

Original research article

## Comparison Of Levobupivacaine And Levobupivacaine With Fentanyl Combination In Infraumbilical Surgeries Under Spinal Anaesthesia.

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### ABSTRACT

**INTRODUCTION:** When the intrathecal opioid drug was administered with the local anaesthetic in Spinal anaesthesia they develop the superior quality of analgesia. Fentanyl was found to provide safe potentiate of local anaesthetic effects by its increased lipophilic quality and decreased rostral spread. The present study was conducted to compare block characteristics of equal doses of isobaric levobupivacaine 0.5% (10 mg) with normal saline and isobaric levobupivacaine 0.5% (10 mg) plus fentanyl (25 µg), in infraumbilical surgeries under spinal anaesthesia.

**MATERIALS AND METHODS:** The present prospective observational study was conducted in tertiary health centre from January 2020 to June 2021 amongst 120 patients belong to ASA physical status I and II aged between 20 to 65years who underwent infraumbilical surgeries. Study population were divided into Group L: Group of 60 patients received 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 0.5 ml normal saline and Group LF: Group of 60 patients received 2 ml of 0.5% isobaric levobupivacaine (10mg) + 0.5 ml fentanyl (25 µg).

**RESULTS:** The mean time for onset of sensory blockade at T10 dermatome in group L (7.1±1.4 min) was late than in group LF (5±1.6 min). Higher dermatomal level of sensory blockade was achieved by addition of fentanyl. The mean time for maximum sensory blockade was earlier in group LF (8.1±1.7min) than in group L (15.6±2.1min.). Maximum motor blockade was achieved significantly earlier in group LF than group L. The total duration of sensory blockade was significantly prolonged in group LF than in group L. Total duration of analgesia in group L was 199.2 ± 10.7 min and in group LF was 263.2 ± 14.7 min.

**CONCLUSION:** It was concluded that addition of fentanyl to levobupivacaine leads to early onset of sensory blockade and prolonged duration of sensory blockade, motor blockade, stable hemodynamics and prolonged postoperative analgesia thus decreasing the doses of rescue analgesics.

**KEY WORDS:** Fentanyl, Levobupivacaine, Spinal anaesthesia, infraumbilical, adjuvant

### Introduction

Spinal anaesthesia is one of the most commonly used technique for surgeries in the infraumbilical region because of its reliability, cost effectiveness, effective analgesia effects, muscle relaxation and prolonged postoperative analgesia[1]. Spinal anaesthesia has advantages over general anaesthesia by decreasing poly pharmacy, minimal stress response,

optimal operating condition, ease of the technique, fast onset, effective sensory and motor blockade, intra and post operative pain relief, less failure rates, less chance of post-operative morbidity, cost benefits, early recovery, full preservation of mental status and normal reflexes.[2]

Levobupivacaine is an amino amide local anaesthetic which is the pure S (-) enantiomer of racemic bupivacaine, has strongly emerged as a safer alternative for regional anaesthesia than bupivacaine. Levobupivacaine has been found to be equally efficacious as bupivacaine, but with superior pharmacokinetics profile.[3] It is a long-acting amide local anaesthetic producing the differential neuraxial block which is with an early onset and longer duration of sensory block along with the shortest duration of motor block and less cardiac toxicity.[4]

To improve the block characteristics of intrathecally administered low dose local anaesthetics, addition of adjuvant is must. Intrathecal opioids enhance the sensory block without prolonging the motor and sympathetic block.[5] Opioids drugs were one of the important methods of postoperative pain managing technique as these drugs help to manage the neuroendocrine stress responses with regard to pain. When the opioid drug was administered with the local anaesthetic then they would develop the superior quality of analgesia in any type of surgical procedures.[6] Fentanyl was found to provide safe potentiate of local anaesthetic effects by its increased lipophilic quality and decreased rostral spread.[7] It has rapid onset of action, bind strongly to plasma proteins and potentiate afferent sensory blockade and facilitate reduction in dose of local anaesthetics.[8] The present study was conducted to compare block characteristics of equal doses of isobaric levobupivacaine 0.5% (10 mg) with normal saline and isobaric levobupivacaine 0.5% (10 mg) plus fentanyl (25 µg), in infraumbilical surgeries under spinal anaesthesia.

