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Comparative evaluation between fascia iliaca compartment block and intravenous fentanyl administration for painless positioning during spinal Anaesthesia in fracture femur surgeries: A randomized controlled study

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Abstract
Background: Pain poses a unique challenge to anaesthesiologist. Femur fracture is one such condition where patient experiences spikes of excruciating pain whenever patient is subjected to move or position for delivering central neuraxial anaesthesia which further increases stress response and results in poly-pharmacy to tackle its consequences. This study is designed to compare the efficacy of ultrasound guided Fascia Iliaca Compartment Block with bupivacaine over intravenous fentanyl for positioning during spinal anaesthesia in femur fracture cases
Methodology: A single blinded, randomised study was carried out with 60 patients of ASA grade I and II aged between 18 to 70 years undergoing Femur fracture surgeries under spinal anaesthesia, patients are randomly allocated into two groups
Group FICB: will be given ultrasound guided Fascia Iliaca Compartment Block preoperatively with 30ml of 0.25% bupivacaine, the block will be done 15 minutes before the sub arachnoid block. **Group FENT:** will be administered intravenous fentanyl preoperatively according to their calculated body weight as 2mcg/kg body weight I.V.
Results: The VAS scores (P<0.0029), quality of patient positioning(P<0.0024) ,patient satisfaction(P<0.0284),Time to perform subarachnoid block (P<0.0001) heart rate (P<0.0022), Respiratory rate (P<0.0001) during positioning, Time for first rescue analgesic dose (P<0.0001)were comparatively better in the femoral nerve block group compared to intravenous fentanyl group and no statistically significant difference was observed in relation to mean arterial pressure, peripheral capillary oxygen saturation during positioning among both groups
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 cases.

Keywords: Fascia illiacablock, ultrasound guided fascia illiaca block, fentanyl, bupivacaine, perioperative analgesia

Introduction
Regional anaesthesia is the most widely used anaesthetic technique for orthopaedic procedures in lower limbs as it has many advantages over general anaesthesia, as it provides a good perioperative pain relief [1], reduces systemic analgesic requirements, decreases poly pharmacy, avoids unnecessary airway manipulation, permits early ambulation and decreases chances of deep vein thrombosis [2].

Anaesthesia for femur surgeries is usually provided by subarachnoid block. Proper positioning during subarachnoid block is essential for a successful procedure. However, over riding of bone ends during movement worsens pain, delays positioning which in turn increases pain further [3]. Alleviating pain increases patient comfort and also provides better patient positioning for subarachnoid block [4]. Various drugs like Non-steroidal anti-inflammatory drugs, opioids, midazolam, ketamine, propofol have been in use to reduce the pain preoperatively and improve positioning in these patients. Among which Fentanyl a phenylpiperidine derivative synthetic opioid agonistis chosen for study as it is 50-80 times more potent analgesic than morphine and has little hypnotic or sedative activity, has no

reported neural toxicity and has more rapid onset of action than other opioids, itinturn decreases the MAC of co-administered volatile agents and increases the affect of non-depolarising Muscle relaxants, potential risk only being respiratory depression which will be monitored and counteracted as per requirement [5].

Nerve blocks have come up as an effective and a safe alternative to provide pain relief [6].Ultrasound has provided anaesthesiologists, an effective tool for the identification and safe blockade of nerve fibres by precisely controlling the amount of drug to be delivered [7, 8, 9] hence ultrasound guided Fascia illiaca block is a promising technique for painless positioning of patient for central neuraxial blocks in fracture femur surgeries.

In this current study the field block is achieved with 30ml (within calculated toxicity dose as per patient) of 0.25% plain Bupivacaine a local anaesthetic, it has greater in-vivo relative potency, has higher protein binding capability thus increasing the duration of action. Potential risk for nerve blockades being the accidental administration of the local anaesthetic drug (Bupivacaine)into blood vessels or administering more than calculated toxic dosage, it results in seizures, cardiotoxicity causing cardiovascular collapse which can be prevented by careful administration of drug [7]within the toxic dosage and by careful monitoring for toxicity signs like perioral-numbness, diaphoresis. Toxic affects if any are managed symptomatically and by lipid emulsion administration [8]. This study is designed to compare efficacy of Ultrasound guided Fascia Iliaca Compartment Block with bupivacaine over intravenous fentanyl for positioning during spinal anaesthesia in femur fracture cases

Materials and Methods

Study Design: Prospective, Randomized, single-blind, Controlled study, with 60 patients divided into two groups

Group FICB: ultrasound guided Fascia Iliaca Compartment Block preoperatively with 30ml of 0.25% bupivacaine

Group FENT: Intravenous fentanyl preoperatively according to their calculated body weight as 2mcg/kg body weight I.V.

