

Role of Clonidine in Fascia Iliaca Compartment Block for Preoperative Analgesia in Post Hip Fracture Patients: A Comparative Study

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Abstract

Background: Fractures around the hip joint are associated with considerable moderate to severe pain. Adequate preoperative analgesia in these patients is difficult to assess and often an overseen aspect of their care. This study was aimed to assess the efficacy of adding clonidine as adjuvant in fascia iliaca compartment block (FICB) in relieving pain and increasing the pain free duration in the preoperative period.

Methods: Sixty patients were divided into three groups of 20 each. Patients in group A received 40 ml of 0.25% bupivacaine + 100µg clonidine and patients in group B received 40 ml of 0.25% bupivacaine + 50µg clonidine whereas group C (the control group) patients were given only 40 ml of 0.25% bupivacaine. Changes in heart rate and blood pressure were recorded in each group.

Results: There was significant improvement in VAS and Sitting Score in both the groups after the block and the findings of paired t test on VAS at 1Hr, 2Hr, 6Hr was comparable ($P>0.05$) but showed significant difference the next morning ($P<0.05$). The patients of group A had a total pain free sleep of more than 12 hrs after the block.

Conclusion: The results suggest that 100µg clonidine is superior to 50µg clonidine and the control group and is the appropriate dose in fascia iliaca compartment block and provides significant benefit in terms of pain relief at rest as well as during transportation and more importantly also facilitates positioning required for proper imaging in the preoperative period.

Keywords: Clonidine; Analgesia; Fascia iliaca compartment block (FICB)

Introduction

Hip fractures can cause considerable pain when untreated or under treated that justifies preoperative control. Since surgery is very often delayed for more than 24 hours for a variety of reasons in these patients [1] and fracture immobilization can also be a very difficult task without proper analgesia, providing satisfactory analgesia is a major challenge while patients await surgery. This pain can be alleviated by a simple fascia iliaca compartment block that can be performed at the bedside without the need of a nerve stimulator. [2,3] FICB is a feasible, efficient pre-operative supplement to conventional pain-treatment for patients with hip fractures.

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 and post-operative pain relief for injuries involving the hip, anterior thigh, and knee.

The α_2 agonists are assuming greater importance as anesthetic adjuvants and analgesics. Their primary effect is sympatholytic. Clonidine hydrochloride, is a centrally acting α_2 agonist hypotensive agent. Several experimental and clinical studies have shown that it was able to prolong the duration of action of local anesthetics or to produce analgesia after central and peripheral neuraxial administration. [4,5,6,7,8]

The aim of this study was to evaluate whether addition of clonidine to bupivacaine prolongs the duration of action of bupivacaine as compared to placebo, and to apply this to a clinical setting such as fractures around the hip joint where the importance of providing satisfactory analgesia cannot be overemphasized. Our intention was also to find out whether this goal could be accomplished after a simple single shot fascia iliaca compartment block Where clonidine by

prolonging the action of bupivacaine can obviate the need of catheter, otherwise needed to provide continuous analgesia.

Material and Methods

60 patients of ASA class I - II were randomly assigned by random computer generated method to one of the three groups:-

Group A: 20 patients received 0.25% plain bupivacaine 40ml + clonidine 100µg.

Group B: 20 patients received 0.25% plain bupivacaine 40ml + clonidine 50µg .

Group C: 20 patients received 0.25% plain bupivacaine 40ml only.

Both the groups A and B were compared with group C as a controlled group.

Patients were explained regarding the possible risks and complications before taking written consent. After securing i.v access with appropriate cannula, all the patients were preloaded with 10ml/kg of ringer's lactate within 30 minutes before the block. No premedication was given.

