

A PROSPECTIVE RANDOMIZED STUDY FOR COMPARISON OF 0.5% LEVOBUPIVACAINE AND 0.5% BUPIVACAINE WITH FENTANYL FOR EPIDURAL ANAESTHESIA IN PATIENTS UNDERGOING HYSTERECTOMY

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Abstract

Keywords

Levobupivacaine,
Bupivacaine, Fentanyl,
Epidural, Hysterectomy.

Introduction: Epidural anaesthesia is one of the best accepted and most versatile procedure in modern anaesthesiology for lower abdominal surgeries as it provides good sensory and motor block with contracted bowels, retaining spontaneous respiration, haemodynamic stability, and also an indwelling catheter which facilitates further administration of analgesic drugs for the postoperative period.

Aim: This study was aimed to compare racemic bupivacaine and levobupivacaine in epidural anaesthesia for hysterectomies using fentanyl as common adjuvant.

Material and Methods: A randomised prospective study was conducted on sixty patients of age group between 18-60 years of age with ASA grade 1 and 2 undergoing hysterectomy under epidural anaesthesia. Patients were randomly divided into two groups, Group A [n=30] received 0.5% levobupivacaine [15-20ml] with fentanyl [75 mcg] and Group B received 0.5% bupivacaine [15-20ml] with fentanyl [75mcg].

In both groups's onset of sensory and motor block, duration of analgesia, level of sedation, haemodynamic parameters and complications were assessed perioperatively.

Results: Mean duration of onset of sensory block in group A was 6.42 and 6.18 mins in group A and B respectively and mean duration of onset of motor block was 16.62 and 16.40 min in group A and B respectively, which were comparable for both groups as p value was >0.05. The mean duration of analgesia in group A was 5.33 hrs and in group B was 5.45 hrs, which was comparable in both groups with p value of 0.300 [>0.05]. Haemodynamic parameters and complications were statistically non significant in both groups [>0.05].

Conclusion: combination of levobupivacaine and fentanyl is equipotent to bupivacaine and fentanyl in epidural anaesthesia for hysterectomies as both provided stable haemodynamics with adequate sensory and motor anaesthesia devoid of any significant adverse effects.

Introduction

Epidural anaesthesia is now frequently used for gynaecological surgery due to its favourable effects on various aspects of operative outcome such as reduced intraoperative blood loss, minimal stress response to surgery, decreased postoperative catabolism, decreased incidences of postoperative nausea and vomiting, reduced incidences of thromboembolic events and improved postoperative pulmonary functions.^[1,2,3] It also provides good sensory and motor block with contracted bowels, retains spontaneous respiration, haemodynamic stability and also an indwelling catheter can be used to provide analgesia in postoperative period.^[4]

Local anaesthetics are the mainstay of therapy for obtaining analgesia or anaesthesia in an epidural technique.^[5] Bupivacaine is a long-acting amide and is widely used as local anaesthetic for epidural anaesthesia. It has a beneficial ratio of sensory to motor block in epidural anaesthesia and also provides high quality analgesia in the post-operative

period^[6] but racemic bupivacaine is more toxic to central nervous system and the cardiovascular system.^[7] Levobupivacaine is the pure S (-) enantiomer of bupivacaine and in recent years has emerged as a safer alternative for regional anaesthesia than its racemic parent.^[8] It has a lower risk of cardiotoxicity and neurotoxicity due to its decreased potency at the sodium channels and faster protein binding rate.^[9]

The use of adjuvants with local anaesthetics has gained widespread popularity as the addition of opioids or other additives allows the reduction of amount of local anaesthetic and decreases incidence of side effects.^[10] It also accelerates the onset of sensory blockade, provides sedation, maintain stable hemodynamics and provide prolonged postoperative analgesia.^[11]

Among opioids, fentanyl and sufentanyl are most commonly used in combination with local anaesthetics. Fentanyl, a highly lipid soluble, pure mu agonist with rapid onset and short duration of action, has been used with various local anaesthetics for wide variety of surgical procedures^[12].

