

## **Effect of Ketamine versus Fentanyl as an Adjuvant in Intrathecal Injection of 0.5% Hyperbaric Bupivacaine in Lower Limb Surgeries.**

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### **Abstract**

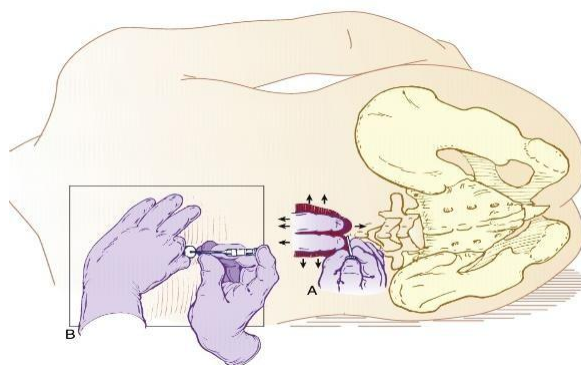
A prospective, randomized study was the effect of ketamine versus fentanyl as an adjuvant in intrathecal injection of 0.5% hyperbaric bupivacaine in lower limb surgeries. The present study includes the prospective double-blind randomized trial to ascertain the duration of sensory blockade when using ketamine versus fentanyl as an adjuvant in intrathecal injection of 0.5% hyperbaric bupivacaine in lower limb surgeries.

**Keywords :** fentanyl, bupivacaine, Quincke's needle, regression time and VAS Score

### **1. Introduction**

However, the most widely employed method for spinal surgery is due to its quick and effective density and neuromuscular blockade because of this allows the operation to last for a very long time. The patients' recovery from general anesthesia Due to the known dangers of using high amounts of bupivacaine, this combination with a local anesthetics, an attempt can be made to diminish the amount of the local side effects in order to the minimum necessary concentration; then, if the use of large volumes doesn't eliminate any of them, a smaller amount of the local side effects would, no anesthetic is enough. anesthetics, such as antidepressants, alpha agonists, are usually added in order to overcome the hemodynamic instability; as in this case, neostigmine, vasoconstrictor, ketamine, and other adjuvants such as M The needle is used to administer adjuvants like bupivacaine, epidurally, p to counteract the occurrence of vascular constriction or unstable bone anesthetics, as well as to keep them from disappearing. A provides an option to avoid or decrease the amount of general anesthesia, allowing you to avoid or/reduce the risk of nausea and/allows you to avoid or risk of nausea, allows you to stay awake when having an operation 6. There are several

benefits to the use of anesthetics, such as lower likelihood of complications and long response periods, such as shivering, but longer-acting varieties include the usage of long- anesthetic actions have to it that many medications are applied due to the fact that there is concern about toxicity and the length of anesthetics Of interest in this analysis is the review of the additive effects on intrathecal administration of Bupivir and hyperbaric-induced anesthesia of incapnea parameters.



**Figure1: Method of insertion of the spinal needle**

## 2. MATERIALS AND METHODS

This study was done in 60 patients who are divided into two groups. Written informed consent was taken from all patients. It was a prospective randomized double blinded study where the lots were picked randomly. The 60 patients were randomly allocated into two groups 30 each.

Group K - received Hyperbaric Bupivacaine	0.5%	3ml	with
5mg preservative free Ketamine			
Group F - received Hyperbaric Bupivacaine	0.5%	3ml	with
10mg Fentanyl			

### Inclusion criteria :

- ASA I, II patients
- Age 20 – 75 years

- Height: 150 – 170 centimeters
- Patients undergoing elective lower limb surgeries with duration less than 2 hrs.

**Exclusion criteria :**

- Patient refusal
- Morbidly Obese patients
- Spinal deformity
- Patients with neurological disease
- Other contraindications
- Coagulopathies
- Any other

**Preoperative preparation:**

- Routine pre-operative assessment as for all elective surgery.
- Name, IP No., Age, Sex, Weight, Height, ASA, Diagnosis, type of surgery and duration of surgery are to be recorded

**Procedure Details:**

- Anesthesia workstation list, which involves routine checking of the crash cart, has been completed Ana-anesthetics are stored ahead of time and prepared ahead of time
- S and pulse oxim and thermod ramp up to baseline are all minimum requirement sets of sensors that are attached to the patient and diastolic and systolic blood pressure, as well as the patient's heart rate, oxygen saturation, and pulse rate. IV cannulation has been completed. A Ringer's solution is being preloaded into the patient.
- strictly anaerobic precautions, an epidural is done in the epidural space of 25 gauge isostric. following making sure the CSF flow is clear, the medication is injected patients will be shifted into the supine position after the injections are completed
- Once the extent of sensory block has been reached, the surgeons will ask the patient to continue with the operation.

