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Comparison of Clonidine & Dexamethasone as Additive to Bupivacaine in Fascia Iliaca Compartment Block for Postoperative Analgesia in Patients Undergoing Lower Limb Orthopaedic Surgery

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Abstract

Background & Aim: *Major lower limb surgeries are associated with severe postoperative pain and requires good postoperative analgesia. The use of Fascia Iliaca Compartment Block (FICB) is a safe and effective approach to postoperative analgesia. The aim was to compare the efficacy of clonidine or dexamethasone as an adjuvant to bupivacaine in FICB for relieving postoperative pain in lower limb orthopaedic surgery.*

Materials and Methods: *In this prospective, randomized controlled study 100 patients of 18 to 65 years of age of either sex belonging to ASA Class I, II and III were randomly divided into 2 groups with 50 patients in each group. The study was conducted on elective cases of hip & femur shaft surgery under spinal anaesthesia. After completion of surgery FICB was given in supine position using loss of resistance technique. Group-1 received FICB with 38 ml of 0.25% bupivacaine + 50 mcg Clonidine diluted with Normal Saline up to 2 ml. Group-2 received FICB with 38 ml of 0.25% bupivacaine + 8mg Dexamethasone (2ml). All patients were assessed for postoperative pain using VAS score at 30 min,1,3,6,12,24 hours, total duration of postoperative analgesia and total rescue analgesics consumption in 24 hours.*

Result: *There was significant difference noted in both groups in terms of mean VAS score at rest and during movement at 12 hours after surgery. Mean VAS score at rest was 3.4±1.4 in Group-1 and 2.46±1.9 in Group-2 (P Value=0.006). Mean VAS score during movement was 4.84±0.99 in Group-1 and 4.22±1.49 in Group-2 (P Value=0.015). Total duration of postoperative analgesia was 11.2±2.19 hours in Group-1 compared to 12.44±2.54 hours in Group-2 which was statistically significant (p value=0.010). Mean requirement of number of rescue analgesics was 1.94±0.71 in Group-1 and 1.60±0.67 in Group-2, which was statistically significant (P Value=0.018).*

Conclusion: *We conclude that adding Dexamethasone (8mg) to Bupivacaine for FICB significantly prolongs the duration of postoperative analgesia and decreases the requirement of rescue analgesics as compared to patients who received Clonidine (50mcg) as additive to Bupivacaine.*

Keywords: *Fascia Iliaca Compartment Block (FICB), Dexamethasone, Clonidine, postoperative analgesia.*

Introduction

Major lower limb surgery is often painful and requires aggressive postoperative pain management. Poorly treated pain can have negative impact on recovery especially owing to disruption in physiotherapy resulting in stiffness of joints and slow progress in mobility[1]. Optimization of pain control in perioperative orthopaedic patients contributes to improved patient satisfaction, early mobilization, decreased length of hospital stay and decreased associated hospital and patient cost. Postoperative pain relief can be achieved by a variety of conventional modes including parenteral NSAIDS, neuraxial local analgesics and narcotics, epidural analgesia, peripheral nerve block, wound infiltration and patient controlled IV analgesia with opioids[2]. In comparison to epidural analgesia, peripheral nerve blocks, not only provide effective unilateral analgesia but also reduce the incidence of opioid related and autonomic side effects, produces less motor blockade & have less neurological complications. The use of peripheral nerve blocks is a safe effective approach to perioperative pain management. Peripheral nerve blocks are suitable substitutes for analgesia after lower limb surgery which provides better pain relief, greater patient satisfaction, more cost effective analgesia, more favourable postoperative recovery and rehabilitation profile. One of the most common peripheral nerve blocks to facilitate postoperative analgesia for lower limb surgery is the Fascia iliaca compartment block (FICB) which was originally described for use in paediatric patients. This block reported consistent capture of the three nerves innervating the lower extremity, combined with the anatomical safety profile and the ease in placing the block, has made the FICB a viable alternative to 3-in-1 block[3]. Fascia iliaca compartment block endeavors to block the femoral nerve, lateral femoral cutaneous nerve of thigh and obturator nerve in a single shot given deep to Fascia iliaca. This is a simple block for pre-operative and post-operative pain relief for injuries involving the hip, anterior thigh, and knee. Present study was conducted to compare the efficacy of clonidine or dexamethasone as an adjuvant to bupivacaine in FICB for relieving postoperative pain and facilitating physiotherapy in patients with lower limb operated under spinal anaesthesia.

