Informed Consent Form

Project Name: A Prospective Evaluation of Early Acupuncture for Immediate Continence Enhancement after Prostatectomy

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Informed Disclosure Page

Dear Sir:

We invite you to participate in a research study: "A Prospective Study on the Effect of Early Acupuncture Intervention on Immediate Urinary Control After Prostatectomy." This study has been reviewed and approved by the Clinical Research Ethics Committee of Zhongda Hospital, Southeast University (Approval No.: 2025ZDSYLL366-P01).

Before you decide whether to participate, please read the following information carefully. It will help you understand the study, why it is being conducted, the procedures and duration, and the potential benefits, risks, and discomforts of participating. You may discuss this with your relatives and friends, or ask your doctor for explanations to help you make your decision.

I. Background, Purpose, and Methods

1. Study Background

Prostate cancer (PCa) has become a major threat to the health of the male genitourinary system. The 2022 global cancer statistics report from the WHO International Agency for Research on Cancer shows 1.5 million new cases of prostate cancer worldwide, accounting for 7.3% of all malignant tumors and ranking second in incidence among men, only after lung cancer. The incidence of prostate cancer varies significantly by geography and ethnicity. Historically, Asia has had a lower incidence rate compared to regions like Europe, America, Australia, and New Zealand. However, with an aging population, changes in lifestyle, and the popularization of screening methods such as prostate-specific antigen (PSA), the incidence of prostate cancer in China is also showing a year-by-year upward trend. This growth has placed China among the world's leaders in both absolute new cases and deaths from prostate cancer, marking its transition from a relatively rare tumor to a major public health problem threatening the health of Chinese men.

Radical Prostatectomy (RP) is the standard treatment for localized prostate cancer, effectively removing tumor tissue and extending patient survival. However, this life-saving surgery also brings almost inevitable functional sequelae. Postoperative urinary incontinence, especially the problem of immediate urinary control after catheter removal, severely impacts the patient's quality of life. Studies show that some patients face urine leakage or control difficulties immediately after catheter removal, with an incidence rate between 5% and 48%. One study, using the 24-hour pad test to precisely quantify leakage, found that in the first week after catheter removal, the average daily urine leakage could be as high as 408.0 mL, a level sufficient to cause severe social embarrassment and psychological distress, urgently requiring effective interventions.

Currently, the treatment for post-RP urinary incontinence mainly relies on conservative therapies such as Pelvic Floor Muscle Training (PFMT). However, these measures are usually implemented *after* the catheter is removed and cannot meet the need for immediate urinary control post-removal. Furthermore, the therapeutic effect of PFMT requires long-term adherence, patient compliance is generally poor, and most importantly, the intervention timing is delayed. Traditional surgical interventions, such as artificial urinary sphincter (AUS) implantation or male slings, can improve

symptoms but carry risks of infection, mechanical failure, etc., and not all patients are suitable for such invasive treatments. In terms of drug therapy, the several classes of drugs currently studied (including anticholinergics, PDE5 inhibitors, duloxetine, etc.) are still in a state of lacking evidence and controversy, and cannot be used as standard therapy for post-RP urinary incontinence patients. There is currently a lack of effective and widely accepted solutions for immediate urinary control after catheter removal.

Against the backdrop of existing treatments failing to meet clinical needs, this study proposes early postoperative acupuncture as an innovative and scientifically rational intervention strategy. Acupuncture is not merely an "alternative therapy" but an effective "non-invasive peripheral neuromodulation technique" confirmed by modern medical research. Its application to improve immediate postoperative urinary control is based on a solid neurophysiological foundation and evidence from previous clinical studies. The core pathology of post-RP urinary incontinence is neuromuscular dysfunction. Acupuncture therapy, by stimulating specific acupoints on the body surface, can activate corresponding neural pathways, thereby regulating bladder and urinary sphincter function. Its possible mechanisms include: **direct sacral nerve modulation** (the deep anatomical location of the Baliao points corresponds precisely to the sacral foramina, and needle stimulation can directly act on the sacral nerve roots. This is mechanistically similar to Sacral Neuromodulation (SNS) therapy, which is already widely used clinically) and **activating the pudendal nerve-sphincter pathway** (by stimulating sacral acupoints like Baliao, it can activate the afferent and efferent fibers of the pudendal nerve, enhancing the tone and closure function of the external urinary sphincter, thereby increasing urethral resistance and preventing involuntary urine leakage).

