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COMPARISON OF THE EFFECTS OF ORAL TIZANIDINE AND ORAL TRAMADOL ON INTRA- AND POST-OPERATIVE SHIVERING IN PATIENTS UNDERGOING SPINAL ANAESTHESIA FOR TRANSURETHRAL RESECTION OF PROSTATE- A RANDOMIZED CLINICAL STUDY.

Anaesthesiology

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ABSTRACT

Introduction: Hypothermia can complicate Transurethral resection of prostate(TURP) and especially geriatric patients are predisposed to the risk of hypothermia induced shivering under anaesthesia. Shivering escalates oxygen consumption, lactic acidosis and carbon dioxide production, thus predisposing a patient with low cardiopulmonary reserve to potential harm. Various drugs have undergone investigative trial to reduce perioperative shivering with more or less similar efficacy. **Materials and Methods:** A prospective, double blind, randomised study was conducted on 90 patients belonging to age group 40-80 years, ASA PS 1 & 2 posted for elective surgery under spinal anaesthesia. Group A received oral tramadol 50mg (n=30), Group B received oral tizanidine 4mg (n=30), Group C received oral placebo (n=30), all at 90 minutes before spinal anaesthesia. Heart rate, mean arterial pressure, respiratory rate, arterial oxygen saturation, skin surface temperature were recorded at the beginning, then every 10 minutes during the operation. The incidence of nausea, vomiting, frequency of shivering during surgery and recovery were recorded. The observed data were analysed by SPSS 20 and Microsoft Excel 2016. **Result:** In terms of frequency of shivering during surgery, significant difference was seen between tramadol and placebo(p=0.04) and between tizanidine and placebo(p=0.04). A significant difference was observed between tramadol and placebo(p=0.0001) and between tizanidine and placebo(p=0.0001) with respect to severity of shivering. A significant difference was noted between tizanidine and the other two groups in terms of sedation, calculated by modified Ramsay sedation score (p=0.0001). **Conclusion:** Both oral tramadol and oral tizanidine were equally effective in prevention of postspinal shivering with stable hemodynamics.

KEYWORDS

Tramadol, Tizanidine, shivering, sedation.

INTRODUCTION

Geriatric patients undergoing Transurethral resection of prostate (TURP) are predisposed to cardiac complications and risk of hypothermia induced shivering under anaesthesia. Neuraxial block impairs the regulation of body temperature by inhibition of vasomotor and shivering responses. Under neuraxial blockade, hypothermia may not be perceived by patients who typically feel less cold after induction of the block[1]. The temperature threshold for vasoconstriction and shivering is consequently reduced in unblocked (spinal segments) dermatomal regions of the body and hence more shivering is a requisite to avert further hypothermia. Shivering is both morbid and uncomfortable for patients and may interfere with monitoring of electrocardiogram, blood pressure and pulse oxygen saturation[2]. It escalates oxygen consumption, lactic acidosis and carbon dioxide production, thus predisposing a patient with a low cardiopulmonary reserve to potential harm[3]. Maintaining strict normothermia may prevent shivering during regional anaesthesia. Intravenous tramadol is used as an analgesic and also used to reduce perioperative shivering[4]. Oral tramadol is economical in comparison to intravenous tramadol. Tizanidine mediates central muscle relaxant activity[5]. This study was intended to compare the prophylactic effectiveness of enteral formulations of tizanidine and tramadol for prevention of perioperative shivering. Proving their efficacy might integrate the use of these drugs as premedication in future.

The primary objective of the study is to assess the frequency, severity of shivering and changes in mean body temperature in three groups after spinal anaesthesia. The secondary objectives are to assess the frequency of nausea and vomiting, intraoperative sedation, intraoperative hemodynamics.

MATERIALS AND METHODS

Ninety patients of ASA physical status 1 and 2 posted for TURP done under spinal anaesthesia was included for the study. This study was approved by ethical committee in our institution and the study was conducted after obtaining informed written consent from patients.

Inclusion Criteria

- Age 40-80 years.
- ASA PS 1 and 2.
- Elective TURP.
- Valid Informed Consent.

