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Original Research Article

Comparative evaluation of dexmedetomidine with tramadol for post spinal anaesthesia shivering: a prospective randomized comparative study

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ABSTRACT

Background: Shivering after spinal anaesthesia is an unpleasant complication that also results in increased oxygen demand. Researchers have looked at various dosages of tramadol to see whether it helps with shivering after spinal anaesthesia. We compared dexmedetomidine with tramadol 1 mg/kg for the management of post-spinal anaesthesia shivering.

Methods: We selected 50 patients who developed shivering after subarachnoid block and split them in half; each group had 25 individuals. One group was administered 1mg/kg intravenous tramadol diluted in 100 ml normal saline, while the other group received 0.5 mcg/kg of dexmedetomidine diluted in 100 ml normal saline. Response time, defined as the duration until shivering stopped after drug administration, was the primary outcome measure. Response rate (defined as a complete cessation of shivering within 15 minutes of administering the drug), recurrence of shivering, changes in clinical parameters and pharmacological side effects were considered secondary outcomes.

Results: When compared to tramadol (8.91±1.36 minutes), dexmedetomidine (6.74±1.38 minutes) had a considerably shorter response time ($p<0.001$). Both groups showed a 96% response rate and 8% recurrence of shivering. There was 1 case of hypotension with dexmedetomidine and 2 cases of nausea with tramadol. All patients in group T recorded a sedation level of 1, whereas all patients in group D recorded a sedation score of 2 ($p<0.001$).

Conclusions: Both dexmedetomidine and tramadol are effective in treating post spinal anaesthesia shivering, but the time taken for shivering to stop completely was significantly lesser with dexmedetomidine(0.5 µg/kg) than with tramadol(1 mg/kg).

Keywords: Dexmedetomidine, Post spinal anaesthesia shivering, Tramadol

INTRODUCTION

Lower limb and abdominal procedures often use spinal anaesthesia as a regional anaesthetic approach. Post spinal anaesthesia shivering is a complication that causes discomfort to the patient. It is an unpleasant feeling that also results in increased oxygen demand and myocardial depression. This becomes more detrimental in cardiac patients and increases the risk of myocardial infarction. Shivering can also cause stretching of surgical incision, increasing postoperative pain.[1] It interferes with monitoring and increases heart rate, blood pressure and intracranial pressure.[1] The hypothalamus regulates the body's core temperature, keeping it within a range that includes the points where perspiration and vasodilation are possible and the points where shivering and vasoconstriction are conceivable. Minimally reduced core temperature triggers vasoconstriction and shivering.[2] The drop in core body temperature after spinal anaesthesia is

due to vasodilation and heat redistribution from the heated core to the periphery.[3-5]

The treatment of shivering after spinal anaesthesia has included a wide range of pharmacological and non-pharmacological approaches. Non-pharmacological methods to prevent hypothermia are forced-air warming, blankets, warm intravenous fluids and maintaining the temperature of the operation theatre. Postoperative shivering may be alleviated by many drugs, the most common of which are pethidine, clonidine and tramadol. Opioid agonist tramadol is useful for postoperative shivering management, but it comes with unpleasant side effects such as vomiting and nausea, particularly at higher dosages.

Additionally, research has shown that the centrally active alpha agonist dexmedetomidine may effectively prevent shivering after spinal anaesthesia. Mohta M et al, compared different doses of tramadol and reported that 3 mg/kg had effective anti-shivering effects, but it was linked to an increased risk of nausea and vomiting.[6] Most studies comparing tramadol and dexmedetomidine have used 0.5 mg/kg dosages of tramadol.[7-10] We compared the effectiveness and adverse effects of dexmedetomidine 0.5 mcg/kg with 1 mg/kg tramadol for management of shivering after spinal anaesthesia.

METHODS

Study design

This prospective single-blind randomized comparative clinical trial was done in the Department of Anaesthesiology, St. Stephen's Hospital, Delhi, from January 2, 2017, to April 9, 2018, after receiving appropriate clearance from the ethics committee. The research included patients with ASA grades I and II, aged 18 to 65 years, scheduled to have lower abdomen or lower limb procedures. Using a computer-generated random number and allocation concealment, we allocated 50 patients who developed shivering after subarachnoid block into two groups of 25 each.

Two groups were administered the drug tramadol at a rate of 1 mg/kg body weight and 0.5 mcg/kg body weight of dexmedetomidine, respectively, slowly IV in 100 ml of normal saline.