Hence the purpose of this study was to compare 0.5% plain levobupivacaine with fentanyl and 0.5% plain bupivacaine with fentanyl for epidural anaesthesia in patients undergoing hysterectomies and comparing the haemodynamic changes, sensory blockade and motor blockade.

Material and Methods

After the approval from hospital ethical committee patients were explained about the procedure and after having written consent were included in this study. A prospective randomised study conducted in 60 patients between age group of 18-60 years with ASA grade of 1 and 2 undergoing hysterectomies under epidural anaesthesia in Department of Anaesthesiology and Obstetrics and Gyane at Rajindra Hospital, Government Medical College, Patiala. They were randomly allocated in 2 groups of 30 patients each.

After arrival in operation theatre, all routine investigations, pre-anaesthetic evaluation and patients consent form was checked. Patients were preloaded with 15ml/kg ringer lactate intravenously before procedure. H.R,SBP,DBP,MAP SPO₂,RR were recorded.

After proper positioning, back cleaned with antiseptic solution and draped. Local anaesthetic, 1-2 ml of 2% xylocaine was injected subcutaneously at L3-L4 space. Sise introducer was introduced and taken out. The 18G disposable Tuohy's needle was inserted at L3-L4 interspinous space in midline and was advanced upto epidural space by loss of resistance technique. Then 18G PORTEX epidural catheter was passed through the epidural needle in upward direction and the catheter was fixed to the back using adhesive tape.

A test dose of 3 ml of 1.5% lignocaine with adrenaline was given after initial negative aspiration for blood and cerebrospinal fluid. Then, 15-20 ml of 0.5% plain levobupivacaine along with 75 mcg fentanyl was injected into the epidural space in Group A patients and in Group B patients 15-20 ml of 0.5% plain bupivacaine was administered epidurally with addition of 75 mcg fentanyl.

Statistical Analysis

The information collected regarding all the selected cases were recorded in master chart. Analysis was conducted using IBM SPSS statistics (version 22.0). Numerical data was expressed as mean and standard deviation and statistically analysis was done using the independent Student t-test to compare the two groups. For skewed data/scores Mann-Whitney U-test was used. Gender, ASA grading, diagnosis and type of surgery was compared using Person Chi square test. The p value of <0.05 was considered statistically significant and the p value of <0.001 was considered statistically highly significant.

Results

There was no statistical significant difference among the two groups with respect to age, sex, weight, duration of surgery and haemodynamic variation.

The mean time for onset of sensory block in Group A was 6.42 and in group B was 6.18. The difference was statistically non significant as the p value was 0.121 (not < 0.05).

The mean time for maximum sensory block in Group A was 12.58 and in Group B was 12.37. This difference was statistically non significant as the p value was 0.270 (not < 0.05).

The mean time for onset of motor block in group A was 16.62 and in group B was 16.40. It was statistically not significant as the p value was 0.159 (not < 0.05).

