Femoral Nerve Block Versus Intravenous Analgesia As Preemptive Analgesic For Positioning Of Spinal Anaesthesia In Fracture Femur: A Randomised Comparative Study.

by

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Dissertation submitted to

In partial fulfillment for the degree of

DOCTOR OF MEDICINE
IN
ANAESTHESIA

Under the Guidance of

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DEPARTMENT OF ANAESTHESIA

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2019

ABBREVATIONS

ASA- American Society of Anaesthesiologists

ECG- Electrocardiogram

FNB- Femoral Nerve Block

IVF- Intravenous Fentanyl

IVA- Intravenous Analgesia

HR- Heart rate

BP- Blood Pressure

I.V- Intravenous

NIBP- Non-invasive Blood Pressure

SPO_2- Oxygen Saturation

S.D- Standard Deviation

VAS- Visual Analog Scale

USG- Ultrasonography

mcg- Microgram

mg- Milligram

kg- Kilogram

mL- Millilitre

hrs- Hours

min- Minutes

n- Number of Subjects

p- ‘p’ value

C.I- Confidence Interval

CSE- Combined Spinal and Epidural

NB- No Block

S (-) - Levorotatory

R (+) – Dextrorotatory

$t_{½}$ - Half life

MHz- Mega Hertz

Sl. No.- Serial number

ABSTRACT

Background: Fracture femur is one of the most common orthopaedic problem following trauma in patients of all ages. The preferred method of anaesthesia in these patients is central neuraxial blockade such as spinal anaesthesia which requires correct positioning. This randomised comparative study was conducted to compare the analgesic effects of Femoral Nerve Block using Ropivacaine with intravenous (I.V) Fentanyl prior to positioning for central neuraxial blockade using spinal anaesthesia in patients undergoing fracture femur surgeries.

Aim: This study was conducted to evaluate better analgesic mode in terms of pain relief on visual analog scale during positioning, time to perform spinal anaesthesia, the quality of positioning and acceptance of patients with fracture femur.

Objectives: Comparison of the analgesic effects of Femoral Nerve Block (FNB) with Intravenous Fentanyl 15 minutes prior to positioning for a spinal block in patients with fracture femur with the aid of primary outcomes like efficacy of analgesia, ease of positioning for spinal anaesthesia, patient satisfaction, time to perform spinal anaesthesia. Secondary outcomes like duration of spinal anaesthesia, first rescue analgesic dose after spinal anaesthesia and complications.

Methodology: This randomised comparative study was conducted on 80 ASA I and II patients of either gender aged between 30 – 70 years posted for fracture femur surgeries**.** The patients were randomly selected and divided by computer generated random number tables in to two groups with 40 patients in each group. Group I patients were given Femoral Nerve Block with 15 ml of 0.2 % Ropivacaine using USG. Group II patients were given I.V. Fentanyl 0.5 mcg/kg. Data was analysed using chi-square test and 't' test.

Results: Significant difference was observed between the two groups in efficacy of analgesia (group I- 3.750±1.1929 and group II- 5.900±1.1503; $p<0.001$), time to perform spinal

anaesthesia (group I- 4.050±1.280 and group II- 6.725±1.0857; p<0.001), duration of spinal anaesthesia (group I- 3.925±0.4319 and group II- 3.300±0.2953; p<0.001), first rescue analgesic dose (group I- 6.325±1.3134 and group II- 4.013±0.473; p<0.001). The percentage of patients with successful positioning for spinal anaesthesia and patient satisfaction were statistically significant and higher and had considerably lower percentage of complications in group I than in group II.

Conclusion: Femoral Nerve Block is a better preemptive analgesia than intravenous Fentanyl to facilitate positioning for central neuraxial blockade in patients undergoing fracture femur surgeries.

KEY WORDS: Femoral Nerve Block, Intravenous Fentanyl, USG.

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INTRODUCTION

Fracture femur is a prevalent orthopaedic issue in patients of all ages following trauma. Because the periosteal tissue is richly innervated with nerve fibers from the femoral nerve, it has the smallest pain threshold among the deep somatic structures, which makes fracture femur extremely painful.[1]

The preferred method for anaesthesia in fracture femur is the central neuraxial block such as spinal anaesthesia. Correct positioning is the prerequisite for a successful spinal anaesthetic block procedure.[2]

However, limb immobility and extreme pain are the deterrents for an ideal positioning for this procedure. Any movement of the fractured limb in such patients lead to aggravation of pain.

So various methods like hot fomentation, oral, intramuscular and intravenous analgesics using NSAID's, analgesic patches of NSAID's and opioids, intravenous opioids and nerve blocks using local anaesthetics have been tried to deal with these challenges so as to provide quality anaesthesia services in the day to day practice based on both evidence based medicine and logical empiricism.[1]

Fentanyl belongs to the family of phenylpiperidines. It is 80 to 100 times more potent than morphine. Over 80% of the administered dose can be distributed from plasma to highly vascular tissues such as heart, lung and brain in less than 5 minutes after an intravenous bolus. It provides cardiovascular stability, but the concentration-effect relation between fentanyl and respiratory depression is directly related.[3] Other side effects include cognitive impairment, vomiting and urinary retention, which limits its clinical utility.[1]

Previous studies suggest that use of local anaesthesia using Femoral Nerve Block (FNB) is a safe and effective method. These methods can be carried out during prehospital care, emergency department and in the preoperative setting.[1]

Femoral Nerve Block (FNB) increases comfort and also been shown to improve positioning for a spinal block in such patients. Ropivacaine has emerged as a safer anaesthetic for local and regional anaesthesia and has replaced previously used anaesthetic drugs.[1]

Hence, this randomised comparative study was conducted to compare the analgesic effects of Femoral Nerve Block using Ropivacaine with intravenous (I.V) Fentanyl prior to positioning for central neuraxial blockade using spinal anaesthesia in patients undergoing fracture femur surgeries.

AIM AND OBJECTIVES

Aim:

To evaluate better analgesic mode in terms of pain relief on visual analog scale during positioning, time to perform spinal anaesthesia, the quality of positioning and acceptance of patients with fracture femur.

Objectives:

Comparison of the analgesic effects of Femoral Nerve Block (FNB) with intravenous Fentanyl 15 minutes prior to positioning for a spinal block in patients with fracture femur with respect to:

Primary Outcome:

- Efficacy of analgesia.
- Ease of positioning for spinal anaesthesia.
- Patient satisfaction.
- Time to perform spinal anaesthesia.

Secondary Outcome:

- Duration of spinal anaesthesia.
- First rescue analgesic dose after spinal anaesthesia.
- Complications –

A. Femoral Nerve Block: Vascular puncture, Intravascular injection and anaesthetic toxicity, Hematoma and Nerve damage.

B. I.V Fentanyl: Sedation, Cognitive impairment, Nausea, Vomiting, Respiratory depression, Dryness of mouth, Urinary retention.

REVIEW OF LITERATURE

- **Haddad FS, William RL (1995)** studied 50 patients with extracapsular fractures of the femoral neck to receive either a bupivacaine femoral nerve block or systemic analgesia alone. A femoral nerve block was found to be an easy and effective procedure which significantly reduced perioperative analgesic requirements and postoperative morbidity.[4]

- **Sia S, Pelusio F, Barbagli R, Rivituso C (2004)** studied Analgesia before performing a spinal block in the Sitting Position in Patients with Femoral Shaft Fracture: A Comparison between Femoral Nerve Block and Intravenous Fentanyl. Five minutes before the placement of spinal block, one group patients (n = 10) received a femoral nerve block with lidocaine 1.5% 15 mL, and second group patients (n = 10) received I.V fentanyl 3 mcg/kg to facilitate sitting position to give spinal block .They found that visual analogue scale measurement, time required to give position for spinal block is lesser in femoral nerve block than iv fentanyl. In one group IV fentanyl patient, an oxygen saturation <90% was recorded during the procedure. They concluded that femoral nerve block is better than I.V fentanyl for giving position for spinal block in femur surgeries.[5]

- **Christos SC, Chiampas G, Offman R, Rifenburg R (2009)** conducted a study of Ultrasound-Guided Three-In-One Nerve Block for Femur Fractures and concluded that USG guided FNB is a safe and easy procedure that can be performed with minimal USG training for femoral fractures. The 3-in-1 FNB provides rapid, effective anaesthesia and has also been shown to decrease the opioid and volume of local anaesthetic requirement for pain management. Finally, with informal questioning, they received very favourable

feedback from their orthopaedic surgeons, nursing staff and great satisfaction from their patients.[6]

- **Iamaroon A, Raksakietisak M, Halilamien P, Hongsawad J, Boonsararuxsapong K (2010)** studied Femoral nerve block versus fentanyl: Analgesia for positioning patients with fractured femur. Sixty-four ASA I–III patients aged 18–80 years undergoing surgery for femur fracture were randomised into two groups. Fifteen minutes before spinal block, the Femoral Nerve block group received nerve stimulator-assisted femoral nerve block with a mixture of 20 mL bupivacaine 0.5% and 10 mL normal saline 0.9%, and the fentanyl group received two doses of IV fentanyl 0.5 mcg/kg with a five-minute interval between doses. Numeric rating pain scores were compared. During positioning, fentanyl in 0.5 mcg/kg increments was given every five minutes until pain scores were ≤4.[7]

- **Durrani H, Butt KJ, Khosa AH, Umer A, Pervaiz M (2013)** conducted a study to enlighten better technique in terms of pain relief (on visual analogue scale) during positioning, time to perform spinal anaesthesia, the quality of position and acceptance of patients. Eighty-four ASA I–II patients aged 18–80 years undergoing surgery for femur fracture under spinal block were selected and randomised into two groups (42 in each group). Fifteen minutes before positioning for spinal block, the FNB group received femoral nerve block with a mixture of 15 mL lignocaine with adrenaline and 5mL distilled water and the IVA group received 6mg intravenous nalbuphine. Results showed that pain assessed on visual analogue scale (VAS) during positioning was significantly less in FNB group (1.40±0.66) versus IVN group (3.02±1.39), p=0.000. Time to perform spinal block was significantly shorter in FNB group (2.15±0.78min) versus IVA (3.50±1.46min),

p=0.001. Quality of patient positioning during spinal was significantly better in FNB group (2.45±0.55) than IVA group (1.88±0.80), p=0.000. Acceptance of patient was very significantly higher among FNB group (40/42=95.24%) than IVA (28/42=66.67%) group, p =0.001. The results of this study reflected that femoral nerve block provides better analgesia resulting in adequate positioning, rapid performance of spinal and higher acceptance among patients with femoral fracture during positioning for administration of spinal anaesthesia.[8]

- **Newman B, McCarthy L, Thomas PW, May P, Layzell M, Horn K (2013)** conducted a comparative study of pre-operative nerve stimulator-guided femoral nerve block and fascia iliaca compartment block in patients with a femoral neck fracture and concluded that Femoral nerve block provided superior pre-operative analgesia for fractured neck of femur compared with fascia iliaca compartment block. The difference in the mean reduction of pain score after the block was 0.9 (95% CI 0–1.8); p = 0.047. Patients receiving a femoral nerve block required less morphine after the block than those receiving fascia iliaca compartment block (p = 0.041).[9]

- **Jadon A, Kedia SK, Dixit S, Chakraborty S (2014)** conducted a study with the aim to compare the analgesic effect provided by Femoral Nerve Block and IV Fentanyl prior to positioning for central neuraxial block in patients undergoing surgery for femur fracture. Demographic data and base line values for heart rate, mean arterial pressure and type of surgery were comparable in both the groups. There was no significant change noticed in heart rate between two groups (p = 0.75); however, mean arterial pressure was significantly lower in Fentanyl group (p = 0.0019). Visual analog scale values during

positioning (median ± SD) were lower in group Femoral Nerve Block 0.57 ± 0.31 versus Fentanyl 2.53 ± 1.61 (p = 0.0020). Time to perform spinal anaesthesia (mean ± SD) was shorter in group Femoral Nerve Block: 15.33 ± 1.64 min versus Fentanyl 19.56 ± 3.09 min (p = 0.000049). Quality of patient positioning for spinal anaesthesia was higher in group Femoral Nerve Block 2.67 ± 0.606 versus Fentanyl 1.967 ± 0.85 (p = 0.000027). Patient acceptance was less in group Fentanyl (p = 0.000031). SpO2 was significantly lower in Fentanyl group (p = 0.001).The most important finding of study was that femoral nerve blockade offered superior analgesia compared to IV fentanyl during position for spinal anaesthesia in cases of fracture femur. In addition, Femoral Nerve Block was associated with greater patient satisfaction. They concluded that Femoral nerve block provides better analgesia, patient satisfaction, less time for anaesthesia and satisfactory positioning than IV fentanyl for central neuraxial block in patients undergoing surgery for femur fractures.[(2)]

- **Bhosle P, Prakash A, Aphale S (2015)** conducted a study to evaluate the usefulness of femoral nerve block (FNB) for positioning during regional anaesthesia in patients with femur fracture. 60 patients between the age group of 30 to 80 years, of ASA grade I, II and III, scheduled for elective surgeries of femur fracture were evaluated in 2 groups. Group FNB received femoral nerve block with 15mL of 1.5% lignocaine and Group. NB was not given any block. Assessment of pain before and after performing femoral nerve block was done by VAS score along with assessment of performance time and quality of patient's positioning during regional anaesthesia. Results showed that 60 % of patients receiving FNB showed the VAS score of 1.4 ± 0.498 while 40% had VAS score of 4.03 ± 0.32 in Group NB and good pain relief for positioning for combined spinal epidural (CSE) in Group FNB and lesser performance time(16.2 ± 2.7 min) in comparison to patients not

receiving nerve block it was (19.23 ± 2.674 min). The data analysed for quality of positioning observed in FNB group 2.10 ± 0.305, While in NB group it was1.13 ± 0.346. They concluded that Femoral nerve block is not only effective in reducing pain during procedure but also decreases the performance time and gives better quality of positioning during regional anaesthesia for patients with fracture femur.[10]

- **Hartmann FV, Novaes MR, de Carvalho MR (2015)** conducted a study to compare the analgesic efficacy of intravenous fentanyl versus femoral nerve block before positioning to perform spinal anaesthesia in patients with femoral fractures assessed by Pain Scales. Nerve blockade seemed to be more effective than intravenous fentanyl for preventing pain in patients suffering from a femoral fracture. It also reduced the use of additional analgesia and made lower the risk for systemic complications. Femoral nerve block reduced the time to perform spinal anaesthesia to the patient who will be subjected to surgery and facilitate the sitting position for this. They concluded that the use of femoral nerve block can reduce the level of pain and the need for additional analgesia. There are less adverse systemic events associated with this and the procedure itself does not offer greater risks.[3]

- **Reddy ED, Rao BD (2016)** conducted a study to compare the efficacy of femoral nerve block over fentanyl. 72 patients between the ages of 18 – 70 years, who had femur fracture and unable to sit due to extreme pain were included into the study. The patients were divided into 2 groups based on the random number table, to receive Femoral Nerve Block (FNB group) and intravenous fentanyl (IVF group). Vital statistics, visual analog scale for pain measurement and patient satisfaction was noted. Results were, the VAS scores 15 minutes after analgesic in FNB group were 3.1 ± 2.1 compared to 3.9 ± 1.9 in IVF group

and during the positioning, 6.2 ± 2.1 and 7.2 ± 2.7 respectively. Time to perform surgery was 2.0 minutes ± 1.9 in FNB group and 3.6 ± 1.4 in IVF group while patient satisfaction was 32 and 26 respectively in the FNB and IVF groups. Their study revealed that femoral nerve block was a better analgesic drug compared to intravenous fentanyl for positioning of the hip during spinal anaesthesia in femoral fracture surgeries.[11]

