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Comparative study of intrathecal use of levobupivacaine and fentanyl versus bupivacaine and fentanyl in patients

undergoing lower abdominal surgeries

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Abstract

Introduction: Levobupivacaine ,the newer congener of bupivacaine is considered to be much safer local anesthetic agent than bupivacaine as per the literature review. But its efficacy and safety in spinal anesthesia for lower abdominal surgeries are yet to be established for indian population by comparing it with bupivacaine. This has become the aim of the study.

Method: Total 90 patients were enrolled (45 in each group) with double blinding randomization method. [Group A] received 7.5 mg (1.5 ml) of 0.5% isobaric levobupivacaine plus 1 ml of 5% dextrose and fentanyl 25 μ g (0.5 ml) making a total volume of 3 ml. [Group B] received 7.5 mg (1.5 ml) of 0.5% hyperbaric bupivacaine plus 1ml of normal saline and fentanyl 25 μ g (0.5 ml) making a total volume of 3 ml. Vital parameters, onset of sensory and motor blockage, two

segment regression time and duration of analgesia were compared using statistical analytic software

Observation and results:

Similar quality of sensory and motor blockade was found in levobupivacaine group like bupivacaine group. Only the onset time was slightly delayed in comparison with bupivacaine. Cardio stability, duration of analgesia, duration of analgesia were higher in contrast with bupivacaine (statistically significant)

Conclusion: Levobupivacaine is safer alternative to bupivacaine in spinal anesthesia for lower abdominal surgeries.

Keywords: Levobupivacaine, bupivacaine,

fentanyl, spinal anaesthesia

Introduction

Spinal administration of local anesthetics is a preferred technique for lower abdominal procedures as it produces analgesia, anesthesia, and motor block. Bupivacaine is the preferred drug in clinical practice as it provide rapid onset of anesthesia, analgesia, low cost, reduced risk of pulmonary aspiration, early patient mobilization and shorter hospital stay. However, this effect depends upon the volume, concentration, and doses of the drug used. (1) The enantiomer of bupivacaine (levobupivacaine) is less cardiotoxic and less neurotoxic in cases of accidental intravascular injection and has shorter duration of motor block than racemic bupivacaine. ⁽²⁾ Merging of local anesthetic drugs with adjuvants intrathecal have gained widespread popularity. Fentanyl is preferred adjuvant to bupivacaine as it increases the duration of sensory and motor blockage with minimum or no sedation.⁽³⁾ Very few clinical studies are available in with comparison of bupivacaine with fentanyl versus levobupivacaine with fentanyl for spinal anesthesia were done till now.

Aim

To compare anesthetic and analgesic effectiveness of low dose hyperbaric levobupivacaine(0.5%) and fentanyl (Group A) with low dose hyperbaric bupivacaine (0.5%) and fentanyl (Group B) in spinal anesthesia in lower abdominal surgeries.

Objectives

- To assess and compare the onset time and duration of sensory and motor block in both the groups
- To assess and compare hemodynamic variables in both the groups
- To assess and compare the duration of analgesia in both the groups
- To find out and compare proportion of cases with complications in both the groups

Materials and Methods:

After approval from the institutional ethical committee, 90 patients (45 in each groups) with American Society of Anesthesiologist risk grade I and II who were posted for elective lower abdominal surgeries included in this study.

Inclusion Criteria

- Age group between 20 and 50 years
- Weight of the patient between 40-70 Kgs
- Height of the patient > 145cm
- Patients belonging to ASA class-I and II
- Patients undergoing lower abdominal surgery

Exclusion Criteria

- Patient refusal for consent.
- Any deformity or local sepsis in spinal lumbar region
- Severe hypovolemia
- Increased intracranial pressure
- Any bleeding or coagulation abnormalities
- Uncooperative patients
- Patients with compromised airway or morbid obesity

Study Design, Patient Selection and Group Allocation:

This was Hospital based, comparative, randomized controlled, double blind interventional study. All patients under the study were subjected to a detailed pre anaesthetic examination and investigations. Patients were randomly divided using simple random technique through chit in box method, into two groups of 45 patients each.

