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Randomized controlled study to compare the analgesic efficacy of Continuous Epidural block with Continuous Fascia Iliaca Compartment Block for femur surgery done under subarachnoid block.

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Abstract:

The aim of the study is to compare the analgesic efficacy of Continuous Epidural block with Continuous Fascia Iliaca Compartment Block for femur surgery done under subarachnoid block. A total of 120 (n=120) consented patients fulfilling the inclusion criteria who underwent elective surgery for fracture femur were selected. They were randomized to group F (n = 60) and group E (n = 60) to receive either Fascia iliaca compartment block or Epidural block respectively for postoperative analgesia. The technique of spinal anaesthesia were standardised in both the groups. The patients were evaluated for VAS score and hemodynamic parameter at 1,2,4,8,12,16,and 24th hour.

Results were analysed There was no substantial demographic difference between both the groups ($P > 0.05$). The mean VAS score in both the groups were comparable ($P > 0.05$). The other hemodynamic parameters and side effects were comparable between both the groups. Concluded that FICB holds considerable promise as an effective postoperative analgesia with less side effects compared to Epidural analgesia.

Introduction:

Femur fractures cause moderate to severe pain which requires effective analgesia both preoperatively and postoperatively. Multimodal analgesic regimens which include Non steroidal anti-inflammatory drugs, opioids & various regional analgesic techniques have been used in femur surgeries so far. NSAIDs even in moderate dose cause adverse effects, especially in the elderly population. Although opioids are potent analgesics, they are associated with serious adverse effects like drowsiness, nausea, respiratory depression, constipation etc. limiting their use.

Epidural analgesia is considered by many as the gold standard analgesic technique for femur surgeries. Apart from effective analgesia it decreases the neuro-endocrine stress response, central sensitization & muscle spasm that occur in response to painful stimuli. There is a substantial evidence showing reduced blood loss and fewer thromboembolic complications following neuraxial blockade.

However Lumbar epidural analgesia is also commonly associated with various problems like hypotension, urinary retention, undesired bilateral sensory and motor blockade and delay in mobilization.

Perineural analgesia is becoming popular as it provides comparable pain relief and decreases the side effects associated with central neuraxial blockade. Peripheral nerve blockade was initially done with either paresthesia technique or nerve stimulation based technique.

Ultrasound guided needle & catheter placement is observed to be technically superior, more accurate, being placed in peripheral location probably increases the safety of such techniques compared with others.

Fascia iliaca compartment block was initially described by Dalens et al on children using landmark technique. It is relatively simple, easier to perform, and provides perioperative analgesia in patients with painful conditions affecting the thigh, hip joint and femur. The use of ultrasound to aid identification of the fascial planes may lead to faster onset and dense motor blockade. This increases the rate of successful blocks.

Aim of the study:

To compare the analgesic efficacy of Continuous Epidural block with Continuous Fascia Iliaca Compartment Block for femur surgery done under subarachnoid block. Primary objective is to assess the postoperative pain by Visual Analogue scale. Secondary outcomes are Postoperative Nausea and vomiting, Rescue Analgesic requirement, Patient satisfaction, Therapeutic / technical failure rate, Complications (hypotension, bradycardia, respiratory depression).

Materials and Methods:

This study is a randomized prospective interventional clinical trial. Study population is 120. Computerized randomization was done by allocating the patients to either the Fascia iliaca group (Group F-60) or Epidural group (Group E-60). Included Patients between the ages 18-60 years, under ASA PS I,II Undergoing elective surgery (fracture femur surgery includes neck of femur, total/hemi hip replacement, proximal femur) under spinal anaesthesia. Pt with Coagulopathy, Drug allergy, Skin lesions at the side of the blocks, Chronic Pain, Previous femoral bypass surgery were excluded from this study. After obtaining approval from the institutional ethical committee. Patients were explained about the procedure in detail and informed written consent was obtained for the same.

On the day of surgery, patients were shifted to pre-medication room started with 18G iv cannula & iv fluid. Standard Monitors NIBP, pulse oximeter, ECG were attached. Patients from both the groups underwent fracture femur surgery, under spinal anaesthesia with 3.5 ml 0.5% Bupivacaine (heavy).

Group E

Patient was placed in sitting position. The back was prepared with povidone iodine solution and sterile drapes applied. 2ml of 2% Lignocaine was used for local infiltration at space L3- L4 space.

