

Research Article

A comparative study of hyperbaric bupivacaine versus hyperbaric bupivacaine and fentanyl (12.5 mcg) in subarachnoid anesthesia for lower abdominal and lower extremity surgeries

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ABSTRACT

Background: This study evaluated the effects of adding Fentanyl 12.5 mcg to hyperbaric Bupivacaine 0.5% for spinal anesthesia with regards to the onset of sensory block, maximum sensory level reached and the time to achieve it, time to two dermatome segment regression, onset of motor block, time for maximum motor blockade, duration of motor block, hemodynamic parameters and incidence of side effects.

Methods: Sixty patients, male and female, ASA I or ASA II, aged 18 to 65 years scheduled for elective lower abdominal and lower extremity surgeries were randomized into two groups. Group C (Control group) received 0.5% hyperbaric bupivacaine 13 mg (2.6 ml) and Group S (Study group) received 0.5% hyperbaric bupivacaine 13 mg (2.6 ml) and 12.5 mcg of fentanyl (0.25 ml). Intraoperatively, sensory parameters were assessed by pin-prick method and motor parameters were assessed by modified Bromage scale at different time intervals. Haemodynamic parameters were monitored and side effects were also observed.

Results: Both groups were comparable with respect to age, height, weight and duration of surgery. There was statistically significant difference with regard to the onset of sensory block, maximum dermatome level, time to achieve it and time to two segment regression between the two groups. Motor parameters did not differ.

Conclusions: It was concluded that the addition of 12.5 mcg Fentanyl to 13 mg of hyperbaric Bupivacaine 0.5% for spinal anesthesia significantly decreases the onset of sensory block, enhances the maximum dermatome level and also prolongs the time to segment regression with better hemodynamic stability.

Keywords: Spinal anaesthesia, Hyperbaric bupivacaine, Fentanyl 12.5 mcg, Sensory block

INTRODUCTION

Spinal anesthesia is a safe, convenient and economical form of regional anesthesia technique. It results in sympathetic blockade, sensory analgesia, and motor blockade depending on the dose, concentration or volume of local anesthetic agent administered.¹ Bupivacaine is the most common local anesthetic agent used. The desired effect is to block the transmission of nerve signals to and from the affected area.²

Spinal anesthesia has many advantages over general anesthesia which makes it the anesthesia of choice in the present surgical practice. Its advantages include:³ Profound muscle relaxation, decreased intra-operative blood loss, preferable in patients suffering from respiratory diseases, early return of gastrointestinal function after surgery, suppress the neuroendocrine response to surgery, better analgesia than parenteral opioids in the postoperative period, reduce perioperative

morbidity and mortality in high- risk patients, reduction in hypercoagulable state associated with surgery.

However, these advantages are oppressed by limited duration of action of spinal anesthesia and by uncomfortable postoperative period when its action wears off.

In order to prolong the duration of analgesia, using a higher dosage of local anesthetic agent can lead to undesirable hemodynamic disturbances such as hypotension and bradycardia as a result of a high block.³

Hence, various adjuvants have been added to intrathecal bupivacaine and they include; adrenaline, clonidine, ketamine, phenylephrine, midazolam, neostigmine and opioids such as morphine and fentanyl.⁴

In view of the above, this study was undertaken to evaluate the effects of hyperbaric bupivacaine in combination with fentanyl (12.5 mcg) in subarachnoid block for lower abdominal and lower extremity surgeries.

METHODS

This prospective, randomized, comparative study was conducted on 60 patients during the period from April 2015 to July 2015 at Mamata General and Superspeciality hospital, Khammam, Telangana, India. Permission from the hospital ethics committee was obtained.

60 patients, both male and female, aged between 18 to 65 years were chosen and categorized as either ASA Physical Status I or II. They were randomly divided into two groups having 30 patients each:

1. Group C (control group) received intrathecal 13 mg (2.6 ml) of hyperbaric Bupivacaine 0.5% only.
2. Group S (study group) received intrathecal 13 mg (2.6 ml) of hyperbaric Bupivacaine 0.5% and 12.5 mcg of fentanyl (0.25 ml).

Exclusion criteria: Emergency surgery, any infection at puncture site, bleeding tendencies, any previous allergic reaction to bupivacaine or fentanyl, kyphoscoliosis

Preoperative evaluation was done and informed written consent was taken.

