

Effect of Pericapsular Nerve Group Block with Different Concentrations and Volumes of Ropivacaine on Functional Recovery in Total Hip Arthroplasty: A Randomized, Observer-Masked, Controlled Trial

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Purpose: The pericapsular nerve group (PENG) block provides satisfactory postoperative analgesia without hampering motor function for total hip arthroplasty (THA); however, unexpected motor block has been observed clinically. It is unknown whether this motor block is related to the dose of ropivacaine. We aimed to conduct a prospective randomized trial to test whether reducing the volume or concentration of ropivacaine was better for less motor block after PENG block.

Patients and Methods: Ninety-nine patients with fracture or femoral head necrosis scheduled for THA were randomly allocated to receive 20 mL 0.5% ropivacaine (Group A), 20 mL 0.25% ropivacaine (Group B), and 10 mL 0.5% ropivacaine (Group C). The primary outcome was the incidence of postoperative quadriceps motor block at 6 hours. Secondary outcomes were the incidence of postoperative quadriceps motor block at 0, 12, 24 and 48 hours; pain scores on the numeric rating scale (NRS) at all postoperative time points (0, 6, 12, 24, and 48 hours); the time to first walk; the incidence of rescue analgesia; side effects such as dizziness, ache, nausea, and vomiting; and patient satisfaction.

Results: Compared with Group A, Group C resulted in a lower incidence of quadriceps motor block at 0 hours, 6 hours and 12 hours postoperatively ($P < 0.05$), while Group B only resulted in a lower incidence of motor block at 12 hours postoperatively ($P < 0.05$). No intergroup differences were found in terms of postoperative pain scores, the incidence of rescue analgesia, adverse events or patient satisfaction ($P > 0.05$).

Conclusion: A higher incidence of motor blockade was observed when 20 mL of 0.5% ropivacaine was administered, which was mainly caused by the excessive volume. Therefore, we recommend performing PENG block with 10 mL 0.5% ropivacaine.

Keywords: pericapsular nerve group block, analgesia, motor recovery, ropivacaine

Introduction

Total hip arthroplasty (THA) is a widely used method for treating hip fractures and femoral head necrosis. However, acute pain is common and can lead to a series of postoperative complications, such as delirium, reduced patient satisfaction, and decreased functional outcomes.¹⁻³ Nerve blocks are commonly used for postoperative analgesia, such as femoral nerve block (FNB) and suprainguinal fascia iliaca block (SIFIB), but they may result in quadriceps weakness, thereby hindering postoperative mobilization.^{4,5}

The pericapsular nerve group block (PENG block) was first applied to THA by Girón-Arango et al⁶ in 2018, and it provided sufficient analgesic effect without resulting in quadriceps weakness.⁶ However, this feature does not seem to be well confirmed in clinical randomized controlled experiments. Studies^{7,8} that performed PENG block with local

anaesthetic of 20 mL 0.5% and 0.75% reported inadvertent quadriceps weakness. The mechanism of motor block is still unclear. Anatomically, PENG only involves sensitive fibres,⁹ so the concentration of local anaesthetic will not affect postoperative quadriceps strength. However, if a mixed nerve such as the femoral nerve (FN) is accidentally blocked with a large volume, the effect of concentration on muscle strength cannot be ignored. Therefore, we must take the local anaesthetic volume and concentration into account for unexpected motor block after PENG block.

Our primary objective was to conduct a prospective randomized trial to test whether reducing the volume or concentration of ropivacaine was better for less motor block after PENG block.

Materials and Methods

This was a single-centre, double-blinded, randomized comparative trial conducted at the Third Affiliated Hospital of Anhui Medical University (Hefei First People's Hospital), Hefei, Anhui, China. Before enrolment, the ethics committee of Hefei First People's Hospital approved (approved No. of ethic committee: 2021 (52)) this study, and the study was registered at Clinical Trials prior to commencement (trial registration number: ChiCTR2100052511; principal investigator: Huangying; date of approval: 30/10/2021). This trial was conducted in accordance with the principles of the Declaration of Helsinki. After obtaining written informed consent, 108 patients who presented for THA were enrolled. The study lasted from October 31, 2021, to March 1, 2023.

