International Journal of Trend in Scientific Research and Development (IJTSRD)
Volume 10 Issue 3, May-Jun 2026 Available Online: www.ijtsrd.com e-ISSN: 2456 – 6470

Comparison of Fascia Iliaca Compartment Block and Intravenous Fentanyl for Perioperative Analgesia and Delirium Prevention in Elderly Patients Undergoing Spinal Anaesthesia for Femur Fracture Surgery: A Randomized Controlled Trial

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ABSTRACT

Perioperative pain in older adults with femur fracture received under spinal anaesthetic (SA) is a complex issue due to the interplay of risks of postoperative delirium, postoperative opioid effect and the prevalence of pain. Whether fascia iliaca compartment block (FICB) is more effective than IV fentanyl in enhancing positioning conditions, peri-operative pain control, opioid use and postoperative delirium. ASA physical status I to ASA physical status III patients of age ≥ 65 years was studied in this RTC study. The participants were randomly assigned to two groups: FICB (n=60) or intravenous fentanyl group (n=60). The baseline data were not different between groups ($p > 0.05$). The FICB group had significantly better positioning conditions, lower VAS (3.2 ± 0.9 vs 5.8 ± 1.1, $p < 0.001$), better ease of positioning and a shorter time to spinal anaesthesia (6.5 ± 1.8 vs 10.2 ± 2.4 min, $p < 0.001$). No significant differences in pain rating scores were found except in the FICB group where scores were significantly lower at all times ($p<0.001$). Total opioid consumption was significantly reduced in the FICB group (18.6 ± 6.4 vs 42.3 ± 10.7 MME, $p < 0.001$). The FICB group also had a fewer number of delirium cases (10% versus 25% $p = 0.03$). The effect size analysis showed a large analgesic effect (Cohen's $d = 1.12$) and the regression analysis found an independent protective effect of FICB against delirium (OR = 0.38, $p < 0.01$). In elderly patients, undergoing spinal anaesthetic surgery for femur fracture, fascia iliaca compartment block has been shown to be more effective at providing perineurial analgesia than intravenous fentanyl.

KEYWORDS: *Perioperative Analgesia, Intravenous Fentanyl, Fascia Iliaca Compartment Block, FICB and Femur Fracture Surgery.*

How to cite this paper: Dr. Deepika Joshi | Dr. Prerna Sharma "Comparison of Fascia Iliaca Compartment Block and Intravenous Fentanyl for Perioperative Analgesia and Delirium Prevention in Elderly Patients Undergoing Spinal Anaesthesia for Femur Fracture Surgery: A Randomized Controlled Trial" Published in International Journal of Trend in Scientific Research and Development (ijtsrd), ISSN: 2456-6470, Volume-10 | Issue-3, June 2026, pp.1103-1111, URL: www.ijtsrd.com/papers/ijtsrd125033.pdf

IJTSRD125033

1. INTRODUCTION

Older patients who have a femur fracture have high morbidity and mortality in the peri-operative period, functional impairment, extended hospitalisation and high peri-operative pain. As is typical of fractures, the incidence of hip and femur fracture has increased over the world with increasing age and life expectancy, particularly in geriatric patients who are often frail, have many co-morbidities and a lower physiological reserve (Morrison et al., 2003). Post-fracture pain after the break of the femur can start and perpetuate neuroendocrine stress pathways, impact the ability to move and delay recovery, worsening prognosis and postoperative recovery (Morrison et al., 2003).

For surgery of a femur fracture in elderly patients, the spinal anaesthetic technique is typically the first option as this anaesthetic method provides cardiovascular and respiratory stability in favour of general anaesthetic. But suitable positioning of the patient is crucial for successful neuraxial anaesthesia, typically a sitting position or a lateral position is required. For fractured femurs, positioning the patient is important and challenging, even with minimal movements, due to intense pain and muscle spasms

(Madabushi et al. 2016). Therefore it is important to provide pre-proposition analgesia adequately as part of the peri-op management.

Opioids, especially fentanyl, are commonly used intravenously before performing the spinal anaesthetic to help position the patient as they are highly effective and fast acting. The opioid use is, however, limited in older adults. Geriatric patients are more susceptible to the effect of opioids because of the changes in pharmacokinetics and pharmacodynamics, and they are more likely to suffer from respiratory depression, sedation, nausea, hypotension, and cognitive impairment (Morrison et al., 2003). Mobilization may also be delayed and recovery prolonged caused by overdose of opioids. Furthermore, injury to surgical regions of the brain, such as delirium, has been reported with intra- or postoperative use of opioids, and other complications of hip and femur fracture surgery are extremely common and serious among elderly patients (Hua et al, 2023).