Exclusion Criteria

- Allergy to tramadol and tizanidine.
- Ischemic heart disease.
- Diabetic autonomic neuropathy.
- Initial body temperature < 36.0℃ or >37.5℃
- Use of monoamine oxidase inhibitors, selective serotonin reuptake inhibitors, vasodilators, benzodiazepines.
- Duration of surgery more than 1.5 hours.

The patients were seen preoperatively the day before surgery. Patients were advised fasting for 8 hours duration and antacid prophylaxis given before shifting the patient to operating room. Patients were randomly assigned into three groups using computer generated tables. Group A (n=30) received oral tramadol 50 mg 90 minutes before spinal anaesthesia, Group B (n=30) received oral tizanidine 4 mg 90 minutes before spinal anaesthesia and Group C (n=30) received oral placebo 90 minutes before spinal anaesthesia. Patients were shifted to operation theatre and pulse oximeter, electrocardiograph, non invasive blood pressure, surface temperature (right chest wall) probe were attached. The operating room temperature was maintained at 23 to 25°C. The anaesthesia machine, all airway gadgets, suction apparatus, emergency drugs were kept ready. Intravenous access was secured with 18G IV cannula and patients were preloaded with 10 ml/kg of ringer lactate solution over 15 minutes before performing spinal anaesthesia. Under strict aseptic precaution, patient in sitting position, subarachnoid block given at L3-L4 interspaces using 25G Quincke spinal needle and 2-3 ml hyperbaric bupivacaine was injected. All patients received supplemental oxygen through facemask during surgery. Irrigation and Intravenous fluids were administered at room temperature. All patients were covered with a single layer of surgical drape. The level of spinal anaesthesia attained was at T8-T10. Motor block was assessed by using modified Bromage scale and sensory block assessed by pinprick test. Shivering is graded on a scale validated by Wrench et al[6].

0= No shivering
1= Piloerection or peripheral vasoconstriction without visible shivering
2= Muscular activity involving only one muscle group
3= Muscular activity involving more than one muscle group but not generalised
4= Shivering involving the whole body

Sedation score was assessed by using modified Ramsay sedation scale[7].

1. Awake and alert, minimal or no cognitive impairment.
2. Awake but tranquil, purposeful responses to verbal commands at conversation level.
3. Appears asleep, purposeful responses to verbal commands at conversation level.
4. Appears asleep, purposeful responses to verbal commands but at

louder than usual conversation level or requiring light glabellar tap.
5. Asleep, sluggish purposeful responses only to loud verbal commands or strong glabellar tap.
6. Asleep, sluggish purposeful responses only to painful stimuli.
7. Asleep, reflex withdrawal to painful stimuli only (no purposeful response).
8. Unresponsive to external stimuli including pain.

Heart rate, mean arterial pressure, respiratory rate, arterial oxygen saturation, skin surface temperature were measured and recorded at the beginning and then every 10 minutes during the operation. Severity (grade) of shivering and level of sedation were observed for the intraoperative period. The incidence of nausea, vomiting, frequency of shivering during surgery and recovery(2 hours postoperative) were recorded. Bradycardia defined as heart rate below 50 per minute was treated with IV 0.6 mg atropine. Hypotension defined as a decrease in mean arterial pressure of more than 20% from baseline was treated with 6 mg IV ephedrine and ringer lactate infusion. Patients developing nausea and vomiting was treated with IV ondansetron 8 mg. Intravenous tramadol 50 mg was given to shivering patients.

RESULTS

There was no significant statistical difference in terms of age and BMI among the three groups. There was significant statistical difference in terms of shivering between tramadol and placebo (p=0.04) and between tizanidine and placebo (p=0.04) during surgery (figure 1).The frequency of shivering was less in tramadol and tizanidine group. There was no significant statistical difference in frequency of shivering between three groups during recovery (p=0.535). As per ANOVA test, a significant statistical difference was observed in terms of severity of shivering between tramadol and placebo (p=0.0001) and between tizanidine and placebo (p=0.0001) during surgery (figure 2).Low grades of shivering seen in tramadol and tizanidine group. No significant statistical difference was observed between tramadol and tizanidine group with respect to severity of shivering (p=0.795). There was no significant statistical difference, as per Fischer's extract test, between the three groups in terms of incidence of nausea during surgery and recovery (p>0.05). There was no incidence of vomiting in all three groups during surgery and recovery. No significant statistical difference was noted in mean arterial pressure before and during surgery in the three groups (p=0.998).As per ANOVA test, no significant difference was seen among the three groups with respect to mean heart rate (0.972) and mean arterial oxygen saturation before and during surgery. Significant statistical difference was noted between group C and group A,B in terms of mean body temperature (p=0.001) as per ANOVA test. There was significant statistical difference between tizanidine and the other two groups in sedation score as calculated by modified Ramsay sedation score (p=0.0001) (figure 3). Sedation score was higher in tizanidine group.