After checking the fasting status, consent for surgery monitors were attached as continuous pulse rate, NIBP, ECG and SpO2 monitoring. Aseptically, a 25 G Quincke's spinal needle was used to provide a subarachnoid block after securing the intravenous cannula. All operating rooms were kept at a constant temperature of around 24 to 26 degrees Celsius. A face mask was used to provide 6 L/min of oxygen. Patients were not actively warmed but were draped. Anesthetics and intravenous fluids were given at room temperature. We monitored vital signs such as heart rate, blood oxygen saturation and non-invasive blood pressure (NIBP) every 5 minutes for the first half an hour and every 10 minutes thereafter. After administering the drug under evaluation, the patient was monitored for 60 minutes.

Grades of shivering, as undermentioned, were noted. [11] "Grade 1: Piloerection, peripheral vasoconstriction and peripheral cyanosis with no visible muscle activity. Grade 2: Visible muscle activity which is confined to one muscle group. Grade 3: Visible muscle activity seen in more than one muscle group. Grade 4: Visible muscle activity that involves the whole body."[11]

The research included patients who had shivering of grade 3 or 4. All the patients were divided into two significant groups without knowing which drug was being given to them to maintain single blinding in the study.

Individuals in Group D were slowly administered 0.5 mcg/kg of dexmedetomidine intravenously in 100 ml of normal saline, while those in Group T were given 1 mg/kg of tramadol intravenously in 100 ml of normal saline. Response time, defined as the duration until shivering stopped after drug administration, was the primary outcome measure. Recurrence of shivering, response rate (defined as shivering halting after 15 minutes of administering the drug), changes in clinical parameters during shivering treatment and side effects, if any, of the respective drugs were considered secondary outcomes. If shivering recurred, patients in the respective groups were given an extra dosage of either tramadol (1 mg/kg) or dexmedetomidine (0.5 mcg/kg).

The following side effects were recorded: nausea, vomiting, bradycardia (heart rate<50/min), hypotension (blood pressure<20% of baseline) and sedation. A bolus dose of atropine (0.02 mg/kg) was administered intravenously to treat bradycardia". Hypotension was treated with 6 mg ephedrine IV boluses. Metoclopramide 10 mg intravenously was administered as needed to alleviate nausea and vomiting.

Following administration of the drug under study, the level of sedation was assessed using a four-point scale in accordance with Filos et al.[12] "Grade 1: Awake and alert, Grade 2: Drowsy, responsive to verbal stimuli, Grade 3: Drowsy, arousable to physical stimuli, Grade 4: Unarousable."[12]

Statistical analysis

The data was analyzed using SPSS 18.0 and the R environment ver.3.2.2, while graphs, tables and other visual representations were created using Microsoft Word and Excel.

The current investigation included descriptive and inferential statistical analyses. Number (%) is used to represent the results of categorical data, whereas Mean (SD) (Min-Max) is used to represent the results of

continuous measures. The threshold of significance is determined at 5%. The following assumptions on data are made: Assumptions: First, all dependent variables must have a normal distribution. Second, all samples must be randomly selected from the population. Third, all sample cases must be really independent.

As part of the intergroup analysis, the relevance of the study's continuous scale parameters on the metric parameters was determined using a two-tailed, independent Student t-test. Leven's test was executed to evaluate the homogeneity of variance.

For non-parametric qualitative data analysis, the chi-square/Fisher exact test has been used to determine the significance of research parameters on a categorical scale between two or more groups. Fisher exact test used for tiny cell samples.

According to a prior study conducted by Geeta et al, on shivering management, a sample size of 50 (25 in each group) was deemed sufficient for a two-group comparative clinical study with a minimum difference of 0.53 min and a standard deviation of 0.81.[13] The study was conducted at a 5% level of significance and had 90% statistical power.

A study with research hypotheses has two potential results: either the null hypothesis (Ho) states that m1=m2 or the alternative hypothesis (Ha) states that m1=m2+d, where d is the difference between the two means and n1 and n2 are the sample sizes for group I and group II, respectively, so that N=n1+n2. For ethical, financial, logistical or any other reason that may necessitate an uneven sample size, the researcher takes the ratio r=n1/n2 into consideration.

