine M. Wade, MPH; Priscilla D. Abercrombie, RN, NP, PhD, AHN-BC; Denise Gomolak, MSN, FNPc

ABSTRACT
Context • Dysmenorrhea, the occurrence of painful menstrual cramping of the uterus, is a major cause of activity restriction and absences from school and work among young women. Standard pharmaceuticals used to treat dysmenorrhea are not effective for all women and have side effects that limit their use. Studies elsewhere have shown beneficial effects for use of vitamin K1 as an acupoint treatment, but the acceptability of this treatment to women in the United States has been unknown.

Objective • The study intended to examine the feasibility, acceptability, and preliminary effects of acupuncture point injection of vitamin K1 as an alternative treatment for primary dysmenorrhea among US women.

Design • The research team conducted a pilot study using a blinded, randomized, crossover trial design.

Setting • The study took place at the University of California, San Francisco (UCSF).

Participants • The study was conducted in the San Francisco Bay Area among women 18 to 25 y of age who had been diagnosed with primary dysmenorrhea. Fourteen women completed all of the study’s visits.

Intervention • Women with primary dysmenorrhea were randomized into 2 groups to receive bilateral injections of vitamin K1 in the Spleen-6 (SP-6) acupuncture point at the start of menstruation and then, following a 2-mo washout period, saline in a nonacupuncture point at the start of menstruation. One group received the vitamin K1 injection first, while the other group received the saline injection first.

Outcome Measure • Dysmenorrhea pain intensity was measured using a 0-10 numeric rating scale (NRS), before and after injections.

Results • Women had an average 2.5-point decrease in pain after a vitamin K1 injection in the SP-6 acupoint (P < .001), as compared with a 1.8-point decrease after a saline injection (P < .001). Change scores for vitamin K1, as compared with a saline injection, approached statistical significance (P < .10). Intensity and duration of menstrual symptoms, as measured by the Cox retrospective symptom scale, also decreased following injections. After participating, 94% of the women remained agreeable to receiving the injection therapy, and 77% reported they would come every month were the treatment available.

Conclusions • Findings suggested high acceptability for an acupuncture point injection of vitamin K1 as treatment for primary dysmenorrhea among young women in San Francisco. Pain decreased with both treatments, with a trend toward greater pain reduction for the vitamin K1/SP-6 injection. This finding is consistent with outcomes from the Obstetrics and Gynecology Hospital in Shanghai, China, where the protocol was developed. (Altern Ther Health Med. 2014;20(1):49-56.)

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Dysmenorrhea, the occurrence of painful menstrual cramping of the uterus, is a major cause of activity restriction and absences from school and work among young women. It is a common complaint, affecting as many as 85% of women; up to 20% of them experience severe pain and may be incapacitated for 1 to 3 days each menstrual cycle. Primary dysmenorrhea, defined as menstrual pain not caused by any specific disease pathology, typically begins 6 to 12 months following menarche, after ovulatory cycles are established. Dysmenorrhea is caused by an excess release of prostaglandins that causes uterine cramping; these contractions lead to uterine hypoxia. Other symptoms, such as backache, nausea, vomiting, and diarrhea, that accompany dysmenorrhea are also thought to result from the release of prostaglandins. Standard treatments for dysmenorrhea in the United States and Europe include nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen and naproxen, and hormonal contraceptive methods, such as oral contraceptive pills (OCs). NSAIDs act as antiprostaglandins and have well-established efficacy for treating dysmenorrhea. NSAIDs, however, have a failure rate as high as 20% to 25% and are associated with side effects, such as gastrointestinal complaints and mild neurological symptoms. OCs are frequently prescribed for the treatment of dysmenorrhea despite limited evidence that they decrease pain. Many women prefer not to use hormonal contraception, and others discontinue use due to side effects, such as breakthrough bleeding. About 54% of women discontinue the use of OCs in the first year of use, primarily due to side effects. Other options are needed for women with unmitigated dysmenorrhea because NSAIDs and OCs are not efficacious among all women and have side effects that limit their use.

