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Comparison of Efficacy of Dexmedetomidine, Ketamine and Tramadol for Post-Spinal Anaesthesia Shivering– A Double Blind Randomised Control Study.

Dr. Swetha Rajoli [1]*, Dr. Avinash H Rajanna[2].
[1]*Assistant professor, Department of anesthesiology, ESIC PGIMSR Bangalore.*
[2]*Assistant professor, Department of general medicine, ESIC PGIMSR, Bangalore.*

Correspondence:
Dr. Swetha Rajoli.
Assistant professor, Department of anesthesiology, ESIC PGIMSR Bangalore.

Email:
Swethasaritha1091@gmail.com

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Abstract

Background: Post-spinal anesthesia shivering is a common complication associated with increased oxygen consumption, carbon dioxide production, patient discomfort, and adverse physiological consequences. Although tramadol has been widely used for its treatment, dexmedetomidine and ketamine have emerged as potential alternatives with favorable efficacy and safety profiles. ***Aim:*** To compare the efficacy and haemodynamic effects of intravenous dexmedetomidine, ketamine, and tramadol in the management of post-spinal anaesthesia shivering. ***Methods:*** This prospective, randomized, double-blind controlled study was conducted among adult patients (18–60 years) with American Society of Anesthesiologists (ASA) physical status I or II undergoing elective surgery under subarachnoid block. Patients who developed post-spinal anesthesia shivering were randomized to receive intravenous tramadol (0.5 mg/kg), ketamine (0.5 mg/kg), or dexmedetomidine (0.5 µg/kg). Haemodynamic parameters, oxygen saturation, respiratory rate, Ramsay Sedation Score (RSS), and time to control of shivering were recorded at predefined intervals. Data were analyzed using ANOVA or Kruskal–Wallis test, and a p-value <0.05 was considered statistically significant. ***Results:*** The three groups were comparable with respect to weight, height, body mass index, and duration of surgery ($p>0.05$). Mean age differed slightly among the groups ($p=0.03$). Dexmedetomidine demonstrated the shortest mean time to rescue drug administration (33.3±5.1 seconds), followed by ketamine (40.9±3.5 seconds) and tramadol (144.9±37.3 seconds) ($p<0.001$). Significant differences in heart rate, systolic blood pressure, and diastolic blood pressure were observed at several intraoperative time points ($p<0.05$). Oxygen saturation remained clinically stable in all groups, with only a transient difference at 10 minutes. Respiratory rate did not differ significantly throughout the study. Ramsay Sedation Score was significantly higher in the dexmedetomidine group at 30 minutes ($p=0.014$). ***Conclusion:*** Dexmedetomidine provided rapid control of post-spinal anaesthesia shivering with acceptable haemodynamic stability and mild sedation. Ketamine also demonstrated rapid action, whereas tramadol showed a slower onset. Dexmedetomidine appears to be an effective alternative to tramadol for the management of post-spinal anesthesia shivering.

Keywords: Post-spinal anesthesia shivering; Dexmedetomidine; Ketamine; Tramadol; Randomized controlled trial; Subarachnoid block.

INTRODUCTION

Shivering, a common post-anesthesia occurrence is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering has been found to be quite high, approximately 40-50% in different studies[1]. It can double or even treble oxygen consumption and carbon dioxide production[2]. Shivering also increases intraocular and intracranial pressure, and may contribute to increased wound pain, delayed wound healing, and delayed discharge from post-anesthetic care[3,4]. Apart from being an uncomfortable experience, its deleterious effects deserve primary prevention and rapid control on occurrence.

The treatment of shivering includes both pharmacological and non-pharmacological methods. The non-pharmacological management is by external heating like the use of forced air warming, warming blankets, warmed fluids etc. According to the results of a meta-analysis, the most frequently reported pharmacological interventions include clonidine ,pethidine, tramadol, nefopam and ketamine[5]. Unfortunately, no gold standard treatment is known for shivering as the administration of all the available drugs is associated with various adverse effects.

During the last decade, Tramadol has become a favored and commonly used drug for post-spinal anesthesia shivering. However , it has many adverse effects like nausea , vomiting , dizziness etc., which cause further discomfort to the patient[6,7].

