Original Article

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Comparative Study of Isobaric Levobupivacaine Alone and Isobaric Levobupivacaine with Fentanyl for Spinal Anaesthesia in Lower Abdominal Surgeries

Chandana M H[1], P G Raghvendra[2]

Author's Affiliation:

[1]Assistant Professor, Department of Anesthesia, Vijaynagar Institute of Medical Sciences, Ballari, Karnataka 583104, India. [2]Assistant Professor, Department of Anesthesia, Raichur Institute of Medical Sciences, Raichur, Karnataka 584102, India.

Abstract

Introduction: Levobupivacaine 0.5% and racemic bupivacaine 0.5% are equally effective in spinal anaesthesia with less systemic toxicity seen with levobupivacaine. Fentanyl has been used as an adjunct to racemic bupivacaine in spinal anaesthesia. This study was designed to study on the intrathecal use of 0.5% levobupivacaine with fentanyl in elective lower abdominal surgeries.

Methods: A prospective randomized controlled double blind study was conducted in100 patients of ASA I and II physical status posted for elective lower abdominal surgeries under subarachnoid block, randomized into 2 groups with 50 patients each, received either 3 ml of 0.5% isobaric levobupivacaine (group L) or 2.8 mL of 0.5% levobupivacaine with fentanyl 10 µg in 0.2 mL (group F). Hemodynamic parameters, time for onset of sensory and motor blockade, maximum height of sensory block and total duration of sensory and motor blockade were recorded. Intraoperative or postoperative side effects werenoted.

Results: There were no significant differences between the two groups in the haemodynamic changes, and quality of sensory and motor block. Anaesthesia was adequate and patient satisfaction was good in all cases. Side-effects were minor and infrequent with both regimes.

Conclusions: We conclude that,in terms of efficacy, 2.8 mL of 0.5% levobupivacaine with fentanyl 10µg is comparable to 3 mL of 0.5% levobupivacaine alone in spinal anaesthesia for lower abdominal surgeries. Further studies may be directed to find the optimal combination of levobupivacaine and opioid for spinal anaesthesia.

Keywords: Levobupivacaine; Analgesics; Opioid; Fentanyl; Anesthetic techniques; Anaesthesia; Spinal.

Introduction

Subarachnoid anaesthesia (SAB) is the most popular as well as effective technique for infraumbilical surgeries. It provides fast onset and effective sensory and motor blockade. Spinal anaesthesia is widely used, providing afast onset and effective sensory and motor blockade. It has many advantages like simplicity, easy to perform, rapid onset of action and good muscle relaxation. It has an added advantage of preventing complication of General Anaesthesia like poly pharmacy, pressor response from intubation, nausea, vomiting, sore throat, excessive sedation etc.

Racemic bupivacaine is one of the most common

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Corresponding Author: PG Raghvendra, Assistant Professor, Department of Anesthesia, Raichur Institute of Medical Sciences, Raichur, Karnataka 584102, India.

Email: drpgraghavendra@gmail.com

local anaesthetics used for spinal analgesia and levobupivacaine is its S-enantiomer. Clinical studies comparing levobupivacaine and racemic bupivacaine in epidural and spinal analgesia show that both are equally effective.[1-6] During epidural use, levobupivacaine and racemic bupivacaine have the same analgesic potency, however levobupivacaine is 13% less potent on a percentage weight per volume basis for motor block.[7] Hence, in the epidural route, levobupivacaine has greater sensory–motor dissociation in blockade than racemic bupivacaine. It is likely that similar sensory–motor dissociation is also present in the intrathecal use of levobupivacaine. Fentanyl is a lipophilic opioid which has been used as an adjunct to local anaesthetics, including racemic bupivacaine, for enhancement of analgesia without intensifying motor and sympathetic block in spinal analgesia.[8,9] It is possible that the addition of fentanyl to levobupivacaine may result in a mixture for spinal anaesthesia with minimal motor block and hypotension. At the time this study was designed, no study had been published on the intrathecal use of 0.5% levobupivacaine with fentanyl. We performed this clinical study to compare the clinical efficacy, motor block and haemodynamic effects of using 2.8mL of 0.5% levobupivacaine with fentanyl 10μg (0.2 mL) and 3 mL of 0.5% levobupivacaine alone in spinal anaesthesia for elective lower abdominal surgeries requiring sensory block to at least the tenth thoracic (T10) dermatome.

Aims

To study and compare the clinical effects and block characteristics of isobaric levobupivacaine alone and isobaric levobupivacaine with fentanyl for spinal anaesthesia in lower abdominal surgeries.