Acupuncture point injection is the hypodermic injection of a small amount of drug, vitamin, saline, or plant extract at an acupuncture point. This innovative technique has evolved from traditionally based Asian medicine and has been in routine use in China and Korea for the past 40 years. Compared to standard acupuncture, which usually involves needles inserted at multiple points and left in place for 20 to 60 minutes, acupuncture point injection is (1) easily administered, (2) less time-intensive, and (3) easily standardized and replicated. Clinical benefits of acupuncture point injection may include enhanced pain relief, rapid treatment response, and prolonged treatment effects across a variety of pain conditions, such as arthritis, musculoskeletal pain, and chronic headaches. Acupuncture point injection has also been used for the treatment of dysmenorrhea since at least 1985. Studies conducted at the Menstrual Disorder Center at the Obstetrics and Gynecology Hospital in Shanghai, China indicated that acupuncture point injection with vitamin K at Spleen-6 (SP-6) (1) relieved pain from dysmenorrhea within 30 minutes, (2) increased participation in daily activities, (3) reduced the number of hours in bed, and (4) reduced the amount of pain medication ingested. Whether this treatment is acceptable to women in the United States has been unknown.

Use of acupuncture has risen in the United States, but acupuncture point injection is relatively uncommon. This study was designed to (1) assess the feasibility and acceptability of treatment with acupuncture point injections for dysmenorrhea among a sample of women in the United States and (2) collect and compare preliminary data on the efficacy and safety of acupuncture point injection of vitamin K at SP-6 versus an active control (ie, saline injection at a nonacupuncture point) for the treatment of primary dysmenorrhea. The current study focused on vitamin K because it is the form of vitamin K widely available in clinical settings in the United States. Vitamins K and K have similar prophylactic effects for hemorrhage among newborns but have different safety profiles. High doses of vitamin K are not associated with toxicity, whereas vitamin K has been associated with liver toxicity, jaundice, and hemolytic anemia in infants. The extent to which vitamins K and K have comparable therapeutic benefits for dysmenorrhea is unknown, but a pilot study using vitamin K that was conducted in Italy reported similar effects to studies using vitamin K conducted in China.

**METHODS**

**Participants**

Young women between the ages of 18 and 25 years with primary dysmenorrhea were eligible for this study. The study defined primary dysmenorrhea as recurrent painful periods for 6 months or more that was not relieved, or was only partially relieved, by any other treatment. Participants were English-speaking women who (1) had never given birth, (2) had had regular menstrual cycles for the prior 6 months, and (3) had a working telephone. Exclusion criteria included (1) current pregnancy or history of term pregnancy; (2) history of abdominal surgery; (3) diagnosis of or suspected chronic conditions requiring ongoing medical care (eg, hypertension, asthma, systemic allergic conditions); (4) concomitant therapy for acute or chronic pain; (5) use of hormonal contraception; (6) current treatment with anticoagulant drugs for any reason; (7) intolerance to NSAIDs or aspirin; (8) known allergy to vitamin K; (9) history of pelvic inflammatory disease or chlamydia in the past year; (10) bleeding or noncyclic pelvic pain; (11) any plans to be out of area during the study’s 5 months of treatment cycles; and (12) dysmenorrhea due to any other suspected or recognized causes.

The study’s participants (1) were recruited from outpatient clinics at local community health centers in San Francisco, (2) were referred by physicians and nurses at the obstetrics and gynecology department of local hospitals, or (3) responded to flyers and advertisements. Prospective participants who contacted the study’s staff were prescreened by telephone based on the study’s inclusion and exclusion criteria. Prior to enrollment, the study’s coordinator reviewed the study’s details with participants, verified their understanding of those details, and obtained consent. Diagnosis of primary
Dysmenorrhea was confirmed by a nurse practitioner based on the participant's history and physical examination. All in-person consent and screening procedures were conducted at the University of California, San Francisco (UCSF) Clinical Research Center. The study's visits were conducted at one of UCSF's clinic sites, based on convenience for each participant. Participants were offered an incentive of $40 in cash for each injection visit and a $10 gift card for follow-up surveys completed.

The UCSF's Committee on Human Research and its Clinical Research Center reviewed and approved all of the study's procedures.

