Section A-Research paper

COMPARATIVE STUDY OF THE DEXMEDETOMIDINE AND TRAMADOL FOR POST SPINAL ANAESTHESIA SHIVERING

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ABSTRACT:

Background: Aim of this study to evaluate and to compare the effectiveness, haemodynamic effects, adverse effects and sedation score between dexmedetomidine and tramadol for post spinal anaesthesia shivering. **Methods:** 110 patients were divided into two groups with 55 each patient in each group and the patients receive either dexmedetomidine 0.5 µg/kg grouped as group D or the other group receive tramadol 0.5mg/kg grouped as group T. Grade of shivering, onset of shivering, time for cessation of shivering, recurrence of shivering, hemodynamic effects, adverse effects and sedation score were observed at scheduled intervals. Chi square test was used for analysis of data. **Results:** Time taken for cessation of shivering and recurrence of shivering was significantly less with dexmedetomidine when compared with tramadol. Sedation score is significantly high in dexmedetomidine group. Haemodynamically there is no significant difference between two groups. **Conclusion:** We conclude that the use of IV dexmedetomidine reduced the time taken for cessation of shivering compared to IV tramadol. Moreover, dexmedetomidine has negligible side effects, whereas tramadol is associated with significant nausea and vomiting.

Keywords: Dexmedetomidine, Tramadol, shivering

INTRODUCTION:

Shivering is a common and distressing experience to many patients which occurs either during or immediately after the surgery[1]. It is defined as an involuntary, repetitive activity of skeletal muscles. The processing of thermoregulatory response has three components: Afferent thermal sensing, central regulation and efferent responses[2]. A review of different studies showed that the median incidence of shivering after neuraxial anaesthesia was 55%.[3] Shivering is a normal thermoregulatory mechanism as evidence by the presence of vasoconstriction. But in patients undergoing neuraxial anaesthesia it impairs the thermoregulatory mechanism by inhibiting the vasoconstriction which plays an important role in the temperature regulation. After spinal anaesthesia there is redistribution of core heat to the periphery from the trunk. Both these effects lead to hypothermia and shivering. Shivering hinders the monitoring of blood pressure, ECG, oxygen saturation and gives erroneous values. It can increase the consumption of oxygen,[4] production of carbon dioxide, synthesis of catecholamines and causes production of lactic acidosis. These changes in metabolic requirement are difficult in the patients with existing intra pulmonary shifts and decreased cardiopulmonary reserve. Both pharmacological and non-pharmacological are modalities for anti-shivering treatment. Non pharmacological management includes external warming such as forced air warming and use of warmed fluids. Pharmacological method includes drugs such as meperidine, pethidine, clonidine, ketamine and tramadol have been used for treatment of shivering[5]. There is no gold standard management till now.

MATERIALS AND METHODS:

This was designed to be observational prospective cohort study which was conducted after obtaining approval from Institutional ethic committee (IEC KMC MLR 03-2021/79) between time period of march 2021 to September 2022. By convenience non randomized sampling method, patients who fulfilled the inclusion criteria and did not fulfil the exclusion criteria for the observational study were included. The inclusion criteria were all oriented ASA 1 and 2 patients between the age of 18 and 60 years, elective surgeries undergoing under spinal anaesthesia, lower abdominal and lower limb surgeries. Exclusion criteria includes patient refusal, known hypersensitivity or allergy to study drugs, cardio-pulmonary, renal or hepatic impairment and pregnancy were excluded from the study. The study protocol was explained to the patients and informed written consent was obtained from the patients participating in the study. Monitors such as Electrocardiogram, Pulse oximetry and non-invasive blood pressure were connected and baseline vitals noted. To give fluids and medications appropriate intravenous cannula secured and patient shifted to operation theatre. OT temperature was maintained at an ambient temperature of around 24ºC-25ºC and forced warmers are not used. Under adequate aseptic precautions, subarachnoid block was performed using 25G Quincke-Babcock needle, injected 0.5% heavy bupivacaine at L3-L4 or L4-L5 space. Intraoperative shivering was observed using a shivering grade. Grades of shivering[6]- Grade0-No shivering, Grade1-Without visible muscle activity, Grade 2-Visible muscle activity but confined to one muscle group, Grade 3- Visible muscle activity more than one group, Grade 4- Gross muscle activity more than one group. Patients who developed grade 3 or grade 4 received either one of the study drugs and it is decided by the anaesthesia consultant. The study groups were sub divided into two, each containing 55 participants each: **Group D:** Received 0.5mcg/kg dexmedetomidine diluted in 10ml normal saline given slow IV and **Group T:** Received 0.5mg/kg tramadol diluted in 10ml normal saline given slow IV. Parameters such as blood pressure, heart rate, sedation score, oxygen saturation, time required for cessation of shivering and recurrence of shivering was monitored and noted till the end of the procedure.

$$n = 2\left[\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{2}\right]^2$$

$$= 2\left[\frac{1.96+0.84}{2}\right]^2$$

Z1-α/2 = 1.96 at 5% level of significance

Z1-β = 0.84 at 80% power

σ = Pooled SD = 13.09[cite]

d = clinically significant differences = 70 [cite]

Each group 55: Total 110

STATISTICS:

Data were entered into Microsoft Excel and statistical analysis was carried out in SPSS software version 17.0. Quantitative variables like heart rate, mean arterial pressure, spo2 at intra-Op, 0 minutes, 5 minutes, 10, 15, 30 and 45 minutes and sedation scores were presented as mean with standard deviation. Qualitative variables like recurrence, nausea and vomiting between the tramadol and Dexmedetomidine were reported with proportions. Bar diagrams were used for graphical representation of data.

