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# A comparative study to assess the effects of intrathecal fentanyl and intrathecal tramadol combined with 0.5% bupivacaine heavy in patients undergoing elective urological surgeries: A prospective randomized study

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## ABSTRACT

**Background:** Urological operations frequently involve the use of spinal anesthesia. In the present scenario, adding different adjuvants to local anesthetic improve its quality and duration has become common. **Aims and Objectives:** In patients undergoing elective urological procedures, the purpose of this study was to assess the effects of intrathecal fentanyl or tramadol with 0.5% bupivacaine heavy. **Materials and Methods:** Patients were divided into two groups of 30 patients each, a total of 60 patients aged 20–60 years undergoing elective urological surgeries participated in this prospective, randomized study in which 25 µg fentanyl and 2.5 mL of 0.5% bupivacaine heavy were given to Group F, while 25 mg tramadol and 2.5 mL of 0.5% bupivacaine heavy were given to Group M. The onset and duration of sensory and motor blockage, the duration of analgesia, post-operative Visual Analog Scale score, hemodynamic changes, and adverse effects were evaluated. **Results:** Fentanyl had a lower mean time of onset for sensory (2:33 ± 0:22 min vs. 4:50 ± 0:33 min) and motor block (3:36 ± 0:28 min vs. 5:52 ± 0:38 min) ($P < 0.001$), the duration of sensory (185.67 ± 3.155 min vs. 152.60 ± 4.264), motor block (172.00 ± 4.177 min vs. 136.40 ± 5.575 min), and post-operative analgesia was longer in the fentanyl group ($P < 0.001$), whereas the incidence of adverse effects such as pruritus, shivering, and nausea was lower in the tramadol group. **Conclusion**: The quality and duration of spinal anesthesia were found to be significantly increased by the use of fentanyl as an adjuvant in our study. However, tramadol also produced stable hemodynamics and exhibited fewer adverse effects than fentanyl.

**Key words:** Fentanyl; Tramadol; Urological procedures; Spinal anesthesia

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## INTRODUCTION

Spinal anesthesia offers a safe and economical approach, providing sufficient surgical anesthesia and prolonged post-operative pain relief through the use of diverse local anesthetics. It delivers a swift onset and effective sensory and motor blockage.[1]

Patients who undergo surgery under subarachnoid block for endoscopic urological operations usually have a comorbid cardiac, pulmonary, or other illness. Limiting the negative pulmonary and hemodynamic effects of spinal block in these elderly patients is crucial. Small amounts of local anesthetics may prevent these side effects, but they might not give adequate pain relief. When used with local

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anesthetics, opioids enhance intraoperative analgesia and increase the length of post-operative analgesia.[2]

Incorporating intrathecal opioids into spinal anesthesia extends sensory block duration without delaying motor function recovery.[3,4]

Fentanyl, a synthetic opioid and μ receptor agonist, possesses high lipid solubility. On intrathecal administration, it swiftly diffuses into the spinal cord and promptly attaches to dorsal horn opioid receptors. This results in rapid onset of pain relief with minimal upward spread. Despite opioids being linked to various adverse effects such as respiratory depression, nausea, vomiting, itching, urinary retention, and fluctuations in blood pressure,[5] they do not impede motor recovery.[6] In addition, they carry a lower risk of delayed respiratory depression.[7]

Tramadol is a synthetic opioid. It inhibits serotonin and norepinephrine reuptake in the spinal cord and has no reported neural toxicity. Tramadol has a minimum respiratory depressant effect because it has 6000-fold less affinity for μ receptors compared to morphine. It is central neuraxial administration has the potential to offer effective pain relief following surgery, without the risk of respiratory depression.[8]

In this study, we have compared intrathecal tramadol versus fentanyl citrate as an adjuvant to 0.5% bupivacaine heavy in spinal anesthesia for urological surgeries.

