# Utilization of Erector Spinae Plane Blocks in a Multimodal Analgesic Pathway for Instrumentation and Fusion of Adolescent Idiopathic Scoliosis: A Feasibility Study

FUNDER: Department of Anesthesiology

PROTOCOL NO.: 2019-2131

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# PROTOCOL SYNOPSIS

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| **Protocol Title:** | Utilization of Erector Spinae Plane Blocks in a Multimodal Analgesic Pathway for Instrumentation and Fusion of Adolescent Idiopathic Scoliosis: A Feasibility Study |
| **Protocol Number:** | 2019_2131 |
| **Protocol Date:** | 1/28/2022 |
| **Sponsor:** | Department of Anesthesiology |
| **Principal Investigator:** | Jordan Ruby, MD |
| **Objective:** | This study will investigate the feasibility and efficacy of utilizing preoperative erector spinae plane blocks (ESPB) to decrease opioid needs/consumption and to decrease numeric rating scale (NRS) pain scores in pediatric patients undergoing spinal fusion for adolescent idiopathic scoliosis (AIS). |
| **Study Design:** | Prospective, randomized feasibility study |
| **Enrollment:** | 24 |
| **Subject Criteria:** | 1. Patients undergoing multilevel posterior spinal instrumentation and fusion<br>2. Patients between the ages of 10 years old to 19 years old<br>3. Undergoing surgery for correction of AIS<br>4. Patients under the care of participating surgeons: Drs Widmann and Blanco<br>5. English Speakers |
| **Data Collection:** | Sources: EPIC, Medical Records, and Patient Reported.<br>Variables: DOB, Race, ASA Class, Gender, Ethnicity, NRS pain scores at rest and with movement, Name, Cumulative opioid consumption morphine equivalents, ORSDS, Number of patients/parents agreeing to ESPB, Workflow issues in performing block: Time to perform, incidence of surgeon request to not perform, ability to perform bilateral blocks, Blinding assessment (Bang's Blinding Index), Cobb angle/spine curvature, length of hospital stay, Patient/parent satisfaction, Intraoperative variable: surgeon, anesthesiologist, surgical duration (time from incision-to-procedure end), anesthetic duration (time from induction-to-extubation), blood loss, total fluid administration |
| **Statistical Analysis:** | • Primary outcome will be presented as number and rate of patients who received ESPB successfully and completed all assessment |

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| | • This is a feasibility study so power and sample size calculations are not appropriate. Classically feasibility studies use a sample size of approximately 12 subjects per group (Julious, 2005). The primary outcome will be descriptive, and presented as number of patients/parents approached: number of patients/parents enrolling in the study.<br>• Secondary outcomes for safety and efficacy comparison will be presented primarily in a descriptive way between 2 groups, including incidence of complications, NRS pain scores measured at multiple time points, time to 1st opioid use, incidence of opioid related side effects, and patient satisfaction. Continuous outcome will be presented as mean +/- standard deviation (opioid consumption, time to first opioid, NRS scores, patient/parent satisfaction). If results are skewed, data will be presented as medians (1st and 3rd quartiles). Normality of distribution will be determined via Shapiro-Wilk testing, where significance of >0.05 indicates normally distributed data. Categorical variables (incidence of complications, incidence of opioid related side effects) will be presented as counts and percentages. The balance of baseline patient characteristics will be compared between 2 groups using standardized difference.<br>• Alpha level: N/A<br>• Beta or power level: N/A |

## 1.0 INTRODUCTION

Idiopathic scoliosis is the most common type of scoliosis (70% of all cases) with a prevalence of curves greater than 30 degrees to be approximately 0.2% to 0.3%. Surgical correction for idiopathic scoliosis is often indicated when the spine curvature is greater than 45-50 degrees as measured by Cobb's method or if there is coexisting cardiopulmonary compromise. Curves necessitating surgical correction are particularly skewed toward females with a ratio of approximately 10:1.

