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FASCIA ILIACA BLOCK VS INTRAVENOUS KETOROLAC AS AN ANALGESIC TECHNIQUE BEFORE POSITIONING FOR SUBARACHNOID BLOCK IN PATIENTS UNDERGOING SURGERY FOR FEMUR FRACTURE

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ABSTRACT

Background: Femur fracture is a common orthopaedic injury that causes a lot of pain and distress to the patients as the periosteum is more sensitive to pain. Proper positioning while giving neuraxial block is important but pain due to overriding of fractured bone ends makes it difficult. Over the years various techniques, drugs and blocks have been studied to reduce this discomfort and make patients more comfortable during positioning. Our study compares efficacy of Fascia Iliaca Compartment Block & intravenous Ketorolac during positioning for subarachnoid block in femur fracture patients.

Method: Prospective double blinded randomized control trial, n=60 patients; computer-based allocation into Group FICB (n=30)- Fascia Iliaca Compartment Block, landmark technique with 20 ml of 0.25% bupivacaine; Group KETO (n=30)- 0.5 mg/kg Inj Ketorolac (max 30mg) in 100 ml normal saline; 15 minutes prior to subarachnoid block; aged between 18-65 years, ASA class I and II, for elective femur fracture surgeries. VAS was studied till positioning for subarachnoid block and patient positioning, patient satisfaction & time to give subarachnoid block were also noted. The comparison was studied using the Chi-square test or Fisher's exact test as appropriate, with the P value reported at the 80% confidence interval. $P<0.05$ was considered statistically significant.

Result: VAS score, quality of patient positioning, patient satisfaction was significantly better in Group FICB than Group KETO. Also, time to give subarachnoid block was less in Group FICB.

Conclusion: Fascia Iliaca Compartment Block is more efficacious than intravenous ketorolac for positioning during subarachnoid block in surgery for the fracture femur. Fascia Iliaca Compartment Block is easy and a wonderful block as it provides superior analgesia, a better quality of patient positioning, and greater patient satisfaction thereby reducing the time taken to perform subarachnoid block.

Keywords: Fascia Iliaca Block, Ketorolac, Patient Positioning, Subarachnoid Block, Spinal Anaesthesia

INTRODUCTION

Femur fractures are very commonly seen in trauma patients. As periosteum is most sensitive, pain due to fracture fragments is excruciating. Management of pain during positioning for subarachnoid block is important and difficult task for anaesthesiologists as pain is an unpleasant sensory and emotional experience for patients.[1] Femur fractures are more common in old aged patients who generally have a lower pain threshold and it's beneficial to use regional anaesthesia over general anaesthesia to avoid its problem with airway manipulation and polypharmacy.

It is important to decrease time to give subarachnoid block as repeated movement during positioning increases duration and intensity of pain. Also improper positioning may lead to inadequate spinal block. By reducing discomfort due to pain, patients are more comfortable and can be positioned more optimally for subarachnoid blocks.

Over the years various techniques and methods have been tried to help during patient positioning in femur fracture cases for subarachnoid block. Initially, intravenous medications like NSAID, opioids, ketamine, dexmedetomidine etc. were used to provide analgesia for positioning in femur fracture patients for subarachnoid block.

In research by Bantie et al.[2] patients with femur fractures received 1 μg/kg of IV fentanyl five minutes before positioning for subarachnoid block.

Moussa M et al.[3] used IV ketamine 0.25mg/kg in patients with femur fractures to help in positioning for subarachnoid block.

Forouzan et al.[4] used IV morphine 0.1mg/kg to help in reducing pain in femur fracture patients.

Regional anaesthesia is still an unexplored area in our field with new and upcoming blocks coming up for better pain relief. In patients with femur fractures, nerve blocks are a useful approach to help ease the discomfort of positioning for subarachnoid block. Various blocks with different methods have been tried and tested.

Szucs et al.[5] used the landmark technique of femoral nerve block with the help of a nerve stimulator with 0.25% bupivacaine to assess the reduction in pain in femur fracture patients for subarachnoid block.

Ranjit et al.[6] evaluated positioning for subarachnoid block in femur fracture patients by administering 20 ml of 2% lignocaine in the femoral nerve block under ultrasound guidance.