### Aims and objectives

The aim of this study was to compare the effects of intrathecal fentanyl 25 μg versus intrathecal tramadol 25 mg as adjuvants with 2.5 mL of 0.5% bupivacaine heavy.

#### *Primary objective*

The objective was to evaluate the onset and duration of sensory and motor block and duration of analgesia with both adjuvants.

#### *Secondary objective*

The objective was to compare hemodynamic changes in both groups. Assess the incidence of adverse effects if any.

## MATERIALS AND METHODS

Following approval from the Institutional Ethics Committee, this prospective randomized study was conducted at G.R. Medical College and the JAH group of hospitals from 2022 to 2024.

### Inclusion criteria

The following criteria were excluded from the study:

Patients giving consent to participate in the study and scheduled for elective neurosurgery such as Transurethral resection of prostrate, ureteroscopic lithotripsy, transurethral resection of bladder tumour, transurethral cystoscopic laser lithotripsy.

- Aged between 20 and 60 years.
- ASA grade I and II.

### Exclusion criteria

The following criteria were excluded from the study:

- ASA grade III and IV
- Patients with respiratory, cardiovascular, hepatic, and renal diseases, obesity, and pregnancy
- Age below <20 years and above >60 years
- Any bleeding disorder and patient on anticoagulants
- Neurological and musculoskeletal disease
- Local infection at the injection site
- Patient already receiving any analgesic, opioid agonist or antagonist in preceding 6 h of surgery.

### Sample size calculation

Considering the average duration of analgesia as 183.75 min with a standard deviation 47.01 min in the bupivacaine+fentanyl group and average duration of analgesia as 143.07 min with standard deviation 14.22 min in the bupivacaine+tramadol at 95% confidence interval and 80% power of test, using the formula

$$\frac{n = 2(a+b)^2\sigma^2}{(\mu_1 - \mu_2)^2}$$

$$n = \frac{15.7 \times 2500}{1654}$$

We obtain n approximately 23.73, so the minimum sample size required for the current study is 24, that is, increased to 30 in each group for better results. Hence, total sample size required for the study will be 60. Selected 60 patients were randomly divided into two groups (n=30 each) by sealed envelope method as below:

- Group F (n=30)
- 2.5 mL of 0.5% bupivacaine heavy with 0.5 mL of fentanyl (25 μg)
- Group T (n=30)
- 2.5 mL of 0.5% bupivacaine heavy with 0.5 mL of tramadol (25 mg).

Before anesthesia, as per institutional protocol, a pre-anesthetic assessment was conducted to screen for and evaluate any significant systemic illnesses. Informed consent was obtained from all patients participating in the study, and they were briefed about the spinal anesthesia procedure and educated on the use of the "VAS" (Visual Analog Scale). The day before surgery, all patients underwent a comprehensive

general, physical, and systemic examination. In addition, all necessary routine investigations were performed.

All patients were instructed to abstain from oral intake for a minimum of 8 h before the procedure.

On the patient's arrival in the operating theater, an 18 G cannula was inserted into the patient's forearm for intravenous access and preloading was carried out with approximately 10 mL/kg of ringer's lactate solution or with normal saline. Standard monitors, including a pulse oximeter, blood pressure cuff, and electrocardiogram, were applied, and observations were documented using a multipara monitor.

Following meticulous aseptic measures, a lumbar puncture was performed in the sitting position at the L3-L4 interspace through a midline approach using a 25G quincke spinal needle. Subsequently, spinal anesthesia was administered, the study drug was injected, and the patient was positioned supine for the duration of the study. Intraoperatively, various characteristics and outcomes of the spinal anesthesia were recorded and documented in a pro forma for subsequent statistical analysis.