Objectives

The following parameters were studied and compared.

- The time for onset, level and duration of sensory blockade.
- The time for onset, degree and duration of motor blockade.
- Time for 2 segment regression of sensory block.
- The hemodynamic variations.
- Adverse effects if any.

Methods

A Prospective randomized controlled, double blind study was conducted in hundred patients undergoing elective lower abdominal surgeries under spinal anaesthesia at Basaveshwara General and Teaching Hospital attached to Mahadevappa Rampure Medical College, Gulbarga after getting approval by Internal Ethics Committee. The study was conducted from November 2016 to January 2018. By keeping the confidence limits at 95% and power of study at 80%, to detect a minimum of 10% difference in proportion of hypotension between the two groups, the minimum sample size required is 25 in each group. We included 50 patients in each group for better validity of results after obtaining informed and written consent. 100 patients chosen for the study were divided into 2 groups in a ratio of 1:1, Group L and Group F, of 50 each, by permuted block randomization technique in the ratio 1:1 .

Statistical Methods

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact probability test has been used to find the significance of study parameters on categorical scale between two or more groups. Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1 ,Systat 12.0 and R environment ver.2.11.1 were used.

The inclusion criteria were aged between 50 and 75 yr, ASA I–III and body weight between 45 and 80kg. The exclusion criteria were known hypersensitivity to amide local analgsics, contraindication to spinal analgesia Group L received 3 mL of 0.5% levobupivacaine alone and Group F received 2.8 mL of 0.5% levobupivacaine with fentanyl 10 μg (0.2 mL). an intravenous (i.v.) infusion of 10mLkg1 of Ringer lactate solution was given before initiation of the spinal anaesthesia. The anaesthesiologist who performed the intrathecal injection and assessment of the spinal block, was blinded to the group of study solution. The study solution was prepared by another anaesthesiologist who was not involved in the clinical care of the patient. Insertion of the spinal needle was undertaken in aseptic conditions using a 25-G Quincke needle at the lumbar L3–L4 interspace with midline or paramedian approach. The patient was in the left lateral position when the spinal needle was inserted. Upon completion of the intrathecal injection, the patient was immediately turned back to a supine position. All patients were given supplementary nasal oxygen of 2 L min.[1] During the procedure electrocardiogram (ECG), heart rate (HR) and pulse oximetry were monitored

continuously. Non-invasive blood pressure was taken before the conduct of spinal anaesthesia, every 3 min for 15 min after the initiation of spinal anaesthesia and every 5 min thereafter. Sensory blockade was monitored using pin prick test, which was performed every 2.5 min for 15 min after the initiation of spinal anaesthesia and again at the end of the procedure. Motor blockade was assessed according to a modified Bromage Scale (0: no paralysis, able to flex hips, knees and ankles; 1: able to flex knees, unable to raise extended leg; 2: able to flex ankles, unable to flex knee; 3: unable to flex ankle, knee and hip) every 2.5 min for 15 min and at the end of the operation. The operation was started after the initiation of spinal anaesthesia if the level of sensory block had reached T10 or above. If the level of sensory block was inadequate, then general anaesthesia was given. Hypotension was defined as a decrease in the systolic blood pressure of more than 30% from the baseline or mean arterial pressure less than 65 mm Hg. This was treated with i.v. boluses of mephentermine 5 mg. Bradycardia was defined as a heart rate of less than 50 beats/ min and was treated with i.v. injection of atropine 0.5 mg. The onset of adequate sensory block was defined as the achievement of a sensory block level of T10 dermatome or higher. The addition of any sedative drugs, if required, was recorded. Patient satisfaction was assessed as good, fair or poor at the end of the operation. Adequacy of anaesthesia was assessed by the attending anaesthesiologist as good, fair or poor.

Results

50 patients were recruited in each group. There were no significant differences between the two groups for patient characteristic data, ASA classification and type of operation (Table 1). The baseline and intraoperative haemodynamic parameters were similar in both groups. The onset time for adequate level of sensory block, the highest level of sensory block (table 2) and degree of motor block were also similar in both groups (Table 3). The efficacy of both levobupivacaine alone and levobupivacaine with fentanyl was good. Anaesthesia was adequate and patient satisfaction was good in all cases. Two patients, one in each group, required supplementary sedation with i.v. midazolam 1 mg and 2 mg, respectively. Side-effects of anaesthesia with these two regimes were minor and infrequent. Three patients (12%) in the Group L had shivering. Hypotension occurred in four patients (16%), one in Group L and three in Group F. No patient had nausea, vomiting or pruritus.

