

## A Comparative Study of Low Dose Bupivacaine - Fentanyl with Plain Bupivacaine in Spinal Anaesthesia for Transurethral Prostatectomy

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### Abstract

*Context:* Elderly patients exhibit the alterations in their physiological system. This affects the action of anesthetic agent in terms of spread, onset of action on motor block. *Aims:* Evaluating the efficacy of intra-thecal Fentanyl as an adjuvant to intra-thecal Bupivacaine (Hyperbaric) in patients undergoing transurethral resection of prostate. *Settings and Design:* Hospital based cross sectional study was conducted at SVS Hospital and Medical College, Mahabubnagar. *Methods and Material:* This study was conducted from November 2014 to November 2015. Informed consent was taken. 100 eligible patients as per inclusion and exclusion criteria were randomly grouped into 2 groups with 50 patients each. Group I received 1.5 ml of 0.5% hyperbaric Bupivacaine (7.5 mg). Group II received 1 ml of 0.5% hyperbaric Bupivacaine + 25 µg Fentanyl. Parameters like Onset of motor block, Onset of sensory block, Time for two segment regression, and Total duration of analgesia were studied. *Statistical Analysis:* The data was analyzed using statistical methods like Chi square Test, Repeated measure ANOVA, Independent samples T test. *Results:* Addition of Fentanyl 25 µg to Bupivacaine resulted in significant faster onset of sensory block and motor block. The time taken to reach T10 dermatome level was also faster in group II. Time for two segment regression was faster in group II and was significant. Duration of analgesia was significantly prolonged in group II. Patients were aerodynamically more stable in group II. *Conclusion:* Intra-thecal Fentanyl 25 µg with 5 mg of hyperbaric Bupivacaine provides adequate and satisfactory anesthesia for TURP.

**Keywords:** Intra-Thecal; Fentanyl; Bupivacaine; Anesthesia; Hypotension; Bradycardia.

### Introduction

Most commonly elderly patients undergo Transurethral Resection of Prostate (TURP). They have various co-existing health issues when they present with this condition. Hence spinal anesthesia is the commonly used technique for them. This is because, they can tolerate it and the signs and symptoms associated with TURP can be detected easily among them [1].

For elderly patients, to control the pulmonary and hemodynamic disturbances, it is necessary to properly limit the spinal block distribution. Hyperbaric 5% lignocaine was the drug of choice for decades

especially for bladder related operations while giving spinal anesthesia. But many studies have shown that it leads to Transient neurological symptoms (TNS) [2].

Hence there was need of an alternative anesthetic agent which could be used safely with effectiveness. When opioids were added, they produced a synergistic effect and did not cause the prolonged motor recovery [3].

Spinal opioids were used first in 1979. Since then their use became widespread. The objective was clear i.e. to have good quality analgesia without side effects even with small doses. Thus this view initiated the use of morphine. But it was found to have multiple

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side effects like vomiting, nausea and respiratory depression. Then it was thought that more lipophilic agents may be more useful. Fentanyl was found to be more effective, it demonstrated a rapid uptake, it has an action of short duration, and it has low concentration in the cerebrospinal fluid and fewer side effects as compared to morphine [4].

Elderly patients exhibit the alterations in their physiological system compared to young. This affects the action of anesthetic agent in terms of spread, onset of action on motor block etc. These are due to alteration in the nerve physiology among the elderly, degenerative changes of the spinal cord, and changes in the reflexes of the cardiovascular system. This scenario compels the anesthetist to use the local anesthetic agent in combination with lipophilic opioids in small doses. They should be given intrathecally. This is useful to have quality anesthesia and at the same time to have lesser side effects [5].

The present study is aimed at evaluating the efficacy of intra-thecal Fentanyl as an adjuvant to intra-thecal Bupivacaine (Hyperbaric) in patients undergoing transurethral resection of prostate.

## Material and Methods

This study was conducted from November 2014 to November 2015. Informed and written consent was taken. 100 eligible patients as per inclusion and exclusion criteria were studied. They were randomly grouped into 2 groups with 50 patients in each group. Group I patients received 1.5 ml of 0.5% hyperbaric Bupivacaine (7.5 mg). Group II patients received 1 ml of 0.5% hyperbaric Bupivacaine + 25 µg Fentanyl. Parameters like Onset of motor block, Onset of sensory block, Time for two segment regressions, and Total duration of analgesia were studied.

### *Inclusion Criteria*

1. Patients posted for TURP
2. ASA grades II & III
3. Age group between 60 and 80 years

### *Exclusion Criteria*

1. ASA grade IV
2. Age <60 and >80 years.
3. Patients with spinal deformities, neurological disorders, mental disturbances, acute/chronic infection, known hypersensitivity to local anesthetic agents and bleeding disorders were excluded from the study.

