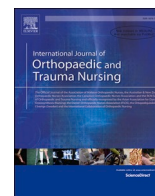


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Nurse-led ultrasound-guided femoral nerve block: A randomised controlled trial of two different patient flow systems in an emergency department

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ABSTRACT

Introduction: Elderly with hip fractures present complex challenges. Effective pain management is crucial for recovery and quality of life. However, pain control can be difficult and requires customized care.**Methods:** We conducted an unblinded, randomised controlled trial investigating the effects of ultrasound-guided femoral nerve block in patients with hip fracture performed by specially trained nurses (Group Nurse) compared to anaesthesiologists (Group Anaesthesiologist). The hypothesis was that a single shot ultrasound-guided femoral nerve block would result in a total summarized lower dynamic numeric rating scale score for pain intensity during the first 120 min after admission for patients in Group Nurse compared to Group Anaesthesiologist measured in five timepoints. The primary outcome was measured by a cumulative numeric rating scale score for dynamic pain (with flexion of the hip until maximum 30° from bed surface) during the first 120 min after admission to the emergency department.**Results:** From February 2020 to June 2021, 263 patients were screened, of which 42 (16.0%) consented and were randomly allocated; 21 in each arm. The primary outcome was not different between groups ($p = 0.24$), and displayed no substantial superiority of specially trained nurses over anaesthesiologist. No complications or adverse effects were observed in either group. The use of systemic analgesics and the development of delirium was similar between the two groups. In the Nurse Group, patients were administered their ultrasound-guided femoral nerve block earlier.**Conclusion:** Our study did not demonstrate a statistically significant beneficial effect of specially trained nurses over anaesthesiologist on cumulative pain in performing ultrasound-guided femoral nerve blocks, while no side-effects/complications or adverse effects were observed in either group.**Clinicaltrial:** The trial was registered on October 31, 2019 at [Clinicaltrials.gov](https://clinicaltrials.gov) (NCT04145752).

1. Introduction

Hip fractures are common in the aging population and are related to increased mortality and a high cost to society (Abrahamsen et al., 2009; Papadimitriou et al., 2017; Pollmann et al., 2019). Human aspects like pain, physical dysfunction and high risk of delirium are also important factors. Pain control can be difficult and requires customized care as elderly patients may experience adverse events by opioid administration (Christos et al., 2010) including dizziness, sedation, nausea, vomiting, constipation, urinary retention, and respiratory depression (Benyamin

et al., 2008). Consequently, undertreatment of pain is common (Morrison et al., 2016; Morrison et al., 2003; Unneby et al., 2022). Paradoxically, inadequate analgesia appears to be a risk factor for delirium in frail patients and research suggests that totally avoiding opioids or using very low doses may increase this risk (Morrison et al., 2003).

2. Background

Femoral nerve block is a valuable alternative to systemic analgesic for hip fracture patients as it provides analgesia to the fractured area,

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thereby reducing the need for systemic opioids (Guay et al., 2017; Munirama and McLeod, 2013). Moreover, using ultrasound to perform femoral nerve block increases the success rate of the procedure by providing a direct visualization of the anatomic structures and makes it possible to track the local anaesthetic spreading in real time (Marhofer et al., 1997).

Williams et al. (2003) found that nurse-led fracture clinics have favourable results such as shorter waiting time, higher patient satisfaction and better patient follow-up. An ultrasound-guided femoral nerve block (UGFNB) might be another task that could be transferred vertically, such as from a physician to a registered nurse (RN). Few studies have investigated peripheral nerve blocks performed by professionals other than physicians. Some exceptions are studies where fascia iliaca compartment blocks have been performed by non-physicians, which have shown promising results (Dochez et al., 2014; Gawthorne et al., 2021; McRae et al., 2015; Randall et al., 2008). There have been few recent studies on nurse-led femoral nerve block with or without ultrasound in hip fracture patients. Layzell (2010) described a nurse-training program in the technique, but there are, to our knowledge, no randomised controlled trials (RCT) comparing nurse-led UGFNB vs. where the block is performed by anaesthesiologists.

The objective of this study was to compare two different intra-hospital patient flow systems where UGFNB in patients with hip fracture were performed in the emergency department (ED) by specially trained registered nurses (Group Nurse) vs. where UGFNB was performed by an anaesthesiologist on call (Group Anaesthesiologist) where both time spending, effectiveness and adverse events are interesting factors.

