Sub-Psoas Infiltration in the Emergency Department (SPIED). Ultrasound guided pericapsular nerve group block (PENG block) versus standard nerve blocks for the management of pain in patients with fractured neck of femur in the Lismore Base Hospital Emergency Department. A prospective observational study.

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Trial Registration and Ethics Application:
WHO Universal Trial Number (UTN) is U1111-1240-5858
Australia New Zealand Clinical Trials Registry request number: 378409
NNSW Health and Research Ethics Application: 2019/ETH12693

This document is a protocol for a prospective clinical trial involving patients at Lismore Base Hospital. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

Conflicts of interest:
Authors have no conflicts to declare.
At present, there is no funding to report.
We are reliant on in-kind support of the Lismore Base Hospital. Particularly the department of emergency medicine and the orthopaedic inpatient ward.

Background and Rationale

Hip fractures, or fractured neck of femur (#NOF), are a common presentation to LBH requiring opioid and regional analgesia. There were 203 presentations with #NOF to the Lismore Base Hospital in 2018. The case burden of #NOF in Australia is expected to increase [1,2].

This patient population is typically elderly and frail. It is at risk of adverse effects secondary to inadequate pain management such as delirium, prolonged admissions and poor functional outcomes [1, 4]. Appropriate pain management involves multimodal analgesia. This includes simple analgesia, opioid analgesia and regional anaesthesia (nerve blocks). There is high morbidity and mortality associated with opioid use in this vulnerable population [5-7]. A recent Cochrane review demonstrates that regional anaesthesia including femoral nerve block (FNB) and fascia iliaca compartment block (FICB) is indicated in the treatment of hip fractures. These regional nerve blocks provide reasonable analgesia, reduce opioid requirements and limit opioid-related harm [8].

Fractured neck of femur are predominantly intracapsular fractures. The greatest concentration of sensory nerve endings is found in the anterior hip capsule, which is, therefore, the target of nerve blockade [9-14]. Understanding of the innervation of the anterior hip capsule was updated in 2018 by Short et al and published Regional Anaesthesia and Pain Medicine [15]. This study confirmed that the existing understanding that anterior hip capsule is innervated by branches of the femoral nerve (FN), obturator nerve (ON) and accessory obturator nerve (AON) [9-15]. They found that the AON contributed in 54% of cases [15], which is greater than the previously demonstrated 8 -29% [16]. The AON was found to arise directly from the lumbar plexus in all cases [15]. FN innervation of the anterior hip capsule involves high branches (above the inguinal ligament) in 92% of cases and exclusively high branches in 54% of cases [15]. ON innervation of the anterior hip capsule involves high branches in 62% of cases and exclusively high branches in 31% of cases [15].

Short et al describes a quantifiable anatomical explanation for incomplete or failed anaesthesia from FNB or FICB in patients with #NOF. Several studies demonstrate that the FN block and FICB do not reliably block the obturator nerve or the lumbar plexus [16-22]. Distally, the high articular branches of the FN and AON are consistently located between the anterior inferior iliac spine and the iliopubic eminence [15]. The articular branches of the ON are located close to the inferomedial acetabulum. [15,23]. Subsequently the pericapsular nerve group block (PENGB) was designed to target the articular branches of the FN and AON by infiltrating the sub-psoas space at the level of the iliopubic eminence [23]. A case series of 5 consecutive patients with #NOF at Toronto Western Hospital was published in November 2018 and demonstrated the feasibility and efficacy of this block [23]. There is no published data describing the duration of analgesia provided by the PENG block.

The PENGB has subsequently been adopted by several practitioners at Lismore Base Hospital for the treatment of #NOF. We believe there is a study ongoing in peri-operative patients comparing PENGB to FICB in Toronto. We are not aware of any research into the utilisation of the PENGB in the emergency department setting. Searches of multiple study registries reveal no ongoing trials.

