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Original Article

COMPARISON OF INTRAVENOUS CLONIDINE AND TRAMADOL FOR POST SPINAL ANAESTHESIA SHIVERING: A RANDOMIZED STUDY

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ABSTRACT

Objective: Post-spinal anesthesia shivering is a frequent complication that can affect patient recovery and comfort. Clonidine and tramadol are both used to treat this condition, but direct comparisons of their effectiveness and safety are limited.

Methods: This prospective, randomized study included 120 patients undergoing surgery under spinal anesthesia, divided equally into two groups to receive either clonidine or tramadol upon the onset of shivering. Outcomes measured included incidence of shivering, heart rate, and temperature changes, analyzed using chi-square and t-tests.

Results: There were no significant differences in age, weight, and ASA status between the groups, indicating a homogeneous sample. Both drugs effectively managed temperature and heart rate during and after shivering, with no significant differences in efficacy or safety observed.

Conclusion: Both drugs are effective for managing post-shivering but Clonidine is more effective then tramadol for managing post-spinal anesthesia shivering, suggesting that treatment choice can be guided by individual patient needs and drug availability.

Keywords: Post-spinal anesthesia shivering, Clonidine, Tramadol, Anesthesia complications, Randomized controlled trial

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INTRODUCTION

Post-spinal anesthesia shivering (PSAS) is a common and distressing complication observed in 40-60% of patients undergoing surgeries under spinal anesthesia. This phenomenon not only contributes to patient discomfort but also poses risks such as increased oxygen consumption, altered hemodynamic responses, and impaired wound healing. Despite its prevalence, the optimal management of PSAS remains under-explored, necessitating further research into effective therapeutic strategies [1, 2].

Clonidine and tramadol, two pharmacological agents with distinct mechanisms of action, have been independently used to mitigate shivering. Clonidine, a central alpha-2 adrenergic agonist, reduces sympathetic outflow, potentially stabilizing the thermal regulatory responses altered during anesthesia. On the other hand, tramadol, primarily recognized for its analgesic properties, also activates mu-opioid receptors and inhibits the reuptake of serotonin and norepinephrine, which may help in controlling thermoregulatory disturbances [3-5].

Previous studies have shown variable efficacy of these drugs when used as monotherapy for PSAS. For instance, clonidine has been favored for its dual role in providing sedation and sympatholysis, while tramadol is preferred for its rapid onset of action and minimal hemodynamic effects. However, direct comparisons between clonidine and tramadol in the context of PSAS are sparse, with existing literature providing inconclusive results. This ambiguity in clinical outcomes highlights the necessity for a rigorous evaluation of these agents under controlled conditions [6-8].

This randomized study aims to fill this research gap by comparing the efficacy and safety of intravenous clonidine and tramadol in preventing PSAS [9]. By analyzing various clinical outcomes, such as the incidence of shivering, patient comfort scores, hemodynamic stability, and adverse effects, this study seeks to provide a clear evidence-based guideline for managing PSAS effectively. The implications of this research are significant, promising enhanced patient care and potentially revising existing protocols to incorporate the most efficacious and safe treatment modality for post-spinal anesthesia shivering.

MATERIALS AND METHODS

Study design and location

This hospital-based, prospective, randomized study was conducted at the Department of Anaesthesiology, Jhalawar Medical College and attached group of hospitals, Jhalawar. The study spanned from 2023 to December 2024, following the approval from the institutional ethical committee.

Study population

The study universe comprised 120 patients scheduled for surgery under spinal anesthesia. Written informed consent was obtained from each patient after a complete explanation of the study protocol and procedures involved. The consent process ensured patients were fully aware of their participation and the nature of the treatments involved.

Sample size

A sample size of 60 patients per group was determined to be adequate, aiming for a 95% confidence level and 80% power to detect a mean duration difference of 3.40 min (±0.81) in controlling shivering between the two groups.

Group allocation

Patients were assigned into two groups via the sealed envelope randomization method. Each group consisted of 60 patients:

- Group C (n=60): Patients received intravenous clonidine at a dose of 0.5 mcg/kg, diluted to 10 ml with saline, upon the onset of shivering.
- Group T (n=60): Patients were administered intravenous tramadol at a dose of 0.5 mg/kg, diluted to 10 ml with saline, when shivering occurred.

Inclusion criteria

Participants included in the study met the following criteria:

- Provided written informed consent and had no known allergies to the study drugs.

- Were between 20 to 60 y of age.
- Had a height of at least 145 cm.
- Weighed between 40 and 80 kg.
- Were classified as ASA grade I-II.
- Developed intraoperative shivering during surgery performed under spinal anesthesia.

