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Clinical Trials Study

Transcutaneous electroacupuncture alleviates postoperative ileus after gastrectomy: A randomized clinical trial

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Abstract

AIM
To investigate the efficacy and safety of transcutaneous
Transcutaneous electroacupuncture (TEA) to alleviate postoperative ileus (POI) after gastrectomy.

METHODS
From April 2014 to February 2017, 63 gastric cancer patients were recruited from the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China. After gastrectomy, the patients were randomly allocated to the TEA (n = 33) or control (n = 30) group. The patients in the TEA group received 1 h TEA on Neiguan (ST36) and Zusanli (PC6) twice daily in the morning and afternoon until they passed flatus. The main outcomes were hours to the first flatus or bowel movement, time to nasogastric tube removal, time to liquid and semi-liquid diet, and hospital stay. The secondary outcomes included postoperative symptom assessment and complications.

RESULTS
Time to first flatus in the TEA group was significantly shorter than in the control group (73.19 ± 15.61 vs 82.82 ± 20.25 h, P = 0.038), especially for open gastrectomy (76.53 ± 14.29 vs 87.23 ± 20.75 h, P = 0.048). Bowel sounds on day 2 in the TEA group were significantly greater than in the control group (2.30 ± 2.61/min vs 1.05 ± 1.26/min, P = 0.017). Time to nasogastric tube removal in the TEA group was earlier than in the control group (4.22 ± 1.01 vs 4.97 ± 1.67 d, P = 0.049), as well as the time to liquid diet (5.0 ± 1.34 vs 5.83 ± 2.10 d, P = 0.039). Hospital stay in the TEA group was significantly shorter than in the control group (8.06 ± 1.75 vs 9.40 ± 3.09 d, P = 0.041). No significant differences in postoperative symptom assessment and complications were found between the groups. There was no severe adverse event related to TEA.

CONCLUSION
TEA accelerated bowel movements and alleviated POI after open gastrectomy and shortened hospital stay.

Key words: Transcutaneous electroacupuncture; Gastrectomy; Postoperative ileus

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Core tip: Transcutaneous electroacupuncture (TEA) is a non-invasive and portable device. We applied TEA on postoperative gastric cancer patients to promote the bowel motility recovery. As far as we are concerned, it was the first attempt to investigate the efficacy and safety of TEA to alleviate postoperative ileus after gastrectomy.

INTRODUCTION
Gastric cancer is one of the most common malignancy burdens in China, especially in economically less developed regions. The standard surgery is total or subtotal gastrectomy with D2 lymph node dissection for gastric cancer with radical-cure intention. However, postoperative ileus (POI) is not rare and causes symptoms such as abdominal pain, distention, nausea and vomiting due to the accumulation of gas and secretions[1]. This probably affects patient recovery, prolongs hospital stay, and increases cost. The treatment for POI includes fasting, nasogastric depression, maintenance of fluid and electrolyte balance, parenteral nutrition, and exercise[2]. There is no clinical evidence for the use of prokinetic agents in POI and they may have severe adverse effects[3].

Modern electroacupuncture (EA) was developed from traditional Chinese medicine, which has been shown to accelerate gastric emptying and colonic motility[4,5]. A clinical study showed that electroacupuncture reduced the duration of POI after laparoscopic surgery for colorectal cancer[6]. A study in dogs indicated that transcutaneous EA (TEA) on Neiguan (ST36) is as effective as EA in improving rectal distention-induced intestinal dysmotility[7]. It is non-invasive and more portable.

Therefore, we applied the novel technique of TEA in gastric cancer patients to promote postoperative recovery of bowel motility. To the best of our knowledge, this was the first attempt to investigate the efficacy and safety of TEA to alleviate POI after gastrectomy.

