ORIGINAL RESEARCH

Comparative efficacy of intravenous tramadol and intravenous dexmedetomidine in the management of post-anaesthesia shivering: A one year randomized clinical trial

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ABSTRACT

Background: Shivering is a prevalent perioperative complication that arises due to the occurrence of postanesthesia hypothermia. The objective of this current randomized clinical trial was to assess and compare the effectiveness of intravenous tramadol and intravenous dexmedetomidine in the prevention of post-anaesthesia shivering.

Material & Methods: A total of 80 adult patients with ASA status I and II were randomly allocated into two groups. Group A consisted of 40 patients who received dexmedetomidine, while Group B consisted of 40 patients who received tramadol. The attending anesthesiologist would document the following information: the onset time of shivering following spinal anesthesia, the severity of the shivering, the rate of response to treatment, and the duration until the shivering subsided. The data were presented as the mean ± standard deviation (SD) or as a percentage. A significance level of $p < 0.05$ was deemed to indicate statistical significance. A p-value less than 0.001 was deemed to be highly significant.

Results: In the current study, Group A consisted of 24 male patients and 16 female patients, while Group B comprised 21 male patients and 19 female patients. The average age of patients in group A was 48.76 years, while in group B it was 65.45 years. In group A, there were a total of 40 patients, with 20 classified as ASA grade I and 20 classified as ASA grade II. In group B, there were a total of 40 patients, with 15 classified as ASA grade I and 25 classified as ASA grade II.The duration of surgery in group A was recorded as 76.48 minutes, while in group B, it was observed to be 120.54minutes.The duration of spinal surgery in group A was recorded as 80.78 minutes, while in group B it was observed to be 130.29 minutes. There were no statistically significant differences observed between the two groups in terms of the time it took for shivering to begin, the intensity of shivering, and the time at which shivering recurred. The average duration from drug administration (dexmedetomidine and tramadol) to the point at which shivering completely stopped was significantly shorter in the dexmedetomidine group.

Conclusion: The study's findings indicated that the average duration from the administration of dexmedetomidine and tramadol to the complete cessation of shivering was significantly shorter in the group receiving dexmedetomidine.

Keywords: Dexmedetomidine, tramadol, shivering.

INTRODUCTION

Shivering is a physiological response characterized by rhythmic, involuntary contractions of skeletal muscles. It serves as an innate defense mechanism against the decline in body temperature. The human body employs shivering as a mechanism to increase metabolic heat production in order to restore homeostasis.[1] The interthreshold range, also referred to as the thermo neutral zone, is a narrow range of temperatures, typically between 36.5 and 37.5 °C, within which the core temperature in humans is typically regulated. Thermoregulatory responses, such as vasoconstriction and shivering, are elicited in instances where the core temperature of an organism decreases below the established range typically considered as normal.[2] According to the second source, Postanesthesia adverse events are frequently observed, occurring at a rate ranging from 40% to

70%.[3]Neuraxial anesthesia induces vasodilation, which promotes efficient dissipation of heat and the redistribution of body heat from the core to the periphery, resulting in a reduction in core temperature. Consequently, the point at which shivering is initiated is reached at an earlier stage, necessitating a greater degree of shivering in order to mitigate the progression of hypothermia.[4] Tramadol, a substance that activates opioid receptors, functions as a suppressor of serotonin (5-hydroxytryptamine) and norepinephrine re-uptake within the spinal cord. This process enables the release of 5-hydroxytryptamine, which subsequently exerts an influence on thermoregulatory control. Currently, it is a commonly employed pharmaceutical agent for the management of involuntary muscle contractions known as shivering. However, it should be noted that tramadol has the potential to induce adverse effects such as nausea and vomiting, which can significantly impact the well-being of the individual receiving treatment. Hence, it is imperative to identify an improved pharmaceutical agent that exhibits a reduced incidence of adverse reactions.[5] The efficacy of dexmedetomidine, an alpha 2-adrenergic agonist, in the management and prophylaxis of shivering during different surgical procedures has been established through its ability to lower the shivering threshold.[6] The objective of this randomized clinical trial was to assess the comparative effectiveness of intravenous tramadol and intravenous dexmedetomidine in the prevention of post-anaesthesia shivering.

