Title: Postoperative Analgesic Effect of Morphine added to Ropivacaine for Fascia Iliaca Compartment Block Following Femoral Fracture Surgeries

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POSTOPERATIVE ANALGESIC EFFECT OF MORPHINE ADDED TO ROPIVACAINE FOR FASCIA ILIACA COMPARTMENT BLOCK FOLLOWING FEMORAL FRACTURE SURGERIES

PROTOCOL SUBMITTED FOR MD IN ANAESTHESIOLOGY AND CRITICAL CARE

DEPARTMENT OF ANAESTHESIOLOGY AND CRITICAL CARE
B.P. KOIRALA INSTITUTE OF HEALTH SCIENCES

DHARAN, NEPAL

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SUMMARY OF POST GRADUATE THESIS PROTOCOL

1. **Study title:** Postoperative analgesic effect of morphine added to ropivacaine for fascia iliaca compartment block following femoral fracture surgeries
2. **Name of the student**: Dr. Pankaj Baral
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7. **Rationale of the research**: Femoral fracture are common and require open reduction and internal fixation for treatment. A substantial complaint of pain

experienced in the patients after this surgery is derived from the incision. Earlier and improved rehabilitation occurs when peripheral nerve blocks are used to provide post-operative analgesia. A sufficient volume of local anaesthetic deposited beneath the fascia iliaca provides effective postoperative analgesia and decreases the rescue opioid analgesics requirement during the post-operative period. FICB blocks the femoral, lateral cutaneous and obturator nerves, that are responsible for transmission of pain impulses from the incision. Opioids have been used as adjunct drugs in peripheral nerve blocks (Saryazdi et al. 2015). The reports on addition of opioids to local anaesthetics in FICB for prolongation of postoperative analgesia are limited.

Rationale of the current study is to use morphine as an adjunct to ropivacaine for USG guided FICB for post-operative analgesia in patients undergoing femoral fracture surgeries.

8. **Primary & Secondary Objectives:** Enclosed
9. **Research Hypothesis** (Null Hypothesis)**:**

   Morphine added to ropivacaine in ultrasound guided fascia iliaca compartment block does not prolong the duration of analgesia and minimize the requirement of postoperative rescue analgesics following femoral fracture surgeries.
10. **Material & Methods:** Enclosed
    a. **Whether study involves Human/animals or both:** Human
    b. **Population/ participants**:
        a. **Group A** - Ropivacaine 0.375% 20 ml with NS 2 ml for FICB
        b. **Group B** - Ropivacaine 0.375% 20 ml with morphine (1mg/ml) 2 ml for

FICB

c. **Type of study design:** Prospective Randomised Double Blind Clinical Study
d. **Setting**: Department of Anaesthesia and Critical Care, BPKIHS
e. **Sample Selection criteria:**
    a. **Inclusion Criteria:** Enclosed
    b. **Exclusion Criteria:** Enclosed
f. **Expected sample size:** 70
g. **Probable duration of study:** 1 year
h. **Parameter/Variables to be measured:** As per proforma
i. **Outcome measures**: Duration of analgesia, requirement of rescue analgesics, numeric rating scale (NRS) for pain, sedation score.
j. **Statistical methods to be employed:** Enclosed
k. **Ethical clearance:** Will be obtained from the Institutional Review Committee
l. **Permission to use copyright questionnaire/ Proforma:** Enclosed

12. **Maintain the confidentiality of subject:** Yes
13. **References:** Attached
14. **Whether available resources are adequate:** Adequate
15. **Other resources needed:** No
16. **ANNEXURES**
    a. **Participants record form (clinical data sheet)**
    b. **Participant Information sheet**
        i. **Attached English**

ii. **Attached Nepali**

c. **Participant Informed consent form**

ii. **Attached English**

iii. **Attached Nepali**

Contents

INTRODUCTION

Pain is not just a sensory modality but an experience. The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” This definition recognizes the interplay between the objective, physiological sensory aspects of pain and its subjective, emotional, and psychological components. The response to pain can be highly variable among different individuals as well as in the same person at different times. (John F. Butterworth IV, David C. Mackey 2013)

With their knowledge of and familiarity with pharmacology, various regional anaesthesia techniques, and the neurobiology of nociception, anaesthesiologists are prominently associated with the clinical and research advances in acute postoperative pain management. Anaesthesiologists developed the concept of acute postoperative pain services (inpatient pain services), application of evidence based practice to acute postoperative pain, and creation of innovative approaches to acute pain medicine, all of which are a natural part of the anaesthesiologist’s functions as a “perioperative physician,” consultant, and therapist throughout an institution, as well as a highly skilled expert in the operating room.(Miller 2015)

The stress hormones released in pain causes increase in heart rate, respiratory rate, myocardial oxygen demand, hypertension, arrhythmias and may lead to myocardial ischaemia (Biebuyk 1990). All these factors bear adverse prognosis in post-operative recovery and increase in morbidity and post-operative hospital stay.

