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COMPARATIVE STUDY OF INTRATHECAL TRAMADOL AND FENTANYL AS ADJUVANTS IN LOWER ABDOMINAL SURGERIES

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Spinal anesthesia is preferred choice of anesthesia in lower abdominal surgeries for a long time. However, the problem with this is limited duration of action, so for long duration surgeries alternatives are required.

The aim: to compare the intra-operative effects of a low dose of intrathecal tramadol and intrathecal fentanyl with hyperbaric bupivacaine hydrochloride.

Materials and methods: prospective randomized control study for a duration of study is one year. 50 patients, aged 18 years to 60 years, belonging to ASA physical status I and II, posted for elective lower abdominal surgeries under spinal anaesthesia were chosen.

These patients were divided into two groups: group BT- this group of patients received 2.5 mL volume of 0.5 % hyperbaric bupivacaine with 25 mg of tramadol intrathecally. Group BF- this group of patients received 2.5 mL volume of 0.5 % hyperbaric bupivacaine with 25 µg of fentanyl intrathecally.

Results: demographic parameters in both the groups are not statistically significant. The association between the differences in duration of surgeries of both the study groups is not statistically. The association between the differences in mean time of onset of sensory block and motor block of both the study groups was comparable with $p > 0.05$

The duration of sensory block (analgesia) and duration of motor block difference between the two means was statistically significant with $p < 0.0000001$. The difference between the mean VAS score at 3 hours and at 20 hours was statistically significant with $p < 0.05$. Among the study BT group, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p < 0.000002$. The association between the hemodynamic variables between both the groups at the end of procedure was statistically significant with $p < 0.05$.

Conclusions: Intrathecal fentanyl and tramadol produced a similar onset of sensory and motor blocks. Fentanyl provided better duration and quality of postoperative analgesia compared to tramadol

Keywords: fentanyl, tramadol, postoperative analgesia, sensory block, motor block, bupivacaine, intrathecally, heart rate, systolic BP, diastolic BP, visual analogue scale (VAS)

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1. Introduction

Spinal anaesthesia is advantageous in that it uses a small dose of the anaesthetic, is simple to perform, and offers a rapid onset of action, reliable surgical analgesia and good muscle relaxation. These advantages are sometimes offset by a relatively short duration of action and complaints of post-operative pain when it wears off. Due to lack of step-down units where nurses can monitor epidural infusions and lack of PCA (Patient Controlled Analgesia) equipment, patients often have break-through pain post-operatively. If we could provide post-operative analgesia in a simple and inexpensive manner, it could go a long way in alleviation of pain and suffering. Spinal anaesthesia with hyperbaric Bupivacaine Hydrochloride is preferred for longer procedures due to its longer duration of action. But there is a need to increase the intensity and duration of sensory blockade without increasing the intensity and duration of motor blockade to prolong the duration of postoperative analgesia and promote early ambulation. The addi-

tion of opioids has been suggested as a method to accomplish these goals [1, 2].

Intrathecal opioids are among the most popular, commonly combined with local anesthetics to improve the onset time of block, duration, and quality of analgesia both intra operatively and post operatively. The addition of morphine and fentanyl have been used regularly. Fentanyl, a lipophilic opioid, has rapid onset of action following intrathecally administration. It does not tend to migrate to the fourth ventricle in sufficient concentration to cause delayed respiratory depression when administered intrathecally. In the present study, we have attempted to evaluate and compare the effect of intrathecal fentanyl, tramadol, clonidine mixed with bupivacaine for peri and post-operative pain relief and quality of block in lower abdominal surgery.

This study is designed to quantitatively examine the effects of adding fentanyl and tramadol to Hyperbaric Bupivacaine Hydrochloride on duration and recovery of sensory and motor blockade.

2. Materials and methods

Prospective randomized control study was conducted at Gandhi Medical College and Hospital, Secunderabad, duration of study is one year from August 2019 to July 2020. Following institutional ethical and scientific committee approval title – “Comparative study of intrathecal tramadol and fentanyl as adjuvants in lower abdominal surgeries.” (IEC19102002003D, 1/8/2019), patients were thoroughly explained regarding the nature of the study and an informed written consent was taken from all the patients.

