Original research article

An Observational Study of 0.125% Bupivacaine and 0.1% Bupivacaine with 2mcg/ml Fentanyl to Provide Post-Operative Epidural Analgesia in Patient Undergoing Elective Lower Limb Surgery

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Abstract

Background: Epidural analgesia is the most commonly used technique for inducing postoperative analgesia in lower limb surgeries. Higher concentrations of bupivacaine have been found to be greater motor blockade and it can be minimized by using lower concentrations of bupivacaine (0.1% -0.125%).

Aim: To evaluate the block characteristics, hemodynamic response, and post-operative epidural analgesia between 0.125% Bupivacaine versus 0.1% Bupivacaine in patients scheduled for lower limb surgeries.

Material and Method: This observational study included 60 ASA grade 1 and 2 patients posted for lower limb surgeries. In the study, Group 1 received 0.125% bupivacaine + 2 µg/ml fentanyl, and Group 2 received 0.1% bupivacaine + 2 µg/ml fentanyl.

Result: The onset of sensory blockade was significantly earlier in patients of Group 1 (15.17 ± 1.46 min vs 19.07 ± 1.85min), and the onset of motor blockade was significantly earlier in patients of Group 1 (28.57 ± 1.71 vs 34.5 ±1.73). Duration of analgesia was longer in group 1 when compared to group 2.

Conclusion: 0.125% bupivacaine with 2 µg/ml was more effective and provided a longer duration of analgesia as compared to 0.1% bupivacaine with 2 µg/ml for lower limb surgeries.

Keywords: Bupivacaine, Fentanyl, Epidural Analgesia.

Introduction

For lower limb surgeries the major concern is postoperative analgesia. Inadequately controlled pain negatively affects the quality of life, functional recovery, and the risk of post-surgical complications and risk of persistent post-surgical pain. [1] Planning for proper postoperative pain management is a necessary component of good anesthetic practice since the consequences of untreated pain can be devastating [2].

A central neuraxial blockade is the most popular regional anesthesia technique used for lower limb surgeries for postoperative analgesia [3]. Epidural anesthesia is the most commonly used technique for postoperative analgesia in lower limb surgeries[4]. Epidural analgesia can maintain continuous analgesia after epidural catheter placement, thus making it suitable for

continued post-operative analgesia relief. Bupivacaine is a long-acting amide local anesthetic with many advantages, strong analgesic effects, low minimum impact concentration low impact time, andrapid onset. The present study was undertaken to evaluate the onset of analgesia, duration of analgesia, and hemodynamic changes with 0.125% bupivacaine and 0.1% bupivacaine with 2 µg/ ml fentanyl for postoperative epidural analgesia in a patient undergoing lower limb surgery

Materials and Methods:
The observational study that includes 60 patients was conducted in the Department of Anaesthesiology (Gandhi medical college, Bhopal) from January 2020 to July 2021. Institutional ethical committee approval was obtained.

Inclusion Criteria
1. Patients of ASA grade I and II,
2. Age group of 20-60 years,
3. Both males and females,
4. Patients undergoing elective lower limb surgery,
5. Patients who provided informed written consent.

Exclusion Criteria
1. Patients on anti-coagulation treatment (INR >1.5),
2. Patients with infection at the site of injection,
3. Patients with coagulopathy, bleeding diathesis, congenital abnormalities of the lower spine and meninges, spine/neurological deformity,
4. History of allergy to local anesthetics,
5. Patients with uncontrolled systemic illness like diabetes mellitus, hypertension, and uncorrected hypovolemia.

Patients were randomly divided into 2 groups, each with 30 cases. Group 1 was given 10ml of 0.125% Bupivacaine along with 2 µg/ ml fentanyl and Group 2 was given 10ml of 0.1% Bupivacaine along with 2 µg/ ml fentanyl.

