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Comparative Study of Analgesic Effects Between Plain Bupivacaine and Bupivacaine with Dexamethasone in Fascia iliaca Compartment Block in Acute Trauma Patients

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ABSTRACT

The benefits of Regional Analgesia are likely most influential when it is initiated as early as possible in Acute Trauma Patients on Arrival and the performance of regional nerve blocks both in the emergency room has been shown to provide quality pain relief with an excellent safety profiles. Present study was aimed to compare analgesic effects between plain bupivacaine and bupivacaine with dexamethasone in fascia iliaca compartment block in acute trauma patients on arrival. Material and Present study was single-center, prospective, comparative study conducted in patients of either sex, of all ages, ASA grade 1/2/3/4, with acute trauma. Patients were randomly divided into two groups as Group A (Bupivacaine plus Dexamethasone) and Group B (Plain Bupivacaine). All patients received Fascia Iliaca Compartment Block under USG. Significant difference was seen in VAS score at 5 min, at 6 hrs, at 8 hrs between group A and B. (p<.05) Proportion of patients who required first rescue analgesia (hrs) at 12 hrs, at 16 hrs was significantly higher in group A as compared to group B. Mean duration of analgesia (hrs) in group A was 12.33±2.78 which was significantly higher as compared to group B (8.67±2.37). (p<0001). Mean duration of onset of analgesia(minutes) in group B was 21.5±14.39 which was significantly higher as compared to group A (13.33±11.99). (p = 0.02). Mean total dose of rescue analgesia required(mg) in group B was 1500±131.31 which was significantly higher as compared to group A (1033.33±126.85). (p<.0001) Addition of dexamethasone to Bupivacaine in fascia iliaca compartment block results in early, prolonged and safe analgesia with decreased consumption of opioids and overall patient satisfaction in management of acute trauma patients.

INTRODUCTION

Trauma is a significant health problem and a leading cause of death in all age groups. Approximately 5.8 million people die each year as a result of Traumatic injuries^[1] This accounts for 10% of the world death, more than the number of fatalities from Malaria, Tuberculosis and HIV/AIDS combined^[1,2]. Pain related to trauma is frequently severe but is often undertreated in the trauma population.

Although Opioids are widely used to treat pain in injured/trauma patients they have a wide range of side effects such as Neurological and Respiratory Impairment as compared to Regional Nerve Block gives best site-specific pain relief which is free from major side effects and also reduces opioid consumption. In addition it is safe and easy to perform especially nowadays where Ultra Sound (USG) guided and PNS (Peripheral Nerve Stimulator) devices are available for good precision^[3,4].

Amongst the procedures, Fascia Compartment Block is believed to be advantageous because of its safety and efficacy. The benefits of Regional Analgesia are likely most influential when it is initiated as early as possible in Acute Trauma Patients on Arrival and the performance of regional nerve blocks both in the emergency room has been shown to provide quality pain relief with an excellent safety profiles^[5,6]. Pain management in the trauma patients is challenging where using traditional analgesics such as opioids and nsaids could be risky as patients neurological condition doesn't allow use of opioids and for NSAIDS, Renal function and Liver function profile is unknown especially in ASA 2/3/4 patients limiting their use^[5,6]. Present study was aimed to compare analgesic effects between plain bupivacaine and bupivacaine with dexamethasone in fascia iliaca compartment block in acute trauma patients on arrival.

MATERIALS AND METHODS

Present study was single-center, prospective, comparative study conducted in Department of Anaesthesia, Dr. Vaishampayan Memorial Government Medical College, Solapur. Study duration was of 2 years (January 2021 to December 2022). Study approval was obtained from institutional ethical committee.

