Original Research Article

Comparison of safety and efficacy of pethidine and tramadol in shivering patients for surgeries under regional anesthesia

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Abstract

Background: Post-operative shivering is common complication of the regional anesthesia. This study was mainly undertaken to compare the efficacy of pethidine and tramadol in controlling the post-operative shivering.

Materials and methods: A randomized controlled study was conducted among 80 patients undergoing different surgeries. All the patients were assessed for shivering grades, its disappearance, hemodynamic status and complications if any. Sedation scores were recorded and shivering scores were also recorded.

Results: There was no statistically significant difference in the age, weight, sex and ASA grades between the tramadol and pethidine groups. All the hemodynamic responses were same in both the groups. The shivering stopped at an earlier point of time in tramadol group when compared to the pethidine group which was statistically significant. Sedation characteristics are significant at 5 minutes and 10 minutes for pethidine. Pethidine causes more sedation tramadol at 5 and 10 minutes.

Conclusion: Tramadol was shown to be superior in efficacy when compared with the pethidine.

Key words

Shivering, Pethidine, Tramadol, Hemodynamic response, Sedation.

Introduction

Regional anesthesia is considered as a safe and popular anesthetic technique for different surgeries. Shivering is a common complication of the regional anesthesia. Shivering can be very unpleasant and physiologically stressful for the patient. It increases the metabolic rate and oxygen consumption up to 100-600%. It can induce arterial hypoxemia and acidosis. It increases intraocular pressure and intracranial tension. It causes stretch on suture lines. It interferes, with monitoring like ECG, pulse oximetry and non-invasive blood pressure measurement. It can be detrimental to patients with low cardio respiratory reserve [1].

The literature available shows that the incidence of post anesthetic shivering is high in surgical patients. The patient experiencing shivering is an unpleasant occurrence of advance of modern anesthesia.

A number of physical and physiological interventions are often used to decrease the incidence of shivering. The non-pharmacological methods use specialized equipments to prevent or control shivering is found to be expensive and not practical in all clinical settings [2].

Pharmacological agents included pethidine, clonidine, magnesium sulphate, Amytryptyline, Urapidil, Dolastron, Doxapram are often used to control shivering. These drugs have side effect including respiratory depression, bradycardia, hypotension etc. [2]. A number studies have shown that, pethidine and tramadol are often found to be effective in control of shivering. Tramadol is used as an analgesic for labor pain and without adversely affecting the mother or the new born. It also offers pharmacodynamic advantage of causing less respiratory depression and sedation, with its unique state of being a non-controlled drug, tramadol has the potential use in controlling shivering. Hence it is emerging as a new and safe drug to be used for treatment of post anesthetic shivering [3]. This study was undertaken to evaluate the safety and efficacy of pethidine and tramadol to control shivering in patient for surgeries under regional anesthesia and to determine which of these pharmacological interventions serves best to achieve therapeutic effect with minimal side effect.

Materials and methods

A randomized controlled trial was undertaken at Deccan College of Medical Sciences, Bangalore during the December 2017 to September, 2019. Clearance from the institution ethics committee was taken before the study was started. A total of 80 patients of both the gender aged between 20 – 60 years, of ASA grade I or II undergoing different surgeries under regional anesthesia who subsequently developed shivering were included. An informed, written and bilingual consent was taken from all the patients before they were included in to the study. Patients with significant cardiovascular, renal, hepatic, respiratory or neurological diseases, patients with fever, thyroid disease, obesity, patients with known hypersensitivity to tramadol or pethidine, patients with long term phenothiazines and MAO inhibitors were excluded from the study.

The patients were randomly divided to two equal groups. Group – T included 40 patients received 0.5 mg/kg tramadol intravenously and group – P included 40 patients who received 0.5 mg/kg of pethidine intravenously. Ambient temperature was noted, baseline vital parameters were recorded, IV access was obtained with 18 G cannula and IV fluids were started. The volume of local anesthetic, volume of preloading fluid, use of vasopressors were determined by the attending anesthesiologist and was not affected by inclusion in the study. A standard double layered blanket was used to cover the chest and upper limb of the patient. All the preloading fluids and drugs were given at room temperature. Oxygen at the rate of 4 litre / min administered through face mask to all the patients. Monitoring of NIBP, pulse oxymetry, ECG was done throughout the procedure. After premedication in the form of Inj. Ondansetron intravenously,

baseline preoperative axillary temperature was noted in all the patients.

