Validation of a sham acupuncture procedure in a randomised, controlled clinical trial of chronic pelvic pain treatment

Shaun Wen Huey Lee, Men Long Liong, Kah Hay Yuen, Wing Seng Leong, Nurzalina Karim Khan, John N Krieger

ABSTRACT

Background Acupuncture is an attractive treatment option for chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) that has proved refractory to conventional medical treatments. Unfortunately, it is difficult to determine the benefit of acupuncture because few studies have employed controls or had physiological outcome measures.

Objective To determine the feasibility of a sham, or minimally invasive, acupuncture as a control for studies evaluating the efficacy of acupuncture treatment for chronic pelvic pain.

Methods Participants were recruited from a double-blind randomised trial comparing acupuncture with a sham procedure for patients with CP/CPPS. Acupuncture or sham procedures were performed over a 10-week period. Sham acupuncture involved placement of short needles at sites 0.5 cm away from true acupuncture points (CV1, CV4, SP6 and SP9). Participants were asked to determine their procedure allocation at the end of treatment. A total of 35 participants also agreed to have blood analyses of cortisol, β-endorphin and leucine-enkephalin.

Results Thirty-five (78%) of the 45 participants randomised to the sham treatment thought they had received acupuncture compared with 27 (61%) of the 44 participants randomised to acupuncture (p=0.11). Biochemical data showed no differences between the groups immediately after treatment. Thirty-two (73%) of 44 acupuncture participants met the predefined clinical response criterion compared with 21 (47%) of 45 sham acupuncture participants (p=0.017, relative risk 1.81, 95% CI 1.3 to 3.1). At the end of the study, β-endorphin and leucine-enkephalin levels were both higher in the acupuncture group (p<0.01).

Conclusions Minimally penetrating acupuncture was found to be a valid sham control and may prove useful for evaluating the efficacy of acupuncture for other conditions.

(ClinicalTrials.gov number, NCT00260637)

INTRODUCTION

There is a resurgence in interest among patients and clinicians in the use of acupuncture to treat chronic pain syndromes for which conventional treatments have proved ineffective. Among the most attractive explanations for acupuncture’s efficacy are the ‘gate control,’ ‘endorphin,’ and ‘neurotransmitter’ theories. According to the gate control theory, acupuncture increases neural impulses, effectively overwhelming the central nervous system to block pain impulses. The endorphin theory suggests that acupuncture stimulates release of the body’s natural opiates, endorphins and enkephalins, to provide pain relief benefit for patients. The neurotransmitter theory suggests that acupuncture stimulates release of neurotransmitters like serotonin or noradrenalin. Although aspects of these proposed mechanisms overlap, there is a need for convincing data documenting the effective and precise mechanism of acupuncture treatment for chronic pain and other syndromes.

Acupuncture treatment is especially attractive as a treatment to provide pain relief where conventional medical treatment is unavailable or ineffective. Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a debilitating syndrome affecting 5–16% of men worldwide who have no evidence of infection or other clear aetiology. Patients usually complain of pelvic pain, voiding and sexual dysfunction that substantially decreases their quality of life. Various treatments have been suggested for the treatment of CP/CPPS but none has proved effective so far.

In drug studies, double-blind, randomised controlled trials remain the ‘gold standard’ for clinical research because blinding and an appropriate placebo or control treatment can eliminate many forms of bias. Designing appropriate controls to study procedures presents special challenges, especially for complementary and alternative medical treatments such as acupuncture. Most evidence supporting the use of acupuncture was obtained without randomisation, blinding of investigators or of subjects, or suitable control treatments. Thus, the effectiveness of acupuncture for most conditions remains controversial. Despite these scientific reservations, acupuncture treatment is increasingly popular. It is estimated that...
3.1 million US adults use acupuncture, with the number increasing by approximately 0.8% annually.2 7 8 Several acupuncture trials have employed varied control arms.9–13 Most used forms of sham acupuncture as the control treatment. Sham acupuncture usually involves needle placement.14 In contrast to acupuncture, such sham needles are usually placed superficially away from true acupuncture points, and needles are not stimulated. This experimental design might prove helpful to determine the effects of acupuncture at specified acupuncture points, but the sham acupuncture approach has not been validated. Other methodological problems with published sham acupuncture procedures are lack of blinding of both practitioners and patients and lack of reproducibility, since acupuncture and sham procedures were typically performed by a single practitioner.15 Some researchers used new acupuncture needles that have been shown to improve blinding of patients or practitioners.9 To date, the best sham acupuncture studies evaluated participant blinding only and used self-administered questionnaires without supporting biochemical data. Here, we report patient questionnaire and biochemical data documenting the effectiveness of sham acupuncture as a control for acupuncture treatment in our randomised clinical trial for patients with CP/CPPS.