The inclusion criteria were as follows: (1) American Society of Anaesthesiologists (ASA) physical status I to III, (2) aged 18 years and older, and (3) patients with fracture or femoral head necrosis undergoing THA. The exclusion criteria were as follows: (1) contraindications to peripheral nerve block (allergy to lidocaine or ropivacaine, infection in the injection site), (2) disagreement to participate in this study, (3) coagulation dysfunction, (4) sepsis, (5) liver or renal failure, and (6) opioid intake at home. Eligible subjects were enrolled and allocated at random into three groups.

Intervention, Randomization and Blinding

Patients were randomly assigned to receive either 0.5% ropivacaine 20 mL (Group A), 0.25% ropivacaine 20 mL (Group B) or 0.5% ropivacaine 10 mL (Group C). A computer-generated random number table was used for randomization. The patient grouping data were sealed in sequentially numbered opaque envelopes, which were opened by the researchers on the day of surgery.

Operatives, anaesthesiologists, nursing staff and patients were blinded to the intervention. To ensure blinding, the anaesthesiologist placing the block before the operation was different from the anaesthesiologist managing patients during and after the operation. To ensure normal operation, various patient indicators were checked before surgery. All patients fasted for 8 hours before the operation and stopped taking any medicine. After patients entered the operating room, their blood pressure, pulse and heart rate were monitored. General anaesthesia was selected as the main anaesthesia technique, which was induced by propofol, rocuronium and sufentanil. In addition, general anaesthesia was maintained by sevoflurane and target-controlled infusion of propofol and remifentanyl.

The PENG block, according to the technique described by Giron-Arango,⁶ was performed with the patient in the supine position after the induction of general anaesthesia and before surgical incision. The low-frequency linear ultrasound probe (Navi s, Wisonic, Shenzhen China) was placed parallel at the level of the anterior superior iliac spine, and the probe was rotated approximately 45 degrees counterclockwise to obtain an image of the femoral artery (FA), iliacus muscle, psoas tendon (PT) and iliopubic eminence (IPE). Puncture was performed in a lateromedial direction until the needle tip reached the plane between the iliopsoas tendon and periosteum and between the anterior inferior iliac spine (AIIS) and IPE (Figure 1).⁶ After a negative aspiration test, Group A (20 mL 0.5%), Group B (20 mL 0.25%) and Group C (10 mL 0.5%) were injected in the plane beneath the iliopsoas muscle to see the diffusion of local anesthetic (LA). The block was always performed by the same two anaesthetists (DCS, WJ). Each had almost 5 years of clinical experience focused on regional anaesthesia.

All patients received 5 µg sufentanil 15 min before the end of the surgery. Postoperatively, all patients received the same multimodal analgesia, which included flurbiprofen 50 mg intravenous (i.v.) every 12 h and acetaminophen 1 g i.v. three times per day. In addition, patient controlled analgesia (PCA) with 100 mL of 0.5 µg/mL sufentanil was performed. The PCA settings were as follows: no background infusion, single dose 3 mL, and locking time 20 min.



Figure 1 Images of ultrasound-guided pericapsular nerve group (PENG) block. The needle tip was positioned between the psoas tendon and the pubic ramus using an in-plane approach. The needle is outlined by the arrows; arrow, needle pathway.

Abbreviations: LA, local anesthetic; AIIS, anterior inferior iliac spine; IPE, iliopubic eminence; PT, psoas tendon; FA, femoral artery.

Primary Outcome

The primary outcome was the incidence of postoperative quadriceps motor block (paresis or paralysis) at 6 hours using the knee extension test,¹⁰ which was graded according to a 3-point scale: 0=normal strength (extension against gravity and against resistance); 1=paresis (extension against gravity but not against resistance); 2=paralysis (no extension possible).

Secondary Outcomes

Secondary outcomes were the incidence of postoperative quadriceps motor block (paresis or paralysis) at 0, 12, 24 and 48 hours and numeric rating scale (NRS) pain scores at all postoperative time points (0, 6, 12, 24, and 48 hours after surgery). Patients were asked to indicate perceived pain at rest and upon movement using the NRS (ranging from 0, no pain, to 10, worst imaginable pain). Additional secondary outcomes included the time to first walk, the incidence of rescue analgesia, side effects (such as dizziness, ache, nausea, vomiting) and patient satisfaction. Outcome assessment was performed by the same group of three clinicians (LQ, LL, BHF) who were blinded to the group allocation.