Randomization: In this study both blinding and randomization were done by chit in box method. A total of 90 chits (45 per group) were made, each chit mentioning a particular study group. One of the anaesthesiologist asked the patient to pick up a chit from the box. Patient was allocated to group mentioned on the chit. Study drug was loaded by other anaesthesiologist and was administered to the patient. **Levobupivacaine Group [Group A]** (n=45): Patients received 7.5 mg (1.5 ml) of 0.5% isobaric levobupivacaine plus 1 ml of 5% dextrose and fentanyl 25 μ g (0.5 ml) making a total volume of 3 ml

Bupivacaine Group [Group B] (n=45): Patients received 7.5 mg (1.5 ml) of 0.5% hyperbaric bupivacaine plus 1ml of normal saline and fentanyl 25 g (0.5 ml) making a total volume of 3 ml

The solutions were prepared by the anaesthesiologist blinded to the study.

Basis of Sample Size - Sample size is calculated at 80% study power and alpha error of 0.05 assuming SD of 19.32 minutes in total duration of sensory block as found in study of Ayesha Goyal et al. 46 For minimum detectable difference of 12 minutes in total duration of sensory block,41 patients in each group were required as sample size. It was further enhanced to 45 patients in each group as final sample size for present study assuming 10% dropout/attrition.

After taking written informed consent from study participants, all routine monitors were attached and preoperative baseline readings of blood pressure (BP), Heart Rate (HR) and oxygen saturation were noted. A good IV line was secured with 18G cannula and Ringer Lactate infusion was started. Under all aseptic precautions, spinal anesthesia was performed in the operating room at the L3 – L4 or L2 – L3 interspace, with the patient in the sitting position. The drug combination was prepared by one anesthesiologist and was given by another experienced one who was blinded to the study drug used and did not take further part in the study. A volume of 3 ml was injected slowly through a 25-gauge spinal needle. Patient was placed in supine position with a 20° head down tilt immediately after spinal injection to achieve level of block of T6.

Both patients and the observer were blinded regarding to the study drug or the group.

Intra-Operative Monitoring

Vital parameters

All the below vital parameters were recorded at were recorded at 2, 5,10,15,30,40,50,60 min interval and post operatively at 30 min interval or until rescue analgesic given.

- Heart rate (HR)
- Noninvasive blood pressure (NIBP)
- Respiratory rate (RR)
- SpO2

Sensory Block

The level of sensory block was tested by pin prick bilaterally at midclavicular line which was done at every 2 minutes for 10 minutes after spinal injection, at the end of surgery and in recovery room until S2 segment regression.

Onset of sensory block was taken as the time taken to attain sensory level of T10 dermatome.

Time of onset of motor block was assessed using modified Bromage scale. Onset of motor block was taken as the time taken to achieve Bromage grade 1 block from the time of subarachnoid injection. Onset of highest motor block was recorded as time to reach highest scale of motor block. Motor block duration was recorded as time to complete termination of motor block.

Duration of surgery recorded as time taken from administration of local anesthetics till complete closure.

Complications

• Hypotension (MBP < 60 mmHg or greater than 25% below the baseline)

- Bradycardia (Heart Rate < 50/min)
- Respiratory depression (oxygen saturation less than 90%)

• Pruritus

- Nausea and vomiting
 - Headache

Management of complications

Episodes of intra-operative **hypotension** were managed with crystalloids 5-7 ml/kg, colloids 3 ml/kg and if required with bolus doses of inj. mephenteramine 6 mg intravenously. Bradycardia was treated with 0.01 mg/kg of inj. atropine intravenously. Intra-operative nausea was treated with inj. ondansetron 4mg and any pruritus was treated using antihistaminics.

Immediately after operation patients were shifted to recovery room. Following observations were recorded: Vital Parameters

Heart Rate, NIBP, SpO2 were recorded at regular interval of 30 min for 4 hours.

Two segment regression time (time of regression of sensory block by two segments from the highest level attained).

