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ORIGINAL RESEARCH ARTICLE

A Prospective Randomised Comparative Study of Intravenous Tramadol versus Intravenous Ketamine for Control of Shivering in Patients Undergoing Spinal Anaesthesia for Infraumbilical Surgeries

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ABSTRACT

BACKGROUND

Shivering is distressing for the patients undergoing surgery under both regional and general anaesthesia. The aim of this randomized study is to compare the efficacy of intravenous tramadol and ketamine in controlling shivering after spinal anaesthesia in infraumbilical surgery.

AIM

To study the efficacy of tramadol and ketamine in preventing intraoperative shivering after spinal anaesthesia.

METHODS

A total of 76 patients in the age group 18–65 years of age from ASA physical grades I and II were randomized into two equal groups of 36 each: group T (tramadol) patients received 0.5 mg/kg of i.v. tramadol and group K (ketamine) patients received 0.5 mg/kg of i.v. ketamine after development of shivering (grade 3 and more) under spinal anaesthesia.

RESULTS

There was no significant difference in terms of age ($p = 0.125$), gender ($p = 0.475$), or comorbidities (22.3% in ketamine and 30.6% in tramadol had comorbidities, and hypertension was the most common comorbidity in both groups). Weight ($p = 0.356$), height ($p = 0.081$), sites of surgery (16.7% in the ketamine group and 36.1% in the tramadol group had abdominal surgeries, ,66.6% in the ketamine group and 41.7% in the tramadol group had lower limb surgeries, 16.7% in the ketamine group and 22.2% in the tramadol group had urological surgeries), and ASA status ($p = 0.637$) between the groups. There was no significant difference in grade of shivering between the two groups at the time of recruitment ($p = 0.691$), after 5 minutes ($p = 0.276$), or at the time of recurrence ($p = 0.343$) of shivering. The time taken to

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stop shivering (in ketamine it was 9.85+0.84 min, while in tramadol it was 10.28+0.78) was less in ketamine but was not significant (p = 0.029).

CONCLUSION

We thus concluded that tramadol, when given for shivering that developed after spinal anaesthesia, more efficaciously reduced shivering than ketamine, with fewer recurrences and minor side effects that could be prevented, and there was no sedation in the group that was seen with ketamine. Hence, tramadol showed a benefit over ketamine when used for shivering post-spinal anaesthesia.

KEYWORDS

Post Spinal Shivering, Tramadol, Ketamine, Shivering.

INTRODUCTION

The term shivering is described as an involuntary and spontaneous repetitive muscular event.[1] Shivering increases the expenditure of cardiac energy and systemic energy.[2] Even though shivering is not a fatal event, it can lead to a lot of dilemmas especially in those patients who have undergone surgery and more so in those who have comorbidities that include the respiratory system and the cardiovascular system.[3]

Shivering causes an increase in the demand for oxygen supply, and in those who have already compromised systems, it can lead to hypoxia and lactic acidosis, along with an increase in the production of carbon dioxide. It is also known that shivering can lead to an elevation in the pressure in the eyes and brain.[3]

It also makes intraoperative hemodynamic monitoring difficult. To add to this, it also worsens the surgical site pain that is experienced in the postoperative period.

Following spinal anesthesia, as a result of vasodilation, there will be a loss of heat and redistribution.[3, 4]. The hypothermia that results from vasodialatation increases the threshold of the patient for the phenomenon of sweating, leading to increased chances of shivering.

There are various pharmacological methods that have been advocated that have proven to reduce the incidence of post-spinal shivering. There are five commonly used agents in the management of postanaesthetic shivering: opioids, magnesium sulfate, biogenic amines, cholinomimetic agents, and N-methyl D-asparate receptor antagonists. [5,6]

Some of the commonly used agents are ketamine, an NMDA antagonist, and tramadol, an opioid receptor agonist, both of which have been found to effectively reduce the incidence of post-spinal shivering.[5,6]

As compared to other drugs, both ketamine and tramadol have a predictable duration of action, and not many serious adverse effects are seen, even though the two are very commonly used medications.

Aim

To study the efficacy of tramadol and ketamine in preventing intraoperative shivering after spinal anesthesia.

