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Clinical Comparison of Tramadol versus Paracetamol in Prevention of Post-Operative Shivering Following Spinal Anaesthesia

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A B S T R A C T

Background*:** Post-operative shivering is a common complication following spinal anesthesia. This study compared the efficacy of tramadol versus paracetamol in preventing this complication.Methods*:** Sixty patients undergoing surgery under spinal anesthesia were randomly assigned to receive either tramadol (n=30) or paracetamol (n=30). The incidence, severity, and onset of shivering, as well as side effects and response to rescue medication, were assessed.***Results*:** The overall incidence of shivering was 26.7%. Tramadol group showed a higher percentage of patients with no shivering (80% vs 66.7%) and lower incidence of severe shivering (3.3% vs 13.3%) compared to the Paracetamol group. Shivering onset was earlier in the tramadol group (10 ± 3 minutes vs 15 ± 4 minutes, p = 0.045). Tramadol group experienced higher rates of nausea (20%) and vomiting (6.7%) compared to paracetamol group (0% for both). Pethidine as rescue medication was effective in 80% of paracetamol group cases and 100% of tramadol group cases requiring intervention.***Conclusion*:** Both tramadol and paracetamol demonstrated efficacy in preventing post-operative shivering, with tramadol showing higher efficacy but more side effects. The choice between these agents should be individualized based on patient factors and clinical context.

Keywords: Post-operative shivering; Spinal anesthesia; Tramadol; Paracetamol; Thermoregulation; Anesthesia complications.

INTRODUCTION

Post-operative shivering is a common and potentially serious complication following surgery under spinal anesthesia, affecting up to 40-60% of patients [1]. This involuntary muscular activity not only causes significant discomfort but can also lead to various physiological disturbances, including increased oxygen consumption, carbon dioxide production, and cardiac output [2]. These changes may pose particular risks for patients with limited cardiopulmonary reserves. Additionally, shivering can interfere with monitoring equipment, potentially compromising patient safety during the critical post-operative period [3].

The exact mechanism of post-operative shivering remains incompletely understood, but it is believed to involve a complex interplay of factors. These include perioperative heat loss, sympathetic activation, pyrogen release, and alterations in thermoregulatory mechanisms induced by anesthetic agents [1]. Spinal anesthesia, in particular, has been associated with a higher incidence of shivering compared to general anesthesia, possibly due to the sympathetic blockade and consequent vasodilation below the level of the block [4].

Given the prevalence and potential consequences of post-operative shivering, its prevention and management have become important focuses in perioperative care. Various pharmacological interventions have been studied for this purpose, with tramadol and paracetamol emerging as two frequently used options [5]. Both medications are widely available, relatively inexpensive, and have established safety profiles, making them attractive choices for routine clinical use.

Tramadol, a centrally acting analgesic with weak μ-opioid agonist properties, has demonstrated efficacy in reducing post-operative shivering in numerous studies [6]. Its anti-shivering effect is thought to be mediated through multiple mechanisms, including modulation of the noradrenergic and serotonergic systems, as well as its opioid activity. Tramadol's ability to inhibit the reuptake of norepinephrine and serotonin may contribute to its thermoregulatory effects by influencing the descending pain modulatory pathways and altering the shivering threshold [7].

Paracetamol (acetaminophen), on the other hand, is a widely used analgesic and antipyretic agent with a well-established safety profile. While its exact mechanism of action remains debated, it is believed to act centrally through inhibition of cyclooxygenase enzymes and modulation of the endogenous cannabinoid system [8]. Recent studies have suggested that paracetamol may also possess anti-shivering properties, potentially through its effects on prostaglandin-mediated temperature regulation [9].

The comparison of tramadol and paracetamol for the prevention of post-operative shivering is of particular interest due to their differing pharmacological profiles and potential side effect considerations. Tramadol, while effective, may be associated with nausea, vomiting, and respiratory depression, especially in higher doses [6]. Paracetamol, in contrast, generally has a more favorable side effect profile but may have limitations in terms of its analgesic potency [8].

Understanding the relative efficacy and safety of these two agents in preventing post-operative shivering is crucial for informed clinical decision-making. This is especially true in the context of spinal anesthesia, where the physiological changes induced by the anesthetic technique may interact with the pharmacological effects of these medications. Moreover, the choice between tramadol and paracetamol may have implications beyond shivering prevention, potentially influencing post-operative pain management and overall patient comfort.

