



Pericapsular nerve group (PENG) block provides improved short-term analgesia compared with the femoral nerve block in hip fracture surgery: a single-center double-blinded randomized comparative trial

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ABSTRACT

Background The femoral nerve block (FNB) may be used for analgesia in hip fracture surgery. The pericapsular nerve group (PENG) block is a novel regional technique and may provide better pain reduction while preserving motor function, but these blocks have not been directly compared.

Methods In a single-center double-blinded randomized comparative trial, patients presenting for hip fracture surgery received analgesia with either FNB or PENG block. The primary outcome measure was pain scores (Numeric Rating Scale (NRS) 0 to 10). Secondary outcomes were postoperative quadriceps strength, opiate use, complications, length of hospital stay, and patient-reported outcomes.

Results Sixty patients were randomized and equally allocated between groups. Baseline demographics were similar. Postoperatively in recovery (day 0), the PENG group experienced less pain compared with the FNB group. (In the PENG group, 63% experienced no pain, 27% mild pain, and 10% moderate to severe pain. In comparison, 30% of the FNB group reported no pain, 27% mild pain, and 36% moderate to severe pain; $p=0.04$). This was assessed using an 11-point Likert NRS. Quadriceps strength was better preserved in the PENG group in the recovery unit (assessed using Oxford muscle strength grading, 60% intact in the PENG group vs none intact in the FNB group; $p<0.001$) and on day 1 (90% intact vs 50%, respectively; $p=0.004$). There was no difference in other outcomes.

Conclusions Patients receiving a PENG block for intraoperative and postoperative analgesia during hip fracture surgery experience less postoperative pain in the recovery room with no difference detected by postoperative day 1. Quadriceps strength was better preserved with the PENG block. Despite the short-term analgesic benefit and improved quadriceps strength, there were no differences detected in the quality of recovery.

INTRODUCTION

Approximately 1.5 million people experience a hip fracture globally each year. Due to the growing and aging population, this is projected to increase to 7–21 million by 2050.¹ Seventy per cent of the patients with a hip fracture are 80 years or older,

with an often frail preoperative status and extensive comorbidities.² The UK's National Hip Fracture Database has named key performance indicators to guide patient care in this vulnerable population, including prompt mobilization after surgery.³

Anesthesiologists aim to decrease perioperative pain through regional analgesia techniques such as the femoral nerve block (FNB), as adequate pain management has been shown to decrease complications and facilitate postoperative mobilization.⁴ Previous studies have shown that the FNB results in a Numeric Rating Scale (NRS) pain score reduction of 3.4 points on an 11-point Likert scale.⁵ However, its benefits are offset by the FNB, resulting in quadriceps weakness, impeding postoperative mobility.⁶ The ideal regional technique for hip surgery would be one with a high pain score reduction that does not cause delayed mobilization and discharge.

In 2018, Girón-Arango *et al* described a novel technique for regional hip analgesia and named it the pericapsular nerve group (PENG) block.⁷ They reported an NRS pain score reduction of 7 points (out of 10) compared with a baseline of intravenous opiates only for analgesia. They noted a purely sensory blockade, so without motor impairment. These claims were based on a small case series of only five patients who received the PENG block. Additional series have not included large patient numbers either.⁸ Therefore, the current study was conducted to test the PENG block in a double-blinded randomized comparative fashion.

PATIENTS AND METHODS

This is a single-center, double-blinded, randomized comparative trial conducted at Flinders Medical Centre (FMC), a tertiary trauma hospital in Adelaide, Australia. Written informed consent was acquired from all participants. The trial was registered prior to commencement (NTR; NL8043; principal investigator: D-YL; date of registration: September 12, 2019, URL: <https://www.trial-register.nl/trial/8043>). This study conforms to the Consolidated Standards of Reporting Trials (CONSORT) and the CONSORT extension for trials reporting patient-related outcomes.^{9 10} The study ran from February 12 to September 25, 2020 and was paused temporarily from March 18 to

