Section: Anaesthesiology

Original Research Article

A PROSPECTIVE, RANDOMIZED CLINICAL TRIAL TO COMPARE THE EFFICACY OF FASCIA ILIACA COMPARTMENT BLOCK WITH INTRAVENOUS FENTANYL FOR POSITIONING THE PATIENT DURING SPINAL ANAESTHESIA POSTED FOR FEMUR FRACTURE SURGERY

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Abstract

Background: The most used anaesthetic method for orthopaedic surgeries is regional anaesthesia1. In comparison to general anaesthesia, regional anaesthesia has many benefits, including better perioperative pain relief, reduces the need for systemic analgesics, less polypharmacy, avoids needless airway manipulations, earlier ambulation, and a lower risk of deep vein thrombosis2. In addition to improving patient comfort, pain treatment helps position patients more optimally for subarachnoid blocks. . It has been demonstrated that nerve blocks are a reliable and secure solution for pain alleviation. This study is designed to compare ultrasound-guided fascia iliaca block and intravenous fentanyl for positioning during spinal anesthesia for femur fracture surgeries. The aim is to compare the efficacy of ultrasound-guided fascia iliaca compartment block and intravenous fentanyl for positioning during spinal anesthesia in femur fracture surgeries. The objective is to compare Patient comfort and Time taken for giving spinal anaesthesia, Hemodynamic parameters. Study Design Randomized Prospective Study. **Materials and Methods:** Patients meeting the inclusion criteria were selected and informed about the risks and benefits of the study. After informed consent was obtained, patients who were willing to be included in the study were enrolled. They were preoperatively evaluated, clinically examined and assessed. A total of 60 patients were included in the study. They were randomly divided into two groups. FICB group: ultrasound guided Fascia Iliaca Compartment Block was administered preoperatively 15 mins before subarachnoid block. FENT group: intravenous fentanyl was administered preoperatively.1st dose-0.5mcg/kg I.V ,2nd dose -0.25mcg/kg ,3rd dose -0.25mcg/kg administered with an interval of 5 minutes between doses. **Conclusion:** It is concluded that Fascia Iliaca Compartment Block is more efficacious than intravenous fentanyl for positioning during spinal anaesthesia in surgery for fracture femur. Fascia Iliaca Compartment Block provides superior analgesia, better quality of patient positioning, greater patient satisfaction thereby reducing the time taken to perform spinal anaesthesia in sitting position compared to i.v. fentanyl in fracture femur surgery.

INTRODUCTION

The most used anaesthetic method for orthopaedic surgeries is regional anaesthesia.[1] In comparison to general anaesthesia, regional anaesthesia has many benefits, including better perioperative pain relief, reduces the need for systemic analgesics, less polypharmacy, avoids needless airway manipulations, earlier ambulation, and a lower risk of deep vein thrombosis.[2]

The periosteum has the lowest pain threshold of the deep somatic structures, making fracture of the femur a common orthopaedic injury that causes the patient

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severe pain.[3] In addition to improving patient comfort, pain treatment helps position patients more optimally for subarachnoid blocks. Midazolam, ketamine, opioid, and nonsteroidal anti-inflammatory drug (NSAID) medications are used to lessen preoperative pain and help these patients get into a better position. It has been demonstrated that nerve blocks are a reliable and secure solution for pain alleviation.

Nerve fibres have been located and blocked using a variety of methods. From early blind techniques that caused paresthesia through the use of peripheral nerve stimulators and, more recently, the use of ultrasonography, peripheral nerve block has come a long way. Ultrasound has become more significant recently and offers anesthesiologists a useful alternate technique for locating and securely blocking nerve fibres.

This study is designed to compare ultrasound-guided fascia iliaca block and intravenous fentanyl for positioning during spinal anesthesia for femur fracture surgeries.

Anatomy of Fascia Iliaca

The iliaca fascia forms the posterior wall of the femoral capsule in the medial compartment, also known as the lacuna vasorum. It houses the genitofemoral nerve's femoral branch as well as the femoral vessels. The fascia iliaca forms the roof of the lateral compartment, known as the lacuna musculorum, which transmits the femoral nerve and the iliopsoas muscle.

