COMPARISON OF BUPIVACAINE AND BUPIVACAINE WITH FENTANYL IN LOWER LIMB ORTHOPAEDIC SURGERIES

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Article Info: Received 03 July 2019; Accepted 04 August. 2019

DOI: <https://doi.org/10.32553/ijmbs.v3i8.446>

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Conflict of interest: No conflict of interest.

Abstract

INTRODUCTION: A commonly used technique for lower limb surgeries is subarachnoid blockade. If there is inadequate control of pain, will affect quality, and functional recovery, also there is chance of postsurgical complications, and the risk of persistent postsurgical pain. Use of epidural analgesic technique for lower limb surgeries should provide better pain relief with minimal side effects, leading to improved outcome. Bupivacaine hydrochloride is a local anaesthetic drug, which was used clinically in 1963. Bupivacaine acts mainly by blockade of voltage-gated Na⁺ channels in the axonal membrane and possibly has a further effect on presynaptic inhibition of calcium channels. Fentanyl is a powerful synthetic opioid which is similar to morphine but is 50 - 100 times more potent, which is used to treat patients with severe pain, especially after surgeries.

MATERIAL AND METHODS: This prospective randomized study was conducted in the department of anaesthesiology at Rajiv Gandhi Institute of Medical Science, Adilabad, to compare single shot epidural 8ml 0.5 % bupivacaine alone verses 8ml 0.5% bupivacaine along with 0.50 mcg Fentanyl. Total of 80 patients with ASA(American society of anaesthesiologists) I and II with age group between 24 to 56 years were included and 40 patients each were randomly placed in bupivacaine alone group (Group 1) and fentanyl in combination with bupivacaine group (Group 2). Written informed consent from all the patients was obtained.

RESULTS: Mean (SD) systolic blood pressure was observed to be 128.45(12.47) and 130.25(11.55) in group 1 and group 2 respectively. Mean time for T₁₀ sensory block was significantly earlier in group 2 12.03(1.12) compared to group 1 18.24(2.54). Onset of motor block was observed to differ significantly, where onset was significantly earlier in group 2 23.17(1.77) in comparison to group 1 28.45(1.49). The first analgesic requirement in Group 1 was earlier at 198.20 + 11.49 min as compared to Group 2 at 279.34 + 18.42 min.

CONCLUSION: Bupivacaine with Fentanyl enhances the onset of action and duration of effect for two segment regression. In present study the time to achieve T₁₀ sensory block was early in Group 2 12.03(1.12) compared to group1 18.24(2.54). Onset of group2 23.17(1.77) in comparison to group1 28.45(1.49). Time of first analgesic requirement was found to be earlier at 279.34 + 18.42 minutes in group2 in comparison to group1 198.20 + 11.49 minutes.

Introduction:

For lower limb surgeries subarachnoid blockade is a commonly used technique. This procedure is easier to perform by injecting anesthetic drug into the subarachnoid space and with rapid onset of anesthesia, which provides intra- as well as post-operatively analgesia. less than half of patients who undergo surgery report adequate postoperative pain reliefⁱ. If there is inadequate control of pain, will affect quality, and functional recovery, also there is chance of postsurgical complications, and the risk of persistent postsurgical pain. Studies have shown that

multimodal analgesia by various techniques is associated with better pain relief and decreased opioid consumption as compared with the use of a single medication administered through one technique^{ii, iii}. Use of epidural analgesic technique for lower limb surgeries should provide better pain relief with minimal side effects, leading to improved outcome.^{iv}.

Bupivacaine is chemically 1-*n*-butyl- DL-piperidine-2-carboxylic acid-2,6 dimethylanilide hydrochloride^v. Bupivacaine hydrochloride is a local anaesthetic drug, which was used clinically in 1963. Bupivacaine acts

mainly by blockade of voltage-gated Na⁺ channels in the axonal membrane and possibly has a further effect on presynaptic inhibition of calcium channels^{vi}.

Fentanyl is a powerful synthetic opioid which is similar to morphine but is 50 - 100 times more potent^{vii}, which is used to treat patients with severe pain, especially after surgeries^{viii}.

This study was conducted to compare the efficacy of bupivacaine alone and fentanyl in combination with bupivacaine for postoperative analgesia in lower limb orthopaedic surgery.

MATERIAL AND METHODS

This study was conducted in the department of anaesthesiology at Rajiv Gandhi Institute of Medical Science, Adilabad; to compare single shot epidural 8ml 0.5 % bupivacaine alone versus 8ml 0.5% bupivacaine along with 0.50 mcg Fentanyl.

