Research Project Design Document

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

Institution Address/Postal Code: 87 Dingjiaqiao, Gulou District, Nanjing, Jiangsu Province, 210009

Principal Investigator: Bin Xu

Telephone/Email: +86 18012949196

Supervising Department: Zhongda Hospital, Southeast University

Version:02
Version Date: Aug 25, 2025

1. Rationale

Prostate cancer (PCa) has become a major threat to male urogenital health. The global cancer statistics report published by the WHO's International Agency for Research on Cancer (IARC) showed 1.5 million new cases of prostate cancer worldwide in 2022, accounting for 7.3% of all malignant tumors and ranking second only to lung cancer in male morbidity. The incidence of prostate cancer shows significant geographical and ethnic differences. 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) testing, the incidence of prostate cancer in China is also showing a year-on-year upward trend. This growth has positioned China among the world leaders in both absolute numbers of new prostate cancer cases and deaths, signaling that prostate cancer has transformed from a relatively rare tumor into a major public health issue threatening the health of Chinese men [1].

Radical Prostatectomy (RP) is the standard method for treating 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 immediate continence issue after catheter removal, severely impacts patients' quality of life. Studies show that some patients face immediate urine leakage or control difficulties after catheter removal, with an incidence rate between 5%-48% [2]. One study accurately quantified the amount of urine leakage using the 24-hour pad test, finding that in the first week after catheter removal, the average daily urine leakage could be as high as 408.0 mL [3]. This level is 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 initiated *after* catheter removal and cannot meet the need for immediate continence upon removal. Furthermore, the efficacy of PFMT requires long-term adherence, patient compliance is generally poor, and most importantly, **the timing of the intervention is delayed**. Traditional surgical interventions, such as the implantation of an artificial urinary sphincter (AUS) or male sling surgery, can improve symptoms but carry risks like infection and mechanical failure, and not all patients are suitable for such invasive treatments [2]. In terms of drug therapy, the several classes of drugs currently under investigation (including anticholinergics, PDE5 inhibitors, duloxetine, etc.) still lack evidence and remain controversial [4], and cannot be used as standard therapy for post-RP urinary incontinence patients. There is currently a lack of effective and widely recognized solutions for immediate continence intervention 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 theoretical basis for improving immediate postoperative continence is built on solid neurophysiological foundations 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 modulating the function of the bladder and urinary sphincter. Its possible mechanisms of action include: **Direct sacral neuromodulation** (The deep anatomical location of the Baliao (BL31-BL34) acupoints 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 [5].) and **Activation of the pudendal nerve-sphincter pathway** (Stimulating sacral acupoints like Baliao can activate the afferent and efferent fibers of the pudendal nerve, enhancing the tension and closure function of the external urinary sphincter, thereby increasing urethral resistance and preventing involuntary urine leakage [6]).

Multiple studies have already shown that acupuncture has a certain effect in alleviating postoperative urinary incontinence. For example, in a study conducted by Yang Hao et al. [7], a clear conclusion was drawn by comparing the effects of "pudendal nerve electroacupuncture stimulation" versus "pelvic floor biofeedback electrical stimulation" in treating 81 patients with post-prostatectomy urinary incontinence. The study found that electroacupuncture therapy 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 on 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 continence after catheter removal.

Therefore, the core innovation of this study lies in the **"timing" of the acupuncture treatment**, specifically **early acupuncture therapy**. To be precise, we will perform acupuncture treatment during the postoperative window **before catheter removal** (while the bladder is in a "resting" state with continuous drainage via the catheter). The core hypothesis is: By applying neuromodulatory stimulation in advance, the urinary control system can be **"pre-activated" and "functionally reorganized"** *before* it faces the actual challenge (i.e., bladder filling and urination after removal). This may be achieved through the following pathways: **Re-establishing neural connections** (Activating and "awakening" neural pathways temporarily suppressed

by surgical trauma.), **Enhancing baseline sphincter tone** (Preemptively increasing the resting tension of the external urinary sphincter through 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 local microenvironment for functional recovery.) This "pre-emptive" intervention aims to adjust the patient's neuromuscular system to a better state of readiness, enabling it to more effectively cope with the pressure of bladder filling at the moment of catheter removal, thereby achieving a smoother transition in urinary control function and shortening or even avoiding a severe immediate incontinence period.

