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Exploring the Efficacy of Intravenous Tramadol and Dexmedetomidine for Preventing Post-Anesthesia Shivering: A Year-long Randomized Clinical Trial

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ABSTRACT

Background and aim: Regional anesthesia is a widely used procedure for various surgical procedures However, it can lead to undesirable effects such as hypotension, bradycardia, and shivering. The aim of this research was to investigate the effectiveness, hemodynamic impacts, and potential adverse reactions associated with the administration of dexmedetomidine and tramadol in the management of post-anesthesia shivering.

Materials and Methods: A randomized study was carried out involving 60 patients, who were categorized into two groups: Group-T and Group-D. These groups comprised individuals of both genders with ASA Grades 1 and 2, aged between 18 and 50 years, and scheduled for various surgical procedures under general anesthesia. In each group, 30 patients were administered an intravenous bolus of dexmedetomidine (50 mcg) and tramadol (50 mg). The study observed the grade of shivering, onset of shivering, recurrence, response rate, and adverse effects at designated intervals. Data analysis was performed using an unpaired t-test.

Results: Injection Tramadol and injection Dexmedetomidine was nearly equally effective at preventing post-anesthesia shivering. Dexmedetomidine provided better pain management and a lower incidence of nausea and vomiting than tramadol, however it was related with bradycardia and hypotension.

Conclusion: We find that, although both medications prove to be efficacious, the duration needed to alleviate shivering was practically the same for both dexmedetomidine and tramadol. Also, dexmedetomidine has little side effects, but tramadol causes considerable nausea and vomiting.

Keywords: *Randomized clinical trial, Tramadol, Post anesthesia shivering Dexmedetomidine.*

1. INTRODUCTION

Regional anesthesia is a widely used and safe method of anesthesia for various surgical procedures when administered appropriately. However, it can lead to undesirable effects such as hypotension, bradycardia, and shivering. Shivering, observed in 40-60% of individuals undergoing regional anesthesia, is an involuntary, repetitive contraction of skeletal muscles triggered by core hypothermia [1]. Spinal anesthesia, by inhibiting tonic vasoconstriction, causes a shift of core heat from the trunk to peripheral tissues, putting patients at risk of hypothermia and shivering [2].

The consequences of shivering extend beyond discomfort, impacting factors like metabolic rate, oxygen consumption, and CO_2 production [3]. This may result in arterial hypoxia and increased acidity. Moreover, shivering can elevate intraocular and intracranial pressure, potentially contributing to heightened wound discomfort, suture line stretch, delayed wound healing, and prolonged post-anesthesia care unit stay [4, 5]. Individuals with a low cardiorespiratory reserve are particularly vulnerable to these effects [6].

The experience of extreme cold and shivering is highly uncomfortable and distressing for patients. Therefore, it is crucial to emphasize preventive measures and promptly address shivering if it occurs. Various methods can be employed during surgery to prevent and manage shivering, including both pharmacological and nonpharmacological interventions. Nonpharmacological options encompass techniques such as forced air warming, warming blankets, and administration of warm fluids [7].

Tramadol, an opioid analgesic, primarily affects μ receptors, with limited influence on kappa and delta receptors. Its stimulation of monoaminergic receptors in the descending spinal inhibitory pain pathway accounts for its opioid impact. The anti-shivering effect of Tramadol is attributed to its opioid, serotonergic, and noradrenergic activity or a combination of these factors [8-10]. Widely used to address post-anesthesia shivering, Tramadol has gained popularity in managing post-spinal anesthesia shivering. However, its use is associated with side effects such as nausea, vomiting, and dizziness, contributing to patient discomfort [11-12].

Dexmedetomidine, a compound akin to clonidine, acts as a highly specific agonist for α2-adrenoceptors. It serves as a sedative and has been proven to raise the shivering threshold. Numerous studies have verified its efficacy in reducing shivering, emphasizing its benefits as a medication with minimal side effects and excellent hemodynamic stability [13-15].