### **Parameters recorded:**

### **Hemodynamic parameters:**

- An non-invasive blood pressure and oxygen saturation was checked twice (including during surgery) before the hour, as well as every 15 minutes after the procedure to see if the pulse rate returned to normal after 1 hour
- to reduce drop in mean arterial pressure 20% or less than 90 mm Hg systolic pressure is treated with an epinephrine bolus (6 mg).
- Regardless of the age of the patient's age, any amount of decreased heart beat that is less than 60 per minute (min) should be treated with atropine 0.6 mg

### **Sensory blockade:**

- This is done by measuring the three different body temperatures for 1 minute, then doing pricking the line in the mid axillary artery, and finally asking people to report how their discomfort has changed It should be reported that the greatest sensory blockade would be reached.
- The onset of sensory block is characterized as the time from when the drug is administered at L1.
- When the pinprick feeling at the L5 dermatome has recovered, the sense of expansion is taken to be significantly reduced
- Also known as sensory level recovery time, L1 to the return of sensory loss, sensory recovery time is the period between the beginning of sensory block and its decay.
- It was noted that it takes two segments to go from the peak of sensory to original and down to the trough of sensory.
- At the most skin sensitizing, there is no discernible block in the upper dermatome dermatome It is also known how long it takes to hit the highest dermatome.

### **Motor blockade :**

Motor block is assessed by the Modified Bromage score

<b><i>SCORE</i></b>	
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1	He was unable to move or do something about his feet or legs for weeks
2	Almost complete block (able to move feet only)
3	Partial block (Just able to move knees)
4	The presence of some sag in the prone position is a bad sign, but the greater degree of sag in the less flexible side could be cause for concern.
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend.

- Once motor block has arisen, the current should be held at 1 mA for one minute.
- the moment at which the medication has been administered, whether from the method of giving the injection but not seeing it take effect, or when the onset occurs (Bromage Score-1). the length of time over which one's motor recovery has been described as '6' bromage Score 6 is defined as total return of motor power.
- the recovery period of full recovery time is described as the time from the onset of complete motor block to the first partial recovery

#### Quality of block is graded as

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**Adequate**      **no sedation / analgesia**  
**required.**

**Inadequate**      **need for additional analgesia.**  
**Failed**              **GA required.**

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- If the level of analgesia is inadequate or failed the regimen is switched to GA and excluded from the study.
- After attaining adequate level of sensory block,

the surgeons would be asked to proceed with the surgery.

- Duration of surgery is noted.
- Post-operative VAS scoring is also recorded for comparison.

### Statistical Tools:

a large database for each of details on all of the selected was entered into a Master Chart 1 that can store 2, which allows for data recording on everything about everything InSackler to investigate disease trends and growth patterns of all humans in the population of Equestria to examine the influence of computers on human diseases and development (EPI 2008).

