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COMPARISON OF INTRAVENOUS DEXMEDETOMIDNE AND TRAMADOL FOR POST SPINAL ANAESTHESIA SHIVERING: A RANDOMIZED STUDY

Anaesthesiology

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ABSTRACT

INTRODUCTION: Spinal anaesthesia significantly impairs the thermoregulation system by inhibiting tonic vasoconstriction, which plays a significant role in temperature regulation. It also causes a redistribution of core heat from the trunk (below the block level) to the peripheral tissues. These factors predispose patients to hypothermia and shivering. The present study aims to compare the efficacy of I.V. Tramadol, and I.V. Dexmedetomidine in the treatment of post spinal anaesthesia shivering in patient undergoing infra umbilical surgeries.

MATERIAL AND METHODS: A prospective randomised comparative study was conducted after institutional ethical committee's approval on 60 patients of ASA grade 1 and 2 who developed shivering of grade 3 and 4 after spinal anaesthesia. Patients were randomly allotted in to two groups, namely group T(n=30) who received Tramadol 0.5mg/kg i.v. and group D (n=30) who received dexmedetomidine 0.5µg/kg i.v. Vital parameters of the patient such as Heart rate, Blood pressure, SPO2, RR and temperature were monitored at regular intervals and noted. Onset of shivering, time taken to stop shivering, recurrence of shivering and side effects like nausea, vomiting, bradycardia, hypotension and sedation were also noted.

RESULTS: The mean temperature at which patient in group T developed shivering was 36.22±0.190C and in group D was 36.27±0.160C ($p > 0.05$). The mean duration of shivering to occur following spinal anaesthesia was also comparable in both the groups. Both the groups had 100% response rate in controlling the shivering. Mean time required for cessation of shivering after treatment was 5.48±0.50 minutes in group T and 2.83±0.42 minutes in group D ($p < 0.05$).

CONCLUSION: Both dexmedetomidine and tramadol are effective in treating patients with post-spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to tramadol, the difference being statistically significant. Furthermore, dexmedetomidine causes fewer adverse effects like nausea and vomi

KEYWORDS

INTRODUCTION

Shivering is defined as an involuntary, repetitive activity of skeletal muscles. Shivering is physiological response to core hypothermia in an attempt to raise metabolic heat production. 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 in completely understood.

Spinal anaesthesia significantly impairs the thermoregulation system by inhibiting tonic vasoconstriction, which plays a significant role in temperature regulation. It also causes a redistribution of core heat from the trunk (below the block level) to the peripheral tissues. These factors predispose patients to hypothermia and shivering.[1] 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.[2]

Various methods are available for the control of shivering. These may be non-pharmacological or pharmacological. Intra-operative hypothermia can be minimized by any technique that limits cutaneous heat loss to the environment such as those due to cold operating room, evaporation from surgical incisions and conductive cooling produced by administration of cold intravenous fluids.

The non-pharmacological management is by external heating like the use of radiant warmer, pre warming of patients, warm fluids [3] etc. Various pharmacological treatments like i.v. opioids (ie. Alfentanil and pethidine), cholinomimetic agent physostigmine, nalbuphine and meperidine, 5-HT3 antagonist (ondansetron, dolasetron) have been used; however, side effects like hypotension, sedation, respiratory depression, nausea and vomiting, limit their use. Hence, the hunt for ideal anti-shivering agent is continuing.

Our study was designed to compare a small dose of dexmedetomidine, a α_2-adrenoceptor agonist, with that of tramadol, an opioid analgesic for control of shivering during spinal anaesthesia. These drugs are easily available and cost effective.

AIM AND OBJECTIVES

The aim of our study is to compare Dexmedetomidine and tramadol for control of shivering in post spinal anaesthesia in terms of following objects:-

Primary objective:

- To determine the mean of time taken for cessation of shivering after medication in both group.

Secondary objective:

- Reappearance of shivering/ refractory shivering.
- To compare the side effects, if any.

MATERIALS AND METHODS

This prospective randomised study was conducted at the **JHALAWAR MEDICAL COLLEGE, JHALAWAR (RAJASTHAN).** After approval of The Institutional Ethical Committee, written informed consent was taken from each patient. 60 patients of American Society of Anaesthesiologists (ASA) grade I & II undergoing surgery under subarachnoid block, were included in this prospective randomized study.

All cases were divided into two groups:

Group - D (n=30) during shivering patient treated with inj. Dexmedetomidine 0.5mcg/kg diluted to 10 ml saline.

Group – T (n=30) during shivering patient treated with inj. Tramadol 0.5 mg/kg diluted to 10 ml saline.

SELECTION OF PATIENTS

INCLUSION CRITERIA:-

- Either sex (M/F) Patients aged 20-60yrs.
- Height ≥ 150 cms.
- Weight 50-80 kgs.
- Patients who gave written informed consent and not known allergic to study drug.
- ASA grade I-II.
- Patients who developed post spinal anaesthesia shivering intraoperatively.