**Design**

The study employed a crossover design in which all participants received 2 sets of injections in the course of the study. Participants were randomly assigned to one of 2 groups. The first group received bilateral acupuncture point injections with vitamin K1 in SP-6 at Time 1; following a washout period of at least 2 months, they received bilateral saline injections in a nonacupuncture point at Time 2. Participants randomized to the second group received the injections in the reverse order, saline at Time 1 and vitamin K1, at Time 2. All injections were administered within 2 days of onset of painful menstruation. If participants did not have pain during the first 2 days of their menstrual cycle, they could choose to delay injection until their next painful menstrual cycle. Patient symptoms were recorded during 5 menstrual cycles: (1) baseline, (2) first injection, (3) 1-month follow-up after first injection, (4) second injection, and (5) 1-month follow-up after second injection.

**Intervention**

Because injection is outside the scope of practice for licensed acupuncturists in the state of California, the study's procedures were performed by nurse practitioners. Prior to the study's implementation, 2 nurse practitioners were trained by a senior acupuncturist with extensive traditional Chinese medicine (TCM) training and clinical experience in the United States and in China. The nurse practitioners were trained to (1) identify the acupuncture point SP-6, (2) identify the designated nonacupuncture control point, and (3) conduct the injections at the 2 points. Training also included a discussion of TCM needling philosophy regarding *de qi*, defined as a patient's sensation of dull ache or heaviness near needle insertion and a practitioner's perception of needle grasp, which is thought to enhance the benefits of acupuncture treatment. De qi may have occurred during injections, but it was not an expected or measured outcome.

The 2 trained nurse practitioners performed all injections involved in the study, administering them to the study's participants during the first 2 days of each of 2 painful menstrual cycles. The practitioners administered the acupuncture point injections bilaterally in both legs at SP-6, which is located on the lower leg, 3 *cun* (width of thumb) or 3 transverse lengths of the patient's middle phalanx of the index finger, proximal to the peak of the medial malleolus. This area is just along the posterior aspect of the tibial bone. SP-6 can sometimes be palpated as a depression on the posterior border of the tibial bone. The injected muscle was the soleus.

After ascertaining the correct placement of the needle, the practitioner cleaned the skin around SP-6 with an alcohol solution. Using a No. 23 gauge, a 2.5-cm needle, the nurse practitioner inserted the needle into the point and injected 5 mg/0.5 mL of vitamin K1 intramuscularly. The practitioner removed the needle and patted the point with gauze pads if bleeding was present.

Saline injection was used as the control for this study. Volume and syringe needles were identical to those used for acupuncture point injection of vitamin K1. Both the right and left leg of the participant were injected intramuscularly in a standardized, nonacupuncture point located 1 *cun* medial to the Liver channel and 5 *cun* above the medial malleolus. Previous research among women with pelvic pain had used this location as a control for the acupuncture point SP-6.25 The nurse practitioners used the usual injection procedure, as described above. As an additional quality assessment, nurse practitioners completed forms following each visit that rated their level of certainty about point identification for an injection.

UCSF's Pharmacy Services assured consistent sourcing, quality, and storage of vitamin K1. The study's participants were blinded, and syringes were covered with tape to mask any color variation between solutions of vitamin K1 and saline. Anatomic points of injection differed, although both SP-6 and the nonacupuncture control point were located on the medial side of the leg, and injections were into the soleus. To minimize reporting bias, a research assistant, who was not present during the injections, obtained participants' reports of their levels of dysmenorrhea pain intensity before and after the intervention.

**Outcome Measures**

**Rating Scales**

The primary measure of efficacy in this study was intensity of menstrual pain using a 0 to 10 unit numeric rating scale (NRS) from baseline to 60 minutes after injection. For both types of treatment, the study's research assistant obtained the NRS immediately before injection of vitamin K1 or saline during a visit. Participants stayed in the clinic, and the assistant recorded the NRS at 5, 15, 30, and 60 minutes after the injection.