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Received December 25, 2010; **Accepted** February 14, 2011; **Published** February 15, 2011

Citation: Tomar GS, Tiwari A, Agrawal S, Sethi A, Kriplani TC, et al. (2011) Role of Clonidine in Fascia Iliaca Compartment Block for Preoperative Analgesia in Post Hip Fracture Patients: A Comparative Study. J Anesthe Clinic Res 2:121. doi:10.4172/2155-6148.1000121

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Patient was positioned supine on the bed and proper illumination was given at the site of the block.

Study type- Cross sectional double blind hospital based study.

Study duration- 15th april 2010 to 15th july 2010.

Study subjects- 60 patients admitted in the orthopedic wards with fractures involving the hip were selected for the study.

Sampling technique- Time Based Simple Random Sampling.

Selection of sample- During the study duration i came across around 200 cases and out of them 60 elderly patients of either sex were selected for the study by using simple random sampling .

- **Inclusion criteria-** Clinical criteria of hip fracture as assessed by the resident on call orthopedics and patient should have intact cognitive status on admission.

- **Exclusion criteria-** Patient having allergy to local anesthetics, bleeding diathesis, infection at the injection site, previous surgery in affected hip, any major substance abuse and refusal on consent agreement were excluded from this study.

Ethical consideration: After obtaining approval for conducting this study from the institutional ethics committee, the present study was conducted in the department of Anesthesiology and Critical care, N.S.C.B. Medical College, Jabalpur (M.P). Informed consent was obtained after properly explaining the procedure.

Data collection: For the collection of sample all the variables were assessed and a pretested semi structured performa was used containing information regarding sociodemographic details of patient variables.

- **Preoperative data collection-** A complete pre-anaesthetic evaluation was carried out, baseline pulse rate, blood pressure, respiratory rate and SpO₂ were recorded.

- **Post-block monitoring-** all the patient were monitored intermittently at the interval of 15 minutes for the first 1 hour; 30 min for the next 2 hours and 1 hourly subsequently follow up manually for blood pressure and with pulse oximetry for pulse and SpO₂.

Data processing and analysis: After collection of data, they were put in excel sheet and SPSS 17th version and later on got analyzed with the help of colleagues and all departmental members.

Statistical tests which were used to analyze the data of this study were:

Independent student t-test, Turkey Kramer – Multiple comparison test.

Landmarks: The line joining the pubic tubercle to anterior superior iliac spine is divided into three equal parts. The site of insertion is 1cm below the junction of lateral one third and medial two third of this line, which at least 2cm lateral to the femoral artery.

A short beveled 23G needle was then vertically introduced 1cm below the union of lateral one third with the medial two third, which at least 2cm lateral to the femoral artery. During needle insertion two pops i.e. loss of resistance sought. The first one occurs as the tip of needle crosses the fascia lata, and the second one occurs as the fascia iliaca is pierced.

After piercing fascia iliaca attach the syringe to the needle aspirate, if nothing comes then inject drug 0.25% plain bupivacaine (Sensorcaine

0.25% - Astra Zeneca) 40ml + clonidine (Cloneon – Neon Lab.) 100µg or 50µg according to the group injecting a sufficient volume and massaging the swollen area favor the spread of solution to the inner surface of fascia iliaca, improving the chances to block distant lumbar plexus nerves such as obturator nerve.

Pain was assessed using visual analogue scale and objective sitting scale before the block and at 1hr, 2hr, 6hr, 12hr and next morning after the block respectively. Level of sedation was assessed by using sedation scale. Throughout the period of block pulse rate and S_pO₂ was monitored continuously and blood pressure half hourly.

Pain intensity was evaluated by using a 10cm visual scale, one end(0 point of VAS) of which shows no pain and other end (10 point of VAS) worst possible pain. [9] This does have its limitations, but for all practical purposes, it is the easiest and simplest type.

Sedation was assessed by using the sedation score described by Culebras et al. [10] which was graded as follows:

1. Awake and alert
2. Sedated, responding to verbal stimulus
3. Sedated, responding to mild physical stimulus
4. Sedated, responding to moderate or severe physical stimulus
5. Not arousable .