1. Sensory blockade onset time (up to T10) was evaluated using the pinprick method
2. Motor blockade onset time was assessed according to the Bromage scale (up to modified Bromage score 3), where:
    - 0=No motor block
    - 1=Ability to bend the knee (hip blocked)
    - 2=Ability to dorsiflex the foot (hip and knee blocked)
    - 3=Complete motor block (hip, knee, and ankle blocked).
3. The duration of sensory blockade extended until regression to L1, and motor blockade until regression to modified Bromage score 0.
4. Analgesic duration (from induction to VAS >3) and post-operative VAS scores were recorded at 30, 60, 120, and 180 min. If VAS exceeded 3, rescue analgesia with paracetamol (PCM) infusion (15 mg/kg) was administered.
5. Hemodynamic parameters (pulse rate [PR], systolic blood pressure [SBP], diastolic blood pressure [DBP], and mean arterial pressure [MAP]) were assessed at 0, 5, 10, 15 30, 45, 60, 90 120, 150, and 180 min post-induction. Any decrease in MAP below 20% of baseline prompted a bolus dose of mephentermin 6 mg i.v., while PR below 60 beats/min was addressed with atropine sulfate 0.3–0.6 mg i.v.
6. Adverse effects and complications associated with the study drugs and technique were observed and recorded.

### Statistical method

The data were organized in a suitable spreadsheet format, such as Excel, and analyzed using the Statistical Package for the Social Sciences (SPSS), version 20.0. Following compilation, statistical analysis was performed utilizing SPSS software.

To compare the two groups concerning various characteristics of spinal anesthesia, normality assumptions were checked. Subsequently, the Chi-square test and unpaired t-test were employed. The significance level was set at a 95% confidence level ($P<0.05$).

## RESULTS

As shown in Table 1, age, sex, and weight were comparable between the groups, $P>0.05$ which was statistically insignificant.

As shown in Table 2, the onset of sensory and motor blockade was faster in Group F, also the duration of both the blockade and duration of analgesia was more in Group F, $P<0.001$ which was statistically highly significant. Furthermore, as shown in Table 3, the time for post-operative VAS score >3 was more in Group F ($P<0.001$).

## DISCUSSION

Urological procedures including TURP, TURBT, and URSL are performed under spinal anesthesia because it is safe, quick, and cost-effective. Various intrathecal adjuvants improve spinal anesthesia quality and prolong duration. We conducted a prospective randomized comparative study to assess the effects of intrathecal fentanyl and intrathecal tramadol combined with 0.5% bupivacaine heavy in patients undergoing elective urological surgeries.

Our study included 60 ASA grade I and II patients aged 20–60 who were randomly divided into two groups of 30 each. Group F received 25 μg fentanyl with 2.5 mL 0.5% bupivacaine heavy intrathecally, while Group T received 25 μg tramadol with the same drug.

Our study examined the onset and duration of sensory and motor blockade after spinal anesthesia. Both study groups were compared for analgesic duration, hemodynamic parameters, and adverse effects such as hypotension, bradycardia, shivering, pruritus, respiratory depression, nausea, and vomiting.

In our study, both groups had similar demographic features

**Table 1: Demographic profile (mean±SD) associated with the groups**

| Demographic parameter | Group F (n=30) | Group T (n=30) | P-value |
|---|---|---|---|
| Age | 41.47±12.30 | 47.30±13.17 | 0.082 |
| Sex | Male: 90% Female: 10% | Male: 86.7% Female: 13.3% | 0.688 |
| Weight (kg) | 74.50±6.07 | 72.37±8.67 | 0.274 |

**Table 2: Parameters of spinal anesthesia**

| Parameters | Group F (n=30) | Group T (n=30) | P-value |
|---|---|---|---|
| Onset of sensory block (min) | 2:33±0:22 | 4:50±0:33 | P<0.001 |
| Onset of motor block (min) | 3:36±0:28 | 5:52±0:38 | P<0.001 |
| Duration of sensory block (min) | 185.67±3.155 | 152.60±4.264 | P<0.001 |
| Duration of motor block (min) | 172.00±4.177 | 136.40±5.575 | P<0.001 |
| Duration of analgesia (min) | 200.17±3.174 | 158.47±3.104 | P<0.001 |