- **Singh AP, Kohli V, Bajwa SJ (2016)** conducted a study to compare the analgesic effects of Femoral Nerve Block with intravenous I.V fentanyl prior to positioning for a spinal block in patients with fracture femur and to compare the analgesic requirements in both groups. In Group I, Femoral Nerve Block was given whereas in Group II patients, I.V. fentanyl 0.5 mcg/kg was given 15 min before administration of spinal anaesthesia. Pain scores were assessed using a numerical verbal scale (0 - no pain, 10 - most severe pain). Visual Analog Scale values were checked regularly after 2 min, 5 min, 10 min, 15 min, and during positioning of the patient. Group I (Femoral Nerve Block group) had lower Visual Analog Scale scores compared to Group II (I.V. fentanyl) and the difference was statistically significant ($p < 0.001$). Satisfaction score was better in Group I when compared with Group II at all times (0.67 ± 0.547 v/s. 0.20 ± 0.407). Time to perform spinal anaesthesia was shorter in Group I versus Group II ($p < 0.001$) (17.80 ± 1.064 min v/s. 25.03 ± 1.771 min). For I.V. fentanyl group, the duration of postoperative analgesia was significantly shorter as compared to Femoral Nerve Block group. They concluded that Femoral Nerve Block using 15 mL of 0.2% ropivacaine is a safe and effective method to alleviate pain as preemptive analgesia than I.V. fentanyl. Femoral Nerve Block reduces the time to perform spinal anaesthesia, increases the postoperative duration of analgesia and reduces analgesic requirements postoperatively.[1]

- **Ranjit S, Pradhan BB (2016)** conducted a study to compare between ultrasound guided femoral nerve block with lignocaine and intravenous fentanyl in providing effective analgesia before positioning patient with femur fracture in sitting position for subarachnoid block. 40 patients undergoing surgery for femur fracture were randomised to either femoral nerve block (FNB) or intravenous fentanyl (IVF) group. Group FNB (n=20) received 20 mL of 2% lignocaine around femoral nerve under ultrasound guidance. IVF group (n=20) received 2 mcg/kg of fentanyl intravenously. Pain score on effected limb was assessed after five minutes. If Visual Analog Scale (VAS) was ≤ 4, the patient was positioned in sitting for subarachnoid block. On failure to achieve this with the above treatment, intravenous fentanyl 0.5 mcg/kg was administered and repeated as necessary before positioning. VAS during positioning was documented and compared between the two groups. Similarly, secondary outcomes of the intervention including quality of patient position, rescue analgesia and duration of the procedure were also compared. Data were subjected to Mann Whitney U-test and chi-square test. Level of significance was set at 0.05. Results were, FNB group had significantly less VAS scores (median) than IVF group 2 v/s 3; p=0.037) during positioning for spinal anaesthesia. Procedure time (median) for spinal anaesthesia was also significantly less in FNB than in IVA group (10 v/s 12 min; p=0.033). They concluded that Ultrasound guided femoral nerve block was more effective than intravenous fentanyl for reducing pain in patients with proximal femur fracture before spinal anaesthesia.[12]

- **Ningawal BK, Acharya G, Arora KK (2016)** studied the comparison of analgesic effects of femoral nerve block (FNB) with intramuscular tramadol prior to shifting the patients with fractured femur into operation theatre for spinal block. Seventy- five ASA I–II patients aged 18–60 years undergoing surgery for femur neck fracture were compared

between three groups. Thirty minutes before spinal block, the FNB group received femoral nerve block with classical landmark approach with a mixture of 20 mL bupivacaine 0.5%, and the tramadol group received injection tramadol 100 mg intramuscular and control group received neither the block nor the analgesic. The patients were then observed and evaluated for onset of analgesia, intensity of pain, assessment of sensory block, degree of pain relief, complications and patient's acceptance. Results showed that FNB provides almost total pain relief and abolition of muscle spasm within few minutes as compare to tramadol group, FNB causes little change in hemodynamic parameters in patient compared to intramuscular tramadol. Concluded that FNB provided quick onset and more effective pain relief with statistically significant change in hemodynamic parameters as compared to intramuscular tramadol.[13]

- **Purohit S, Ejjapuredi S, Badami RN (2017)** conducted a study to evaluate the effectiveness of femoral nerve block (FNB) in positioning the patients for regional anaesthesia. 100 patients between the ages 18 to 80 years, of ASA grade I, II and III, scheduled for elective surgeries of femur fracture were evaluated in 2 groups. Group FNB (n=50) received femoral nerve block with 15mL of 1.5% lignocaine and Group. Non FNB (n=50) was not given any block. Assessment of pain was carried out using visual analog scale (VAS). This was rated before, during and after the procedure of positioning for spinal/combined spinal epidural anaesthesia (CSE). Vital parameters were tabulated. Results showed that VAS scores were noted at 0, 2, 5, 10, 15 minutes and at the time of positioning. VAS scores at 15 minutes after FNB was 1.473 ±0.1639 and 8.250±0.3615 in patients without FNB. Time taken for CSE was significantly less in FNB group (13.026±0.4628) minutes as compared to non FNB group (19.660 ±0.3742) minutes. Patient satisfaction scores were significantly higher in FNB group (45/50) 1.4952±0.033

as compared to non FNB group (10/50) 0.3460±0.1786. Quality of patient positioning was better in FNB group (2.782±0.1273) as compared to non FNB (1.382±0.2473). They concluded that this study concludes that FNB is highly effective in giving good pain relief for positioning for regional anaesthetic procedures improving performance time and offers higher acceptance among patients with femoral fractures.[14]

- **Unneby A, Svensson O, Gustafson Y, Olofsson B (2017)** conducted a study to investigate whether preoperative femoral nerve block reduced acute pain and opioid use after hip fracture among elderly patients, including those with dementia. In this randomised controlled trial involving patients aged 70 years with hip fracture (trochanteric and cervical), including those with dementia, we compared femoral nerve block with conventional pain management, with opioid use if required. The primary outcome was preoperative pain, measured at five time points using a visual analogue scale (VAS). Preoperative opioid consumption was also registered. The study sample comprised 266 patients admitted consecutively to the orthopaedic ward. The mean age was 84.1±6.9 years, 64% of participants were women, 44% lived in residential care facilities, and 120 (45.1%) had dementia diagnoses. Patients receiving femoral nerve block had significantly lower self-rated pain scores from baseline to 12 hours after admission than did controls. Self-rated and proxy VAS pain scores decreased significantly in these patients from baseline to 12 hours compared with controls ($p < 0.001$ and $p = 0.003$, respectively). Patients receiving femoral nerve block required less opioids than did controls, overall (2.3 ± 4.0 v/s. 5.7 ± 5.2 mg, $p < 0.001$) and in the subgroup with dementia (2.1 ± 3.3 v/s. 5.8 ± 5.0 mg, $p < 0.001$). They concluded that patients with hip fracture, including those with dementia, who received femoral nerve block had lower pain scores and required less opioids before surgery compared with those receiving conventional pain management.

Femoral nerve block seems to be a feasible pain treatment for elderly people, including those with dementia.[15]

PAIN

Pain is described as physical sensation induced by disease or injury that is extremely unpleasant. Pain comes from the Latin term "Poena" which implies penalty. Hippocrates and Aristotle saw pain and pleasure as feelings that originated in the heart rather than the brain.[16,17] Pain was theorized to originate outside the body before the renaissance in Europe. Prayer was the most prevalent therapy choice, as it was thought to be God's penalty.[18] RenéDescartes theorized in 1644 that pain was a disturbance going through the nerve cells until the disturbance reached the brain, a development that changed the perception of pain from a spiritual, mystical experience into a physical, mechanical experience.[19,20] This moved the centre of pain sensation and perception from the heart to the brain.

Pain was described in three dimensions by Melzack R, Casey KL (1968)[21] : "sensory-discriminative" (sense of the magnitude, location, quality and duration of the pain), "affective-motivational" (unpleasantness and willingness to get away with it) and "cognitive-evaluative" (cognitions such as assessment, cultural beliefs, distraction and hypnotic suggestion.

Now pain has been described in terms of danger very aptly by the International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage”.[22]

Pain Physiology:

Pain is a defensive mechanism of the body. It occurs whenever tissues are being harmed and cause the individual to act upon to get relieved from the painful stimulus. Thus pain may

be defensive, protective and diagnostic. Pain, as a sensation is a function of nerve impulses that ascend from the periphery and are modulated by mechanisms to appreciate and then evoke appropriate reaction.

Classification of Pain:

There are two major types.

Fast Pain:

It is also known as sharp pain, pricking pain, acute pain and electrical Pain. It occurs within 0.1 seconds when a painful stimulus is applied. They are transmitted via peripheral nerves to spinal cord by small myelinated type A delta fibers at a velocity between 6-30 m/sec.[23,24]

Slow Pain:

It is also known as burning pain, aching pain, and throbbing pain or noxious pain. It is transmitted by unmyelinated type C fibers at a velocity of 0.5-2 m/sec. Their threshold for stimulation is higher than A delta fibers and is responsible for more delayed burning pain. It is usually associated with tissue damage and can cause prolonged unbearable distress.[23,24]

Pain Receptors:

Nociceptors are tissue receptors that are activated by painful stimuli in particular. The receptors transform this noxious data into an electrical signal and transmit it along axons from the periphery to the central nervous system.[25]

Types of nociceptors:

• High-threshold mechanoreceptors (HTM), that react to mechanical distortion.

• Polymodal nociceptors (PMN), that react to a multitude of tissue-damaging signals such as prostaglandins, 5-hydoxytryptamine (5HT), leucotrienes, bradykinine, hydrogen ions, histamine and cytokines.[25]

Nociceptors are the free nerve endings of primary afferent A delta and C fibers. They are distributed throughout the body (skin, viscera, muscles, joints, meninges) and can be stimulated by mechanical, thermal or chemical stimuli.[25]

Neurotransmitters in Pain Pathway:

These are chemical substances and enzymes are released from the damaged tissues, increasing the transduction of painful stimuli. These include prostanoids (prostaglandins, leukotrienes and hydroxyacids) and kinins, such as bradykinin, kallidin, etc.[23]

Several neuro-peptides and excitatory amino acids function as neurotransmitters for afferent neurons sub serving pain. The most important of these peptides are substance P and calcitonin gene related peptide (CGRP). Glutamate is the most important excitatory amino acid.[23,24]

The other neurotransmitters that help in sub serving pain glutamate are aspartate and adenosine triphosphate (ATP) which are excitatory in function. Somatostatin, acetylcholine, enkephalins, β (beta) endorphins, nor epinephrine, adenosine, serotonin, γ(gamma) amino butyric acid (GABA) and glycine are inhibitory in function.[24,25]

Inflammatory mediators [e.g., bradykinin, serotonin, prostaglandins, cytokines, and H^+ (hydrogen ions)] are released from tissue damage and may directly activate nociceptors. They can also act to lower nociceptors ' activation threshold so the stimulus needed to trigger activation is lower. This process is called as primary sensitisation.[23,24,25]

Prostaglandins and bradykinin sensitize nociceptors to be activated by low-intensity stimuli. When applied straight to nerve endings, histamine and 5-hydoxytryptamine (5-HT) cause pain. 5-hydoxytryptamine (5-HT) and hydrogen ions act directly upon the cell membrane's ion channels, but most others bind to membrane receptors and stimulate second-messenger systems through G proteins.[24,25]

Pain Pathways:

Impulses from these receptors utilize separate pathways for transmitting acute sharp pain and chronic pain. The impulses are conducted along sensory afferent fibers. They are the A delta (myelinated large fibers) and C (unmyelinated small fibers) in peripheral nerves. A delta conducted pain is felt quickly and well localised. They have conduction velocity 12-20 meters per second.[26,27,28]

They transform in to free nerve endings in the superficial layers of the dermis. They respond particularly well to pinching or pinprick. They conduct sharp pain produced by pinprick and are responsible for withdrawal reflex. C fibers are small, fine and non myelinated and have a conduction velocity of 0.1to 2 meters per second or less. They also form part of the free nerve ending network of the skin. Their threshold for stimulation is higher and they are probably responsible for delayed noxious pain.[26,27,28]

Primary afferent neurons are situated at each level of the spinal cord in the dorsal ganglia that exists in the vertebral foramina. Each neuron has a one axon that subdivides, sending one end to the innervated peripheral tissue and the other to the spinal cord's dorsal horn. The majority of first-order neurons at each cervical, thoracic, lumbar and sacral level bring the proximal end of their axons into the spinal cord via the dorsal (sensory) spinal root.

It has been shown that some unmyelined afferent (C) fibers enter the spinal cord via ventral nerve (motor) root.

In the dorsal horn, other than synapsing with neurons of second order, in the grey matter of ipsilateral dorsal horn neurons, the axons of the first order neurons may synapse with interneurons, sympathetic neurons and ventral horn with neurons of second order. Afferent fibers after entering the spinal cord, differentiate according to size, with large myelinated fibers becoming medial, and small unmyelinated fibers becoming lateral.[26,27,28])

Pain fibers can ascend or descend one to three spinal cord segments in the Lissauer's tract before synapsing. The axons of majority second-order neurons cross the midline near to their level of origin (at the anterior commissure) to the contra lateral side of the spinal cord before forming the spinothalamic tract and sending their fibers to the thalamus, the nucleus raphe magnus, the reticular formation, and the periaqueductal grey. Second order neurons synapse in thalamic nuclei with third order neurons, which send projections through the internal capsule and corona radiata to the post-central gyrus of the cerebral cortex.

The spinothalamic tract which is a major pain pathway, lies in the white matter of the spinal cord anterolaterally. This very ascending tract is divided as lateral and medial spinothalamic tract.[26,27,28)]

The lateral spinothalamic tract projects mainly in to the ventral posterolateral nucleus of the thalamus and carries differentiating features of pain such as intensity, location and duration. The medial spinothalamic tract projects to the medial thalamus and is responsible for mediating the autonomic as well as unpleasant perception of pain. Some spinothalamic fibers also project to the periaqueductal grey and they may be an important link between the ascending and descending pathways. Collateral fibers project to the reticular activating system and the hypothalamus; these are likely to be responsible for the arousal response to pain.[26,27,28)]

The spinoreticular tract, spinomesencephalic tract, spinohypothalamic tract and spinotelencephalic tract are also other pathways, which help in pain perception. Spinocervical tract ascends uncrossed to the lateral cervical nucleus, which relays the fibers to the contralateral thalamus; this tract is a major alternative pathway.[26,27,28]

Neurophysiology of Pain:

Nociception is the encoding and processing of harmful stimuli in the nervous system, and therefore, ability of the body to sense potential harm. The nociceptive mechanism (prior to the perceptive event) consists of a multitude of events as follows:

Transduction:

Transduction is the conversion of one form of energy to another. It starts when the free nerve endings (nociceptors) of A-delta fibers, C fibers and the primary afferent neurons react to noxious stimuli. Nociceptors are susceptible to noxious stimuli when tissue deformation and inflammation happens as a result of trauma, infection, inflammation, ischemia and surgery. This stimulation causes release of chemical mediators from the damaged cells including bradykinin, histamine, substance P, prostaglandin, potassium, seretonin etc.