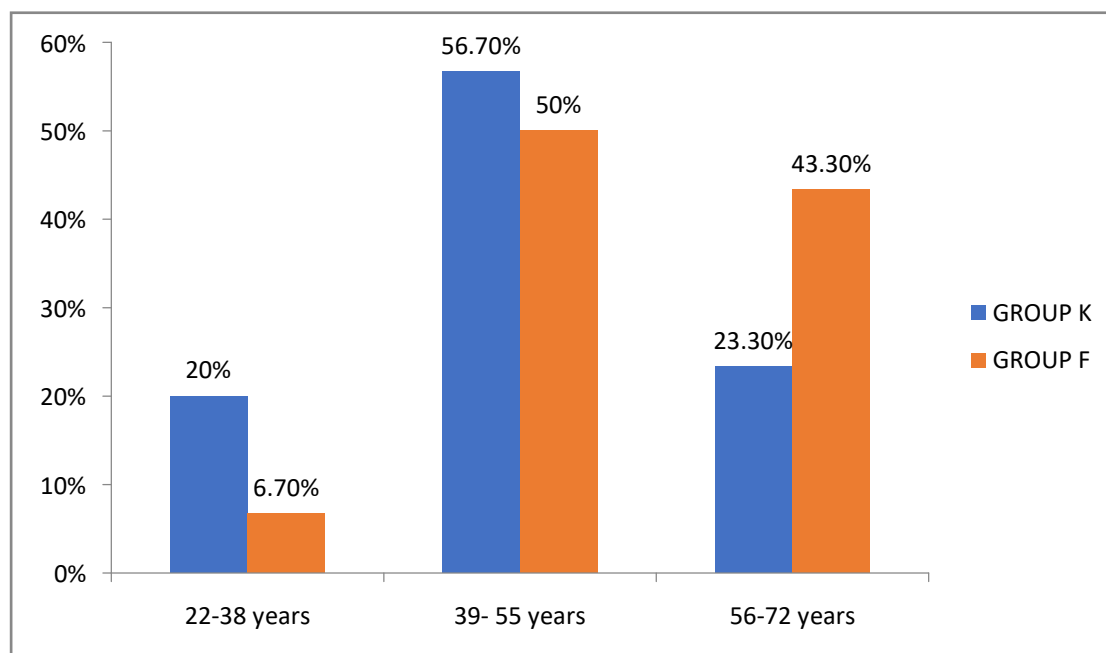
Using these software functions, frequencies, statistics, degrees of freedom, standard deviation, 'p' values, and the chi-square and 'p' values, a new probabilities were estimated. The Kruskal Wallis test was applied to determine the importance of the two groups' qualitative differences and Yate's test was used to evaluate the discrepancy between the two variables Where a 'p' value is less than 0.05, you are saying that the association between two variables is a big.

### 3. Results

Age (in years)	GROUP F	%	GROUP K	%	p- value
22-38 years	2	6.7%	6	20%	0.141
39- 55 years	15	50%	17	56.7%	
56-72 years	13	43.3%	7	23.3%	
<b>TOTAL</b>	30	100.0	30	100.0	

**TABLE 1: Age of the participants across the both groups**

Among the total cases, In Group K, majority (56.7%) belonged to the age group of 39-55 years, followed by 56-72 years (23.3%). In Group F as well, majority belonged to the age group of 39-55 years, that is 50%, followed by 56-72 years which corresponds to 43.3 %. There was no statistically significant difference across both the group ( $P > 0.05$ ), which means both the group were comparable.



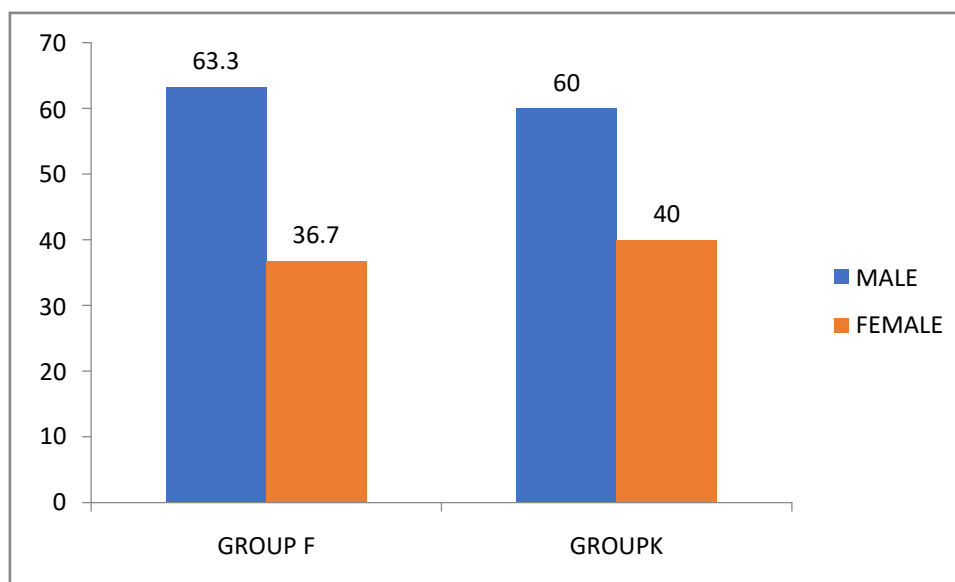
**Figure 8: Age group of participants across both the groups**