An intravenous line was secured with 16-18G cannula and patients were preloaded with approximately 10 ml/kg of Ringer's lactate solution over 20 minutes.⁵ Basic vital parameters noted. Under strict aseptic conditions subarachnoid block was performed at the level of L4-L5 interspace with 25 g pencil point spinal needle in sitting position. The drug injected at the rate of 0.2 ml/sec. Patient was then immediately placed in the supine position with the operation table in neutral position. Oxygen 2 L/min was administered through nasal cannula

throughout the surgery. All the preoperative and procedural criteria for subarachnoid block were strictly followed.

Parameters observed and recorded

- 1) Assessment of sensory blockade
 - A) Onset of sensory block. Assessed by pin-prick method every one minute interval after intrathecal injection, till T12 dermatome was reached.
 - B) Maximum level of sensory block reached.
 - C) Time to reach maximum level of sensory block.
 - D) Time to 2 segment regression. Two dermatome segment regression time from the highest sensory level was assessed at every 15 minutes interval.
- 2) Assessment of motor blockade
 - A) Onset of motor block. - Patient's inability to lift straight extended leg. (Bromage grade 1). It was assessed at every one minute interval after intrathecal injection.
 - B) Degree of muscle relaxation-Recorded according to modified Bromage scale at every one minute interval after intrathecal injection.
 - C) Duration of motor block.
- 3) Vital parameters

Patient's baseline pulse rate and blood pressure were recorded. These parameters were again recorded after subarachnoid block, at every 2 minutes interval up to 20 minutes and then every 10 minutes thereafter till 120 minutes.

- 4) Side effects/complications, if any

Incidence of bradycardia, hypotension, nausea, vomiting, pruritus, respiratory depression (SpO₂) value of less than 90% and urine retention were noted and treated.

Data collection

Data was collected by filling the case record form which contained background information such as age, gender, weight, height, type and duration of surgery, relevant laboratory investigations results, sensory parameters, motor parameters, hemodynamic changes & side effects.

Analysis of data

Collected data was analyzed using SPSS software version 19.0. Demographic data was analyzed by Student's t-test.

Quantitative data was analyzed by Student’s t-test for independent samples whereas qualitative data was analyzed by Pearson’s Chi-square test. All values were expressed as mean ± standard deviation and p value <0.05 was considered statistically significant.

RESULTS

Demographic profile:

Mean age distribution of patients involved in the study.

Mean scores of two groups showed no significant statistical difference with regards to age (p value >0.05).

Male-female ratio between the two group:

In group C, 66.7% male patients and 33.3% female patients. In group S, 60.0% male patients and 40.0% female patients.

Mean weight, height and duration of surgery of both groups:

Both groups were comparable with regards to weight, height and duration of surgery (p value >0.05).

Types of surgeries performed in both groups:

The distribution of surgeries performed was approximately same in both groups.

Study results

Sensory Parameters

Onset of sensory block (Table 1):

Mean time for onset of sensory block was 4.60 ± 0.53 min for control group while for study group; it was 3.07 ± 0.47 min. Independent Samples t-test was used. This was statistically significant with a p-value < 0.05. Box and whisker diagram plot shows that onset of sensory block was faster in study group compared to control group (Figure 1).

Table 1: Mean onset of sensory block between two groups (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Onset of sensory block (min)	Control	30	4.6033	0.52816	0.09643	<0.001
	Study	30	3.0667	0.47149	0.08608	

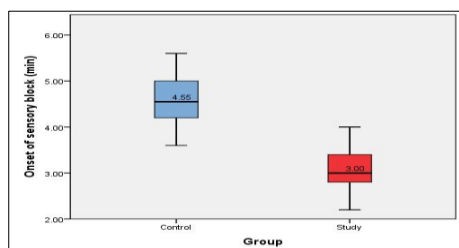


Figure 1: Mean onset of sensory block of two groups (in min).

Maximum sensory level reached (Table 2) (Values are in number and percentage).

Pearson’s Chi-square test was used to investigate on the difference between two groups. It was statistically significant with a p value <0.05. This implied that highest sensory level was achieved in study group.

Highest sensory level recorded for control group was T4 for study group it was T6 (Figure 2).

Table 2: Maximum sensory level. Group cross tabulation.