On the previous day of surgery pre-anesthetic check up was done. Investigations were carried out. All the patients were kept nil by mouth over night. Any narcotic or sedative was not given to any patient before surgery. 30 min before surgery all patients were given Inj. Ondansetron 4 mg IV and inj. Ranitidine 50 mg IV. As soon as patients came to OT, baseline parameters like blood pressure, pulse rate, SPO<sub>2</sub>, ECG, temperature and respiratory rate were noted. 18 G intra-cath was used for intravenous line. Under all aseptic precautions, subarachnoid block was given at L2-L3/L3-L4 level in either lateral or sitting position. This was done with local anesthetic agent: 2% lignocaine, 2 CC. Free flow of cerebrospinal fluid was ensured and anesthetic agents were given as per grouping. Patients were kept in supine position after completion of block. After ensuring adequate analgesia, surgery was started in supine lithotomy position.

### *Criteria of Block*

#### *Onset of Sensory Block*

Every 30 seconds by pin prick method, sensory block was assessed. At the L-1 level, if the patient failed to perceive pain on prick, it was regarded as onset of sensory block.

#### *Onset of Motor Block*

Until the surgery started, Modified Bromage Scale was used to assess motor block and recorded every 5 minutes. After surgery, total duration of motor blockade was noted.

#### *Bromage Scale [6]:*

Grade-0: No block – full flexion of knee and feet.

Grade-I: Partial block - just able to flex knee but full flexion on feet.

Grade-II: Almost complete block – unable to flex knee but complete flexion of feet possible.

Grade-III: Complete block: Unable to flex knee and feet.

#### *Peak Level of Sensory Block*

It was taken as the difference of time between drug injection to its reach at the highest dermatome level. Every 2 minutes, dermatomal levels were tested for four times till the level stabilized. Until 2 segment regression, testing was done every 10 minutes. Then

in recovery room, testing was done every 20 minutes until recovery of the S-2 dermatome.

### Hemodynamic Changes

Every 3 min vitals were recorded for first 15 min and then every 15 min till the end of operation. After surgery, vitals were recorded every 30 min till the patient was stable for discharge. As and when required, IV fluids were given. If blood pressure was less than 30% of pre-induction value, it was taken as hypotension. It was treated with IV fluids and mephentermine 15 mg IV if required. Fall in heart rate > 20% of pre-induction value, it was taken as bradycardia. It was managed by inj. Atropine 0.6 mg IV.

All the patients were observed for intra-operative complication and managed appropriately. Postoperatively all patients were assessed hourly for 3 hours and then hourly up to 12 hours in recovery room.

Duration of sensory and motor block was recorded. Post-operative complications were observed.

### Statistical Method

The data was analyzed using statistical methods like cross tabs procedure, descriptive statistics, Chi square Test, Repeated measure ANOVA, Independent samples T test.

### Results

Table 1 shows distribution of study subjects as per the age. Maximum patients were in the age group of 60-65 years followed by 66-70 years of age. Both the groups had almost similar number of patients.

Table 2 shows the distribution of study subjects as per the co-existing disease. 13 (13%) patients were found to have cardiac problems and 18 (18%) patients had respiratory problems and 32 (32%) of patients were hypertensive and 1 (1%) patient had both hypertension and respiratory.

Table 3 shows distribution of study subjects as per height of Analgesia. Highest level of sensory level reached in group II was T8 in two cases (4%) and majority of patients in both groups the maximum level of sensory block attained T10 (78% in group I and 72% in group I).

Table 4 shows distribution of study subjects as per mean pulse rate. Mean pulse rate were comparable in both groups and found to be statistically insignificant.

Table 5 shows distribution of study subjects as per mean arterial pressure (MAP). MAP was compared in both groups and was found to be statistically insignificant.

Table 6 shows distribution of study subjects as per mean Respiratory rate (RR). Mean respiratory rate was lower in group II and was statistically insignificant with P value < 0.702.

Table 1: Distribution of study subjects as per the age

Age (years)	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
60-65	24	48	21	42	45	45
66-70	13	26	16	32	29	29
71-75	10	20	05	10	15	15
76-80	03	06	08	16	11	11
Total	50	100	50	100	100	100

Table 2: Distribution of study subjects as per the co-existing disease

Co-existing disease	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
None	18	36	18	36	36	36
Cardiac	05	10	08	16	13	13
Respiratory	09	18	09	18	18	18
Hypertension	18	36	14	28	32	32
Hypertension + respiratory	00	00	01	02	01	01
Total	50	100	50	100	100	100

**Table 3:** Distribution of study subjects as per height of Analgesia

Height of analgesia	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
T8	00	00	02	04	02	02
T9	11	22	12	24	23	23
T10	39	78	36	72	75	75
Total	50	100	50	100	100	100

