TITLE: Pericapsular Nerve Group (PENG) Block vs. the Fascia Iliaca Compartment (FIC) Block for Patients with Isolated Hip Fractures in the Emergency Department

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INTRODUCTION

Ultrasound-guided nerve blocks are an important tool for treating pain due to orthopedic injury in the ED. They provide long lasting, opioid-sparing pain relief that is generally safe and well-tolerated by patients[1]. Elderly patients with hip fractures commonly present to the ED, and their injury can be painful. Commonly used opioid pain regimens can have deleterious side effects, especially in elderly patients, like somnolence, delirium, hypotension and respiratory depression.
The fascia iliaca compartment (FIC) block has become a familiar technique to emergency physicians as a pain control treatment for hip fractures[2]. The pericapsular nerve group (PENG) block has recently been proposed as a novel method to treat pain due to hip, acetabular and pelvic fracture by targeting the terminal sensory articular nerve branches of the femoral nerve (FN), obturator nerve (ON), and accessory obturator nerve (AON)[3,4]. At this time there has been no study comparing the efficacy of the two nerve blocks, PENG and FIC.
This study is a prospective, randomized study assessing the efficacy of the PENG block compared to that of the FIC block in providing analgesia during the acute phase of the injury while in the ED.

STUDY OBJECTIVES

This study will aim to show that the PENG block will be non-inferior to the FIC block used to treat acute pain due to hip fracture in the ED setting.

Primary Objective: To shows that PENG block has non-inferior efficacy to FIC block.
Secondary Objectives: Preservation of hip flexor muscle motor function. To determine if the use of PENG blocks resulted in a significant decrease in systemic analgesia administered.

HYPOTHESIS

We hypothesize that the PENG block is as good as the FIC block and will potentially result in a higher reduction in pain scores. We aim to demonstrate that PENG block is non-inferior to FIC block.

STUDY DESIGN

This is a single center, randomized, prospective clinical trial with a convenience sample conducted in the ED of an urban Level 1 trauma center.

1. Identify patients who present to the ED with a suspected hip fracture by a physician in the ED that can potentially be enrolled. Once an isolated hip fracture is confirmed on x-ray and the patient has a resting pain score greater than or equal to 5, the patient may be enrolled. Specific inclusion and exclusion criteria are below. The research associate will determine that a patient is a candidate to be enrolled in the study and will notify the ultrasound faculty. The research assistant will consent the patient. Ultrasound faculty will place the block. The research assistant will assess the pain scores, motor function and record any additional pain medication administered.

   All patients in the study who the treating physician deems to require analgesia for severe pain will receive analgesia at any time prior to the consenting for the study.

2. Initial Analgesia post consent:

a. All patients will be administered 4 mg morphine intravenous as initial analgesia after consenting to the study and prior to the nerve block.

3. Randomization

a. An online randomizer will be used to randomly allocate patients. The study group will be sealed in consecutively numbered opaque envelopes which will be opened consecutively by the ultrasound faculty member to indicate the type of block to be performed. The research assistant will not have access to contents of the envelope and will therefore be blinded to the type of block. The ultrasound faculty member cannot be blinded as they will be performing the procedure. Both the patient and the clinician caring for the patient will be blinded to the type of block performed.

4. Procedure

a. Patient consent will be obtained once a proximal femur (hip) fracture confirmed on x-ray. The laterality and type of fracture will be recorded.
b. The type and amount of systemic analgesia prior to nerve block will be recorded
c. A baseline pain score using the NRS scoring system from 0 to 10 will be determined.
d. Time out will be performed on all patients prior to performing the procedure.
e. Patient will be placed on a cardiac monitor and positioned supine in bed with the hip and groin area exposed.
f. Maximum dosage of local anesthesia will be calculated based on the patient's self-reported weight so as to ensure that the prescribed dosage described below doesn't exceed the safe dose for the patient.
g. After randomization, the physician will proceed with either the FIC block (section h) or the PENG block (section i).
h. Fascia Iliaca Compartment (FIC) block

i. Under sterile technique, the physician will identify relevant landmarks, including the femoral artery, femoral vein, femoral nerve, iliacus muscle with overlying fascia iliaca.
ii. Using in-plane technique with constant visualization, a needle will be inserted through the skin and soft tissue targeting the fascial plane above the iliacus muscle.
iii. As the needle tip reaches the target, a small volume of normal saline will be injected to hydrodissect the tissue. Fluid will start to spread along the fascial plane, confirming proper positioning.
iv. Normal saline will then be switched to the anesthetic (40mL of Bupivacaine 0.25%).
v. After the full volume of anesthetic has been injected, a small volume (5mL) of normal saline will be injected to flush the line of remaining anesthetic. The needle will then be withdrawn.

