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Pericapsular Nerve Group Block Versus Fascia Iliaca Block for Pre- and Post-Operative Analgesia in Elderly Patients with Hip Fracture

Protocol of thesis

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Introduction

Hip fracture is a common type of bone fractures that is extremely painful and requires surgical repair. Its incidence is more in the older age groups ^[1].

Due to multiple comorbidities associated with this age group, regional anesthesia is preferred rather than general anesthesia ^[2]. Regional anesthesia was associated with a lower adjusted odds of mortality compared to general anesthesia in fracture hip surgeries^[3]. However, positioning the patient to receive spinal anesthesia resembles a special challenge to the anesthesiologist as even minimal overriding of the fracture ends is extremely painful which in turn would increase the need to additional doses of opioids or even sedation with more side effects in geriatric patients ^[4].

Actually pain management in these cases should be started from the time of incidence of the fracture to facilitate examination, transportation and radiological investigations ^[5]. Furthermore it should extend to the postoperative period for early ambulation and physiotherapy which will achieve better surgical results ^[6].

Opioids were the most frequently used method to control orthopedic pain. However, multiple complications has been encountered with the use of opioids in elderly patients such as delirium, hypotension, respiratory depression, prolonged hospital stay or post-discharge side effects as addiction or dependence ^[7]. Fentanyl can be considered the most suitable among different opioids due to its potency, rapid onset, short duration and minimal depressive effect on respiration ^[8].

Regional nerve blocks can efficiently reduce pain associated with hip fracture, with rapid-onset, site-specific analgesia that is more effective than standard systemic analgesia alone. There is also moderate evidence that nerve blocks contribute to reduce rates of delirium, and some suggestion of reduced length of inpatient stay, morbidity and mortality^[9]. Therefore, regional analgesia provides a safer alternative for opioids with even stronger analgesia and fewer complications. The use of regional analgesia is not limited to operation room (O.R), it can be started from the emergency department to facilitate patient examination, transportation and radiological investigations ^[10].

With ultrasound guidance, regional analgesia became easier, more accurate, more specific and requires less amounts of local anesthetic. Regional analgesia for hip fractures was strongly recommended by both pain management pathway by Health Quality Ontario ^[11] and by the evidence based guidelines published by the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine and the American Society of anesthesiologists ^[12].

There is multiple techniques to provide analgesia for hip fractures through peripheral nerve block while patient in supine position including femoral nerve block, 3-in-1 block, fascia iliaca block, intraarticular injections and local anesthetic infiltration in soft tissues surrounding surgical site (the last is suitable for postoperative pain) ^[13].

One method widely used to provide regional analgesia for hip fractures is ultrasound guided Fascia Iliaca block in which local anesthetic is injected between fascia iliaca and psoas muscle to block femoral, obturator and lateral cutaneous nerves ^[14].

Recently, the anterior capsule was found to be the richest part of the hip joint in nerve supply. A recent anatomical study by Short et al. stated that the femoral nerve (FN) and obturator nerve (ON) consistently provided innervation to the anterior hip capsule. They also found that the accessory obturator nerve (AON) is present in higher percentage of the specimens than previously suggested (54% vs. 8%-29%). When the AON is present, it contributes innervation to the anterior capsule. The key point of that study was that the articular branches of these three nerves to the anterior hip capsule have a constant relationship to the space between the anterior inferior iliac spine (AIIS) and iliopubic eminence that can be used as a potential site for radiofrequency ablation in case of osteoarthritis ^[15].

Girón et al. in 2018 used the previous anatomical description to develop a new technique using ultrasonography to block the articular branches to the anterior capsule of the hip at the point they cross the iliopectenial eminence, they called it the pericapsular nerve group (PENG) block. ^[16].

Rationale

Pain is a major problem that has to be dealt with in case of hip fracture, as it resembles an obstacle for examination, positioning for receiving neuroaxial anesthesia and postoperative mobility and physiotherapy.

With the introduction of ultrasound in regional anesthesia and peripheral nerve blocks, regional analgesia float to the surface as a substitute for opioids with less side effects. Of the many techniques to provide regional analgesia for hip fractures; fascia iliaca block was widely used with good results. In 2018 Pericapsular Nerve Group Block was introduced to provide regional analgesia for hip fractures with interesting results.

Up to our knowledge ultrasound guided pericapsular nerve group block was not used before in Zagazig university hospitals for pre- and post-operative analgesia in elderly patients with hip fracture.

