

A STUDY TO EVALUATE THE EFFICACY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS INTRAVENOUS TRAMADOL FOR TREATMENT OF INTRAOPERATIVE RIGORS AFTER NEURAXIAL ANAESTHESIA

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Abstract

Background: Shivering is a common complication after spinal anaesthesia. Due to the increased oxygen demand during shivering, serious consequences like arterial hypoxia and myocardial ischemia can occur. Both pharmaceutical and non-pharmacological approaches are used to treat shivering. Pethidine, tramadol, and ondansetron were frequently used as medications for shivering. These medications did have certain disadvantages, like significant levels of sedation, nausea, vomiting, and allergies. As a result, their use is now decreasing. Clonidine and dexmedetomidine were recently discovered to have anti-shivering effects. The primary objective of the study is to compare the effectiveness of intravenous dexmedetomidine and intravenous tramadol on reducing the shivering after spinal anaesthesia. **Materials and Methods:** This double blinded randomised controlled trial was conducted in Department of Anaesthesia in Trichy SRM College, Trichy, among patients posted for spinal anaesthesia, who developed intraoperative shivering, during various surgeries. A total of 60 patients were enrolled for this study. They were allocated into two groups with 30 each Group A and Group B in which Group A received intravenous dexmedetomidine 0.5 mcg/kg over 10 minutes, Group B received intravenous tramadol (0.5 mg/kg) over 10 minutes. The response rate, time to cessation of shivering and side effects (if any) was noted. Data collected were entered in Microsoft Excel and analysed in SPSS version 21.0. Data analysis was done using SPSS and continuous variables and categorical variables were interpreted using frequencies (mean±SD) and proportions (%). All the results were analysed using Student's t test and Chi square test. **Results:** All patients who received dexmedetomidine as well as tramadol had cessation of shivering. The time to cessation of shivering was significantly less with dexmedetomidine (164.14±16.12 s) than with tramadol (285.45±21.14s) (P < 0.001). The recurrence rate of shivering with dexmedetomidine was less (3.3%) as compared to tramadol (6.6%). Nausea and vomiting was found to be higher in the case of tramadol and it was found to be statistically significant (p value 0.044). **Conclusion:** Our results suggest that dexmedetomidine provides effective prophylaxis against postoperative shivering associated with spinal anaesthesia without any major adverse effect during the perioperative period when compared to tramadol.

INTRODUCTION

Shivering is characterized as an involuntary, repetitive activity of skeletal muscles. It occurs frequently after anaesthesia, with a 40–70% incidence rate. Intraoperative shivering is the most frequent and uncomfortable side effect of spinal anaesthesia.^[1] It is a very distressing experience that affects patients, perioperative physicians and

operating surgeons leading to physiological stress. Intraoperative shivering leads to various consequences which includes pain, discomfort to patient, obstruct monitoring techniques, increase intraocular and intracranial pressures, intraoperative heat loss, double or even triple oxygen intake, systemic release of pyrogens and postoperative increased sympathetic tone.^[2,3]

There are several factors responsible for shivering during spinal anaesthesia which includes central thermoregulation disturbance, internal body heat redistribution, and body heat loss to the environment.^[4] Several techniques have been employed for the prevention and treatment for shivering after anaesthesia. Tramadol, an opioid receptor agonist is an inhibitor of serotonin (5-hydroxytryptamine) reuptake and norepinephrine in the spinal cord.^[5,6] This simplifies the release of 5-hydroxy-tryptamine, which affects control over thermoregulation. It is a common medication used at present for treatment of shivering.

Recently to prevent these consequences α -2 agonists like dexmedetomidine have been used to reduce the intraoperative shivering. Dexmedetomidine is a highly selective α -2 adrenoceptor agonist with potent effects on the central nervous system.^[7] It also decreases the sympathetic tone with attenuation of the neuroendocrine and hemodynamic responses to anaesthesia and surgery. Hence it shows dual effects controlling the unwanted effects of shivering provoked by hypothermia by vasoconstriction and increased shivering thresholds.^[8] There is a paucity of literature comparing the efficacy of dexmedetomidine with tramadol hence we proposed this study.

Objectives

- To compare the effectiveness of intravenous dexmedetomidine and intravenous tramadol on reducing the shivering after spinal anaesthesia.

MATERIALS AND METHODS

Study design

- A Prospective randomised controlled study

Study area

- Department of Anesthesia, SRM medical college, Trichy

Study duration

- Six months

Study population

- Patients posted for elective surgeries under spinal anaesthesia, who develop shivering intraoperatively.