	Control group		Study group		Total	p value
	Count	%	Count	%		
Maximum sensory level	T4	0	0.0	1	3.3	<0.001
	T6	5	16.7	12	40.0	
	T7	2	6.7	11	36.7	
	T8	13	43.3	6	20.0	
	T9	7	23.3	0	0.0	
	T10	3	10.0	0	0.0	
Total	30	100	30	100	60	

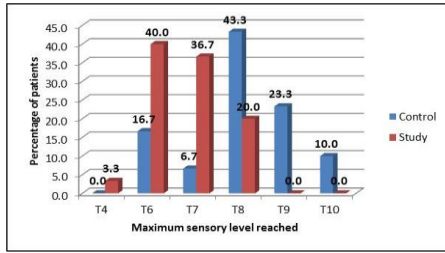


Figure 2: Maximum sensory level achieved.

Table 3: Mean time to reach maximum sensory level (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Time to reach maximum sensory level	Control	30	22.5000	3.40132	0.62099	<0.001
	Study	30	17.9333	2.16450	0.39518	

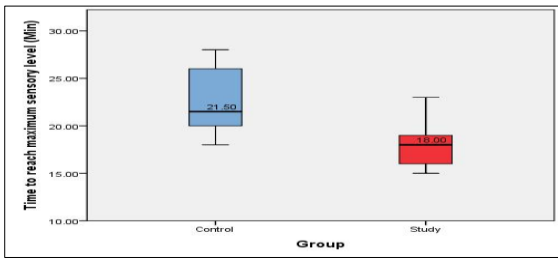


Figure 3: Mean time to reach maximum sensory level (in min).

Time to reach maximum sensory level (Table 3):

Mean time to reach maximum sensory level was 22.50 ± 3.40 min for control group and 17.93 ± 2.62 min for study group. Student’s t-test for Independent Samples was used. The difference was statistically significant with a p value <0.05. Box and whisker diagram plot shows that mean time to reach maximum sensory level was less in study group compared to control group (Figure 3).

Time to 2 segment regression (Table 4):

Mean time to two segment regression was 88.73 ± 9.09 min for control group and 112.43 ± 6.55 min for study group. Student’s t-test for Independent Samples was used to compare mean scores. This difference was statistically significant with a p value <0.05.

Box and whisker diagram plot shows that mean time to two segment regression was considerably more in study group compared to control group (Figure 4).

Table 4: Mean time to two segment regression (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Time to 2 segment regression	Control	30	88.7333	9.09313	1.66017	<0.001
	Study	30	112.4333	6.54788	1.19547	

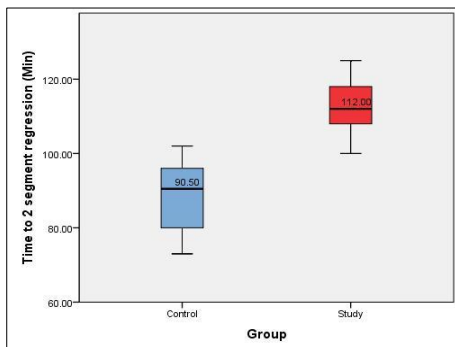


Figure 4: Mean time to two segment regression of both groups (in min).

Motor parameters

Onset of motor block (Table 5): In both the groups there was no statistically significant difference (p value >0.05)

Time to reach maximum motor block (Table 6): Difference on mean time to reach maximum motor block between two groups was found to be insignificant (p value >0.05).

Duration of motor block (Table 7): There was no statistically significant difference between two groups with regards to duration of motor block (p value >0.05).

Table 5: Mean time for onset of motor blockade (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Onset of motor block (min)	Control	30	3.2500	0.40578	0.07408	0.745
	Study	30	3.2833	0.38424	0.07015	

Table 6: Mean time to reach maximum motor block (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Time to reach motor block	Control	30	9.4500	1.30219	0.23775	0.193
	Study	30	9.9300	1.51114	0.27590	

Table 7: Mean duration of motor blockade (in min).

	Group statistics					
	Group	N	Mean	Std. Deviation	Std. Error Mean	p value
Duration of motor block	Control	30	183.3000	12.02053	2.19464	0.620
	Study	30	184.8667	12.35044	2.25487	

Hemodynamic parameters

1) Pulse rate

Difference between two groups was not significant at any evaluation times as evidenced by the p values >0.05. A decrease in mean pulse rate was noted for both groups, with stabilization after 30 minutes (Figure 5).