These chemical mediators stimulate and/or sensitise the nociceptors to the noxious stimuli. This causes an exchange of potassium and sodium ions (re-polarisation and depolarisation) at the cell membranes which results in generation of an action potential.[28,29,30]

Stages of transduction:

• Events of stimulation to tissue chemical events.

• Tissue chemical and synaptic cleft events to Electrical events in neurons.

• Electrical events in neurons to tissue chemical events at synapses.

Transmission:

Electrical signals are transmitted along neuronal systems, while molecules are transferred from one cell surface to another in the synaptic cleft. The method of transmission takes place in three phases. The pain impulses are transmitted:

1. From the transduction site along the fibers of the nociceptor to the spinal cord's dorsal horn.

2. From the spinal cord to the brain stem.

3. Through the connections between the thalamus, cortex and higher levels of the brain.

These are chemicals, which are formed in the nerve endings and act on specific receptors. Example: Serotonin, Acetylcholine, Bradykinin, Potassium ions, Acids, Histamine and proteolytic enzymes. Prostaglandins enhance the sensitivity of pain in the nerve endings.[28,29,30]

Modulation:

Pain modulation takes place at the nociceptor level peripherally, in the spinal cord, or in supraspinal structures. This modulation can either inhibit or activate pain.

Peripheral Modulation: Inflammatory mediators as well as prolonged, intense or repeated noxious stimulation, or both can sensitize the nociceptors. These nociceptors exhibit a low threshold for stimulation. Peripheral (nociceptor) sensitization plays a vital role in central sensitization and pain states like allodynia and hyperalgesia.[28,29,30]

Central Modulation: This can either activate or inhibit pain.

The mechanisms for activation are:

• Sensitization of second order neurons.

• Receptive field expansion.

• Flexion responses' hyperexcitability.[28,29,30]

Inhibitory mechanisms: can be either Supraspinal or Spinal.

Spinal:

Segmental inhibition involves stimulation of large afferent fibers that subserve wide dynamic range (WDR) neuron and spinothalamic activity inhibitory epicritic sensation. Glycine and gamma amino butyric acid (GABA) are amino acids that act as neurotransmitters that are inhibitory. GABA 'b' receptor activity, which increases potassium conductance across the cell membrane, appears to mediate segmental inhibition.[28,29,30]

Supraspinal:

There is a supraspinal inhibition where several supraspinal structures send fibers down the spinal cord to prevent dorsal horn-level pain. These include peri aqueductal grey, reticular formation, and nucleus raphe magnus (NRM). Axons from these structures operate on the main afferent neurons presynaptically and on cells (or interneurons) of the second order neurons post-synaptically.[28,29,30]

These inhibitory pathways use monoamines as neurotransmitters, such as noradrenaline and serotonin, and end with nociceptive neurons in the spinal cord as well as spinal inhibitory interneurons that store and release opioids. Using α(alpha) 2 receptors, noradrenaline facilitates this action. The opiate endogenous mechanism acts through enkephalins and β(beta)-endorphins. These operate predominantly presynaptically, while exogenous opiates act post-synaptically.[28,29,30]

Brainstem neurons may control nociceptive transmission by:

• Direct action on dorsal horn cells

• Inhibition of excitatory dorsal horn neurons

• Excitation of inhibitory neurons

Perception:

The experience of pain is complex and subjective, and is affected by factors such as cognition, mood, beliefs and genetics. Pain perception is an uncomfortable recognition of some portion of the body, characterized by a strikingly unpleasant feeling and adverse emotion that is best defined as a threat. There is involvement of both cortical and limbic system structures. Nociceptive input from some projection neurons flows through the thalamus to the somatosensory contralateral cortex, where the input is somatotopically mapped to maintain data about the place, severity, and quality of pain.[28,29,30]

Types of Pain:

Nociceptive Pain: Includes visceral and somatic pain and refers to pain due to peripheral stimulation of nociceptors in the visceral or somatic structures.[29,30]

Neuropathic Pain: Pain involves peripheral or central afferent neural pathway and is commonly described as burning type of pain. It is caused by impulse generation within the pathway proximal to nociceptor.[29,30]

Visceral Pain: Pain receptors in viscera are comparable to those in the skin, but in somatic structures they are more widely dispersed and are not linked with intense pain. If any incident that triggers nerve stimulation occurring throughout the viscera, it creates intense pain that is diffuse, poorly localized and often related with nausea and signs of autonomic activation of the nervous system such as either pulse or blood pressure surge or fall. Visceral pain is frequently correlated with muscular rigidity and hyperesthesia. Typically, visceral pain radiates and can be referred to the body's surface area with the same dermatome as the affected viscera.[29,30]

Somatic Pain: It is described as sharp, stabbing, well localized pain that typically arises from skin, skeletal muscle and peritoneum. Superficial pain in general is well localized showing dermatomal pattern. Deep pain has a dull aching character and it may be accompanied by an unpleasant sickening sensation due to autonomic response. It is poorly localized.[29,30]

Referred Pain: Deep pain whether visceral or somatic in origin, may be felt in some part of the body other than the site of stimulation. Visceral pain tends to have characteristic localization for each organ and commonly referred to the dermatome of spinal segments through which the afferent fibers enter. The diaphragmatic pain referred to the shoulder is well known example. The neurophysiologic basis of referred pain depends upon convergence of several cutaneous and visceral afferent fibers on the same secondary neuron at some point in pain pathway.[29,30]

Neuropathic Pain: It can be of three types such as:

- Neural injury pain
- Nerve compression pain
- Complex regional pain syndrome

Neural injury pain involves anatomic abnormality in peripheral nerves, in pain receptors or central pain pathway. It has dermatomal distribution. Nerve compression pain occurs when there is extrinsic pain on the neural structures. It can be central or peripheral depending on site of origin of pain impulse.[29,30]

Theories of Pain:

Specificity Theory: Specificity theory proposes that all sensation including pain are receptor specific and that pain receptors respond only to noxious stimuli.[29,30]

Intensity Theory: Intensity theory holds that stimulation of any sensory receptor will cause pain if stimulus is excessive.[29,30]

Pattern Theory: Pattern theory proposes that sensory impulses are coded according to the number of receptors stimulated and the rate of their discharge.[29,30]

Gate theory for control of pain: Melzack and wall (1965) proposed this theory, which states that dorsal horn at the spinal cord mainly the substansia gelatinosa function as gates for controlling entry of pain signals into the pain pathway.[29,30]

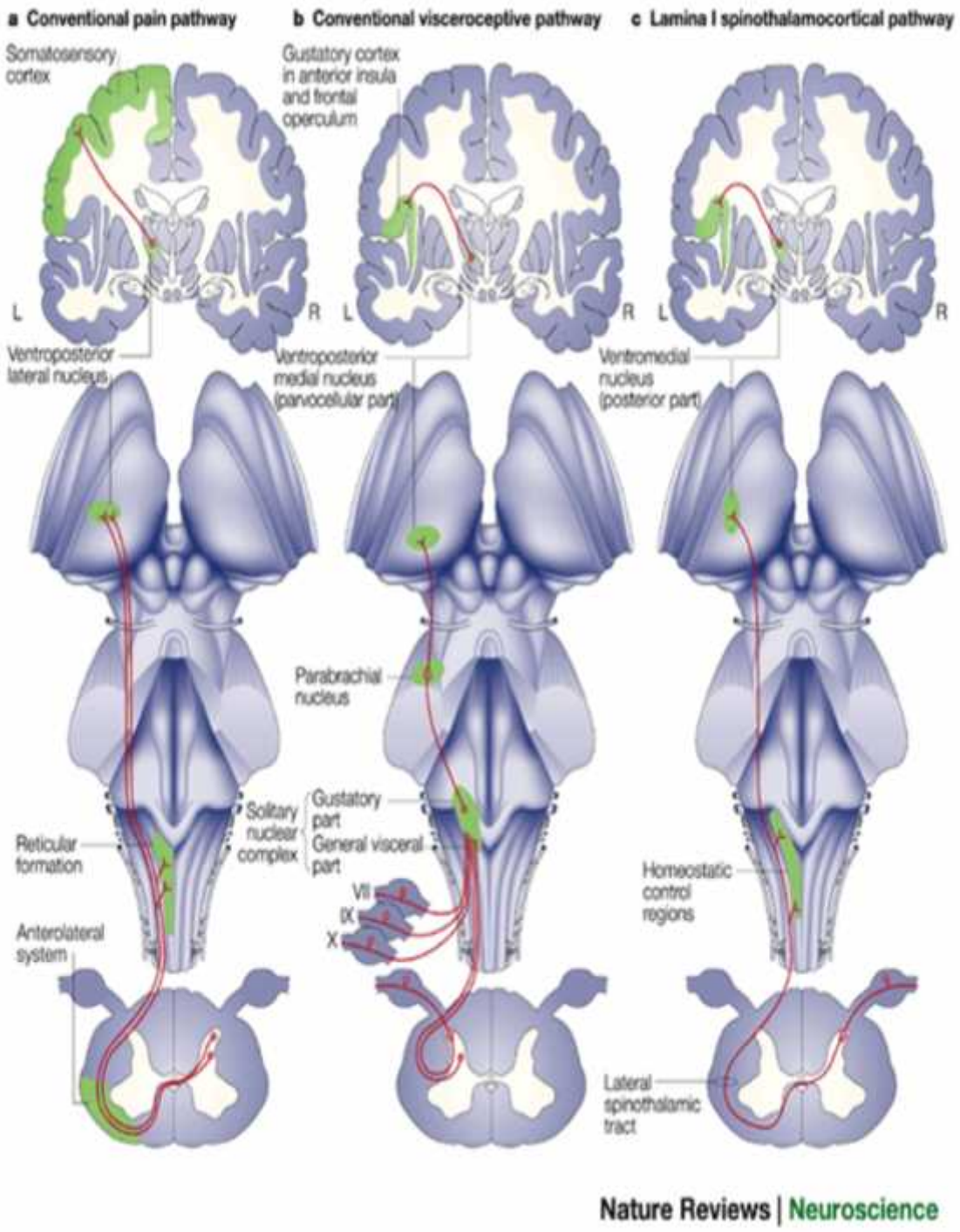


Figure 1: Pain Pathways

Pain Assessment Scales:

Pain is a complex and subjective experience. The evaluation of pain is the vital precondition for effective pain management. Deciding the initial medication plan is helpful, but also revaluating the degree of accomplishment. This treatment and reassessment cycle will continue until a good result has been achieved.[31]

In the immediate postoperative period, physiological responses such as pulse rate, blood pressure, respiratory rate are important indicators of pain. The following one dimensional pain assessment scales were used in this study.[31]

Visual analogue scale: It is 10 cm scale with end points labelled 0 for NO PAIN and 10 for WORST POSSIBLE PAIN. The person was asked to compare the severity of current pain with worst pain he ever faced in his life.[31]

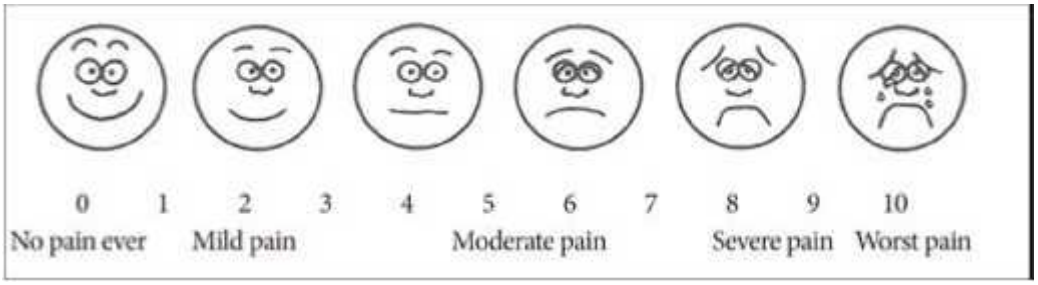


Figure 2: Visual Analogue Scale

Visual Rating Scale (Prince Henry Scale):

Scores	Severity of Pain
1	No pain on coughing
2	Pain on coughing or movements but not on deep
3	Pain on deep breathing but not on rest
4	Slight pain at rest
5	Severe pain at rest

Table 1: Point Scale of Prince Henry for Postoperative Pain Assessment

Numerical rating: With the two anchors of NO PAIN and AGONISING PAIN, it is comparable to the visual analog scale, but it has numbers across the scale from 0-10. This scale needs the patient to realize how their severity of pain can be translated into number. It is less sensitive in calculating the intensity of small changes.[31]

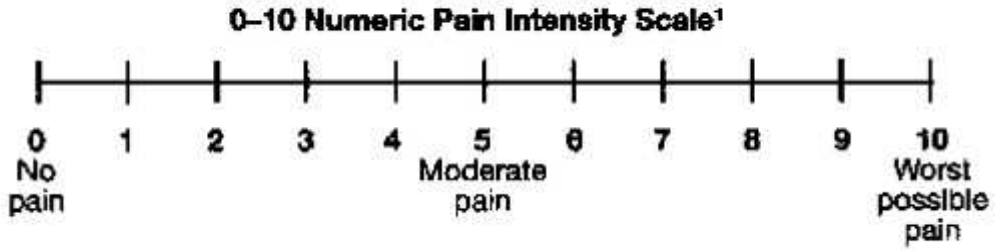


Figure 3: Numerical Rating Scale

FEMORAL NERVE BLOCK

Anatomy:

The lumbar plexus (L2 – L4) forms the femoral nerve. The femoral nerve reaches the thigh by passing below the inguinal ligament, laterally to the femoral artery encircled by the fascia iliaca that demarcates it from the femoral artery and vein. Distal to the inguinal ligament, the femoral nerve divides into the anterior branch, giving sensory supply to the skin. The posterior branches, innervate the skin of medial side of calf with the muscles of quadriceps and medial knee. The femoral nerve block must be executed just distal to the inguinal ligament in order to avoid missing anaesthesia to one of the branches. The obturator and lateral cutaneous nerve supply medial and lateral skin sensation respectively.[32,33,34,35]

Superficial to the femoral nerve are the skin, subcutaneous tissue, the fascia lata (a thin medial continuation of the iliotibial tract) and the fascia iliaca which covers the iliopsoas muscle and appears as a curved hyper-echoic line on ultrasound blending into the femoral sheath. Lateral and anteriorly is the belly of sartorius. Medially is the femoral artery and vein enclosed in their femoral sheath and then more medially lymphatic tissues and the pectineus muscle. The femoral nerve is outside of the femoral sheath.[32,33,34,35]

The femoral artery gives of several important branches in this region – the large profunda femoris artery and the lateral femoral circumflex artery that run laterally between the branches of the femoral nerve. Care must be taken to avoid these vessels when performing this block. The femoral vein and profunda femoris vein are usually medial and inferior to the artery and can be easily compressed with probe pressure. It would seem sensible to ease probe pressure to confirm their positions prior to performing the block.[32,33,34,35]