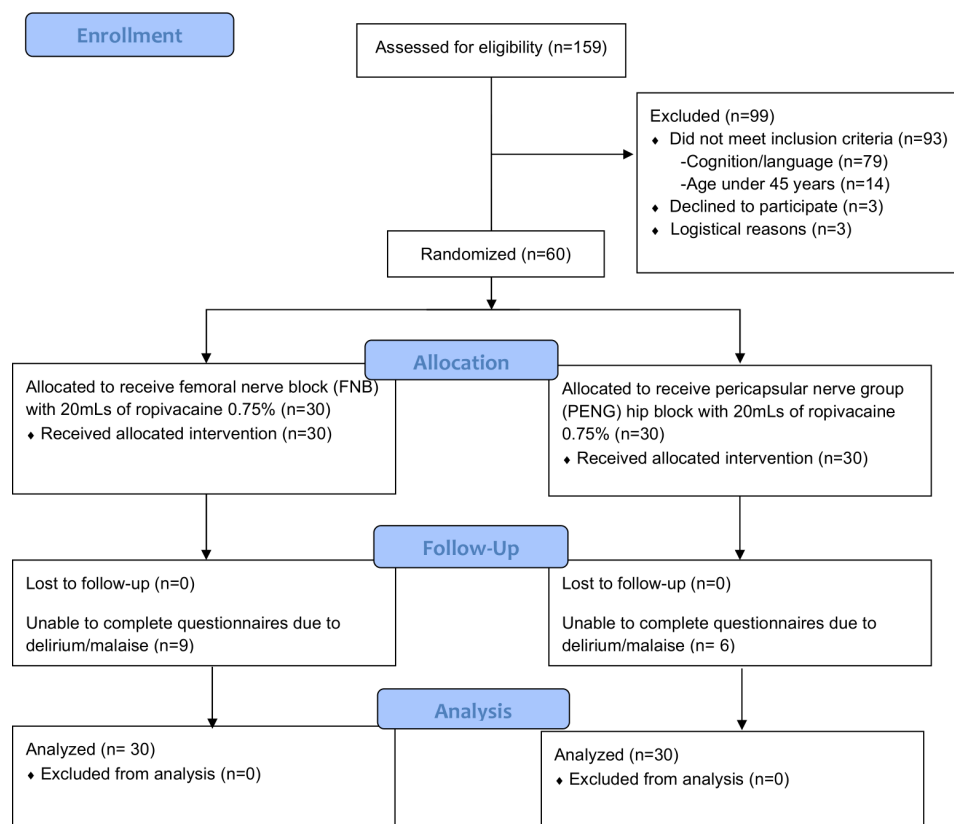


Figure 1 CONSORT study flowchart. CONSORT, Consolidated Standards of Reporting Trials; FNB, femoral nerve block; PENG block, pericapsular nerve group block.

May 5, 2020 due to local SARS-2 COVID-19 virus pandemic restrictions.

The inclusion criteria were patients with a hip fracture presenting for surgery, aged 45 years and older, without contraindications for regional anesthesia, who were able to provide informed consent and reliably report symptoms to the research team. The exclusion criterion was an inability to provide first party consent due to cognitive impairment or a language barrier.

Randomization, blinding and study intervention

Randomization was performed by an online randomization computer generator (www.sealedenvelope.com) on a 1:1 basis.

Members of the surgical, anesthetic, Acute Pain Service (APS), study and nursing staff were blinded for the intervention, as well as the patient. To ensure blinding, the anesthesiologist placing the block preoperatively was different from the anesthesiologist managing the patient intraoperatively and postoperatively.

The allocated block was placed 15–45 min preoperatively using ultrasound guidance. All blocks used 20 mL of 0.75% ropivacaine. (See online supplemental appendix 1 for the technical descriptions and ultrasound images of block placement.)

Surgical technique and type of anesthesia were performed at the discretion of the treating physicians, using a local protocol that allowed for variation within a small range. The study was designed to represent daily practice and to achieve high external validity.

Pain scores were recorded using an NRS ranging from 0 to 10, with 0 being the absence of pain and 10 the worst pain imaginable. Pain scores were obtained preoperatively (baseline), 4 hours postoperatively in the recovery unit (day 0),

and on postoperative day 1. The maximum pain score during active movement (quadriceps strength test) was the pain score used.