Inclusion Criteria

- Patients with age group 18-60 years.
- Both sex
- Patients belonging to American society of anaesthesiologists grade 1 & 2

Exclusion Criteria

- Participants not willing to give consent
- Patients with severe systemic illness.
- Patient with known history of substance or alcohol abuse.
- Patient who are allergy to study medicines.
- Pregnant women and Nursing women

Sampling technique

- Non- Probability Convenient sampling

Sample size: 60

- Measurement of variables
- Age was a continuous variable expressed in numbers.

- Gender was a categorical variable (male/female)

Data collection

This double blinded randomised controlled trial was conducted in Department of Anaesthesia in Trichy SRM Medical College, Trichy among patients posted for spinal anaesthesia for various surgeries. The patients were selected using convenient sampling methods, and those who developed shivering were enrolled in this study. A total of 60 patients were enrolled for this study. They were allocated into two groups with 30 each Group A and Group B in which Group A received intravenous dexmedetomidine 0.5 mcg/kg over 10 minutes, Group B received intravenous tramadol (0.5 mg/kg) over 10 minutes.

All patients were monitored continuously and vitals including non-invasive blood pressure (NIBP), pulse rate, SpO₂ and axillary temperature were recorded in the beginning of the surgery and at the onset of shivering from the monitoring chart, after cessation of shivering and then every 10 min till the end of surgery was measured.

Grading of shivering was done using Bedside Shivering Assessment Score (BSAS) describes as follows:

- Grade 0: No shivering
- Grade 1: there is no muscle contraction but mild fasciculation of face or neck or peripheral vasoconstriction but no visible shivering.
- Grade 2: there is visible muscle activity confined to one muscle group.
- Grade 3: there is visible muscular activity in more than one muscle but not generalized.
- Grade 4: Gross muscle activity involving the whole body.

Patients who developed either Grade 3 or Grade 4 of shivering were included in the study. Same criteria were used for grading shivering during recurrence and patients with Grade 3 or 4 shivering were included.

The attending anaesthesiologist would record:

1. Onset of shivering after spinal anaesthesia and the time of recurrence, if present
2. Severity of the shivering
3. Response rate
4. Time to disappearance of shivering (in seconds)
5. Side effects like nausea, vomiting, itching, bradycardia, hypo and hypertension (changes from 20% of baseline of systolic blood pressure/diastolic blood pressure [SBP/DBP]) were also recorded.

Data collected were entered in Microsoft excel 2019 and analysed using software SPSS (Statistical Package of Social Sciences) version 21. Continuous variables and categorical variables were interpreted using frequencies (mean \pm SD) and proportions (%). Student t-test is used to compare the statistical difference between the two groups.

Ethical issues

- Participants were informed about the study and informed consent was obtained
- This study was presented to Institutional Ethical Committee of SRM Medical College, Trichy.

RESULTS

This double blinded randomised controlled trial was conducted among patients posted for spinal anaesthesia for various surgeries to compare the efficacy of intravenous dexmedetomidine and

intravenous tramadol for treatment of intraoperative shivering in patients. The patients were selected using convenient sampling methods, and those who developed shivering were enrolled in this study. They were allocated into two groups, Group A and Group B in which Group A received intravenous dexmedetomidine 0.5 mcg/kg over 10 minutes, Group B received intravenous tramadol (0.5 mg/kg) over 10 minutes.

Group A and Group B were comparable in regards to age, gender, weight and type of procedure.

Table 1: Describes demographic data of participants

S No	Characteristics	Group A (n = 30)	Group B (n = 30)	p value
1	Age (years)	34.1±8.511	35.43±8.523	0.547
2	Weight	63.8±4.143	63.33±5.0187	0.675
3	Gender			
	Male	16 (53.33%)	17 (56.6%)	0.795
	Female	14 (46.66%)	13 (43.3%)	
4	Procedure			
	Inguinal hernioplasty	6 (20%)	7 (23.33%)	0.694
	Stripping of varicose veins	4 (13.3%)	3 (10%)	
	Scrotal surgery	1 (3.33%)	3 (10%)	
	Hysterectomy	5 (16.66%)	6 (20%)	
	LSCS for IUD	3 (10%)	2 (6.66%)	
	Laparotomy for ectopic pregnancy	1 (3.33%)	1 (3.33%)	
	Orthopedic surgeries	8 (26.66%)	6 (20%)	
	Haemorrhoidectomy	2 (6.66%)	2 (6.66%)	

The mean ambient temperature in operating room was 21.36±0.467° C and 21.78±0.564° C and in the recovery room the mean ambient temperature was 24.56±0.647° C and 23.78±0.53° C respectively among Group A and Group B.