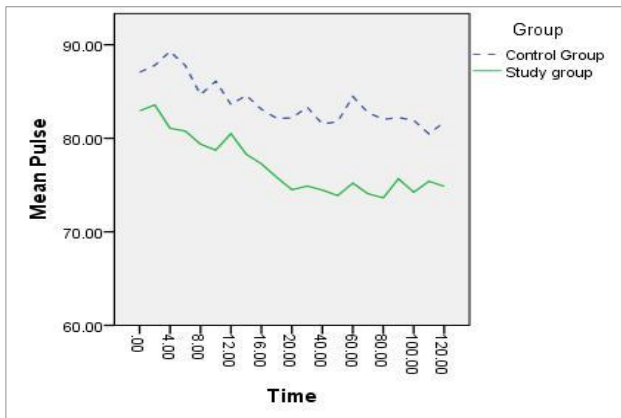


Figure 5: Mean heart rate of both groups (BPM).

2) Systolic blood pressure

Difference between mean intra-operative systolic blood pressure was found to be statistically significant (p value <0.05) during initial 30 min. A decrease in mean systolic blood pressure for both groups was reflected in the graph, which eventually stabilized after 30 minutes (Figure 6a).

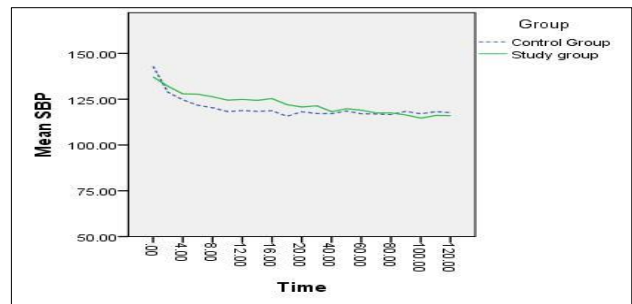


Figure 6a: Mean systolic blood pressure of two groups (in mmHg).

3) Diastolic blood pressure

It can be noted from the graph that there was a decrease in mean diastolic blood pressure for both groups, which got stabilized after 30 minutes (Figure 6b).

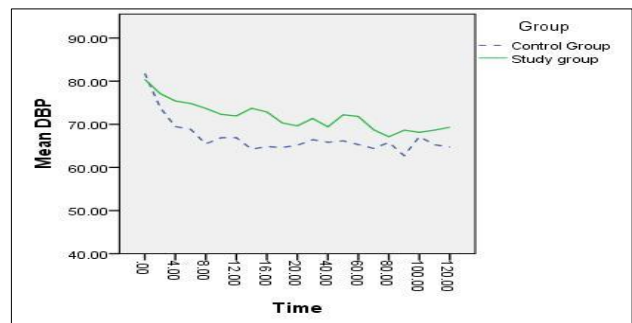


Figure 6b: Mean diastolic blood pressure of both groups (in mmHg).

4) Mean arterial pressure

The difference between two groups was found to be statistically significant (p value <0.05) during initial 60 minutes. Drop in mean arterial pressure was of higher magnitude in control group compared to study group (Figure 6c).

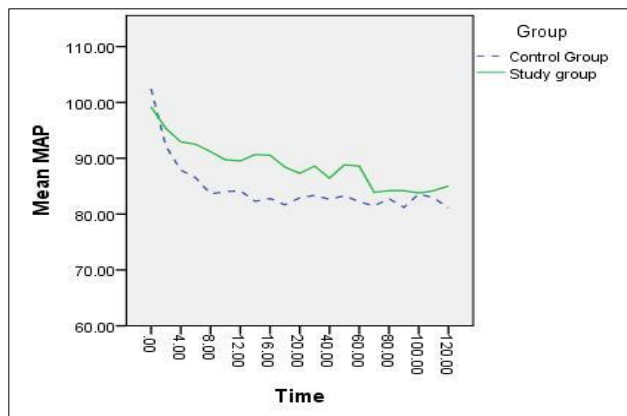


Figure 6c: Mean arterial pressure of both groups (in mmHg).

5) Oxygen Saturation (SpO₂)

Both groups did not differ significantly with respect to oxygen saturation (p value >0.05).

Complications (Table 8)

In study group, 4 patients had pruritus compared to none in control group. This was statistically significant with p value <0.05. There was no statistically significant difference among other side effects like bradycardia, hypotension, nausea, vomiting and urine retention.

Table 8: Complications observed.

	Control group		Study group		p value
	Count	% of patients	Count	% of patients	
Bradycardia	7	23%	2	7%	0.071
Hypotension	5	17%	4	13%	0.718
Nausea & vomiting	4	13%	1	3%	0.161
Pruritus	0	0%	4	13%	0.038
Respiratory depression	0	0%	0	0%	NA
Urine retention	1	3%	2	7%	0.554

DISCUSSION

Subarachnoid block is commonly employed for lower abdominal and lower extremity surgeries as it is a simple and reliable technique with many potential advantages.

