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The Effect of Dexmedetomidine and Tramadol for Prevention of Perioperative Shivering in Patients Undergoing Lower Abdominal Surgeries Under Spinal Anaesthesia

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Abstract
Shivering is a frequent complication following spinal anaesthesia with an incidence of 36-85%. It is distressing and unpleasant experience for patients. Dexmedetomidine, is an a2 adrenoceptor agonist, commonly used for sedation, also has anti-shivering potential. Its use to control and treat post spinal anaesthesia shivering has been inadequately studied. The patients were randomized into two groups of n=60 each to receive either dexmedetomidine 0.5µg/kg or tramadol 0.5mg/kg as intravenous infusion in 100ml normal saline. Incidence and intensity of shivering in group D was 8%, compared to group T- 18.4% (p=0.107). High incidence of sedation observed in group D-80% (p=<0.001), whereas nausea, vomiting was higher in group T-28% (p=0.001). Dexmedetomidine offers better results than tramadol with additional sedation effect and fewer side effects.

INTRODUCTION

Shivering is a frequent complication following spinal anaesthesia. It is distressing and unpleasant experience for patients. The incidence of shivering has been reported to be about 36-85% after spinal anaesthesia. It is due to impairment of thermoregulatory vasoconstriction below the blockage which could inhibit tonic vasoconstriction and redistribute core heat[1,2].

Shivering during neuraxial block could have potentially detrimental effects and may contribute to increased wound pain, increasing oxygen demand, hampers patient monitoring, increases catecholamine levels subjecting the patient to a higher risk of cardiovascular complications and increases intracranial and intraocular pressure[3].

Various pharmacologic agents have been used for prophylaxis and treatment of post-spinal shivering ranging from opioids like fentanyl, tramadol[3], meperidine, anti-cholinergics physostigmine, analgesic nefopam, N-methyl-d-aspartate (NMDA) receptor antagonist ketamine[4] and a-2 blockers clonidine and dexmedetomidine[5]. Even though tramadol is commonly used drug for post spinal anaesthesia shivering, it has many adverse effects like nausea, vomiting, dizziness etc., which causes further discomfort to the patient[6].

Dexmedetomidine, a congener of clonidine, is a highly selective alfa-2 adrenoceptor agonist. It has been successfully used as adjunct to local anaesthetics in neuraxial anaesthesia and peripheral nerve blockade, as sedative agent during surgery and in ICU, as well as supplementation of postoperative analgesia. It also exhibits anti-shivering effects through its centrally mediated actions.

Very few Indian studies have explored the anti-shivering potential and have inferred that dexmedetomidine is an effective drug without any major adverse effect and provides good hemodynamic stability.

Hence we intend to conduct a comparative study on the effect and safety of dexmedetomidine and tramadol when used for control of post spinal anaesthesia shivering.

MATERIALS AND METHODS

Data was collected from all consenting patients who were scheduled for lower abdominal surgeries under spinal anaesthesia, in the department of Anaesthesiology, Pain and Critical Care.

Inclusion Criteria:

- Patients willing to sign written consent form.
- Patients undergoing elective lower abdominal surgeries under spinal anaesthesia.
- Belonging to American Society of Anaesthesiologists (ASA) Physical status I or II
- Patients of either gender, aged between 18-60 years.

Exclusion Criteria:

- Patients with contraindications to regional anaesthesia.
- Hypersensitivity to amide local anaesthetics or dexmedetomidine.
- Patients with hyperthyroidism, cardiopulmonary disease, hepatic failure psychiatric illness, renal failure, severe diabetes with autonomic neuropathy, severe bradycardia and hypotension.
- Excessive haemorrhage needing transfusion.
- Failure or incomplete spinal block.
- Those with a known history of alcohol or substance abuse.
- Belonging to ASA physical status 3 and 4.

Institutional Ethical committee approval was obtained prior to the commencement of the study. Informed written consent was obtained from all the patients, following which detailed pre-anaesthetic checkup was done. A total of 120 patients planned for elective lower abdominal surgeries under spinal anaesthesia, were enrolled in this prospective, randomized study. All the patients were randomly divided into two groups of 60 patients each, using computer generated random number table into Group D and Group T to receive either intravenous dexmedetomidine 0.5µg/kg in 100 ml saline or intravenous tramadol 0.5mg/kg in 100 ml saline respectively ten minutes after administration of spinal anaesthesia. Anaesthesiology resident (observer 1) who prepared the study drugs for administration was involved later in the study.

Upon patient arrival in the anaesthesia room, 18-gauge intravenous cannula was inserted and fixed in the upper limb. Patients were then preloaded with lactated Ringer's solution (10 mL/kg). Fluids were stored at room temperature. Basic monitoring, including non-invasive blood pressure, electrocardiography and pulse oximetry, were connected for all patients and baseline values were recorded.