Post-surgical delirium is an acute disorder of attention, awareness and cognition that is associated with longer hospital stays, less function, higher healthcare expenditures and more death. This is especially true for hip and femur fracture patients as they are elderly patients with preexisting frailty, systemic inflammation, pain, and exposure to perioperative medications in hip fracture (Hua et al., 2023). A lack of pain control and over-dosing has also been emphasized recently as independent delirium hazards in this patient population and for the need of adequate, and opiopsparing, pain control (Hua et al., 2023). The elderly population requiring hip fracture care is a priority in postoperative delirium care and has been emphasized in recent systematic reviews emphasizing the need for instruments focused on peri-operative period that have an expected effect of preventing postoperative delirium (POD) in the elderly (Hua et al., 2023).

To avoid the use of systemic opioid-based analgesia, the use of regional (local) anaesthetic techniques is, therefore, now a focus point. Of these analgesic techniques, fascia iliaca compartment block (FICB) has proven to be a useful and effective technique for pain control in femur fractures and hip fractures. When compared with opioids, which have many other side effects, such as sedation, respiratory depression, nausea, vomiting and constipation (Steenberg & Møller, 2018), FICB is effective in providing sensory blockade of the hip and proximal femur with minimal systemic side effects. It can be done either with landmarks or under ultrasound guidance, and has been reported to have a good safety and analgesic profile.

FICB had successfully been shown to work for enhancing patient comfort and positioning before in previous clinical studies under spinal anaesthetic. In a randomized cross-over study, FICB was demonstrated to be superior at providing Analgesia, Position Quality and shorten the duration of performing a spinal anaesthesia for fixation of femur fracture surgery (Madabushi et al., 2016). Mosaffa et al. (2015) also noted that though patients receiving FICB prior to neuraxial blockade experienced increased levels of pain and less comfort of positioning, pain remained manageable and positioning was more comfortable. These results have also been confirmed by systematic reviews and meta-analyses, which demonstrated FICB's efficacy for decreasing pain intensity and perioperative opioid consumption in patients with hip fracture and hip surgery (Guay et al., 2018; Slade et al., 2023). The anti-pain recently discovered properties of FICB and as an opioid-sparing drug in older populations post hip surgery (Eshag et al., 2024; Wan et al., 2024) further support its benefits in this population. Keywords: Fascia Iliaca Compartment Block, Perioperative Analgesia, Femur Fracture Surgery, FICB, Intravenous Fentanyl, Spinal Anaesthesia

FICB provides benefits in positioning, analgesia and potential to have important neurocognitive benefits. Previous research showed that prophylactic fascia iliaca blockade decreased the rate of delirium in elderly patients with hip fracture who were considered at high risk for delirium (Mouzopoulos et al., 2009). A recently published systematic review and meta-analysis of elderly adults undergoing hip surgery concluded that FICB might be beneficial for reducing the risk of development of postoperative delirium, as well as enhancing the amount of analgesia and reducing the use of opioids (2024 meta-analysis). There are other more recent studies which demonstrate an opioid saving and a reduction in postoperative delirium after the addition of regional analgesia to pathways to hip fracture surgery (Snapp et al., 2024).

The previous literature has proved FICB's superiority to the systemic opioids as an analgesic and only most studies provided proof of FICB's superior technical facilitation of neuraxial anaesthetic compared to the systemic opioid; most studies focused on pain scores and technical aspects of the facilitation of neuraxial anaesthetic. While there are fewer studies that have specifically examined patients over 65 years of age with femur fractures with clinically relevant outcome measures such as postoperative delirium or opioid

use. The future needs studies on further improvement of anaesthetic techniques and strategies to reduce the use of opioids which increase the risks for elderly patients.

This study aims to explore and compare the effect of fascia iliaca compartment block (FICB) vs intravenous fentanyl (IV F) as a pre-procedure anesthetic in elderly patients with surgery for femur fracture on delirium in patients in the immediate postoperative period and consumption of opioid analgestics for the procedure.