MATERIAL AND METHODS

The study was a prospective controlled comparative study conducted at the Department of Anaesthesia, Yashoda Hospital, a Multi-Superspeciality Hospital in Secunderabad, Telangana,

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India. ASA grade I and II inpatients of Yashoda Hospital Secunderabad, posted for elective infraumbilical surgeries under spinal anaesthesia were included in the study.

Patients of either gender aged between 18 and 65 years. With ASA (American Society of Anesthesiologists) physical status 1 and 2 and who developed shivering after elective infraumbilical surgeries were evaluated.

Patients with ages less than 18 or more than 65 years, ASA grades III and IV**, p**atients receiving blood transfusions, patients on drugs that affect the autonomic nervous system, history of allergy to any of the study drugs, surgeries lasting more than 2 hours, any major systemic illness, fetal compromise, active diseases of the CNS, such as meningitis, poliomyelitis, intracranial hemorrhage, and acute combined degeneration of the spinal cord, Spinal stenosis and active disease (spondylosis, TB, tumours), cardiopulmonary, renal, or hepatic impairment coagulation disorders, history of chronic pain conditions or daily intake of analgesics and steroids, history of ongoing drug or alcohol abuse, daily use of gabapentin, pregabalin, tricyclic antidepressants, serotonin-norepinephrine reuptake inhibitors, and tramadol were excluded.

Study Procedure

All patients who underwent spinal anesthesia were counseled, and those who developed shivering in grades 3 and above were included in the study.

They were randomly allotted to one of the two groups, namely the tramadol (T) group and the ketamine (T) group. The envelope containing the study drug was sealed and placed with the patient in the PAC room so that the observer (a fellow anesthesiologist) was blinded to the study drug that was given.

The study drugs that were blinded were sent to the operating room and used only if the patient developed grade 3 or more shivering. Tramadol group received i.v. 0.5 mg/kg diluted in a 10 ml syringe given slowly. The ketamine group received i.v. 0.5 mg/kg diluted in a 10 ml syringe and given slowly. Vital parameters of the patients, such as heart rate, blood pressure, SpO2, and temperature, were monitored at regular intervals as per protocol.

Once the patients were shifted to the operation theater, baseline parameters were recorded using monitors. Operation theater temperature was maintained at 22^0C - 25^0C.

Baseline temperature was recorded using a temperature probe in the axilla placed in the vicinity of the axillary artery. The following parameters were monitored using monitors: hemodynamic changes, heart rate, blood pressure (SBP and DBP), oxygen saturation, ECG, temperature, All the patients were preloaded with Ringer's lactate (10 mL/kg) before giving neuraxial blockade. The i.v. fluids were pre-heated to 37°C before being used for the patients. The temperature of the OT was maintained at 24±1°C; 22^0C - 25^0C for all the patients. Neuraxial anesthesia was instituted at either L3-4 or L4-5 interspaces using 2.8 mL (14 mg) of hyperbaric bupivacaine 0.5% (with 8.5% dextrose) using a 25-gauge Quincke's spinal needle. Oxygen supplementation by facemask (5 liters/min).

During surgery, the shivering scale was recorded at 5 minutes for the first 10 minutes and then every 10 minutes in intervals up to 90 minutes of surgery. The hemodynamic variables (heart rate, blood pressure, SBP, and DBP) was noted again at the time of shivering. The level of shivering using the TSAI and CHU scales and the surface temperature measured by a temperature probe were observed manually.

Shivering is graded using a scale validated by Tsai and Chu: grade 0 = no shivering, grade 1 = piloerection but no visible shivering, grade 2 = muscular activity in only one group, grade 3 = muscular activity in more than one muscle group but not generalized, and grade 4 = shivering involving the whole body.

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Sedation was assessed on a 4-point scale using Ramsey's sedation score. The test drug is regarded as ineffective if the patients exhibit grade 3 or more shivering any time after the first episode of shivering, which has subsided after administering the test drug, and then i.v. pethidine 25 mg is administered as a rescue drug.

The rescue was also considered failed if the shivering did not stop or reduce in its initial intensity after 15 minutes of administering the test drug.

Statistical Analysis

Qualitative outcome measures were compared using the chi-square test and quantitative variables using the student's t-test. Correlation coefficients were calculated for detecting the correlation where the variables are quantitative. Statistical tests like the chi-square test and the student's t-test were applied to the collected data.