Materials and Methods

After obtaining approval from hospital ethical committee and written informed consent, this clinical study was carried out on 100 ASA grade I, II and III patients of either sex, aged 18-65 years posted for hip & femur shaft surgery under spinal anaesthesia in the year of 2017 to 2018.

All patients underwent pre-anesthetic evaluation one day before the scheduled surgery. Before the procedure, visual analogue scale (VAS) on 0-10 cm was explained to the patient for the assessment of pain where 0 denotes no pain and 10 denotes worst pain.

The study population was randomly divided into 2 groups with 50 patients in each group.

Group-1 Patients received Fascia iliaca compartment block with 38 ml of 0.25% bupivacaine + 50 mcg Clonidine diluted with Normal Saline up to 2 ml. Group-2 Patients received Fascia iliaca compartment block with 38 ml of 0.25% bupivacaine + 8 mg Dexamethasone (2ml).

Exclusion: Patient not giving consent, coagulation disorder, infection at the site of block, past history of any drug reaction, neurological diseases affecting lower limb, history of previous femoral bypass surgery, patient having psychiatric illness, morbid obesity, patient having polytrauma.

Preoperative pulse rate, BP, SPO2 and respiratory rate were noted. After securing IV. line, preloading was done with Inj. Ringer Lactate 10-15 ml/kg I.V.

Spinal anaesthesia was given under all aseptic precaution using 25G Quinke's spinal needle with 2.5-3.0 ml of 0.5% Bupivacaine (Heavy) at L2-L3 or L3-L4 intervertebral space.

At the end of surgery FICB was given in supine position as technique described by Dalens et al. with line drawn on skin connecting the anterior

superior iliac spine to pubic tubercle at the level of inguinal ligament. This line is divided into three equal parts. At the junction of lateral one third and medial two third, a second line is drawn perpendicular to line joining anterior superior iliac spine (ASIS) and pubic tubercle. One cm below this line is the insertion point. A Tuhoy's (18G) needle was inserted perpendicular to the skin at this point.

A pop up or loss of resistance is felt as the needle passes through the fascia lata, and a second loss of resistance is felt as it passes through fascia iliaca. After this, angle is reduced to 30 degrees and needle is advanced 1-2 mm further. Anaesthetic solution containing drugs according to group was injected after negative aspiration for blood. Distal compression was applied immediately caudal to needle puncture site for ten minutes to favour the proximal spread of local anaesthetic drug.

Follow up and Assessment:

The time was noted when the block was performed initially, after 3 hours of giving spinal anaesthesia (when we expect that the effect of spinal anaesthesia has weared off) we checked sensory blockade of opposite limb using pin prick test and motor blockade by checking movement of great toe.

After that sensory blockade of operated limb on the territories of femoral nerve (anterior aspect of thigh), obturator nerve (medial aspect of thigh), LFC nerve (lateral aspect of thigh) was evaluated using pin prick test.

The result of sensory blockade was reported as either "yes" (complete sensory blockade) or "no" (partial or absent sensory blockade) of a given nerve territory.

The patients were assessed for pain using 10 points visual analogue scale at 30 min, 1, 3, 6, 12, and 24 hours after performing block. In postoperative period, Inj. diclofenac sodium 1.5 mg/ kg IV was given as rescue analgesic when VAS ≥ 4. The time of first analgesic requirement after performing the block (duration of analgesia), total doses of analgesic requirement during 24 hours was also noted.

Patients were also asked to rate their satisfaction to postoperative analgesia (excellent, good, poor). Complications like intra vascular injection, hematoma at injection site, local anaesthetic toxicity and block failure were noted.

