Auricular acupressure in relieving PONV and promoting gastrointestinal function recovery in females after bariatric surgery: study protocol for a prospective multicenter randomized controlled trial

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Research Article

Keywords: Auricular acupressure, Laparoscopic sleeve gastrectomy, Postoperative nausea and vomiting, Randomised controlled trial

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Abstract

Background

The incidence of postoperative nausea and vomiting (PONV) after laparoscopic sleeve gastrectomy (LSG) is up to 80% in China, and the current antiemetic means is mainly the use of antiemetics. This is a randomized, controlled, single-blind study to evaluate the safety and efficacy of auricular acupressure (AA) after LSG.

Methods

A multicenter, randomized, controlled, single-blind, superiority trial (RCT) was designed, and the relevant ethics committee approved the trial protocol. This study used AA as the experimental group and the control group act as a blank group. The primary evaluation index was the INVR score. The secondary indexes were time to first postoperative bed release, time to first anal defecation and time to return to fluid intake after surgery. A total of one hundred patients who met the inclusion and exclusion criteria were randomly grouped, and baseline measurements and outcome indicators were assessed preoperatively and postoperatively, respectively.

Discussion

This trial is a standardized, scientific clinical trial designed to evaluate the effect of AA on the degree of relief of nausea and vomiting and recovery of gastrointestinal function after LSG. We expect the study to provide a basis for promoting this therapy in clinical practice.

Trial registration


Administrative Information
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<td>Name and contact information for the trial sponsor</td>
<td>The 2022 Nursing Research Fund of the First Affiliated Hospital of Jinan University</td>
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<td>Role of sponsor</td>
<td>The corresponding authors* (Qingran Lin, Wah Yang) are members of the academic staff of the First Affiliated Hospital of Jinan University &amp; Jinan University and has the ultimate responsibility for the study design. The first authors# (Zhonghui Han, Hanlin Tang and Lilian Gao ) are responsible for data collection, study management, data analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication. Other authors acted as participants and supporters for this project. The funder has no role in the study design, data collection and analysis, decision to publish, or preparation of the protocol.</td>
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**Introduction**

Obesity and overweight are global public health problems¹, and people with obesity gradually accept its treatment as an emerging treatment for weight loss surgery and traditional weight loss methods. Among many bariatric surgery procedures, the most common one is LSG, which reduces food intake and absorption by removing the greater curvature of the stomach and reducing its volume of the stomach, thus changing the shape of the stomach to an intestinal tube². LSG is the preferred surgical procedure for non-overweight patients because of its simplicity, low postoperative complication rate, and long-term postoperative outcome³. It accounts for approximately 50% of bariatric surgery in various countries⁴–⁵.
The most common short-term complication after LSG is postoperative nausea and vomiting (PONV), which occurs in more than two-thirds of patients\(^6\). Women are an independent risk factor for the development of PONV\(^7\), and other risk factors include morbid obesity\(^8\), preoperative reflux or regurgitation symptoms\(^9\), preoperative anxiety\(^10\), altered gastric compliance due to the surgical approach\(^11\), etc. The occurrence of PONV can bring about consequences such as an imbalance of water-electrolyte balance in patients, aspiration pneumonia, and poor postoperative wound healing. In general, the occurrence of PONV will increase the patient's pain and prolong the patient's time, medical costs, and the number of readmissions\(^12\). In contrast, the recovery of gastrointestinal function has been the focus of laparoscopic surgery. And Studies have shown that if intestinal obstruction occurs after gastrointestinal surgery, it will bring a series of adverse consequences, including flatulence, delayed defecation, abdominal pain and bloating\(^13\).

Nevertheless, if left untreated, it will bring more severe complications, including gastrointestinal perforation, hospital infection, malnutrition and muscle atrophy. These complications are one of the most important factors contributing to prolonged hospital stay after abdominal surgery\(^14\). Moreover, a prolonged hospital stay increases the risk of hospital infection while increasing the financial burden on the patient\(^15\).

