Comparative assessment of effectiveness and safety of Lumbar Erector Spinae Plane Block (L-ESPB) versus absence of locoregional block in hip surgery

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Pragmatic single-centre parallel group randomized clinical trial.

1. Introduction

Hip surgery accounts for a high percentage of both emergency and elective surgical procedures in hospitals. Regardless of surgery being prescribed to treat a fracture or coxarthrosis, patients are usually elderly with multiple associated comorbidities (1). When faced with this patient profile, there is a tendency to undertreat pain for fear of the side effects and pharmacological interactions of conventional analgesic drugs (2).

The hip joint consists of the coxal bone (acetabulum) and the head of the femur, both lined by the hyaline cartilage. A protective and strong hip capsule seals the joint hermetically. Three strong ligaments (iliofemoral ligament, ligament of Bertin, or ischiofemoral ligament, and pubofemoral ligament) link the hip bones to the thigh. Its innervation is complex; it will depend essentially on the lumbar and lumbosacral plexuses. The anterior and more proximal region is that of the lumbar plexus (the major nerve of which is the femoral nerve) and the posterior face is innervated by the lumbosacral plexus (of which the major nerve is the sciatic nerve) (3).

Ultrasound-guided regional anesthesia applied in orthopedic and trauma surgery has been shown to reduce the doses of opioids and conventional analgesics, to ease deambulation and early recovery, to improve respiratory dynamics and to reduce vein thrombosis and pneumonias (4, 5). Our study aims to verify whether L-ESP block is effective in the hip and proximal femur surgeries and allows to lower the dosage of opioids in these patients.

2. Material and methods

The clinical trial shall be carried out at the *Hospital Universitario Álvaro Cunqueiro* [Álvaro Cunqueiro Teaching Hospital] of Vigo. The recruitment period shall run from 1 July 2024 to December 2025. Patients recruited and included in the study shall previously sign a written informed consent.

2.1 Inclusion and exclusion criteria

This study shall include all patients of both sexes over 18 years of age having undergone hip surgery, ASA I-III (classification system used by the American Society of Anesthesiologists where I is low anesthetic risk and IV is high risk), with the capacity to comprehend the principles of pain assessment using the VAS visual analogue scale and having previously signed an informed consent.

Exclusions shall apply to patients with contraindications for the technique and/or the drugs used in this context, in cases of technical inability to perform the block, to patients presenting with severe cognitive impairment or prior mental disabilities described in their medical records, or to patients already included in other clinical trials.

2.2 Randomization

Upon signing the informed consent and after the surgery, a systematic randomization shall be carried out by means of a computer system which shall define the arm to which a specific patient belongs.

There will be two groups of patients (a group on which ultrasound-guided L-ESP shall be carried out at the L3-L4 level with 30 mL of levobupivacaine 0.25% and a control group which shall be handled with conventional intravenous analgesia). A total of 180 patients, 90 in each group, shall be randomized.

Use of the locoregional technique renders it impossible to blind the study both to the patient and the anesthetist delivering it. Even so, a blind assessment of the objectives shall be carried out, as the nurses who will collect data from the first hours post-surgery and the unit staff nurses who will collect data in the subsequent hours will not know the group to which each patient belongs.

2.3 Intervention

It is a clinical trial designed and conducted by researchers in which the industry does not take part. It is included within a pragmatic randomized low interventional single-centre parallel non blinded design with blinded assessment of the objectives. All patients to undergo emergency or elective hip surgery who meet the inclusion criteria and do not meet any of the proposed exclusion criteria shall be included. The main variable shall be pain control (assessed with the VAS scale) after hip surgery. There will be two groups of patients (a group on which ultrasound-guided ESP-L shall be carried out at the L3-14 level with 30 mL of levobupivacaine 0.25% and a control group which shall be handled with conventional intravenous analgesia) (Appendix I).

L-ESP block shall be carried out using a portable ultrasound machine with a linear or convex transducer, and a 50 mm or 80 mm Pajunk® 22G needle, depending on the target block depth. The patient shall be placed in the lateral decubitus position opposite to the leg to be blocked. We shall locate the transverse apophyses at the L3-L4 level with a parasagittal incision. Once this objective is located, a 22G 50 mm or 80 mm needle is inserted, depending on the depth of the same, from cranial to caudal in the plane of the ultrasound probe. We will advance through the erector spinae muscles, subsequently performing hydrodissection and injection of 30 mL of levobupivacaine 0.25% once negative aspiration has been carried out.