Outcome measures

Primary outcome was the postoperative NRS pain score measured in the recovery unit (day 0) at 4 hours postoperatively.

Secondary outcomes were NRS pain scores on day 1 postoperatively, postoperative quadriceps strength, perioperative opiate use, postoperative complications, length of hospital stay, patient satisfaction and patient-reported outcomes measures (PROMs).

Quadriceps strength was assessed using the knee extension test¹¹ and Oxford muscle strength grading¹² with grouped scores of intact (5/5), reduced (1–4/5) and absent (0/5).

Opiate use was reported as use intraoperatively, on day 0, use for each postoperative day for 3 days, and the total opiate use. Quantities were converted to oral morphine equivalents.

On day 1, parameters of patient satisfaction, pain experienced, and quality of recovery were evaluated using the Patient-Reported Outcomes Measurement Information System (PROMIS) item banks for evaluation of depression and pain interference, Brief Pain Inventory (BPI) and the Quality of Recovery (QoR-15) questionnaires (online supplemental appendix 2). The APS assessed patient satisfaction and pain management on day 1. Patients were asked to recall the time the block wore off, defined as return of motor (if initially impaired) and/or sensory recovery.

Complications were reported according to the Clavien-Dindo classification.¹³

Table 1 Patient and preoperative characteristics

	Femoral nerve block (n=30)	PENG (n=30)	P value
Age in years, mean (\pm SD)*	79.7 (\pm 11.5)	77.2 (\pm 11.6)	0.39
Gender , n (%)†			0.10
Male	7 (23)	14 (47)	
Female	23 (77)	16 (53)	
Weight in kg, mean (\pm SD)*	65.0 (\pm 15.7)	65.6 (\pm 17.8)	0.89
BMI in kg/m ² , median (IQR)‡	23.8 (20.8–27)	24.5 (20–28)	0.84
Mobility , n (%)§			0.60
Independent, no aids	17 (57)	19 (63)	
Assisted (stick, walker or wheelchair)	13 (43)	11 (37)	
Residence , n (%)†			0.25
Home	28 (93)	24 (80)	
Assisted living or nursing home	2 (7)	6 (20)	
ASA score , n (%)§			0.68
I	2 (7)	1 (3)	
II	3 (10)	5 (17)	
III	21 (70)	22 (73)	
IV	4 (13)	2 (7)	
Chronic opiate use , n (%)†			0.27
Yes	7 (23)	12 (40)	
No	23 (77)	18 (60)	
Anxiety and/or depression , n (%)§			0.29
Yes	10 (33)	14 (47)	
No	20 (67)	16 (53)	
Mechanism of injury , n (%)§			0.37
Mechanical fall	25 (84)	28 (94)	
Medical collapse	4 (13)	1 (3)	
High velocity trauma	1 (3)	1 (3)	
Fracture side , n (%)§			0.60
Left	12 (40)	14 (47)	
Right	18 (60)	16 (53)	
Type of fracture , n (%)†			0.66
Intracapsular	10 (33)	9 (30)	
Extracapsular	20 (67)	21 (70)	
Type of surgical repair , n (%)§			0.95
Gamma nail	13 (43)	11 (36)	
Cannulated screw	5 (17)	5 (17)	
Hemiarthroplasty	8 (27)	9 (30)	
Total hip replacement	4 (13)	5 (17)	
Preoperative pain score (NRS) , n (%)§			0.49
None (0)	0 (0)	0 (0)	
Mild (1–4)	4 (13)	2 (7)	
Moderate (5–7)	6 (20)	4 (13)	
Severe (8–10)	20 (67)	24 (80)	
Preoperative pain score (NRS) , median (IQR)‡	8 (7–10)	9 (8–10)	0.25
Type of anesthesia for surgery , n (%)§			0.43
General	20 (67)	18 (60)	
Spinal	10 (33)	13† (43)	
Intrathecal morphine , n (%)†			0.42
Yes	2 (7)	5 (17)	
No	28 (93)	25 (83)	
Intravenous dexamethasone , n (%)§			0.16
No	13 (43)	10 (33)	
4 mg	8 (27)	4 (13)	
8 mg	9 (30)	16 (54)	

Continued

Table 1 Continued

	Femoral nerve block (n=30)	PENG (n=30)	P value
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*Student's t-test used.