Multiple studies have shown that acupuncture has a certain effect in alleviating postoperative urinary incontinence. For example, in a study by Yang Hao et al., comparing "pudendal nerve electroacupuncture stimulation" with "pelvic floor biofeedback electrical stimulation" in treating 81 patients with post-prostatectomy urinary incontinence, clear conclusions were drawn. The study found that electroacupuncture not only took effect faster (improvement at 4 weeks vs. 8 weeks for the control group) but also had a significantly higher total effective rate at 12 weeks (73.17% vs. 37.50%). Furthermore, the electroacupuncture group outperformed the control group in all quality of life and functional scores, and its efficacy remained stable during a follow-up period of up to 6 months, demonstrating good long-term effects. However, most existing research focuses on the treatment of long-term postoperative urinary incontinence, with few studies addressing the improvement of immediate urinary control after catheter removal.

Therefore, the core innovation of this study lies in the **"timing"** of the acupuncture treatment, i.e., early acupuncture treatment. Specifically, we will perform acupuncture in the window period *after* surgery but *before* catheter removal (while the bladder is continuously drained and "at rest" via the catheter). The core hypothesis is: by applying neuromodulation stimulation in advance, we can "pre-activate" and "functionally reorganize" the urinary control system before it faces the actual challenge (i.e., bladder filling and urination after catheter removal). This may be achieved through the following pathways: **rebuilding neural connections** (activating and "awakening" neural pathways temporarily suppressed by surgical trauma), **enhancing baseline sphincter tone** (pre-emptively increasing the resting tone of the external urinary sphincter via pudendal nerve stimulation), **stabilizing detrusor function** (inhibiting potential, uncoordinated detrusor contractions to prepare for stable bladder filling), and **reducing local inflammatory response** (acupuncture has a recognized anti-inflammatory effect, which can help reduce surgical site edema and nerve irritation, creating a more favorable microenvironment for functional recovery). This "one step ahead" intervention aims to adjust the patient's neuromuscular system to an optimal state of readiness, so that at the moment of catheter removal, it can more effectively cope with the pressure of bladder filling, achieve a smoother transition in

urinary control function, and shorten or even avoid a period of severe immediate urinary incontinence.

In summary, the early acupuncture intervention protocol proposed in this study not only has a solid neurophysiological basis and sufficient supporting evidence but also represents a clinical paradigm shift from "passive treatment" to "active prevention." By implementing non-invasive neuromodulation during a critical time window, it is expected to fill a significant gap in current clinical practice and provide a new, safe, effective, and economical way to improve the immediate postoperative quality of life for prostate cancer patients.

2. Study Purpose

To evaluate a prospective study on the effect of early acupuncture intervention on immediate urinary control after prostatectomy.

3. Study Design

3.1 Study Methods Information of patients who have undergone radical prostatectomy will be obtained from the electronic medical record (EMR) systems of Zhongda Hospital, Lishui People's Hospital in Nanjing, and Xishan People's Hospital in Wuxi. Patients meeting the inclusion and exclusion criteria will be screened. Using block randomization, they will be allocated 1:1 to either the treatment group or the control group. They will then receive electroacupuncture treatment or sham electroacupuncture treatment for this clinical trial to study the patients' postoperative urinary incontinence prognosis.

3.2 Study Participating Units and Expected Enrollment Number Participating Units: Department of Urology, Zhongda Hospital, Southeast University; Department of Urology, Nanjing Lishui People's Hospital; and Department of Urology, Wuxi Xishan People's Hospital. Expected Enrollment: 144 subjects.

Enrollment numbers for each center:

Zhongda Hospital, Southeast University: 84 cases

Nanjing Lishui People's Hospital: 30 cases

Wuxi Xishan People's Hospital: 30 cases

3.3 Expected Study Duration Expected Study Duration: August 2025 to August 2027.

3.4 Main Inclusion Criteria for Subjects

Patients who have undergone radical prostatectomy with a confirmed pathological diagnosis of prostate cancer.

One week post-RP.

Karnofsky Performance Status (KPS) score ≥ 60 or ECOG score 0-1.

