Combined electroacupuncture and auricular acupuncture to alleviate pain after gynaecological abdominal surgery: a randomised sham-controlled trial (abridged secondary publication)

WL Lam, HYS Ngan, KKL Chan, H Chen, CW Cheung, F Jiang, CKH Wong, WF Yeung, L Lao *

KEY MESSAGE

Perioperative acupuncture is safe and effective in alleviating pain after gynaecological laparotomy. However, a large sample size trial is warranted to confirm the efficacy. Hong Kong public hospitals may consider providing inpatient perioperative acupuncture services to such patients.

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[1] **WL Lam**, [2] **HYS Ngan**, [2] **KKL Chan**, [3] **H Chen**, [4] **CW Cheung**, [5] **F Jiang**, [6] **CKH Wong**, [7] **WF Yeung**, [1] **L Lao**

[1] *School of Chinese Medicine, The University of Hong Kong*
[2] *Department of Obstetrics and Gynaecology, The University of Hong Kong*
[3] *School of Chinese Medicine, The University of Hong Kong*
[4] *Department of Anaesthesiology, The University of Hong Kong*
[5] *Department of Statistics and Actuarial Science, The University of Hong Kong*
[6] *Department of Family Medicine and Primary Care, The University of Hong Kong*
[7] *School of Nursing, The Hong Kong Polytechnic University*

* Principal applicant and corresponding author: llao@vuim.edu

Introduction

Postoperative pain affects recovery. Although analgesics such as opioids are effective in lowering postoperative pain, they have adverse effects such as dizziness, nausea, and vomiting. Acupuncture is effective in reducing pain after abdominal surgeries. However, perioperative inpatients are not able to opt for acupuncture service in Hong Kong. This study aims to assess the safety, feasibility, efficacy, and cost-effectiveness of adding acupuncture to the usual postoperative pain control plan for patients with gynaecological laparotomy.

Methods

A total of 72 adults who planned to undergo a laparotomy with a midline or horizontal incision for gynaecological diseases were recruited between 12 October 2016 and 6 November 2018 from Queen Mary Hospital or Kwong Wah Hospital (Fig). We excluded those who were very ill, taking analgesics for chronic pain, having recent acupuncture experience, or not suitable for receiving acupuncture (eg heart diseases, bleeding disorders or skin lesions).

Participants were randomised evenly into either the acupuncture group or the sham control group. Block randomisation using random block sizes (4-8) was conducted. Only the acupuncturist could read the allocation code just before the first treatment. Usual care was provided to all participants. Standard protocols for anaesthesia, surgery, and postoperative pain management were recommended. Acupuncture and sham acupuncture were administered within 2 hours before surgery, immediately upon arrival at the ward, and then once a day during hospitalisation up to 5 days after surgery.

The semi-standardised acupuncture treatment protocol included electroacupuncture and auricular acupuncture. Five fixed basic acupoints (bilateral LI4, ST36, SP8, SP10, and LR3) were used in all sessions, and four to five selective points were chosen by the acupuncturist in every session. An electric-stimulator (4 Hz, continuous wave) produced electrical current to stimulate four pairs of acupoints (preoperatively: bilateral LI4-ST36, bilateral ST25, CV4-CV12; postoperatively: acupoints across the wound, bilateral ST36) for 30 minutes. For auricular acupuncture, filiform needles (0.22×15 mm) were needled on the auricular points and retained for 30 minutes in the preoperative session. Adhesive tape was also applied to the body acupoints. In the acupuncture sessions after surgery, intradermal needles (0.20×1.5 mm) were inserted, rather than filiform needles. The intradermal needles were retained and replaced every 3 days.

The sham control group received sham acupuncture with the same procedures and schedule, except that sham acupoints were located at 1-2 cun beside the true acupoints and were stimulated by non-invasive sham acupuncture devices.

The primary outcome measure was pain at rest measured by a numerical rating scale (NRS) for 5 days