Duration of analgesia was observed and recorded following pain scoring system – Visual analogue score (VAS). The VAS consisted of a 10cm horizontal paper strip with two endpoints labelled —No Pain (0 point) and Worst pain ever (10 points). When patient complaint of pain in ward or recovery room, patient was asked to mark the strip at a point that corresponded to the level of pain intensity, they felt.

VAS score (4)

0	No Pain
1, 2, 3	Mild Pain
4, 5, 6	Moderate Pain
7, 8, 9	Severe Pain
10	Worst imaginable Pain

VAS score was serially assessed at half an hour interval starting from 60mins to 300 mins or till the patient complained of pain (VAS >3).

Duration of effective analgesia was measured as time from the intrathecal drug administration to the patient's VAS score > 3 either in the recovery room or the ward, and was recorded in minutes. **Patient's VAS>3 and administration of rescue analgesia constituted the end point of the study.** Inj. diclofenac (75mg) IM was given as rescue analgesic and 100 mg inj. tramadol IV through infusion if required. Patient was kept under observation for a total period of 24 hours for routine post-operative monitoring.

Degree of motor block was assessed by using 4 points Modified Bromage scale ⁽⁵⁾ which states that

1(Complete block)	Unable to move feet and knee
I(Complete block)	Unable to move feet and knee
2Almost complete	Unable to move the hip but is
	able to move the knee and ankle
3Partial block	Unable to move the hip and knee
	but is able to move the ankle
4(Between score 3	Unable to move the hip, knee
and 5)	and ankle
5(Full flexion at	No detectable weakness of hip
knee)	flexion whiule supine
6	Able to perform partial knee
	bend

Total duration of motor block was measured from anesthetic injection until the time to reach a Bromage score of 6.

Duration of sensory block was recorded from time to subarachnoid injection to complete reversal of sensory block.

Statistical analysis

Linear variables were summarized as mean and SD whereas nominal/categorical variables were

summarized as proportions (%). Unpaired t-Test was used for analysis of linear variables while Chi Square test/Fisher Exact test was used for nominal/categorical variables. For analysis within the group, Paired t-Test was used and between the groups, Student t-Test was used. For significance in difference in proportion of

cases with complications, Chi – Square test of significance was used. For significance, cut off values are as follows: p > 0.05 = not significant p < 0.05 = significant p = 0.05 = just significant p < 0.001 = highly significant (HS). Medcalc 12.2.1.0 version of software was used for all statistical calculations.

Observations and Results

Comparison of Demographic Data and Duration of Surgery

Table 1: Distribution of Cases According to Age, Weight and Height

	Group	N	Mean	Std. Deviation	P Value*
	Group A	45	34.91	7.70	
Age	Group B	45	34.29	7.33	0.695
	Group A	45	56.16	8.14	
Weight	Group B	45	54.73	7.82	0.400
	Group A	45	160.53	6.02	
Height	Group B	45	160.40	6.27	0.918

*Unpaired t'test

Table 2: Distribution of Cases According to Sex

	Group A		Group B		Total	
Sex	No.	%	No.	%	No.	%
Male	22	48.89	21	46.67	43	47.78
Female	23	51.11	24	53.33	47	52.22
Total	45	100.00	45	100.00	90	100.00

Fisher Exact Test P = 1.000

Table 3: Distribution of Cases According to ASA Grade

ASA Grade	Group A		G	roup B]	Total	
	No.	%	No.	%	No.	%	
Ι	36	80.00	34	75.56	70	77.78	
II	9	20.00	11	24.44	20	22.22	
Total	45	100.00	45	100.00	90	100.00	

Fisher Exact Test

P = 0.800

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	Group A		Group B		
	Mean	SD	Mean	SD	P-Value b/w Gps
Duration of Surgery (min.)	26.7	8.5	28.8	9.9	0.2909

Table 4: Distribution of Cases According to Duration of Surgery

Table 1,2,3 and 4 shows that both groups were comparable regarding mean value of age, weight, height, gender,

