Saint Petersburg State University Hospital

Study Protocol

Pre-incisional Wound INfiltration and Hypogastric PLEXus Block Using Ropivacaine in Laparoscopic Myomectomy

A Prospective, Randomized, Double-Blind, Placebo-Controlled Trial

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Background and Rationale

Uterine leiomyomas represent the most common benign tumor of the female reproductive system, with prevalence rates reaching up to 77% among women of reproductive age (1). Although symptomatic in only 20–50% of cases, fibroids substantially affect quality of life and reproductive potential (2).

Laparoscopic myomectomy is the current gold standard for fertility-preserving surgical management of fibroids. Its minimally invasive nature aligns well with Enhanced Recovery After Surgery (ERAS) principles, reducing surgical trauma, lowering postoperative pain, and facilitating earlier mobilization (3).

Effective perioperative analgesia is fundamental to successful ERAS implementation. Standard regimens rely heavily on NSAIDs, acetaminophen, and opioids. However, opioid use may undermine recovery by causing sedation, nausea, vomiting, ileus, impaired mobilization, and possibly opioid-induced hyperalgesia or immunosuppression (4).

Pain after laparoscopic myomectomy is multifactorial. Given the complex somatic and visceral innervation of the uterus—including sympathetic fibers traveling through the superior hypogastric plexus—traditional infiltration analgesia may not adequately address the visceral component (5).

Superior hypogastric plexus block (SHPB) has demonstrated analgesic efficacy in patients with pelvic malignancies, dysmenorrhea, endometriosis, and following abdominal hysterectomy or cesarean delivery (6). Yet its preventive use in laparoscopic myomectomy has never been systematically assessed.

This study evaluates whether combining pre-incisional wound infiltration with an intraoperative SHPB using ropivacaine can improve postoperative pain control compared with standard approaches.

Study Objective

The aim of this study is to assess an impact of laparoscopic superior hypogastric plexus (SHP) block combined with preemptive troacar site infiltration on postoperative pain intensity following laparoscopic myomectomy

Study Design

This is a **single-center, prospective, randomized, double-blind, placebo-controlled, three-arm trial**.

Participants are randomized 1:1:1 into:

1. **Group A (Full Analgesia):**
   Pre-incisional wound infiltration + SHPB with 0.2% ropivacaine.
2. **Group B (Wound Analgesia Only):**
   Wound infiltration with ropivacaine + SHPB with placebo.
3. **Group C (Placebo):**
   Placebo for both wound infiltration and SHPB.

Randomization is performed using Sealed Envelope® with opaque sequentially numbered envelopes. Allocation is concealed from investigators, surgeons, anesthesiologists, and study personnel. Only an anesthesiologist not involved in patient care opens the envelope and prepares syringes.

Inclusion Criteria

- Women aged ≥18 years.
- Indication for laparoscopic myomectomy due to ≥6 cm fibroid(s) or multiple fibroids.
- Ability to provide informed consent.

Exclusion Criteria

- FIGO type 7 subserosal pedunculated myoma.
- Conversion to laparotomy.
- Severe presacral adhesions preventing safe SHPB.
- Concomitant pelvic or abdominal surgery.

Interventions

Surgical Procedure

All participants undergo standardized laparoscopic myomectomy performed under uniform technique using harmonic scalpel dissection, multilayer myometrial closure, and in-bag morcellation. No drains are placed.

Analgesic Interventions

Wound Infiltration

Ropivacaine or placebo is administered pre-incision using a patented method: infiltration volume (mL) equals the incision length (mm).

Superior Hypogastric Plexus Block (SHPB)

After trocar placement, the promontory is exposed, the peritoneum tented, and a 1-mm laparoscopic needle introduced. Ten milliliters of study solution (ropivacaine or saline) are injected into the presacral space.

Postoperative Analgesia (Standardized for All Groups)

- Ketorolac IV every 8 h (first 24 h), then q12h.

- Paracetamol IV every 8 h (first 24 h), then q12h.
- Rescue opioid: intramuscular promedol 1 mg when NRS >4.

Pain scores and pain type are assessed at predetermined time points. Mobilization is attempted on the evening of surgery; mobilization time is recorded.

Outcome Measures

Primary Endpoint

Pain intensity at 4 hours postoperatively (Numeric Rating Scale, NRS 0–10).

Secondary Endpoints

- NRS pain score at all remaining time points (2, 6, 8, 12, 24 h).
- Time to mobilization.
- Proportion of patients requiring opioid rescue.
- Patient-reported pain character (visceral vs somatic).

Study Procedures

Baseline (Preoperative)

- Informed consent.
- Demographic and clinical data collection.

Randomization and Intraoperative Phase

- Allocation concealed until patient is in the OR.
- Preparation of masked syringes.
- Administration of wound infiltration and SHPB per protocol.

Postoperative Assessments

- NRS pain scores at 2, 4, 6, 8, 12, and 24 h.
- Pain type questionnaire at 4 h.
- Documentation of opioid use.
- Recording mobilization time.

Study Completion

- Final assessment at discharge.
- Verification of completeness of data.

Study Instruments

- **Numeric Rating Scale (NRS):** 0–10 score assessing pain intensity.
- **Pain Character Questionnaire:** differentiates visceral (deep, "menstrual-like") vs somatic (superficial, "muscle strain-like") pain.

Ethical Considerations

The study complies with:

- ICH-GCP guidelines
- Declaration of Helsinki (2000 revision)
- National and institutional regulatory requirements

Ethics Committee approval will be obtained prior to study initiation.

All participants will sign written informed consent. Confidentiality is ensured by coded identifiers. Patient welfare takes precedence over scientific objectives.

Sample Size and Statistical Analysis

Sample Size

Based on G*Power calculations assuming:

- 50% baseline incidence of significant postoperative pain
- Expected difference of ~25% between groups
- $\alpha = 0.05$, power = 90%

The required sample size is **198 patients** (66 per group).

Statistical Analysis

Analysis will be performed using IBM SPSS 29.0.

- Normality: Kolmogorov–Smirnov test
- Nonparametric data: median (IQR)
- Intergroup comparisons: Kruskal–Wallis test with Dunn's post-hoc analysis
- Categorical variables: Pearson χ^2 or Fisher's exact test
- Pain dynamics: Friedman test for repeated measures
- Significance threshold: $p < 0.05$ (two-sided)

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