Research Question

Which is more effective as an ultrasound guided regional analgesic technique for pre- and post-operative analgesia in elderly patients with hip fracture, Pericapsular Nerve Group Block or Fascia Iliaca block?

Hypotheses

Null hypothesis:

There is no difference between ultrasound guided Pericapsular Nerve Group Block and ultrasound guided Fascia Iliaca Block as a regional analgesic techniques for pre- and post-operative analgesia in elderly patients with hip fracture.

Alternative hypothesis:

There is a difference between ultrasound guided Pericapsular Nerve Group Block and ultrasound guided Fascia Iliaca Block as a regional analgesic techniques for pre- and post-operative analgesia in elderly patients with hip fracture.

Aim of the work

The aim of the present study is to improve quality of pain control in the pre- and post-operative periods in elderly patients with hip fracture.

Objectives

1. To compare the time of performance and the analgesic effect in the pre- and post-operative periods between ultrasound guided Pericapsular Nerve Group (PENG) block, fascia iliaca block and intravenous fentanyl (control group).
2. To assess the quality of patient's positioning during performance of spinal anesthesia by operator satisfaction score.
3. To assess time of onset of postoperative ambulation.

Patients and Methods

I. Technical design:

● **Site of the study:**

This study will take place at Zagazig University Hospitals after approval of Institutional Review Board (IRB).

● **Duration of the study:**

Two years.

● **Sample size:**

Assuming that mean \pm SD for VAS scores at positioning for spinal anesthesia in intravenous fentanyl versus fascia iliaca block were 3.5 ± 2.5 versus 2.1 ± 0.9 [4] with confidence level 95% and power of test 80%.

The total sample size is 51 (17 in each group) calculated by OpenEpi[®].

● **Inclusion criteria:**

1. Patient acceptance.
2. Accepted mental state of the patient.
3. Gender: both sexes.
4. Age above 65 years old.
5. Body mass index 18.5-35 kg/m².
6. ASA physical status II and III.
7. Unilateral hip fracture assigned for surgical fixation.
8. Expected duration of surgery \leq 3 hours.

● **Exclusion criteria:**

1. Associated trauma or multiple fractures.
2. Peripheral neuropathy.
3. Coagulopathy.
4. Infection at site of injection.
5. Allergy to the drugs used in the study.
6. Advanced kidney, liver or heart disease.

- **Withdrawal criteria:**

The patient has the right to withdraw from the study at any time without any negative consequences on their medical or surgical treatment plan.

II. Operational design:

- **Type of the study:**

This study is a randomized double-blind controlled clinical trial.

- **Parameters of the study:**

All patients will be visited on the day before surgery at the ward, for all patients a full history (personal, medical and family) will be taken, physical examination will be done. We will order a full laboratory work up: complete blood picture (CBC), kidney function tests (KFTs), liver function tests (LFTs), random blood sugar (RBS), prothrombin time (PT), partial thromboplastin time (PTT), international normalized ratio (INR), serum electrolytes and 12-lead ECG and the results will be revised. We will order any consultation required to prepare the patient (cardiology consultation will be done routinely).

Explanation of the whole procedure to the patient and a written informed consent will be obtained. Instructions will be given for preoperative fasting (6 hrs for light meals and 2 hrs for clear fluids). Visual analogue score for pain will be explained to all patients.

An intravenous cannula will be inserted for preoperative medications and blood sample will be sent for blood group matching to insure availability of blood of the same group before the operation.

On the day of surgery one hour before the operation, all patients will receive intravenous pantoprazole 40 mg and cefotaxime 1 gm.

On arrival to the operating room:

1. Monitoring: Standard operative monitoring will be applied to all patients including electrocardiogram (ECG), peripheral pulse oximeter and non-invasive blood pressure (NIBP). Basal readings of heart rate (HR), mean arterial pressure (MAP), oxygen saturation (SpO₂) and body temperature will be recorded.
2. Fluid preloading: Lactated ringer in a dose of 6 ml/kg over 30 minutes.
3. Revision on the resuscitation equipment including anesthetic machine, ventilator, face mask, oral airway, laryngeal mask, laryngoscope, endotracheal tubes, DC shock and drugs as atropine, ephedrine, hydrocortisone, antihistaminic, epinephrine and general anesthesia induction drugs.
4. Each patient will be asked for (his/her) pain by visual analogue pain score during rest and we will do the 15 degrees leg raising test and record VAS, heart rate and mean blood pressure both during rest and 15 degrees leg raising test. The records will be done by the anesthesiologist responsible for administration of spinal anesthesia and blinded to the groups' assignment.