3. Materials and methods

This study is a randomised, controlled, parallel group, unblinded, single-centre, superiority trial carried out in a 20-bed ED at a regional hospital in Norway. RNs regularly meet patients at an earlier stage in the intra-hospital patient flow than anaesthesiologists. Furthermore, anaesthesiologists on call are often struggling with contemporary conflicts, which could lead to down-prioritization of certain tasks. Therefore, to incorporate both the response and effect time, our hypothesis was that a single shot UGFNB would result in a total summarized lower dynamic numeric rating scale (NRS-D) score (Hawker et al., 2011) for pain intensity during the first 120 min after admission to the ED for patients in Group Nurse compared to Group Anaesthesiologist measured in five timepoints. Accordingly, this study was designed as a superiority trial.

For this study center, a typical intra-hospital care pathway for a patient when paramedics suspect a hip fracture is immediate transportation to the radiology department for an X-ray. After being diagnosed with a hip fracture by the radiologist, the patient is transferred to the ED for further clinical examination, monitoring, initiation of treatment and preoperative preparations. All patients are generally offered an UGFNB, performed by the anaesthesiologist on call. However, clinical conflicts and other organizational circumstances often result in delayed or none UGFNB for some patients.

3.1. Recruitment

The nurses were selected based on the following qualifications: experience as senior staff, showed eagerness to learn advanced procedures, held a certification in advanced cardiopulmonary resuscitation, and were contracted to work at least a 75% position. Five RNs went through a one-day training course and subsequently performed a minimum of three UGFNBs on admitted patients supervised bedside by an anaesthesiologist. The RNs did not have any ultrasound background or had not previously practiced the technique of placing needles in plane for ultrasound-guided procedures. The one-day course consisted of theoretical and practical training: 1) infection prevention; 2) anatomy of

the inguinal area; 3) practical use of ultrasound; 4) drug information and corrective treatment to be taken in the event of complications; 5) consideration of indications and contraindications of a nerve block; 6) practical exam. Finally, after completing and passing exam, RNs had to perform a minimum of three UGFNB under the supervision of trainee anaesthesiologists. Before the inclusion of patients started, the RNs went through meticulous training in monitoring, assessing pain using NRS and measuring the angle of the hip during elevation of the fractured limb. The hip angle was measured by providing the RNs with a bedside illustration of the different angles. The trainee anaesthesiologists (n = 9), who had followed the regular training program in the anaesthesia department, had a mean duration of experience of 25.5 months with the UGFNB procedure. No special selection of these anaesthesiologists was made other than they all were residents on-call.

For administrative reasons, all patients were enrolled on weekdays between 7:30 a.m. and 10:00 p.m. Consecutive patients between February 2020 and June 2021 admitted to the hospital with confirmed hip fracture were screened. Enrolment of patients was paused from 12 March until April 27, 2020 due to reorganization of the ED during the outbreak of the Covid-19 pandemic. Recruitment of patients was initiated by the RNs on call. The RNs or principal investigator conducted an interview in person to confirm the participant's eligibility, obtain their informed written consent, and collected baseline data prior to randomisation. The inclusion criteria were: 1) 18 years or older; 2) American Society of Anesthesiologists (ASA) classification (American Society of Anesthesiologists, 2014) I-IV; 3) a hip fracture confirmed by X-ray. Exclusion criteria were: 1) allergy to ropivacaine; 2) infection at the injection site; 3) The use of anticoagulants was permitted, with the exception of acetylsalicylic acid and dipyridamole. However, a patient could be included if the international normalized ratio, measured no more than 2 h prior to enrolment, was less than 1.5.4) multi-traumatized patients; 5) patients suffering from dementia or confirmed cognitive failure; 5) head injuries with reduced cognition (Glasgow Coma Scale below 12); 6) patients on dialysis; 7) patients who had received more than 10 mg of morphine pre-hospital.

Written informed consent was obtained from all participating subjects, and all anaesthesiologists and nurses. Randomisation was accomplished by an independent internet-based randomisation program performed by a person not participating in the clinical setting (GraphPad Software, 2018). The randomisation codes were placed in sealed sequentially numbered envelopes at a specified location in the ED. The patients were randomly allocated 1:1 to the two arms. After giving informed consent, each enrolled patient received an envelope consecutively by number. For practical reasons, neither study participants nor the health personnel performing the UGFNB were blinded.

3.2. The procedure

Group Nurse patients received a single-shot UGFNB from trained nurses in the ED after hip fracture diagnosis (X-ray) was diagnosed, while patients in Group Anaesthesiologist was administered a single-shot UGFNB according to standard of care, meaning a single-shot UGFNB performed by trainee anaesthesiologists. If the patient was randomised to Group Nurse, the time measurements started (0 min) at the time when the sealed envelope was opened and read. The RN started preparing for the nerve block and performed the block without delays. If the patient was randomised to Group Anaesthesiologist, the RN called the anaesthesiologist without any delay. The time measurements started (0 min) when the conversation with the anaesthesiologist ended. If the anaesthesiologist did not answer at the first call, the time measurement (0 min) started 1 min after. Thereafter, a new call was made. If still no answer, the RN repeated the call every 10th minute.