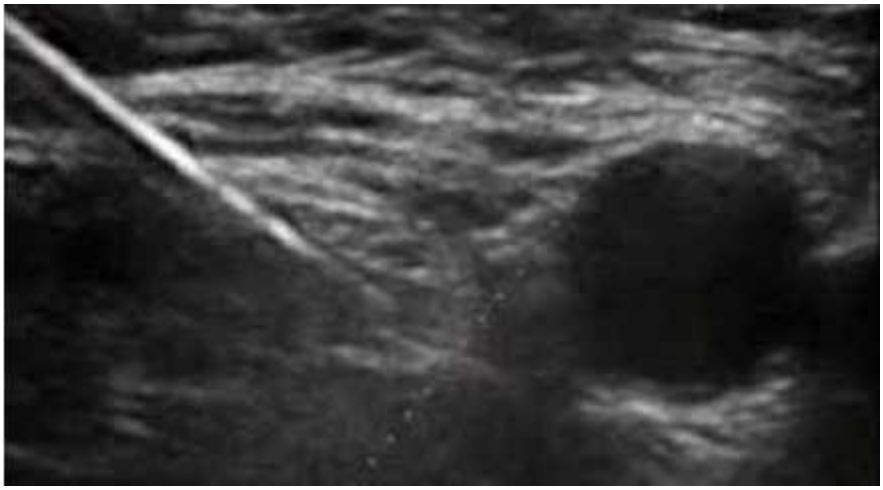


Figure 4: Sonoanatomy of Femoral Nerve with Femoral Artery

Scanning Technique:

A high frequency (6 – 18 MHz) linear array probe is preferred and used with depth initially set between 4 and 6 cm and adjusted as needed. A curvilinear probe can be used if more depth is warranted. The probe is placed in the inguinal crease, parallel to the inguinal ligament and transverse to femoral vein and artery with the indicator towards the patient's right. The leg is slightly externally rotated if possible. The probe is slid medial to lateral until the femoral vessels are seen. The nerve lies about 1-2 cm lateral to the artery, positioned below fascia iliaca and lata and above the ilieopsoas muscle and contained within a triangular-shaped sheath of fascia by the ligamentum ileopectineus. The nerve itself can have a triangular or oval shape and is often not clearly visualized. Because of this, the triangle created by the femoral artery medially, fascial planes anteriorly and the iliopsoas muscle posterioly is used as the target for the block. The nerve becomes visualized after injection.[32,35]

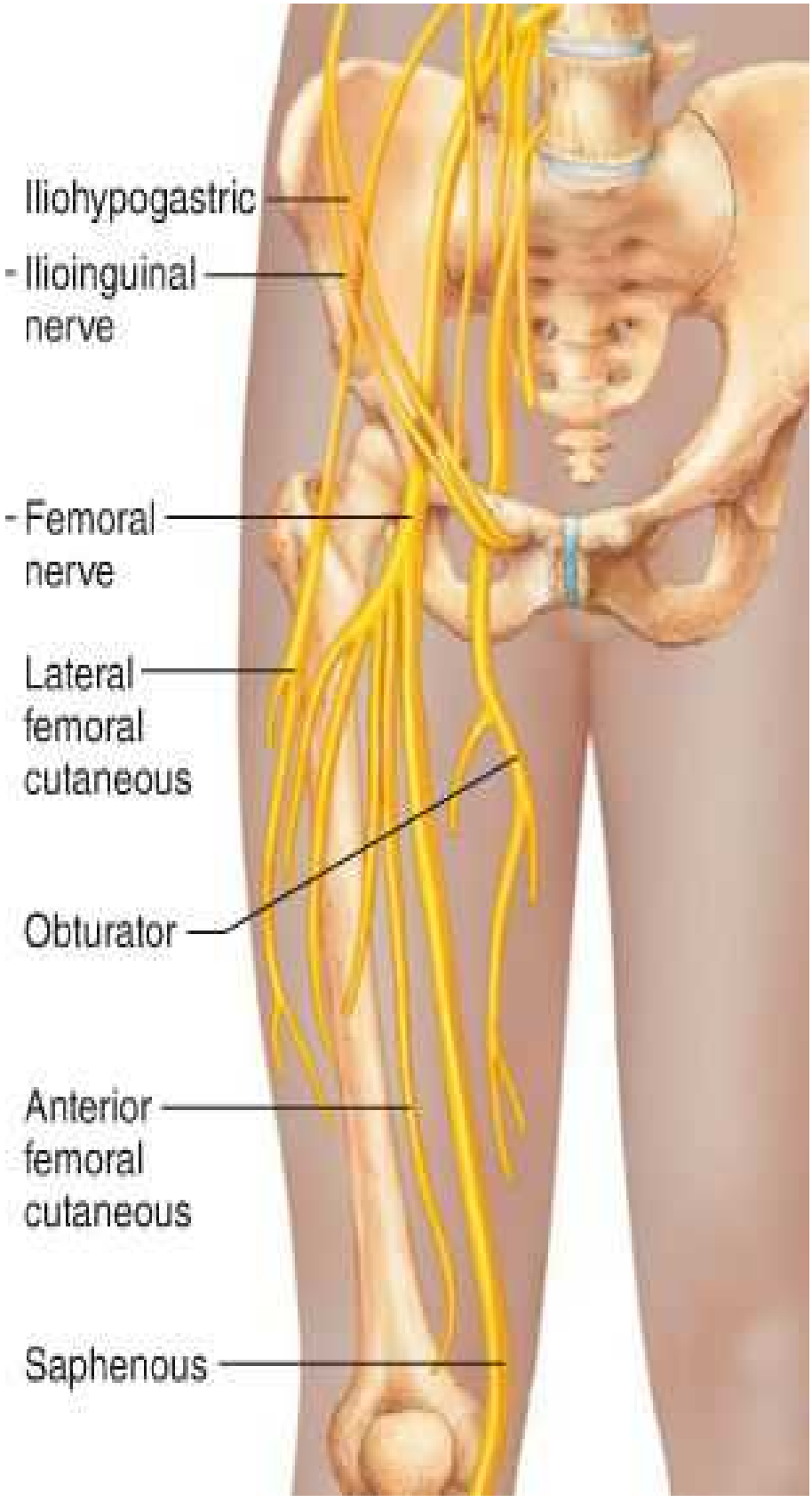


Figure 5: Anatomy of the Femoral Nerve

Distribution of Anaesthesia:

For the whole of anterior thigh, knee, and femur, the femoral nerve block offers anaesthesia. In addition, skin anaesthesia is given via the terminal branches of the femoral nerve over the medial part of the distal lower extremity. The ease with which the femoral nerve can be identified makes this block an excellent option for orthopaedic injuries to the lower extremity. The femoral nerve block is well tolerated with very less number of side effects or complications.[33,34,35]

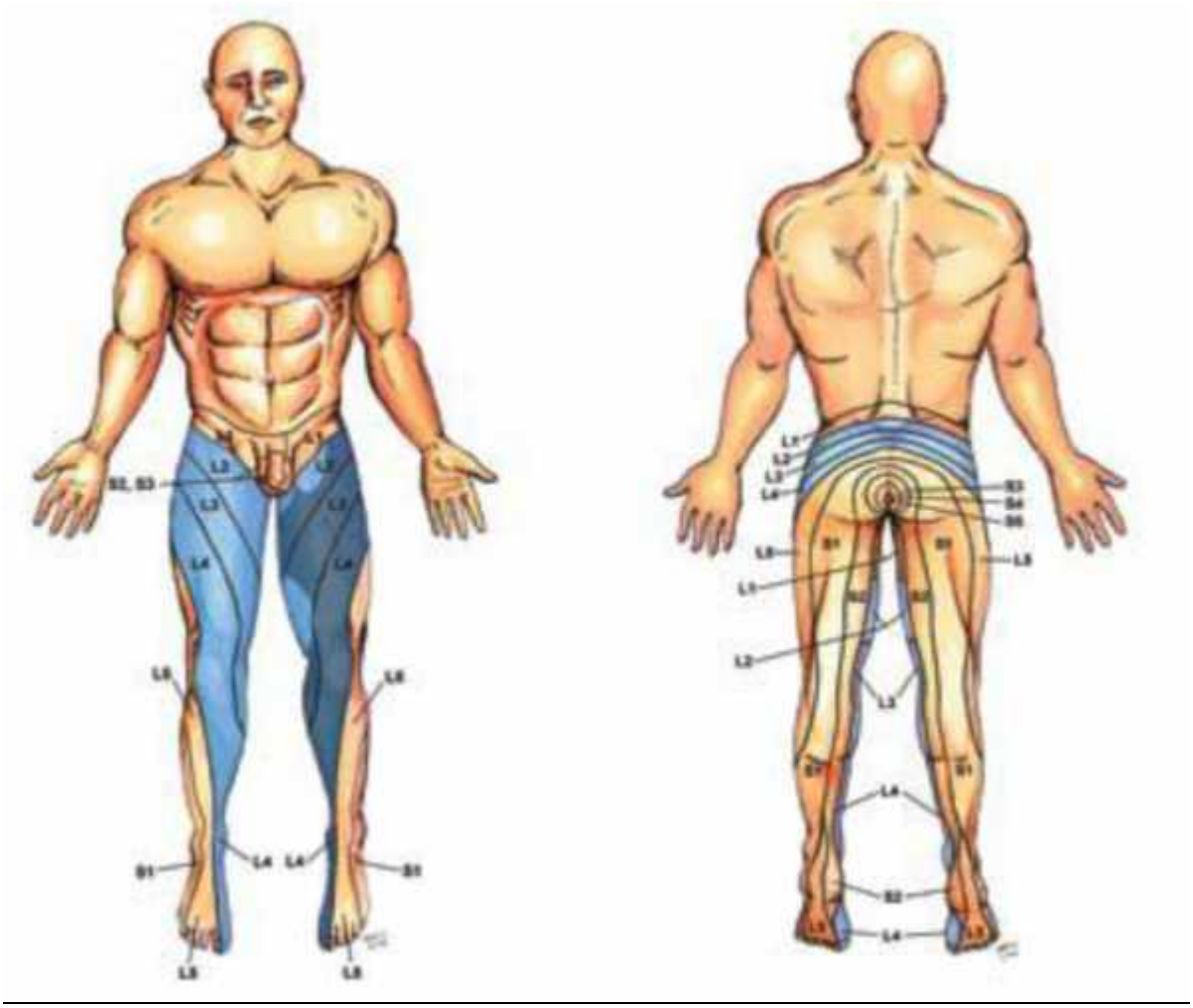


Figure 6: Dermatomes Anesthetized with the Femoral Nerve Block (Blue Colour)

PHARMACOLOGY

FENTANYL:

Fentanyl is an opioid group of analgesics. It acts on opioid receptor and therefore when given pre-emptively gives hemodynamic stability and analgesia. Fentanyl is vital to balanced general anaesthesia by its quality of covering all characteristics of balanced anaesthesia like analgesia, narcosis and attenuation of stressor responses.[36]

Chemical Structure:

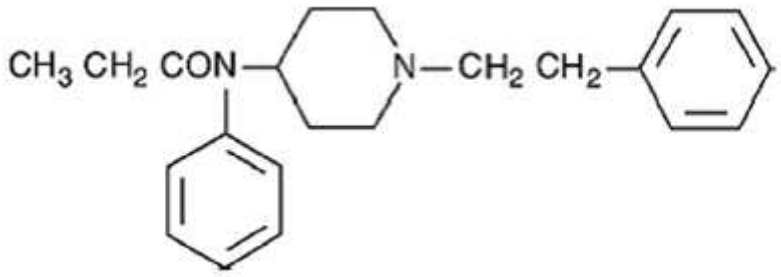


Figure 7: Fentanyl Chemical Structure

Mechanism of Action:

Opioid receptors:

Fentanyl binds to the different opioid receptors and activates them to perform actions. There are three important classes of opioid receptors and these are:

- **mu receptors** - This receptor has three subtypes, the receptors mu 1, mu 2 and mu 3. Activation of these receptors in the brainstem and thalamus may lead in relief of pain, sedation and euphoria, as well as respiratory depression, constipation and physical dependence.[36]

- **kappa receptors** - This receptor is present in the limbic system, the diencephalon, brain stem, and spinal cord. This receptor activation produces pain relief, sedation, respiratory depression and dependency.[36]
- **delta receptors** - This receptor is widespread in the brain as well as in the spinal cord and gastrointestinal tract. This receptor's stimulation contributes to both analgesic and antidepressant implications, but may also trigger respiratory depression.[36]

Pharmacokinetics:

Fentanyl's lipophilic structure means it readily crosses the blood–brain barrier which shows as a characteristic delta wave appearing on the EEG. There is significant variation in fentanyl pharmacokinetics between individuals. Plasma levels decrease quickly after an intravenous dose of bolus (half-life distribution approximately 13 min). Its terminal half-life in normal individuals is 3–4 hours, but in some patients it may be as long as 7–8 hours. Due to its elevated lipid solubility and comprehensive tissue uptake, the volume of distribution is comparatively high (almost 4 Litres/kg), and clearance is slightly lower than hepatic blood flow. Fentanyl is largely metabolized in the liver by N- dealkylation and hydroxylation, and within 1–2 minutes metabolites can be identified in the blood. Over a period of several days, about 70% of the medication is excreted in urine as inactive metabolites.[36]

Fentanyl dose:

The analgesic dose of fentanyl is 1-2 mcg/kg. It is also available as skin patches.[36]

Adverse effects:

Being an opioid it has its adverse effects like:

- respiratory depression,
- nausea,
- vomiting,
- itching

Fentanyl, like other opioid analgesics, causes respiratory depression in a dose-dependent manner. Cardiovascular stability is evident even in higher doses. High doses (50–150 mcg/kg) causes profound sedation and unconsciousness may occur. When given in high doses muscular rigidity of the chest wall may occur, high dose fentanyl anaesthesia also reduces or eliminates the stress response to surgery.[37]

ROPIVACAINE:

One of the most significant characteristics of a long-acting local anaesthetic is to inhibit nerve impulses reversibly, causing a continuous sensory or motor blockade suitable for anaesthesia in various kinds of surgery.

The acute pain relief acquired in postoperative and labor patients at reduced doses due to sensory blockage is sometimes plagued by associated motor blockade, which does not serve any purpose and is quite unwanted.

Ropivacaine is a long-acting, structurally associated regional anaesthetic of Bupivacaine. It is a pure S(-) enantiomer created to reduce potential toxicity and improve comparative sensory and motor block profiles, unlike Bupivacaine.[38]

Stereospecificity:

Enantiomers occur in two distinct spatial settings, such as gloves on the right and left hands, and are present in a racemic solution in equal quantities. Their impacts on the surface rotation of a polarized light into dextrorotatory [clockwise rotation R(+)] or levorotatory [counter clockwise rotation S(-)] stereoisomers are optically active and can be distinguished.

The physicochemical characteristics of the two enantiomeric molecules are identical, but for either the site of action or the sites engaged in the generation of side effects, the two enantiomers may have significantly distinct behaviours in their contact.[38]

Local anaesthetic enantiomers R(+) and S(-) have been shown to have distinct affinities for seperate sodium, magnesium and calcium ion membranes, resulting in a significant reduction in the central nervous system (CNS) and cardiovascular toxicity (cardiotoxicity) of the S(-) enantiomer relative to the R(+) enantiomer. The technological advances made it

possible to create Ropivacaine from the parent chiral molecule propivacaine as an optically pure S(-) enantiomer.