The study's overall sample size is then calculated as follows.

$$N = \frac{(r+1)(Z_{\alpha/2} + Z_{1-\beta})^2 \ \sigma^2}{r\, d^2}$$

Where Z is the normal deviate at the level of significance (Z is 1.96 for a 5% level of significance and 2.58 for a 1% level of significance). Z1 is the normal deviate at 1-% power with % of type II error (0.84 at 80% power and 1.28 at 90% statistical power). r=n1/n2 is the ratio of sample size required for two groups, generally it is one for keeping equal sample size for two groups.

RESULTS

Both groups were similar in age, weight, number of surgeries, gender breakdown and shivering severity (Table 1). The response rate was 96% in both groups (Figure 1a). In contrast, the dexmedetomidine group had a significantly shorter response time (Figure 1b). Response time in group T was 8.91±1.36 and group D was 6.74±1.38 minutes. 8% of patients showed a recurrence of shivering in both groups (Figure 2).

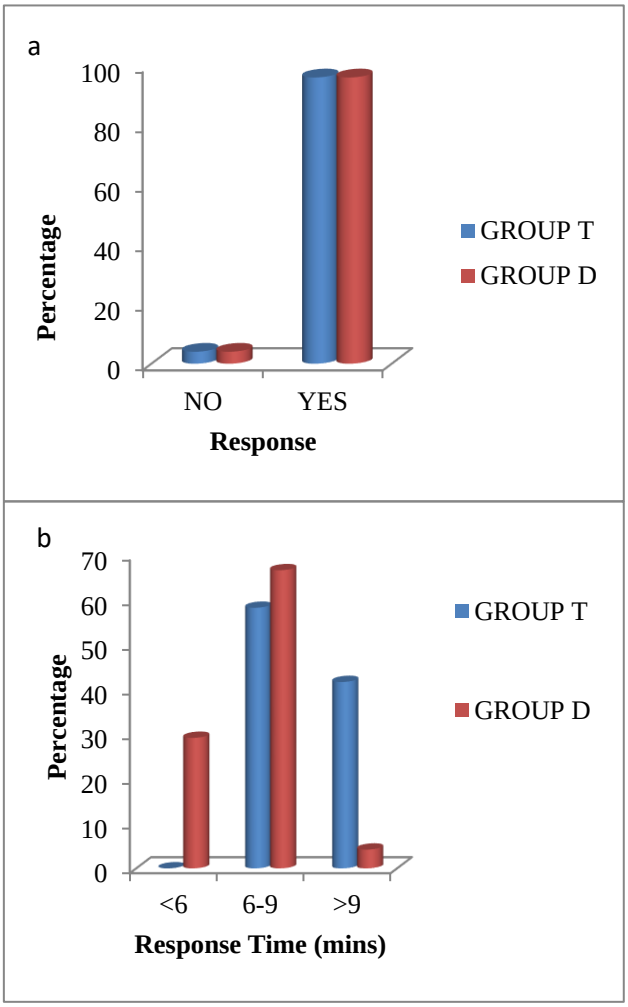

Figure 1 (a and b): Comparison of response rate between the two groups. Comparison of response time between the two groups.

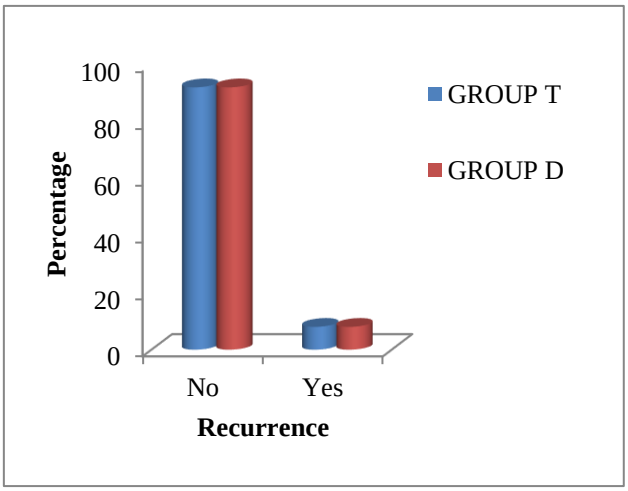

Figure 2: Comparison of recurrence of shivering between the two groups.