Inherent to surgical correction is a significant amount of morbidity to pediatric patients including postoperative acute pain. Practitioners have utilized a number of analgesic techniques to treat acute postoperative pain including intravenous patient controlled analgesia (PCA), intrathecal opioids, epidural catheters, wound catheters, and multimodal analgesia. However, many of these techniques have either limited evidence, inconclusive results regarding their efficacy, or barriers to use (such as changes in neurological function) that limit their utilization postoperatively. Nevertheless, any technique that utilizes opioids subjects an already at risk patient (young, low BMI, females) population for further nausea/vomiting, which could delay recovery, prolong hospitalizations, and decrease patient/parent satisfaction. To date, there only exists a single case report using ESPB for PSF in pediatric patients. Furthermore, the patients in this report were 21 and 22 years old. Other reports of this technique in pediatrics have been limited to surgeries of the abdomen and thorax. Given the overall absence of evidence to support ESPB for pediatric spine surgery, this study is proposed to determine the feasibility and efficacy of bilateral ESPB on postoperative pain, opioid consumption, and patient satisfaction within a comprehensive enhanced recovery pathway (ERP) for complex spine surgery.

Canale ST, Beaty JH. Campbell's Operative Orthopaedics. 13th ed. Philadelphia, PA: Elsevier Mosby; 2017:1897–2120.
Chin KJ et al. Opioid-sparing multimodal analgesia with bilateral bi-level erector spinae plane blocks in scoliosis surgery: a case report of two patients European Spine Journal https://doi.org/10.1007/s00586-019-06133-8
Seki et al. Postoperative pain management in patients undergoing posterior spinal fusion for idiopathic scoliosis: a narrative review. Scoliosis and spinal disorders. 2018. 13:17.

The ESPB was first described as a regional anesthetic technique in 2016 (Foreo) as a modality to block both the ventral and dorsal rami of the thoracic spinal nerves. Since its initial account, there have been hundreds of case reports (Almeida 2019; Chin 2019), many case series (Melvin 2018; Singh 2018) and, some retrospective cohort studies (Ueshima 2019) in adult regional anesthesia that have highlighted its application to spine surgery. Each concludes a significant opioid-sparing capacity and improved NRS pain scores in patients who receive ESPB for a variety of spine surgery procedures.

Within pediatric anesthesia, there have been significantly fewer reports using the ESPB for postoperative analgesia. Most reports suggest the utility of the ESPB for analgesia

of the anterior spinal rami in cardiac, thoracic, and abdominal surgery (Wong 2018, Patel 2019, Hernandez 2018,) There exists only one recent case report of bilateral ESPB in two patients undergoing PSF for idiopathic scoliosis as a multimodal analgesic strategy for these patients. Given only this single case report, there is a dearth of evidence for utilization of this regional anesthetic technique in this patient population. Furthermore, this case is limited in suggesting the feasibility and efficacy of the technique given it was only reported on two patients.

Almeida CR, Oliveira AR, Cunha P. Continuous bilateral erector spine plane block at T8 for extensive spine fusion surgery: Case report. Pain Pract 2019; Feb 13. doi: 10.1111/papr.12774

Canale ST, Beaty JH. Campbell's Operative Orthopaedics. 13th ed. Philadelphia, PA: Elsevier Mosby; 2017:1897–2120.

Chin KJ et al. Opioid-sparing multimodal analgesia with bilateral bi-level erector spinae plane blocks in scoliosis surgery: a case report of two patients European Spine Journal https://doi.org/10.1007/s00586-019-06133-8

Chin KJ, Lewis S. Opioid-free analgesia for posterior spinal fusion surgery using erector spinae plane (ESP) blocks in a multimodal anesthetic regimen. Spine (Phila Pa 1976) 2019;44(6):E379-383. 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.

Hernandez, MA et al. Erector spinae plane block for inguinal hernia repair in preterm infants. Paediatr Anaesth. 2018 Mar;28(3):298-299.

Melvin JP, Schrot RJ, Chu GM, Chin KJ. Low thoracic erector spinae pane block for perioperative analgesia in lumbosacral spine surgery: a case series. Can J Anaesth 2018;65(9):1057-1065.

Patel, N et al. Erector Spinae Plane Catheter for Postoperative Analgesia After Thoracotomy in a Pediatric Patient: A Case Report. A A Pract. 2019 May 1;12(9):299-301.

Singh S, Chaudhary NK. Bilateral ultrasound guided erector spinae plane block for postoperative pain management in lumbar spine surgery: A case series. J Neurosurg Anesthesiol. 2018; Jun 29. doi: 10.1097/ANA.0000000000000518.