EXCLUSION CRITERIA:-

- All contraindications to spinal block.
- Pregnancy.

- Chronic history of headache and backache.
- Spinal deformity or infection at the local site.
- Patient allergic to drug.
- Failed spinal block.
- Patient refusal.
- H/O Acute infection, fever, sepsis.

PROCEDURE

All patients were thoroughly examined pre-operatively which will included history, physical examination, all routine investigation, vital parameters of the patients (blood pressure, pulse rate, respiratory rate, temperature), examination of respiratory, cardiac, CNS and alimentary system.

The procedure was explained to the patients and a written informed consent for spinal anaesthesia and operation was taken.

Patient was taken to the OT, fasting status was confirmed, monitors were attached to the patient; base line HR, SBP, DBP, ECG and SpO2, and temperature were recorded. All operation theatres in which the operations were performed maintained at constant humidity (70%) and an ambient temperature of around 21ºC to 23ºC.

A good IV line was secured with 18G/20G cannula, RL was started and no means of active re-warming were used.

Under all aseptic precautions spinal anaesthesia was performed at the $L_3 - L_4$ interspace, with the patient in sitting position. A volume of 3 ml of inj. bupivacaine 0.5% (heavy) was injected over 30 seconds through a 25-gauge spinal needle. Patient was placed in supine position with a 15° head down tilt immediately after spinal injection to achieve level of block of T5-T6. Oxygen (4L/min) was administered via mask.

Vitals were checked every 5 minute for first 30 minutes and after that every 15 minutes till the end of the surgery. Temperature was recorded with thermometer in axilla every 5 minute for 30 minutes and after that every 15 minutes till the end of the surgery.

When patient developed shivering of grade 3 & 4 were noted and were randomized in two groups (using sealed envelop method) and study drug was given.

Time taken to relieve shivering was recorded, reappearance of shivering/refractory shivering (not relieved by study drug in 15 min. of administration), if occurred then, patients were given rescue dose of Dexmedetomidine or Tramadol in respective group.

Hypotension, defined as a decrease of mean blood pressure by more than 20% from baseline, was treated with incremental IV doses of mephentermine 5 mg and IV fluid as required. Bradycardia, defined as heart rate < 50 bpm, was treated with IV atropine 0.3-0.6 mg. After the end of surgery patients were shifted to recovery room and sedation score was noted.

The grade of shivering was graded on four point scale as per wrench et al[4], which is as follows:

Grade 0: No shivering
Grade 1: One or more of the following: piloerection, peripheral vasoconstriction, peripheral cyanosis, but without visible muscles activity
Grade 2: Visible muscle activity confined to one muscle group
Grade 3: Visible muscle activity in more than one muscle group
Grade 4: Gross muscle activity involving the whole body

Patients developing grade 3 or 4 shivering as per Wrench criteria were included and drug therapy as per following group:-

Group D Dexmedetomidine 0.5 mcg /kg iv diluted in 10 ml normal saline.
Group T Tramadol 0.5 mg/kg iv diluted in 10 ml normal saline.

Following parameters are noted:-

- Time of appearance of shivering
- Grade of shivering
- Time of drug administered
- Time at which shivering disappeared
- Total time to subside shivering
- Response rate (Percentage of patients in which shivering controlled within 15 minutes)
- Recurrence of shivering (an additional dose of i.v. Dexmedetomidine or tramadol was administered in respective group.)
- Side effect and complications are noted

INTRA OPERATIVE MONITORING-

Pulse rate, blood pressure, oxygen saturation and body temperature (in axilla) recorded before administration of spinal anaesthesia and at various time intervals throughout the surgery.

SIDE EFFECTS MONITORED

- Nausea and Vomiting
- Hypotension and Bradycardia
- Sedation
- Dry mouth, Skin ras h and Extent of shivering

Sedation score was assessed as per Filos et al[5]:
1.Awake and alert
2.Drowsy, responsive to verbal stimuli
3.Drowsy, arousable to physical stimuli
4.Unarousable

RESULTS

Both the groups were comparable with respect to sex, age, weight, ASA grade, duration of surgery, type of procedure done and the duration of spinal block (**Table 1**).

Table 1

Parameters	Group D	Group T	p value
Age (in years)	41.6±8.31	40.16±9.19	0.527
Weight (in kgs)	61.13±6.30	61.53±5.92	0.801
Duration of surgery (in minutes)	60.00±12.58	64.40±15.02	0.271

There was no statistically significant difference in time for the onset of shivering between the two groups. Mean Pre operative Temperature and Temperature during Shivering was also comparable in both the groups. Both the groups had 100% response rate in controlling the shivering. However, the difference in the time interval between administration of drug after the onset of shivering and cessation of shivering was significantly shorter in the dexmedetomidine group (2.83±0.42 minutes) when compared to tramadol group (5.48±0.50 minutes). There was recurrence of shivering in 2 patients in tramadol group and in none of the patient in dexmedetomidine group (**Table 2**).