The approach used for epidural technique was midline approach. Technique chosen for identification of epidural space was loss of resistance technique using a air filled syringe, using the Bromage grip. 18 G Tuohy needle was inserted at L3 –L4 interspace and epidural space is identified at 3.5-5 cm from skin level by loss of resistance technique. An Epidural catheter was threaded and fixed so that 5 cm of the catheter was in epidural space.

After negative aspiration test dose is given with 3ml of 1.5% Lignocaine with 15microg adrenaline. Then patients was given spinal anaesthesia with 0.5% hyperbaric Bupivacaine 3.5ml at L4-L5 space using 25G quinckes needle after local infiltration with 2% lignocaine.

Group F:

Group F patients were given spinal anesthesia with 3.5 ml of injection 0.5% hyperbaric bupivacaine at L4-L5 interspace using 25G Quinckes needle. At the end of the surgical procedure patient received Ultrasound guided Fascia iliaca compartment block. Patient was placed in the supine position. After preparation of the skin with povidone iodine solution, a sterile high frequency USG probe (8-12Mhz) is placed at anterior superior iliac spine pointed midway between umbilicus and xiphisternum.

Then slide the probe medially along the inguinal ligament to get hourglass pattern.

Then the epidural needle was inserted through the Sartorius muscle in a In Plane approach after a skin wheel is made .Needle entry point was 3-4cm from the edge of the transducer. This allows for a decreased needle angle trajectory to fascial plane ,which optimizes the angle of incidence of the ultrasound beam relative to the needle.

Then the needle was advanced until we feel the pops as we pierced fascia iliaca.

Once the needle entered the fascia iliaca compartment, 4-5ml of 0.9% normal saline was injected to confirm the correct needle placement. Optimal needle location was indicated by the appearance of an anechoic fluid collection separating the fascia iliaca from iliacus muscle and visibly expands the compartment, usually reached at an average depth of 4-6cm from skin level.

The epidural catheter was introduced 4-6cm beyond the tip of needle into the compartment. The correct location of catheter tip may be confirmed by either direct visualization via usg or local anaesthetics accumulation in fascia iliaca compartment. 20 ml of 0.125% bupivacaine injected via the catheter the local anaesthetics was injected the fascial compartment expands due to hydrodissection. This will result in separation of fascia from iliacus muscle.



Epidural catheter visualized using Ultrasound

In the recovery room both Group F and Group E was started continuous infusion via catheter at the rate of 8ml/hr for 24 hours .

Outcomes Measured:

Primary Outcome:

Assessment of postoperative pain by Visual Analogue scale (VAS score)

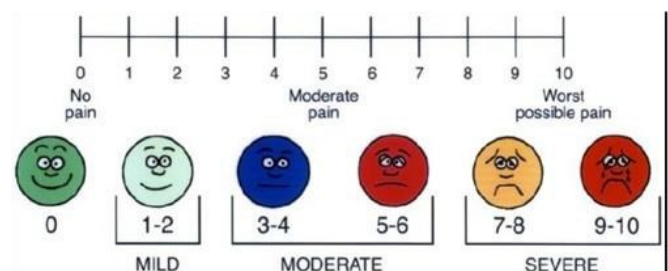


Figure showing visual analog score

Secondary Outcome measures:

- Requirement of rescue analgesia: if the post operative pain score as measures by visual analogue scale is > 3 then rescue analgesia will be given with iv tramadol 100mg
- Postop nausea and vomiting :Patients were assessed for nausea by nausea scores .None-0,Mild-1,Moderate-2,Vomiting-3.Rescue antiemetics were given to patient patients with nausea score greater than or equal to 2 with inj ondansetron 4mg

- Patient Satisfaction:

Patient satisfaction were assessed based on their postoperative analgesia at the end of 24 hours.1 – not satisfying, 2 - satisfying,3 – very satisfying

- Therapeutic failure is defined as inadequate pain relief from surgical wound and drains.
- Technical Failure is the inability to insert catheter as a result of poor tissue planes.
- Hypotension was defined as fall in systolic blood pressure to more than 20% of the baseline value.
- Bradycardia is defined as decrease in pulse rate to more than 20% of the base line value.