In summary, the early acupuncture intervention protocol proposed in this study not only possesses a solid neurophysiological basis and ample supporting evidence but also represents a shift in clinical thinking from "passive treatment" to "active prevention." By implementing non-invasive neuromodulation at a critical time window, it is expected to fill a huge gap in current clinical practice and provide a safe, effective, and economical new pathway for improving the immediate postoperative quality of life for prostate cancer patients. The specific objective is: To systematically evaluate the efficacy of early acupuncture treatment by comparing the **treatment group** (early acupuncture + standard care) versus the **control group** (no acupuncture + standard care) in terms of urine leakage volume, proportion of complete continence, pad usage, and patient satisfaction within 24 hours after catheter removal.

References:

[1] Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2024). *Global Cancer Observatory: Cancer Today*. Lyon, France: International Agency for Research on Cancer.

[2] Sandhu JS, Breyer B, Comiter C, Eastham JA, Gomez C, Kirages DJ, et al. Incontinence after Prostate Treatment: AUA/SUFU Guideline. Journal of Urology [Internet]. 2019 Aug 1 [cited 2025 Jul 12];202(2):369–78.

[3] Sathianathen NJ, Johnson L, Bolton D, Lawrentschuk NL. An objective measurement of urinary continence recovery with pelvic floor physiotherapy following robotic assisted radical prostatectomy. Transl Androl Urol. 2017 Jul;6(Suppl 2):S59-S63.

[4] Castellan P, Ferretti S, Litterio G, Marchioni M, Schips L. Management of Urinary Incontinence Following Radical Prostatectomy: Challenges and Solutions. Ther Clin Risk Manag. 2023 Jan 15;19:43-56. doi: 10.2147/TCRM.S283305.

[5] Paik SH, Han SR, Kwon OJ, Ahn YM, Lee BC, Ahn SY. Acupuncture for the treatment of urinary incontinence: A review of randomized controlled trials. Exp Ther Med. 2013 Sep;6(3):773-780. doi: 10.3892/etm.2013.1210IF: 2.3 Q3 . Epub 2013 Jul 9.

[6] Yang M, Zhu L, Yao H, Chen Y, Liu Z. Effects of electroacupuncture on chronic urinary retention after pelvic or lumbosacral tumor resection surgeries: a retrospective cohort study. Transl Androl Urol. 2024 Mar 31;13(3):397-405. doi: 10.21037/tau-23-468. Epub 2024 Mar 14.

[7] 杨浩,吕婷婷,吕笑,等.阴部神经电针刺激疗法治疗前列腺根治术后尿失禁的疗效观察[J].中华男科学杂志,2002,26(12):1119-1123.DOI:10.13263/j.cnki.nja.2020.12.011

Study Rationale and Significance

This study focuses on the impact of early postoperative acupuncture intervention on immediate urinary continence after catheter removal, filling a gap in existing research. Early postoperative intervention may accelerate the recovery of urinary control function by stimulating relevant nerves and muscles, reducing the risk of immediate urine leakage after removal. If the study yields positive results, early electroacupuncture treatment can provide patients with a non-invasive and safe treatment option, significantly improving postoperative quality of life and reducing the use of pads and the associated psychological burden.

Our team expects to conduct a prospective randomized controlled study (a collaboration between the Department of Urology at Zhongda Hospital, Southeast University; the Department of Urology at Nanjing Lishui People's Hospital; and the Department of Urology at Wuxi Xishan People's Hospital). Information on patients receiving treatment will be obtained from the electronic medical record (EMR) systems of Zhongda Hospital, Nanjing Lishui People's Hospital, and Wuxi Xishan People's Hospital. Patients meeting the inclusion and exclusion criteria will be screened and subsequently receive electroacupuncture treatment postoperatively. By following up with these patients and comparing them with postoperative patients receiving placebo electroacupuncture, we will study the impact on patient prognosis.

II. Study Content

1. Study Objectives

To evaluate the effect of early electroacupuncture intervention on immediate urinary continence after prostatectomy in a prospective study.

2. Study Content

(1) Selection of Study Sites: This study will be conducted at the Department of Urology, Zhongda Hospital, Southeast University; the Department of Urology, Nanjing Lishui People's Hospital; and the Department of Urology, Wuxi Xishan People's Hospital.