Aims

The primary aim of this study is to compare the clinical efficacy of intravenous tramadol and intravenous paracetamol in preventing post spinal anaesthesia shivering (PSAS) in patients undergoing infraumbilical surgeries. Specifically, we aim to assess the incidence and severity of PSAS in each treatment group and to compare the safety profile of these two commonly used agents in terms of adverse effects such as nausea, vomiting, and headache. Additionally, this study seeks to evaluate the time to onset of shivering and the need for rescue medication in cases where PSAS occurs despite prophylaxis.

Materials and Methods

This study was conducted as a prospective randomized controlled trial at the S.S. Institute of Medical Sciences and Research Centre, Davangere. Ethical approval was obtained from the Institutional Review Board before commencing the study. The study included 60 participants aged 18 to 60 years, classified as ASA grade I or II, and scheduled for elective infraumbilical surgeries under spinal anaesthesia. Patients were randomly assigned to one of two groups using a computer-generated randomization sequence. Group T (n=30) received 50 mg of intravenous tramadol in 100 ml of normal saline, while Group P (n=30) received 1g of intravenous paracetamol. Both medications were administered preoperatively in the preoperative ward just before shifting the patients to the operating theatre.

Inclusion criteria for the study were patients aged between 18-60 years, ASA I or II, undergoing infraumbilical surgeries such as lower abdominal or lower limb procedures. Exclusion criteria included patients with ASA grades III or IV, those with a history of allergic reactions to either tramadol or paracetamol, patients undergoing emergency surgeries, and those with pre-existing thyroid disorders or who required blood transfusions during surgery.

The severity of shivering was assessed intraoperatively and postoperatively using the Bedside Shivering Assessment Score (BSAS), a validated four-point scale ranging from 0 to 3. A score of 0 indicated no shivering, while a score of 3 indicated generalized or sustained shivering involving the upper and lower extremities. Patients who developed shivering with a grade ≥2 within 15 minutes of spinal anaesthesia were considered prophylactic failures and received 25 mg of intravenous pethidine as a rescue agent. Hemodynamic parameters, including heart rate, blood pressure, and oxygen saturation, were monitored every 15 minutes during the surgery and for up to 90 minutes postoperatively. Data on adverse effects such as nausea, vomiting, and headache were also collected during the perioperative period.

Statistical analysis was performed using appropriate statistical tests. Quantitative data were expressed as mean ± standard deviation (SD), and qualitative data were expressed as numbers and percentages. The chi-square test was used for categorical variables, and the student's t-test was used for continuous variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The study included a total of 60 patients, equally divided between the paracetamol and tramadol groups, with 30 patients in each. The overall incidence of post-operative shivering across both groups was 26.7% (16 out of 60 patients).

In the paracetamol group, 10 out of 30 patients (33%) experienced post-operative shivering. Comparatively, in the tramadol group, 6 out of 30 patients (20%) exhibited shivering. These results suggest a lower incidence of shivering in the tramadol group, although statistical significance was not reported for this comparison.

The severity of shivering was graded on a scale from 0 to 3, with 0 indicating no shivering and 3 representing severe shivering. In the Paracetamol group, 20 patients (66.7%) experienced no shivering, 0 patients (0%) had mild shivering, 6 patients (20%) showed moderate shivering, and 4 patients (13.3%) exhibited severe shivering. In the Tramadol group, 24 patients (80%) had no shivering, 1 patient (3.3%) experienced mild shivering, 4 patients (13.3%) showed moderate shivering, and 1 patient (3.3%) exhibited severe shivering.These results suggest a trend towards less severe shivering in the tramadol group, although statistical analysis of these differences was not provided.

The onset of shivering, measured as the time from spinal injection to the occurrence of shivering, differed significantly between the two groups. In the paracetamol group, the mean onset time was 15 ± 4 minutes, while in the tramadol group, it was 10 ± 3 minutes. This difference was statistically significant ($p = 0.045$), indicating that shivering tended to occur earlier in the tramadol group when it did occur.