$P > 0.05$ was considered statistically insignificant, $P < 0.05$ statistically significant, $P < 0.01$ statistically highly significant, and $P < 0.001$ statistically very highly significant.

RESULTS

Age Group (in years)	**Ketamine**	**Tramadol**
≤ 20	6 (16.7%)	1 (2.8%)
21 – 40	19 (52.8%)	24 (66.7%)
41 – 60	11 (30.6%)	11 (30.6%)
Total	36 (100%)	36 (100%)
Chi-square test = 4.153, p-value = 0.125 (not significant)		
	Age (in years)	
	Mean	SD
Ketamine	34.42	12.37
Tramadol	35.58	11.76
Gender		
Gender	**Ketamine**	**Tramadol**
Male	19 (52.8%)	22 (61.1%)
Female	17 (47.2%)	14 (38.9%)
Total	36 (100%)	36 (100%)
Chi-square test = 0.510, p-value = 0.475 (not significant)		
Anthropometry		
	Ketamine	**Tramadol**
Weight (Kgs)	57.28 ± 7.28	59.14 ± 9.57
Height (cms)	160.36 ± 9.29	164.33 ± 9.75

Table 1: Sociodemographic Details and Anthropometry

The mean age of the study population in the ketamine group was 34.42 ± 12.37 years, and in the tramadol group, it was 35.58 ± 11.76 years. In both groups, the majority of the population was between 21 and 40 years old, i.e., 52.8% and 66.7% in the ketamine and tramadol groups, respectively. There was no statistically significant difference between the two groups.

In the ketamine group, 52.8% were male and 47.2% were female. In the tramadol group, 61.1% were male and 38.9% were female. There was no statistically significant difference between the two groups. The mean weight in the ketamine group was 57.28 ± 7.28 kg, and in

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the tramadol group it was 59.14 ± 9.57 kg, with no statistically significant difference between the two groups.

The mean height in the ketamine group was 160.36 ± 9.29 cm and in the tramadol group was 164.33 ± 9.75 cm, with no statistically significant difference between the two groups.

ASA Grade	Ketamine	Tramadol
I	18 (50%)	20 (55.6%)
II	18 (50%)	16 (44.4%)
Total	36 (100%)	36 (100%)
Chi-square test = 0.223, p-value = 0.637 (Not significant)		

Table 2: Comparison of ASA Grading between Two Groups

50% of the ketamine group and 55.6% of the tramadol group belonged to the ASA I category. 50% of the ketamine group and 44.4% of the tramadol group belonged to ASA II. There was no statistically significant difference between the two groups. In the ketamine group, 22.3% and in the tramadol group, 30.6% had comorbidities.

Hypertension was the most common comorbidity in both groups. 16.7% in the ketamine group and 36.1% in the tramadol group had abdominal surgery. 66.6% in the ketamine group and 41.7% in the tramadol group had lower limb surgery, and 16.7% in the ketamine group and 22.2% in the tramadol group had urological surgery.

The baseline body temperature (OC) in the ketamine group was 37.08 ± 0.23 and in the tramadol group was 37.10 ± 0.21, with no statistically significant difference between the two groups.

The baseline SBP (mm of Hg) in the ketamine group was 112.78 ± 7.21 and in the tramadol group was 115.61 ± 8.41, with no statistically significant difference between the two groups.

The baseline DBP (mm of Hg) in the ketamine group was 76.83 ± 4.45 and in the tramadol group was 77.86 ± 4.98, with no statistically significant difference between the two groups.

The time for onset of shivering (min) in the ketamine group was 6.75 ± 1.99 and in the tramadol group was 7.05 ± 2.38, with no statistically significant difference between the two groups.

At the time of recruitment, in the ketamine group, the grade of shivering was 3 in 91.7% and 4 in 8.3%. In the tramadol group, the grade of shivering was 3 in 88.9% and 4 in 11.3%. There was no statistically significant difference between the two groups.

The body temperature at the time of shivering (OC) in the ketamine group was 36.23 ± 0.25 and in the tramadol group was 36.28 ± 0.34, with no statistically significant difference between the two groups.

