



RESEARCH ARTICLE

EFFICACY AND SAFETY OF PARACETAMOL IN PREVENTING POSTOPERATIVE SHIVERING IN PATIENTS UNDERGOING ABDOMINAL SURGERIES UNDER GENERAL ANESTHESIA

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ABSTRACT

Background: Postoperative shivering is a common and distressing complication. Although it's a protective reflex mechanism to hypothermia, it's also seen in normothermic patients. It is important to prevent and treat postoperative shivering as it is associated with many adverse effects. **Aims:** The aim of our study was to evaluate the effect of prophylactic dose of 1 g paracetamol IV to prevent shivering in patients undergoing abdominal surgeries under general anaesthesia. **Methodology:** In this prospective randomized double-blind study 130 patients of either sex and ASA class I & II were randomized into group P (Paracetamol) and group NS (Normal saline). Group NS received 100 ml of NS (n=65) and Group P received 1gm paracetamol in 100ml NS (n=65) IV over a period of 15 minutes after induction of anesthesia. Core body temperature was recorded in all patients using tympanic thermometer before induction of anaesthesia, after induction of anaesthesia, at the end of surgery and in recovery room every 15min for 1hr. Adverse events if any, were also noted in recovery room. **Results:** Incidence of postoperative shivering was 9/65(13.84%) in group P and 33(50.76%) in group NS. Core body temperature dropped in both groups after induction of anaesthesia which was statistically similar (p>0.05). **Conclusion:** The prophylactic use of paracetamol is effective in preventing postoperative shivering without significant side effects.

INTRODUCTION

Postoperative shivering is one of the frequent causes of discomfort in patients recovering from anaesthesia. Incidence varies from 20 to 70% in general anaesthesia.^[1,2] Shivering is usually triggered by hypothermia. However, it can occur in normothermic patients. In hypothermic patients shivering occurs in an attempt to increase body temperature, next step after peripheral vasoconstriction.^[3] In normothermic patients it may be associated with pain modulation, surgical stress and emergence from inhalational anaesthetics. Postoperative shivering is defined as detectable tremor or fasciculation involving the head, neck, trunk, shoulders and extremities, or generalised and visible shaking resembling normal thermogenic shivering.^[4,5] It's reported as remarkably uncomfortable experience by patients. Shivering may intensify pain by stretching wounds. It is believed to increase oxygen consumption and increase the risk of hypoxemia.^[6] It may induce acidosis, carbon dioxide production and increased catecholamines release leading to systemic complications such as increasing cardiac output, peripheral resistance, intraocular and intracranial pressure.^[7-9] Various non pharmacological methods such as increasing operating room temperature, active body surface warming and fluid warming are not sufficient to prevent postoperative shivering alone.^[10,11] Various studies have shown the effectiveness of different drugs such as alpha-2 agonists, opiates, tramadol, ketanserin, magnesium sulphate, corticosteroids, physostigmine, doxapram, methylphenidate, nefopam and serotonin 5-HT₃ antagonists in preventing postoperative shivering.^[10,12] But they are associated with number of side effects. Paracetamol is an effective, safe synthetic non-opioid analgesic and antipyretic.^[13,14]

Acetaminophen acts by inhibiting cyclooxygenase-mediated prostaglandin synthesis to decrease the hypothalamic temperature set point.^[14,15] The aim of our study was to evaluate the effect of a prophylactic dose of 1 g paracetamol IV to prevent shivering in patients undergoing gynaecological laparotomy under general anaesthesia.

MATERIAL AND METHODS

This prospective randomized double-blind study was conducted in Government Medical college Jammu. Institutional ethical clearance was obtained before commencing study. Study included 130 patients of either sex, 18-60 years of age, ASA class I & II undergoing elective abdominal surgeries under general anaesthesia. Exclusion criteria included history of allergic reaction to paracetamol, history of alcohol abuse, liver disease, renal disease (creatinine >1.5mg/dL), cardiopulmonary disease, diabetes temp >38 or <36°Celsius. Patients receiving blood transfusion and non-crystalloids were also excluded from study. Preanesthetic checkup was done day before surgery and informed written consent was obtained from all the participants. All patients were kept NPO 8hrs before surgery. Patients were randomly allocated into group P (Paracetamol) and group NS (Normal saline). Randomization was achieved using computer generated tables. Group NS received 100 ml of NS (n=65) and Group P received 1gm paracetamol in 100ml NS (n=65) IV over a period of 15 minutes after induction of anaesthesia. Anaesthesia technique was similar in both the groups. The routine monitoring was applied and baseline parameters were noted before induction of Anaesthesia. Standard monitoring was implemented throughout the procedure and included non-invasive arterial blood pressure measurement, heart rate measurement, heart rhythm assessment using 3-lead electrocardiography (lead II), and fingertip oxyhemoglobin saturation (SpO₂) measurement, EtCO₂ (End