ASA grade and duration of surgery (P value >0.05). Statistically non-significant

Sensory Block Characteristics

Figure 1: Onset of Sensory Blockade (T 10)



Figure 1 shows that time to reach T10 sensory level was significantly delayed in group A as compared to group B. In group A, time to sensory onset was $(5.0 \pm 1.4 \text{ min.})$ and in group B was $(4.0 \pm 1.3 \text{ min.})$, **P = 0.001 (HS)**

 $\tilde{P}_{age}290$





Time to achieve highest level of blockade was $(9.2 \pm 2.5 \text{ min})$ in group A and $(7.4 \pm 1.9 \text{ min})$ in group B. P value between the groups is **<0.001 (HS)**. Thus, we observed that time to achieve highest level of sensory block was significantly delayed in group A. (Fig. 2)

Figure 3: Duration of Sensory Block



Mean duration of sensory blockade in group A was (186.6 ± 25.1 min) and in group B was (173.8 ± 22.3 min). Thus, we observe that group A produced longer duration of sensory block than group B and the difference was statistically significant (**P**<**0.05**). (Fig. 3)

Figure 4: Time to Two Dermatome Sensory Regression





Time for 2 segment regression was found to be $(90.0 \pm 14.9 \text{ min})$ in group A and $(85.6 \pm 16.3 \text{ min})$ in group B. The difference between two segment regression times was not significant in both groups (**P** >0.05). (Fig. 4). Figure 5: Onset of Motor Block



Mean time to motor onset in group A was $(3.5\pm1.5 \text{ min})$ and in group B was $(2.3\pm0.9 \text{ min})$. P value was < 0.001 (HS). This shows that group A has delayed onset of motor block as compared to group B. (Fig. 5)



Figure 6: Duration of Motor Block /Time Taken To Return To Bromage Score 0

Mean duration of motor block was $(85.9\pm11.4 \text{ min})$ in group A and $(138.6\pm27.4 \text{ min})$ in group B. Group A produced shorter duration of motor block than group B and the difference was highly significant (**P** <**0.001**). (Fig. 6)

 $\bar{\rm P}_{age}292$

Figure 7: Duration of Analgesia



Mean duration of analgesia was in group A was ($228.64 \pm 26.22 \text{ min}$) and in group B was ($210.06 \pm 35.25 \text{ min}$). We observed that group A produced longer duration of analgesia than group B and the difference was statistically highly significant (**P**<**0.001**). (Fig. 7).

Figure 8: Trend of HR over different time intervals in both groups



Figure 9: Trend of MBP in group A and B

Both groups were comparable with respect to MBP values over different time intervals. There was no significant fall in MBP in both groups at any time interval. (**P>0.05**). (Fig. 9)

 $\tilde{P}_{age}293$



Figure 10: Trend of VAS SCORE at Different Time Intervals



Trend of VAS score in both groups at different time intervals. VAS Score at 180 min was 2.3 in group A and 2.5 in group B. Rescue analgesic was given for VAS Score \geq 4. (Fig. 10).

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Table 5: Distribution of Cases According to the Surgery

Name of Surgery	Group	A	Group B	
	No.	%	No.	%
Inguinal Hernia	19	42.22	17	37.78
Infraumblical Incisional Hernia	10	22.22	11	24.44
Medical Termination of Pregnancy+	9	20.00	10	22.22
Sterilization				
High Inguinal Orchidectomy	7	15.56	7	15.56
Total	45	100	45	100

Table 5 shows that both the groups were comparable regarding the distribution of cases according to surgery.

Figure 11: Distribution of Cases According to Complications / Side Effects (Intra-Operative and Early Post-Operative)



Figure 11 shows that there was no significant difference in the incidence of side effects (e.g. hypotension, bradycardia, nausea and vomiting, shivering, pruritus) in both groups. (**P>0.05**).

Discussion

In this present study, combination of fentanyl with lowdose levobupivacaine induced delayed onset and long duration of sensory blockade and less motor blockade than low-dose bupivacaine in lower abdominal surgery under spinal anaesthesia. Low-dose levobupivacaine and low-dose bupivacaine combined with fentanyl did not produce any significant changes in hemodynamic parameters in both the groups.