	Ketamine	Tramadol	P-Value [Unpaired T-Test]
Pulse Rate (beats/min)	74.94 ± 10.69	73.28 ± 10.72	0.511 (NS)
SBP (mm of Hg)	94.78 ± 7.21	97.61 ± 8.41	0.129 (NS)
DBP (mm of Hg)	64.83 ± 4.45	65.86 ± 4.98	0.359 (NS)

Table 3: Comparison of Vital Parameters at Time of Shivering between Two Groups

The vital parameters were comparable between groups with no statistical significant difference between two groups.

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After 5 mins after test drug, in ketamine group the grade of shivering was 2 in 80.6% and 3 in 19.4%. In tramadol group the grade of shivering was 2 in 69.4% and 3 in 30.6%. There was no statistical significant difference between two groups.

Level of Sedation	Ketamine	Tramadol
No Sedation	28 (77.8%)	36 (100%)
Minimal	7 (19.4%)	0
Moderate	1 (2.8%)	0
Total	36 (100%)	36 (100%)
Chi-square test = 9.000, p-value = 0.011 (Significant)		

Table 4: Level of Sedation after Test Drug

In the ketamine group, the level of sedation after drug administration was minimal in 19.4% and moderate in 2.8%. In the tramadol group, after drug administration, none of the patients were sedated. There was a statistically significant difference between the two groups with a high level of sedation in the ketamine group.

	Time Taken to Stop First Shivering (min)		
	Mean	**SD**	
Ketamine	9.85	0.84	t-value = -2.226
			& p-value = 0.029
Tramadol	10.28	0.78	(Sig.) [unpaired t-test]
	Time Taken to Develop Recurrence of Shivering (min)		
	Mean	**SD**	
Ketamine	21.19	3.97	t-value = -0.313
			& p-value = 0.757
Tramadol	21.77	4.89	(NS) [unpaired t-test]

Table 5: Comparison of Time Taken to Stop First Shivering and Recurrence of Shivering between Groups

The time taken to stop first shivering (min) in the ketamine group was 9.85 ± 0.84 and in the tramadol group was 10.28 ± 0.78, with a statistically significant difference between the two groups.

The baseline body temperature (OC) post-shivering in the ketamine group was 36.42 ± 0.25 and in the tramadol group was 36.48 ± 0.34, with no statistically significant difference between the two groups.

The mean pulse rate, systolic blood pressure, and diastolic blood pressure were also comparable between the two groups, with no statistically significant difference.

In the ketamine group, the rate of recurrence of shivering was 44.4%, while in the tramadol group, it was 22.2%. There was a statistically significant difference between the two groups, with a high level of recurrence in the ketamine group.

The time taken to develop a recurrence of shivering (min) in the ketamine group was 21.19 ± 3.97 and in the tramadol group was 21.77 ± 4.89, with no statistically significant difference between the two groups.

Shivering grade at recurrence in the ketamine group was 1 in 62.5%, 2 in 25%, and 3 in 12.5%. The shivering grade at recurrence in the tramadol group was 1 in 50% and 2 in 50%. There was no statistically significant difference between the two groups.

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Nausea and vomiting were most common in the tramadol group (16.7%) when compared to the ketamine group (2.8%), with a statistically significant difference between the two groups.

8.3% of cases in the ketamine group had headaches, while none in the tramadol group had headache. There was a statistically significant difference between the two groups (p = 0.006).

DISCUSSION

Spinal anaesthesia is a safe and popular anaesthesia technique used the world over for various surgeries. Spinal anaesthesia is a type of central neuraxial blockade; the other commonly used technique is epidural anaesthesia.[1,2]

It is important to recognize and immediately treat perioperative shivering that occurs because it not only impairs the intra-operative monitoring of the patient but is also associated with a number of adverse effects, like increased consumption of oxygen, activation of the stressor response leading to increased catecholamine production, cardiac output, and minute ventilation.[5,6]

In the present study, we administered the study drugs after spinal anaesthesia and only when shivering developed, while most of the other studies are using the drugs as prophylactic measures just after spinal anaesthesia and before the development of shivering. Using the study drugs whenever required may prevent the untoward effects of tramadol and ketamine, which sometimes cause discomfort to the patients. So, in this study, we used the drugs only after the patient shivered post-spinal anaesthesia.

