PROTOCOL
for a
clinical study

Study Title

Efficacy of the Deep Rectus Sheath (Preperitoneal) Block for Postoperative Analgesia in Abdominal Surgery: A Prospective Observational Clinical Study

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Sponsor: Department of Anesthesia and Intensive Care, Crotone Hospital
Coordinating Center: Crotone Hospital

Principal Investigator: Dr. Tommaso Sorrentino, Consultant Anesthesiologist, Department of Anesthesia and Intensive Care, Crotone Hospital – Crotone

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Contact Information

Sponsor Contact:
Dr. Tommaso Sorrentino
Consultant Anesthesiologist, Department of Anesthesia and Intensive Care, Crotone Hospital – Crotone
+39 0962 924193
tommaso.sorrentino@asp.crotone.it

This study protocol has been designed and will be conducted in accordance with the principles of Good Clinical Practice (GCP), where applicable, and in compliance with the Declaration of Helsinki.

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1. Introduction and Rationale

Postoperative pain following abdominal surgery, both open and laparoscopic, primarily originates from the somatic component of the abdominal wall and from the parietal and visceral peritoneum, a richly innervated and highly nociceptive structure. Despite the adoption of multimodal analgesic protocols (including anterior and posterior abdominal wall fascial plane blocks such as TAP, QL, and ESP blocks), pain control may remain suboptimal and associated with postoperative opioid consumption.

The rectus sheath block provides somatic analgesia of the midline abdominal wall but may be insufficient for controlling peritoneal pain. Recently, the Deep Rectus Sheath (DRS) block has been described, involving injection of local anesthetic beneath the posterior rectus sheath into the preperitoneal compartment. This technique may provide broader analgesia by involving the parietal peritoneum and potentially modulating the visceral component of pain.

Current evidence is limited to case reports and small case series suggesting good pain control and a significant opioid-sparing effect. However, structured observational studies systematically evaluating the clinical efficacy and safety of the DRS block are lacking.

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2. Study Objectives

Prospective, monocentric (with potential multicenter extension), non-interventional observational clinical study.

2.1 Primary Objective

To evaluate the quality of postoperative recovery in patients undergoing abdominal surgery receiving a Deep Rectus Sheath (Preperitoneal) Block, using the Quality of Recovery-15 (QoR-15) questionnaire at 24 hours after surgery.

The Quality of Recovery-15 (QoR-15) score was introduced in 2013 for objective assessment of postoperative recovery quality.

The QoR-15 consists of 15 questions with a total score ranging from 0 to 150 points. The five assessment domains include pain, physical comfort, physical independence, psychological support, and emotional state.

Lower scores indicate poorer recovery quality, whereas higher scores indicate better recovery.

2.2 Secondary Objectives

Evaluation of postoperative pain using the Numerical Rating Scale (NRS) at rest and during movement (movement of the operated limb and patient mobilization) at 0, 2, 4, 6, 8, 12, 24, and 48 hours after surgery; patient satisfaction using the Likert scale at 24 hours postoperatively; total analgesic consumption; time to first analgesic request (duration of analgesia); time to first mobilization (patient standing and able to walk); occurrence of complications such as nausea and vomiting; and use of antiemetics.

Special attention will be paid to the observation of potential adverse/side effects:

- During block performance (vascular puncture, paresthesia, pain, LAST – Local Anesthetic Systemic Toxicity)
- Thirty minutes after the block (pain, hematoma, LAST)
- Occurrence of postoperative neurological deficits or other delayed/persistent disturbances at 7 days (telephone follow-up by the investigator)

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3. Materials and Methods

3.1 Study Population

The study will include patients undergoing abdominal surgery, both open and laparoscopic, aged >18 years, ASA physical status I–III, with an expected hospital stay of at least 24 hours, who have provided informed consent for general and/or locoregional anesthesia, abdominal wall/fascial plane blocks, and participation in the study.

Group allocation is not randomized and reflects routine clinical practice. Patients will be retrospectively classified according to the perioperative analgesic strategy actually performed:

- **Group A – Standard care:** systemic analgesia according to local guidelines/protocols (e.g., paracetamol ± NSAIDs; opioids), without abdominal wall blocks.
- **Group B – DRS:** bilateral Deep Rectus Sheath (preperitoneal) block + standard care.
- **Group C – Alternative/additional fascial blocks** (at the anesthesiologist's discretion): TAP / ESP / QL blocks (or combinations) + standard care.