**Table 3: Comparison of post-operative VAS score**

| Time intervals | Tramadol mean±SD | Fentanyl mean±SD | t-value | P-value |
|---|---|---|---|---|
| 0 min | 0.00±0.000 | 0.00±0.000 | - | - |
| 30 min | 0.77±0.774 | 0.20±0.610 | 3.149, df=58 | 0.003* |
| 60 min | 2.83±0.592 | 1.10±0.960 | 8.420, df=58 | 0.000* |
| 120 min | 4.00±0.000 | 3.10±0.310 | 15.021, df=54 | 0.000* |
| 180 min | - | 4.00±0.000 | - | - |

VAS: Visual Analog Scale

including age, sex, and weight (Table 1). All these variables showed P>0.05, indicating no significant differences between the groups. Similar demographics were seen in a study conducted by Desai et al.,[22] Atallah et al.,[23] also found similar results in the demographics of their study (P>0.05).

Group fentanyl had a sensory blockage onset time of 2:33±0:22 min, while group tramadol took 4:50±0:33 min. The significant difference (P<0.001) (Table 2) between the two groups suggests that fentanyl may cause sensory blockade faster than tramadol. Dalvi and Patil[9] studied intrathecal (25 μg) fentanyl-bupivacaine and tramadol (25 mg)-bupivacaine's effects on sensory and motor blockade onset and duration in which fentanyl group achieved higher sensory block earlier (3.77±0.72 vs. 5.13±0.77 min), which was statistically significant and was comparable to our study. Similar results were found by Kalyani et al.[10] In their study, the fentanyl group had a significantly faster onset of sensory block (1.37±0.49 min) compared to the tramadol group (2.69±0.69 min) (P=0.001). The study revealed that the fentanyl group experienced faster onset of motor blockade (Bromage 3) at an average time of 3:36±0:28 min, compared to the tramadol group at 5:52±0:38 min. Statistical analysis revealed a significant difference (P<0.001), with fentanyl causing motor block faster than tramadol (Table 2). Similarly Kalyani et al.,[10] found a significant difference in motor blockade onset between fentanyl and tramadol groups, with fentanyl taking 1.73±0.45 min and tramadol taking 2.3±0.65 min (P<0.001). The fentanyl group had average sensory block duration of 185.67±3.155 min, while the tramadol group had 152.60±4.264 min. Statistical analysis showed a significant difference in mean duration between the two groups (P<0.001) (Table 2). Our study was in accordance with Dalvi and Patil[9] who found prolonged sensory block with fentanyl. Ozer and Turk[11] also showed intrathecal fentanyl has a longer sensory block (183.75±47.01 min) than intrathecal tramadol (143.07±14.22 min). In another study by Bogra et al.,[12] intrathecal fentanyl prolonged sensory block. Similarly, Jain and Yadav[13] found that fentanyl prolonged sensory block greater than intrathecal tramadol. In our study, motor block duration (Bromage 0) averaged 172.00±4.177 min in the fentanyl group and 136.40±5.575 min in the tramadol group which was statistically significant (P<0.001) (Table 2). Dalvi and Patil[9] found the duration of motor block was longer in group fentanyl as compared to group tramadol and was statistically highly significant (263.66±40.97 vs. 214.66±26.61 min, P<0.001). Ozer and Turk,[11] Jain and Yadav,[13] Shende et al.,[14] reported similar intrathecal fentanyl outcomes. The tramadol group experienced analgesia lasting 158.47±3.104 min, while the fentanyl group experienced 200.17±3.174 min (Figure 1). The mean duration of pain alleviation differed significantly across groups (P<0.001) (Table 2). Kamshetty and Panshetty[15] also found that intrathecal fentanyl with hyperbaric bupivacaine provided longer analgesia in spinal anesthesia for lower abdominal and lower extremity surgeries. In another study, Singh et al.,[16] found in adult male patients that fentanyl prolonged

bupivacaine's sensory block and analgesia. It also lowered post-bupivacaine spinal block rescue analgesic use. Dalvi and Patil,[9] Ozer and Turk,[11] and Afolayan et al.,[17] discovered that intrathecal fentanyl plus hyperbaric bupivacaine provided prolonged analgesia than intrathecal tramadol. Another study conducted Zahid et al.,[19] showed that intrathecal tramadol as adjuvant with bupivacaine heavy in lower limb orthopedic surgery patients prolonged analgesia.

