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A CLINICAL STUDY COMPARING EFFICACY OF EPIDURAL PLAIN BUPIVACAINE AND BUPIVACAINE PLUS FENTANYL IN ABDOMINAL AND LOWERLIMB SURGERIES

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ABSTRACT

Introduction: Epidural anesthesia is a type of neuraxial anesthesia; used for anesthesia of abdominal, pelvic, and lower extremity procedures and, less commonly, thoracic procedures and as a supplement to general anesthesia for thoracic, abdominal, and pelvic procedures and for postoperative analgesia following aforementioned procedures.

Aims: A clinical study comparing efficacy of epidural plain Bupivacaine and combination of Bupivacaine plus Fentanyl in abdominal and lower limb surgeries.

Materials and Methods: The present clinical study has been carried during 2017-2019,The Study was under taken to compare the efficacy of Bupivacaine and combination of Bupivacaine with fentanyl regarding onset, duration and quality of analgesia when given extraduraly.The study was conducted on 100 adult patients of ASA grade I and II.

Results: The time of onset of analgesia was determined by pin prick method every one minute till there was absence of pain sensation and maximum sensory blockade. The quality of analgesia was recorded as excellent, good, fair and poor. Duration of analgesia was deduced by testing every 15 minutes with pinprick method for return of sensation in two dermatomes below the highest level of block achieved i.e., 2-segment regression. The complications were noted.

Conclusion: The onset of analgesia was quick and time for complete analgesia was earlier in Bupivacaine and Fentanyl combination group when compared to Bupivacainegroup.The quality of analgesia was excellent in Bupivacaine and Fentanyl group when compared to Bupivacainegroup.

Keywords: Bupivacaine, Fentanyl, onset of analgesia, sensory blockade.

INTRODUCTION

Improvement in pain relief and satisfaction is seen in surgical patients due to advances in perioperative anesthesia and analgesia which can reduce or eliminate the perioperative physiological stress responses to surgery and thereby decrease surgical complications and improve outcome.[1,2]Neuraxial anesthesia and analgesia techniques include epidural, combined spinal epidural and spinal which are most commonly used for lower extremity and lower abdominal surgery. When compared with general anesthesia and intravenous analgesia, neuraxial anesthesia and analgesia provides more perioperative benefits, including better pain relief, shortened length of stay in the ICU and hospital, and reduced morbidity and mortality.[3]

Epidural anesthesia is a type of neuraxial anesthesia; used for anesthesia of abdominal, pelvic, and lower extremity procedures and, less commonly, thoracic procedures and as a supplement to general anesthesia for thoracic, abdominal, and pelvic procedures and for postoperative analgesia following aforementioned procedures. The usual technique involves siting a catheter in the epidural space and Local anesthetic solution (LA) and\or adjuvants are

injected into the epidural space to anesthetise the spinal nerve roots that traverse the space which are administered through the catheter, both to initiate and maintain anesthesia for the duration of the surgical procedure.

Many drugs such as Lignocaine, Bupivacaine , Ropivacaine, Tetracaine etc., can be used for epidural anaesthesia of which Bupivacaine an amideamino group of local anaesthetics, commonly used because of long duration of action, however the use of epidural local anesthetics alone is inconsistent in maintaining a level of sensory analgesia in the postoperative period duration of analgesia being long.[4]

Several classes of medications may be added to the LA solution as adjuvant medications, which shorten latency, prolong the duration of anesthesia, and increase the density of sensory and motor blockade. Out of all epidural analgesiausing local anaesthetics, opioids have gained popularity, the technique by which the somatic pain is relieved by local anaesthetics and visceral pain by opioids effectively and via a synergistic mechanism.Present times, various opioids such as Fentanyl, Morphine, Diamorphine have been used successfully both alone and in combination with local anesthetic drugs which could improve the quality of intra-operative anesthesia, postoperative analgesia, aid early ambulation, early recovery of motor block, reducing the incidence of associated side effects; is the concept behind the multimodal analgesia. However when used alone epidural opioids have been unable to provide adequate analgesia but the addition of the short acting, lipid soluble opioid fentanyl to bupivacaine has been more successful.[5]

Hence a clinical study was undertaken, by adding fentanyl to epidural bupivacaine to compare onset, duration and quality of analgesia, with plain bupivacaine, taking its advantage of high lipid solubility and blockade of spinal opioid receptors.