All parameters measured at
1hour ,2,4,8,12,16,and 24th hour

Observation and Results:

After collecting the data, all the variables are examined for outliers and non-normal distributions. The Categorical variables are expressed as Frequency and Percentage. The Quantity variables are expressed as mean and standard deviation. Descriptive statistics are used to evaluate baseline characteristics.

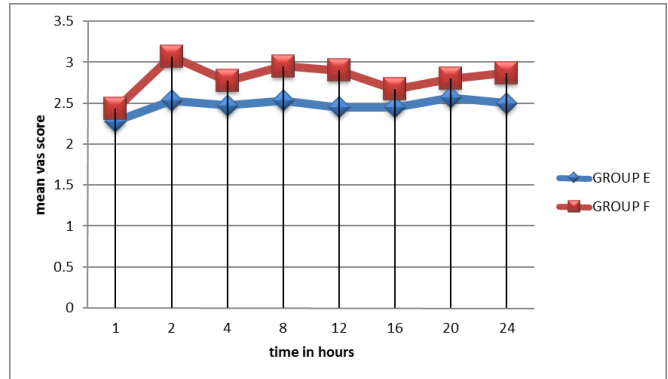
Student's t-test was used to analyze the parametric data, and discrete (categorical) variables were analyzed using the Chi-Square test, with a $P < 0.05$ considered statistically significant. The statistical analysis was carried out using statistical software package SPSS 20.0.

Demographic profile of the two groups such as age ,sex, height, weight, distribution of surgical procedures, ASA classification, duration of surgery were not statistically significant ($P > 0.05$)

Distribution of mean VAS score over the entire 24 hour was comparable between the two groups. P value is not statistically significant.

TIME (IN HOURS)	GROUP E MEAN ± SD	GROUP F MEAN ± SD	P VAL- UE
VAS 1	2.28± 0.804	2.43 ± 0.851	0.323
VAS 2	2.88±1.0 5	2.55± 1.28	0.123
VAS 4	2.47 ± 1.321	2.77 ± 1.332	0.218
VAS 8	2.53 ± 1.268	2.95 ± 1.111	0.058
VAS 12	2.45 ± 1.096	2.90 ± 1.515	0.065
VAS 16	2.45 ± 1.185	2.67 ± 1.410	0.364
VAS 20	2.57 ± 1.212	2.80 ± 1.493	0.349
VAS 24	2.50 ± 1.127	2.87 ± 1.321	0.105

DISRIBUTION OF MEAN VAS SCORE



Rescue analgesics were provided when Visual Analogue Score (VAS) scores ≥ 4 , or on patient demand. Out of 60 patients in Group F, 15 of them required rescue analgesics, and in Group E also 9 patients required rescue analgesics .p value is 0.171 not statistically significant.

Postoperative nausea vomiting (p-0.378), therapeutic failure (p-0.224), patient satisfaction (p-0.509) were not statistically significant. Other parameters such as systolic ,diastolic and mean blood pressure , pulse rate, were comparable. There were no respiratory depression, urinary retention observed in both groups.

Discussion:

Patients with femur fracture requires a continuum of pain management from the time of pre-hospital admission till final rehabilitation. Optimal perioperative analgesia is an issue to be addressed. A good postoperative analgesic regimen is critically important to attenuate stress response in the postsurgical period to improve postoperative outcomes. Inadequate pain control may lead to serious medical issues such as tachycardia, myocardial ischemia, venous thromboembolism. Adequate postoperative analgesia facilitates earlier patient mobilisation and satisfaction.

The surgeries for fracture neck of femur includes Hemi arthroplasty and DHS. The site of skin incision is in the junction of medial and lateral thigh about 2cm from the ASIS. The cutaneous distribution of this area is covered by the femoral and lateral cutaneous nerve of thigh. The Fascia lata and the Vastus muscles which are retracted during the procedure are supplied by the femoral nerve. A small part of the posterior acetabulum alone is supplied by the nerve to quadratus femoris.

The FICB effectively blocks femoral and lateral cutaneous nerve of thigh, thus provides effective pre and post operative analgesia in patients with fracture neck of femur, femoral shaft fracture, Trochanteric fracture and total hip replacement.