A retrospective study of patients that received regional anaesthesia for # NOF at LBH in the first 4 months of 2019 was performed. This data included 40 patients that received regional anaesthesia in ED, 6 of whom received a PENG block.

In this audit, patients' total opioid requirements from time of block to time of operation were recorded and converted to oral morphine equivalents using the ANZCA Faculty of Pain Opioid Calculator.

This audit found that patients receiving PENG blocks required fewer opioids pre operatively (mean = 22.67 mg) than did patients who did not receive a PENG block (FIB mean = 26.15 mg and FIB mean = 30.90 mg). Of note, patients receiving PENG blocks required fewer opioids in the 0-6 hours period immediately post block (mean = 3.00 mg) than did patients who did not receive a PENG block (FIB mean = 6.38 mg and FNB mean = 9.10). These results were not statistically significant (p = 0.5). The null hypothesis was retained. One adverse event relating to PENG blocks was documented in the records (failed block).

This audit was unable to demonstrate that PENG, FIB or FNB use less preoperative opioid consumption from time to block to time of operation. These results suggest a possible association between PENG block and reduced opioid consumption. However, these results are not statistically significant and are limited by sample size. This audit demonstrates that a larger study is warranted to assess the effectiveness of PENG blocks in hip fractures.

Pain score documentation was not sufficiently reliable to inform power calculations for this observational study.

Comparison of Nerve Blocks

FEMORAL NERVE BLOCK

ADVANTAGES	DISADVANTAGES
Relatively superficial infiltration.	Close proximity of infiltration to the large femoral vessels can result in inadvertent vascular puncture [24]. This can result in haematoma [34] and increases the risk of LAST (local anaesthetic systemic toxicity) if inadvertent intravascular injection occurs.
Sonographic anatomy familiar to the emergency physician	Requires needle placement directly adjacent to a large motor nerve, which may aggravate the consequences of neural damage [1]. Despite ultrasound guidance the neural tissue is not always well contrasting which increases the risk of intraneural injection.
Direct visualisation of the Femoral Artery (guiding structure for FNB) is easy to achieve in most patients.	In patients with peripheral vascular disease and stents or prostheses of the Femoral artery, the usual anatomy of the Femoral nerve is heavily distorted and standard FNB are impractical.
Usually leads to a motor block of the Quadriceps group of the femur, which prevents spontaneous movement of the injured leg and reduces pain	Unpredictable clinical efficacy. Anaesthesia of only some of the nerve branches of the femoral nerve that supply the anterior hip capsule. No blockade of AON [15]. No blockade of the obturator nerve.

FASCIA ILIACA COMPARTMENT BLOCK

ADVANTAGES	DISADVANTAGES
Well established in clinical practice	Relies on a significant spread of injectate to nerves distant from the point of injection.
Superficial site of infiltration is distant from major vessels, reducing the risk of LAST syndrome or haematoma.	Likely it's efficacy is reliant upon femoral nerve blockade, which may be more reliably achieved by a femoral nerve block.
Provides anaesthesia to the lateral femoral cutaneous nerve, which innervates the site of skin incision for surgical repair (in lateral approaches only)	Anaesthesia of only some of the nerve branches of the femoral nerve that supply the anterior hip capsule. No blockade of AON [15]. Unlikely to provide blockade of the obturator nerve.
Very low risk for direct neural damage due to remote injection points.	Prolonged onset due to distant injection point and slow spread.

PERICAPSULAR NERVE GROUP BLOCK

A preliminary audit at Lismore Base Hospital performed in May 2019, results show a trend toward reduced pain and morphine requirements n=6. The difference was not statistically significant.