†Fisher's exact test used.

‡Mann-Whitney U test used.

§ χ^2 test used.

¶One patient converted from spinal to general anesthesia.

ASA, American Society of Anesthesiology; BMI, body mass index; NRS, Numeric Rating Scale; PENG, pericapsular nerve group block.

Sample size calculation and statistical analyses

The a priori power calculation was carried out using PASS V.14 Power Analysis and Sample Size Software (Kaysville, Utah, USA) based on pain score reductions reported in previous publications.^{5,7} These reports showed a mean pain score reduction after FNB of 3.4 points and 7 points after PENG block (both out of 10) on the day of the procedure, with an SD of 2 points.⁷ There are no studies directly comparing the two, hence we have compiled the results for FNB from the Cochrane review and the PENG block from the case series. We incorporated that, despite clinical familiarity with the PENG block, we would be less experienced than the group who described the PENG block first, and selected an SD of 3. A two-tailed independent samples t-test for the difference between two unpaired means with an alpha error of 0.05, beta error of 0.2, and power of 0.95 were used. This showed that, to detect a pain score difference of 3 (out of 10) with an SD of 3 points, 30 patients in each arm would be required, including an attrition rate of 15%, giving a total number of 60 patients for more than 95% power.

Data entry and statistical analyses were conducted in a blinded fashion. The analysis was performed on an intention-to-treat basis using SPSS V.27 (IBM) and GraphPad Prism V.8 (GraphPad

Table 2 Postoperative pain and motor outcomes

	Femoral nerve block (n=30)	PENG (n=30)	P value
Maximum postoperative pain score (NRS) in recovery unit (day 0), n (%)*			0.04
None (0)	9 (30)	19 (63)	
Mild (1–4)	8 (27)	8 (27)	
Moderate (5–7)	7 (23)	1 (3)	
Severe (8–10)	4 (13)	2 (7)	
Unable to assess due to delirium	2 (7)	0 (0)	
Quadriceps strength in recovery, n (%)*			<0.001
Intact	0 (0)	18 (60)	
Reduced	11 (37)	8 (26)	
Absent	12 (40)	2 (7)	
Unable to assess	7 (23)	2 (7)	
Maximum postoperative pain score (NRS) on day 1, n (%)*			0.53
None (0)	2 (7)	6 (20)	
Mild (1–4)	11 (37)	12 (40)	
Moderate (5–7)	7 (23)	7 (23)	
Severe (8–10)	7 (23)	5 (17)	
Unable to assess due to delirium	3 (10)	0 (0)	
Quadriceps strength on day 1, n (%)*			0.004
Intact	15 (50)	27 (90)	
Reduced	10 (33)	2 (7)	
Absent	0 (0)	0 (0)	
Unable to assess	5 (17)	1 (3)	

* χ^2 test used.

†Fisher's exact test used.

NRS, Numeric Rating Scale; PENG, pericapsular nerve group block.

Table 3 Postoperative outcomes

	Femoral nerve block (n=30)	PENG (n=30)	P value
Complications, n (%)			
Pneumonia	2 (7)	4 (13)	
Renal failure	3 (10)	2 (7)	
Blood transfusion	7 (23)	3 (10)	
Wound infection	1 (3)	0 (0)	
Reoperation	1 (3)	0 (0)	
Delirium	6 (20)	6 (20)	
In-hospital collapse	1 (3)	3 (10)	
STEMI/NSTEMI	1 (3)	2 (7)	
Unplanned ICU admission	3 (10)	1 (3)	
Death	1 (3)	0 (0)	
In-hospital falls, n (%)*			0.50
Fall as inpatient	2 (7)	0 (0)	
No fall recorded	28 (93)	30 (100)	
Clavien-Dindo complication scale, n (%)†			0.07
0	14 (47)	15 (50)	
I	1 (3)	8 (27)	
II	9 (30)	6 (20)	
III	2 (7)	0 (0)	
IV	3 (10)	1 (3)	
V	1 (3)	0 (0)	
Grouped Clavien-Dindo complications, n (%)*			0.10
None-mild (grade 0–II)	24 (80)	29 (97)	
Moderate-severe (grade III–V)	6 (20)	1 (3)	

*Fisher's exact test used.

