

Study Protocol

Video-Assisted Ablation of Pilonidal Sinus (VAAPS) Combined with Loose
Glove-Edge Seton Drainage for Postoperative Self-Care: A Prospective Single-Arm
Cohort Study (PKUPH-PS01)

Sponsor: Peking University People's Hospital

Principal Investigator: Bozhi Hu, MD, MD

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This document contains no identifiable participant information.

1. Study Title

Video-Assisted Ablation of Pilonidal Sinus (VAAPS) Combined with Loose Glove-Edge Seton Drainage for Postoperative Self-Care: A Prospective Single-Arm Cohort Study (PKUPH-PS01)

2. Study Design

This is a single-center, prospective, single-arm interventional cohort study. All enrolled participants undergo video-assisted ablation of pilonidal sinus (VAAPS) combined with loose glove-edge seton drainage. Outcome data are collected prospectively at predefined time points. The study is conducted at the Department of Gastrointestinal Surgery, Peking University People's Hospital, Beijing, China.

3. Background and Rationale

Pilonidal sinus disease is a chronic inflammatory condition of the sacrococcygeal intergluteal cleft with an incidence of approximately 26 per 100,000 person-years. Traditional surgical approaches produce large wounds with prolonged healing and high recurrence rates. VAAPS, first described by Milone in 2014, is a minimally invasive endoscopic technique that leaves a wound of approximately 5 mm. A randomized trial in JAMA Surgery demonstrated significantly shorter time off work (1.6 vs. 8.2 days) and less pain compared with conventional surgery, with comparable recurrence rates at 5 years. However, VAAPS requires daily saline flushing and regular follow-up at the operating center. At our institution, over 60% of patients travel from other provinces and cannot attend standardized daily wound care. To address this, we developed a loose glove-edge seton technique that maintains tract patency without flushing, enabling postoperative self-care at home. This study prospectively evaluates the outcomes of this approach.

4. Objectives

Primary Objective:

To describe time off work after VAAPS combined with loose glove-edge seton drainage in out-of-town patients performing postoperative self-care.

Secondary Objectives:

- To describe postoperative pain scores (VAS) at 6 hours, day 1, weeks 1, 2, 4, and 6
- To describe time to complete wound healing
- To describe early postoperative complication rates (infection, delayed healing, hematoma, seroma)
- To describe 1-year and 3-year recurrence rates
- To describe patient satisfaction (PSS) and cosmetic outcome (WES)
- To assess feasibility, adherence, and patient experience of postoperative self-care

5. Study Population

Inclusion Criteria:

- Age $\geq$ 18 years

- Clinically diagnosed sacrococcygeal pilonidal sinus by physical examination and MRI
- Surgical indication for VAAPS
- Unable to attend long-term postoperative care at the operating center (out-of-town patients)
- ASA physical status class I or II
- Able to provide written informed consent
- Able to complete postoperative follow-up

Exclusion Criteria:

- Sinus tract length < 1 cm, or presence of an unhealed open wound
- Severe major organ dysfunction or uncontrolled comorbidities
- Coagulation disorder or ongoing anticoagulation
- Active infection, immunodeficiency, or autoimmune disease
- Pregnant or breastfeeding women
- Unable to comply with follow-up
- Contraindication to anesthesia or prone positioning

6. Intervention

All patients undergo standard VAAPS: a sinusoscope is inserted through the external opening to identify side tracts, remove hair, and ablate the tract wall under direct vision. At completion of the procedure, two thin strips cut from sterile surgical glove edges are loosely looped around the upper and lower sinus openings and secured to the surrounding skin. No postoperative saline flushing is required. Patients perform routine dressing changes at a local clinic or at home. The first seton strip is removed at approximately 1 week postoperatively, and the second strip at approximately 3 weeks. Before discharge, patients receive standardized wound care education and a 24-hour contact number.

7. Sample Size

Assuming a 90% complete wound healing rate, 95% confidence level, and 10% margin of error, the required sample size is approximately 35 patients. Accounting for 10-15% loss to follow-up and subgroup analyses, the target enrollment is 50 patients. At our center, approximately 80 VAAPS procedures are performed annually, with 60-70% being out-of-town patients, allowing completion within 2 years.

8. Follow-up Schedule

Short-term follow-up: postoperative day 1, weeks 1, 2, 4, and 6. Long-term follow-up: months 3, 6, 12, and 36. Follow-up methods include in-person visits, telephone, WeChat, and online medical platform. For out-of-town patients, telephone and WeChat are primary modes.

9. Outcome Measures

Primary Outcomes:

- Time off work (days from surgery to return to normal work/study)

- Time to complete wound healing (days from surgery to full epithelialization)
- Postoperative pain score (VAS 0-10) at multiple time points

Secondary Outcomes:

- 1-year and 3-year recurrence rates
- Patient Satisfaction Score (PSS) at months 3 and 12
- Cosmetic outcome by Wound Evaluation Scale (WES) at month 6
- Early complication rates (infection, delayed healing, hematoma, seroma)
- Time to pain-free walking and pain-free sitting
- Self-care adherence and patient experience

10. Ethics and Informed Consent

This study will be conducted in accordance with the Declaration of Helsinki. The protocol has been approved by the Ethics Committee of Peking University People's Hospital. All participants provide written informed consent. Participants may withdraw at any time without affecting their routine medical care. All data are anonymized and stored securely.

11. Study Timeline

Enrollment: September 2026 - December 2028. Short-term follow-up completion: December 2028. 1-year follow-up completion: December 2029. 3-year follow-up completion: December 2031.