Effect of intraoperative electroacupuncture on postoperative pain, analgesic requirements, nausea and sedation: a randomised controlled trial

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ABSTRACT

Background: Acupuncture has potential value in producing analgesia in the postoperative period, but previous trials have inconsistent results. We aimed to study the effect of electroacupuncture on pain and nausea and the requirement for postoperative analgesia via patient-controlled analgesia.

Method: 107 patients who were undergoing abdominal hysterectomy or laparoscopic cholecystectomy were randomised to receive either electroacupuncture (n = 56) or no additional treatment (n = 46) during the operative period. We measured the use of patient-controlled analgesia and time in recovery as well as pain, postoperative nausea and vomiting, and sedation. 102 patients were included in the analysis. The majority of patients were female: the laparoscopic cholecystectomy group included 10 males. Adhesive dressings were placed over all acupuncture points in both groups, to ensure blinding of patients and assessors during the recovery period.

Results: The electroacupuncture group had a longer duration of operation but the difference was not statistically significant. There were no significant differences between the groups for the requirement for patient-controlled analgesia or total time in recovery. Pain scores were marginally lower in the acupuncture group, but not significantly, and there were no differences between the groups in nausea or sedation scores.

Conclusion: Electroacupuncture at 10 Hz given under general anaesthetic has no effect on postoperative nausea or analgesic requirement. Future studies should investigate acupuncture given before or after surgery.

Postoperative pain is an inevitable result of injury and its advantage in terms of survival is presumably to prevent movement and thereby hasten healing of the wound. However, pain distresses the patient and any lack of activity and movement increase the risk of postoperative deep venous thrombosis and chest infection. Postoperative pain is mainly nociceptive, but central sensitisation also occurs. At the periphery, inflammatory mediators (prostaglandins, histamine, serotonin, bradykinin and substance P) increase the sensitivity of nociceptors. Central sensitisation occurs as a result of functional reorganisation in the dorsal horn of the spinal cord. Both these processes result in an exaggerated response to noxious stimuli, spread of hyper-responsiveness to non-injured tissue in adjacent spinal segments, and reduction in the pain threshold.

Much attention has been paid to the importance of achieving adequate analgesia throughout the operative period, with widespread use of patient-controlled analgesia. But this carries the potential risks of side effects of the drugs, so an effective non-drug alternative such as acupuncture would be welcome.

The mechanisms of the effects of acupuncture stimulation on the pathways of the central nervous system are increasingly well understood, and it seems that these mechanisms are potentially highly appropriate for treating postoperative pain. Considering the good safety record of acupuncture and the lack of serious side effects, acupuncture is a candidate for contributing to postoperative pain management. A number of studies have shown that acupuncture reduces postoperative pain, both in oral and general surgery. However, other studies have not shown acupuncture to be effective in treatment of postoperative nausea and vomiting (PONV), or postoperative pain. This controversy was the stimulus for our study, which aims at investigating the effect of intraoperative electroacupuncture on postoperative pain, PONV and sedation in patients undergoing laparoscopic cholecystectomy or abdominal hysterectomy.

METHOD

Study design

A randomised, double-blind, comparative study was conducted in Scunthorpe & Goole Hospitals. Patients all received patient-controlled analgesia (PCA), either with acupuncture (PCA + acupuncture) or without acupuncture (PCA alone). Double blinding was achieved by placing adhesive dressings on all acupuncture sites in all patients, to ensure that neither the patients themselves nor the staff caring for the patients knew which treatment each patient received. The anaesthetist who delivered the acupuncture was not involved in the assessment of the patients.

Patients were allocated to treatment groups on the basis of a computer-generated randomisation list using Statistical Package for Social Sciences (SPSS). In consecutive order, patients were allocated to one or other group after consulting the list. All consenting patients who were undergoing elective laparoscopic cholecystectomy or abdominal hysterectomy were approached by the researchers to be recruited into the study. Patients were given full information about the study, including the method of acupuncture. All consenting patients were aware that they might or might not have acupuncture. All patients were also given an information booklet on how to use a PCA pump.
Male or female patients were included if they were at least 18 years of age and had an American Society of Anaesthesiology score of either I or II. All patients gave written informed consent prior to entering the study.

Patients were excluded from the study if they were pregnant (pregnancy test was performed on all women of childbearing potential when considered for the study), diagnosed with a coagulopathy, over the age of 70 years, or undergoing surgery additional to the intended operation.

Assessments
The recovery time was measured in both groups from the time the patient arrived in the recovery room until the patient was able to respond to a verbal command. Pain was measured using a four-point rating scale in response to a direct question by the nurse: 0 = no pain; 1 = mild pain; 2 = moderate pain; and 3 = severe pain. Observations were made at intervals of 1 h for the first 4 h; 2 h for the next 12 h; and 4 h for the remaining 8 h. PONV was measured using a dichotomous measure applied by the nurse at the same time: 0 = no PONV; 1 = presence of PONV. Sedation was measured using a sedation score: 0 = awake; 1 = dozing intermittently; 2 = mostly sleeping; and 3 = difficult to waken.