Inclusion criteria:

 Patients of either sex, of all ages, ASA (American Society of Anaesthesiologists) grade 1/2/3/4, with acute trauma, relatives willing to participate in present study

Exclusion criteria:

Patients not willing for the procedure are also excluded from study

- Patients allergic to the study drugs
- Known bleeding diathesis
- Peripheral neuropathy
- Previous femoral bypass surgery
- Inguinal hernia
- Inflammation or infection over injection site
- Morbid obesity
- Patient on previous opioid therapy

Study was explained to relatives in local language and written consent was taken for participation and study. As all the Participants are trauma patient initial consent was taken from the relative as patient were in severe pain. As soon as patient received in trauma with injury involving lower limb having severe pain, general condition, VAS score were assessed. Fascia Iliaca Compartment Block was given with the help of ultrasonography. Patients were randomly divided into two groups:

- **Group A (n = 30):** Bupivacaine plus Dexamethasone was given
- Group B(n = 30): Plain Bupivacaine was given

Drugs labelled as Drug A or Drug B were be given in the block. Date and Time of Fascia Iliaca Compartment Block will be noted followed by visual analog scale pain score immediately at 5 minutes, 30 min, 45 min, 1hr, 2nd, 4th, 6th, 12th and 24th hrs of block. Patients were monitored with electrocardiography pulse oximetry and non invasive blood pressure prior to fascia iliaca compartment block and through the procedure. Identification of the Fascia Iliaca Compartment was done by USG. All cases were assessed with respect VAS score, analgesic consumption, clinical presentation/examination, associated morbidity and mortality.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. p>0.5 was considered as statistically significant.

RESULTS

In present study, 60 patients of either sex and of all ages with ASA grade of 1-3 and 4 were included. Mean±SD of age(years), gender, weight (kg), height (inches) and ASA grade were comparable between group A and B. (p>0.05).

No significant difference was seen in various parameters such as SpO₂ (%), pulse rate(per minute), systolic blood pressure(mmHg), diastolic blood pressure (mmHg) and respiratory rate(per minute) at

| Table | 1 | Gonoral | cha | racto | arictics |
|-------|---|---------|-----|-------|----------|

| Characteristics | Group A (n = 30) | Group B (n = 30) | Total | p-value |
|-----------------|------------------|------------------|-------------|--------------------|
| Age(years) | 41.23±12.18 | 41.37±10.52 | 41.3±11.28 | 0.964* |
| Gender | | | | |
| Female | 10 (33.33%) | 9 (30%) | 19 (31.67%) | 0.781 [‡] |
| Male | 20 (66.67%) | 21 (70%) | 41 (68.33%) | |
| Other | | | | |
| Weight (kg) | 67.33±6.23 | 65.13±5.65 | 66.23±6 | 0.157* |
| Height (inches) | 5.53±0.15 | 5.48±0.15 | 5.51±0.15 | 0.202* |
| ASA grade | | | | |
| I | 24 (80%) | 22 (73.33%) | 46 (76.67%) | 0.542 [‡] |
| II | 6 (20%) | 8 (26.67%) | 14 (23.33%) | |

* Independent t test, * Chi square test

Table 2: Diagnosis

| Table 2. Diagnosis | | | | |
|---------------------------|----------------|----------------|-------------|--------------------|
| Diagnosis | Group A (n=30) | Group B (n=30) | Total | P value |
| Left acetabular fracture | 7 (23.33%) | 3 (10%) | 10 (16.67%) | 0.108 [‡] |
| Left femur neck fracture | 15 (50%) | 11 (36.67%) | 26 (43.33%) | |
| Right acetabular fracture | 5 (16.67%) | 6 (20%) | 11 (18.33%) | |
| Right femur neck fracture | 3 (10%) | 10 (33.33%) | 13 (21.67%) | |