An UGFNB was performed under sterile conditions in supine position using an ultrasound machine (VENUE™, GE Healthcare, WI 53226, USA) with a high frequency (10–15 MHz) linear probe. After confirmation of an acceptable ultrasound visualization of the femoral nerve,

the needle tip (Pajunk™ single shot cannula, GM medical HS, Geislingen, Germany) was guided close to the nerve. An injection containing ropivacaine (Ropivacain™, Fresenius Kabi, Oslo, Norway) 7.5 mg/ml, 20 ml was administered to encircle the nerve at the level of the inguinal ligament. All patients received IV access and were monitored for 120 min with blood pressure, heart rhythm, and peripheral oxygen saturation. Data was recorded in the form of handwritten case report forms filled out by either a RN or an investigator.

3.3. Measurements

The primary outcome was assessed by evaluation of NRS-D score during passive movement (maximum 30-degrees flexion in the fractured hip) during the first 120 min after admission from radiology department to the ED (time of inclusion), measured by five time points at 0, 30, 60, 90 and 120 min.

Secondary outcome measures were the NRS-R (assessed before NRS-D measurements) and single NRS-D scores during the first 120 min and the time spending performing the procedure. Furthermore, the maximum angle reached for every passive flexion of the hip was noted. The flexion was stopped before reaching 30° if the patient protested further elevation. A double control of the NRS-R and NRS-D was obtained from RNs in ED with no association with the study. Development of possible side effects and complications were monitored throughout the hospital stay at a daily basis. Injection sites were inspected regarding development of hematomas and infections. Signs of nerve damage was assessed at discharge by checking for joint movements in the lower extremity and if there were any paraesthesia. Adverse circulatory symptoms were assessed continuously during the first 120 min after injection of the local anaesthetics. Lipid emulsion and acute care equipment were immediately available at all times during and several hours after the procedure.

Opioid and paracetamol requirements were extracted from electronic medical records. Additionally, to assess the pre-admission mental state of the patients, the Informant Questionnaire on Cognitive Decline in the Elderly Short Form (IQCODE-SF) scores were registered (Jorm, 2004) at admission from the closest relatives. Additionally, to screen for delirium and cognitive failure we collected the 4 'A's Test (4AT) scores at admission and at 1st postoperative day (Lisk et al., 2020).

3.4. Ethical considerations

The regional ethics committee considered the study to be health services research (2019/343 REK - South-East). The Norwegian Centre for Research Data (ID 533039/2019) and local hospital data protection officer (ID 06011/2019) approved the study.

3.5. Sample size

An apriori sample size calculation was performed. Based on a study where non-anaesthesiologists performed an UGNFB, the median (IQR) pain intensity score at rest (NRS-R) at 120 min after the block was reported (Ketelaars et al., 2018). By corresponding with the authors, we were given access to the calculated mean and SD (1.14 and 1.77, respectively) (R. Ketelaars, email, September 7, 2018). The primary outcome was cumulative dynamic patient-reported pain, thus we considered a mean difference of at least two points between the groups as clinically relevant. Assuming a significance level of 5% and a power of 90%, we needed 18 patients in each group to detect this difference (Farrar et al., 2000). To account for dropouts, we strove to include 25 patients in each group.

3.6. Data analysis

Descriptive statistics are presented as mean with standard deviation (SD) and median with interquartile range (IQR) and range for

continuous variables and as frequencies with proportions for categorical variables. Comparison of groups was performed using independent sample *t*-test and presented as between group mean differences with 95% confidence interval (CI), and Wilcoxon rank-sum test with exact *p*-values. Graphically, data are presented as cumulative and marginal means by group. All tests were two-sided, with a 5% significance level. Statistical analyses were performed in Stata version 17 (StataCorp LLC, Texas, USA) and EpiData version 4.2 (EpiData Association, Odense, Denmark).

4. Results

A total of 263 patients were assessed for eligibility. Patient were enrolled in this study from February 19, 2020 until June 23, 2021. A total of 42 patients participated in the study (Fig. 1).