Pain following femur surgeries is more pronounced in the first two postoperative days. The pain is aggravated during mobilization. Patients usually receive intravenous opioids for postoperative analgesia. But systemic opioids provide only static analgesia and doesn't alleviate the dynamic component of pain. Dynamic analgesia is provided mainly by regional anaesthesia techniques in the postoperative period³⁸. The gold standard technique that has been used for postoperative pain relief is epidural analgesia. Epidural block with local anesthetics with or without an opioid are superior to other forms of analgesia, but can cause severe hypotension, nausea vomiting, urinary retention, delayed ambulation. There is also risk of developing an epidural hematoma with concomitant use of postoperative anticoagulation.

Peripheral nerve blocks can be used alternative to epidural analgesia, but failure rate was high in peripheral nerve blocks in anatomic landmark based approaches. With the advent of ultrasound, peripheral nerve blocks gain popularity for lower limb surgeries like lumbar plexus block (posterior approach psoas compartment block & anterior approach femoral 3in 1 block), fascia iliaca block, sciatic block. One of the most easiest USG guided peripheral nerve block used for postoperative pain relief especially for femur surgery is the Fascia Iliaca Compartment Block (FICB).

The FICB effectively blocks femoral and lateral cutaneous nerve of thigh, thus provides effective pre and postoperative analgesia in patients with fracture neck of femur, femoral shaft fracture, Trochanteric fracture and total hip replacement.

While there are various studies comparing epidural analgesia with conventional systemic analgesia and there are also studies comparing USG guided FICB with systemic opioids for post-operative pain relief, there are only a few studies comparing epidural analgesia with USG guided FICB.

In this study we compared the pains scores between epidural group and FICB group over 24 hours. In addition post-operative nausea and vomiting, patient satisfaction at 24 hours, rescue analgesia with injection tramadol, complications associated with the procedure were evaluated between the 2 groups. The hemodynamic parameter over a period of 24 hours was also compared between FICB group and epidural group. Study was a randomized clinical trial. Study was a double blind study, with both the observer and analyser blinded to the study. Sample size selected was 120, based on previous published article. Based on the proportion of success rate for the two groups, the Epidural group and the FICB group and assuming the significance level of 5% with power of 80%, the required sample size for the study was computed to be 112 minimum.

Patients from FICB group and Epidural group were analyzed for the demographic profile such as age, sex, height, weight. The demographic profile as computed by students t-test and Chi-square test were similar between the FICB group and the Epidural group.

Group E patients received epidural catheter at the time of spinal anaesthesia preoperatively. Group F patients received FICB catheter at the end of the procedure. In group E, patients received epidural analgesia via epidural catheter. 18G Tuohy needle was used to identify epidural space with loss of resistance technique, using midline approach.

In Group F patients, USG guided FICB was performed using high frequency USG probe (6-12MHz). Recognition of hour glass pattern formed by internal oblique, Sartorius and Iliacus muscle, provides reliable, easier and reproducible end points while performing this block based on the study by Harshimran et al. In this technique the needle trajectory is unlikely to encroach on major blood vessels and nerve trunks. Hence the safety and simplicity of this block and its efficacy augmented by ultrasound makes the block most potential for hip fractures. For the same reason it would be very easy to teach and could be performed by healthcare professionals even with limited experience of ultrasound.

18G Tuohy needle was used in an in plane approach under USG guidance, it goes through the Sartorius muscle and when it pierces the fascia iliaca, popup is felt. Drug is injected between fascia iliaca and iliacus muscle. 18G Tuohy needles were clearly defined under realtime USG. Visualisation of the needle tip and large volume of local anaesthetic drug injection since it is a compartment block was the most important factor determining the success of the block. Optimal needle location is indicated by the appearance of an “anechoic” fluid collection. Then the epidural catheter is inserted 4-6cm beyond the needle tip and 20ml of 0.125% bupivacaine is given and direct visualization of drug spread under fascia by using ultrasound is confirmed.

The local anaesthetic that was used in both the groups was bupivacaine. Bupivacaine is a commonly used drug both in epidural analgesia as well as USG guided FICB block. In the postoperative recovery room both groups were started with continuous infusion of 0.125% Bupivacaine at a rate of 8ml/hr. Since the mean duration of the surgery was approximately 112 minutes. The groups were comparable in terms of activation of FICB catheter and epidural catheter.

The primary outcome measure that was compared between the FICB group and epidural group, was the pain scores graded by visual analog scores. The VAS scores were graded on a 0-10 cm scale. VAS scores were observed over a period of 24 hour in the postoperative period. VAS scores were observed at 1 hour, 2 hours, 4 hours, 8 hours, 12 hours, 16 hours, 20 hours, 24 hours.