METHODS

Study setting and participants

We designed our randomised controlled clinical trial to compare prospectively an acupuncture procedure with a sham acupuncture procedure for patients with CP/CPPS by including evaluations of the efficacy of the blinding procedures and biochemical evaluations. Details of the main study have been published.16 Briefly, participants were selected from patients attending the urology clinic at Lam Wah Ee Hospital. Participants were men aged ≥20 years with a National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) total score ≥15 (scale 0–43) and symptoms for ≥3 months within the preceding 6 months. Exclusion criteria included bacterial prostatitis, urinary tract infection within 1 year, any traditional or complementary alternative medicine (traditional Chinese medicine (TCM)) treatment within 6 weeks, or any consensus CP/CPPS exclusion criterion. The protocol was approved by the Joint School of Pharmaceutical Sciences, University of Science Malaysia-Penang Hospital Committee on Clinical Studies and the University of Washington Institutional Review Board. Figure 1 shows the study scheme.

Blinding of providers and participants

Because acupuncturists could not be blinded to the treatment assignment, they were deliberately excluded from examining and enrolling patients, and from all outcome assessments. Interactions between acupuncturists and patients were limited to the time required for needle placement and withdrawal, and only essential verbal communications took place. A supervisor/research nurse independently observed and recorded all procedures to limit interactions between the acupuncturists and patients and ensure that the protocol was adhered to strictly. Primary and secondary end-point assessments were performed by a separate research coordinator and also by the patients’ urologists, who were responsible for the clinical assessments.

Acupuncture and sham acupuncture procedures were performed by three highly trained and experienced acupuncturists who were employed by the TCM division of the hospital located in a building adjacent to the urology department. Each treating acupuncturist was trained as a TCM doctor specialising in acupuncture with a minimum of 2800 h of training and had practised as an acupuncturist for a minimum of 5 years. Treatments were administered without any needle stimulation. Each needle placement lasted for 30 min, with the subjects in a supine position. The study protocol included two treatments a week for 10 weeks (20 total treatments).

Acupuncture and sham acupuncture procedures

In both procedures, treatment points were prepared with 70% alcohol prep pads (Becton Dickinson, Franklin Lake, New Jersey, USA). Sterile, stainless steel disposable 0.3 mm × 25 mm, 0.30 mm × 40 mm, 0.30 mm × 50 mm and 0.30 mm × 60 mm needles (Suzhou HuanQiu Acupuncture Medical Supplies, Suzhou, China) were used. Standard blood and body fluid precautions were followed, assuming that all subjects were potentially infected with blood-borne pathogens.

Acupuncture procedures

A Medline search using the MESH terms ‘acupuncture’ and ‘prostatitis’ was conducted to identify all acupuncture studies for CP/CPPS published from 1990 to 2004. The articles were reviewed to determine efficacy and technical procedures, including the acupuncture points used for treating CP/CPPS-like symptoms. This was supplemented by recommendations from textbooks and articles published in Chinese journals and extensive discussions with expert practitioners and faculty teaching acupuncturists from Fujian University of TCM, China. Acupuncture points for CP/CPPS that were most cited as efficacious were then chosen, including: CV1—Guan Yuan, CV4—Huiyin, SP6—Sanyinjiao and SP9—Yinlingquan.15 17–23 These acupoints were felt to be the most orthodox and most effective points for treating CP/CPPS symptoms as recommended by the textbooks and journals. Additionally, clinical trials with acupuncture incorporating these acupoints have also shown efficacy for ameliorating symptoms of CP/CPPS.15 18 21 23 We decided not to employ needle stimulation, herbal medicines or other acupuncture approaches because these techniques would prove difficult to standardise or to reproduce.24