In the group of patients without locoregional block, we will also collect data on post-surgery pain using the Visual Analogue Scale (VAS), use of opioids and complications associated with said use.

We will collect the age, sex, height, weight, ASA, date of admission and date of surgery, type of surgery (prosthesis/osteosynthesis), type of anesthesia and pre-block VAS.

When the locoregional technique is performed, the zero hour moment is deemed to be the time within the first two hours of the postoperative period when the patient presents with VAS >1.
An analgesic postoperative protocol shall be available in which, after performing the locoregional technique (for the patients in that group), 1000 mg of paracetamol shall be administered every eight hours, as well as 50 mg of dexketoprofen or 400 mg of ibuprofen every eight hours. 1000 mg of metamizol every eight hours shall be prescribed for patients allergic to NSAIDs or paracetamol, or if needed for rescue. If VAS ≥4, 2 mg of morphine shall be concurrently prescribed. In the latter case, we shall reassess after 15 minutes. Should VAS ≥4 persist after delivery of the bolus, the same dose of morphine shall be repeated with subsequent assessment in 15 minutes, up to a maximum of 12 mg of morphine in twenty-four hours (see Appendix 2).
We shall assess VAS at 30 minutes and 2, 6, 12, 24 and 48 hours, as well as the adverse effects of the locoregional block and the opioids; the degree of satisfaction of the patient and the technical ease of the block shall also be assessed.

2.4 Objectives

Primary objective
To compare the analgesic effectiveness and safety of lumbar ESP block versus absence of block after hip and proximal femur surgeries by means of the VAS scale with pain reduction of at least 1 point in the first two hours after surgery.

Secondary objectives
We shall compare the analgesic postoperative needs after performing L-ESP block versus a control group of patients having undergone hip or proximal femur surgeries and the postoperative consumption of opioids in both groups; we shall assess and compare the technical ease of the surgery (L-ESP block) and the side effects in both lines of treatment. Finally, we shall assess the level of satisfaction of the patients.

2.5 Statistical analysis

The analysis shall be carried out using the IBM SPSS software platform. A descriptive analysis of all variables collected shall be carried out in which frequency and percentage shall be stated for categorical and mean variables, standard deviation and range for quantitative normal variables or mean and interquartile range for non-normal variables. Normality shall be assessed using the Kolmogorov-Smirnov test.

Comparisons throughout monitoring of variables both of effectiveness and safety between both groups shall be analyzed with the Chi-square test for categorical variables and T-Student test for numerical variables, while for intragroup comparisons, the McNemar test shall be used for qualitative variables and the T-Student test for samples related to quantitative variables. If data from quantitative variables do not follow a normal distribution, the equivalent nonparametric Mann-Whitney U tests shall be used for independent groups and Wilcoxon tests for related samples.

In all the hypothesis contrasts, statistically significant differences shall be deemed to exist when $p<0,05$.

3. Discussion

Hip fractures have major health, social and economic impact. This kind of fracture accounts for a high percentage of both urgent and elective surgeries in hospitals. Regardless of surgery being prescribed to treat a fracture or coxarthrosis, patients are usually elderly with multiple associated comorbidities (1). When faced with this patient profile, there is a tendency to undertreat pain for fear of the side effects and pharmacological interactions of conventional analgesic drugs (6). Poor analgesic control of these patients results in a slower recovery with longer hospital stays, increased incidence of chronic pain and increased cardiovascular risks; hence the importance of a good management of said control (7).

When dealing with a hip fracture, the conventional treatment shall be reduction and surgical fixation. In patients who are not candidates for surgery due to their high rate of comorbidities, pain control will be a challenge for healthcare professionals. Recent studies have even suggested using chemical denervation techniques to improve the quality of life in its final years. In countries such as Hong Kong, about 4% of these fractures are treated conservatively, as the patients are rejected for surgery (2).

The Hospital Complex of Vigo, covering a healthcare area populated by 570,000 residents, has recorded 315 hip fractures in the last year. Average age of the patients was 85 years and 82% of them were women.
In our center, regional anesthesia prevails significantly over general anesthesia for this kind of surgery. Both techniques have been found to be equally efficient, without major differences in morbimortality

(8). Still, some revisions claim the superiority of regional anesthesia in these surgeries, with better postoperative results, and link general anesthesia to higher risk of hospital mortality, respiratory failure, longer average stays and higher rates of readmission (9). Ultrasound-guided regional anesthesia used in orthopedic and trauma surgery is on the rise, as it has been shown to reduce the doses of opioids and conventional analgesics (10, 11).
Several peripheral blocks validated in hip surgery have been described in scientific literature. Among them are the fascia iliaca block, femoral nerve block, lateral femoral cutaneous nerve block, PENG block or the quadratus lumborum block, among others (12).

