PROTOCOL for Clinical Study

Study Title

Effectiveness of the "Quadro-Iliac Plane Block" in Hip Arthroplasty: A Prospective Observational Clinical Study

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

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1. Introduction

Total hip arthroplasty is a widely performed surgical procedure in the elderly population aimed at relieving pain caused by osteoarthritis or trauma and improving functional recovery.

Locoregional anesthesia plays a crucial role in lower-limb orthopedic surgery by allowing appropriate surgical management, avoiding general anesthesia, and providing postoperative analgesia with optimal pain control without opioid use, thereby facilitating early rehabilitation and recovery.

Several locoregional anesthesia techniques have been employed for hip arthroplasty surgery and postoperative analgesia, including neuraxial anesthesia (including epidural anesthesia), lumbar plexus block, femoral nerve block, and sciatic nerve block.

To limit quadriceps motor paralysis while still ensuring adequate analgesia of both the anterior and posterior hip compartments, current literature and international guidelines support the use of the fascia iliaca block (FIB) for postoperative analgesia after total hip arthroplasty, although newer approaches are increasingly showing promising efficacy. The Pericapsular Nerve Group (PENG) block offers an additional option for pain management after hip arthroplasty due to its motor-sparing advantages. By targeting the articular sensory branches of the femoral and obturator nerves, the PENG block avoids the motor weakness and foot drop associated with traditional femoral nerve or lumbar plexus blocks, thereby facilitating early rehabilitation without masking potential intraoperative injuries.

The erector spinae plane (ESP) block was initially described in 2016 for the treatment of thoracic neuropathic pain. It was subsequently applied for postoperative analgesia in various body regions, ranging from the shoulder to the hip.

The sacral erector spinae plane block (sacral ESP block) is a more recent approach, first described in 2019, and current literature supports its use in several surgical settings (pediatric, anorectal, pelvic, and orthopedic surgery) due to its potential spread toward the sacral, pudendal, and lumbar plexus nerves. It has already been documented for analgesia in lumbar discectomy surgery, hip surgery (hip arthroplasty and proximal femoral fractures), and knee arthroplasty in several trials and case reports.

More recently, the Quadro-Iliac Plane (QIP) block has been introduced into clinical practice with promising results for postoperative pain control after hip surgery. This approach, described by Tulgar, may be considered a simplified variation of the well-known quadratus lumborum (QL) block, as it involves injection of local anesthetic between the erector spinae and quadratus lumborum muscles at the most posterior and inferior point, specifically at the insertion of the quadratus lumborum muscle onto the iliac crest, thereby directing the local anesthetic toward deeper planes involving the iliohypogastric and ilioinguinal nerves, the lumbar plexus, and the retroperitoneal space.

2. Study Objective

This prospective observational clinical study aims to evaluate postoperative recovery, quality of hospitalization, and analgesic efficacy of the different locoregional anesthesia techniques currently used in clinical practice at our hospital for patients undergoing hip arthroplasty, with particular focus on the effectiveness of the QIP block. The study will provide useful data for improving postoperative recovery, pain management, and patient satisfaction, particularly through comparison among the different blocks utilized.

The study will be conducted in accordance with the protocol, GCP, and applicable regulatory requirements.

The following endpoints have been identified for evaluation in this study.

2.1 Primary Endpoint

Assessment of postoperative recovery quality using the Quality of Recovery-15 (QoR-15) score at 24 hours after surgery.

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

The QoR-15 consists of 15 questions with a total score of 150 points. The five evaluated domains include:

* pain,
* physical comfort,
* physical independence,
* psychological support,
* emotional state.

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

2.2 Secondary Endpoints

Assessment of postoperative pain using NRS scores 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 assessed by Likert scale at 24 hours after surgery; total analgesic consumption; time to first analgesic request (duration of analgesia); time to first mobilization (standing and walking); occurrence of complications such as nausea and vomiting; and use of antiemetics.

Particular attention will be paid to observation of potential side effects/adverse events:

* during block performance (vascular puncture, paresthesia, pain, LAST – Local Anesthetic Systemic Toxicity);
* 30 minutes after the block (pain, hematoma, LAST);
* occurrence of postoperative neurological deficits or other late/persistent disorders within 7 days (telephone follow-up by the investigator).

