Original Article

Evaluation of two doses (20 mL and 15 mL) of 0.25% bupivacaine in pericapsular nerve group block for patient positioning for sub-arachnoid block during hip fracture surgery: A single-centre, randomised comparative trial

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Submitted: 29-Mar-2023
Revised: 10-Jan-2024
Accepted: 11-Jan-2024
Published: 13-Mar-2024

Access this article online
Website: https://journals.lww.com/ijaweb
DOI: 10.4103/ija.ija_258_23
Quick response code

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ABSTRACT

Background and Aims: Peri-capsular nerve group (PENG) block is a novel ultrasound (US)-guided technique to achieve regional analgesia in hip fractures. We compared the effectiveness of two doses of 0.25% bupivacaine (20 mL and 15 mL) in the US-guided PENG block for positioning patients for sub-arachnoid block (SAB) during hip fracture surgery. **Methods:** The randomised trial included 60 patients aged 40–90 years undergoing hip fracture surgery under SAB. PENG block was given by a US-guided approach with the patient in a supine position 20 minutes before SAB, and a total of 20 mL and 15 mL of bupivacaine (0.25%) were given in groups A and B, respectively. The primary outcome was to measure and compare the ease of positioning (EOP) of patients for the conduct of SAB. The secondary outcome was the pain assessment at rest and 15° leg raise position at baseline and 10 and 20 minutes post block using the verbal analogue scale (VAS). Continuous variables were compared using the *t*-test, and categorical variables were analysed using Pearson's Chi-square test or Fisher's exact test. **Results:** The mean (standard deviation) grade of EOP for SAB was significantly better in group A (2.47 (0.73) (95% confidence interval [CI]: 2.19–2.69)) than in group B (1.86 (0.62) (95% CI: 1.65–2.1)) ($P = 0.001$). The decrease in VAS scores was significantly higher in group A compared to group B at resting and 15° leg raise position at all-time points ($P < 0.05$). **Conclusion:** A dose of 20 mL of 0.25% bupivacaine shows better outcomes than 15 mL regarding the patient's positioning during the SAB.

Keywords: Anaesthetics, analgesia, bupivacaine, ease of positioning, hip fractures, nerve block, pain, pericapsular nerve group block, positioning, sub-arachnoid block

INTRODUCTION

Fractures of the hip joint are quite common, especially in older people; most require surgical reduction and fixation as the definitive treatment. The major cause of morbidity in these patients is the associated severe pain,[1] which makes the positioning of patients quite difficult while instituting sub-arachnoid block (SAB) during surgery.

Regional nerve blocks such as the femoral nerve block (FNB) and the fascia iliaca block (FIB) are often used to achieve effective perioperative analgesia and facilitate the positioning of patients for spinal anaesthesia.[2,3] However, the analgesic effect of FNB and FIB blocks is only moderate because the obturator

How to cite this article: Sharma A, Rana S, Gupta B, Ranaut A, Khanoria R, Bhardwaj N. Evaluation of two doses (20 mL and 15 mL) of 0.25% bupivacaine in pericapsular nerve group block for patient positioning for sub-arachnoid block during hip fracture surgery: A single-centre, randomised comparative trial. Indian J Anaesth 2024;68:323-8.

nerve (ON) is not adequately affected as it is close to the inferno-medial acetabulum.[3]

The pericapsular nerve group (PENG) block is a novel method recently introduced by Girón-Arango *et al*.[4] to provide regional analgesia in hip fractures. It is an ultrasound (US)-guided technique that targets the articular branches of the femoral nerve, accessory ON, and possibly ON. A local anaesthetic (LA) agent is deposited in the musculo-fascial plane between the psoas muscle and pubic ramus.[5] The data for evaluating different volumes of LA agents for instituting the PENG block is lacking. Various researchers have used LA volumes ranging from 10 to 30 mL at different concentrations in the PENG block.[6]

This study was planned with a primary objective to evaluate and compare the effectiveness of two volumes of 0.25% bupivacaine (20 mL and 15 mL) by using the US-guided PENG block to relieve pain and improve the ease of positioning (EOP) of patients for instituting SAB. We hypothesised that 15 mL of 0.25% bupivacaine should give as desirable effects as 20 mL in the PENG block for positioning patients during SAB.