Currently, antiemetics are mainly used to alleviate postoperative PONV after LSG, including a series of measures to prevent PONV in a perioperative multidisciplinary approach\(^16\), using the antiemetics dexamethasone and gastroflucan to treat postoperative PONV after LSG. Dexamethasone can be used as a preoperative prophylactic antiemetic drug and in combination with other drugs that can produce certain therapeutic effects\(^17\). However, studies have shown that even with the combined use of two or more prophylactic and antiemetic therapeutic measures in the perioperative period of bariatric surgery, the incidence of PONV in patients with multiple PONV risk factors is still as high as 70%\(^18\). Fewer studies related to interventions for postoperative PONV after LSG through nursing measures. A randomized controlled study of perioperative transcutaneous electrical acupoint stimulation (TEAS) of two acupuncture points in patients to prevent postoperative PONV after LSG showed that the combination of TEAS with dexamethasone and toltestrone reduced the severity of postoperative PONV in female patients after LSG. Less attention has been paid to the aspect of function recovery. Currently, the main clinical focus is promoting the recovery of gastrointestinal function in patients from accelerated rehabilitation surgery\(^19\). And related measures include the absence of postoperative gastric tubes, drains, catheters, and restriction of fluid administration, which can increase patients' willingness to get out of bed on their own\(^20\text{–}21\). Encouraging patients to eat orally as early as possible after upper gastrointestinal surgery has also been found to promote recovery of gastrointestinal function and shorten the length of hospital stay\(^22\).

AA as a TCM nursing technique has been successfully applied to relieve patients' PONV after various laparoscopic surgeries and to promote gastrointestinal tract function recovery because of its safety, noninvasiveness, ease of operation, and low cost, and studies have shown that AA can regulate
gastrointestinal tract function by stimulating the vagus nerve in the ear, which in turn transmits stimulation to the vagus nerve in the stomach. However, AA has not been used to alleviate PONV after LSG and promote recovery of gastrointestinal tract function after LSG.

Therefore, this study aimed to observe the clinical efficacy of relieving PONV after LSG and postoperative gastrointestinal function recovery in women. The results of this study may provide new ideas for the prevention and relief of postoperative PONV after LSG and for the recovery of gastrointestinal function.

**Objectives**

The objective was to apply auricular pressure therapy to women undergoing laparoscopic sleeve gastric surgery to observe its effectiveness in relieving possible nausea and vomiting and promoting recovery of postoperative gastrointestinal function.

**Trial Design**

This study aimed to observe the clinical efficacy of AA in relieving PONV after LSG in women and promoting recovery of postoperative gastrointestinal function.

**Methods: Participants, Interventions And Outcomes**

**Study setting**

The study is a multicenter, randomized, controlled, single-blind, superiority trial (RCT) registered in the Chinese Clinical Registry on June 13, 2021. The registration number is ChiCTR2100047381. The trial centers are the First Affiliated Hospital of Jinan University in Guangzhou, Guangdong Province, China and Luoyang Hospital of traditional Chinese medicine in Luoyang City, Henan Province, China, and the study design and protocol manuscript followed CONSORT specifications.

**Eligibility criteria**

**Inclusion criteria**

- Age: between 18 to 65 years of age.
- Female patients with a physical status of I or II according to the American Society of Anesthesiologists (ASA) classification criteria; and who have completed their first LSG procedure under general from October 2021 - April 2022.
- BMI ≥ 27.5.

**Exclusion criteria**
• Contraindications of AA, such as skin rash or local infection in the skin area stimulated by acupoints;
• History of chemotherapy within 4 weeks or radiotherapy within 8 weeks;
• Nausea and vomiting occurred 24 hours before the operation;
• Hormone use within 1 week;
• Abnormal liver and kidney function;
• Gastroesophageal reflux disease
• Investigator was unable to complete the study for other reasons;
• Those who regain weight after weight loss and metabolic surgery.

Who will take informed consent?

Written informed consent was obtained from potential participants who met the inclusion and exclusion criteria by a pre-trained researcher. The informed consent form was written in Chinese, explaining the study to the person, asking whether the patient was willing to participate, and asking the patient to sign the informed consent form if they agreed.

Additional consent provisions for the collection and use of participant data and biological specimens

Prior trained study staff will explain this to participants simultaneously as they sign the informed consent form.

