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Dexmedetomidine and Tramadol for Prevention of Perioperative Shivering in Patients Undergoing Lower Abdominal Surgeries: Hemodynamic Changes

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Abstract
Many drugs have been used for prevention or treatment of post anaesthesia shivering. However, dexmedetomidine may be a good choice among them due to its dual effects of anti-shivering and conscious sedation. Clonidine has also been used safely and effectively. Dexmedetomidine, on the other hand, is a short acting α2 agonist with less hypotensive effect and an added sedative effect. 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. Four patients (6.7%) in our study in dexmedetomidine group had bradycardia and the lowest heart rate was 46 bpm for which rescue drug atropine 0.6mg was given intravenously. Six patients (10%) had hypotension, the lowest blood pressure recorded was 90/50 mm Hg for which rescue drug, ephedrine 6mg was given intravenously.

INTRODUCTION

The maintenance of normothermia is an important function of autonomic nervous system in homeothermic mammals such as man, as cellular and tissue dysfunction become evident at even minor deviations from normal core body temperature. In humans, core temperature is normally maintained within narrow limits of 36.5-37.5 °C[1], even in the presence of an adverse environmental temperature by a combination of behavioral and physiological responses[2].

Thermoregulation is achieved by a physiological control system consisting of peripheral and central thermoreceptors and uses negative and positive feedback mechanisms to minimize perturbations from pre-set, normal values. Normal core body temperature varies by at least 1 °C based on circadian and menstrual cycles. But at any given time, core temperature is tightly regulated, to within a few tenths of a degree during day with slightly more variability at night[3].

Many drugs have been used for prevention or treatment of post anaesthesia shivering. However, dexmedetomidine may be a good choice among them due to its dual effects of anti-shivering and conscious sedation. Clonidine has also been used safely and effectively. Dexmedetomidine, on the other hand, is a short acting α2 agonist with less hypotensive effect and an added sedative effect[4].

The antishivering effect of dexmedetomidine is mediated by binding to α2 receptors that causes vasoconstriction and reduces shivering thresholds. In addition, it has hypothalamic thermoregulatory effects. Dexmedetomidine decreases the concentration-response curves for vasoconstriction and shivering in a linear fashion. Therefore, thermoregulatory responses were inhibited within a wider range of temperatures.

Dexmedetomidine displays specific and selective α2 adrenoceptor agonism in the brain and spinal cord. The responses to activation of these receptors include decreased sympathetic tone with attenuation of neuro-endocrine and hemodynamic responses to anaesthesia and surgery. Thus, it can mediate both beneficial and the unwanted effects of shivering provoked by hypothermia, such as increased catecholamine concentrations, oxygen consumption, blood pressure and heart rates[5].

α2 agonists are characterized by decreased heart rate and systemic vascular resistance, indirectly decreasing systemic blood pressure.

Tramadol is available as a racemic mixture (R-and S-stereoisomers). The volume of distribution is 203 L after parenteral administration and 306 L after oral administration. After oral administration, it takes about one hour for analgesic effect and peak action in 2-4 hours. The opioid antagonist, naloxone can only partially reverse its analgesic effect. The available formulations are tablets, capsules for extended-release formulations, injections for intramuscular and intravenous routes[6].

MATERIALS AND METHODS

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,

Table 1: Comparison of mean heart rate between study groups

Heart Rate	Group D	Group T	p-value
	Mean± SD	Mean± SD	
Pre-operative	81.92± 6.38	91.63± 9.60	<0.001*
At 10 min	82.53± 7.90	91.10± 9.53	<0.001*
At 20 min	79.62± 11.10	89.13± 11.13	<0.001*
At 30 min	79.45± 9.12	86.00± 9.89	<0.001*
At 60 min	80.30± 8.28	83.32± 8.52	0.052
At 90 min	79.33± 7.45	82.00± 7.33	0.050
At 120 min	79.50± 7.30	82.93± 6.73	0.008*

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

Table 2: Comparison of mean systolic blood pressure between study groups

Systolic blood	Group D	Group T	p-value
Pressure	Mean± SD	Mean± SD	
Pre-operative	124.37± 7.78	124.77± 5.18	0.741
At 10 min	115.10± 10.04	121.17± 5.24	<0.001*
At 20 min	116.90± 9.98	116.87± 6.52	0.983
At 30 min	117.10± 8.52	113.27± 5.72	0.005*
At 60 min	119.83± 6.32	111.87± 4.55	<0.001*
At 90 min	119.13± 6.22	110.90± 4.46	<0.001*
At 120 min	118.93± 6.00	113.80± 4.23	<0.001*