Age between 50 and 85 years.

Signed informed consent.

II. Subject Responsibilities

Before you are enrolled in the study, the researcher will ask for and record your medical history. If you are eligible, you may voluntarily participate in the study and sign the informed consent form. If you do not wish to participate, we will respect your decision.

If you volunteer to participate, the following steps will be taken: The urinary catheter will be removed for all patients on Postoperative Day 14 (POD14). Early electroacupuncture treatment (including real and sham electroacupuncture) will be initiated on Postoperative Day 7 (POD7), with subsequent sessions on POD9 and POD11, for a total of 3 sessions.

If you agree to participate in this study, you will be randomly assigned to one of the following two groups. We use this method to compare the effects of the two interventions scientifically and fairly.

Electroacupuncture Treatment Group: The study doctor will place fine acupuncture needles at specific acupoints on your back and lumbosacral region. These will be connected to an instrument that produces a mild, comfortable electrical stimulation sensation. The entire process will last about 30 minutes.

Placebo Control Group: You will undergo a procedure very similar to the treatment group. The study doctor will perform operations on the corresponding parts of your body. During the procedure, you will also feel a sensation similar to acupuncture and see the same instrument working. This procedure mimics the real electroacupuncture treatment in appearance and sensation as much as possible, but it does not include some of the key therapeutic components.

To ensure all subjects receive consistent standard postoperative rehabilitation guidance and to control for potential confounding variables, all patients successfully enrolled in this study (regardless of their group) will receive a standardized Pelvic Floor Muscle Training (PFMT) health education session on POD7 (the same day as the first intervention).

During this time, the doctor must record any local or systemic adverse reactions and adverse events, and note whether the treatment was

stopped and whether any measures were taken. Throughout the treatment, the doctor will collect and evaluate data from all subjects.

Receiving acupuncture treatment is investigational. If you do not participate in this study, you will not need to receive the project's treatment.

Other matters requiring your cooperation: You will need to come to the hospital for follow-up visits at the times agreed upon with your doctor. Your follow-up is very important, as the doctor will evaluate the effect of the study measures based on it. Follow-ups are planned at 1 week, 4 weeks, 8 weeks, 12 weeks, and 24 weeks after your catheter removal. At the 1-week, 4-week, and 24-week follow-ups, you will undergo a 1-hour pad test to assess your early and long-term postoperative urinary control.

If you need any other treatment, please contact your study doctor in advance.

III. Subject Rights

Your participation in this study is voluntary. Information related to your participation is confidential. You may refuse to participate or withdraw from the study at any time without facing discrimination or reprisal, and your medical treatment and rights will not be affected.

You may choose not to participate in this study, or you may withdraw midway. You can ask the researcher about alternative treatment options that may be available, such as surgical interventions or drug therapies. You are not required to participate in this study in order to receive treatment for your condition.

If you require other treatments, if you do not comply with the study plan, or for any other reasonable cause, your doctor or the researcher may suspend your participation in this study at any time, acting in your best interest.

If you withdraw from the study for any reason, you may be asked about your condition after receiving the acupuncture treatment. If your doctor deems it necessary, you may also be asked to undergo laboratory tests and physical examinations. This is beneficial for protecting your health.

If any significant new information arises during the study that might affect your willingness to continue participating, your doctor will inform you or your legal guardian in a timely manner.

You may access information and progress related to this study at any time. If you have any questions related to this study, or if you experience any discomfort or injury during the trial, or if you have questions about your rights as a study participant, you may consult the researcher at any time.

Researcher Name: Contact Number:

If you have any complaints about participating in this study, please contact the Clinical Research Ethics Committee of Zhongda Hospital, Southeast University, at 025-83272015.

IV. Possible Benefits of Participation

We hope that through this study, we can help reduce the incidence of post-prostatectomy urinary incontinence or improve your urinary incontinence condition. However, this cannot be guaranteed. It is possible that you may not receive any direct health benefits from participating.

Whether or not you benefit directly, the information you provide by participating in this study may help us develop new treatment methods for other patients with similar conditions in the future.