Singh S, Choudhary NK, Lalin D, Verma VK. Bilateral ultrasound-guided erector spinae plane block for postoperative analgesia in lumbar spine surgery: A randomized control trial. J Neurosurg Anesthesiol. 2019; doi: 10.1097/ANA.0000000000000603.

Tsui BCH, Fonesca A, Munshey F, McFadyen G, Caruso TJ. The erector spinae plane (ESP) block: A pooled review of 242 cases. J Clin Anesth 2019;53:29-34.

Ueshima H, Inagaki M, Toyone T, Otake H. Efficacy of the erector spinae plane block for lumbar spinal surgery: A retrospective study. Asian Spine J 2019;13(2):254-257.

Yayik AM, Cesur S, Ozturk F, Ahiskalioglu A, et al. Postoperative analgesic efficacy of the ultrasound-guided erector spinae plane block in patients undergoing lumbar spinal decompression surgery: A randomized controlled study. World Neurosurg 2019; doi.org/10.1016/j.wneu.2019.02.149.

Wong, et al. Bilateral continuous erector spinae plane blocks for sternotomy in a pediatric cardiac patient. J Clin Anesth. 2018 Jun;47:82-8

## 2.0 OBJECTIVE(S) OF CLINICAL STUDY

The feasibility and efficacy of utilizing preoperative erector spinae plane blocks (ESPB) to decrease opioid needs/consumption and to decrease numeric rating scale (NRS) pain scores in pediatric patients undergoing spinal fusion for adolescent idiopathic scoliosis (AIS).

1. What is the feasibility of performing bilateral US-guided ESPBs in this patient population?

2. What is the rate of recruitment to perform ESPB in this patient population?

3. What is the rate of adherence to perform the ESPB in this patient population (i.e., number who receive the intervention and complete all assessments/ number who enroll)?

4. Can patients be successfully randomized under the proposed study design?

5. Can patients be successfully blinded to group allocation under the proposed study design?

6. Are there factors that limit placing ESPBs after induction of anesthesia/prior to surgical incision (including time to perform block, time to secure IV access and place arterial line(s), surgeon/anesthesiologist preference, and patient-related factors. These include OR work-flow and timing issues, surgeon request to forego ESPB due to OR delay, and the anesthesiologist's assessment of the ultrasound features that may preclude ESPB placement)?

7. What is the incidence of complications for the ESPB in this patient population?

8. What is the opioid requirement (in morphine equivalents) in the first 24 hours after surgery in patients who received ESPB compared to those who did not?

9. What is the pain burden (in NRS, 0-10) in the first 24 hours after surgery in patients who received ESPB compared to those who did not?

By completing this study, we hope to assess the feasibility of performing this block for this particular operation in this patient population. To date, there are a limited number of applications of regional anesthesia for pediatric spinal fusion in a comprehensive ERP. Further, the optimal block composition is unknown, and the study will help to define this. Utilization of this technique may demonstrate an opioid sparing effect, which may have multiple benefits including a decrease in opioid-related side effects and increased patient satisfaction. If beneficial, the ESPB may become part of routine care for complex spine surgery in this patient population.

## 3.0 STUDY HYPOTHESES

1. It will be feasible to perform bilateral ultrasound-guided ESPB as part of a standardized pathway of analgesic care for pediatric patients undergoing spinal fusion for adolescent idiopathic scoliosis (AIS).

2. Patients who receive ESPB will have lower opioid requirements and lower NRS pain scores in the first 24 hours after surgery, compared to patients who do not have the block.

## 4.0 STUDY DESIGN

### 4.1 Endpoints

#### 4.1.1 Primary Endpoint

- The primary outcome will be the number of patients who receive bilateral, pre-incision ESPB (i.e., the rate of adherence, as defined in Specific Aim 3, above and as number who receive the intervention and complete all assessments / number who enroll).