METHODS

This randomised, double-blinded (patient and assessor-blinded), comparative, parallel-group trial was conducted from March 2022 to January 2023. The approval for the research was obtained from the institutional ethics committee (vide no. HFW-H (DRPGMC) Ethics/2021/89, dated 29/09/2021), and the trial was registered at the Clinical Trials Registry-India (vide no. CTRI/2022/03/040748; URL: https://ctri.nic.in/Clinicaltrials). The study followed the guidelines as laid down in the Declaration of Helsinki (2013).

Informed written consent was obtained from the patients for participation in the study and for the use of data for research and educational purposes. Patients scheduled to undergo hip fracture surgery under SAB, belonging to the 40–90 years age group, American Society of Anesthesiologists (ASA) physical status I–III, body mass index (BMI) 18.5–29.9 kg/m^2 were included in this study. Patient refusal for spinal anaesthesia, infection at the puncture site, coagulopathies, neuropathies, parturients and any other contraindication to SAB were excluded from this study.

Sixty eligible patients were randomly allocated into two groups of 30 each to receive either 20 mL (group A) or 15 mL (group B) of 0.25% bupivacaine in the PENG block [Figure 1]. Different investigators were involved in the various steps of randomisation, blinding, concealment, and

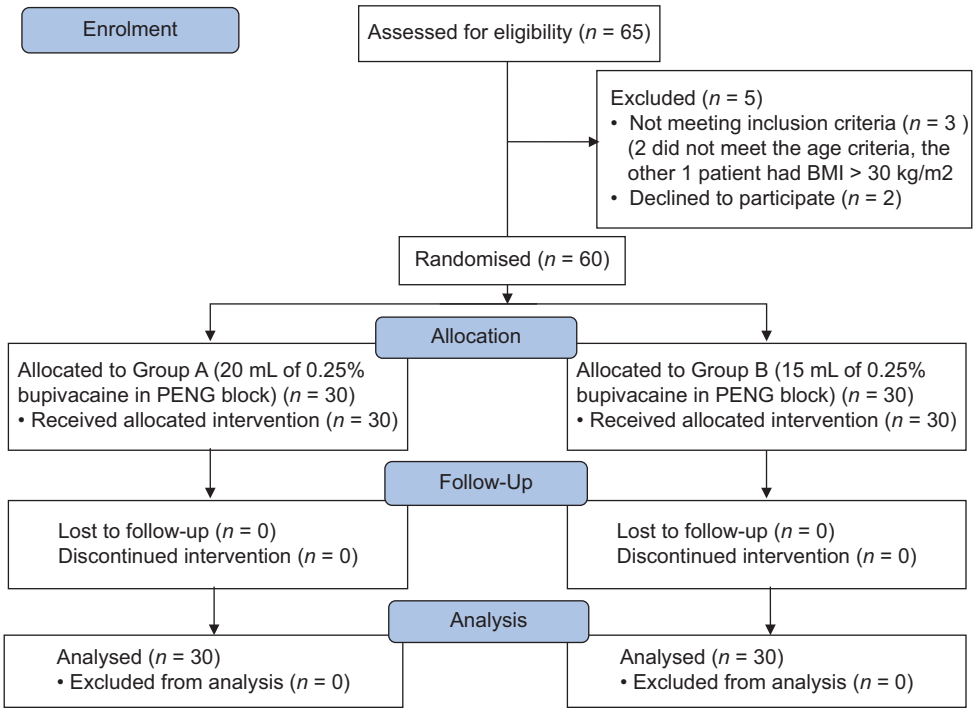

Figure 1: Study flow diagram according to Consolidated Standards of Reporting Trials (CONSORT) guidelines. n = number of patients, BMI = body mass index, PENG- pericapsular nerve group block

intervention. A computerised table generated the sequences for group randomisation on a 1:1 basis, and treatment allocation was concealed using consecutively numbered, sealed, opaque envelopes. Patients and members of the anaesthesia, surgical, and nursing teams were further blinded for the intervention. The blocks were placed by the same anaesthesiologist in all patients with adequate experience with the procedure technique. The anaesthesiologist placing the block preoperatively differed from the anaesthesiologist who managed the patient intraoperatively; the latter was also involved in noting the values of various study parameters.