The effectiveness of the block was assessed by using an Objective Sitting Scale described by Candal Couto JJ [1] which is as follows:

Score 1= if the patient could only lie flat or use a maximum of two pillows because of pain,

Score 2=if the patient could become semi-recumbent and was able to tolerate more than two pillows,

Score 3=if the patient was able to sit upright with the support of many pillows and could reach a glass of water on the (Table 1) across the bed,

Score 4=if the patient was able to sit up in bed independently without support and was able to lean forward to reach an object down the bed.

Results

There were no significant intergroup difference with regards to

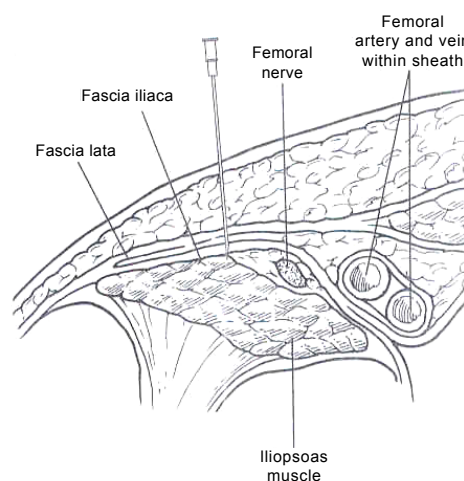


Figure 1: Landmarks of fascia iliaca compartment block.

Demo. Paramtrs.	Intervention Groups				Control group	
Mean age (\pm S.D.)	Group A 56.8(\pm 12.72)		Group B 57.6(\pm 13.76)		Group C 57.2(\pm 10.20)	
Mean body wt. (\pm S.D.)	52.62(\pm 4.84)		53.02(\pm 3.80)		51.86(\pm 4.68)	
Sex	No.	%	No.	%	No.	%
Male	13	65	12	60	11	55
Female	7	35	8	40	9	45

This table shows the age, sex and body weight wise distribution of patients of each group.

Table 1: Demographic data distribution of patients.

	baseline	1 hr	2hr	6hr	12hr	Next morning	After 24 hrs.
VAS Score							
Group A	8.15 \pm 0.51	3.35 \pm 0.17	3.40 \pm 0.18	4.30 \pm 0.23	4.4 \pm 0.24	4.5 \pm 0.25	5.12 \pm 0.30
Group B	7.96 \pm 0.49	3.4 \pm 0.18	3.6 \pm 0.20	4.3 \pm 0.23	4.6 \pm 0.27	4.8 \pm 0.27	5.86 \pm 0.32
Group C	8.2 \pm 0.5	4.5 \pm 0.25	4.7 \pm 0.26	5.3 \pm 0.30	5.8 \pm 0.35	6.1 \pm 0.40	7.51 \pm 0.40
Sedation Score							
Group A	1.0 \pm 0.0	3.2 \pm 0.16	2.9 \pm 0.14	2.6 \pm 0.12	2.4 \pm 0.11	2.25 \pm 0.10	1.74 \pm 0.12
Group B	1.0 \pm 0.0	2.5 \pm 0.12	2.3 \pm 0.10	2.0 \pm 0.09	1.85 \pm 0.08	1.75 \pm 0.08	1.42 \pm 0.10
Group C	1.0 \pm 0.0	1.0 \pm 0.0	1.0 \pm 0.0	1.0 \pm 0.0	1.0 \pm 0.0	1.0 \pm 0.0	1.0 \pm 0.0
Sitting Score							
Group A	1.5 \pm 0.0	3.2 \pm 0.16	3.25 \pm 0.16	3.0 \pm 0.14	2.6 \pm 0.12	2.5 \pm 0.11	2.25 \pm 0.10
Group B	1.5 \pm 0.0	2.9 \pm 0.13	2.9 \pm 0.13	2.5 \pm 0.12	2.4 \pm 0.11	2.3 \pm 0.10	2.0 \pm 0.80
Group C	1.5 \pm 0.0	2.5 \pm 0.12	2.4 \pm 0.11	2.1 \pm 0.09	1.9 \pm 0.08	1.82 \pm 0.09	1.64 \pm 0.06