The iliac fascia separates the lacuna musculorum from the lacuna vasorum with fibers that connect to the capsule of the hip joint, forming a functional partition between the two lacunae.

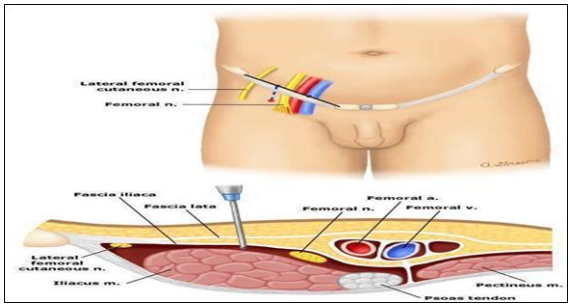

Figure 1: Anatomy of Fascia Iliaca. Fascia Iliaca Compartment

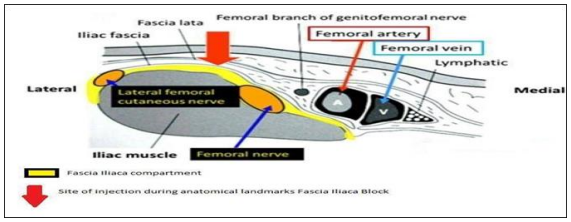

Figure 2: Fascia iliaca compartment. Fascia iliaca compartment block

The following are relations to the Fascia Iliaca Compartment. Below the iliacus muscle and the psoas major muscle, the area is covered above by the posterior fascia iliaca surface. The gap between the quadratus lumborum muscle and its fascia is continuous craniomedially with the space on the medial side, which is restricted by the spine. The inner lip of the iliac crest restricts the area craniolaterally.

Using the orientation technique, Dalens et al,[14] were the first to describe the Fascia Iliaca block in children. It can be carried out in the preoperative context, the emergency room, and prehospital care. For patients with femur fractures, it is a reasonably simple, safe, and successful technique to administer intraoperative analgesia.[15] This block can be performed by landmark technique and also with Ultrasound guidance.The success rate of the block will rise with ultrasound guidance.[16]

The femoral and lateral femoral cutaneous nerves, as well as the obturator nerve, are periodically blocked by the fascia iliac compartment block, which entails injecting a local anaesthetic directly below the iliac fascia. Because the injection is carried out outside the femoral artery and nerve, there is very little chance of neurovascular problems.

Landmark approach:[17]

The inguinal ligament and femoral pulse are identified and the length of the inguinal ligament is divided into thirds. One centimetre distal to the intersection of the centre and outer thirds, a blunt-tipped needle is inserted. The fascia lata and iliaca are pierced using a blunt-tipped needle that is inserted slightly cephalad. You will hear two "pops" as the needle pierces these two structures. Afterward, 30 to 40 ml of local anaesthetic are administered following negative aspiration.

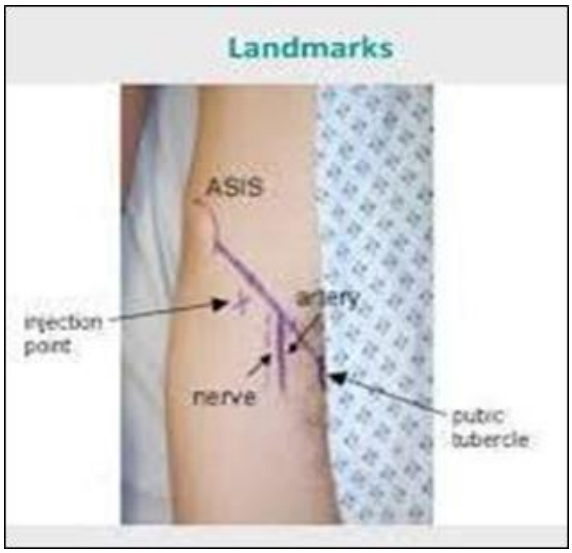

Figure 3: Fascia Iliaca Compartment block- Landmark technique

Ultrasound guided approach:[18]