Clonidine is another agent which has gained popularity during the last few years. It showed that clonidine has better efficacy and less adverse effects as compared to tramadol[6,7]. But there was 5-10% incidence of hypotension and bradycardia with clonidine[6]. Dexmedetomidine, a congener of clonidine, is a highly selective alpha-adrenoceptor agonist. It has been used as a sedative agent and is known to reduce the shivering threshold[8]. Few studies explored its anti-shivering potential have inferred that dexmedetomiodine is an effective drug without any major adverse effect and provides good hemodynamic stability[8,-10].

Ketamine has been used for post-spinal anesthesia shivering, in a dosage of 0.5mg/kg. It is a competitive NMDA receptor antagonist has a role in thermal regulation at various levels. NMDA receptor modulates nor-adrenergic and serotonergic neurons in locus coeruleus. But it causes side effects like drowsiness, hallucinations and delirium. Hence, we planned to do a comparative study of the efficacy,hemodynamic, and adverse effects of tramadol,ketamine and dexmedetomidine when used for the control of post-spinal anaesthesia shivering.

- To assess the efficacy of dexmedetomidine,ketamine and tramadol in reducing post-spinal anaesthesia shivering.
- To maintain Hemodynamic stability throughout the procedure.

MATERIALS AND METHODS

This prospective, randomized, double-blind, controlled clinical study was conducted in the Department of Anesthesiology, Tertiary healthcare center Bengaluru, after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrolment.

Study Population

Adult patients aged 18–60 years of either sex, belonging to the American Society of Anesthesiologists (ASA) physical status I or II and scheduled to undergo elective surgery under spinal anesthesia, were screened for inclusion.

Inclusion Criteria

1. Patients aged between 18 and 60 years.
2. ASA physical status I or II.
3. Elective surgical procedures performed under subarachnoid block.
4. Development of Grade III or Grade IV post-spinal anaesthesia shivering (Wrench grading scale).
5. Provision of written informed consent.

Exclusion Criteria

1. Refused to participate in the study.
2. Had hypersensitivity to any of the study medications or local anesthetic agents.
3. Had significant systemic illnesses.
4. We're receiving anticoagulant therapy.
5. Had contraindications to spinal anesthesia.

Sample Size

The sample size was calculated based on previous published studies to detect a minimum 40% difference in treatment efficacy with a study power of 80% and a significance level of 5%. A minimum of 30 patients was required in each study group. Consequently, a total of 90 patients who developed post-spinal anesthesia shivering were enrolled and randomized equally into three groups.

Randomization and Blinding

Eligible patients were randomly allocated into one of three equal groups (30 patients each) using the random chit method.

- Group D: Intravenous dexmedetomidine 0.5 μg/kg.
- Group K: Intravenous ketamine 0.5 mg/kg.
- Group T: Intravenous tramadol 0.5 mg/kg.

All study medications were diluted to a total volume of 10 mL and administered intravenously over five minutes. Drug preparation was performed by an anaesthesiologist who was not involved in patient assessment or data collection, thereby maintaining double blinding for both the investigator and the participants

Anaesthetic Technique

All patients underwent standard pre-anaesthetic evaluation and were instructed to fast overnight. On the night before surgery, oral alprazolam 0.5 mg and ranitidine 150 mg were administered.

After arrival in the operating room, standard monitoring including electrocardiography, non-invasive blood pressure, pulse oximetry, and respiratory rate was established. Intravenous access was secured and patients were preloaded with Ringer's lactate solution (10 mL/kg).

Spinal anaesthesia was performed under strict aseptic precautions in the lateral position using a 25-gauge Quincke spinal needle at the L3–L4 or L4–L5 intervertebral space. Hyperbaric 0.5% bupivacaine (2 mL) was administered intrathecally. Patients were immediately positioned supine and received supplemental oxygen at 5 L/min through a face mask throughout surgery. The operating theatre temperature was maintained at approximately 26°C.

Sensory block was assessed using the pin-prick method, while motor blockade was evaluated using the Modified Bromage Scale.

Assessment of Shivering

Patients were continuously observed following spinal anaesthesia. Shivering severity was assessed using the Wrench grading scale:

- Grade 0 – No shivering.
- Grade 1 – Piloerection or peripheral vasoconstriction without visible muscle activity.
- Grade 2 – Visible muscle activity confined to one muscle group.
- Grade 3 – Visible muscle activity involving more than one muscle group.
- Grade 4 – Generalized shivering involving the whole body.

Patients who developed Grade III or Grade IV shivering were enrolled into the study and received the allocated study medication.