## 2. Distribution of the participants according to the gender across both the groups

GENDER	GROUP F	%	GROUP K	%	p-value
MALE	19	63.3	18	60	1.00
FEMALE	11	36.7	12	40	
TOTAL	30	100	30	100	

**TABLE 2: Distribution of the participants according to the gender across both the groups**

Both the groups had majority of males – 63 % and 60 % in Group F & Group K respectively. Both the groups were statistically comparable and were not statistically significant. ( $P=1.00$ )



**Figure 9: Distribution of the participants according to the gender**

### 3. Distribution of the participants according to the Height

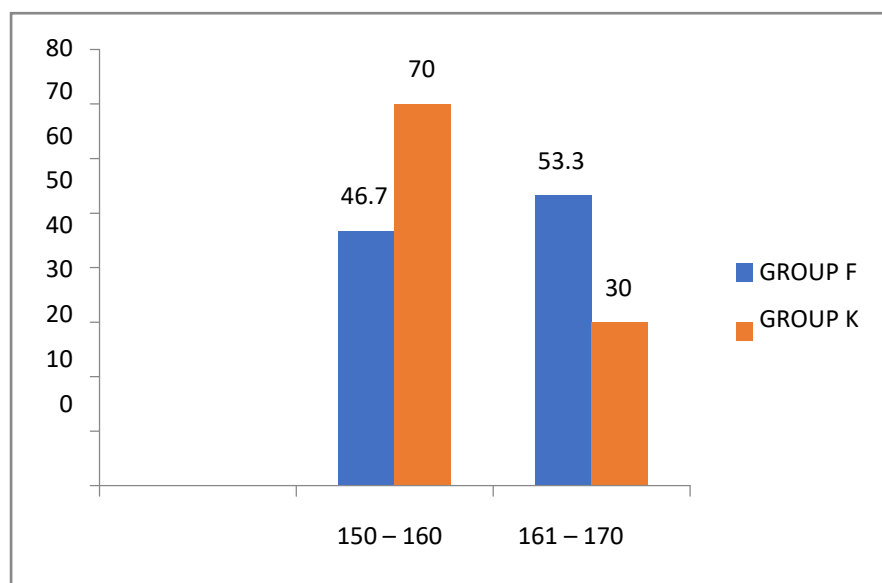
HEIGHT (cm)	GROUP F	%	GROUP K	%	p-value
150 – 160	14	46.7	21	70	0.3147
161 – 170	16	53.3	9	30	
<b>TOTAL</b>	30	100	30	100	

**TABLE 3: Distribution of the participants according to the Height**

Group F had 53.3% of the samples from the height between 161 – 170 cm and 46.7 % from the height between 150 – 160 cm whereas Group K had 70 % from the height 150



– 160 cm and 30% from the height between 161 – 170 cm. Both the groups were statistically comparable and showed a statistical insignificance. ( $P > 0.05$ )