MATERIAL & METHODS

Following the acquisition of approval from the Institutional Ethical Committee and the collection of written informed consent, a randomized double-blind study was undertaken. The study involved a sample of 80 adult patients of the Indian Society of Anesthesiologists and had a status of ASA I or II. The patients, who were of both sexes and above 18 years of age, experienced shivering during surgeries conducted under spinal anesthesia (SA). Among the participants, 40 individuals were assigned to receive dexmedetomidine (Group A), while the remaining 40 were assigned to receive tramadol (Group B). The study excluded individuals who met the following criteria: coagulopathy, advanced age (greater than 65 years), bradycardia (heart rate less than 60 beats per minute), heart blocks, pregnancy or lactation, and allergies to either the specific drugs used or the drug group as a whole.The study was conducted over a period of one year. The participants were assigned to either Group A or Group B in a random manner. The computer-generated group designation (Group A or Group B) was placed inside a sealed, non-transparent envelope. An individual who does not possess a direct affiliation with the field of study, specifically an anesthesia nurse, was requested to unseal the sealed envelope containing a computer-generated group number at the onset of shivering in the patient. The drug was prepared in a 50 ml syringe and subsequently distributed for use without proper labeling indicating its identity. However, the individual responsible for this action maintained a record documenting the drug's details. Upon the necessity of administering a second dose of the drug, she once again dispatched it within an unlabeled syringe. The anesthesiologist responsible for administration was unaware of the specific drug being administered. The individual would complete the study proforma by recording the various parameters, and subsequently, the anesthesia nurse would retrieve the proforma and return it to the torn envelope. Upon the conclusion of the study, the envelopes were transferred to the principal investigator.The monitoring of patients involved the use of noninvasive blood pressure (NIBP), pulse rate, SpO2, and axillary temperature measurements.The subarachnoid block was initiated through the injection of heavy bupivacaine 0.5% dose at the interspace of L2-3 or L3-4. Patients did not receive active warming, and the fluids were administered at ambient temperature. The ambient temperature within the entirety of the operation theater complex, pharmacy area, and surgical recovery room was maintained at a consistent range of 21 to 24°C. The vital signs, namely non-invasive blood pressure (NIBP), pulse rate, oxygen saturation (SpO2), and axillary temperature, were documented at the start of the surgical procedure and at the onset of shivering based on the monitoring chart. These measurements were also taken after the shivering stopped and subsequently every 10 minutes until the conclusion of the study.In Group A: Dexmedetomidine (0.5 mcg/kg) in the concentration of 1 mcg/ml was given over 10 min if there was shivering in patient after initiation of subarachnoid blockIn Group B: Tramadol was administered at a dosage of 0.5 mg/kg, with a concentration of 1 mg/ml, over a duration of 10 minutes. In the event of shivering occurring in the patient following the initiation of a subarachnoid block, this intervention was implemented..Shivering was graded using a five scale point scale.[7]The study included patients who experienced either Grade 3 or Grade 4 shivering. The grading of shivering during recurrence was conducted using identical criteria, and patients exhibiting Grade 3 or 4 shivering were included in the analysis.

The attending anesthesiologist would record:

1. The onset of shivering following the administration of SA and the subsequent recurrence, if applicable, are characterized by the time at which shivering commenced and the duration between the cessation of shivering after the initial drug dose and the reappearance of shivering, respectively.
2. The intensity of the shivering
3. The response rate refers to the proportion of patients in which shivering ceased within 15 minutes after treatment.

4. The duration of shivering cessation (in seconds).

If the cessation of shivering did not occur within a duration of 15 minutes, it was determined that the treatment yielded ineffective results. The observation of shivering episodes was also documented. Patients who did not exhibit a response or experienced a recurrence of shivering were administered an additional dose of dexmedetomidine (0.25 μg/kg IV) or tramadol (0.25 mg/kg IV) in their respective groups. In the event that certain patients exhibit a lack of response to the supplementary dosage, they would be classified as experiencing treatment failure. This method would be employed for the purpose of computing the response rate. Adverse effects such as nausea, vomiting, pruritus, bradycardia (heart rate <60 beats per minute), hypotension (a reduction of more than 20% from baseline systolic blood pressure/diastolic blood pressure [SBP/DBP]), and sedation level were documented.The results were subjected to analysis using the Student's t-test and Chi-square test. The data were represented as the mean ± standard deviation (SD) or as a percentage. A significance level of $p < 0.05$ was deemed to indicate statistical significance. A p-value less than 0.001 was deemed to be statistically highly significant.