It is a clinical randomized controlled double blind study with 100 patients randomly divided into 2 groups of 50 patients each, using permuted block randomisation technique in the ratio 1:1.

Group F – receiving intrathecal levobupivacaine with fentanyl. Group L– receiving intrathecal levobupivacaine alone

They were evaluated for hemodynamic variations, onset and duration of sensory and motor blockade, side effects of the drugs if any.

Demography

The groups are matched with respect to age and gender.

The mean age in Group L is 38.02±11.12 years and in Group F 37.42±10.82 years.

Weight and Height in this samples in the groups were matched.

Table 1: Surgical procedures carried out among the two groups.

Procedure	Levobupivacaine		Levobupivacaine with fentanyl	
	No	%	No	%
Anatomical repair hernia	7	14	6	12
Open appendicectomy	9	18	11	22
TURP	2	4	4	8
Post Laparotomy 2° suturing	3	6	1	2
Inguinal hernia mesh repair	15	30	12	24
Jabouley's procedure	3	6	5	10
Lumbar sympathectomy	3	6	3	6
Palmo's procedure	4	8	4	8
DJ stenting	4	8	4	8

Mean duration of surgery is statistically similar in two groups studied P = 0.091.

Table 2: Onset and duration of sensory blockade at L1 and T10.

Parameters	LevoLevobu-pivacaine group (n=50)	levobupivacaine with fentanyl Group (n=50)	P value
Onset of sensory block at L1 (min)	2.88±1.81	2.02±0.34	>0.05
Onset of sensory block at T10 (min)	5.14±3.76	3.24±1.98	>0.05

Table continued ...

Total duration of sensory block (regression to <L1)	190.04±35.19	209.02±34.74	>0.05

Table 3: Onset and total duration of motor blockade.

Parameters	LevoLevobu-pivacaine group (n=50)	Levobupivacaine with fentanyl group (n=50)	P value
Onset of Motor block B1(min)	3.12±1.62	3.02±0.65	>0.05
Total duration of motor block (B1- B0) min	176.65±40.64	179.46±30.84	>0.05

Discussion

This study was conducted to evaluate the hemodynamic variations, sensory and motor blocking properties of isobaric levobupivacaine 0.5% (15 mg) and isobaric levobupivacaine 0.5% (15 mg) with 10 mcg fentanyl.

Demographic data comparing age, sex, weight, height, ASA grade shows no statistically significant difference among both the groups.

This study found that 2.8 mL of 0.5% levobupivacaine with fentanyl 10 µg was an effective mixture for spinal anaesthesia in lower abdominal surgeries that required a sensory block to the T10 dermatome. The onset time, level of sensory block, degree of motor block and haemodynamic effects were similar between 3 mL of 0.5% levobupivacaine alone and 2.8 mL of 0.5% levobupivacaine with fentanyl 10 µg. Levobupivacaine has been found to be as effective as racemic bupivacaine in spinal anaesthesia.[5,6] The effect of adding fentanyl to bupivacaine for spinal anaesthesia has been studied. Ben-David and colleagues (1997) compared the use of 0.17% bupivacaine 3 mL with and without fentanyl 10 µg in spinal anaesthesia for arthroscopy.[8] The sensory blockade was significantly more intense with a lower failure rate in the group with fentanyl. Ben-David and colleagues (2000) compared the use of bupivacaine 4 mg with fentanyl 20µg and bupivacaine 10 mg in spinal anaesthesia for surgical repair of hip fracture in geriatric patients.[9] Both regimes were effective with less hypotension in the group with Levobupivacainefentanyl.