Drug which is most commonly used for subarachnoid block is bupivacaine. One disadvantage of using bupivacaine alone for spinal anesthesia is that analgesia ends with sensory regression of the block. This leads to an early need for analgesics to abolish postoperative pain. Despite recent advances in the development of newer analgesics, many patients continue to experience considerable pain after surgery, which cause discomfort and adverse effects on cardio-respiratory system.

Spinal anesthesia with hyperbaric bupivacaine can be prolonged with addition of adjuvants such as epinephrine and phenylephrine. However, they have been found to cause neurological side-effects due to reduced blood supply to the spinal cord.⁵ Intrathecal Ketamine leads to delirium, nystagmus, nausea, vomiting, sedation and hypersalivation.⁶ Other additives which can be used include; buprenorphine, clonidine, dexamethasone, midazolam & neostigmine. Midazolam produces sedation and Neostigmine causes excessive nausea and vomiting.

Effective pain control is essential for optimum care of all patients in postoperative period. Addition of an opioid like fentanyl to bupivacaine can provide effective intraoperative as well as postoperative analgesia with minimal side effects. Potential synergism between fentanyl and bupivacaine has been reported by Ben-David B et al.⁷

In the present study advantage of hyperbaric Bupivacaine 0.5% and 12.5 mcg (0.25 ml) of Fentanyl intrathecally was assessed.

Demographic profile across the group

Both groups were comparable with respect to age (p value 0.176), weight (p value 0.574), height (p value 0.322) and duration of surgery performed (p value 0.438). In Group C, male patients were 66.7% and female patients were 33.3%. In Group S, there were 60.0% male patients and female patients were 40.0%.

Sensory parameters

Onset of sensory block

In present study, the mean time for onset of sensory block in Group C was 4.60 ± 0.53 min and 3.07 ± 0.47 min in Group S. (Table 1 and Figure 1). Onset of sensory block was faster in Group S compared to Group C. Faster onset of sensory block in study group can be explained by the fact that Fentanyl is highly lipid soluble and rapidly binds to opioid receptors present in the dorsal horn of spinal cord.⁸ Independent Samples t-test was used to investigate on the significance of difference between two groups. The latter was found to be statistically significant at 5% level of significance as a p value <0.001 was revealed by the procedure. This was similar to a study done by Motiani P et al.⁹ where they found a significantly quicker onset of sensory block in all those patients who belonged

to fentanyl group (4.73 ± 1.77 min) as compared to those patients who belonged to control group (7.26 ± 2.10 min).

Highest sensory level achieved

In control group, none of the patients attained T4 level. In study group, 3.3% patients reached T4 level, 40.0% achieved T6 level, 36.7 % achieved T7 level, 20.0% achieved T8 level (Table 2 and Figure 2). Results show that highest level of sensory block was achieved in study group. Fluctuating pressure changes occur in cerebrospinal fluid due to respiration and cardiac cycle. This creates a backward and forward movement of cerebrospinal fluid such that after intrathecal injection, net transfer of fentanyl occurs in a cephalad direction.⁸ This explains the higher sensory levels achieved in fentanyl group compared to control group. p value was found to be <0.001 . Singh H et al.¹⁰ found similar results in his study where highest sensory level was achieved in fentanyl group (T7) as compared to control group (T8).

Time to reach maximum sensory level

Time to reach maximum sensory dermatome level in Group C was 22.50 ± 3.40 min compared to 17.93 ± 2.16 min in Group S. (Table 3 and Figure 3). This difference was statistically significant with p value <0.001 . Similarly, Seewal R et al.¹¹ noted that time to reach maximum sensory level was less in fentanyl group (6.2 ± 3.0 min) as compared to control group (10.3 ± 2.9 min). Above results show that bupivacaine 13 mg in combination with Fentanyl 12.5 mcg has helped to reduce the time to achieve maximum dermatome level.

Time to two segment regression

Time to two sensory segment regression in group C was 88.73 ± 9.09 min compared to 112.43 ± 6.55 min in Group S. (Table 4 and Figure 4). Duration of action of intrathecal heavy bupivacaine 0.5% is 90-200 minutes¹ whereas duration of action of intrathecal fentanyl is 4-6 hours.⁸ This explains the considerably longer duration of analgesia in the study group when compared to using bupivacaine alone.

