

# Analgesic Efficacy of Ultrasound-guided Fascia Iliaca Block and Three-in-one Block in Elderly Patients Undergoing Hip Surgeries: A Randomised Double-blinded Clinical Trial

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## ABSTRACT

**Introduction:** Hip surgery is a common surgical procedure in the elderly population, leading to significant pain. Ultrasound (USG) guided regional nerve blocks are a newer, safe, and effective postoperative pain control modality for elderly patients.

**Aim:** To compare the analgesic efficacy of Fascia Iliaca Compartment Block (FICB) with the three-in-one block for postoperative analgesia in elderly patients after lower limb orthopaedic surgeries.

**Materials and Methods:** It was a randomised double-blinded study performed at Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh, India on 60 elderly patients of American Society of Anaesthesiologists (ASA) class I-II scheduled for elective hip and femur shaft surgery under spinal anaesthesia. All patients were randomly allocated into two groups. Group A received ultrasound-guided FICB with 35-40 mL of 0.25% bupivacaine, and group B received ultrasound-guided three-in-one block with 35-40 mL of 0.25% bupivacaine after completion of surgery. In the postoperative period, pain was assessed using the Visual Analogue Scale (VAS), and inj. diclofenac sodium 1.5 mg/kg intravenous (i.v.) was given as rescue analgesic whenever VAS was  $\geq 4$ . The primary outcome was changes in VAS scores at rest and during passive leg elevation between the two groups at various time

intervals within 24 hours. Secondary outcomes measured were the duration of analgesia and total rescue analgesic required in 24 hours. Qualitative variables were compared between groups using the Chi-square test. A p-value  $< 0.05$  was considered statistically significant.

**Results:** Demographic data were comparable in both groups, with a mean age of  $65.11 \pm 1.89$  years in Group A and  $65.57 \pm 1.46$  years in Group B. The VAS score at rest was significantly lower in Group A compared to Group B at the 6<sup>th</sup> hour ( $1.21 \pm 1.17$  vs.  $1.61 \pm 0.78$ ) and 12<sup>th</sup> hour ( $2.80 \pm 0.12$  vs.  $3.33 \pm 0.92$ ), respectively. The VAS score during passive movement was significantly lower in Group A at the 6<sup>th</sup> hour and 12<sup>th</sup> hour compared to Group B. The mean time for the first demand of rescue analgesic was  $9.27 \pm 2.16$  hours in the Fascia Iliaca Compartment Block (FICB) group and  $6.67 \pm 1.45$  hours in the three-in-one group. The difference was significant, with a p-value of 0.006. The mean requirement of total rescue analgesia was  $133.33 \pm 33.27$  mg in Group A and  $198.53 \pm 29.16$  mg in Group B, which was statistically significant.

**Conclusion:** The fascia iliaca block had lower pain scores both at rest and during passive movement compared to the three-in-one block. Total analgesic requirement was lower in the fascia iliaca group compared to the three-in-one block group.

**Keywords:** Bupivacaine, Postoperative period, Rescue analgesia, Ultrasonography

## INTRODUCTION

Hip surgery is a common surgical procedure in the elderly population, leading to significant pain in the postoperative period. Poor pain management can hinder rehabilitation because it interferes with physiotherapy, leading to stiff joints, delayed mobility, and delayed improvement [1-5]. Multimodal analgesia has been critical in facilitating early recovery and rehabilitation in these patients [4,5]. Regional blocks alone or combined with other modalities have been used as a safe alternative in elderly patients [5-7]. Three-in-one nerve blocks are among the most popular peripheral nerve blocks used to assist postoperative analgesia following lower limb surgery. They concurrently inhibit the femoral, Lateral Femoral Cutaneous (LFC), and obturator nerves. These three nerves provide major sensation to the lower extremity, and the ability to inhibit the individual distribution allows for successful analgesia and anaesthesia for lower limb surgeries [8].