[‡] Chi square test

Table 3: Comparison of VAS score between group A and B

| VAS score (Mean±SD) | Group A(n = 30) | Group B(n = 30) | Total | p-value |
|---------------------|-----------------|-----------------|-----------|---------|
| At 0 min | 7.77±0.82 | 7.47±0.86 | 7.62±0.85 | 0.171* |
| At 5 min | 0.47±0.78 | 1.13±1.59 | 0.8±1.29 | 0.044* |
| At 30 min | 0.13±0.43 | 0.2±0.48 | 0.17±0.46 | 0.577* |
| At 45 min | 0±0 | 0±0 | 0±0 | 1* |
| At 1 hrs | 0±0 | 0.03±0.18 | 0.02±0.13 | 0.326* |
| At 2 hrs | 0.23±0.5 | 0.37±0.56 | 0.3±0.53 | 0.335* |
| At 4 hrs | 1.13±0.63 | 1.37±0.61 | 1.25±0.63 | 0.152* |
| At 6 hrs | 2.03±0.56 | 2.47±0.94 | 2.25±0.79 | 0.034* |
| At 8 hrs | 2.9±0.61 | 3.27±0.58 | 3.08±0.62 | 0.02* |
| At 12 hrs | 3.5±0.57 | 3.67±0.48 | 3.58±0.53 | 0.227* |
| At 16 hrs | 3.43±0.57 | 3.33±0.48 | 3.38±0.52 | 0.464* |
| At 24 hrs | 3.53±0.51 | 3.53±0.51 | 3.53±0.5 | 1* |

* Independent t test

Table 4: Comparison of rescue analgesia between group A and B.

| Rescue analgesia | Group A (n = 30) | Group B (n = 30) | Total | p-value |
|-------------------|------------------|------------------|-------------|---------------------|
| At 1 hrs | | | | |
| Not required | 30 (100%) | 30 (100%) | 60 (100%) | - |
| At 2 hrs | | | | |
| Not required | 30 (100%) | 30 (100%) | 60 (100%) | - |
| At 4 hrs | | | | |
| Not required | 30 (100%) | 30 (100%) | 60 (100%) | - |
| At 6 hrs | | | | |
| Not required | 29 (96.67%) | 22 (73.33%) | 51 (85%) | 0.026 [†] |
| Inj PCM 1gm IV | 1 (3.33%) | 8 (26.67%) | 9 (15%) | |
| At 8 hrs | | | | |
| Not required | 26 (86.67%) | 17 (56.67%) | 43 (71.67%) | 0.02 [†] |
| Inj PCM 1gm IV | 4 (13.33%) | 13 (43.33%) | 17 (28.33%) | |
| At 12 hrs | | | | |
| Not required | 12 (40%) | 12 (40%) | 24 (40%) | 0.011 [†] |
| Inj PCM 1gm IV | 17 (56.67%) | 9 (30%) | 26 (43.33%) | |
| Inj PCM 500 mg IV | 1 (3.33%) | 9 (30%) | 10(16.67%) | |
| At 16 hrs | | | | |
| Not required | 21 (70%) | 17 (56.67%) | 38 (63.33%) | <.0001 [†] |
| Inj PCM 1gm IV | 8 (26.67%) | 0 (0%) | 8 (13.33%) | |
| Inj PCM 500 mg IV | 1 (3.33%) | 13 (43.33%) | 14 (23.33%) | |
| At 24 hrs | | | | |
| Not required | 30 (100%) | 22 (73.33%) | 52 (86.67%) | 0.005 [†] |
| Inj PCM 1gm IV | 0 (0%) | 1 (3.33%) | 1 (1.67%) | |
| Inj PCM 500 mg IV | 0 (0%) | 7 (23.33%) | 7 (11.67%) | |

Table 5: Comparison of time of requirement of first rescue analgesia (hrs)

| Time of requirement of first rescue analgesia (hrs) | Group A (n = 30) | Group B (n = 30) | p-value |
|---|------------------|------------------|----------|
| At 6 hrs | 1 (3.33%) | 8 (26.67%) | <u> </u> |
| At 8 hrs | 4 (13.33%) | 13 (43.33%) | |
| At 12 hrs | 17 (56.67%) | 9 (30%) | |
| At 16 hrs | 8 (26.67%) | 0 (0%) | <.0001 |
| ter to the second second | | | |

