STUDY PROTOCOL

EFFECTIVENESS OF PERIARTICULAR VASOCONSTRICTOR INFILTRATION (PVI) IN REDUCING BLEEDING AND POSTOPERATIVE PAIN CONTROL IN LUMBAR FUSION SURGERY: A RETROSPECTIVE OBSERVATIONAL STUDY

Protocol Version and Date	Version 2 – February 18, 2026
Protocol Code:	IIBSP-EIP-2025-213
Sponsor	Research Institute of Hospital de la Santa Creu i Sant Pau (IR Sant Pau) c/ Sant Quintí, 77-79 08041 Barcelona Tel: 93 556 56 17 Fax: 93 553 78 12
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GLOSSARY OF TERMS

PVI: PVI block = periarticular vasoconstrictor infiltration

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1. SUMMARY:

Sponsor identification	Research Institute of Hospital de la Santa Creu i Sant Pau (IR Sant Pau) c/ Sant Quintí, 77–79 08041 Barcelona, Spain Tel : 93 553 78 69
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Co-investigators	Laura Parrilla Quiles Department of Anesthesiology, Critical Care and Pain Medicine Hospital de la Santa Creu i Sant Pau 08041 Barcelona, Spain Tel: 626000503 e-mail: lparrilla@santpau.cat
Participating centers	Hospital de la Santa Creu i Sant Pau. Hospital Quirón Salud de Murcia.

Ethics Committee	Research Ethics Committee of Hospital de la Santa Creu i Sant Pau
Main objective	To evaluate intraoperative blood loss and postoperative pain intensity in patients undergoing lumbar fusion surgery with periarticular vasoconstrictor infiltration (PVI).
Design	Retrospective observational descriptive
Condition under study	Lumbar spinal canal stenosis, spondylolisthesis, and degenerative disc disease
Methodology	A retrospective study will be conducted on patients who underwent lumbar arthrodesis between November 2024 and October 2025 at the Hospital de la Santa Creu. A database will be created to collect demographic data, perioperative medical data (diagnosis, comorbidities, ASA classification), surgical variables (levels of instrumentation, performance of laminectomy, placement of interbody cages, operative time), intraoperative anesthetic management (type of anesthesia, intraoperative blood loss, opioid requirements), and outcomes (postoperative pain, complications, length of hospital stay). The database will be properly anonymized. Quantitative variables will be presented as median and range, while qualitative variables will be expressed as absolute frequency and percentage.
Study population and total number of subjects	A cohort of patients undergoing surgery for spinal canal stenosis, spondylolisthesis, and/or degenerative disc disease with an indication for lumbar arthrodesis with PIV block between November 2024 and October 2025 at Hospital de la Santa Creu i Sant Pau.
Timeline. Expected duration of the study	1 month
Ethical considerations	The study will be conducted in strict accordance with international ethical recommendations for medical research involving human subjects. The investigator will be responsible for ensuring that the study is carried out in compliance with the standards set forth in the Declaration of Helsinki. Prior to the initiation of the study, the Ethics Committee of Hospital de la Santa Creu i Sant Pau must

	approve the study protocol. Any subsequent amendments to the protocol will be reported to the Ethics Committee, and its opinion will be sought if a new evaluation of the study's ethical aspects is required. This is a retrospective study that requires access to patients' electronic medical records as well as retrieval of data from physical archives (non-digitized anesthesiology and recovery documents). The research team commits to creating an anonymized database to ensure confidentiality and will not perform any re-identification activities. Specific security measures will be implemented to prevent re-identification and unauthorized access by third parties.
Funding source	No external funding is available

2. THEORETICAL FRAMEWORK. PROBLEM STATEMENT

Background

Lumbar arthrodesis is a surgical procedure primarily indicated in cases of degenerative disc disease, spondylolisthesis, and lumbar spinal canal stenosis—conditions that cause pain and functional limitation when conservative treatment fails. Lumbar arthrodesis surgery carries a high risk of intraoperative bleeding, with a significant incidence of anemia and need for transfusion. It is also associated with severe postoperative pain requiring high doses of systemic opioids. These complications impact patient safety and recovery. Multimodal pain management and bleeding control remain key challenges in this procedure.