The FICB was described as a substitute for the three-in-one block for usage in paediatric patients [9]. FICB is a modified form of the femoral nerve block. FICB has emerged as a competitive alternative to the three-in-one block due to its anatomical safety profile and convenience of placement. Local anaesthetic is injected beneath

the fascia iliaca, blocking the femoral nerve and the LFC nerve [10]. The obturator nerve is variably blocked in FICB, not blocked all the time. There is limited research comparing FICB and three-in-one block techniques for postoperative pain management in elderly patients [11-14]. The present study was conducted to compare the analgesic efficacy of ultrasound-guided FICB and three-in-one block in patients with lower limb surgeries operated under spinal anaesthesia.

## MATERIALS AND METHODS

It was a randomised double-blinded study carried out at Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh, India after clearance from the Institutional Ethical Committee (Ethical clearance no: 80/2019-20). All the procedures were conducted in compliance with the 2013 Helsinki Declaration from January 2020 to June 2021. All patients were given a thorough description of the procedure before providing informed written consent.

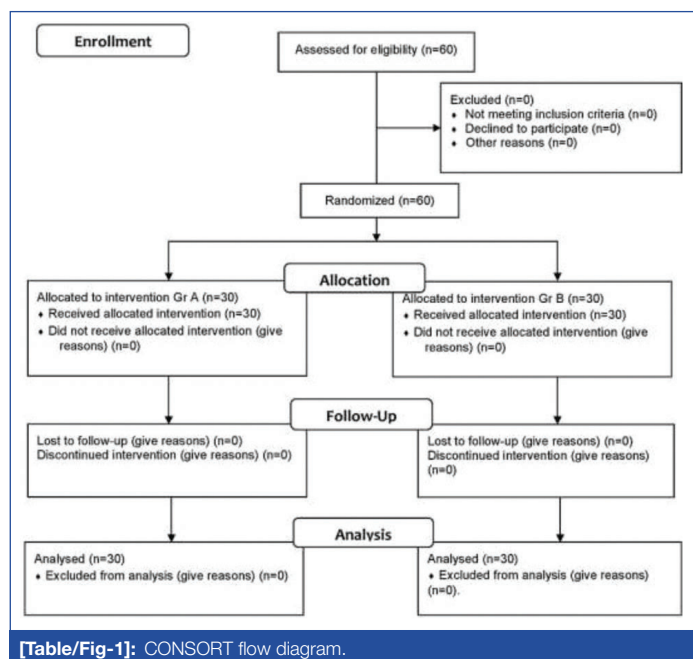
**Sample size calculation:** The formula used to determine the sample size was  $n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2/r)}{(\mu_1 - \mu_2)^2}$ , where 'n' is the sample size,  $\alpha = 0.05$ ,  $\mu_1$  (mean in Group-1) = 3.43,  $\sigma_1$  (Standard Deviation in Group-1) = 2.36,  $\mu_2$  (Mean in Group-2) = 4.57,

$\sigma_2$  (Standard Deviation in Group-2)=0.15, at 12 hours with Ratio (Group-2/Group-1)=1 (as found in a prior study by Pandya M and Jhanwar S), it yielded a result of 60 with 80% power [15].

**Inclusion and Exclusion criteria:** The study comprised 60 patients above 60 years of age who were American Society of Anaesthesiologists (ASA) class-I or II candidates of either sex, scheduled for hip and femur shaft surgery. The present study excluded participants with a history of amide local anaesthetic allergy, hepatic or renal insufficiency, and any contraindication to regional anaesthesia.

### Study Procedure

A total of 60 patients were enrolled for the study, divided into two groups of 30 each by computer-generated random numbers. All patients completed the study, and none were lost to follow-up as depicted in Consolidated Standards of Reporting Trails (CONSORT) flow chart [Table/Fig-1]. All patients were given a thorough description of the procedure before providing informed written consent. An anaesthesiologist who was not involved in the data gathering process opened the envelope containing the computer-generated random sequence numbers and revealed them in the procedure area. All the blocks were given by the same person experienced in USG-guided nerve blocks. The data recorder was not present at the time the block was given. Thus, they were unaware of the assigned group. All patients were instructed to use the VAS (0-10), where 0 denoted no pain and 10 denoted the most intense agony they had ever felt. The patients were then asked to choose the number on the scale that most accurately reflected their level of discomfort. For both groups, patients were kept nil per oral 6-8 hours before surgery.