All patients who underwent pre-anesthetic evaluation were shifted to the procedure room on the day of surgery. All the equipment and emergency drugs necessary to administer epidural anesthesia were checked and kept ready and an IV line was secured using18 G cannula, 500 ml of RL infusion was started which was given to all patients half an hour before the anesthetic procedure as pre-loading. Baseline vitals were recorded. The patient was placed in a sitting position and the back was painted with betadine. With all aseptic measures, the skin over the L3-L4 interspinous space was anesthetized with 2ml of 2% Lignocaine. A 18G Touhy needle was passed through this space and advanced slowly until it enters the epidural space which was confirmed by the loss of resistance technique. Then a 18 G epidural catheter was passed through the needle into the epidural space and secured with a minimum of 3-4 cm within the space.3ml of 2% with adrenaline 1:200000 was given as a test dose to confirm the proper placement of the catheter. Then the patient was anesthetized under a Subarachnoid block by using hyperbaric 0.5% Bupivacaine. At the end of surgery (i.e., 30 min before completion of surgery), study drug 0.125% Bupivacaine (10 ml) with Fentanyl 2µg/ml or 0.1% Bupivacaine (10 ml) with Fentanyl 2µg/ml was given through epidural catheter . Then patient was shifted to the recovery room.

Parameters monitored

After Spinal anaesthesia, Level of sensory block (Time taken to attain a sensory level of T10 by pinprick method), Level of motor block (based on the Bromage scale: 0 – able to move hip, knee, ankle, and toes (0% block), 1- just able to flex knee but still full flexion of ankle possible (33%, possible block), 2-unable to flex knees but flexion of ankles possible (66%, acceptable bock), 3-unable to move knees and ankle (100%, complete block). After the given study drug, the Duration of analgesia was the time from the onset of the sensory block until the patient's complaints of pain or when the VAS score >3. Post-operative analgesia was assessed by the 10-point visual analog scale≥5 (0=no pain, 10= worst pain possible) from the end of surgery till the patient complained of pain. The vitals and hemodynamic parameters were regularly monitored at 5, 30, 60, 120, and 180 min intervals and postoperatively at 30 min intervals until rescue analgesia.

Statistical Analysis:

Software Epi info 7 was used for performing the statistical analysis. Results were expressed in terms of mean, standard deviation, and frequency. The following statistical data were analyzed using the chi-square test, two-tailed Fisher's exact test, and t-test. The data so obtained was compiled systematically. In the significant tests, P-values <0.05 was considered significant.

Results:

Table 1:- Demographic data -

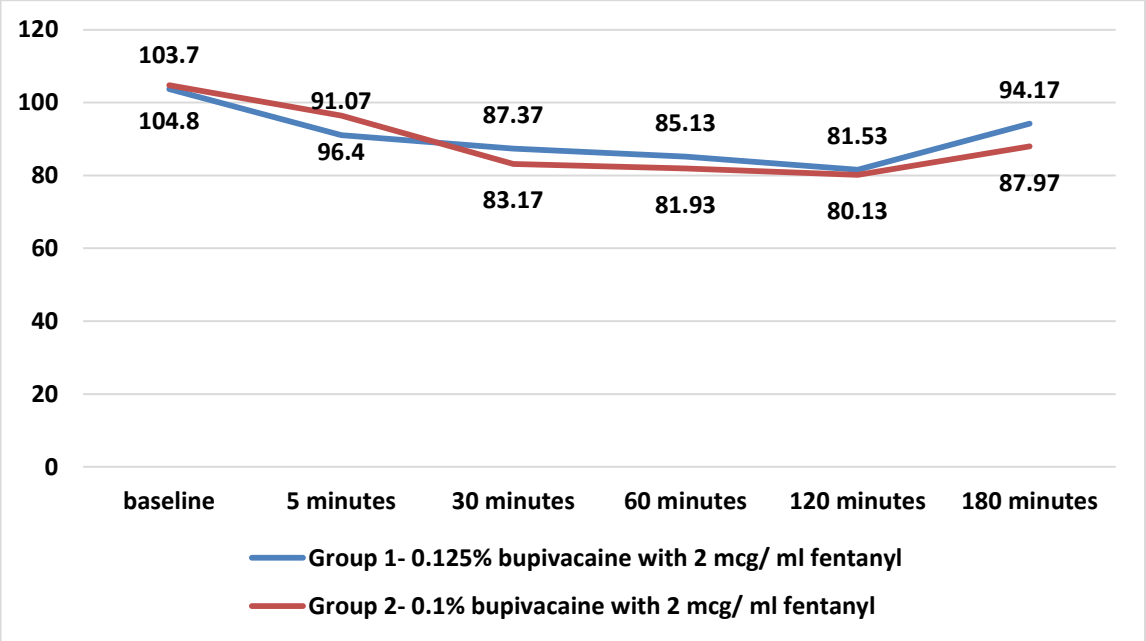
Parameter	**Group 1**	**Group 2**	**P value**
	Mean ±SD	Mean± SD	
Age (yrs)	40.40 ±9.36	37.60± 8.19	0.22
Gender (Male/Female)	25 /5	28 /2	0.42
ASA grading (I/II)	24 /6	25 /5	0.73