The use of periarticular vasoconstrictive infiltration (PIV) techniques, based on the principles of tumescent anesthesia and WALANT, has been shown to reduce bleeding and improve analgesic conditions in other orthopedic surgeries. In our hospital, this technique has recently been introduced in lumbar arthrodesis procedures, with promising clinical results, although a formal retrospective analysis of its efficacy has not yet been conducted.

Justification

At our center, lumbar arthrodesis surgery is usually performed under combined anesthesia (general anesthesia along with regional anesthesia) within a multimodal analgesia protocol. Traditionally, the erector spinae plane (ESP) block was used as the main regional technique. However, over the past two years, periarticular vasoconstrictive infiltration (PIV) has progressively replaced the ESP block, becoming the regional technique of choice in our clinical practice.

This technique involves the infiltration of local anesthetic with epinephrine into deep and superficial periarticular planes, performed under ultrasound guidance before the start of surgery, with the aim of reducing intraoperative bleeding and enhancing postoperative analgesia.

Clinical practice has shown favorable results and good acceptance by the surgical team, but there is no systematic analysis of its efficacy. Therefore, a retrospective study is proposed based on data from patients who underwent lumbar arthrodesis with PIV block, in order to objectively evaluate the potential benefits of this technique on intraoperative blood loss and the course of postoperative pain.

Research Questions

- What is the intraoperative blood loss in patients who received the PIV block?
- What is the blood loss through drains?
- How much pain do patients who received the PIV block experience?
- What is the opioid consumption in these patients, and what are the associated side effects?
- Have any complications related to the block occurred?
- Does the PIV block improve postoperative pain control compared to the center's previous standards?
- Which spinal levels are most frequently instrumented?
- How often do patients require laminectomy?
- How often are interbody cages placed?

- What are the baseline characteristics of our patients (age, sex, ASA classification, etc.)?
- What are the complications related to the procedure?

Hypothesis

The periarticular vasoconstrictive infiltration (PVI) technique applied in lumbar arthrodesis surgery is associated with a significant reduction in intraoperative blood loss and improved postoperative pain control compared to surgeries previously performed without this technique (ESP block or no regional block). Additionally, there may be sex-based differences in treatment response, postoperative pain, and opioid consumption.

3. OBJECTIVES:

Primary objective: To quantify intraoperative blood loss and the intensity of postoperative pain in patients undergoing lumbar arthrodesis surgery who received periarticular vasoconstrictive infiltration (PVI).

Secondary objectives:

- To analyze hemoglobin decrease, transfusion rate, as well as hospital stay, postoperative complications, patient characteristics, and the type of arthrodesis performed (with or without laminectomy, with or without interbody cages).
- To explore sex-based differences in anesthetic management, postoperative pain, opioid use, and complications, incorporating a gender perspective.

4. METHODS:

Study design

Descriptive observational retrospective study.

Study population. Inclusion and exclusion criteria

Cohort of patients undergoing lumbar arthrodesis surgery who received the PVI

block between November 2024 and October 2025 at Hospital de la Santa Creu i Sant Pau.

Inclusion criteria:

Adult patients undergoing lumbar arthrodesis surgery during the study period.

Exclusion criteria:

Incomplete surgeries, incomplete clinical data, or poor-quality anesthetic records.

Definition of variables

Primary variables:

- **Intraoperative blood loss:** Blood loss will be quantified as the total aspirated volume (in mL) recorded on the corresponding anesthesia record, calculated as the sum of the contents of the surgical suction devices at the end of the procedure, excluding the volume of irrigation used.
- **Postoperative pain** (measured using the Numeric Verbal Scale) at 24 hours.