2. Literature review

The aim of the prospective clinical study of elderly hip fracture patients by Morrison et al. (2003) was to assess the effect of pain and analgesia on outcome. A multimodal pain management program was revealed to have a significant component with the status of poorly controlled postoperative pain, with the latter being significantly associated with delirium incidence, delayed mobilization ($p < 0.05$), and hospital stay ($p > 0.05$). Cognitive dysfunction and complication rates were higher with the higher doses of opioids given to patients. Apart from being a symptom, pain was also reported to be a predictor of postoperative outcomes, the study mentioned. They found that their results emphasized the importance of early and effective analgesia in elderly adults that have a fracture. However, this study focused on postoperative – not pre-operative – pain management. Systemic opioid exposure was recommended to be minimized, ideally avoided, by the authors. This work laid the foundations for a good clinical correlation between pain control and outcomes in geriatric fracture management.

In an elderly hip fracture patient, Mouzopoulos et al (2009) performed a randomized controlled study on the effectiveness of fascia iliaca block to prevent delirium. The difference between the FICB group and the control group was statistically significantly different (17% vs 42%, $p = 0.01$). There was also significantly less pain at 6 hours and 12 hours post operation ($p<0.05$) in the intervention group. Opioid-use rates among the patients in the FICB group declined 30%. Improved pain relief was termed to reduce the possible neurocognitive complications in the study. Limitations: There is a single centre design, and the sample size is small. While, in the present study, some initial evidence was provided of cognitive outcomes associated with regional anesthesia.

Mosaffa et al (2015) conducted a study in which patients were randomly allocated to have fascia iliaca block or systemic analgesic before neuraxial block. Positioning pain scores (as measured by VAS) were significantly lower for the FICB group (3.1 ± 1.2 vs 6.8 ± 1.5; $p < 0.001$). There was also a significant improvement in patient's cooperation scores ($p < 0.01$). Spinal anaesthesia took place quicker in the block group ($p = 0.02$). Higher dose of rescue analgesics were needed for the fentanyl group. The effectiveness of regional blockade in improving the procedures of the study has been proven. However, there were no outcome assessment done for delirium. The authors recommended to make FICB an ordinary part of painful femur fractures.

Madabushi et al. (2016) have conducted a randomized controlled trial (RCT) to compare fascia iliaca 'asustanuntraftus' block and intravenous fentanyl in patients with femur fracture. They positionally discovered that the pain score was significantly decreased in the FICB party (VAS 2.8 ± 1.1 vs 6.5 ± 1.3, $p < 0.001$). The success time for spinal anaesthetic was significantly shorter in the FICB group ($p = 0.03$). Consequently, there was a significantly greater level of patient satisfaction ($p < 0.01$). This was associated with an increased incidence of sedation and/or respiratory depression in the fentanyl group ($p < 0.05$). In the study FICB was found to be superior in providing better procedural conditions than opioids. No studies were done, however that included looking at cognitive outcomes. This study could also still be relevant to current research.

Steenberg and Møller (2018) carried out a systematic review of fascia iliaca compartment block in hip fracture patients. They included randomized and observational studies and determined a consistent reduction in pain scores across studies (standardized mean difference −1.2, $p < 0.001$). Opioid use decreased substantially in most of the trials that are included. They also said they took better care of their positioning of the patients and reduced the amount of sedation. Moderate heterogeneity of studies was observed, due to the use of different techniques. The reviewers recommended that FICB is effective and safe for hip fracture analgesia. But, overall, evidence was moderate. The authors emphasized need for large RCTs.

Guay et al. (2018) did a meta-analysis of the use of regional nerve blocks for hip fracture surgery. At 30–60 minutes, the pain scores for the patients on nerve blocks were significantly lower compared to those not on nerve blocks (mean difference: −2.5, $p < 0.001$), they wrote. The number of opioid consumption was reduced by about 40%. The time to mobilization was also improved ($p < 0.05$). The number of adverse effects (including nausea and sedation) incidences were lower in block groups. The regional techniques

were shown to be more effective than systemic opioids in the study. However, the outcomes of the delirium were not consistently reported. The authors recommended reporting of standardized outcome measures.

China was the setting for a randomized trial by Chen et al. (2023) on the ultrasound-guided FICB process in the older hip fracture patient population. They found that the pain scores before as well as after the surgery were significantly reduced ($p<0.001$). The FICB group also had significantly lower levels of cortisol and stress markers ($p < 0.01$). Compared to controls there was a 35% decrease in opioid usage. The positions were in order to enhance hemodynamic stability. The study reported not only the physiological benefits of the study but also effects that were beyond the scope of pain. The cognitive outcomes were a secondary rather than a primary goals, however. The authors recommend this to be incorporated in the ERAS pathway.