[Table/Fig-1]: CONSORT flow diagram.

Preloading was performed with injection Ringer's lactate at a dose of 10-15 mL/kg after establishing the intravenous line, and injection midazolam at a dose of 0.5-1 mg i.v. was administered. Under strict aseptic conditions, spinal anaesthesia was administered using a 25-gauge Quincke's spinal needle with 2.5-3.0 mL of 0.5% bupivacaine heavy at L2-L3 or L3-L4 intervertebral spaces. Continuous monitoring was carried out.

At the end of the surgery, patients in Group A received ultrasound-guided FICB in the supine position using a portable ultrasound machine (Sonosite M-Turbo, with a linear transducer of 13-6 MHz; Fujifilm Medical Systems, Lexington) as per the procedure outlined by Range C and Egele C [14]. The transducer was positioned in a sterile manner to locate the femoral artery, iliopsoas muscle, and fascia iliaca. The transducer was moved laterally until the sartorius muscle was identified. A skin wheal was raised after the identification of the

Sartorius muscle, and the 21G block needle was inserted in-plane. A "pop" was felt as the needle entered the fascia iliaca. An anaesthetic solution of 35-40 mL of 0.25% bupivacaine was administered following a negative blood aspiration, with the needle tip confirmed by ultrasonography. For ten minutes, distal compression was administered caudal to the site of the needle puncture to encourage the proximal diffusion of the local anaesthetic medication.

Patients in Group B received an ultrasound-guided three-in-one block in the supine position with legs slightly abducted, and the groin was prepared and draped in a sterile fashion. The ultrasound was placed to the right of the patient's bed, and then ultrasound gel was applied to the probe. Sterile gloves were donned, and the sterile probe cover was placed over the probe. The transducer was placed over the inguinal ligament, and the inguinal ligament was noted as a linear hyperechoic structure. As the probe was slid caudally, the large femoral vein and the non compressible femoral artery were identified. Lateral to these structures, the femoral nerve sheath was visualised and appeared as a hyperechoic triangular structure. A small skin wheal over the target site with local anaesthetic was made. The injection was made using a 21G block needle, which was inserted 2 cm distal to the inguinal ligament in a lateral to medial direction at a 30-degree angle. Once the needle came into view on the US monitor, the tip was positioned as close as possible to the femoral nerve, and after negative aspiration for blood, 35-40 mL of 0.25% bupivacaine was injected. The anaesthetic solution was spread in a cephalad direction and appeared as an expanding hypoechoic area within the fascial space surrounding the nerve sheath. Distal pressure was applied during and shortly after injection for proximal spread.

The primary outcome was changes in VAS scores at rest and during passive elevation of the leg between the two groups at various time intervals within 24 hours. Secondary outcomes measured were the duration of analgesia and the total rescue analgesic required in 24 hours.

All the patients were assessed for pain using a 10-point visual analogue scale and haemodynamic parameters such as heart rate and mean arterial pressure at 0 min (baseline), 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 12 hours, and 24 hours after performing the block. In the postoperative period, inj. diclofenac sodium at a dose of 1.5 mg/kg i.v. was given as rescue analgesic when VAS was  $\geq 4$ . The time to the first analgesic (duration of analgesia) and the total doses of analgesic required during 24 hours were also noted. Side-effects such as haematoma at the injection site, intravascular injection, and local anaesthetic toxicity were noted.

### STATISTICAL ANALYSIS

The quantitative variables were expressed as mean $\pm$ SD and compared between groups using unpaired t-tests and within groups across follow-ups using paired t-tests. Qualitative variables were compared between groups using the Chi-square test. A p-value  $<0.05$  was considered statistically significant. The data were stored in an MS Excel spreadsheet, and statistical analysis was performed using IBM Statistical Package for Social Sciences (SPSS) version 20.0.