It is a pipecoloxylidides group of local anaesthetics, and has a propyl group on the piperidine nitrogen atom compared to the butyl group of bupivacaine.[38]

Chemical Structure:

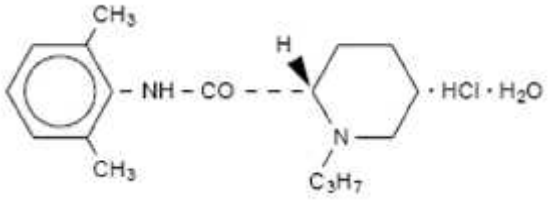


Figure 8: Ropivacaine Chemical Structure

Mechanism of Action:

Ropivacaine creates reversible sodium ion influx inhibition and thus blocks nerve fibers' impulse conduction. This action is potentiated by potassium channel dose-dependent inhibition.

Ropivacaine is less lipophilic than bupivacaine and is therefore less probable to penetrate big myelinated nerve motor fibers, having selective action on the pain-transmitting nerves Aβ and C rather than the motor functioning A beta fibers.[38]

Pharmacodynamics:

Effects on Central Nervous System and Cardiovascular System:

Ropivacaine is less lipophilic and stereoselective than bupivacaine which adds to ropivacaine having a considerably greater cardiotoxicity limit and toxicity to CNS than bupivacaine in individuals.

During an intravenous (I.V) infusion of local anesthetic (10 mg/min of ropivacaine or bupivacaine) in human volunteers, the CNS impacts happened sooner than cardiotoxic symptoms and the infusion was halted at this stage.

Significant modifications in cardiac function involving contractility, conductive time and QRS width happened and the change in QRS width with ropivacaine was discovered to be considerably lower than with bupivacaine.[38]

Other effects:

Ropivacaine inhibits platelet aggregation in plasma at concentrations of 3.75 and 1.88 mg/mL (0.375% and 0.188%), which relates to those that could happen in the epidural space during infusion.[38]

Ropivacaine has antibacterial activity in vitro, inhibiting the growth of Pseudomonas aeruginosa, Staphylococcus aureus and Escherichia coli.

Pharmacokinetics:

- **Absorption and distribution :**

The ropivacaine plasma concentration relies on the complete dose given and the route of administration, as well as the patient's haemodynamic and circulatory condition and the administration site's vascularity. The epidural space absorption of ropivacaine 150 mg is complete and biphasic. The initial phase's mean half-life is about 14 minutes, followed by a slower stage with a mean t1/2 absorption of about 4.2 hours.

Ropivacaine is bound to 94 percent plasma proteins, primarily to glycoprotein α(alpha)1-acid. The complete rise in plasma concentration during ongoing ropivacaine epidural infusion is triggered by an rise in protein binding degree and subsequent decline in ropivacaine clearance.

Ropivacaine quickly crosses the placenta for the caesarean section during epidural administration, leading in an almost full balance of the free fraction of ropivacaine in the maternal and fetal circulation. However, in the fetal circulation, the complete plasma concentration of ropivacaine was smaller than in the maternal circulation, reflecting the binding of ropivacaine to α(alpha)1-acid glycoprotein, which is more maternal than fetal plasma concentrations.[38]

- **Metabolism and excretion :**

Ropivacaine is widely metabolized in the liver by cytochrome P450 CYP1A2 and N-dealkylation to 2',6'-pipecoloxylidide by CYP3A4, predominantly through aromatic hydroxylation to 3'-hydroxy-ropivacaine.

The kidney is the ropivacaine's primary excretory organ, accounting for 86% of the drug's urine excretion after a single intravenous dose. After intravenous and epidural administration, it has a mean ± S.D terminal half-life of 1.8 ± 0.7 hrs and 4.2 ± 1.0 hrs respectively.[38]

- **Relative potency :**

There is a rigid correlation between the local anaesthetic's lipid solubility and its potency and toxicity. According to research of minimum local anaesthetic concentration (MLAC) based on efficient analgesia in 50% of patients, ropivacaine has close potency to bupivacaine at greater doses (e.g. doses needed for peripheral nerve blocks for surgical anaesthesia).At reduced doses, such as those used for epidural or intrathecal analgesia, ropivacaine is less powerful than bupivacaine and levobupivacaine.

For most patients, providing anaesthesia or analgesia is more clinically important than MLAC and this distinction in potency is not always apparent at greater doses used in clinical practice.[38]

METHODOLOGY

SOURCE OF DATA:

This study was carried out in the department of anaesthesiology.

METHOD OF COLLECTION OF DATA:

Study Design:

A randomised comparative study.

Study Period:

One and half year, from December 2017 to August 2019.

Sample Size:

The sample size was calculated on the basis of study conducted by Singh AP, Kohli V, Bajwa SJ (2016)[1] The anticipated average mean and standard deviation of patient satisfaction scores of two groups [0.67 ± 0.547 v/s 0.20 ± 0.407] at 95% level of confidence and 90% power, the required minimum sample size is 40 per group, a total sample size of 80. It was calculated using the formula:

$$n = 2\left[\frac{(Z_{1-\alpha/2}+z_{\beta})*S}{d}\right]^2$$

$Z_{1-\alpha/2}$ Level of confidence = 95 %

$Z_{1-\beta}$ Power of the study = 90 %

S- Standard deviation [From previous study] [1]

d - Clinically significant difference in means

Statistical Methods:

- Data was presented using mean ± standard deviation, percentage and diagrams.
- Quantitative variables were compared using unpaired t-test and paired t-test.
- Qualitative data was compared using chi square test.

Randomization:

The study population of 80 with age and sex matched was randomly selected and divided by computer generated random number tables in to two groups with 40 patients in each group.

Group I: Patients were given Femoral Nerve Block with 15 mL of 0.2% Ropivacaine.

Group II: Patients were given I.V Fentanyl 0.5 mcg/kg.

Results were recorded using a pre-set proforma.

Inclusion Criteria:

- American society of anaesthesiologists (ASA) grade I and II physical status.
- Patients with age group of 30 to 70 years.

Exclusion Criteria:

- Patients with multiple fractures.
- Patients with bleeding disorders.
- Patients with coagulopathy and anticoagulants.
- Patients with psychiatric disorders.
- Patients allergic to local anaesthetics.
- Patients having spinal deformities such as kyphosis and scoliosis.
- Inability and refusal to consent.
- Patients having local infection.
- Patients with pre-existing neuropathy.

Preanaesthetic Evaluation:

Patients were included in the study by thorough preanaesthetic evaluation which includes the following:

History:

History of the underlying medical illness, previous history of surgery, anaesthetic exposure and hospitalization were elicited.

Physical Examination:

- General condition of the patient.
- Vital signs – heart rate, blood pressure, respiratory rate.
- Weight.
- Examination of cardiovascular system, respiratory system, central nervous system and the vertebral system (spine).
- Airway assessment by Mallampatti grading.

Investigations:

Investigations required in this study were routine standardized procedures like:

Complete blood count, BT, CT, Urine routine, Random blood sugar, Blood urea, Serum creatinine, Chest radiograph, ECG, HIV and HBsAg.

Equipment for Femoral Nerve Block:

- Sterile tray and a trolley
- 10cc disposable syringes.
- Ultrasound Machine (sonosite M-Turbo).
- Povidine Iodine, Spirit, cotton ball and Sponge holding forceps.
- Long needle and 3 way with 10 cm extension.
- Drug- 0.2 % Ropivacaine.

Figure 9: Equipments for Femoral Nerve Block

Position of Patient:

The patients were supine position with both legs extended to facilitate better block performance.

Procedure:

- Informed written consent was taken from the patient.
- Patients were kept nil by mouth for at least six hours prior to the surgery.
- The following monitoring devices: Pulse Oximeter, NIBP, ECG were connected and baseline values were recorded.
- IV line was secured with 20 Gauge I.V cannula and patients were premedicated with inj. Glycopyrrolate 0.01mg/kg I.V, inj. Midazolam 0.1mg/kg I.V and inj. Ondansetron 0.15 mg/kg I.V.

- The preoperative loading was carried out by infusion of lactated ringer's solution (10mL/kg) and oxygen was given to all patients via face mask.
- Drugs and equipments necessary for resuscitation were kept ready.
- Patients in the group I, received 15 mL of 0.2% of Ropivacaine Femoral Nerve Block guided by sonosite M-Turbo USG machine 15 minutes prior to positioning for spinal anaesthesia.
- The procedure was carried out by placing the patient supine, after identifying the anterior superior iliac spine and the pubic symphysis, a line was drawn between these two landmarks. This line represents inguinal ligament.
- Then, palpation of the femoral pulse was done and marked at the inguinal crease.
- The block site was painted with povidine iodine and spirit then draped with sterile towel. Sterile gel was applied to the ultrasound probe and probe covered by sterile cover. The USG probe was placed just below the inguinal ligament. The pulsating femoral artery was visualized, the probe was moved to locate the individual nerve and the artery.
- The point of needle (5cm hypodermic 24 Ggauge needle) entry was directly lateral (1 – 1.5cm) to the artery in the inguinal crease in the plane of USG probe. At this landmark the femoral nerve is maximally wide and superficial.
- The needle was directed cephalad towards the centre of the inguinal ligament line at approximately 30 to 45 degree angle.
- The nerve being superficial lies within 3cm from the skin and lateral to the femoral artery.
- 15mL of 0.2% Ropivacaine was injected.

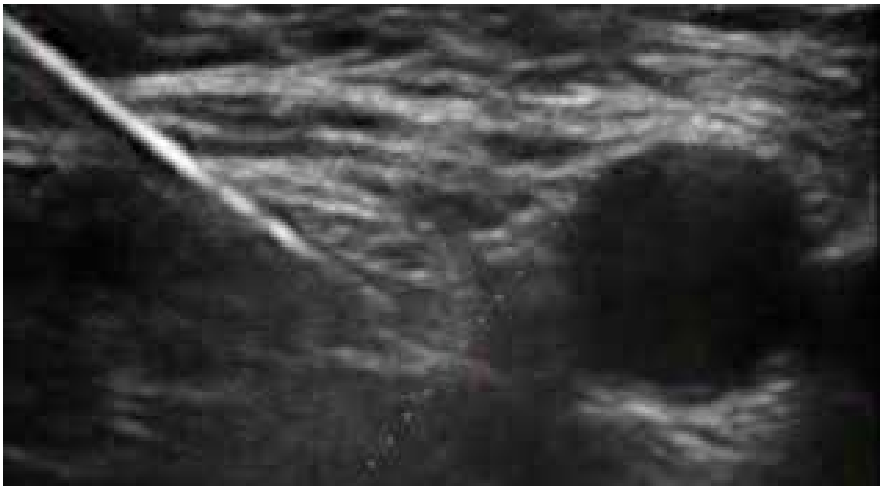


Figure 10: Sonoanatomy of Femoral Nerve with Femoral Artery

- Patients in Group II were given I.V Fentanyl 0.5 mcg/kg 15 minutes prior to positioning of the patient for spinal anaesthesia.
- After performing Femoral Nerve Block or giving I.V Fentanyl in respective groups, quantitative relief of pain using visual analog scale (VAS) was assessed at interval of 2 min, 5 min, 10 min and 15 min.
- Then spinal anaesthesia was performed in sitting position after 15 min of giving preemptive analgesia while checking VAS during positioning.

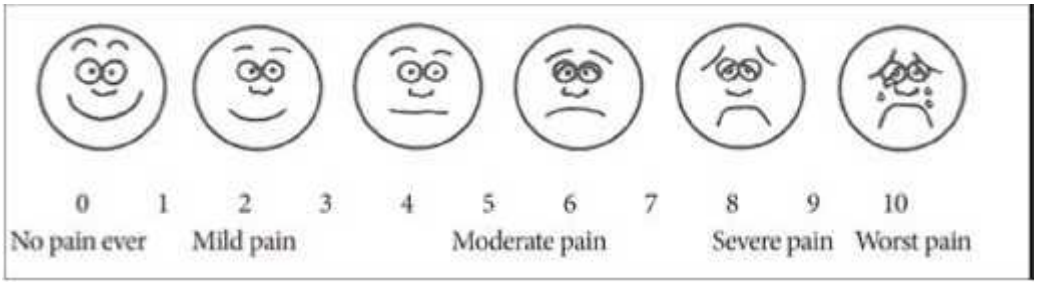


Figure 11: Visual Analog Scale

- Time to perform spinal anaesthesia was noted. Intra-operatively the time of onset, maximum level and duration of sensory block were recorded.

- All patients were observed for side effects such as:

a) For Femoral Nerve Block: Vascular puncture, Intravascular injection and anaesthetic toxicity, Hematoma and Nerve damage.

b) For I.V Fentanyl: Sedation, Cognitive impairment, Nausea, Vomiting, Respiratory depression, Dryness of mouth, Urinary retention.

OBSERVATIONS AND RESULTS

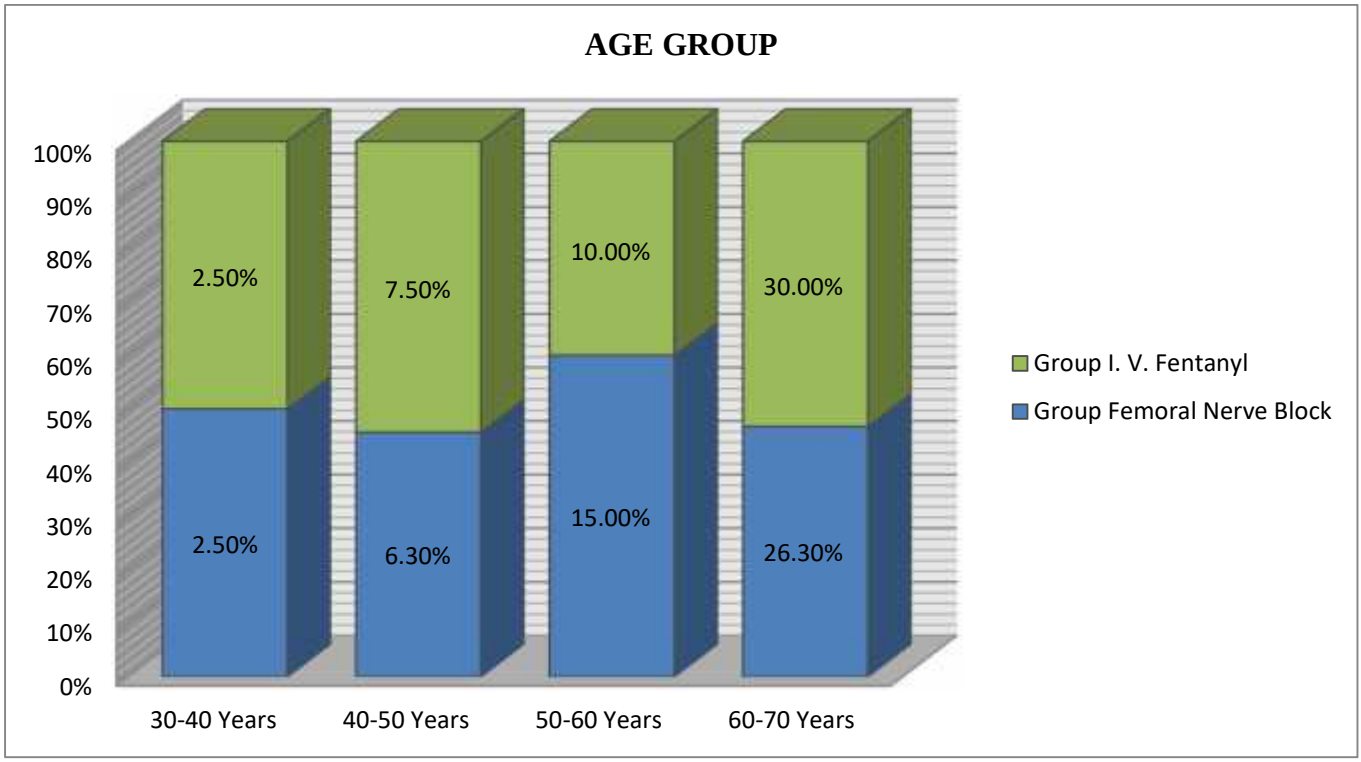
Table 2: Percentage Distribution of Patients According to Age and Sex:

AGE GROUP	GROUP		Total	Chi-squared statistic/ p-value
	Femoral Nerve Block:	**I. V. Fentanyl:**		
30-40 Years	2 2.5%	2 2.5%	4 5.0%	1.091 p-value=0.779 (Not Significant)
40-50 Years	5 6.3%	6 7.5%	11 13.8%	
50-60 Years	12 15.0%	8 10.0%	20 25.0%	
60-70 Years	21 26.3%	24 30.0%	45 56.3%	
Total	40 50.0%	40 50.0%	80 100.0%	
SEX	**Femoral Nerve Block:**	**I. V. Fentanyl:**	**Total**	
Male	23 28.7%	17 21.3%	40 50.0%	1.800 p-value=0.180 (Not Significant)
Female	17 21.3%	23 28.7%	40 50.0%	
Total	40 50.0%	40 50.0%	80 100.0%	

The association between age group and gender among Femoral Nerve Block and Intravenous Fentanyl group

- Mean age for Group I (FEMORAL NERVE BLOCK) participants is 60.225 ± 3.011.
- Mean age for Group II (I. V. FENTANYL) participants is 61.171 ± 3.244.