50 patients, aged 18 years to 60 years, belonging to ASA physical status I and II, posted for elective lower abdominal surgeries under spinal anaesthesia were chosen.

These patients were divided into two groups:

Group BT: this group of patients received 2.5 mL volume of 0.5 % hyperbaric bupivacaine with 25 mg of tramadol intrathecally.

Group BF: this group of patients received 2.5 mL volume of 0.5 % hyperbaric bupivacaine with 25 µg of fentanyl intrathecally.

Inclusion criteria: patients aged between 18 to 60 years of ASA grade I or II scheduled for elective lower abdominal surgeries.

Exclusion criteria: allergic to any of the drugs, heart block/dysrhythmia, use of pain modifying drugs, contraindicated for spinal anaesthesia.

Pre-anesthetic check-up including history, clinical examination, systemic examination of cardiovascular, respiratory, and central nervous systems and examination of spine for deformity or local infection was done.

All basic laboratory examinations were done. An informed written consent was obtained from the patient and their relatives. Patients were asked to fast for 6 hours for solids and 2 hours for clear fluids preoperatively. The procedure of spinal anaesthesia was explained and the patient was explained to communicate regarding perception of any pain or discomfort during surgery.

In the operation theatre, an intravenous line was secured. Baseline heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate (RR), Oxygen saturation (Spo2) were recorded for all the patients, and they received 10 ml/kg of ringer lactate solution as preload within 20–30 minutes.

Subarachnoid block was performed under strict aseptic conditions in sitting position after infiltrating the

skin with 2 % lignocaine at the level of L3–4 intervertebral space using 25G QB’s spinal needle. Following subarachnoid block, the patients were put in supine position.

Intraoperatively HR, SBP, DBP, RR, and SPO₂ were recorded at regular intervals.

Hypotension (MAP<60 mm of Hg) was treated with fluid boluses and 6 mg intravenous mephenteramine, bradycardia was treated with 0.6 mg of atropine. Respiratory rate <8 breaths/min or SPO₂ of <90 % on room air was treated with supplemental oxygen via facemask at 6 l/min.

Statistics. Data was entered in Microsoft Excel and analysis was done using SPSS version 20. Descriptive statistical analysis was done. Results on continuous measurements are presented as Mean & Standard Deviation. Results on categorical measurements are presented as percentages.

Significance is assessed at 5 % level of significance. Student t test (independent, two tailed) has been used to find out the significance of study parameters on a continuous scale between two groups. χ^2 test is used to find out the significance of study parameters on a categorical scale between two groups.

3. Results

Among the BT group majority (48 %) of the patients belonged to the age group of 21–25 years, followed by 26–30 years (32 %), >30 years (12 %). 8 % belonged to the age group of less than or equal to 20 years. The mean age was 25.43±7.2 years.

Among BF group majority (52 %) of the patients belonged to the age group of 21–25 years, followed by 26–30 years which contributed to 24 %. Age group of >30 years and less than or equal to 20 years contributed to 12 % each. The mean age was 24.47±8.3 years.

The association between the differences in age group of both the study groups is not statistically significant.

Gender distribution was same among both the groups. 48 % were males and 52 % were females.

Among BT group, 88 % belonged to ASA – I, 12 % belonged to ASA – II.

Among BF group, 92 % belonged to ASA – I, 8 % belonged to ASA – II.

The mean height and weight among both the groups is not statistically significant (Table 1).

Table 1

Age distribution of patients				
Age group	Group BT	Frequency (%)	Group BF	Frequency (%)
Less than or equal to 20 years	2	8	3	12
21–25 years	12	48	13	52
26–30 years	8	32	6	24
>30 years	3	12	3	12
Total	25	100	25	100
Mean±Standard Deviation	25.43±7.2 years		24.47±8.3 years	
Gender				
Male	12	48	12	48
Female	13	52	13	52
ASA physical status				
I	22	88	23	92
II	3	12	2	8
Height, cm	156.2±6.9		154.2±9.5	
Weight, kg	59.5±7.9		60.9±8.7	

The association between the differences in duration of surgeries of both the study groups is not statistically significant with $p>0.3$.