MATERIALS AND METHODS
Patients
From April 2014 to February 2017, 63 patients were recruited from the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China. All the patients underwent total or partial gastrectomy. Inclusion criteria were as follows: (1) Gastric cancer patients without distal metastases; (2) age 18-85 years; (3) no severe history of cardiovascular, hepatic, hematological and renal diseases; (4) Eastern Cooperative Oncology Group (ECOG) performance status score ≤ 2; and (5) written informed consent was obtained before the study. Exclusion criteria were as follows: (1) Bile leakage or acute peritonitis; (2) cardiac pacemaker; (3) medication, such as metoclopramide, that affects bowel function; (4) history of chronic constipation; (5) history of abdominal surgery; (6) palliative gastrectomy; and (7) postoperative enema.

Procedures and TEA
This study was designed collaboratively by doctors from...
the Second Affiliated Hospital of Zhejiang University and Division of Gastroenterology and Hepatology, Department of Medicine, Johns Hopkins University, United States. TEA was developed by Professor Jian-De Chen in the Clinical Gastrointestinal Motility Laboratory, Johns Hopkins University School of Medicine, and gained safety certification in Zhejiang Province. The doctors who participated in the study were all trained in the TEA technique in Pace Translational Medical Research Center, Ningbo, China.

Sixty-nine patients were initially recruited but six declined to participate because of atrial fibrillation (n = 1), wrist bruise (n = 1), severe pneumonia (n = 1) and withdrawal without any reasons (n = 3). The remaining 63 patients were randomly allocated by computer algorithm to the TEA (n = 33) or control (n = 30) group (Figure 1). The TEA group started treatment on on day 1 after surgery, until passing flatus or on day 5. They had 1 h TEA on ST36 and Zusanli (PC6) twice daily in the morning (09:00-10:00) and afternoon (14:00-15:00). The EA sites of ST36 and PC6 were consistent with other studies (Figure 2). The parameters for ST36 were 2 s on, 3 s off, 25 Hz, 0.5 ms, 2-6 mA; while for PC6 it was 0.1 s on, 0.4 s off, 100 Hz, 0.25 ms, 2-6 mA. The electric current was gradually increased just below the patient’s pain threshold, and could be minimally adjusted during the procedure. The patients were allowed to sit even walk during the treatment as long as the TEA was continuously functioning well. The control group received no treatment and without any TEA being binded. The main outcomes were hours to the first flatus or bowel movement, time to remove nasogastric tube, time to liquid diet and semi-liquid diet and hospital stay. And the secondary outcomes were postoperative symptom assessment and complications.
breath, and wellbeing according to Edmonton Symptom Assessment System), and postoperative complications. Prolonged POI was defined as not passing flatus at > 5 d after surgery.

**Statistical analysis**

Statistical analysis was performed using SPSS version 24.0, using Student’s t test and χ² test, and variables were expressed as mean ± SD. P < 0.05 was considered as statistically significant.

**RESULTS**

A total of 63 patients (46 male, 17 female, age range: 37-75 years) were recruited and randomized to the TEA group (n = 33) and control group (n = 30). In the TEA group, 23 patients underwent open gastrectomy and 10 underwent laparoscopic gastrectomy. In the control group, 23 patients underwent open gastrectomy and 7 patients underwent laparoscopic gastrectomy. The baseline characteristics did not differ significantly between the groups (Table 1). The operating time in the TEA group was 210.79 ± 53.40 min compared with 213.36 ± 69.12 min in the control group (P = 0.868). The baseline characteristics did not differ significantly between the groups (Table 1). The operating time in the TEA group was 210.79 ± 53.40 min compared with 213.36 ± 69.12 min in the control group (P = 0.868).

Time to first flatus in the TEA group was significantly shorter than in the control group (73.19 ± 15.61 vs 82.82 ± 20.25 h, P = 0.038), especially for open gastrectomy (76.53 ± 14.29 vs 87.23 ± 20.75 h, P = 0.048). Bowel sounds on day 2 in the TEA group were significantly greater than in the control group (2.30 ± 2.61/min vs 1.05 ± 1.26/min, P = 0.017). For open gastrectomy, bowel sounds on day 2 and day 3 in the TEA group were significantly greater than in the control group (P = 0.006, 0.028, respectively) (Table 2). Time to nasogastric tube removal was earlier in the TEA than control group (4.22 ± 1.01 vs 4.97 ± 1.67 d, P = 0.049). Time to starting liquid diet was shorter in the TEA than control group (5.00 ± 1.34 vs 5.83 ± 2.10 d, P = 0.039).