Statistical analysis: To collect required information from eligible patients a pre structured pre tested proforma was used. For data analysis Microsoft excel and statistical software SPSS version 22.0 was used and data were analysed with the help of percentage, mean, SD in the form of tables, diagrams. The results were statistically analyzed by student's t-test for quantitative data and Chi-square test for qualitative data.

p Value > 0.05 - Insignificant

p Value < 0.05 – Significant

p Value < 0.001 – Highly significant

Results

Both the groups were statistically comparable regarding age, weight and sex distribution. (P> 0.05). (Table-1)

The differences of basic vital parameters and ASA grade in both groups was found statistically insignificant (p-value>0.05).

There was no significant difference regarding type and duration of surgery in both groups (p-value>0.05).

No significant difference was found in both groups in terms of mean VAS score up to 6 hours and at 24 hours postoperatively at rest and during movement but significant difference was noted only at 12 hours after surgery both at rest (p= 0.006), and during movement (p = 0.015) (Table2)

The duration of analgesia was significantly longer in Group-2 by 1.24 hours when compared to Group-1(12.44 ± 2.54 vs 11.2 ± 2.19 hours), (p < 0.05). (Table-3)

Total doses of rescue analgesics required were significantly higher in Group-1 as compared to Group-2 (1.94 ± 0.71 vs 1.60 ± 0.67), (p < 0.05). (Table-4)

In our study we did not encounter any complication while doing the procedures and also by adding clonidine or dexamethasone.

Table-1: Patients Demographic Data

PARAMETERS	GROUP 1	GROUP 2	p value
Mean age (years) (Mean ± SD)	42.36 ± 16.62	43.2 ± 17.76	0.70
Mean body weight(kg) (Mean ± SD)	61.38 ± 7.02	60 ± 7.0	0.33
Sex (M/F)	41/9	38/12	0.623

Table-2: Mean VAS score at different time intervals

Time after block (hours)	At rest			During movement		
	Group 1	Group 2	p value	Group 1	Group 2	p value
1/2	0	0	>0.99	0	0	>0.99
1	0	0	>0.99	0	0	>0.99
3	0	0	>0.99	0	0	>0.99
6	0	0	>0.99	1.54 ± 1.4	1.08 ± 1.34	0.096
12	3.4 ± 1.4	02.46 ± 1.9	**0.006**	4.84 ± 0.99	4.22 ± 1.49	**0.015**
24	5.1 ± 0.54	5.12 ± 0.81	0.85	6.62 ± 0.60	6.66 ± 1.03	0.75

Table-3: Duration of Postoperative Analgesia

Duration of Analgesia	Group 1	Group 2	p value
Time (hours) (Mean ± SD)	11.2 ± 2.19	12.44 ± 2.54	**0.01**

Table-4: Analgesic dose required in 24 hours

Total analgesic dose required in 24 hours	Group 1	Group 2
1	14	25
2	25	20
3	11	05
(Mean ± SD)	1.94 ± 0.71	1.60 ± 0.67
p value	**0.016**	