Both groups were comparable in age, gender, and ASA grading and were statistically insignificant between the groups (p>0.05).

Table 2: Comparison of onset of sensory and motor blockade between the groups

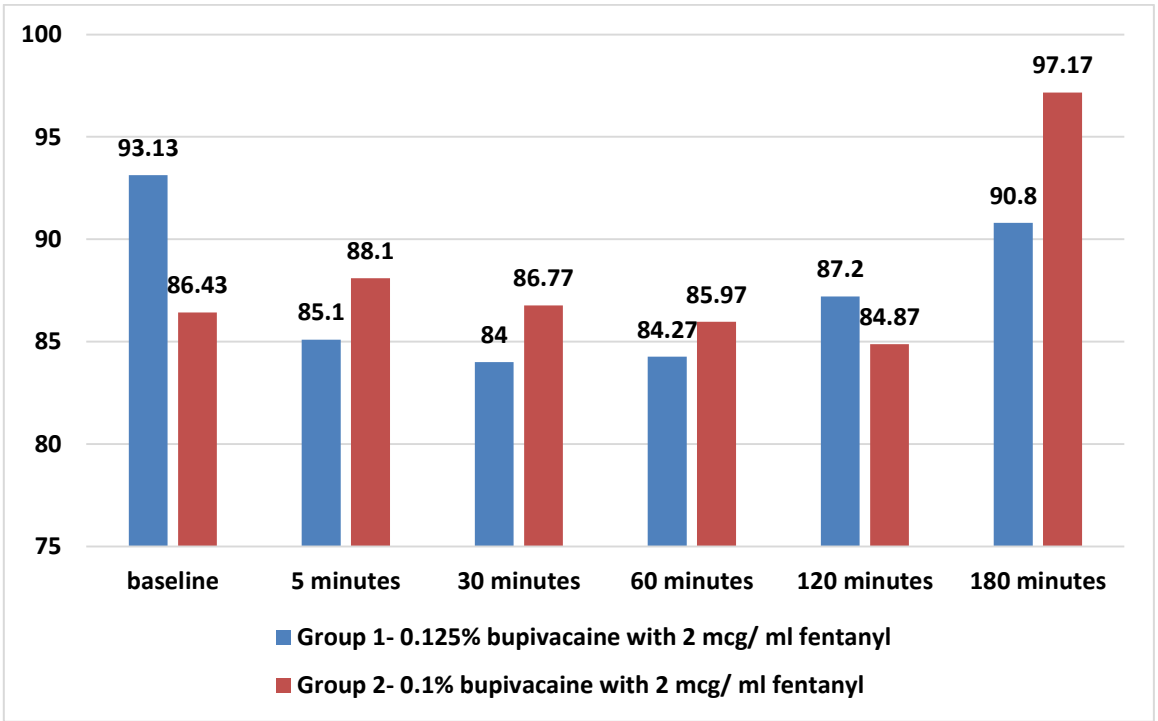
Parameters	**Group 1**	**Group 2**	**P value**
	Mean ± SD	Mean ± SD	
Onset of sensory block(min)	15.17 ± 1.46	19.07 ±1.85	<0.05
Onset of motor block(min)	28.57 ± 1.71	34.5 ± 1.73	<0.05
Duration of sensory block(min)	173.50 ± 17.67	138.17 ± 7.82	<0.05
Duration of motor block(min)	151.67 ± 11.69	108.17 ± 7.8	<0.05

The onset of sensory block and motor block was significantly faster and longer in group 1 when compared to group 2 (p<0.05).