The association between the differences in mean time of onset of sensory block and motor block of both the study groups was comparable with $p>0.05$. In duration of sensory block (analgesia) difference between the

two means was statistically significant with $p<0.0000001$. The mean duration of motor block difference between the two was statistically significant with $p<0.0000001$ (Table 2).

The difference between the mean VAS score at 3 hours and at 20 hours was statistically significant with $p<0.05$ (Table 3).

Table 2

Variable of sensory and motor block

Parameter	Group BT	Group BF	p
Average duration of surgery	41.67±6.23	43.56±7.56	0.3
Time of onset of sensory block in minutes	2.06±1.98	2.01±0.94	0.9
Time of onset of motor block in minutes	3.27±0.86	3.25±0.76	0.9
Duration of sensory block (analgesia) in min	184.66±22.08	295.66±38.56	<0.0000001**
Duration of motor block in min	136.65±29.65	245.87±35.64	<0.0000001**

Table 3

VAS scores

Time	Group BT	Group BF	p
At 3 hours	5.7±2.6	1.1±0.9	<0.0000001**
4 hours	4.1±1.9	3.4±1.5	0.15
5 hours	3.5±1.5	3.5±1.6	0.9
8 hours	3.0±1.2	3.0±0.9	0.9
12 hours	2.8±0.8	2.4±0.6	0.05
16 hours	2.5±0.6	2.7±0.5	0.2
20 hours	5.9±2.0	4.2±1.98	0.004**
24 hours	4.1±1.8	3.5±1.56	0.2

Among the study group BT, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p<0.000002$ (Table 4).

Among the study group BT, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p<0.000002$ (Table 4).

Among BT group, the baseline mean systolic blood pressure was 125.73±10.72 mmHg, which dropped to 115.56±6.5 mmHg by the end of the procedure.

Among BF group, the baseline mean systolic blood pressure was 122.74±11.1 mmHg, which dropped to 110.42±7.82 mmHg by the end of the procedure (Fig. 2).

Among the study group BT, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p<0.000002$ (Table 4).

The association between the hemodynamic variables between both the groups at baseline was not statistically significant with $p>0.05$.

The association between the hemodynamic variables between both the groups at the end of procedure was statistically significant with $p<0.05$ (Table 5).

Table 4

No. of rescue analgesics needed in 24 hours

Total no. of analgesics	Group BT	Frequency (%)	Group BF	Frequency (%)
1	0	0	14	56
2	13	52	11	44
3	12	48	0	0
Total	25	100	25	100