Exclusion criteria

Patients were excluded based on the following:

- Refusal to participate in the study.
- History of acute infection, fever, or sepsis.
- Any contraindications to spinal block.
- Pregnancy status.
- Chronic history of headaches and backaches.
- Presence of spinal deformity or infection at the injection site.
- Known allergy to the study drugs.
- Failure to achieve an effective spinal block.

RESULTS

This randomized study assessed the efficacy and safety of intravenous clonidine versus tramadol in controlling post-spinal anesthesia shivering across two groups of 60 patients each. The analysis did not reveal any statistically significant differences in baseline characteristics between the two groups, with respect to age and body weight. The mean age was 41.22±4.18 y in Group C and 41.15±3.92 y in Group T, with a p-value of 0.928, indicating no significant difference. Similarly, the mean body weight was 62.58±4.50 kg for Group C and 62.37±4.58 kg for Group T, resulting in a p-value of 0.794, confirming no significant variance (tables 1 and 2).

Further analysis of the ASA Physical Status showed no significant difference between the two groups, with 71.67% of patients in Group C and 68.33% in Group T categorized under ASA Grade I, and the remainder under ASA Grade II. The p-value of 0.693 supports the non-significance of this distribution, demonstrating homogeneity in the clinical baseline of participants (table 3).

Temperature measurements indicated significant differences in the thermal response during shivering between preoperative and intraoperative periods. Group C exhibited a decrease from a preoperative mean temperature of 37.11 °C to 36.29 °C during shivering, and Group T from 36.99 °C to 36.22 °C. The changes were statistically significant with p-values<0.001 and 0.0003, respectively (table 4). These findings highlight the thermal effects of spinal anesthesia and subsequent shivering.

Heart rate monitoring during and after the control of shivering showed no statistically significant differences between the groups. During shivering, the heart rates were 73.57 for Group C and 74.40 for Group T (p-value = 0.224), and post-control rates were 72.33 for Group C and 71.97 for Group T (p-value = 0.565). These results suggest that both clonidine and tramadol manage the cardiovascular response to shivering comparably (table 5).

Overall, these findings confirm that while both treatments effectively manage the physiological parameters associated with shivering, there is no significant advantage of one drug over the other in terms of age, weight, ASA status, or cardiovascular response under the conditions of this study.

Table 1: Age/body weight/Asa physical status distribution (mean±SD)

Group	Number of patients	Age (Years)	SD	P-value
Group C	60	41.22	4.18	0.928
Group T	60	41.15	3.92	

Table 2: Mean preoperative temperature and temperature during shivering

Temperature in degree cent	Group C (N=60)	Group T (N=60)	P value
Pre-operative (Mean±SD)	37.11±0.30	37.05±0.40	0.3545
During shivering (Mean±SD)	36.80±0.21	36.70±0.37	0.0712

Table 3: Mean time required for cessation of shivering after treatment

Group	Number of patients	Duration (min)		P value
		Mean	SD	
Group C	60	2.85	0.61	0.001
Group T	60	4.90	1.13	

Table 4: Mean heart Rate/SBP/DBP/mean BP during shivering and after control of shivering

HR condition	Group C (N=60)	Group T (N=60)	P-value
During Shivering	73.57	74.40	0.224
After Control of Shivering	72.33	71.97	0.565

DISCUSSION

The findings from this randomized study indicate that both intravenous clonidine and tramadol are viable options for managing post-spinal anesthesia shivering, with no significant differences observed in their efficacy. Previous studies have acknowledged the roles of clonidine and tramadol in shivering control but lacked direct comparisons, which this study sought to address. The lack of significant differences in age, weight, and ASA physical status between the groups suggests that the study population was homogeneously distributed, allowing for a fair comparison of the drug effects on shivering [10, 11].

Notably, while both drugs effectively managed the temperature changes associated with shivering, as evidenced by the significant changes from preoperative to intraoperative periods, there was no advantage of one drug over the other in controlling the cardiovascular responses during and after shivering. These results

are consistent with prior research which demonstrated that both agents could be effective, albeit through different mechanisms—clonidine through sympatholysis and tramadol through its action on opioid receptors and serotonin reuptake inhibition [12, 13].

The absence of a significant difference in heart rate control post-shivering may suggest that any potential advantages of one drug over the other are likely minimal in clinical practice. Furthermore, this could imply that the choice of drug could be based on other factors such as patient-specific contraindications, cost, and availability, rather than efficacy differences in shivering control alone [14, 15].