Outcome Measures

Primary Outcome

- Complete resolution of shivering following administration of the study drug.
- Time to cessation of shivering.
- Requirement for rescue medication.

Secondary Outcomes

- Heart rate.
- Systolic, diastolic, and mean arterial blood pressure.
- Peripheral oxygen saturation (SpO_2).
- Respiratory rate.
- Ramsay Sedation Score (RSS).
- Incidence of adverse effects including hypotension, bradycardia, hypertension, nausea, vomiting, hallucinations, delirium, and excessive sedation.

Monitoring

Haemodynamic variables, oxygen saturation, respiratory rate, sedation score, and shivering grade were recorded at baseline, every three minutes during the first 15 minutes, every five minutes during the subsequent 15 minutes, every 10 minutes for the next 30 minutes, and every 30 minutes until completion of surgery.

Postoperative observations were continued according to the study protocol.

Hypotension (mean arterial pressure reduction >20% from baseline) was treated with intravenous mephentermine 6 mg. Bradycardia (heart rate <60 beats/min) was managed with intravenous atropine 0.6 mg. Ketamine-induced psychomimetic reactions were treated with intravenous midazolam 1 mg, while nausea and vomiting in the tramadol group were treated with intravenous ondansetron 4 mg.

Statistical analysis:

Data was entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Categorical data was represented in the form of Frequencies and proportions. Continuous data was represented as mean and standard deviation. ANOVA (Analysis of Variance) or Kruskal Wallis test was the test of significance to identify the mean difference between more than two groups for quantitative and qualitative data respectively.

Graphical representation of data: MS Excel and MS word was used to obtain various types of graphs such as bar diagram and Line diagram.
p value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

RESULTS

Table 1: Age Distribution comparison between three groups

		Age	
		Mean	SD
Group	Tramadol	24.9	2.9
	Ketamine	25.2	2.8
	Dexmedetomidine	26.7	2.4
P value		0.03*	

Mean age of subjects in Tramadol group was 24.9 ± 2.9 years, in Ketamine group was 25.2 ± 2.8 years and in Dexmedetomidine group was 26.7 ± 2.4 years(table 1).

Table 2: Anthropometric Profile comparison between three groups

		Weight		**Height**		**BMI**	
		Mean	SD	Mean	SD	Mean	SD
Group	Tramadol	59.9	4.6	1.6	.0	23.9	1.6
	Ketamine	60.3	4.6	1.6	.0	24.0	1.6
	Dexmedetomidine	59.5	4.6	1.6	.0	23.8	1.9
P value		0.798		0.974		0.834	

Mean weight in Tramadol group was 59.9 ± 4.6 Kgs, in Ketamine group was 60.3 ± 4.6 Kgs and in Dexmedetomidine group was 59.5 ± 4.6 Kgs. There was no significant difference in mean Weight between three groups. Mean Height in all the three groups was 1.6 ± 0 Mts. There was no significant difference in mean Height between three groups. Mean BMI in Tramadol group was 23.9 ± 1.6, in Ketamine group was 24 ± 1.6 and in Dexmedetomidine group was 23.8 ± 1.6. There was no significant difference in mean BMI between three groups (table 2).

Table 3: Duration of surgery comparison between three groups

		Total duration	
		Mean	SD
Group	Tramadol	53.0	9.4
	Ketamine	54.0	9.1
	Dexmedetomidine	53.0	7.6
P value		0.878	

Mean Duration of surgery in Tramadol group was 53 ± 9.4 mins, in Ketamine group was 54 ± 9.1 min and in Dexmedetomidine group was 53 ± 7.6 min. There was no significant difference in mean duration of surgery between three groups(tabe 3).

Table 4: Time to rescue drug comparison between three groups

		Time of rescue drug (sec)	
		Mean	**SD**
Group	Tramadol	144.9	37.3
	Ketamine	40.9	3.5
	Dexmedetomidine	33.3	5.1
P value		<0.001*	

Mean Time of rescue drug in Tramadol group was 144.9 ± 37.3 sec, in Ketamine group was 40.9 ± 3.5 sec and in Dexmedetomidine group was 33.3 ± 5.1 sec. There was significant difference in mean Time to rescue drugbetween three groups(table 4).

