Abdominal Acupuncture for Gastrointestinal Function Recovery After Gynecologic Laparoscopic Surgery: A Randomized Clinical Trial

Guangdong Provincial Hospital of Chinese Medicine,

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Information Leaflet for Informed Consent

Dear Patient:

Your physician has confirmed that you are a postoperative patient following laparoscopic total hysterectomy.

We would like to invite you to participate in a clinical study investigating the efficacy of abdominal acupuncture in promoting gastrointestinal functional recovery after gynecological laparoscopic surgery. This is a randomized controlled trial designed to collect data on symptoms, clinical examinations, and laboratory outcomes in order to evaluate the therapeutic effectiveness of the intervention.

Before deciding whether to participate, please take time to read the following information carefully. It will help you understand the purpose of this study, its procedures and duration, as well as the potential benefits, risks, and discomforts that may be associated with participation. If you wish, you may ask your physician for further explanation, or discuss the study with your family and friends to assist you in making an informed decision.

Study background and objectives

Postoperative gastrointestinal dysfunction (POGD), commonly referred to as postoperative ileus (POI), is a well-recognized complication following abdominal surgery. Contemporary studies indicate that POI typically persists for three to five days and is characterized by transient impairment of gastrointestinal function, involving mucosal injury, disruption of barrier function, and impairment of gastrointestinal motility. Clinically, patients present with diverse manifestations, most frequently nausea, vomiting, abdominal pain, diarrhea, difficulty in defecation, and diminished or absent bowel

sounds.

The pathogenesis of POGD is multifactorial and complex. It is influenced by surgical techniques and intraoperative manipulation, alterations in the internal environment, changes in blood perfusion, anesthetic and analgesic agents, postoperative inflammatory responses, and neuroendocrine reactions. Among gynecological patients, specific physiological characteristics, psychological distress, and surgical positioning further increase susceptibility. Consequently, effective prevention and management of POGD are of paramount clinical importance.

Conventional Western medical approaches include general therapies such as enemas and fluid replacement, pharmacological interventions using agents such as metoclopramide and mosapride, endoscopic procedures, gastrointestinal pacemakers, and surgery. However, pharmacological treatments often introduce adverse effects, including drowsiness, irritability, or even additional gastrointestinal symptoms; while procedural and surgical interventions carry inherent risks, which may exacerbate rather than alleviate dysfunction.

Traditional Chinese Medicine (TCM) has shown promising results in the treatment of POGD through oral herbal formulations, acupuncture, moxibustion, herbal enemas, and acupoint injections. These approaches are currently employed mainly as complementary therapies and present unique advantages, including individualized treatment strategies based on syndrome differentiation, well-established efficacy, high safety, and low cost. Nevertheless, limitations remain, as treatment regimens often rely heavily on physician experience, research designs lack methodological rigor, diagnostic criteria are not standardized, mechanisms of action remain unclear, and safety analyses are not comprehensive. Moreover, both Chinese and Western medicine currently lack targeted research

specifically addressing gastrointestinal dysfunction following gynecological laparoscopy. It is therefore important to further explore TCM-based therapies, particularly their contributions to improving overall postoperative quality of life, while highlighting the simplicity, cost-effectiveness, and practicality of traditional methods.

According to prior clinical and experimental studies, abdominal acupuncture may offer distinctive advantages, including broad indications, minimized discomfort, relatively stable efficacy, and potential bidirectional regulatory effects. Its therapeutic rationale lies in stimulation of abdominal acupoints to regulate the flow of qi, thereby restoring physiological balance. Among existing approaches, Bo-style abdominal acupuncture is most commonly applied. This method leverages the unique therapeutic potential of abdominal points to augment intestinal peristalsis, promote gastric emptying, facilitate normalization of gastrointestinal hormones, and ultimately enhance gastrointestinal recovery. Compared with standard Western or integrative therapies, abdominal acupuncture is associated with fewer adverse effects. Furthermore, relative to traditional body acupuncture, patients generally experience less discomfort, with milder sensations of soreness, numbness, distension, or pain during treatment.

The aim of the present study is to evaluate, through a randomized controlled clinical trial, the efficacy of abdominal acupuncture in accelerating gastrointestinal recovery after gynecological laparoscopic surgery. In addition, the study seeks to assess its effects on postoperative pain, disease activity, and overall quality of life. This single-center trial will be conducted in the Department of Gynecology at Guangdong Provincial Hospital of Traditional Chinese Medicine (Dade Road General Hospital campus), with an expected enrollment of 76 voluntary participants.

The study will be led by Dr. Yi Chen, a Chief Physician of TCM, Professor, Doctor of Medicine, and postgraduate supervisor. She has been recognized as one of the first Young Distinguished TCM Physicians of Guangdong Province, is listed among Guangzhou's outstanding mid-career doctors, and has received the honorary title of "Yangcheng Good Doctor." Her research focuses primarily on integrative approaches to the management of gynecological malignancies, and she has led or participated in multiple projects funded by the National Natural Science Foundation of China and the Guangdong Provincial Bureau of Traditional Chinese Medicine. With extensive clinical and academic experience, she is fully qualified to conduct this investigation.