The utilization of Tramadol as a therapeutic intervention to manage shivering after spinal anesthesia has not received adequate attention. Consequently, we aimed to undertake a comparative study to explore the effectiveness, impact on hemodynamic parameters, and potential side effects of intravenous (IV) dexmedetomidine and tramadol in the treatment of post-spinal anesthesia-induced shivering.

Shivering affects around 40-60% of patients following general anesthesia and 33% of patients after regional anesthesia. Peri-operative hypothermia, a common precursor to post-anesthesia shivering, has been linked to various adverse consequences, including activation of the sympathetic nervous system, metabolic acidosis, delayed recovery, reduced platelet activity, and compromised immune responses [1].

Preventing post-anesthesia shivering offers several advantages, such as decreased morbidity and blood loss, enhanced wound healing, and a shorter hospital stay.Various treatments for postoperative shivering exist, including tramadol, 2 agonists, opiates, ketanserin, MgSO4, steroids, and 6HT3 antagonists. A thorough examination of the literature revealed that tramadol, clonidine,[16] and dexmedetomidine [17] have all shown efficacy in treating postoperative shivering.[18] However, no randomized comparative trial has been conducted to assess their relative effectiveness. In this RCT, study participants are randomly assigned to receive both the drugs under groups T and D being studied and the outcomes are compared between the groups.

2. MATERIALS AND METHODS

This research, carried out at XXX Charitable Hospital and Medical Research Centre, spanned from January 2021 to December 2021. It was a randomized and prospective study that received approval from the Institutional Ethics Committee. Prior to their involvement, all participants furnished written informed consent.

Sample Size:

Based on prior studies' statistical analyses, a sample size of 60 was determined. The minimum sample size formula is based on the following factors: mean and standard deviation are as follows.

$$n = \frac{(Z_\alpha + Z_\beta)^2 (s_1^2 + s_2)}{(X_1 - X_2)^2}$$

In the scenario where the test's power is denoted by "z" and the test's significance level is represented by "α," Z values correspond to 1.96 for a significance level of 5% and 0.84 for a test power of 80%.

In the first group, the mean (X1) is 137.4, and in the second group, the mean (X2) is 127.7. The standard deviation for the first group is denoted as s1 (13.8), while for the second group, it is represented as s2 (8.6). With these parameters, a sample size of 22 was initially used. To improve the study's conclusions, the sample size in each group will be expanded to 30.

Inclusion criteria:

American Society of Anaesthesiologists (ASA) Grade I and II consenting individuals of either gender aged 18-50 years and weighing between 50 and 70 kgs were scheduled, the study involved patients who underwent planned surgery while being unconscious from general anesthesia, with the surgeries lasting between 60 to 120 minutes.

Exclusion criteria:

Patients with known morbidly obese patients (BMI>30 Kg/m2), Concurrent health conditions like Ischemic Heart Disease (IHD), Hepatic and Renal insufficiency, Neuromuscular Disorders, and psychiatric disturbances existing together.Body temperature below 35°C while undergoing surgery and the study did not include patients who had a fever before surgery or

those with either underactive thyroid (hypothyroidism) or overactive thyroid (hyperthyroidism) before their operation.

In Group D, patients got 50 mcg of injection dexmedetomidine (100 mcg diluted in 20 ml N.S. in which 10 ml was given over 10 minutes); In Group-T, patients received 50 mg of Injection Tramadol (100 mg diluted in 20 ml N.S. in which 10 ml was given over 10 minutes) just after the completion of intubating the patient. For the first hour, vital signs were taken every ten minutes; the next hour, they were taken every 20 min. The internal temperature of the tympanic membrane was monitored before to induction, shortly after induction, and then every 30 minutes for the duration of the 2 hours of surgery. H.R., B.P., spo2, and tympanic membrane temperature were monitored at the moment of admission to the recovery room (T0), after 10 minutes (T10), after 20 minutes (T20), after 30 minutes (T30), and subsequently every half hour for the following hour, there was a rise in post-anesthesia shivering, feelings of nausea, occurrences of vomiting, and a requirement for post-operative pain relief medication.