MATERIAL AND METHODS

The present clinical study on hasbeen carried out at Mahatma Gandhi Memorial Hospital, Kakatiya medical college, Warangal during 2017-2019, the institution ethical committee has approved the study.The Study was under taken to compare the efficacy of Bupivacaine and combination of Bupivacaine with fentanyl regarding onset, duration and quality of analgesia when given extraduraly.The study was conducted on 100 adult patients of ASA grade I and II, of either sex, belonging to 20-65 years of age, posted for elective lower abdominal in general surgery, urology and lower limb surgeries were selected for the study. Lower abdominal surgery is defined as the incision below the umbilicus and different surgeons performed the surgery.

Pre- anaesthetic evaluation:

Patients were visited on the previous day of the surgery, a detailed clinical history was taken, general and systemic examinations were done basic laboratory investigations like complete haemogram, bleeding time, clotting time, blood sugar, blood urea, serum creatinine and urine analysis were carried out routinely on all patients. ECG was done in patients more than 40 years of age and chest x-ray when indicated

The patients were explained about the epidural technique, its advantages and disadvantages.The 100 patients studied were divided into 2 groups.

Group-I (Control): Total number of patients 50.This group received 20ml of 0.5%Bupivacaine + 2ml of 0.9% normalsaline.

Group-Il (Study): Total number of patients 50.

This group received 20ml of 0.5% Bupivacaine + 2ml (100µg) of fentanyl.

Prior to scheduled operation a written and informed consent was taken as per hospital ethical committee. Irrespective of the group studied, patients were explained about the procedure of the epidural analgesia i.e., about the position the technique which is going to be performed,

effects of the procedure and the parameters to be studied to gain confidence and co-operation of the patients

Inclusion criteria:18-60 years of either sex, American society of Anesthesiologist physical status (ASA) grade I andII.

Exclusion criteria: Patients with cardio-respiratorydisorders, renal and / or hepaticdisorders.**,**Contraindications for epiduralanesthesia, physically dependent onnarcotics, history of hypersensitivity to studydrug**,** Head injurycases.
Patients in whom epidural anaesthesia was not adequate and supplemented with other types ofanaesthesia.
The parameters observed were time of onset of completeanalgesia ,Intensity of sensoryanalgesia
The duration of analgesia was taken as a time from complete pain relief to the time when the patients first complained of pain (inminutes/seconds).Recording the blood pressure, pulse rate and the respiratory rate every 5minutes.Complications arisingintraoperativelyPostoperative complications, ifany ,The time of onset of analgesia was determined by pin prick method bilaterally every 1min, till there was absence of pain sensation and maximum sensory level.
Intensity and the degree of sensory blockade were recorded by using the following score:
Excellent All sensationslost.
Good Slight discomfort, but no need forsupplementation.
Discomfort and additional dose of narcotic withgas, oxygen given through amask.
Discomfort and pain, general anaesthesia has to be administered.
Total duration of analgesia was deduced by testing every 15 minutes with pin prick method for return of the sensation in 2 dermatomes below the highest level of block achieved i.e., 2 segment regression.Any necessity of supplementation of anaesthesia was looked for in event of inadequate block, patchy analgesia etc.The vital parameters, blood pressure, pulse rate and respiratory rate were noted every 5 minutes. The fall in blood pressure was intervened with drugs only in the event of a fall more than 25% of the preoperative level. The pulse rate below 60/min was treated with Atropine.