PENG (pericapsular nerve group) block is a type of nerve block in which local anaesthetic is deposited in the musculofacial plane between the psoas muscle and superior pubic ramus. Allard et al.[7] did a study where she used this block via ultrasound guidance to assess pain in femur fracture patients.

One such nerve block is also the Fascia iliaca block. It was described first by Dalens et al.[8] in 1989 and is a single injection technique which anaesthetizes the femoral nerve, obturator nerve and lateral cutaneous nerve. It is an inexpensive and technically easy block to give using the landmark approach. It can be given in peripheral setups where ultrasound machines are not always available with a comparatively low failure rate. As it blocks not just the femoral nerve but also the other two nerves, its action has been studied as being more effective to femoral nerve blocks.

Also in this study, we decided to give 20 ml of 0.25% Bupivacaine injection as it is a potent local anaesthetic of the amide group. It is longer acting, with fewer adverse effects, affordable and easily available local anaesthetic.

The comparative agent used in this study is ketorolac. It is a highly efficient parenterally active nonsteroidal anti-inflammatory medication (NSAID), commonly given during and after surgery. It was chosen instead of opioids because ketorolac has opioid-sparing properties that can help with pain management with decreased opioid-related adverse effects (e.g., nausea, vomiting, constipation, urinary retention, cardiorespiratory depression, pruritus, and sleep disturbances) which can speed up the recovery.[9]

As there are various techniques and methods available, our study compares efficacy of fascia iliaca block and an intravenous ketorolac during patient positioning in femur fracture patients for subarachnoid block.

METHODOLOGY

After obtaining Ethics Committee approval (IESC/PGS/2020/150) and CTRI no (CTRI/2021/11/038110), this prospective, double blinded, randomized controlled trial was conducted in a tertiary care hospital over a period of six months. The study was done in accordance with the principles of the Declaration of Helsinki.

Femur fracture patients with ASA (American Society of Anaesthesiologists) Grade I or II status, aged 18 to 65 years with availability of informed consent were selected. Exclusion criteria were patients with ASA physical status III or more, with major systemic abnormalities, contraindication to subarachnoid block, with known allergy to the study drug, with previous femoral bypass surgeries and infection over injection site and polytrauma.

These 60 patients were enrolled and randomized into two groups of 30 each using a computer-generated balanced allocation table. After attaching all standard monitors and securing an appropriate IV cannula.

Group FICB: Patients were given Fascia Iliaca Compartment Block by landmark technique with 20 ml of 0.25% bupivacaine 15 minutes prior to giving subarachnoid block.

After preparation of Local anaesthetic syringe, landmarks were identified. The landmarks for this block are the anterior superior iliac spine (ASIS) and the pubic tubercle of the same side. Middle finger is placed on the ASIS and the other middle finger on the pubic tubercle. A line was drawn between these two points. This line was divided into thirds. The point 1cm caudal from the junction of the lateral and middle third was marked. This was the injection entry point. Ipsilateral femoral nerve was also palpated and a safe distance from injection site was confirmed. Using a blunted or short-bevelled needle skin was pierced at a right angle to its surface. Once through the skin, needle angle was adjusted to about 60 degrees directing the tip cranially. The needle was kept in the sagittal plane to avoid the major vessels (medially) and peritoneal cavity (cranially). The needle was advanced through two distinct "pops" as it perforates first the fascia lata, then the fascia iliaca (the latter of which gives a more subtle "pop"). Drug was given after confirming negative aspiration and also after every 5 ml injection. It is described in figure 1.

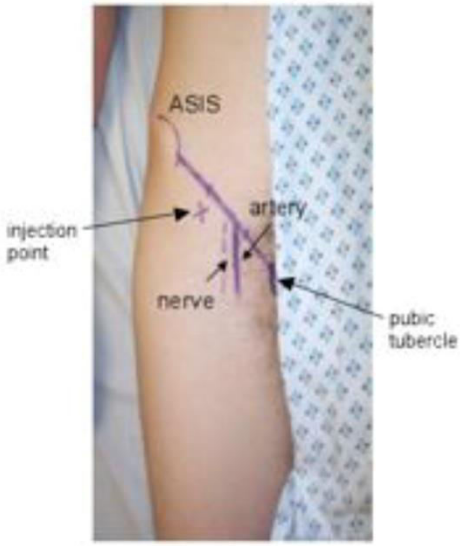

Figure 1: Injection point for landmark technique

Group KETO: Patients were administered intravenous ketorolac 0.5mg/kg (maximum 30 mg)in 100 ml normal saline 15 minutes prior to giving subarachnoid block.