Inclusion Criteria

1. Patients belonging to ASA grade I and II.
2. Patients of either sex, between the age group 18 to 70 years.
3. Patients with fracture femur, posted for surgery under sub-arachnoid block.
4. Patients who give a valid informed consent.

Exclusion Criteria

1. Patients not satisfying inclusion criteria.
2. Patients belonging to ASA grade III or IV.
3. Patients with hemorrhagic diathesis, neurological disorders, psychiatric disorders.
4. Previous femoral bypass surgery.
5. Patients with allergy to local anaesthetics or opioids.
6. Patients with polytrauma, infection over the injection site.
7. Patients on previous opioid therapy.
8. Morbid obesity.
9. Patients who will be administered with supplementary epidural or general anaesthesia. (In patients with prolonged surgeries when conversion is required).
10. Patients with spinal deformities.
11. Patients who decline consent
12. Patients with language barrier.

Methodology

This study was conducted on sixty patients undergoing fracture femur surgeries at Konaseema Institute of medical sciences and research foundation between August 2019 to February 2020 Patients satisfying the inclusion criteria were selected, counselled about the risks and benefits involved in the study. After obtaining informed consent, patients who are willing to be included in the study were enrolled. They were preoperatively evaluated, clinically examined and assessed and were randomly allocated into two groups

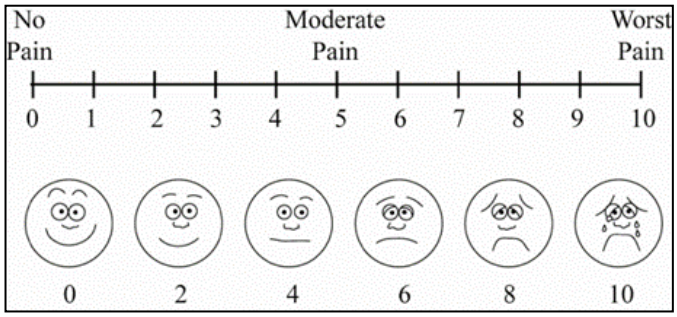
Group FICB: Given ultrasound guided Fascia Iliaca Compartment Block preoperatively.

Group FENT: Administered intravenous Fentanyl preoperatively.

All patients were kept nil per oral for at least 6 hours before the procedure. Patients were shifted inside the operation theatre half an hour before the scheduled procedure. Baseline vitals such as pulse rate, non-invasive blood pressure, saturation in room air, respiratory rate, ECG pattern were recorded. Intravenous access was obtained with18G IV cannula and IV fluid was started. Oxygen was given via Hudson's mask at rate of 4 lit/min.

Group FICB patients were placed in supine position. The local anaesthetic solution was prepared with 15 mL of 0.5% bupivacaine and 15ml of distilled water and hence 30ml of 0.25% bupivacaine. The Ultrasound Machine was powered on and the linear array probe was covered with sterile dressing after applying ultrasound gel. The probe was placed in horizontal direction over the anterior part of thigh just below the inguinal ligament. The ultrasound setting used to visualise was at a frequency of 10 MHz and a depth of 3-4cm. The gain and focus were adjusted according to the image scanned. Femoral artery was identified first. Then the iliacus muscle covered by fascia iliaca was identified lateral to the artery. An 18G needle was then inserted in plane to the ultrasound beam. The needle was advanced until the tip of the needle placed beneath the fascia iliaca (appreciating the give as the fascia is perforated) and after negative aspiration, the local anaesthetic was injected and its spread was visualized on the ultrasound screen. The fascia iliaca compartment block was done 15 minutes before the sub arachnoid block.