#### 4.1.2 Secondary Endpoints

- 1. Feasibility outcome: rate of recruitment (number enrolled/number screened), measured after study end.
- 2. Feasibility outcome: success of patient and Research Assistant blinding to group allocation (based on Bang's Blinding Index, measured at 24 hours after surgery)
- 3. Feasibility outcome: type and incidence factors preventing performance of block (patient, surgical, anesthetic, and/or work flow related barriers), assessed in realtime.
- 4. Feasibility outcome: attrition (number of patients who enroll, but do not receive the intervention and/or study assessments, and the reasons), measured and reported in real time.
- 5. Incidence of intra- and postoperative complications attributed to ESPB (interference with intraoperative neuromonitoring, infection, local anesthetic toxicity, bleeding/hematoma, extremity weakness)
- 6. NRS pain scores (after recovery from anesthesia in PACU; and 8, 12, and 24 hours post-surgery, and at discharge).
- 7. Total opioid consumption as measured in oral morphine equivalents (OME) (over the first 24 hours post-surgery).
- 8. Time to first opioid use (oral, or via IV PCA).
- 9. Incidence of opioid-related side effects (measured via the ORSDS in the first 24 hours post-surgery).
- 10. Patient/parent satisfaction with pain management (at hospital discharge, via Likert scale rating from 0-10, where 10 is the highest satisfaction)

### 4.2 Study Sites

This study will take place at the main campus of the Hospital for Special Surgery (HSS).

## 5.0 STUDY POPULATION

### 5.1 Number of Subjects

24

### 5.2 Inclusion Criteria

Subjects of either gender will be included if:

1. Patients undergoing multilevel posterior spinal instrumentation and fusion
2. Patients between the ages of 10 years old to 19 years old
3. Undergoing surgery for correction of AIS
4. Patients under the care of participating surgeons: Drs. Widmann and Blanco
5. English Speakers

### 5.3 Exclusion Criteria

Subjects will be excluded from the study if:

- Patients younger than 10 years old or greater than 19 years old
- Neuromuscular scoliosis
- Any other HSS surgeon performing the procedure
- History of chronic opioid therapy (>4 weeks) to treat back pain attributed to scoliosis tolerance, as defined by CDC criteria (>60 OME daily for over 2 weeks)
- Chronic pain conditions necessitating neuromodulating medications (gabapentin, pregabalin)
- Allergy, intolerance or contraindication to any protocol/study medication/technique
- Patient or Parent refusal
- Non-English speakers

## 6.0 PROCEDURES

### 6.1 Intraoperative Protocol

Half of patients will be randomized to bilateral ESPB (0.25% bupivacaine plus 2mg preservative free dexamethasone) or no block. The maximum allowable dose based on the patient's weight will be divided equally to each side with a maximum of 30mL total per side. All patients will undergo anesthetic care under a standardized intraoperative regimen. The postoperative analgesic regimen will likewise be standardized for patients by the pediatric anesthesiologist. Global anesthetic management discussion with patient/parent with a set of expectations and goals from a pain management perspective (targeted NRS 4/10 or better, at rest). The anesthesiologist will describe multimodal analgesia and the role of opioids in recovery and pain management.

Intraoperative:

- Sedation: midazolam (up to 2-5 mg, iv) as needed (at the discretion of the anesthesiologist).
- Induction of general anesthesia to facilitate endotracheal intubation: propofol (1-2 mg.kg-1), methadone (0.1-0.2mg.kg-1) with maximum induction dose 10mg, ketamine (0.5mg.kg-1) with maximum induction dose 25mg, fentanyl (1.5-3mcg.kg1) is permitted at the discretion of the anesthesiologist to decrease the sympathetic response on induction
- Maintenance of general anesthesia: propofol (100-200 mcg.kg.hr-1) titrated by the anesthesiologist; remifentanil (0.05-0.5 mcg.kg.min-1) is permitted, titrated to effect by the anesthesiologist; ketamine (0.25.mg.kg.hr-1) bolus each hour with maximum cumulative dose of 50mg.
- Multimodal analgesia: acetaminophen (15 mg.kg-1) during cutaneous closure of surgical incision; ketorolac (0.5mg.kg- 1,maximum 30mg each dose)
- PONV prophylaxis: dexamethasone (0.5mg.kg-1 up to 10mg) prior to surgical incision; ondansetron (0.1 mg.kg-1, maximum 4mg) during cutaneous closure of surgical incision.
- Prophylaxis against blood loss: tranexamic acid will be given to all eligible patients, per HSS standard of care (30 mg.kg-1 bolus over 30 minutes followed by and 10 mg.kg.hour-1 infusion until closure of the incision)
- Antibiotic prophylaxis: per HSS standard of care (cefazolin as first line agent; vancomycin for patients with cephalosporin allergy).
- Intravenous fluid administration: at the discretion of the anesthesiologist; titrated to hemodynamic status with goal, normovolemia.
- External warming device (upper and lower), fresh gas flow humidification, and fluid warmer, targeting normothermia.