During the first 24 h of postoperative care, all patients received morphine sulphate via the PCA route. The concentration of morphine in the PCA pump was 1 mg/ml; the lock-out time was 5 minutes. Any medication which the patient was taking prior to surgery was recommenced as soon as was practicable, in line with the individual treatment regime. Any such medications that are classed as analgesics were documented in the study and taken into account in discussing the results and making recommendations at the end of the study.

The study was approved by the local ethics committee. Patients were informed that they had the right to withdraw from the study at any time for any reason, without prejudice to their treatment. A patient could also be withdrawn from the study at the researcher’s discretion at any time should they feel it would be to the patient’s detriment to continue, or if they no longer met the inclusion criteria.

Study protocol
All patients who were scheduled to have surgery were approached and given time to read the information sheet, and entered into the study after signing the consent form. Consent was obtained the night before the operation if the patient was in the ward, or before the preoperative visit by the anaesthetist. The admitting nurse taught the patient how to use the PCA pump, as is standard practice.

All anaesthetists involved in the study agreed on a standard premedication that was given to all patients prior to surgery: diazepam 5–10 mg was given orally 1 h before operation according to the weight of the patient (5 mg for patients below 60 kg and 10 mg for patients above 60 kg). Patients were anaesthetised by one of the three authors or by another anaesthetist not involved in the study, following a standardised anaesthetic protocol. The anaesthetists were not blinded to the patient’s group allocation, but were not involved in the assessment of the patients. Propofol was the induction agent, and a standard dose of droperidol 1 mg was given to all patients as a baseline antiemetic. Tracheal intubation was facilitated by using atracurium, or another muscle relaxant (vecuronium, rocuronium or cisatracurium), in dosage according to the body weight. Anaesthesia was maintained by nitrous oxide 50–60%, oxygen 40–50% and isoflurane 1–2%. At the end of the operation, muscle relaxation was reversed using a suitable dose of neostigmine and glycopyrrolate. Intravenous morphine was given intraoperatively just before skin incision, 100 μg/kg body weight.

Patients who were randomised to receive acupuncture had the acupuncture needles inserted after induction of anaesthesia. In patients undergoing hysterectomy the following points were used: GV2, GV4 in the midline and BL52, BL23, LI4 and PC6, bilaterally. In patients undergoing laparoscopic cholecystectomy, the following points were used: LR3, SP6, LI4 and PC6, all bilaterally. The points were selected on the bases of guidelines
from Chaitow. Needles (size 1 or 0.16 × 30 mm, Seirin) were attached to the acupuncture stimulator (Medical Electro-Acupuncture Unit, IC-4107, RDG Medical Ltd, Croydon, UK) for the duration of the operation. The needles were connected in the following pairs: GV2 with BL32, GV4 with BL23, LI4 with PC6, and LR3 with SP6. The frequency used was 10 Hz, and the intensity was 7/10 on the intensity scale of the electroacupuncture unit. Occasional muscle twitches were noticed (suggesting that muscle relaxation was not optimal). After the needles were connected to the electroacupuncture stimulator, they were secured by adhesive tape. No local anaesthetics were used at the end of surgery. Stimulation was stopped and needles removed before the patient was transferred to the recovery room.

In the recovery room, patients were attached to the PCA pump, and all observations were documented according to the patient booklet. The recovery nurse who was assessing the patient was blinded to the technique, since patients in both groups came to the recovery room with a dressing covering the acupuncture point. Patients were transferred to the General Surgical or Gynaecological wards for the remainder of their stay. All observations were performed as standard for the postoperative period for these procedures.

### Statistical methods

The primary outcome for comparing the groups was the mean dose (mg) of morphine used. This was calculated for 4 h and for 24 h in order to be able to detect any time-related effects of acupuncture. All continuous data showed a positive skew and therefore a non-parametric test (Mann–Whitney U test) was used. The categorical data (rating scales for pain and nausea and vomiting) were analysed by chi-square test and Fisher’s exact tests. The level of significance was set at \( p = 0.05 \).

Unfortunately the statistician became ill after performing the data entry and initial analysis. The original data remained inaccessible, including baseline variables such as age, the progression of use of analgesic drugs, pain score and PONV score over time, and results for the two operations separately.

### RESULTS

The trial was conducted in 1999. A total of 107 patients were included (see fig 1). Five patients were withdrawn: two patients in the PCA + acupuncture group scheduled for laparoscopic cholecystectomy withdrew their consent because they did not want to have acupuncture. Three patients, all in the PCA alone group (one with abdominal hysterectomy, and two with laparoscopic cholecystectomy) were withdrawn either because they received other forms of analgesia such as an epidural or because of a change in the scheduled procedure, for example from laparoscopic cholecystectomy to open surgery when it proved difficult to remove the gall bladder laparoscopically. Therefore, in total 102 patients completed the study, distributed as shown in table 1.

