Original Research Article

A prospective randomized clinical trial for comparison of tramadol and dexmedetomidine for the control of intraoperative shivering under spinal anaesthesia

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Abstract

Background and Aims: Pharmacological methods using variety of drugs like pethidine, morpine, tramadol, clonidine, doxapram, ketansarine, neofam, neostigmine, magnesium sulfate have been tried in post spinal shivering. In the hunt of more safe and efficacious drug, in our study, we compared two easily available and safe drugs dexmedetomidine and tramadol, intravenously administered for treating shivering in patients who received spinal anaesthesia for various surgical procedures. **Methods:** A prospective, randomised, study was conducted in 40 ASA I and II patients of either gender, aged between 20 and 60 years, scheduled for various surgical procedures under spinal anaesthesia. The patients were randomised in two groups of 20 patients each to receive either dexmedetomidine 1µg kg-1 or tramadol 1mg kg-1 as a slow intravenous bolus over 5 minutes. Grade of shivering, onset of shivering, time for control of shivering, recurrence and adverse effects were observed at scheduled intervals. **Results:** Time taken for cessation of shivering was 205.25±18.13 (sec) for dexmedetomidine and 413±16.92 (sec) for tramadol with ("p" value - 0.00). Nausea and vomiting was observed only in tramadol group. The sedation profile of both the drugs was comparable. **Conclusion:** Patients with post spinal anaesthesia shivering can be treated effectively by using dexmedetomidine (1 µg kg-1) and tramadol (1mg kg-1). Dexmedetomidine consumes less time for control of shivering compared to tramadol. It has advantage over tramadol due to reduced side effects like nausea and vomiting

Key Word: tramadol, dexmedetomidine.

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INTRODUCTION

Spinal anaesthesia is a popular and safe anaesthesia technique for various surgeries. Shivering is the most common problem occurring in 19-33% of patients undergoing spinal anaesthesia.[1,2] Shivering is unpleasant for the patient, anaesthesiologist and the surgeon besides being physiologically stressful for the patient. The physiologic role of shivering is to provide heat, but its occurrence in relation to anaesthesia is inconsistent and incompletely understood. Shivering occurs in patients receiving regional anaesthesia and patients recovering from general anaesthesia. It causes several undesirable physiologic consequences including increase in oxygen consumption, carbon dioxide and minute ventilation. It may induce arterial hypoxemia, lactic acidosis, increased intra ocular pressure (IOP) and intra cranial pressure (ICP) and interfere with patient monitoring like electrocardiography(ECG), non-invasive blood pressure (NIBP) and oxygen saturation (SpO_2) etc. Shivering may damage dental prosthesis and poor-quality teeth. It may

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negate orthopaedic procedures like fractures and dislocations and can be detrimental to patients with low cardiopulmonary reserve[3].Spinal anaesthesia is known to decrease the vasoconstriction and shivering thresholds. There is core to periphery redistribution of heat due to spinal induced vasodilatation and shivering is preceded by core hypothermia and vasoconstriction above the level of block[2.4] Fascinatingly, core hypothermia following spinal anaesthesia may not trigger sensation of cold as the cutaneous vasodilatation resulting from sympathetic blockade increases skin temperature leading to a sensation of warmth although accompanied by thermoregulatory shivering[5].Shivering can be controlled through several methods such as non-pharmacological and pharmacological. Intraoperative hypothermia can be reduced by limiting cutaneous heat loss to the environment constituting cold operating room, evaporation from surgical incisions and conductive cooling produced by administration of cold intravenous fluids. Fluid warmers[6], ambient operating room temperature, space blankets[7], surgical drapes and active circulating water mattress have been used for limiting heat loss. Pharmacological methods uses variety of drugs like pethidine, morpine, tramadol[8,9] clonidine, doxapram, ketansarine, neofam, neostigmine, magnessium sulphate[10] have been tried. These drugs are easily available and cost effective.In the hunt of safe and efficacious drug, in our study, we compared two easily available and safe drugs dexmeditomedine and tramadol, intravenously (IV) administered for treating shivering in patients who received spinal anaesthesia for various surgical procedures. The aim and objective of this study is to compare the efficiency of two drugs 1 µg kg-1 dexmedetomidine and 1mg kg-1 tramadol with respect totime from drug administration to control of shivering, Recurrence of shivering after administration of drug, adverse effects and hemodynamic changes.