Data were also collected to assess presence and severity of recurrences of menstrual pain based on 2 measures, the Cox retrospective symptom scale and the Moos Menstrual Distress Questionnaire (MMDQ). The Cox scale includes 17 symptoms commonly associated with menstrual distress. For each symptom, the scale measures both intensity and duration, with a range from 0 (not perceivable) to 4 (extremely upsetting). The MMDQ assesses the presence of 6 symptoms—muscle stiffness, headache, cramps, backache, fatigue, and general aches and pains—each measured using a range from 0 (not present) to 4 (severe).
During each cycle, the study’s participants were also asked to report (1) activity restrictions—absences from school or work, restrictions on other normal daily activities, and hours in bed; (2) use of analgesic and rescue medications—type, quantity, frequency, and side effects; and (3) any information on adverse events. These data were collected as part of follow-up surveys conducted 1 week following injection and 1 menstrual cycle after injection, within 7 days of menstrual onset. Surveys were completed online using SurveyMonkey. Each follow-up survey took approximately 10 minutes to complete. Surveys also included questions about participants’ use of analgesic medications, activity restrictions, and menstrual symptoms.

**Descriptive Measures**

At the baseline visit prior to treatment, the study’s nurse practitioners collected data on medical history, including (1) age at menarche; (2) days of menstrual cycle; (3) days with pain; (4) the time at which pain usually occurred during a cycle; (5) bleeding disorders; (6) abnormal vaginal bleeding; (7) use of herbs, supplements, and medications; (8) self-care measures for dysmenorrhea; (9) past experience with acupuncture; (10) pregnancy history; (11) past and present sexual activity; (12) use of birth control; and (13) standard medical and family history.

At baseline to assess treatment expectations, the research assistant asked participants how confident they were that the treatment would reduce pain. At follow-up, an online survey asked participants in which order they thought they had received the injections—vitamin K1 first or saline first. To examine the acceptability of the treatment to participants, the online exit survey asked participants (1) what their overall experience with the treatment and the study was, (2) whether they would recommend the treatment to a friend with dysmenorrhea, and (3) if they would change anything about the study.

**Sample Size and Statistical Analysis**

Based on other studies of women in this age group, the research team anticipated an attrition rate of 20% among recruited participants.26 The team aimed to recruit 20 women for the study for a final sample size of 16. Data were entered after each interview and imported into Stata (StataCorp LP, College Station, TX, USA). Means were calculated for continuous variables such as hours in bed, number of medications, and number of days absent from school or work. The team calculated differences in means, standard deviations, and 95% confidence intervals over the five menstrual cycles included in the study, and t tests were used to analyze the significance of a change in means. For the categorical outcome measurements, a proportion of each category was calculated and assessed with exact statistical methods for small samples. The primary outcome of interest, change in self-reported pain on the NRS from baseline to 60 minutes after injection, was analyzed using analysis of variance (ANOVA). Assessments were conducted to test for differences between groups at baseline, and differences within persons at treatment time points, for possible carryover effects.

**RESULTS**

A total of 20 women enrolled in the study (Figure 1); 15 were randomly assigned to the 2 groups and 14 completed all of the study’s visits. Of the 6 women that the team had enrolled but who did not complete the study’s visits, 3 moved out of the San Francisco Bay Area, 1 started a graduate program that limited her availability, and 2 did not return e-mails or telephone calls after repeated attempts. Primary reasons reported for agreeing to participate in the study were curiosity (100%) and a desire to contribute to scientific research (71%).

The study’s participants were, on average, 22 years of age (range = 19-25) and were 50% white, 14% Asian, 29% other races, and 1% multiple races; 27% were Latina (Table 1). Four participants (29%) had received acupuncture in the past for health reasons other than dysmenorrhea, such as stress relief, migraines, and general health. Among the study’s participants, the average age at menarche was 12.5 years (range = 11-15), and their average cycle length was 28.0 days (Table 2). On a scale of 0 to 10, the average level at baseline of worst pain from menstrual cramps was 7.5.

**Effects of Vitamin K<sub>1</sub> vs Saline Injection**

No differences in pain severity were found between the 2 randomized groups at baseline. The primary outcome measure was the change in pain intensity on the NRS from baseline to 60 minutes after injections. For acupuncture point injection of vitamin K<sub>1</sub>, in SP-6, participants had an average 2.5-point decrease in pain from 4.1 to 1.6 (<i>P</i> < .001). See Figure 2. When receiving saline in the nonacupoint, average pain decreased by 1.8 points, from 4.5 to 2.6 (<i>P</i> < .001). Changes in NRS with vitamin K<sub>1</sub> compared with saline approached statistical significance (<i>P</i> < .10).