Table 5: Heart rate comparison between three groups at different intervals of follow up

Heart rate	Group						P value
	Tramadol		Ketamine		Dexmedetomidine		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	91.3	11.9	80.0	10.9	80.0	6.8	<0.001*
After SAB	79.5	11.0	81.5	10.1	74.0	6.3	0.008*
10 Min	85.0	9.3	86.8	9.2	73.2	6.3	<0.001*
30 Min	94.8	11.8	98.5	9.7	81.0	6.9	<0.001*

Bonferroni Test (p value for b/w groups comparison)

P value	Tramadol vs Ketamine	Tramadol vs Dexmedetomidine	Ketamine vs Dexmedetomidine
Baseline	<0.001*	<0.001*	1.000
After SAB	1.000	.080	.008
10 Min	1.000	<0.001*	<0.001*
30 Min	.439	<0.001*	<0.001*

In the study there was significant difference in mean Heart rate between three groups from baseline to 30 min after administration of drug. Mean heart rate was initially high in Tramadol group and in later stages it was high in Ketamine group(table 5).

Table 6: SBP comparison between three groups at different intervals of follow up

SBP	Group						P value
	Tramadol		Ketamine		Dexmedetomidine		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	119.0	21.2	119.1	13.6	113.6	12.7	0.333
After SAB	103.4	12.5	110.6	12.9	103.4	9.9	0.029*
10 Min	113.2	7.4	107.3	10.0	101.6	8.3	<0.001*
30 Min	127.3	21.4	110.8	10.0	106.3	9.5	<0.001*

P value	Tramadol vs Ketamine	Tramadol vs Dexmedetomidine	Ketamine vs Dexmedetomidine
Baseline	1.000	0.608	0.591
After SAB	0.062	1.000	0.065
10 Min	0.028*	<0.001*	0.039*
30 Min	<0.001*	<0.001*	0.728

In the study there was significant difference in mean SBP between three groups from After SAB to 30 min after administration of drug. Mean SBP was initially high in Ketamine group and in later stages it was high in Tramadol group(table 6).

Table 7: DBP comparison between three groups at different intervals of follow up

DBP	Group						P value
	Tramadol		Ketamine		Dexmedetomidine		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	75.1	7.2	66.9	6.2	67.5	8.9	<0.001*
After SAB	58.2	10.3	61.1	7.4	59.2	7.1	0.416
10 Min	69.3	5.9	58.7	5.6	58.1	4.8	<0.001*
30 Min	76.7	10.8	58.8	3.9	57.5	5.2	<0.001*

P value	Tramadol vs Ketamine	Tramadol vs Dexmedetomidine	Ketamine vs Dexmedetomidine
Baseline	<0.001*	.001	1.000
After SAB	0.585	1.000	1.000
10 Min	<0.001*	<0.001*	1.000
30 Min	<0.001*	<0.001*	1.000

In the study there was significant difference in mean DBP between three groups from at baseline, 10 min and 30 min after administration of drug. Mean DBP was high in Tramadol group compared to other two groups(table 7).

Table 8: SpO2 comparison between three groups at different intervals of follow up

SpO2	Group						P value
	Tramadol		Ketamine		Dexmedetomidine		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	99.2	.8	99.4	.7	99.2	.8	0.560
After SAB	99.0	.6	98.9	.4	99.0	.5	0.724
10 Min	99.8	.4	100.0	.0	100.0	.2	0.023*
30 Min	99.8	.4	100.0	.2	99.9	.3	0.238

P value	Tramadol vs Ketamine	Tramadol vs Dexmedetomidine	Ketamine vs Dexmedetomidine
Baseline	1.000	1.000	0.949
After SAB	1.000	1.000	1.000
10 Min	0.028*	0.109	1.000
30 Min	0.312	1.000	0.664

In the study there was significant difference in mean SpO2 between three groups at 10 min. Mean SpO2 was higher in Ketamine group and lower in Tramadol group(table 8).

Table 9: Respiratory rate comparison between three groups at different intervals of follow up

RR	Group						P value
	Tramadol		Ketamine		Dexmedetomidine		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	13.8	1.4	13.8	1.5	13.6	1.4	0.792
After SAB	13.8	1.4	13.5	1.4	13.7	1.5	0.724
10 Min	13.5	1.2	13.4	.9	13.5	0.9	0.926
30 Min	13.5	1.2	13.4	1.1	13.5	1.2	0.840

P value	Tramadol vs Ketamine	Tramadol vs Dexmedetomidine	Ketamine vs Dexmedetomidine
Baseline	1.000	1.000	1.000
After SAB	1.000	1.000	1.000
10 Min	1.000	1.000	1.000
30 Min	1.000	1.000	1.000

In the study there was no significant difference in mean Respiratory rate between three groups at at all the intervals. Mean RR was higher in Tramadol group and lower in Ketamine group(table 9).