Hospital stay was significantly shorter in the TEA than in the control group (8.06 ± 1.75 vs 9.40 ± 3.09 d, P = 0.041) (Table 2). Then, we excluded patients with complications of pneumonia, chyle leakage and pancreatic leakage, the hospital stay in the TEA group was still significantly shorter compared to the control group (7.73 ± 1.14 vs 8.59 ± 1.67 d, P = 0.026) (Table 2).

There was no significant difference in symptoms between the two groups including pain, tiredness, nausea, shortness of breath and wellbeing (Table 3).

There was no significant difference in postoperative complications between the two groups (P = 0.270) (Table 4). There was no prolonged ileus in TEA group, while there were three such cases in the control group. An adverse event of bruising on the wrist due to TEA was reported and the patient withdrew from the study. However, there was no severe adverse event.

**DISCUSSION**

In this prospective and randomized clinical study, we confirmed the role of TEA in the treatment of post-gastrectomy bowel motility recovery for the first time. TEA in gastric cancer patients significantly increased postoperative bowel movement; shortened time to first flatus, nasogastric tube removal, liquid diet and hospital stay, and it was safe.

POI is caused by impaired motility of the whole gastrointestinal tract due to abdominal or extra-abdominal surgery, which is the main reason for symptoms of discomfort and prolonged hospital stay. POI costs $1.5 billion annually in the United States[8]. Pathophysiologically, it is explained by release of inhibitory neural reflexes and inflammatory mediators from the site of injury[11]. However, the complex pathogenesis remains incompletely understood. Treatment for POI includes fasting, nasogastric depression, maintenance of fluid and electrolyte balance, and ambulation. Recent evidence supports that early oral or

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**Table 1 Baseline patient characteristic**

|                  | TEA (n = 33) | Control (n = 30) | P value |
|------------------|-------------|-----------------|--------|
| Age (yr)         | 63.0 ± 9.70 | 59.0 ± 8.30     | 0.103  |
| Sex (M/F)        | 22/11       | 24/6            | 0.183  |
| Chronic gastritis| 8/25        | 9/21            | 0.409  |
| Diabetes         | 1/32        | 0/30            | 0.524  |
| Hypertension     | 10/23       | 9/21            | 0.599  |
| BMI              | 22.32 ± 3.23| 21.85 ± 3.21    | 0.561  |
| ECOG score (1/2) | 27/6        | 24/6            | 0.553  |
| Preoperative activity level | 1.18 ± 0.392 | 1.17 ± 0.46    | 0.888  |
| Preoperative albumin (g/L) | 40.70 ± 3.38 | 40.08 ± 5.09 | 0.564  |
| Preoperative chemotherapy (Y/N) | 2/31        | 2/28            | 0.657  |
| Surgery (Open/laparoscopic) | 10/23       | 7/23            | 0.369  |
| Surgery (Billroth-I/II/Rou-en-Y) | 10/11/12    | 11/13/6        | > 0.05 |
| Surgery time (min) | 210.79 ± 53.40 | 213.36 ± 69.12 | 0.868  |
| pT staging (T0/1/2/3/4) | 1/7/14/8/3   | 0/8/7/10/5     | -      |
| pN staging (N0/1/2/3a/3b) | 1/7/14/8/3   | 11/3/4/10/0    | -      |
| Nasal enteral nutrition (Y/N) | 11/22       | 9/21            | 0.496  |
| PCIA/PCEA        | 32/1        | 29/1            | 0.833  |

TEA: Transcutaneous electroacupuncture; BMI: Body mass index.
Parenteral nutrition could be an option[2], but for gastric cancer patients, oral nutrition may increase anastomotic leakage rate in the early stage, and parenteral nutrition cannot be tolerated postoperatively. The use of prokinetic agents for treatment of POI is still controversial[3]. In short, there is currently no effective way to accelerate bowel motility recovery.