Patients included were, ASA (American society of anaesthesiologists) physical status Classes I and II and those who were posted for elective lower limb surgery in orthopaedics department. Age group of patients included were 24 to 56 years. Only surgeries lasting up to 2 hours were included.

Patients with cardiac disease, renal failure, hepatic dysfunction, chronic pulmonary disease, diabetes mellitus and neuromuscular disorder were excluded from the study. Patients having infections, bleeding disorder and allergy or sensitivity to any of the study drugs were also excluded from the study.

Total of 80 patients with ASA I and II with age group between 24 to 56 years were included and 40 patients each were randomly placed in bupivacaine alone group (Group 1) and fentanyl in combination with bupivacaine group (Group 2). Written informed consent from all the patients was obtained.

Postoperatively at every 30 min interval, pain was assessed using 10-point visual analog scale (VAS). Score of 0 indicated no pain and a score of 10 indicated worst pain imaginable. Duration of analgesia was recorded as the first complaint of pain (VAS >4) in the postoperative period and rescue analgesic was administered. Rescue analgesic as 10

ml 0.25% bupivacaine was administered at the onset of pain (VAS >4) in postoperative period and at each incidence of complaint of pain (VAS >4) in next 24 h. The number of rescue analgesic epidural doses was recorded during the first 24 h.

Patients were kept nil by mouth overnight or for 8 hours before surgical procedure. Preanesthetic check-up was performed on each patient; non-invasive monitors like pulse oximeter, non-invasive blood pressure (NIBP), and ECG were attached. Baseline parameters were recorded. Intravenous (IV) access was secured.

Under all aseptic precautions, needle was inserted into L₂-L₃ interspinous epidural space. Group 1 received single shot epidural 8ml 0.5 % bupivacaine alone and group 2 received 8ml 0.5% bupivacaine along with 0.50 mcg fentanyl.

Hemodynamic parameters were recorded at baseline (B), immediately after the study drug is given (T1), then every 15 min till end of surgery and postoperatively till first analgesic was given. Postoperatively at every 30 min interval, pain was assessed using 10-point visual analog scale (VAS) . Score of 0 indicated no pain and a score of 10 indicated worst pain imaginable .Duration of analgesia was recorded as the first complaint of pain (VAS >4) in the postoperative period and rescue analgesic was administered. The number of rescue analgesic epidural doses was recorded during the first 24 h.

The statistical analysis was done using SPSS (Statistical Package for Social Sciences) software all data was entered in the Excel sheet version 2013. Values were represented in number (%) and mean ± standard deviation. P value of < 0.05 was considered as statistically significant.

OBSERVATIONS AND RESULTS

A total of 80 patients posted for elective lower limb orthopaedic surgery were included in the study and 40 patients each were randomly placed in bupivacaine alone group (Group 1) and fentanyl in combination with bupivacaine group (Group 2).

Table 1: group wise distribution

Group	Number	%
Group 1(bupivacaine)	40	50%
Group 2 (fentanyl with bupivacaine)	40	50%

Table 2: Demographic variables in groups

Demographic variables	Group 1	Group 2
Age (mean $\pm$ SD)	36.27 $\pm$ 10.24	34.56 $\pm$ 11.44
Male	26 (65%)	28(70%)
Female	14(35%)	12(30%)

In this study it is observed that mean (SD) age of patients in group 1 was 36.27(10.24) and in group 2 was 34.56(11.44). There were 65% males and 35% females in group 1 whereas group 2 had 70% males and 30% females. The observations were not statistically significant.

Table 3: Hemodynamic variables

Hemodynamic variables	Group 1 (mean $\pm$ SD)	Group 2 (mean $\pm$ SD)	't' test	'p' value
Systolic BP	128.45 $\pm$ 12.47	130.25 $\pm$ 11.55	0.67	0.5050
Diastolic BP	86.44 $\pm$ 7.79	85.87 $\pm$ 9.54	-0.293	0.7705
Pulse rate	96.20 $\pm$ 16.57	95.44 $\pm$ 11.58	-0.238	0.8127

Mean (SD) systolic blood pressure was observed to be 128.45(12.47) and 130.25(11.55) in group 1 and group 2 respectively. In group 1 diastolic BP was 86.44(7.79) while in group 2 it was found to be 85.87(9.54). Pulse rate in group 1 and group 2 were observed to be 96.20(16.57) and 95.44(11.58) respectively. There was no statistically significant difference observed in systolic BP, diastolic BP and pulse rate between group 1 and group 2.

