J. Dhaka National Med. Coll. Hos. 2018; 24 (02): 06-09

Original Article

Evaluation of efficacy of oral Tramadol as premedication in preventing post operative shivering after General Anesthesia – A Prospective Study

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Abstract

Background: Postoperative shivering (POS) is one of the most common complications after surgery. There are two methods to reduce the shivering, including pharmacological and non-pharmacological methods.

Aim of the study: The present study is designed to compare the efficacy of 50 mg oral tramadol as premedication with placebo on prevention of POS after general anesthesia.

Material and methods: This prospective study consisted of 80 adult patients scheduled for ENT surgery under general anesthesia. The patients were randomized into two groups of 40 patients each. Group I (tramadol group) received 50 mg of oral tramadol and group II (placebo) received an oral placebo 90 minutes before operation. All patients were assessed for postoperative shivering in the recovery room.

Results: Regarding the efficacy of 50 mg oral tramadol as premedication in preventing POS the study revealed that incidence of POS was 10% in group I (Tramadol group), 45% in group II (Placebo group) and there was statistically significant difference between the groups according to incidence and severity of shivering.

Conclusion: Oral tramadol premedication adequately prevents postoperative shivering after general anesthesia.

Keywords: Tramadol, Premedication, Postoperative shivering (POS)

Introduction:

Postoperative shivering, a very common complication of surgery owing to postoperative pain and post anesthesia hypothermia, is distressing for both patients and clinicians.[1] It can be defined as involuntary and oscillatory muscular activities that increase the metabolic rate by two to three folds to maintain the core temperature, with the increment of heat production by about 200% in adults.[2] Both neuraxial (epidural and spinal anesthesia) and general anesthesia are associated with a significant incidence of shivering, and the incidence is 40%-60% in regional anesthetic patients[3] and up to 60% in general anesthetic ones.[4] Shivering can be associated with severe adverse effects by increasing the oxygen consumption and carbon dioxide retention. It can cause arterial hypoxia, increase cardiac output and the risk of myocardial ischemia. Besides, the movement of shivering interferes with the electrocardiogram, blood pressure, and pulse oximetry.[5] Recent years, with increasing awareness of its undesirable aftermath, effective prevention of postoperative shivering (POS) is being imperative. It has been reported that POS could be prevented by warming skin-surface[6] and warming the administered fluid,[7,8] but it is not a perfect way. Many drugs have been shown to be effective on prevention of POS, such as opioids, α_2-agonist, anticholinergic, CNS stimulant, corticosteroid,[9] however, few of them were recommended for the prevention of POS due to various side-effects. For instance, Clonidine, a partial α_2 adrenergic agonist, is related to bradycardia, hypotension and sedation.[10]

Opioids have significant role among the identified drugs because the effects of different opioids have been studied frequently in this regard and some of them such as pethidine are commonly used for both treatment and prevention of POS and it considered as the most effective anti-shivering drug.[11,12] But some

adverse effects such as respiratory depression, especially in patients with previous history of opioids and anesthetics administration, hypotension, postoperative nausea and vomiting have limited its use.[13]

Recent studies have investigated the effectiveness of tramadol, a synthetic opioid with low risk of respiratory depression, tolerance, and dependence, in treatment and prophylaxis of POS.[14-16] Tramadol is a centrally acting analgesic with a dual mechanism of action which inhibits the reuptake of 5HT, norepinephrine, and dopamine, and also facilitates 5-hydroxytryptamine 5HT release.[17]

This study was intended to investigate the effect of orally administrated tramadol in the prevention of this common complication of general anesthesia.

Materials and methods:

In this prospective randomized double-blind clinical trial, 80 ASA I and II patients aged 20-50 years, scheduled for elective ENT surgery under general anesthesia in National Institute of ENT Dhaka, during July to September 2017, were enrolled.

Patients with a history of convulsions and drug history of using antidepressants, carbamazepine, sedatives, narcotic or patients who had recent febrile disorder were excluded from the study. In addition, patients who were hemodynamicaly unstable or had severe renal or hepatic insufficiency were excluded. The patients were randomly allocated into Group I (Tramadol group) to receive 50 mg oral tramadol and Group II (Placebo group) to receive placebo capsule with 50 ml water, 90 minutes before surgery by an anesthesiologist who was blinded to the name of drugs.

The anesthetic management of the patients was performed according to the standard protocol similarly in the two study groups. The anesthesia was induced with IV fentanyl 2mcg/kg, propofol 2mg/kg and vecuroneum 0.1mg/kg. After orotracheal intubation, anesthesia was maintained with nitrous oxide 60% in oxygen and halothane. Oxygen saturation, electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetery (SpO_2), and end-tidal carbon dioxide ($EtCO_2$) were recorded during surgery. Systolic and diastolic BP was monitored before induction of anesthesia and every 5 min till the end of surgery. Residual neuromuscular blockade was antagonized using neostigmine 0.04 mg/kg and atropine 0.02 mg/kg at the end of surgery, then patients were extubated and send to recovery room. During surgery, skin surface and IV fluid warming were not used. The operating room temperature was set at 22°C-25°C. In the recovery room, all patients were evaluated for POS for 1 hour by a four-grade scale validated by Crossley & Mahajan[18] and Tsai & Chu[19] by another anesthesiologist who was not aware of the drugs used. In cases with grade 3-4 shivering for more than 4 min duration, the prophylaxis was considered ineffective and intravenous pethidine 25 mg was administered.