Group FENT patients were given dose of Inj. Fentanyl 2mcg/kg I.V as per their individual body weight Hemodynamic variables heart rate, non-invasive blood pressure, saturation of oxygen, respiratory rate were recorded after the block/ iv fentanyl and at five minutes intervals till positioning.



The analgesia provided by either of the modes was assessed by using Visual analogue scale scores 15 minutes (I.e. during positioning) after the block/ I.V. Fentanyl.

Visual Analogue Scale score

Subarachnoid block was performed in the sitting posture under strict aseptic precautions in the L3-L4 space using 25G Quincke needle with 3ml of 0.5%Bupivacaine (hyperbaric, dextrose 80mg/ml) with or without adjuvant. The quality of patient positioning for administering spinal anaesthesia was recorded by another anaesthesiologist blinded to the mode of analgesia with scores of 0-3.0-Not satisfactory 1-satisfactory 2-good 3-optimalTime to perform spinal anaesthesia was recorded (time from beginning of positioning to end of spinal) Patient satisfaction was also recorded 1- satisfactory 2- not satisfactory Post-operative analgesia was standardized in all patients of both groups with Inj. Tramadol 50 mg I.V. 8th hourly; first dose was given when the patient complained pain. The collected data was recorded for statistical analysis.

Results

The results of 60 patients were as follows.

Table 1: Vas During Positioning

VAS During Positioning - Groups	FICB Group	%	FENT Group	%
VAS 0	15	50.00	5	16.67
VAS 2	13	43.33	18	60.00
VAS 4	2	6.67	5	16.67
VAS 6	0	0.00	2	6.67
Total	30	100	30	100

p value 0.0029 as per unpaired t test, Significant

50% of patients in group FCIB had VAS score of 0 when compared to 5% of
patients in group FENT. This observation was statistically significant

Table 2: Quality of Patient Positioning

QOP Positioning - Groups	FICB Group	%	FENT Group	%
QOPP 0	0	0.00	2	6.67
QOPP 1	2	6.67	5	16.67
QOPP 2	13	43.33	18	60.00
QOPP 3	15	50.00	5	16.67
Total	30	100	30	100

P value 0.0024 as per unpaired t test, Significant

50% of pts feel optimal during positioning when compared to 16.67% in case of fentanyl group which was statistically significant.

Table 3: Patient Satisfaction

Patient Satisfaction - Groups	FICB Group	%	FENT Group	%
Yes	29	96.67	23	76.67
No	1	3.33	7	23.33
Total	30	100	30	100
P value Fishers Exact Test			0.	0284

p value 0.0284 as per unpaired t test, Significant

Patient satisfaction is 96.67% for FICB group when compared to 76.67% for FENT group which was statistically significant

Table 4: Time to Perform Sub Arachnoid Block

Time to Perform SAB - Groups	FICB Group	%	FENT Group	%
≤ 5.00 mins	17	56.67	3	10.00
5.01-6.00 mins	13	43.33	16	53.33
6.01-7.00 mins	0	0.00	8	26.67
7.01-8.00 mins	0	0.00	3	10.00
Total	30	100	30	100

p value 0.0001 as per unpaired t test, Significant

The mean time to perform subarachnoid block was significantly shorter in FICB group compared to FENT group by a mean difference of 58 seconds (16% shorter). which was significant statistically

Table 5: Heart Rate

Heart Rate (beats per min)		Before Block	5 mins	10 mins	15 mins (During Positioning)
FICB Group	Mean	86.93	87.67	86.90	86.13
	SD	8.77	8.18	8.41	8.44
FENT Group	Mean	88.70	85.63	82.37	79.67
	SD	7.55	7.29	7.19	7.13
P value Unpaired t Test		0.4065	0.3138	0.0027	0.0022

p value 0.0022 as per unpaired t test, Significant

The mean heart rate was significantly lower in FENT group compared to FICB group by a mean difference of 6 bpm (6% lower). which is statistically significant

