Erector Spinae Plane Block versus conventional analgesia in complex spine surgery: A randomized controlled trial

FUNDER: Anesthesiology Research Department

PROTOCOL NO.: 2019-1282

VERSION & DATE: 1/2/2024

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PROTOCOL SYNOPSIS

Protocol Title:	Erector Spinae Plane Block versus conventional analgesia in complex spine surgery: A randomized controlled trial
Protocol Number:	2019-1282
Protocol Date:	1/3/2024
Sponsor:	Anesthesiology Department
Principal Investigator:	Ellen Soffin, MD
Products:	N/A
Objective:	The purpose of this study is to conduct a randomized controlled trial on patients undergoing complex spine surgery to whether bilateral erector spinae plane block (ESPB) reduces opioid consumption and pain scores and improves the quality of patient recovery.
Study Design:	Randomized Clinical Trial
Enrollment:	46
Subject Criteria:	Inclusion: • Age 18-80 • Planned primary complex spine surgery: >2 level-lumbar and/or thoraco-lumbar spine fusion with or without decompression. • Planned stand-alone posterior surgical approach. • Able to follow study protocol. • Able to communicate in English (outcome questionnaires validated in English)
	Exclusion: • Age <18 or >80 • Revision surgery • BMI > 35 • planned prolonged intubation/intubation overnight on night of surgery. • Unable to communicate in English. • History of chronic pain condition requiring gabapentin/pregabalin/antidepressant medication longer than 3 months • Opioid tolerance (>60 OME daily for >2 weeks) • Allergy, intolerance, or contraindication to any protocol component/study medication/technique • Patient refusal of regional analgesia (ESPB)

Study Duration:	• 5 years
Data Collection:	**Sources:** EPIC, Medical Records, and Patient Reported. **Variables:** DOB, Race, Gender, NRS pain scores at rest, Name, Opioid consumption, Time to opioid consumption, Pathway process measures, Side effects, QoR15, Blinding assessment
Statistical Analysis:	Proposed analysis: Two sample t-test Wilcoxon rank-sum test Interim analysis planned? No Alpha level: 0.05 Beta or power level: 0.80 Number of groups being compared: 2 Resulting number per group: 21 Total sample size: 46 (40+ 10% to account for attrition)

1.0 INTRODUCTION

Enhanced recovery pathways (ERPs) emphasize evidence-based, multimodal anesthetic and analgesic choices to minimize opioid consumption while providing adequate pan control after surgery. Although ERPs for spine surgery are now being described, few pathways include regional analgesia. The ESPB may represent a novel opportunity to incorporate regional analgesia into ERPs for spine surgery. To date, there is minimal data to support the utility of ESPB in spine surgery, and this block has not yet been evaluated in complex spine surgery. The purpose of this study is to determine the efficacy of bilateral ESPB on postoperative pain and opioid consumption within a comprehensive ERP for complex spine surgery.

2.0 OBJECTIVE OF CLINICAL STUDY

It is currently unclear if ESPB improves outcomes after complex spine surgery. This study may improve outcomes by minimizing opioids and opioid-related side effects, while providing adequate analgesia. If beneficial, the ESPB may be introduced into routine care, representing a valuable opportunity to apply regional techniques to the anesthetic management of spine surgery patients. Finally, the study offers an opportunity to refine the way we manage post-operative pain and opioids and to improve recovery after complex spine surgery.

3.0 STUDY HYPOTHESES

Hypothesis: An ERP for complex spine surgery which includes bilateral ESPB (compared to no block) will reduce opioid consumption and pain scores and improve patient recovery during the first 24 hours after surgery.

4.0 STUDY DESIGN

4.1 Study Duration

5 years

4.2 Endpoints

4.2.1 Primary Endpoint

- Total opioid consumption up to the first 24 hours after surgery (intraoperative + postoperative) in mean oral morphine equivalents (OME).

4.2.2 Secondary Endpoints

- Pain scores: numeric rating scale (NRS) pain at rest, at PACU/hour 0 (initial), 6, 12, and 24 hours after surgery.

- Pain scores: NRS pain with movement at PACU/hour 0 (initial), 6, 12 and 24 hours after surgery.
- Quality of recovery: QoR 15 at baseline (holding area) and at 24 and 72 hours after surgery.
- Opioid related side effects (nausea/vomiting, pruritus, apnea, GI function, as indicated by passage of flatus ileus/GI side effects), assessed continuously up to 24 hours after surgery.
- Blinding assessment: Bang blinding inventory at 24 hours after surgery
- Time to opioid use (will include both time to pressing iv PCA and time to requesting first oral opioid)

4.3 Study Sites

Hospital for Special Surgery – Main Campus

5.0 STUDY POPULATION

5.1 Number of Subjects

A total of 46 subjects will be enrolled.