The efficacy of neuraxial local anesthetics is enhanced by the addition of intrathecal opioids. It also allows the use of very low doses of local anesthetic, which contributes to more stable hemodynamics. Intrathecal opioids used as adjuncts are capable of producing

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analgesia of prolonged duration and allow early ambulation of patients. ⁽³⁾ This study was conducted in 90 patients scheduled to undergo elective lower abdominal surgery under spinal anesthesia. Low doses of hyperbaric levobupivacaine (7.5 mg) and hyperbaric bupivacaine (7.5 mg) were compared when combined with fentanyl (25 μ g) in spinal anesthesia.

Both our study groups were comparable with respect to age, height, weight, sex, ASA physical status and duration of surgery. (Table 1-4)

A) SENSORY BLOCK CHARACTERISTICS

1) Onset of sensory block and Time to highest level achieved

In our study time to onset of sensory block (time to reach T10 sensory block) was $(5.0 \pm 1.4 \text{ min})$ and $(4.0 \pm 1.4 \text{ min})$ \pm 1.3 min), P = 0.001 (HS) in groups A and B respectively. (Fig. 1 and 2). Mean time to reach highest sensory level was $(9.2 \pm 2.5 \text{ min})$ in group A and $(7.4 \pm$ 1.9 min) in group B, P<0.001 (HS). Thus we observed that onset of sensory block and time to achieve highest level significantly delayed sensory was in Levobupivacaine group as compared to bupivacaine group. Erdil F et al ⁽⁶⁾ in a prospectively randomised study compared 1.5 ml plain levobupivacaine 0.5% and 1.5 ml bupivacaine in combination with fentanyl 15 μ g for spinal anesthesia in eighty patients undergoing TURP. They found that time to reach T10 sensory block level and peak sensory block level as well as time to onset of motor block were significantly faster in bupivacaine group (P<0.05)

2) Duration of sensory block (Time to full recovery of sensory block)

Mean duration of sensory blockade in group A was $(186.6\pm25.1 \text{ min})$ and in group B was $(173.8\pm22.3 \text{ min})$. (P=0.0120). (Fig 3) This indicated that

Levobupivacaine had significantly longer duration of sensory block as compared to bupivacaine.

Similarly, Burnacu CL et al $^{(7)}$ demonstrated that regression time of spinal anesthesia was significantly longer in levobupivacaine group (210 ±63 min) than bupivacaine group (190 ±51 min). (P<0.05)

3) Two segment regression times and highest level of block achieved

Time for 2 segment regression was found to be $(90.0 \pm 14.9 \text{ min})$ in group A and $(85.6 \pm 16.3 \text{ min})$ in group B. The difference between two segment regression times was not significant in both groups (P >0.05). (Fig. 4). There was no significant difference in highest level of block achieved in both the groups, (P>0.05)

In similar study of Vanna O et al $^{(8)}$, 70 patients undergoing elective transurethral endoscopic surgery who received 2.5 ml of either 0.5% isobaric levobupivacaine (n = 35) or 0.5% hyperbaric bupivacaine (n = 35) intrathecally, in a randomized, double blind study. They found that two groups were similar in terms of time to Discussion 84 block suitable for surgery, duration of sensory block, time to two segments regression and time to T12 regression.

B) Motor Block Characteristics

1) Time to onset of motor block

The mean time to onset of motor block in group A was $(3.5\pm1.5 \text{ min})$ and in group B was $(2.3\pm0.9 \text{ min})$. This shows that group A has delayed onset of motor block as compared to group B. (P<0.001, HS) (Fig 5)

Goyal A et al ⁽⁹⁾ in there study, found that the time of onset of motor block in group bupivacaine (2.2 ± 0.59 min) was significantly shorter than group levobupivacaine (3.9 ± 0.71 min). Motor block developed faster and lasted longer with the hyperbaric bupivacaine.