Sham acupuncture procedures

The literature searches were also reviewed to identify sham acupuncture methods used in clinical studies. These approaches included shallow needling,13 use of inactivated...
lasers,\textsuperscript{11} transcutaneous electrical nerve stimulation,\textsuperscript{4} placebo needles,\textsuperscript{9,12,13} use of adjuvant\textsuperscript{6} and random needling of points not related to acupuncture meridians\textsuperscript{14} (table 1). We decided to follow other authors’ suggestions\textsuperscript{6,25} to avoid techniques, such as placebo needling, that deviate substantially from usual acupuncture practice. We elected to employ shallow needling at sites corresponding to the selected acupoints but off the site of each meridian point. Various studies have shown that this type of approach can produce minimal non-specific physiological stimuli while maintaining the same psychological effects.\textsuperscript{6,14} All other variables were kept similar to the acupuncture treatment to limit the potential for bias.

### Outcomes

#### Primary outcome

To test the effectiveness of blinding, participants were asked the global question, ‘Which treatment did you think you received?’ after completing the acupuncture or sham treatment protocol (week 10).

#### Secondary outcomes

Ten millilitres of blood were obtained (Vacuette; Becton Dickinson) from participants who consented to assays for cortisol and two endogenous opiates, β-endorphin and leucine-enkephalin, using ELISA methods according to manufacturers’ instructions (MD Biosciences, Zurich, Switzerland). Briefly, blood samples were obtained in the afternoon between 14:00 and 15:30 immediately (within 10 min) at baseline, and after the 10th and 20th treatments with acupuncture or sham. Straight after collection, plasma was separated by centrifugation at $1600 \times g$ for 10 min at 4°C. Peptides were extracted using C$_{18}$ cartridges and evaporated to dryness in a centrifugal concentrator (RCT-60; Jouan Inc, Winchester, Virginia, USA) for 12 h. Samples were evaluated in duplicate within 1 month of extraction. Briefly, 50 μl of samples were placed in each well together with 25 μl of anti-serum and biotinylated β-endorphin or leucine-enkephalin, and then incubated at room temperature for 2 h. The wells were then washed with buffer, reincubated with streptavidin–horseradish peroxidase for 1 h, then the process was repeated with substrate solution. Absorbance was read at 450 nm, then peptide concentrations were calculated.

In addition to providing blood samples, participants completed a visual analogue scale questionnaire (range 0–10) that asked them to rate their pain during treatments after the 1st, 5th, 10th and 20th treatments. The NIH-CPSI, a 43-point questionnaire was used to determine treatment efficacy. A six-point drop in total score was used as the primary end point as outlined in our report describing the main study.\textsuperscript{16}

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**Figure 1** Study flow chart on participants who had agreed to have their blood taken for the study (CONSORT diagram).

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Statistical analyses

Descriptive and outcome analyses

Descriptive analyses were performed to compare the study groups for all demographic and clinical variables. The Mann–Whitney U test was used to compare biochemical data for the two populations. Repeated measures analysis of variance was used to compare NIH-CPSI pain subscale data, followed by contrast analysis comparing the mean for each session with the previous mean. In the event of an omnibus significant F, testing of trend components was done sequentially, proceeding from linear to quadratic, to cubic. At each step, a non-significant finding resulted in termination of further testing for higher-order trend components. Analyses were performed using the Statistical Program for Social Sciences (version 18.0; SPSS, Chicago, Illinois, USA).