Singh H et al.¹⁰ observed that the time to two segment regression in control group was 74 ± 18 min and in fentanyl group it was 110 ± 33 min. Their results were also similar to this study. Similarly, Choi DH et al.,¹² Wong CA et al.,¹³ Techanivate A et al.¹⁴ and Bogra J et al.¹⁵ found that time to two segment regression was prolonged in fentanyl group compared to control group.

Seewal R et al.¹¹ found that addition of 10 mcg of fentanyl to 11 mg of heavy bupivacaine 0.5% enhanced the duration of analgesia. Seewal R et al.¹¹ study showed that no further benefit was noted when the dose of fentanyl was increased to 20, 30, or 40 mcg. The results of this study correlate with the above-mentioned studies.

Onset and duration of motor blockade

In Group C, mean time for onset of motor block was 3.25 ± 0.41 min, mean time to reach maximum motor block was 9.45 ± 1.30 min and mean duration of motor block was 183.30 ± 12.02 min. In Group S, mean time for onset of motor block was 3.28 ± 0.38 min, mean time to reach maximum motor block was 9.93 ± 1.51 min and mean duration of motor block was 184.87 ± 12.35 min (Table 5, 6, 7). There was no statistically significant difference between the two groups in terms of onset (p value 0.745), time to reach maximum motor block (p value 0.193) and duration of motor block (p value 0.620). Since duration of motor block was not prolonged in fentanyl group, venous return to right side of the heart was maintained by calf muscles contraction. Similar to this study, Singh H et al.,¹⁰ Choi DH et al.,¹² Bogra J et al.¹⁵ and Motiani P et al.⁹ found that complete muscle relaxation was observed in all of the studied patients. Moreover, addition of fentanyl to bupivacaine had no effect on the onset and duration of motor block.

Hemodynamic parameters

Two groups did not differ significantly with respect to heart rate at any interval (p value >0.05). During first 30 minutes following intrathecal injection, a general decrease in average pulse rate was noted for both groups. However, after 30 minutes pulse rate for both groups got stabilized (Figure 5).

It was also noted that drop in systolic and mean arterial pressure during initial 30 minutes following intrathecal injection was of higher magnitude in control group compared to the study group. This difference was found to be statistically significant (Figure 6a, 6b, 6c). After approximately 20-30 min, the blood pressure in both groups got stabilized. Bogra J et al.¹⁵ found that the maximum drop in systolic blood pressure occurred after 25 minutes in all the groups and they also concluded that addition of fentanyl to hyperbaric bupivacaine improved hemodynamic stability. Wang et al.¹⁶ observed that when fentanyl was combined with intrathecal bupivacaine, it acted synergistically to enhance the effect of bupivacaine on sensory afferent pathways without any effect on sympathetic outflow. This explains the stable hemodynamic parameters in fentanyl group despite the fact that higher sensory levels were achieved.

Comparison of side effects (Table 8)

Oxygen saturation remained stable throughout the intraoperative period. There was no statistically significant difference between the incidence of bradycardia, hypotension, nausea, vomiting, urine retention and Respiratory depression between both the groups. However, 4 patients complained of pruritus in fentanyl group and none in the control group. This difference was statistically significant with p value of 0.038. The etiology of pruritus is not fully understood but

it is believed to be due to the cephalad migration of fentanyl to the trigeminal nucleus which is rich in mu opioid receptors. Incidence of pruritus in this study was more in the facial areas. Similar observations were made by Kuusniemi KS et al.,¹⁷ Martyr JW et al.,¹⁸ Wong CA et al.,¹³ Seewal R et al.¹¹ and Motiani P et al.⁹ who reported that incidence of pruritus was more in fentanyl groups. Varassi G et al.¹⁹ observed that in elderly patients, episodes of pruritus, nausea and vomiting occurred when either 25 or 50 mcg of fentanyl were added to 15 mg of bupivacaine. Along with pruritus, nausea and vomiting, they also noted an increased incidence of respiratory depression in 50 mcg fentanyl group. No such side-effects were observed in the group where only 12.5 mcg of fentanyl was used.

CONCLUSION

On the basis of this clinical comparative study, it was concluded that addition of 12.5 mcg of fentanyl to 13 mg of hyperbaric bupivacaine 0.5% for spinal anesthesia:

- Significantly decreases onset of sensory block, enhances maximum dermatome level and prolongs the time to segment regression with better hemodynamic stability.
- Does not have any effect on the onset of motor block and it does not prolong the motor recovery time.
- Produces minimal intraoperative and postoperative side effects.

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Conflict of interest: None declared

Ethical approval: The study was approved by the hospital ethics committee

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