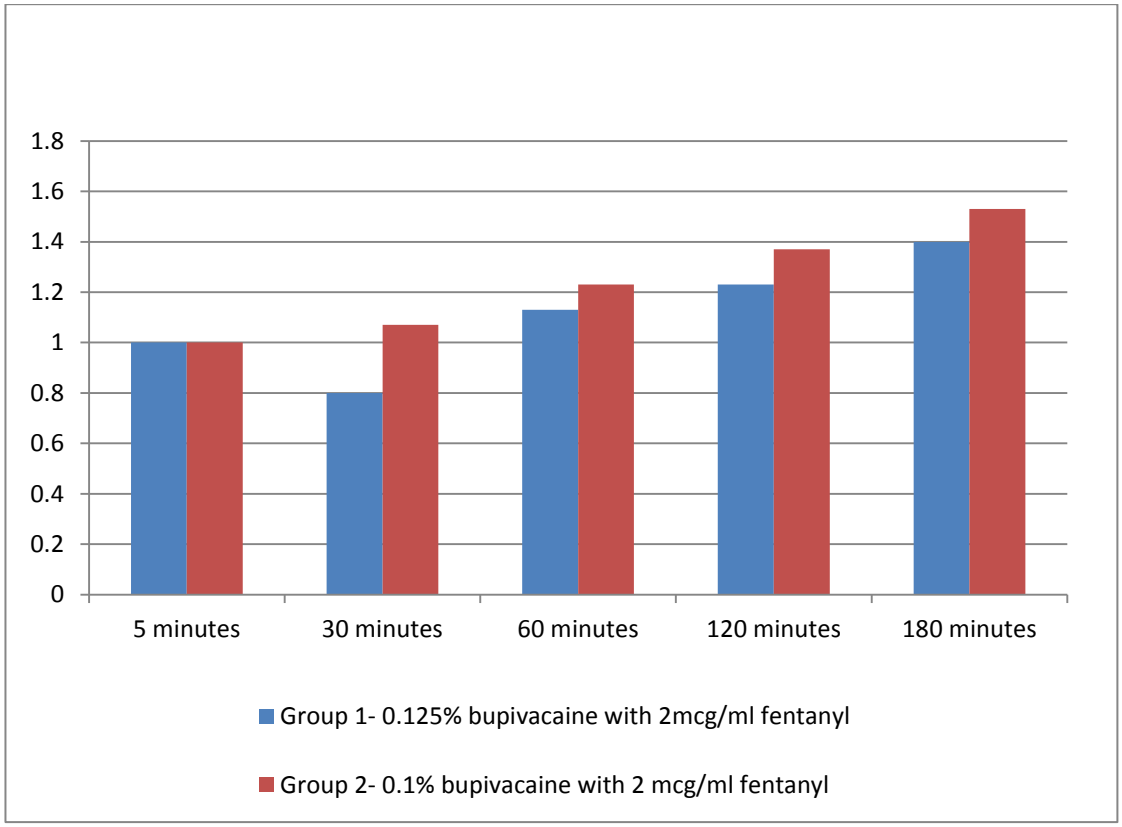
Graph 1:- Comparison of heart rate at different time intervals –

Heart rates were showed slightly raised in Group 2 compared to Group 1 which was found to be statistically significant ($p<0.05$) except at baseline ($p>0.05$).



Graph 2: Comparison of Mean Arterial Pressure at different time intervals –

Mean arterial pressure was less in Group 1, at baseline, at 5 minutes, and at 180 minutes was found to be statistically significant ($p<0.05$). Apart from this, MAP was comparable at 30min, 60 min, and 120 min and it was statistically insignificant ($p>0.05$).



Graph 3: Comparison of mean pain score (VAS) at different time intervals-

The mean pain scores were less in group 1 compared to group 2 at all times which was significant 30 min after the administration of drugs. At all other times, the difference noted among the groups was insignificant (P>0.05).

Table 3: Adverse effects-

Adverse effects	**No. of persons with adverse effects (%)**		**'p-value**
	Group 1	**Group 2**	
Nausea	2 (6.7)	1(3.3)	1.000
Vomiting	1 (3.3)	0(0)	1.000
Bradycardia	2 (6.7)	0(0)	0.491
Pruritus	1 (3.3)	1 (3.3)	1.000
Hypotension	3 (10)	0(0)	0.237

All these adverse events were comparable in both groups and found to be statistically insignificant(P>0.05).