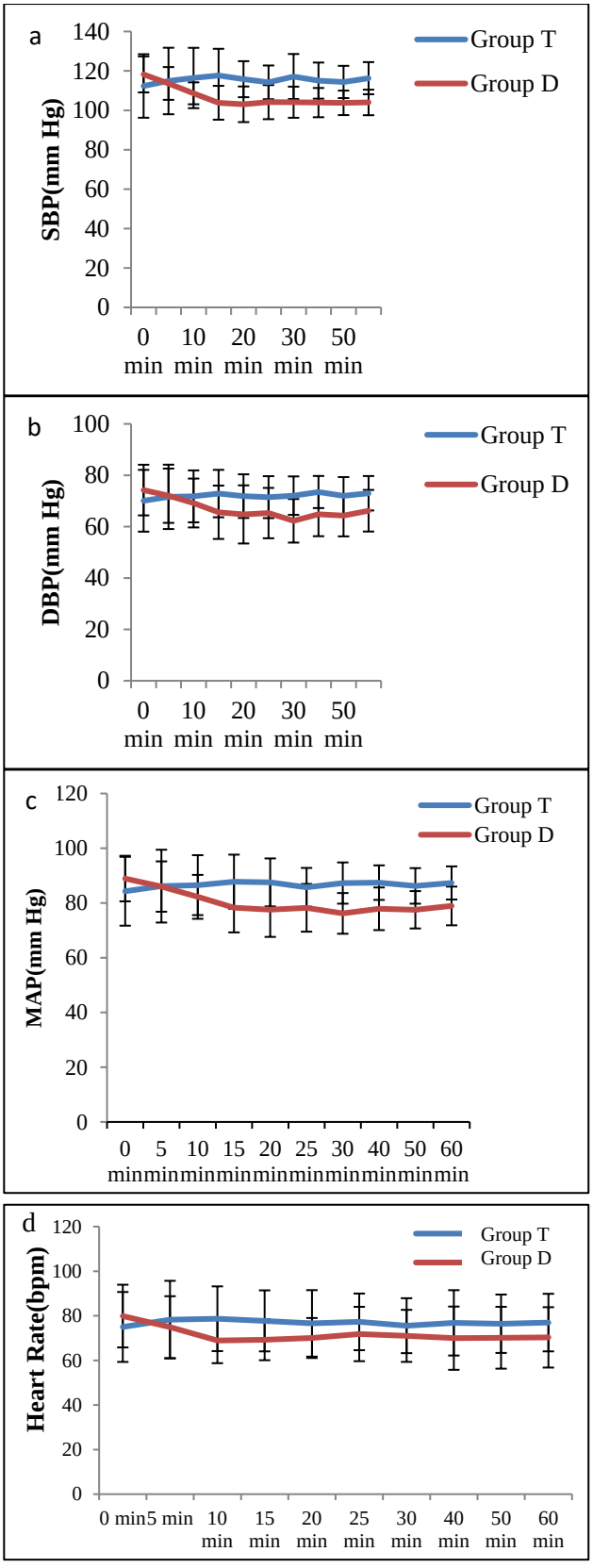

Figure 3: (a) Comparison of SBP between the two groups (b): Comparison of DBP between the two groups (c): Comparison of MAP between the two groups. (d): Comparison of heart rate between the two groups.

In the entire study group, only 3 patients showed side effects (Table 3). All patients in Group T recorded a sedation score of 1, whereas all patients in Group D recorded a sedation score of 2 (p<0.001).

Table 1: Demographic parameters.

Parameters	Group T (n=30)	Group D (n=30)	P value
Age (in years)	38.44 (17.03)	36.4 (13.11)	0.637*
Mean (SD)			
Gender			
Male/Female (N)	14/11	17/8	0.382#
Weight (kg)	61.32 (5.98)	60.00 (4.43)	0.380*
Mean SD			
ASA I/II/ ()	20/5	19/6	0.733#
Grades of shivering I/II/III/IV	0/0/15/10	0/0/15/10	1$
Duration of surgery	75.40 (25.82)	77.20 (26.62)	0.809*

*student t-test, #chi square test, $Fischer exact test

Table 2: Response time distribution of patients in two groups studied.

Response time	Group T	Group D	Total
<6	0 (0%)	7 (29.2%)	7 (14.6%)
6-9	14 (58.3%)	16 (66.7%)	30 (62.5%)
>9	10 (41.7%)	1 (4.2%)	11 (22.9%)
Total	24 (100%)	24 (100%)	48 (100%)
Mean±SD	8.91±1.36	6.74±1.38	7.83±1.74

p<0.001, Significant, Student t-test.