Sample Size Calculation

The primary outcome was muscle strength. Traditional PENG block with 20 mL 0.5% ropivacaine suggests that the incidence of no motor block (normal strength) at 6 hours hovers approximately 75%.⁸ We hypothesized that PENG block with ropivacaine of 10 mL 0.5% and 20 mL 0.25 would increase its incidence to 100% according to case reports¹¹ and our preliminary experiments. Thus, a sample size of 70 would achieve 90% power to detect an effect size (W) of 0.4264 using a 2 degrees of freedom chi-square test with a significance level (alpha) of 0.05000, and 24 patients per group were needed. Ultimately, a total of 99 subjects were recruited to account for possible dropouts.

Statistical Analysis

The analysis was performed using SPSS 26.0 (IBM). The Shapiro–Wilk test was used to test normality. Continuous data with normal distributions are presented as the means (SD) and non-normally distributed data are presented as medians (IQR [range]). For continuous data, one-way ANOVA and Kruskal–Wallis tests were used. For categorical data, the chi-squared test and Kruskal–Wallis *H*-tests were used and presented as numbers (proportions). Fisher's exact test was used when any cell for the aforementioned categorical data had an expected count of less than five. Comparisons in muscle strength at each time point between the three groups were performed by the Bonferroni test. A *p* value of <0.05 was considered statistically significant.

Results

Of 108 patients who were assessed for eligibility, four refused to sign informed consent forms, and five did not meet the inclusion criteria and were therefore excluded. The remaining 99 patients were randomly and equally allocated between three groups; however, 3 patients per group were lost to follow-up, and 30 people were therefore ultimately included in each group (Figure 2). No clinically relevant differences were apparent from the group characteristics (Table 1).

Primary Outcome

The incidence of postoperative quadriceps motor block at 6 hours was 50% vs 33.3% vs 16.7%, respectively ($p < 0.05$) (Table 2). Then, after three to two comparisons, there was no statistical difference between Group A and Group B, but both groups showed statistical differences from Group C (Table 2 and Figure 3).

Secondary Outcomes

The incidence of postoperative quadriceps motor block was significantly different between the three groups at 0 hours (43.3% vs 36.7% vs 13.3%; $p < 0.05$) and 12 hours (43.3 vs 16.7% vs 6.7%; $p < 0.05$) (Table 2). Then, after three to two comparisons,