The patient is placed in the supine position. Just below the inguinal ligament, a high-frequency linear ultrasound probe is positioned horizontally across the front of the thigh. The femoral artery is first located. The iliac fascia-covered iliac muscle is then located

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laterally to the artery. Following that, the needle is inserted either in-plane or out-of-plane. Observing the rebound as the fascia is perforated, the needle is advanced until its tip is below the iliac fascia. Local anaesthetic is applied after a negative aspiration, and the spread of the anaesthetic should be apparent on the ultrasound machine.

Figure 4: Fascia Iliaca Compartment block under USG guidance. Probe position

MATERIALS AND METHODS

Inclusion Criteria

- Patients with ASA grades I and II.
- Patients of both sexes, in the age group of 18 to 55 years.
- Patients with a femur fracture planned for elective surgeries.
- Patients who give valid informed consent

Exclusion Criteria

- Patients not meeting the inclusion criteria.
- Patients belonging to ASA grade III or IV.
- Patients with hemorrhagic diathesis, neurological disorders, psychiatric disorders.
- Previous femoral bypass surgery.
- Patients with an allergy to local anesthetics or opioids.
- Patients with polytrauma, infection at the injection site.
- Patients on previous opioid treatment.
- Patients with spinal deformities.
- Patients who refuse consent

Materials

- Boyle's machine
- Laryngoscope with different blade sizes
- Endotracheal tubes
- Other airway aids used in case of difficult intubation
- Mind Ray ultrasound device with a linear probe
- Ultrasonic jelly
- Sterile tray with sterile towel, gauze bags, sponge tongs
- 25G Spinal needle (Quincke's)
- 18G venflon needle

Monitors

- NIBP
- ECG
- Pulse oximeter

Methodology

Patients meeting the inclusion criteria were selected and informed about the risks and benefits of the study. After informed consent was obtained, patients who were willing to be included in the study were enrolled. They were preoperatively evaluated, clinically examined and assessed. A total of 60 patients were included in the study. They were randomly divided into two groups.

- FICB group: ultrasound guided Fascia Iliaca Compartment Block was administered preoperatively.
- FENT group: intravenous fentanyl was administered preoperatively.

All patients was kept nil per oral for at least 6 hours prior to method. Patients moved to the operating room half an hour before the planned procedure.

Basic vital signs, such as heart rate, non-invasive blood pressure, oxygen saturation in room air, respiratory rate, ECG pattern was recorded. Intravenous access was provided using an 18G IV cannula and IV fluid was started. A local anesthetic test dose of 0.1 ml Inj. Lignocaine 2% intradermally administered the night before surgery. All patients were premedicated with Inj.Ondansetron 0.1 mg/kg intravenously. Oxygen was administered by Hudson mask @ 4 L/min.

The FICB patient group was be placed in the supine position. Local anesthetic solution was prepared with 15 ml of 0.5% levobupivacaine and 15 ml of distilled water and thus 30 ml of 0.25% levobupivacaine. The ultrasound machine was turned on and the linear array probe was covered with a sterile bandage after application of ultrasound gel. The probe placed horizontally across the front of the thigh just below inguinal ligament. The ultrasound setting used for visualization was on a frequency 10 MHz and depth 3-4 cm. Gain and focus was adjusted according to the scanned image. The femoral artery was identified first. Then the hip muscle covered by the fascia iliaca identified laterally to the artery. The 18G needle then was introduced in the ultrasound plane beam. The needle advanced until the needle tip is located under fascia iliaca (pop-up felt when the fascia is pierced) and after negative aspiration, a local anesthetic was injected and its spread visualized on the ultrasound screen. Fascia iliaca compartment the block was performed 15 minutes before the subarachnoid block.

A group of patients in FENT group received titrated doses of Inj. Fentanyl i.v 1st dose-0.5mcg/kg I.V ,2nd dose -0.25mcg/kg ,3rd dose -0.25mcg/kg administered with an interval of 5 minutes between doses.