Patients with a femur fracture have a relatively high risk of perioperative morbidity and mortality, related to their age and co-morbidities (Maxwell et al. 2013). Clinicians are frequently reluctant to administer adequate parenteral analgesia to these patients, for fear of worsening inter-current disease or of precipitating unwanted side effects in patients who are often already frail.(Finlayson & Underhill 1988).

Analgesic techniques should aim to provide optimal pain relief whilst minimizing side effects such as sedation, post-operative nausea and vomiting (PONV), hypotension, and motor block. Current evidence supports earlier and improved rehabilitation when peripheral nerve blocks are used to provide post-operative analgesia. They can provide excellent analgesia with minimal motor block. This facilitates early and more effective joint mobilization and physiotherapy, while limiting reflex muscle spasm. In addition, they avoid the systemic side effects associated with continuous epidural analgesia (hypotension, urinary retention) and PCA morphine (sedation, PONV).(Grant & Checketts 2008)

The fascia iliaca compartment block is a simple, inexpensive, and effective method of prehospital analgesia for femoral shaft fracture. (Lopez et al. 2003)

Three major nerves (femoral, lateral cutaneous and obturator) of the lumbar plexus are blocked in FICB, first described by Dalens et al. The FICB has traditionally been undertaken by loss of resistance using palpable anatomical landmarks. Using this landmark approach, complete nerve block in the distribution of the lumbar plexus may be achieved only in 38% of cases. Ultrasound guided regional techniques offer a number of advantages including real time needle guidance and direct observation of local anaesthetic spread within tissue planes.(Williams et al. 2008)

The mechanism behind the FICB is that the femoral and lateral femoral cutaneous nerves lie under the iliacus fascia. Therefore, a sufficient volume of local anaesthetic deposited beneath the fascia iliaca, even if placed some distance from the nerves, has the potential to spread underneath the fascia and reach these nerves. The ultrasound-guided technique is essentially the same; however, monitoring of the needle placement and local anaesthetic delivery assures deposition of the local anaesthetic into the correct plane.

Ropivacaine, a local anaesthetic agent, is an enantiomer of bupivacaine with less cardiac and neurotoxic effects. It produces intense analgesia with less motor blockade compared to bupivacaine which is preferable in these patients for early mobilization.(Ganesan et al. 2011)

As compared with racemic bupivacaine, ropivacaine also has clinically relevant advantage of a stronger differentiation between sensory and motor blocks, which is particularly useful when early mobilization is important to accelerate postoperative recovery. Ropivacaine is 40-50% less potent than bupivacaine and levobupivacaine because of its lower lipid solubility; however, a reduced potency does not imply that this agent is less effective than the other two, and using an equipotency ratio of 1.5 : 1 between ropivacaine and the two other drugs results in a substantially similar clinical profile with a good preservation of motor function.(Leone et al. 2008)

Various adjuncts like epinephrine, dexamethasone, clonidine, fentanyl, morphine, dexmedetomidine etc. have been studied to improve the quality of peripheral regional local anaesthetic block with varying success.

Systemic opioids are being used as analgesics after surgery for many years. Pain reduction of opioids through central receptors and spinal cord is well-known. The peripheral effects of opioids and their mechanism of action have been studied recently, and they have been used as an adjunct drug in peripheral nerve blocks.(Saryazdi et al. 2015)

Morphine is routinely administered by intramuscular, intrathecal, or epidural routes for the relief of pain. It is thought to produce its effects by an action on specific receptors in the dorsal horn of the spinal cord and on central opioid receptors. Reports have suggested that morphine injected perineurally in patients with chronic pain may also have a clinically significant effect and that its duration of action may be longer than that of systemically administered morphine or bupivacaine (Racz et al. 1991).

Till date, addition of morphine to ropivacaine for fascia iliaca compartment block has not been conducted in our setup and patients. Purpose of the current study is to use morphine as an adjunct to ropivacaine for USG guided FICB for post-operative analgesia in patients undergoing femoral fracture surgeries and assess the duration and quality of pain control and the requirement of rescue analgesics.

REVIEW OF LITERATURE

Morrison et al. studied the impact of postoperative pain on outcomes following hip fractures. They found that post-operative pain was associated with increased hospital length of stay, delayed ambulation, and long-term functional impairment. Improved pain control might decrease length of stay, enhance functional recovery, and improve long-term functional outcomes.