### RESULTS

Demographic data were comparable in both groups, with a mean age of 65.11 $\pm$ 1.89 years in Group A and 65.57 $\pm$ 1.46 years in Group B.

No statistically significant differences were found between the groups regarding the patients' clinical characteristics [Table/Fig-2].

Postoperatively, pain was assessed by VAS at 0 minutes, 30 minutes, 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 6 hours, 12 hours, and 24 hours both at rest and during movement. A significant difference was found in VAS scores for pain between groups A and B, both during rest and passive movement. The VAS scores at rest

Characteristics	Group A (n=30) (Mean±SD)	Group B (n=30) (Mean±SD)	p-value
Age (in years)	65.11±1.89	65.57±1.46	0.750
Gender (male/female)	19/11	23/7	0.130
ASA I/II	18/12	18/12	0.500
BMI (kg/m <sup>2</sup> )	22.63±1.63	22.53±1.14	0.392
Duration of surgery (min)	82.07±7.01	81.00±6.35	0.270

**[Table/Fig-2]:** Comparison of demographic data of patients.

Unpaired student t-test for age, BMI and duration of surgery, Chi-square test for gender and ASA class, SD: Standard Deviation; ASA: American Society of Anaesthesiologists physical status; BMI: Body Mass Index, Group A: Fascia iliaca block, Group B: Three in one block

were higher and statistically significant in group B compared to group A at the 6<sup>th</sup> hour (mean pain score in Group B=1.61±0.78 vs Group A=1.21±1.17), and at the 12<sup>th</sup> hour (mean pain score in Group B=3.33±0.92 vs Group A=2.80±0.12). The VAS score during passive movement was higher and statistically significant in Group B at the 6<sup>th</sup> hour (mean pain score in Group B=3.01±1.1 vs Group A=1.95±0.9), and at the 12<sup>th</sup> hour (mean pain score in Group B=3.60±0.12 vs Group A=2.85±0.92) [Table/Fig-3].

Time after block	At rest Group A Group B	p-value	During passive elevation Group A Group B	p-value
0 min	0.00 0.00	-	0.00 0.00	-
30 min	0.00 0.00	-	0.00 0.00	-
1 h	0.00 0.00	-	0.00 0.00	-
2 h	0.00 0.00	-	0.00 0.00	-
3 h	0.00 0.00	-	0.03±0.18 0.00	0.161
4 h	0.00 0.00	-	0.73±0.87 0.97±0.89	0.154
5 h	1.33±0.71 1.43±0.82	0.308	2.01±0.89 2.17±1.01	0.446
6 h	1.21±1.17 1.61±0.78	0.012*	1.95±0.9 3.01±1.1	0.001*
12 <sup>th</sup> h	2.80±0.12 3.33±0.92	0.015*	2.85±0.92 3.60±0.12	0.016*
24 <sup>th</sup> h	3.33±1.21 3.70±1.24	0.125	5.60±1.13 5.47±1.07	0.321

**[Table/Fig-3]:** Mean Visual Analogue Scale (VAS) at different time intervals.

Using Unpaired t-test\* = Significant, h=hour, Group A=Fascia iliaca block, Group B=Three in one block

The mean time for the first demand of rescue analgesic was 9.27±2.16 hours in the FICB group and 6.67±1.45 hours in the three-in-one group. The difference was significant with a p-value of 0.006. The mean requirement of total rescue analgesia was 133.33±33.27 mg in Group A and 198.53±29.16 mg in Group B, which was statistically significant with p-value=0.001 [Table/Fig-4].