Central neaxial blockade or peripheral neural blockade was administered according to the surgical procedures. A modified Crossely and Mahajan scale was used to assess the degree of shivering [4]. The drugs were administered by another anesthetic personnel who is blinded to whether the drug contains pethidine or tramadol. The same person assessed the effect of the drug administration based on the format provided. All the patients were assessed for shivering grades, its disappearance, hemodynamic status and complications if any. Patients were observed at intervals of 1 min till 5 minutes, and thereafter at 10, 20, 30, 45, and 60 minutes. Baseline Pulse rate, B.P, SPO_2, Respiratory rate, and temperature was noted, 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 0.25 mg/kg iv was given in respective groups. Attending anesthesiologist recorded the time of disappearance of shivering from the time of administration of the drug either Tramadol or Pethidine. Ramsey sedation score was used to assess the sedation characteristics. An independent Sample T test was used compare the two groups for quantitative parameters and chi – square or Fisher exact test was used for categorical variables.

Results

Table - 1 shows that there was no statistically significant difference in the age, weight, sex and ASA grades between the tramadol and pethidine groups. Hence the two groups were comparable with respect to these parameters.

There was no statistically significant difference in HR between the two group except at 2nd min where tramadol has significant advantage over pethidine for maintaining the heart rate (**Chart – 1**).

Table – 1: Demographic characteristics and ASA grade of the patients.

	Group T	**Group P**	**P value, Sig**
Age in years (Mean ± SD)	37.7 ± 12.7	40.1 ± 13.5	0.06, NS
Weight in Kgs (Mean ± SD)	57.9 ± 11.4	60.6 ± 11.2	0.08, NS
Sex F/M	13/27	17/23	0.6, NS
ASA grade I/II	33/9	33/7	0.8, NS

Chart - 1: Comparison of heart rate between two groups.

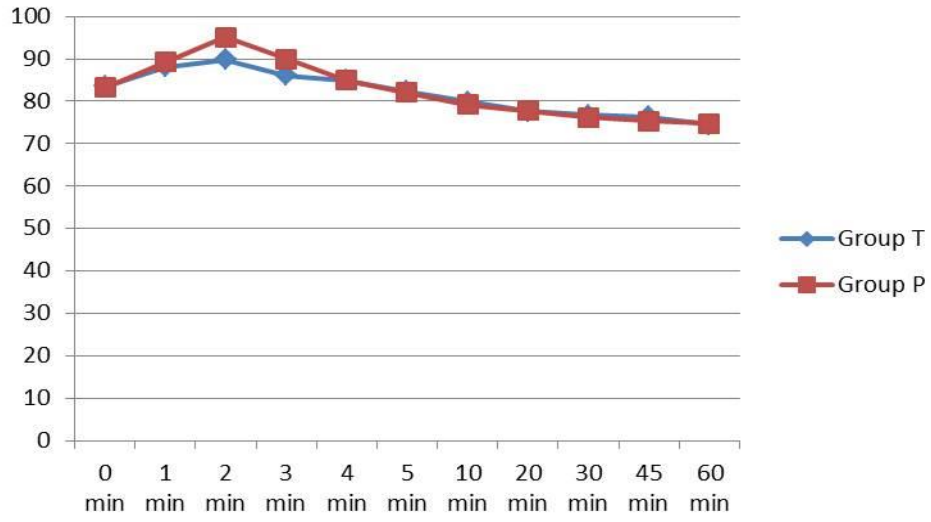

Chart - 2: Systolic blood pressure of the study groups.