Table 2:

gender distribution, age and weight. Mean VAS before the block in group A, B and C were (8.15 \pm 1.2), (7.96 \pm 1.34) and (8.02 \pm 1.14) which decreased to (3.35 \pm 0.78), (3.4 \pm 0.83) and (4.24 \pm 0.32) respectively after the block (Table 2). The extent of reduction in the VAS in the groups A and B were almost the same. In this study VAS at 12 hours, the next morning and after 24 hours in intervention groups A and group B were (4.4 \pm 0.85), (4.5 \pm 0.86), (5.12 \pm 0.30) and (4.6 \pm 0.86), (4.8 \pm 0.91), (5.86 \pm 0.32) respectively ;while in control group C, VAS reduced to just (5.62 \pm 0.42), (6.71 \pm 0.31) and (7.51 \pm 0.40) respectively.

Sedation was assessed by using the sedation score described by Culebras et al [10] Mean sedation score was 1 in all the groups before the block (Table 2). Next day morning, patients that received 100 μ g Clonidine were considerably more sedated (mean sedation score 2.25 \pm 0.26) than the group that received 50 μ g Clonidine (mean sedation score 1.75 \pm 0.30) while no sedation seen in patients of group C.

Sitting score using objective sitting scale at end of 12 hr, next day morning and after 24 hrs in intervention groups A, B were (2.6 \pm 0.12), (2.5 \pm 0.11), (2.25 \pm 0.10) and (2.4 \pm 0.11), (2.3 \pm 0.10), (2.0 \pm 0.80) respectively while in control group C score was just (1.9 \pm 0.08), (1.82 \pm 0.09) and (1.64 \pm 0.06) respectively.

Patient vitals including pulse rate, blood pressure and arterial saturation before and after the block at regular intermittent monitoring follow ups remained as invariable.

Discussion

The present study was conducted to evaluate the effect of Clonidine added to Bupivacaine on post hip fracture analgesia after fascia iliaca compartment block. Our intention was to find out whether this goal can be accomplished after a single shot fascia iliaca compartment block and whether addition of clonidine to bupivacaine prolong the duration of analgesia to such an extent (16 – 18 hours) that it can obviate the need of catheter, otherwise needed to provide continuous analgesia in such a setting.

We performed the study as a prospective case series and as the mean age of patient was 57.2 years there was no evidence of cognitive impairment in any of the patients taken up for the study. Patient vitals including pulse rate, blood pressure, arterial saturation before and after the block at regular intermittent monitoring follow ups remained unaffected, proving its safety in elderly age group.

The mean age of the study groups was comparable. Overall mean age 57.2 was less in comparison to study of Monzon DG et al. [11] i.e.,73.5 years and Høgh A et al. [12] which was 80.7 years. This may be attributed to early osteoporosis due to poor nutrition in patients of low socioeconomic class that visit this hospital.

In order to achieve a more objective measurement of block effectiveness, we then measured the patient's ability to sit up by using objective sitting score. With this novel functional assessment we found that the block reliably improved the patient's ability to sit up and pain free periods.

The extent of reduction in the VAS in the two intervention groups were almost the same when compared to VAS before the block as compared to the control group. In this study VAS at 12 hours, the next morning and after 24 hours in group A were 4.4, 4.5 and 5.12 respectively and in group B it was 4.6, 4.8 and 5.86 respectively while in group C, VAS reduced to 5.6, 6.7 and 7.51 which was statistically significant indicating that addition of Clonidine prolongs the duration of analgesia as compared to the studies of Candal-Couto JJ et al. [1] and of Monzon DG et al. [11] in which analgesia lasted for about 7-8 hours. There study excluded patients with intracapsular fractures.