i. Pericapsular Nerve Group (PENG) block

i. Under sterile technique, the physician will identify the relevant landmarks including the femoral artery, femoral vein, femoral nerve, ileopubic eminence (IPE), anterior inferior iliac spine (AIIS), psoas tendon (PT). Target area is the bony space between AIIS and IPE adjacent to PT.
ii. Using in-plane technique with constant visualization, a needle will be inserted through the skin and soft tissue targeting the fascial plane below the psoas tendon, above the ilium bone. This landmark lies between the AIIS and IPE, just lateral to the psoas tendon.
iii. As the needle tip reaches the target, a small volume of normal saline will be injected to hydrodissect the tissue. Fluid will start to spread along the fascial plane, lifting the psoas tendon from the ilium, confirming proper positioning.
iv. Normal saline will then be switched to anesthetic (20mL of Bupivacaine 0.50%).

v. After the full volume of anesthetic has been injected, a small volume (5mL) of normal saline will be injected to flush the line of remaining anesthetic. The needle will then be withdrawn.

5. Post-procedure monitoring
a. The patient will be observed for signs/symptoms of local anesthetic systemic toxicity (LAST) for 30 minutes after the block.
b. Any side effects reported or observed will be recorded.
6. Pain scores
a. The research associate will complete the post-block data sheet at the 30-minute and again at the 60-minute mark to assess the level of pain the patient is experiencing on a scale of 0 to 10.
b. If breakthrough pain is experienced post block the physician may order opioid rescue medication at their discretion.
c. Breakthrough pain scores will be recorded as usual at 30 & 60 minutes with a note stating there was breakthrough pain.
7. Motor function
a. The research associate will ask the patient to contract the quadriceps muscle group to assess for motor function of this muscle group. Contraction will be answered, in a binary yes or no.
8. Analgesia used
a. The amount of systemic analgesia used prior to the nerve block will be recorded.
b. The research assistant will record if there was any additional rescue systemic analgesia delivered to the patient while they were in the ED after their nerve block was placed.

Subjects:
Adult patients presenting to the Emergency Department at Maimonides Medical Center with an isolated hip fracture during the study period.

Eligibility Criteria:

Inclusion Criteria

- Adult Patients over 18 years of age
- Isolated hip fracture, Intertrocanteric or more proximal
- Pain score of 5 or greater on a scale of 0 to 10 just prior to the nerve block placement

Exclusion Criteria

- Patients with multi-system trauma
- People who are unable to communicate their level of pain
- Pregnant patients
- Pediatric patients (less than 18 years of age)
- Intoxicated patients
- Abnormal vital signs (HR>120bpm, MAP<65, PulseOx < 95%)
- Patients on long term systemic opioid analgesia
- Allergy to amide local anesthetics

Design:

This is a single-centered, prospective, randomized, blinded study involving patients who present to the ED with an isolated hip fracture. Patients who meet inclusion criteria will be consented for the study and then randomized to receive either a FIC block or a PENG block. Patients who are potentially to be enrolled in the study will receive standardized systemic analgesia while awaiting x-rays. If needed, patients will be administered morphine for breakthrough pain after the nerve blocks are placed. The exception to this standardization will be patients with a morphine allergy.

The research associate will screen for patients and confirm with the attending physician that the subject is eligible for enrollment and is able to give consent. The patient consented by a member of the research team, who will assess the patient's pain score on a scale of 0 to 10 prior to the block. The patient will then be randomized to receive either the FIC block or the PENG block to be performed by a member of the ultrasound faculty. The research associate will be blinded to the type of block being performed by the ultrasound faculty member. The research associate will then reassess the patient's pain score on the 0-10 scale at the 30 minute and 60-minute mark. They will also assess for any adverse events after the block is performed. The research associate will note the motor function in the quadriceps muscle 30 min and 60 min after the nerve block is placed. Any rescue medication given after the nerve block is placed in the ED will be recorded.

Data Analysis:

The pain score before (0 minutes) and 30 minutes and 60 minutes after the nerve block will be recorded. The amount of opioid medication required for adequate pain control before and after the block will also be recorded. The data will be summarized by the use of descriptive statistics, using percentages for all categorical variables and using means with standard deviations or medians with lower and upper ranges for all continuous variables. Bivariate analyses will be used for comparison between and within the groups. Multivariate linear regression analyses will be used when the outcome is continuous and multivariate logistic regression analysis will be used when the outcome is dichotomous. Ninety-five percent confidence intervals around the odds ratios will be calculated for the multivariate logistic regression analyses. All multivariate analyses will be adjusted for all demographic variables and all other key (confounding) variables. Levels of significance will be tested at $P<0.05$ and 95% Confidence Interval. Analyses will be conducted using SPSS (version 27.0). Av

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