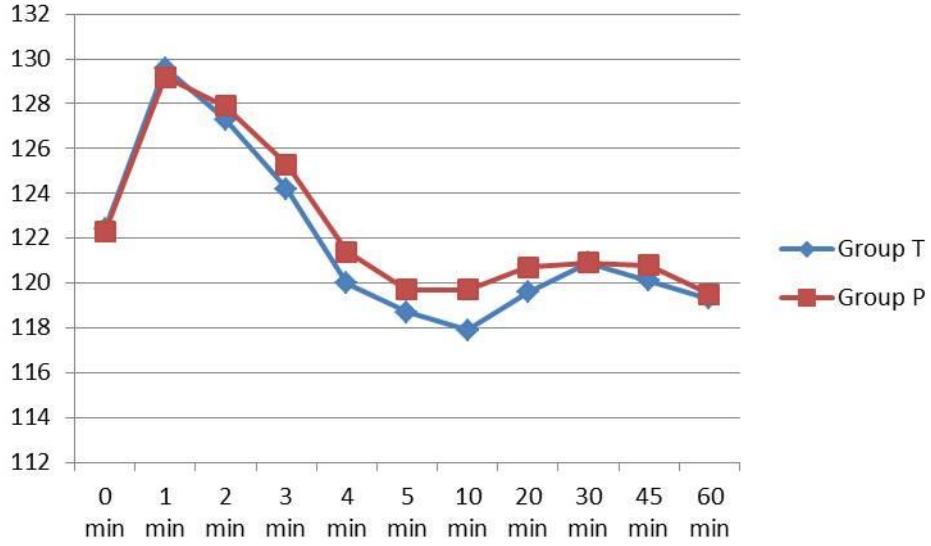

Chart - 3: Diastolic blood pressure of the two groups.

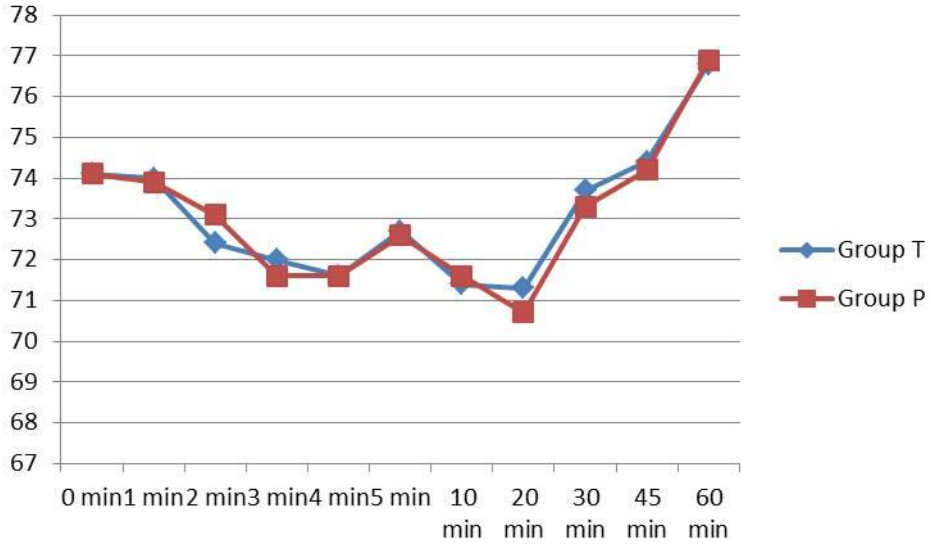

Table - 2: Time at which shivering stopped (In minutes).

Incident	Group T	Group P	P value, Sig
Shivering stopped at	4.58 ± 0.59 min	8.02 ± 5.15 min	0.018, Sig

The systolic blood pressure was increased immediately after the injection of the drug in both the groups. There was no statistically significant difference in SBP among the two groups (**Chart – 2**).

The diastolic blood pressure decreased till 4 min after injection of the drug in both the groups and increased after 20 min. This difference in blood pressure was not statistically significant between the two groups (**Chart – 3**).

The shivering stopped at an earlier point of time in tramadol group when compared to the pethidine group which was statistically significant. Hence, tramadol has significant advantage over pethidine for stopping the shivering (**Table – 2**).

