ORIGINAL RESEARCH PAPER

Anaesthesiology

KEY WORDS: Postoperative analgesia, fascia iliaca compartment block, dexmedetomidine, ultrasound, fracture femur.

ULTRASOUND GUIDED FASCIA ILIACA COMPARTMENT BLOCK USING EITHER BUPIVACAINE OR BUPIVACAINE WITH DEXMEDETOMIDINE FOR POSTOPERATIVE ANALGESIA IN PATIENTS WITH FEMUR FRACTURES.

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ABSTRACT

Background: Femur fractures are extremely painful due to the lowest pain threshold of the periosteum among the deep somatic structures. Perioperative Fascia Iliaca Compartment Block (FICB), when administered using a local anesthetic agent, bupivacaine, can reduce morbidity by providing satisfactory pain relief. Dexmedetomidine, an alpha-2 agonist, is known to prolong the local anesthetic effects without causing any significant side effects. We compared analgesic duration of ultrasound guided FICB with bupivacaine alone and bupivacaine with dexmedetomidine for postoperative analgesia. **Materials And Method:** A prospective, randomized, double blinded study was conducted on 50 patients aged 18 to 65 years undergoing femur fracture surgeries. Patients were divided into 2 groups of 25 each. Both groups received USG guided FICB. Group A received 28 ml 0.25% bupivacaine and 2 ml normal saline (NS). Group B received 28 ml 0.25% bupivacaine and 30 mcg dexmedetomidine in NS. Pain scores were assessed every 5 minutes until 15 minutes post FICB, during positioning for subarachnoid block and every 2 hours until 24 hours post-operatively. Total duration of analgesia, cumulative analgesia requested in 24 hours, Ramsay sedation and patient satisfaction scores were recorded. **Results:** The mean duration of analgesia in Group A was 419.4 ± 115.35 minutes (95%CI: 374.2 – 464.6) and in Group B was 656.6 ± 137.99 minutes (95%CI: 602.5 –710.7), p <0.001. Mean VAS score during positioning for SAB in Group A was 1.60 ± 0.50 and in Group B was 0.96 ± 0.68. **Conclusion:** USG guided FICB with dexmedetomidine is superior in providing prolonged post-operative analgesia in comparison to bupivacaine alone.

INTRODUCTION:

Femoral bone fractures in the elderly are the most commonly encountered fractures in the emergency department either due to road traffic accidents or slip and fall. Even minimal overriding of fracture ends is extremely painful. Pain arises from the periosteum of the bone which is very sensitive and causes muscle spasm which further displaces fracture ends, worsening the pain. These fractures can have profound physiological and psychological changes [1] which may lead to sympathetic activation causing tachycardia, hypertension, increased cardiac work that may compromise high-risk cardiac patients. There is also increased incidence of deep vein thrombosis resulting from venous stasis, impaired immune system which further results in increase in infection rates, fatigue and delay in return of muscle function. [2]

After the landmark publication [3] with the observation that more than 80% of the post-operative pain is not treated, more attention has been focused towards it. The management of postoperative pain is associated with good clinical outcomes. Many drugs like opioids, non-steroidal anti-inflammatory drugs have been used, which carry increased risk of gastric bleeding, hypotension, respiratory depression and increased morbidity in elderly. [3] Focused peripheral nerve blocks will overcome these disadvantages while providing a complete analgesia without any motor weakness. Hence, it is ethical and more humane that analgesia is provided in the patients with the femur fracture in a more effective way.

Fascia iliaca compartment block (FICB) is a compartment block that covers femoral nerve, lateral femoral cutaneous nerve of thigh and obturator nerve in a single injection given deeper to fascia iliaca. This is a simple block and proved to be a safe and easy technique for pre and post-operative pain relief for injuries involving the hip, thigh, and knee. [4,5] When FICB was performed under real time ultrasound (USG) guidance, it was free from complications because of the ability to visualize the major nerves and vessels and avoided injury during needle insertion. [6] The success rate of USG guided FICB increased by 82% - 87% [7,8] when compared to pop technique which had a low success rate of 35 - 47%. [7,9] Bupivacaine, a long-acting local anesthetic agent, has been traditionally used to provide postoperative analgesia. Many additives such as opioids, steroids like dexamethasone were added to bupivacaine in various nerve blocks to prolong the duration of analgesia. [10] Dexmedetomidine is assuming greater importance as an analgesic supplement and an anaesthetic adjuvant. [11-14] Thus, we hypothesized that adding dexmedetomidine as an adjuvant to bupivacaine in USG guided FICB will prolong the duration of postoperative analgesia without any side effects and will facilitate early recovery and reduce the hospital stay.