**Effects on Intensity and Duration of Menstrual Symptoms**

As measured by the Cox scale, participants experienced significant decreases in intensity and duration of menstrual symptoms after both acupuncture point injection of vitamin K<sub>1</sub> and after saline injection (Table 3). Differences in change scores between vitamin K<sub>1</sub> and saline were not significant on these measures (data not shown). Compared to baseline, a significant decrease on the MMDQ was observed at 1-month follow-up after acupuncture point injection of vitamin K<sub>1</sub> but not after the saline injection (Table 3). No notable differences were observed in activity limitations or use of drugs or herbs throughout the 5 cycles of the study (data not shown).

**Safety, Feasibility, and Acceptance**

Four women experienced minor side effects that resolved prior to the end of the study’s visits (mild itching, pain during injection, or minor bleeding). Follow-up surveys included questions to assess feasibility and acceptability of the
Figure 1. Consort Flowchart of Participants

Assessed for eligibility (N = 105)

Excluded (n = 85)
- Did not meet inclusion criteria (n = 72)
- Declined to participate (n = 9)
- Other reasons (n = 4)

Enrollment

Enrolled (n = 20)

Excluded (n = 8)
- Did not meet inclusion criteria (n = 72)
- Declined to participate (n = 9)
- Other reasons (n = 4)

Randomized (n = 15)

Enrolled but not randomized (n = 5)
(Moved out of area, lack of availability, lost to follow-up)

Allocation

Allocated to intervention Group 1 (n = 8)
- Received allocated intervention (n = 7)
- Did not receive allocated intervention (withdrew due to schedule change) (n = 1)

Allocated to intervention Group 2 (n = 7)
- Received allocated intervention (n = 7)
- Did not receive allocated intervention (n = 0)

Follow-up

Lost to follow-up (n = 0)

Lost to follow-up (n = 0)

Analysis

Analyzed (n = 7)
- Excluded from analysis (n = 1)

Analyzed (n = 7)

Note: Intervention Group 1: vitamin K₁ first, saline second; intervention Group 2: saline first, vitamin K₁ second.

Table 1. Demographics of the Study’s Participants

<table>
<thead>
<tr>
<th>Sociodemographic Factors</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>50 (7)</td>
</tr>
<tr>
<td>Asian</td>
<td>14 (2)</td>
</tr>
<tr>
<td>Other</td>
<td>29 (4)</td>
</tr>
<tr>
<td>&gt;1 race</td>
<td>7 (1)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Latina</td>
<td>27 (3)</td>
</tr>
<tr>
<td>Non-Latina</td>
<td>72 (8)</td>
</tr>
<tr>
<td><strong>Highest level of education</strong></td>
<td></td>
</tr>
<tr>
<td>College</td>
<td>92 (12)</td>
</tr>
<tr>
<td>Graduate school</td>
<td>8 (1)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
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</tr>
<tr>
<td>Employed</td>
<td>15 (2)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>8 (1)</td>
</tr>
<tr>
<td>Full-time student</td>
<td>46 (6)</td>
</tr>
<tr>
<td>Working student</td>
<td>31 (4)</td>
</tr>
<tr>
<td><strong>Primary language spoken at home</strong></td>
<td></td>
</tr>
<tr>
<td>Spanish</td>
<td>7 (1)</td>
</tr>
<tr>
<td>English</td>
<td>64 (9)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (1)</td>
</tr>
<tr>
<td>&gt;1 language</td>
<td>21 (3)</td>
</tr>
</tbody>
</table>

Table 2. Baseline Characteristics of Participants’ Menstrual Cycles and Symptoms

<table>
<thead>
<tr>
<th></th>
<th>Mean (SE)</th>
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</thead>
<tbody>
<tr>
<td>Current age (y)</td>
<td>21.9 (0.50)</td>
</tr>
<tr>
<td>Age at menarche (y)</td>
<td>12.5 (0.39)</td>
</tr>
<tr>
<td>Cycle length (d)</td>
<td>28.0 (0.79)</td>
</tr>
<tr>
<td>Time until regular cycle (mo)</td>
<td>11.0 (2.95)</td>
</tr>
<tr>
<td>Length of worst cramps, with no medicine (h)</td>
<td>12.2 (2.23)</td>
</tr>
<tr>
<td>Length of worst cramps, with medicine (h)</td>
<td>6.5 (1.79)</td>
</tr>
<tr>
<td>Missed school or work in past month (d)</td>
<td>1.4 (0.23)</td>
</tr>
<tr>
<td>Worst pain from menstrual cramps (scale = 0-10)</td>
<td>7.6 (0.31)</td>
</tr>
</tbody>
</table>