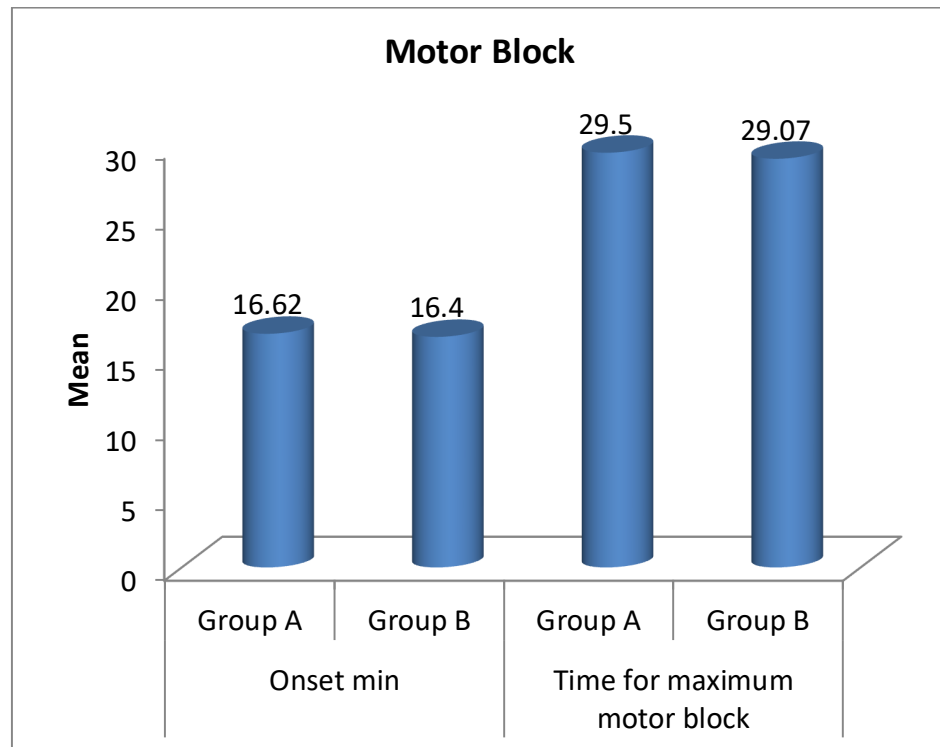
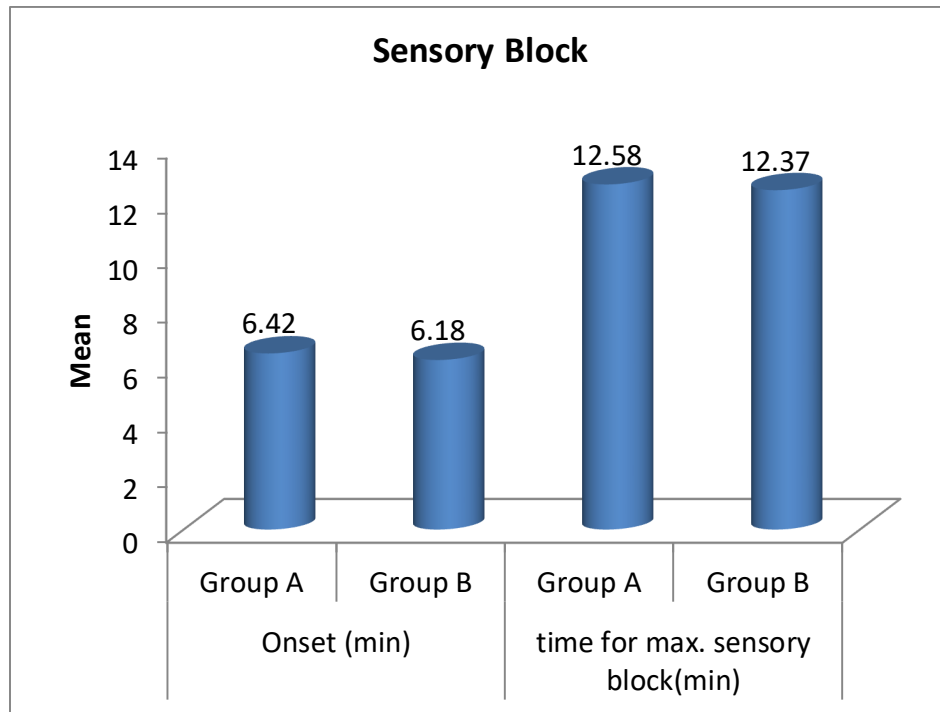
The mean time for maximum motor block in Group A was 29.50 and in Group B was 29.07. This difference was statistically non significant as the p value was 0.221 (not < 0.05).

The duration of analgesia was 5.33 hrs. in group A and 5.45 hrs. in group B and it was statistically non significant as the p value was 0.3 [i.e. >0.05].

Table 1: Demographic Data

Demographic profile	Group A	Group A	Pvalue
Age(years)	48.87±10.02	48.17±6.43	0.749
Sex(M/F)	0/30	0/30	1.00
Weight(kg)	61.20±2.63	60.37±2.37	0.203
Mean duration of surgery(mins)	96.67	101.67	0.185

Block Characteristics	Groups	Mean	p value	Significance
Onset Of sensory block (min)	Group A	6.42	0.121	NS
	Group B	6.18		
time for max. sensory block(min)	Group A	12.58	0.270	NS
	Group B	12.37		
Onset of motor block(min)	Group A	16.62	0.159	NS
	GROUP B	16.40		
Time for maximum motor block(min)	Group A	29.50	0.221	NS
	Group B	29.07		
Duration of analgesia (hrs)	Group A	5.33	0.300	NS
	Group B	5.45		



