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Original Research Article

Intrathecal Morphine versus Fascia Iliaca Compartment Block for Post Operative Pain Control in Femur Fracture: A Randomised Controlled Prospective Study

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Abstract:

Background: Fracture femur leads to considerable pre and post-operative pain which is one of the most common medical causes of delayed recovery and discharge [1]. Optimal pain control not only decrease complications but also facilitates faster recovery during the immediate postoperative period. Fascia iliaca compartment block (FICB) is a regional block of lumbar plexus which is an alternative to central neural block and can provide adequate unilateral analgesia with fewer adverse effects. Hence we conducted the study to compare the efficacy of FICB to that of Intrathecal Morphine administration in fracture femur cases with regards to the duration of analgesia, patient satisfaction and side effect profiles.

Material and Method: The study is a prospective, randomized, double blinded study. 80 patients were divided into 2 groups. Group ITM (Group A) received 0.5% Bupivacaine (heavy) with 150 mcg of morphine as an adjuvant after CSF aspiration, then patient was made to lie in supine position. Group FICB (Group B) -patients received spinal anaesthesia with 3ml of 0.5% Bupivacaine (heavy) and later facia iliaca block was given with USG guidance after confirmation of correct needle position, with 20ml of 0.5% Bupivacaine and 20ml of 2% xylocaine with adrenaline. Patients were monitored for post-operative pain scores, tramadol consumption, vital parameters including heart rate, blood pressure, oxygen saturation and adverse effects like nausea vomiting, itching, respiratory depression and sedation at 1,2,4,6,12 and 24 hrs.

Results: The mean NRS score at 1,2 and 4 hours were not statistically significant and had nearly equal NRS score. However at 6, 12 and 24 hour the mean NRS score was statistically significant and lower in group A than in Group B. The mean time to first rescue analgesia in Group A was 18.75±1.81 hrs and in Group B 10.53±1.54 hrs (p=0.000) which was statistically significant. The overall patient satisfaction score at 12 hours and 24 hours postoperatively was found to be considerably higher in Group B than in Group A (p=0.000).

Conclusion: Intrathecal morphine in spinal anaesthesia provided prolonged duration of analgesia up to 24 hours as compared to USG guided (FICB) fascia iliaca compartment block in patients undergoing femur fracture surgery with few side effects.

Keywords: Morphine, Fascia Iliaca Compartment Block, Bupivacaine, Spinal Anesthesia, Pain Score.

Introduction

Fracture femur leads to considerable pre and post-operative pain which is one of the most common medical causes of delayed recovery and discharge[1]. Optimal pain control not only decrease complications but also facilitates faster recovery during the immediate postoperative period. Multimodal analgesia is widely used to deal which such pain. This includes regional techniques,

systemic opioids and postoperative administration of gabapentin. Fascia iliaca compartment block (FICB) and intrathecal morphine (ITM) are seldom used alone for the management of postoperative pain, though they are known to provide excellent analgesia [1]. The fascia iliaca block was first described in 1989 by Dalens et al [3] as an alternative to 3-in1nerveblock in children. Fascia iliaca compartment block (FICB) is a regional block of lumbar plexus that involves the anterior thigh, if the injected local anaesthetics are positioned posterior to the fascia iliaca, it diffuses to its internal layer then to the femoral, genitofemoral, lateral femoral cutaneous and obturator nerves which was radiologically confirmed later on. It is an alternative to central neural block and can provide adequate unilateral analgesia with fewer adverse effects than epidural analgesia. FICB provide effective rapid onset analgesia following traumatic hip and femur fractures in the elderly [3]. Intrathecal Morphine is widely used regional central neuraxial technique used to manage this pain and has excellent post-operative pain relief with few side effects like itching.

FICB being newer block technique not many articles are there to compare its efficacy with the conventionaly and traditionaly used intrathecal Morphine .Hence we conducted a randomized controlled trial to compare the efficacy of FICB block with that of intrathecal morphine for post-operative pain.

Methodology

After approval from the ethical committee with ethical number DMR\IMS.SH\SOA\180243 and written informed consent, n=80 patient was selected for the study based on the inclusion and exclusion criteria. Using computerized randomized selection, patients were assigned into two groups-Intrathecal morphine (Group ITM) and Fascia iliaca group (Group FICB).On the day of surgery, patients are prepared by noticing the nil per oral status and shifted to pre-operative room,18G or 20 G IVcannula secured and Inj. Ondensetrone 4mg IV & Inj. Pantoprazole 40mg IV was given to all patients. This study was a randomized prospective interventional clinical trial. Randomization was done by using a computer generated numbers to decide who will receive spinal anaesthesia with intrathecal morphine (ITM) or fascia iliaca compartment block (FICB). Study was a double blinded study. Patients were divided into 2 groups of 40 each.