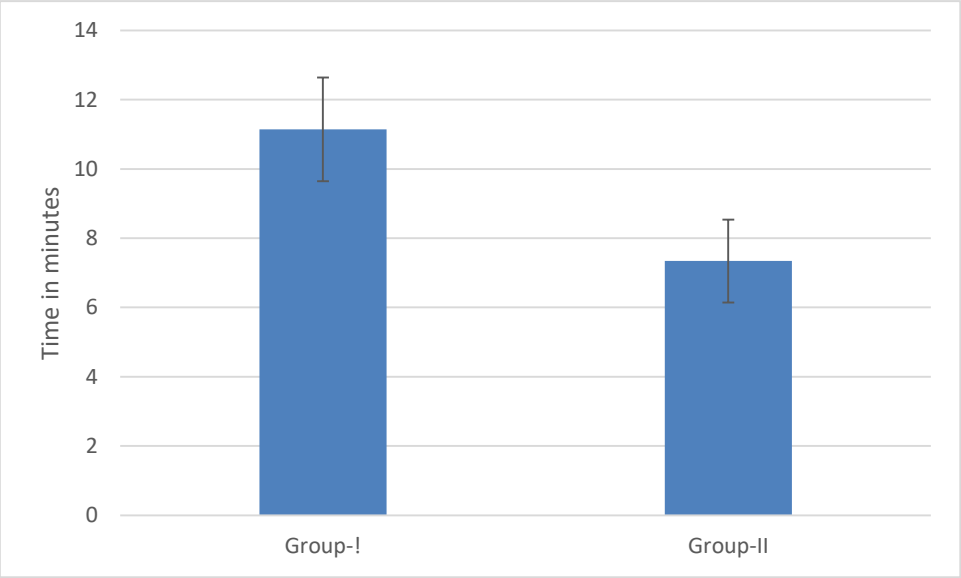
RESULTS

Table-1: Showing distribution of age

41-50 years age group is common in both group-I and II, followed by 31-40 years and 21-30 years.

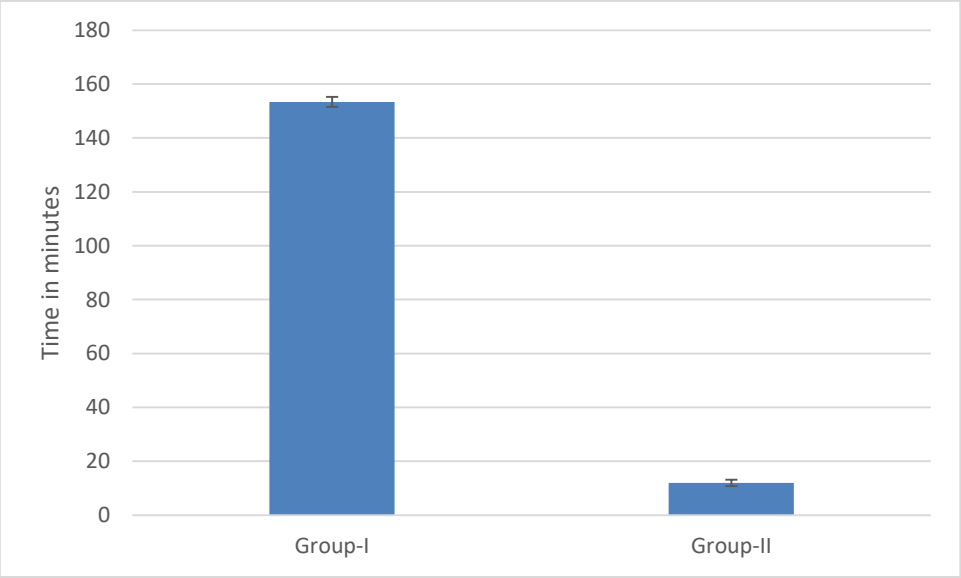
Age in years	Group I		Group II	
	No of Patients	Percentage %	No. of Patients	Percentage %
21-30	12	30	15	30
31-40	17	34	13	26
41-50	18	36	20	40
51-60	3	6	2	4

Figure-1: Comparision of onset of analgesia



From the above table it is observed that the time of onset of analgesia in group II is less than group I, indicating that the onset of analgesia is faster in the group II compared to group I,the standard error of difference between two means is 0.272,the p value falls below 0.0001,which is statisticallysignificant.