Table 4: comparison of analgesic characteristics

Variables	Group 1 (mean $\pm$ SD)	Group 2 (mean $\pm$ SD)	't' test	'p' value
Time for T 10 sensory block	18.24 $\pm$ 2.54	12.03 $\pm$ 1.12	-14.148	<0.0001
Time for maximum sensory level	25.47 $\pm$ 2.44	19.54 $\pm$ 1.88	-12.176	<0.0001
Onset of motor block	28.45 $\pm$ 1.49	23.17 $\pm$ 1.77	-14.43	<0.0001
Achievement of complete motor block	31.24 $\pm$ 1.65	26.42 $\pm$ 1.57	-13.38	<0.0001

Mean time for T 10 sensory block was significantly earlier in group 2 12.03(1.12) compared to group 1 18.24(2.54). There was statistically significant difference in mean time for maximum sensory level between group 1 25.47(2.44) and group 2 19.54(1.88). Onset of motor block was observed to differ significantly, where onset was significantly earlier in group 2 23.17(1.77) in comparison to group 1 28.45(1.49). It was seen that achievement of complete motor block was significantly earlier in group 2 26.42(1.57) compared to group 1 31.24(1.65).

Table 5: Postoperative requirement of analgesic

	Group 1 (mean $\pm$ SD)	Group 2 (mean $\pm$ SD)	P – value
Time in minutes	198.20 + 11.49	279.34 + 18.42	<0.0001

The first analgesic requirement in Group 1 was earlier at 198.20 + 11.49 min as compared to Group 2 at 279.34 + 18.42 min. Difference in time of first analgesic requirement between the above two groups was found to be statistically significant ($P < 0.001$)

DISCUSSION

For lower limb surgeries mode of anaesthesia can be local, regional (spinal or epidural), or general anaesthesia, but neuraxial blockade is the preferred mode. Recently use of adjuvants during epidural anaesthesia has gained popularity which prolong the duration of block, better success rate, patient satisfaction, and faster recovery as compared with general anaesthesia^{ix}. With the aim of prolonging the duration of block, faster recovery, better success rate, decreased resource utilization compared with general anaesthesia, and patient satisfaction, adjuvant are used during epidural anaesthesia and this use has been popular lately.

Total 80 patients posted for elective lower limb orthopaedic surgery were included in the study and 40 patients each were randomly placed in bupivacaine alone group (Group 1) and fentanyl in combination with bupivacaine group (Group 2). In present study the mean (SD) age of patients in group 1 was 36.27(10.24) and in group 2 was 34.56(11.44).

In present study it was seen that mean (SD) systolic blood pressure was 128.45(12.47) and 130.25(11.55) in group 1 and group 2 respectively where as diastolic BP was 86.44(7.79) in group 1 while in group 2 it was found to be 85.87(9.54). Pulse rate in group 1 and group 2 were observed to be 96.20(16.57) and 95.44(11.58) respectively. There was no statistically significant difference observed in systolic BP, diastolic BP and pulse rate between group 1 and group 2. Similar results were reported in a study by Arindam Sarkar et.al. Except for pulse rate where it was higher for fentanyl group. Significant difference between hemodynamic parameters was found in a study by Prakash *et al.* among placebo, fentanyl, and dexmedetomidine group with dexmedetomidine group having minimum mean values as compared to other two groups^{9, x}.

Mean time for T 10 sensory block was significantly earlier in group 2 12.03(1.12) compared to group 1 18.24(2.54). There was statistically significant difference in mean time for maximum sensory level between group1 25.47(2.44) and group2 19.54(1.88). In a study by Arindam Sarkar et.al. mean time taken to achieve maximum block level was 13.23 ± 1.43 min in dexmedetomidine group and 20.80 ± 1.85 min in fentanyl group. This difference was statistically significant with lower mean time taken to achieve maximum block level in dexmedetomidine group. In another study by Gupta et.al maximum block level

achieved was higher in dexmedetomidine group compared to fentanyl group. Mahendru *et al.* in their study did not report a significant difference between fentanyl and dexmedetomidine group in mean time to achieve maximum block level^{9, xi, xii}.

Onset of motor block was observed to differ significantly, where onset was significantly earlier in group 2 23.17(1.77) in comparison to group 1 28.45(1.49). Similar results were reported in studies by Gupta et al. and Mahendru et al. *with respect to onset time*, onset time to be shorter in fentanyl group. In contrast to these results, Gill *et al.* Reported shorter *onset time* in dexmedetomidine group as compared to fentanyl group^{11, xiii, xiv}.