Group A: patients receiving spinal anaesthesia with morphine (ITM)
Group B: patients receiving spinal anaesthesia with fascia iliaca compartment block (FICB)

Inclusion Criteria

1. Patients between the ages 18-60 years
2. Both gender
3. ASA 1,2
4. Undergoing elective surgery unilateral femur fracture.

Exclusion Criteria

1. Refusal by patient to participate in study
2. Allergies to local anaesthetic agents or to the study drug
3. Any contraindication to regional anaesthesia (patient refusal, local infection or coagulopathy)
4. ASA 3,4
5. Patients having other concomitant fracture
6. Neurological disease (Alzheimer, dementia) or deficit.
7. Converting regional anesthesia to general anesthesia intra operatively due to any reason.

Intraoperative

Standard Monitors – NIBP, pulse oximeter, ECG was attached and baseline vitals were noted for the patients of both groups undergoing fracture femur surgery. Group ITM- patient received spinal anaesthesia with 3.ml 0.5% Bupivacaine(heavy) with 150 mcg of morphine as an adjuvant after CSF aspiration, then patient was made to lie in supine position. Group FICB-patients received spinal anaesthesia with 3ml of 0.5% Bupivacaine(heavy) and later facia iliaca block was given by same investigator after giving spinal anaesthesia .

Group1: Patients receiving spinal anaesthesia with Morphine (ITM):

Procedure was performed by same investigator every time. Patient was placed in sitting position. The skin was disinfected with 10 % chlorhexidine and sterile drapes were applied. 2ml of 2% Lignocaine was use for local infiltration at space L3- L4 space.

The approach used for spinal technique was midline approach. After identifying L3- L4 inter vertebral space, lumbar puncture was done with 25-G Quincke spinal needle keeping bevelled tip longitudinally, free flow of CSF noted and 3ml of bupivacaine 0.5% heavy with morphine 150mcg is injected after csf aspiration. Then patient is made to lie in supine position.

Group 2: Patients receiving spinal anaesthesia with fascia iliaca compartment block (FICB):

The block was performed under ultrasound guidance by the same investigator every time after giving spinal anaesthesia with 3ml bupivacaine 0.5% heavy in L3-L4 inter-vertebral space with 25-G Quincke spinal needle.

Patient was placed in the supine position. Skin was disinfected with 10% chlorhexidine. Sterile drape

was placed. Linear array ultrasound probe with 6-13 MHz frequency was used. Probe was placed transversely on thigh, just inferior to inguinal ligament in a transverse orientation, 1/3 of distance away from anterior superior iliac spine to the pubic tubercle. After visualising fascia lata and fascia iliaca as 2 hyperechoic lines, a 90-mm, 23-G Quincke spinal needle inserted lateral to medial, parallel to the transducer.

Then after puncturing through fascia iliaca, negative aspiration was done and 2ml of 5% dextrose is injected. Needle tip location was verified and confirmed with the fascia lift up off of the nerve. Optimal needle location is indicated by the appearance of an anechoic fluid collection separating the fascia iliaca from iliacus muscle and visibly expands the compartment, usually reached at an average depth of 4-6cm from skin level. After confirmation of correct needle position, 20ml of 0.5% Bupivacaine and 20ml 2% xylocaine with adrenaline was injected. Both Groups were continuously monitored during and after procedure for 24 hrs.