#### **MATERIALS AND METHODS:**

The present prospective observational study was conducted in Tertiary health centre from January 2020 to June 2021 amongst 120 patients belong to ASA physical status I and II aged between 20 to 65years who underwent infraumbilical surgeries selected after thorough history taking and clinical examination. Written valid Informed consent was taken from the patients for the procedure. Institutional Ethics Committee permission was granted.

#### **Sample Size:**

Total number of sample size derived from following formula:

$$n = 2 Z^2 S^2$$

d<sup>2</sup>

Z1=1.644 (alpha value), S2=1.480 (Pooled SD), d=0.5 (Absolute precision) will get n=47, by 10% of non-response rate adding in calculated value and rounding will get 60 in each group.

Study population were divided into two groups of 60 each, Group L and Group LF.

Group L: Group of 60 patients received 2 ml of 0.5% isobaric levobupivacaine (10 mg) plus 0.5 ml normal saline.

Group LF: Group of 60 patients received 2 ml of 0.5% isobaric levobupivacaine (10mg) + 0.5 ml fentanyl (25 µg).

Pre anaesthetic evaluation was done along with basic laboratory investigations. The entire procedure was explained to the patient in their own language.

**Inclusion Criteria:** Patients belonging to ASA-I or II, patients between the age of 20-65 years, patients giving written and informed consent and patients undergoing elective infra-umbilical surgeries were included in the study.

**Exclusion Criteria:** Patients refusal to participate in the study, history of allergy to local anaesthetic or opioids, septicaemia. Patients belonging to ASA- III to V, having pre-existing systemic disease, deformed spine and patient with history of bleeding disorder or anticoagulant disorder, patient with psychiatric disorder, local infection at the site of injection were excluded from the study.

### **Methodology:**

The procedure of spinal anaesthesia was explained to the patient. They were kept nil orally 10 pm onwards on the previous night and pre-medication was given in the morning Injection (inj.) ondansetron 4 mg. Before the commencement of anaesthesia, patients were instructed on the method of sensory and motor assessments. Under all aseptic pre-cautions and standard spinal anaesthesia was given. Patients in the group L administered with 2 ml 0.5 %levobupivacaine (10mg) with 0.5 ml normal saline. Group LF were administered with 2 ml 0.5 %levobupivacaine (10mg) with 0.5 ml of fentanyl (25 µg) Assessment of sensory and motor blockade was done using pin prick and Bromage scale respectively. The point of completion of injection of study drug was taken as the starting time.

The various characteristics of block were observed like, Time of onset of sensory block to T10, Maximum Level of sensory blockade, Time taken for maximum level of sensory blockade, Grade of maximum motor block achieved, Time for maximum motor block, Time taken to regression to T10 dermatome, Total duration of sensory blockade, Total duration of motor blockade, Total duration of analgesia, Total number doses of rescue analgesia, Haemodynamic parameters, Side effects like nausea and vomiting, hypotension, bradycardia, respiratory depression, urinary retention, pruritus if any were noted.

Degree of Sensory response was assessed by pin prick (Hollmen scale).

Degree of motor block assessed by Bromage scale

The surgical position was made in every patient after complete establishment of sensory and motor blockade. Cardio-respiratory parameters were monitored continuously and recordings were made every 5 min for first 30min, every 10min for next 30min and every 15min thereafter during intra operative period till the end of surgery.

Pain scoring was done using VAS score.

Rescue analgesia given to the patient experiencing pain of VAS  $\geq 4$  with inj. Diclofenac sodium 75 mg IM/IV.

After completion of surgery patients were shifted to recovery room. After observation in recovery room, patients were shifted to ward.

### **Statistical Analysis:**

Statistical analysis was performed with SPSS version 20. The results were compiled by using suitable tables and graphs whenever necessary. Quantitative data was presented with the help of Mean, Standard Deviation (SD). Qualitative data was presented with frequency and percentage tables. For Quantitative data Z test for large samples was applied and for Qualitative data Chi square test was applied. P value < 0.05 is taken as significant and P value < 0.001 as highly significant.

**RESULTS:**

The data was analysed amongst the 120 patients enrolled to compare block characteristics of equal doses of isobaric levobupivacaine 0.5% (10 mg) with normal saline and isobaric levobupivacaine 0.5% (10 mg) plus fentanyl (25 µg), in infraumbilical surgeries under spinal anaesthesia.