Due to planned administrative reorganizations involving the Group Nurse and relocation of the ED, the study was terminated early, on June 23, 2021. Nevertheless, the numbers of patients included in each group were within the calculated limits from the sample size calculation. All subjects were randomised to either Group Anaesthesiologist (*n* = 21) or Group Nurse (*n* = 21). One patient in Group Anaesthesiologist had missing NRS data from 60 min onwards. All patients were followed to discharge. Characteristics of the study population were balanced between the two groups with respect to age, gender, body mass index, previous diagnosis, and fracture types (Table 1). An IQCODE-SF assessment showed that 14 of 36 of the patients had pre-fracture cognitive impairment.

The mean (SD) [95%CI] time between inclusion and the initiation of the block was 18.9 [0.45–37.4] minutes longer in Group Anaesthesiologist (73.5 (31.5) [58.7–88.2]) compared to Group Nurse (54.5 (27.0) [42.3–66.8], *p* = 0.045). However, Group Nurse (7.9 (5.0) [5.6–10.1]) spent a mean of 2.9 [0.2–5.5] more minutes than Group Anaesthesiologist (5.0 (3.3) [3.5–6.5], *p* = 0.04) on the procedure itself. All patients except one completed the primary endpoint. No significant difference in NRS-D score at time of inclusion was found between the two groups (Table 2). Compared to patients in the Group Anaesthesiologist, the cumulative NRS-D in the Group Nurse was 4.3 [–2.97–11.62] (*p* = 0.24) lower during the first 120 min after admission to ED.

The NRS-D score was significantly higher than the NRS-R at the time of inclusion, and the mean NRS-D at 120 min indicates moderate pain level in both groups. We observed no significant differences in NRS-D and NRS-R scores at 120 min after admission to ED between the two groups (Table 2), nor at any of the other time points (Fig. 2) A, B, C). At 1st postoperative day the mean (SD) NRS-D score was 4.2 (2.5) in Group Anaesthesiologist (*n* = 17) vs. 4.7 (2.7) in Group Nurse (*n* = 17) (*p* = 0.60). The median (IQR) [range] maximal angle of the fractured hip before the nerve block was performed was 20 (10–30) [10–30] degrees in the Group Anaesthesiologist vs. 20 (10–30) [0–30] in the Group Nurse (*p* = 0.98). Repeated measurements 120 min after the nerve block showed a non-significant increase in the maximal angle, 30 (20–30) [10–30] degrees in the Group Anaesthesiologist vs. 30 (30–30) [10–30] in the Group Nurse (*p* = 0.24). New measurements on the 1st postoperative day showed a maximal angle of 30 (30–30) [20–30] degrees in the Group Anaesthesiologist vs. 30 (15–30) [0–30] in the Group Nurse (*p* = 0.05). Median (IQR) [range] length of stay at the hospital was 3 (3–4) [2–7] in the Group Anaesthesiologist vs. 4 (3–4) [2–10] in the Group Nurse (*p* = 0.50).

The median (IQR) [range] 4AT scores at admission were 0 (0–1) [0–4] in Group Anaesthesiologist and 0 (0–0) [0–5] in the Group Nurse (*p* = 0.14). At the 1st postoperative day the 4AT score were 1 (0–6) [0–12] in Group Anaesthesiologist (*n* = 21) and 0.5 (0–5.5) [0–12] in the Group Nurse (*n* = 20) (*p* = 0.77). In the total population (*n* = 41) changes from admission to 1st postoperative day in the 4AT score were 0 (0–4) [–1–12].

The systemic analgesics administered prehospital and in the ED are given in Table 1. The total amount of opiates given during the entire