**Figure 10: Distribution of the participants according to the Height**

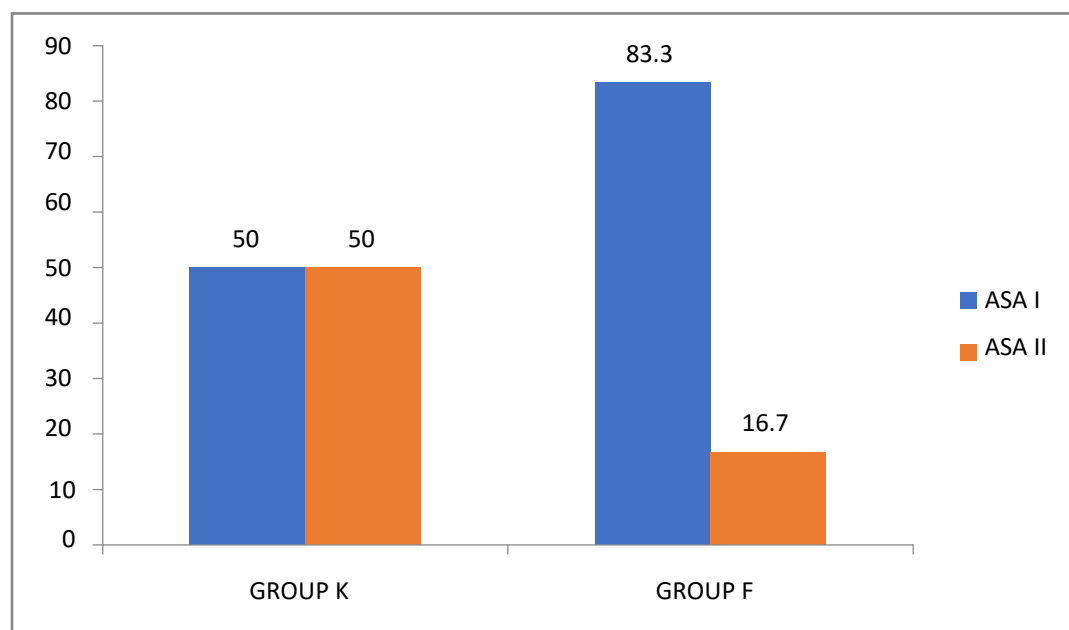
#### 4. ASA CLASSIFICATION across both the groups

ASA CLASSIFICATION	GROUP F	%	GROUP K	%	p-value
ASA I	25	83.3	15	50	0.013
ASA II	05	16.7	15	50	
TOTAL	30	100	30	100	

**TABLE 4: ASA CLASSIFICATION across both the groups**

In group K equal participant belonged to ASA I and ASA II. While in group F, 83% were from ASA I.

There was statistically significant difference across the groups with p value=0.013 ( $P < 0.05$ )



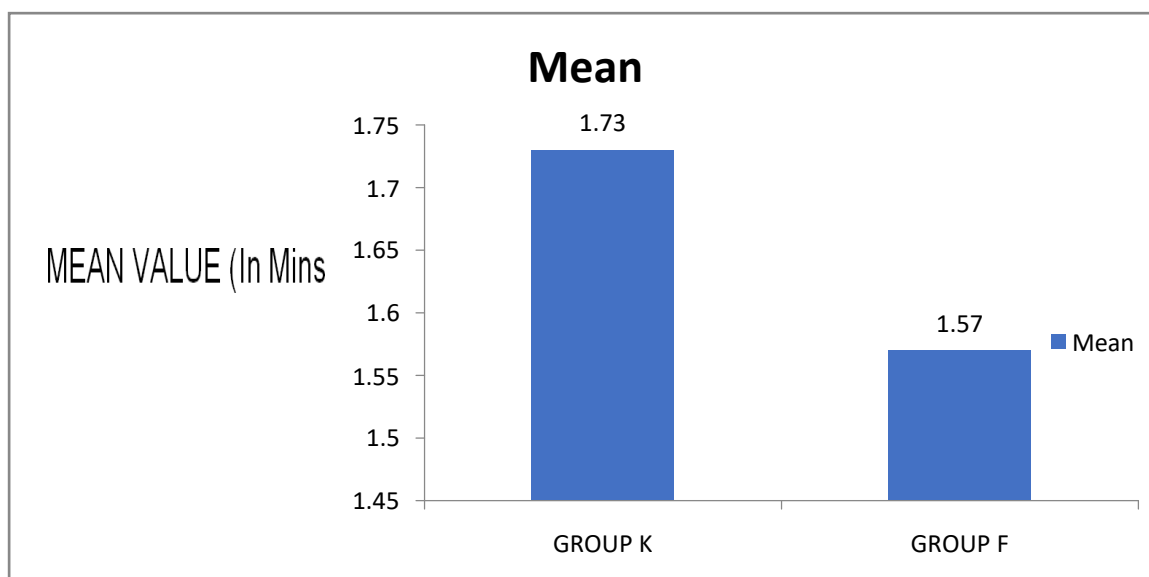
**Figure 11: ASA classification across both the groups**

## 5. ONSET OF SENSORY BLOCK

ONSET OF SENSORY BLOCK (Min)	GROUP F	GROUP K	p-value
Range	1-3	1-3	0.0412
Mean	1.57	1.73	
SD	0.626	0.640	
TOTAL	30	30	

**TABLE 5 : ONSET OF SENSORY BLOCK**

Group K had mean onset of sensory block in 1.73 minutes & Group F had the mean onset of sensory block is 1.57 minutes. Statistically significant difference was seen in the onset of sensory block across both the group.