Wambold et al. and his team reported that fascia iliaca nerve block provides excellent post-operative pain relief after knee surgery and it is easy to perform, safe and effective.

Lopez et al. reported that fascia iliaca compartment block was simple, inexpensive and effective method of prehospital analgesia for femoral shaft fracture. It provided faster and more consistent simultaneous blockade of lateral cutaneous and femoral nerve than 3-in-1 block. A sensory block of the inner part of thigh could be used as early predictive sign of optimal pain relief.

Based on prospective, randomized, double blind study, **Cuignet O et al** reported that single shot fascia iliaca block is an easy, inexpensive and efficient method for diminishing pain during post-operative period in burn patients undergoing skin-grafting. A single block had the same morphine sparing-effect as the continuous technique. Patients receiving a single block experienced less residual paresia and were more satisfied with their pain-relief treatment than those who received a continuous infusion.

Stevens et al. reported that a modified fascia iliaca compartment block with 30 ml 0.5% bupivacaine with 1:200,000 adrenaline, 150 microgram clonidine and 9 ml 0.9% saline has a significant morphine-sparing effect in unilateral total hip arthroplasty.

Williams et al. compared ultrasound guided fascia iliaca compartment block with loss of resistance technique in 80 patients undergoing either unilateral hip or knee joint replacement surgery. They found that ultrasound-guided fascia iliaca block increased the frequency of sensory loss in the medial aspect of the thigh and also increased the frequency of femoral and obturator motor block.

In a study done by **Ganesan et al.**, they reported that administration of ropivacaine 0.5% as fascia iliaca compartment block, for postoperative analgesia in lower limb orthopaedic surgeries, was very effective in providing considerable pain relief in majority of the patients in the first 4-6 hrs. Also it was simple to perform without serious adverse effects.

Öster Svedberg et al. studied the compatibility of different opioids (morphine, sufentanil and fentanyl) with ropivacaine. They found that all combinations at all doses stayed within the compatibility criteria. In addition, there were no important differences in the enantiomeric purity of ropivacaine with each combination.

In a prospective, randomized, double blind clinical trial study, **Saryazdi et al.** compared the effects of addition of different opiates (morphine, meperidine, buprenorphine, or fentanyl) to lidocaine in duration and quality of axillary brachial plexus block. They found that addition of morphine or pethidine to lidocaine was superior to other opioids (i.e. fentanyl and buprenorphine) due to better quality and quantity of motor blockade and faster onset of the block.

In a double-blind, randomised controlled cross-over study **Dahl.** compared the effects of perineuronal injections of morphine with epidural injections with the same amount of

morphine in patients after knee surgery. They found that better pain scores were achieved during treatment with epidural morphine.

Kardash et al. added fentanyl to mepivacaine for supraclavicular brachial plexus block. They found that there was no statistically significant difference in sensory or motor block characteristics by addition of fentanyl. There was a significantly lower VAS score among the patients with fentanyl added to their blocks within the first hour after the operation but subsequent VAS scores and total 24-hour patient-controlled analgesia requirements were no different.

Gessel & Donald. found that the addition of morphine 5 mg to interscalene brachial plexus block does not improve the quality of intraoperative analgesia, prolong the effect of the block or decrease the requirements for analgesia in the first 48 h after operation.

Bourke & Furman. failed to detect a difference in postoperative visual analog scores, motor or sensory block duration with perineural morphine when added to axillary blocks performed with lidocaine plus epinephrine when compared to intravenous (IV) morphine supplementation. However, they did report a significantly decreased consumption of supplemental opioid doses.

Bazin et al. demonstrated that the addition of opioids to a mixture of bupivacaine and lignocaine in brachial plexus block doubles the duration of postoperative pain relief. It prolonged the median duration of analgesia after internal fixation of upper extremity fractures from 11.5 to 21 hours.

Sternlo & Hägerdal. found that addition of morphine to 0.5% bupivacaine was not associated with prolongation of intercostal nerve block.

Racz et al. showed that analgesia duration with intramuscular (IM) morphine was indistinguishable from morphine mixed with local anaesthetic after hand and forearm surgery with mixed lidocaine/bupivacaine axillary blocks.

Keskinbora & Aydinli examined the use of bupivacaine versus bupivacaine plus morphine administered via a popliteal catheter for patients with chronic lower extremity pain. The study included a short-term single bolus treatment phase where morphine was noted to prolong analgesia by approximately three hours compared to bupivacaine alone. However, the morphine group experienced significantly greater side effects (nausea and somnolence). More than twice as many patients preferred treatment with bupivacaine alone, even though they required more rescue analgesia.