5.2 Inclusion Criteria

Subjects of either gender will be included if they:

- Age 18-80
- Planned primary complex spine surgery: >2 level- lumbar and/or thoraco-lumbar spine fusion with or without decompression.
- Planned stand-alone posterior surgical approach.
- Able to follow study protocol.
- Able to communicate in English (outcome questionnaires validated in English)

5.3 Exclusion Criteria

Subjects will be excluded from the study if they:

- Age <18 or >80
- Revision surgery
- BMI > 35
- planned prolonged intubation/intubation overnight on night of surgery.
- Unable to communicate in English.
- History of chronic pain condition requiring gabapentin/pregabalin/antidepressant medication longer than 3 months
- Opioid tolerance (>60 OME daily for >2 weeks)
- Allergy, intolerance, or contraindication to any protocol component/study medication/technique

- Patient refusal of regional analgesia (ESPB)

5.4 Randomization

A computer-generated, 1:1 ratio randomization schedule with blocks of sizes 4 and 6 will be created by a statistician not otherwise involved in the study. Participants will be randomized to 1 of 2 groups:

- Group 1 Control
- Group 2 Bilateral ultrasound guided ESPB

6.0 PROCEDURES

6.1 Surgical Procedure

Planned primary complex spine surgery: >2 level-lumbar and/or thoraco-lumbar spine fusion with or without decompression.

6.2 Medical Record Requirements

EPIC

6.3 Data Collection

The following data will be collected:

Pre-operative/Baseline

- basic demographic data
- patient weight & height, BMI
- NRS Pain
- QoR15

Surgical procedure

- date of surgery
- type of surgery
- surgery details
- anesthesia details

Follow-up visits (PACU, Post-op Hour 6, 12, 24, 72)

- NRS Pain
- Opioid consumption
- Time to opioid consumption
- QoR15
- Blinding Assessment
- Side effects

6.4 Schedule of Assessments

Procedures	Pre-Op	PACU	Post op Hour 6	Post op Hour 12	Post op Hour 24	Post op Hour 72
Identify eligible patients on schedule day before surgery	X					
Obtain consent	X					
NRS Pain	X	X	X	X	X	X
Opioid consumption					X	
Time to opioid consumption					X	
QoR15	X				X	X
Blinding Assessment					X	
Side effects					X	

7.0 STATISTICAL ANALYSIS

Proposed analysis:

Two sample t-test

Wilcoxon rank-sum test

Interim analysis planned? No

Alpha level: 0.05

Beta or power level: 0.08

Number of groups being compared: 2

Resulting number per group: 2

Total sample size: 46

8.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report. Definitions for Adverse Event (AE) used in this study are listed below and are based on FDA and international guidelines:

8.1 Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product which does not necessarily have to have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether considered related to the medicinal (investigational) product.

8.2 Serious Adverse Events (SAE)

The event is serious and should be reported to FDA when the patient outcome is:

Death, Life-threatening, Hospitalization (initial or prolonged), Disability or Permanent Damage, Congenital Anomaly/Birth Defect, Required Intervention to Prevent Permanent Impairment or Damage (Devices), Other Serious (Important Medical Events).

8.3 Adverse Event Relationship

Relationship to study: definitely, probably, possibly, not related.

9.0 INVESTIGATOR RESPONSIBILITIES, RECORD AND REPORTS

9.1 Subject Consent and Information

Research assistants will screen the co-investigating surgeons' patients undergoing ambulatory total knee arthroplasty surgery. Screening will involve reviewing the patient's EPIC chart to ensure that they meet the inclusion criteria and are not excluded due to any of the exclusion criteria listed. Patients who meet the inclusion criteria will be identified as potential study participants. After the investigating anesthesiologists have confirmed the eligibility of all potential participants, one of the investigating anesthesiologists will approach the potential patients in the pre-operative holding area, explain the rationale for the study, and ask if the patient is interested in participating.

9.2 Subject Data Protection

Subject privacy and confidentiality will be maintained through the storage of study data in a password-protected computer database maintained by the Research Director and accessible only to the principal investigator, in addition to other IRB-approved study personnel. Each subject will be assigned a unique study number for identification in the study database. This unique study number will not be derived from or related to information about the individual. The key linking this unique study number to patient identifiers (i.e., name, medical record number, date of birth, registry number) will be maintained in a different password-protected database maintained by Research Director, to which only the primary investigator will have access.

9.3 Staff Information

Primary Investigator: Ellen Soffin, MD
Research Coordinator: Pa Thor, PhD, 646-797-8535

9.4 Protocol Reviews

Study protocol reviewed and approved by:

- Anesthesiology CRP
- Hospital for Special Surgery Institutional Review Board

10.0 REFERENCES

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