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tidal carbon dioxide) monitoring. Core body temperature was recorded in all patients using tympanic thermometer before induction of anaesthesia(baseline), after induction of anaesthesia, at the end of surgery and in recovery room every 15min for 1hr. Intraoperative hypothermia was minimised using several techniques such as use of HME filter, using warm intravenous fluids and maintaining OT between 22-24 °c. Induction was done with propofol (2 mg/kg), fentanyl (1.5–2.0 µg/kg), and atracurium (0.5mg/kg). It was maintained with O2 + N2O+ Isoflurane+ Atracurium (0.1mg/kg). Neuromuscular blockade was reversed with neostigmine (0.05mg/kg)and glycopyrrolate(0.01mg/kg).The patients were extubated when they had a good respiratory pattern and were awake enough to maintain their airway. Duration of the surgery was recorded for each patient. The patients were covered by a layer of a cotton blanket and transferred to the recovery room and monitored for 30 minutes. The temperature of the recovery room was the same for all patients and no heating device was separately used. In PACU patients were observed for nausea and vomiting, vitals and shivering grade. Shivering grades was measured by

Crosslyand Mahajan: 0 :No shivering, 1: piloerection or peripheral vasoconstriction but no visible shivering, 2: muscular activity in only one muscle group, 3: muscular activity in more than one muscle group, but not generalized shivering, 4: shivering involving the whole body. Shivering grade 3 or more was considered as shivering in this study and treated with Tramadol as the treatment agent. Patients with nausea and vomiting were treated with Ondansetron. Pain was measured with visual Analog Scale and if patient had score 3 and higher was treated by 75 mg of intravenous Diclofenac. Side-effects like hypotension (MAP <20% from baseline), bradycardia (HR <50 beats/min), respiratory depression (respiratory rate ≤8/min or SPO₂ ≤92%), nausea, vomiting and headache were recorded and managed accordingly.

STATISTICAL ANALYSIS

In our study, we planned to recruit 130 patients with 65 patients in each group. As per sample size analysis, 62 patients were required in each group to achieve a power of 90% with an alpha error of 5%. Accounting for dropouts, we planned to recruit 130 patients with 65 patients in each group. Statistical Package for the Social Sciences (SPSS) software version 25.0 (SPSS Inc., Chicago, IL, USA) was used to analyze data. Data was presented as mean and standard deviation (± SD) for quantitative parametric data and median and interquartile range for quantitative nonparametric data. Frequency and percentage was used for presenting qualitative data. Suitable analysis was done according to the type of data obtained. Student’s t test was used to analyze quantitative data while Chi square test and Fisher exact test was used to analyze qualitative data. P value < 0.05 was considered statistically insignificant.

RESULTS

130 patients who fulfilled all the inclusion criteria were randomized into two equal groups, each consists of 65 patients namely group P (Paracetamol group) and group NS (Normal saline group). Demographic data and baseline parameters were recorded for each patient at the beginning of the study and were compared statistically as shown in Table 1.

Table 1. Comparison of demographic and baseline characteristics

Parameters	Group P (n=65)	Group NS (n=65)	P value
Age (years)	45 ± 12.35	44.53 ± 14.22	0.869
Gender			0.898
Male	39 (60%)	38 (58.46%)	
Female	26 (40%)	27 (41.53%)	
Weight (kg)	59.11 ± 10.21	62.32 ± 10.76	0.153
Height (cm)	159.91 ± 8.74	159.91 ± 7.97	0.999
ASA			0.957
I	50 (76.92%)	51 (78.46%)	
II	15 (23.07%)	14 (21.53%)	

Data are presented as mean ± SD, ratio of patients p value > 0.05 is considered statistically non-significant. There was no statistical difference between both groups as regards demographic data. There was a fall in core temperature in both the groups after induction of anaesthesia, which was statistically similar (P > 0.05) as shown in (Table 2).

Table 2. Core temperature and its variation in two groups (Mean ± SD)

	Group NS	Group P	P value
Pre-anaesthesia temperature(°C)	36.88±0.07	36.87±0.08	0.911 [#]
After induction of anaesthesia(°C)	35.78±0.11	35.73±0.16	0.093 [#]
Temperature at the end of surgery	35.76±0.11	35.72±0.16	0.092 [#]
PACU 0 min	35.79±0.11	35.76±0.18	0.25 [#]
PACU 15 min	35.84±0.14	35.83±0.12	0.576 [#]
PACU 30 min	35.87±0.13	35.86±0.12	0.677 [#]
PACU 45 min	35.90±0.15	35.89±0.12	0.593 [#]
PACU 60 min	35.99±0.19	35.98±0.15	0.750 [#]

[#] ANOVA: The number of patients with postoperative shivering in the recovery room till 60 minutes after surgery were significantly less in group P (paracetamol) compared to group NS (saline), as shown in (Table 3).