● **Equipment:**

○ **Ultrasound:**

Mindray diagnostic ultrasound system, model: M5, SN: MR-55006765. Made in China.

○ **Transducers:**

- Mindray high frequency transducer, model: 10L4s, SN:MLW3C101256. Made in China.
- Mindray low frequency transducer, model: C5-2s, SN: NDX54023456. Made in China.

○ **Needle for performing the block:**

22-gauge, 80-mm Quincke spinal needle.

- **Needle for spinal anesthesia:**

25-gauge, Quincke spinal needle.

- **Local anesthetics:**

Bupivacain 0.5% diluted to 0.25% solution and magnesium sulphate as an additive for regional blocks and heavy bupivacaine 0.5% for spinal anesthesia.

- **Randomization:**

Patients will be randomly allocated by computer generated randomization table into three equal groups (17 patients each):

Group C (Control group):

Control group (n=17): Patients will be assigned to receive opioids analgesia before spinal anesthesia in the form of intravenous fentanyl in a dose of 1mic/kg divided into two boluses with 5 minutes interval in between before positioning the patient for spinal anesthesia.

Group P:

PENG block group (n=17): Patients will be assigned to receive Pericapsular Nerve Group Block (PENG Block) before positioning the patient for spinal anesthesia.

After disinfection of the skin from the anterior superior iliac spine (ASIS) to the inguinal ligament with alcohol on the affected side, sterile drapes will be used to surround the area of the block. While the patient in the supine position, a curvilinear low-frequency ultrasound probe (2–5MHz) will be first placed in a transverse plane over the anterior inferior iliac spine (AIIS), then rotated caudally about 45 degrees to be aligned with the pubic ramus. At this point the view on the screen will be viewing from medial to lateral; the pectineus muscle, the femoral artery, the iliopectineal eminence (IPE), the iliopsoas muscle and tendon and the AIIS. A 22-gauge, 80-mm spinal needle will be inserted from lateral to medial in an in-plane approach to place the tip in the musculofascial plane between the psoas tendon anteriorly and the pubic ramus posteriorly. After negative aspiration, the local anesthetic solution will be injected in 5-

mL increments while observing for adequate fluid spread in this plane for a total volume of 20 mL of 0.25% bupivacaine + 250 mg magnesium sulphate. A hypoechoic expanding shadow should be visualized between the psoas tendon and the pubic ramus indicating proper site of injection [16].

Group F:

Fascia Iliaca block group (n=17): Patients will be assigned to receive Fascia Iliaca Block (F.I Block) before positioning for spinal anesthesia.

After disinfection of the skin over the upper thigh with alcohol on the affected side, sterile drapes will be used to surround the area of the block. While the patient in the supine position, a linear high-frequency ultrasound probe (10–15MHz) will be placed in the inguinal crease to identify the femoral artery and vein in the short axis. Then the ultrasound probe will be slid laterally while identifying the psoas muscle until the most anterior position of the curve of the psoas muscle is identified. A 22-gauge, 80-mm needle is inserted and advanced using an in-plane technique until the tip of the needle is positioned at that point, noting the ‘pop’ through the fascia lata and fascia iliaca. A small test injection is made to ensure that the fluid is seen to lift the fascia iliaca and flow between the fascia and the psoas muscle. After negative aspiration, 30 mL of 0.25% bupivacaine + 250 mg magnesium sulphate is injected in 5 mL increments under ultrasound visualization, with repeating test aspiration after every 5 mL. An expanding anechoic collection just below the fascia iliaca separating it from the psoas muscle should be certainly visualized indicating correct placement of anesthetic solution [17].

In the three groups, the onset of analgesia will be detected by 15 degrees leg raising test and will be recorded. The 15 degrees leg raising test will be used after 10 minutes from injection of local anesthetic in the groups received regional analgesia and after 2 minutes from intravenous injection in the fentanyl group. While the patient is supine, we will try to passively elevate the patient’s leg on the affected side for 15 degrees. If the patient complains of intolerable pain on moving his leg, the test will be aborted and we will wait for a minute before repeating the test. The test will be repeated every minute until we detect the onset of the analgesia that will be represented by dynamic VAS ≤ 4 . For all patients visual analogue pain

score (VAS) is used to evaluate pain. VAS is done by drawing a 10cm vertical line on a piece of paper with its limits “no pain” (0) on one side and “extreme pain” (10) on the other side. The patient will be asked to point where the pain (he/she) experiences lies on the line and the score is recorded ^[18]. Patient will be asked to evaluate his pain on VAS scale before and after the analgesic technique (starting 10 minutes after regional blocks and repeated every minute and 2 minutes after fentanyl injection). Once $VAS \leq 4$, patient will be positioned to receive spinal anesthesia. Vital signs will be recorded with each VAS reading.