† χ^2 test used.

N/A, not applicable; NSTEMI, non-ST elevation myocardial infarction; PENG, pericapsular nerve group block; STEMI, ST elevation myocardial infarction.

Software, La Jolla, California, USA). Parametricity of continuous variables was determined using the Shapiro-Wilk test. Normally distributed continuous variables are expressed as mean with SD, and non-parametric variables as median with range. Univariate analysis was carried out using the χ^2 test or Fisher's exact test

Table 4 Patient outcome questionnaires

	Femoral nerve block (n=20)*	PENG (n=25)†	P value
QoR-15, mean (\pm SD)‡	94.1 (\pm 4.6)	94.0 (\pm 4.1)	0.99
Brief Pain Inventory, mean (\pm SD)‡	2.0 (\pm 0.8)	2.50 (\pm 0.5)	0.80
PROMIS Pain Inference, median (IQR)§	21 (18–24)	23.5 (18–26)	0.49
PROMIS Emotional Distress, median (IQR)§	14 (12–20)	12 (10–17)	0.49
Patient satisfaction, n (%)¶			0.02
Unsatisfied	1 (3)	0 (0)	
Satisfied	21 (70)	29 (97)	
Ambivalent	8 (27)	1 (3)	
Would have the block again, n (%)¶			0.02
Yes	26 (87)	30 (100)	
No	1 (3)	0 (0)	
Ambivalent	3 (10)	0 (0)	

*Nine patients were unable to complete surveys due to delirium or patient refusal.

†Six patients were unable to complete surveys due to delirium or patient refusal.

‡Student's t-test used.

§Mann-Whitney U test used.

¶ χ^2 test used.

PENG, pericapsular nerve group block; PROMIS, Patient-Reported Outcomes Measurement Information System; QoR-15, Quality of Recovery 15.

for categorical variables; the Mann-Whitney U test for non-parametric continuous variables and the Student's t-test for parametric continuous variables. A p value of <0.05 was considered statistically significant.

RESULTS

During the study period, 159 patients were admitted to FMC with a hip fracture requiring surgery and screened for eligibility. Ninety-three patients did not meet the inclusion criteria: 14 were younger than 45 years old, and 79 patients had dementia, other cognitive impairments or a language barrier. Three patients declined to participate and another three could not be recruited due to logistical reasons, leaving 60 patients who were consented and randomized equally between both groups for inclusion (Figure 1). All patients completed the study and could be included in the final analysis as intention to treat without loss to follow-up.

The preoperative demographics of both groups were similar, including baseline NRS pain scores, incidence of chronic pain and anxiety or depression. Anesthetic and surgical techniques used were also similar between both groups (table 1).

Primary outcome

Postoperative pain scores in the recovery unit (day 0) were significantly different between groups, with 19 patients (63%) in the PENG group experiencing no pain, compared with 9 patients (30%) in the FNB group ($p=0.04$). In both groups, eight patients (27%) reported mild pain, defined as an NRS score of 1–4 points. In the PENG group, a total of 3 patients (10%) experienced moderate or severe pain compared with 11 patients (36%) in the FNB group (table 2).

Two patients could not provide answers to the questions due to sedation or confusion in recovery.

Secondary outcomes

On day 1, pain scores were similar between both groups ($p=0.53$). Three patients were unable to report a pain score due to confusion or delirium.