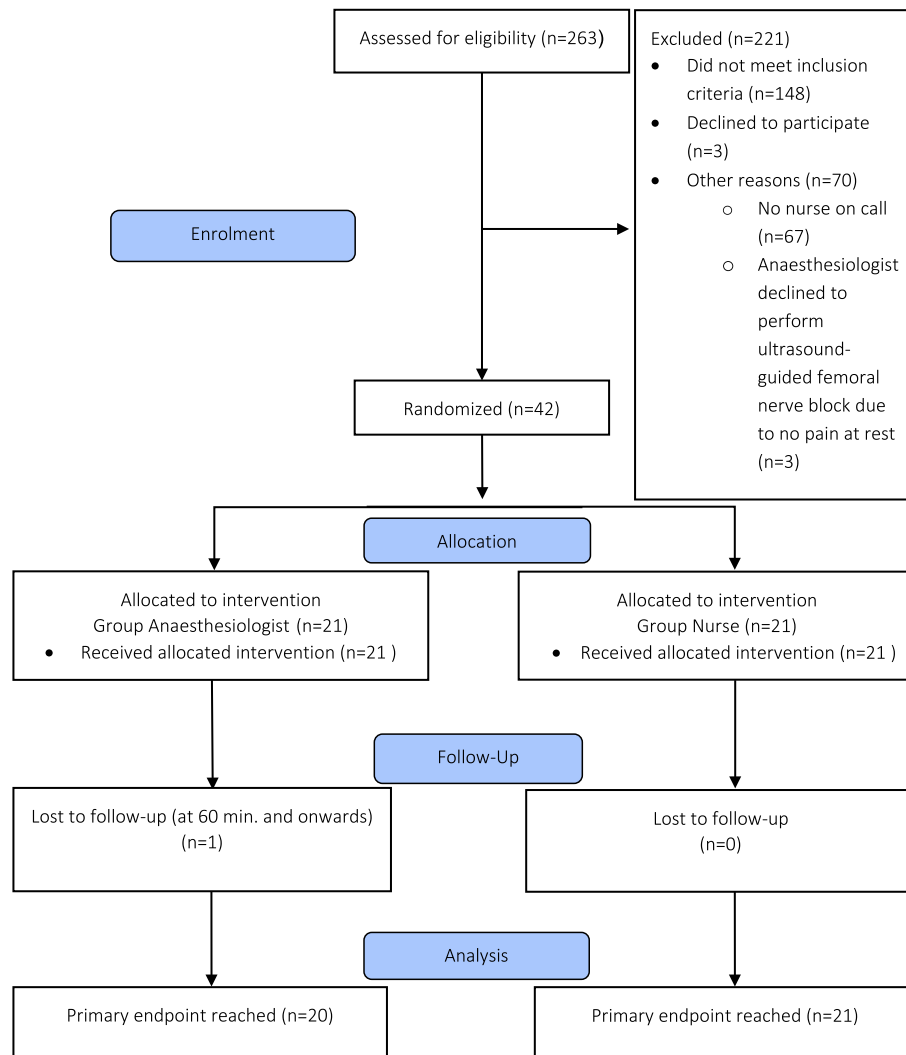


Fig. 1. CONSORT diagram. Flow diagram of patient distribution showing number of patients enrolled, screened, randomized, treated and reaching primary endpoint.

course of the current disease (prehospital to discharge from the hospital) was median (IQR) [range] 90.0 (60.0–185.5) [22.5–279.5] mg morphine equivalents in Group Anaesthesiologist vs 94.5 (75.0–181.5) [7.5–1020.0] mg in Group Nurse ($p = 0.97$). No difference was found between the two groups in terms of adverse events during the hospital stay.

5. Discussion

In this superiority study we did not find any difference in the primary endpoint by measuring cumulative NRS-D at 120 min after admission to ED, where a single shot UGFNB in patients with hip fracture were performed either by specially trained nurses vs. where UGFNB was performed by an anaesthesiologist. No side effects in either group were registered during the total length of stay at the hospital. Although the hypothesis was not confirmed, we observed that patients in Group Nurse received an UGFNB on average 16 min earlier compared to patients in Group Anaesthesiologist. The design of the study was intended to put none of the two health groups at an advantage and make an equipoise at the start of the inclusion. In the Group Anaesthesiologist we strived to mimic current patient flow system where an anaesthesiologist is performing an UGFNB. Nevertheless, the anaesthesiologists received a repetitive reminding call every 10th minute which is more frequent than in ordinary practice. In addition, the study was unblinded and well known by all anaesthesiologists during the inclusion period. We

speculate that these factors may have led to a faster and more responsive follow-up in Group Anaesthesiologist than the investigators' subjective experience in the hospital's current patient flow practice. If this is the case, any potential difference between the groups could be erased. In Group Nurse the procedures lasted approximately 3 min longer vs. Group Anaesthesiologist. This is not unexpected since the RNs received a limited amount of training before the study was initiated compared to Group Anaesthesiologist where the blocks were performed mainly by experienced trainee anaesthesiologists.

Two studies have previously been performed to evaluate similar procedures being performed by health professionals other than anaesthesiologists (Gawthorne et al., 2021; Ketelaars et al., 2018). This RCT supports studies that have explored task shifting from physicians to other health care workers. However, there are limited studies available on task shifting UGFNB in an ED setting, and no RCT studies. A recent prospective cohort study of 322 patients who received an ultrasound-guided fascia iliaca block administered by either a nurse or a physician found that emergency nurses provided safe and effective blocks (Gawthorne et al., 2021). Similar to our study, there was no significant difference between the two groups for mean pain score 1 h after the performed block. Furthermore, three studies involving specially trained nurses and paramedics performing fascia iliaca compartment blocks show convincing pain relief without registering major complications (Dochez et al., 2014; McRae et al., 2015; Randall et al., 2008). These studies and the current study indicate that with

Table 1

Characteristics of the study population in Group Anaesthesiologist and Group Nurse ($N = 42$). Values are in mean (SD) [range] or frequency (%).