Rescue analgesia	Group A		Group B		p-value
	Mean	±SD	Mean	±SD	
Time of 1 <sup>st</sup> rescue analgesia (h)	9.27	±2.16	6.67	±1.45	0.006*
Mean rescue analgesic used in 24 h (mg)	133.33	±33.27	198.53	±29.16	0.001*

**[Table/Fig-4]:** Comparison of duration of analgesia and mean rescue analgesic used in 24 hour.

Using unpaired t-test, \*Significant, SD: Standard deviation, h: hour, Group A=Fascia iliaca block, Group B=Three in one block

In Group A, patients demanded a single dose of rescue analgesic in 12 patients and two doses in 18 patients, whereas in Group B, three patients demanded a single dose of rescue analgesic, two doses in 12 patients, three doses in 12 patients, and four doses in three patients during 24 hours. This difference was statistically significant [Table/Fig-5].

The haemodynamic parameters in both groups were comparable. There was no significant difference between the heart rate and mean blood pressure in the two groups. In a study done by Kratz T et al., 52 patients undergoing hip arthroplasty were included for statistical analysis [Table/Fig-6,7] [19].

None of the patients in either group had any complications such as haematoma at the injection site, intravascular injection, or local anaesthetic toxicity.

Total number of analgesic demands in 24 hour	Number of patients in Group A	Number of patients in Group B	p-value
Demand 1	12	3	0.0001*
Demand 2	18	12	0.0001*
Demand 3	0	12	0.0001*
Demand 4	0	3	0.019*

**[Table/Fig-5]:** Comparison of the number of patients requiring postoperative rescue analgesia between the groups.  
Sample proportion test, \* Highly significant

## DISCUSSION

There is a continuous search for various available options that aim to reduce postoperative pain in elderly patients after hip surgery. It is crucial in an attempt to hasten functional recovery and minimise the systemic side effects related to analgesics. Regional nerve block under ultrasound guidance is the favoured alternative these days. The present randomised double-blinded study was done to compare the analgesic efficacy of FICB and the three-in-one block for postoperative pain relief after hip surgeries in elderly patients. It has shown that both ultrasound-guided FICB and ultrasound-guided three-in-one block provided good quality of postoperative analgesia after femur shaft and hip surgery, as evidenced by low VAS scores and low postoperative analgesic requirements.

In the present study, the block was applied in both groups after the completion of surgery. Patients did not feel pain in the immediate postoperative period due to the effect of spinal anaesthesia. The VAS score started to increase after four hours in both groups, and supplemental analgesia was required after the 6<sup>th</sup> hour. The VAS score was significantly lower in Group A at rest and during passive movement at the 6<sup>th</sup> and 12<sup>th</sup> hour. Similarly, in a study done by Pandya M and Jhanwar S, who compared FICB and the three-in-one block after spinal anaesthesia, observed that the VAS score was significantly lower in the FICB group at the 12<sup>th</sup> hour than in the three-in-one block group [15]. The findings of the present study were similar to the research by Ingle J et al., who compared FICB with the three-in-one block and found that the three-in-one block had higher pain scores than the FICB group at the 6<sup>th</sup> and 12<sup>th</sup> hour in the postoperative period [16]. Reavley P et al., also found that patients of the FICB group had better pain relief compared to the three-in-one block group [17]. Chen L et al., studied the FICB block in elderly patients and concluded that for elderly patients with hip fractures, FICB provided longer analgesia compared to the control group [18].

The total duration of analgesia was 9.27±2.16 hours in the fascia iliaca group and 6.67±1.45 hours in the three-in-one group in the present study. In a similar study done by Pandya M and Jhanwar S, the duration of analgesia was 12 hours in the FICB group and 10 hours in the three-in-one block group [15]. The duration of analgesia was longer in the FICB group (12 hours versus 9.27 hours) compared to the three-in-one block group in a similar study by Ingle J et al., [16]. The findings were consistent with the study by Reavley P et al., who found a longer duration of analgesia in the FICB group (11 hours versus 9 hours) compared to the three-in-one block group [17].

In the present study, the total dose of analgesic required in 24 hours was 198.53±29.16 mg in Group B, compared to Group A with a mean value of 133.33±33.27 mg. Pandya M and Jhanwar S studied the consumption of the total analgesic in both groups [15]. They found that the total consumption of analgesic in 24 hours in the FICB group was lower, which was consistent with the present study. Ingle J et al., and Reavley P et al., also studied the consumption of total analgesic in 120 patients undergoing lower limb orthopaedic surgeries under subarachnoid block [16,17]. In their study, the total consumption of analgesic was lower in the FICB group compared to the three-in-one block group.