Fig. 1 Mean VAS score at rest

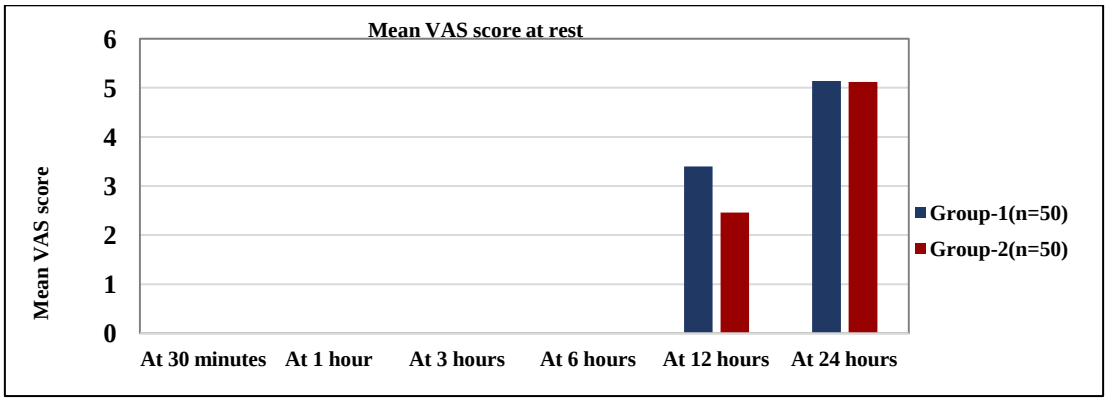


Fig. 2 Mean VAS score during movement

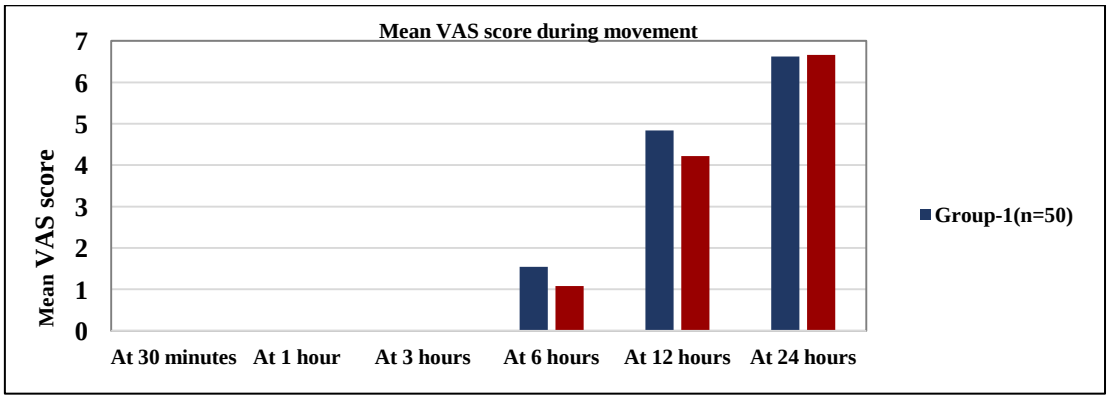


Fig. 3 Duration of Postoperative Analgesia

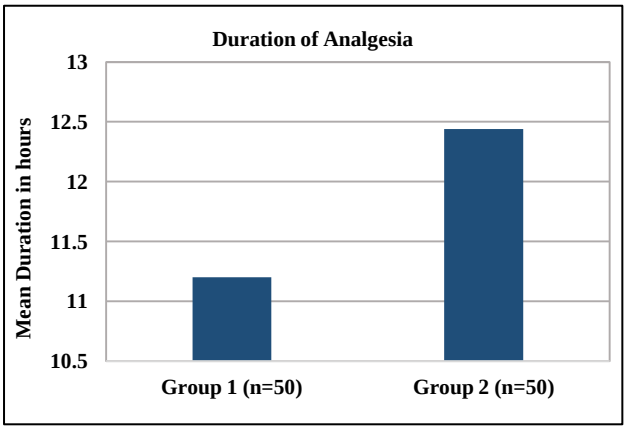
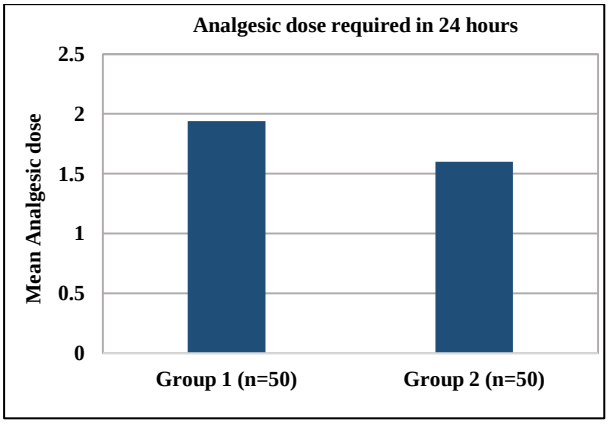


Fig. 4 Analgesic dose required in 24 hours



Discussion

Peripheral nerve blocks (PNB) are suitable substitutes for analgesia after lower limb surgery. They provide better pain relief, greater patient satisfaction, fewer pulmonary and cardiac complications, a reduced risk of deep vein thrombosis, faster recovery with less likelihood of the development of neuropathic pain, and reduced cost of care.