	Group Anaesthesiologist n = 21	Group Nurse n = 21
Age		
Years	80.0 (9.1) [56–93]	80.0 (9.9) [57–95]
Gender		
Men	7 (33)	5 (25)
Women	14 (67)	16 (75)
Body mass index kg/m ²	24.3 (5.1) [16.4–36.3]	24.8 (4.1) [16.9–31.2]
ASA classification		
1	2 (10)	0 (0)
2	11 (52)	7 (33)
3	7 (33)	14 (67)
4	1 (5)	0 (0)
NRS-D at time of inclusion ^a	7.0 (2.9) [0–10]	6.2 (3.2) [0–10]
Type of fracture		
Femoral neck	10 (48)	10 (48)
Petrochanteric	9 (43)	10 (48)
Subtrochanteric	2 (10)	1 (5)
Previous medical conditions		
Yes/No	19/2	17/4
Hypertension	13 (62)	10 (48)
Diabetes	1 (5)	7 (33)
Stroke	4 (19)	2 (10)
Chronic pain	5 (24)	5 (24)
Osteoporosis	4 (19)	0 (0)
Coronary disease	8 (38)	2 (10)
Renal failure	0 (0)	2 (10)
COPD/asthma	1 (5)	5 (24)
Concomitant medication		
Opiates	3 (14)	2 (10)
Acetylsalicylic	7 (33)	8 (38)
Warfarin	1 (5)	0 (0)
Dipyridamole	0 (0)	0 (0)
Glucocorticoids	1 (5)	2 (10)
Prehospital analgesic		
Acetaminophen	15 (74)	17 (81)
Morphine	9 (43)	9 (43)
Morphine IV. (mg)	5.4 (2.6) [3.4–7.5]	6.0 (3.0) [3.7–8.4]
ED-analgesic^b		
Acetaminophen	0 (0)	4 (19)
Morphine ^c	2 (10)	4 (19)

n: Number of participants.

Abbreviations: ASA: American Society of Anesthesiologists, ED: emergency department, IV.: intravenous, NRS-D Dynamic Numeric Rating Scale, SD: standard deviation, UGFNB: ultrasound guided femoral nerve block.

^a Time point 0.

^b First 120 min in ED.

^c The Morphine IV dose was 3 mg and 4 mg for the two patients in the Group Anaesthesiologist and 1.5 mg, 2.5 mg, 3 mg, and 5 mg for the patient in the Group Nurse.

time-limited training programs, non-physician healthcare workers are able to master these types of nerve block, providing effective analgesia without jeopardizing patients. In addition, the fact that patients needed almost no IV morphine during the 2 h post-procedure indicate the effectiveness of the block.

Nonetheless, it's important to note the significant disparities in nurse accessibility worldwide. This research was conducted in Northern Europe, an area with relatively high nurse availability compared to regions like South-East Asia and Africa (World Health Organization, 2016). In nations where there is a shortage of nurses, alternative healthcare personnel might be more appropriate for performing a UGFNB, such as those in pre-hospital services (Dochez et al., 2014; McRae et al.). Therefore, decisions about task delegation and the personnel to whom these tasks are assigned may be influenced by local challenges, resources, and needs. Another key point is that hip fracture patients often report low pain intensity at rest, but the pain is increasing

Table 2

Pain scores in Group Anaesthesiologist and Group Nurse. Values are in mean [95% CI].

	Group Anaesthesiologist n = 20 ^a	Group Nurse n = 21	Difference and p-value ^b
Primary endpoint during 120 min			
Cumulative	27.9 [22.6–33.1]	23.5 [18.1–28.9]	4.3 [-3.0–11.6] p = 0.24
NRS-D			
Secondary endpoints at 120 min after admission to ED			
NRS-D	4.3 [2.9–5.6]	3.7 [2.4–5.0]	0.53 [-1.3–2.3] p = 0.55
NRS-R	1.6 [0.50–2.7]	1.9 [0.89–2.9]	-0.30 [-1.8–1.1] p = 0.67

^bP-value from independent sample t-test.

Abbreviations: CI: confidence interval, ED: emergency department, NRS-D: dynamic numeric rating scale, NRS-R: resting numeric rating scale.