We provided the patients with information about the Visual Analog Scale (VAS) throughout the pre-operative time. After confirming that the patient was fasting (nil by mouth), the intravenous (IV) cannula was properly inserted, and the patient was transferred to the operating room. Upon entering the operating room, the patient's baseline vital signs, including heart rate, blood pressure, respiration rate, oxygen saturation, and body temperature (measured at the tympanic membrane), were recorded. The operating room temperature was maintained at 22 °C. Prior to commencing the anesthesia procedure, administer Glycopyrrolate at a dosage of 0.005 mg/kg, midazolam at 0.05 mg/kg, ondansetron at 8 mg, and Fentanyl at 2 mcg/kg, with each medication given at 5-minute intervals.

A quantity of 2 milligrams per kilogram of Propofol was given as a dosage. The process of tracheal intubation was facilitated by administering a bolus dose of Inj. succinylcholine at 2 milligrams per kilogram.Onceend-tidal carbon dioxide($etco_2$) confirmed tracheal tube alignment and the auscultation test demonstrated bilateral equal air entry, a 0.1 mg/kg vecuronium injection was given as a loading dosage. Oxygen, nitrous oxide, isoflurane, and vecuronium (0.025 mg/kg) were once utilised to maintain anaesthesia.

An individual with visual impairment carried out and documented all the observations. Throughout the process, patients were draped in surgical cloths and were not actively warmed. The vital signs, including heart rate (HR), blood pressure (BP), and respiration rate (RR), were monitored at intervals of 10 minutes during the initial hour and 20 minutes in the subsequent hour. The core temperature of the patient was measured using an infrared tympanic membrane thermometer before the induction of anesthesia, immediately after induction, and then every 30 minutes for the next two hours. To counteract the neuromuscular blockade post-surgery, Neostigmine at a dose of 0.05 mg/kg and Glycopyrrolate at a dose of 0.01 mg/kg were administered intravenously.Trachea was extubated once the patient's breathing was stable and he or she could follow spoken directions. After the surgical procedure, the individual received oxygen through a facial mask at a flow rate of 5 liters per minute and was covered with a solitary blanket. Heart rate (H.R.), blood pressure (B.P.), respiratory rate (RR), and temperature of the tympanic membrane were observed upon entry into the recovery room (T0), after 10 minutes (T10), at the 20-minute mark (T20), 30 minutes following the initial assessment (T30), and then at half-hour intervals throughout the subsequent hour. Additionally, instances of pain, nausea, vomiting, and shivering experienced by the patient were documented.

Statistical analysis:

The assessment involved the use of PSS 20 for statistical analysis, with Student's t-test applied to continuous variables and the Chi-square test for categorical variables. Mean±standard deviation (SD) was used for reporting continuous data, while number (%) was used for categorical data. Significance was set at $p<0.05$. Microsoft Word and Microsoft Excel were employed for creating text, graphs, and tables.

3. RESULTS

The figure displays the CONSORT flow chart illustrating the distribution of patients. Within the study, the group administered with tramadol (group-T) had the largest participant count among the 60 individuals. Demographic details are shown in table 1. The statistical analysis revealed that age, weight, and comparison groups did not exhibit a statistically significant relationship (Table-1). The intra-operative mean heart rate in the Dexmedetomidine and Tramadol groups are shown in table 2. Similarly the post-operative heart rate are shown in table 3. Similarly intra-operative systolic blood pressure shown in table 4. Post-operative systolic blood pressure in the Dexmedetomidine group ranged from 115.37 to 149.40. Post-operative systolic blood pressure ranged from 126.53 to 140.30 in the Tramadol group (Table 5).