2) Duration of Motor Block

We observed that mean duration of motor block was $(85.9\pm11.4 \text{ min})$ in group A and $(138.6\pm27.4 \text{ min})$ in group B. Group A produced shorter duration of motor block than group B and the difference was highly significant (P <0.001).(Fig 6)

Hakan Erbay R et al $^{(10)}$ observed in their study that time to a Bromage score of zero (duration of motor block) was shorter in group levobupivacaine (105±19 min) than in group bupivacaine (113±7 min), (P=0.04).

3) Degree of Motor Block

We observed that complete motor block (Bromage grade 3) was obtained in 24.44 % of patients in group A and 86.67 % of patients in group B in our study. (Fig 7) Camorcia M et al ⁽¹¹⁾ reported that intrathecal 0.5 % levobupivacaine had weaker motor block potency than 0.5 % bupivacaine in elective cesarean cases with CSE anesthesia technique.

C) Duration Of Analgesia

Mean duration of analgesia in group A was $(228.64\pm26.22 \text{ min})$ and in group B was $(210.06\pm35.25 \text{ min})$. (Fig. 7) This indicates that levobupivacaine fentanyl group produced longer duration of analgesia than bupivacaine-fentanyl group with significant difference (P<0.05)

Turkmen A et al ⁽¹²⁾ compared the anesthetic effects of intrathecal 7.5mg of 0.5% levobupivacaine + 15 μ g fentanyl (group L; n=25) and 7.5mg of 0.5% bupivacaine + 15 μ g fentanyl (group B; n=25) in patients posted for elective cesarean section. They observed that the duration of analgesia was longer in group levobupivacaine (118min) compared to group Bupivacaine (102 min), (P < 0.05).

D) Hemodynamic Parameters

Although levobupivacaine is less cardiotoxic and less neurotoxic as compared to bupivacaine, in our study, no clinically significant changes occurred in hemodynamic parameters (HR and MBP) in both the groups. (Fig 8, 9) This may be attributed to the low doses of local anesthetics used in our study. Many studies have shown similar results.

Lee YY et al ⁽¹³⁾ reported that 2.6 ml 0.5% Discussion 89 racemic bupivacaine and levobupivacaine have a nearly equivalent clinical profile and hemodynamic effects.

E) Complications/ Side Effects

There was no significant difference with respect to side effects (hypotension, bradycardia, Post-Operative Nausea Vomiting, shivering and pruritis in both the groups. (P>0.05). (Fig. 11)

Our findings are consistent with the study of Akcaboy EY et al ⁽¹⁴⁾ which states that haemodynamic parameters were comparable and stable during the procedure in both groups.

Misirlioglu K et al ⁽¹⁵⁾ studied seventy-two patients undergoing cesarean section with spinal anaesthesia using low-dose 0.5% levobupivacaine (7 mg) plus fentanyl 25 µg (group L) or low-dose 0.5% bupivacaine (7 mg) plus fentanyl 25 µg (group B) and found clinically effective anesthesia and block qualities. This study is in favor with our study findings of clinically comparable sensory and motor blockage with duration of analgesia with higher margin of safety with levobupivacaine group. Fatorrini F et al ⁽¹⁶⁾ compared VAS score as well as time for rescue analgesia in levobupivacaine versus bupivacaine group for orthopedic major surgeries and their conclusion was Levobupivacaine group was better alternative to bupivacaine for post-operative VAS score and time for rescue analgesia which is also in favor to our study.

Levobupivacaine, a new local anaesthetic, has been recently introduced into clinical practice because of its lower toxic effects for heart and central nervous system. It is a safe alternative to bupivacacine and can be used with fentanyl without clinically significant side effects for spinal anesthesia.

Conclusion

We concluded that low dose spinal anesthesia provides hemodynamic stability. Also levobupivacaine plus fentanyl is a better alternative to bupivacaine plus fentanyl as it provides longer duration of sensory block, good post-operative analgesia and lesser degree and shorter duration of motor block allowing early ambulation and faster discharge.

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