Note: p value* significant at 5% level of significance

Table 3: Comparison of mean diastolic blood pressure between study groups

Diastolic blood	Group D	Group T	p-value
Pressure	Mean± SD	Mean± SD	
Pre-Op	76.43± 5.06	79.97± 3.71	<0.001*
At 10 min	69.05± 7.60	78.33± 4.28	<0.001*
At 20 min	69.77± 7.27	74.87± 4.01	<0.001*
At 30 min	70.70± 5.83	71.93± 3.97	0.178
At 60 min	71.40± 4.31	70.20± 3.66	0.103
At 90 min	71.43± 4.51	69.97± 4.56	0.079
At 120 min	72.07± 4.34	72.37± 5.52	0.741

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

Table 4: Comparison of mean arterial pressure between study groups

Mean arterial	Group D	Group T	p-value
Pressure	Mean± SD	Mean± SD	
Pre-operative	92.38± 5.36	94.95± 3.74	0.003*
At 10 min	83.20± 7.54	92.60± 3.78	<0.001*
At 20 min	85.52± 7.35	88.82± 4.09	0.003*
At 30 min	86.05± 5.81	85.70± 3.91	0.699
At 60 min	87.63± 3.65	83.98± 3.05	<0.001*
At 90 min	87.30± 3.95	83.43± 4.00	<0.001*
At 120 min	87.65± 3.84	86.20± 4.15	0.049*

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

Table 5: Comparison of side effects between study groups

Side effects	Group D		Group T		p-value
	N	%	N	%	
Bradycardia	4	6.7%	0	0.0%	<0.001*
Hypotension	6	10.0%	0	0.0%	
Nausea & Vomiting	0	0.0%	17	28.3%	

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

20, 30 and 60 minutes and every half an hour thereafter till the end of surgery were observed and recorded.

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.

RESULTS AND DISCUSSIONS

Heart rate during the study period was statistically significant between two groups upto 30 minutes with p<0.001 and at 120 minutes with p value of 0.008. However clinically was not significant.

Systolic blood pressure during the study showed statistical significance between two groups except at

pre op and 20th minute. The p values were <0.001 at 10, 60, 90 and 0.05 at 30 minutes. However, it was not clinically significant.

Diastolic blood pressure during the study showed no statistical significance between two groups except at pre op, 10th and 20th minute with p<0.001. However, it was not clinically significant (Table 12) (Fig. 22).

Mean arterial pressure during the study showed statistical significance between two groups except at 30th minute. The p values were 0.003, <0.001, 0.003, 0.699, <0.001, <0.001 and 0.049 at pre-op, 10, 20, 60, 90 and 120 minutes respectively. However, it was not clinically significant.

There were four patients requiring intervention for bradycardia (lowest heart rate was 46 bpm for which injection atropine 0.6mg given intravenously) and six patients requiring intervention for hypotension (lowest blood pressure recording was 90/50 mm hg for which injection ephedrine 6mg given intravenously) in group D. Seventeen patients in group T developed nausea and vomiting requiring intervention (injection ondansetron 4mg given intravenously). These side effects were not clinically significant.

Four patients (6.7%) in our study in dexmedetomidine group had bradycardia, and the lowest heart rate was 46 bpm for which rescue drug atropine 0.6mg was given intravenously. Six patients (10%) had hypotension, the lowest blood pressure recorded was 90/50 mm Hg for which rescue drug, ephedrine 6mg was given intravenously. We feel that in well monitored patients, these haemodynamic changes like hypotension and bradycardia due to dexmedetomidine can be recognized and treated without any consequences. None of the patients had respiratory depression.

Hypotension and bradycardia were seen in dexmedetomidine group but, is of lesser incidence in a study by Usta B *et al.* In their study, three patients developed bradycardia (10%) and one patient developed hypotension (3.3%)[7].

Hypotension and bradycardia are the known haemodynamic side effects of dexmedetomidine but only few patients develop those side effects which is acceptable and the same was concluded by Verma A *et al.* In their study, three patients developed bradycardia (5%) and three patients developed hypotension (5%)[8] which were similar to our study.

No other side effects like respiratory depression, headache, nausea and vomiting were noted in dexmedetomidine group.

In our study, tramadol caused nausea in 28.3% and vomiting in 15% of patients which were distressing to patients when compared to dexmedetomidine and was similar to studies done by Verma A *et al.,* who showed 25% incidence of nausea and 13% vomiting in tramadol group[8].

In our study 17 (28.3%) out of 60 patients in tramadol group developed nausea and 9 (15%) patients developed vomiting, which was distressing for patients and none of the patients in dexmedetomidine group developed these effects.

CONCLUSION

In well monitored patients, haemodynamic changes like hypotension and bradycardia due to dexmedetomidine can be recognized and treated without any consequences. None of the patients had respiratory depression.

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