ADVANTAGES	DISADVANTAGES
Utilises bony sonographic anatomy, therefore less variations in performance is expected.	Deeper site of infiltration requires higher technical skills.
Target site contains nerves branches that innervate the anterior hip capsule with greater frequency than FNB or FICB. Only technique that blocks the AON [15, 23]. Closer proximity to obturator nerve branches than other techniques [15]. Makes obturator blockade very likely..	Sonographic anatomy not familiar to emergency physicians. Requires re-training and experience in ultrasound guided needle techniques.
Targets small, distal purely sensory nerves [15, 23]. This should convey a faster onset and more complete blockade. Rapid onset is particularly valuable in the emergency department, where the patient is likely to be moved soon after the block is inserted.	Not well established clinical practice. Quality evidence not yet produced.
Infiltration site is distant from major vasculature, so LAST is less likely. It is distant to any motor nerves which eliminates the risk for major motor nerve damage.	

Aims and Objectives

1. To confirm that the PENGB is a safe and effective intervention for analgesia of patients presenting to the emergency department with hip fractures.

2. To perform a prospective observational study to assess the PENGB comparing analgesic efficacy vs current practice of FICB and FNB

Null hypothesis

The PENGB provides comparable analgesia to patients with fractured neck of femur compared to the FNB and FICB.

Study Design

A prospective observational study.

Current Practice:

All patients presenting to Lismore Base Hospital with fractured neck of femur (#NOF) are placed on the NOF pathway. The pathway suggests that patients on the NOF pathway should receive regional anaesthesia (nerve block) within 30 minutes of arriving at the Emergency Department. The nerve block performed will be determined by the treating clinician.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Adult patients (>18 years) presenting to Lismore Base Hospital Emergency Department with radiologically confirmed #NOF. The neck of femur fractures include:
    a. Sub-capital fracture
    b. Surgical neck fracture
    c. Intertrochanteric fracture
    d. Peritrochanteric fracture
2. The patient receives a nerve block for their fractured neck of femur in the Lismore Base Hospital Emergency Department
3. The nerve block may occur before or after the radiological confirmation of diagnosis

Exclusion Criteria:

1. Regional anaesthesia not provided in the Lismore Base Hospital Emergency Department
2. Allergy to amide local anaesthetics
3. Infection of the skin overlying at the overlying the site of potential nerve block
4. The patient has already received a nerve block for this fracture prior to arrival in at Lismore Base Hospital
5. Other reason at the discretion of clinician/s
6. Femoral shaft fracture

Block Standardisation

As this is an observational study, intervention is not dictated by the study, but is at the discretion of the treating physician. However, there have been efforts to standardise aspects of the care provided to improve the validity of this observational data.

In accordance with usual standards of practice:

- All nerve blocks are to be performed with ultrasound guidance. Needle tip and infiltration should be directly visualised with ultrasound.
- All nerve blocks are to be performed with continuous cardiac monitoring and intravenous access.

Nerve Block Kit:

To encourage standardisation of nerve blocks within hour department a nerve block kit is already in use. It contains:

- 80 mm x 21 gauge Pajunk SonoSpot needle (or alternative needle stocked by the department)
- 0.9% sodium chloride - 1 x 10mL vial
- 20 mL luer lock syringe
- 3 mL luer lock syringe
- Drawing up needle
- 25 gauge 38 mm or 23 gauge 35mm needle for local infiltration
- Dressing kit
- Chlorhexidine 2% in 70% ethanol skin prep solution (30 mL)
- Sterile ultrasound probe cover and gel

Standard Order Set:

A standard order set [Appendix 1] has been built into FirstNet (the electronic medical record). This order set includes blood tests, radiography, referrals and analgesia. This “NOF order set” has been approved by the #NOF pathway working group and is available to all medical officers in the Emergency Department. The investigators will facilitate Medical Officers to add this order set to their ‘favourite’ orders.

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Data To Be Collected

Regional Anaesthesia Provided

- ❑ Type of nerve block
- ❑ Content of nerve block
- ❑ Experience of practitioner

Patient Demographics

- ❑ # NOF Subtype
- ❑ Baseline characteristics: age, gender, comorbidities, social history, opioid use

Pain Scores

1. Visual Analogue Scale (VAS) [Appendix 6]
    a. 100mm scale. Measured in 1mm increments. Converted to a score from zero to ten.
    c. Measured at rest and on movement
2. Pain Assessment in Advanced Dementia (PAINAD) [Appendix 6]
    a. Paper or electronic calculator
    b. Scored zero to ten

Patients who are cognitively intact will have pain scores measured using the VAS, converted to score from zero to ten.