Table 6: Mean Arterial Pressure

Mean Arterial Pressure (mm Hg)		Before Block	5 mins	10 mins	15 mins (During Positioning)
FICB Group	Mean	100.17	99.83	98.20	97.73
	SD	7.34	5.97	6.06	5.61
FENT Group	Mean	101.87	100.80	99.20	98.17
	SD	6.77	5.77	5.36	5.56
P value Unpaired t Test		0.3548	0.5262	0.5010	0.7649

P=0.7649 (*P*>0.05) as per unpaired t test

This implies there was no statistically significant difference in relation to mean arterial pressure between FICB group and FENT group

Table 7: Peripheral Capillary Oxygen Saturation

Peripheral Capillary Oxygen Saturation (%)		Before Block	5 mins	10 mins	15 mins (During Positioning)
FICB Group	Mean	98.03	98.73	99.13	99.27
	SD	0.76	0.69	0.63	0.52
FENT Group	Mean	98.10	98.97	99.17	98.94
	SD	0.76	0.67	0.70	0.89
P value Unpaired t Test		0.7359	0.1892	0.8467	0.1118

P=0.118(*P*>0.005) as per unpaired t test

This implies there was no statistically significant difference in relation to peripheral capillary oxygen saturation distribution between FICB group and FENT group

Table 8: Respiratory Rate

Respiratory Rate (breaths per min)		Before Block	5 mins	10 mins	15 mins (During Positioning)
FICB Group	Mean	17.40	17.40	17.17	16.70
	SD	1.38	1.19	0.91	1.12
FENT Group	Mean	17.33	16.97	15.57	14.57
	SD	0.96	1.16	1.17	1.48
P valueUnpaired t Test		0.8287	0.0873	<0.0001	<0.0001

P value< 0.0001 as per unpaired t test, Significant

The mean respiratory rate was significantly lower in FENT group compared to FICB group by a mean difference of 2 breaths per minute (11% lower)

Table 9: First Rescue Analgesic Postoperative

First rescue analgesic Postoperative -Groups	FICB Group	%	FENT Group	%
≤ 3.00 hrs	0	0.00	30	100.00
3.01-5.00 hrs	3	10.00	0	0.00
5.01-7.00 hrs	26	86.67	0	0.00
7.01-9.00 hrs	1	3.33	0	0.00
Total	30	100	30	100

P value < 0.0001 as per unpaired t test, Significant

The mean time of first postoperative analgesic need was significantly delayed in FICB group compared to FENT group by a mean difference of 4 hours and 15 minutes (72%more delayed), which was statistically 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 patients [9, 10].

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 [11]. 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 injury [12]. 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 bupivacaine 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% bupivacaine under ultrasound guidance fifteen minutes before positioning, while group FENT received dose of Inj. Fentanyl 2mcg/kg I.V. given 15 minutes before positioning.

The mean age was 46.07±10.76 in FICB group and 45.53 ±9.27 in FENT group The sex distribution in FICB group was 19 males and 11 females while in FENT group, there were 20 males and 10 females. The mean weight in FICB group was 62.77 ±5.46 while in FENT group it was 63.20 ±5.10. 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 duration since fracture to surgery was (FICB- 4.53±1.50 days; FENT- (4.67±1.54) was comparable too. (P>0.05)

The Visual Analogue Scale score during positioning was 1.13 ±1.25 in FICB group and 2.27±1.55 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 bupivacaine is 5 to 10 minutes [13]. The analgesic dose of fentanyl is 1-2 mcg/kg i.v and the peak plasma concentration of fentanyl occurs at 6-7 minutes [14, 15]. 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±0.63 when compared to FENT group which had a mean of 1.87±0.78. 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=0.0284).

The time taken to perform subarachnoid block (time from beginning of positioning to end of spinal) was shorter in FICB group 4.90±0.55 compared to FENT group 5.86±0.83. 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 MAP and oxygen saturation between the two groups. The respiratory rate was significantly less in FENT group at 10 and 15 minutes (*P*<0.0001) though none of the patients had a respiratory rate of < 12/minute or a saturation of < 95%.

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).
There were no complications of block like infection, block failure, vascular puncture, nerve damage [16] or systemic toxicity of bupivacaine.
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

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.

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