Discussion:

Epidural anesthesia is one of the most used perioperative and postoperative analgesia procedures in lower limb surgeries. Lower concentration of bupivacaine (i.e., <0.125%) is used to minimize the motor block as studies using bupivacaine in higher concentration (>0.125%) have been found to be associated with the greater motor blockade. This can be minimized by using a lower concentration of local anesthetics (0.1% -0.125%). Using Fentanyl as an adjuvant to local anesthetic for epidural administration to achieve the desired anesthetic effects[5]**.** The addition of opioids to local anesthetics reduces its requirement by synergistic effects of opioid receptors in the spinal cord. This reduces the chances of motor blockade and hemodynamic perturbation [6]. It provides a dose-sparing effect of local anesthetic and high-grade analgesia.

In our study, both groups were comparable with respect to age, sex, and ASA grading. We have observed that the onset of sensory block was achieved earlier in Group 1 patients (15.17 ± 1.464 min) compared to Group 2 patients (19.07 ± 1.856 min) which was statistically significant (P<0.001). This is similar to the study conducted by **Aysegul K et [7]** had observed that the onset of sensory block was faster in the group with a higher concentration of bupivacaine.

The onset of motor block was achieved earlier in Group 1 patients (28.57± 1.716) compared to Group 2 patients (34.5 ± 1.737) which was found statistically significant (P <0.001). The study conducted by **Gayathri Devi B U, et al[8],** compared the epidural Bupivacaine 0.125% and Ropivacaine 0.2% with fentanyl combination for postoperative analgesia in lower abdominal and lower limb surgeries. Both groups were clinically comparable.

Group 1 had a longer duration of sensory block (173.50 ± 17.67 min) and motor block (151.67± 11.695 min) compared to Group 2 (138.17 ± 7.82 min /108.17 ± 7.82) which was found statistically significant (p<0.001). A study done by **M C Atienzar et al[9]** found that sensory and motor block duration was greater in the bupivacaine group compared to levobupivacaine(p<0.01).

The present study showed slightly raised heart rate values for Group 2 compared to Group 1 which was found to be statistically significant (p<0.05) except at baseline (p>0.05).

The mean VAS scores were less in Group 1 compared to Group 2 which was significant at 30 minutes (p<0.05) after administration of the drug. At all other times, the difference noted among both groups was insignificant (p>0.05). A similar result obtained by **Lyson GR et al [10],** reported that the VAS score was comparatively low in the group with a 0.125% bupivacaine than the 0.25% bupivacaine group.

In the present study, we observed that the Systolic and Diastolic BP were comparable and within the normal limits in both groups, i.e. within 20% of baseline blood pressure and there was no significant change in both groups after administration of the study drug until 180 minutes except SBP was found to be significantly low in Group 1 at 30 min i.e., p<0.025 and DBP was found to be significantly high in Group 2 at 180 min i.e., p<0.001as compared to baseline value and it was statistically significant (p<0.001).In a study conducted by **Kalpana Kulkarni et al[11]**, There was no significant difference in systolic and diastolic blood pressure between the groups except at 360 min where diastolic pressure was low in group 2.

The Mean arterial pressure in our study was less in Group 1 compared to group 2, at baseline, 5 minutes, and at 180 minutes, and was found to be statistically significant (p<0.05). Apart from this, MAP was comparable at 30, 60, and 120 min and it was statistically insignificant (p>0.05).

In a study conducted by Anurag Yadava et al[12] , 112 patients observed no statistically significant differences in hemodynamics when compared in both groups.
The incidence of nausea, vomiting, pruritus, bradycardia, and hypotension was comparable and statistically insignificant in both groups ($p>0.05$). The incidence of hypotension was higher in group 1 compared to group 2.

Conclusion:
It can be concluded that 0.125% bupivacaine with 2µg/ml fentanyl cause an early onset and prolonged duration of sensory and motor blockade and analgesia in comparison to 0.1 % bupivacaine with 2 µg/ml fentanyl.

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