A total of 58 patients were analysed in the PCA arm and 44 in the PCA + acupuncture arm. Ninety-two patients were female; 50 underwent abdominal hysterectomy and 42 underwent laparoscopic cholecystectomy. There were 10 male patients in the laparoscopic cholecystectomy group; eight were randomised to PCA alone.

The operation time for the PCA + acupuncture group was 20 minutes longer than the PCA group, but the difference was not significant (table 2). There were no significant differences between the groups for use of PCA at different periods, or for total requirement for analgesic medication. The PCA + acupuncture group did not spend less time in recovery, and required PCA for an additional 13 h, though the difference was not significant.

Pain scores are shown in table 3 and fig 2, but unfortunately the exact measurement points are unknown because of the problems with the analysis described above. Although no patients in the PCA + acupuncture group scored greater than 1, the difference between the groups was not significant (chi square = 5.560, degrees of freedom (df) = 3, \( p = 0.147 \)). For PONV scores, 87.5% of the PCA group had no symptoms compared with 89.1% in the PCA + acupuncture group (chi square = 0.799, \( df = 1, p = 0.065 \)). Similarly for sedation scores (fig 3), the difference was not statistically different (chi square = 0.751, \( df = 2, p = 0.574 \)).

### DISCUSSION

This study found no significant effect of intraoperative electroacupuncture at 10 Hz in reducing postoperative requirement for PCA, nor time to recovery, nor scores for pain, nausea and vomiting or sedation in the postoperative period. This finding is limited by the fact that the patients in the
acupuncture group experienced longer operations, though the difference was not significant. There was a non-significant trend towards patients in the PCA + acupuncture group experiencing less pain. Other potential postoperative benefits of acupuncture include patient satisfaction, reduction in paralytic ileus or early discharge of the patient, but these were not measured in this study.

The study has the strengths of rigorous design including blinding of assessors, and quality of acupuncture; the researchers who provided the acupuncture are experienced, medically qualified acupuncturists and used a consistent technique.

Our results are somewhat limited by loss of access to the data from different time periods, which might show interesting differences. Another potentially important limitation to our findings is that the two groups were not homogenous for sex or the type of surgery, and it is possible, for example, that patients who underwent the relatively mild stimulus of laparoscopy experienced little postoperative pain, so no effect of acupuncture could be shown. The results for each operation should be analysed separately, but in this study the data were not collected separately.

Another limitation of this study is the choice of a single frequency of 10 Hz. It is possible that a frequency of 2–4 Hz would release endorphins more effectively than 10 Hz. Low frequency is associated with slow onset of analgesia, while high frequency (50–200 Hz) has rapid onset but short duration. There is no consensus on the optimum frequency, waveform or intensity for postoperative analgesia. The frequency used (10 Hz) was chosen with the intention of having features of both, but instead may have been inappropriate for releasing neurotransmitters. Different results might be achieved with the use of dense disperse mode of frequency (eg alternating 2 and 80 Hz) to stimulate the release of dynorphin as well as endorphin.

Another candidate for postoperative analgesia. Acupuncture stimulates the A delta nerve fibres and thereby activates three centres: the spinal cord, midbrain, and hypothalamic-pituitary axis, to cause analgesia. At the spinal site, enkephalin and dynorphin are released by stimulation at low frequency and block incoming nociceptive signals. Other transmitters (eg gamma-aminobutyric acid) may be released by stimulation at high frequency. In the midbrain, beta endorphin is released, which activates the descending system thus inhibiting spinal cord pain transmission through the effect of the monoamines, serotonin and noradrenaline. In the midbrain there is also a neuronal circuit that bypasses the endorphinergic links at high-frequency stimulation. Finally at the hypothalamic-pituitary axis, acupuncture may stimulate the pituitary to release beta endorphin to cause analgesia at a distance, and adrenocorticotrophic hormone which stimulates the adrenal gland to secrete the natural steroids which have an anti-inflammatory effect. Also, the hypothalamus spends axons to the midbrain, activating the descending inhibitory system. The hypothalamus may be activated only by low-frequency stimulation.

In their recent systematic review of 15 clinical trials, Sun and colleagues showed that, compared with sham acupuncture, acupuncture was associated with reduced morphine consumption, reduced pain scores and a lower incidence of opioid-related side effects such as nausea, dizziness, sedation, pruritus and urinary retention. The authors concluded that perioperative acupuncture may be a useful adjunct for acute postoperative pain management.

In conclusion, acupuncture given under general anaesthesia is unlikely to have a clinically useful effect, but research into preoperative acupuncture is likely to lead to improved patient care.

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