The drugs were prepared by the same anaesthesiologist who gave the block and intravenous ketorolac.

- **Visual Analogue Scale-** The analgesia provided by either of the modes was assessed by using Visual analogue scale scores till 15 minutes (i.e. during positioning) after the block/ I.V. Ketorolac by an anesthesiologist blinded to the mode of analgesia. Position for subarachnoid block was given after 15 minutes. It is shown in figure 2.

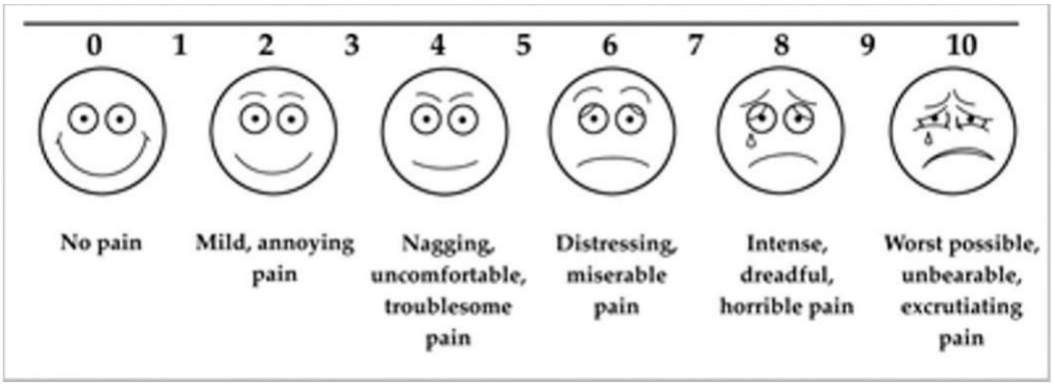

Figure 2: Visual Analogue Scale

Sub-arachnoid block was performed by a senior anesthesiologist with atleast 10 years of experience in the sitting posture under strict aseptic precautions.

- **Quality of Patient Positioning-** The quality of patient positioning for administering subarachnoid block was recorded by another anesthesiologist blinded to the mode of analgesia with scores of 0-3 by asking the anaesthesiologist giving subarachnoid block if the position was:
  0-Not satisfactory

  1-satisfactory

  2-good

  3-optimal

- **Time to perform subarachnoid block-** Time from beginning of palpating the spine to end of giving drug for subarachnoid block was recorded.
- **Patient satisfaction-** Patient satisfaction was also recorded by asking the patient a simple question if there was any reduction in pain from before.
  1- satisfactory

  2- not satisfactory

Assuming the mean and SD of Group FICB and Group KETO from different studies and mean difference between both groups and entering the details in the WINPEPI Application. At significance level of 0.05, Power of 80%. Then the equal sample size in 2 groups came to be 5 per group. However for better validation of results, total sample size of 60 was taken, 30 in each group.

All cases were completed within the stipulated time. Data was collected, compiled and tabulated. The presentation of Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the mean with Standard Deviation (SD) and as median with 25^{th} and 75^{th} percentile (interquartile range). The data normality was

checked by using Kolmogorov- Smirnov test. The cases in which data was not normal, non parametric tests were used. The following statistical tests were applied for the results:

The comparison of the variables which were quantitative and not normally distributed in nature were analyzed using Mann- Whitney Test and variables which were quantitative and normally distributed in nature were analyzed using independent t test.

The comparison of the variables which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then Fisher's exact test was used. The data entry was done in Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacture, Chicago, USA, version 25.0. For statistical significance, p value of less than 0.05 was considered statistically significant.

RESULTS

Table 1:-Comparison of demographic characteristics between FICB and KETO group.