^a One missing follow-up in Group Anaesthesiologist.

significantly with movements. Preoperative examinations, diagnostic procedures, and daily care lead to inevitable manoeuvres of the fractured limb, causing an exaggerated sensation of pain. Consequently, to determine whether a patient has reduced mobility due to pain, it is of paramount importance to measure dynamic pain intensity of the fractured extremity (Wennberg et al., 2018). Other studies have also used dynamic NRS scoring for pain assessment. In an RCT, Foss et al. (2007) showed a significantly reduced pain intensity when comparing fascia iliaca compartment block performed by junior anaesthesiologists to morphine. In another RCT including 100 patients with a proximal femoral fracture, patients were randomised to either a catheter-mediated femoral nerve block or systemic analgesia. Pain intensities were recorded during passive flexion of the hip to 30° and showed significant pain relief in patients who received a nerve block (Gille et al., 2006). The results in our study clearly show that although the NRS scores at rest do not change remarkably in the first 120 min, one noticeably observed less pain measured by both NRS-D and an increase in the maximal achieved angle as an expression of a good effect of the nerve block, suggesting that the patient will better tolerate painful but necessary health care activities. Of notice, in the Group Anaesthesiologist the anaesthesiologist, with the argument that there was no pain at rest, excluded three patients from the study. We will argue that solely asking the patient about pain intensity at rest will provide unsatisfactory and incomplete information about the pain condition and we advocate to incorporate both dynamic NRS score and maximal achieved angle during flexion of the hip for a comprehensive assessment of pain.

A fairly large proportion of patients ($n = 263$) were assessed for eligibility in this study, but only 16% were included. Seventy patients were excluded because none of the five RNs were on call at the time of the admission. To educate all ED nurses in general at the hospital in performing an UGFNB will result in more available nurses with this competence at any time of the day. The number of excluded patients due to just five available nurses is therefore not surprising. Many patients ($n = 148$) were also excluded due to not fulfilling the inclusion- and exclusion criteria. A substantial number of patients (19 %) used direct-acting oral anticoagulants or had an International Normalized Ratio (INR) above 1.5. Consequently, they were all excluded for security reasons. Additionally, after initial discussions with the regional ethics committee, we were encouraged and advised not to include patients with cognitive impairment and dementia which accounted for 20% of the screened patients. Still, the study population included must be seen as a frail group of patients with impaired mental capacity. An IQCODE-SF assessment showed that 39% of the patients had pre-fracture cognitive impairment defined as IQCODE-SF ≥ 3.44 (Jorm, 2004). Combined with the 4AT scores these results show that this frail group of patients are in great risk of undetected cognitive failure.

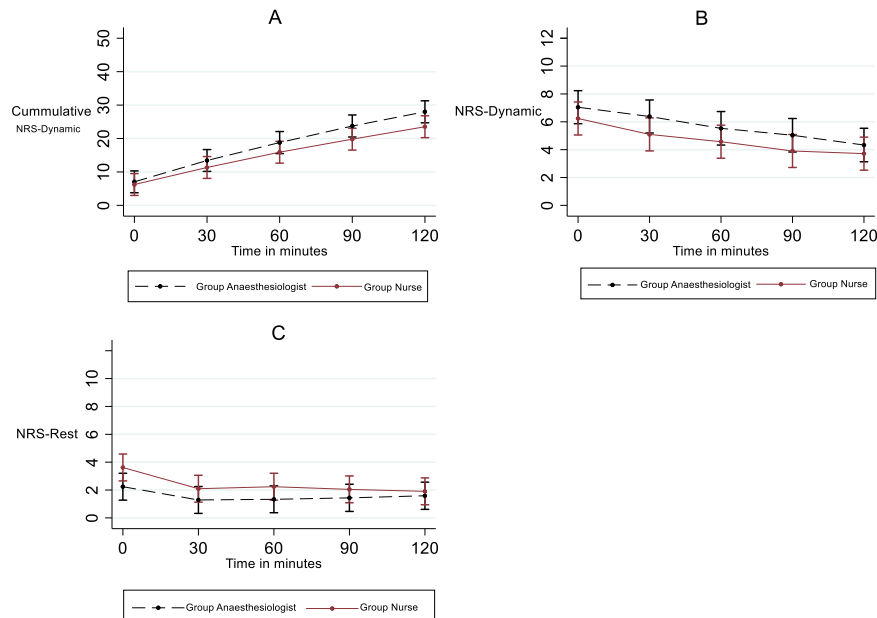


Fig. 2. Cumulative NRS-D score (A), NRS-D score (B), NRS-Rest score (C) after ultrasound-guided femoral nerve block in Group Anaesthesiologist vs. Group Nurse with 95% CI.