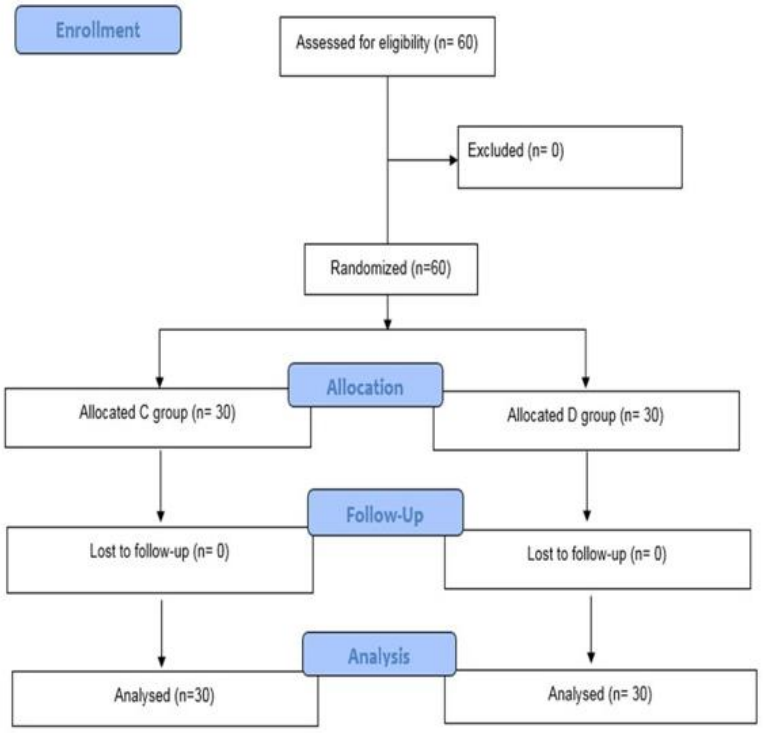

Figure. CONSORT flow chart utilized during conduct research

Table 1: Demographic Profile of Both Groups

Variable	Group D	Group T	P value
Age (in years)	36.77±10.75	37.43±10.51	0.8
Sex (F:M)	19:11	17:13	
Weight	57.10±2.77	56.76±4.3	0.7

Table 2: Intra-operative Heart Rate

		Heart Rate				P Value
		Group-D		Group-T		
		Mean ± SD	Min-Max	Mean ± SD	Min-Max	
Intra-operative	Pre-op	90.83 ±15.35	74 -145	79.27±12.40	45-106	0.0022*
	5 min	93.97 ±20.06	65-138	80.87±17.26	42-118	0.0088*
	15 min	91.80±20.00	61-136	80.87±18.15	38-118	0.0305*
	25 min	87.50±18.20	59-132	81.23±14.22	39-108	0.1427
	35 min	76.67±15.70	56-116	83.67±15.02	43-110	0.0829
	45 min	69.97±11.08	55-104	81.90±12.94	45-108	0.0003*
	55 min	67.27±9.10	51-88	82.70±12.55	46-109	<0.0001*

	75 min	63.93±7.65	49-83	83.73±14.99	45-111	<0.0001*
	95 min	64.33±8.64	50-85	82.13±12.85	47-99	<0.0001*
	115 min	65.73±9.35	51-84	87.37±13.43	48-114	<0.0001 *
	120 min	73.17±9.79	56-98	94.64±16.43	48±123	<0.0001*

(* Significant)

Table 3: Post-Operative Heart Rate

		Heart Rate				P -value
		Group-D		Group-T		
		Mean ±SD	Min-Max	Mean±SD	Min-Max	
Post-operative	Post-op	69.07 ±7.75	56-91	90.13±18.05	49-121	<0.0001*
	0 min	93.97 ±20.06	65-138	80.87±17.26	42-118	<0.0001*
	10 min	63.43±7.17	51-84	85.23±15.77	53-119	<0.0001*
	20min	60.80±8.18	47-83	81.80±15.22	50-124	<0.0001*
	30 min	62.60±7.98	51-81	80.80±13.82	53-116	<0.0001*
	60min	62.03±8.07	49-85	81.03±12.19	51-108	<0.0001*
	90min	62.73±8.56	51-89	79.60±12.41	43-103	<0.0001*
	120 min	62.66±7.80	53-87	80.52±13.88	41-108	<0.0001*