- Hemodynamic variables such as heart rate, noninvasive blood pressure, oxygen saturation, respiratory rate were recorded after blockade/IV fentanyl and at five-minute intervals until positioning.
- Analgesia provided by either regimen was assessed using a visual analog scale score 15

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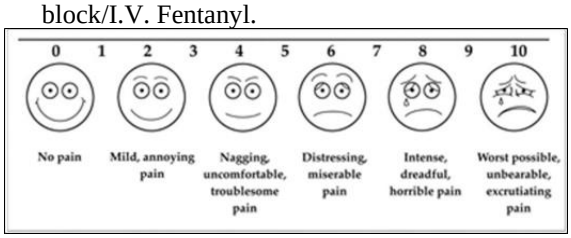
minutes (ie, during positioning) after the block/I.V. Fentanyl.



The subarachnoid block was performed in a sitting position under strict aseptic precautions in the L3-L4 space using a 25G Quincke needle 0.5% bupivacaine (hyperbaric, dextrose 80mg/ml) + 25mcg of fentanyl.

- The quality of patient positioning for spinal anesthesia was scored by another anesthesiologist blinded to the method of analgesia with a score of 0,1,2,332

0-Unsatisfactory
1 - satisfactory
2-good
3-optimal

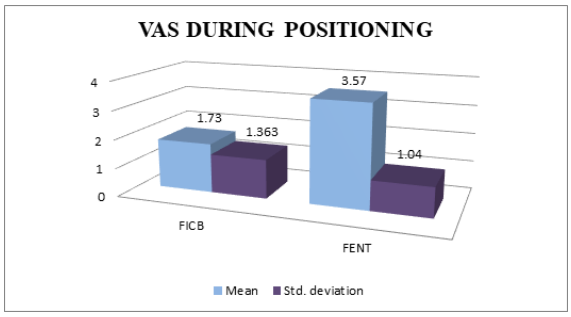
- The time of spinal anesthesia was recorded (time from the beginning of positioning to the end of the administration of drug).
- Patient satisfaction was also recorded

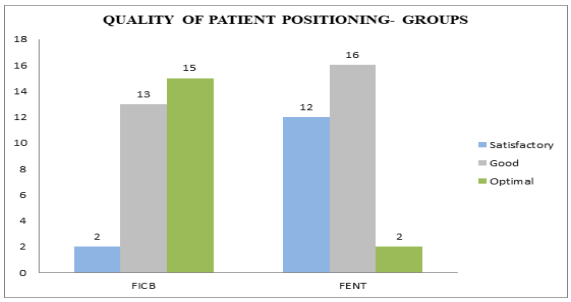
1 - satisfactory
2- unsatisfactory

- Postoperative analgesia was standardized in all patients of both groups using Inj. Tramadol 50 mg I.V. 8th hour; the first dose was given whenever the patient complained of pain.

The collected information were recorded and proceeded for statistical analysis.