Abbreviation: SE = standard error.
Table 3. Menstrual Symptoms at 5 Time Points

<table>
<thead>
<tr>
<th></th>
<th>Vitamin K₁</th>
<th></th>
<th>Saline</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>During cycle with injection</td>
<td>During cycle with injection</td>
</tr>
<tr>
<td>Pain NRS</td>
<td>7.54</td>
<td>7.23</td>
<td>6.69a</td>
</tr>
<tr>
<td>MMDQ</td>
<td>1.90</td>
<td>1.67</td>
<td>1.54a</td>
</tr>
<tr>
<td>Intensity of menstrual symptoms (Cox scale)</td>
<td>1.25</td>
<td>0.97a</td>
<td>0.85a</td>
</tr>
<tr>
<td>Duration of menstrual symptoms (Cox scale)</td>
<td>1.59</td>
<td>1.34a</td>
<td>1.28a</td>
</tr>
</tbody>
</table>

Abbreviations: NRS = numeric rating scale; MMDQ = Moos Menstrual Distress Questionnaire.

*Statistically significant difference compared to baseline (P < .05).

study's procedures. After participating in the study, 94% of those treated would seek injection therapy again, and 77% would come every month if the treatment were available. Randomization procedures were satisfactory to all participants in the study. The largest challenge of the study's implementation was scheduling injection visits to coincide with the start of participants' menstrual cycles and the availability of the nurse practitioners. All participants found study procedures satisfactory.

Assessment of Participants Blinding

As part of the exit interview, participants were asked in which order they thought they had received the injections. Combined, 43% (n = 6) were correct about the order of injections, with no differences between the 2 groups. These data suggest that blinding procedures were effective.

DISCUSSION

This study contributes to the sparse literature on vitamin K and dysmenorrhea. Previous research examined use of vitamin K₁ or K₃ for dysmenorrhea.₁₆,₁₈,₁₉ The current pilot is the first experimental study conducted in the United States of acupuncture point injection using vitamin K₁ for dysmenorrhea. The study's findings suggest that this treatment is highly acceptable for primary dysmenorrhea among US women aged 18 to 25 years old. The study's implementation demonstrated feasibility in the United States where acupuncture innovation is not commonplace.

Acupuncture point injection of vitamin K₁ may provide an effective alternative treatment for women whose pain is not alleviated by standard treatments. Pain research has suggested that a 2-point reduction on the 11-point NRS is a clinically important difference.²⁷ Thus, the current study's finding that women had an average decrease of 2.5 points in pain suggests clinically meaningful changes in pain intensity after acupuncture point injection of vitamin K₁. The research team observed greater decreases in pain intensity after acupuncture point injection of vitamin K₁ compared with saline injections. This within-group data suggests the potential therapeutic benefits of vitamin K₁/SP-6, although the change-score differences between the 2 treatments only approached statistical significance. This study's findings are consistent with the literature, indicating that the therapeutic effects of acupuncture for chronic pain conditions tend to be modestly larger than the effects of sham controls.²⁸ Larger sample sizes than were included in this pilot study are necessary to determine whether the effects of acupuncture point injection of vitamin K₁ are statistically significant and clinically meaningful compared to the effects of saline injection for alleviating the symptoms of dysmenorrhea.

Acupuncture point injection of vitamin K₁ may be a welcome alternative treatment for women who have had unsatisfactory treatment outcomes with NSAIDs or OCs and for women who prefer not to take medications. Women who participated in the study were satisfied overall with the injection treatment and reported that they were interested in coming back for the injection if their painful menstrual cramps returned. Although further safety and efficacy studies are needed, the risks of this procedure in the clinical setting appear minimal. Vitamin K₁ is readily available in US
hospitals because it is routinely administered to newborn infants.