Considering the safety profile, neither drug showed a superior edge, which aligns with the findings from other comparative studies in similar settings. The comparable safety profiles support the use of either medication as part of a tailored approach to managing post-spinal anesthesia shivering, depending on individual patient factors and healthcare provider preference.

This study contributes valuable insights to the existing literature by reinforcing the notion that both clonidine and tramadol can be effectively integrated into clinical protocols for PSAS management. However, further studies might be needed to explore long-term outcomes and potential subtle differences that could not be detected in this study due to its scope and sample size.

CONCLUSION

Both Clonidine and tramadol are effective in treating the patients with post spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with Clonidine group as compare to tramadol, difference being statistically significant. The Clonidine offer an excellent advantage of no adverse effects like nausea and vomiting.

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AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

REFERENCES

1. Sessler DI. Perioperative thermoregulation and heat balance. Lancet. 2016;387(10038):2655-64. doi: 10.1016/S0140-6736(15)00981-2, PMID 26775126.
2. Kurz A, Sessler DI, Lenhardt R, Study of Wound Infection and Temperature Group. Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization. N Engl J Med. 1996;334(19):1209-15. doi: 10.1056/NEJM199605093341901, PMID 8606715.
3. Alfonsi P. Postanaesthetic shivering: epidemiology pathophysiology and approaches to prevention and management. Drugs. 2001;61(15):2193-205. doi: 10.2165/00003495-200161150-00004, PMID 11772130.
4. Buggy DJ, Crossley AW. Thermoregulation mild perioperative hypothermia and postanaesthetic shivering. Br J Anaesth. 2000;84(5):615-28. doi: 10.1093/bja/84.5.615, PMID 10844839.
5. Doufas AG, Lin CM, Suleman MI, Liem EB, Lenhardt R, Morioka N. Dexmedetomidine and meperidine additively reduce the shivering threshold in humans. Stroke. 2003;34(5):1218-23. doi: 10.1161/01.STR.0000068787.76670.A4, PMID 12690216.
6. Horn EP, Sessler DI, Standl T, Schroeder F, Bartz HJ, Beyer JC. Non-thermoregulatory shivering in patients recovering from isoflurane or desflurane anesthesia. Anesthesiology. 1998;89(4):878-86. doi: 10.1097/00000542-199810000-00012, PMID 9778005.
7. Sessler DI. Temperature monitoring and perioperative thermoregulation. Anesthesiology. 2008;109(2):318-38. doi: 10.1097/ALN.0b013e31817f6d76, PMID 18648241.
8. Williams MR, Ward DS, Carlson D. Evaluation of a novel technology for temperature measurement in the operating room. Anesth Analg. 2010;111(1):63-7.
9. Sessler DI. Temperature monitoring and perioperative thermoregulation. Anesthesiology. 2008;109(2):318-38. doi: 10.1097/ALN.0b013e31817f6d76, PMID 18648241.
10. Wason R, Jain N, Gupta P, Gogia AR. Randomized double blind comparison of prophylactic ketamine clonidine and tramadol for the control of shivering under neuraxial anaesthesia. Indian J Anaesth. 2012;56(4):370-5. doi: 10.4103/0019-5049.100821, PMID 23087460.
11. Hassan HG, El Sharkawy TY, Renck H, Mansour G. Clonidine versus nefopam for prevention of postanesthetic shivering. Middle East J Anesthesiol. 2005;18(3):483-95.
12. Talke P, Tayefeh F, Sessler DI, Jeffrey R, Noursalehi M, Richardson C. Dexmedetomidine does not alter the sweating threshold but comparably and linearly decreases the vasoconstriction and shivering thresholds. Anesthesiology. 1997;87(4):835-41. doi: 10.1097/00000542-199710000-00017, PMID 9357885.
13. Gautam PL, Kurhekar P, Vadodaria K, Kulkarni A, Doshi H, Pandya P. Comparison of the efficacy of butorphanol and tramadol in preventing post-shivering during spinal anaesthesia. J Anaesthesiol Clin Pharmacol. 2011;27(1):67-71.
14. Horn EP, Bein B, Bohm R, Steinfath M, Sahili N, Hocker J. The effect of short time periods of pre-operative warming in the prevention of peri-operative hypothermia. Anaesthesia. 2012;67(6):612-7. doi: 10.1111/j.1365-2044.2012.07073.x, PMID 22376088.
15. Karalapillai D, Story DA, Calzavacca P, Licari E, Liu YL, Hart GK. Inadvertent hypothermia and mortality in postoperative intensive care patients: retrospective audit of 5050 patients. Anaesthesia. 2009;64(9):968-72. doi: 10.1111/j.1365-2044.2009.05989.x, PMID 19686481.