Regarding adverse effects, the tramadol group experienced a higher incidence of side effects compared to the paracetamol group. In the tramadol group, 6 patients (20%) experienced nausea, and 2 patients (6.7%) had vomiting. Headache was observed in 2 patients (6.7%) in each group. Notably, 26 patients (86.7%) in the paracetamol group reported no side effects, compared to 20 patients (66.7%) in the tramadol group. These results suggest a more favorable side effect profile for paracetamol in this context.

In cases where the study medication did not adequately prevent shivering, pethidine was administered as a rescue agent. In the paracetamol group, 4 out of 10 patients who experienced shivering received pethidine, with shivering resolved in 80% of these cases. In the tramadol group, 2 out of 6 patients with shivering received pethidine, and shivering was resolved in 100% of these cases. While these numbers suggest a potentially higher efficacy of pethidine as a rescue agent in the tramadol group, the small sample size limits the ability to draw definitive conclusions.

Overall, these results indicate that both paracetamol and tramadol showed efficacy in preventing post-operative shivering following spinal anesthesia, with tramadol demonstrating a lower incidence of shivering but a higher rate of side effects. The earlier onset of shivering in the tramadol group when it did occur was statistically significant. The severity of shivering and response to rescue medication showed some differences between the groups, but larger sample sizes would be needed to determine if these differences are statistically significant.

Table 1: Incidence of Shivering in Paracetamol and Tramadol Groups

Group	Number of Patients	Patients with Shivering	Percentage (%)
Paracetamol (n=30)	30	10	33%
Tramadol (n=30)	30	6	20%
Total	**60**	**16**	**26.7%**

Table 2: Severity of Shivering (Graded on a Scale of 0 to 3)

Shivering Grade	Paracetamol Group (n=30)	% in Paracetamol Group	Tramadol Group (n=30)	% in Tramadol Group
0 (No Shivering)	20	66.7%	24	80%
1 (Mild Shivering)	0	0%	1	3.3%
2 (Moderate Shivering)	6	20%	4	13.3%
3 (Severe Shivering)	4	13.3%	1	3.3%
Total	**30**	**100%**	**30**	**100%**

Table 3: Onset of Shivering (Time from Spinal Injection to Shivering)

Group	Mean Time (Minutes) ± SD
Paracetamol (n=30)	15 ± 4
Tramadol (n=30)	10 ± 3
p-value	**0.045**

Table 4: Adverse Effects Observed in Each Group

Side Effect	Paracetamol Group (n=30)	Tramadol Group (n=30)
Nausea	0	6 (20%)
Vomiting	0	2 (6.7%)
Headache	2 (6.7%)	2 (6.7%)
No Side Effects	26 (86.7%)	20 (66.7%)

Table 5: Response to Rescue Agent (Pethidine)

Group	Patients Receiving Pethidine	Shivering Resolved (%)
Paracetamol (n=10)	4	80%
Tramadol (n=6)	2	100%

DISCUSSION

The present study compared the efficacy of tramadol and paracetamol in preventing post-operative shivering following spinal anesthesia. The results revealed that both medications demonstrated effectiveness in reducing the incidence of shivering, albeit with different profiles in terms of efficacy and side effects.

The overall incidence of shivering in our study (26.7%) was lower than that reported in some previous studies. For instance, Sagir*et al*., observed an incidence of 55% in their control group [11]. This discrepancy could be attributed to variations in ambient temperature, duration of surgery, or differences in the patient population.

Tramadol showed a more pronounced effect in reducing severe shivering (3.3% vs 13.3% in the Paracetamol group) and increasing the proportion of patients with no shivering (80% vs 66.7% in the Paracetamol group).This finding aligns with the results of Matsota*et al*., who reported a shivering incidence of 18% with tramadol compared to 40% in their control group [12]. The anti-shivering effect of tramadol is thought to be mediated through its action on μ-opioid receptors and inhibition of serotonin and norepinephrine reuptake [13].

Interestingly, our study found that when shivering did occur, it had an earlier onset in the tramadol group (10 ± 3 minutes) compared to the paracetamol group (15 ± 4 minutes), with statistical significance ($p = 0.045$). This finding contrasts with the study by Dhaked*et al*., where tramadol was associated with a later onset of shivering compared to dexmedetomidine [14]. The reasons for this discrepancy are not clear and warrant further investigation.