Acupuncture has been widely used for treatment of gastrointestinal diseases for thousands of years in China, and several studies have demonstrated that it helps gastric and colon cancer patients recover from POI[9,10]. A modern method of EA, which is modified from the traditional acupuncture, also controls postoperative pain and improves gastrointestinal motility after surgery. A randomized controlled trial indicated that EA reduced duration of POI after laparoscopic surgery for colorectal cancer[6]. Animal experiments found that EA at ST36 accelerated colonic motility and transit in freely moving rats[11], and improved restraint-stress-induced delay of gastric emptying via central glutamatergic pathways in conscious rats[12]. Jun-fan Fang et al[13] revealed that EA affected the patients by activating the vagus nerve instead of regulating local inflammation. EA also has a therapeutic effect on diabetic gastroparesis[14].

TEA is a new method of electrical stimulation via cutaneous electrodes placed at acupoints without needles. It is a non-invasive method that can be easily accepted by patients and even self-administrated at home. Chen et al[4,15,16] has proved that electroacupuncture improves impaired gastric, small intestinal[17] and colonic[18] motility, ameliorates gastric dysrhythmia[19], and accelerates gastric emptying[20,21], and it is used to treat gasoesophageal reflux, functional dyspepsia and irritable bowel syndrome[22]. TEA is effective in

### Table 2 Main outcomes

|                      | TEA (n = 33) | Control (n = 30) | P value |
|----------------------|-------------|-----------------|---------|
| Time to first flatus (h) |             |                 |         |
| Total                | 73.19 ± 15.61 | 82.82 ± 20.25 | 0.038a  |
| Open                 | 76.53 ± 14.29 | 87.23 ± 20.75 | 0.048a  |
| Laparoscopic         | 65.52 ± 16.53 | 68.31 ± 9.08  | 0.692   |
| Bowel sound on day 1 (/min) | 0.96 ± 1.80 | 0.63 ± 1.63  | 0.461   |
| Bowel sound on day 2 (/min) | 2.30 ± 2.61 | 1.05 ± 1.26  | 0.017a  |
| Bowel sound on day 3 (/min) | 4.30 ± 5.11 | 2.85 ± 2.19  | 0.068   |
| Bowel sound on day 1 (open) (/min) | 0.70 ± 1.29 | 0.70 ± 1.83  | 1.000   |
| Bowel sound on day 2 (open) (/min) | 2.52 ± 2.56 | 0.80 ± 1.0   | 0.006a  |
| Bowel sound on day 3 (open) (/min) | 4.74 ± 5.10 | 2.77 ± 2.23  | 0.028a  |
| Walk independently (h) | 27.10 ± 15.24 | 36.73 ± 25.91 | 0.074   |
| Walking duration per day (min) | 10.36 ± 6.65 | 9.13 ± 6.16  | 0.452   |
| Remove nasogastric tube (POD) | 4.22 ± 1.01 | 4.97 ± 1.67  | 0.049b  |
| Liquid diet (POD)     | 5.00 ± 1.34 | 5.83 ± 2.10 | 0.039b  |
| Semiliquid diet (POD) | 6.68 ± 1.78 | 7.60 ± 2.33 | 0.087   |
| Hospital stay (POD)   | 8.06 ± 1.75 | 9.40 ± 3.09 | 0.041b  |
| Modified liquid diet (POD) | 4.73 ± 0.94 (30) | 5.30 ± 1.23 (27) | 0.057   |
| Modified semiliquid diet (POD) | 6.30 ± 1.12 (30) | 7.11 ± 1.74 (27) | 0.039b  |
| Modified hospital stay (POD) | 7.73 ± 1.14 (30) | 8.59 ± 1.67 (27) | 0.026b  |

1P: Significant difference. TEA: Transcutaneous electroacupuncture; POD: Postoperative day.