† Fisher's exact test

1 hrs, at 2 hrs, at 4 hrs, at 6 hrs, at 8 hrs, at 12 hrs, at 16 hrs and at 24 hrs between group A and B (p>0.05). Distribution of diagnosis was comparable between group A and B. (Left acetabular fracture: 23.33% vs 10% respectively, Left femur neck fracture 50% vs

36.67% respectively, Right acetabular fracture 16.67% vs 20% respectively, Right femur neck fracture 10% vs 33.33% respectively) (p value = 0.108). Significant difference was seen in VAS score at 5 min, at 6 hrs, at 8 hrs between group A and B. (p<.05) Mean±SD of

Table 6: Analgesia characteristics

| Characteristics | Group A(n = 30) | Group B(n=30) | Total | p-value |
|--|-----------------|---------------|----------------|---------------------|
| Duration of analgesia (hrs) | 12.33±2.78 | 8.67±2.37 | 10.5±3.16 | <.0001* |
| Duration of onset of | | | | |
| Analgesia (min) | 13.33±11.99 | 21.5±14.39 | 17.42±13.76 | 0.02* |
| Number of times rescue analgesia required | | | | |
| One time | 28 (93.33%) | 1 (3.33%) | 29 (48.33%) | <.0001 [†] |
| Two times | 2 (6.67%) | 28 (93.33%) | 30 (50%) | |
| Three times | 0 (0%) | 1 (3.33%) | 1 (1.67%) | |
| Total dose of rescue analgesia required (mg) | | | | |
| 1000 mg | 28 (93.33%) | 1 (3.33%) | 29 (48.33%) | <.0001 [†] |
| 1500 mg | 2 (6.67%) | 28 (93.33%) | 28 (46.67%) | |
| 2000 mg | 0 (0.00%) | 1 (3.33%) | 3 (5%) | |
| Mean±SD | 1033.33±126.85 | 1500±131.31 | 1266.67±267.86 | <.0001* |

Independent t test, [‡] Chi square test [†] Fisher's exact test

VAS score at 5 min, at 6 hos, at 8 hrs in group B was 1.13 ± 1.59 , 2.47 ± 0.94 , 3.27 ± 0.58 respectively which was significantly higher as compared to group A $(0.47\pm0.78(p=0.044), 2.03\pm0.56 (p=0.034), 2.9\pm0.61(p=0.02))$ respectively.

None of the patients required rescue analgesia at 1 hrs, at 2 hrs and at 4 hrs. Proportion of patients required rescue analgesia at 6 hrs was significantly lower in group A as compared to group B. (Inj PCM 1gm IV 3.33% vs 26.67% respectively) (p = 0.026). Proportion of patients required rescue analgesia at 8 hrs was significantly lower in group A as compared to group B. (Inj PCM 1gm IV 13.33% vs 43.33% respectively). (p = 0.02). Proportion of patients required rescue analgesia at 12 hrs was significantly higher in group A as compared to group B. (Inj PCM 1gm IV 56.67% vs 30% respectively). Proportion of patients required rescue analgesia at 12 hrs inj PCM 500 mg IV was significantly lower in group A as compared to group B. (Inj PCM 500 mg IV: 3.33% vs 30% respectively).

Proportion of patients who required rescue analgesia at 16 hrs inj PCM 1gm IV was significantly higher in group A as compared to group B. (Inj PCM 1gm IV 26.67% vs 0% respectively). Proportion of patients who required rescue analgesia at 16 hrs inj PCM 500 mg IV was significantly lower in group A as compared to group B. (Inj PCM 500 mg IV: 3.33% vs 43.33% respectively). This is because 26.67% of patients in group A required analgesia first time and on the contrary, 43.33% of patients in group B required analgesia second time. (p<0.0001) Proportion of patients who required rescue analgesia at 24 hrs was significantly lower in group A as compared to group B. (0% vs 23.33% respectively) (p = 0.005).