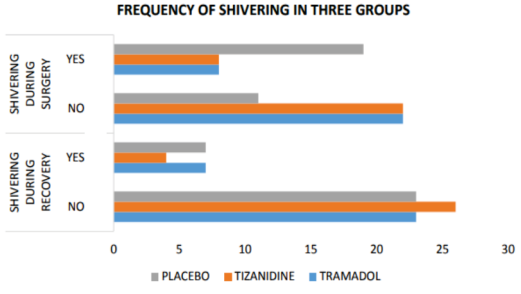

Figure 1: Frequency Of Shivering In Three Groups.

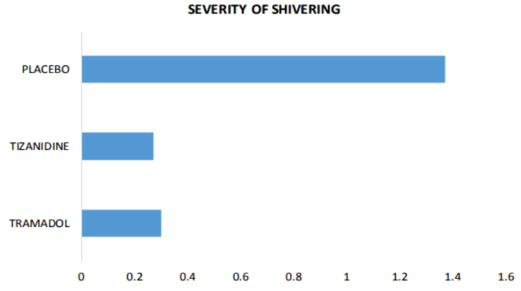

Figure 2: Severity Of Shivering In Three Groups.

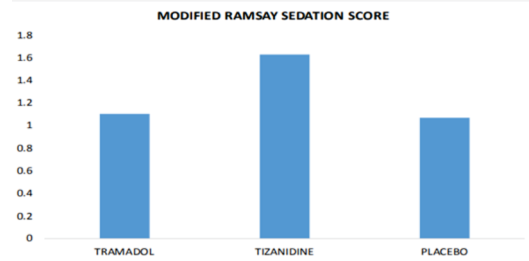

Figure 3: The Mean Modified Ramsay Sedation Score In Three Groups.

DISCUSSION

Intraoperative and postoperative shivering can lead to multiple complications. Prevention is preferable than treatment. Tizanidine reduces the central thermosensitivity and release of norepinephrine from axonal terminals in hypothalamus. It causes vasoconstriction by binding to alpha 2 receptors, thereby decreasing shivering. Tramadol inhibits reuptake of serotonin and norepinephrine in the spinalcord, thereby facilitating the release of serotonin, which activates mu (μ) receptors and influences the thermoregulatory control . In the study done by Leili Adinehmehr et al, there was no significant statistical difference in mean body temperature measured at axilla in all three groups[9]. But in our study, when the mean body temperature was compared, the placebo group had a p value of 0.001, compared to tizanidine and tramadol groups. The severity of shivering observed in tramadol group ranges from grade 1 and 2, whereas in tizanidine group, it ranges from grade 1 and 3. In our study, it was found that there was significant statistical difference in sedation between tizanidine and other two groups (p=0.0001). Similarly, in a study by Usha Shukla et al, it was found that the patients who received clonidine (alpha 2 agonist) were more sedated than the patients in tramadol and placebo groups[7]. The metabolic cost of shivering is an increase in oxygen consumption ranging from 300% to 800%[10]. Tizanidine and tramadol would be effective in preventing shivering but not hypothermia. Hence, maintaining strict normothermia along with premedication with either tizanidine or tramadol can prevent shivering during regional anaesthesia.

CONCLUSION

We conclude that the use of oral tramadol 50 mg or oral tizanidine 4 mg are effective as a prophylactic agent to reduce the incidence and severity of perioperative shivering in patients undergoing transurethral resection of prostate under spinal anaesthesia with less incidence of nausea and vomiting. Oral tizanidine had better sedation profile when compared to oral tramadol. Both tramadol and tizanidine were equally effective without any respiratory depression.

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