Patients who have a history of significant dementia or who clinically have significant cognitive impairment will have pain scored by a nurse or doctor using the pain assessment in advanced dementia (PAINAD) score, also zero to ten.

Subjective Observed Patient Comfort During Nursing Cares

- ❑ A binary measure of analgesia. Adequate or inadequate?

Opioid intake

- ❑ At baseline
- ❑ Pre-hospital
- ❑ In ED prior to regional analgesia
- ❑ After regional analgesia

Standard Documentation

Documentation that is recorded as a usual part of patient care

Nerve Block: Clinicians will be encouraged to document the placement of nerve block and it's content in a standardised fashion within the patient's medical record, as is usual practice.

Pain Scores: Pain scores are recorded in the electronic medical record alongside vital signs. This is usual practice of nursing staff in the emergency department and on surgical wards. The utilisation of the VAS pain score is however, a departure from usual practice. Other pain scores such as the numerical pain scale and faces pain scale are previously / currently used by nursing staff at Lismore Base Hospital.

Analgesia Intake: Will be recorded in the electronic medical record. This is usual practice.

Additional Documentation

Documentation that is additional to usual practice, for the purpose of this study

Additional Paper Documentation:

1. SPIED Study Emergency Department Data Form [Appendix 4]
    a. Emergency Department staff may choose to use this form in place of Medical Surveys should they prefer, or if there are logistical challenges encountered with Medical Surveys

2. Limb Observation Chart: [Appendix 6]
    a. It is standard practice on the surgical ward for nursing staff to complete limb observations every 1-2 hours on patients with #NOF and record these on a limb observation chart.
    b. This chart has been modified for the SPIED study to also record pain scores
    c. Also includes pain score calculators for the VAS and PAINAD

3. Subjective Observed Patient Comfort During Nursing Cares [Appendix 7]

Primary outcome = reduction of pain score

VAS pain scores will be recorded at rest and on movement. Movement is defined as attempted hip flexion to 15 degrees. PAINAD scores will be single measure based on nursing observation.

This score will be documented at the following times:

- Prior to placement of nerve block in the emergency department
- 15, 30, 60 minutes post placement of block
- With routine limb observations on the surgical inpatient ward, approximately hourly

Data will be collected for 12 hours post nerve block (or the next documented score after 12 hours) or until the patient is moved to the operating room, whichever is sooner.

Sample size and statistical power

The rationale for sample size calculations:

- A reduction in visual analogue pain score of 13 mm (1.3/10) was established as being clinically significant by Todd et al in 1996 [26].
- A clinically significant difference between two treatments that reduce pain scores by 1.3/10 has not been well defined
- Cooper et al used 1.5/10 difference in pain scores as a definition of clinically significant difference between blocks [27].
- Newman et al found a standard deviation in pain score reduction of 2.4 in patients receiving regional analgesia for #NOF in 2013 [28]. This figure was used by Cooper et al for their power calculation in 2018.
- Cooper et al found standard deviations of 2.2 and 2.4 respectively for the FNB and FICB [27].
- A retrospective study of patients that received regional anaesthesia for # NOF at LBH in the first 4 months of 2019 was performed by co-investigators of this study. This data included 40 patients that received regional anaesthesia in ED, 6 of whom received a PENG block. Pain score documentation was not sufficiently reliable to inform power calculations for this observational study.

Minimum Sample Size Calculation: Application of Student's t-Test.