V. Possible Adverse Reactions, Risks, Discomforts, and Inconveniences

Participants in the study may be exposed to adverse reactions, risks, and discomforts associated with acupuncture treatment. Acupuncture-related adverse reactions may include:

- **Local reactions:** Itching, allergies, infection, pain, or pigmentation.
- **Systemic reactions:** Dizziness, nausea, fatigue, syncope (fainting), allergic reactions, dyspnea (difficulty breathing), or palpitations.

If you experience any discomfort, any new changes in your condition, or any unexpected events during the study, regardless of whether it is related to the research, you should notify your doctor immediately. He/she will make a judgment and provide appropriate medical treatment.

VI. Related Costs

Costs related to your participation in this study on acupuncture treatment for post-prostatectomy urinary incontinence, including consumables for acupuncture treatment and consumables required for subsequent follow-up tests (such as pads), will be borne by the researcher. You do not need to pay these related fees.

You are responsible for the costs of the normal treatments and examinations you require, which are not covered free of charge.

Costs for treatments and examinations required for other concurrent diseases you may have, as well as costs incurred from switching to other treatments due to ineffective treatment, will not be covered.

VII. Related Compensation

The researcher will make every effort to prevent and treat any harm that may result from this study. If a study-related injury occurs during the research period, you will receive timely and free treatment. At the same time, the researcher will provide corresponding compensation or indemnification in accordance with laws and regulations.

VIII. Confidentiality of Personal Information

Your medical records and data will be kept complete at the hospital. The researcher, the Ethics Committee, drug regulatory authorities, and health commission administrative departments will be permitted to review your medical records. Any public reports regarding the results of this study will not disclose your personal identity. We will protect the privacy of your personal medical information to the extent permitted by law.

In accordance with medical research ethics principles, trial data, excluding personal privacy information, will be made available for public inquiry and sharing. Inquiry and sharing will be limited to web-based electronic databases, ensuring that no personal privacy information will be leaked.

It is possible that your medical records and pathological specimens may be used again in other future research. You may declare now your refusal to allow your medical records and pathological specimens to be used in research other than this study.

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Consent Declaration

I have read the above introduction to this study, and I have had the opportunity to discuss this study with the researcher and ask questions. All my questions related to the study have been answered, and my family and I have had sufficient time to consider this.

I understand the potential risks and benefits of participating in this study. I am aware that participation is voluntary, and I understand that:

- This study has been approved by the Clinical Research Ethics Committee of Zhongda Hospital, Southeast University.
- All my information is confidential.
- My rights to privacy, medical treatment, and compensation are protected.
- I can consult the researcher for more information at any time.
- I can choose not to participate in this study, or I can withdraw at any time without suffering discrimination or reprisal, and my medical treatment and rights will not be affected.
- If I withdraw midway through the study, especially if I withdraw due to reasons related to the acupuncture treatment, I should inform the researcher of any changes in my condition and complete the corresponding physical and laboratory examinations, which will be very beneficial to the entire study.
- If I need to take any other treatment due to changes in my condition, or if I do not comply with the study plan, I will seek the researcher's opinion in advance or inform the researcher truthfully afterward. The researcher may terminate my continued participation in this study for these or other reasonable reasons.
- I agree to allow drug regulatory authorities, health commission administrative departments, the Ethics Committee, or the sponsor's representatives to review my research data.
- I will receive a signed and dated copy of this informed consent form.

Finally, I decide to agree to participate in this study and promise to follow the study procedures as much as possible.

I agree□ refuse□ to the use of my medical records and pathological specimens in research other than this study.

Subject's Signature:_____ Date:

Contact Phone：_____

Guardian's Signature (if applicable):_____ Date: ___ Year ___ Month ___ Day ___ Hour ___ Min

Subject's Name (Printed): _____ Guardian's Relationship to Subject: _____

Guardian's Contact Phone: _____

Impartial Witness's Signature (if applicable): _____ Date: ___ Year ___ Month ___ Day ___ Hour ___ Min

Impartial Witness's Contact Phone: _____ Impartial Witness's ID Number: _____

I confirm that I have explained the details of this study to the subject, including their rights and the potential benefits and risks, and have answered their questions. The subject has voluntarily agreed to participate in this study, and I have given them a signed copy of the informed consent form.

Investigator's Signature: _____ Date: ___ Year ___ Month ___ Day ___ Hour ___ Min

Investigator's Contact Phone: _____