However, Subedi et al.,[18] found that intrathecal tramadol provided longer post-operative analgesia than intrathecal fentanyl in cesarean section patients.

Both groups' post-operative VAS scores were obtained at 0, 30, 60, 120, 180, 240, and 360 min. A significant mean VAS score difference was observed at 30, 60, and 120 min (P<0.001) (Table 3). Our study found that fentanyl controlled pain better than tramadol at 1, 2, 3, and 4 h after induction (Figure 2). VAS score at 30 min

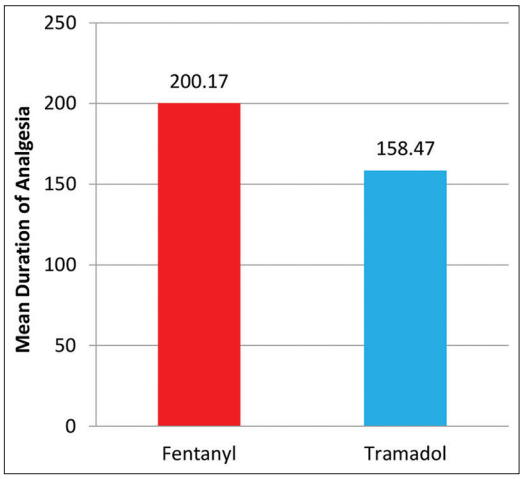


**Figure 1:** Comparison of total duration of analgesia in both groups

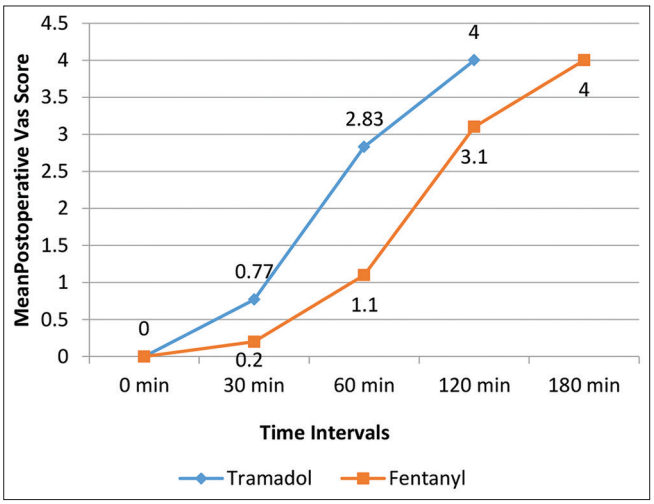


**Figure 2:** Comparison of post-operative Visual Analog Scale score

post-operative in Group F was 0.20±.610 and in Group T, 0.77±0.774. Group F: 1.10±0.960 at 60 min, and Group T: 2.83±0.592. At 120 min, Group F had 3.10±0.310 while Group T had 4.00±0.000. Group F had a 4.00±0.000 score at 180 min. Rescue analgesia with inj. PCM 100 mL infusion (15 mg/kg) (as per institute procedure) was used to relieve post-operative pain in patients with VAS score >3. Fentanyl improves the length and quality of analgesia more than tramadol, hence patients in F Group had lower VAS scores postoperatively and rescue analgesia was delayed compared to Group T. Dalvi and Patil[9] found that only 12 of 30 fentanyl-treated patients needed a single analgesic dose, while all tramadol-treated patients needed more than one. Within 24 h, 18 patients from both groups needed two analgesics. Twelve tramadol patients needed three analgesics, but none of the fentanyl patients did. Therefore, intrathecal fentanyl added to hyperbaric bupivacaine increased post-operative analgesia. In a randomized, double-blinded research, Kalyani et al.,[10] tested intrathecal fentanyl and tramadol as adjuvants to hyperbaric bupivacaine 0.5% in elective cesarean delivery patients. They found that fentanyl provided longer-lasting analgesia than tramadol. Afolayan et al.,[17] found that tramadol patients need early rescue analgesic more than fentanyl patients.