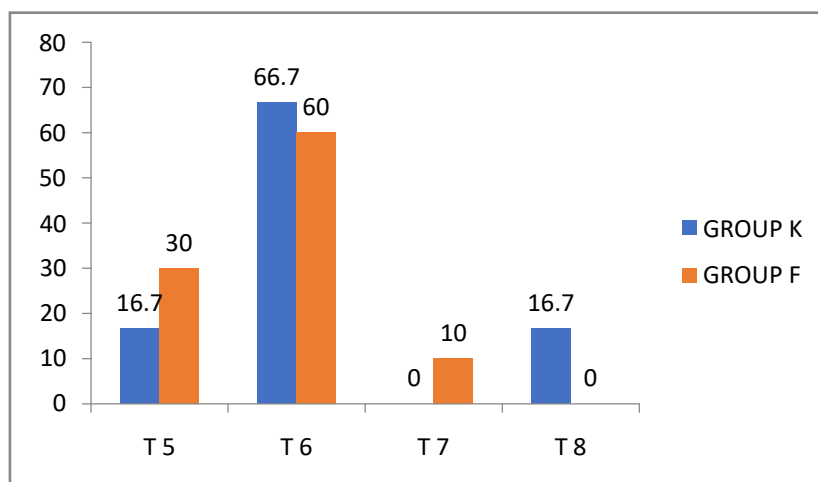
**Figure 12: ONSET OF SENSORY BLOCK**

## 6. MAXIMUM SENSORY LEVEL

MAXIMUM SENSORY LEVEL	GROUP F	%	GROUP K	%
T 4	0	0	0	0
T 5	9	30.0	5	16.7
T 6	18	60.0	20	66.7
T 7	3	10.0	0	0
T 8	0	0	5	16.7
TOTAL	30	100	30	100

**TABLE 6: MAXIMUM SENSORY LEVEL**

In Group K the maximum sensory level ranges in T5, T6 and T8. Maximum level reached is T6 that is 66%. In Group F the maximum sensory level ranges from T5 -T7 and in 60% of cases the maximum level reached is T6.



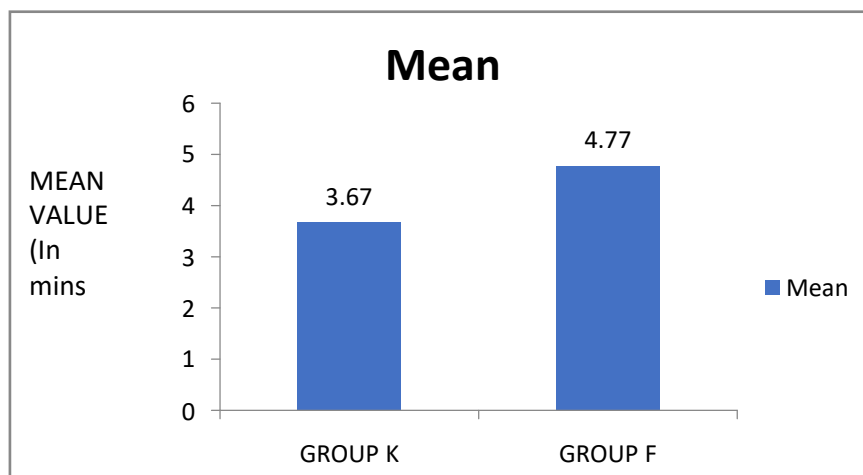
**Figure 13: MAXIMUM SENSORY LEVEL**

## 7.TIME TO REACH MAXIMUM SENSORY HEIGHT

TIME TO REACH MAXIMUM SENSORY HEIGHT (Min)	GROUP F	GROUP K	p- value
Range	2-8	2-6	0.060
Mean	4.77	3.67	
SD	1.695	1.322	
TOTAL	30	30	

**TABLE 7: TIME TAKEN TO REACH THE MAX.  
SENSORY HEIGHT**

In Group K the time taken to reach the highest sensory level is 3.67 minutes.  
In GROUP F the time taken to reach the highest sensory level is 4.77 minutes. Both groups are comparable and it not statistically significant.