(* Significant)

Table 4: Intra-operative Systolic Blood Pressure

		Systolic blood pressure				p value
		Group-D		Group-T		
		Mean ±SD	Min-Max	Mean±SD	Min-Max	
Intra-Operative	Pre-op	131.53±14.82	110-170	123.93±13.80	90-150	0.0443*
	5 min	140.10±19.89	99-170	121.90±13.72	100-148	0.0001*
	15 min	139.53±28.03	40-171	123.83±20.85	90-158	0.0168*
	25 min	138.23±15.95	106-170	125.27±16.16	91-157	0.0028*
	35 min	126.90±19.02	90-173	129.60±14.14	98-152	0.5350
	45 min	114.73±13.56	90-151	128.53±15.37	100-160	0.0005*
	55 min	113.87±14.02	94-156	130.30±14.42	100-158	<0.0001*
	75 min	112.97±12.10	98-150	130.77±14.31	100-154	<0.0001*
	95 min	111.83±13.49	89-148	130.27±16.45	100-186	<0.0001*
	115 min	114.90±14.12	90-148	133.63±14.15	108-166	<0.0001*
	120 min	127.00±14.88	98-156	140.21±15.90	101-169	0.0018*

(* Significant)

Table 5: Post-operative Systolic Blood Pressure

		Systolic blood pressure				p value
		Group-D		Group-T		
		Mean ±SD	Min-Max	Mean±SD	Min-Max	
Post-operative	0 min	125.10±15.98	97-166	140.30±14.03	108-160	0.0002*
	10 min	117.87±15.67	91-149	134.40±13.39	101-152	0.0001*
	20 min	116.83±15.13	90-147	130.83±12.85	103-152	0.0003*
	30 min	117.03±13.62	96-147	129.03±11.84	110-150	0.0006*
	60 min	115.37±14.78	91-147	129.27±12.46	108-149	0.0002*
	90 min	116.77±13.87	98-155	126.53±11.69	106-147	0.0046*
	120 min	149.40±181.06	91-150	127.48±12.00	103-158	0.5181

(* Significant)

Intra-operative diastolic blood pressure ranged from 5 minutes to 120 mins in the Dexmedetomidine cluster, accompanied by an average mean range of 67.80 to 88.23. The intra-operative diastolic blood pressure in the Tramadol group ranged from 5 to 120 minutes, with a mean range of 75.07 to 82.64. The mean post-operative diastolic blood pressure of Group-D patients ranged from 68.43 to 76.67. It ranged from 73.37 to 82.30 in Group-T patients.

Between 5 and 120 minutes, the average intra-operative respiratory rate for patients in Group D varied from 12.30 to 13.53. During 5 to 120 minutes, the mean in Group-T patients ranged from 12.37 to 13.87.Due to this, it was not significant. From 10 minutes to 120 minutes, the respiratory rate of patients in Group-D after surgery fluctuated with a mean range of 11.33 to 12.43. The post-operative respiratory rate in Group-T patients varied from 10 to 120 minutes, with a mean range of 12.67 to 15.07.

From 0 to 120 minutes, the intra-operative temperature of Group-D patients ranged with a mean range of 98.06 °F to 98.53 °F. The intra-operative temperature in Group-T patients varied from 0 to 120 minutes, with a mean range of 97.66 °F to 98.46 °F. Around 90 to 120 minutes, and it was significant. As a result, it was statistically significant at 90 and 120 minutes. From 0 to 60 minutes, and it was insignificant . As a result, from 0 to 60 minutes, intraoperative temperature was statistically negligible. Similarly, the post-operative temperature of Group-D patients ranged from 98.06 °F to 98.23 °F from 0 to 30 minutes. The post-operative temperature in Group T patients ranged from 0 to 30 minutes, with a mean range of 97.78 °0F to 98.02 °F. from 0 to 30 minutes. As a result, from 0 to 30 minutes, the difference is statistically significant.