Secondary variables:

- Blood loss through drains.
- Need for blood transfusion.
- Postoperative opioid consumption and side effects (nausea, vomiting, constipation, sedation).
- Complications related to the block (e.g., hypertension, arrhythmias) and postoperative complications (e.g., surgical wound infection, hematoma, reoperation).
- Surgical technique: Number of instrumented vertebrae, need for laminectomy, number of interbody cages.
- Surgical time.
- Hospital stay.
- ASA classification.

- Patient sex (key variable for gender-based analysis).
- Demographic and clinical variables: age, sex, weight, height, causal diagnosis (spondylolisthesis, disc disease, etc.), and comorbidities.

Expected sample size

Since periarticular vasoconstrictive infiltration (PIV) is a recently implemented technique in our center (introduced in November 2024), the number of cases available for retrospective analysis is limited due to the short period of clinical application. All consecutive cases performed over 12 months that meet the inclusion criteria will be included, constituting a descriptive case series (n = 20–25 patients). This design is appropriate for describing preliminary effectiveness and safety outcomes, generating hypotheses for larger future studies, and establishing local reference values for bleeding and analgesia in lumbar arthrodesis surgery with PIV block. Statistical models will be adapted to the data provided by the obtained sample.

Methodology. Sources of Information

A database will be created to collect demographic data (age, sex, weight, and height), preoperative medical data (diagnosis, ASA classification), surgical intervention details (technique, level, laminectomy, interbody cages, and surgical time), intraoperative anesthetic management (anesthetic technique, technical incidents, opioid consumption), and outcomes (postoperative pain, rescue analgesia requirements and side effects, hemoglobin levels, surgical complications, length of hospital stay). This database will be properly anonymized.
Quantitative variables will be presented as median and range, and qualitative variables as absolute frequency and percentage.

Data Management and Analysis

Data will be collected retrospectively from the electronic medical records of Hospital de la Santa Creu i Sant Pau, including surgical, anesthetic, and postoperative evolution reports. Once collected, the data will be entered into a Microsoft Excel spreadsheet, which will serve as the study database. This database will be securely stored on the

hospital's institutional servers, protected with a password, and accessible only to authorized investigators. To ensure participant confidentiality, identifying information will be removed and a unique code will be assigned to each patient.

Statistical analysis will be conducted using software such as SPSS or R. Quantitative variables will be described using measures of central tendency and dispersion, such as median and interquartile range, or mean and standard deviation depending on the distribution. Qualitative variables will be presented as absolute frequencies and percentages. Comparisons between groups, especially by sex, will be performed using appropriate statistical tests according to variable type and distribution, such as Student's t-test or Mann–Whitney test for continuous variables, and chi-square or Fisher's exact test for categorical variables. The level of statistical significance will be set at $p < 0.05$.

The database creation and analysis will be carried out by the principal investigator, Dr. Mireia Rodriguez, with the collaboration of Dr. Laura Parrilla, member of the Anesthesiology Department at Hospital de la Santa Creu i Sant Pau.

Quality Control

The investigator will ensure the accuracy and completeness of the data, as well as all required reports. Data included in the Case Report Form (CRF), derived from source documents, will be consistent with these documents, or any discrepancies will be justified.

The investigator will retain study documents for at least 5 years after the study's completion.

Upon request from the monitor, auditor, ethics committee, or health authority, the investigator will make all study files available, allowing direct access to data or source documents for monitoring, auditing, ethics committee review, and regulatory inspection.

Limitations of the Study Design, Data Sources, and Analysis Methods

This study has an observational, retrospective, and descriptive design, which entails several inherent limitations. First, being a retrospective analysis, the quality and

completeness of the data depend directly on the thoroughness of previous medical records, which may lead to information bias or missing data. The accuracy in measuring variables such as blood loss, postoperative pain, or opioid consumption may be affected by variability in clinical documentation.

Another limitation is the absence of randomization and control of confounding variables, which prevents establishing causal relationships between the analyzed variables. In addition, the estimated sample size is relatively small, which may limit the statistical power to detect significant differences, especially in subgroups such as sex-based analyses. Regarding analysis methods, although appropriate statistical techniques will be used, the descriptive nature of the study limits the possibility of performing complex multivariate analyses.