Both groups showed no significant difference in SBP (p=0.119) before the administration of a drug. However, the difference was significant (p=0.021) at 10 minutes and this difference remained significant (p<0.005) in the rest of the observation period, i.e. till 60 mins (Figure 3a). Both groups showed no significant difference in DBP (p=0.187) before the administration of the drug. However, the difference was significant(p=0.012) at 15 minutes and beyond this difference remained significant (p<0.05) (Figure 3b).

Both groups showed no significant difference in MAP (p=0.130) before administration of a drug. However, the difference was significant (p=0.001) at 15 minutes and beyond this difference remained significant (p<0.005) (Figure 3c).

Both groups showed no statistically significant difference in heart rate (p=0.252) before drug administration. At both 10 and 15 minutes, there was a statistically significant difference between groups D and T in terms of heart rate

(p=0.008 and p=0.014, respectively). Although the difference was not statistically significant, a decrease in heart rate was seen up to 15 minutes (Figure 3d). There was no fall in oxygen saturation with no significant difference between the two groups (p=1).

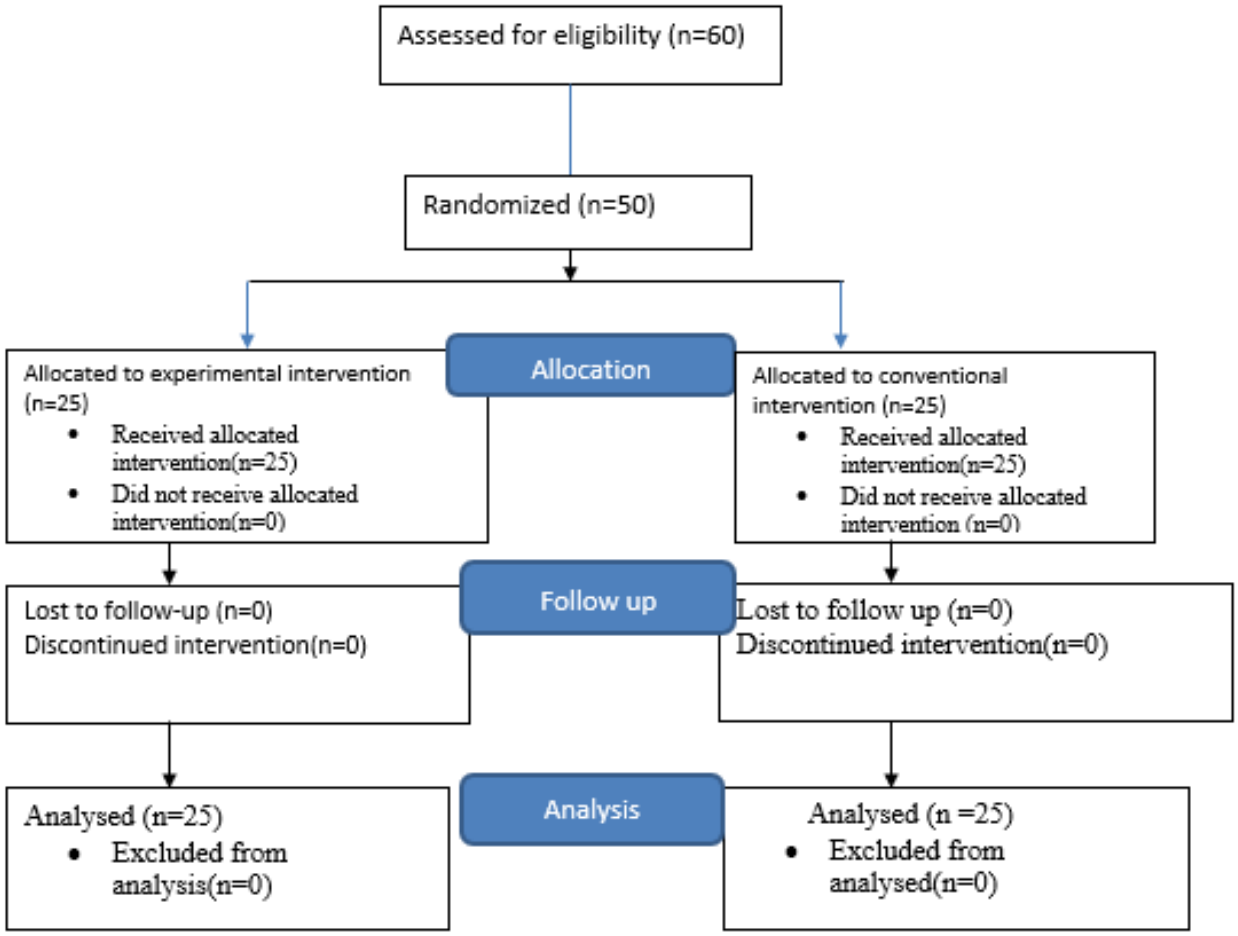

Figure 4: Consort flowchart of participants.

