VOLUME-9, ISSUE-5, MAY -2020 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Anaesthesiology

A RETROSPECTIVE COMPARATIVE STUDY BETWEEN TRAMADOL & PETHIDINE FOR THE CONTROL OF SHIVERING DURING INTRAOPERATIVE & POSTOPERATIVE PERIOD

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ABSTRACT

Introduction : Around 40-60% of the patients under regional anaesthesia develop shivering. Aim of this study was to compare the interventional use of tramadol and pethidine as anti-shivering agents for spinal anaesthesia induced shivering rug for the treatment of shivering, in the quest for more safer and efficacious drug. We conducted this study to compare the efficacy, potency, haemodynamics effects and complications or side effects of Tramadol with that of Pethidine for the control of shivering **Methods:** This was a Retrospective study . Data of 100 Cases from either gender, , BMI range of 18.5-25, systolic blood pressure of 120 to 140 mmHg & aged between 20-60 yrs of ASA PS I, II or III undergoing various surgeries under regional anaesthesia were taken for the study. Patients were randomly allocated into two groups of 50 each. Randomization was done using computer tables in selecting data. The intergroup comparisons were made by Student's t-test and chi-square test for categorical variable. **Results:** There was no significant difference between different Age , weight , gender , duration of surgery, axillary temperature as well as shivering grades in two groups. The differences observed in baseline HR, SBP, DBP, and mean blood pressure between the two groups were statistically insignificant. Onset of Disappearance of Shivering was earlier in Tramadol group. Recurrence of shivering was more in Pethidine group **Conclusion :** We can derive at a conclusion that Tramadol is effective in treating shivering under regional anaesthesia due to its rapid onset, effective control, less recurrence rate and minimum side effects when compared to Pethidine.

KEYWORDS : Regional Anaesthesia , Retrospective study , Tramadol , Pethidine ,Shivering .

INTRODUCTION

Regional anaesthesia / Spinal Anaesthesia is a safe and popular anaesthetic technique for various surgeries. Around 40-60% of the patients under regional anaesthesia develop shivering.[1,2]

Shivering can be very unpleasant and physiologically stressful for the patients after enjoying the comforts of modern anaesthetics. Mild shivering increases oxygen consumption to a level that is produced by light exercise, whereas severe shivering increases metabolic rate and oxygen consumption up to 100-600%. It may induce arterial hypoxemia, lactic acidosis, increased IOP and ICT and interferes with ECG monitoring, pulse rate, B.P etc.3,4,5 Shivering may be detrimental to the patients with low cardiorespiratory reserves.6 It is uncomfortable to the parturients as well as to the operating room personnel, especially during regional anaesthesia7. In lower limb orthopaedic surgery, regional anaesthesia provides useful benefits such as reduced incidence of peri-operative deep vein thrombosis and better postoperative pain relief compared with general anaesthesia. The deleterious effect of shivering warrant a prompt and rapid control on occurrence.

Spinal anaesthesia is a safe and increasingly popular anaesthetic technique. The effective care of patients under regional anaesthesia can be a challenge especially in resource poor setting where limited option of drugs to use exists. Shivering occurring intraoperatively can be distressing. The non availability of opioids is a major factor in managing spinal anaesthesia induced shivering. Opioids, being controlled by the government regulations are not readily available.Tramadol, though a weak opioid is commonly available. Its lack of addiction aids its availability as it is not subject to strict control. Spinal anaesthesia is increasingly being used for lower limb and lower abdominal operative procedures in the sub region3,4. The planning and execution of an anaesthetic care protocol that achieves better comfort for the patient is desirable.

Various methods are available for the control of shivering during anaesthesia. Non-pharmacological methods using equipments to maintain normothermia are effective but may be expensive and are not practical in all the settings. Pharmacological methods using various drugs like Pethidine, Clonidine, Doxapram, Ketanserine, Tramadol, Nefopam etc. have been tried which are simple, cost effective and easily available.

Here we have compared Tramadol, a synthetic opioid with Pethidine, the gold standard The aim of this study was to compare the interventional use of tramadol and pethidine as anti-shivering agents for spinal anaesthesia induced shivering rug for the treatment of shivering, in the quest for more safer and efficacious drug.

We conducted this study to compare the efficacy, potency, haemodynamics effects and complications or side effects of Tramadol with that of Pethidine for the control of shivering.