GRAPH 1: Proportion Graph Representing Percentage of Different Age Groups with Respect to their Percentage Proportion among the Two Groups:



GRAPH 2: Graph Representing Percentage Gender Distribution among the Two Groups:

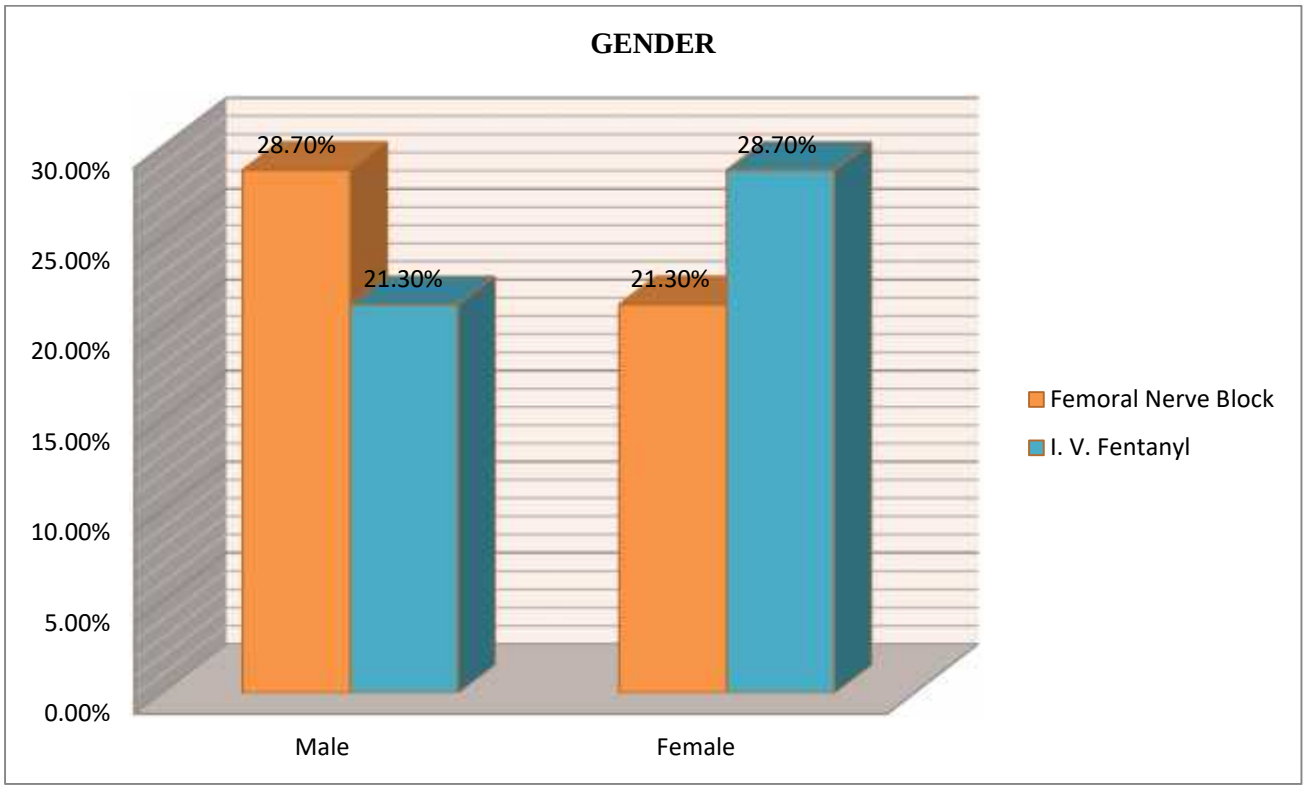


Table 3: Represents the Age Group and Sex Wise Distribution of Study Population among the Two Groups:

AGE GROUP	Group		TOTAL
	Femoral Nerve Block:	**I V Fentanyl:**	
30-40 Years	2 2.5%	2 2.5%	4 5.0%
40-50 Years	5 6.3%	6 7.5%	11 13.8%
50-60 Years	12 15.0%	8 10.0%	20 25.0%
60-70 Years	21 26.3%	24 30.0%	45 56.3%
Total	40 50.0%	40 50.0%	80 100.0%
SEX	**Femoral Nerve Block:**	**I V Fentanyl:**	**TOTAL**
MALE	23 21.3%	17 28.7%	40 50.0%
FEMALE	17 28.7%	23 21.3%	40 50.0%
TOTAL	40 50.0%	40 50.0%	80 100.0%

- It is found that there is no significant association between age and gender among the two groups. Hence age and sex are not confounding factors in the study.
- In our study the demographic data (age and sex) was comparable in both the groups. The age of the cases were ranging from30 to 70 years with the mean for Group-I was 60.225 ± 3.011 and for Group-II was 61.171 ± 3.244.
- Out of 40 participants, in Group-I, 23 were males and 17 were females. In Group-II, 17 were males and 23 were females out of the 40 participants. ‘p’ values of age and sex were 0.779 and 0.180 respectively.
- Thus, the demographic data of the two groups were not statistically significant; which means, both the groups were comparable and randomised properly.

GRAPH 3: Graph Representing Percentage Distribution of Different Age Groups among the Two Groups:

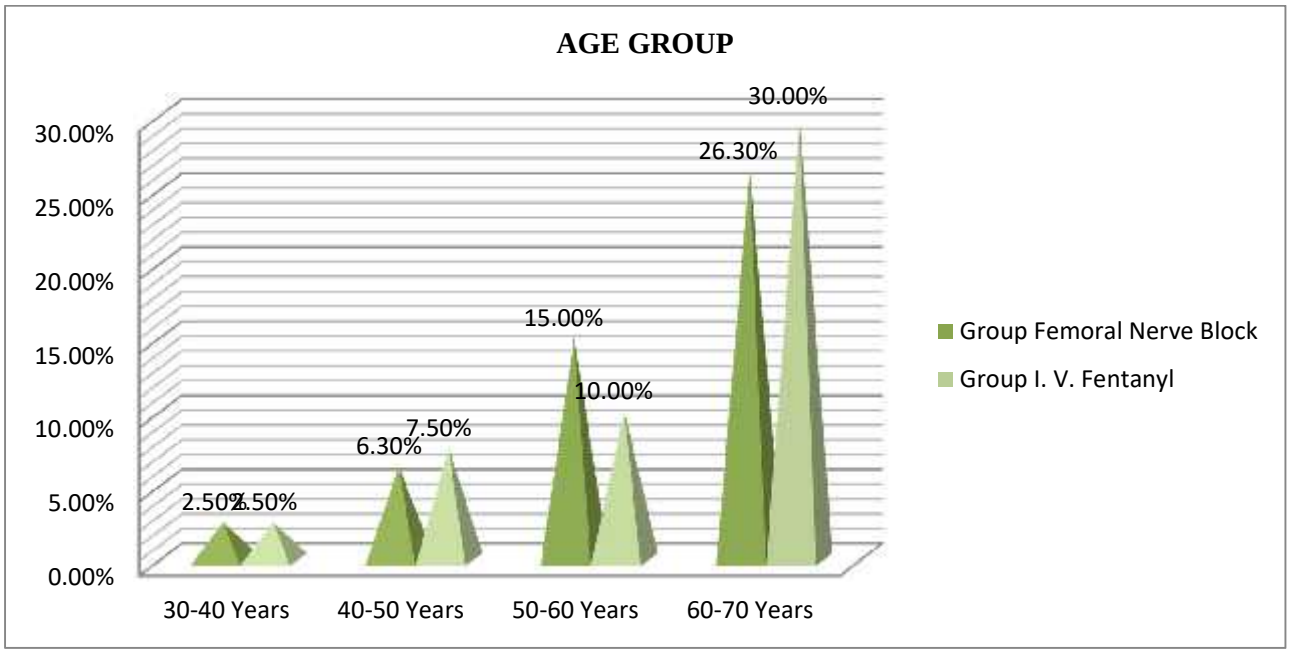


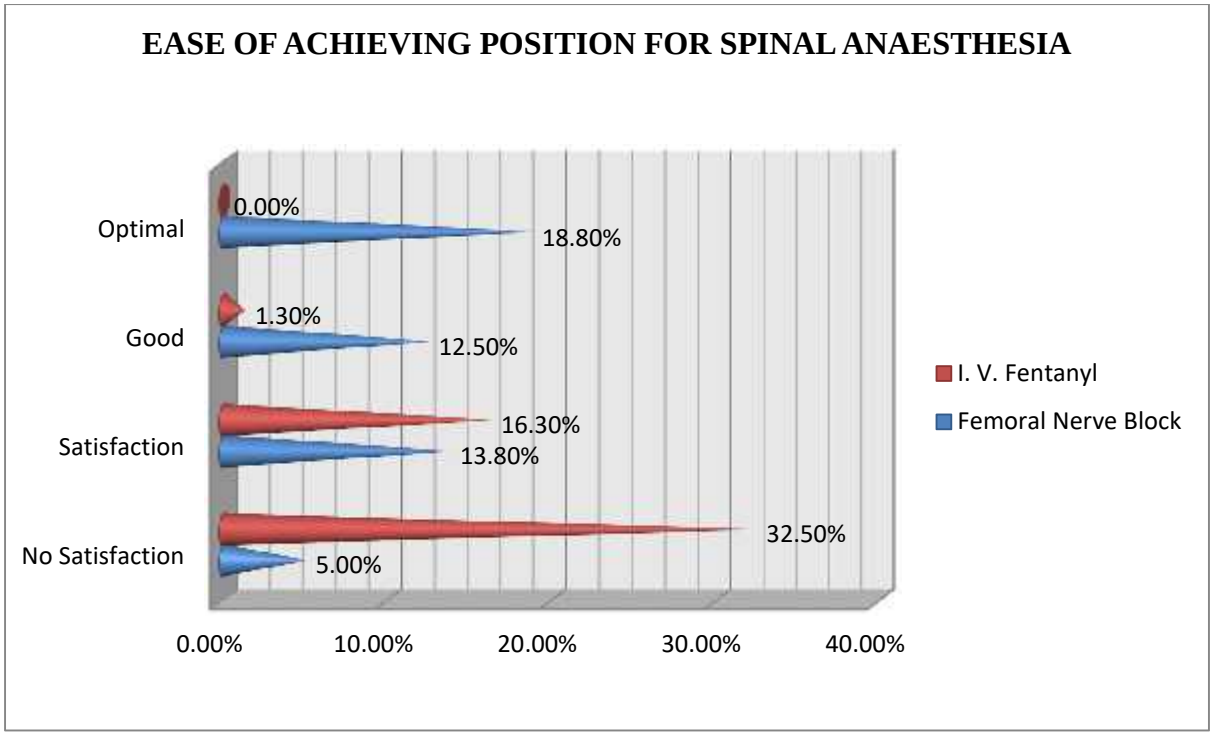
Table 4: Represents the Association Between Ease of Achieving Position For Spinal Anaesthesia and Patient Satisfaction among the Two Groups:

EASE OF ACHIEVING POSITION FOR SPINAL ANAESTHESIA	Group		Total	Chi-squared statistic/ p-value
	Femoral Nerve Block	I. V. Fentanyl		
No Satisfaction	4 5.0%	26 32.5%	30 37.5%	38.664 p-value=0.000* (Significant)
Satisfaction	11 13.8%	13 16.3%	24 30.0%	
Good	10 12.5%	1 1.3%	11 13.8%	
Optimal	15 18.8%	0 0.0%	15 18.8%	
Total	40 50.0%	40 50.0%	80 100.0%	
PATIENT SATISFACTION	**Femoral Nerve Block**	**I. V. Fentanyl**	**Total**	
Yes	35 43.8%	8 10.0%	43 53.8%	36.656 p-value=0.000* (Significant)
No	5 6.3%	32 40.0%	37 46.3%	
Total	40 50.0%	40 50.0%	80 100.0%	

- Percentage of patients with optimal positioning in Group-I was 18.8% and in Group-II was 0%.
- Percentage of patients with good positioning in Group-I was 12.5% and in Group-II was 1.3%.
- Percentage of patients with satisfactory positioning in Group-I was 13.8% and in Group-II was 16.3%.

- Percentage of patients with unsatisfactory positioning in Group-I was 5% and in Group-II was 32.5%.
- Percentage of patients who were satisfied with the preemptive analgesia was 43.8% of 80 patients in Group-I when compared to 10% in Group-II. 40% of the total patients were unsatisfied with analgesia provided via I. V. Fentanyl.
- It is found that there is a significant association among the two groups with respect to the two parameters: Ease of achieving position for spinal anaesthesia as well as Patient satisfaction.