Interventions

Eligible participants will be divided into two groups, one for the control group and one for the experimental group. The control group was treated with conventional antiemetic drugs. The experimental group was based on conventional antiemetic drugs taking the three auricular acupoints "Shenmen(TF4), Stomach(CO4), occiput(AT3), Inferior cortex(AT4), Sympathetic nerve(AH6a), as the main acupoints and "Small intestine point(CO6) and Large intestine point(CO7)" as the supporting acupoints. After disinfection of the ear with a 75% alcohol cotton ball, the left hand fixed the auricle. The right hand held the vascular clamp and put the adhesive tape (0.8cm×0.8cm) with magnetic beads in the above ear points, and gave the patient pressure on the ear points within 24h before surgery and 48h after surgery, using the index finger and thumb to twist the pressure in front of and behind the ear, with light and heavy hand, pressing each point for 3~5min, 3~4 times a day, once every other day, rotating between the two ears, with the intensity to produce soreness, numbness, swelling, pain and heat in the ear.

Intervention description
The study is conducted 24 hours before and 48 hours after the patient's surgery. The auricular patches needed for this study will be purchased from a fixed manufacturer, and the antiemetic medication will be from the same company.

**Criteria for discontinuing or modifying allocated interventions**

Patients may withdraw from this study at any time during the study period if they feel any discomfort with the intervention.

**Strategies to improve adherence to interventions**

First, we will adhere to the principle of voluntary participation of patients in this trial.

We will establish a good relationship with the patients during the experiment to win their trust and cooperation. During the patient's hospitalization, we will strengthen the education on postoperative nausea and vomiting, knowledge of gastrointestinal function recovery, and knowledge of AA, a Chinese medicine nursing technique, to draw the patient's attention to this trial; and explain to the patient the purpose of the study, the content of the intervention, and how the patient needs to cooperate. During the education process, we pay attention to user-friendly language, maintain a gentle and friendly attitude, and show due compassion to make patients feel relieved and trust the researcher. We will also inform patients about possible adverse reactions and treatments during treatment, which will help reduce patients' non-compliance.

**Relevant concomitant care permitted or prohibited during the trial**

No changes to the usual care pathway are required for this study, and these elements of care will be used for all trial groups.

**Provisions for post-trial care**

There is no anticipated harm and compensation for trial participation.

**Outcomes**

1. **Baseline data**

   a. Demographic data included: demographic data were recorded using our designed basic data questionnaire, including marital status, occupation, education level, history of smoking, history of alcohol consumption, history of previous surgery, history of the previous PONV, history of PONV, menstrual status, whether auricular pressure treatment had been performed, and whether auricular pressure was considered effective.

   b. Clinical data included: anesthesia protocol, operation time, anesthesia time, intraoperative blood loss, intraoperative blood transfusion, vital signs (temperature, heart rate, respiratory rate, blood pressure) and
other data.

2. Primary outcome measure

Each patient will be assessed for PONV three times during the study using the INVR scale at 12h, 24h and 48h after the end of the procedure.

3. Secondary outcome measures

Time of the first PONV

Time to the first anal evacuation of bowels

Time to resume fluid intake after surgery

Time to first postoperative bedtime activity

Study endpoint: patients 48h postoperatively.

Participant timeline

A nursing postgraduate who knows the grouping will conduct the study to document and assess the patients. The INVR scale will be used to assess the patient's PONV three times during the trial with 12h postoperatively, 24h postoperatively and 48h postoperatively, as well as to record secondary observations of the patient at any time. After obtaining informed consent from patients, patients in the experimental group will receive auricular pressure 1-2 times within 24h preoperatively, 3-4 times within 24h postoperatively, and 2-3 times within 48h postoperatively.

Sample size

The literature reports that PONV is still as high as 70% with the routine use of antiemetics after LSG. This study expects the incidence of PONV in the experimental group to be reduced to 35%; the study was divided into 2 groups, the test criteria \( \alpha = 0.05 \), test efficacy \( 1 - \beta = 0.90 \), based on the above parameters, calculating the sample size according to this formula

\[
n = \frac{Z_{\alpha} \sqrt{2 \times p(1-p)} + Z_{\beta} \sqrt{p_1(1-p_1) + p_0(1-p_0)}}{(p_1 - p_0)^2}^2,
\]

yielding \( n_1 = n_2 = 42 \) cases, resulting in a sample size of 42 cases per group and an expected potential loss to follow-up of 20%, for a total of 100 patients to be recruited (approximately 50 patients per group).