Table 3. Incidence of postoperative shivering and shivering score

	Group P	Group NS	P Value
Incidence of shivering	9(13.84%)	33(50.76%)	<0.05
Shivering score			
0	26 (40%)	18 (27.6%)	
1	18 (27.6%)	5 (0.07%)	
2	12 (18.4%)	9 (0.13%)	
3	8 (12.3%)	28 (43.07%)	< 0.05
4	1 (0.015%)	5 (0.07%)	

Thirty three patients (50.76%) shivered at grade 3 or 4 in group NS, and only 9 patients (13.84%) reached grade 3 or 4 shivering in group P [Table 3]. There were no significant differences in postoperative nausea and vomiting or hypotension between the two groups (P >0.05)(Table 4)

Table 4. Comparison of adverse effects

	Group NS	Group P	P value
Hypotension	2	3	0.208*
Nausea	6	5	0.099*
Vomiting	1	3	0.309*

*chi square test

DISCUSSION

Postoperative shivering is a common (20-70%) and unpleasant experience for patients. This can be either thermogenic (associated with hypothermia) or non-thermogenic (associated with pain modulation, surgery and emergence from inhalational anaesthetics). During postanaesthetic period, shivering is an important, harmful, and widespread side effect caused by general anaesthesia.^[1] It can cause hypoxia, pain, and lactic acidosis. It may lead to incidental trauma, disruption of medical devices and interference with ECG and saturation monitoring. It is detrimental for patients with cardiac and neurological disorder as it leads to increased oxygen consumption, increased CO₂ production, increased catecholamine secretion, increased ICP increased in IOP etc. Thus, prevention of shivering is important especially in patients with cardiopulmonary disease or elderly patients.^[16,17] Various drugs have been used to prevent postoperative shivering but they are associated with number of side effects such as sedation, respiratory depression, nausea & vomiting, psycho mimetic reactions. Paracetamol is widely used as an analgesic in perioperative period. It acts as an antipyretic by inhibiting prostaglandin synthesis to decrease the hypothalamic temperature set point. It has predictable onset and duration.

In our study we compare the effect of intravenous paracetamol with placebo on prevention of postoperative shivering. We found that patients who received paracetamol had significantly ($p < 0.05$) lower incidence of postoperative shivering as compared to placebo group (13.84% vs 50.76%). After induction of Anaesthesia there was fall in body temperature in both the groups but there was no significant difference in both groups. ($p > 0.05$). There are few studies done on paracetamol as prophylactic agent for postoperative shivering and they have found it helpful in preventing postoperative shivering. Our study is in concordance with that of Khalili et al.^[18] They found that use of paracetamol just before induction in patients undergoing upper limb surgery under GA have significant effect on prevention of postoperative shivering as compared to those patients in whom placebo was used. In addition, patients receiving paracetamol had lower pain scores.

Gholami and Hadavi^[19] used paracetamol 15 minutes after delivery of baby to prevent postoperative shivering in 110 patients undergoing elective LSCS under GA. They found that there was significantly lower incidence of postoperative shivering in parturients who received paracetamol than who received placebo (9.1% vs 50.9%). Similar fall in body temperature was noted in both groups. They concluded that its use can decrease use of opioids and opioid related side effects. Another study by Kinjo et al.^[20] used paracetamol as prophylactic agent in patients undergoing gynaecological laparotomy. They found that paracetamol significantly decreased incidence of postoperative shivering as compared to placebo. However they prematurely terminated their study due to ethical issues before adequate no of patients could be enrolled. Wahdan et al.^[21] in their study on patients undergoing liposuction surgery under combined epidural and GA concluded that paracetamol is effective in decreasing the incidence and severity of postoperative shivering administered at the end of the surgery. kashif et al.^[22] conducted a study in patients undergoing septoplasty under general anaesthesia to compare effects of paracetamol and ketorolac on preventing postoperative shivering and pain. They found that paracetamol is effective in decreasing the incidence of postoperative shivering. Studies have found paracetamol effective in preventing post-spinal shivering.^[23]

CONCLUSION

Paracetamol is an effective and safe agent in preventing postoperative shivering. It prevents shivering by suppressing increase in body temperature set point and may lead to inadvertent hypothermia. Hence it should be used with active warming measures.

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