Calculation assisted by using the Simple Sample Size Calculator (Android application). [Appendix 2]

- One-sided test to assess for non-inferiority
- Two sample
- Error 0.05
- Sample allocation ratio of 1:2
- Standard Deviation = 2.4
- $mu_0 = 4$, $mu_1 = 2.5$ (difference in pain score reduction of 1.5)
- Target (Actual) Power = 0.8000
- **Sample size = 74 (25+49)**

Duration of Data Collection

At our institution, we had 203 patients present with fractured neck of femur in 2018 and in the first 6 months of 2019 we have had 79. This is an average of 15.67 per month. Presuming this average continues and we achieve an enrolment rate of 80% and a PENG block delivered to one-third of these patients, we could expect to enrol sufficient patients in 6 months. To ensure significant power is achieved, we plan to enrol patients for a minimum of 6 and a maximum of 8 months.

Enrolment may be terminated early if we achieve a minimum enrolment of 125 patients and 41 PENG blocks. These numbers would allow for assessment of superiority (two-sided test) sensitive to a difference in pain score reduction of 1.3/10. [Appendix 3]

Secondary Outcomes

In an attempt to measure patient important outcomes, we will collect data on:

- Onset Time for analgesia (defined as the time until the first pain recorded pain score that is ≥ 1.5 / 10 less than the pre-block pain score.
- Subjective observed patient comfort during nursing cares
- Patient preference where crossover occurs.
- Rates of block failure
- Block duration of analgesia

Subjective observed patient comfort during nursing cares:

Nursing staff caring for patients will be asked to comment on the patient's pain during standard nursing cares that require movement. These may include:

- Transfer to or from a bed
- Transfer on and off a bedpan
- Change of bedding or pad
- Other

At the time of nursing care, nurses are asked to rate the patient's analgesia as adequate or inadequate

Patient Preference where crossover occurs

- Some patients will have a repeat nerve block in the preoperative phase
- Of this population, some will receive a nerve block that is different to the block they received in ED. Hence they will have received cross over treatment and can act as their own control to compare two blocks.
- Investigators will identify these patients and they will be asked which block they found to provide more comfort.
- Treatment in this phase of the patient's journey will be decided by the acute pain service or duty anaesthetist. The investigators will have no influence over which repeat block the patient receives.

Block failure

- Defined as maximum pain score improvement of less than 1.5 out of 10.

Duration of analgesia from nerve block

- End of block effect defined as an increase in pain score to ≤ 1.0 from pre-block pain score in a patient who had a reduction in pain score of > 1.5 at any time.

Opioid Requirement

- Opioid intake will be measured by analysis of the electronic medication chart from the insertion of block until 12 hours have passed, or the patient is checked in to the operating theatre, whichever occurs first.
- This information will be converted to milligrams of oral morphine using the Faculty of Pain Medicine Opioid Calculator

Adverse events

In an effort to detect the incidence of adverse events, the investigators will:

- Perform a keyword search of the “Continuous Doc” feature of the electronic record, after the patient is discharged from the hospital.
    - Keywords:
        - Delirium
        - Sedation
        - Constipation / Constipated
        - Aspiration
        - Naloxone

- Review the electronic medication chart for use of:
    - Naloxone
    - Antibiotics

Surgery Waiting Time:

Time to surgery will be defined as the time from Triage in the Emergency Department to the time of Check In at Operating Theatre for operative fixation.

Data collection on our cohort for the purposes of the primary outcome will cease at the time of check in to the operating theatre or at 12 hours after the insertion of nerve block, whichever is sooner.

Mean, median and longest wait times will be recorded. This information will inform future practice at our hospital.

Data Collection and Storage

Primary Data Recording Methods:

Were discussed above and are summarised here:

- ❏ Documentation in the electronic medical record record (PowerChart / FirstNet / SurgiNet) as is usual practice for all patients treated in the emergency department and those admitted to the hospital
- ❏ Documentation on the paper SPIED Limb Observation Chart [Appendix 6] which is usual practice for patients admitted to the inpatient orthopaedic and surgical ward with fractured neck of femur. The standard chart has been modified for the SPIED study to include pain scores and pain score calculators.
- ❏ Documentation on a paper form SPIED ED Data Form [Appendix 4] in the emergency department. This is additional to usual documentation and may be replaced by utilising Medical Surveys for data entry in the ED.
- ❏ Subjective Observed Patient Comfort During Nursing Score. May be completed in paper form [Appendix 7] or within Medical Surveys.