Our primary objective was to study the efficacy of USG guided FICB using bupivacaine with dexmedetomidine for postoperative analgesia in patients undergoing surgery for femur fractures when compared to using bupivacaine alone. The secondary objectives were to observe for pain relief during positioning for subarachnoid block, the requirement of total number of analgesic doses in 24 hours, patient satisfaction score (PSS), Ramsay sedation score (RSS) and any side effects like bradycardia, hypotension, respiratory depression.

MATERIALS AND METHODOLOGY:

After obtaining institutional ethics committee clearance (reference No.EC-143) and clinical trial registration (CTRI/2021/03/032154), a prospective, randomized, double blinded study was conducted on 50 patients after obtaining written informed consent. The study was conducted over one year from March 2021 to February 2022 at our tertiary care hospital.

Based on the results of a previous study [10] conducted on fracture femur patients by Kumar NS et al., using the mean duration of analgesia of 16.33 +/- 5.69 with 95% confidence level, power of 80% and effect size of 30%, a sample size of 42 was deemed adequate. In order to compensate for the possible dropouts and for consistent results, 50 patients were included in the study.

Patients posted for elective femur fracture surgeries, aged between 18 and 65 years with American Society of Anesthesiologist's physical status (ASA-PS) 1-2 were included in the study. Patients with history of known allergy to local anesthetic agent and/or dexmedetomidine, pregnancy and lactation, infection at the block site, neurological deficit in lower limbs, impaired cognition/ dementia, multiple injuries requiring pain medications, and substance / opioid abuse were excluded from the study. The patients were randomized using computer generated random numbers and group assignment and concealment was done by sequentially numbered opaque envelopes. The patient and assessor were blinded to group allocation.

All patients underwent pre-anaesthetic evaluation and optimization before surgery. They were counseled about the study protocol, visual analogue scale (VAS) for assessment of the pain during pre and post-operative period. The study population were allocated to 2 groups with 25 patients each. Group A received USG guided FICB using 28 ml of 0.25% bupivacaine with 2 ml NS. Group B received USG guided FICB using 28 ml of 0.25% bupivacaine and 30 mcg dexmedetomidine in 2 ml NS. All patients received oral premedication of oral tablet ranitidine 150 mg and ondansetron 8 mg the night before surgery. In the preoperative room, standard ASA monitoring, i.e., heart rate (HR), pulseoximeter (SpO2), non-invasive blood pressure (NIBP), electrocardiogram (ECG) were attached, baseline hemodynamic values were noted. VAS scores assessed and all patients were preloaded with fluid ringer lactate at 10 ml/kg. Under real-time USG guidance (Sonosite ultrasound system) patient in supine position, a high-frequency, 6–13 MHz, linear transducer probe was placed parallel to inguinal ligament at the junction of middle and lateral third to facilitate accurate needle placement. Under strict asepsis and local infiltration with 2% lidocaine, a 23-gauge lumbar puncture needle was used in a lateral-to-medial orientation, with in-plane approach to allow visualization of the full length of the needle throughout the procedure. The two fascial planes, the fascia lata and the fascia iliaca were sonographically visualized as two hyper echoic lines. After confirming that the needle had perforated the fascia iliaca and negative aspiration, a total of 30 ml of the study drug was injected over 2–3 minute period by intermittent aspirations based on group allotted. The adequacy of the drug deposition was confirmed by the ultrasound device. Sensory blockade was evaluated using loss of cold perception in the lateral, anterior and medial part of the thigh corresponding to lateral femoral cutaneous nerve (LFCN), femoral nerve (FN) and obturator nerve (ON) sensory distributions respectively. Complete, partial block and total block failure were defined as blocks in all three thigh regions, in one or two thigh regions and in no thigh region respectively. If there was a block failure, the patient was excluded from the study analysis.

The dynamic VAS scores were assessed every 5 minutes until 15 minutes after administration of FICB. Fifteen minutes after the block, patients were shifted to the operation theatre and were put in sitting position for administering SAB. The dynamic VAS score was assessed and recorded during positioning of the patient. SAB with 0.5% hyperbaric bupivacaine 3.0 ml was given using 25G Quincke's needle at L3–L4 space. HR, blood pressures (systolic-SBP, diastolic-DBP, mean arterial pressures-MAP), and oxygen saturation (SpO2) were recorded till the end of the surgery. Any significant intra operative episode of bradycardia (less than 50 beats/minute) was treated with intravenous (IV) atropine 0.6 mg and hypotension defined as more than 20% fall from the baseline was treated with intravenous ephedrine 6 mg boluses.