Recruitment

Before starting this study, we introduced the study in detail to the head of the Department of Metabolic and Bariatric Surgery of Jinan University, obtained their consent, and then started this study.
The study content was explained to the participants one day before the participants’ surgery, and the participants were asked if they had volunteered to participate in this study.

**Assignment of interventions: allocation**

**Sequence generation**

Patients participating in the trial will be randomly assigned to either the experimental group (ear group) or the control group (blank group). A simple random sequence will then be generated by a member of the study team according to a random number table, and the sequence will be placed in a sealed and opaque envelope. Female patients who meet the inclusion and exclusion criteria, sign an informed consent form, and ultimately undergo LSG will be given a random number that corresponds to the previous simple randomization sequence corresponding to the previous simple randomization sequence. An investigator opens the envelope at the end of the experiment in front of the patient to unblind her.

**Concealment mechanism**

This was not applicable because the participants could see who administered auricular compression therapy and only used conventional antiemetic therapy.

**Implementation**

The randomization sequence was generated by one researcher according to a random number table, and another researcher was responsible for registering the allocation between groups.

**Assignment of interventions: Blinding**

In this study, the researchers responsible for the statistical data are blind. In addition, the experimental process will periodically evaluate whether the experimental process conforms to the CONSORT statement. Variables that do not fall within the scope of intervention but may affect the study results were recorded.

The study design was open, and only the outcome entrants were blinded, so there was no unblinding.

**Data collection and management**

On the day of the study, patients were asked if they volunteered to participate in the study and were surveyed using a specially designed paper-based questionnaire that included patient demographics, history of PONV and any other causes of nausea and vomiting other than surgery, as well as knowledge of AA therapy and whether they had received it previously.

In this study, the INVR scale was used to assess PONV in patients. The INVR scale assesses the severity of PONV within 12 hours using three dimensions: nausea, vomiting, and dry vomiting, as well as the frequency, duration, and severity of each of the three symptoms, and is scored on a five-point Likert scale.
The higher the score, the more severe the PONV, Mei R. Fu51[23] and other scholars Chineseized the INVR scale in 2002 and applied it to measure nausea and vomiting in oncology patients undergoing chemotherapy and mothers. The advantages of this scale are: (1) it is evaluated once every 12 hours, and the time division is accurate; (2) the symptoms of nausea, vomiting and dry vomiting can be evaluated separately, and the symptoms of nausea, vomiting and dry vomiting can also be scored together; (3) it is convenient for clinical workers to grasp the situation of patients more comprehensively, and in clinical medical research, each symptom can also be studied separately, and the data obtained are count data, which is convenient for subsequent statistical analysis. The INVR scale is the most accurate evaluation tool among the currently available evaluation tools. Therefore, the INVR scale was selected to evaluate patients' PONV symptoms in this study.

A researcher visited the patient daily for 24 hours before and 48 hours after surgery to inquire about PONV, observe whether the auricular patch was in the appropriate position, and observe whether the patient was experiencing any adverse effects from the AA treatment, and also to inform the patient to notify the health care provider of any discomfort.

Data management

To ensure the research quality, it has been revised by relevant experts of the Department of Metabolic and Bariatric Surgery of Jinan University, acupuncture experts, medical statisticians and research Methodists. Finally, strict inclusion and exclusion criteria were established. To ensure the objectivity of the data, the data entry personnel are blind, and the implementation personnel of the project have completed the training in auricular point sticking therapy. The experimental materials used in this study are purchased uniformly. In conclusion, this study can ensure that the findings of the experiment are reliable. We require the researchers to be careful in the data entry and attach the corresponding evaluation report. The original data cannot be changed at will. If it needs to be modified, a detailed description should be made and signed by the staff who modified. This study includes two levels of quality inspection systems. The first level is quality control inspection. A quality inspector appointed by the study leader will design a quality checklist and monitor all raw data, data reports and adverse event records according to the checklist. The second level is quality supervision. Quality supervision is assumed by the research team leader, who is responsible for (1) monitoring the whole process of research design and project implementation of researchers; (2) Confirm the authenticity, accuracy and completeness of data records and CRF-related data; (3) Ensure the consistency of original data.