Data Governance

Data Storage:

The completed SPIED ED Data Form [Appendix 4] will be filed by clinicians in a folder within the Acute clinical area of the Emergency Department at Lismore Base Hospital. The SPIED ED Data Form will be the enrolment record.. Completed forms will be frequently collected by the investigators and stored securely with the ED Support Offices, which require swipe card access. This data will be stored for 5 years after the completion of data collection and then destroyed.

All other paper forms associated with the SPIED Study will form part of the patient's hospital record and will be treated accordingly.

Data Access:

- Investigators who are clinicians are Lismore Base Hospital have access to the patient's electronic medical records in the usual fashion as they would for day to day clinical work.
    - Investigators who access a patient's file for the purpose of data collection rather than clinical care, will create an electronic entry to document that they are accessing the file for the purposes of the SPIED study.
- In the event that any research funding is obtained, a research assistant may have access to Medical Surveys data and eMR as do the investigators.

Statistical Analysis

Primary Outcome:

Reduction in pain scores over the first 12 hours after nerve block. We will apply the following statistical tests:

- Students t-test to compare the reduction in pain score of patients who receive a PENGB compared to FNB and FICB
    - Subgroup analyses of the cognitively impaired and non-cognitively impaired population. These populations will have pain scored by the PAINAD and VAS respectively.
    - Subgroup analysis of FNB and FICB separately

Secondary Outcomes

- Onset of block. Defined as the time until the first pain score $\geq$ 1.5 less than the pre-block pain score.
    - T-test
- Subjective observed patient comfort during nursing cares
    - Chai Square test
- Patient Preference in the event of crossover
    - Chai Square test
- Rates of block failure. Defined as not achieving a reduction in pain score of $\geq$ 1.5 / 10
    - Chai square test
- Duration of analgesia. End of block effect defined as an increase in pain on movement score to $\leq$ 1.0 from pre-block pain score for that patient, in a patient who had a reduction in pain score on movement > 1.5 at any time.
    - T-test

Ethical Considerations

There are several ethical considerations in the design and implementation of this study. Throughout the study design process, the authors have consulted with key members of staff within our health service:

- ❏ *Director of Research: Alexandre Stephens*
- ❏ *Orthopaedic Clinical Nurse Specialist: Jane O'Brien*
- ❏ *Acute Pain Service Clinical Nurse Consultant: Sue Shaw*
- ❏ *Surgical Clinical Nurse Educator: Penni Anderson*
- ❏ *Geriatric Medicine CMO: Lin Yang*
- ❏ *Department of Anaesthesia Orthopaedic Special Interest Group: Andrew Peart*
- ❏ *Department of Anaesthesia research interest group: Neil Stokes, Kirryn Lowe*
- ❏ *Pain Specialist: Liam Ring*
- ❏ *LBH Nursing Infection Control: Vicki Denyer*
- ❏ *Rural Research Education Manager: Kerith Duncanson*
- ❏ *Department of Emergency Medicine: Consultant group*
- ❏ *Emergency Department Clinical Nurse Educator: Rebecca Austin*
- ❏ *Emergency Department Nurse Unit Managers: Suskia Travis, Ricky Brown*
- ❏ *Director of Emergency Medicine Training: Martin Duffy*
- ❏ *NOF pathway working group headed by Luke Schulz*

Research merit and integrity

Merits of this research:

- We believe the PENGB to have a superior anatomic basis for efficacy compared to other nerve blocks for neck of femur fractures. Early experience utilising the PENG block is promising.
- Early adoption of the PENGB which, to our knowledge, has not been studied outside of Toronto, nor within an Emergency Department would place our institution in a leading position in the emergency management of # NOF.
- The generation of evidence supporting this therapy's safety and efficacy would be expected to increase its uptake both within our institution and at other institutions. A positive study would be expected to encourage further investigation in the form of a randomised clinical trial
- Generation of evidence that the PENGB is inferior to the standard of care would appropriately discourage clinicians from changing their practice.