Postoperatively

All patients were transferred to the post-anaesthesia care unit(PACU). Pain was assessed by Numeric Rating Scale (NRS), a 10 cm long scale on which 0 is taken as no pain and 10 being worst possible pain. NRS ≤3 will be taken as satisfactory pain relief. Injection Tramadol 2mg/kg(max 100mg) was given as rescue analgesia if pain score is >4 or on patient's demand. Nausea vomiting was treated with Injection Ondansetron 4 mg IV. Pruritus (itching) was treated with Injection Dexamethasone 4 mg IV. Hypotension (decrease in mean blood pressure more than 20% of the base line value) was treated with IV fluids and IV Inj.Ephedrine 5mg boluses. Bradycardia (heart rate less than 50/min) was treated with Atropine 0.01mg/kg IV. Respiratory depression (rate less than 10/min or Oxygen saturation less than 92% on room air) was treated by oxygenation and trial for arousal. Patients were monitored for post-operative pain scores, tramadol consumption, vital parameters including heart rate, blood pressure, oxygen saturation and adverse effects like nausea vomiting, itching, respiratory depression and sedation at 1,2,4,6,12 and 24 hrs. Ramsay sedation score was used to assess post-operative sedation. At the end of 24 hrs, patients were asked to rank the quality of pain relief on a four-point patient satisfaction scale where 1-Excellent, 2-Very good, 3-satisfactory, 4-Poor.

Statistical Analysis

- The data were analyzed using software "statistical package for the social sciences, version 25, SPSS inc., Chicago, Ilionois, USA".
- The "quantitative variables were expressed as mean and standard deviation whereas; categorical variables are expressed in frequency percentage".
- All quantitative variables were analyzed through "Student t test".
- However categorical variables were analyzed by "chi-square test/Fischer exact test".
- p value <0.05 was statistically significant.

Results

80 patients were included in study and were randomly assigned in two groups. In group A, 40 patients (26 male and 14 female) underwent femur fracture operation with intrathecal morphine (150mcg) in 0.5% heavy bupivacaine 3ml, and in Group B, 40(23male and 17 female) patients underwent femur fracture operation with 0.5% heavy bupivacaine 3ml as spinal anaesthesia and fascia iliaca compartment block by 0.2% lignocaine with adrenaline 20ml and 0.5% plain bupivacaine 20 ml for postoperative analgesia after fracture femur operation. There was a male predominance seen in patients undergoing fracture femur operation. However sex in both the group were comparable and statistically insignificant (p=0.647). The mean age (mean ± S.D) in Group A was 41.73±12.62 years and in Group B it was 41.05±12.61 years. The groups were comparable in terms of age and was insignificant (p=0.812). The mean duration of surgery was 2.51±0.54 hrs and 2.46±0.62 hrs in group A and B respectively was comparable and statistically insignificant (p=0.702). Postoperative pain: The mean NRS score at 1,2,4,6,12,24 hours in Group A were 0, 0, 0, 0.18±0.50, 1.15±0.48, 2.77±0.66 respectively and in Group B were 0,0,0,1.58±0.64,2.88±0.76, 4.57±1.01 respectively {Table 1}.The mean NRS score at 1,2 and 4 hours were not statistically significant and had nearly equal NRS score. However at 6, 12 and 24 hour the mean NRS score was statistically significant and lower in group A than in Group B.

Postoperative Vitals: This study found that mean vitals like HR, SPO2, MAP and RR were stable at all times however HR at 2nd, 6th and 24th hours; MAP up to 6th hour; RR up to 12th hours were significantly lower in group A as compared to group B.{ Table2,3,4}. Mean time of first rescue analgesia (duration of analgesia): The mean time to first rescue analgesia in Group A was 18.75±1.81 hrs and in Group B 10.53±1.54 hrs (p=0.000) which was statistically significant{Table-5}. Total analgesic requirement: The mean consumption of total rescue analgesia 1 being 100mg, 2- 200mg and 3- 300mg. here in this study group A people required mostly 100mg analgesia in total 24 hrs whereas in group B higher number of patients required 300mg making it statistically significant (p=0.000){Table-6}. Patient satisfaction score: the

overall patient satisfaction score at request of 1st rescue analgesia, 12 hours and 24 hours postoperatively was found to be considerably higher in Group B than in Group A(p=0.000){Table-7,8}

Side effects: There were very less side effects, there were no cases of local anaesthetic systemic toxicity(LAST)or hematomas (Group B), 2 cases of PONV and 1 case of pruritus was noted in ITM (Group A) but was statistically insignificant (p=0.241).

Since all the patients were catheterised so we excluded urinary retention from our study. Sedation was not noted in patients with our dose {Table -9}.