Confidentiality

All patients participating in this study will be assigned a number, and all data on participants will be stored securely in a computer dedicated to the study, requiring a password to access this data. The collection and processing of personal data on participants enrolled in this study will be limited to those aspects necessary for this study.
Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use

This study did not involve the collection of biological specimens.

Statistical methods

Statistical analysis was performed using SPSS 27.0 software and analyzed data were expressed as mean ± standard deviation, median (four-digit range), or numbers (percentages). To compare the general information and clinical characteristics of the two groups, the Shapiro-Wilk test was used to confirm the normal distribution of the data. A two-sample t-test was then used for analysis; otherwise, the Wilcoxon rank sum test was used. The Pearson chi-square test or Fisher exact test was used to compare the differences in the incidence of PONV between the two groups.

We do not anticipate that this study will present problems that would be harmful to participants, and therefore, no interim analysis will be conducted.

Methods for additional analyses

No subgroup analysis was required for this study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

Participants with complete data will be analyzed using the statistical methods in the study protocol, and for participants with only pre- or post-intervention data, we will exclude such data.

Plans to give access to the full protocol, participant level-data and statistical code

Public access will be granted to the full protocol, participant-level dataset and statistical code.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee
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<td>Luoyang Hospital of traditional Chinese medicine</td>
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<td>Principal investigator:</td>
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</table>
Composition of the data monitoring committee, its role and reporting structure

The event will be investigated by our safety supervisor, an experienced nurse, who will interview the subject, check the subject’s health status and fill out an adverse event form if an adverse event occurs.

Adverse event reporting and harms

When an adverse event occurs, whether or not it is related to the treatment method of this study, researchers involved in the treatment of the subject should keep detailed records, including the time of
occurrence, the time of discontinuation and the duration of the event (which can be recorded in days or h), the severity and frequency, the treatment method and results. The analysis of the causal relationship between the adverse event and the trial treatment method, the follow-up of adverse events and serious adverse events, etc. All clinical information about the adverse event should be kept in the original file.

**Frequency and plans for auditing trial conduct**

The trial steering group and ethics committee will review the entire trial process.

**Plans for communicating important protocol amendments to relevant parties**

During the review process, the results of amendments to the study protocol will be submitted to the Ethics Committee for review and approval, and subjects will be informed of changes in the study.

**Dissemination plans**

The results of this study will be disseminated through participation in academic conferences and the publication of academic papers.

**Discussion**

PONV after LSG surgery occurs mainly in the postoperative 48h. There are fewer studies on PONV after LSG, and clinical healthcare providers will be more inclined to focus on other serious complications caused by PONV rather than simple nausea, vomiting, and dry heaving\. At the same time, nursing researchers are more likely to conduct studies on aspects such as long-term postoperative diet and exercise. Whereas PONV can bring a series of adverse consequences, most commonly severe PONV can increase patient suffering. How to make the perioperative period of the sleeve stomach smoother for patients and improve patient satisfaction in hospital is now a growing concern. And auricular pressure as a noninvasive, fast-acting, easy-to-use and inexpensive treatment modality has been used after laparoscopic surgery, mainly gynaecological laparoscopy, to relieve PONV.

This study was conducted based on a long clinical experience to explore the efficacy of auricular pressure on PONV in female patients undergoing LSG. One hundred subjects will be included in the study and divided into experimental and control groups according to the randomization principle. The variables that will be assessed postoperatively are INVR scale score, time to first PONV, time to first anal discharge and defecation, time to return to fluid intake postoperatively, and time to first postoperative bed activity. To avoid bias, all subjects included in this study had their anesthesia done by the same team of anesthesiologists and all postoperative treatments were performed by the same medical team.

