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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

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 ($2.30 \pm 2.61/\text{min}$ vs $1.05 \pm 1.26/\text{min}$, $P = 0.017$). 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.

Chen KB, Lu YQ, Chen JD, Shi DK, Huang ZH, Zheng YX, Jin XL, Wang ZF, Zhang WD, Huang Y, Wu ZW, Zhang GP, Zhang H, Jiang YH, Chen L. Transcutaneous electroacupuncture alleviates postoperative ileus after gastrectomy: A randomized clinical trial. *World J Gastrointest Surg* 2018; 10(2): 13-20 Available from:

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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

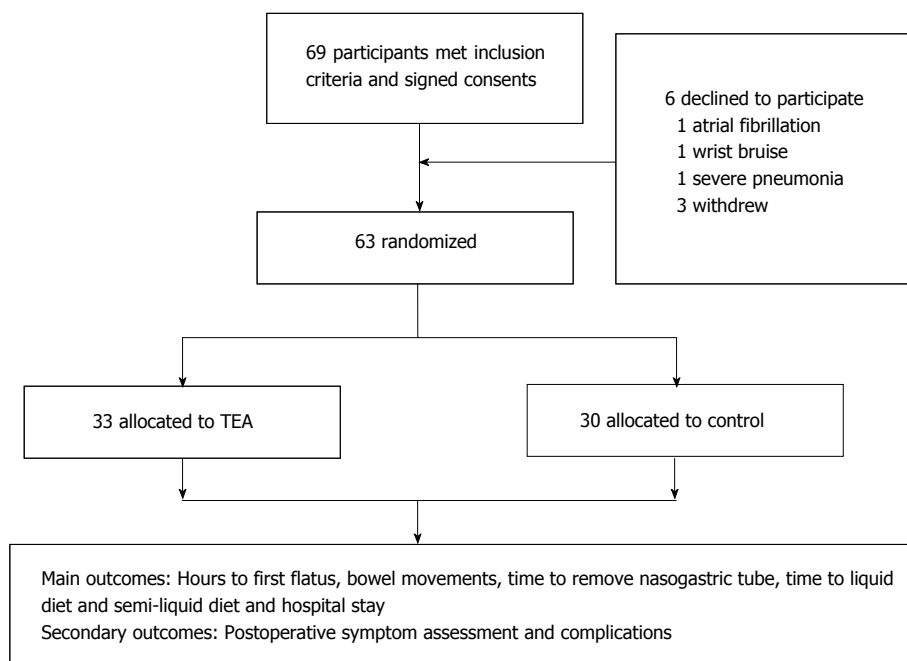


Figure 1 Flow chart of study participants. TEA: Transcutaneous electroacupuncture.

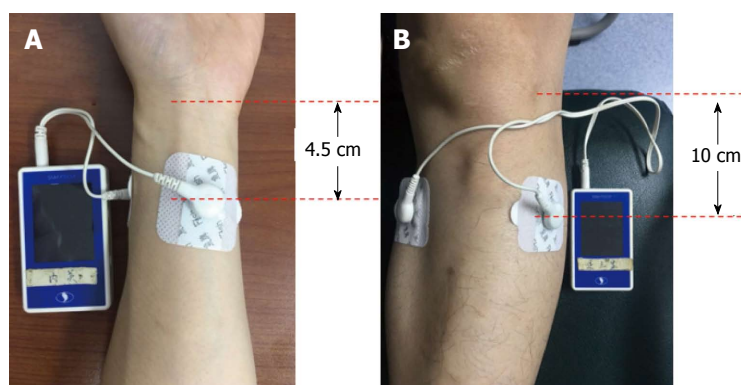


Figure 2 Transcutaneous electroacupuncture sites used in this study. A: Neiguan (ST36): Two electrodes were oppositely attached on the skin approximately 4.5 cm below the wrist wrinkle; B: Zusanli (PC6): Two electrodes were oppositely attached on the skin 10 cm below the lateral patella pit.

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 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 nasogastric tube removal, time to liquid and semi-liquid diet, and hospital stay. And the secondary outcomes were postoperative symptom assessment based on each patient's subjective scale (0-10, including pain, tiredness, nausea, shortness of

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	11/5/4/10/0	-
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.

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 χ^2 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).

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^[1]. 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

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	0.038 ^b
Open	76.53 ± 14.29	87.23 ± 20.75	0.048 ^b
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	0.017 ^b
Bowel sound on day 3 (/min)	4.30 ± 3.11	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	0.006 ^b
Bowel sound on day 3 (open) (/min)	4.74 ± 3.10	2.77 ± 2.23	0.028 ^b
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	0.049 ^b
Liquid diet (POD)	5.00 ± 1.34	5.83 ± 2.10	0.039 ^b
Semiliquid diet (POD)	6.68 ± 1.78	7.60 ± 2.33	0.087
Hospital stay (POD)	8.06 ± 1.75	9.40 ± 3.09	0.041 ^b
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)	0.039 ^b
Modified hospital stay (POD)	7.73 ± 1.14 (30)	8.59 ± 1.67 (27)	0.026 ^b

^bP: 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.

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^[5,20], and it is used to treat gastroesophageal reflux, functional dyspepsia and irritable bowel syndrome^[4]. TEA is effective in

Table 4 Postoperative complications

	TEA (n = 33)	Control (n = 30)	P value
Prolonged postoperative ileus	0	3	0.102
Wound infection	1	1	0.730
Pneumonia	1	1	0.730
Chyle leakage	2	1	0.182
Ventricular premature beat	1	0	0.524
Liver impairment	1	0	0.524
Pancreatic leakage	0	1	0.476
Total	6	7	0.270

TEA: Transcutaneous electroacupuncture.

treatment of functional dyspepsia^[21] and chemotherapy-induced nausea and vomiting^[22]. Experiments in dogs 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 needleless 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^[6], inguinal hernia 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^[32]. 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 ($2.30 \pm 2.61/\text{min}$ vs $1.05 \pm 1.26/\text{min}$, $P = 0.017$). 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 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. 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.

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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