Quadriceps strength was better preserved in the PENG group, both in the recovery unit (day 0) ($p<0.001$) and on day 1 ($p=0.004$). In recovery, 18 patients (60%) in the PENG group had intact quadriceps strength, 8 (26%) had reduced quadriceps strength, and 2 (7%) had no motor capability. Two patients (7%) could not be assessed due to confusion or refusal. In comparison, no patient in the FNB group had intact quadriceps strength, 11 (37%) had reduced strength and 12 patients (40%) had no motor capability. Seven patients (23%) could not be assessed (table 2).

On the 0–5 Clavien-Dindo scale, as well as the pooled categories, complication rates were similar between both groups. Specifically, the incidence of delirium was also similar: six patients (20%) in each group (table 3).

Patients were more satisfied with the analgesia received in the PENG group: 29 patients (97%) were satisfied and 1 patient (3%) was ambivalent. No patient was dissatisfied. In the FNB group, 21 patients (70%) were satisfied, 8 patient (27%) ambivalent, and 1 patient (3%) was dissatisfied ($p=0.02$). There was no difference in the patient-reported outcomes in the questionnaires (table 4). Twelve patients (six in each group) could not complete the postoperative questionnaires due to delirium, and three declined to complete the questionnaires due to general malaise or tiredness.

Postoperative opiate use was similar between both groups (table 5).

Table 5 Postoperative opiate use

	Femoral nerve block (n=30)	PENG (n=30)	P value
Postoperative opiate use in morphine equivalents (mg), median (IQR)*			
Intraoperative	22.5 (8.8–53)	20 (0–50)	0.37
Day 0 (total)	55 (36.5–80.1)	53.25 (32.3–86)	0.85
Day 1	17.5 (8–33.8)	13.5 (8–32)	0.59
Day 2	12.25 (7–32.5)	8 (0–28.5)	0.41
Day 3	8 (0–16.8)	0 (0–17.8)	0.62
Total	105.25 (54.6–175)	82.5 (0–165.5)	0.65

*Mann-Whitney U test used.

mg, milligrams; PENG, pericapsular nerve group block.

Adverse events and protocol deviations

In one case, the patient and the APS became unblinded for which block the patient had received, after unintentional mention of this by an observing trainee anesthesiologist. Another patient had his/her spinal anesthesia converted to general anesthesia due to a large hemoptysis and aspiration during surgery.

DISCUSSION

This randomized comparative trial shows that the PENG block provides better perioperative analgesia than the FNB. Postoperative pain scores were significantly improved in the PENG group compared with the FNB group.

Previous publications on the PENG block have been limited to case series including small numbers of patients only. Girón-Arango *et al* included five patients and suggested a postprocedure 7-point NRS reduction.⁷ This is consistent with other published case series.^{14–17} The authors of the first PENG block publication compared the PENG block efficacy with the already published results of the FNB from a Cochrane systematic review by Guay *et al*.⁵ The FNB showed a pain score reduction of 3.4 points. The current randomized comparative trial now confirms these preliminary conclusions that the PENG block offers improved pain relief compared with the FNB.

Postoperative quadriceps strength in the recovery unit on day 0 and on day 1 was significantly better maintained in the PENG group compared with the FNB group. Better preserved quadriceps strength allows patients to mobilize earlier following their hip fracture surgery, which is associated with less complications, lower mortality, less pain, and shorter length of stay.^{18–20}

Some PENG patients did experience loss in muscle strength. Both patients with no motor capability had received spinal anesthesia, and the motor effect was bilateral at 4 hours postoperative. Hence, we believe this is likely a residual effect of the spinal anesthetic.^{21,22} Also, we found that patients were sometimes still residually sedated in recovery, or could not fully understand instructions. It could also be due to the high concentration of local anesthetic used in this trial for both the FNB and PENG block (20 mL of 0.75% ropivacaine). It is possible that this produces some motor weakness, which is an aspect that would have to be investigated further. This could have resulted in a higher than expected impedance of quadriceps strength after PENG and FNB blocks. In future studies, we plan to decrease our concentration of local anesthesia as the pain relief is likely to be sufficient also at a lower dose.

There were two in-hospital falls recorded in the FNB group, while none were seen in the PENG group. The effect of the FNB could have been a contributing factor, although the number of incidents was too low to show this statistically, as the trial was not powered for this complication ($p=0.50$).²³

Furthermore, no adverse events directly related to block placement were reported in either group.