Demographic characteristics	FICB(n=30)	KETO(n=30)	Total	P value
Age group(years)				
18-20 years	0 (0%)	4 (13.33%)	4 (6.67%)	0.216*
21-30 years	3 (10%)	3 (10%)	6 (10%)	
31-40 years	4 (13.33%)	5 (16.67%)	9 (15%)	
41-50 years	2 (6.67%)	5 (16.67%)	7 (11.67%)	
51-60 years	5 (16.67%)	3 (10%)	8 (13.33%)	
61-65 years	16 (53.33%)	10 (33.33%)	26 (43.33%)	
Mean ± SD	54.43 ± 13.93	46.3 ± 16.88	50.37 ± 15.88	0.073§
Median(25th-75th percentile)	62.5(45.5-65)	45.5(33.25-63.5)	58.5(39.5-65)	
Range	24-65	18-65	18-65	
Gender				
Female	15 (50%)	12 (40%)	27 (45%)	0.436†
Male	15 (50%)	18 (60%)	33 (55%)	
Total	30 (100%)	30 (100%)	60 (100%)	
Weight(kg)				
51-60 kg	14 (46.67%)	11 (36.67%)	25 (41.67%)	0.692*
61-70 kg	15 (50%)	17 (56.67%)	32 (53.33%)	
71-80 kg	1 (3.33%)	2 (6.67%)	3 (5%)	
Mean ± SD	62.77 ± 5.46	63.2 ± 5.1	62.98 ± 5.24	0.912§
Median(25th-75th percentile)	62(59-67.75)	64(58.25-67.75)	63.5(58.75-68)	

Range	53-71	55-73	53-73	

[§] Mann Whitney test, [*] Fisher's exact test, [†] Chi square test

Patients in both the groups did not show statistically significant differences in their age (P = 0.216), gender (P = 0.912), weight distribution (P = 0.692). It is shown in Table 1.

Table 2:- Comparison of VAS during positioning group between FICB and KETO group.

VAS during positioning group	**FICB(n=30) No of patients**	**KETO(n=30) No of patients**	**Total**	**P value**
VAS 0	3 (10%)	0 (0%)	3 (5%)	<.0001[*]
VAS 1	8 (26.67%)	0 (0%)	8 (13.33%)	
VAS 2	6 (20%)	0 (0%)	6 (10%)	
VAS 3	12 (40%)	0 (0%)	12 (20%)	
VAS 4	1 (3.33%)	1 (3.33%)	2 (3.33%)	
VAS 5	0 (0%)	13 (43.33%)	13 (21.67%)	
VAS 6	0 (0%)	15 (50%)	15 (25%)	
VAS 7	0 (0%)	1 (3.33%)	1 (1.67%)	
Total	30 (100%)	30 (100%)	60 (100%)	

[*] Fisher's exact test

Proportion of patients with VAS at positioning: - VAS 0, 1, 2 and 3 was significantly higher in FICB as compared to KETO and proportion of patients with VAS during positioning group:- VAS 5, VAS 6, VAS 7 was significantly lower in FICB as compared to KETO (p value <0.0001). It is shown in table 2.

Median (25th-75th percentile) of VAS during positioning in KETO was 6(5-6) which was significantly higher as compared to FICB (2(1-3)). (p value <.0001). It is shown in figure 3.

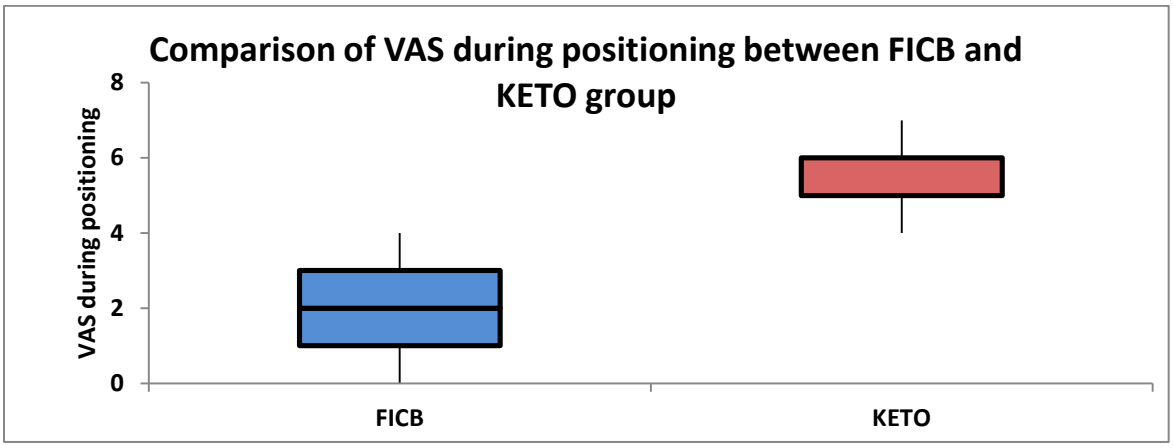

Figure 3: Comparison of VAS during positioning between FICB and KETO group. (non-parametric variable, Box-whisker plot)

Table 3: Comparison of quality of patient positioning between FICB and KETO group.