RESULTS

Participants

A total of 89 participants were recruited into the study. The mean age of participants in the two groups was 40.9 ± 11.0 years (SD) in the acupuncture group and 42.8 ± 9.4 years in the sham acupuncture group, respectively (p = 0.06). The two groups were similar in all demographic and clinical variables assessed (table 2). A total of 18 participants randomised to acupuncture and 17 to sham acupuncture also consented to the biochemical analyses. No significant differences were observed between participants who consented to the biochemical analyses and those who declined to participate in this portion of the protocol (data not shown.).

Primary outcome

When participants were asked which treatment they thought they had received, 27 (61%) of 44 participants in the acupuncture group and 35 (78%) of 45 participants in the sham acupuncture group thought they had received acupuncture treatment (Fisher’s exact test p = 0.11).

Table 1  Advantages and disadvantages of various sham methods

<table>
<thead>
<tr>
<th>Sham method</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo needling</td>
<td>Similar sensation to needling with no skin penetration</td>
<td>Technique is time consuming, increasing patient-practitioner contact</td>
</tr>
<tr>
<td></td>
<td>Same psychological impact as actual needling</td>
<td>Problematic in hairy areas</td>
</tr>
<tr>
<td>Manipulation to achieve needling</td>
<td>Manipulation provides greater effects</td>
<td>Effective form of acupressure</td>
</tr>
<tr>
<td>(de qi)</td>
<td></td>
<td>Needle manipulation is difficult</td>
</tr>
<tr>
<td>Varying depth of needling</td>
<td>Same psychological impact as true acupuncture</td>
<td>Higher risk of adverse effects especially with moxibustion</td>
</tr>
<tr>
<td>Needling at incorrect sites</td>
<td>Same psychological impact as true acupuncture</td>
<td>Japanese acupuncture considers superficial needling effective</td>
</tr>
<tr>
<td>Homoeopathy/other treatments</td>
<td>Study acupuncture versus physiologically inert technique</td>
<td>Cannot be considered physiologically inert</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suggestion that 100 extra points off normal points at meridian</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difficulty in blinding patients</td>
</tr>
</tbody>
</table>

Secondary outcomes

Pain associated with acupuncture or sham acupuncture

The mean visual analogue scale pain score was higher for the acupuncture group than for the sham acupuncture group throughout the whole treatment period (F (1,78) = 325, p<0.001). Trend analysis showed a tendency for pain to decrease over the 10-week treatment period in both groups, with a mean pain score of 3.8 (range 0–10) in acupuncture patients and 2.1 in sham acupuncture patients at the first treatment declining to 2.5 in acupuncture patients and 1.8 in sham acupuncture patients after the last treatment session (table 2).

Biochemical studies

The mean baseline cortisol level immediately after treatment was 8.0 ± 4.5 μg/dl in the acupuncture group and 9.2 ± 5.3 μg/dl (Mann–Whitney U test, p=0.47, 95% CI −4.52 to 2.12) in the sham acupuncture group. No significant differences were observed between the levels of cortisol after the 10th and 20th treatment sessions (table 3). There was no difference between the groups in baseline levels of the endogenous opiates β-endorphin or leucine-enkephalin. After the last treatment (20th session), levels of both β-endorphin and leucine-enkephalin were higher in the acupuncture group than in the sham acupuncture group (p<0.01, table 3).

Efficacy of acupuncture and correlations with presumed treatment assignment and biochemical data

Thirty-two (73%) of 44 patients randomised to receive acupuncture met the predefined clinical response criterion for improvement (at least a six-point drop in NIH-CPSI total score) compared with 21 (47%) of 45 patients treated with sham acupuncture (p=0.017, relative risk 1.81, 95% CI 1.3 to 3.1). Trend analysis showed no correlation between demographics or clinical characteristics evaluated during treatment, the levels of endogenous opiates or cortisol with assigned treatment group. Similarly, when compared between treatment groups, clinical response did
DISCUSSION

Our penetrating sham acupuncture treatment away from the actual acupuncture sites proved a suitable control treatment to evaluate the efficacy of acupuncture treatment. More than three-quarters (78%) of participants assigned to sham acupuncture thought they had received active acupuncture treatment which was similar to the 61% of patients in the acupuncture group who thought they had received active acupuncture treatment (p=0.11). For a study to have a valid control, it is imperative that the treatments are kept as identical as possible between all variables. Although various sham methods have been suggested, to our knowledge, this is the first rigid validation of any sham procedure to study the efficacy of acupuncture treatment for a chronic pain condition. Many would consider this approach was ‘double blind’ since both the participants and doctors assessing treatment efficacy were blinded to treatment assignment.