GRAPH 4: Graph Representing the Ease of Achieving Position among the Two Groups:



GRAPH 5: Graph Representing Patient Satisfaction among the Two Groups:

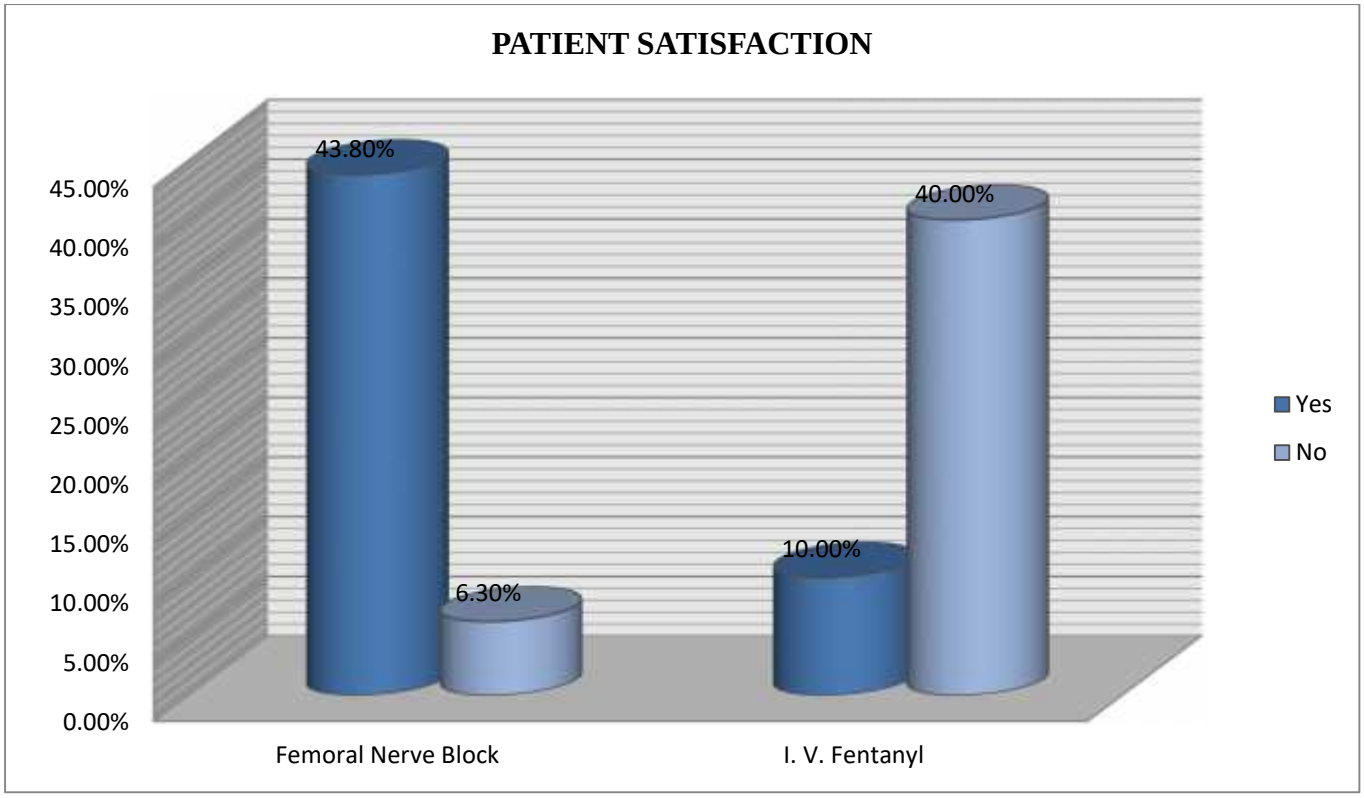


Table 5: Represents the Mean Scores Comparison between the Two Groups for Efficacy of Analgesia Using Visual Analog Scale (VAS), Time to Perform Spinal Anaesthesia, Duration of Spinal Anaesthesia and First Rescue Analgesic Dose:

Efficacy of analgesia using visual analog scale(VAS):	Group:	N:	Mean ± Standard Deviation	t-statistic/Significance:
2 Minutes	Femoral Nerve Block	40	7.350 ± 0.6222	-3.287
	I. V. Fentanyl	40	7.775 ± 0.5305	p-value<0.05 (Significant)
5 Minutes	Femoral Nerve Block	40	6.200 ± 0.6485	-6.197
	I. V. Fentanyl	40	7.125 ± 0.6864	p-value<0.001 (Significant)
10 Minutes	Femoral Nerve Block	40	5.050 ± 0.9323	-5.953
	I. V. Fentanyl	40	6.375 ± 1.0546	p-value<0.001 (Significant)
15 Minutes	Femoral Nerve Block	40	3.750 ± 1.1929	-8.206
	I. V. Fentanyl	40	5.900 ± 1.1503	p-value<0.001 (Significant)
Time To Perform Spinal Anaesthesia (In Minutes):	Femoral Nerve Block	40	4.050 ± 1.2800	-10.079
	I. V. Fentanyl	40	6.725 ±1.0857	p-value<0.001 (Significant)
Duration Of Spinal Anaesthesia (In Hours):	Femoral Nerve Block	40	3.925 ± 0.4319	7.555
	I. V. Fentanyl	40	3.300 ± 0.2953	p-value<0.001 (Significant)
First Rescue Analgesic Dose After 'X' Hours Of Spinal Anaesthesia:	Femoral Nerve Block	40	6.325 ± 1.3134	10.479
	I. V. Fentanyl	40	4.013 ± 0.4735	p-value<0.001 (Significant)

The efficacy of analgesia was assessed using visual analog scale (VAS) at 2 minutes, 5 minutes, 10 minutes and 15 minutes after giving Femoral Nerve Block or I. V. Fentanyl.

- The mean VAS score after 2 minutes was 7.350±0.6222 in Group-I and 7.775±0.5305 in Group-II.
- The mean VAS score after 5 minutes was 6.200±0.6485 in Group-I and 7.125±0.6864 in Group-II.
- The mean VAS score after 10 minutes was 5.050±0.9325 in Group-I and 6.375±1.0546 in Group-II.
- The mean VAS score after 15 minutes was 3.750±1.1929 in Group-I and 5.900±1.1503 in Group-II.
- The mean scores of VAS are statistically significant among the two groups.

The mean time in minutes to perform spinal anaesthesia was 4.050±1.2800 in Group-I and 6.725±1.0875 in Group-II; which shows significant differenc between the two groups.

Duration of spinal anaesthesia in hours was recorded. The mean time in hours for which spinal anaesthesia acted was 3.925±0.4319 in group-I and 3.300±0.2953 in Group-II.

The first rescue analgesic dose after ‘X’ number of hours of performing spinal anaesthesia was noted. The mean time in hours in Group-I was 6.325±1.313 and in Group-II was 4.013±0.4735.

Thus, the above two parameters were statistically significant with considerable increase in time of duration of spinal anaesthesia and need for first rescue analgesic dose.

Figure 12: Diagramatic Representaion of Mean Scores of Efficacy of Analgesia by Visual Analog Scale at Different Time Intervals among the Two Groups at 95% Confidence Interval:

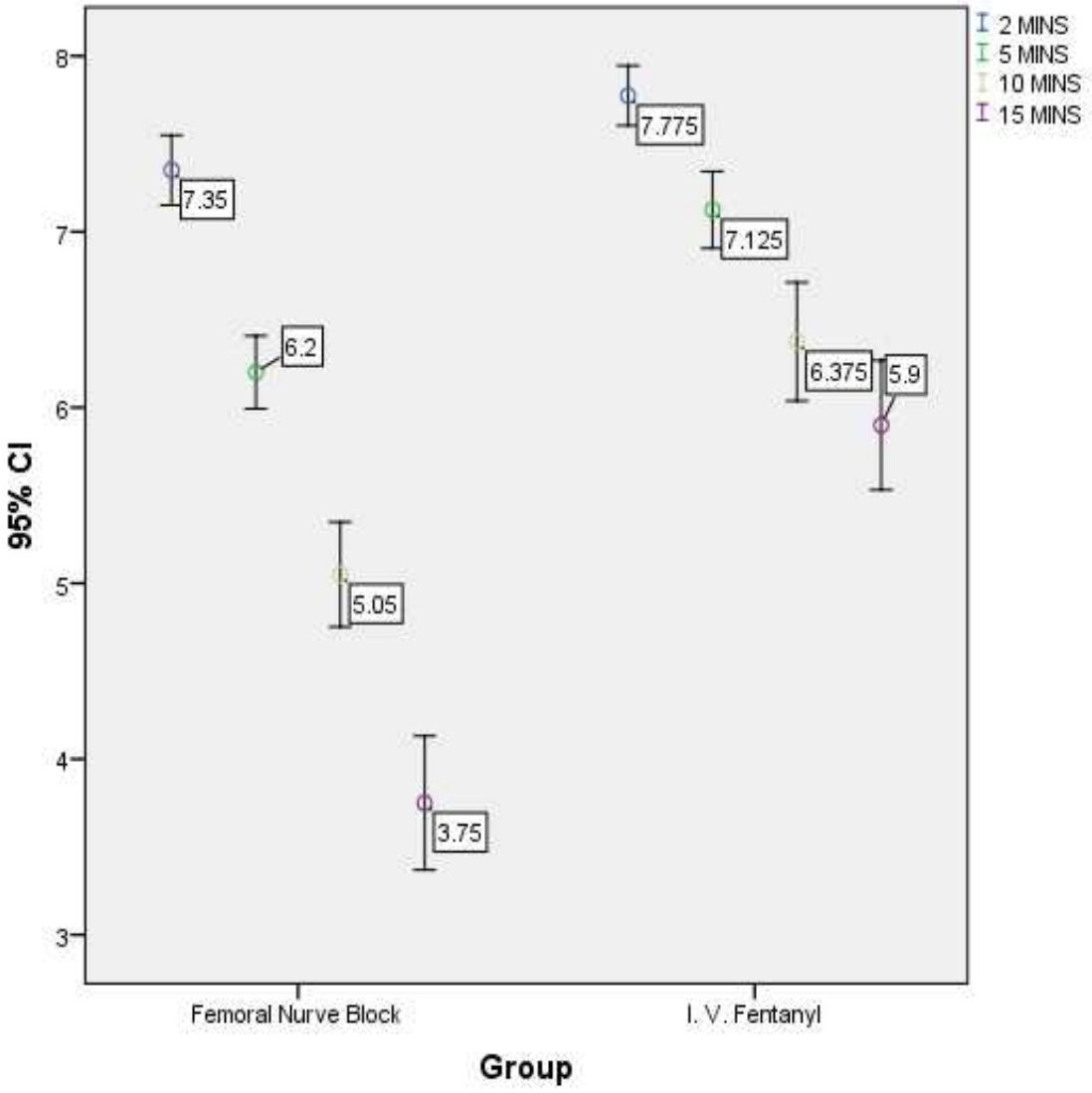


Table 6: Represents Femoral Nerve Block's Complications or Side Effects:

Vascular Puncture	**Frequency**	**Percent**
Yes	6	15.0
No	34	85.0
Intravascular Injection And Anaesthetic Toxicity	**Frequency**	**Percent**
Yes	----	----
No	40	100.0
Haematoma	**Frequency**	**Percent**
Yes	4	10.0
No	36	90.0
Nerve Damage	**Frequency**	**Percent**
Yes	----	----
No	40	100.0

Table 7: Represents Intravenous Fentanyl Complications or Side Effects:

Sedation	**Frequency**	**Percent**
Yes	15	37.5
No	25	62.5
Cognitive Impairment	**Frequency**	**Percent**
Yes	----	----
No	40	100.0
Nausea	**Frequency**	**Percent**
Yes	12	30.0
No	28	70.0
Vomiting	**Frequency**	**Percent**
Yes	2	5.0
No	38	95.0
Respiratory Depression	**Frequency**	**Percent**
Yes	1	2.5
No	39	97.5
Dryness Of The Mouth	**Frequency**	**Percent**
Yes	1	2.5
No	39	97.5
Urinary Retention	**Frequency**	**Percent**
Yes	1	2.5
No	39	97.5

- Results from tables 6 and 7 reveal there is significant increase in the number of complications or side effects in I. V. Fentanyl group when compared with Femoral Nerve Block group.

STATISTICAL ANALYSIS:

All characteristics were summarized descriptively. For continuous variables and quantitative data summary statistics of mean, standard deviation were used. For categorical data, the numbers and percentages were used in data summaries. Chi-square test was employed to determine the significance of differences between groups of categorical data and qualitative data.

The difference of the means of analysis variables between two independent groups was tested by 't' test. The 't' test compares two means and tells if they are different from each other. The 't' test also tell how significant the differences are. If the 'p' – value was <0.05, then the results were considered to be statistically significant else not significant. Data was analysed using SPSS software version 23.0 and Microsoft office.

DISCUSSION

Fracture femur is one of the most painful orthopaedic problem which occurs across all age groups. Intertrochanteric and femoral neck fractures account for 90% of the proximal femoral fractures occurring in elderly patients which require surgical intervention. Proximal femoral fractures are very common in patients older than 50 years which are mostly pathological. In younger patients, proximal femoral fractures are usually the result of high-energy physical trauma (road traffic accidents) and usually occur in the absence of disease. Displaced fractures are very painful and do not allow the patient to move. It is very difficult to give proper positioning during administration of neuraxial blockade in such patients because of pain. Fracture femur is a particularly painful bone injury because the periosteum has the lowest pain threshold of the deep somatic structure.[39]

Parker MJ, Griffiths R, Appadu B (2002)[40] reported that nerve blocks reduced pain score and analgesic requirements.

Singh AP, Kohli V, Bajwa SJ (2016)[1] in their study concluded that Femoral Nerve Block using ropivacaine is a safe and effective method to alleviate pain as preemptive analgesia than I.V. fentanyl.

In our study, the demographic data (age and sex) was comparable in both the groups. The age of the cases were ranging from 30 to 70 years with the mean for Group-I was 60.225 ± 3.011 and for Group-II was 61.171 ± 3.244.

Out of 40 participants, in Group-I, 23 were males and 17 were females. In Group-II, 17 were males and 23 were females out of the 40 participants. ‘p’ values of age and sex were 0.779 and 0.180 respectively.

Thus, the demographic data of the two groups were not statistically significant; which means, both the groups were comparable and randomised properly.

In our study, Group-I patients were given Femoral Nerve Block with 15 mL of 0.2% Ropivacaine under USG guidance and Group-II patients were given I. V. Fentanyl 0.5 mcg/kg, 15 minutes prior to positioning for spinal anaesthesia.

The ease of achieving position for spinal anaesthesia was assessed qualitatively under parameters: optimal, good, satisfactory and not satisfactory in our study.

Percentage of patients with optimal positioning in Group-I was 18.8% and in Group-II was 0%. Percentage of patients with good positioning in Group-I was 12.5% and in Group-II was 1.3%. Percentage of patients with satisfactory positioning in Group-I was 13.8% and in Group-II was 16.3%. Percentage of patients with unsatisfactory positioning in Group-I was 5% and in Group-II was 32.5%. Percentage of patients who were satisfied with the preemptive analgesia was 43.8% of 80 patients in Group-I when compared to 10% in Group-II. 40% of the total patients were unsatisfied with analgesia provided via I. V. Fentanyl.

Thus, higher percentage of patients were able to achieve better position for spinal anaesthesia in Group-I when compared to Group-II. The percentage of patients with unsatisfactory positioning for spinal anaesthesia was higher in Group-II.

Our study findings correlate with, Sia S, Pelusio F, Barbagli R, Rivituso C (2004)[5] who studied Analgesia before performing a spinal block in the Sitting Position in Patients with Femoral Shaft Fracture, a comparison between Femoral Nerve Block and Intravenous Fentanyl. Group Femoral nerve block patients received a femoral nerve block using a peripheral nerve stimulator. 15 mL of lidocaine 1.5% was injected slowly after a negative aspiration test. Group Intravenous Analgesia patients received fentanyl 3 mcg/kg I.V. They concluded that femoral nerve block is better than I.V. fentanyl for giving position for spinal block in femur surgeries.

Durrani H, Butt KJ, Khosa AH, Umer A, Pervaiz M (2013)[8] conducted a study to enlighten better technique in terms of pain relief (on visual analogue scale) during positioning, time to perform spinal anaesthesia, the quality of position and acceptance of patients. Fifteen minutes before positioning for spinal block, the FNB group received femoral nerve block using the conventional landmark technique with a mixture of 15 mL lignocaine with adrenaline and 5mL distilled water and the IVA group received 6mg intravenous nalbuphine. The results of this study reflected that femoral nerve block provides better analgesia resulting in adequate positioning, rapid performance of spinal and higher acceptance among patients with femoral fracture during positioning for administration of spinal anaesthesia.