5.1. Strength and limitations

A strength of this study is the efforts made to train staff to collect data according to the protocol and to avoid sources of bias on primary outcome by having a RN colleague to double check and sign on measurements on NRS-D and NRS-R. However, there are several limitations to this study. First, the study was conducted at a single site. However, this study demonstrates reproducibility with results comparable to prior RCTs on task shifting and nerve blocks (Dochez et al., 2014; Gawthorne et al., 2021; McRae et al., 2015; Randall et al., 2008). Second, since cognitively impaired subjects and patients using anticoagulants were not available for inclusion, the study population may not represent the total population admitted with hip fracture. Third, the current study was unblinded to patients, investigators, and healthcare professionals, creating a risk of bias. Fourth, there was a limited time interval for analgesia assessment in our primary outcome. Since pain was only recorded up to 120 min, pain measurements were not fully assessed for the whole duration of the block. However, the use of morphine equivalents during the total admission, NRS scores, and the maximal angle reached at 1st postoperative day revealed no significant difference between the groups.

Another remark, which may be considered a strength, was the similarity of the technique, the type and amount of local anaesthetic, and the ultrasound machines used in both groups. However, this means that the results apply only to the specific local anaesthetic type, concentration and volume administered. Even though the study did not include the intended number of patients, the sample size was sufficient and still within what we calculated in the power analysis. Finally, the selection of the nurses is subject to a selection bias. Those selected were experienced and highly motivated nurses, while the anaesthesiologist were ordinary trainees without any other selection criteria. Hence, to generalise these results to all employed nurses in an ED is not necessarily appropriate. Accordingly, this study may be considered a pilot study for a larger randomized study where all nurses in an ED are trained in an UGFNB procedure.

6. Conclusion

To our knowledge, this is the first RCT to date that directly compares the combination of effectiveness, response time and time spending of UGFNBs performed by nurses and physicians. We are unable to assert the superiority of nurses in this clinical context. These results suggest that the specially trained nurses did not demonstrate a noteworthy advantage in performing UGFNBs when compared to anaesthesiologist. However, the results of this study indicate that it is feasible for nurses to perform UGFNBs after a short and simple training program and coaching. Our findings indicate that there are no more adverse events in UGFNBs performed by RNs than in those performed by anaesthesiologists, although this was not what the current study was designed to investigate. Also, there may be some benefits of using dynamic NRS score and measure maximal angle reached during passive leg raise of the fractured extremity. Furthermore, relieving doctors of one of their many tasks may distribute workloads better in a busy ED and the utilization of nurses can lead to the UGFNB being cost effective due to less expenditure on wages and develop the nurses' role through increased responsibility and knowledge linked to pain management.

Overall, this may limit stressors for a frail patient population, thereby reducing the incidence of delirium and opioid adverse effects (Clegg et al., 2013). This study was not powered to investigate this issue. Further research is needed to examine the impact of nurse-led UGFNBs with respect to complications, adverse events, and the development of delirium as primary outcomes.

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Ethical Statement

Hereby, I Elin Saga consciously assure that for the manuscript *Nurse-led ultrasound-guided femoral nerve block: a randomised controlled trial of two different patient flow systems in an emergency department*, the following is fulfilled:

- 1) This material is the authors' own original work, which has not been previously published elsewhere.
- 2) The paper is not currently being considered for publication elsewhere.
- 3) The paper reflects the authors' own research and analysis in a truthful and complete manner.
- 4) The paper properly credits the meaningful contributions of co-authors and co-researchers.
- 5) The results are appropriately placed in the context of prior and existing research.
- 6) All sources used are properly disclosed (correct citation).
- 7) All authors have been personally and actively involved in substantial work leading to the paper, and will take public responsibility for its content.

I agree with the above statements and declare that this submission follows the policies of International Journal of Orthopaedic and Trauma Nursing as outlined in the Guide for Authors and in the Ethical Statement.

CRedit authorship contribution statement

Elin Saga: Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing, Data curation. **Ragnhild S. Falk:** Formal analysis, Writing – review & editing, Data curation, Supervision, Visualization. **Pia C. Bing-Jonsson:** Conceptualization, Supervision, Writing – review & editing. **Kirsti I. Skovdahl:** Conceptualization, Supervision, Writing – review & editing. **Espen Lindholm:** Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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List of abbreviations:

ASA	American Society of Anesthesiologists
ED	Emergency department
INR	International Normalized Ratio
IV	Intravenous
NRS	Numeric Rating Scale
NRS-D	Dynamic Numeric Rating Scale
NRS-R	Resting Numeric Rating Scale
RCT	Randomised controlled trial; RN: Registered nurse
UGFNB	Ultrasound-guided femoral nerve block

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