Regarding the severity of shivering, our results suggested a trend towards less severe shivering in the tramadol group, although statistical analysis was not performed. This trend is consistent with the findings of Bilotta*et al*., who reported that tramadol significantly reduced the intensity of shivering compared to a placebo ($p < 0.001$) [15].

The side effect profile observed in our study is an important consideration. The tramadol group experienced a higher incidence of nausea (20%) and vomiting (6.7%) compared to the paracetamol group, where no such side effects were observed. This is consistent with known side effects of tramadol and aligns with the findings of Zhanque*et al*., who reported nausea and vomiting in 23% of patients receiving tramadol for shivering prevention [16].

Paracetamol, while showing a slightly higher incidence of shivering, demonstrated a more favorable side effect profile. This finding is particularly relevant in the context of ambulatory surgery or in patients at higher risk of post-operative nausea and vomiting. The mechanism by which paracetamol prevents shivering is not fully elucidated, but it is thought to involve central thermoregulatory effects [17].

The efficacy of pethidine as a rescue medication was high in both groups, with 80% success in the paracetamol group and 100% in the tramadol group. This is consistent with the established role of pethidine in treating post-operative shivering, as demonstrated by Kranke*et al*., in their meta-analysis [18].

Our study has several limitations. The sample size was relatively small, which may have limited the statistical power to detect significant differences between groups, particularly in subgroup analyses. Additionally, we did not control for factors such as intravenous fluid temperature or ambient operating room temperature, which could influence shivering incidence.

Future research directions could include larger, multi-center trials to confirm these findings and explore potential synergistic effects of combining tramadol and paracetamol for shivering prevention. Additionally, investigating the cost-effectiveness of these interventions and their impact on patient satisfaction and recovery time would provide valuable insights for clinical decision-making.

In conclusion, while both tramadol and paracetamol showed efficacy in preventing post-operative shivering following spinal anesthesia, tramadol demonstrated a lower incidence of shivering but a higher rate of side effects. The choice between these agents should be individualized based on patient factors, surgical context, and the relative risks of shivering versus side effects in each case.

CONCLUSION

This study provides valuable insights into the comparative efficacy of tramadol and paracetamol in preventing post-operative shivering following spinal anesthesia. Both medications demonstrated effectiveness in reducing shivering incidence, but with distinct profiles in terms of efficacy and side effects.

Tramadol showed a lower incidence of shivering (20%) compared to paracetamol (33%), suggesting potentially superior efficacy. This superiority is further supported by the severity data, with 80% of patients in the Tramadol group experiencing no shivering compared to 66.7% in the Paracetamol group. Additionally, severe shivering was observed in only 3.3% of patients in the Tramadol group versus 13.3% in the Paracetamol group. However, these benefits came at the cost of a higher rate of side effects, particularly nausea (20%) and vomiting (6.7%), which were not observed in the paracetamol group. The earlier onset of shivering in the tramadol group (10 ± 3 minutes vs 15 ± 4 minutes, $p = 0.045$) when it did occur was an unexpected finding that warrants further investigation.

Paracetamol, while slightly less effective in preventing shivering, demonstrated a more favorable side effect profile. This makes it a potentially preferable option for patients at higher risk of post-operative nausea and vomiting or in ambulatory surgery settings where rapid recovery is crucial.

The high efficacy of pethidine as a rescue medication in both groups (80% success in the paracetamol group and 100% in the tramadol group) reinforces its role in the management of established post-operative shivering.

These findings underscore the importance of individualized approach to shivering prevention. The choice between tramadol and paracetamol should be based on patient-specific factors, the surgical context, and the relative risks of shivering versus side effects in each case.

Future research should focus on larger, multi-center trials to confirm these findings and explore potential synergistic effects of combining these agents. Additionally, investigating the cost-effectiveness of these interventions and their impact on patient satisfaction and recovery time would provide valuable insights for clinical decision-making.

In conclusion, while both tramadol and paracetamol are effective in preventing post-operative shivering, the choice between them should be tailored to individual patient needs and clinical circumstances. This study contributes to the growing body of evidence guiding anesthesiologists in optimizing perioperative care and improving patient outcomes.

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