Fascia iliaca compartment block (FICB) is a simple, safe and effective procedure. It results in blockade of femoral nerve, obturator nerve and lateral femoral cutaneous nerve of thigh with a single injection without eliciting paresthesia. The FICB is devoid of any major side effects. Present study was conducted as a controlled, randomized, double blind, prospective study to compare the efficacy of clonidine and dexamethasone as an adjuvant to bupivacaine in FICB for relieving postoperative pain and facilitating physiotherapy in a patient with lower limb operated under spinal anaesthesia. Dexamethasone when combined with local anesthetics prolongs analgesia either by inducing vasoconstriction and reducing the absorption of local anesthetic or by increasing the activity of inhibitory potassium channels on nociceptive c-fibers, decreasing their activity and prolonging sensory and motor blockade.

There have been four proposed mechanisms for the action of clonidine in peripheral nerve blocks. These mechanisms are centrally mediated analgesia, α2 adrenoceptor mediated vasoconstrictive effects, attenuation of inflammatory response and direct action on peripheral nerve.

In our study there was no significant difference found in both groups in terms of mean VAS score at 30 mint to 6 hours postoperatively at rest and during movement but significant difference was noted only at 12 hours after surgery both at rest and during movement where mean VAS score at rest was 3.4 in Group-1 and 2.46 in Group-2 ($p = 0.006$), and mean VAS score during movement was 4.84 in Group-1 and 4.22 in Group-2 ($p = 0.015$), so there was low VAS score in Group-2 as compared to Group-1. No significant difference was found in both groups at 24 hours after surgery in terms of mean VAS score.

The duration of analgesia was significantly longer in Group-2 (dexamethasone group) when compared to Group-1(clonidine group). Total duration of analgesia was 12.44 ± 2.54 h in Group-2 compared to 11.2 ± 2.19 h in Group-1 (p value=0.010). Saied NN et al.[4] did an observational study and found that dexamethasone or clonidine when added as adjuvants to ropivacaine in Brachial Plexus Block, both prolongs the duration of postoperative analgesia, but dexamethasone is the most effective. Kumar S et al.[5] observed that prolongation of block duration was 1.5 to 2 times when dexamethasone was added as an additive to plain bupivacaine. K. C. Cummings et al.[6] also observed that dexamethasone significantly prolonged the duration of ropivacaine and bupivacaine when used for the interscalene block.

Bafna et al.[7] and Patil et al.[8] found that clonidine when added to ropivacaine in supraclavicular brachial plexus block significantly prolonged sensory and motor block and provides better post-operative analgesia. Tomar GS et al.[9] observed that Clonidine as adjuvant to 0.25% bupivacaine in fascia iliaca compartment block (FICB) effectively prolongs the duration of analgesia.

In our study, there was less consumption of rescue analgesics in Group-2 (dexamethasone group) as compared to Group-1 (clonidine group) which was statistically significant. Mean requirement of number of rescue analgesic was 1.60 ± 0.67 in dexamethasone group compared to 1.94 ± 0.71 in clonidine group. Sharma Uma Datt et al.[10] found that patients of dexamethasone containing Group RD had lower tramadol requirement compared to Group RS (ropivacaine + normal saline) [223.33 ± 56.83 mg] vs. [293.33 ± 25.71 mg] in USG-guided TAP block.

No incidence of complications like hematoma, accidental intra vascular injection, block failure, or local anaesthetic toxicity were seen during the study in any patients of both the groups.

Conclusion

We conclude that adding Dexamethasone (8mg) to Bupivacaine for FICB significantly prolongs the duration of postoperative analgesia and decreases the requirement of rescue analgesics as compared to patients who received Clonidine (50mcg) as additive to Bupivacaine. However larger prospective randomized trials are required to establish the superior efficacy of dexamethasone.

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