**Figure 14: TIME TAKEN TO REACH THE MAX.**

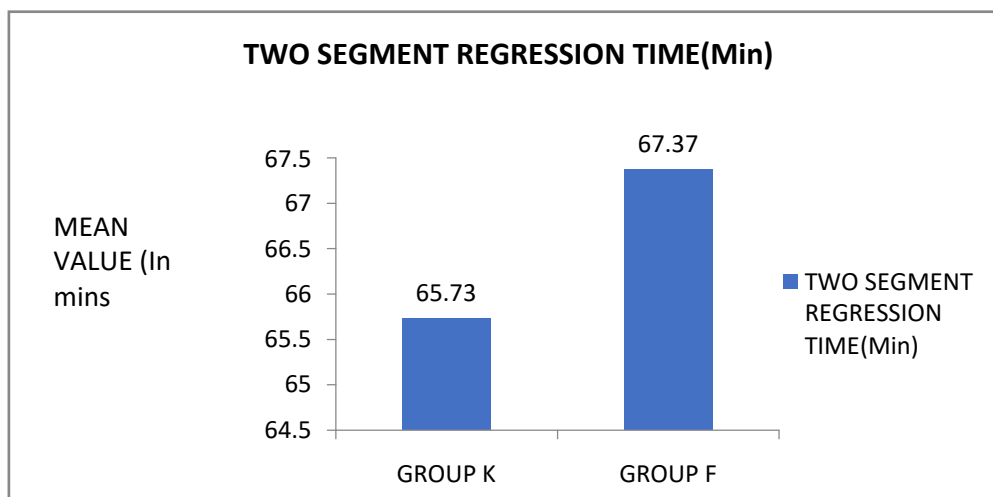
### **SENSORY HEIGHT**

#### **8. TWO SEGMENT REGRESSION TIME**

<b>TWO SEGMENT REGRESSION TIME(Min)</b>	<b>GROUP F</b>	<b>GROUP K</b>	<b>p-value</b>
<b>Range</b>	39-88	36-88	0.56
<b>Mean</b>	67.37	65.73	
<b>SD</b>	13.484	16.49	
<b>TOTAL</b>	30	30	

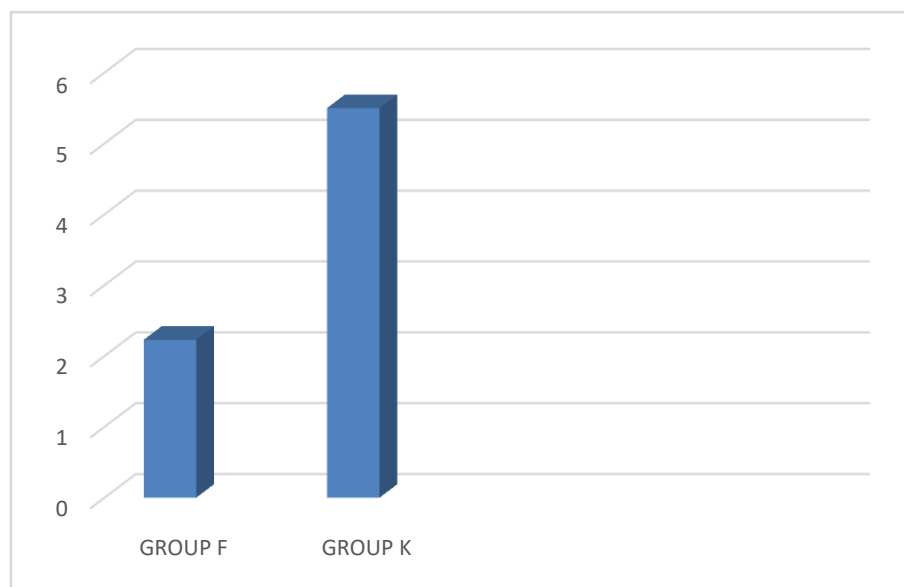
**TABLE 8: TWO SEGMENT REGRESSION TIME  
(MINUTES)**

In group K, the mean value of time taken for two segment regression is 65.73minutes. In GROUP F, the mean value of time taken for two segment regression is 67.37minutes. No statistically significant difference was seen across both the groups.