**Table 1: Distribution of patients according to Demography.**

Parameter	Group - L (Mean ±SD) N=60	Group - LF (Mean ±SD) N=60	P value
Age (in years)	42.33 ± 9.07	43.60 ± 8.44	0.4228
Body Weight (Kgs)	66.86±9.38	66.93±8.44	0.9658
ASA Grade- I	38(49%)	40(51%)	0.1465
ASA Grade- II	22(52%)	20(48%)	

Table no.1 shows that in the present study mean age distribution of patients in group L was 42.33 ± 9.07 years and group LF 43.60 ± 8.44 years. There were 38 patients of group L and 40 patients of group LF were ASA grade 1, 22 patients of group L and 20 patients of group LF were ASA grade 2. The mean body weight in group L was 66.86 ± 9.38 kg and in group LF it was 66.93± 8.44 kg. On applying Z test it was found that the difference was statistically not significant. (P value =0.9658).

**Table 2: Types of infraumbilical surgery in both the groups, N=120**

Type Of Surgery	Group L Frequency (%)	Group LF Frequency (%)
Hernioplasty	17(52)	16(48)
Hydrocele	16(48)	17(52)
Vesical calculus	6(50)	6(50)
Fistulectomy	5(56)	4(44)
Haemorrhoidectomy	6(46)	7(54)
Herniorrhaphy	4(44)	5(66)
Cystoscopy	6(55)	5(45)
Total	60(100)	60(100)

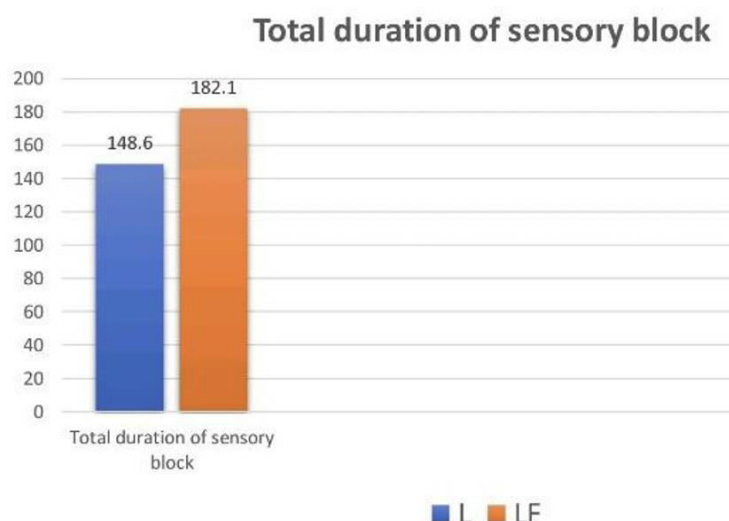
The various types of infra umbilical surgeries were comparable between two study groups. Hernioplasty, Hydrocele, Vesical calculus, Fistulectomy, Haemorrhoidectomy, Herniorrhaphy, Cystoscopy were the surgeries performed in both the groups.

**Table 3: Distribution of patients according to Sensory block.**

Indicator	Group - L (Mean ±SD)	Group - LF (Mean ±SD)	P value
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	(Min.) N=60	(Min.) N=60	
Onset of sensory block (mins)	7.1±1.4	4.7±1.5	<0.0001
Time to achieve highest sensory level(mins)	15.6±2.1	8.1±1.7	<0.0001
Regression to T 10 dermatome (min)	95.9±4.8	106.9±5.4	<0.0001
Total Duration of Sensory Blockade	148.6±6.5	182.1±5.9	<0.0001

Table no.3 shows that the mean time for onset of sensory blockade at T10 dermatome in group L was  $7.1 \pm 1.4$  min and  $4.7 \pm 1.5$  min in group LF. The dermatomal sensory level up to T6 was found in 21 patients in group L and 36 patients in group LF and up to T8 was 38 patients in group L and 20 patients in group LF. The time for maximum sensory blockade was  $15.6 \pm 2.1$  min in group L and  $8.1 \pm 1.7$  min in group LF. The mean total duration of sensory blockade was  $148.6 \pm 6.5$  min in group L and in group LF it was  $182.1 \pm 5.9$  min. It was found that mean total duration of sensory blockade was prolonged in group LF as compared to group L. On applying Z test the difference was found to be statistically highly significant. (P value<0.0001).