Studies have shown that stimulation of the auricular region will cause an increase in the discharge of the solitary bundle nucleus and the dorsal nucleus of the vagus nerve while promoting gastric motility\. The vagus nerve of the stomach has a role in regulating the function of the gastrointestinal tract, which will be stimulated by massaging the magnetic beads pasted on the ear in order to transmit the
stimulation to the vagus nerve of the stomach and regulate the function of the gastrointestinal tract, thus relieving patients of PONV and other uncomfortable symptoms. However, AA has not yet been used to relieve PONV after LSG. The researcher selected the main points "shenmen (TF4)," "stomach (CO4)," "occiput (AT3)," "inferior cortex (AT4)," "sympathetic nerve (AH6a)," and the supporting points "small intestine point (CO6)," "large intestine point (CO7)" to calm and relax the mind by pressing "shenmen" and "occiput." Pressing the "inferior cortex" regulates the higher nerve centers, inhibits the excitation of the cerebral cortex of the digestive system to stop vomiting and has the effect of regulating gastrointestinal function; pressing the "sympathetic nerve" regulates plant nerve function and relieves PONV caused by stimulation of the vagus nerve endings; pressing the "stomach" regulates qi and broadens the middle, lowering the rebellion and stopping vomiting (preventing food from being vomited out of the stomach); pressing the matching point "small intestine point" and "large intestine point" can promote intestinal peristalsis and relieve flatulence.

Although changes in patient medication are discouraged in this study for ethical reasons, we anticipate a reduction in consumption, particularly for medications that subjects administer as needed for symptom control. This study will only record changes in the amount of antiemetic-related medicines taken by the subjects during their hospitalization.

In conclusion, the use of AA to relieve PONV after LSG in women and to promote gastrointestinal function recovery may not only reduce the pain caused by PONV after LSG in patients but also provide new ideas for the prevention and relief of PONV after LSG, as well as reduce the cost of PONV after LSG treatment and reduce the economic burden on patients and improve patient satisfaction in hospital. The primary purpose of this study is to help female patients to spend 48h after LSG more smoothly, to reduce the postoperative pain caused by PONV, to promote patient recovery, and improve patient satisfaction in the hospital[7].

The assumption is that this study ultimately yields positive results. In that case, it will be possible to recommend the implementation of this technique in the treatment protocol for female patients undergoing LSG as well as for male patients and to justify new cost-effectiveness studies or other studies in which symptoms of PONV occur after surgery.

**Trial Status**

The project received ethical approval in June 2021. The first patient was randomly assigned in January 2021 and we hope to include the calculated sample size within 8 months. The trial is expected to end in October 2022.

**Abbreviations**

LSG
Laparoscopic sleeve gastrectomy
Declarations

Acknowledgements

We thank Jinan University, the Department of Metabolic and Bariatric Surgery of Jinan University, and the Department of Gastrointestinal Surgery of Luoyang Hospital of Traditional Chinese Medicine for their support of this research project.

Authors’ contributions

Wah Yang is the Principal Investigator; He conceived the study and led the proposal and protocol development. Qingran Lin contributed to the study design and the development of the proposal. Hanlin Tang and Zhonghui Han was the lead trial methodologist. All authors read and approved the final manuscript.

Funding

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Availability of data and materials

The principal investigator and designated study personnel will have access to the final trial data set. We do not disclose any contractual agreements that limit this access for the investigators.

Ethics approval and consent to participate

Participation in this study was strictly voluntary, and patients were allowed to withdraw from the study at any time without cause. All subjects in this study were informed about the experimental procedure through an informed consent form, and all subjects signed the informed consent form. The study protocol, patient information and informed consent were approved by the Ethics Committee of the First Affiliated Hospital of Jinan University. In addition, patients who refused to participate in this study will be treated according to clinical criteria. Such patients will not be included in the study and will not receive specific follow-ups.
Consent for publication

The model consent form and other related documentation will be provided on request.

Competing interests

The authors declare that they have no competing interests.

References


Figures
sympathetic nerve (AH6a) • shenmen (TF4)
small intestine point (CO6) • stomach (CO4)
large intestine point (CO7) • occiput (AT3)
inferior cortex (AT4)