Following surgery, patients were shifted to post anesthetic care unit and hemodynamics monitored. Considering administration of the block as time zero, post-operative pain was assessed at every 2 hours until 24 hours, at rest and on movement. The time to first postoperative rescue analgesia as evidenced by VAS ≥ 3 was noted and rescue analgesia in the form of IV diclofenac sodium 75 mg in 100 ml NS was administered. The cumulative analgesia request and sedation as assessed using Ramsay sedation scale during the 24 hour post-operative period was recorded. At the end of study, Patient Satisfaction Score (PSS) was recorded as adopted by Ittichaikulthol et al. [15] Complications like intravascular injection, local anesthetic systemic toxicity, hematoma at injection site, paresthesia, nausea, vomiting, hypotension, bradycardia and hypoventilation (breathing rate <8 breaths/min), if any, were recorded and treated.

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 (IBM SPSS Statistics, Somers NY, USA) version software. Categorical data was represented as frequencies and proportions. Chi-square test or Fischer's exact test was used as test of significance for qualitative data. Continuous data was represented as mean and standard deviation. Independent t test or Mann Whitney U test was used as test of significance to identify the mean difference between two quantitative variables and qualitative variables respectively. The p value < 0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS:

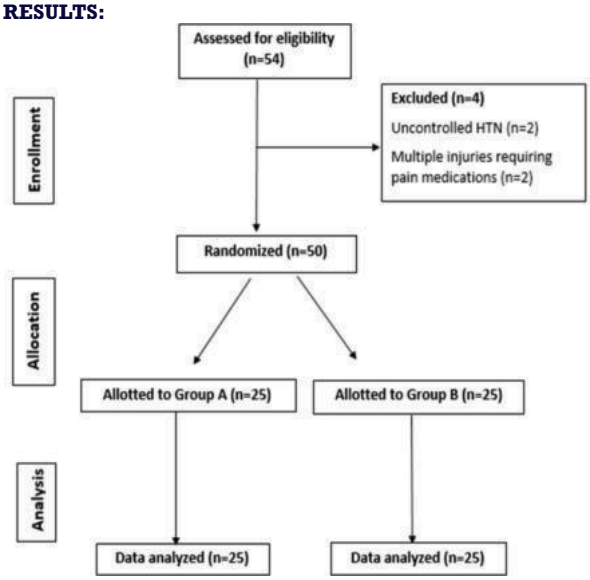

Figure 1: CONSORT flow diagram

The demographic data of the patients in both the groups were comparable and did not show any significant statistical difference (table 1). Fifty patients were included in the study. All patients had successful blocks and no patients were excluded. The hemodynamic variables like HR, SBP, DBP and MAP were comparable in both groups.

Table 1: Demographic characteristics of patients among both the groups

	Group A (n=25)	Group B (n=25)	p value
Mean age (years)	54.08 ± 10.18	53.36 ± 10.65	0.808
Male	13	13	1.000
Female	12	12	
ASA I	18	14	0.239
ASA II	7	11	
Mean duration of surgery (min)	123.60 ± 22.66	120.40 ± 26.65	0.649

The mean total duration of analgesia is described in table 2. There was significant difference noted in duration of analgesia between both groups (p value < 0.001).

Table 2: Comparison of total duration of analgesia between the two groups

	N	Mean	SD	95% Confidence Interval for Mean		Min	Max
				Lower Bound	Upper Bound		
Group A	25	419.40	± 115.347	371.79	467.01	250	740
Group B	25	656.60	± 137.989	599.64	713.56	440	1030

There was significant difference in mean VAS scores at rest between two groups at post-op 0 – 4 hours. At other intervals VAS was below 3, although there was no statistically significant difference. The dynamic VAS, below 3 was observed 15 minutes after the block. While positioning for SAB, all patients were free from pain with VAS < 3. The onset of action of block was rapid in Group B than in Group A, which is statistically significant (table 3).

