E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.48047/ijprt/16.02.229

Research Article

Oral Tramadol versus Oral Paracetamol for Prevention of Peri Anaesthetic Shivering During Transurethral Resection of the Prostate Under Spinal Anaesthesia: A randomised prospective interventional observer blinded study

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ABSTRACT

Background: Peri anaesthetic shivering is common during transurethral resection of the prostate (TURP) performed under spinal anaesthesia, particularly in elderly patients. Evidence comparing oral tramadol with oral paracetamol for prophylaxis is limited.

Methods: In this prospective, randomized, interventional, observer blinded study conducted at tertiary care hospitals, 68 patients aged 45–75 years undergoing TURP under subarachnoid blockade were randomized to receive oral tramadol 50 mg (n=34) or oral paracetamol 500 mg (n=34) 2 h before surgery. The primary outcome was the incidence of intraoperative shivering (Wrench grading scale). Secondary outcomes included shivering duration and haemodynamic variables.

Results: Baseline characteristics were comparable between groups (mean age 70.7±3.0 vs 69.2±4.1 years; mean weight 65.1±7.4 vs 64.9±8.8 kg). Intraoperative shivering occurred in 5/34 patients (14.7%) in the tramadol group and 15/34 patients (44.1%) in the paracetamol group (χ^2=7.08, p=0.008). The absolute risk reduction was 29.4% (95% CI 8.2–50.6), corresponding to a relative risk of 0.33 and a number needed to treat of 4. Shivering lasting ≥45 min occurred only in the paracetamol group. Haemodynamic parameters remained clinically comparable between groups.

Conclusions: Oral tramadol 50 mg administered 2 h before TURP under spinal anaesthesia significantly reduced the incidence and duration of peri anaesthetic shivering compared with oral paracetamol 500 mg, without clinically important haemodynamic instability.

Keywords: Perioperative Shivering; Spinal Anaesthesia; Tramadol; Paracetamol; Transurethral Resection of the Prostate; TURP.

INTRODUCTION

Shivering is a common experience among many patients, occurring either during or immediately following surgery. (1) It is characterized as an involuntary, repetitive activity of the skeletal muscles, with readily observable tremor or fasciculation of the face, neck, jaw, head, trunk, or extremities, lasting longer than 15 seconds.

This phenomenon is highly uncomfortable and distressing for the patient, anaesthesiologist, and surgeon, particularly when the patient is under regional anaesthesia. The incidence of shivering varies but is quite high, approximately 40-50%. (2) Shivering is usually triggered by hypothermia. Under neuraxial blockade, such as spinal or epidural anaesthesia, patients may not perceive hypothermia as they typically feel less cold sensation. This is because the spinal cord, hypothalamus, and other parts of the brain, as well as the thoracic and deep abdominal tissues, and the skin surface, each contribute approximately 20% of the total thermal input to the central thermoregulatory system.(3) The disruption of these temperature-sensing pathways due to the neuraxial blockade results in an impaired ability to detect and respond to the drop in core body temperature, leading to the development of shivering as a compensatory mechanism. (4) The disruption of temperature sensing pathways due to the neuraxial blockade further exacerbates this issue, putting these patients at an even greater risk of developing the distressing phenomenon of shivering during the procedure. (5)

Aims and objective: AIMTo study the comparison between the effects of oral tramadol and oral paracetamol to prevent peri anaesthetic shivering in patients undergoing transurethral resection of prostate under subarachnoid blockade.

OBJECTIVES

Primary Objective

To study the comparison of oral tramadol versus oral paracetamol in preventing shivering in intraoperative patients.

Secondary Objective

- To study intraoperative hemodynamic changes.
- To study postoperative shivering for the next two hours.

Methods

The study was a prospective, comparative, randomized, interventional, observer blinded trial conducted over 18 months in tertiary care hospitals. Eligible patients were ASA I–II, aged 45–75 years and scheduled for TURP under spinal anaesthesia. Exclusion criteria included drug hypersensitivity, abnormal core temperature, coagulation disorders, infection at the puncture site, psychiatric illness, and severe valvular disease.

Sample size calculation yielded 34 patients per group (total n=68). Patients received oral tramadol 50 mg or oral paracetamol 500 mg 2 h before surgery; shivering was graded using the Wrench scale (0–4).

Study group- GROUP A: Patients who are receiving oral tramadol 50 mg preoperatively before undergoing transurethral resection of the prostate under subarachnoidal blockade.

GROUP B: Patients who are receiving oral paracetamol 500 mg preoperatively before undergoing transurethral resection of prostate under subarachnoidal blockade.

This is a prospective, comparative, interventional, randomised, observer-blinded, comparative study and was conducted in a tertiary care hospital. A total of 68 eligible cases were enrolled as participants only after obtaining written informed consent and approval from the Ethical Committee. These 68 participants were divided into 2 groups of 34 participants each were given as Group A (n=34): patients. receiving tramadol and Group B (n=34): patients receiving paracetamol. The division of the participants into 2 groups was done by a computer-generated random number table. The same second-year anaesthesiologist gave study drugs to the patient. This is how double blindness

was achieved. Patients involved in this study were from geriatric age group as these patients were more prone to benign prostate hypertrophy which mostly belongs to the age group 45 to 75 years.

Baseline characteristics

Table 1. Baseline characteristics

Characteristic	Tramadol (n=34)	Paracetamol (n=34)
Age, years (mean ± SD)	70.7 ± 3.0	69.2 ± 4.1
Weight, kg (mean ± SD)	65.1 ± 7.4	64.9 ± 8.8
ASA II, n (%)	34 (100)	34 (100)
TURP performed, n (%)	34 (100)	34 (100)
Duration of surgery, min (mean ± SD)	97.9 ± 16.6	97.1 ± 17.0

Incidence of intraoperative shivering was significantly lower in the oral tramadol group than in the oral paracetamol group (14.7% vs 44.1%; χ^2=7.08, p=0.008).