Table 2

Parameters	Group D	Group T	p value
On set of shivering (in minutes)	21.7±3.58	22.36±2.28	0.398
Pre operative temperature (in ^{o}C)	37.02±0.16	37.00±0.13	0.597
Temperature during shivering (in ^{o}C)	36.27±0.16	36.22±0.19	0.274
Time for cessation of shivering after medication (in minutes)	2.83±0.42	5.48±0.50	< 0.0001
Response rate	100%	100%	N/A
Recurrence	0/30 (0%)	2/30 (6.66%)	N/A

Both the groups were comparable in terms of intra operative hemodynamic parameters. Mean heart rate was comparable in both the groups at all times and there was no incidence of significant bradycardia. Mean arterial blood pressure was also com parable i n both the groups.

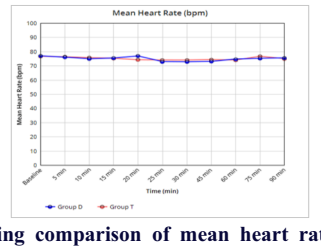

Figure :-showing comparison of mean heart rate in both the groups.

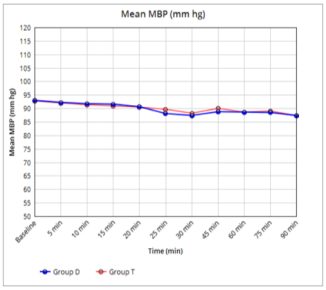

Figure:- showing comparison of mean MBP in both the groups.

Nausea and vomiting was observed only in tramadol group, and there was no incidence in the dexmedetomidine group. Almost similar number of patients was sedated in both groups. There was no evidence of respiratory depression, hypotension or bradycardia in any of the patients. HR, mean blood pressure, body temperature, and SPO_2 remained within normal limits throughout the procedure in both groups **(Table 3)**.

Table 3

Complication	Group D (n=30)	Group T (n=30)
Nausea	0	9 (30%)
Vomiting	0	5 (16.6%)
Hypotension	0	0
Bradycardia	0	0
Sedation	5 (16.6%)	6 (20%)

DISCUSSION

Shivering is known to be a frequent complication in patients undergoing surgery under neuraxial anesthesia. The neurotransmitter pathways involved in shivering are multiple and involve opioids, α_2 adrenergic, serotenergic, and anticholinergic receptors. Hence, drugs acting on these systems which include opioids (pethidine, nalbuphine, or tramadol), ketanserin, propofol, doxapram, clonidine, ketamine and nefopam are utilized in the treatment of shivering. However, adverse effects such as hypotension, hypertension, sedation, respiratory depression, nausea and vomiting limit their use. Hence, the hunt for an ideal anti-shivering agent is continuing.

In this study, we studied the efficacy of dexmedetomidine in the treatment of post-SA shivering in adults and compared its efficacy with tramadol for the treatment of shivering after SA in patients undergoing various elective surgeries. Although tramadol is an established drug in the treatment of shivering, in this study, we found that dexmedetomidine is equally effective as tramadol in treating post-SA shivering.

Dexmedetomidine is an α_2 adrenoceptor agonist, with antihy pertensive, sedative, analgesic, and anti-shivering properties.[6] The anti-shivering effects of alpha adrenoceptor agonists are mediated by binding to α_2 receptors that mediate vasoconstriction and the anti-shivering effect. In addition, it has hypothalamic thermoregulatory effects. Dexmedetomidine comparably reduces the vasoconstriction and shivering thresholds, thus suggesting that it acts on the central thermoregulatory system rather than preventing shivering peripherally.

With same dose, that is, 0.5 mg/kg of tramadol, the response rate reported by Shukla *et al*[7] was 92.5% and by Reddy and Chiruvella[8] as 95.56%. We found 100% response rate in our study. The recurrence rate in the study by Shukla *et al*[7]. was 5%, which is similar to our results. The incidence of nausea and vomiting with tramadol in our study was 30% and 16.6%, respectively. The results correspond with that of other studies by Reddy and Chiruvella[8], Tsai and Chu; Bansal and Jain[9].

All patients had cessation of shivering behaviour within 5 min following the completion of dexmedetomidine administration. There was no recurrence of shivering and no adverse effects occurred. We found a response rate of 100% and apart from sedation, there was no other adverse effect observed.

The results of this study indicate that dexmedetomidine takes lesser time to control shivering. The incidence of adverse effects like nausea and vomiting was found to be higher in case of tramadol compared to dexmedetomidine.

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 for the surgeon, anaesthetist as well as the patient. It provided more comfort to the patient, maintained more cardio-respiratory stability, improved surgical conditions and also provided amnesia during surgery.

CONCLUSION

Both dexmedetomidine (0.5 µg/kg) and tramadol (0.5 mg/kg) are effective in treating patients with post-spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to tramadol, the difference being statistically significant. Furthermore, dexmedetomidine causes fewer adverse effects like nausea and vomiting. Sedation caused by dexmedetomidine provides additional comfort to the patient.

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