Patients were informed about the 11-point numerical rating verbal analogue scale (VAS) for pain assessment ranging from 0 to 10, with 0 being 'no pain' and 10 being 'the worst imaginable pain'. In the operation room, monitors for non-invasive blood pressure (NIBP), 5-leads continuous electrocardiogram (ECG), and pulse oximeter (SpO_2) were attached. Under all aseptic precautions, with the patient in the supine position, a curvilinear US probe (3–5 MHz) (USG machine Edge II, Fujifilm Sonosite, Inc., USA) was placed at the anterior inferior iliac spine, directed towards the pubic ramus. It was moved medially and caudally to view the ilio-pubic eminence (IPE), iliopsoas tendon and muscle, pubic ramus, and a superficial pulsating femoral artery above the iliacus muscle. After instituting local anaesthesia at the point of needle entry, a 23-G spinal needle[7] was advanced using an in-plane lateral to medial approach till it reached the IPE. Here, a total of either 20 mL or 15 mL of LA drugs (bupivacaine 0.25%) was delivered (groups A and B, respectively) between IPE and iliopsoas tendon by connecting the 10 mL syringe to the needle by de-aired extension tubing. After assessing all the study parameters, the SAB was instituted after 20 minutes of the PENG block.

The study's primary outcome was to measure the EOP of patients with hip fractures to conduct SAB. This was graded as[8] 0: Not satisfactory (Patient is extremely uncomfortable, complaining of pain with a VAS score of 8–10 during positioning), 1: Satisfactory (Patient is uncomfortable and required support during positioning with a VAS score of 4–7), 2: Good (Patient is comfortable and needed minimal support during positioning with a VAS score of 1–3), and 3: Optimal (Patient is comfortable and required no support with a VAS score of 0 during positioning). Block failure was defined if the patient had an EOP of grade 0 for the conduct of SAB (extremely uncomfortable, complaining of pain with a VAS score of 8–10 during positioning). The secondary outcome was to measure the pain assessment at the rest and 15° leg raise positions before the block (T0), at 10 minutes (T10), and 20 minutes (T20) after the block (by utilising VAS score).

Based on a previous study, the sample size was calculated by considering the mean [standard deviation (SD)] of the EOP for SAB to be 2.65 (0.67).[8] Assuming there would be a 20% reduction in the values in the 15-mL group, with 80% power and an alpha error of 0.05, a sample size of 25 was obtained in each group. With a 20% non-response rate, the sample size of 60, with 30 patients in each group, was considered sufficient.

The data were recorded in Microsoft Excel, and results were evaluated using appropriate statistical tests in Epi Info software version 7.2 (CDC, Atlanta, Georgia, USA). The data's normality was checked using the Shapiro–Wilk test. Normally distributed variables (VAS pain scores and EOP grades) were described as mean (SD) (95% confidence interval (CI)) and compared using the *t*-test (paired for values within groups and unpaired for values across groups). Non-normally distributed variables such as age were mentioned as median and interquartile range and compared using the Wilcoxon test. Categorical variables (sex, type of fracture, patients with different grades, and patients requiring/not requiring support) were presented as *n* and compared using Chi-square and Fisher's exact test where appropriate. A *P* value of <0.05 was considered significant.

RESULTS

Sixty-five patients were assessed for eligibility; two refused to participate in the study. Two other patients did not meet the age inclusion criteria, while one had a BMI of $>30 kg/m^2$ [Figure 1]. Both groups were comparable concerning age, gender distribution, and ASA physical status [Table 1]. Both groups were also comparable concerning the type and side of the fracture.

The mean (SD) grade of EOP for spinal anaesthesia was 2.47 (0.73) (95% CI 2.19, 2.69) in group A and 1.86 (0.62) ((95% CI 1.65, 2.10) in group B ($P = 0.001$). The positioning for SAB was optimal (grade 3), good (grade 2), and satisfactory (grade 1) in 60%,

26.6%, and 13.3% of patients in group A and 13.3%, 60%, and 26.6% of patients in group B, respectively. All the blocks were placed successfully, as none of the group patients graded the EOP outcome as unsatisfactory (grade 0; VAS score 8–10) [Table 2]. Furthermore, 13.33% of patients required support during the positioning while instituting SAB in group A compared to 26.6% in group B. The SAB was initiated within 5–10 minutes after positioning in both groups.