METHODS

A prospective, randomized comparative study was conducted after a written informed consent from the patients and approval from Institutional Ethics Committee.40 American Society of Anaesthesiologists (ASA) Grade I and II consenting patients of either gender aged 20-60 years scheduled for elective lower abdominal, lower limb, orthopaedic, urology and plastic surgeries under spinal anaesthesia were included in the study. 20 patients were selected in each group with confidence interval > 95% and power > 95% to detect a mean difference of 3 min in the time for shivering control based on the literature reference[11]. All patients included in the study were pre-medicated with tablet diazepam 10mg on the night before the surgery. Patients with known hypersensitivity to dexmedetomidine or tramadol, cardio-pulmonary, renal or hepatic disease, hyperthyroidism, psychiatric disorder, urinary tract infection, severe diabetes or autonomic neuropathies, known history of substance or alcohol abuse, patients receiving any pre-medication were not included in the study. Patients were shifted to operation theatre and baseline parameters were recorded using standard monitors. They were preloaded with 10ml kg-1 of Ringers Lactate solution. Baseline temperature was recorded using a mercury thermometer in the axilla placed in the vicinity of the axillary artery[5]. Operation theatre temperature was maintained at 22-25°C.All patients in our study received spinal anaesthesia in left lateral position using 26G Quincke needle via midline approach in the L3-L4 intervertebral space under strict aseptic precautions and local anaesthesia to the skin. Following free flow of CSF, 0.5% bupivacaine (hyperbaric) was injected depending on the requirement of surgery (3-4ml).They were administered 2 liters per minute of oxygen by Hudson transparent face mask and were adequately covered with surgical drapes. Those who developed shivering after administering spinal anaesthesia were included in the study. Shivering of grades 2 and 3 proposed by Crossley and Mahajan scale was considered to require treatment. Those who developed shivering of abovementioned grades were randomly allotted to one of the two study groups. Group D- dexmeditomedine group receiving single intravenous bolus dose of 1mcg kg-1 over 5 min. Group T – tramadolgroup patients receiving 1 mg kg-1 tramadol IV over 5 minute. The study drug was then administered IV as per the allotted group. The time from drug administration till the disappearance of shivering was accurately noted in seconds. All the patients were monitored at intervals of 1 minute, 3min, 5min and thereafter 10, 20 and 30 minutes till the end of surgery. They were observed for failure of drug treatment, recurrence of shivering and side effects such as nausea, vomiting, bradycardia (<50/min),hypotension(>20% of baseline),dizziness and sedation score were recorded. Sedation score was assessed with a fourpoint scale as per Filos, [1]awake and alert[2]drowsy, response to verbal stimuli[3] drowsy, arousable to physical stimuli [4]unarousable. Bradycardia, hypotension and vomiting was treated with atropine, mephentamine and metoclopramide, respectively, in titrated doses when required. Parameters studied were; time for onset of shivering (min), grade of shivering: as per Crossely and Mahajan Scale.(Grade0-no shivering, Grade1-piloerection, peripheral vasoconstriction, peripheral cyanosis without other cause but without visible muscular activity, Grade 2-visible muscular activity confined to one muscle group, Grade 3-visible muscular activity more

than one muscle group. Grade 4 gross muscular activities involving the entire body, temperature at onset of shivering, time from drug administration to control of shivering, recurrence of shivering after drug administration, hemodynamic changes and adverse drug effects. Data was analyzed with independent 't' test for parametric data, Chi-square test and Fischer's exact test for non-parametric data.

RESULTS

In our study total 40 patients met the inclusion criteria. They were randomly divided in to two groups i.e. Group D and Group T. Group D refer to dexmedetomidine and Group T to tramadol.

Table 1: Demographic profile of patients of both groups

	N=20		
	Group D (%)	Group T (%)	P Value
Age (Years)	38.6±12.6	37.1±11.3	0.69
Gender(Male/Female)	12/8	6/14	0.06
Weight (Kg)	61.4±9.6	61.25±8	0.96
Grade 2/Grade 3 Shivering	7/13	11/9	0.34

Both groups are comparable with respect to Age, Gender, Weight and Grade of Shivering.

Table 2: Temperature Monitoring and Time of Onset and control of Shivering

	Group D (%)	Group T (%)	P Value
Temperatureprior to spinal anaesthesia (°C)	37.7±0.34	37.07±0.34	1
Temperature during Shivering (°C)	36.17±0.32	36.35±0.37	0.10
Time of onset of shivering (min)	39.95±9.60	41.05±7.02	0.68
Timefrom drug administration to control of shivering (Sec)	205±18.3	413±16.9	0

Both groups are comparable with respect to temperature during shivering and time of onset of shivering. There is significant difference between the two groups with respect to control of shivering with P value < 0.01.