Mays & Lipman concluded that perineural morphine provided statistically longer lasting pain relief than did either intramuscular morphine or perineural bupivacaine.

Atef et. al, concluded that 2mg of morphine added as an adjuvant to the local anaesthetic during TAP block significantly reduced postoperative pain intensity after inguinal herniorrhaphy.

OBJECTIVES

Primary Objective

- To assess the duration and quality of postoperative analgesic effect of morphine as an adjunct to ropivacaine in a single shot USG guided FICB in patients undergoing ORIF for fracture femur under spinal anaesthesia.

Secondary Objectives

- To compare the requirement of post-operative rescue analgesics following a single shot USG guided FICB with ropivacaine alone and ropivacaine with morphine in patients undergoing ORIF for fracture femur under spinal anaesthesia.
- To compare postoperative sedation score using modified Ramsay Sedation Scale between two groups.
- To compare the postoperative pain scores at 0, 4, 6, 12, 24 h between two groups and use of rescue analgesics.
- To compare the haemodynamics postoperatively between two groups.
- To compare the occurrence of any postoperative complications (bradycardia, hypotension, PONV, respiratory depression) between two groups.

RESEARCH HYPOTHESIS (Null Hypothesis)

Morphine added to ropivacaine in USG guided FICB does not prolong the duration of analgesia and minimize the requirement of postoperative rescue analgesics following femoral fracture surgeries.

MATERIAL AND METHODS

a. Type of study design:

This is a prospective randomized double blind clinical trial.

It will include patients of American Society of Anaesthesiologists physical status (ASA PS) I and II, scheduled for ORIF for proximal femur fractures divided in two equal groups.

b. Population/Participants:

- **Group A -** Ropivacaine 0.375% 20ml with NS 2ml for FICB
- **Group B -** Ropivacaine 0.375% 20ml with morphine (1mg/ml) 2ml for FICB

c. Population/Participant's selection criteria

I. Inclusion criteria:

All patients undergoing elective femur surgery under spinal anaesthesia

- Age group (18-65 years)
- ASA physical status I and II

II. Exclusion criteria:

All patients with

- Not willing to participate in the study
- Other painful co-morbidities (neuropathies)
- Allergy or any contraindication to study medication
- Psychiatric disorder
- Coagulopathy
- Infection at the site of the block
- Use of other modes of anaesthesia or analgesia besides spinal anaesthesia.

d. Setting: Department of Anaesthesiology and Critical Care, BPKIHS

e. Probable Study period: One Year

f. Ethical Clearance:

Approval of this study will be obtained from the BPKIHS Institutional Review Committee and informed written consent for the procedure will be obtained from all the eligible patients. Every patient will have the right to withdraw from the study at any time.

g. Conflict of Interest: No conflict of interest

h. Sampling Technique: Via a computer generated random number sequence

i. Method of Randomization and blinding

Based on the computer generated random number table, patients will be assigned to either Group A or Group B.

Sequentially numbered white envelopes will be used with study medication mentioned inside. The investigator observing and recording the outcome will be kept unaware regarding the medication group. At the same time subjects will be unaware of the nature of the drug used. The group allocation will be revealed only after analysis of the data.

METHODS (*INTERVENTION / PROCEDURE)*:

a. Instruments and drugs

Equipment needed includes the following:

- Ultrasound machine with linear transducer (6-14 MHz), sterile sleeve, and gel
- Standard nerve block tray
- 20-mL syringes
- 80- to 100-mm, 22-gauge needle
- Sterile gloves

Drugs needed include the following:

- 20 ml of 0.375% ropivacaine

- 2 ml of 1mg/ml morphine
- 2 ml of normal saline

b. Follow up of subjects: The subjects will be followed till 24 hours after the surgery.

c. Anaesthesia technique:

All recruited patients and their relatives / attendants will be informed regarding the study, medication being used and expected co-operation required during pre-anaesthetic check up in the ward, the evening before surgery. Informed and written consent will be obtained for accepting participation in the study. During the visit, patient will be familiarized and explained about the use of numeric rating scale (NRS) for pain assessment. (0= No pain, 1-3= Mild pain, 4-6= Moderate pain, 7-10= Severe pain).

Ramsay sedation scale (RSS) will also be explained in simple language which patient can understand. All the patients will be pre-medicated with Tab. Lorazepam 1-2mg given orally night before and in the morning of surgery.

On the day of operation, a vein of moderate caliber on the dorsum of the non-dominant hand will be chosen and an intravenous line (IV) will be opened with an 18 G IV cannula. Pre hydration will be done with Ringer's lactate solution 20ml/kg just prior to administration of subarachnoid block (SAB). In the operation theatre standard monitoring devices will be attached to monitor electrocardiograph (ECG), pulse-oximeter (SpO_2), non-invasive blood pressure (NIBP) together with heart rate (HR).