χ^2 value: 26.17, Degree of Freedom: 2, $p<0.000002$ **

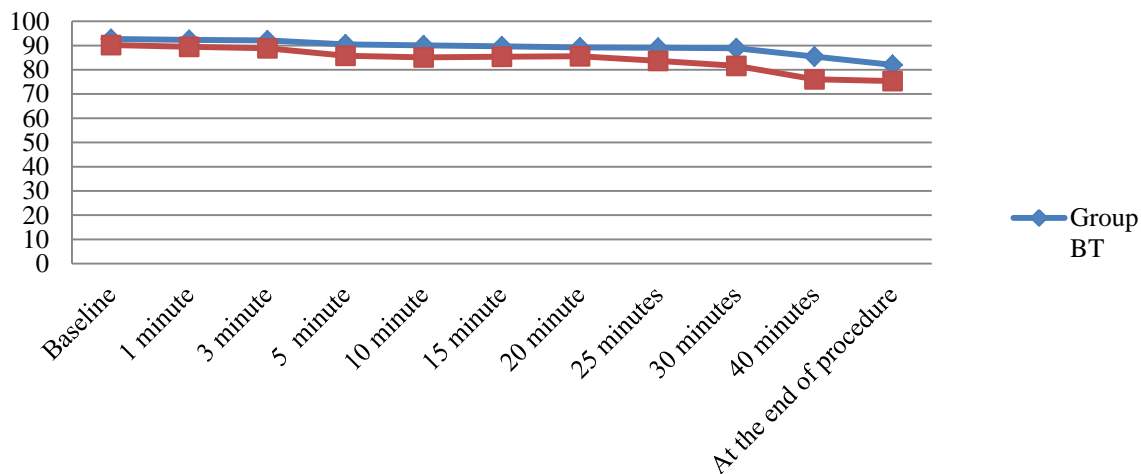


Fig. 1. Mean heart rate of study population

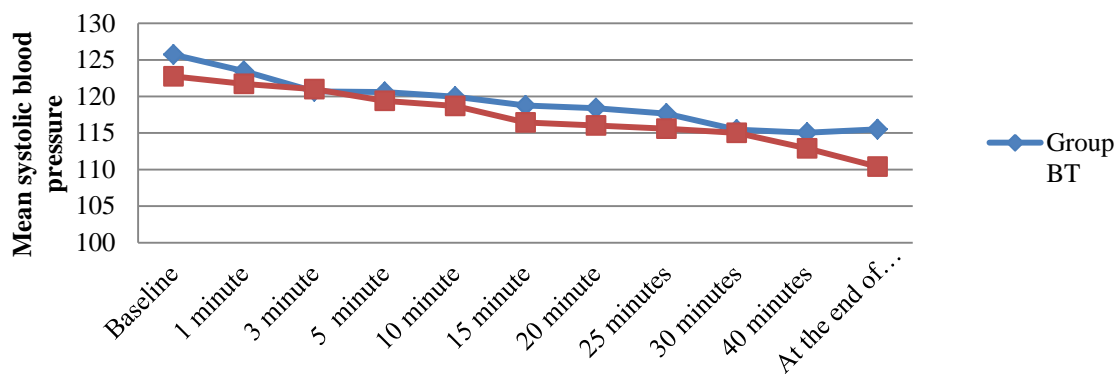


Fig. 2. Mean systolic blood pressure in mmHg of study population

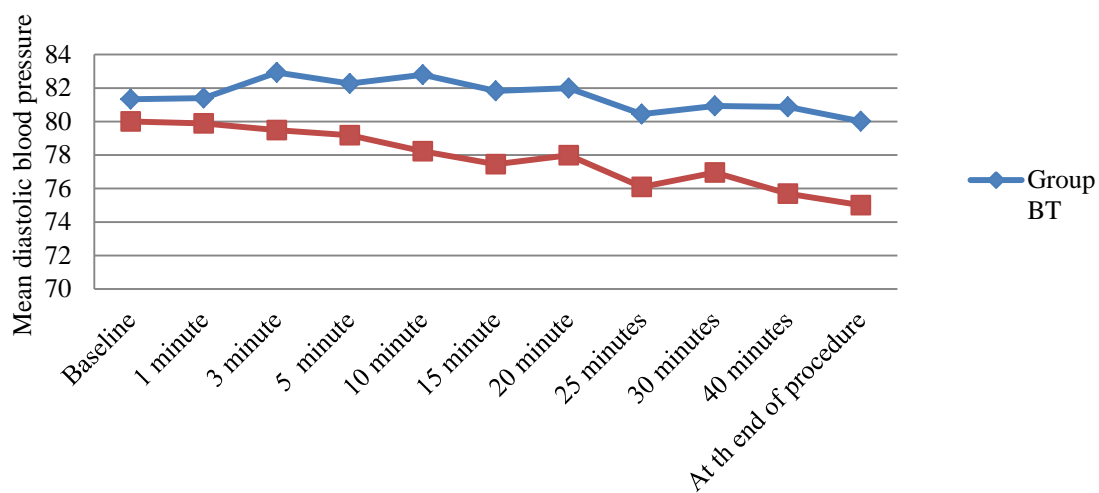


Fig. 3. Mean diastolic blood pressure in mmHg of study population

Table 5

Association between hemodynamic variables

Parameter	Group BT	Group BF	p
Mean heart rate (beats per minute)	Baseline reading	92.7±11.5	0.43
	At the end of the procedure	82.0±6.5	0.006
Mean Systolic Blood Pressure (mmHg)	Baseline reading	125.73±10.72	0.3
	At the end of the procedure	115.56±6.5	<0.000001
Mean Diastolic Blood Pressure (mmHg)	Baseline reading	81.33±6.7	0.47
	At the end of the procedure	80.01±7.4	0.00005