Quality of patient positioning	FICB(n=30) No of patients	KETO(n=30) No of patients	Total	P value
Not satisfactory	0 (0%)	18 (60%)	18 (30%)	<.0001†
Optimal	17 (56.67%)	0 (0%)	17 (28.33%)	
Good	11 (36.67%)	0 (0%)	11 (18.33%)	
Satisfactory	2 (6.67%)	12 (40%)	14 (23.33%)	
Total	30 (100%)	30 (100%)	60 (100%)	

† **Chi-square test**

Proportion of patients with quality of patient positioning: - good, optimal was significantly higher in FICB as compared to KETO and proportion of patients with quality of patient positioning: - Not satisfactory, satisfactory was significantly lower in FICB as compared to KETO (p value <0.0001). It is shown in table 3.

Median (25th-75th percentile) of time to perform SAB (minutes) in KETO was 3.5(3.4-4) which was significantly higher as compared to FICB (1.42(1.258-2)). (p value <.0001). It is shown in figure 4.

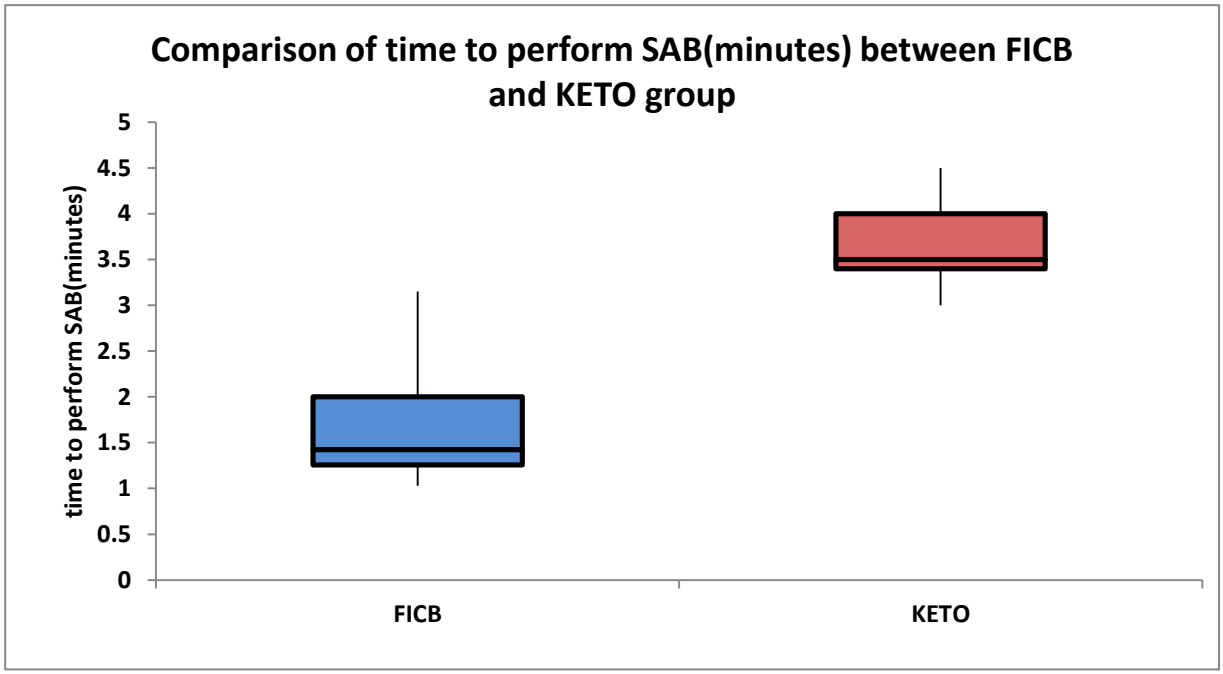

Figure 4: Comparison of time to perform SAB (minutes) between FICB and KETO group. (non-parametric variable, Box-whisker plot)

Proportion with patient satisfaction: - satisfactory was greater in FICB in comparison to KETO and not satisfactory was significantly lower in FICB as compared to KETO (p value <0.0001). It is shown in figure 5.