(2) Selection of Study Subjects: Information on patients receiving acupuncture treatment and control group patients will be obtained from the multi-center EMR systems. Patients meeting the inclusion/exclusion criteria will be screened. Using block randomization, they will be allocated 1:1 into either the treatment group or the control group and receive either acupuncture treatment or sham acupuncture treatment for inclusion in the clinical study.

Number of subjects to be enrolled at each center:

- Department of Urology, Zhongda Hospital, Southeast University: 84 cases
- Department of Urology, Nanjing Lishui People's Hospital: 30 cases

- Department of Urology, Wuxi Xishan People's Hospital: 30 cases

Sample Size: This study is a prospective, multi-center, randomized, placebo-controlled clinical trial designed to assess the efficacy of early electroacupuncture intervention in improving immediate urinary continence after radical prostatectomy (RP). The Primary Endpoint has been determined as the urine leakage volume (in grams) measured by the 1-hour pad test administered immediately after catheter removal (within the first 1 hour post-removal). This calculation is based on a test comparing two independent sample means. The required parameters include the expected mean difference between groups (effect size, δ), the within-group standard deviation (σ), the Type I error probability (α), and the Type II error probability (β). We set the two-sided significance level $\alpha = 0.05$, statistical power $(1-\beta) = 0.80$, and a 1:1 allocation ratio for the two groups (treatment vs. sham acupuncture).

In the absence of a perfectly matched study focusing on post-RP males, comparing electroacupuncture versus sham acupuncture, and using the 1-hour pad test (grams) as the primary endpoint, we have, after rigorous screening, selected a high-quality, large-scale (N=504), multi-center randomized controlled trial published by Liu et al. in the Journal of the American Medical Association (JAMA) in 2017 as the primary basis for parameter estimation. That study's methodological design (electroacupuncture vs. sham acupuncture) and primary outcome measure (1-hour pad test leakage volume) are highly consistent with our study, representing the best available evidence. Although its study population was women with stress urinary incontinence, we consider its reported effect size and variability data to be the most reasonable reference for this calculation, given the cross-gender commonality of the core physiological mechanism (sacral neuromodulation via electroacupuncture) for regulating urinary control.

Based on the results from Liu et al.'s study:

- **Expected Effect Size (δ):** The electroacupuncture group showed 7.4 grams more reduction in 1-hour pad test leakage compared to the sham acupuncture group. We use this as the expected mean difference between groups.
- **Within-group Standard Deviation (σ):** Based on the reported 95% confidence interval of the effect size, we extrapolated the pooled standard deviation for the "change value" in leakage volume (before and after intervention) to be approximately 14.9 grams.

Based on the parameters above, using the sample size formula for comparing two independent means: $n = [(Z\alpha/2 + Z\beta)^2 \times 2\sigma^2] / \delta^2$

The calculation shows that to achieve 80% power, **each group requires at least 64 subjects**.

Considering the short intervention cycle and clear follow-up nodes of this study, we estimate a dropout or withdrawal rate of approximately 10%. To compensate for this potential sample loss, the adjusted number of recruits needed per group is $64 / (1 - 0.10) \approx 71.11$. Rounding up, we determine that **each group needs to recruit 72 subjects**.

In summary, this study plans to enroll a total of **144 subjects** (72 in the treatment group, 72 in the control group). This sample size is sufficient to statistically and effectively test the core hypothesis of this study and is feasible within the multi-center collaborative framework. An interim analysis will assess whether the sample size needs adjustment based on actual enrollment and data variability.

Reference: Liu Z, Liu Y, Xu H, et al. Effect of Electroacupuncture on Urinary Leakage Among Women With Stress Urinary Incontinence: A Randomized Clinical Trial. JAMA. 2017;317(24):2493–2501. doi:10.1001/jama.2017.7220

(3) Study Period 2025.08.01——2027.08.01

Study Subject Sampling and Allocation Method

This study will employ a prospective, multi-center, randomized controlled trial design. All patients undergoing radical prostatectomy during the study period who meet all inclusion criteria, do not meet any exclusion criteria, and voluntarily sign the informed consent form will be enrolled consecutively. To ensure the scientific rigor of the allocation process, subject allocation will utilize a **centralized, stratified block randomization** method. We will use participating hospitals as the stratification factor, generating independent random sequences for each center to eliminate potential inter-institutional bias. Within each stratum, we will use mixed block sizes (sizes 4 and 6) for random allocation to maintain a close dynamic balance between the treatment and control groups at all stages of the study. To achieve allocation concealment, the random sequences will be generated by an independent statistician (not involved in clinical work) and deployed within a secure central randomization system. On-site researchers will only be able to obtain the patient's group assignment through the system *after* the patient is formally enrolled, thereby preventing selection bias. This study plans to randomly allocate a total of 144 subjects to the treatment group and the control group in a 1:1 ratio.