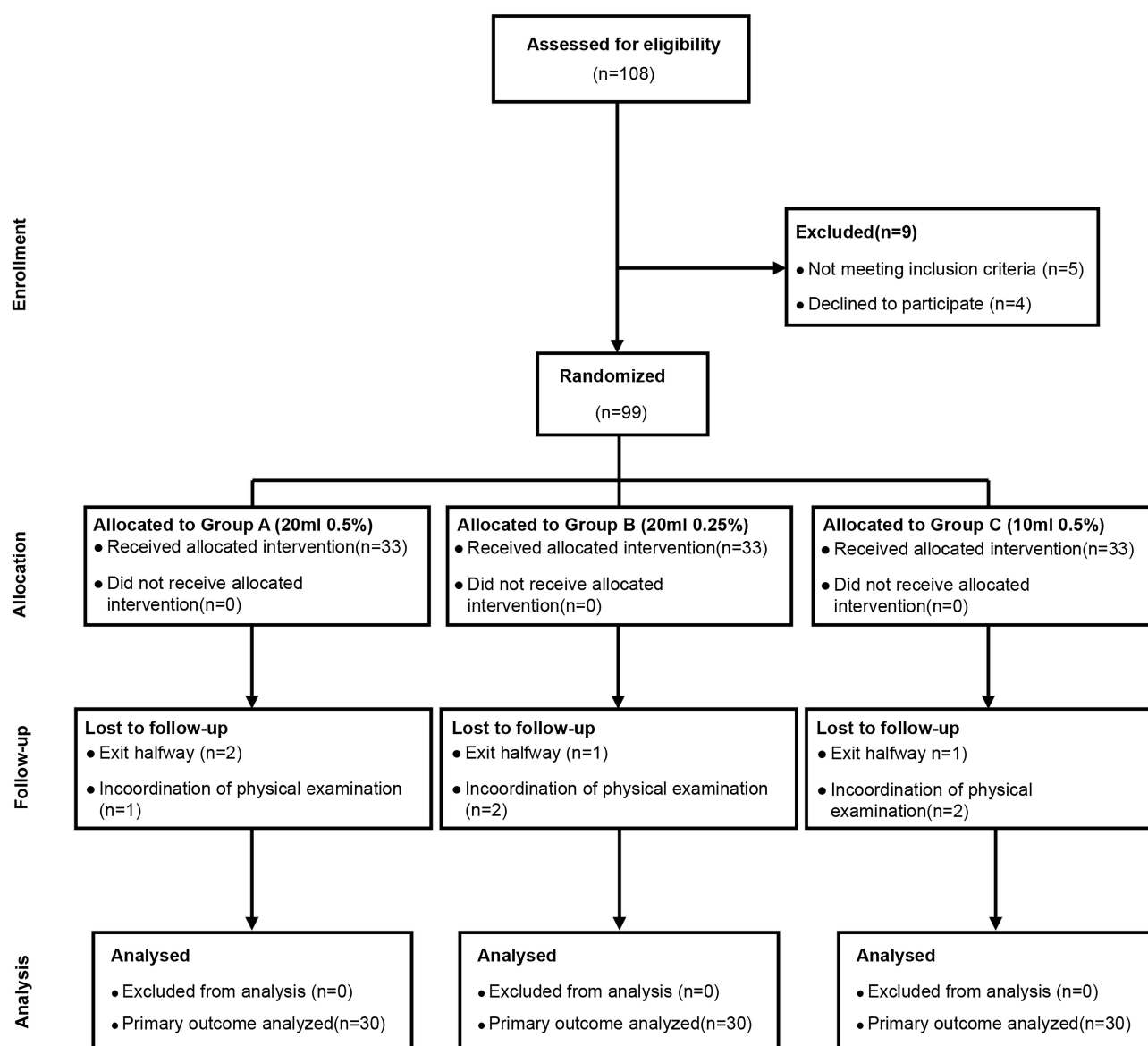


Figure 2 Flow diagram of the patients' recruitment. Group (A) Control group (N=30). Group (B) low concentration group (N=30). Group (C) low volume group (N=30).

Table 1 Demographic Data and Patient Characteristics

Patient Characteristics	Group A	Group B	Group C	P
Age (y)	71.20±7.77	66.90±10.08	70.07±5.99	0.146
Sex (male/female) (n)	17/13	16/14	12/18	0.393
Height (cm)	162.50±5.73	163.67±6.55	163.18±6.63	0.778
Weight (kg)	62.70±7.34	61.90±8.54	60.47±9.60	0.497
ASA status (II/III)	24/6	25/5	23/7	0.812
Duration of surgery (min)	76.50±31.88	77.70±25.73	75.77±31.89	0.769
Preoperative diagnosis (n)				
Fracture/ femoral head necrosis	20/10	20/10	20/10	1.000
Mobility (n)				
Independent/Assisted	8/22	10/20	11/19	0.736

Notes: Data are presented as mean (SD) or number; ASA, American Society of Anesthesiologists.

Table 2 Postoperative Motor Outcomes

Postoperative Motor Outcomes	Group A			Group B			Group C			P
	Intact	Reduced	Absent	Intact	Reduced	Absent	Intact	Reduced	Absent	
Quadriceps strength at 0hour, n (%)	17 (56.7)	9 (30)	4 (13.3)	19 (63.3)	8 (26.7)	3 (10)	26 (86.7)	4 (13.3)	0 (0)	0.023*
Quadriceps strength at 6hour, n (%)	15 (50)	11 (36.7)	4 (13.3)	20 (66.7)	7 (23.3)	3 (10)	25 (83.3)	5 (16.7)	0 (0)	0.018*
Quadriceps strength at 12 hour, n (%)	17 (56.7)	11 (36.7)	2 (6.6)	25 (83.3)	5 (16.7)	0 (0)	28 (93.3)	2 (6.7)	0 (0)	0.002*^
Quadriceps strength at 24 hour, n (%)	21 (70)	8 (26.7)	1 (3.3)	26 (86.7)	4 (13.3)	0 (0)	28 (93.3)	2 (6.7)	0 (0)	0.065
Quadriceps strength at 48 hour, n (%)	25 (83.3)	5 (16.7)	0 (0)	28 (93.3)	2 (6.7)	0 (0)	30 (100)	0 (0)	0 (0)	0.054