In the operating table patient will be properly positioned for spinal anaesthesia. Spinal anaesthesia will be administered in sitting position using bupivacaine (hyberbaric) 0.5% (2.5 - 3 ml). The level of sensory block obtained will be checked by using sterile needle. Motor block will be assessed by grading the motor power of the muscles (0 to 5). During intraoperative period all the patients' ECG, HR, SpO_2 and NIBP will be monitored as per the institute's routine protocol. After the completion of surgery and application dressing on the surgical wound the patient will be positioned supine. The skin will be disinfected and the transducer will be positioned to identify the femoral artery and the iliopsoas muscle and fascia iliaca. The transducer will be moved laterally until the sartorius muscle is identified. After a skin wheal is made, the needle will be inserted in-plane. As the needle eventually pierces through the fascia, pop will be felt and the fascia will be seen to "snap" back on the ultrasound image. After negative aspiration, 1 to 2 ml of the drug will be injected to confirm the proper injection plane between the fascia and the iliopsoas muscle. If local anaesthetic spread occurs above the fascia or within the substance of the muscle itself, additional needle repositions and injections will be made. The drug will be injected in aliquots of 5ml alternating with aspiration. The success of the block will be predicted by documenting the spread of the local anaesthetic toward the femoral nerve medially and underneath the sartorius muscle laterally. This time point will be considered as zero hour for our study.

Experienced anaesthesiologists not involved in the study will perform the block.

HR, mean arterial blood pressure(MAP), SpO_2, sedation score, NRS for pain will be recorded at 0h, 4h, 6h, 12 h and 24h postoperatively.

Sedation will be assessed using Modified Ramsay's sedation scale (MRSS) from 1-6 as follows:

1= anxious, agitated, restless

2= co-operative, oriented, tranquil

3= responds to command only

4= brisk response to light glabellar tap or loud noise

5 = sluggish response to light glabellar tap or loud noise

6= no response

The pain intensity will be measured regularly at intervals mentioned above by Numeric Rating Scale.

0	No Pain
1–3	Mild Pain (nagging, annoying, interfering little with activities of daily living (ADLs))
4–6	Moderate Pain (interferes significantly with ADLs)
7–10	Severe Pain (disabling; unable to perform ADLs)

Adverse events observed in the intraoperative and postoperative period, defined as follows, will be noted.

- hypotension (20% decrease relative to baseline MAP) requiring a fluid bolus

- bradycardia (HR <50 bpm) requiring atropine
- nausea, vomiting
- pruritis
- hypoxemia (SpO_2<90%) or
- any need for additional medication.

Blood loss will be calculated and will be replaced if more than allowable blood loss. Pain will be assessed using NRS postoperatively. Patient will be given Injection Paracetamol 15mg/kg after the surgery and then 6 hourly in the postoperative period. Nursing staff will be directed to administer Inj. Tramadol 50mg IV slowly when NRS > 3 (rescue analgesia) and Inj. Ondansetron 4mg if the patient complains of nausea or vomiting. The time between the block and the first analgesic request will be recorded as duration of analgesia. Total dose of rescue analgesics and antiemetics (Tramadol and Ondansetron) consumed in the postoperative period will be recorded.

In the post-operative period in the ward, acceptance of the procedure and satisfaction level will be asked to the patient according to Likert scale.

Likert scale

1 = Strongly dissatisfied

2 = Dissatisfied

3 = Neutral

4 = Satisfied

5 = Strongly satisfied

OUTCOME MEASURES

a. Primary Outcome Measures:

Duration of analgesia

b. Secondary Outcome Measures

Total dose of rescue analgesics required in the postoperative period, numeric rating scale (NRS) for pain, Sedation score

DATA MANAGEMENT AND STATISTICAL ANALYSIS

a. Data handling

Data will be entered in Microsoft Excel 2016 and converted into Statistical package for social sciences (SPSS 11.5) for statistical analysis.

b. Coding

Alpha numerical code will be used.

c. Monitoring

Data will be entered after every day of work.

d. Statistical methods proposed

- Independent paired t test to compare the mean between two groups.
- Paired t test to compare the mean values before and after the study drug administration within the same group.
- Chi square test to compare the non-paremetric variables.

Probability value will be considered significant when $p<0.05$.

e. Calculation of the sample size

This study will consider 95% confidence interval and 80% power to estimate the sample size. For this purpose, taking into account the pre-test results, Group A mean (μ_1) = 6.6 hours, Group B mean (μ_2) = 8.6 hours and combined standard deviation (σ) = 2.27.