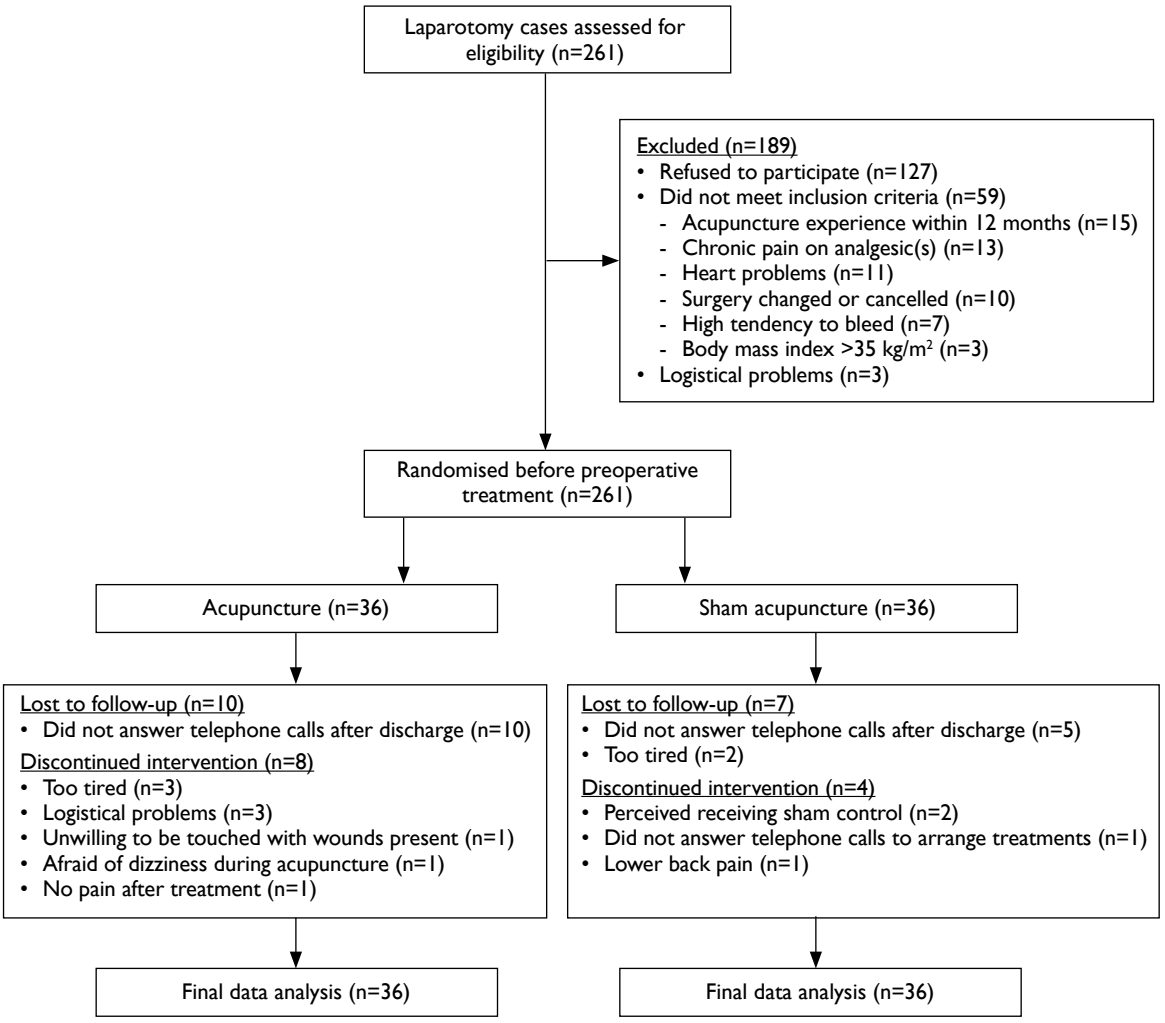

FIG. Patient recruitment flowchart

after surgery. Secondary outcomes included pain while coughing, analgesics consumption, quality of life, time to recovery, the incidence of opioid-related adverse effects, patients' satisfaction, the patients' perception of the credibility of the treatment, and the blinding success. The pain NRS scores and patient-controlled analgesia attempts (tries/ goods) were taken hourly for the first 6 hours after surgery, then every 4 hours up to day 2, every 6 hours up to day 3, and then once a day. All other outcomes were measured once a day. The last measurement was taken on day 5 after surgery. Patients who were discharged <5 days after surgery were followed up with telephone calls.

The sample size was calculated based on the effect size (pain at rest for 5 days after surgery) calculated from an electroacupuncture study for postoperative pain control.[1] R (version 3.6.0) was used for statistical analyses. We adopted the intention to treat approach and verified the results with a post hoc complete case analysis. Missing data were imputed through linear interpolation, whereas those time-independent, baseline, and last missing outcomes were imputed by multiple imputation 10 times. Independent two-sample t test or linear regression models adjusted for regressors such as type of incision were used to compare the continuous variables. Chi squared test or a multinomial logistic regression model adjusted for similar regressors were used to compare the categorical variables. Survival analysis was also conducted for the time to recovery variables. All tests were two-tailed, and the statistically significant level was set at 0.05.

Health economics analysis was based on the perspective of the health service providers on the direct medical costs. The healthcare costs were estimated by the number of hospital stay multiplied by the day cost taken from the Hong Kong government's Gazette, whereas the intervention costs were measured by the time of preparation and

TABLE 1. Pain scores across time

	Missing rate, %			Intention to treat analysis					Complete case analysis				
	Acupuncture group	Sham acupuncture group	Total	Acupuncture group, mean	Sham acupuncture group, mean	Mean difference	95% confidence interval	P value	Acupuncture group, mean	Sham acupuncture group, mean	Mean difference	95% confidence interval	P value
Baseline													
Rest	5.6	5.6	5.6	5.4	4.8	0.6	-1.4 to 2.3	0.604	5.5	4.7	0.7	-1.8 to 2.220	0.813
Cough	11.1	13.9	12.5	6.7	6.2	0.5	-2.2 to 1.8	0.826	6.7	6.3	0.4	-3.0 to 1.3	0.450
At 22 hours													
Rest	13.9	11.1	12.5	2.6	4.0	-1.4	-2.7 to -0.2	0.029	2.5	3.9	-1.4	-3.0 to -0.0	0.044
Cough	22.2	19.4	20.8	5.2	6.3	-1.1	-2.9 to 0.4	0.119	5.1	6.3	-1.2	-3.8 to 0.0	0.050
At 96 hours													
Rest	11.1	13.9	12.5	1.2	1.7	-0.5	-1.4 to 0.6	0.423	1.2	1.7	-0.5	-1.8 to 0.6	0.314
Cough	13.9	16.7	15.3	3.9	3.6	0.3	-1.1 to 1.8	0.608	4.0	3.6	0.4	-1.5 to 1.7	0.906