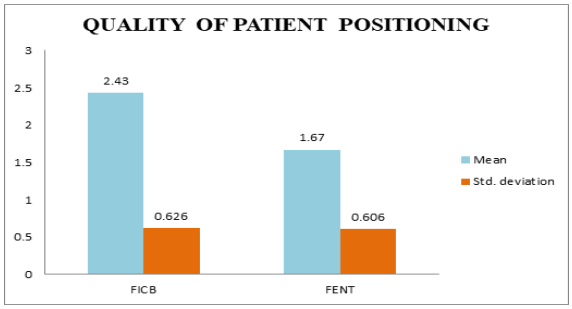
RESULTS

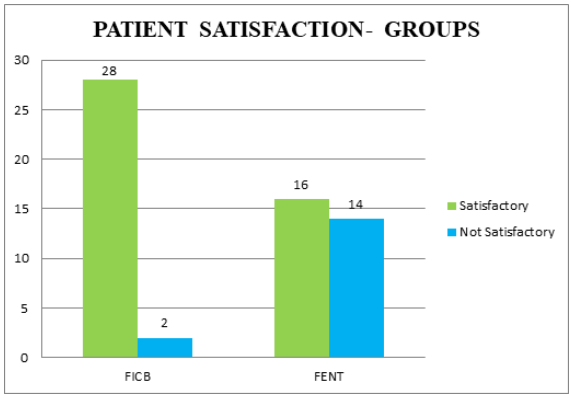




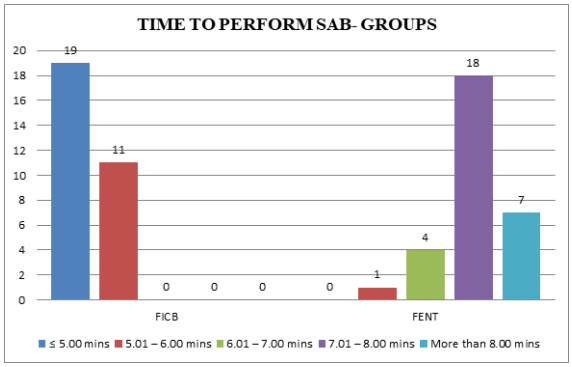
Quality of Patient Positioning

Data analysis: Descriptive statistics was done for all data and were reported in terms of mean values and percentages. Suitable statistical tests of comparison were done. Continuous variables were analyzed with the unpaired t test. Categorical variables were analyzed with the Chi-Square Test. Statistical significance was taken as $P < 0.05$. The data was analyzed using SPSS version 29.0.0.0. and Microsoft Excel 2007.

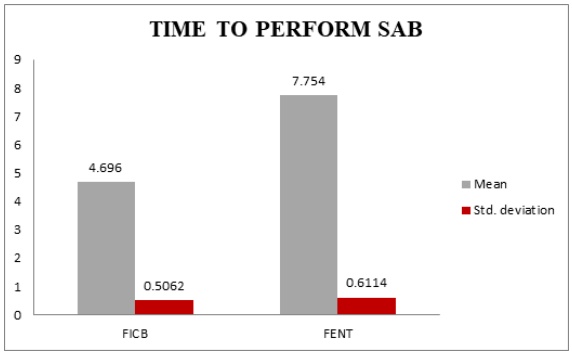




Patient Satisfaction



Time to perform sab:



There is a significant difference in relation to patient satisfaction status between FICB groups

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(Satisfactory =93.3%, Not Satisfactory =6.7%) and FENT group (Satisfactory =53.3%, Not Satisfactory =46.7%) with a p value of <0.001 when tested using chi square test.

The positive patient satisfaction status was significantly higher in FICB group compared to FENT group by a percentage difference of 40.

There is a significant difference in relation to time to perform subarachnoid block between FICB group (mean=4.696, SD=0.506) and FENT group (mean=7.754, SD=0.611) with a p value of <0.001 when tested using unpaired t- test.

Table 1

Group	**Intervention**	**Number**
FICB Group	Fascia Iliaca Compartment Block	30
FENT Group	Intravenous fentanyl	30
Null hypothesis:		
Null Hypothesis: H0	Fascia iliaca compartment block with Levobupivacaine is equal in effect to intravenous fentanyl for positioning in patients undergoing spinal anaesthesia in fracture femur surgery	
Alternate Hypothesis: H1	Fascia iliaca compartment block with Levobupivacaine is better in effect to intravenous fentanyl for positioning in patients undergoing spinal anaesthesia in fracture femur surgery	

Table 2

VAS During Positioning- Groups	**FICB Group**	**%**	**FENT Group**	**%**
VAS 0	9	30.0	0	0
VAS 2	16	53.3	4	13.3
VAS 3	0	0	13	43.3
VAS 4	5	16.7	5	16.7
VAS 5	0	0	8	26.7
Total	30	100.0	30	100.0

VAS During Positioning	**FICB Group**	**FENT Group**
N	30	30
Mean	1.73	3.57
Std. deviation	1.363	1.040
P- value Unpaired t- Test		<0.001*
Significant		

There is a significant difference in relation to VAS score during positioning between FICB group (mean=1.73, SD=1.363) and FENT group (mean=3.57, SD=1.040) with a p value of <0.001 when tested using unpaired t- test. The mean VAS score during positioning was significantly lesser in FICB group compared to FENT group by a mean difference of 1.84 scoring points.