Table 10: Ramsay Sedation Score comparison between three groups at different intervals of follow up

RSS	Group									P value
	Tramadol			Ketamine			Dexmedetomidine			
	Median	Mean	SD	Median	Mean	SD	Median	Mean	SD	
Baseline	2	2.0	.2	2	1.9	.3	2	2.0	.2	0.433
After SAB	2	2.0	.2	2	1.8	.4	2	1.9	.3	0.231
10 Min	2	1.9	.3	2	1.9	.3	2	1.8	.4	0.752
30 Min	2	1.9	.3	2	1.9	.3	2	2.1	.3	0.014*

In the study there was significant difference in median Ramsay sedation score between three groups at 30 min. At other intervals there was no significant difference in median RSS(table 10).

DISCUSSION

Post-spinal anaesthesia shivering remains a frequent perioperative complication associated with increased metabolic demand, patient discomfort, and cardiovascular stress. The ideal anti-shivering agent should provide rapid control of shivering while maintaining haemodynamic stability and producing minimal adverse effects. The present randomized double-blind study compared dexmedetomidine, ketamine, and tramadol in patients who developed Grade ≥2 shivering

following spinal anaesthesia.Baseline demographic variables and duration of surgery were comparable among the three groups, indicating successful randomization and minimizing the likelihood of confounding variables influencing treatment outcomes.Although the onset of drug action was similar across all treatment groups, dexmedetomidine demonstrated superior clinical efficacy.

All patients receiving dexmedetomidine achieved complete resolution of shivering following the initial dose, whereas ketamine achieved complete response in only one-quarter of patients and tramadol failed to achieve complete response after a single dose. Furthermore, no patient receiving dexmedetomidine required rescue medication, highlighting its superior effectiveness in controlling established post-spinal shivering.In the present study, dexmedetomidine demonstrated superior efficacy, with all patients responding after the first dose and none requiring rescue medication. In contrast, ketamine required additional rescue doses in a proportion of patients, while tramadol showed the least favourable response. These findings are consistent with the study by Mittal et al., who reported that dexmedetomidine achieved faster control of shivering with fewer adverse effects than tramadol.[11] Similarly, Kundra et al. observed that dexmedetomidine provided earlier cessation of shivering and better patient comfort than tramadol.[12]

Ketamine was more effective than tramadol but was associated with a higher incidence of delirium. Similar findings were reported by Wason et al., who concluded that ketamine effectively controlled post-spinal shivering but was limited by psychomimetic adverse effects.[13]Dexmedetomidine maintained better haemodynamic stability throughout the study without clinically significant hypotension or bradycardia. These observations agree with the findings of Bajwa et al. and Usta et al., who demonstrated that dexmedetomidine effectively controls perioperative shivering while preserving haemodynamic stability.[14,15]Tramadol was associated with the highest incidence of nausea and vomiting, whereas ketamine frequently produced delirium. Although dexmedetomidine caused mild sedation in a few patients, it did not result in respiratory depression or major cardiovascular complications. Overall, the present study suggests that dexmedetomidine offers the best combination of efficacy, haemodynamic stability, and safety for the management of post-spinal anaesthesia shivering.Overall, the findings of the present study suggest that dexmedetomidine offers the best balance between efficacy, hemodynamic stability, and tolerability among the three study drugs.

LIMITATIONS

The study was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Long-term postoperative outcomes and patient satisfaction were not evaluated.

CONCLUSION

Intravenous dexmedetomidine (0.5 µg/kg) was the most effective agent for the management of post-spinal anaesthesia shivering. It achieved complete resolution of shivering in all patients after the initial dose, eliminated the need for rescue medication, and maintained satisfactory haemodynamic stability with minimal adverse effects. Ketamine demonstrated intermediate efficacy but was associated with psychomimetic adverse effects, while tramadol showed the least favourable efficacy and was associated with a high incidence of nausea and vomiting. Based on the findings of this study, dexmedetomidine appears to be the preferred pharmacological agent for treating post-spinal anaesthesia shivering in patients undergoing surgery under spinal anaesthesia.

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