## 6.2 Postoperative Protocol

Multimodal analgesia:

• Dilaudid iv PCA (doses strictly in accordance with pediatric order set according to weight, maximum dose of 2 mg.hr-1)

• Oxycodone 0.05mg.kg-1 q4H PRN mild/moderate pain

• Oxycodone 0.1mg.kg-1 q4H PRN moderate pain

• Oxycodone 0.15mg.kg-1 q4H PRN severe pain

• Ketorolac 0.5mg.kg-1 q6H x6 additional doses (max 30mg each dose)

• Ibuprofen 10mg.kg-1 q8H after completion of ketorolac

• Acetaminophen 15mg.kg-1 IV q6H scheduled x3 doses

• Acetaminophen 15mg.kg-1 PO q6H scheduled after completion of IV APAP

• Diazepam 0.05-0.1mg.kg-1 PO q6H PRN muscle spasms

• Nubain 0.05mg.kg-1 q6H PRN itching

• Ondansetron 0.1mg. kg-1 IV (max 4mg) q8H PRN nausea

Additional opioids may be administered at the discretion of the anesthesiologist

- Physical therapy: goal, POD #1, dangle legs from bedside on POD #0

Surgical drains and Foley catheter: placement and removal guided by surgical team

- Oral intake: diet to be advanced as tolerated by the patient with early intake encouraged as soon as the patient has recovered, but guided by the surgical team

References:

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Pendi, A., et al. Perioperative Ketamine for Analgesia in Spine Surgery: A Metaanalysis of Randomized Controlled Trials. Spine (Phila Pa 1976). 2018 March 01; 43(5): E299–E307. doi:10.1097/BRS.0000000000002318

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Vigneault, L., Turgeon, A.F., Côté, D. et al. Can J Anesth/J Can Anesth (2011) 58: 22. https://doi.org/10.1007/s12630-010-9407-0

### 6.3 Data Collection

The following data will be collected:

**Pre-operative/Baseline**

- DOB
- MRN
- Race
- ASA Class

- Gender
- Ethnicity
- NRS pain scores at rest and with movement
- Name
- Height, Weight, BMI
- Cobb Angles

**Surgical procedure (Intra-operative)**

- Workflow issues in performing block: time to perform; incidence of surgeon request to not perform; ability to perform bilateral blocks
- Surgeon, anesthesiologist
- Surgical duration (time from incision to procedure end)
- Anesthetic duration (time from induction to extubation)
- Blood loss,
- Total fluid administration

**Post-Operative Day 0 (POD 0)**

- PACU: NRS pain scores at rest and with movement
- 8 hours post-surgery: NRS pain scores at rest and with movement
- 12 Hours post-surgery: NRS pain scores at rest and with movement

**Post-Operative Day 1 (POD 1)**

- NRS pain scores at rest and with movement
- Cumulative opioid consumption morphine equivalents
- ORSDS
- Blinding assessment

**Post-Operative Day of Discharge**

- NRS pain scores at rest and with movement
- Cumulative opioid consumption morphine equivalents
- ORSDS
- Patient Satisfaction and Parent satisfaction
- Time of Discharge, length of stay
- Complications occurring during patients stay

## 7.0 STATISTICAL ANALYSIS

- Proposed analysis: This is a feasibility study so power and sample size calculations are not appropriate. Classically feasibility studies use a sample size of approximately 12 subjects per group (Julious, 2005).
- Interim analysis planned: No
- Alpha level: N/A
- Beta or power level: N/A

- Primary outcome variable estimate: The primary outcome will be descriptive, and presented as number of patients/parents approached: number of patients/parents enrolling in the study.
- Number of groups being compared: 2
- Effect size or change expected between groups: N/A
- Resulting number per group: 10
- Total sample size required: 20 (maximum plan to enroll: 24)

Descriptive statistics will be used. Data will be presented as mean +/- standard deviation (opioid consumption, NRS scores, patient/parent satisfaction). If results are skewed, data will be presented as medians (1st and 3rd quartiles). Normality of distribution will be determined via Shapiro-Wilk testing, where significance of >0.05 indicates normally distributed data. Continuous variable will be presented as means and categorical variables as counts and percentages

## 8.0 ADVERSE EVENT ASSESSMENT

All Adverse Events (AEs) will be reported in the final study report.