Proportion of patients who required first rescue analgesia (hrs) at 12 hrs, at 16 hrs was significantly higher in group A as compared to group B. (At 12 hrs 56.67% vs 30% respectively, At 16 hrs 26.67% vs 0% respectively). Proportion of patients who required first rescue analgesia (hrs) at 6 hrs, at 8 hrs was significantly lower in group A as compared to group B. (At 6 hrs 3.33% vs 26.67% respectively, At 8 hrs 13.33% vs 43.33% respectively) (p<0.0001). Mean±SD of duration of analgesia(hours) in group A

was 12.33 ± 2.78 which was significantly higher as compared to group B (8.67 ±2.37). (p<.0001). Mean \pm SD of duration of onset of analgesia (minutes) in group B was 21.5 ± 14.39 which was significantly higher as compared to group A (13.33 ±11.99). (p = 0.02).

Proportion of patients with analgesia required one time was significantly higher in group A as compared to group B. (One time 93.33% vs 3.33% respectively). Proportion of patients with rescue analgesia required two times, three times was significantly lower in group A as compared to group B. (Two times 6.67% vs 93.33% respectively, Three times 0% vs 3.33% respectively) (p<0.0001).

Proportion of patients with total dose of rescue analgesia required(mg) 1000mg was significantly higher in group A as compared to group B (1000mg 93.33% vs 3.33% respectively). Proportion of patients with total dose of rescue analgesia required (mg) 1500 mg was significantly lower in group A as compared to group B (1500 mg 6.67% vs 93.33% respectively) (p<0.0001).

Mean±SD of total dose of rescue analgesia required(mg) in group B was 1500±131.31 which was significantly higher as compared to group A (1033.33±126.85) (p<.0001).

DISCUSSIONS

Patients in acute trauma are always in severe unbearable pain and in need of immediate pain relief before evaluation and other surgical treatment, so patient needs on arrival pain relief so that further management can start pain free and comfortably like cast application, shifting to ICU, Operation Theater etc. Conventional pain treatment (NSAIDs, paracetamol and IV morphine) has undesirable side-effects, many of those being particularly contraindicated in patients with high co-morbidity. Opioids may cause respiratory depression, hypotension, dizziness, mental confusion, constipation, itching, urine retention and nausea. NSAIDs may cause gastrointestinal hemorrhage and affect renal function^[7,8].

Amongst the procedures, Fascia Iliaca Compartment Block is believed to be advantageous because of its safety and efficacy. It has been demonstrated that fascia iliaca compartment block (FICB) provides effective analgesia for fracture in acute trauma patients on arrival, as soon as possible^[7,8]. Many adjuvants like epinephrine, clonidine, opioids, ketamine and midazolam were combined with local anaesthetics to prolong the duration of analgesia from nerve blocks, but have met with limited success. However, the glucocorticoid dexamethasone has been shown to be effective in a small number of preclinical and clinical studies^[9-12].

Study done by Weheba *et al.*^[13] shows that median VAS score in group A and group B at 0 min was 4 and 4 respectively, at 30 min it was 2 and 2 respectively, at 1 hrs it was 1 and 1 respectively, at 2 hrs it was 1 and 1 respectively, at 2 hrs it was 1 and 1 respectively, at 4 hrs it was 1 and 2 respectively, at 6 hrs it was 2 and 2 respectively, at 8 hrs it was 2 and 4 respectively, at 12 hrs it was 3 and 4 respectively, at 24 hrs it was 4 and 4 respectively. This shows that, addition of Dexamethasone to Bupivacaine decreases post-operative pain and shows low VAS score values as compared to bupivacaine alone. Similar findings were noted in present study and in study done by Babu *et al.*^[14]