In this study with the addition of clonidine improved duration of pain relief in all patients having intracapsular as well as extracapsular fracture and benefit lasts up to 16-18 hours.

Monzon DG et al. [11] studied single shot fascia iliaca compartment block with bupivacaine alone and needed rescue analgesia with oral diclofenac after 8 hours but in this study we did not need any rescue analgesia with the addition of clonidine to bupivacaine.

Improvement in the ability to sit upright provided by fascia iliaca compartment block may aid patient care in the preoperative period. Objective sitting score as described by Candal-Couto JJ et al. [1] in 2005 was used which showed no significant difference up to 6 hours in both group A and B. Sitting score at 12 hours and next morning in group A showed statistically significant difference compared to group B and group C indicating addition of 100 μ g Clonidine effectively prolongs the duration of analgesia. In our study duration of analgesia was seen even beyond 24 hours but effectively up to 16-18 hours in group A i.e. with 100 μ g Clonidine and it's up to 10-12 hours in group B i.e. with 50 μ g Clonidine while this was just effective up to 5-6 hours in control group C i.e. without clonidine.

Prolongation of analgesic action of bupivacaine by clonidine *in vivo* is unclear and not mediated by an α -adrenergic mechanism but attributed to its direct inhibitory effect on peripheral nerve conduction by A and C fibres [13].

Side effects associated were dose limiting. None of the patient reported bradycardia, hypotension and dry mouth after successful completion of block in any group. These side effects are more commonly seen with clonidine dose higher than 100 μ g. Sedation was an only side effect of clonidine adjunct observed in intervention groups A and B, not with the control group C. Sedation was assessed by using the sedation score described by Culebras et al. [10] Mean sedation score was 1 in both the groups before the block (Table 2). The patients that received 100 μ g Clonidine were considerably more sedated (mean sedation score 2.25) than the group that received 50 μ g Clonidine (mean sedation score 1.75). We continuously measured the oxygen saturation to detect any respiratory depression secondary to sedation and found that there was no significant desaturation at any time and although more sedation occurred with addition of 100 μ g Clonidine than with addition of 50 μ g Clonidine, it served a useful purpose as it aided initiation of restful sleep in patients, who were in considerable agony and stress before the block.

Our results were in accordance with other studies highlighting the usefulness of a variety of nerve blocks of the lumbar plexus and its descendent nerves in the management of patients with hip fracture.

Major limitation of this study could be that it was conducted on small scale by taking smaller sample sizes, if it was carried out at large scale and by taking larger sample sizes like randomized controlled trial, then the results and conclusions would be more generalizable and implicable. Another limitation of our study could be we didn't measure serum concentration of clonidine so as to rule out the possibility of add on systemic effects of clonidine contributing to its analgesia due to its absorption from the local site of injection.

Conclusion

Addition of clonidine enhanced pain relief. Addition of both 100 μ g and 50 μ g clonidine to bupivacaine increases the duration of analgesia. Novel findings in this study were that after successful completion of block, addition of 50 μ g clonidine produces effective analgesia up to 10-12 hours as compared to control group C in which effect last up to 5-6 hours without Clonidine while addition of 100 μ g clonidine produces effective pre-emptive analgesia up to 16-18 hours that may even reaches up to 24 hours with acceptable range of side effects in patients of extra capsular as well as intra capsular hip fractures.

As far as safety profile is concerned addition of Clonidine usually associated with sedation, bradycardia and hypotension, but in our

study we found that there was no bradycardia or hypotension noted with both 50 & 100 μ g clonidine. Although sedation was more with 100 μ g than 50 μ g clonidine, but it served a useful purpose as it aided initiation of restful sleep in patients, who were in considerable agony and stress before the block.

Thus we conclude that clonidine adjunct in appropriate dose in single shot fascia iliaca compartment block is a feasible and effective method of pre-emptive analgesia for patients with hip fractures with a minimal risk approach and acceptable safety profile.

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