Informed Consent of Study Subjects

Signing of the informed consent form.

Outcome Measures

Follow-up on patient's urinary continence at 1 week, 4 weeks, 8 weeks, 12 weeks, and 24 weeks after catheter removal (half-year follow-up).

1. **Primary Endpoint:** Urine leakage volume (grams) measured by the first 1-hour pad test during the follow-up at 1 week post-catheter removal.
2. **1-hour Pad Test Results:** Conducted at the 4-week and 24-week follow-ups.
3. **ICIQ-SF Questionnaire Score:** At 1, 4, 8, 12, and 24 weeks post-removal to evaluate incontinence symptoms and their impact on quality of life. The proportion of completely continent patients (zero leakage) will directly quantify immediate continence.
4. **Self-Rating Anxiety Scale (SAS) Score:** To assess the potential improvement in patients' psychological state due to the acupuncture intervention.
5. **Voiding Diary and IPSS:** Patients will maintain a voiding diary and complete the International Prostate Symptom Score (IPSS) questionnaire at each follow-up node to assess nocturia and provide a comprehensive evaluation of urinary function.

(7) Treatment Methods

All patients will have their urinary catheter removed on postoperative day 14 (POD14). The early electroacupuncture intervention (including real electroacupuncture and sham electroacupuncture) will be initiated on postoperative day 7 (POD 7), with subsequent sessions on POD 9 and POD 11, for a total of 3 sessions.

Treatment Group: Receive electroacupuncture at acupoints including Shenshu (BL23), Pangguangshu (BL28), and Baliao (BL31-34), 30 minutes each time. A continuous wave of 2Hz will be used initially, with the intensity gradually increased to a level that is comfortable for the patient. The current intensity will be 1-5mA and can be gradually increased to the maximum tolerable level for the patient.

Control Group: Will use non-invasive sham acupuncture needles: validated blunt-tip, non-penetrating needles (such as Park or Streitberger needles). When pressure is applied, the needle tip retracts into the handle, giving the patient a sensation of pressure on the skin, but it does not puncture the skin. The procedure will be performed at **non-acupoints** (points 1-2 cm away from the real acupoints but not on the same meridian). The electroacupuncture device clips will also be attached to the sham needle handles, and the device will be turned on (emitting the same sound or light indicators), but **no electrical current will be delivered**. This ensures the entire treatment scenario is visually and auditorily identical to the real treatment group.

To ensure all subjects receive consistent standard postoperative rehabilitation guidance and to control for potential confounding variables, all successfully enrolled

patients (regardless of group) will receive standardized Pelvic Floor Muscle Training (PFMT) health education on POD 7 (the same day as the first intervention).

3. Research Methods

Research Design

This trial will adopt a randomized controlled prospective study design.

Inclusion and Exclusion Criteria

Subject Inclusion Criteria are as follows:

1. Patients who have undergone radical prostatectomy with a clear pathological diagnosis of prostate cancer.
2. One week post-RP.
3. Karnofsky Performance Status (KPS) score $\ge$ 60 or ECOG score 0-1.
4. Age between 50 and 85 years.
5. Signed informed consent.

Subject Exclusion Criteria are as follows:

1. Pathology report shows positive surgical margins.
2. Has undergone treatment for postoperative urinary incontinence, such as cystostomy, urinary sphincter reconstruction, or urethral sling surgery.
3. Currently receiving or has received treatments with similar principles to acupuncture (e.g., electroacupuncture, moxibustion, warm needling) within the past six months.
4. Patients with urinary tract infections (excluding asymptomatic lower urinary tract infections).
5. Known severe cardiac diseases, such as severe arrhythmia, severe cardiac insufficiency, acute myocarditis, constrictive pericarditis, cardiac tamponade, or severe valvular disease.
6. Known liver damage or potential severe liver disease (ALT or AST > 10 times normal).
7. Known severe renal impairment (eGFR < 25 mL/min/1.73m^2) , or planning/undergoing dialysis, or acute contrast-induced nephropathy at screening.
8. Known severe primary diseases in other vital organs or the hematopoietic system.
9. Known coagulation dysfunction (with typical clinical diagnosis or definitive laboratory test results).
10. Patients with psychiatric disorders or cognitive impairment; severe depression, alcohol dependence, or history of drug abuse.