In our study, proportion of patients who required first rescue analgesia(hrs) at 12 hrs, at 16 hrs was significantly higher in group A as compared to group B. (At 12 hrs 56.67% vs 30% respectively, At 16 hrs 26.67% vs 0% respectively). Proportion of patients who required first rescue analgesia (hrs) at 6 hrs, at 8 hrs was significantly lower in group A as compared to group B. (At 6 hours: 3.33% vs 26.67% respectively, At 8 hrs 13.33% vs 43.33% respectively) (p<0.0001). Study done by Babu et al.[14] shows that time of request for first analgesia dose (min) was 297.83±29.56 in study group and 175.50 \pm 29.17 in control group. (p = <0.001) In our study, Mean±SD of duration of analgesia (hrs) in group A was 12.33±2.78 which was significantly higher as compared to group B (8.67±2.37) (p<.0001). Study done by Ravi et al.[15] shows that mean duration of analgesia in Bupivacaine+Dexamethasone combination is 16.33±5.69 hrs and in Bupivacaine only group it was 7.85±1.62 hrs. This shows that addition of dexamethasone to bupivacaine increases duration of analgesia.

Study done by Weheba *et al.*^[13] shows that mean duration of sensory block in Bupivacaine + Dexamethasone combination is 3.15 ± 0.81 hrs and in Bupivacaine only group it was 3.3 ± 0.7 hrs. It also shows that mean duration of motor block in Bupivacaine + Dexamethasone combination is 2.39 ± 0.61 hours and in Bupivacaine only group it was 2.41 ± 0.56 hrs.

In our study, Mean±SD of total dose of rescue analgesia required(mg) in group B was 1500±131.31 which was significantly higher as compared to group A (1033.33±126.85). (p<.0001). Study done by Ravi *et al.*^[15] shows that total doses of rescue analgesics required were significantly higher in bupivacaine only group than Bupivacaine +

Dexamethasone combination. Candal-Couto $et~al.^{[16]}$ demonstrated that fascia iliaca compartment block allows patients being able to tolerate a sitting position with femoral neck fractures. Fascia iliaca compartment block is more effective in blocking lateral cutaneous nerve of thigh and femoral nerve as per demonstrated in study done by Morau $et~al.^{[17]}$

The Fascia iliaca compartment block is not only easy to perform but it is also associated with minimal risk as the analgesic is injected at a safe distance from the femoral artery and femoral nerve. It is always safe to perform the FICB prior to spinal anaesthesia as the patient can respond during administration of the local anaesthetic and can prevent intraneuronal injections as demonstrated in a study by Capdevila *et al.*^[18] There are reports of postoperative neuropathy when FICB was attempted after spinal anaesthesia as demonstrated in a study done by Gros *et al.*^[19]

We observed that prolongation of block duration was 1.5 to 2 times when dexamethasone was added as an additive to plain bupivacaine. This block prolongation was also observed when dexamethasone was combined with mepivacaine for supraclavicular blocks as shown by Parrington $et\ al.^{[20]}$ Similarly, Cummings 3rd $et\ al.^{[21]}$ also observed that, dexamethasone significantly prolonged the duration of ropivacaine and bupivacaine when used for the interscalene block. However, the existing literature supports the clinically important benefit we observed in our study.

Elderly patients with fracture femur are more prone to delirium because of pain and medications. Adequate analgesia not only prevents delirium but also, allows increased mobility and shorter hospital stay as demonstrated in a study by Mouzopoulos *et al.*^[22] Analgesia provided by femoral nerve blockade can be compared to that of epidural analgesia but with a lower incidence of hypotension as shown in a study done by Fowler *et al.*^[23] Choi *et al.*^[24] and Richman *et al.*^[25]

Our study shows that adding Dexamethasone (8 mg) to Bupivacaine for FICB significantly prolonged the duration of block and decreased the requirement of rescue analgesics as compared to patients who received Bupivacaine alone. FICB is relatively easy and safe to perform. In our study we did not encounter any complication while doing the procedures and also by adding dexamethasone.

CONCLUSION

Addition of dexamethasone to Bupivacaine in fascia iliaca compartment block results in early, prolonged and safe analgesia with decreased consumption of opioids and overall patient satisfaction in management of acute trauma patients. We recommend using 8 mg dexamethasone with 0.25% Bupivacaine routinely in fascia iliaca compartment

block for management of pain in acute trauma and also for better analgesic efficacy with no complications.

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