Anaesthesiology resident (observer 2) who was blinded to the study drugs performed spinal anaesthesia under aseptic technique with patient in sitting position, at the L3-L4 or L4-L5 interspace using a 25-gauge spinal Quincke-tip needle. On confirming free flow of cerebrospinal fluid, 0.5% bupivacaine heavy 3 ml was injected intra-thecally. All patients were turned to the supine position immediately and positioned for surgery ten minutes later. Supplemental oxygen was administered at the rate of 5 L/min via a face mask. The level of sensory block (defined as loss

of pinprick sensation) was recorded every minute. Once the level reached T6 to T4 level, surgery was proceeded. The peak sensory block level was recorded. The temperature of the operating room and post-anaesthesia-care unit was kept at 22 °C-26 °C throughout the study. During the operation, the whole body of the patient, except the head, neck, and operation site, was covered with one layer of surgical drapes. In the post-anaesthesia care unit, the patient's body was covered with one cotton blanket.

Systolic, diastolic and mean arterial pressure, heart rate, oxygen saturation, time interval from spinal block to shivering occurrence, shivering score, sedation score, body temperature at the beginning and 0, 10, 20, 30 and 60 minutes and every half an hour thereafter till the end of surgery were observed and recorded.

The incidence of shivering was assessed by close observation of the patients during the operation and in the post anaesthesia room.

RESULTS AND DISCUSSIONS

The level of sensory block at 5 minutes was T4 in 13 patients and T6 in 47 patients in group D and was T4 in 14 patients and T6 in 46 patients in group T which was clinically not significant.

Out of 60 patients, only 5 patients in group D had shivering as compared to 11 patients in group T, with a p value of 0.107 which is statistically insignificant.

Out of 11 patients who had shivering in group T, 8 patients had grade one shivering, two patients had grade two and one patient had grade three, when compared with group D, where 3 patients had grade one shivering and other two patients had grade two. This was statistically insignificant with p value of 0.077

Out of 60 patients in group D, 48 patients had grade three-sedation, two patients had grade two and one patient had grade one, when compared with group T, 43 patients had grade one sedation and 11 patients had grade two sedation. There was clinically and statistically significant difference between both the groups with $p<0.001$.

The mean onset time of shivering in group D was at 77 minutes as compared to 72.84 minutes in group T, with a p value of 0.181.

The mean axilliary temperature was comparable between the two groups with no statistical difference.

Shivering is one of the least addressed and distressing complaint in many of the patients during surgery and in immediate postoperative period. The reasons for shivering under spinal anaesthesia may be multiple and complicated. It leads to patient agitation and other detrimental effects.

Unfortunately, there is no gold standard therapy in the management of this commonly encountered problem. Many drugs possess anti-shivering properties which act on neurotransmitter pathways involved in shivering like opioid receptors, alpha 2 receptors, serotonergic and anticholinergic receptors[5]. But adverse effects such as nausea, vomiting, respiratory depression, hypotension and unreliable sedation limit their use. So, search for an ideal anti-shivering drug with fewer side effects is still continuing.

Many studies are available for treatment of intraoperative shivering but only few studies are available for the prevention of shivering by prophylactic administration of anti-shivering agents.

Alpha 2 adrenergic agonists are widely becoming popular nowadays in anaesthesia. Dexmedetomidine is an a-2 adreno-receptor agonist, with antihypertensive, analgesia, sedative and anti-shivering properties. The anti-shivering effects are mediated by binding to a-2 receptors that mediate vasoconstriction[7].

Dexmedetomidine comparably reduces the vasoconstriction and shivering thresholds, thus suggesting that it acts on central thermoregulatory system rather than preventing shivering peripherally. It mediates both beneficial and unwanted side effects of shivering provoked by hypothermia, increased catecholamine concentrations, oxygen consumption, blood pressure and heart rates. In addition, dexmedetomidine produces conscious comfortable sedation which removes anxiety in patients.

Though tramadol is used for prevention and treatment of post anaesthesia shivering, it has high incidence of nausea and vomiting, which is unpleasant for the patients. It has delayed onset of action and low efficacy.

And hence, we undertook this study to compare the effectiveness of dexmedetomidine and tramadol, in the prevention of intraoperative shivering in patients undergoing elective lower abdominal surgeries under spinal anaesthesia. Also, we compared the side effects profile of these drugs.

We did not observe any correlation between age, gender, height, weight and duration of surgery between the two groups. We had chosen ASA physical status 1 or 2 patients for the study and to standardize the type of surgery, we included patients who were scheduled for lower abdominal surgeries. In all cases, the operating room temperature was maintained uniform at 26 °C and intravenous fluids for infusion were maintained at room temperature.