The Department of Gynecology, founded in the 1930s, has since evolved into a large, comprehensive unit integrating clinical care, research, and education. It is staffed by a team of distinguished experts with high-level theoretical training and broad clinical experience. The department was designated a National Key Discipline in 2002 and serves as the leading unit of the Gynecology and Obstetrics Committee of the Guangdong Association of TCM. It has been recognized as a key specialty by the National Administration of TCM, the Ministry of Education, and the Ministry of Health, and is classified as a provincial-level top TCM discipline.

This study has been reviewed and approved by the Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine. Ethical review confirmed that the research adheres fully to the principles of the Declaration of Helsinki and complies with the requirements of medical ethics.

If you agree to take part in the study, you will need to do the following:

1. Prior to enrollment, you will undergo the following assessments to determine your eligibility for participation in this study.

Your physician will inquire about and document your medical history, current and previous treatment regimens, as well as prior examination results. In addition, you will be required to provide preoperative test results, including complete blood count, liver function tests, emergency biochemical profile, and electrocardiography.

2. If these assessments confirm your eligibility, the study will proceed according to the following steps.

You will first complete the standard postoperative examinations, including gastrointestinal evaluations, along with three validated scoring instruments: the Visual Analogue Scale (VAS) for pain, the gastrointestinal symptom scale, and the Gastrointestinal Quality of Life Index (GIQLI). This process will require approximately 15 to 30 minutes.

Once the study begins, a computer-generated randomization sequence will determine whether you will receive abdominal acupuncture plus conventional postoperative care or conventional postoperative care alone. Each participant has a 50% probability of allocation to either group. Neither you nor your physician will know or be able to influence the assigned treatment in advance. The observation period will last 19 days, during which you will be asked to complete questionnaires and cooperate with necessary examinations both before treatment initiation and at the end of the intervention. These evaluations are intended to provide valuable insight into your recovery and overall quality of life after surgery.

The treatment procedures are as follows. Intervention group: In addition to standard postoperative management, you will receive abdominal acupuncture. Lying in the supine position with the abdominal area fully exposed, your skin will be disinfected according to routine practice. A sterile disposable acupuncture needle (0.30 mm × 40 mm) will then be inserted perpendicularly into designated

acupoints. Gentle rotational techniques will be applied without lifting or thrusting. Every effort will be made to minimize or eliminate discomfort. Primary acupoints will be needled to the Di level (depth: 1.0–1.5 cun), while secondary acupoints will be inserted to the Ren level (depth: 0.5–1.0 cun). Needle depth will be adjusted according to individual body habitus, and the typical needle sensations of soreness, numbness, distension, or heaviness will not be required. Needles will be retained for 30 minutes, during which infrared radiation therapy will be simultaneously applied for warming. Control group: Routine postoperative management will be provided, including fasting followed by early feeding, fluid supplementation, and antibiotic therapy, among others.

Throughout the treatment period, your physician will collect daily records of your symptoms and clinical signs, along with repeated completion of the VAS and the gastrointestinal symptom scale.

At the conclusion of the intervention, your physician will again record your medical history, symptoms, signs, and examination results, while you complete the VAS, the gastrointestinal symptom scale, and the GIQLI. This assessment will take approximately 15 to 30 minutes.

Finally, 14 days after completion of the treatment course, a follow-up will be conducted either in person at the hospital or through online consultation. During this session, you should report any changes in your condition truthfully. Your physician will record your history and relevant symptoms and administer the GIQLI once more. This process is also expected to require about 15 to 30 minutes.

3. Additional Requirements for Your Cooperation

You are expected to follow the treatment plan prescribed by your physician. Please record your condition objectively and in a timely manner in the Case Observation Form before treatment, throughout the course of therapy, at its conclusion, and again 14 days after completion. These records

are essential, as they will enable your physician to determine whether the treatment is truly effective.

You should also complete follow-up visits at the times agreed upon with your physician. These visits are of great importance, since they allow your physician to assess whether the treatment exerts a sustained impact on your long-term postoperative quality of life.

During the study period, you may not use additional medications, acupuncture, or other therapies that could influence gastrointestinal function. Should alternative treatments be deemed necessary, you must first consult your physician.

Following each treatment session, you will be advised to avoid exposure to cold and to refrain from sitting directly under air conditioning or fans.