Further support for the validity of our sham acupuncture procedure was provided by the biochemical data. Participants assigned to sham acupuncture and acupuncture had similar cortisol, \( \beta \)-endorphin and leucine-enkephalin levels throughout the study period. However, after the final treatment procedure, \( \beta \)-endorphin and leucine-enkephalin levels were significantly higher in the acupuncture group. These findings further support the use of penetrating sham as a control treatment for acupuncture studies since these data support the presence of a psychological response to acupuncture treatment. Our data are also consistent with previous studies showing that acupuncture releases endogenous opiates that may play a part in amelioration of pain symptoms.

According to TCM theory, acupuncture represents a dynamic treatment in which acupuncture points are chosen based on doctors’ diagnoses supplemented with tongue and pulse examinations. We decided not to follow such TCM approaches, but selected a standardised acupuncture treatment with fixed points to facilitate more rigorous evaluation of the efficacy of acupuncture in our patient population. This approach allowed us to conduct a rigorous randomised clinical trial documenting the efficacy of acupuncture treatment for CP/CPPS that had proved refractory to other treatment options. We recognise that our methods do not correspond to the best technique advocated by most TCM practitioners. Our approach does, however, offer a reproducible and reliable method to objectively evaluate the efficacy of acupuncture treatment in clinical trials. Other limitations of our study include the relatively small number of participants, which limited statistical power for many desired subanalyses, especially the small number of patients who provided biochemical data and the relatively short follow-up.

While we feel that a minimally invasive acupuncture procedure may be the best choice for a sham, we cannot completely exclude the possibility that a needle inserted 0.5 cm away from the acupuncture point may elicit some neuropsychological effects. We do not know if results would have been better if we had used additional acupoints or other treatments such as needle manipulation, supplemental TCM treatments such as herbs, or combination treatments with other orthodox Western medical treatments.

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Table 2  Demographics and clinical characteristics of participants recruited into the study

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Acupuncture (N=44)</th>
<th>Sham acupuncture (N=45)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean years (SD)</td>
<td>40.9 (11.0)</td>
<td>42.8 (9.4)</td>
<td>0.06</td>
</tr>
<tr>
<td>Duration of symptoms, mean months (SD)</td>
<td>22.4 (28.4)</td>
<td>27.5 (26.9)</td>
<td>0.80</td>
</tr>
<tr>
<td>Living status, N (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alone</td>
<td>14 (31.8)</td>
<td>7 (15.6)</td>
<td>0.08</td>
</tr>
<tr>
<td>Partnered</td>
<td>30 (68.2)</td>
<td>38 (84.4)</td>
<td></td>
</tr>
<tr>
<td>Employment status, N (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>41 (93.2)</td>
<td>38 (84.4)</td>
<td>0.35</td>
</tr>
<tr>
<td>Unemployed</td>
<td>0 (0)</td>
<td>1 (2.2)</td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>3 (6.8)</td>
<td>6 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Treatment history, N (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12 (27.3)</td>
<td>9 (20.0)</td>
<td>0.42</td>
</tr>
<tr>
<td>≥1 Treatment</td>
<td>32 (72.7)</td>
<td>36 (80.0)</td>
<td></td>
</tr>
<tr>
<td>Other significant medical conditions, N (%)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12 (27.3)</td>
<td>9 (20.0)</td>
<td>0.46</td>
</tr>
<tr>
<td>≥1</td>
<td>32 (72.7)</td>
<td>36 (80.0)</td>
<td></td>
</tr>
<tr>
<td>Needling pain VAS score at baseline, mean (SD)</td>
<td>3.8 (2.3)</td>
<td>2.1 (2.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Needling pain VAS score at end of treatment, mean (SD)</td>
<td>2.5 (1.4)</td>
<td>1.8 (1.5)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*p Values based on two-sample t-test; †χ² tests were used. VAS, visual analogue scale.
Acupuncture was found to be a promising treatment for CP/CCPS, with almost twice as many participants (73%) responding to acupuncture treatment as to sham acupuncture treatment (47%, p<0.02). This represents better results than most drug treatments evaluated to date in double-blind randomised clinical trials, with a mean improvement of between 40% and 60%. For example, a recent study by the Chronic Prostatitis Collaborative Research Network found that both, drug treatment and placebo helped in 49.3% of participants treated over a 12-week period (p=.99, 95% CI –11.2 to 11.0).