Figure-2: Comparision of time of complete analgesia



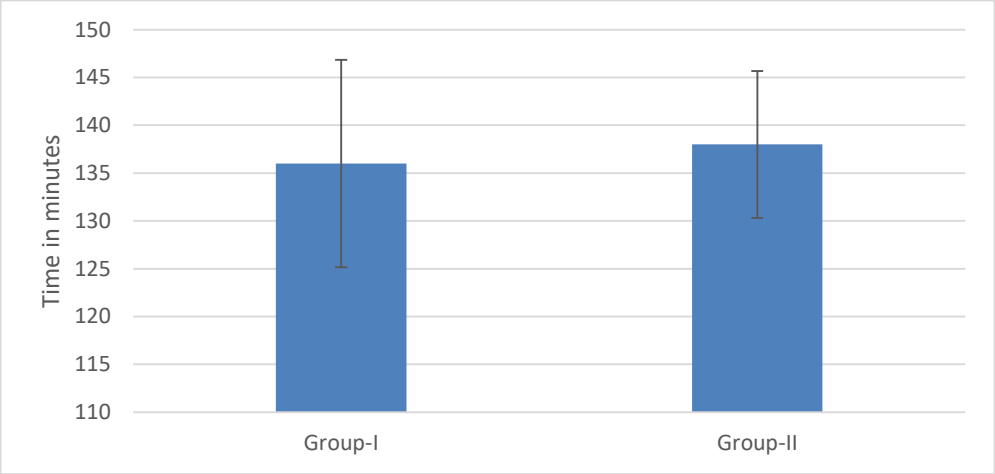
From the above table it is observed that the time of complete analgesia in group II is less than group I, indicating that the time for complete analgesia in group II is shorter when compared to group I, the standard error of difference between means is 0.314 ,the P value falls below 0.0001, which is statisticallysignificant.

Table-2: Showing highest level of analgesia

	Group I		Group II	
Dermatome Level	No of Patients	Percentage	No. of Patients	Percentage
T6	17	34	18	36
T8	30	60	29	58
T10	3	6	03	06

From the above table it observed that in most of the patients,the highest level of analgesia was above T8.

Table-3: Comparison of duration of analagesia(2-segment regression)



So,the duration of analgesia in group II is not prolonged significantly when compared to group I. The standard error of difference between two means is 1.879 which are statistically insignificant.

Table-3: Side effect in present study.

Complications	Group I	Group II
Nausea\vomiting	3	5
Bradycardia	4	4
Shivering	7	4
Pruritis	0	7
Hypotension	5	2
Urinary retention	0	1
Respiratory depression	0	0

DISCUSSION

Many drugs find place in drug armamentarium in epidural anaesthetic technique of abdominal and lower limb surgeries such as local anaesthetics and opioids which provide satisfactory analgesia with quick onset and long duration of action.Bupivacaine, an amide group of local anaesthetic, is better agent of choice for epidural analgesia for labour. It has long duration of action and produces excellent sensory blockade with less motor block.[6]The advantage of long duration of action is offset by its long latent period.In the current study Fentanyl is added to Bupivacaine to reduce the onset time of analgesia and increase the duration of analgesia attributing to its high lipid solubility. The fentanyl crosses the lumbar dura and penetrates quickly the lipid phase of underlying tissue of the cord. Thus analgesia will be rapid, intense, and sharply segmental with few side effects from migration of the opioid in a rostral direction.

In our study a total of 100 patients were selected and randomly divided in to two groups. Irrespective of groups studied the volume of local anaesthetic was kept constant because volume of local anaesthetic injected into the epidural space plays a role in the outcome of the level of analgesia. The parameters observed were onset of analgesia, time for complete analgesia, duration and quality of analgesia. Other than this the other parameters noted are pulse rate, blood pressure, Sp02, level of sensory block. Beside these side effects were also noted if any.