Notes: Data are presented number (proportion). *denotes statistical significance ($p < 0.017$) compared with Group C; ^ denotes statistical significance ($p < 0.017$) compared with Group B.

Group C resulted in a lower incidence of motor block than Group A at the above two time points (Table 2 and Figure 3). Group B resulted in a lower incidence of motor block than Group A only at 12 hours postoperatively (Table 2 and Figure 3). Quadriceps strength was similar among the three groups at 24 and 48 hours postoperatively (Table 2 and Figure 3, $p > 0.05$).

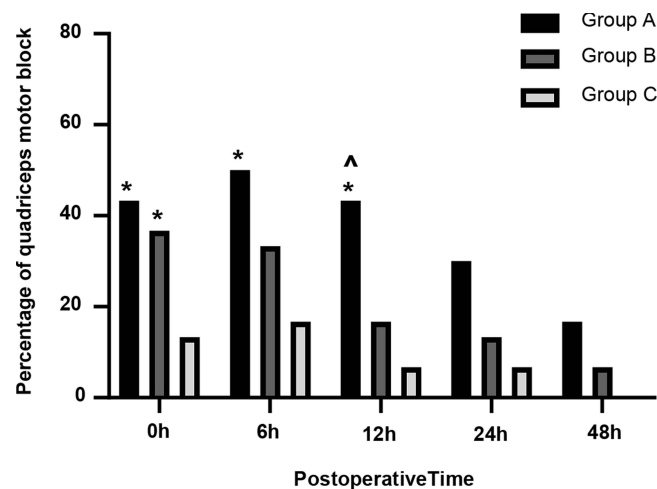


Figure 3 The percentage of postoperative quadriceps motor block in three study groups reported during five postoperative intervals. *Denotes statistical significance ($p < 0.017$) compared with Group C; ^ denotes statistical significance ($p < 0.017$) compared with Group B.