The mean (SD) VAS scores of patients in groups A and B were comparable at baseline at T0 at both resting and leg raise positions. After the institution of the block, there was a significant decrease in VAS scores in both groups at 10 minutes ($P < 0.001$) and 20 minutes in both resting and 15° leg raise positions ($P < 0.001$) [Figure 2].

Comparative analysis revealed that the decrease in mean VAS pain scores was significantly more in group A as compared to group B at resting and 15° leg raise positions after both 10 minutes (resting: $P = 0.0004$; 15° leg raise: $P = 0.04$) and 20 minutes of the block (resting: $P = 0.001$; 15° leg raise: $P < 0.01$), respectively [Figure 2 and Table 3].

DISCUSSION

The EOP for SAB improved with both 20 mL and 15 mL volumes in the PENG block, but patients could sit much more comfortably and without support when 20 mL of the drug was used. In addition, the VAS pain scores decreased significantly with both doses of the drug in the PENG block at all time points, but the decrease in the pain scores was much more significant with 20 mL of 0.25% bupivacaine.

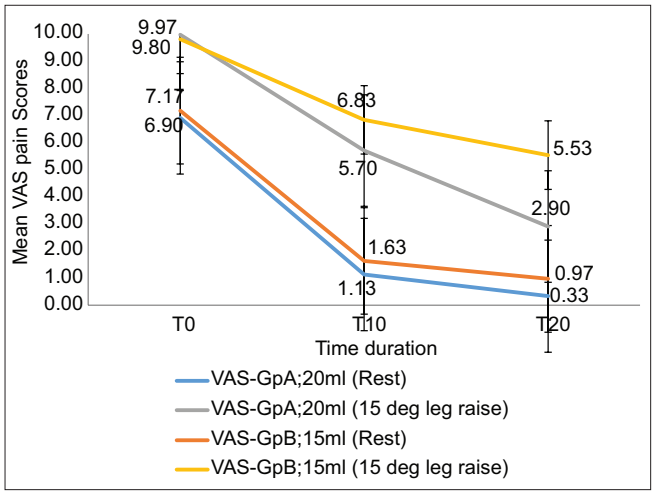

Figure 2: Comparative decline in VAS pain scores in both treatment groups over varied time points. VAS = verbal analogue scale, Gp=Group

PENG block is an effective technique to achieve perioperative analgesia and anaesthesia alone or in combination with other conventional techniques. With time, various aspects of the block, such as the volume of LA needed, its concentrations, and its use in combination with other blocks, are being explored.[6]

Girón-Arango *et al*.,[4] in the initial description of this block, used 20 mL of LA in five patients with hip fractures and found a significant reduction in the pain scores after 30 minutes of the block. This study formed the basis of further work on the PENG block and it's

Table 1: Demographic parameters

Parameter	Group A (*n*=30)	Group B (*n*=30)
Age (years)	70.50 (55.75–79.25)	71 (64–71.85)
Gender (Male/Female)	17/13	15/15
American Society of Anesthesiologists physical status (I/II)	7/23	5/25
Type of fractures (inter-trochanteric/ sub-trochanteric)	20/10	17/13

Data presented as median (interquartile range) or numbers. *n*=Number of patients

Table 2: Comparison of ease of positioning of patients for SAB in two groups

Parameters	Group A (*n*=30)	Group B (*n*=30)	*P*
Ease of positioning	2.47 (0.73) (2.19-2.69)	1.87 (0.63) (1.65-2.1)	0.001
Ease of positioning Grade 1/2/3	4/8/18	8/18/4	0.001
Positioning - Support required/ No or minimal support required	4/26	8/22	0.330

Data presented as mean (standard deviation) (95% confidence interval) or numbers. SAB=Sub-arachnoid block, SD=Standard deviation, CI=Confidence interval, *n*=Number of patients