Table 1: Mean pain scores at various times

	Group A	Group B	p value
Pain at 1hr	0.00±0.00	0.00±0.00	-
Pain at 2hrs	0.00±0.00	0.00±0.00	-
Pain at 4hrs	0.00±0.00	0.00±0.00	-
Pain at 6hrs	0.18±0.50	1.58±0.64	0.000
Pain at 12hrs	1.15±0.48	2.88±0.76	0.000
Pain at 24hrs	2.77±0.66	4.57±1.01	0.000

Table 2: Mean HR at different time intervals

	Group A	Group B	p value
HR at 1hr	83.23±7.16	85.80±6.74	0.102
HR at 2hrs	83.35±7.00	86.63±6.74	0.036
HR at 4hrs	82.97±7.24	85.80±6.74	0.075
HR at 6hrs	83.35±7.00	86.63±6.74	0.036
HR at 12hrs	83.18±7.19	85.80±6.74	0.096
HR at 24hrs	82.58±7.27	88.85±5.67	0.000

Table 3: Mean MAP at different time intervals

	Group A	Group B	p value
MAP at 1hr	80.22±7.28	85.43±7.32	0.002
MAP at 2hrs	80.63±7.43	85.50±7.33	0.004
MAP at 4hrs	80.22±7.28	85.43±7.32	0.002
MAP at 6hrs	80.63±7.43	85.50±7.33	0.004
MAP at 12hrs	98.10±4.25	98.40±6.09	0.799
MAP at 24hrs	98.88±4.58	98.40±6.09	0.695

Table 4: Mean SpO2 at different time intervals

	Group A	Group B	p value
SpO2 at 1hr	97.68±1.00	98.18±0.96	0.025
SpO2 at 2hrs	97.73±1.01	98.15±0.95	0.056
SpO2 at 4hrs	97.68±1.00	98.18±0.96	0.025
SpO2 at 6hrs	97.73±1.01	98.15±0.95	0.056
SpO2 at 12hrs	97.68±1.00	98.18±0.96	0.025
SpO2 at 24hrs	98.10±1.13	98.40±1.01	0.213

Table 5: Mean time for request of 1st rescue analgesia

Time of First analgesia	Group A	Group B	p value
required (in Hrs)	18.75±1.81	10.53±1.54	0.000

Table 6: Total rescue analgesic requirement in 24 hours

	Group A	Group B	p value
Total analgesic requirement (24hrs)			0.000
1	39	00.0%	
2	100.0%	11	
3	1	91.7%	
	8.3%	29	
	00.0%	100.0%	

Table 7: Patient satisfaction at the time of request of 1st rescue analgesia

		Group A	Group B	p value
patient satisfaction score (at request of 1st analgesia)	Excellent Very good Satisfactory Poor	16 100.0% 24 96.0% 00.0% 00.0%	0 0.0% 1 4.0% 24 00.0% 15 100.0%	0.000

Table 8: Patient satisfaction score at 24th hour

		Group A	Group B	p value
patient satisfaction score at 24hrs	Excellent Very good Satisfactory Poor	16 100.0% 24 96.0% 00.0% 00.0%	0 0.0% 1 4.0% 24 00.0% 15 100.0%	0.000

Table 9: Postoperative side effects

		Group A	Group B	P Value
Side Effects	N P PONV	37 48.1% 1 100.0% 2 100.0%	40 51.9% 00.0% 00.0%	0.241

Discussion

Fracture femur is commonly seen following trauma in young individual or a trivial fall in the elderly. Fracture femur poses unusual problems to anaesthesiologist. These fractures are extremely painful. Surgery is the definitive treatment of fracture femur cases[4]. Early mobilization and short hospital stay are considered to be important end points of functional recovery. Several factors including poor postoperative pain relief can contribute towards delayed recovery and home discharge. Not only good pain relief is important for patient satisfaction, it also means that patient can be mobilized early and thereby return to normal body functions quickly[3].

Our study dealt with pain relief, patient satisfaction, hemodynamic changes and side effects in fracture femur patients by comparing two different procedures, ITM and FICB. So in patients undergoing fracture femur operations, we found that rescue analgesic consumption, pain score, hemodynamic changes like HR, MAP, SpO2 and RR were lower when ITM was used, compared to FICB. Side effects such as nausea, vomiting and pruritus were insignificant when compared in both the groups. In our study we compared spinal morphine and fascia iliaca compartment block. The analgesia achieved after 150µg spinal morphine is usually satisfactory and lasts upto 24hrs, which means it is cost effective, efficacious and easily applied as studied by Bujedo BM et al.[5]. However, side-effects such as pruritus, nausea, vomiting, respiratory depression and sedation as found in one study conducted by Jacobson L et al. [8], have resulted in attempts to find other methods. We were therefore interested in assessing whether FICB could achieve similar analgesia as spinal morphine, without the side-effects mentioned above. FICB has been studied earlier but mostly for patient positioning, compared with other block techniques like femoral block, 3-in-1 block, NSAIDS and even with IV opiods. But there is one study by Kearns et al.[2] they conducted first ever study comparing ultrasound guided FICB with spinal morphine in hip arthroplasty.