3. Materials and Methods

3.1 Inclusion Criteria

* Age ≥ 18 years
* Patients undergoing hip arthroplasty surgery, either elective or for proximal femoral fracture
* Expected postoperative hospital stay ≥ 24 hours
* ASA physical status I–III
* Receipt of neuraxial and/or locoregional anesthesia according to standard clinical practice
* Provision of informed consent for participation in the study

3.2 Exclusion Criteria

* Absence of informed consent
* Contraindications to locoregional and/or spinal anesthesia
* Allergy to local anesthetic agents
* Cognitive impairment preventing reliable assessment of outcomes
* Coagulation and platelet abnormalities
* Antiplatelet or anticoagulant therapies contraindicating spinal anesthesia
* Presence of localized infection/sepsis at treatment sites

3.3 Study Procedures

At Crotone Hospital, several locoregional anesthesia techniques (also in combination with one another) are routinely used for hip arthroplasty surgery and postoperative analgesia, including neuraxial anesthesia (including epidural anesthesia), lumbar plexus block, femoral nerve block, sciatic nerve block, fascia iliaca block, PENG block, sacral ESP block, lumbosacral ESP block, and more recently the QIP block.

All patients receive standard monitoring and anesthesia management according to current regulations, protocols, and routine clinical practice. Standard monitoring includes vital signs monitoring, venous cannulation, isotonic fluid administration, and preoperative antibiotic prophylaxis.

All locoregional blocks are performed under aseptic conditions with ultrasound guidance according to national and international guidelines and clinical practice. Blocks are performed by the attending anesthesiologist experienced in locoregional anesthesia techniques, after obtaining both surgical and study informed consent from the patient. Before block performance, patients receive anxiolysis and analgesia (midazolam and/or fentanyl) and local anesthesia (2 mL lidocaine 2% infiltration at the puncture site).

The following are always available during block performance:

* sterile materials (gloves, drapes, needles, syringes, probe covers, 2% chlorhexidine in 70% isopropyl alcohol);
* ultrasound machine with linear and convex probes;
* standard vital signs monitoring;
* peripheral venous access;
* emergency drugs and equipment;
* oxygen and ventilation support devices;
* lipid emulsion (antidote) for LAST (local anesthetic systemic toxicity).

Block performance follows standard technical and sonoanatomical recommendations from the literature. Ultrasound recordings include:

* baseline anatomical scan (imaging time);
* needle approach scan (needling time);
* spread of injectate scan (blocking time).

A short procedural clip is also recommended whenever feasible.

Approved local anesthetic agents for perineural infiltration are used according to standard practice. Typical regimens include:

* Femoral nerve block: 15 mL ropivacaine 0.5%
* Sciatic nerve block: 20 mL ropivacaine 0.5%
* Lumbar plexus block: 20 mL ropivacaine 0.5%
* Fascia iliaca block: 40 mL ropivacaine 0.2%
* PENG block: 20 mL ropivacaine 0.375%
* Sacral ESP block: 30 mL ropivacaine 0.375%
* Lumbosacral ESP block: 20 mL ropivacaine 0.375% at lumbar level and 20 mL ropivacaine 0.2% at sacral level
* QIP block: 30 mL ropivacaine 0.375%

Intravenous dexamethasone 8 mg may be administered at the anesthesiologist's discretion after block performance to optimize duration and efficacy. Naturally, all blocks are performed on the operative limb after verification before puncture.

After block performance, patients are transferred to the operating room. Spinal anesthesia is performed under aseptic conditions using 2.5 mL levobupivacaine or ropivacaine 0.5% at the L3–L4 intervertebral space.

After surgery, patients are transferred to the recovery room for clinical observation and monitoring for at least one hour in the absence of complications before ward transfer. All parameters are recorded in the medical chart.

All patients receive postoperative:

* paracetamol 1 g IV three times daily;
* rescue analgesia with tramadol 1 mg/kg IV if NRS > 4;
* ondansetron 4 mg IV.

Patients complete QoR questionnaires at 24 hours after surgery, and endpoints are recorded using dedicated case report forms.

Data collection and monitoring are generally performed by an anesthesiologist assisted by an experienced ward nurse.

3.4 Statistical Analysis

The study sample size for comparison between groups (QIP block versus FIB) was estimated using the QoR-15 score as the primary outcome. Previous literature suggests that a 6-point difference in QoR-15 represents the minimal clinically important difference.

In a previous study of patients undergoing THA, the control group reported a mean QoR-15 score of 100.69 (SD 7.65).