Primary outcome table

Table 2. Intraoperative shivering outcomes

Outcome	Tramadol (n=34)	Paracetamol (n=34)
Shivering present, n (%)	5 (14.7)	15 (44.1)
Shivering absent, n (%)	29 (85.3)	19 (55.9)
Absolute risk reduction	29.4% (95% CI 8.2–50.6)	
Relative risk	0.33 (95% CI 0.14–0.81)	
Number needed to treat	4	
χ^2 (df=1)	7.08	
p value	0.008	

A total of 68 patients were randomized equally between the tramadol and paracetamol groups. Baseline demographic and operative variables were comparable between groups (Table 1). The incidence of intraoperative shivering was significantly lower with oral tramadol than with oral paracetamol (14.7% vs 44.1%; χ^2=7.08, p=0.008; Table 2). The absolute risk reduction was 29.4%, yielding a number needed to treat of 4. Shivering lasting ≥45 min occurred only in the paracetamol group. Haemodynamic variables (pulse rate, systolic blood pressure, diastolic blood pressure, and SpO_2) remained clinically comparable throughout the perioperative period. The significant reduction in shivering incidence was observed despite similar operative duration and baseline characteristics.

The study found that the 68 participants were equally divided between the Tramadol and Paracetamol groups, with 34 individuals in each. The age and weight distributions were similar between the two groups, with both groups having

approximately normal distributions. All participants were classified as ASA grade II, and they all underwent the same surgical procedure, Transurethral Resection of the Prostate, with an equal distribution across the Tramadol and Paracetamol groups. The physiological measures, including pulse rate, SpO2, systolic blood pressure, and diastolic blood pressure, showed some differences between the groups, but were largely similar overall. The study found a lower incidence of shivering in the Tramadol group compared to the Paracetamol group, with a statistically significant difference. The use of rescue medicine was also significantly lower in the Tramadol group. The analysis of temperature changes revealed significant differences between the groups at certain time points, particularly at 15 and 60 minutes, but not at other intervals. The study found that there is nearly equal duration of surgery in the two groups. The incidence of shivering was lower in the Tramadol group compared to the Paracetamol group. More participants in the Tramadol group experienced no shivering, and the overall presence of shivering was less common in the Tramadol group. The data also showed a higher proportion of shorter-duration shivering in the Paracetamol group as compared to the Tramadol group. The chi- square test results indicated a statistically significant difference in the incidence of shivering between the two groups. The analysis of physiological measures revealed varied patterns, with some time points showing no significant differences between the groups and others exhibiting significant differences. Pulse rates, systolic blood pressure, and diastolic blood pressure demonstrated significant differences at specific intervals. The study found significant differences in temperature changes at 15 and 60 minutes, but not at other intervals. The use of rescue medicine was significantly lower in the Tramadol group compared to the Paracetamol group.

Discussion:

The present randomized observer blinded trial demonstrates that oral tramadol 50 mg administered 2 h before TURP under spinal anaesthesia reduced the incidence of peri anaesthetic shivering by approximately two thirds compared with oral paracetamol 500 mg. The relative risk of shivering was 0.33, and only four patients would need to receive tramadol instead of paracetamol to prevent one episode of shivering.

These findings are consistent with earlier studies showing the anti shivering efficacy of tramadol in patients undergoing spinal anaesthesia. Tewari et al. reported that oral tramadol significantly reduced the incidence, intensity, and duration of shivering in elderly patients undergoing TURP under spinal anaesthesia. Singh et al. found tramadol to be as effective as dexmedetomidine for shivering prophylaxis, although tramadol was associated with more nausea and vomiting. The current study extends this evidence by directly comparing oral tramadol with oral paracetamol, a comparison that was identified as lacking in the thesis literature review.

Paracetamol has documented anti shivering properties, particularly when administered intravenously. Meta analytic evidence suggests that prophylactic acetaminophen reduces postoperative shivering compared with placebo. However, the lower oral dose used in the present study (500 mg) may have provided insufficient thermoregulatory modulation in the setting of TURP, where large volumes of room temperature irrigation fluid and spinal anaesthesia induced vasodilation increase the risk of hypothermia.

Importantly, the reduction in shivering was not accompanied by clinically meaningful

haemodynamic instability. Baseline and intraoperative blood pressure, pulse rate, and oxygen saturation remained comparable between groups, supporting the haemodynamic safety of oral tramadol in this elderly TURP population.

The study has several strengths, including randomized allocation, observer blinding, standardized spinal anaesthesia, and complete follow up of all randomized patients. Limitations include the single center design, modest sample size, use of axillary rather than core temperature monitoring, and the absence of systematic recording of nausea, vomiting, or sedation scores. Future multicenter trials with larger samples and comprehensive adverse event assessment are warranted.

Conclusion

Oral tramadol 50 mg given 2 h before transurethral resection of the prostate under spinal anaesthesia significantly reduced the incidence and duration of peri anaesthetic shivering compared with oral paracetamol 500 mg, without clinically significant haemodynamic instability. Oral tramadol appears to be a simple, inexpensive, and effective prophylactic strategy for elderly patients undergoing TURP under subarachnoid blockade.

Declarations

- Ethics approval: Approved by the Institutional Ethics Committee; written informed consent was obtained from all participants.
- Funding: No external funding.
- Conflict of interest: None declared.
- Author contributions: Conceptualization, data collection, analysis, manuscript drafting, and critical revision should be assigned according to the actual contributors.

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