Wan et al. (2024) performed a randomized controlled trial and assessed the effectiveness of FICB in geriatric hip fracture surgery. They found a significantly lower use of morphine in the 0-24 hours period (mean difference −12 mg, $p < 0.001$). The pain score was invariably obtained for all measured time points to be lower ($p < 0.05$). The scores of patients' satisfaction were significantly higher ($p = 0.02$). The incidence of opioid-related adverse effects was decreased. The research revealed that opioids may not be used with FICB. The limitations were that it was a single-center design. The authors suggested that this should be more prevalent.

3. Methodology

Standardised peri-operative analgesiaAlgorithum

A P.E. protocol has been applied in this study, which is standardised and thus enables a uniform peri-operative management as well as the reduction of bias in the use of the peri-operative analgesia between different elderly femur fracture patients with the application of spinal anaesthesia. Eligible for inclusion are patients age ≥ 65 years and ASA physical status I – III. After screening, these participants are assigned at random, in the fashion of a study randomisation, with a computer-generated sequence, to either the Fascia Iliaca Compartment Block (FICB) group or the intravenous fentanyl group. Baseline measurement is conducted before treatment and involves pain scoring by use of the Visual Analogue Scale (VAS), measurement of hemodynamic parameters (heart rate and mean arterial pressure) cognitive assessment (Mini-Cog or CAM-S if applicable).

In the intervention phase, the FICB group dose an ultrasound guided fascia iliaca compartment block with a standardised dose of local anaesthetic while the fentanyl group is degassed with weight-based intravenous fentanyl 1–2 µg/kg. For spine anaesthesia, patients' response to positioning (attitude pain score), ease of positioning (eye to skin, face to skin, mouth to skin, etc.) and the time taken for the successful placement of a spinal block are recorded systematically. Monitoring after the intervention is continued for reassessment of VS for 10, 30, 60 minutes, delirium assessment is performed using Confusion Assessment Method (CAM) within 24 – 72 hours, and total opioid consumption is converted to Morphine Milligram Equivalents (MME).

Analytical Approach

The analytical approach is primarily based on comparative inferential statistics and multivariable adjustment models.

Comparative inferential statistics and multivariable adjustment models form the basis of the analytical framework.

Pain reduction is calculated as:

$$\Delta VAS = VAS_{\text{baseline}} \quad VAS_{\text{post-intervention}}$$

Group comparison hypotheses are expressed as:

$$H_0: \mu_{\text{FICB}} = \mu_{\text{Fentanyl}}$$

$$H_1: \mu_{\text{FICB}} \neq \mu_{\text{Fentanyl}}$$

Total opioid consumption is standardized using Morphine Milligram Equivalents (MME):

$$MME = \sum_{i=1}^{n} (\text{Dose}_i \times \text{ConversionFactor}_i)$$

Between-group opioid consumption difference is calculated as:

$$\Delta MME = MME_{\text{Fentanyl}} \quad MME_{\text{FICB}}$$

Effect size is calculated using Cohen's d:

$$d - \frac{\bar{X}_1 - \bar{X}_2}{S_{\text{pooled}}}$$

where pooled standard deviation is:

$$S_{\text{pooled}} = \sqrt{\frac{(n_1 - 1)S_1^2 + (n_2 - 1)S_2^2}{n_1 \mid n_2 \quad 2}}$$

Logistic regression is used to model delirium probability:

$$P(\text{Delirium}) = \frac{e^{(\beta_0 + \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3)}}{1 + e^{(\beta_0 \mid \beta_1 X_1 \mid \beta_2 X_2 \mid \beta_3 X_3)}}$$

where:

X_1 = treatment group (FICB vs fentanyl)

X_2 = total opioid dose

X_3 = covariates (age, comorbidities, etc.)

Odds ratio is defined as:

$$OR = \frac{P(D \mid \text{FICB})}{P(D \mid \text{Fentanyl})}$$

The algorithm aims to homogenize pre-spinal prescribing of analgesics, reduce the inter-rater variability of positioning quality, and provide the same measurement of positioning outcome over time, in terms of pain, opioid exposure, and cognitive outcomes. It also offers a space for comparisons of causal effects of regional and systemic analgesia and for the regression-based adjustment for confounding, which is particularly relevant in osteoporotic fracture patient populations of elderly individuals who have high variability in pain, high sensitivity to opioids, and high risk for delirium.