Here in our study the primary objective was to measure the time of 1st request of analgesia and duration, which was not done before in any studies to best of our knowledge and it was significantly lower in ITM group when compared with FICB. A previous study evaluated analgesic efficacy of USG guided FICB with epidural analgesia in knee replacement surgery by Gallardo et al. [7]. In that study NRS/VAS scores were evaluated between the 2 groups.

This was considered as the primary outcome measure. Postoperative nausea and vomiting, patient satisfaction at the end of 24 hours, rescue analgesia with tramadol, success rate were the other parameters evaluated. But the hemodynamic parameters were not compared between the 2 groups in that study. So, we conducted a study comparing the NRS pains scores between ITM group and FICB group over 24 hours. In addition, post-operative nausea and vomiting, patient satisfaction at 24 hours, dose of rescue analgesia

with injection tramadol, complications associated with the procedure were evaluated between the 2 groups. The hemodynamic parameter over a period of 24 hours was also compared between FICB group and ITM group. Study was a randomized double blinded clinical trial with both the observer and analyser blinded to the study.

Sample size selected was 80, based on previous published article. The outcome measure was compared between the FICB group and ITM group, the NRS scores were graded on a 0-10 cm scale. NRS scores were observed over a period of 24 hour in the postoperative period at 1st hour, 2nd hour, 4th hour, 6th hour, 12th hour and 24thhours. The mean NRS scores at 6th, 12th and 24thhour were statistically significant between the two groups. So the analgesic efficacy of USG guided FICB as measured by NRS pain scores was less comparable with ITM.

The next outcome measure was postoperative satisfaction score. A score of 1 which is excellent was observed in 16 patients in ITM group as compared to 0 in FICB group at the end of 24 hours; 37 in ITM as compared to 6 in FICB at the end of 12 hours. The mean postoperative satisfaction was better in the ITM group with significant p value.

The secondary outcome, the hemodynamic parameters are concerned there was no instability in mean arterial pressure, heart rate, saturation and respiratory rate at all the time during study period but the data were significantly lower in ITM group.The other outcome regarding side effects were insignificant as only 1 patient had pruritus and 2 had single episode of PONV. Similar results with side effects of morphine were found by a meta-analysis conducted by Gehling M et al. [8]. This was in contrast to study conducted by Kato k et al. [9], where they found delayed respiratory depression with intra-thecal morphine. Both spinal anaesthesia and peripheral nerve blockade are commonly used for femur fracture surgery.

Conclusion

From this study it can be concluded that the (ITM) intrathecal morphine in spinal anaesthesia provided prolonged duration of analgesia up to 24 hours compared to USG guided (FICB) fascia iliaca compartment block in patients undergoing femur fracture surgery. FICB is not only significantly less effective in providing analgesia, but confers no advantage in reducing the side effect profile and it have to be used with other anaesthetic procedure like central neuraxial blockade or general anaesthesia for surgery purposes as this is only for sensory blockade. Minor complication as nausea, vomiting, pruritus etc. were noted in few cases, which is statistically insignificant but ITM in spinal anaesthesia is very simple in technique and doesn‟t need any expensive machine, easy learning curve to perform it when compared with FICB. Hence we arrived at a conclusion that the ITM holds effective postoperative analgesia with fewer side effects in lower doses as compared to FICB with better patient satisfaction.

Limitations

- Small sample size.
- In FICB we have not used any additives which could have modified the outcome.

FICB efficacy was not assessed before administering the spinal anaesthetic. This could have resulted in patients in the fascia iliaca group having higher analgesic requirements due to inadequacy of the block. There were several reasons for not checking block efficacy. The routine method for checking block efficacy is by assessing sensation in the distribution of the lateral cutaneous nerve of thigh and the femoral nerve, and motor power in the distribution of the obturator nerve. This, however, is time-consuming and not representative of usual clinical practice. Furthermore, any assessment of the efficacy of the block could have unblinded both the patient and the anaesthetist performing the block.

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