The % of Group-D patients who had nausea was 3.33%, was 1 in 30. Patients with nausea in Group-T were 36.7%, or 11 out of 30 patients, the presence of nausea was shown to be statistically significant in relation to the intervention groups. Group-T individuals had much more nausea than Group-D patients.The percentage of Group-D patients who vomited was Nil, which meant that 100% of Group-D patients were not vomiting (30 out of 30). In Group-T, 10% (3 out of 30 patients) experienced vomiting, there was no statistically meaningful correlation observed between the different intervention groups and the occurrence of vomiting.

The percentage of Group-D patients who used rescue analgesia was 40% out of 100%, or 12 in 30 patients, In Group-T, 70% of patients used rescue analgesia, or 21 out of 30 patients; a significant correlation was observed between the intervention groups and the incidence of nausea. Patients in Group-T experienced a notably higher incidence of nausea. Both Tramadol and Dexmedetomidine proved to be effective in preventing post-anesthesia shivering.

4. DISCUSSION

In this controlled experiment with randomization, we assess the efficacy of intravenous dexmedetomidine and tramadol in the treatment of post-surgery shivering among adult patients who have undergone anesthesia. Our findings indicate that in the present study, both Tramadol injection and Dexmedetomidine injection demonstrated similar effectiveness in preventing shivering following anesthesia. Dexmedetomidine, however, exhibited superior pain control and a reduced occurrence of nausea and vomiting compared to tramadol. It is worth noting that the use of dexmedetomidine was associated with instances of bradycardia and hypotension. According to some studies the tramadol group demonstrated the least occurrence of shivering, with the dexmedetomidine group following closel, some studies reported 15% shivering incidence [19-21].

A study also reported occurrence of nausea and vomiting was 26.7% within the tramadol group [22]. These results align with

prior studies conducted [22,10]. In contradictory a study reported an exceptionally high prevalence of nausea at 77.5% [11], some reported 4% incidence of nausea and vomiting [23]. In our own research, a notable distinction in the intra-operative average heart rate was noted between Group-D and Group-T within the timeframe of 45 to 120 minutes.

The mean heart rate for Group-D ranged from 63.93 to 73.17, while for Group-T, it ranged from 81.9 to 94.62. Similarly, when examining the post-operative heart rate within the first 120 minutes, We noticed notable differences between Groups D and T. The mean heart rate for Group-D ranged from 60.80 to 69.07, and for Group-T, it ranged from 79.60 to 90.13. A study proved that clinically and statistically, the heart rates, respiratory rates, and mean arterial pressure of Group D patients differed significantly over the postoperative phase [13]. In our current research, we observed fluctuations in intra-operative systolic blood pressure within Group-D and Group-T, both showing a distinct average value. Likewise, post-operative systolic blood pressure displayed variations between 5 minutes and 120 minutes in both Group-D and Group-T, with a mean value. In the present study, intraoperative diastolic blood pressure significantly varied with a mean in both Groups D and T. Similarly, post-operative diastolic blood pressure ranged from 0 to 120 minutes in both Group-D and Group-T, with a mean difference and significance. A study done with 90 patients who were randomly divided into three group proved the dexmedetomidine group exhibited lower systolic and diastolic blood pressure compared to the clonidine and tramadol groups. [24]