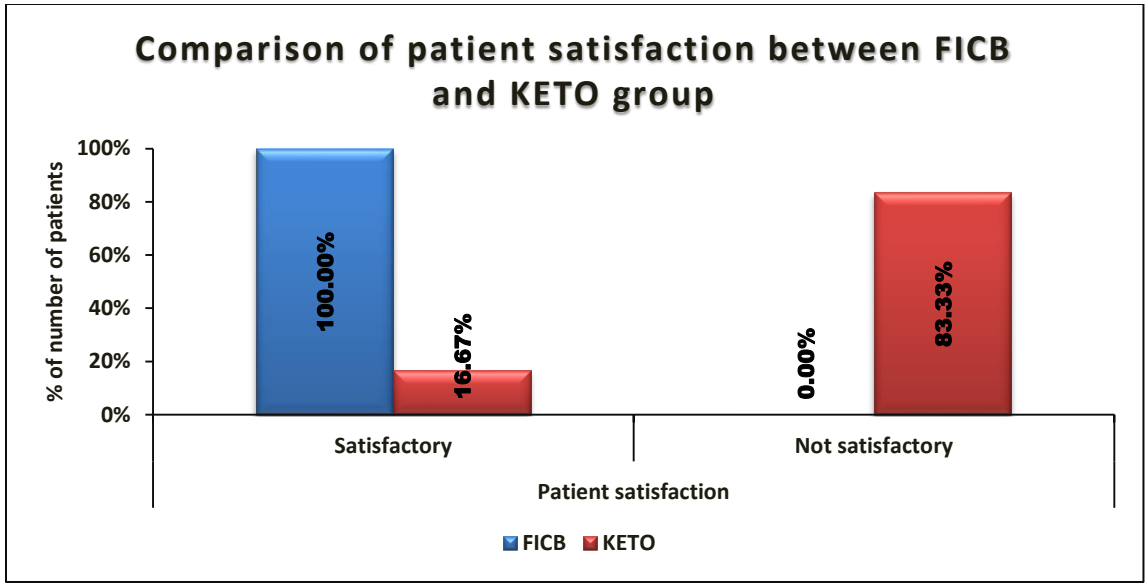

Figure 5: Comparison of patient satisfaction between FICB and KETO group.

DISCUSSION

Success in a neuraxial blockade is the result of many factors. An important factor that is commonly overlooked is patient positioning, which is highly dependent on patient cooperation and comfort. Lower limb fractures especially femur fractures are very painful to the patient due to movement and overriding of fractured bone ends which makes patient positioning more challenging. Also, femur fractures are more common in the elderly age group in whom pain threshold is already reduced and performing subarachnoid block is generally difficult.

The most popular anaesthesia technique practiced in orthopaedic procedures for lower limb fractures is subarachnoid block. For these patients, a variety of systemic analgesics are being administered to relieve discomfort while they are being positioned for subarachnoid block. Ketorolac is a well-known systemic analgesic that is known to be very effective, have opioid-sparing properties, and minimises opioid-associated adverse effects such as respiratory depression, nausea, vomiting, and urinary retention, particularly in older people. As an additional method to relieve pain and improve positioning in these patients, regional blocks such as the 3-in-1 block, femoral nerve block, and fascia iliaca compartment block have all been developed.

First described by Dalens et al.[8], Fascia iliaca compartment block is a simple, easy and safe technique that can be used during prehospital care, emergency department and in the preoperative setting. It blocks the femoral, lateral femoral cutaneous nerve and occasionally, the obturator nerve. Additionally, because the site of injection is far from the artery and nerve, there is very little chance of neurovascular harm.

In this prospective, randomized trial, the efficiency of a fascia iliaca compartment block by the landmark technique with bupivacaine was compared to intravenous ketorolac when positioning patients for subarachnoid block undergoing femur fracture surgeries. The 60 patients who met the inclusion requirements were split into two groups of 30 each. Group FICB received 20ml of 0.25% bupivacaine by landmark technique fifteen minutes before positioning, while group KETO received 0.5 mg/kg of Inj. Ketorolac (maximum 30mg) in 100 ml of normal saline fifteen minutes before positioning.