In present study difference in time of first analgesic requirement was found to be statistically significant between both groups with first analgesic requirement in Group 1 earlier at 198.20 + 11.49 min as compared to Group 2 at 279.34 + 18.42 min.

CONCLUSION:

Bupivacaine with Fentanyl enhances the onset of action and duration of effect for two segment regression. In present study the time to achieve T10 sensory block was early in Group 2 12.03(1.12) compared to group1 18.24(2.54). Onset of group2 23.17(1.77) in comparison to group1 28.45(1.49). Time of first analgesic requirement was found to be earlier at 279.34 + 18.42 minutes in group2 in comparison to group1 198.20 + 11.49 minutes.

REFERENCES

1. Kehlet H, Jensen TS, Woolf CJ. Persistent postsurgical pain: Risk factors and prevention. *Lancet* 2006;367:1618-25.
2. McDaid C, Maund E, Rice S, Wright K, Jenkins B, Woolacott N, *et al.* Paracetamol and selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs) for the reduction of morphine-related side effects after major surgery: A systematic review. *Health Technol Assess* 2010;14:1-153, iii-iv.
3. Elia N, Lysakowski C, Tramèr MR. Does multimodal analgesia with acetaminophen, nonsteroidal antiinflammatory drugs, or selective cyclooxygenase-2 inhibitors and patient-controlled analgesia morphine offer advantages over morphine alone? Meta-analyses of randomized trials. *Anesthesiology* 2005;103:1296-304.
4. Wheatley RG, Schug SA, Watson D. Safety and efficacy of postoperative epidural analgesia. *Br J Anaesth* 2001;87:47-61.

5. Stoelting RK, Hillier SC. Local anaesthetics. In: Flood P, Rathmell JP, Shafer S, editors. *Pharmacology and Physiology in Anesthetic Practice*. 4th ed., Ch. 7. Philadelphia: Lippincott Williams & Wilkins; 2006. p. 179-99.
6. Gomaa HM, Mohamed NN, Zoheira HA, Mohamad SA. A comparison between post-operative analgesia after intrathecal nalbuphine with bupivacaine and intrathecal fentanyl with bupivacaine after cesarean section. *Egypt J Anaesth* 2014;30:405-10. [Doi: 10.1016/j.egja.2014.03.008].
7. Volpe DA, Tobin GAM, Mellon RD, et al. Uniform assessment and ranking of opioid Mu receptor binding constants for selected opioid drugs. *Regul Toxicol Pharmacol*. 2011;59(3)
8. Nelson L, Schwaner R. Transdermal fentanyl: Pharmacology and toxicology. *J Med Toxicol*. 2009;5(4):230-241.
9. Sarkar A, Bafila NS, Singh RB, Rasheed MA, Choubey S, Arora V. Comparison of epidural bupivacaine and dexmedetomidine with bupivacaine and fentanyl for postoperative pain relief in lower limb orthopedic surgery. *Anesth Essays Res* 2018;12:572-80
10. Prakash R, Kushwaha BB, Shashi B, Bhatia VK, Chandra G, Singh BP. A comparative study of bupivacaine 0.25% alone and with fentanyl or dexmedetomidine for percutaneous nephrolithotomy (pcnl) under epidural anaesthesia. *Indian J Sci Res* 2014;5:39-46.
11. Gupta R, Verma R, Bogra J, Kohli M, Raman R, Kushwaha JK, et al. A comparative study of intrathecal dexmedetomidine and fentanyl as adjuvants to bupivacaine. *J Anaesthesiol Clin Pharmacol* 2011;27:339-43.
12. Mahendru V, Tewari A, Katyal S, Grewal A, Singh MR, Katyal R, et al. A comparison of intrathecal dexmedetomidine, clonidine, and fentanyl as adjuvants to hyperbaric bupivacaine for lower limb surgery: A double blind controlled study. *J Anaesthesiol Clin Pharmacol* 2013;29:496-502.
13. Mahendru V, Tewari A, Katyal S, Grewal A, Singh MR, Katyal R, et al. A comparison of intrathecal dexmedetomidine, clonidine, and fentanyl as adjuvants to hyperbaric bupivacaine for lower limb surgery: A double blind controlled study. *J Anaesthesiol Clin Pharmacol* 2013;29:496-502.
14. Gill RS, Acharya G, Rana A, Arora KK, Kumar D, Sonkaria LK. Comparative evaluation of addition of fentanyl and dexmedetomidine to ropivacaine for epidural anaesthesia and analgesia in lower abdominal and lower limb orthopedic surgeries. *EJPMR* 2016;3:200-5.