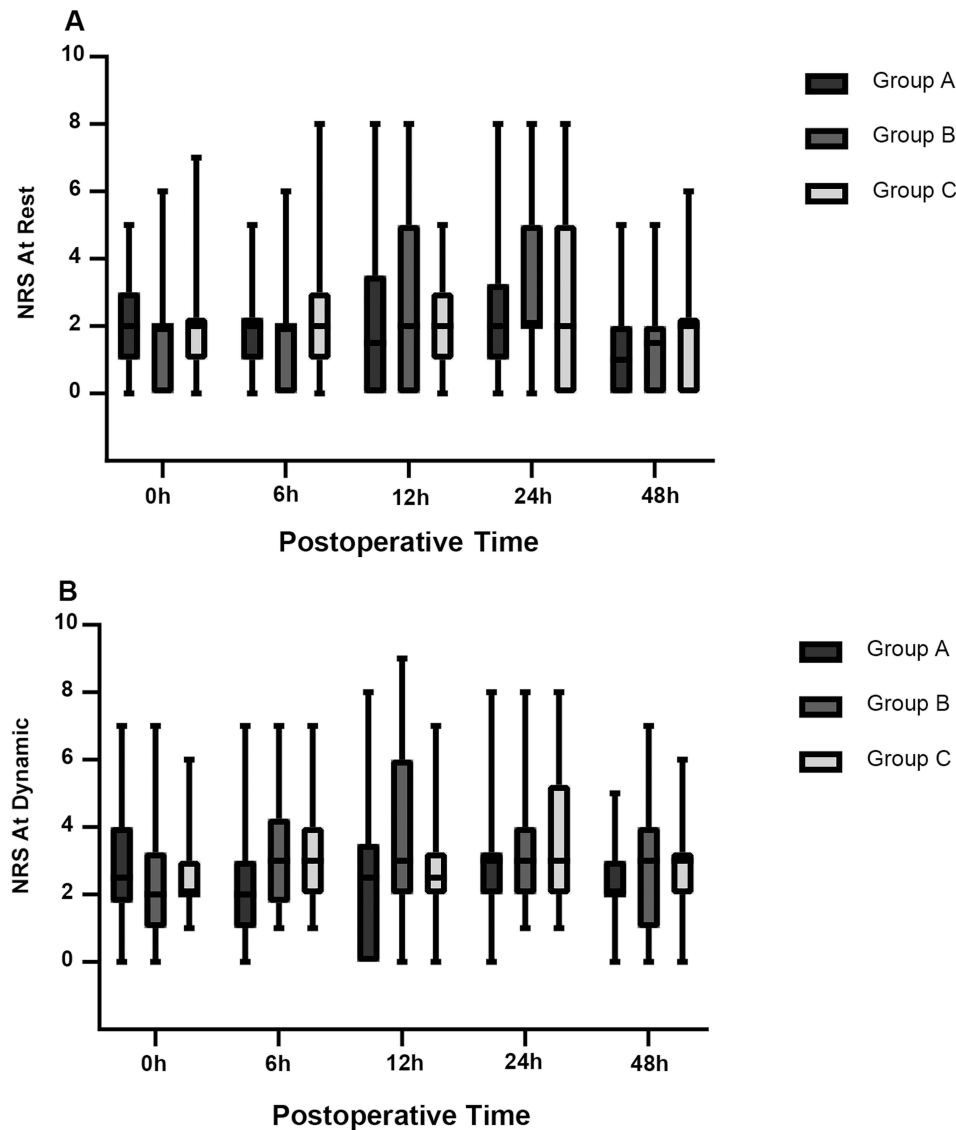


Figure 4 (A) Postoperative (numeric rating scale) pain scores at rest in three study groups reported during five postoperative intervals. Values are median (horizontal bars), IQR (box) and range (whiskers). **(B)** Postoperative (numeric rating scale) pain scores at dynamic in three study groups reported during five postoperative intervals. Values are median (horizontal bars), IQR (box) and range (whiskers).

There were no differences in postoperative pain scores among the three groups at any time point at rest and dynamic (Figure 4A and B, $p > 0.05$). Furthermore, Group B and Group C had a shorter time to the first walk than Group A (Table 3, $p < 0.001$). No intergroup differences were found in terms of adverse events or patient satisfaction (Table 3, $p > 0.05$).

Table 3 Other Postoperative Outcomes

	Group A	Group B	Group C	P
Time to first walk (min)	27.55±2.58	25.57±1.22	25.22±0.93	<0.001*^
Rescue analgesic, n (%)	7 (23.3)	6 (20)	8 (26.7)	0.830
Dizziness, n (%)	3 (10)	1 (3.3)	2 (6.7)	0.868
Ache, n (%)	2 (6.7)	0 (0)	0 (0)	0.129
Nausea/vomiting, n (%)	6 (20)	4 (13.3)	7 (23.3)	0.602
Satisfaction, n (%)	28 (93.3)	25 (83.3)	27 (90)	0.592

Notes: Values are mean (SD) or number (proportion). *Denotes statistical significance ($p < 0.017$) compared with Group C; ^Denotes statistical significance ($p < 0.017$) compared with Group B.

Discussion

This randomized comparative trial shows that PENG block with 20 mL 0.5%, 20 mL 0.25%, and 10 mL 0.5% ropivacaine provides equally effective pain control, while a higher incidence of motor blockade was observed when 20 mL 0.5% ropivacaine was administered.

PENG block is a novel regional analgesia technique to block hip articular ramification from femoral and accessory obturator nerves, and it has the advantage of no motor block.^{12,13} However, its variations differ in the technique's details, such as the needle approach and recommended dose of local anaesthetic. Moreover, there is always unexpected motor block clinically.^{7,8,14} Then possible explanations for accidental motor block include the details of the PENG block technique, such as accidental injury of the FN when the needle is inserted,¹⁵ more than one needle pass was required,¹⁶ misplacement of the needle tip causing medial injection or intramuscular injection.¹⁷ However, this explanation is not valid in our trial due to the lack of a difference in technique details among the three groups. Thus, there is just another explanation that a large volume and high concentration of ropivacaine weakens the advantage of no motor block brought by PENG block.