In our study, the incidence of nausea and vomiting in group A was 4% and group B was 12%. The result was statistically non significant as p value was 0.604 (not < 0.05) and the incidence of pruritis in group A was 0% and in group B was 4%. The result was statistically non significant as p value was 0.154 (not < 0.05)

None of the patients in both groups develop Urinary Retention, Headache, Respiratory Depression, Paresthesias and Hallucinations.

		Group A	Group B	P value	Significance
Nausea and Vomiting	Present	3	2	0.640	NS
	Absent	27	28		
Urinary Retention	Present	0	0	-	-
	Absent	30	30		
Headache	Present	0	0	-	-
	Absent	30	30		
Pruritis	Present	2	0	0.154	NS
	Absent	30	30		
Respiratory Depression	Present	0	0	-	-
	Absent	30	30		
Paraesthesias	Present	0	0	-	-
	Absent	30	30		
Hallucination	Present	0	0	-	-

Discussion

Epidural anaesthesia provides excellent pain relief with early mobilization of patients particularly when a local anaesthetic agent is combined with an adjuvant like opioids. It avoids invasive dural penetration technique with spinal needle & has the potential to provide complete analgesia.

In our study, mean time for onset of sensory block was 6.42 mins. in A group & 6.18 mins in B group. Statistically the difference in time of onset of sensory block was non significant as p value was 0.121[>0.05]. The results were comparable with study conducted by Kavita jain et al^[13], Fesih Kara et al^[14] and C.R Cox et al^[16]

In our present study mean time for maximum sensory block was 12.58 mins. in A group & 12.37 mins in B group. Statistically the difference in time of onset of sensory block was non significant as p value was 0.270[>0.05], indicating that statistically there is no significant difference in time for maximum sensory block in two groups. The result of our present study are consistent with those given by Fesih Kara et al^[14], S. Muneeruddin Ahmed et al^[15], C.R.Cox et al^[16].

In our the present study the mean time of onset of motor block in group A was 16.62 minutes and in group B was 16.40 minutes. It was statistically not significant as the p value was 0.159 [i.e. not<0.05]. Thus the results of our study was comparable with the results given by Kavita Jain et al^[13], Fesih Kara et al^[14], S.Muneeruddin Ahmed et al^[15] and C.R Cox et al^[16].

In our present study mean time for maximum motor block was 29.50 mins. in A group & 29.07 mins in B group. Statistically the difference in time of onset of motor block was non significant as p value was 0.221[>0.05]. The result of our study was consistent with the result given by Fesih Kara et al^[14].

In the present study the duration of analgesia is 5.33 hrs (319.8 mins) in group A and 5.45 hrs (327 mins) in group B and it is statistically non significant as the p value was 0.3 [>0.05]. The results of our study were comparable with the results given by Sreelakshmi Vangli et al^[17], Fesih Kara et al^[14] and Casimiro C et al^[18].

In our present study 3 patients in group A and 2 patients in group B had incidence of nausea – vomiting. The result was statistically insignificant as p value was 0.640 (i.e >0.05). The results of our study were comparable with the results given by Sudarshan M Boregodwa et al^[19], Sreelakshmi Vangali et al^[17], Kavita Jain et al^[13] and Fesih Kara et al^[4].

In our present study 2 patents in group A and 0 patient in group B had pruritis. The result was statistically insignificant with p value of 0.154 (>0.05). The results of our study were comparable with the results given by Sreelakshmi Vangali et al^[17], and Kavita Jain et al^[13]

Conclusion

So we concluded that combination of levobupivacaine and fentanyl is equipotent to bupivacaine and fentanyl in epidural anaesthesia for hysterectomies as both provided stable haemodynamics with adequate sensory and motor anaesthesia devoid of any significant adverse effects. Rather levobupivacaine is better because the side effects like nausea vomiting and pruritis were noticed in less number of patients though the results were non significant when analysed statistically.

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