Patient satisfaction was significantly better after PENG block ($p=0.02$). The other PROMs were similar between groups. The relatively high number of patients who declined to complete the questionnaires due to general malaise, especially in the FNB group, could have been a contributing factor to this. The scores obtained from the QoR-15 in both groups were lower than those reported by Myles *et al*. However, these PROMs were conducted in younger and less frail patients.²⁴ Trials involving elderly patients with extensive comorbidities reported similar QoR-15 scores to those found in this study.²⁵

The similar opiate use in both groups could have been due to the advanced age of patients with hip fracture, their low baseline opiate use and the hospital's threshold to administer opioids in view of its side effects in elderly. This study was not powered to detect a difference in opiate use between the groups; a much larger cohort study would be needed to investigate this in the future.

Limitations

Some limitations of the study have to be addressed. This trial was conducted in a relatively small number of patients. However, because the power calculation was based on small PENG reports, we decided to increase the patient numbers for the current trial in the power calculations in order to minimize the risk of an underpowered study. Therefore, we are confident that the significant difference between groups for the primary outcome (postoperative pain) reflects a true difference between both blocks. It is possible that the secondary outcomes would have also reflected a difference, but our power calculation was based on the primary outcome. Hence, this study is likely too small to detect differences in the secondary outcomes such as opiate use reduction and incidence of complications, specifically in hospital falls.

We adopted a pragmatic approach, allowing surgeons and anesthesiologists to select their own treatments. This was to allow daily practice to be reflected in this study, as variation at our center is minimal due to institutional standards of care. Further sensitivity analysis did not show a trend toward significance for the choice of spinal or general anesthesia.

Patients with hip fracture are mostly elderly and frail, with a high incidence of dementia.²⁶ Due to our stringent patient selection to eliminate patients with any degree of cognitive impairment, a large number of patients had to be excluded, potentially inflicting a selection bias. The next step to further investigate the PENG block would be a large cohort study in the general hip fracture population.

Ideally, we would have conducted the PROMs preoperatively also to obtain a baseline for each patient. This, however, was not feasible due to the emergency nature of hip fracture surgery.

CONCLUSION

Patients receiving a PENG block for intraoperative and postoperative analgesia during hip fracture surgery experience less postoperative pain in the recovery room with no difference detected by postoperative day 1. Quadriceps strength was better preserved with the PENG block. Despite the short-term analgesic benefit and improved quadriceps strength, there were no differences detected in the quality of recovery. For hip fracture surgery, the PENG block should be considered to reduce perioperative pain.

Correction notice This article has been corrected since it published Online First. The author affiliations have been updated.

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Contributors D-YL: This author conceived, designed, submitted to Ethics and Governance, and realized the study protocol. This author also formulated and completed the database, prepared the drafts, analyzed and prepared the data, and approved and submitted the final manuscript. CM: This author conceived, assisted with designing, writing and submitting the protocol to Ethics and Governance, realized the study, acquired the data, and approved the final manuscript. BB: This author conceived, assisted with designing, writing and submitting the protocol to Ethics and Governance, realized the study, acquired the data, completed the database, and approved the final manuscript. AS: This author reported appropriate patients to the study team for inclusion, conducted post-operative assessments in a blinded fashion, and approved the final manuscript. RP: This author assisted with protocol implementation, and approved the final manuscript. MV: This author assisted with protocol implementation, and approved the final manuscript. SRA: This author assisted with protocol implementation, and approved the final manuscript. TSL: This author assisted with protocol implementation, and approved the final manuscript. JD: This author conceived, assisted with designing, writing and submitting the protocol to Ethics and Governance, realized the study, and approved the final manuscript. HK: This author conceived, assisted with designing, writing and submitting the protocol to Ethics and Governance, analyzed and prepared the data, critically revise the drafts, and approved the final manuscript. RJ: This author conceived, assisted with designing, writing and submitting the protocol to Ethics and Governance, realized the study, lended departmental support, revised the drafts, and approved the final manuscript.

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