Onset of sensory blockade is taken as the time from the completion of the injection of the study drug till the patient does not feel the pin prick at desired level- in our study, the mean time of onset of analgesia in group I (Bupivacaine) was 11.14 ± 1.5(S.D) minutes and in group II (bupivacaine plus fentanyl) was 7.34 ± 1.2(S.D) minutes. Majority of patients in group I had onset of analgesia between 10-13 minutes whereas in group II between 6-9 minutes. Statistical analysis showed that onset of analgesia was faster in group II compared to group I($p< 0.0001$).The results indicate that there is quick onset of analgesia and short duration of time for complete analgesia in group II patients who received Bupivacaine and Fentanyl.

Our study supported by Shirasaka T, Shimizu Y& Takasaki M[7] who in their study concluded that the onset time of cold sensory block, and onset time of analgesia was significantly shorter in Bupivacaine and Fentanyl group when compared to Bupivacaine alonegroup. Study conducted by Milon D, Noury D, Allain H[8]also proved significantly shortened onset of analgesia as well as a significant reinforcement of thisanalgesia.SurajDhale and Vaishali Shelgaonkar[9] in studied different doses of epidural fentanyl (25µg, 50µg, 75µg) with 0.5% bupivacaine for perioperative analgesia found that 50µg had a quicker onset of analgesia within 9.53 min which is close to our observation.

Moore, D. C., et al[10]reviewed 2,077 Cases and proposed that Bupivacaine, a long-acting local anesthetic agent at concentrations of 0.5 with and without a vasoconstrictor drug, when used in, epidural block showed onset occurred in 4 to 10 minutes, when used alone showed the onset with a mean of 5.2± 1.2(SD) .He also inferred that concentration of 0.5% was satisfactory in epiduralblock for (1) pain relief of labor; (2) vaginal delivery; (3) perineal surgery; and (4) extremitysurgery.P. Nageswararao., et al[11] conducted clinical study and stated that, the onset of epidural analgesia in group BF (10ml of 0.5% Bupivacaine + 50µg Fentanyl) was varied from 2- 4 minutes (mean 5.27 minutes), The onset of analgesia was more rapid (4-8 min; mean 4.92) with the addition of 100 µg fentanyl to 20 ml 0.5% plainBupivacaine.Paech, M. J., et al[12] studied the effect of adding fentanyl 100 µg to bupivacaine 0.5% plain to establish epidural anaesthesia for elective caesarean section in a double-blind study of sixty healthy women. The onset of epidural sensory anaesthesia were similar in both groups, at approximately thirty minutes.

Parate, L., et al[13] in a randomized, parallel group, double blind, placebo controlled study evaluated the analgesic effect of addition of 50µg fentanyl to epidural 0.5% bupivacaine in patients undergoing elective caesarean section using visual analogue scale. A comparison of characteristic of epidural block showed no difference in time of onset of analgesia and total dose of bupivacaine in both groups. The mean duration of onset of analgesia in the control group was 21 ± 2.21 min and in the combination group 21.07 ± 2.39 min (P =0.911).NamaNagarjunaChakravarthy, et al[14] studied the effects of epidural 0.5%Bupivacaine with nalbuphine and 0.5% bupivacaine with fentanyl in lower abdominal and lower limb surgeries found that onset and mean in fentanyl group is 5.76±1.61.

Table-4: Comparision of onset of analgesia with other studies

Studies	Group II- Bupivacaine plus fentanyl
SurajDhale., et al[9]	9.53 min
Moore, D. C., et al[10]	5.2± 1.2 min
P.Nageswararao., et al[11]	4.92 min
Parate, L., et al.[13]	21.07 ± 2.39 min
NamaChakravarthy, et al[14]	5.76 ± 1.61 min
Paech, M. J., et al.[12]	31 min
Present study	7.34 ±1.2 min

Time for maximum motor blockade is defined as the time from the completion of the injection of the study drug to the maximum motor blockade attained. In our study, the mean time of complete analgesia in group I (bupivacaine) was 15.34 ± 1.872(S.D) minutes and in group II (fentanyl plus bupivacaine)was 11.98± 1.20(S.D) minutes. Majority of patients in bupivacaine group hadonset of analgesia between 12-20 minutes whereas in fentanyl group between 10-15 minutes. Statistical analysis showed that onset of analgesia was faster infentanyl group compared to Bupivacaine group ($p< 0.0001$).