METHEDOLOGY

This Retrospective study involved Prior Consent from Hospital Authorities / Medical Superintendent of the tertiary care hospitals to see the records of the patients & were found within ethical standards. Patients who were admitted in the various Surgical units of tertiary care hospitals in Randomly selected Hospitals including Our Teaching Hospital of our city . Data of various surgeries were selected which used Tramadol & Pethidine as anti-shivering agents for spinal anaesthesia induced shivering during Spinal Anaesthesia in last 2 years Randomization was done using computer tables in selecting data.

A total of 100 patients from either gender, , BMI range of 18.5-25, systolic blood pressure of 120 to 140 mmHg & aged between 20-60 yrs of American Society of Anaesthesiologists (ASA) PS I, II or III undergoing various surgeries under regional anaesthesia were taken for the study.

Those candidates with any history of Patients with fever, thyroid disease, obesity, diabetes, drug allergy, compromised cardiorespiratory conditions and patients on long term

phenothiazines and MAO inhibitors along with uncontrolled clinical condition, such as high blood pressure and cardiovascular diseases, were excluded from study.

All Patients underwent standard clinical examinations, routine biochemical and haematological investigations. Medical record numbers were used to generate the data for analysis. After premedication in the form of inj. Atropine or Glycopyrrolate I.V. Baseline preoperative axillary temperature was noted in all the patients. Central neural blockade (Spinal, Epidural And Combined Spinal and Epidural) or peripheral neural blockade was given accordingto the surgical procedures. Patients who experienced shivering of grades as shown in the table 1 were enrolled for the study.

Table 1 – Shivering Grades according to ASA

Grades	Shivering status
Grade 0	No Shivering
Grade 1	Mild fasciculations of face or neck, ECG disturbances in absence of voluntary activity of arms.
Grade 2	Visible tremors involving more than one group of muscle.
Grade 3	Gross muscular activity involving the entire body, bed shaking

All the patients who experienced shivering were randomly divided into Group 1 and Group 2 . Group 1 received 1% Tramadol in a dose of 1 mg/kg and Group 2 received 1% Pethidine in a dose of 1 mg/kg. All the patients were assessed for shivering grades, its disappearance, haemodynamic status, and complications if any. Patients were observed at intervals of 1 min till 5 mins, and thereafter at every 10 mins interval till 60 mins. Pulse rate, B.P, SPO2 , Respiratory rate, and temperature were noted immediately after regional anaesthesia, and also during shivering, and thereafter the drug administration at regular intervals. Recurrence of shivering was also noted and an additional dose of either Tramadol or Pethidine in a dose of 0.5 mg/kg was given in respective groups.

Continuous data were expressed as mean ± standard deviation (SD) . The intergroup comparisons were made by Student's t-test and chi-square test for categorical variable. The data were analyzed by IBM SPSS Statistics 23. Overall, < 0.05 was proposed to represent statistical significance after correction.

Physiological Variables	Group 1 who received Tramadol n = 50	Group 2 who received Pethidine n = 50	p value
Age in years	34. 16±10.39	35.72 ±11.43	>0.05 (Not Significant)
Gender (M:F)	29:21	28:22	>0.05 (Not Significant)
ASA PS	24:26	23:27	>0.05 (Not Significant)
Temperature (C)	36.3 +0.3	36.4 +0.4	> 0.05 (Not Significant)
Shivering Grades	2.27 +0.449	2.3 +0.466	> 0.05 (Not Significant)

Also , There was no significant difference found in the duration of surgery, axillary temperature as well as shivering grades at the start of study between the two groups

The onset of disappearance of shivering was found at around 1 minute and 3 minutes in Group 1 and Group 2 respectively. Regarding the disappearance of shivering in both the groups ,we found a statistically significant difference as shown in the table-3 Stoppage of shivering occurred earlier in Group 1 or Tramadol group in comparison to Group 2 or Pethidine ($P<0.001$) as shown in Table 3.

Table -3 Onset of Disappearance of Shivering

Time	Tramadol (n=50)	Pethidine (n=50)	p value
1 min	26 (52%)	3 (6%)	<0.05 (Significant)
3 mins	41 (82%)	8 (16%)	>0.05 (Not Significant)

Haemodynamically there was no significant difference found between the two groups. The differences observed in baseline HR, SBP, DBP, and mean blood pressure between the two groups were statistically insignificant.

The recurrence of shivering was observed approximately after 50-60 0 minutes and the incidence of recurrence was 40% in Pethidine group while only in 6 % in Tramadol group

Complications like nausea and vomiting occurred in 12% in Pethidine group while only 8 % in Tramadol group. However the difference is statistically insignificant.