Key challenges to implementing this type of treatment include scheduling logistics and provider training. Given the unpredictability of many women’s menstrual cycles, scheduling of appointments can be challenging. Women would need to be able to access services in the first 2 days of menstruation. Since the visit for the injection would be brief and can be done by ancillary staff, the acupuncture point injection could be offered on a drop-in basis. The nurse practitioners involved with the current study received training in both the procedure and the location of the SP-6 acupuncture point in fewer than 30 minutes. Licensed health care providers whose scope of practice includes administering injections can be trained in the procedure easily. Some providers may, however, have difficulty accessing those trained in acupuncture point injection, since it is only part of the scope of practice for TCM providers in 7 states in the United States.

The potential biological mechanism of acupuncture point injection of vitamin K, on dysmenorrhea is unknown. NSAIDs alleviate the pain of menstrual cramps through their effect on prostaglandin levels. Although acupuncture at SP-6 does not change prostaglandin levels,29 the association between vitamin K and prostaglandin levels has not been examined to the research team’s knowledge. Vitamin K is typically studied in the context of blood clotting and bone health, although recent research suggests that vitamin K may play a role in reproductive health.30 Although they are beyond the scope of the current study, the pharmacokinetics of vitamin K and possible effects of prostaglandin inhibition warrant additional research.

The Study’s Limitations

Aspects of the study’s design and implementation limit the generalizability of its findings. Due to resource constraints, the research team opted for a design for the current study that allowed for an assessment of acupuncture point injection of vitamin K as a whole treatment. With a 2-arm trial, the therapeutic effects resulting from vitamin K versus stimulation of the acupuncture point SP-6 cannot be isolated. In addition, the current study used a washout period of 2 months between treatments. If acupuncture point injection of vitamin K has effects that endure beyond a 2-month period, as has been suggested by previous research, differences between vitamin K and saline injection may have been underestimated in this study.16

Recruitment and scheduling challenges resulted in a sample of 14 randomized participants who completed the study’s visits. This small sample size affects estimates of treatment effects and the generalizability of the study’s findings. Studies in China suggest that acupuncture point injection of vitamin K is most effective among women suffering from severe symptoms of dysmenorrhea.28 Due to scheduling challenges, the study’s participants were not always able to come for injection visits at the height of their pain. Although the study’s findings suggest the beneficial effect of acupuncture point injection on moderate menstrual pain, effect sizes may have been larger if participants had been able to receive the treatment when they were most in pain. In addition, being acupuncture naïve was not an inclusion criterion for the current study, and 29% of participants had previously experienced acupuncture. Expectancy about the effectiveness of acupuncture can affect treatment outcomes.31 Although prior acupuncture experience may have led to an overestimation of treatment effects in the current study, effective blinding procedures addressed this bias to a certain degree. Lastly, licensed acupuncturists are trained to obtain a de qi sensation as part of needling and de qi may be an important aspect of the therapeutic effects of acupuncture for dysmenorrhea.32 In the current study, procedures were performed by skilled nurse practitioners trained in acupuncture point injection but not necessarily in obtaining de qi while needling.

CONCLUSIONS

The current study is part of a research portfolio of a network of international collaborators working on an evidence-based approach to Chinese medicine and women’s health. The study demonstrates the feasibility and acceptability of administering the treatment in the United States, and together with studies conducted in China and Italy, suggests that the treatment provides rapid pain relief.16,19,22 The planned next step is a randomized, pragmatic trial conducted in China, the United States, and Italy, which would compare acupuncture point injection of vitamin K to use of NSAIDs, a standard-of-care treatment that is well-tested against placebo. Such a trial would require a coordinated international effort and a large sample size to evaluate comparative effectiveness.

ACKNOWLEDGEMENTS

Support for the study was provided by the Mount Zion Health Fund. Additional resources were provided by the UCSF Clinical Research Center (UL1 RR024131) and the Vitamin K Laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. The research team thanks Stephanie Goodman, Siri, for assistance with the study’s administration. The first author received salary support from the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH), T32AT003997 and KO1AT006545. The manuscript’s contents are solely the responsibility of the authors and do not necessarily represent the official views of NIH or NCCAM.

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