Regarding the factor of volume, our study showed that PENG block with low volume represented sufficient analgesia without motor block. In a cadaver study,¹⁸ 10 mL of methylene was sufficient to stain the entire anterior hip joint capsule to cover the nociceptive nerve fibres identified by Gerhardt et al,¹⁹ Donghong²⁰ also showed that 0.25% ropivacaine (10 mL) can provide a good analgesic effect without affecting quadriceps muscle strength. For unexpected motor block in clinical practice, some authors^{21,22} are concerned that high local anaesthetic volume may spread to the FN, causing inadvertent quadriceps weakness. And a recent cadaveric study¹⁶ indicated that for PENG block, the maximum effective volume of dye in 90% of cases (MEV90) of methylene blue required to spare the FN is 13.2 mL, which indicates that motor weakness may result from high volume of ropivacaine spread to FN. Furthermore, Kim JY²³ reported the anatomical spread of injectate during PENG block and found that the articular branches of the FN were stained with dye in nearly all 20 mL and 30 mL specimens, which was consistent with the quadriceps weakness observed clinically after PENG block. In addition, theoretically, if PENG block only blocks the sensory fibres, the change in concentration will not lead to a change in postoperative muscle strength but will only affect the postoperative sensation at most. However, in our experiment, it was found that under a certain volume (20 mL ropivacaine), the change in concentration affected the postoperative muscle strength. This further confirmed that 20 mL ropivacaine blocks the femoral nerve, thus causing muscle weakness.

In addition, concentration may have a negative effect on postoperative muscle strength. Although ropivacaine has been reported to have little impact on the motor nerve in patients,²⁴ a previous study showed that ropivacaine anaesthesia requires a threshold volume and concentration, and concentration primarily determines motor blocks.²⁵ Claus Behrend Christiansen²⁶ compared the effects of different concentrations of ropivacaine on the duration of common peroneal nerve block and found that local anaesthesia dilution could reduce the time of motor block. It may be that motor block is sensitive to it, which plays a great role in the recovery of muscle strength after operations.²⁴ This is similar to the conclusion of our experiment. Below a certain volume, reducing the concentration of ropivacaine will reduce the incidence of postoperative motor block.

Compared with Group A, Group B represents a low concentration, and Group C represents a low volume. There was always a significant difference between Group C and Group A in muscle strength at 0 hours, 6 hours and 12 hours, while there was only a significant difference between Group B and Group A at 12 hours. Therefore, local anaesthetic volume has a greater negative impact on postoperative muscle strength for PENG block.

However, this study has some limitations. First, some relevant and confounding factors have not been evaluated. Since the outcome here is muscle strength, it is difficult to have an idea of the basic pain scores and what painkillers they took in the ward because pain can decrease functional outcomes. In addition, factors such as frailty and days between fracture and surgery need to be very balanced between the study groups to avoid a relevant bias source. Second, we did not record the consumption of medication used for rescue analgesia, only the frequency of rescue analgesia. Third, the time from injury to surgery and the time between the block and surgery were not mentioned.

Conclusion

PENG block with 20mL 0.5%, 20mL 0.25%, and 10mL 0.5% ropivacaine provided equally effective pain control for THA, but a higher incidence of motor blockade was observed when 20 mL of 0.5% ropivacaine was administered, which was mainly caused by excessive volume. Therefore, we recommend performing PENG block with 10 mL 0.5% ropivacaine.

Data Sharing Information

Raw data (de-identified) used in this clinical trial are available from the corresponding author Chun-Shan Dong.

Ethics Statement

This is a randomized controlled clinical trial comparing the analgesic effect of pericapsular nerve group block of hip joint with different concentrations and volumes of ropivacaine in elderly patients undergoing hip replacement. This study conforms with Helsinki Declaration.

Acknowledgments

The authors would like to thank the reviewer, Wen-rui Zhang, for the effort and the time spent in the linguistic revision of the manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosure

The authors declare no competing interests in this work.

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