Heart rate, SBP, DBP, MAP, and $SpO_2$ were measured perioperatively at 0, 5, 10, 15, 30, 60, 90, 120, and 150, 180 min (relative to induction). PR, SBP, DBP, MAP, and $SpO_2$ were not significantly different between groups (P>0.05) (Figure 3). Dalvi and Patil[9] Ozer and Turk[11] and Afolayan et al.,[17] found similar results. Bandreddy et al.,[20] discovered that low-dose bupivacaine with tramadol for TURP procedures stabilized hemodynamics when paired with hyperbaric bupivacaine for spinal anesthesia. In gynecological procedures, Chakraborty et al.,[21] found intrathecal tramadol hemodynamically stable with bupivacaine.

Adverse effects like pruritus occurred in 16.7% of Group F and none in Group T. Shivering occurred in 30% of Group F patients and 6.7% of Group T patients. Nausea was 3% in Group F but not in Group T. Other adverse effects were absent in both groups. The aforementioned results show that Group F had greater adverse effects than Group T, and the difference was statistically significant (Figure 4). Dalvi and Patil[9] found that 7 fentanyl and 14 tramadol patients reported nausea, while 3 and 11 experienced vomiting in each group respectively. Eleven of 30 fentanyl patients had pruritus. Ozer and Turk[11] also found that fentanyl caused more pruritus than tramadol. Chandra et al.,[22] found that Group B (20%) receiving intrathecal fentanyl had a considerably higher incidence of