It was suggested that the intrathecal use of fentanyl had a synergistic effect with the low-dose bupivacaine in the achievement of a functional sensory blockade for surgical anaesthesia. The use of a low dose of bupivacaine was associated with a less sympathetic blockade resulting in lower incidence of hypotension. Choi and colleagues (2000) found that the intrathecal use of hyperbaric bupivacaine 8 mg with 10 µg of fentanyl was as effective as hyperbaric bupivacaine 12 mg in Caesarean section.[10] The addition of fentanyl had the advantage of a low incidence of excessively high block. Martyr and Clark (2001) compared the use of 7.5 mg hyperbaric bupivacaine with fentanyl 20 µg and 12.5 mg hyperbaric bupivacaine alone.[11] Both groups were equally effective with no differences in the incidence or severity of hypotension. Korhonen and colleagues (2003) found that 3 mg of hyperbaric bupivacaine with 10µg of fentanyl was as effective as 4mg of hyperbaric bupivacaine for knee arthroscopy.[12] The recovery of motor function was faster in the group with fentanyl. These studies confirmed the local anaesthetic dosesparing effect of fentanyl when it was added to bupivacaine for intrathecal use. This might be associated with less hypotension during spinal anaesthesia. The use of racemic bupivacaine with fentanyl in spinal anaesthesia for urological surgery is effective. Kuusniemi and colleagues (2000) studied the effect of adding fentanyl 25 µg to bupivacaine for spinal anaesthesia.[13] They found that the addition of fentanyl 25 µg to 5 mg of bupivacaine resulted in effective anaesthesia with motor block of short duration. While the addition of fentanyl 25 µg to 10 mg of bupivacaine increased the intensity and duration of motor block in comparison to bupivacaine 10mg alone. The incidence of pruritus in all patients with fentanyl was 30%. Goel and colleagues (2003) studied the addition of fentanyl to bupivacaine 5mg in spinal anaesthesia.[14] It was concluded that the addition of fentanyl 12.5µg provided better surgical anaesthesia and improved the reliability of block than fentanyl 7.5 or 10µg. Haemodynamic stability was good in all patients. The incidence of pruritus was 33%. Kararmaz and colleagues (2003) compared the intrathecal injection of bupivacaine 4 mg with fentanyl 25 µg (Group F) and bupivacaine 7.5 mg (Group B).[15] The density and duration of motor block were more in Group B. Both groups had adequate sensory block for surgery. Hypotension was more significant in the Group B (25% vs. 0%). The incidence of pruritus was 75% in Group F. These studies showed that the addition of fentanyl to bupivacaine for spinal anaesthesia would augment the effect of bupivacaine. This would allow the reduction in the dose of bupivacaine used and would increase the reliability of lower dose of bupivacaine used for spinal anaesthesia. This might result in less intensity of motor block and less hypotension. However,

the use of intrathecal fentanyl was associated with significant incidence of pruritus. The addition of fentanyl to levobupivacaine has been found to have a dose-sparing effect on the requirement of levobupivacaine for epidural analgesia in labour.[16] Intrathecal use of levobupivacaine has been studied. Our previous study with 2.6 mL of 0.5% levobupivacaine and that of Glaser and colleagues both found that 0.5% levobupivacaine and 0.5% bupivacaine have similar clinical effects, including sensory and motor block.[5,6] Intrathecal injection of an opioid with levobupivacaine had been studied by Vercauteren and colleagues.[17] They used 2 mL of 0.125% levobupivacaine or racemic bupivacaine with sufentanil 0.75 μg mL1 and epinephrine 1:800000 as the initial intrathecal injection for combined spinal–epidural analgesia in labour. They found that the levobupivacaine produced no motor block in comparison with 34% of patients in the bupivacaine group had motor block of Bromage Score 1. Our study found that 2.3 mL of 0.5% levobupivacaine with fentanyl 15μg was as effective as 2.6 mL of 0.5% levobupivacaine alone in spinal anaesthesia. The haemodynamic effects, the characteristics of sensory and motor block were similar. Hence, the addition of fentanyl had a dose-sparing effect with levobupivacaine in spinal anaesthesia. Nevertheless, the potential advantages of less motor block and less hypotension were not unveiled in the dose used in our study. The potential side-effects of spinal fentanyl such as the pruritus, nausea and vomiting did not occur in our patients. The potency ratio of levobupivacaine to racemic bupivacaine was 0.98 for epidural analgesia in labour pain.[4] Their potency ratio in intrathecal use has not been determined. Our choice of comparing 2.6 mL of levobupivacaine with 2.3 mL of levobupivacaine and fentanyl 15μg was based on our previous study on the efficacy of 2.6 mL of levobupivacaine in spinal anaesthesia for urological surgery and published result in the use of fentanyl with bupivacaine.[6,14] Further studies can be directed to find the optimal combination of levobupivacaine and opioid with maximal haemodynamic stability and least motor block, which may be useful for spinal anaesthesia in ambulatory surgery.

Conclusion

To conclude, our study demonstrates that 3 ml 0.5% isobaric levobupivacaine appears to be an similar to 2.8 ml 0.5% levobupivacaine with 10 mcg fentanyl for spinal anaesthesia in lower abdominal surgeries, in terms of similar hemodynamic changes, side effect, characteristics of sensory and motor blockade. The addition of fentanyl has a dose-sparing effect with 0.5% levobupivacaine in spinal anaesthesia. Both regimes are effective with minimal side-effects.

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