4. Discussion

The aim of intraoperative and postoperative pain relief is to provide comfort and to inhibit trauma-induced nociceptive impulses, thereby blunting autonomic and somatic reflex responses to pain. Postoperative analgesia plays a pivotal role in medical practice, enabling faster restoration of physiological functions. Spinal anesthesia is a popular anesthetic technique for lower abdominal surgeries. Though subarachnoid block provides effective analgesia in the initial postoperative period, the effect is very short lasting. Hence, additional analgesics are needed to lengthen the duration of analgesia provided. The use of potent opioid analgesics systemically is associated with respiratory depression, nausea, and vomiting, itching, and urinary retention. Hence, attempts were made to increase the duration of analgesia produced by subarachnoid block by addition of various intrathecal adjuvants [3].

Analgesic effect of opioids arises from their ability to inhibit the ascending transmission of nociceptive information from the dorsal horn of the spinal cord directly and to activate the pain control circuits that descend from the midbrain, via the rostral ventromedial medulla, to the dorsal horn of the spinal cord.

Fentanyl, a lipophilic opioid, is a strong μ and κ receptor agonist and 100 times more potent than morphine as an analgesic. It acts on the μ receptors present in substantia gelatinosa of the dorsal horn of the spinal cord, causing inhibition of substance P release which results in alteration of pain perception and inhibition of pain pathway. It does not tend to migrate to the fourth ventricle in sufficient concentration to cause delayed respiratory depression when administered intrathecally.

Tramadol is a centrally acting opioid. It binds to the μ -receptor and to a lesser extent to the δ - and κ -opioid receptors but is 5 to 10 times less potent than morphine as an analgesic. It enhances the function of spinal descending inhibitory pathways by inhibition of neuronal reuptake of norepinephrine and serotonin as well as presynaptic stimulation of 5-hydroxytryptamine release. It has lower incidence of cardiovascular and respiratory depression as compared to other opioid agonists [4, 5].

In the present study, among BT group majority (48 %) of the patients belonged to the age group of 21–25 years, followed by 26–30 years (32 %), >30 years (12 %). 8 % belonged to the age group of less than or equal to 20 years. The mean age was 25.43±7.2 years.

In the present study, among group the difference in the means of demographic parameters in both the

groups is not statistically significant. The findings of the present study are comparable with the Dalvi NP et al. study [6].

In the present study, among BT group, the mean duration of surgery was 41.67±6.23 minutes. Among BF group, the mean duration of surgery was 43.56±7.56 minutes. The association between the differences in duration of surgeries of both the study groups is not statistically significant with $p>0.3$. Dalvi NP et al and Patil S et al. study [6–9].

In the present study, among group BT, the mean time of onset of sensory block was 2.06±1.98 minutes and mean time of onset of motor block was 3.27±0.86 minutes. Among group BF, the mean time of onset of sensory block was 2.01±0.94 minutes and mean time of onset of motor block was 3.25±0.76 minutes. The association between the differences in mean time of onset of sensory block and motor block of both the study groups was not statistically significant with $p>0.05$ (Table 2).

In the present study, the duration of analgesia in BT group was 184.66±22.08 minutes. The duration of analgesia among BF group was 295.66±38.56 minutes. The difference between the two means was statistically significant with $p<0.0000001$ (Table 6).

The duration of analgesia was longer in the fentanyl group when compared to tramadol group. Fentanyl provided better analgesia than tramadol. In the present study, the mean duration of motor block in BT group was 136.65 min and among BF group was 245.87 minutes. The difference between the two was statistically significant with $p<0.0000001$.

In the present study, among BT group, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p<0.000002$ (Tables 3, 4).

In the present study, among BT group, the baseline heart rate was 92.7±11.5 beats per minute, which dropped to 82.0±6.5 beats per minute by the end of the procedure. Among BF group, the baseline heart rate was 90.2±11.1 beats per minute, which dropped to 75.36±9.65 beats per minute by the end of the procedure. The decline in the heart rate is more in BT group when compared with group BF. Fentanyl component in the low dose bupivacaine group contributed to higher hemodynamic stability (Fig. 1). Among BF group, the baseline mean systolic blood pressure was 122.74±11.1 mmHg, which dropped to 110.42±7.82 mmHg by the end of the procedure.

Table 6

The findings of the present study are comparable with the following studies

No	Author	Group BT	Group BF	p
Sensory component				
1	Present study	2.06±1.98 minutes	2.01±0.94 minutes	>0.05
2	Dalvi NP et al., ⁶	1.47±0.5 minutes	1.37±0.5 minutes	>0.05
Motor component				
1	Present study	3.25±0.86 minutes.	3.25±0.76 minutes.	>0.05
2	Desai D et al. ⁸	2.6±0.62 minutes.	2.47±0.776 minutes.	NS
Duration of analgesia				
1	Present study	184.66±22.08 min	295.66±38.56 min	<0.000001**
2	Dalvi NP et al., ⁶	261.6±27.92 min	314.66±49.25 min	<0.001
3	Patil S et al., ⁷	378.64	472.24	Significant
4	Waghmare et al.,	295±44.6min	184±23.3 min	<0.0001
Mean duration of motor block				
1	Present study	136.65±29.65 min	245.87±35.64 min	<0.0000001
2	Dalvi NP et al.,	214.66±26.61 min	263.66±40.97 min	<0.001
Number of analgesic doses				
1	Present study	2 doses – 52 % 3 doses – 48 %	1 dose – 56 % 2 doses – 44 %	0.000002
2	Dalvi NP et al.,	2 doses – 60 % 3 doses – 40 %	1 dose – 40 % 2 doses – 60 %	<0.0001

Among the study group BT, 52 % needed 2 analgesics and 48 % needed 3 doses of analgesics. Among BF group, 6 % needed only one dose of analgesics and 44 % needed 2 doses of analgesics. The difference between the two was statistically significant with $p < 0.000002$ (Table 4).

In the present study, among BT group, the baseline mean diastolic blood pressure was 81.33 ± 6.7 mmHg, which dropped to 80.01 ± 7.4 mmHg by the end of the procedure.

Among BF group, the baseline mean diastolic blood pressure was 80 ± 6.5 mmHg, which dropped to 75.01 ± 6.9 mmHg by the end of the procedure. The decline in the systolic blood pressure is more in BT group when compared with BF group. Fentanyl component in the low dose bupivacaine group contributed to higher hemodynamic stability. However, there were no hypotension cases reported, though there was decline in the diastolic blood pressure of group BT, they did not need any vasopressors or hypotension treatment (Fig. 3).

The association between the hemodynamic variables between both the groups at baseline was not statistically significant with $p > 0.05$. The association between the hemodynamic variables between both the groups at the end of the procedure was statistically significant with $p < 0.05$ (Table 5).

No side-effects were reported in either group. In a recent study, Subedi et al [10] demonstrated that for cesarean section under subarachnoid block with hyperbaric bupivacaine, intrathecal tramadol 10 mg produces a longer duration of pain relief with a lower incidence of shivering compared to intrathecal fentanyl 10 mg. Afolayan et al [11] demonstrated that intrathecal tramadol 25 mg is equipotent with 25 µg of intrathecal fentanyl during bupivacaine subarachnoid block for appendectomy. Singh [12] compared bupivacaine with bupivacaine tramadol and bupivacaine-fentanyl and found that duration of analgesia is prolonged with

both tramadol and fentanyl, but is more prolonged with fentanyl.

Study limitations. Rotational error was not included; study period was not long; sample size was small. Our patient population did not include geriatric patients or obese patients, who are more likely to benefit from a faster recovery from anesthesia.

Prospects for future research. Future studies are needed to validate for post-operative assessment of cognitive dysfunction in elderly patients (over 65 years) and compare its usefulness with other relevant neuropsychological tests. Our study design needs to have follow-up to see if the benefits of early recovery from anesthesia extended into the intermediate and late recovery period.

5. Conclusion

Intrathecal fentanyl and tramadol produced a similar onset of sensory and motor blocks. Fentanyl provided better duration and quality of postoperative analgesia compared to tramadol. The difference between both the drugs was statistically significant with $p < 0.05$. No side effects were reported in either group.

Conflict of interest

The authors declare that they have no conflicts of interest.

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