T=8.214, P<.000

**Table 4:** Distribution of study subjects as per mean pulse rate

Mean Pulse rate/min	Pre	0 min	10 min	20 min	30 min	40 min	60 min	90 min
Group I	77.08	76.18	73.72	72	71.92	71.92	71.46	71.3
Group II	76.88	75.18	73.42	73.42	72.08	71.8	73.12	73.82
Total	76.98	75.68	73.57	72.17	72	71.86	72.29	72.56

F change = 16.416, P < .000, F change x groups = 1.682, P < .110

**Table 5:** Distribution of study subjects as per mean arterial pressure (MAP)

MAP rate/min	Pre	0 min	10 min	20 min	30 min	40 min	60 min	90 min
Group I	99.96	95.96	92.54	89.94	89.06	88.86	87.86	87.98
Group II	95.22	93.72	91.82	91.06	89.6	89.86	89.78	89.62
Total	97.59	94.84	92.18	90.05	89.33	89.36	88.82	88.8

F change = 112.76, P < .000, F change x groups = 14.066, P < .000

**Table 6:** Distribution of study subjects as per mean Respiratory rate (RR)

RR rate/min	Pre	0 min	10 min	20 min	30 min	40 min	60 min	90 min
Group I	15.74	15.84	15.74	15.78	16.24	16.02	15.94	16
Group II	15.42	15.44	15.78	15.84	15.78	15.84	15.68	15.92

P < 0.702

**Table 7:** Distribution of study subjects as per Intraoperative complications

Intra-operative complications	Group I		Group II		Total	
	Number	Percentage	Number	Percentage	Number	Percentage
Nil	27	54	41	82	68	68
Hypotension	07	14	00	00	07	07
Bradycardia	06	12	02	04	08	08
Hypotension and bradycardia	01	02	00	00	01	01
Pruritus	00	00	05	10	05	05
Nausea	04	08	00	00	04	04
Vomiting	00	00	00	00	00	00
Shivering	05	10	02	04	07	07
Respiratory depression	00	00	00	00	00	00
Total	50	100	50	100	100	100

P < 0.001

Table 7 shows distribution of study subjects as per Intraoperative complications. In group I seven patients (14%) had hypotension as compared to 0 % in group II. Bradycardia was observed in 6 patients (12%) in group I and 2 patients (4%) in group II. Hypotension and

Bradycardia was observed in 1 patient (2 %) in group I. Pruritus was observed in 5 patients (10%) in group II and was not observed in group I. Nausea was observed in 4 patients (8%) in group I. Shivering was noted in 5 patients (10%) in group I and 2 patients (4%) of group II.

**Table 8:** Comparison of parameters among the two groups (mean values)

Parameters	Group I	Group II	P value
Mean onset of sensory block (min)	3.15	2.35	0.000
Mean time taken for sensory level to reach T10	5.32	3.73	0.000
Mean onset of motor block (min)	6.39	5.26	0.000
Mean time for two segment regression (min)	66.06	63.08	0.000
Mean time of post operative analgesia (min)	177.28	214.7	0.000

Table 8 shows comparison of parameters among the two groups. It was found that the mean onset of sensory block was significantly shorter in group II patients. The patients in group II reached the T10 level earlier than group I patients. Mean onset of motor block was quicker and statistically significant in group II patients. Mean time for two segment regression was also less in group II patients. The group II patients had lesser requirement of rescue analgesia as is evident from the mean time of post operative analgesia which was more among them.

### Discussion

In the present study the mean onset of sensory block was quicker in group II compared to group I and this was statistically significant ( $p = 0.000$ ). Most of the authors have not mentioned this observation. It was noted that the time taken to reach dermatome level T10 was significantly shorter in group II (mean 3.7 minutes) compared to group I (Mean 5.3 minutes). This is in correlation with Diana et al [7], who reported in their study that the time to reach dermatomal level T 10 was 13.5 minutes in plain Bupivacaine group and 10.1 minutes in Fentanyl group. This was because the dose of Bupivacaine used was higher (12.5 mg). Maximum level reached was T8 in 2 (4%) patients in group II and this could not be explained. The addition of adjuvant to local anesthetic solutions may reduce the density of the latter. In theory, it may appear hypobaric but no effect has been shown in clinical practice [8].

This study showed that the time of two segment regression was significantly shorter in group II (mean 63.08 minutes) as compared to group I (mean 66.06 minutes). Kararmaz et al [1] observed that the time of two-segment regression was 88.4 minutes in Fentanyl group and 92.8 minutes in Bupivacaine group.