**Figure 1: Total duration of sensory blockade**

**Table no.4: Distribution of patients according to Motor block.**

Indicator	Group - L (Mean ±SD) (Min.) N=60	Group - LF (Mean ±SD) (Min.) N=60	P value
Degree of Maximum motor blockade Bromage -II	53	52	0.7825
Degree of Maximum motor blockade Bromage -III	7	8	
Time for Maximum Motor blockade	11.8±2.2	8.2±1.7	<0.0001
Duration of motor block(mins)	151.5±9.4	188.2±9.8	<0.0001

Table no.4 shows that the mean of maximum degree of motor block in both group L and

group LF was grade II of Bromage scale and was not significant.

The mean time for maximum motor blockade was  $11.8 \pm 2.2$  min in group L and  $8.6 \pm 1.7$  min in group LF. The mean duration of motor blockade was  $151.5 \pm 9.4$  min in group L while it was  $188.2 \pm 9.8$  min in group LF. Total duration of motor blockade was prolonged in group LF than group L, the difference was found to be statistically highly significant. ( $P < 0.0001$ ).

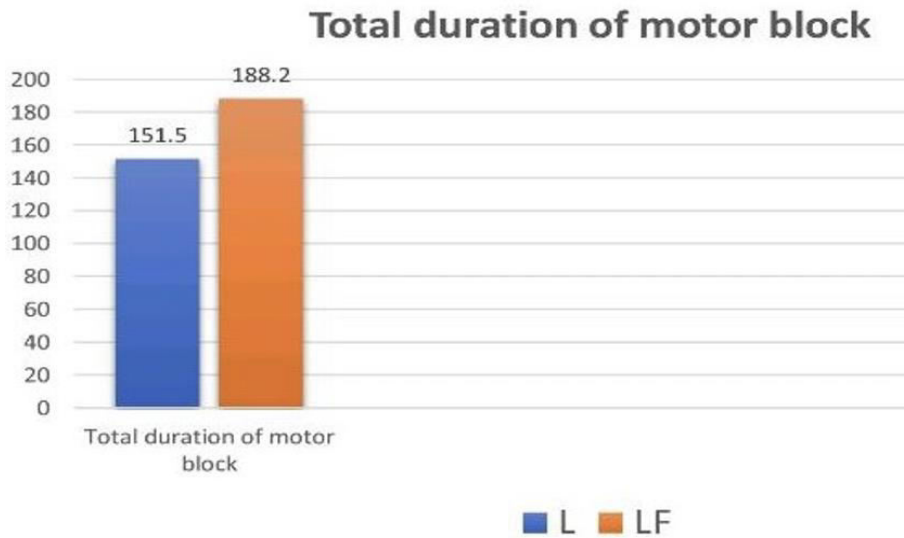
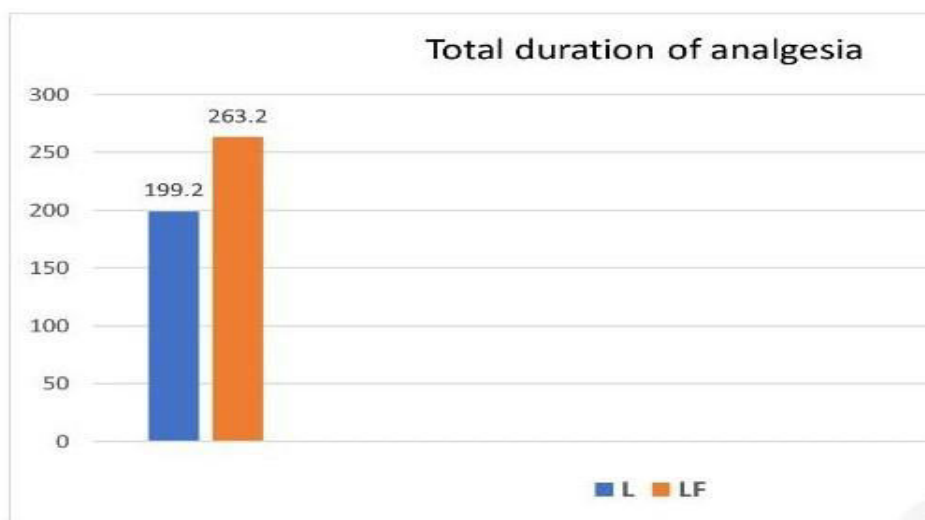


Figure 2: Total duration of Motor blockade

Table 5: Distribution of patients according to total duration of analgesia.