Table 3: Comparison of mean pre-operative 'dynamic VAS' between two groups at different time intervals

	Group A				Group B				P Value
	Mean	SD	95%CI for Mean		Mean	SD	95%CI for Mean		
			Upper Bound	Lower Bound			Upper Bound	Lower Bound	
Pre-Op	6.40	0.71	6.122	6.678	6.32	0.63	6.073	6.567	0.674
05 Min	5.72	0.68	5.453	5.987	4.76	0.78	4.454	5.066	< 0.001 *
10 Min	4.40	0.76	4.102	4.698	3.36	0.86	3.023	3.697	< 0.001 *
15 Min	2.84	0.62	2.597	3.083	2.12	0.67	1.857	2.383	< 0.001 *
Positioning for SAB	1.60	0.50	1.404	1.796	0.96	0.68	0.693	1.227	< 0.001 *

There was significant difference in total number of analgesic doses required in 24 hours between two groups. In Group A, 13 patients required 1 dose, 9 patients required 2 doses and 3 patients required 3 doses of analgesia. In Group B, 19 patients required 1 dose and 6 patients required 2 doses of analgesia. The third dose was not needed in any patient.

Figure 2: Comparison of Patient satisfaction score (PSS) among the patients

There was a significant difference in mean RSS when compared between two groups at pre-op 10 min, during positioning for SAB, postoperatively at 4 hours and 12 hours. At other intervals there was no significant difference. With a few exceptions, the majority of patients in Group A reported being well satisfied whereas, all the patients in Group B were highly satisfied (figure 2). No side effects was noted in patients of either group.

DISCUSSION:

Fracture shaft of femur are extremely painful as the pain arises from the periosteum and are subjected to major muscle forces that may deform the thigh and angulate the bone fragments further, thus worsening the pain. These muscular forces complicate the intraoperative reduction of the fracture. Hence, all the muscles acting on the femur need to be completely paralyzed intraoperatively. [16] SAB is a commonly used anaesthetic technique for reduction and fixing of fracture. Positioning of these patients for SAB is extremely challenging and requires the administration of large amounts of intravenous analgesics. The most frequently used drugs are midazolam, ketamine, propofol and opioids like fentanyl, remifentanil, morphine, nitrous oxide and sevoflurane. [17] The nerve blocks were used infrequently. The beneficial effect of FICB in patients with radiologically confirmed hip fracture is well known with studies reporting a good outcome [18,19] when compared to NSAIDS and opioids. [20]

FICB was first performed in 1989 in children by Dalens B. et al., and it was observed that injecting local anaesthetic agent into fascia iliaca compartment almost always resulted in easy and effective block of three nerves i.e., femoral, obturator and lateral cutaneous nerves in children undergoing lower limb surgery. [21] It was concluded that FICB done with landmark technique using bupivacaine and dexmedetomidine prior to SAB for fracture femur surgeries ensured better patient comfort during positioning and significantly prolonged the post-operative analgesia when compared to plain bupivacaine. [22] A retrospective analysis of USG-guided FICB for postoperative analgesia in patients undergoing hip and femur surgeries in 203 patients concluded that, addition of dexmedetomidine to bupivacaine provides prolonged and good quality postoperative analgesia and reduced requirement for rescue analgesic in comparison with bupivacaine alone in FICB. [23]

Use of dexamethasone as adjuvant to bupivacaine for FICB in patients undergoing fracture femur surgery resulted in significantly prolonged duration of block and decreased the requirement of rescue analgesics when compared with those who recieved FICB with bupivacaine alone. [10] When used as adjuvants to bupivacaine during FICB, both dexmedetomidine and dexamethasone were found to be effective in alleviating the pain while positioning for SAB in patients posted for proximal fracture femur surgery. It has also been observed that the duration of postoperative analgesia was prolonged with dexmedetomidine when compared to dexamethasone. [16]

In our study, administration of FICB with bupivacaine and dexmedetomidine provided prolonged postoperative analgesia in addition to providing tranquility and good pain relief during positioning the patient for SAB. The cumulative requirement of analgesic doses in 24 hours was significantly less with adequate sedation and better satisfaction when dexmedetomidine was used as an adjuvant to bupivacaine. There were no side effects due to drug administration and all patients had stable hemodynamics during entire perioperative period. Hence, we can use USG guided FICB with bupivacaine and dexmedetemidine for providing prolonged postoperative analgesia. The only limitation was usage of continuous perineural catheterization would further reduce the perioperative morbidity which was not followed in our study.

CONCLUSION:

In femur fracture surgeries, USG guided FICB with

bupivacaine and dexmedetomidine is superior in providing prolonged post-operative analgesia and reduces requirement of repeated doses of analgesia in 24 hours when compared to bupivacaine alone. It also ensures better patient comfort, tranquillity and compliance while positioning the patients for SAB without causing any side effects.

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