Quality of Patient Positioning- Groups	**FICB Group**	**%**	**FENT Group**	**%**
Satisfactory	2	6.7	12	40.0
Good	13	43.3	16	53.3
Optimal	15	50.0	2	6.7
Total	30	100.0	30	100.0

Quality of Patient Positioning	**FICB Group**	**FENT Group**
N	30	30
Mean	2.43	1.67
Std. deviation	0.626	0.606
P- value Unpaired t- Test		<0.001*
Significant		

There is a significant difference in relation to quality of patient positioning between FICB group (mean=2.43, SD=0.626) and FENT group (mean=1.67, SD=0.606) with a p value of <0.001 when tested using unpaired t- test. The mean quality of patient positioning score was significantly higher in FICB group compared to FENT group by a mean difference of 0.76 scoring points.

Patient Satisfaction- Groups	**FICB Group**	**%**	**FENT Group**	**%**
Satisfactory	28	93.3	16	53.3
Not Satisfactory	2	6.7	14	46.7
Total	30	100.0	30	100.0
P- value Chi- square Test				<0.001*
Significant				

Time to Perform SAB- Groups	**FICB Group**	**%**	**FENT Group**	**%**
≤ 5.00 mins	19	63.3	0	0
5.01 – 6.00 mins	11	36.7	1	3.3
6.01 – 7.00 mins	0	0	4	13.3
7.01 – 8.00 mins	0	0	18	60.0
More than 8.00 mins	0	0	7	23.3

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Total	30	100.0	30	100.0

Time to Perform SAB	FICB Group	FENT Group
N	30	30
Mean	4.696	7.754
Std. deviation	0.5062	0.6114
P- value Unpaired t- Test		<0.001*
Significant		

DISCUSSION

Spinal anaesthesia is the most commonly used anaesthetic technique of choice in orthopaedics for lower limb fractures. While regional anaesthesia has been shown to be more beneficial compared to general anaesthesia, patient positioning for neuraxial blockade may cause severe pain in patients with femur fractures. Various systemic analgesics are being used to provide pain relief during positioning in these patients. Among the systemic analgesics, opioids are widely used but they are known to be associated with side effects like cognitive impairment, vomiting, urinary retention , respiratory depression especially in the elderly. Nerve blocks like the 3 in 1 block, femoral nerve block, fascia iliaca compartment block have all come up as an alternative approach to provide pain relief and improve positioning in these patients39,40.

Fascia iliaca compartment block, first described by Dalens et al is a simple, low skill and safe technique that can be used during prehospital care, emergency department and in the pre operative setting. It blocks the femoral, lateral femoral cutaneous nerve and sometimes the obturator nerve. Also, since the injection is done away from the artery and nerve, there are minimal chances of neurovascular injury42. The usage of ultrasound guidance to visualize the fascia iliaca and to deposit the drug beneath it lateral to the femoral nerve increases the success rate of block and further reduces the risk of neurovascular injury.

In this prospective, randomized study, the efficacy of fascia iliaca compartment block under ultrasound guidance with Levobupivacaine was compared with intravenous fentanyl for positioning during spinal anaesthesia in femur fractures. patients satisfying the inclusion criteria were chosen and divided into two groups of thirty each. Group FICB received 30ml of 0.25% Levobupivacaine under ultrasound guidance fifteen minutes before positioning, while group FENT received titrated doses of Inj. Fentanyl 0.5mcg/kg I.V. 1st dose-0.5mcg/kg I.V ,2nd dose -0.25mcg/kg ,3rd dose -0.25mcg/kg given with an interval of 5 mins between doses.