In our study, we selected doses of intravenous dexmedetomidine as 0.5 µg/kg and tramadol as 0.5mg/kg as infusion in 100 ml saline over 10 minutes. In a similar study by Kumar RA *et al.,* they observed that dexmedetomidine in a dose of 0.5 µg/kg and tramadol in a dose of 50mg/kg given as intravenous infusion in 100 ml saline over 10-15 minutes, were effective in prevention of intra-operative shivering in patients undergoing surgery under subarachnoid block[8].

Table 1: Distribution of level of sensory block between study groups

Level of sensory block at 5 min	Group D		Group T		p-value
	N	%	N	%	
T4	13	21.7%	14	23.3%	0.827
T6	47	78.3%	46	76.7%	
Total	60	100.0%	60	100.0%	

Table 2: Shivering between study groups

Shivering	Group D		Group T		p-value
	N	%	N	%	
Absent	55	91.7%	49	81.6%	0.107
Present	5	8.3%	11	18.4%	
Total	60	100.0%	60	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Table 3: Grading of shivering between study groups

Grading of Shivering	Group D		Group T		p-value
	N	%	N	%	
0	55	91.7%	49	81.7%	0.077
I	3	5.0%	8	13.3%	
II	2	3.3%	2	3.3%	
III	0	0.0%	1	1.7%	
Total	60	100.0%	60	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Table 4: Grade of sedation between study groups

Grade of sedation	Group D		Group T		p-value
	N	%	N	%	
I	1	1.7%	43	71.7%	<0.001*
II	11	18.3%	17	28.3%	
III	48	80.0%	0	0.0%	
Total	60	100.0%	60	100.0%	

Note: p value* significant at 5% level of significance (p<0.05)

Table 5: Onset of shivering between study groups

Parameters	Group D	Group T	p-value
	Mean±SD	Mean±SD	
Onset of Shivering	77.00±5.70	72.84±6.27	0.181

Table 6: Comparison of mean temperature between study groups

Auxiliary temperature	Group D	Group T	p-value
	Mean± SD	Mean± SD	
Pre-op	98.23± 0.51	98.20± 0.53	0.753
At 10 min	98.33 ± 0.54	98.17± 0.51	0.527
At 20 min	98.20± 0.51	98.30± 0.58	0.527
At 30 min	98.23± 0.50	98.17± 0.48	0.611
At 60 min	98.24± 0.49	98.17± 0.58	0.455
At 90 min	98.24± 0.50	98.10± 0.49	0.477
At 120 min	98.23± 0.51	98.17± 0.58	0.527

In our study, out of 120 patients, 5 patients in dexmedetomidine group (8.3 %) and 11 patients in tramadol group (18.4%) developed shivering. Group D patients had shivering with a grade ranging from 0 (91.7%), 1 (5%) and 2 (3.3%) whereas patients in tramadol group had grade 0 (81.7%), 1(13.3%), 2 (3.3%), 3 (1.7%) and were not statistically significant. These results were comparable with the study done by Satyamoorthy *et al.,* They found that 3 (7.5%) patients in dexmedetomidine group and 6 patients (15%) in tramadol group developed shivering of grades 2 or 3, when the study drugs (dexmedetomidine 0.5 mcg/kg, tramadol 1mg/kg in 100 ml NS as infusion) were given prophylactically in patients undergoing elective lower abdominal surgeries under spinal anaesthesia and was not statistically significant[9].

The study by Usta *et al.,* concluded that, dexmedetomidine infusion in perioperative period significantly reduced the incidence (10%) of shivering in patients undergoing surgeries under spinal anaesthesia[10].

In our study, intraoperative sedation scores in dexmedetomidine group were significantly higher and most of the patients achieved sedation score of 2-3 (2-drowsy and arousable to verbal stimuli, 3-drowsy and arousable to physical stimulus). These results were comparable with the studies conducted by Mittal *et al.,* They found that, the sedation due to dexmedetomidine provides additional comfort to the patient without any respiratory depression[11].

The study by Bozgeik S *et al.,* showed, the average sedation score of 3 in dexmedetomidine group which was statistically significant when compared to average score of 2 in tramadol group intraoperatively and concluded that this sedation score of 3 in dexmedetomidine group patients, might have removed anxiety without any adverse effects[12].

CONCLUSION

In conclusion, our study results showed that use of dexmedetomidine in a dose of 0.5µg/kg as intravenous infusion in 100 ml saline for 10 minutes, immediately

after spinal anaesthesia, was effective in reducing both the incidence and intensity of post spinal shivering with added benefit of arousable sedation, without any increased side effects in patients undergoing elective lower abdominal surgeries under spinal anaesthesia.

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