The mean VAS scores at all the time intervals, measured were comparable between the FICB group and the epidural group. The p-value computed was statistically not significant. So the analgesic efficacy of USG guided FICB as measured by visual analog pain scores were comparable with epidural analgesia. Visual analog pain scores were used for grading postoperative pain scores based on previous studies by Dolen J et al on patients undergoing hip arthroplasty in these studies, patient received USG guided FICB for postoperative pain relief.

One of the secondary outcome measures that was analyzed was the postoperative nausea and vomiting. Rescue anti-emetics were given with Injection Ondansetron 4 mg intravenously, when the PONV scores were ≥ 2 . Average PONV scores were similar in both the groups. Incidence of vomiting would have been higher if a narcotics were to be used significantly. However in our study only 0.125% bupivacaine was used for epidural analgesia as continuous infusion at a rate of 8ml/hr.

The next outcome measure was postoperative satisfaction score. A score of 3 which means excellent postoperative satisfaction was recorded in 29 patients in Group E compared to 23 patients in group T. The mean postoperative satisfaction was a shade better in the Epidural group. P value is 0.509, statistically not significant.

Mean VAS scores were comparable between the FICB group and the epidural group. The average post-operative nausea scores were similar in both groups.

In the FICB group, therapeutic failure rate was 13% . In the epidural group the therapeutic failure rate was 7%. Out of the 4 patients in the epidural group who had therapeutic failure 1 patient had bloody aspirate 6 hour after surgery. 3 patients had inadequate pain relief probably due to catheter migration. As far as the FICB catheter group was concerned, out of 8 patients who had therapeutic failure because of inadequate pain relief probably due to either catheter migration, block in the epidural catheter. In all the patients who had therapeutic failure was given rescue analgesia inj Tramadol.

Rescue analgesia was given as per the patient requirement and on patients' demand. Rescue analgesia was given if VAS scores were greater than or equal to 4. Injection ondansetron 4 mg was given before administering tramadol. Rescue analgesia was required in 15 of the 60 patients in the FICB group and 9 of the 60 patients in the epidural group. So requirement of rescue analgesia was comparable in both the groups.

There was no incidence of bradycardia, respiratory depression, in both the groups and those are common when opioids are used in neuraxial blockade. Urinary retention was present in 9 patients of epidural group and 2 patients of FICB group. Based on previous study done by sumit datta et al spinal anesthesia was associated with higher incidence of urinary retention (22.2%) with epidural 14.3% .

Hypotension is the most common side effects seen with sympathetic denervation in central neuraxial blockade. Risk factors associated with hypotension include hypovolemia, preoperative hypertension, high sensory block height, age older than 40 years, obesity. Physiological effect of sympathetic blockade was reason behind this hypotension in epidural group. But there was no incidence of hypotension reported in the FICB group and Epidural group. Since the concentration used here is 0.125% bupivacaine doesn't cause hypotension in epidural group.

As far as the hemodynamic parameters are concerned there was a no fall in systolic blood pressure, diastolic blood pressure as well as mean arterial pressure at periodic time intervals after activation of epidural catheter. So we concluded that USG guided FICB was comparable to epidural analgesia in terms of post-operative pain relief.

Adverse effects of epidural analgesia include dural puncture, transient neuropathy, spinal hematoma, neuraxial infections, catheter migration. Catheter migration can be intrathecal or intravascular. Both can present with catastrophic complications. Hypotension is present in epidural anaesthesia due to sympathetic blockade. Lower limb motor block is uncommon when using low concentrations (0.125%) of bupivacaine. Urinary retention is seen when sacral segments S2 to S4 are blocked by epidural analgesia.

Advantages of this USG guided FICB include unilateral analgesia on the side of surgery, less motor blockade and early ambulation. FICB is devoid of side effects of epidural analgesia such as hypotension, postoperative nausea and vomiting, urinary retention and a motor blockade.

Conclusion:

From this study it can be concluded that the analgesia following the ultrasound guided Fascia iliaca compartment Block though comparable to epidural analgesia, can be an effective alternative to epidural block, because of its relative simplicity in technique and less invasiveness. Hence we arrived at a conclusion that the FICB holds considerable promise as an effective postoperative analgesia with less side effects compared to Epidural analgesia.

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