Indicator	Group - L (Mean $\pm$ SD) (Min.) N=60	Group - LF (Mean $\pm$ SD) (Min.) N=60	P value
Duration of analgesia	199.2 $\pm$ 10.7	263.2 $\pm$ 14.7	<0.0001

Table no.5 shows that the mean time required for rescue analgesia was min. in group L  $199.2 \pm 10.7$  min while it was  $263.2 \pm 14.7$  min. in group LF. Total duration of analgesia was found to be prolonged in group LF as compared to group L. This was found to be statistically highly significant. ( $P < 0.0001$ )



**Figure no. 3: Total duration of analgesia****DISCUSSION:**

Intrathecal opioids as an adjuvant to low dose local anesthetics, produces a synergistic effect by acting directly on the opioid receptors in the spinal cord<sup>64</sup>. Fentanyl a  $\mu$  receptor agonist, phenylpiperidine compound is increasingly used as adjuvant to spinal anaesthesia, stimulates both  $\mu_1$  and  $\mu_2$  receptors and potentiates the afferent sensory blockade<sup>26</sup>. Fentanyl added to local anaesthetic agent seems to be the most frequently used combination to enhance and increase the recovery from spinal anaesthesia.<sup>[9]</sup>

From table no.1 both the groups were comparable in age distribution. The number of male patients in group L was 24 while in group LF it was 52. The number female patients in group L were 36 while in group LF it was 8. Both the groups were comparable in gender distribution.

In our study demographic profile study was found to be statistically not significant. Nimisha P et al [10] also found that there was no statistically significant difference among two groups in terms of demographic data. Girgin et al [11] found there was no statistically significant difference among two groups in terms of demographic data.

From table no.3 it is evident that there was faster onset in group LF as compared to group L, which was found to be statistically significant.

Belgin Akan et al [12] in their study observed onset time of sensory blockade at T10 dermatome to be  $10.2 \pm 2.0$  min in group receiving levobupivacaine alone and  $6.9 \pm 1.70$  min in group receiving levobupivacaine with fentanyl. Thus, they found earlier onset in group of patients receiving fentanyl. which was similar to results of our study.

In the study done by Nesrin et al [13], found time for sensory block to reach T10 dermatome was 11(6-15) minutes in Group of patients receiving levobupivacaine alone and 2.50(1-10) minutes in Group receiving levobupivacaine with fentanyl, which correlates to our study.

Also, we observed in our study that maximum dermatomal sensory level was found to be higher in group LF in comparison to group L. The difference was found to be statistically significant ( $p < 0.05$ ) Wasudeo et al [14] also found that more patients had higher dermatomal level of sensory blockade those who receiving fentanyl (T6) than those who receiving plain levobupivacaine. The result correlates to our study. Nesrin et al [13] found that highest sensory block level was T4, similar in both fentanyl and plain levobupivacaine groups, and no significant difference was observed between two groups.

From results we found that time for maximum sensory blockade in group LF was earlier than in group L which was statistically significant.

Nimisha P et al [10] noticed time for maximum sensory blockade to be earlier in group receiving fentanyl ( $4.26 \pm 0.97$  min.) as compared to group receiving levobupivacaine plain ( $4.28 \pm 1.31$  min.) finding was similar to our study. Wasudeo et al [14] found in their study that group receiving fentanyl had earlier maximum sensory blockade ( $6.90 \pm 2.8$  min.) than in group receiving plain levobupivacaine ( $9.34 \pm 1.93$  min.)

From table no.4 we found that mean maximum degree of motor block in both L and LF group was grade 2 of Bromage scale. It was found to be statistically non-significant. Joginder pal Attri et al [15] also found that mean of maximum motor block achieved in both the groups was Bromage 2. Nimisha P et al [10] observed that mean maximum Bromage grade achieved was 2 in both fentanyl and plain levobupivacaine group. Hence, they concluded that addition

of fentanyl intrathecally did not affect the degree of motor block, which was similar to our study.

