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• Study Protocol

Electroacupuncture for the prevention of postoperative gastrointestinal dysfunction in patients undergoing vascular surgery under general anesthesia: study protocol for a prospective practical randomized controlled trial

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BACKGROUND: Postoperative gastrointestinal dysfunction (PGD) is one of the most common complications following major surgeries under general anesthesia (GA). Despite ongoing research and new drug treatments, abdominal distension within 24 h postoperatively occurs in 8%–28% of all surgeries. We aim to analyze the effectiveness of preventing PGD by preoperatively stimulating Neiguan (PC6), Zusanli (ST36) and Shangjuxu (ST37) bilaterally twice a day compared with sham-acupuncture treatment and standard treatment.
METHODS AND DESIGN: This is a single-center, prospective practical randomized controlled trial. All groups will be given standard treatments. Patients undergoing vascular surgery under GA will be included from the Vascular Surgery Unit in West China Hospital of Sichuan University, China, and divided into three groups. The experimental group will receive routine treatments and acupuncture at PC6, ST36 and ST37 bilaterally with electrical stimulation twice a day for 20 min preoperatively. The sham-acupuncture group will receive pseudo-electroacupuncture at sham acupoints of PC6, ST36 and ST37, which are 1 cun away from the real acupoints. The routine-treatment group will not receive electroacupuncture. The outcomes include the incidence of abdominal distention, abdominal circumference, the degree of abdominal distension, the first time of flatus and defecation, and hospitalization duration.
DISCUSSION: The results from this study will demonstrate whether preoperative electroacupuncture is an effective method for the prevention of PGD in patients undergoing vascular surgery under GA. This study may also provide a standardized acupuncture treatment for reduction of PGD.
TRIAL REGISTRATION: This study is registered with the Chinese Clinical Trial Registry: ChiCTR-TRC-13003649.
KEYWORDS: electroacupuncture; gastrointestinal dysfunction; vascular surgery; study protocol

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1 Introduction

Postoperative gastrointestinal dysfunction (PGD) is one of the most common complications in patients suffered from major surgeries under general anesthesia (GA)[1]. It is caused by intraoperative wound traction, abdominal adhesions or lack of visceral perfusion[2] and may lead to abdominal distension, constipation and other symptoms. Incidence of opioid-induced gastrointestinal dysfunction is as high as 81% in the United States[2]. Despite ongoing research and new drug treatments, abdominal distension within 24 h of operation occurs with 8%–28% of all surgeries[3]. In general, complication rates associated with endovascular surgery have decreased. For example, complications associated with respiratory procedures decreased by 77.27% from 2000 to 2003[4]. However, incidence rates of PGD have not decreased, and in fact, the incidence rate of PGD remained the same between 1974 and 2011 in China[5] and increased by 10% in Japan over a 5-year stretch at the turn of the 21st century[6]. Analysis of more than 5 000 records of patients undergoing major vascular surgery in 206 National Surgical Quality Improvement Program (NSQIP) hospitals from 2008 to 2009[7] showed that more than 25% of cases of endovascular treatment, regardless of the severity, suffered postoperative complications, postoperative intestinal obstruction and other gastrointestinal dysfunctions within 30 d of surgery. Patients suffering from PGD have longer hospital stays, greater financial burdens[8] and higher risks for other complications, like infections.

Because there are few effective treatments for PGD, prevention is paramount[9]. Acupuncture has gradually gained acceptance from physicians as an alternative therapy as clinical studies and basic research have demonstrated its efficacy. For example, a clinical study which enrolled 165 patients demonstrated that electroacupuncture (EA) could reduce the duration of postoperative ileus[10], a small-sample-size trial found that acupoint stimulation is useful for postoperative recovery of intestinal function[11], and another study showed that acupuncture helps in the recovery from stomach distension[12]. Animal experiments have identified factors that contribute to PGD, including reduction in the number of interstitial cells of Cajal and atrophy of their structure[13], activation of sympathetic nervous system and postoperative inflammatory cytokines[14] and leukocyte cell-induced nitrous oxide (NO) release, which restrains gastrointestinal peristalsis and causes intestinal inflammation[15]. Other animal studies have shown that acupuncture can ameliorate PGD by regulating these pathologic changes[16].

Acupuncture is widely used in departments of obstetrics and gynecology[17], gastrointestinal surgery[18] and orthopedics. In this study, our aim is to collect details about patients scheduled for vascular surgical procedures under GA, and to evaluate whether preoperative EA is an effective method for reducing PGD incidence in patients undergoing vascular surgery under GA. This study will also define a standard acupuncture treatment for reducing incidence of PGD.

2 Methods

2.1 Trial design

This is a single-center, prospective randomized controlled trial (RCT). Using a balanced random approach (section 2.6), all participants will be assigned to three groups: Group A (EA), Group B (sham-acupuncture) and Group C (routine-treatment).

2.2 Participants

We will recruit 159 cases scheduled to receive vascular surgery with GA within 24 h. These patients will be recruited from West China Hospital of Sichuan University (WCHSU), China, after meeting the eligibility criteria, and signing the informed consent. We plan to enroll the first patient on November 1, 2014 and end on November 1, 2016.

2.2.1 Inclusion criteria

Patients who meet all of the following conditions will be considered for enrollment: age ≥ 18 years; and patients scheduled for vascular surgical procedures under GA within 24 h.

2.2.2 Exclusion criteria

The exclusion criteria are as follows: patients with a history of hypo- or hyperthyroidism, cardiopulmonary disease, or psychological disorder; patients with history of EA; patients with cardiac pacemaker; menstruating phase of the menstrual cycle; refusal to accept acupuncture; unconscious before surgery; inability to communicate; participation in another clinical trial which could interfere with the primary endpoint of this study; bleeding disorders (hemophilia or fibrinogenemia); serious systemic disease (AIDS or sepsis); initial body temperature > 38.0 ℃ or < 36.0 ℃; known history of alcohol or substance abuse; necessity of systemic sedation for other reasons; emergency procedures; and pregnant or lactating women.

2.2.3 Withdrawal criteria

All withdrawn patients will be reported in the final results to guarantee maximum transparency. The withdrawal criteria are as follows: at the patient's own request or at the request of the legal representative; if, in the investigator's opinion (physician performing the acupuncture or physician performing the examination), continuation of the trial would be detrimental to the subject's wellbeing (*e.g.*, strong pain at the insertion points, allergic reactions, and other independent acute health problems).

2.3 Interventions

Patients receiving acupuncture therapy will be treated bilaterally at three distal acupoints: Neiguan (PC6), Zusanli