The mean and median age was 54.43 ±13.93 and 62.5 in the FICB group and 46.3 ±16.88 and 45.5 in the KETO group respectively. In the FICB group, there were 15 men and 15 women, whereas, in the KETO group, there were 18 men and 12 women. The mean and median body weight in the FICB group was 62.77± 5.46 and 62, respectively, while they were 63.20±5.10 and 64 in the KETO group. Because the P value was not significant (P>0.05), both groups had similar distributions of age, sex, and weight.

Visual Analogue Scale score during positioning was 2 ±1.11 in the FICB group and 5.53±0.63 in the KETO group which was statistically significant with a P value of <0.001. The results demonstrate that the fascia iliaca compartment block offers superior analgesia for patient positioning in fracture femur procedures. A similar study was done by M. J Yun et al.[10] in 2009 compared Fascia Iliaca block with IV alfentanil for positioning for subarachnoid block in femur fracture patients. The VAS score in the Fascia Iliaca Compartment block group during positioning was 2.1 ± 0.9 which was comparable to our study. A study done by Dureja et al.[11] in 2016 comparing fascia iliaca compartment block with IV diclofenac in femur fracture patients shows a median VAS score of 2 for the Fascia iliaca compartment group 20 minutes after the

intervention which is comparable to our result. A study done by Masoumi et al.[12] in 2017 used ketorolac for femur fracture patients for pain relief. Here, 10 mg IV ketorolac was given as a loading dose followed by 5 mg every 5 minutes to 10 minutes if VAS ≥ 4. The mean of the VAS score at the 30-minute interval was 2.39 ± 0.81 whereas in our study where ketorolac was given at a dose of 0.5mg/kg (maximum of 30 mg) had a VAS at positioning as 5.53 ± 0.63. This study by Masoumi et al. was done on patients with femur fractures and compared VAS scores at different time intervals while patients were at rest and the effect on patient positioning was not taken into account. This could be the reason for less VAS score in their study as compared to ours.

Patient positioning was better in the FICB group with a proportion of good and optimal positioning as 36.67% and 56.67% when compared to the KETO group which had a proportion of patients with satisfactory and not satisfactory as 40% and 0% respectively. A P value of <0.001 indicated that it was statistically significant. This indicates that the fascia iliaca compartment block offers superior patient placement for subarachnoid block. When compared to IV. ketorolac. In the FICB group, patient satisfaction was also noticeably higher. (P<0.001). Comparing this to a study done by M.J Yun et al.[10] quality of patient positioning in fascia iliaca block was 2(0-unsatisfactory; 1-satisfactory; 2-good; 3-optimal) which was similar to our study.

Subarachnoid block procedure duration (time from the beginning of palpation of spaces to end of giving drug for subarachnoid block) was shorter in the FICB group 1.74 ±0.65 compared to the KETO group 3.67±0.47. With a P value of <0.0001, it was statistically significant. It suggests that positioning of patient during subarachnoid block was better in FICB and hence shortens the time needed to administer subarachnoid block. Comparing this to a study done by M. J Yun et al.[10] time to perform Sub arachnoid block in the Fascia Iliaca group was 6.9 ± 2.7 which is not in comparison to our study. The time to perform Sub-arachnoid block was calculated from the start of positioning to completion of giving the drug in their study which is not similar to our study and is the reason for the longer duration in performing subarachnoid block in their study.

No block-related problems, such as infection, block failure, vascular puncture, nerve injury, or systemic bupivacaine toxicity, occurred.

In this study, it was observed that Fascia Iliaca Compartment Block was superior to intravenous ketorolac for improving patient positioning in femur fractures for subarachnoid block.

CONCLUSION

It is concluded that Fascia Iliaca Compartment Block is more efficacious than intravenous ketorolac for positioning during subarachnoid block in surgery for the fracture femur. Fascia Iliaca Compartment Block provides superior analgesia, a better quality of patient positioning, and greater patient satisfaction thereby reducing the time taken to perform subarachnoid block compared to I.V ketorolac in fracture femur surgeries.

LIMITATIONS

- The intensity of pain perceived can vary from patient to patient depending on their pain threshold.
- More studies are required to find out time of peak action of block.

- Various adjuvants can be tried to improve the quality of analgesia.

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