11. Existing urinary incontinence due to other reasons.
12. Patients deemed unsuitable for the study by the investigator, or those with a high probability of dropping out, such as frequent changes in work environment leading to difficulty in follow-up.
13. Life expectancy $\le$ 6 months, as judged by the investigator.
14. Currently participating in other clinical trials.

(3) Enrollment and Treatment Protocol

Information on patients who have undergone radical prostatectomy will be obtained from the EMR systems of Zhongda Hospital, Nanjing Lishui People's Hospital, and Wuxi Xishan People's Hospital. After screening patients who meet the inclusion/exclusion criteria and signing the informed consent form , patients will be allocated into groups using a centralized, stratified block randomization method [24]and receive either acupuncture treatment or sham acupuncture treatment.

Trial Treatment Protocol: All patients will have their urinary catheter removed on postoperative day 14 (POD 14). The early acupuncture intervention (including real and sham acupuncture) will be initiated on postoperative day 7 (POD 7), with subsequent sessions on POD 9 and POD 11, for a total of 3 sessions.

Treatment Group: Receive electroacupuncture at acupoints including Shenshu (BL23), Pangguangshu (BL28), and Baliao (BL31-34), 30 minutes each time. A continuous wave of 2Hz will be used initially, with the intensity gradually increased to a level that is comfortable for the patient. The current intensity will be 1-5mA and can be gradually increased to the maximum tolerable level for the patient.

Control Group: Will use non-invasive sham acupuncture needles: validated blunt-tip, non-penetrating needles. When pressure is applied, the needle tip retracts into the handle, giving the patient a sensation of pressure on the skin, but it does not puncture the skin. The procedure will be performed at **non-acupoints** (points 1-2 cm away from the real acupoints but not on the same meridian). The electroacupuncture device clips will also be attached to the sham needle handles, and the device will be turned on (emitting the same sound or light indicators), but **no electrical current will be delivered**. This ensures the entire treatment scenario is visually and auditorily identical to the real treatment group.

To ensure all subjects receive consistent standard postoperative rehabilitation guidance and to control for potential confounding variables, all successfully enrolled patients (regardless of group) will receive standardized Pelvic Floor Muscle Training (PFMT) health education on POD 7 (the same day as the first intervention).

Efficacy Evaluation

1. **Primary Endpoint:** Urine leakage volume (grams) measured by the first 1-hour pad test during the follow-up at 1 week post-catheter removal.
2. **1-hour Pad Test Results:** Conducted at the 4-week and 24-week follow-ups.
3. **ICIQ-SF Questionnaire Score:** At 1, 4, 8, 12, and 24 weeks post-removal to evaluate incontinence symptoms and their impact on quality of life. The proportion of completely continent patients (zero leakage) will directly quantify immediate continence.
4. **Self-Rating Anxiety Scale (SAS) Score:** To assess the potential improvement in patients' psychological state due to the acupuncture intervention.
5. **Voiding Diary and IPSS:** Patients will maintain a voiding diary and complete the International Prostate Symptom Score (IPSS) questionnaire at each follow-up node to assess nocturia and provide a comprehensive evaluation of urinary function.

(4) Statistical Analysis

Statistical analysis will be performed by professional statisticians from the Clinical Evaluation and Analysis Center of Zhongda Hospital, Southeast University, using SPSS Statistics (V.26.0). All analyses will follow the Intention-to-Treat (ITT) principle. Data normality will be assessed using the Shapiro-Wilk test. Imbalances in baseline demographic and clinical characteristics will be adjusted using Analysis of Covariance (ANCOVA). Normally distributed continuous variables will be expressed as mean ± standard deviation; non-normally distributed continuous variables and ordinal variables will be expressed as median (interquartile range); categorical variables will be expressed as counts and percentages. Missing data for primary and secondary endpoints will be handled using multiple imputation, and the primary analysis will be based on the imputed dataset. A series of sensitivity analyses will be conducted to assess the robustness of the study conclusions to different methods of handling missing data. After catheter removal (during the 4-week follow-up), the type of urinary incontinence will be classified through clinical assessment (e.g., medical history, cough stress test). An analysis will then be performed to determine if there are differences in the efficacy of early acupuncture intervention in the subgroup of patients "diagnosed with pure stress urinary incontinence" versus other subgroups, such as "mixed urinary incontinence".