The both group participants were observed for disappearance of shivering after treatment with the drug dexmedetomidine and tramadol. One patient (3.33%) from Group A and two patients (6.66%) from Group B had another episode of shivering where it was treated with second dose.

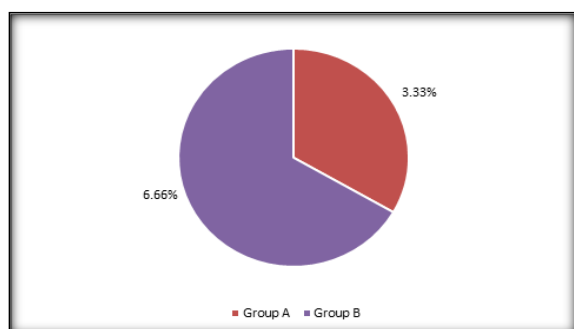


Figure 1: Recurrence of shivering after first dose administration of drug among groups (n = 30)

Table 2 describes anaesthetic parameters among groups. The duration of surgery and duration of spinal anaesthesia was comparable and there was no statistically significant difference among groups. The time for onset of shivering, severity of shivering, and time of recurrence was comparable and there was no statistical significant difference among both groups. The time to disappearance of shivering was significantly lower in Group A compared with Group B.

Table 2: Anaesthetic parameters

S No	Parameters	Group A (n = 30)	Group B (n = 30)	p value
1	Duration of surgery (minutes)	84.14±28.51	85.43±29.423	0.863
2	Duration of spinal anaesthesia (minutes)	131.8±34.24	132.33±35.187	0.953
3	The time for onset of shivering and drug administration (minutes)	73.56±23.456	73.94±24.564	0.951
4	Severity of shivering	3.82±0.214	3.92±0.234	0.089
5	Time to disappearance of	164.14±16.12	285.45±21.14	0.001

	shivering (seconds)			
6	Time of recurrence (minutes)	68.12±14.78	72.44±18.12	0.315

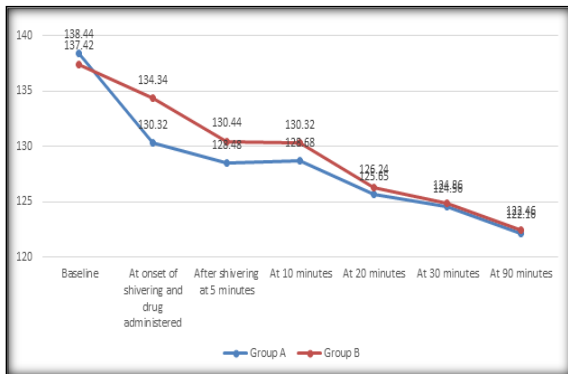


Figure 2: Mean systolic blood pressure among groups (n = 30)

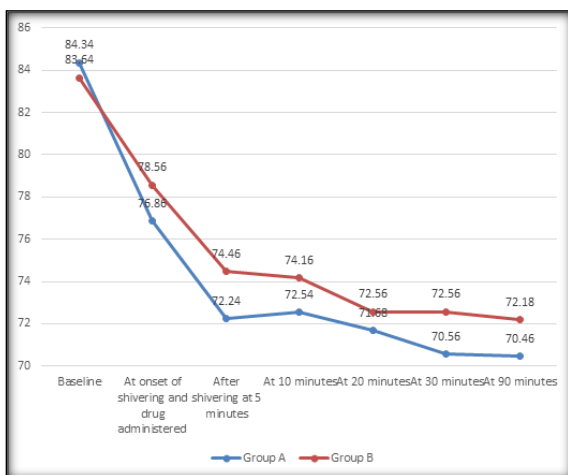


Figure 3: Mean diastolic blood pressure among groups (n = 30)

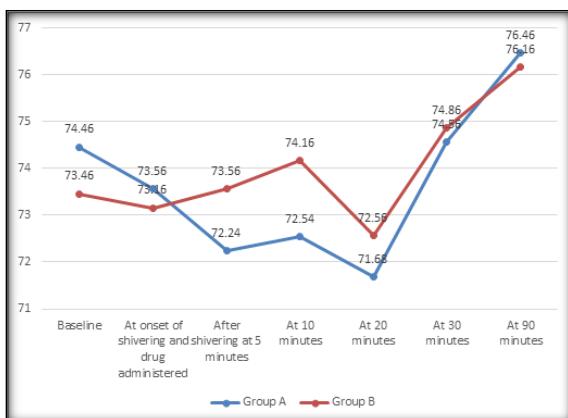


Figure 4: Mean heart rate among groups (n = 30)

Figure 5 shows the incidence of nausea and vomiting among groups. The incidence was higher in Group B and it was found to be statistically significant (p value 0.044).