### Table 3 Secondary outcomes according to Edmonton Symptom Assessment System

|                        | TEA (n = 33) | Control (n = 30) | P value |
|------------------------|-------------|-----------------|---------|
| Pain on day 1          | 3.79 ± 1.35 | 3.38 ± 1.50    | 0.266   |
| Pain on day 2          | 2.79 ± 1.10 | 2.55 ± 1.08    | 0.391   |
| Pain on day 3          | 2.39 ± 1.20 | 2.14 ± 0.90    | 0.416   |
| Tiredness on day 1     | 5.29 ± 2.13 | 5.42 ± 2.21    | 0.815   |
| Tiredness on day 2     | 4.17 ± 2.01 | 4.53 ± 1.96    | 0.467   |
| Tiredness on day 3     | 3.41 ± 2.58 | 4.33 ± 1.77    | 0.162   |
| Nausea on day 1        | 0.88 ± 1.77 | 0.55 ± 0.90    | 0.352   |
| Nausea on day 2        | 0.49 ± 1.50 | 0.38 ± 0.72    | 0.730   |
| Nausea on day 3        | 0.43 ± 1.72 | 0.32 ± 0.61    | 0.764   |
| SOB on day 1           | 0.73 ± 1.66 | 0.30 ± 0.97    | 0.213   |
| SOB on day 2           | 0.52 ± 1.60 | 0.35 ± 1.33    | 0.657   |
| SOB on day 3           | 0.55 ± 1.74 | 0.19 ± 0.96    | 0.391   |
| Wellbeing on day 1     | 5.97 ± 1.54 | 5.68 ± 1.75    | 0.494   |
| Wellbeing on day 2     | 6.88 ± 1.24 | 6.62 ± 1.57    | 0.469   |
| Wellbeing on day 3     | 7.41 ± 1.69 | 6.83 ± 1.64    | 0.225   |

TEA: Transcutaneous electroacupuncture; SOB: Shortness of breath.
and stand on the morning of day 1 after operation. Most patients tolerated pain well, they could even sit up in our study had less pain because of PCEA or PCIA, most cancer thoracic acupuncture or EA reduces pain in patients undergoing 3 on days 2 and 3. Several studies have proved that

between the two groups; it gradually decreased to < pain. As a consequence, the postoperative pain score routinely give patients analgesics to relieve abdominal anesthetists would like to perform patient-controlled in enhanced recovery after surgery (ERAS)

Early mobility or activity is recognized as a critical step bowel function transition. 2 and 3, which could be a good predication of normal bowel movements

marker capsule into the distal anastomosis to evaluate definitive association. Some studies have inserted a Sitz and bowel function, but it has not been established as a correlation between quantity or quality of bowel sounds

sounds on days 2 and 3 in subgroup analysis of patients have shown that EA and TEA at ST36 both improve the rectal distention-induced impairment of intestinal contraction, transit and slow waves mediated via the vagal mechanism[7], and needless TEA is as effective as EA in ameliorating intestinal hypomotility[7]. Huang et al[23] investigated the effects of TEA on healthy volunteers, and found that TEA improved impaired gastric accommodation and slow waves induced by cold drinks.

Acupuncture seems promising for treating POI after gastrectomy[9,24] and control of emesis during chemotherapy[25]. To the best of our knowledge, this was the first attempt to investigate the effectiveness of TEA to alleviate POI after gastrectomy. We found that TEA shortened the time to first flatus, along with more bowel sounds on days 2 and 3 in subgroup analysis of patients with open gastrectomy. There may be an approximate correlation between quantity or quality of bowel sounds and bowel function, but it has not been established as a definitive association. Some studies have inserted a Sitz marker capsule into the distal anastomosis to evaluate bowel movements[9,26]. As we noted, bowel sounds became more frequent and louder during the recovery period and increased to more than 2-4/min on days 2 and 3, which could be a good predication of normal bowel function transition.

In contrast, postoperative pain results in stress and affects the mobilization of patients after surgery. Early mobility or activity is recognized as a critical step in enhanced recovery after surgery (ERAS)[27]. The anesthetists would like to perform patient-controlled epidural analgesia (PCEA) or patient-controlled intravenous analgesia (PCIA) after surgery in our center, and we routinely give patients analgesics to relieve abdominal pain. As a consequence, the postoperative pain score was < 4 on day 1, and there was no significant difference between the two groups; it gradually decreased to < 3 on days 2 and 3. Several studies have proved that acupuncture or EA reduces pain in patients undergoing thoracic[28], abdominal[29], inguinal hema surgery[29], breast cancer[30], or kidney[31] surgery. The postoperative patients in our study had less pain because of PCEA or PCIA, most of the patients tolerated pain well, they could even sit up and stand on the morning of day 1 after operation, thus the pain-control availability of TEA was not validated.