DISCUSSION

Regional anaesthesia including central neural blockade and peripheral nerve blockade is a safe and popular technique for various surgeries. Around 40-60% of the patients under regional anaesthesia develop shivering, though it is found commonly after general anaesthesia.8 The probable mechanism under regional anaesthesia could either be a result of decrease in core body temperature or misinformation from receptors.9The factors causing decrease in core body temperature include, sympathetic block causing peripheral vasodilation, increased cutaneous infusion of cold i.v fluids, direct effect of cold anaesthetic solution upon the thermosensitive structures of spinal cord7,9. Shivering may represent an inappropriate programmed thermal response to rise in body temperature.9 Even local anaesthetic introduced into the extradural space might modify environmental thermal clues, with resultant inappropriate thermal responses to false information.10 Shivering increases oxygen requirement by 100-600%, causes arterial hypoxemia, lactic acidosis, increase in BMR, I.O.P, ICT, and may prove detrimental to patients with low cardiorespiratory reserve. The parturients experienced it to be uncomfortable after enjoying the benefits of modern anaesthesia.

Various nonpharmacological and pharmacological methods have been used to prevent body heat loss.

Nonpharmacological methods like electrical heaters, forced air warmers, blankets, radiant heat, and warming the operating room suite. The use of warm local anaesthetic solutions or warming of i.v fluids are also effective to reduce shivering.11,12 Pharmacological methods using Ketanserine Nefopam, Pethidine, Alfentanyl, Doxapram, Tramadol, Clonidine etc have been tried and compared by many studies. These drugs are used effectively when clinically indicated and they are easily available to all centers and prove to be practical in the many settings. In our study we have compared recently introduced synthetic opioid Tramadol with Pethidine, which was gold standard for control of shivering. Tramadol a synthetic opioid agonist prevents shivering by inhibiting the reuptake of norepinephrine and serotonin, hence activating the descending inhibitory spinal pathways. It also modulates the activity of nucleus median raphe acting centrally on the m opioid receptors predominantly with minimal effects on k and d receptors where as Pethidine acts mainly through opioid receptors namely k? receptors. The mechanism of action of Tramadol is different from that of Pethidine. Tramadol has

minimal effect on k? receptors. The antishivering effect of Tramadol is mediated via serotonergic or noradrenergic receptor or both.6,13 Pethidine controlled shivering better than Fentanyl and Morphine.14 Therefore we undertook a study to compare a newer agent with a time-tested drug.

In our study we observed that shivering disappeared by 1 minute in case of Tramadol and 5 minutes in case of Pethidine and in comparison to earlier study, shivering reduced significantly at 1 minute after Tramadol. The complete disappearance of shivering took Less time in Tramadol group than in Pethidine group. Earlier studies have showed better results with Tramadol group.[6,15]

Regarding recurrence, shivering reappeared after 50-60 minutes in 6 % patients of Tramadol group and 40 % in Pethidine Group. The difference was statistically significant ($P<0.05$). The findings were similar with other studies which noted 8% with Tramadol group13 and 13-50% in Pethidine group11,13 .Thus various studies including ours there was higher rate of recurrence with Pethidine in comparison to Tramadol.

The probable reason for recurrence of shivering could be result of low plasma concentration of the active drug, when hypothermia is still persisting and individual variations in the core temperatures. Till date it is not clear whether higher shivering grades requires a higher doses of the drug.[13]

In our study both the drugs gave good and better haemodynamic stability throughout the course of the study in all the patients. No respiratory depression was observed in any of the cases. Only in 12 % of cases from Pethidine group had nausea and vomiting which was easily treated with H2 receptor blocker and antiemetic drug. Earlier studies have found that use of 1 mg/ kg of Tramadol was associated with higher incidence of nausea and vomiting, and also sedation, which was not observed in our study.9 Some others have suggested that slow injection of Tramadol over 2 minutes, reduces and prevents nausea and vomiting.[6]

CONCLUSION

We can derive at a conclusion that Tramadol is effective in treating shivering under regional anaesthesia due to its rapid onset, effective control, less recurrence rate and minimum side effects in a dose of 1 mg/kg. when compared to Pethidine. Similarly Tramadol was effective and safe in comparison to Pethidine for control of shivering as noted earlier 3,6,11 even recommend for Tramadol on prophylactic basis also.6

ACKNOWLEDGEMENTS

We would like to thank All the Hospital Authorities of the participating tertiary care hospitals for providing data and notes of previous surgeries , Our Head of Department and Dean of Our Institute for their always available guidance.

Compliance With Ethical Standards.
Conflict Of Interest – None.
Funding – None.
Informed Consent - Obtained.

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