This study has several strengths. Our population accepts both TCM and Western medicine approaches. We had well-trained TCM practitioners (trained in Beijing, China), well-trained Western medical consultants (most trained in England, Australia or the United States) and modern clinical laboratories in the same facility that provided us with a unique opportunity to conduct this study. Additionally, several TCM practitioners were employed and rotated throughout the study, enhancing the probability that results are reproducible. This study also measured several important biochemical markers for the physiological responses hypothesised to be important during acupuncture treatment.

In summary, we found that a penetrating sham acupuncture procedure away from actual acupuncture sites was an effective method of blinding, with 78% of participants randomised to sham treatment comparable to the 61% of participants randomised to acupuncture who thought they had received active acupuncture treatment. Biochemical data also showed no significant difference between both treatment groups immediately after treatment. After the final treatment procedure, β-endorphin and leucine-enkephalin levels were significantly higher in the acupuncture group (p<0.001 respectively). Acupuncture proved almost twice as effective as sham treatment for treating CP/CCPS (p<0.02).

**Funding** This work was supported by NIH grants DK065266 and DK38955, National Institutes of Health, Bethesda, Maryland.

**Competing interests** None.

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Levels of cortisol and endogenous opiate levels among the participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Test</strong></td>
<td><strong>Acupuncture (n=18)</strong></td>
</tr>
<tr>
<td>Baseline</td>
<td></td>
</tr>
<tr>
<td>Cortisol level, mean μg/dl (SD)</td>
<td>8.0 (4.5)</td>
</tr>
<tr>
<td>β-Endorphin level, mean ng/ml (SD)</td>
<td>9.4 (2.7)</td>
</tr>
<tr>
<td>Leucine enkephalin level, mean ng/ml (SD)</td>
<td>4.6 (1.6)</td>
</tr>
<tr>
<td>10th Session</td>
<td></td>
</tr>
<tr>
<td>Cortisol level, mean mcg/dl (SD)</td>
<td>8.4 (3.4)</td>
</tr>
<tr>
<td>β-Endorphin level, mean ng/ml (SD)</td>
<td>6.3 (2.7)</td>
</tr>
<tr>
<td>Leucine enkephalin level, mean ng/ml (SD)</td>
<td>1.6 (0.6)</td>
</tr>
<tr>
<td>20th Session</td>
<td></td>
</tr>
<tr>
<td>Cortisol level, mean mcg/dl (SD)</td>
<td>8.9 (4.3)</td>
</tr>
<tr>
<td>β-Endorphin level, mean ng/ml (SD)</td>
<td>9.3 (4.1)</td>
</tr>
<tr>
<td>Leucine enkephalin level, mean ng/ml (SD)</td>
<td>6.6 (2.8)</td>
</tr>
</tbody>
</table>

*Note: p Values based on Mann–Whitney U test.

**Summary points**
- Sham controls for acupuncture are problematic.
- We compared standard needling with shallow insertion and nearby non-points.
- There was no difference in which treatment the groups believed they received.
- In a subgroup, there was a difference in blood opioid levels.

**Ethics approval** This study was conducted with the approval of the Joint School of Pharmaceutical Sciences, University of Science Malaysia-Fenang Hospital Committee on Clinical Studies and the University of Washington Institutional Review.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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