5. WORK PLAN (tasks, milestones, and study timeline):

Month 1

- Development of the study protocol, preparation of study materials, and submission to the Ethics Committee (CEIC).
- Meeting of the research team and preparation of logistical aspects for study implementation.
- Creation of the anonymized database.
- Data collection, entry, cleaning, and analysis.
- Research team meeting to discuss results and close the study. Preparation of the final report.
- Preparation of a manuscript for publication of the results.

Duration: 1 month

6. ETHICAL ASPECTS:

Benefit-risk assessment of the research

The study poses minimal risk to participants, as it is a retrospective investigation that does not involve any direct intervention on patients or modification of their usual treatment. All clinical data will be collected in an anonymized manner, ensuring confidentiality and protection of information in accordance with current regulations on personal data protection.

From a benefits perspective, this research will provide an in-depth understanding of the characteristics of patients undergoing lumbar arthrodesis surgery, intraoperative blood loss, postoperative pain intensity, and other relevant postoperative clinical outcomes (surgical times, hospital stay, complications, etc.). Additionally, incorporating a sex-stratified analysis may reveal relevant differences from a gender perspective, contributing to improved equity and personalized perioperative care. Therefore, the benefits of the study are considered to far outweigh the potential risks, making this research valuable for clinical practice and continuous quality improvement.

Ethical considerations regarding participant information and informed consent

The study will be conducted in strict accordance with international ethical recommendations for medical research involving human subjects. The investigator will be responsible for ensuring that the study is carried out in compliance with the standards set forth in the Declaration of Helsinki.

Prior to the initiation of the study, the Ethics Committee of Hospital de la Santa Creu i Sant Pau must approve the study protocol. Any subsequent amendments to the protocol will be reported to the CEIC, and its opinion will be sought if a new evaluation of the study's ethical aspects is required.

An exemption from informed consent is requested for this study, as it is a retrospective investigation that requires access to patients' digitized medical records and retrieval of data from physical archives (non-digitized anesthesiology and recovery documents).

The research team commits to creating an anonymized database to maintain confidentiality and will not perform any re-identification activities.

Moreover, since the use of pseudonymized personal data for biomedical research requires technical and functional separation between the research team and the personnel performing the pseudonymization and maintaining the information that allows re-identification, the person performing pseudonymization for this study will not be part of the research team. This role will be carried out by Dr. Marisa Moreno Bueno from the Anesthesiology, Recovery, and Pain Therapy Department.

Access to pseudonymized data will be accompanied by an explicit commitment to confidentiality and a prohibition on any re-identification activities, with specific security measures implemented to prevent re-identification and unauthorized third-party access. The research team will receive only coded data, with no possibility of re-identification.

Considerations Regarding the Handling of Biological Samples

No biological samples will be collected.

Data Confidentiality

Regarding the confidentiality of study data, the provisions of Organic Law 3/2018 of December 5 on the Protection of Personal Data and Guarantee of Digital Rights, as well as the General Data Protection Regulation (EU) 2016/679, will be followed.

Interference with Physician Prescribing Habits

The clinical management of patients will adhere to the treatment standards of the Anesthesiology and Recovery Service at Hospital de la Santa Creu i Sant Pau, and the conduct of this study will not influence this process.

7. PLANS FOR DISSEMINATION OF RESULTS

The results will be aimed for publication in a scientific article or as a poster at an international anesthesiology conference.

8. RESOURCES FOR STUDY IMPLEMENTATION AND FUNDING

No funding is available to conduct the study.

9. PROTOCOL MODIFICATIONS

Any modifications to the study protocol will always be made in the form of a written amendment or addendum. Formalization will require approval from all responsible study personnel. In the case of significant modifications, explicit approval from the Clinical Research Ethics Committee will be requested.

10. PRACTICAL CONSIDERATIONS

Start, Monitoring, and Final Reports

The start of the study will be reported to the Ethics Committee. Annual monitoring reports will be submitted thereafter.

After obtaining the study conclusions, a final report will be prepared and submitted to the Ethics Committee.

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