Table 3: Adverse Effects

Adverse effects	Group D (%)	Group T (%)
Nausea	0	20
Vomiting	0	25
Recurrence of shivering	0	10
Bradycardia	0	0
Hypotension	0	0

Adverse effects are observed only in Group T and absence in Group D. Haemodynamically both groups are comparable.

Table 4: Grades of Sedation

Grades of Sedation as per Filos	Group D (%)	Group T (%)
Grade 1	0	80
Grade 2	90	20
Grade 3	10	0

Grade 2 and Grade 3 sedation are seen in Group D and Grade1 and Grade 2 sedation are seen in Group T.

DISCUSSION

Spinal anaesthesia is a safe and popular anesthesia technique used world over for various surgeries. Variety of factors contributes to decrease the core body temperature in patients receiving spinal anaesthesia. These include sympathetic block causing peripheral vasodilation, increased cutaneous blood flow resulting in increased heat loss through skin, cold operating room, rapid IV infusion of cold IV fluids, direct effect of cold anaesthetic solution upon the thermosensitive structures of the spinal cord. Opioid and nonopioid mechanisms of action of tramadol are thought to act synergistically on descending inhibitory pathways in the central nervous system (CNS). Anti shivering effect of tramadol is mediated via its serotoninergic or noradrenergic activity. In healthy volunteers, tramadol decreased the sweating, vasoconstriction and shivering thresholds. dexmedetomidine reduces the vasoconstriction threshold and the shivering threshold and is associated with a lower incidence of shivering[12]. Dexmedetomidine comparably reduces the vasoconstriction and shivering thresholds, thus suggesting that it acts on the central thermoregulatory system rather than preventing shivering peripherally. It may be a good choice because of its dual effects related 'anti-shivering' and sedation. The demographic parameters between the two groups were

comparable, with respect to age, gender and weight. In our study we recorded temperature using mercury thermometer placed in the vicinity of the axillary artery. This was as per deductions by Daniel. L *et al*[5] study wherein he concluded that axillary temperatures were fairly good indicator of core body temperature when the thermometer was placed in the vicinity of the axillary artery. Following spinal anaesthesia the mean temperature at which shivering occurred in patients in our study was 36.17ºC±0.3 for group dexmeditomedine and 36.35ºC±0.3 for group tramadol. The difference was not significant. In a study by Aditi Dhimar *et al*[8] wherein the mean temperature at shivering occurred was 36.2ºC+/-0.4.In our study shivering was controlled in 413±16.92 seconds after drug administration in patients in the tramadol group while it was 205±18.3 seconds with patients in Dexmeditomedine group. The results between the two groups were statistically significant (P =0.00).In a study Blaine E.R et.al[13]all children had a cessation of shivering behavior within 5 min following the completion of dexmedetomidine administration. The onset of effect was 3.5 +/- 0.9 min, which was comparable with our study. Mittal G *et al*[14] reported similar results i.e.control of shivering was 2.52±0.44 in dexmeditomedine group and 5.92±0.81 in tramadol group. The incidence of nausea and vomiting with tramadol in our study was 20% and 25%, respectively. The results correspond with that of other studies by Reddy V S *et al*[11].In a study by Mittal G *et al*[14]the incidence of nausea and vomiting were 28% and 20% respectively, which occurred with our study. Sedation scores were grade 2 in dexmeditomedine in 18(90%) patients and grade 3 in 2(10%) patients. Our study concurs with the report by Karaman *et al*[15] according to whom intra-operative dexmedetomidine infusion caused minimal sedation inspite of using a loading dose of 1 µg kg-1 followed by a maintenance infusion of 0.5 µg kg-1h-1. The sedation scores were grade 2 in tramadol group in 16(80%) patients and grade 1 in 4(20%) patients. There was not much difference in the number of patients who were sedated in either group. The sedation seen with dexmedetomidine, in the absence of nausea and vomiting, is beneficial. The hemodynamic parameters were comparable in both groups which concurs with a study by Mittal G *et al*.[14]. The other α agonist clonidine is associated with a high incidence of hypotension and bradycardia. In that respect, dexmedetomidine has an edge as it causes less variation in hemodynamics. In our study the recurrence rate was 10% seen only in tramadol group. Maheshwari *et al*[16] reported similar recurrence rate with tramadol as in their study (8%). In a study by Mittal G *et al*.[14] recurrence rate was 8%.

CONCLUSION

Patients with post-spinal anaesthesia shivering can be treated effectively by using dexmedetomidine (1 µg kg-1) and tramadol (1mg kg-1). Dexmedetomidine consumes less time for control of shivering compared to tramadol. It has advantage over tramadol due to reduced side effects like nausea and vomiting.

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