Based on these parameters, corresponding to a Cohen effect size of 0.78 (6/7.65), and assuming a type I error of 0.05 and a power of 80%, 17 patients per group are required. Sample size calculation was performed using the following tool:

ClinCalc Sample Size Calculator

Baseline patient characteristics (demographic, clinical, laboratory, and instrumental variables collected in the data forms) will be compared using Student's t-test and Pearson's Chi-square test according to variable type. Equivalent non-parametric tests will be used in the presence of non-normal distribution, formally assessed using the Shapiro–Wilk test.

Linear mixed-effects models will be used to compare repeated-measures outcomes between groups over time. Multivariate analyses may be performed in the presence of baseline imbalance between groups. A p-value < 0.05 will be considered statistically significant.

3.5 Number of Centers Involved

For the present study, the participating center will be Crotone Hospital, with the possibility of extending the study to two additional centers to be defined.

3.6 Direct Access to Source Data/Documents

A reference person responsible for data collection, quality control, and data transmission procedures will be identified at the Center. Monitoring, verification, IRB/IEC review, and regulatory authority inspections related to the study will always be permitted by providing direct access to source data/documents.

3.7 Study Duration

The maximum expected duration of the study is 18 months.

3.8 Insurance

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

3.9 Ethical Aspects

The study will be conducted in accordance with GCP, the ethical principles derived from the Declaration of Helsinki, and current legislation governing clinical studies.

3.10 Informed Consent

Each patient will be offered informed consent for inclusion in the observational study. All necessary information will be provided to allow the patient to give valid and informed consent. Consent will be obtained in written form and attached to the patient's medical record. Each patient will be given sufficient time to read the dedicated information sheet and to ask the investigator for any clarification needed.

4. Ethics Committee

The study and related documentation will be submitted to the competent Ethics Committee for the Local Health Authority. The study will begin only after the required authorizations have been obtained according to the internal procedures of the same institution.

5. Privacy

Sensitive patient data will be collected in the data collection form or case report form (CRF), reporting only the patient's initials and an identification number consisting of a two-digit code specific and unique to the participating center, followed by a three-digit patient identification number assigned progressively from 001 according to enrollment order. The patient will be required to sign specific consent for the processing of personal data in accordance with current legislation, including the information notice pursuant to Article 13 of the General Data Protection Regulation (EU) 2016/679.

6. Document Retention

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

7. Ownership of Scientific Data

The scientific investigator will be the owner of the collected data.

8. Publication Policy and Communication of Results

The scientific investigator undertakes to prepare a final report and a scientific article and to make the results public at the end of the study. Data will be disclosed anonymously and, where required, presented in aggregate form.

9. Conflict of Interest

None.