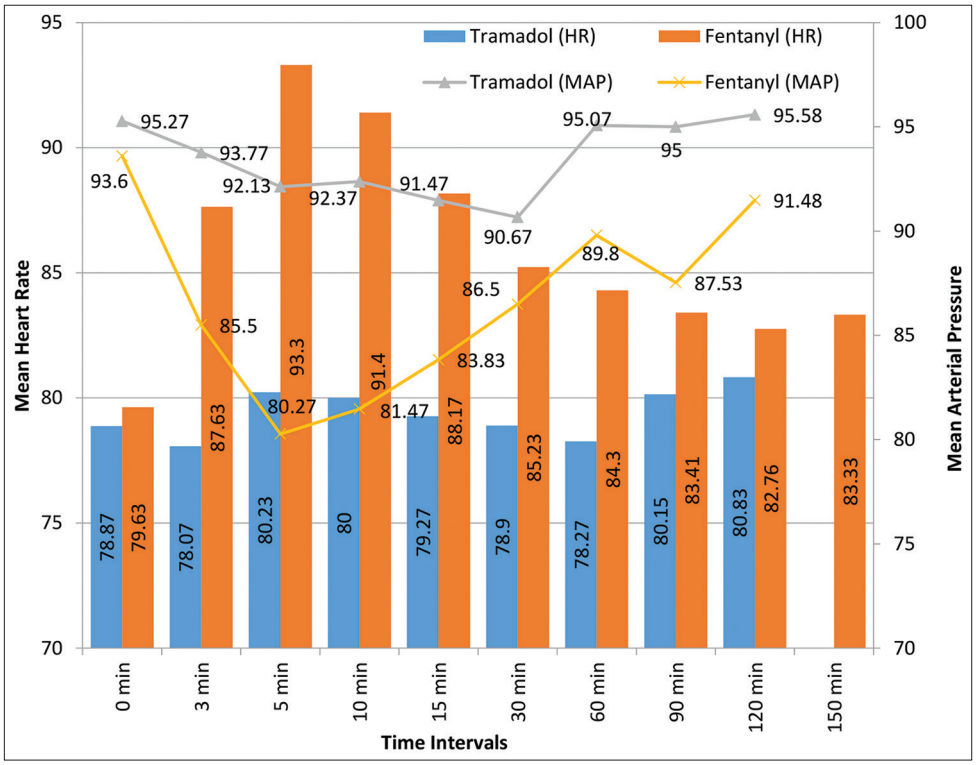


**Figure 3:** Comparison of mean heart rate and mean arterial pressure between the two groups

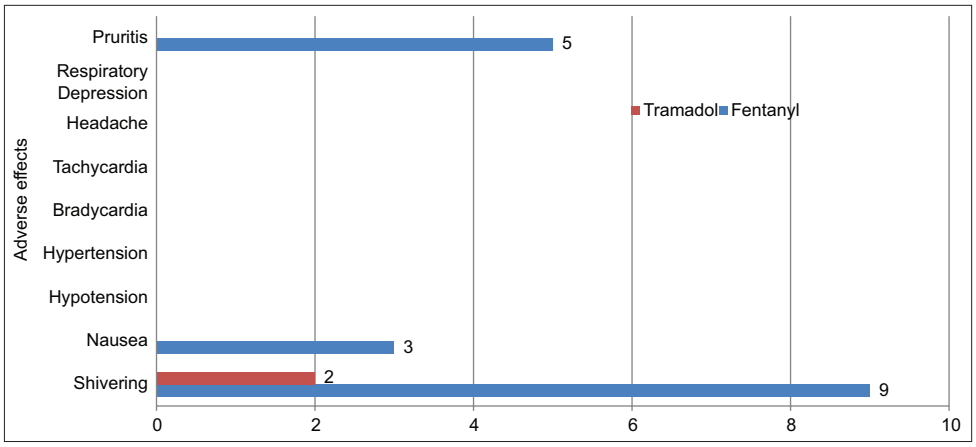


**Figure 4:** Distribution of patients according to adverse effects

nausea (P<0.05) than Group C (10%) receiving sufentanyl with bupivacaine. 35% of Group B and C patients had pruritus.

### Limitations of our study

While the study evaluated various outcome measures such as sensory and motor blockade, duration of analgesia, and hemodynamic parameters, certain subjective endpoints like pain assessment using the VAS could be influenced by individual patient perception and reporting bias. Incorporating objective measures or additional pain assessment tools could provide a more comprehensive evaluation of analgesic efficacy. Future research with extended follow-up periods could provide valuable insights into the sustained effects of intrathecal fentanyl and tramadol.

## CONCLUSION

We concluded from this study that fentanyl when used as an adjuvant with bupivacaine intrathecally shortened the onset of sensory and motor blockade as compared to tramadol, increased the duration of sensory and motor blockade, and also prolonged the duration of analgesia as compared to tramadol. However, the incidence of adverse

effects such as nausea, shivering, and pruritus were more in group fentanyl as compared to group tramadol. Thus the addition of fentanyl as an adjuvant intrathecally to 0.5% bupivacaine heavy in patients undergoing urological surgeries augmented the quality of spinal anesthesia but the addition of tramadol also provided a stable hemodynamic profile and lesser adverse effects as compared to fentanyl and can safely use in low-resource setups.

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**BMW-** Literature survey, prepared the first draft of the manuscript, implementation of the study protocol, data collection, data analysis, manuscript preparation and submission of article; **MJ-** Definition of intellectual content, concept and design, clinical protocol, manuscript preparation, and manuscript revision; **NT-** Concept and design of the study, review manuscript; **NJ-** Concept, manuscript preparation, statistical analysis, coordination, and manuscript revision; **MKV-** Review manuscript, editing, literature survey and preparation of tables and figures.

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