Also, time for maximum motor blockade in group LF was earlier than in group L. The difference was found to be statistically significant. Joginder pal Attri et al [15] also found time for maximum motor blockade earlier ( $8.38 \pm 1.78$  min.) in patients receiving fentanyl than in patients receiving plain levobupivacaine ( $12.26 \pm 1.85$  min.) which was similar to our study.

In the present study total duration of sensory blockade was more in group LF was than in group L. The difference was found to be statistically significant. Joginder pal Attri et al [15] also found total duration of sensory blockade was more in group receiving fentanyl ( $270.98 \pm 28.60$  min.) than in group receiving plain levobupivacaine ( $197.58 \pm 11.20$  min.) Mohan S et al [16] found in their study, total duration of sensory block was more in patients receiving fentanyl ( $361.3 \pm 3.22$  min.) than in patients receiving plain levobupivacaine ( $334.1 \pm 10.65$  min.) which was statistically significant.

In the present study total duration of motor blockade in group LF was more than in group L. The difference was found to be statistically significant. Belgin Akan et al [12] also observed in their study that total duration of motor block was more in patients receiving fentanyl ( $100.0 \pm 21.80$  min.) than in patients receiving plain levobupivacaine ( $152.6 \pm 38.00$  min.), which was similar to our study.

Wasudeo et al [14] in their study observed total duration of motor blockade was more ( $145.35 \pm 19.19$  min.) in patients receiving levobupivacaine with fentanyl than in patients receiving levobupivacaine alone ( $129.23 \pm 18.73$  min.).

In the present study time to regression to T10 dermatome in group LF was prolonged than in group L. The difference was found to be statistically significant. Nesrin et al [13] found in their study, regression time to T10 dermatome was more in patients receiving fentanyl ( $115.71 \pm 23.67$  min.) than in patients receiving plain levobupivacaine ( $101.53 \pm 15.12$  min.) which was similar to our study.

In present study total duration of analgesia was more in group LF than in group L which was statistically significant. Wasudeo et al [14] also observed that total duration of analgesia was more in group receiving fentanyl ( $180.46 \pm 35.13$  min) than in group receiving levobupivacaine plain ( $154.72 \pm 35.23$  min). Which was similar to our study. Joginder pal Attri [15] et al found that that total duration of analgesia was more in group receiving fentanyl ( $265.16 \pm 26.18$  min.) than in group receiving levobupivacaine plain ( $168.16 \pm 11.08$  min). Which was similar to our study.

Inj. Diclofenac (75 mg) consumption was significantly decreased in group LF as compared to group L. Differences in total number of doses of inj. Diclofenac was highly significant ( $P < 0.0001$ ).

Belgin Akan et al [12] had observed that incidence of post operative analgesic request was lower in the group with levobupivacaine combined with fentanyl than the group with levobupivacaine alone. Nesrin et al [13] had observed that additional use of analgesics during the postoperative first 24 hours was significantly lower in the fentanyl group, the use of additional analgesics was highest in the plain levobupivacaine group.



In our study, there was no significant change in HR from baseline in both the groups throughout the study period. Joginder pal attri et al [15] found in their study found that 5 (10%) patients in fentanyl group and 2 (4%) patients in plain levobupivacaine had bradycardia, which was similar to our study.

In present study there was no statistically significant difference in mean arterial pressure between group L and LF. Belgin Akan et al [12] observed that there was no significant fall in MAP in plain levobupivacaine group and levobupivacaine with fentanyl group. Joginder pal Attri et al [15] found in their study found that 6 (12%) patients in fentanyl group and 4 (8%) patients in plain levobupivacaine had fall in MAP. Which was statistically not significant.

Incidence and difference of side effects were found statistically not significant in group L and LF.

Nimisha P et al [10] observed 2 patients in group L and 4 patients in group LF reported nausea and vomiting, pruritus in 3 patients of group LF. They found that side effects were comparable and there was no significant differences in term of side effects among two groups. Wasudeo et al [14] observed that there was no significant difference in incidence of side effects such as headache, nausea and vomiting and pruritus among two groups.

#### **CONCLUSION:**

We concluded that addition of fentanyl to levobupivacaine leads to early onset of sensory blockade and prolonged duration of sensory blockade, motor blockade, stable hemodynamics and prolonged postoperative analgesia thus decreasing the doses of rescue analgesics.

**DECLARATION OF CONFLICT OF INTEREST:** There is no conflict of interest of any author

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