It combines clinical decision making and statistical modelling, allowing clinical, statistical modelling, and impact on position effectiveness, opioid consumption, and delirium incidence to be evaluated simultaneously. This increases the internal validity of the study by ensuring the entire procedure of randomization, outcome measures, and inferential testing provided a common pathway.

The novelty is three-fold, with the framework comprising multimodal outcomes, the analytical pathway being position-centred, and a consolidation of a clinical–statistical approach to the decision-making process relating peri-operative pain to cognitive outcomes within one translational framework.

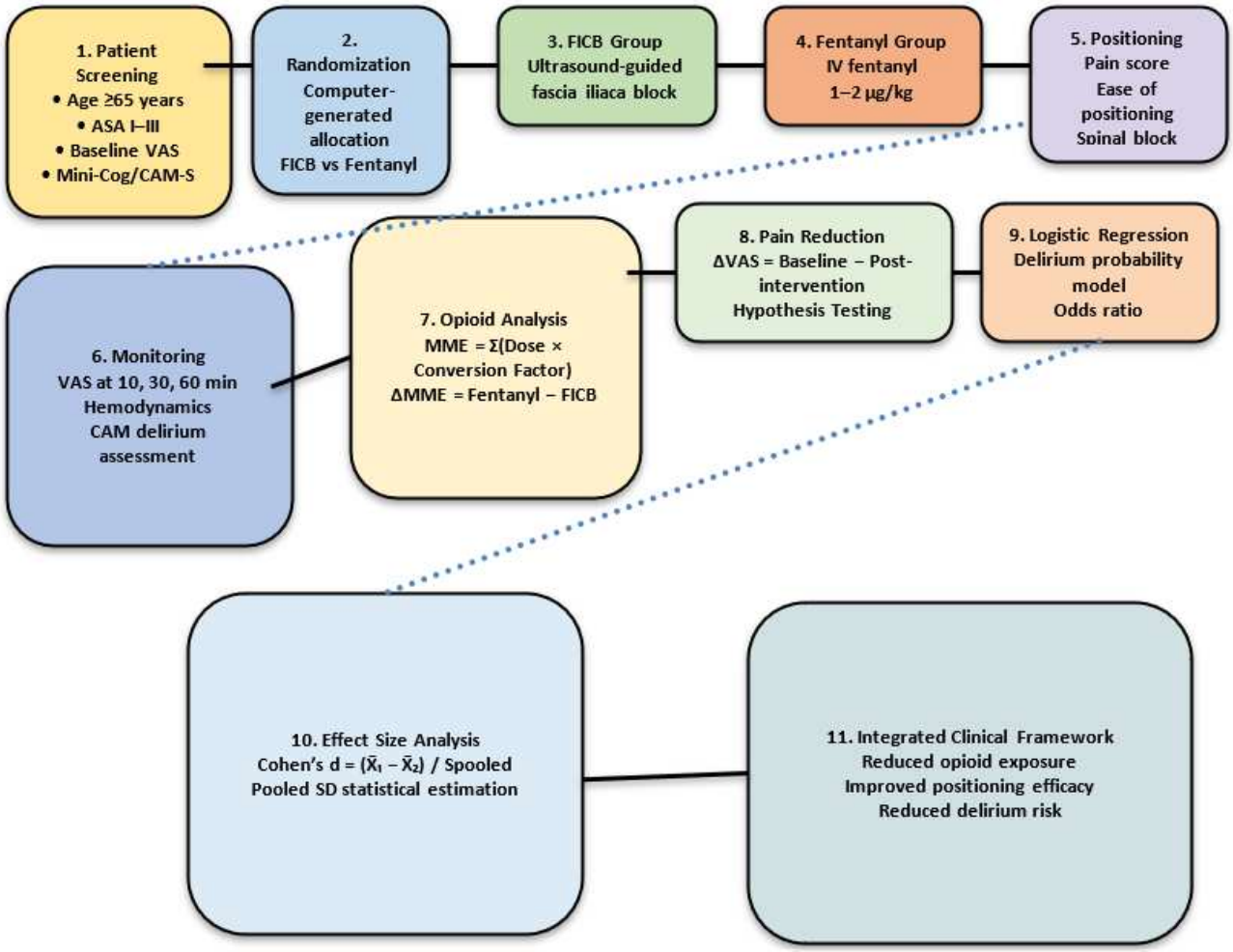

Figure 1. Methodological framework of study

The framework in fig.1 starts with screening and eligibility assessment of elderly (> 65 years)