RESULTS

Table: 1 Demographic data

Parameters	Group A	Group B
Gender		
Male	24	21
Female	16	19
Mean±SD (Yrs)	48.76±11.32	65.45±8.54
ASA grade		
I	20	15
II	20	25
Duration of surgery (min)	76.48±28.09	120.54±28.78
Duration of spinal Anesthesia (min)	80.78±34.05	130.29±30.36

In the current study, Group A consisted of 24 male patients and 16 female patients, while Group B included 21 male patients and 19 female patients. The average age of patients in group A was 48.76 years, while in group B it was 65.45 years. In group A, there were a total of 40 patients, with 20 classified as ASA grade I and 20 classified as ASA grade II. In group B, there were a total of 40 patients, with 15 classified as ASA grade I and 25 classified as ASA grade II.The duration of surgery in group A was recorded as 76.48 minutes, while in group B it was documented as 120.54 minutes. The duration of spinal surgery in group A was recorded as 80.78 minutes, while in group B it was observed to be 130.29 minutes.

Table: 2 Comparison of the time of onset of shivering, severity of shivering, time to disappearance of shivering, and time of recurrence in the two study groups

	Group A	Group B	p-value
Time of onset of shivering (min)	71.34±40.54	71.70±40.89	0.986
Severity of shivering	3.94±0.26	3.98±0.20	0.404
Time of self disappearance (s)	173.18±14.39	275.08±24.38	<0.001
Time of recurrence (min)	70.35±18.32	74.67±22.18	0.787

There were no statistically significant differences observed between the two groups in terms of the time at which shivering began, the intensity of shivering, and the time at which shivering recurred. The average time interval from drug administration (dexmedetomidine and tramadol) to the complete cessation of shivering was significantly shorter in the dexmedetomidine group.

DISCUSSION

Shivering is a commonly observed complication in individuals who are undergoing spinal anesthesia. After the administration of anesthesia, a decrease in core temperature can be observed, which can be divided into three distinct phases. In phase I, the most significant decline occurs at the 30-minute mark. Phase 2 begins one hour after the initial event, followed by phase 3 which commences after a duration of 3 to 5 hours. During phase 3, heat loss is gradually reduced until a state of equilibrium is attained.[8]n the current study, Group A consisted of 24 male patients and 16 female patients, while Group B consisted of 21 male patients and 19 female patients. The average age of patients in group A was 48.76 years, while in group B, it was 65.45 years. In group A, there were a total of 40 patients, with 20 classified as ASA grade I and 20 classified as ASA grade II. In group B, there were a total of 40 patients, with 15 classified as ASA grade I and 25 classified as ASA grade II.The duration of surgery in group A was recorded as 76.48 minutes, while in group B it was documented as 120.54 minutes. The duration of spinal