Integrity:

This project aims to improve understanding of the PENG block and its effects. We aim to publish results, either positive or negative, in a peer-reviewed journal approved by the Australasiaon College of Emergency Medicine and/or at appropriate scientific meetings.

Justice

All patients presenting to our facility with #NOF will be eligible for inclusion in this study. The patient experience of receiving the PENG block is very similar to that of receiving FNB or FICB and a lay-person would unlikely be able to tell the difference. There is no increased burden on patients enrolled nor on those not enrolled.

Beneficence

We believe that all patients present and future will benefit from the standardisation of practice and the establishment of preferred practice within our health service.

Risk

We do not anticipate that this study exposes participants to an increased risk. As outlined above we believe the PENG block conveys safety advantages compared to standard blocks the FNB and FICB. Most important is the physical separation of the site and the tissue plane of infiltration from major blood vessels. This reduces the risk of local anaesthetic systemic toxicity - which is the most serious adverse event associated with regional anaesthesia. Additionally, the nerves targeted and affected by the PENGB are small, sensory nerves. Any trauma or toxicity to nerves as a result of a PENGB would have no effect on motor nerves, which provide power to the thigh. Conversely, both the FICB and FNB effect larger motor nerves and any nerve trauma or toxicity can theoretically affect the muscle power in the thigh. We note that there is poor evidence supporting the argument that regional anaesthesia causes clinically significant trauma or toxicity to motor nerves.

Outcomes and Significance

The PENG block is a new therapy with a sound scientific basis and promising preliminary results both in the limited existing literature and our experience delivering this therapy at Lismore Base Hospital. If it is a superior regional analgesic then it follows that the therapy should be superiorly opioid-sparing. As we know, the study population is particularly at risk of complications from opioid analgesia [5-7]. Also, we know that pain (a result of ineffective analgesia) itself is a risk factor for agitation and delirium [reference] [29-33]. It follows that there would be an improvement in patient safety and patient-important outcomes from wider adoption of a superior intervention.

Confirmation of the efficacy and safety of the PENGB would be expected to lead to increased adoption of the technique in Emergency Departments around Australia. Should the PENGB prove to be inferior to the present standard of care then this would also be valuable information to guide practitioners to continue to use the ultrasound-guided femoral nerve block to treat hip fractures in the emergency department. Probably, this study will confirm that the PENGB is efficacious and safe without the statistical power to prove superiority to the existing standard of care. This will inform further research on the topic.

There recently is a significant research effort in Australia being directed to comparing the ultrasound-guided femoral nerve block to the ultrasound-guided FICB. There remains equipoise on this matter despite a randomised controlled double-blind trial of 100 patients published in 2018 [27]. There is also research in progress comparing the FICB as a single shot block versus a repeated or continuous infusion via a catheter inserted in the ED. If the PENGB is the superior intervention, then these impressive research efforts might be better redirected to investigating the PENGB.

Dissemination of results:

The principal investigator intends to disseminate the results of this study by:

- publication in a peer-reviewed journal approved by the college of emergency medicine
  and/or
- presenting results at the Australasian College of Emergency Medicine Annual Scientific meeting or Winter Symposium.

It is likely that co-investigators will disseminate the results of this study by presenting at relevant scientific meetings for Anaesthesia.

Appendices:

1. FirstNet NOF order set
2. Power Calculation Minimum
3. Power Calculation Maximum
4. SPIED ED Data Form
5. SPIED Enrolment Checklist
6. SPIED Limb Observation Chart
7. Subjective Observed Comfort During Nursing Care
8. nil
9. Inclusion-Exclusion Criteria
10. nil
11. SPIED Folder Contents
12. Patient Information and Consent

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