Administration of spinal anesthesia:

After analgesia is established and fluid preload is given, patient’s position will be changed to sitting position to receive spinal anesthesia. Spinal anesthesia will be administered by an anesthesiologist who is blinded to groups’ assignment.

Anesthesiologist’s satisfaction with patient’s positioning will be evaluated by operator satisfaction score ; 0=unsatisfactory, 1=satisfactory, 2=good or 3=optimal ^[4]. This scoring will be done by the anesthesiologist responsible for spinal anesthesia administration.

During patient positioning for spinal anesthesia, VAS and vital signs (HR, MAP, SpO₂ and body temperature) will be recorded. If a patient reports $VAS \geq 4$ during positioning, the procedure will be stopped, the patient will be recorded as a failure rate and 1 mic/kg of i.v. fentanyl will be administered in any group. Positioning will be reattempted after VAS is reduced to <4.

After patient is in the sitting position, sterilization of the skin of the back will be done by 10% betadine then sterile drapes are used to surround the area of injection. Then 2 cc of 2% lidocaine will be injected to anesthetize the skin and subcutaneous tissue by forming a skin wheel. Spinal anesthesia will be performed by paramedian approach in the intervertebral space (L3/L4) using a 25G Quincke spinal needle with the bevel directed laterally. After correct needle placement in the subarachnoid space which is confirmed by free flow of cerebrospinal fluid (CSF), 2.5 cc of 0.5% hyperbaric bupivacaine (12.5 mg) + 25 mic fentanyl will be

injected in the subarachnoid space and the needle will be extracted. The skin will be dressed and the patient will be placed in the supine position and oxygen will be supplied by a facemask.

Patient will be evaluated for the effect of spinal block regarding both sensory and motor blocks. Sensory level will be evaluated using pin prick. Motor block will be evaluated using the modified bromage scale. Patient is asked to elevate his extended lower limbs and the score is given as follows: ^[19]

Grade 0 = No motor block.

Grade 1 = Inability to raise extended leg; able to move knees and feet.

Grade 2 = Inability to raise extended leg and move knee; able to move feet.

Grade 3 = Complete motor block of the limb.

The surgery will be started after achieving grade 3 on modified bromage scale and sensory level reaching umbilicus (T10). Patients will be monitored for heart rate (HR), oxygen saturation (SpO₂), mean arterial blood pressure (MAP) and body temperature and recorded every 10 minutes till the end of operation. Patients will be also monitored for the possible side effects of the used techniques (spinal anesthesia, regional blocks and parenteral fentanyl).

- Possible complications of spinal anesthesia include hypotension (decrease in systolic blood pressure by >20% of basal value) and bradycardia (decrease in heart rate by >20% of the basal value). Hypotension will be treated by intravenous fluids and vasopressor (ephedrine bolus 5mg repeated after 3 minutes if needed) while bradycardia will be treated by 1 mg of atropine.
- The most feared complication of regional blocks is local anesthetic toxicity. It can be avoided by not exceeding the toxic dose (2-2.5 mg/kg for bupivacaine) and avoiding inadvertent intra-arterial injection by proper visualization of the needle and injected local anesthetic by ultrasound and aspiration test before every increment injection. Manifestations of toxicity includes tingling of the tongue, circumoral numbness, tinnitus, blurred vision, agitation, muscle twitches, convulsions and cardiovascular manifestations as hypotension, bradycardia, heart block and cardiac arrest. Treatment is mainly supportive (respiratory and cardiovascular support), cardiopulmonary

resuscitation in case of cardiac arrest and the antidote is intralipid 20% (1.5 ml/kg over 1 minute then infusion in a rate of 0.25 ml/kg/min).

- In the elderly parenteral fentanyl may cause delirium or respiratory depression. Delirium can be assessed using the confusion assessment method (CAM). The CAM diagnostic algorithm is based on four cardinal features of delirium: 1) acute onset and fluctuating course, 2) inattention, 3) disorganized thinking, and 4) altered level of consciousness. A diagnosis of delirium according to the CAM requires the presence of features 1, 2, and either 3 or 4 [20].