The fascia iliaca block has been endorsed by multiple work groups, Mateusz Klukowski et al among them, who concluded that the patients on who this block was performed required less analgesic interventions (3 as opposed to 11, $p<0.0001$) and showed a significantly lower need for analgesics than patients without block, without complications after performance of said block (13). PENG block, used from 2018 and developed by Girón-Arango et al (14), is currently one of the peripheral nerve blocks most widely used in hip fracture patients. D-Yin Lin et al carried out a single-centre randomized double blind clinical trial which revealed that the patients on who PENG was performed for intraoperative and postoperative analgesia during hip fracture surgery experience less postoperative pain in the recovery room but there are no differences in the first postoperative day (15).

Performance of this type of locoregional analgesia is not only useful for pain control after surgery, but it has even been successfully used prior to surgery. Ali Ishan Uysal et al confirm the effectiveness of the preoperative femoral nerve block in the trochanteric femur fracture surgery and in the prevention of pain during the application of regional anesthesia (16).
Furthermore, given the many therapeutic analgesic options available for this kind of surgery, it is possible to compare them with each other so as to find the option that works best for each type of patient and surgical technique. There is an extensive comparative bibliography on this subject, such as the randomized clinical trial carried out by Faramarz Mosaffa, who concluded that PENG block is a good method for the analgesia of hip fractures and provides better analgesia than the fascia iliaca compartment block (17).

L-ESP block consists in looking for the transverse apophyses at the L3-L4 level and depositing a local anesthetic at this level advancing through the erector spinae muscles to reach the apophyses. Diffusion of the local anesthetic varies depending on whether the block is performed at the thoracic or lumbar level due to the differences in the anatomy of each area; it has been found that at least 5 mL of local anesthetic would be necessary at the lumbar level versus 2.5 mL for the thoracic level (18). Some articles support the notion that the ESP block acts similarly to paravertebral blocks, as studies performed in cadavers have shown expansion of the local anesthetic at this level. The number of intercostal spaces that it may cover ranges between 7 and 3 (19).

Lumbar parasagittal approach at L4 level in ultrasound-guided plane is the classic approach and it may be performed using anatomical landmarks (20). Serkan Turgal et al, among others, have reported extensive and lasting pain relief after a hip arthroscopy using single injection ESP at the L4 transverse apophysis level with bupivacaine 0.25% without significant motor block (21-23). Said publications are limited, as they are series of cases and not protocolized clinical trials. This block has even been used by Ali Ahiskalioglu as an intraoperative anesthetic technique together with sedation in an observational study with fifteen high-risk patients, performing a lumbar ESP block with 40 mL of a mix of local anesthetic (20 mL bupivacaine 0.5%, 10 mL lidocaine 2% and 10 mL of normal saline solution) together with propofol as a sedative; all surgeries were satisfactory, there being no need to change to general or intradural anesthesia (24).

The option to combine this block is feasible and it has proven effective as described by Ince et al when combining the PENG block and the erector spinae plane block to provide treatment for

postsurgery pain to a 4-year-old boy who underwent surgery to treat a congenital hip dysplasia, reducing the need for additional analgesics (25).

Even the application of this block will allow us to compare it with others as Serkan Turgal et al did by means of a prospective study in which they conclude that both L-ESP block and the quadratus lumborum block have a similar effect and both improve the quality of analgesia in patients who undergo hip and proximal femur surgery as against the standard intravenous analgesia regime (26).
In spite of what has been described above, to this day there are very few clinical trials focusing on the L-ESP block applied to hip surgery and its comparison with conventional intravenous analgesia.

4. Conclusions

This pragmatic single-centre parallel group randomized clinical trial will allow us to assess the effectiveness of the L-ESP block in hip surgery. Additionally, we will also assess its safety and potential adverse effects as against conventional analgesia and consumption of opioids. Application of this kind of multimodal analgesia (associating locoregional blocks) will enable us to approach pain more comprehensively to achieve a faster rehabilitation and recovery of the hip surgery patient.

5. Appendices

Appendix 1. Timeline of the trial

Appendix 2. Post-surgery analgesia protocol

6. Bibliography

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