We observed that the duration of analgesia was significantly more in group II (214.7 minutes) as compared to 177.28 minutes in group I. This was comparable to the previous studies [5,6,7] showing the duration of analgesia in Fentanyl group to be

222.1 minutes in Bupivacaine group to be 192.3 minutes and no patients demanded rescue analgesia within this period.

We observed that the onset of motor block was faster in group II (mean 6.39 minutes). Most of the authors have not mentioned on this parameter. Our study showed that duration of motor block was shorter in group II (mean 90 minutes) as compared to 105 minutes in group I patients which was significant. This is in correlation with the previous observations by Kararmaz et al [1] who observed longer duration of motor block in Bupivacaine group (134.2 minutes) and less in Fentanyl group (105.6 minutes).

Hypotension was observed in 7 (14%) patients in group I. There was no hypotension in group II patients, though the patients were more than 76 years (16%) patients and also (16%) of cases had cardiac ailments. Surprisingly, there was no hypotension in these cases also showing that group II was more hemodynamically stable. Bradycardia was encountered in 6 (12%) patients in group I and 2 (4%) patients in group II. 10 (20%) cases of group 1 were anxious and received Inj. Midazolam 1 mg, intra-operatively whereas no such observation was seen in group II. Pruritis was observed in 5 (10%) patients of group II and none of the patients of group 1 had Pruritis. None of the patients required treatment which subsided by itself. Several authors have noted in their study, occurrence of Pruritis as the common adverse effect in patients receiving Fentanyl. Kristiina et al [9], Kararmaz et al [1], Diana-fernandaz et al [7], have all noted Pruritis in their observations. Nausea was felt by 4 (8%) patients in the post-operative period in group I. Shivering was observed in 5 (10%) patients in group I and 2 (4%) patients in Group II. Studies [9,5,3] have shown that using the irrigating fluids which are stored at room temperature and significant absorption of this fluid caused shivering and also that addition of Fentanyl to low doses of Bupivacaine decreased the incidence of shivering during spinal anesthesia in elderly patients. All patients had SpO<sub>2</sub> of 98%, and none of the patients had respiratory depression.

The incidence TURP Syndrome was 0% and none

of our patients required blood transfusion intra-operatively. None of the patients in the present study had TNS. Postoperative voiding could not be assessed as catheterization was done for irrigation of the bladder. Kararmaz et al [1], Diana-fernandaz et al [7], did not observe any post operative complications.

Prajapati J et al [10] observed that for TURP patients, addition of fentanyl to bupivacaine leads to decreased occurrence of shivering and hypotension than the conventional methods of anesthesia.

Akcaoy EY et al [11] noticed that patients receiving 5 mg levobupivacaine with 25 µg fentanyl were more satisfied and concluded that it can be used as an alternative to bupivacaine.

Akcaoy IZN et al [12] in their study observed that 4 mg bupivacaine + 25 µg fentanyl gave better results in terms of anesthesia and hemodynamic stability than intra-theal 50 mg prilocaine + 25 µg fentanyl.

Kim SY et al [13] concluded from their study that for elderly patients undergoing TURP, use of fentanyl or sufentanil provided hemodynamic stability as well as high quality anesthesia.

Gupta S et al [14] observed that for surgeries of bladder endoscopically, addition of fentanyl in the dose of 25 µg helped in achieving good quality anesthesia in elderly patients. They also noted that the patients were hemodynamically more stable.

Vampugalla PS et al [15] noted that for surgeries of lower limb and abdomen, adequate analgesia was achieved when fentanyl was added to ropivacaine.

With the above observations most of our findings are in correlation with the previous studies, showing that addition of 25 µg Fentanyl to a low dose 5 mg of hyperbaric Bupivacaine 0.5% provided satisfactory anesthesia for the procedure with minimal side effects and offered better hemodynamic stability even in the cardiac patients.

## Conclusion

Our observations revealed that addition of Fentanyl was found to be advantageous in the following ways:

1. Quickens onset of sensory and motor block.
2. Provided excellent surgical anesthesia and good muscle relaxation to facilitate the positioning.
3. Provides hemodynamic stability.
4. Earlier motor recovery.
5. No respiratory depression and no intravenous

supplementation.

6. Reduces the incidence of shivering.
7. Can produce mild pruritis which does not require any treatment.
8. No post-operative complications like TNS.

This study shows that intra-theal Fentanyl 25 µg acts synergistically to potentiate Bupivacaine induced sensory block, with early motor recovery good hemodynamic stability, reduces the need for post operative analgesics, without any significant adverse effects.

It is concluded that intra-theal Fentanyl 25 µg with 5 mg of hyperbaric Bupivacaine provides adequate and satisfactory anesthesia for TURP.

## Key Messages

Fentanyl should be used as drug of choice in elderly patients undergoing especially Transurethral Resection of Prostate.

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