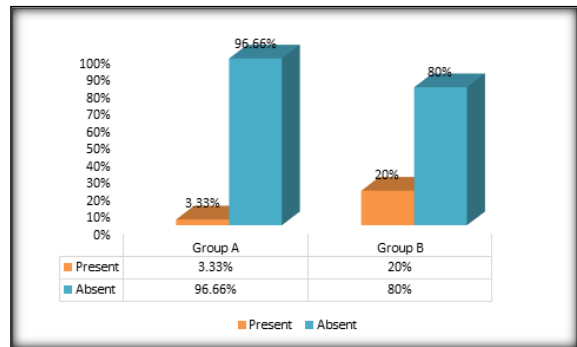


Figure 5: Incidence of nausea/vomiting among groups (n = 30)

There were no reported events of itching, hypotension and bradycardia among both groups.

DISCUSSION

Shivering is known to be a frequent complication in patients undergoing surgery under spinal anesthesia. In our study we found that the time taken for disappearance of shivering in Group A is 164.14±16.12secs and in group B is 285.45±21.14secs though tramadol is a well-known medication for the treatment of shivering, our research shows that dexmedetomidine is equally successful at treating post-Spinal Anaesthesia shivering.

This is similar to a study conducted by Kundra et al.^[9] the time taken for disappearance of shivering is 174.12 ±14.36s and in group B is 277.06 ±23.37s and concluded that dexmedetomidine is effective in reducing intraoperative shivering. A meta-analysis done by Wang et al.^[10] found that dexmedetomidine is superior to tramadol for treating intraoperative shivering due to a greater effective rate of shivering control, an earlier onset of action, and a lower recurrence of shivering which is comparable to our study report.

Another study by Usta B et al also found that dexmedetomidine infusion in the perioperative period significantly reduced the shivering associated with spinal anesthesia during minor surgical procedures without any major adverse effects which is also comparable to our study report.^[11] Our study is similar to a study conducted by Chirag Patel et al.^[12] found that there was a significant statistical significance in response rate for treating shivering between dexmedetomidine and tramadol which is also similar to our study report.

Another study by Easley R et al.^[13] studied the role of dexmedetomidine in the treatment of postoperative shivering in children and they found that dexmedetomidine is used as an alternative to reduce intraoperative shivering which is also comparable to our study report.

Another study by Lim Hern et al.^[14] the response rate to treatment was highest in the dexmedetomidine group, and it was statistically significant when compared to tramadol group ($p = 0.0012$) and concluded that dexmedetomidine 0.5 mcg/kg was more effective than tramadol 0.5 mg/kg and pethidine 0.5 mg/kg which is similar to our study report. A study conducted by Kim YS et al also stated that dexmedetomidine 0.75 or 1.0 mcg/kg provides effective prophylaxis against postoperative shivering as well as an analgesic effect.^[15]

In our study we found the recurrence rate 6.6% is more in group B than group A with the recurrence rate 3.3% which is comparable to a study conducted by Kundra et al stated that six percent patients in tramadol group had recurrence of shivering and none of the patients had recurrence of shivering after receiving dexmedetomidine.

Another study by Paneer et al.^[16] showed that dexmedetomidine took less time to control shivering with no recurrence rate which is comparable to our study report. A study conducted by Mittal et al have also found that injection dexmedetomidine control the shivering with lesser time (2.52 ± 0.44 min compared to 2.23 ± 0.43 min and with less side effects which is comparable to our study report.

In our study we found that the heart rate lower in the dexmedetomidine group when compared with the control group beginning from the 5th minute of infusion until the end of the blockade which is also similar to a study conducted Jalonen et al and Usta et al.^[17]

CONCLUSION

Tramadol can be substituted with dexmedetomidine to treat post-SA shivering. Vomiting and nausea are less common, but shivering is relieved more quickly. Without causing any significant side effects, dexmedetomidine infusion during the perioperative period greatly decreased the shivering brought on by spinal anaesthesia during surgical procedures. Therefore, dexmedetomidine may be considered as an effective drug in shivering control after spinal anesthesia because of its dual effects of anti-shivering and sedation.

Limitations

- Single- centred study with small sample size.
- The study can be conducted using other diversional therapy.
- The study was restricted only to the intraoperative period, no postoperative follow-up for monitoring of shivering.

Conflict of interest

Nil.

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