Moore, D. C., et al[10] proposed that Bupivacaine a long-acting local anesthetic agent at concentrations of 0.5 with and without a vasoconstrictor drug, when used in, epidural block showed that is with a mean of 19.9± 7.2(SD).P. Nageswararao., et al[11] concluded that time of complete analgesia in groupBF(bupivacaine plus fentanyl) that is with the addition of 100 µg fentanyl to 20 ml 0.5% plain Bupivacaine has 8-13min with a mean of 10.8min.

In our study quality of analgesia was excellent in 38% of patients in group I and 70 % in group II, quality of analgesia was good in 42% of patients in group I and 22% of patients in group II, fair quality of analgesia in 20% of patients in group I and 8% in group II.This is supported byMoore, D. C., et al[10] stated that "Bupivancaine was a highly reliable drug and produced excellent sensory and motor anesthesia provided it was used in the correct concentrations for the degree of muscle relaxation required for the operative procedure"

Paech, M. J., et al[12] concluded that the majority of women in both groups were considered to have good or excellent analgesia (93% in the fentanyl group, 74% in the saline group). A significantly greater number however in the fentanyl group had excellent analgesia (81 % versus 48%, $P = 0.01$).

Duration of analgesia is taken from the time of injection till the patient complains of pain at the site of surgery. The time at which patient s complained of pain is noted. That point was taken as the end of fair analgesia and at that point, top up doses were given based onrequirement.In our study the duration of analgesia is deduced by two segment regression. There is no significant difference in the two groups in regard to the duration of analgesia. Mean duration of analgesia in group I was 136±10.84 min and negligible difference with group II with having a mean of 138±7.68 min.This was supported by FS Rucci, M Cardamone; D Maigliori[15] who concluded that the time of regression of analgesic blockade was significantly prolonged only with mixtures containing 200µg of Fentanyl , no effect was demonstrated with lower doses of theopioid.Paech, M. J., et al[12] concluded that Duration of sensory anaesthesia in elective cessarian section with group receiving plain bupivacaine is

319 min and group receiving bupivacaine with fentanyl(100µg) combination is 314 mins. Umapathy, P.etal[16] concluded that that none of the patients had analgesia of less than 1 hour 30 minutes in both plain bupivacaine and bupivacaine plus fentanyl(100µg) groups. The calculated value (1.76) is much less than the tabulated value (9.49) and is highly significant. Thus, we accept the null hypothesis ($p>0.05$). Hence, we conclude that the two-segment regression time was uniformly distributed amongst the two groups.P.Nageswararao., et al[11] found that the duration of analgesia in group bupivacaine plus fentanyl(50µg) lasted for 2-4 hours (mean 2.98). Parate, L.et al[13] inferred that the postoperative duration of analgesiawasprolongedinthefentanyl(50µg)groupwithdurationof275.80 ±177; 13.61 min compared to the saline group duration 191.47±177;12.16 min.

Regarding side effects 4 patients in group I and 2 patients in group II complained of shivering. Mild pruritis was observed in 4 patients of group ll. 2 patients in group I and 3 in group II complained of nausea and vomiting. Hypotension was observed in 3 patients in group I and 1 patient in group II. NO respiratory depression was seen in eithergroup.

CONCLUSION

The onset of analgesia was quick and time for complete analgesia was earlier in Bupivacaine and Fentanyl combination group when compared to Bupivacainegroup.

The quality of analgesia was excellent in Bupivacaine and Fentanyl group when compared to Bupivacainegroup.The duration of analgesia as deduced by 2-segment regression was found to be equal in two groups. It was around 2hrs 15mins.The addition of fentanyl to epidural bupivacaine is beneficial as it causes an early onset of block, improvement in quality of sensory block and had no effect on motor blockade with minor sideeffects.

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