4. Anticipated Circumstances and/or Reasons for Early Termination of Participation

Participation in this trial may be discontinued under the following conditions:

(1) Significant adverse reactions to acupuncture, such as pronounced needle phobia or severe vasovagal syncope, requiring early termination;

(2) Local complications at the primary acupoints during the study, such as subcutaneous hematoma, skin damage, or rash, rendering acupuncture infeasible;

(3) Voluntary withdrawal at your own request for personal reasons;

(4) Occurrence of severe adverse events or complications making continuation of the trial unsafe;

(5) Failure to comply with the prescribed treatment protocol or provision of incomplete records,

thereby compromising the validity of efficacy and safety evaluations.

Possible benefits of participating in the study

You and society at large may derive potential benefits from this study. These benefits include gaining a deeper understanding of your condition, experiencing possible improvement in gastrointestinal symptoms and postoperative quality of life, and contributing to the characterization of the disease, thereby assisting other patients with similar conditions.

Potential adverse reactions, risks, discomforts, and inconveniences of participation

As with all therapeutic interventions, this study carries the possibility of side effects. Potential adverse reactions during treatment may include vasovagal syncope, needle retention, needle breakage, local pain, hematoma, or drug-related toxicities such as hepatic or renal impairment, infections, or gastrointestinal bleeding. Should you experience any discomfort, a change in your condition, or any unexpected event—regardless of whether it appears related to the study—you must promptly inform your physician. Your physician will assess the situation and implement appropriate management, which may include needle removal, advising you to remain in the supine position, or arranging specialist consultation. Every effort will be made to prevent and treat any harm potentially associated with this research.

During the study, you will be required to report your symptoms accurately, attend hospital visits or remote follow-up as scheduled, and complete medical records, relevant examinations, and standardized evaluation forms. These procedures may require a certain investment of your time.

personal information confidential

Your medical records (including study case report forms, laboratory reports, and related documents) will be securely preserved within the hospital, and all examination results will be documented in your inpatient medical chart. The investigator, representatives of the sponsor (if applicable), and the ethics committee may be granted access to your records for oversight purposes. Any public presentation or publication of the study results will not disclose your personal identity. Within the limits permitted by law, every effort will be made to safeguard the confidentiality and privacy of your medical information.

Voluntary principle

Participation in this study is entirely voluntary. You may refuse to take part or withdraw at any point during the study without affecting your relationship with your physician or resulting in any loss of medical care or other benefits to which you are entitled.For reasons of your best interests, your physician or the investigator may also decide to discontinue your participation in the study at any time.

Should you choose not to participate, or if you withdraw partway through the trial, a variety of alternative treatment options remain available to you, such as moxibustion or tailored herbal medicine. Participation in this study is not required for you to receive treatment for your condition. If you withdraw for any reason, you may be asked about your experience during the study. If your physician deems it necessary, you may also be requested to undergo laboratory tests or physical examinations, which are intended to safeguard your health.

Before making your decision, you are strongly encouraged to ask your physician any questions until you fully understand the study. Participation is entirely your choice, and you may wish to discuss your decision with family or friends before reaching a conclusion.

Thank you for taking the time to read this document. If you decide to participate, please inform your physician or the study coordinator, who will make the necessary arrangements for your involvement.

Please keep this information sheet for your records.

Signature Leaflet for Informed Consent

Study Title: Abdominal Acupuncture for Gastrointestinal Function Recovery After Gynecologic Laparoscopic Surgery: A Randomized Clinical Trial

Commissioning Institution: Guangzhou University of Chinese Medicine

Ethics Approval Number: YF-2023-435-01

Consent Statement

I have carefully read the above information regarding this study and have had the opportunity to discuss it with my physician and raise questions. All of my inquiries have been fully and satisfactorily answered. I understand the potential risks and benefits of participating in this study. I acknowledge that participation is entirely voluntary, that I have been given sufficient time to consider my decision, and that I am fully aware of the following:

● I understand that the collection of personal data—including hospitalization records and long-term follow-up information—may be necessary. I acknowledge how my personal information will be kept confidential and therefore consent to its authorized use for research purposes.

● I may seek additional information from my physician at any time.

● I may withdraw from the study at any stage without discrimination or retaliation, and without any compromise to my medical care or legal rights.

Should I require additional medical treatment during the course of this study, I will either seek prior approval from my physician or promptly disclose it afterward.

I consent to allow the drug regulatory authorities, the ethics committee, or sponsor representatives

to review my research records as necessary.

I will receive a signed and dated copy of this informed consent form for my personal reference.

Having considered all the above, I hereby agree to participate in this study.

Subject's signature: Date:

Subject contact number:

Signature of subject's guardian: Relationship to Participant:

Guardian's contact number: Date:

Subject's guardian is required to sign the informed consent if necessary.

I confirm that I have explained to the participant the full details of this study, including their rights as well as the potential benefits and risks, and that I have provided them with a signed copy of the informed consent form.

Investigator Signature: Date:

Investigator's Office Phone: Mobile Number:

In the event of inconsistency or discrepancy between the Chinese version and the English version, the Chinese language version shall prevail.