**Figure 15: TWO SEGMENT REGRESSION TIME  
(MINUTES)**

In Group F the mean Post-operative VAS score was 2.23. In Group K the same was 5.50. The Post-operative VAS score in group K was more as compared to group F. It was found to be statistically significant.



**Figure 25: POSTOPERATIVE VAS SCORE(1-10)**

### Discussion

In this randomized double blinded study conducted in 60 patients, the subjects were allocated

into 2 groups, Group F were having 30 participants, who received: Fentanyl Group K were having 30 participants, who received: Ketamine

1. Out of the total cases, In Group K, majority (56.7%) belonged to the age group of 39-55 years, followed by 56- 72 years (23.3%). In Group F, majority belonged to the age group of 39-55 years, that is 50%, followed by 56- 72 years which corresponds to 43.3 %. In our study majority of the participants were males There was no statistically significant difference across both the group ( $P > 0.05$ ), which means both the group were comparable.
2. In our study Group F had 60 % of the samples from the height between 150 – 160 cm and 40 % from the height between 161 – 170 cm whereas Group K
3. had 46 % from the height 150 – 160 cm and 54 % from the height between 161 – 170 cm. ( $P > 0.05$ ). When ASA classification was studied, the group F had 83.3% from ASA I and 05 % from ASA II & Group K ASA I & ASA has
4. 50%. Each. Thus, Both the groups were statistically comparable and showed a statistical insignificance. ( $P > 0.05$ ).

#### **a) Onset of sensory block:**

In this study, group K had mean onset of sensory block in 1.73 minutes & group F had the mean onset of sensory block is 1.57 minutes. Statistically significant difference was seen in the onset of sensory block across both the group.

#### **b) Maximum sensory level:**

In this study, In group K the maximum sensory level ranges in T5, T6 and T8. Maximum level reached is T6 that is 66% while in group F the maximum sensory level ranges from T5-T7 and in 60% of cases the maximum level reached is T6 . There was no statistically significant difference among the two groups in time to achieve highest sensory block.

#### **c) Time taken to reach the highest dermatome :**

In the present study across group K the time taken to reach the highest sensory level is 3.67

minutes. In group R the time taken to reach the highest sensory level is 4.77 minutes. Both groups are comparable and it not statistically significant.

**d) Two segment regression time :**

In this study among group K, the mean value of time taken for two segment regression is 65.73 minutes. In the group F, the mean value of time is taken for two segment regression is 67.37minutes. No statistically significant difference was seen across both the groups.

**e) Onset of motor block :**

In the present study among group K the mean onset of motor block is 2.40 minutes. In Group F the mean onset of motor blocks is 6.90minutes. The onset of motor block of Group F is delayed when compared to Group K and is statistically significant

**f) Duration of motor block :**

In this study, mean duration of motor block In Group F is 194.60 minutes. Inthe Group R-the mean duration of sensory block is 185.40 minutes. But the duration of sensory block is lesser for Group K compared with Group F but is not statistically significant.

**g) Quality of Block :**

In this study, quality of block was adequate in both groups hence both the block was equally acceptable.

**h) Use of atropine**

Atropine was not used in any of the participants across both the groups. There was no statistical difference across both the groups.

**i) Use of Vasopressor**

Vasopressor is used in one case in Group F and 3 cases in Group K. There was no statistical difference across both the groups.



#### **j) Post operative VAS score**

In Group F the mean Post operative VAS score was 4.50 minutes. In Group K the same was 3.33 minutes. The Post - operative VAS score in group F was more as compare to group K. It was found to be statistically significant.

#### **4. CONCLUSION**

The duration of sensory blockade is more in the Fentanyl group as compared to Ketamine when used as an adjuvant to 0.5% Bupivacaine but is not statistically significant. The duration of Ketamine in motor blockade is less than that of Fentanyl thereby facilitating quicker recovery from spinal anaesthesia which is especially useful in day care surgeries i.e post operative mobilization is quicker. Ketamine is also hemodynamically stable in comparison to Fentanyl thereby given it the safer margin of usage in patients with hypotension. In this study no CNS side effects were observed due to the low dosage of Ketamine used.

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**Ethical approval:** The study was approved by the Institutional Ethics Committee

#### **CONFLICT OF INTEREST**

The authors declare no conflict of interest.

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