Reddy ED, Rao BD (2016)[11] conducted a study to compare the efficacy of femoral nerve block over fentanyl. In the FNB group, the femoral nerve blocker was guided by a peripheral nerve stimulator few minutes before positioning. At the site of entry, 1mL of 1% lignocaine was injected and a 22 gauge needle was introduced are 1cm lateral to the femoral artery and 1.5cm below the inguinal ligament. 20mL 1.5% lignocaine with adrenalin (1:20,000) is injected when the stimulator at 0.3-0.5 milliampere current can bring about a contraction of the quadriceps after a negative aspiration test. The intravenous analgesia group received IV fentanyl; 0.5 mcg/kg was given every 5 min until the pain decreased, 5 minutes before the spinal block was achieved. Their study revealed that femoral nerve block was a better analgesic drug compared to intravenous fentanyl for positioning of the hip during spinal anaesthesia in femoral fracture surgeries.

In our study, the efficacy of analgesia was assessed using visual analog scale (VAS) at 2 minutes, 5 minutes, 10 minutes and 15 minutes after giving Femoral Nerve Block or I.V. Fentanyl. The mean VAS score after 2 minutes was 7.350±0.6222 in Group-I and 7.775±0.5305 in Group-II. The mean VAS score after 5 minutes was 6.200±0.6485 in Group-I and 7.125±0.6864 in Group-II. The mean VAS score after 10 minutes was 5.050±0.9325 in

Group-I and 6.375±1.0546 in Group-II. The mean VAS score after 15 minutes was 3.750±1.1929 in Group-I and 5.900±1.1503 in Group-II.

Thus, in Group-I the VAS scores were significantly reduced whereas in Group-II the VAS scores did not decrease considerably in the same time intervals. The time taken for effect to come (decrease in VAS scores) in Group-I was also less when compared to Group-II.

Our findings were in similar lines with the studies by, Iamaroon A, Raksakietisak M, Halilamien P, Hongsawad J, Boonsararuxsapong K (2010)[7] "Femoral nerve block versus fentanyl; Analgesia for positioning patients with fractured femur" they observed that after 15 minute of administering femoral nerve block pain score in supine position was 2.7±2.6 and during positioning 6.1±2.6 which was significantly lower than the baseline VAS score.

Newman B, McCarthy L, Thomas PW, May P, Layzell M, Horn K (2013)[9] conducted a comparative study of pre-operative nerve stimulator-guided femoral nerve block and fascia iliaca compartment block in patients with a femoral neck fracture. The difference in the mean reduction of pain score after the block was 0.9 (95% CI); p = 0.047. Patients receiving a femoral nerve block required less morphine after the block than those receiving fascia iliaca compartment block (p = 0.041). They concluded that Femoral Nerve Block provided superior pre-operative analgesia for fractured neck of femur compared with fascia iliaca compartment block.

Bhosle P, Prakash A, Aphale S (2015)[10] conducted a study to evaluate the usefulness of femoral nerve block (FNB) for positioning during regional anaesthesia in patients with femur fracture. Results: 60 % of patients receiving FNB showed the VAS score of 1.4 ± 0.498 while 40% had VAS score of 4.03 ± 0.32 in Group NB and good pain relief for positioning for combined spinal epidural (CSE) in Group FNB and lesser performance time(16.2 ± 2.7 min) in comparison to patients not receiving nerve block it was (19.23 ± 2.674 min).

In our study, we noted time to perform spinal anaesthesia in minutes. The mean time in minutes to perform spinal anaesthesia was 4.050±1.2800 in Group-I and 6.725±1.0875 in Group-II.

Thus, the time to perform spinal anaesthesia was considerably reduced in Group-I when compared with Group-II.

Our study correlates with, Singh AP, Kohli V, Bajwa SJ (2016)[1] conducted a study to compare the analgesic effects of Femoral Nerve Block with intravenous I.V fentanyl prior to positioning for a spinal block in patients with fracture femur and to compare the analgesic requirements in both groups. Patients in Group I (*n* = 30), were administered Femoral Nerve Block using nerve stimulator with 0.2% ropivacaine (15 mL) and in Group II patients (*n* = 30), I.V. fentanyl 0.5 mcg/kg was given as preemptive analgesia. Parameters observed included time to spinal anaesthesia, intra-operative and postoperative visual analog scale (VAS) for any pain and postoperative epidural top-ups dosages. They concluded that Femoral Nerve Block using 15 mL of 0.2% ropivacaine is a safe and effective method to alleviate pain as preemptive analgesia than I.V. fentanyl. Femoral Nerve Block reduces the time to perform spinal anaesthesia, increases the postoperative duration of analgesia and reduces analgesic requirements postoperatively.

In our study, Duration of spinal anaesthesia in hours and the first rescue analgesic dose after 'X' number of hours of performing spinal anaesthesia was recorded.

The mean time in hours for which spinal anaesthesia acted was 3.925±0.4319 in group-I and 3.300±0.2953 in Group-II.

The first rescue analgesic dose after 'X' number of hours of performing spinal anaesthesia was noted. The mean time in hours in Group-I was 6.325±1.313 and in Group-II was 4.013±0.4735.

Thus, the above two parameters were statistically significant which showed a considerable increase in the time for need of analgesia after performing spinal anaesthesia in Group-I patients when compared to Group-II patients.

Our study findings were in similar lines with, Singh AP, Kohli V, Bajwa SJ (2016)[1] conducted a study to compare the analgesic effects of Femoral Nerve Block with intravenous I.V fentanyl prior to positioning for a spinal block in patients with fracture femur and to compare the analgesic requirements in both groups. Patients in Group I (n = 30), were administered Femoral Nerve Block using nerve stimulator with 0.2% ropivacaine (15 mL) and in Group II patients (n = 30), I.V. fentanyl 0.5 mcg/kg was given as preemptive analgesia. Parameters observed included time to spinal anaesthesia, intra-operative and postoperative visual analog scale (VAS) for any pain and postoperative epidural top-ups dosages. They concluded that Femoral Nerve Block using 15 mL of 0.2% ropivacaine is a safe and effective method to alleviate pain as preemptive analgesia than I.V. fentanyl. Femoral Nerve Block reduces the time to perform spinal anaesthesia, increases the postoperative duration of analgesia and reduces analgesic requirements postoperatively.

Jadon A, Kedia SK, Dixit S, Chakraborty S (2014)[2] who conducted a study with the aim to compare the analgesic effect provided by Femoral Nerve Block and IV Fentanyl prior to positioning for central neuraxial block in patients undergoing surgery for femur fracture. The most important finding of study was that femoral nerve blockade offered superior analgesia compared to IV fentanyl during position for spinal anaesthesia in cases of fracture femur. In addition, Femoral Nerve Block was associated with greater patient satisfaction. They concluded that Femoral nerve block provides better analgesia, patient satisfaction, less time for anaesthesia and satisfactory positioning than IV fentanyl for central neuraxial block in patients undergoing surgery for femur fractures.

In our study we noted that the complications or side effects that were noted were far less in Group-I when compared with Group-II.

This was also seen in study by, Hartmann FV, Novaes MR, de Carvalho MR (2015)[3] who conducted a study to compare the analgesic efficacy of intravenous fentanyl versus femoral nerve block before positioning to perform spinal anaesthesia in patients with femoral fractures assessed by Pain Scales. They concluded that the use of femoral nerve block can reduce the level of pain and the need for additional analgesia. There are less adverse systemic events associated with this and the procedure itself does not offer greater risks.

CONCLUSION

Femoral Nerve Block with 0.2% Ropivacaine used as preemptive analgesia in fracture femur patients provided better efficacy of analgesia, considerably reduced time to perform spinal anaesthesia, with increased time post procedure for first rescue analgesic dose and increased duration of spinal anaesthesia when compared with 0.5 mcg/kg Intravenous Fentanyl. Patient positioning and patient satisfaction was better achieved; with considerably lesser complications or side effects with the use of Femoral Nerve Block than with Intravenous Fentanyl.

Thus we concluded that Femoral Nerve Block is a better preemptive analgesia than intravenous Fentanyl to facilitate positioning for spinal anaesthesia in patients undergoing fracture femur surgeries.

SUMMARY

This randomised comparative study titled “FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR” was carried out from December 2017 to august 2019 in the department of anaesthesiology.

The study was designed to compare Femoral Nerve Block or Intravenous Fentanyl as preemptive analgesic 15 minutes prior to performing of spinal anaesthesia in fracture femur patients posted for surgery with respect to following parameters: Efficacy of analgesia, ease of achieving position for spinal anaesthesia, patient satisfaction, time to perform spinal anaesthesia, duration of spinal anaesthesia, first rescue analgesic dose after spinal anaesthesia and complications or side effects.

The study population of 80 with age and sex matched was randomly selected and divided by computer generated random number tables in to two groups with 40 patients between the age of 30 years to 70 years of ASA grade I and II in each group:

Group I: Patients were given Femoral Nerve Block with 15 mL of 0.2% Ropivacaine.

Group II: Patients were given I.V Fentanyl 0.5 mcg/kg.

The observations and results were analysed statistically and were as follows: The demographic data of the two groups were not statistically significant; meaning, both the groups were comparable and randomised properly.

Ease of achieving position: higher percentage of patients were able to achieve better position for spinal anaesthesia in Group-I when compared to Group-II.

Efficacy of analgesia using VAS (visual analog scale) in Group-I the VAS scores were significantly reduced whereas in Group-II the VAS scores did not decrease considerably in the same time intervals.

Time to perform spinal anaesthesia: the time to perform spinal anaesthesia was considerably reduced in Group-I when compared with Group-II.

Duration of spinal anaesthesia and First rescue analgesic dose after spinal anaesthesia; both parameters were statistically significant which showed a considerable increase in the time for need of analgesia after performing spinal anaesthesia in Group-I patients when compared to Group-II patients.

Complications or side effects: In our study we noted that the complications or side effects that were noted were far less in Group-I when compared with Group-II.

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ANNEXURE I:

ETHICAL COMMITTEE CLEARANCE CERTIFICATE

ANNRXURE II:

INFORMED CONSENT FORM:

TITLE OF THE PROJECT:

"FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR: A RANDOMIZED COMPARATIVE STUDY"

PRINCIPAL INVESTIGATOR:

PG GUIDE:

PURPOSE OF RESEARCH:

I have been informed that this study is: "FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR: A RANDOMIZED COMPARATIVE STUDY".

I have been explained about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice for either being included or not in the study.

PROCEDURE:

I understand that I will be participating in the study: "FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR: A RANDOMIZED COMPARATIVE STUDY".

RISKS AND DISCOMFORTS:

I understand that my ward may experience some pain during the procedure and I understand that necessary measures will be taken to reduce these complications as and when they arise.

BENEFITS:

I understand that my wards participation in this study will help in finding out: “FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR: A RANDOMIZED COMPARATIVE STUDY".

CONFIDENTIALITY:

I understand that medical information produced by this study will become a part of this Hospital records and will be subjected to the confidentiality and privacy regulation of this hospital.

If the data are used for publication in the medical literature or for teaching purpose, no names will be used and other identifiers such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photograph and videotapes and hear audiotapes before giving this permission.

REQUEST FOR MORE INFORMATION:

I understand that I may ask more questions about the study at any time DR. ---------- ---------- is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study, which might influence my continued participation.

If during this study, or later, I wish to discuss my participation in or concerns regarding this study with a person not directly involved, I am aware that the social worker of the hospital is available to talk with me and that a copy of this consent form will be given to me for keep for careful reading.

REFUSAL OR WITHDRAWL OF PARTICIPATION:

I understand that my participation is voluntary and I may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.

I also understand that DR. ---------- will terminate my participation in this study at any time after she has explained the reasons for doing so and has helped arrange for my continued care by my own physician or therapist, if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely event of injury to me/my ward, resulting directly due to my participation in this study, such injury will be reported promptly, then medical treatment would be available to me, but no further compensation will be provided. I understand that by my agreement to participate in this study, I am not waiving any of my legal rights.

I have explained to _____ the purpose of this research, the procedures required and the possible risks and benefits, to the best of my ability in patient's own language.

Date: (Investigator)

Patient’s signature Witness

STUDY SUBJECT CONSENT STATEMENT:

I confirm that DR. ---------- has explained to me the purpose of this research, the study procedure that I will undergo and the possible discomforts and benefits that I may experience, in my own language.

I have been explained all the above in detail in my own language and I understand the same. Therefore I agree to give my consent to participate as a subject in this research project.

_____ _____

(Participant) Date

_____ _____

(Witness to above signature) Date

ANNEXURE III:

CASE PROFORMA:

STUDY:

"FEMORAL NERVE BLOCK VERSUS INTRAVENOUS ANALGESIA AS PREEMPTIVE ANALGESIC FOR POSITIONING OF SPINAL ANAESTHESIA IN FRACTURE FEMUR: A RANDOMIZED COMPARATIVE STUDY".

PATIENT DETAIL: DATE:

Name: Age/Sex: I.P No.: Wt.:

Ward: Group allotted by randomization: Group I / Group II

Diagnosis:

Surgical procedure:

Past History:

General Physical Examination:

Pallor / Icterus / Cyanosis /Clubbing / Koilonychia / Lymphadenopathy / Edema

Mallampati Grade: Spine:

Vital Parameters:

Pulse: Blood Pressure: Respiratory Rate: Temperature:

Systemic Examination:

Cardiovascular system:

Respiratory system:

Central nervous system:

Per abdomen:

Investigations:

Haemoglobin: TLC:

S. Urea: S. Creatinine:

RBS: Platelet count:

Urine routine: BT: CT:

Chest X-ray: ECG:

HIV: HBsAg:

ASA Grade:

Monitors attached: Pulse Oximeter ECG NIBP

Premedication: inj. Glycopyrrolate inj. Ondansetron inj. Midazolam

Type of preemptive analgesia:

Femoral Nerve Block ( ) I.V Fentanyl ( )

OBSEREVATIONS:

PARAMETERS	GROUP I – FEMORAL NERVE BLOCK	GROUP II – I.V FENTANYL
⁾ Efficacy of analgesia. Visual Analog Scale, (0 = No Pain to 10 = Unbearable, Excruciating pain) at: 2 mins - 5 mins - 10 mins - 15 mins		
⁾ Ease of achieving position for spinal anaesthesia. (0 =not satisfactory, 1 =satisfactory, 2 =good, 3 =optimal)		
⁾ Patient satisfaction. (Yes or No)		
⁾ Time to perform spinal anaesthesia in minutes.		
⁾ Duration of spinal anaesthesia in hours.		
⁾ First rescue analgesic dose after spinal anaesthesia. (after '*x*' hours of spinal anaesthesia.)		

COMPLICATIONS OR SIDE EFFECTS:

Group I- Femoral Nerve Block	Group II- I.V Fentanyl
⁾ Vascular puncture ( )	⁾ Sedation ( )
⁾ Intravascular injection and Anaesthetic toxicity ( )	⁾ Cognitive impairment ( )
⁾ Haematoma ( )	⁾ Nausea ( )
⁾ Nerve damage ( )	⁾ Vomiting ( )
	⁾ Respiratory depression ( )
	⁾ Dryness of the mouth ( )
	⁾ Urinary retention ( )

DATE: SIGNATURE: