PEROPERATIVE AND POSTOPERATIVE SHIVERING CONTROL BY ONDANSETRON AND OPIOIDS FOLLOWING SPINAL ANAESTHESIA- A CLINICAL COMPARATIVE STUDY

Ravi Kumar Goel[1], Pratibha Jain Shah[2], Omprakash Sundrani[3], Durga Shankar Patel[4], Jaya Lalwani[5], Kamal Kishore Sahare[6]

[1]Assistant Professor, Department of Anaesthesiology and Critical Care, Raipur Institute of Medical Sciences, Raipur, Chhattisgarh, India.
[2]Professor and HOD, Department of Anaesthesiology and Critical Care, Pt. JNM Medical College, Raipur, Chhattisgarh, India.
[3]Associate Professor, Department of Anaesthesiology and Critical Care, Pt. JNM Medical College, Raipur, Chhattisgarh, India.
[4]Associate Professor, Department of Anaesthesiology and Critical Care, Government Medical College, Ambikapur, Chhattisgarh, India.
[5]Professor, Department of Anaesthesiology and Critical Care, Pt. JNM Medical College, Raipur, Chhattisgarh, India.
[6]Professor and HOD, Department of Anaesthesiology and Critical Care, Government Medical College, Rajnandgaon, Chhattisgarh, India.

ABSTRACT

BACKGROUND

Shivering occurs as an adverse effect of surgical procedures during regional anaesthesia. Numerous pharmacological interventions have been proposed for the prevention and treatment of shivering. The mechanism of the antishivering effect of these drugs has not yet been completely clearly understood.

The present study will therefore evaluate and compare the efficacy of IV administration of Ondansetron and Opioids (Fentanyl, Tramadol and Pentazocine) in controlling of peroperative and postoperative shivering after spinal anaesthesia.

MATERIALS AND METHODS

This is a prospective, randomised, double-blind controlled study. 120 patients between 18 - 60 years of age of ASA grade I and II of either sex undergoing lower limb or lower abdominal surgery were included in this study.

RESULTS

We observed that the mean pulse rate, systolic and diastolic blood pressure in all the 4 groups were within normal limits and there was no statistically significant difference among the groups. Our study revealed that Ondansetron, Pentazocine, Tramadol and Fentanyl were found to be effective in preventing and reducing the severity of shivering following Spinal Anaesthesia, but Ondansetron was less effective than Opioids.

CONCLUSION

Based on our experience in the present study, we conclude that tramadol is an ideal intravenous drug for intraoperative and postoperative control of shivering following Spinal Anaesthesia.

KEY WORDS

Spinal Anaesthesia, Shivering, Pentazocine, Tramadol, Fentanyl, Ondansetron.

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BACKGROUND

Shivering occurs as an adverse effect of surgical procedures during regional anaesthesia. It interferes with monitoring of ECG, blood pressure and oxygen saturation. It also increases O_2 consumption, CO_2 production, lactic acidosis, defective platelet function, wound infection, poor wound healing, increased blood pressure and heart rate. Shivering can be characterised by its threshold (Triggering core temperature), gain (Incremental intensity increase) and maximum intensity. During regional anaesthesia autonomic and behavioural thermoregulation are impaired, so vasoconstriction and shivering threshold are comparably decreased.

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Corresponding Author:
Dr. Omprakash Sundrani,
Associate Professor,
Department of Anaesthesiology and Critical Care,
Pt. JNM Medical College, Raipur, Chhattisgarh, India.
E-mail: sundraniop@rediffmail.com
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The shivering threshold is reduced approximately by 1°C, but the vasoconstriction threshold remains relatively normal. Such divergence between the shivering and vasoconstriction threshold is an unusual pattern of thermoregulatory impairment. It suggests that mechanism of thermoregulatory impairment during regional anaesthesia may be especially complexed.

Numerous pharmacological interventions have been proposed for the prevention and treatment of shivering. The mechanism of the anti-shivering effect of these drugs has not yet been completely cleared. Tramadol has a weak agonist action at opioid receptors and has serotonin reuptake inhibition property. Fentanyl is a pure μ agonist, pentazocine is a partial agonist- antagonist at opioid receptors. On the other hand, drugs having antagonistic action on serotonin-3 receptors like Ondansetron, Dolasetron and Granisetron also have antishivering property.

For these controversies, the present study will therefore evaluate and compare the efficacy of IV administration of Ondansetron and Opioids (Fentanyl, Tramadol and Pentazocine) in control of peroperative and postoperative shivering after spinal anaesthesia.

Aims and Objectives

1. To compare the efficacy of IV administration of Opioids (Fentanyl, Tramadol, Pentazocine) and Ondansetron in preventing the incidence and severity of peroperative and postoperative shivering following spinal anaesthesia.
2. To compare the effect of drugs on O_2 saturation, pulse rate, blood pressure and respiration, peripheral and core temperature.
3. To assess side effects/ complications related to the drug given.

MATERIALS AND METHODS

This is a prospective, randomised, double-blind controlled study. After obtaining Institutional Ethical Committee approval and caregiver written informed consent, 120 patients between 18 - 60 years of age of ASA grade I and II of either sex undergoing lower limb or lower abdominal surgery were included in this study.

Patients having pyrexial illness, allergy to study drugs, suffering from major illness including thyroid disease, hypertension, diabetes mellitus etc. and with any contraindication for spinal anaesthesia were excluded from the study.

Sample size was taken conveniently.

After a detailed history, general and systemic examination and necessary investigations, patients were randomised using a computerised randomisation table and allocated-

Group A- (40 patients) received IV Ondansetron 0.15 mg/kg
Group B- (40 patients) received IV Pentazocine 0.5 mg/kg
Group C- (40 patients) received IV Tramadol 1 mg/kg
Group D- (40 patients) received IV Fentanyl 0.001 mg/kg

All the studied drugs were administered intravenously 3 - 5 minutes prior to spinal anaesthesia randomly. After securing IV access with 18-G intracath, all patients were preloaded with 500 mL ringer lactate warmed at 37°C. Non-invasive monitors viz. (ECG, NIBP, Pulse oximeter) were attached and vital parameters like heart rate, blood pressure, oxygen saturation, respiratory rate, core and peripheral temperature were continuously monitored and recorded preoperatively and at every 5 minutes for first 30 minutes and thereafter at every 15 minutes interval up to 2 hours after spinal anaesthesia. Core temperature was monitored by temperature probe T1 for nasopharynx and T2 for axillary skin and connected to multipara monitor.

All the patients were monitored for side effects like pruritus, nausea, vomiting, respiratory depression, bradycardia and hypotension.

Under all aseptic precautions, lumbar puncture was performed with 23-Gauge Quincke's type lumbar puncture needle in the L3-L4 interspace. After obtaining clear and free flow of CSF, Inj. Bupivacaine 0.5% (heavy) 4 cc was injected. After spinal injection, patients were placed supine and a sensory block up to T6 was obtained.

During anaesthesia O_2 - 3 L/min was given and patients were covered with drapes, but not actively warmed. All fluids were warmed to 37°C. The operating room temperature was maintained at 22-24°C.

Time of occurrence of shivering was recorded and graded with a scale described by Crossley and Mahajan.

Grade 0– No Shivering.
Grade 1– Piloerection of peripheral vasoconstriction, but no visible shivering.
Grade 2– Muscular activity in one muscle group.
Grade 3– Muscular activity in more than one muscle group.
Grade 4– Shivering involving the whole unblocked body.

Hypotension was defined as systolic blood pressure 20% below the basal level.

Bradycardia was defined as heart rate less than 60 beats/min.

All the observations were recorded and tabulated and all the data were stored on disk and analysed with SPSS (Version 13.0, SPSS Inc., Chicago, IL) statistical software. The male/female distribution between the groups was compared using Chi-square test. Demographic data, blood pressure and heart rate data were compared between the groups using the two-tailed student's test. The quantitative data were expressed as mean (Standard deviation). Results were analysed statistically by two-way repeated measure ANOVA test. A p-value less than 0.05 was considered.

On the basis of results obtained and statistical evaluation, inference was drawn.

RESULTS

In our study, maximum number of patients had a sensory block level of T6 (70%). Rest 30% of patients had a sensory block level of T5 or T7.

Mean time of surgical regression was 126 ± 9.06 mins, 120.5 ± 12.12 mins, 128 ± 8.99 mins and 126.16 ± 9.06 mins in Group A, B, C and D, respectively. There was no statistically significant differences among the groups with respect to time of sensory regression.

Time (mins)	Group-A		Group-B		Group-C		Group-D	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-SAB	83	11	84	10	84	11	83	10
5	84	12	83	12	84	11	82	12
10	82	13	83	13	83	13	83	11
15	82	13	82	14	83	14	82	11
20	82	14	82	14	84	14	81	13
25	81	12	81	13	81	13	80	13
30	79	13	81	12	81	12	79	12
45	79	12	82	11	81	11	79	9.9
60	80	11	82	10	81	11	79	9.5
75	79	10	82	9.4	80	9.7	79	8.5
90	79	9.1	81	8.6	80	8.9	77	8.3
105	78	9	81	7.8	80	7.7	78	7.8
120	78	8.1	80	7.2	79	7.3	78	7.9
Mean	80	1.83	82	0.84	81	1.6	80	1.78

Table 1. Mean Pulse Rate at various Time Intervals

Table-1 shows mean pulse rate at various time intervals. Mean pulse rate throughout the procedure was 80/min, 82/min, 81/min and 80/min in Group A, B, C and D respectively.

Significance Test	Group A and B	Group B and C	Group C and D	Group D and A
P-value	>0.05	>0.05	>0.05	>0.05

There was no statistically significant differences among the groups regarding pulse rate.

Time Interval	Group-A		Group-B		Group-C		Group-D	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-SAB	119	708	119	7.8	120	8.1	109	7.8
5	106	7.6	109	7.3	110	8.1	107	9.2
10	102	7.9	103	6.6	104	8.1	103	7.1
15	102	7.9	103	6.4	103	7.1	103	6.9
20	102	7.6	103	6.5	103	7.1	103	6.9
25	104	7.8	105	5.7	105	6.3	104	6.7
30	105	7.7	106	5.7	107	6.1	106	5.7
45	106	7.7	107	6.1	108	6.8	108	5.8
60	107	7.1	108	6.0	108	6.6	108	5.5
75	107	7.5	108	6.3	109	6.3	108	5.9
90	108	6.9	110	6.1	111	6.4	111	5.8
105	109	7.1	112	5.5	112	5.7	111	5.1
120	111	10	113	6.0	114	5.6	113	5.3
Mean SBP	106.41	4.42	107.75	4.38	108.41	4.55	107.58	4.40

Table 2. Mean Systolic Blood Pressure at various Time Intervals

Table-2 shows mean systolic pressure at various time intervals. Mean systolic blood pressure throughout the procedure was 106.41 ± 4.4 mmHg, 107.75 ± 4.38 mmHg, 108.41 ± 4.55 mmHg and 107.58 ± 4.38 mmHg in Group A, B, C and D respectively.

Significance Test	Group A and B	Group B and C	Group C and D	Group D and A
P-value	>0.05	>0.05	>0.05	>0.05

There was no statistically significant differences among the groups regarding systolic blood pressure.

Time (Min)	Group A		Group B		Group C		Group D	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-SAB	76	6.7	77	7.1	77	6.6	77	6.5
5	68	6.3	69	6.3	68	5.9	68	5.9
10	66	6.7	66	6.7	67	6.6	68	6.1
15	67	6.4	67	6.5	68	6.1	69	5.2
20	69	5.7	70	4.9	70	5.3	70	4.9
25	69	5.2	70	4.1	71	4.0	71	4.5
30	69	5.2	70	4.1	70	4.0	71	4.8
45	70	5.6	72	3.8	72	4.8	71	4.8
60	71	5.2	72	3.8	72	4.8	70	4.1
75	71	5.1	72	3.8	72	4.8	73	4.1
90	72	4.6	72	4.1	72	4.8	72	4.5
105	72	4.8	72	4.1	72	4.8	73	4.7
120	72	4.3	72	4.1	72	4.3	73	4.7
Mean	70	2.54	70.72	2.71	70.91	2.53	71.25	2.38

Table 3. Mean Diastolic Blood Pressure at Various Time Interval

Table 3 shows mean diastolic blood pressure at various time interval in different groups. Mean diastolic pressure was 70 ± 2.54 mmHg, 70.72 ± 2.71 mmHg, 70.91 ± 2.53 mmHg and 71.25 ± 2.38 mmHg in Group A, B, C and D respectively.

Significance Test	Group A and B	Group B and C	Group C and D	Group D and A
P-value	>0.05	>0.05	>0.05	>0.05

There was no statistical difference among groups regarding diastolic blood pressure.

Mean respiratory rate was 16.02 ± 0.27 per min, 16 ± 0 per min, 16.25 ± 0.82 per min and 15.16 ± 0.37 per min in Group A, B, C and D respectively and there was no statistical difference among groups regarding respiratory rate.

Mean SPO2 was 99.58 ± 0.49, 99.83 ± 0.37, 99.75 ± 0.43 and 99.58 ± 0.49 in Group A, B, C and D respectively and the difference was statistically insignificant.

Time (min)	Group A		Group B		Group C		Group D	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-SAB	36.6	0.1	36.6	0.07	36.5	0.1	36.6	0.09
5	36.6	0.09	36.6	0.1	36.6	0.08	36.6	0.11
10	36.4	0.1	36.4	0.15	36.4	0.11	36.4	0.11
15	36.2	0.11	36.2	0.16	36.2	0.16	36.3	0.11
20	36.1	0.13	36	0.2	36.1	0.2	36.2	0.11
25	36	0.2	35.9	0.25	36	0.25	36.1	0.16
30	35.9	0.21	35.8	0.26	35.9	0.28	35.9	0.21
45	35.8	0.22	35.7	0.26	35.7	0.27	35.8	0.22
60	35.7	0.24	35.6	0.27	35.6	0.27	35.7	0.24
75	35.5	0.25	35.5	0.27	35.5	0.28	35.6	0.24
90	35.4	0.27	35.4	0.28	35.4	0.27	35.4	0.26
105	35.4	0.27	35.3	0.29	35.4	0.28	35.4	0.260
120	35.4	0.26	35.4	0.26	35.4	0.27	35.5	0.25

Table 4. Mean Peripheral Temperature (℃) at various Time Intervals

Table-4 shows mean peripheral temperature at various time interval in different groups. These show that there was a gradual fall in peripheral temperature after induction of anaesthesia. This fall in peripheral temperature was maximum during the first 30 mins. At the completion of two hour, the peripheral temperature was 35.4 ± 0.26, 35.4 ± 0.26, 35.4 ± 0.27 and 35.5 ± 0.25℃ in Group A, B, C and D respectively.

Significance Test	Group A and B	Group B and C	Group C and D	Group D and A
P-value	>0.05	>0.05	>0.05	>0.05

There was no statistical difference among groups regarding peripheral temperature.

Time (Min)	Group A		Group B		Group C		Group D	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-SAB	37	0.09	37	0.08	37	0.09	37	0.1
5	36.9	0.1	36.8	0.1	36.9	0.11	36.9	0.1
10	36.7	0.11	36.7	0.12	36.7	0.14	36.7	0.11
15	36.6	0.12	36.6	0.14	36.6	0.14	36.6	0.12
20	36.5	0.14	36.5	0.15	36.5	0.16	36.5	0.13
25	36.4	0.15	36.4	0.16	36.4	0.17	36.4	0.16
30	36.3	0.19	36.3	0.2	36.3	0.2	36.3	0.18
45	36.2	0.19	36.2	0.21	36.2	0.2	36.2	0.18
60	36.1	0.21	36.1	0.22	36.1	0.21	36.1	0.2
75	36	0.22	36	0.23	36	0.22	36	0.22
90	35.9	0.25	35.9	0.26	35.9	0.24	35.9	0.24
105	35.8	0.29	35.9	0.29	35.8	0.29	35.8	0.27
120	35.8	0.31	35.9	0.3	35.9	0.31	35.9	0.28

Table 5. Mean Core Temperature at various Time Interval

Table-5 shows mean core temperature at various time interval in different groups. These shows that there was a gradual fall in core temperature after induction of anaesthesia. The fall in core temperature was maximum during the first 30 mins. At the completion of two hours, the core temperature was 35.8 ± 0.31, 35.9 ± 0.3, 35.9 ± 0.31 and 35.9 ± 0.28°C in Group A, B, C and D respectively.

Significance Test	Group A and B	Group B and C	Group C and D	Group D and A
P-value	>0.05	>0.05	>0.05	>0.05

There was no statistical difference among groups regarding core temperature.

Shivering Grade	Group-A	Group-B	Group-C	Group-D
	No. (%)	No. (%)	No. (%)	No. (%)
Grade-I	0(0%)	1(3.33%)	0(0%)	0(0%)
Grade-II	3(10%)	2(6.66%)	1(3.33%)	3(10%)
Grade-III	1(3.33%)	0(0%)	0(0%)	0(0%)
Grade-IV	0(0%)	0(0%)	0(0%)	0(0%)

Table 6. Incidence and Grading of Shivering

Table-6 shows that incidence of shivering was least in Group C (3.33%) as compared to 10% in Group B and D and 13.33% in Group A. None of the patients in Group B, C and D had shivering of Grade III and IV. Only one patient in Group A had shivering of Grade III.

Time (Min)	Group-A	Group-B	Group-C	Group-D
	No.	No.	No.	No.
21-30	3(10%)	0(0%)	0(0%)	1(3.33%)
31-40	0(0%)	1(3.33%)	0(0%)	0(0%)
41-50	1(3.33%)	2(6.66%)	1(3.33%)	2(6.66%)
51-60	0(0%)	0(0%)	0(0%)	0(0%)
>60	0(0%)	0(0%)	0(0%)	0(0%)

Table 7. Time of occurrence of Shivering

Table-7 shows that shivering if occurred was earlier in Group A (21-30 min) and incidence of shivering was also high in Group A. In Group B, C and D, time of occurrence of shivering was between 41 - 50.

Duration (Min)	Group A	Group B	Group C	Group D
	No. (%)	No. (%)	No. (%)	No. (%)
Hypotension	2(6.66%)	0(0%)	2(6.66%)	1(3.33%)
Bradycardia	0(0%)	0(0%)	0(0%)	1(3.33%)
Respiratory depression	0(0%)	1(3.33%)	1(3.33%)	3(10%)
Emetic episode	0(0%)	2(6.66%)	1(3.33%)	0(0%)
Pruritus	0(0%)	0(0%)	0(0%)	3(10%)

Table 8. Side Effect

Table-8 shows that incidence of hypotension was 2, 0, 2 and 1 in Group A, B, C and D respectively. Incidence of bradycardia was nil among the groups. Incidence of respiratory depression was 3 (10%) in Group D as compared to 0 (0%), 1 (3.33%) and 1 (3.33%) in Group A, B, C and D respectively. Incidence of nausea and vomiting was found in 2 cases (6.66%) in Group B only. Incidence of pruritus was found in 3 cases (10%) in Group D.

DISCUSSION

The aim of the study was to compare ondansetron and opioids for control of peroperative and postoperative shivering following spinal anaesthesia.

All the four groups were comparable with respect to demographic profile, type and duration of surgery.

In our study maximum patients (70%) had achieved a sensory block level up to T6 dermatomes. Maximum sensory block level was up to T5 (10% patients) and minimum sensory block level was up to T7 dermatome (20% patients).

In our study we observed that in maximum number of cases, time of sensory regression was in the range of 120-130 mins. Mean time of sensory regression was 126 ± 9.06 mins, 120.5 ± 12.13 mins, 128.66 ± 8.99 mins and 126.16 ± 9.06 mins in Group A, B, C, D respectively. The 4 groups were comparable to each other and there was no statistically significant difference among the groups ($p > 0.05$).

We observed that the mean pulse rate, systolic and diastolic blood pressure in all the 4 groups were within normal limits and there was no statistically significant difference among the groups.

Kurz A et al in 1995[1] observed that intraoperative hypothermia has only mild effect on postoperative heart rate and blood pressure in relatively young healthy patients.

Bhatnagar S et al 2001[2] reported that there was no significant difference in pulse rate before and after IV administration of Tramadol and Pethidine for shivering control.

Trekova NA et al 2004[3] reported that there was no significant change in heart rate and blood pressure after IV administration of Tramadol or placebo for shivering control.

Hasankhani H et al 2007[4] observed that intraoperative IV fluids warming reduces perioperative changes in haemodynamic parameters and incidence of shivering.

Thus, our study was comparable to those of Kurz A et al 1995,[1] Bhatnagar S et al 2001,[2] Trekova NA et al 2004[3] and Hasankhani H et al 2007.[4] Mean respiratory rate throughout the procedure was around 16 per minute in all the four groups and SpO2 was 99% or above at all the times and there was no difference among the groups.

We observed that there was a gradual fall in peripheral and core temperature in all the four groups after induction of spinal anaesthesia. This fall was maximum during the first 30 minutes. Decrease was less in second hour as compared to first hour in all the four groups and there was no statistically significant difference in peripheral and core temperature among the groups at the end of two hours ($p > 0.05$).

De Witte JL et al 1998[5] reported that Tramadol has only slight thermoregulatory effects and its use is unlikely to provoke hypothermia or to facilitate fever.

Robert M Powell et al 2000[6] reported that Ondansetron 8 mg IV given during the induction of anaesthesia prevents post-anaesthetic shivering without affecting the core to peripheral redistribution of heat during general anaesthesia.

Ryu Komastsu et al 2006[7] observed that Ondansetron did not reduce the shivering threshold in healthy volunteers.

Thus, our study was comparable to those of De Witte JL et al 1998[5], Robert M Powell et al 2000[6] and Ryu Komastsu et al 2006.[7]

We observed that incidence of shivering was least in Group C (3.33%) as compared to Group B and D (10%) and Group A (13.33%). None of the patients in Group B, C and D

had shivering of Grade III or IV. Only 1 patient in Group A had shivering of Grade III. Alfonsi P et al 1995[8] reported that Fentanyl was 77% effective for shivering control.

Chan AM et al 1995[9] concluded that IV Tramadol 0.5 mg was effective for the treatment of intraoperative shivering during caesarean section without affecting newborn Apgar score. Terasako K et al 2000[10] concluded that Pentazocine 7.5 mg IV had no significant role in post-anaesthetic shivering control, whereas Pethidine 17.5 mg was significantly effective in shivering control.

Kelasaka et al 2001[11] reported that Ondansetron and Meperidine were 92% effective in shivering control.

Trekova NA et al 2004[3] reported that Tramadol was 98% effective in shivering control.

Sajedi P et al 2006[12] concluded that Meperidine, Alfentanyl, Sufentanyl, Fentanyl and Tramadol had a similar effect in the treatment of post-anaesthetic shivering.

Thus, our study was comparable to those of Alfonsi P et al 1995[8], Terasako K et al 2000[10], Kelasaka et al 2001[11], Trekova NA et al 2004[3] and Sajedi P et al 2006.[12]

We observed that shivering if occurred was earlier in Group A (21 – 30 mins). In Group B, C and D time of occurrence of shivering was between 41 - 50 mins and the results of our study were comparable to that of Mucio Paranhos de Abreu et al 2002 who observed that there was a significant difference between Fentanyl and Placebo group in shivering occurrence at 60 mins and 90 mins interval after epidural block.

Incidence of hypotension was 6.66%, 0%, 6.66% and 3.335 in Group A, B, C and D respectively. Bradycardia was not observed in any of the cases. Mild respiratory depression was present in 3 cases in Group D and 1 case each in Group B and C, which did not need any intervention. None of the patients in Group A had respiratory depression.

Nausea and vomiting were more commonly present in Group B (2 cases) as compared to Group A and D (0%), whereas one patient in Group C complained of nausea. Mild pruritus was present only in Group D (3 cases).

Tsai YC et al 2001[13] reported that incidence of somnolence was 7% with Tramadol and there was no significant difference in incidence of pruritus, nausea and vomiting as compared to placebo.

Mathews S et al 2002[14] observed that tramadol 1 - 2 mg for shivering control did not increase the incidence of sedation and vomiting.

Trekova NA et al 2004[3] observed mild sedation in 17/50 with the use of IV Tramadol 2 mg/kg for shivering control.

Sajedi P et al 2006[12] observed that there was no significant difference in the incidence of pruritus, nausea vomiting and dizziness following IV administration of Fentanyl, Tramadol, Meperidine and Sufentanyl.

Thus, our study was comparable to those of Tsai YC et al 2001,[13] Mathews S et al 2002,[14] Trekova NA et al 2004[3] and Sajedi P et al 2006.[12]

CONCLUSION

Our study revealed that Ondansetron, Pentazocine, Tramadol and Fentanyl were found to be effective in preventing and reducing the severity of shivering following Spinal Anaesthesia, but Ondansetron was less effective than opioids. Among the opioids, Fentanyl was associated with mild respiratory depression and pruritus. Nausea and vomiting were more common with pentazocine.

Based on our experience in the present study, we conclude that tramadol is an ideal intravenous drug for intraoperative and postoperative control of shivering following Spinal Anaesthesia.

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