10. Bibliography

1. Viganò M, Pennestrì F, Listorti E, Banfi G. Proximal hip fractures in 71,920 elderly patients: incidence, epidemiology, mortality and costs from a retrospective observational study. BMC Public Health 2023;23:1963.
2. Anger M, Valovska T, Beloeil H, Lirk P, Joshi GP, Van de Velde M, et al.; PROSPECT Working Group and the European Society of Regional Anaesthesia and Pain Therapy. PROSPECT guideline for total hip arthroplasty: A systematic review and procedure-specific postoperative pain management recommendations. Anaesthesia 2021;76:1082–97.
3. Pissens S, Cavens L, Joshi GP, Bonnet MP, Sauter A, Raeder J, Van de Velde M, on behalf of the PROSPECT Working Group of the European Society of Regional Anaesthesia and Pain Therapy (ESRA). Pain management after hip fracture repair surgery: a systematic review and procedure-specific postoperative pain management (PROSPECT) recommendations. Acta Anaesth Bel 2024;75:15–31.
4. Wang S, Wu Z, Song Y, Yang X, Zhao P. Application of ultrasound-guided regional blocks in the perioperative period of hip arthroplasty: A systematic review and network meta-analysis. J Clin Anesth 2026;109:112110.
5. Forero M, Adhikary SD, Lopez H, Tsui C, Chin KJ. The Erector Spinae Plane Block: A Novel Analgesic Technique in Thoracic Neuropathic Pain. Reg Anesth Pain Med 2016;41:621–7.
6. Tulgar S, Senturk O, Thomas DT, Deveci U, Ozer Z. A new technique for sensory blockage of posterior branches of sacral nerves: ultrasound guided sacral erector spinae plane block. J Clin Anesth 2019;57:129–30.
7. Gupta A, Kaur J, Kumar R. Unilateral sacral erector spinae plane block for lower limb surgery in children. Anaesth Rep 2022;10:e12199.
8. Mermer A, Simsek G, Mermer HA, Tire Y, Kozanhan B. Effect of sacral erector spinae plane block on post-hemorrhoidectomy pain: A randomized controlled trial. Medicine (Baltimore) 2023;102:e35168.
9. Olgun Keleş B, Tekir Yilmaz E. The effect of an ultrasound-guided sacral erector spinae plane block on the postoperative pain of lumbar discectomy: a randomized controlled trial. Minerva Anestesiol 2024;90:369–76.
10. Satici MH, Tutar MS, Tire Y, Binici O, Çiçekler O, Korkmaz E, Pekince O, Kozanhan B. The effect of sacral erector spinae plane block on the quality of recovery after total hip arthroplasty: a prospective, randomized, controlled, multicenter study. Minerva Anestesiol 2024 Nov 4. doi: 10.23736/S0375-9393.24.18353-8. Epub ahead of print.
11. Marrone F, Paventi S, Tomei M, Failli S, Crecco S, Pullano C. Unilateral sacral erector spinae plane block for hip fracture surgery. Anaesth Rep 2024;12:e12269.
12. Marrone F, Fusco P, Paventi S, Tomei M, Lolli S, Chironna E, Pullano C. Combined lumbar and sacral erector spinae plane (LS-ESP) block for hip fracture pain and surgery. Minerva Anestesiol 2024;90:712–4.
13. Marrone F, Fusco P, Tulgar S, et al. Combination of pericapsular nerve group (PENG) and sacral erector spinae plane (S-ESP) blocks for hip fracture pain and surgery: a case series. Cureus 2024;16:e53815.
14. Marrone F, Pullano C, Paventi S, Tomei M, Fusco P. A unilateral single-level sacral erector spinae plane block for total knee arthroplasty pain. Minerva Anestesiol 2024;90:707–8.
15. Marrone F, Fusco P, Paventi S, Villani A, Tomei M, Pullano C. Combined saphenous (adductor canal) nerve block and sacral erector spinae plane block for total knee arthroplasty pain. Minerva Anestesiol 2024 Oct 22. doi: 10.23736/S0375-9393.24.18446-5.
16. Marrone F, Fusco P, Paventi S, Pullano C. Combined adductor canal (ACB) and sacral erector spinae plane (S-ESP) blocks for total knee arthroplasty pain in hemophilic arthropathy. Saudi J Anaesth 2024;18:565–8.
17. Satici MH, Tutar MS, Kozanhan B, Yildiz M, Yildirim A, Altay N. Recovery after hip arthroplasty with Quadro-Iliac Plane Block: A randomised trial. J Coll Physicians Surg Pak 2025;35:947–52.
18. Marrone F, Sorrentino T, Pullano C, Tulgar S. A novel and feasible option for perioperative analgesia in hip fractures surgery: Quadro-Iliac Plane Block. Minerva Anestesiol 2025;91:592–5.
19. Tulgar S, Ciftci B, Ahiskalioglu A, Bilal B, Sakul BU, Girit M, et al. Ultrasound-guided quadro-iliac plane block: another novel fascial plane block. Pain Med 2024;25:370–3.
20. Diwan S, Blanch XS, Nair AS. Nerves in quadratus lumborum planes: A cadaveric study. Indian J Anaesth 2024;68:500–3.

21. Shakeri A, Alinejadfard M. The quadro-iliac plane block: a systematic review of a promising novel technique. BMC Surg 2025;25:567.
22. Stark PA, Myles PS, Burke JA. Development and psychometric evaluation of a postoperative quality of recovery score: the QoR-15. Anesthesiology 2013;118:1332–40.
23. Myles PS, Myles DB. An updated minimal clinically important difference for the QoR-15 scale. Anesthesiology 2021;135:934–5.
24. Gao Y, Li H, Hu H, Xu Y, Zhou J, Liu Y. Effects of continuous fascia iliaca compartment block on early quality of recovery after total hip arthroplasty in elderly patients: A randomized controlled trial. J Pain Res 2022;15:1837–44.
25. Rosner B. Fundamentals of Biostatistics. 7th ed. Boston, MA: Brooks/Cole; 2011.