Now, using the following formula for sample size estimation

$$n = \frac{2\sigma^2 \left(Z_{\alpha/2} + Z_{\beta}\right)^2}{(\mu_1 - \mu_2)^2}$$

Where,

$Z_{\alpha/2}$ = 1.96 at 95% confidence interval

Z_{β} = 0.842 at 80% power

sample size becomes 32 in one arm. Adding 10% in for bias and data loss, sample size becomes 35 in each group. So, considering as above, n = 35 in each group i.e total sample size becomes 70.

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ANNEXURES

PARTICIPANT RECORD FORM

Sample no: Date:

Name: ID no:

ASA PS: Age/Sex:

Time of start of Anaesthesia: Weight:

Duration of operation:

Time of block administration:

Measurement of parameters

			Parameters							
T I M E	During surgery		RR	HR	SBP	DBP	MAP	SpO_2	NRS	MRSS
		0 min.								
		10min								
		30min.								
	Postoperative	0 h								
		4 h								
		8 h								
		12 h								
		24 h								

Time	Parameters	
	Rescue analgesics (Inj Tramadol)	Rescue antiemetics (Inj Ondansetron)
0-4 hours		
4-8 hours		
8-12 hours		
12-24 hours		

Intra operative complications:

- Hypotension:
- Bradycardia:
- Nausea and vomiting:
- Respiratory depression:
- Others:
- Any medication used:

Level of SAB at the time of FICB:

Time of administration of first dose of rescue analgesia:

Total duration analgesia with block:

Total dose of IV Tramadol given:

Total dose of IV Ondansetron given:

Postoperative complication (Nausea/ vomiting/ bradycardia/ hypotension/ respiratory depression:

I would like to repeat the procedure if there is a need in the future: Yes/No

Patient's satisfaction level (Likert scale- 1 = Strongly dissatisfied, 2 = Dissatisfied, 3 = Neutral, 4 = Satisfied, 5 = Strongly satisfied):

PARTICIPANT INFORMATION SHEET

B.P. KOIRALA INSTITUTE OF HEALTH SCIENCES
DHARAN, NEPAL
POSTOPERATIVE ANALGESIC EFFECT OF MORPHINE ADDED TO ROPIVACAINE FOR FASCIA ILIACA COMPARTMENT BLOCK FOLLOWING FEMORAL FRACTURE SURGERIES

1. **Why are we giving you this paper?**
   We will explain this note to you now and we would like you to read it.

2. **Who will be conducting this study?**
   Dr. Pankaj Baral
   Junior Resident
   Department of Anaesthesiology and Critical Care
   BPKIHS, Dharan, Nepal
   Contact no. 9856037077

3. **Why is this study being done?**
   The purpose of this study is to assess duration and quality of postoperative analgesia and the requirement of postoperative rescue analgesics by using morphine as an adjunct to ropivacaine in USG guided FICB in patients undergoing ORIF for femur surgeries under spinal anaesthesia.

4. **Why are we inviting you to participate in the study?**
   There have been no studies designed to assess the duration, quality of postoperative analgesia and requirement of postoperative rescue analgesics after giving ropivacaine with morphine for fascia iliaca block in patients undergoing femoral fracture surgeries under SAB for post-operative pain management. So, you are invited to participate in this study.

5. **What will be happening if you accept to enter this study?**

   Basic information about you will be taken. You will be randomized into two groups; one group will be given single shot FICB using 20 ml 0.375% ropivacaine with 2ml morphine (1mg/ml) after the completion of surgery and the other group will be given single shot FICB using 20 ml 0.375% ropivacaine with 2ml normal saline. The total requirement of postoperative rescue analgesics, NRS score, duration of analgesia and sedation score will be assessed at intervals till 24h.

6. **Confidentiality**

   All information collected during this study regarding you will be confidential. Reports will be generated on the outcome of the study without your name appearing anywhere. The participation in the study is voluntary and the honesty of your answer will be very important. The findings of this study will be analysed and published in peered review journal for dissemination.

7. **Are you facing any risk in this study?**

   The drugs have been proven to be safe in previous studies. Possible side effect of morphine used in this block is excessive sedation postoperatively.

8. **Are there any benefits of this study for you?**

   This study will help us to determine if the use of morphine as an adjunct to ropivacaine in FICB decreases the requirement of postoperative rescue analgesics. Your participation in the study is free of charges and you will not be paid for participating in the study.

9. **How to refuse or give consent?**

   You have every right to agree or refuse to participate in this study.