Grading scale of postoperative shivering validated by Crossley & Mahajan[18] and Tsai & Chu[19]

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.

Statistical analysis:

Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Independent-samples t-test of significance was used when comparing between two means. Chi-square test of significance was used in order to compare proportions between two qualitative parameters. P-value <0.05 was considered significant. P-value >0.05 was considered insignificant.

Results:

There was no significant difference in terms of age, body weight, sex, ASA status hemodynamics and body temperature between the groups (Table I). In group I four (10%) out of the 40 patients had postoperative shivering (POS), whereas 18 (45%) out of the 40 patients had POS in group II ($P<0.05$). Grade 1 POS was lower number of patients in group I when compared with group II (3 versus 10; $P<0.05$). Grade 2 POS was also lower number of patients in group I when compared with group II (1 versus 6; $P<0.05$) and grade 3 POS was only present in group II (0 versus 2; $p<0.05$. There was no grade 4 POS in either of the two groups (Table II). The baseline values of systolic and diastolic blood pressure, heart rate and temperature in both groups were similar and there was no any adverse effect.

Table-I: Demographic and operative details of patients between Tramadol and Placebo group.

Demographic and operative details	Group I (Tramadol group) n=40	Group II (Placebo group) n=40
Age (Years)	44.34±9.32	45.73±8.92
Weight (Kg)	64.7±7.3	63.9±9.2
Sex M/F	30/10	28/12
ASA physical status I/II	37/3	36/4
Mean basal heart rate (bpm)	77.8±7.3	78.8±8.6
Mean basal systolic BP (mm Hg)	123.23±9.82	126.45±9.12
Mean basal diastolic BP (mm Hg)	78.34±7.86	76.81±7.22
Mean duration of surgery (min)	67.32±11.64	68.54±10.82
Mean body temperatures during surgery (°C)	36.33±0.48	36.44±0.46
Mean body temperature in recovery room (°C)	36.72±0.39	36.58±0.48

Table II: Incidence and severity of postoperative shivering

Postoperative shivering (POS)	Group I (Tramadol group) n=40	Group II (Placebo group) n=40	p value
Incidence of POS number (%)	4 (10%)	18 (45%)	p<0.05
Grading of POS number (%)			
0	36 (90%)	22 (55%)	p<0.05
1	3 (7.5%)	10 (25%)	p<0.05
2	1 (2.5%)	6 (15%)	p<0.05
3	0	2 (5%)	p<0.05
4	0	0	-

Discussion

Tramadol is a synthetic opioid which has duel mechanism of action by blocking norepinephrine and serotonin reuptake and weak activating the mu-opioid receptors.17 Tramadol has higher oral bioavailability and it is highly metabolized and these characteristics make it an appropriate drug for postoperative shivering (POS).

The usefulness of tramadol in POS has been investigated in many studies. They reported equal or even superior effect to pethidine for tramadol in the prevention of POS.[14-16] Considering that tramadol has less respiratory depression effect and low risk of tolerance and dependence than pethidine, the importance of evaluating its effect becomes more useful.

In present study, it was found that, in tramadol group four (10%) out of the 40 patients had postoperative shivering (POS), whereas 18 (45%) out of the 40 patients had POS in placebo group (P<0.05). Grade 1 POS was lower number of patients in tramadol group when compared with placebo group (3 versus 10; P<0.05). Grade 2 POS was also lower number of patients in tramadol group when compared with placebo group (1 versus 6; P<0.05) and grade 3 POS was only present in placebo group (0 versus 2; p<0.05.There was no grade 4 POS in either of the two groups.

In a study[20] on prevention of postoperative shivering by oral tramadol and it was seen in 12.5% patients in the oral tramdol group and 25% patients in the placebo group. In another study[21] on prevention of postoperative shivering by oral tramadol and oral clonidine and POS was found 7.5% and 5% patients respectively.

The result of postoperative shivering in present study (10%) is nearly similar with the study done by Heidari et al[20] (12.5%) and Tewari et al[21] (7.5%).

Mohta et al[22] have investigated the effect of different doses of IV tramadol, i.e., 1, 2, and 3 mg/kg, for prevention of POS and showed that tramadol in a dose of 2 mg/kg had the best combination of anti-shivering and analgesic efficacy without excessive sedation.

Heid et al[23] reported that compared with placebo, intraoperative intravenous administration of tramadol in a dose of 2 mg/kg reduced the incidence and severity of postoperative shivering.

Conclusion:

Oral tramadol can significantly reduce postoperative shivering after general anesthesia.

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