Sedation characteristics are significant at 5 minutes and 10 minutes for pethidine. Pethidine causes more sedation tramadol at 5 and 10 minutes (**Table – 3**).

Table - 3: Mean Sedation characteristics (according to ramsay's sedation scoring).

Time	Group T	Group P	P value, Sig
0 min	2.0	2.0	
1 min	2.0	2.0	
2 min	2.0	2.0	
3 min	2.0	2.0	
4 min	2.0	2.0	
5 min	2.0	2.1	0.01, Sig
10 min	2.0	2.1	0.04, Sig
20 min	2.0	2.0	
30 min	2.0	2.0	
45 min	2.0	2.0	
60 min	2.0	2.0	

Discussion

This study was mainly undertaken to study the efficacy of pethidine and tramadol in control of shivering in patients undergoing surgery under regional anesthesia. In this study, the two groups were comparable with respect to the demographic characteristics. This study had shown that, there was no significant difference in the hemodynamic responses. This study had shown that the time of disappearance of the shivering was lower in tramadol group compared to the pethidine group. The sedation after 4 minutes was higher for pethidine than tramadol.

Many studies have demonstrated the usefulness of Tramadol in control of shivering, studies have also demonstrated that, Tramodol is more effective in treatment of shivering when compared to other drugs like Pethidine and amitriptyline [5, 6, 7, 8]. Different doses of Tramadol from 0.2 mg/kg to 3 mg/kg were used to control post-operative shivering in different studies [9, 10].

Aditi, et al. [1] conducted a study on 60 ASA grade 1 and grade 2 patients who developed shivering after regional anesthesia, they compared the effect of Tramadol 1 mg/kg with Pethidine 1 mg/kg [5, 7]. They concluded Tramadol is superior to Pethidine in control of shivering. In their study, the mean response time for Tramadol group was 1 min and 3 min for pethidine. In the present study there was an increase in the response time in both of the two groups of drugs [1].

Talakoub, et al. [6] studied the effect Tramdol 0.5 mg/kg and Pethidine 0.5 mg/kg on post anesthetic shivering in parturients under spinal anesthesia. In their study, time of cessation of shivering from the time of drug administration was 2.5 min for Tramadol and 5.0 min for pethidine. The time taken for cessation of shivering in the present study is comparable though slightly higher than the above study [6].

Bhatnagar, et al. in their study administered Tramadol at 1 mg/kg and pethidine at 0.5 mg/kg iv for post anesthetic shivering. They found that the number of patients who stopped shivering in 10 min were significantly higher in Tramadol group when compared to pethidine group. This study is also comparable to the present study [11].

The vital parameters like HR, SBP, DBP did not show any significant change with the administration of Tramadol. There was a significant increase in the HR in the pethidine group in the 2nd minute but this is a known characteristic of pethidine. Studies have found that administration of Tramadol 0.2 mg/kg to 3 mg/kg does not affect the hemodynamic and other vital parameters of the patients. One of the limitations of the present study is that core temperature the patients were not measured.

In the present study it was found that recurrence of shivering present in both groups. But in the pethidine group recurrence was seen as early as 30 minutes whereas it was 45 min with Tramadol. Since Tramadol does not cause significant respiratory depression, it can be safely used in management of recurrence of shivering.

The probable reason for recurrence of shivering could be result of low concentration of the active drug, when hypothermia is still persisting and individual variations in the core temperature [1].

This study did not control tightly the various factors which might influence the incidence of shivering, like the temperature of drugs and intravenous fluids and temperature of the operating room. However, this should not have affected the validity of comparisons. First, the current study focused on the response after treatment, rather than the incidence of shivering. Second, by randomization, the two study groups had been subjected to a similar degree of influence of these factors. Some patients developed recurrence of shivering after initial control.

Conclusion

This study was mainly undertaken to compare the efficacy of tramadol and pethidine in controlling the post-operative shivering. From the findings of the study it can be concluded that Tramadol in a dose of 0.5 mg/kg iv is an effective dose of Tramadol for control of shivering in patients undergoing regional anesthesia and it is better than pethidine for the same.

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