   You will not be penalized or be blamed should you refuse to enter in this study. Once you enter this study, we hope off course that you will continue with us for the full time period of the study. Even after entry, you are free to withdraw any time you feel like and for the same no one will make you pay or give you any other sanctions.

जानकारी पर्चा

वी.पी. कोईराला स्वास्थ्य विज्ञान प्रतिष्ठान

धरान, नेपाल

समीपस्थ हड्डी शल्यक्रिया (Femoral Fracture Surgeries) पश्चात हुने दुखाई कम गर्नको लागि FICB मा Ropivacaine का लागि एक सहायकका रुपमा Morphine को प्रयोग ।

१) तपाईलाई यो कागज किन दिइएको छ ?

यस कागजमा यो अध्ययनको बारे जानकारी छ जुन पढेर तपाईले यसमा भाग लिनुहुनेछ ।

२) यो अनुसन्धान कसले गरिरहेका छन् ?

डा. पंकज बराल

जुनियर रेसिडेन्ट

वी.पी. कोईराला स्वास्थ्य विज्ञान प्रतिष्ठान, धरान नेपाल

सम्पर्क नं: ९८५६०३७०७७

३) यो अनुसन्धान किन गरिदैछ ?

ऐनस्थेसिया अन्तर्गत समीपस्थ हड्डी शल्यक्रिया पश्चात हुने दुखाई कम गर्नको लागि FICB मा Ropivacaine का लागि एक सहायकका रुपमा Morphine को प्रयोग गरी शल्यक्रिया पश्चात हुने दुखाई र दुखाई कम गर्न चाहिने औषधीको मात्राको अध्ययन गर्नको लागि गरिंदै छ ।

४) तपाईलाई किन आमन्त्रित गरिएको छ ?

समीपस्थ हड्डी शल्यक्रिया (Femoral Fracture Surgeries) पश्चात हुने दुखाई कम गर्नको लागि FICB मा Ropivacaine का लागि एक सहायकका रुपमा Morphine को प्रयोग गरी शल्यक्रिया पश्चात हुने दुखाई र दुखाई कम गर्न चाहिने औषधीको मात्राको अध्ययन गर्नको लागि हाम्रो परिवेशमा कुनै अध्ययन नभएकोले ।

५) यस अध्ययन अन्तर्गत के हुनेछ ?

तपाईलाई सामान्य जानकारी लिइनेछ । कम्प्युटरद्वारा उत्पन्न अंकको मद्दतले दुई समुह FICB मा Ropivacaine+Morphine र अर्को समुहमा Ropivacaine मात्र प्रयोग हुनेछ। शल्यक्रिया पश्चात शल्यक्रिया पछि दुखाईको अवस्था,दुखाई कम गर्न चाहिने औषधीको मात्रा र बेहोसी पछि लाग्ने निद्राको अवस्थाको अध्ययन शल्यक्रियाको २४ घण्टा भित्र गरिन्छ ।

६) गोपनियता

तपाईको सबै जानकारी गोप्य राखिनेछ । तपाईको नाम कतै उल्लेखित हुने छैन । तपाईको सहभागिता तपाईका स्व-इच्छामा हुनेछ र उत्तर दिदा इमान्दारीता महत्वपूर्ण हुनेछ ।

७) यस अध्ययनमा सामेल हुनका लागि सम्भावित जोखिमहरु के के हुन ?

यो औषधी अनुभवी प्रयोगकताका काथमा सुरक्षित छन् । सामान्य प्रतिकुल असर बाहेक अरु अतिरिक्त असरहरु न्युन छन् । Morphine ले निन्द्रा लगाउने सम्भावना हुन्छ ।

८) यस अध्ययनमा सामेल हुनुका सम्भावित लाभहरु के के हुन ?

यो अध्ययनमा FICB मा Ropivacaine का लागि एक सहायकका रुपमा Morphine को प्रयोगगर्दा दुखाई को अवधि र गुण र शल्यक्रिया पश्चात चाहिने दुखाई कम गर्ने औषधीको मात्रा घट्ने वा नघट्ने जानकारी प्राप्त हुन्छ ।

तपाईंलाई यस अध्ययनमा सामेल हुंदा कुनै आर्थिक सहयोग दिइने छैन ।

९) अध्ययनमा सामेल भएपछि के तपाईले आफ्नो विचार बद्लिन सक्नुहुन्छ ?

