Study Protocol: Impact of perioperative body temperature on postoperative complications and pain in Video-assisted thoracoscopic surgery patients utilizing continuous temperature monitoring

Version 1.0

Document Date: Jun 20th 2025

1. Study Title

Impact of perioperative body temperature on postoperative complications and pain in Video-assisted thoracoscopic surgery patients utilizing a continuous temperature monitoring System: A Prospective Cohort Study

2. Study Summary

2.1 Primary Objective

To investigate the impact of intraoperative hypothermia on postoperative complications (e.g., infections, cardiopulmonary events, prolonged hospitalization) in Video-assisted thoracoscopic surgery (VATS) patients.

2.2 Secondary Objective

To analyze the relationship between intraoperative hypothermia and the incidence of moderate-to-severe postoperative pain.

3. Study Design

Type: Prospective cohort study

Exposure Group: Intraoperative hypothermia (body temperature <36.0°C for ≥30 min at any time during surgery)

Non-Exposure Group: Body temperature consistently ≥36.0°C

Sample Size: 144 participants (72 per group; accounting for 10% dropout)

4. Participants

4.1 Inclusion Criteria:

- Age ≥18 years
- American society of anesthesiology (ASA) class I–III
- BMI 18.5–30 kg/m²
- Scheduled for VATS lung/mediastinal tumor resection (duration ≥1 hour)
- Receiving general anesthesia + regional block (TPVB + SAPB)
- Written informed consent

4.2 Exclusion Criteria:

- Preoperative fever (>37.5°C) or hypothermia (<36.0°C); ASA ≥IV
- Chronic opioid use (>3 months), chronic pain, or immunosuppression
- Emergency surgery or conversion to thoracotomy
- Planned surgery <1 hour or requiring cardiopulmonary bypass
- Failed regional block (sensory block not covering T2–T8 at 4h postoperation)
- Thyroid dysfunction or neurological disorders affecting pain assessment

5. Interventions/Monitoring

Temperature Monitoring: Wireless axillary sensor (non-surgical side), recorded every 5 minutes.

Hypothermia Management: Active warming (forced-air warmer + IV fluid warming) if temperature <36.0°C for ≥30 min.

Regional Block: Ultrasound-guided TPVB + SAPB.
Postoperative Analgesia: PCA with oxycodone (no basal infusion; 5mg bolus, 10-min lockout) + IV flurbiprofen (if no contraindication).

6. Outcome Measures
- Primary outcome: Incidence of Clavien-Dindo grade ≥ II complications (Daily clinical review until discharge)
- Secondary outcome: Moderate-severe pain (NRS ≥4) at 24h/48h/72h/post-discharge; length of stay; ICU admission rate; 30-day readmission rate.

7. Follow-Up Schedule

Timepoint	Assessments	Endpoint Focus
Postop 6h	NRS pain score; Rescue analgesia	Acute pain incidenc
Postop 24h/48h/72h	NRS pain score; Complications; Drain/ambulation	Pain trajectory; Early complications
Discharge	Total LOS; Analgesia use	Hospitalization duration
Postop Day 7	Wound healing; Unplanned visits	Wound complications
Postop Day 30	Complications; Chronic pain (NRS≥3)	30-day morbidity; Persistent pain

8. Statistical Analysis
- Primary Analysis: Multivariable logistic regression (hypothermia → complications), Kaplan-Meier for time-to-event.
- Secondary Analysis:
  - Logistic regression (hypothermia → pain), adjusted for regional block.
  - Interaction testing ("hypothermia × block efficacy").
  - Subgroup analysis by block success level.
- Software: R/Prism 8; Significance: $p<0.05$ (two-sided).

9. Ethics & Quality Control
- Ethics Approval: PKUPH IRB review prior to enrollment.
- Blinding: Outcome assessors masked to temperature group.
- Participant Protection: Voluntary withdrawal; anonymized data.

10. Timeline
- Preparation: Mar-May 2025 (IRB/registration/pilot)
- Enrollment: Jul 2025–Jun 2027
- Analysis: Jul-Aug 2027
- Publication: Dec 2027