implementation of 'acupuncture' treatment and the number of consumables used. All the costs were adjusted to 2018 prices by referring to the Hong Kong Consumer Price Index. The health outcome for cost-effectiveness analysis was the quality-adjusted life years (QALY) measure for 5 days after surgery, using SF-6D and EQ-5D-5L (secondary). Cost-reduction analysis was performed, as the difference between the QALY of the 2 groups was close to 0. Sensitivity analyses were performed in four scenarios with variation in the cost and health outcomes and by bootstrapping (1000 times). The probability of the simulated ICER being cost-effective (threshold: HKD 149838) was estimated.

TABLE 2. Net savings of the acupuncture group in different scenarios of post-laparotomy patients

Scenarios	Mean ± standard deviation total cost, HKD		Net savings, HKD
	Acupuncture group	Sham acupuncture group	
Sham acupuncture	26 014.6±8695.0	30 419.7±9604.7	4405.1
No additional treatment	26 014.6±8695.0	26 491.7±9270.2	477.1

Results

The acupuncture group and the sham control group were similar in terms of characteristics and baseline data, except that the sham control group comprised more patients who received a vertical incision (P=0.029).

With reference to the suggested postoperative analgesic protocol, respectively in the acupuncture group and the sham control group, four and five patients received patient-controlled analgesia, oral paracetamol, and celecoxib, whereas 25 and 27 patients were given both the preoperative and the first postoperative treatments, with a mean of 4±2 and 5±1 in total.

Compared with the sham control group, the acupuncture group had smaller (but not significantly) area under the curve of pain at rest across the 5 days after surgery (285.1±182.6 vs 232.7±210.0, 95% confidence interval [CI]= -144.5 to 63.7, P=0.439, Table 1).

At 22 hours after surgery, the mean NRS pain score at rest was clinically significantly smaller in the acupuncture group than in the sham control group (2.6 vs 4.0, 95% CI=-0.2 to 2.7, P=0.029, Table 1). No significant difference was observed at the other two time points (baseline and 96 hours).

Patients in the two groups shared a similar perception of the credibility of acupuncture. As shown by the Bang Blinding Index, participants in the sham control group were blinded ($BI_{sham\ acup}$ = -0.0472, 95% CI=-0.3015 to 0.2071), but participants in the acupuncture group were not blinded (BI_{acup} = 0.4028, 95% CI=0.1972-0.6084).

There were two missing needle accidents but no serious adverse event. There were four and one events of numbness or pain at needle insertion site in the respective groups and one event of nausea during the preoperative treatment in the acupuncture group.

The QALYs of the two groups were similar. The total cost of each patient was lower in the acupuncture group than in the sham control group (HKD 26014.6±8695.0 vs HKD 30419.7±9604.7, P=0.042, Table 2). The acupuncture group saved HKD 477.1 when the cost of the sham treatment was assumed to be HKD 0 (Table 2). In the complete case analysis and intention to treat analysis, the differences in QALY between the two groups, measured using SF-6D or EQ-5D-5L, across 5 days or 4 days were close to zero. The probability of acupuncture to be more cost-effective than sham acupuncture was 94.9%.

Discussion

The acupuncture group demonstrated a clinically significant superiority in terms of pain at rest over 5 days (mean difference=1.4, 95% CI=-0.2 to -2.7, P= 0.029, post hoc analysis). In the health economic analysis, a saving of HKD 4405.1 per patient was observed in the acupuncture group, compared with the sham control group. No serious adverse events occurred.

The present study used a less frequent postoperative acupuncture protocol (once a day) than a post-hysterectomy pain study[2] (every 4 hours then tapered off) but still observed a significant reduction of the pain at rest. This may be due to the combined use of electroacupuncture and auricular acupuncture.

The present study reported a potential in saving of HKD 477.1 to 4405.1 per patient by adding the acupuncture treatment, compared with a study that reported a net saving of about HKD 42.6 (Euro 4.77) per patient by using an app to follow up patients after surgery.[3]

Conclusion

Perioperative acupuncture treatment was not dominantly superior to sham acupuncture in managing post-laparotomy pain, as evaluated by the area under the curve of pain at rest for 5 days after surgery. However, the acupuncture group showed a significant reduction in pain at rest at 22 hours after surgery.

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Disclosure

The results of this research have been previously published in:

1. Lam WL, Yeung WF, Wong MK, et al. Combined electroacupuncture and auricular acupuncture for postoperative pain after abdominal surgery for gynecological diseases: study protocol for a randomized controlled trial. Trials 2018;19:8.

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