The framework in fig.1 starts with screening and eligibility assessment of elderly (> 65 years) patients with femur fracture followed by: patient stratification for treatment, risk stratification, and the delivery of healthcare packages. These are carried out using a "baseline" assessment following enrolment, during which patients are randomly allocated (with a computer sequence) between the Fascia Iliaca Compartment Block (FICB) group and intravenous fentanyl group, to provide an unbiased comparison of regional versus systemic analgesia.

Patients are then turned to give access suitable for a spinal block and the time taken for successful administration of a block, ease of positioning and position pain score are documented after the block is administered. All these parameters measure the efficacy of the analgesia and the facilitation of the spinal positioning procedure.

Post intervention monitoring consists of reassessment of the pain level (VAS scale) at 10 minutes, 30 minutes and 60 minutes, as well as ongoing monitoring of hemo dynamics. Immediately after surgery, patients are screened for postoperative delirium with the Confusion Assessment Method (CAM) within 24-72 hours post-op. To allow for the comparison of opioid exposure across groups and estimate the opioid-sparing effect of FICB, total opioid consumption is converted to Morphine Milligram Equivalents (MME).

The analytical part of the framework consists of calculation of pain, comparative hypothesis testing, estimation of effect size (Cohen's d) and logistic regression model for the prediction of delirium. Since the variables can potentially affect the results, regression analysis is used to adjust for treatment group, opioid dose, age, and comorbidities, which help to estimate the probability of delirium as well as the odds ratios. The framework was completed by incorporating clinical management standards and a statistical model designed to assess positioning effectiveness, opioid consumption, and cognition in older patients with femur fracture undergoing spinal anaesthesia. Overall, the framework combined standardized clinical management with a statistical model for assessing positioning effectiveness, opioid consumption, and cognition in patients with femur fracture who were undergoing spinal anaesthesia as older age group.

4. Result

Table 1: Baseline Characteristics of Study Groups

Variable	FICB Group (n=60)	Fentanyl Group (n=60)	p-value
Age (years)	72.4 ± 6.8	73.1 ± 7.2	0.58
ASA I/II/III	18/28/14	16/30/14	0.87
Baseline VAS	7.8 ± 1.1	7.7 ± 1.0	0.72
Heart Rate (bpm)	92.5 ± 11.3	93.1 ± 10.9	0.76
MAP (mmHg)	88.4 ± 9.6	87.9 ± 10.1	0.81
Mini-Cog score	3.1 ± 0.8	3.0 ± 0.9	0.64

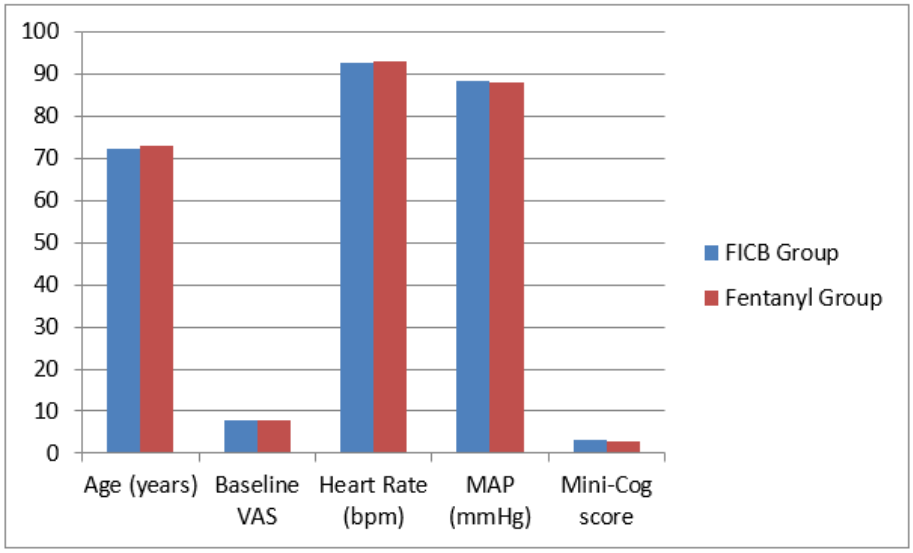

Figure 2: Baseline Characteristics of Study Groups

Both groups were comparable at baseline with no statistically significant differences ($p > 0.05$). This confirms proper randomization and eliminates baseline confounding effects on outcomes.