The dexmedetomidine-treated individuals not only experienced faster relief from shivering but also encountered fewer recurrence episodes. Furthermore, the tramadol group exhibited significantly higher incidences of nausea and vomiting. Noteworthy, there were no significant alterations in blood pressure or heart rate observed in any of the groups. In our present study, there was no significant difference in intraoperative respiratory rates between Group-D and Group-T. However, a statistically significant difference in postoperative respiratory rates was observed between Group-D and Group-T. In our recent investigation, there was a significant difference in intraoperative temperature between Group-D and Group-T from 90 to 120 minutes. However, the intraoperative temperature showed no significance from 0 to 60 minutes. Similarly, the postoperative temperature between Group-D and Group-T exhibited statistical significance from 0 to 30 minutes. It is also know that at the onset of shivering, both groups experienced a temperature decrease of approximately 1°C from the initial baseline. [25] This outcome aligns previous findings which indicated a 2.1°F reduction in core body temperature and identified a positive association with shivering [26]. In contrast, in another study there was no correlation between temperature decline and shivering in their observations [27]. According to our study, the most common negative responses noted among individuals using tramadol were sensations of queasiness and throwing up. The incidence of nausea necessitating the use of rescue antiemetic was approximately 36.67% in the tramadol group, as opposed to 3.33% in the dexmedetomidine group. Percentage of Group-D patients who vomited was 0%; 10% of Group-T patients vomite these findings confirm the almost results that incidence of vomiting among tramadol-treated individuals was 20% [7]. According to Talakoub et al.,[28], antiemetic usage was reported in 30% of tramadol patients. Some studies reported with dexmedetomidine, with no patients complaining of nausea or vomiting [17]. According to other study the time taken for shivering to cease was 3.45 ± 1.23 minutes in the dexmedetomidine group, whereas it was 5.27 ± 1.08 minutes in the tramadol group, indicating a significant distinction [21] . A studuy determined that patients who received a combination of dexmedetomidine and tramadol witnessed a cessation of shivering. Similarly a study proved that both medications successfully prevented shivering. [29] According to a study dexmedetomidine effectively ceased shivering in 98.30% of patients, surpassing the success rate of 86.67% in the tramadol group. [30] However, dexmedetomidine worked faster and had a longer-lasting effect compared to tramadol. The study calculated the average time it took for shivering to stop in both groups. In group D, shivering ceased after approximately 2.9 ± 0.9 units of time, whereas in group T, it took about 3.75 ± 0.9 units of time.

The time required for shivering to cease was notably shorter with dexmedetomidine compared to tramadol. The recurrence of shivering was less frequent with dexmedetomidine (6%) as opposed to tramadol (16%). [31] Tramadol resulted in a higher occurrence of nausea and vomiting. In contrast, dexmedetomidine induced a state of moderate sedation, allowing patients to be easily awakened. According to our findings, 40% of Group-D patients acquired rescue analgesia, while 70% of Group-T patients acquired it. Group-T patients exhibited a notably higher incidence of cases.

In our recent investigation, we observed Group-T and Group-D demonstrate equivalent efficacy in preventing post-anesthesia shivering, with comparable average occurrence rates of 1.77 and 1.37, respectively. It is know that both drugs effectively managed shivering at their designated doses, with dexmedetomidine at 0.5 mcg/kg and tramadol at 0.5 mg/kg administered as IV infusion [25]. This outcome aligns with the results of prior studies [7,14,17,28] indicating that both study drugs effectively control shivering at the specified dosage.

Ameta et al. [32] found that the group receiving dexmedetomidine exhibited more effective shivering control following spinal anesthesia in comparison to other groups. Despite this positive outcome, the administration of dexmedetomidine resulted in notable hypotension, effectively managed with a single dose of mephentermine (3 mg IV). Dexmedetomidine outperforms ketamine and tramadol in preventing shivering post-spinal anesthesia, while also offering ample sedation and improved surgical conditions. A study determined that patients who were administered tramadol had markedly fewer occurrences of shivering compared to those in the clonidine and dexmedetomidine groups. [20]

5. CONCLUSION

It can be concluded that the combination of these drugs may be more successful than either medication alone, but more study is required to establish the optimum dosing and timing of this combination therapy

Data Availability Statement

Data will be shared upon request

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We would like to acknowledge study participants.

Declaration

Authors declare that, the present manuscript is not submitted anywhere else for consideration

Grants and Funding Information

Nil

Conflict of Interest

Authors don't have any conflict of interest

Registration number of clinical trial

CTRI: CTRI/2021/04/032931

Author Contributions

NK: Conducted the study and collected data, SA: collected data and analyzed the data, MS: Designed the study and write the manuscript, CS: Designed the study, PM: Reviewed the manuscript

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