surgery in group A was recorded as 80.78 minutes, while in group B, it was observed to be 130.29 minutes. There were no statistically significant differences observed between the two groups in terms of the time at which shivering began, the intensity of shivering, and the time at which shivering recurred. The average duration from drug administration (dexmedetomidine and tramadol) to the complete cessation of shivering was significantly shorter in the dexmedetomidine group.In their study, Sahi et al conducted a comparative analysis to assess the effectiveness of tramadol, clonidine, and dexmedetomidine in mitigating postoperative shivering and associated adverse effects among individuals undergoing laparoscopic cholecystectomy while under general anesthesia.In this study, Group 1 was administered clonidine at a dosage of 2 µg/kg, Group 2 received tramadol at a dosage of 1 mg/kg, Group 3 received dexmedetomidine at a dosage of 1 mcg/kg, all of which were administered intravenously and diluted in normal saline (NS) to a volume of 5 ml. Group 4, on the other hand, received 5 ml of intravenous normal saline (NS). The prevalence of shivering was observed to be 10%, 3.3%, 13.3%, and 40% in Groups 1, 2, 3, and 4, respectively. The administration of tramadol resulted in a notable reduction in shivering among patients, as compared to those in the clonidine and dexmedetomidine groups ($P < 0.01$).[9]In their study, Kundra et al. conducted a comparative analysis to evaluate the effectiveness of dexmedetomidine and tramadol for managing shivering following spinal anesthesia (SA). Additionally, the researchers aimed to compare the respective side-effect profiles associated with these two interventions. The findings indicated that shivering ceased in all patients who were administered both dexmedetomidine and tramadol. The duration for shivering to stop was significantly shorter when dexmedetomidine was administered (174.12 ± 14.366 s) compared to tramadol (277.06 ± 23.374 s) ($P < 0.001$). The incidence of shivering with dexmedetomidine was found to be lower (6%) in comparison to tramadol (16%). A higher incidence of nausea and vomiting was observed in individuals administered tramadol. In contrast, dexmedetomidine induced a state of moderate sedation, as evidenced by a modified Ramsay sedation score ranging from 3 to 4, wherein the patient could be readily aroused.[5] In their study, Lim Fern et al conducted a comparison between the efficacy of intravenous dexmedetomidine and that of pethidine and tramadol for the management of shivering following neuraxialanesthesia.The research findings indicated that Dexmedetomidine at a concentration of 0.5 µg/ml exhibited superior effectiveness compared to tramadol at a concentration of 0.5 mg/ml and pethidine at a concentration of 0.5 mg/ml. Additionally, both tramadol and pethidine demonstrated comparable efficacy in the management of shivering following neuraxial anesthesia. Nevertheless, the administration of dexmedetomidine resulted in a greater prevalence of hypotension and bradycardia.[10]

CONCLUSION

The study's findings indicated a statistically significant decrease in the average duration between the administration of dexmedetomidine and tramadol and the complete cessation of shivering within the dexmedetomidine group.

REFERENCES

1. De Witte J, Sessler DI. Perioperative shivering: physiology and pharmacology. The Journal of the American Society of Anesthesiologists. 2002 Feb 1;96(2):467-84.10.1097/00000542-200202000-00036
2. KWeant KA, Martin JE, Humphries RL, Cook AM. Pharmacologic options for reducing the shivering response to therapeutic hypothermia. Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy. 2010 Aug;30(8):830-41.**10.1592/phco.30.8.830**
3. Shukla U, Malhotra K, Prabhakar T. A comparative study of the effect of clonidine and tramadol on post-spinal anaesthesia shivering. Indian journal of anaesthesia. 2011 May;55(3):242.10.4103/0019-5049.82666
4. Bilotta F, Pietropaoli P, Sanitá R, Liberatori G, Rosa G. Nefopam and tramadol for the prevention of shivering during neuraxial anesthesia. Regional anesthesia and pain medicine. 2002 Jul 1;27(4):380-4.10.1053/rapm.2002.33563
5. Kundra TS, Kuthiala G, Shrivastava A, Kaur P. A comparative study on the efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering. Saudi journal of anaesthesia. 2017 Jan;11(1):2.10.4103/1658-354X.197344.
6. Blaine Easley R, Brady KM, Tobias JD. Dexmedetomidine for the treatment of postanesthesia shivering in children. Pediatric Anesthesia. 2007 Apr;17(4):341-6.**10.1111/j.1460-9592.2006.02100.x**
7. Blaine Easley R, Brady KM, Tobias JD. Dexmedetomidine for the treatment of postanesthesia shivering in children. Pediatric Anesthesia. 2007 Apr;17(4):341-6.**10.1111/j.1460-9592.2006.02100.x**
8. Taylor RW, editor. Civetta, Taylor, & Kirby's Critical Care. Wolters Kluwer/Lippincott-Williams & Wilkins; 2009.https://doctorlib.info/therapy/critical/53.html
9. Sahi S, Singh MR, Katyal S. Comparative efficacy of intravenous dexmedetomidine, clonidine, and tramadol in postanesthesia shivering. Journal of Anaesthesiology, Clinical Pharmacology. 2016 Apr;32(2):240.10.4103/0970-9185.182109
10. Fern L, Misiran K. Comparison of dexmedetomidine, pethidine and tramadol in the treatment of post-neuraxialanaesthesia shivering. Southern African Journal of Anaesthesia and Analgesia. 2015 Jul 31;21(1):21-6. 10.1080/22201181.2015.1013323