Table 3: Incidence of side effects distribution of patients in two groups studied.

Incidence	Group T (n=25)	Group D (n=25)	Total (n=50)	P value
Nausea	2 (8%)	0 (0%)	2 (4%)	0.490
Vomiting	0 (0%)	0 (0%)	0 (0%)	1.000
Hypotension	0 (0%)	1 (4.0%)	1 (2.0%)	1.000
Bradycardia	0 (0%)	0 (0%)	0 (0%)	1.000

DISCUSSION

Postspinal anaesthesia shivering is a distressing complication. Internal redistribution of body heat, suppression of central thermoregulation and heat loss to the environment are all potential mechanisms. The body's natural reaction to elevate its core temperature is shivering. Tramadol has been used for the management of shivering but it causes nausea and vomiting hence alternative drug has been studied. Most studies compared 0.5 mg/kg tramadol with dexmedetomidine and found cessation of shivering faster with dexmedetomidine.[6] Bozgeyik et al, demonstrated that 100 mg intravenous tramadol and 0.5 mcg/kg dexmedetomidine effectively stopped shivering when compared to saline.[14] We compared dexmedetomidine with tramadol at 1 mg/kg and found similar results, with dexmedetomidine taking lesser time to stop shivering.

Our study showed both drugs to be effective, with a 96% response rate. Geeta et al and Kundra et al, found a 100 % response rate with both drugs. Bhandari et al, found a 98.3% response rate with dexmedetomidine and 86.67% with tramadol.[13,15,16] Geeta Mittal et al and Kundra et al, found similar results with dexmedetomidine 0.5 mcg/kg compared to tramadol 0.5 mg/kg.[13,15] Tramadol can cause nausea and vomiting, while dexmedetomidine can cause bradycardia and hypotension.[17] In our study, the difference in MAP was significant at 15 minutes (p=0.001) and this difference remained significant in the rest of the

observation period. This difference can be attributed to a biphasic blood pressure response of dexmedetomidine. Dexmedetomidine causes a decrease in heart rate, with a significant difference between the two groups at 10 minutes (p=0.008) and 15 minutes (p=0.014).

The initial response, driven by the α-2B AR, lasts for 5 to 10 minutes and is followed by a decrease in blood pressure of about 10% to 20% below baseline. The two phases are thought to be mediated by different α2-AR subtypes. The heart rate declines for 15 minutes. The inhibition of the central sympathetic outflow with dexmedetomidine can explain this fall in heart rate. There was no incidence of bradycardia but 1 case of hypotension with the dexmedetomidine group. In our research, tramadol caused nausea in two individuals. Patients in the dexmedetomidine group were more sedated and arousable on calling, i.e., a sedation score of 2, compared to the tramadol group who were awake, i.e. a sedation score of 1 (p<0.001). Neeharika et al, also concluded that dexmedetomidine may emerge as an alternative to tramadol with a better sedation profile and fewer adverse effects.[18]

In our study, 8% patients showed recurrence of shivering in both the groups. Bhandari et al, showed a recurrence rate of 5% with dexmedetomidine and 8.33% with tramadol.[15] Geeta et al, showed a 4% and 8% recurrence with dexmedetomidine and tramadol, respectively.[13]

The biggest limitation of our research was our inability to assess participants' core body temperatures. As patients were awake in spinal anaesthesia, it would have been uncomfortable to put a temperature probe in the nasopharynx, mid-esophagus or near the tympanic membrane. More studies are required to investigate different dosages of dexmedetomidine to understand its anti-shivering and hemodynamic effects better.

CONCLUSION

Our study concludes that both dexmedetomidine and tramadol are effective in treating post spinal anaesthesia shivering, but dexmedetomidine (0.5 µg/kg) results in faster cessation of shivering than tramadol (1 mg/kg). Sedation caused by dexmedetomidine results in additional comfort to the patient.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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