Groups	Heart rate (beats/min) 0 min 30 min										
				1 h	2 h	3 h	4 h	5 h	6 h	12 h	24 h
Group A	Mean	72.60	72.00	71.73	72.13	72.00	73.13	73.27	73.80	72.20	72.93
	±SD	±8.11	±8.63	±9.08	±8.52	±8.07	±7.93	±7.31	±7.34	±8.24	±7.66
Group B	Mean	70.87	71.00	70.87	70.57	70.67	70.80	72.13	72.53	72.80	72.00
	±SD	±6.9	±7.42	±7.61	±7.89	±6.93	±7.06	±6.58	±7.06	±7.21	±7.18
p-value <sup>1</sup> (A vs B)		0.188	0.316	0.345	0.231	0.248	0.117	0.265	0.249	0.383	0.314

**[Table/Fig-6]:** Changes in heart rate (beats/min) after application of block.  
Using unpaired t-test, SD: Standard Deviation; h: hour, Group A=Fascia Iliaca block, Group B=Three-in-one block

Groups	MAP (mmHg) 0 min 30 min										
				1 h	2 h	3 h	4 h	5 h	6 h	12 h	24 h
Group A	Mean	72.73	73.27	73.33	74.73	74.80	75.00	71.07	71.73	71.80	71.33
	±SD	±6.31	±6.02	±5.29	±5.67	±5.19	±5.25	±12.8	±13.24	±13.09	±12.85
Group B	Mean	72.47	72.67	73.07	72.67	73.80	74.33	74.33	73.53	73.53	73.40
	±SD	±5.84	±5.64	±6.21	±5.81	±5.93	±5.68	±5.31	±5.35	±5.58	±4.93
p-value (A vs B)		0.433	0.346	0.429	0.084	0.245	0.319	0.101	0.246	0.254	0.207

**[Table/Fig-7]:** Mean arterial blood pressure (mmHg) changes between the groups.  
Using unpaired t-test, SD: Standard Deviation; h: hour, Group A= Fascia Iliaca block, Group B=Three-in-one block

There was no significant difference between the heart rate and mean blood pressure in the two groups. In a study done by Kratz T et al., fifty-two patients undergoing hip arthroplasty were included for statistical analysis [19]. The FICB group had significantly lower systolic blood pressures during and after surgery, lower diastolic blood pressure postoperatively, and lower heart rates during surgery and postoperatively when compared to the control group. Thus, block patients have improved perioperative haemodynamic stability most likely attributable to an overall reduced sympathico-adrenergic tone. The present study showed similar results. In a study done by Bergmann I et al., they concluded that peripheral nerve blocks give greater haemodynamic stability [20].

Authors did not encounter any adverse effect of the block. As the block was given under USG guidance, procedure-related side-effects were abolished. In a study by McRae PJ et al., paramedic staff gave the FIC block in a prehospital setting and reported no obvious side-effects [21]. Foss NB et al., also did not observe any side-effects of the FICB technique [22].

### Limitation(s)

The limitation of the present study was that, as the blocks were administered under the effect of spinal anaesthesia, authors were unable to compare the onset of sensory blockade. Also, authors did not measure the motor strengths of the hamstring muscles in the postoperative period, which is a known complication of these blocks.

### CONCLUSION(S)

Ultrasound-guided FICB was found to be more effective for postoperative analgesia in terms of pain score, duration of analgesia, and total rescue analgesic needed when compared to the three-in-one block after orthopaedic surgery of the hip in elderly patients. These blocks were not associated with any complications. Authors thus recommend including the FICB block as part of multimodal analgesia, as its analgesic effect is longer-lasting than the three-in-one block and it can also help avoid opioid-related side effects. Further trials are recommended to evaluate the ideal dose and volume for the FICB block in the management of postoperative pain.

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- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
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