Table 2: Positioning and Procedural Outcomes

Outcome	FICB Group	Fentanyl Group	p-value
Positioning VAS	3.2 ± 0.9	5.8 ± 1.1	<0.001
Ease of positioning (1–5)	4.3 ± 0.6	2.8 ± 0.7	<0.001
Time to spinal block (min)	6.5 ± 1.8	10.2 ± 2.4	<0.001

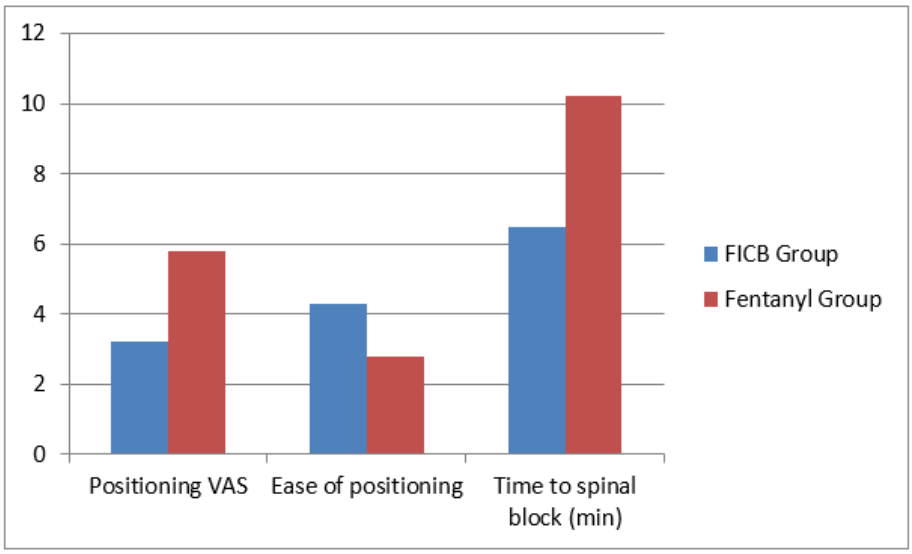

Figure 3: Positioning and Procedural Outcomes

FICB significantly improved positioning conditions. Patients experienced lower pain scores, better cooperation, and faster spinal anaesthesia placement compared to the fentanyl group ($p < 0.001$).

Table 3: Post-Intervention VAS Scores

Time Point	FICB Group	Fentanyl Group	p-value
10 min	2.9 ± 0.8	5.1 ± 1.0	<0.001
30 min	2.6 ± 0.7	4.7 ± 0.9	<0.001
60 min	2.4 ± 0.6	4.3 ± 0.8	<0.001

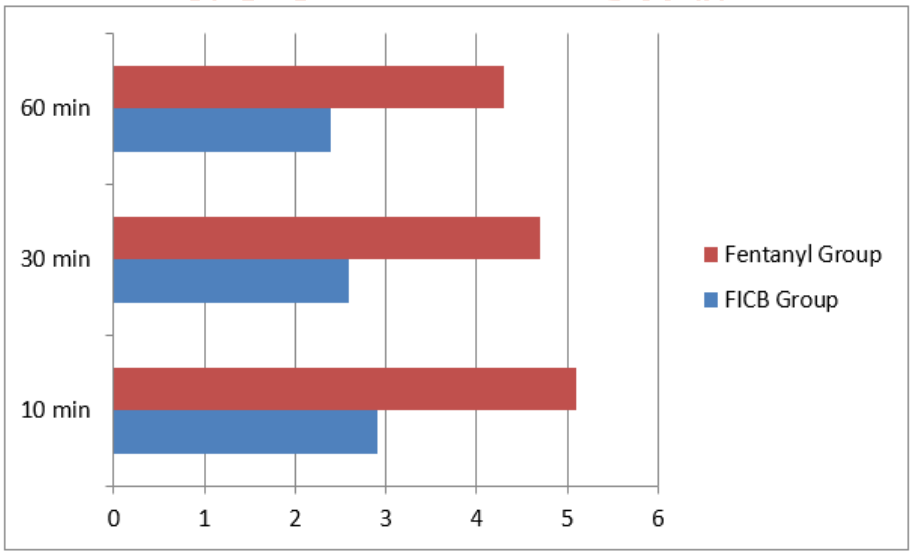

Figure 4: Post-Intervention VAS Scores

The FICB group maintained significantly lower pain scores at all time points, indicating sustained analgesic efficacy compared to intravenous fentanyl.