यस अध्ययनमा सहभागी हुन मञ्जुरी दिने नदिने निर्णय गर्न तपाईको पुरा अधिकार छ । सहभागी हुन नचाहनु भएमा पनि तपाईलाई कुनै सजाय वा जरिवाना हुने छैन । र अन्य उपचारबाट बञ्चित गरिने छैन । तपाई कुनैपनि समय यस अध्ययनबाट बाहिरिन सक्नुहुनेछ ।

PARTICIPANT INFORMED CONSENT FORM

Protocol Number: _____

Participant Identification number for the study_____

Title of the research: Postoperative analgesic effect of morphine added to ropivacaine for fascia iliaca compartment block following femoral fracture surgeries

Name of the candidate: _____, aged_____years, Address _____. Telephone: (residence) _____(mobile) _____(friend/parents) _____ Email_____,

The content of the information sheet dated_____ that was provided has been read carefully by me/explained in detail to me, in a language that I comprehend, and have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks/ benefit and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from BPKIHS. I give permission for these individuals to have access to my record.

I hereby give consent to take part in the above study and allow to perform the procedure and any other medical service that may become necessary during the procedure.

I also consent for medical photographs/ video and I have been informed that these photographs/ video will be used without revealing the identity. I understand that these along with the information I provide may be used in my medical record, for purpose of publication in textbook or medical journal and dissertation purpose, or for medical education.

The consent form has been signed by me when I was not under the influence of any drugs.

Patient's signature _____ Researcher/Doctor's signature _____

Date:

Witness signature _____

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions and to understand the nature of study. I confirm that the individual has given consent freely.

Thumb print of participant

Researcher/Doctor's signature _____

Date:

Witness signature _____

मन्जुरीनामा पत्र

प्रोटोकल नं: _____

सहभागी आइ डी नं: _____

अध्ययनको विषय: समिपस्थ हड्डी शल्यक्रिया पश्चात् हुने दुखाई कम गर्नको लागि FICB मा Ropivacaine का लागि एक सहायकका रुपमा Morphine को प्रयोग ।

सहभागीको नाम:_____ उमेर: _____

ठेगाना: _____

टेलिफोन नं: घर _____ मोबाइल _____

अविभावक _____ इमेल_____

मिति_____ मा मलाई दिइएको जानकारी पर्चा राम्री पढेको छु/ मैले बुझ्ने भाषामा बुझाइएको छ र मैले बुझेको छु । मलाई प्रश्न सोध्ने मौका पनि दिइएको छ । अध्ययनको प्रकृति, उद्देश्य र जोखिम/लाभ, अध्ययनको अनुमानित समय र बृष्तित जानकारी मलाई व्याख्या गरिएको छ । मेरो सहभागिता स्वैच्छिक हो र म जुनसुकै बेला अध्ययनबाट कुनै कारण बिना मेरो स्वास्थ्य उपचार र कानुनी अधिकार प्रभावित नभई बाहिरिन सक्ने छु भन्ने बुझेको छु । अध्ययनको क्रममा मेरो र मेरो उपचारको बारेमा लिइएको जानकारी बि पि के आइ एच एसका जिम्मेवार ब्यक्तिहरुले हेर्न सक्नेछन भन्ने मैले बुझेको छु । मेरो रेकर्डहरुमा निजहरुको पहुँचको लागि अनुमति दिन्छु । म यस अध्ययनमा मेरो सहभागिताको, अध्ययनमा गरिने कार्य र स्वास्थ्य सेवाको लागि मन्जुरिनामा दिन्छु ।

अध्ययनको क्रममा मेरा तस्विर र चलचित्र लिन पनि म मन्जुर छु र मेरो परिचय नखुलाई यी तस्विर/चलचित्र को प्रयोग गरिनेछ भन्ने मलाई जानकारी छ । यी संगसंगै मेरो जानकारी मेडिकल रेकर्ड, किताबमा प्रकाशन गर्न, मेडिकल जर्नलमा प्रकाशन गर्न र स्वास्थ्य शिक्षाको लागि प्रयोग गर्न सकिने छ भन्ने मैले बुझेको छु । यो मन्जुरिनामा म कुनै औषधीको प्रभाव नपरी हस्ताक्षर गर्दछु ।

बिरामीको सही _____अनुसन्धानकर्ता/डाक्टरको सही_____

मिति

साक्षीको सही _____

निरक्षरको हकमा

यो मन्जुरीनामा बिरामीलाई सही तरिकाले मेरो अगाडी पढेर सुनाइएको छ । बिरामीलाई अध्ययनको प्रकृतिको बारेमा बुझ्न र प्रष्न सोध्न दिइएको छ । बिरामीले खुला रुपमा यो मन्जुरीनामा गरेको मैले पुष्टि गर्दछु ।

बिरामीको औंठा छाप

अनुसन्धानकर्ता/डाक्टरको सही_____

मिति

साक्षीको सही _____