To reduce misclassification and heterogeneity, the following variables will be recorded in detail: type of block, timing (pre-incision vs end of surgery), local anesthetic volume/concentration, possible adjuvants, and anesthetic technique used (neuraxial vs general anesthesia).

3.2 Inclusion Criteria

- Age ≥18 years
- Patients undergoing abdominal surgery, open or laparoscopic
- ASA I–III
- Neuraxial or general anesthesia performed according to clinical practice
- Informed consent to participate in the study

3.3 Exclusion Criteria

- Refusal to provide informed consent
- Contraindications to locoregional anesthesia
- Known allergy to local anesthetics
- Coagulation disorders or incompatible anticoagulant therapy
- Infection at the injection site
- Cognitive impairment preventing outcome assessment

3.4 Clinical Procedure

Anesthetic and analgesic strategies (standard care, DRS, TAP/ESP/QL) will be selected by the anesthesiologist according to surgical procedure, patient risk factors, clinical preference, and resource availability. The study will not alter routine clinical practice.

3.4.1 Standard Care (common to all groups)

All patients will receive standard multimodal postoperative analgesia according to institutional protocols and current guidelines (e.g., scheduled paracetamol ± NSAIDs when not contraindicated; opioids reserved as rescue medication for NRS >4).

3.4.2 Deep Rectus Sheath (Preperitoneal) Block – Technique (Group B)

The DRS block will be performed under ultrasound guidance, under aseptic conditions, either before surgery or at the end of the surgical procedure, according to clinical practice.

Ultrasound-Guided Technique

- High-frequency linear ultrasound probe
- Lateral-to-medial in-plane approach
- Target: preperitoneal space beneath the posterior rectus sheath, preferably above the arcuate line
- Volume and concentration: ropivacaine 0.2–0.375%, up to 20 mL per side (at the anesthesiologist's discretion)

3.4.3 Alternative/Additional Fascial Blocks (Group C)

When performed at the anesthesiologist's discretion, the following blocks will be considered comparators:

- TAP block (specific variant specified: subcostal, lateral, posterior, etc.)
- ESP block (level specified)
- Quadratus Lumborum (QL) block (type specified: QL1/2/3, transmuscular, intramuscular)

For each block, the following data will be recorded: technique/approach, side (unilateral/bilateral), timing, local anesthetic volume/concentration, possible adjuvants, and complications.

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4. Statistical Analysis

As this is an exploratory observational study, sample size will be based on feasibility.

Patient groups will be compared regarding baseline characteristics (demographic, clinical, laboratory, and instrumental variables collected in the case report form) using the Student's t-test and Pearson's chi-square test depending on the continuous or categorical nature of the variables.

Equivalent non-parametric tests will be considered in case of non-normal distribution, formally assessed using the Shapiro–Wilk test.

Linear mixed-effects models will be used for comparisons between treatment groups for outcomes involving repeated measures over time.

Multivariable analyses may be considered in the presence of baseline imbalance between comparison groups.

A p-value <0.05 will be considered statistically significant.

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5. Study Duration

The maximum expected study duration is 12 months.

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6. Insurance

Given the observational and non-interventional nature of the proposed study, no additional insurance policies are considered necessary beyond those already provided for routine clinical practice in the context of professional liability coverage.

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7. Ethical Aspects and Consent

The study will be submitted to the appropriate Ethics Committee.

All patients will sign specific informed consent forms for participation in the study and for personal data processing.

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8. Privacy and Data Management

Sensitive patient data will be collected in the case report form (CRF) using only patient initials and a study identification number consisting of a unique two-digit center code followed by a three-digit sequential patient number starting from 001 according to enrollment order.

Patients will sign a dedicated consent form for personal data processing in accordance with applicable regulations (Article 13 of the General Data Protection Regulation (EU) 2016/679).

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9. Document Retention

Study documentation will be available for possible audits or inspections for 10 years after formal study closure.

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10. Ownership of Scientific Data

The scientific data collected will remain the property of the study scientific coordinator.

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11. Publication Policy and Dissemination of Results

The scientific coordinator commits to preparing a final report and a scientific manuscript and to publicly disseminating the study results upon study completion.

Data will be published anonymously and presented in aggregated form where required.

12. Conflict of Interest

None.