The mean age was 41.73 ±14.895 in FICB group and 49.37 ±16.915 in FENT group The sex distribution in FICB group was 16 males and 14 females while in FENT group, there were 14 males and 16 females. The mean weight in FICB group was 61.37 ±10.646 while in FENT group it was 64.90 ±10.623. Thus both the groups were comparable in terms of age, sex and weight distribution as the P value was not significant. (P>0.05).

The Visual Analogue Scale score during positioning was 1.73 ±1.363 in FICB group and 3.57±1.040 in FENT group and was statistically significant with a P value of 0.0029. It shows that fascia iliaca compartment block provides better analgesia for patient positioning in fracture femur surgeries.

A time interval of fifteen minutes before the block/iv fentanyl was chosen as the onset of action of Levobupivacaine is 5 to 10 minutes43. The analgesic dose of fentanyl is 1-2 mcg/kg i.v and the peak plasma concentration of fentanyl occurs at 6-7 minutes.44,45 The time interval allows titration of the dose of fentanyl which reduces possibility of side effects like hypoventilation or apnea. The analgesic effect of bupivacaine may be maximised by increasing the time interval since block.

The quality of patient positioning was higher in FICB group with a mean of 2.43±0.626 when compared to FENT group which had a mean of 1.67±0.60. It was statistically significant with a P value of 0.0024. It means that fascia iliaca compartment block provides better quality of patient positioning for spinal anaesthesia compared to i.v. fentanyl. Patient satisfaction was also significantly better in FICB group (P<0.001)

The time taken to perform subarachnoid block (time from beginning of positioning to end of administration of drug) was shorter in FICB group 4.696±0.560 mins compared to FENT group 7.754±0.611mins. It was statistically significant with a P value of <0.0001. It indicates that FICB reduces the time taken for providing subarachnoid block.

The heart rate was significantly lower in FENT group at 10 and 15 minutes (P<0.05) while there was no significant difference in Respiratory rate and oxygen saturation between the two groups.

There is a significant difference in relation to mean arterial pressure between FICB group and FENT group with a p value of <0.001 at 5 mins, 10 mins and 15 mins. And there is no significant difference in relation to mean arterial pressure between FICB group and FENT group before block with a p value of 0.541 which is > 0.05 when tested using unpaired t- test.

FICB had the advantage of significant post op analgesia as the requirement of first rescue analgesic was after 5.90±0.80 hrs compared to 1.65±0.60 hrs in FENT group. (P<0.0001).

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There were no complications of block like infection, block failure, vascular puncture , nerve damage46 or systemic toxicity of Levobupivacaine.

In this study, Fascia Iliaca Compartment Block proved to be more advantageous than i.v. fentanyl to facilitate patient positioning in femur fractures.

Fascia Iliaca Compartment Block could also be more useful in Procedures like placing an epidural or in patients with spinal abnormalities where the patients may have to be in a sitting position for a longer time. Also, the placement of a catheter in the fascia iliaca compartment and inclusion of additives would further increase the duration of post op analgesia.

CONCLUSION

In this prospective, randomized study, the efficacy of fascia iliaca compartment block under ultrasound guidance with Levobupivacaine was compared with intravenous fentanyl for positioning during spinal anaesthesia in femur fractures. 60 patients satisfying the inclusion criteria were chosen and divided into two groups of thirty each. Group FICB received 30ml of 0.25% Levobupivacaine under ultrasound guidance fifteen minutes before positioning, while group FENT received titrated doses of Inj. Fentanyl 0.5mcg/kg I.V. 1st dose-0.5mcg/kg I.V, 2nd dose -0.25mcg/kg, 3rd dose -0.25mcg/kg given with an interval of 5 mins between doses.

It was interpreted that,

1. Fascia Iliaca Compartment Block provided superior analgesia compared to i.v. fentanyl for positioning during spinal anaesthesia.
2. The quality of patient positioning and the satisfaction of the patient were better in Fascia Iliaca Compartment Block.
3. The time taken to perform subarachnoid block was lesser in Fascia Iliaca Compartment Block compared to I.V. fentanyl.
4. Fascia Iliaca Compartment Block provided better post op analgesia compared to i.v. fentanyl.

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