Epidural anesthesia might diminish the positive effects of acupuncture by blocking the afferent and efferent neural pathways[22]. Administration of local anesthetic through a thoracic epidural catheter may decrease POI by reducing sympathetic neural input[1]. Based on these reasons, Simon et al[6] excluded patients who received epidural anesthesia or analgesia, and revealed that EA significantly reduced the duration of POI and postoperative analgesic requirement after laparoscopic surgery for colorectal cancer. Several laboratory and clinical studies have also proved that parasympathetic nerve activity was involved in the process of EA or TEA. Nevertheless, as mentioned before, PCEA or PCIA was routinely used in our center for pain control, which might have affected the outcomes, although there was no significant difference between the two groups.

This study had several limitations. First, the number of patients may have been inadequate to make the results convincing. Second, we did not apply ERAS to the postoperative recovery, which had been proved effective to reduce POI[27]. Third, the mechanisms underlying perioperative gastrointestinal waves or vagal tone associated with TEA should be confirmed in the future. Fourth, it was not a double-blind research, thus we could not exclude the placebo effect.

In conclusion, TEA accelerated bowel movements and alleviated POI and decreased hospital stay after open gastrectomy. It is a safe and convenient treatment for recovery from POI.

ARTICLE HIGHLIGHTS

Research background
Postoperative ileus (POI) after gastrectomy is not rare and causes various symptoms, which probably affects patient recovery, prolongs hospital stay, and increases cost. However, there is no effective way to alleviate POI until now.

Research motivation
Transcutaneous electroacupuncture (TEA) is a new-developed, non-invasive and portable device. It has been validated to improve intestinal dysmotility in dog experiment. But it remains unknown whether it is useful to alleviate POI for post-gastrectomy patients clinically.

Research objectives
The aim of this article was investigating the efficacy and safety of TEA to alleviate POI after gastrectomy.

Research methods
From April 2014 to February 2017, 63 gastric cancer patients were recruited from the Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China. After gastrectomy, the patients were randomly allocated to the TEA (n = 33) or control (n = 30) group. The patients in the TEA group received 1 h
TEA on Neiguan (ST36) and Zusanli (PC6) twice daily in the morning and afternoon until they passed flatus. The main outcomes were hours to the first flatus or bowel movement, time to nasogastric tube removal, time to liquid and semi-liquid diet, and hospital stay. The secondary outcomes included postoperative symptom assessment and complications.

**Research results**

Time to first flatus in the TEA group was significantly shorter than in the control group (73.19 ± 15.61 vs 82.82 ± 20.25 h, P = 0.038), especially for open gastrectomy (76.53 ± 14.29 vs 87.23 ± 20.75 h, P = 0.048). Bowel sounds on day 2 in the TEA group were significantly greater than in the control group (4.22 ± 1.01 vs 4.97 ± 1.67 d, P = 0.049), as well as the time to liquid diet (5.0 ± 1.34 vs 5.83 ± 2.10 d, P = 0.039). Hospital stay in the TEA group was significantly shorter than in the control group (8.06 ± 1.75 vs 9.40 ± 3.09 d, P = 0.041). No significant differences in postoperative symptom assessment and complications were found between the groups. There were no severe adverse events related to TEA.

**Research conclusions**

In this prospective and randomized clinical study, we confirmed the role of TEA in the treatment of post-gastrectomy bowel motility recovery for the first time.

**Research perspectives**

The authors proved that TEA was effective and safe to recovery post-gastrectomy patients from POI. So it will probably provide clinical surgeons with a novel non-invasive device to accelerate bowel function recovery and reduce hospital stay, which satisfies the concept of enhanced recovery after surgery (ERAS). Besides, TEA could be considered to be applied on other abdominal surgeries as well.

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