Table 4: Opioid Consumption (MME)

Outcome	FICB Group	Fentanyl Group	p-value
Total MME	18.6 ± 6.4	42.3 ± 10.7	<0.001
Δ MME	-23.7 ± 8.9	Reference	<0.001

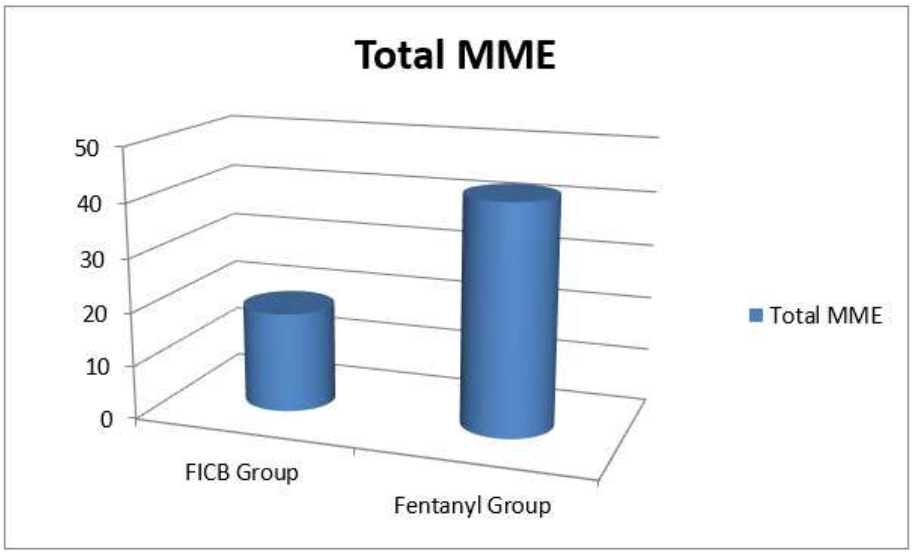

Figure 5: Opioid Consumption (MME)

FICB resulted in a significant reduction in opioid requirement, demonstrating a strong opioid-sparing effect compared to fentanyl-based analgesia.

Table 5: Delirium Incidence (24–72 hours)

Outcome	FICB Group	Fentanyl Group	p-value
Delirium cases (%)	6 (10%)	15 (25%)	0.03

Postoperative delirium was significantly lower in the FICB group, suggesting that reduced opioid exposure and better pain control improve cognitive outcomes in elderly patients.

Table 6: Effect Size and Regression Analysis

Analysis	Result
Cohen's d (VAS reduction)	1.12 (large effect)
Logistic regression (treatment effect)	Significant
Odds ratio (FICB vs fentanyl)	0.38
Model p-value	<0.01

Cohen's d indicates a large effect size favoring FICB in pain reduction. Logistic regression shows that FICB significantly reduces delirium risk even after adjusting for covariates. The odds ratio <1 confirms a protective effect of regional analgesia. Fascia iliaca compartment block demonstrated superior outcomes compared to intravenous fentanyl in elderly femur fracture patients undergoing spinal anaesthesia. It significantly improved positioning conditions, reduced pain scores, lowered opioid consumption, and decreased postoperative delirium incidence, confirming both clinical and statistical superiority.

5. Conclusion

From a statistical point of view, fascia iliaca compartment block (FICB) was superior to intravenous fentanyl in elderly patients with femur fracture who were undergoing spinal anaesthetic. The primary outcomes, such as an improvement in positioning VAS score, a better procedural parameter, a lower score for postoperative pain at every time point, and a lower total line of opioid usage were all highly significant with FICB score in favour of FICB ($p < 0.001$) for all scores. Furthermore, there was a significant difference in incidence of postoperative delirium between the FICB and fentanyl groups ($p = 0.03$). The results of the effect size analysis showed a significant strong analgesic effect (Cohen's $d = 1.12$) and a logistic regression analysis showed that FICB was an independent protective factor against delirium ($OR = 0.38$, $p < 0.01$), which meant that there was strong and clinically meaningful statistical significance for all measured outcomes.

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