Only grade 3 and more shivering were taken into consideration, unlike all other studies, which have taken all grades of shivering into consideration, though those studies are grading the shivering on different scales. Only grade 3 shivering was included, as till grade 2 we can manage by covering with blankets, warmers, switching off the A.C., etc., and many times till grade 2 and less shivering goes unnoticed, and patients may not complain about it.

There was no statistically significant difference between the groups in terms of the age of the patient, the gender of the patient, the body habitus and structure, the body mass index, ASA status, or comorbidities; hence, both groups could be compared as there was no demographic difference. We noticed in our study that hypertension was the most common of all the comorbidities in both comparable groups.

In our study, there was no significant difference in the grade of shivering between the two groups at the time of recruitment (p = 0.691), after 5 minutes (p = 0.276), or at the time of recurrence (p = 0.343) of shivering. The time taken to stop shivering (in ketamine, it is 9.85+0.84 min, while in tramadol, it is 10.28 + 0.78) was less in ketamine but not significant (p = 0.029). The time taken for the development of recurrence of shivering was not significant, though more recurrences were there in the ketamine group (p = 0.045, i.e., statistically significant), with 12.5% of grade 3 shivering at recurrence requiring rescue drug in the ketamine group. Side effects like nausea and vomiting were more common in the tramadol group (p = 0.046, i.e., statistically significant), while headaches were found to be significantly more common in the ketamine group (p = 0.007, i.e., statistically significant). Also, levels of sedation (mild to moderate) were only seen in the ketamine group (p = 0.011, i.e., statistically significant), while none were seen in tramadol.

Efficacy

In this study, shivering disappeared within 9.85±0.84 min of drug administration in patients in the ketamine group, while it was 10.28±0.78 min in patients in the tramadol group. This shows

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there was no statistically significant difference between the two. In another study by Dhimar et al.[7] it was shown that the time taken for the disapperance of shivering after drug administration in tramadol is 5 minutes and in pethidine it is 20 minutes. Bhatnagar et al.[8] showed tramadol-controlled shivering in 10 minutes of drug administration.

We noted that at the time of recruitment, grade 3 shivering was seen in 91.7% (33 cases) in the ketamine group and 88.9% (32 cases) in the tramadol group, and grade 4 shivering was seen in 8.3% (3 cases) in the ketamine group and 11.1% (4 cases) in the tramadol group (p = 0.691 NS). At 5 minutes post drug administration, all cases had shown a declining trend in the grade of shivering to grade 2, i.e., ketamine 80.6% (29 cases) and tramadol 69.4% (25 cases) shivering, while a few remained with grade 3, i.e., ketamine 19.4% (7 cases) and tramadol 30.6% (11 cases) shivering (p = 0.276, NS), while none in both groups had grade 4 shivering. Both the results showed there is no significant difference between the groups in terms of grade of shivering at recruitment and 5 minutes after test drug administration.

Nihar Ameta et al.[9] noted an overall incidence of shivering of 40.5%. In group ketamine, it was 46%; in group tramadol, it was 50%; in group control, it was 42%; and in group dexmedetomidine, it was 24%. Girmay Fitiwi Lema et al.[10] noted that the incidence of shivering was significantly reduced in the ketamine and tramadol groups (41.5% and 53.7%, respectively) compared to the saline group (70.7%; *p = 0.028).* But both studies have no significant results.

So, Nihar Ameta et al.[9] Girmay Fitiwi Lema et al.[10] Andika Dwi Cahyadi et al.[11] and Gajal Lakhe et al.[12] noted that there was no difference in the incidence of shivering between ketamine and tramadol following spinal anaesthesia.

Recurrence

In the present study, recurrence of shivering was seen after drug administration in both groups, but ketamine was found to have more, with 16 cases (44%), whereas in the tramadol group, 8 (22.2%) were seen, and these results show a statistically significant difference between the two groups (p = 0.045, i.e., <0.05), making ketamine less efficacious in one way in the present study. The mean time duration to develop a recurrence of shivering in the ketamine group was 21.19±3.97 and in the tramadol group was 21.77±4.89 with no statistically significant difference between the two groups.