At the end of the procedure patient will be asked to evaluate the analgesic technique used by patient's satisfaction score: Patient will be asked to rate his satisfaction with the technique of analgesia used by giving a score on a 1-3 scale (1 = unsatisfactory analgesia, 2 = satisfactory analgesia, 3 = excellent analgesia) [21].

In the recovery room: Patient will receive 1 gm paracetamol and 30 mg ketorolac by intravenous infusion as a part of standard multimodal analgesia.

In the ward: Postoperative standard analgesia will continue in the form of 1gm paracetamol/8hours and ketorolac 30 mg/12hours. Patient will be monitored for vital signs (HR, MAP, SpO₂ and body temperature), time of offset of spinal anesthesia (time from end of intrathecal injection of hyperbaric bupivacaine till recovery of the lower limbs motor power indicated by achieving grade 0 on modified bromage scale and fine touch sensation indicated by sensing pin brick) and postoperative pain by VAS score. Vital signs and VAS will be recorded at 2, 4, 6, 12 and 24 hours postoperative.

If patient gives VAS \geq 4 or complains of intolerable pain, a rescue analgesia will be given in the form of nalbuphine 0.1 mg/kg. We will record time of first rescue analgesia (the time between complete injection of the local anesthetic in the regional groups or fentanyl injection and the first analgesia requested by the patient), total postoperative rescue analgesic consumption in first 24 hours and time of onset of postoperative ambulation.

• **Collecting data:**

From each patient the following data will be collected:

- Patient characteristics (name, age, gender, body mass index (BMI), ASA grade).
- Fracture type.
- Type and duration of surgery (time from end of skin preparation till suturing the wound).
- Physical examination (mental status, decubitus, chest, abdomen, neurological and examination of the site of injection), laboratory investigations (complete blood count, random blood sugar, international normalized ratio, prothrombin time, partial thromboplastin time, kidney functions tests, liver functions tests and serum electrolytes).
- Vital signs (heart rate, mean blood pressure, respiratory rate, temperature and SpO₂). Vital signs will be recorded before and after the analgesic technique, during positioning for spinal anesthesia and then every 10 minutes till the end of the surgery. Then we will record vital signs at 2, 4, 6, 12 and 24 hours postoperative.
- Intraoperative total fluids given, blood loss and urine output.
- Visual analogue pain score will be recorded before and after analgesic technique used (starting 10 minutes after regional blocks and repeated every minute and 2 minutes after fentanyl injection) and during positioning. VAS will be also recorded at 2, 4, 6, 12 and 24 hours postoperative.
- Time of block performance (time from the end of skin sterilization till end of injection of local anesthetic).
- Onset time of the analgesic technique (time from end of injection of local anesthetic or intravenous fentanyl till reaching VAS \leq 4) by 15 degrees leg raising test. The 15 degrees leg raising test will be used after 10 minutes in the groups received regional analgesia and 2 minutes in the fentanyl group. We will try to elevate the patient's leg for 15 degrees. If the patient complains of pain on moving his leg, the test will be aborted and we will wait for a minute before repeating the test.
- Patient's satisfaction score.
- Anesthesiologist satisfaction score for patient's positioning.
- Possible complications of spinal anesthesia, regional blocks and parenteral fentanyl.

- Time of first rescue analgesia (the time between complete injection of the local anesthetic in the regional groups or fentanyl injection and the first analgesia requested by the patient) and total postoperative rescue analgesic consumption in first 24 hours postoperative.
- Time of onset of postoperative ambulation (time from end of surgery till first ambulation by the patient).
- Duration of spinal anesthesia (time from end of injection of intrathecal hyperbaric bupivacaine till offset of spinal anesthesia effect detected by degree 0 on modified bromage score and return of fine touch detected by sensing pin bricks).

- **Statistical analysis:**

The statistical analysis will be performed using a Statistical Package for the Social Sciences (SPSS®) version 16 (SPSS Inc., Chicago, IL, USA) for windows 10 operating system. Quantitative data will be expressed as means \pm SD while Qualitative data will be expressed as numbers and percentages (%). A probability value (p-value) <0.05 is considered statistically significant.

Presentation of the statistical outcomes will be in the form of tables and graphs that will be performed using the “Microsoft Office Excel® 2013” program.

III. Administrative design:

- **Results:**

Collected data will be tabulated in tables and suitable graphs and analyzed according to standard statistical methods.

- **Discussions:**

Discussion will be done on results compared to related relevant literature and scientific researches.

- **Conclusion & Recommendations:**

They will be derived from the findings of the study.

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