Table 3: Comparison of VAS scores between the groups

	Time	Group A	Group B	*P*; df
VAS at rest position	T0	6.9 (0.80) (6.63–7.19)	7.17 (1.08) (6.77–7.58)	0.284; 1
	T10	1.13 (0.57) (0.92–1.35)	1.633 (0.718) (1.38–1.91)	0.004; 1
	T20	0.333 (0.479) (0.16–0.51)	0.97 (0.51) (0.29–0.65)	0.040; 1
VAS at 15° leg raise	T0	9.967 (0.182) (9.89–10)	9.8 (0.506) (9.64–9.94)	0.094; 1
	T10	5.7 (1.489) (5.17–6.25)	6.833 (0.985) (6.46–7.19)	0.001; 1
	T20	2.9 (1.647) (2.29–3.5)	5.53 (1.105) (5.12–5.91)	<0.001; 1

Data presented as mean (standard deviation) (95% confidence interval). VAS=verbal analogue scale, T0=time 0, T10=after 10 min, T20=after 20 min, SD=standard deviation, CI=confidence interval, df-degree of freedom, *n*=number of patients

effective usage. Our findings correlated with the study by Sahoo *et al*.,[8] who used 20 mL 0.25% bupivacaine with 4 mg dexamethasone in 20 patients and observed significant improvement in EOP for SAB after 30 minutes of the PENG block. The number of patients studied was less in their study, and the duration taken for block assessment was more compared to ours. Acharya and Lamsal[9], in their case series of 10 patients using low concentration (0.125%) 20 mL bupivacaine, also observed a significant reduction in the pain scores after 10 minutes and improvement in patient positioning at SAB, inferring that low concentration of equal volume LA can provide the similar results as noted in our study. Alrefaey and Abouelela[10], in their trial on 60 (30 in each group) patients comparing PENG block (20 mL of 0.375% ropivacaine) with controls, observed that the PENG block was associated with significantly lower pain levels and better patient sitting angle during positioning for spinal anaesthesia compared to the controls. Another randomised controlled trial in 60 (30 in each group) patients comparing the PENG block with controls also observed that the maximum pain score of patients receiving the PENG block was significantly lower than the control group at all time points.[11] Furthermore, a comparative assessment of FNB and the PENG block observed superior results in the PENG group regarding decreased pain levels.[12]

Few researchers have used lower drug volumes of 10 mL, while some preferred using a higher volume of 30 mL.[13-18] A lower drug volume LA (10 mL) in one of the studies decreased the pain scores in five patients with hip fractures before positioning for the neuraxial block. However, the patients did feel pain during the initial part of the positioning, which settled after the final sitting position.[13] Higher volumes of LA administration in the PENG block have been used for analgesia in acetabular fracture surgery.[14] Injecting a large volume of the drug for the PENG block can act as a lumbar plexus block as there is a possibility of the sub-pectineal ON block.[17] The block was performed in three patients with hip fractures using a total volume of 30 mL (20 mL of 0.5% bupivacaine and 10 mL of normal saline) and achieved adequate analgesia after 30 minutes. Although some researchers have documented a few adverse effects, such as quadriceps weakness[18], which might be related to the FNB, the possibility of such effects is extremely low.[19] We did not observe any adverse effects.

The study's strength includes its robust methodology, randomisation technique, and double blinding. Furthermore, this study adds to the existing knowledge about PENG block usage in hip fracture surgeries. The limitation of our study was that the results were evaluated only till the institution of the SAB. The assessment of the effectiveness of block intra-operatively and post-operatively was not done. Patient satisfaction scores were also not assessed, which is another limitation of this study. Furthermore, clinical trials with greater sample size may be needed to define optimal LA volume and concentration used in PENG block in adults and children and to establish the advantages of PENG block over other conventional techniques.

CONCLUSION

The present study infers that 20 mL of 0.25% bupivacaine is more effective than 15 mL volume for instituting a US-guided PENG block for patient positioning for SAB.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

Acknowledgements

Dr Manoj Kumar Gandhi, Senior Resident, Department of Community Medicine, Dr R.P. Govt. Medical College, Tanda, Kangra (H.P.), for the technical help in statistical analysis.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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