In accordance with the present study, Bhatnagar et al.[8] showed no recurrence in the tramadol group. Dhimar et al. 10% recurrence at 50 minutes in patients receiving tramadol. Oranuch Kyokong et al.[13] less recurrence in the tramadol group compared to other drugs in the study.

Grade of Shivering at Recurrence

In the ketamine group, 10 (62.5%) had grade 1, 4 (25%) had grade 2, and 2 (12.5%) had grade 3 shivering. In the tramadol group, grade 1 and grade 2 shivering were seen in 4 (50%) each, whereas no grade 3 shivering was seen. (p=0.343, NS).

But we noticed 12.5% had grade 3 shivering at recurrence requiring rescue drugs.

For efficacy between the two groups, there was no difference in time to stop the shivering or grade of shivering at various time intervals and even at the time of recurrence, but there was a significant difference in the rate of recurrences between the groups (p = 0.045).

In other similar studies, Zia Uddin Ahmed et al.[14] and Seyam et al.[15] showed tramadol is more efficacious than ketamine in controlling shivering under spinal anaesthesia.

In other studies done by Bhatnagar et al.,[8] Mohta et al.,[16] Dhimar et al., Hajji et al.,[17] Oranuch et al.[14] where they compared tramadol with pethidine (which is considered the gold

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standard for shivering control), they found tramadol better than pethidine, as they found recurrence is less and time to control shivering is also less as compared to pethidine.

Adverse Events

In the present study, there is no such hemodynamic parameter, and temperature changes are noted at baseline, at the time of shivering, and after shivering, which is in accordance with the study done by Alaa el-Deen M. Syed et al.[18] and R. Andika et al. In the study by Seyam et al.,[15] hypotension was seen in all the groups after spinal anaesthesia which was treated with i.v. crystalloid and ephedrine.

Nausea and vomiting were most common in the tramadol group (16.7%) when compared to the ketamine group (2.8%), with a statistically significant difference between the two groups ($p = 0.046$, significant). 8.3% of cases in the ketamine group had headaches, while none in the tramadol group had headache. There was a statistically significant difference between the two groups ($p = 0.007$).

Nihar Ameta et al.[9] noticed nausea and vomiting in the tramadol group. Also, Astha Palan et al.[19] noticed a higher incidence of nausea and vomiting with tramadol compared to butorphanol.

In contrast to our study, R. Arun Kumar et al. noted no difference in the adverse effects between tramadol and ketamine.

Level of Sedation

In the ketamine group, the level of sedation after drug administration was minimal in 19.4% and moderate in 2.8%. In the tramadol group, after drug administration, none of the patients were sedated. There was a statistically significant difference between the two groups with a high level of sedation in the ketamine group. ($P=0.011$)

In a study done by Girmay Fitiwi Lema[10] it was shown that grade 1-2 sedation was caused by ketamine. R. Arun Kumar et al. showed sedation in all the groups, with dexmedetmidine being superior, followed by ketamine and then tramadol.

Rescue for Shivering

In this study, we kept pethidine as a rescue drug in case of non-stoppage of shivering or grade 3 shivering recurrence.

The additional rescue for shivering in those who had above grade 3 shivering was seen in two cases, 12.5% in the ketamine group and no case in the tramadol group. Nihar Ameta et al. [9] also noted that the requirement of injection pethidine 25 mg IV for control of higher grades of shivering was 12% in group K and 20% in group T.

Hence, we conclude that tramadol (0.5 mg/kg) administered i.v. can be more efficacious than ketamine (0.5 mg/kg) in controlling shivering in patients following spinal anaesthesia, as ketamine was comparable in all the parameters except rate of recurrence, which was higher in the ketamine group, with 12.5% of grade 3 shivering at recurrence requiring a rescue drug, i.e., pethidine, reducing its efficacy.

CONCLUSION

Tramadol can be considered more efficacious than ketamine based on our observations. We noted that in ketamine, even though the shivering decreased, it reappeared as compared to tramadol, showing a higher rate of recurrence in the ketamine group, which is significantly higher than the tramadol group. We noted that in ketamine, the level of sedation and headache complaints were seen only in this group. Adverse effects of tramadol are minor, most often only nausea that is tolerable; hence, it is better to use tramadol as compared to ketamine for post-spinal shivering.

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