Feasibility Analysis

Theoretical Feasibility

The theoretical feasibility of this study is established on a solid foundation of modern neurophysiology and existing clinical evidence. The core pathology of post-Radical Prostatectomy (RP) urinary incontinence is neuromuscular dysfunction. The early acupuncture proposed in this protocol is not a traditional alternative therapy but rather an evidence-based **"non-invasive peripheral neuromodulation technique"**.

Its scientific basis lies in the stimulation of specific sacral acupoints, such as Baliao (BL31-34), which can directly act on the deep anatomical sacral nerve roots. This mechanism is highly similar to the clinically widespread Sacral Neuromodulation (SNS) therapy, providing strong theoretical support for the intervention's effectiveness. This neuromodulation can activate the pudendal nerve-sphincter pathway, enhancing the tension and closure function of the external urinary sphincter, thereby improving urinary control. Although existing research has primarily focused on long-term postoperative incontinence, clinical trials have already demonstrated that electroacupuncture is fast-acting, effective, and provides stable improvement for post-RP urinary incontinence. This serves as direct supporting evidence that acupuncture can effectively intervene in this functional disorder. The core innovation and theoretical confidence of this study stem from advancing the intervention timing—intervening during the "window period" *before* catheter removal and the subsequent functional challenge. Our core hypothesis is: by applying neuromodulatory stimulation in advance, we can **"pre-activate" and "functionally reorganize"** the neural pathways temporarily suppressed by surgical trauma. This adjusts the patient's neuromuscular system to a better state of readiness, achieving a paradigm shift from "passive treatment" to "active prevention," and hopefully allowing for a smoother functional transition after catheter removal.

Clinical Operational Feasibility

This study is designed as a multi-center, prospective, randomized controlled trial, planned to be conducted at Zhongda Hospital, Southeast University, and other medical institutions. Relying on the mature urological diagnosis and treatment platforms and prostate cancer patient databases at each center ensures the feasibility of patient recruitment. Participant information can be screened through electronic medical record systems. The inclusion criteria are clear and the exclusion criteria are strict, facilitating the rapid identification of the target population. The study expects to recruit 144 patients, 72 in each group; this sample size is calculated based on existing research data and is statistically reasonable.

The acupuncture intervention will be performed by qualified acupuncturists using standardized acupoints (e.g., Shenshu (BL23), Pangguangshu (BL28), Baliao (BL31-34), etc.). The procedure is simple and safe. The intervention is scheduled for one week post-prostatectomy, three times a week, 30 minutes per session. This is compatible with routine postoperative care and does not add burden to the patient. The assessment within 24 hours after catheter removal (e.g., pad test, proportion of complete continence) will be completed using standardized tools, making the outcome measurement objective and easy to implement. The follow-up plan (1 week post-removal and beyond) will be completed via telephone or outpatient visits, combined with the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), making data collection efficient and controllable.

Furthermore, each center is equipped with complete infrastructure, including sterile needles, treatment rooms, and data management systems, ensuring the smooth conduct of the trial. The research team consists of urologists, acupuncturists, and statisticians who have received standardized training, ensuring operational consistency and data quality. All participants will sign an informed consent form, and legal and ethical risks are manageable. In summary, this study is highly feasible at the clinical operational level and is capable of effectively advancing the trial process and obtaining reliable results.

6. Innovative Aspects of the Project

Currently, research on the impact of early acupuncture intervention on immediate urinary continence after catheter removal in post-RP patients is a blank slate. This study aims to fill this research gap by evaluating the effect of early postoperative acupuncture treatment on patients' immediate continence ability through a prospective controlled study. The specific objective is: To systematically evaluate the efficacy of early acupuncture intervention by comparing the intervention group (early acupuncture + standard care) versus the control group (sham acupuncture + standard care) in terms of urine leakage volume, proportion of complete continence, pad usage, and patient satisfaction within 24 hours after catheter removal. If the study results confirm the expectations, it will provide a new, non-invasive intervention for clinical practice, significantly improving the quality of patient's postoperative recovery and reducing the burden on the healthcare system. This study will directly address the core issue of generally low-quality evidence in this field by employing a gold-standard research design. It focuses on the POD 7-14 window, an intervention period not yet systematically studied, to explore the impact of early acupuncture intervention on immediate continence upon catheter removal. It is expected to provide high-level evidence for improving the early postoperative quality of life for prostate cancer patients. Furthermore, this study will promote the integration of traditional Chinese medicine with modern medicine, providing new therapeutic ideas and practical evidence for post-prostatectomy rehabilitation globally.

Expected Research Outcomes

This study anticipates that early acupuncture intervention will significantly improve immediate urinary continence in post-RP patients after catheter removal. This is expected to manifest as reduced urine leakage volume, an increased proportion of complete continence, decreased pad usage, and enhanced patient satisfaction. If the study results confirm these expectations, it will provide a new, non-invasive intervention for clinical practice, significantly improving the quality of patients' postoperative recovery and reducing the burden on the healthcare system. This study will directly address the core issue of generally low-quality evidence in this

field by employing a gold-standard research design, focusing on the POD 7-14 window—a period not yet systematically studied—to explore the impact of early acupuncture intervention on immediate continence upon catheter removal. It is expected to provide high-level evidence for improving the early postoperative quality of life for prostate cancer patients. Furthermore, this study will promote the integration of traditional Chinese medicine with modern medicine, providing new therapeutic ideas and practical evidence for post-prostatectomy urinary incontinence rehabilitation globally.

Work Basis and Conditions

Research Work Accumulation Related to This Project

The Department of Urology at Zhongda Hospital, Southeast University, has established a relatively complete clinical database for urogenital malignant tumors. The department regularly performs radical prostatectomy surgeries and communicates well with patients regarding informed consent. Our team has completed the relevant literature search and has already constructed a knowledge framework regarding post-prostatectomy urinary incontinence symptoms and acupuncture treatment.

Within the team, the project leader, Chief Physician **Xu Bin**, is a senior expert in the field of urology with long-term dedication to the clinical diagnosis, treatment, and research of prostate cancer. He possesses extensive experience in radical prostatectomy (RP) and can provide authoritative control over the research direction, patient screening, and surgical quality from the clinical source. Core members, including Deputy Chief Physician, and Attending Physicians not only focus on post-prostatectomy functional rehabilitation but also actively explore and research the mechanisms and clinical effects of acupuncture therapy on improving urinary dysfunction. They have accumulated a considerable theoretical foundation and preliminary research experience. To further ensure the professionalism of the protocol's execution, we are also in close collaboration with Attending Physician from our hospital's Acupuncture Department, who is responsible for the final supervision and guidance of the standardized operation of the acupuncture and sham acupuncture protocols. This project boasts an outstanding team with a comprehensive professional knowledge structure and deep interdisciplinary research backgrounds, providing a solid foundation for the smooth implementation of the research.

To further verify the feasibility of the research protocol and obtain preliminary data support, we conducted a small-sample preliminary experiment. To date, the team has completed the collection of follow-up data for 15 patients, all of whom were treated with robot-assisted laparoscopic radical prostatectomy by the same surgical team. We divided them into an acupuncture group (n=7) and a control group (n=8)

and conducted a preliminary analysis of the International Consultation on Incontinence Questionnaire-Short Form (ICI-Q-SF) scores for both groups. The data was statistically processed using the Mann-Whitney U test, with the null hypothesis (H0) being "there is no difference in ICI-Q-SF scores between the acupuncture group and the control group." The result showed $P<0.05$, indicating a statistically significant difference between the two groups' scores. The positive results of this preliminary experiment not only verify the feasibility of the research's technical route but also provide initial indications of the potential value of acupuncture therapy in improving post-prostatectomy urinary incontinence, laying a solid data foundation for the comprehensive and in-depth development of this project.

Budget

Funding for this research project comes from the 2025 Zhongda Hospital, Southeast University, internal funding for new technologies and new projects: "Clinical Application of Acupuncture to Improve Immediate Urinary Continence After Radical Prostatectomy," Project No. CZXM-GSP-YW-202535.

The approximate project budget is as follows: Consumables for pad tests: 1000 RMB Purchase of 4 new electroacupuncture devices: 2400 RMB Acupuncture treatment consumables and sham (placebo) acupuncture needle purchase costs: 500 RMB Printing costs for informed consent forms and various questionnaires: 500 RMB Ethics review fee: 500 RMB **Total: 4900 RMB**