Independent or student t test was used to compare the heart rate, mean arterial pressure, spo2, sedation scores and knee functional outcomes between and tramadol and Dexmedetomidine. Chi square test was used to compare the difference in proportion of nausea, vomiting and recurrence between the groups. A p value of less than 0.05 was considered as statistically significant.

Results:

Fig 1: Heart rates at regular intervals till the end of surgery. Comparison with the baseline there is no statistically significant changes in group T tramadol and group D dexmedetomidine.

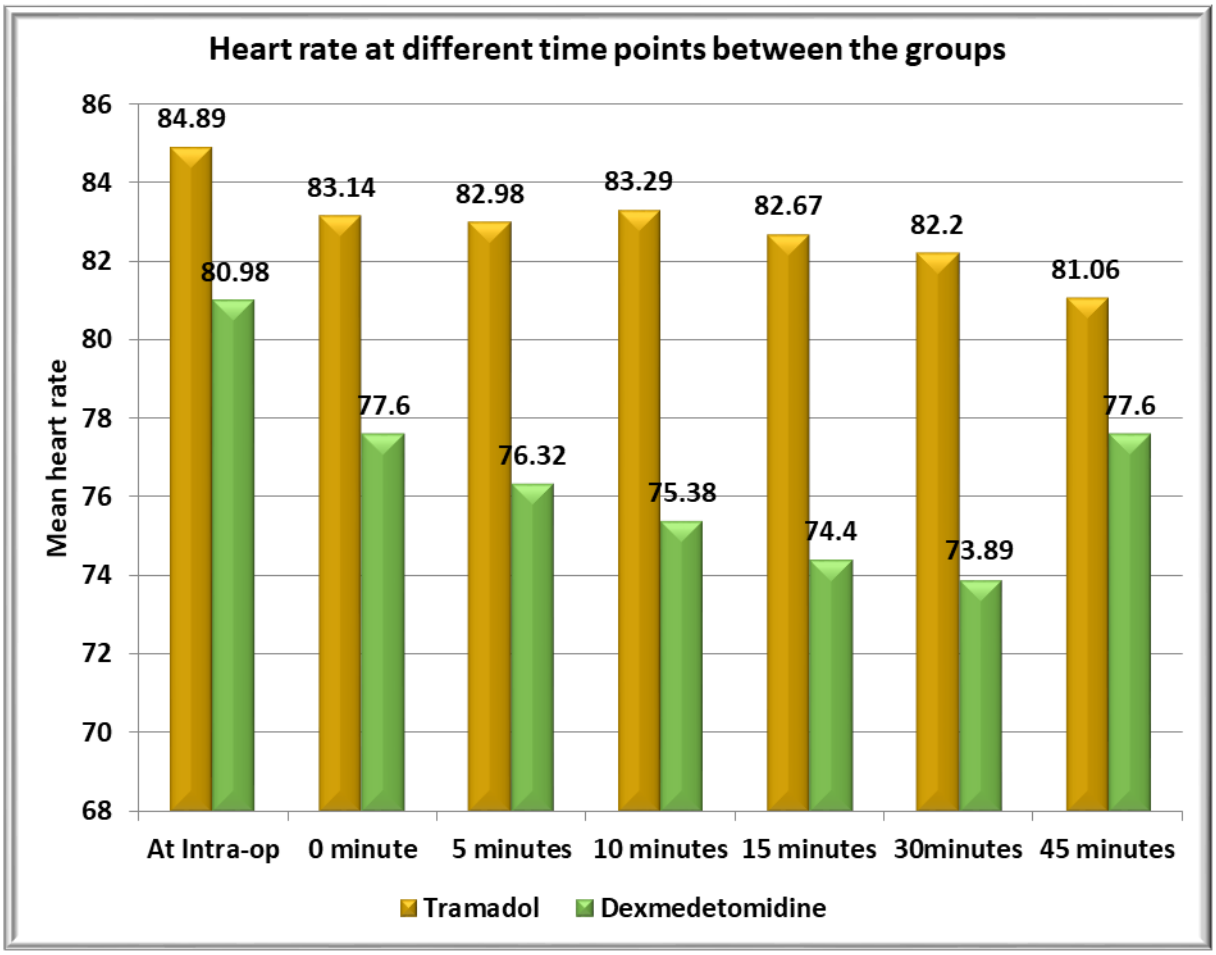


FIG 2: Comparison between MAP at regular intervals between group T tramadol and group D dexmedetomidine

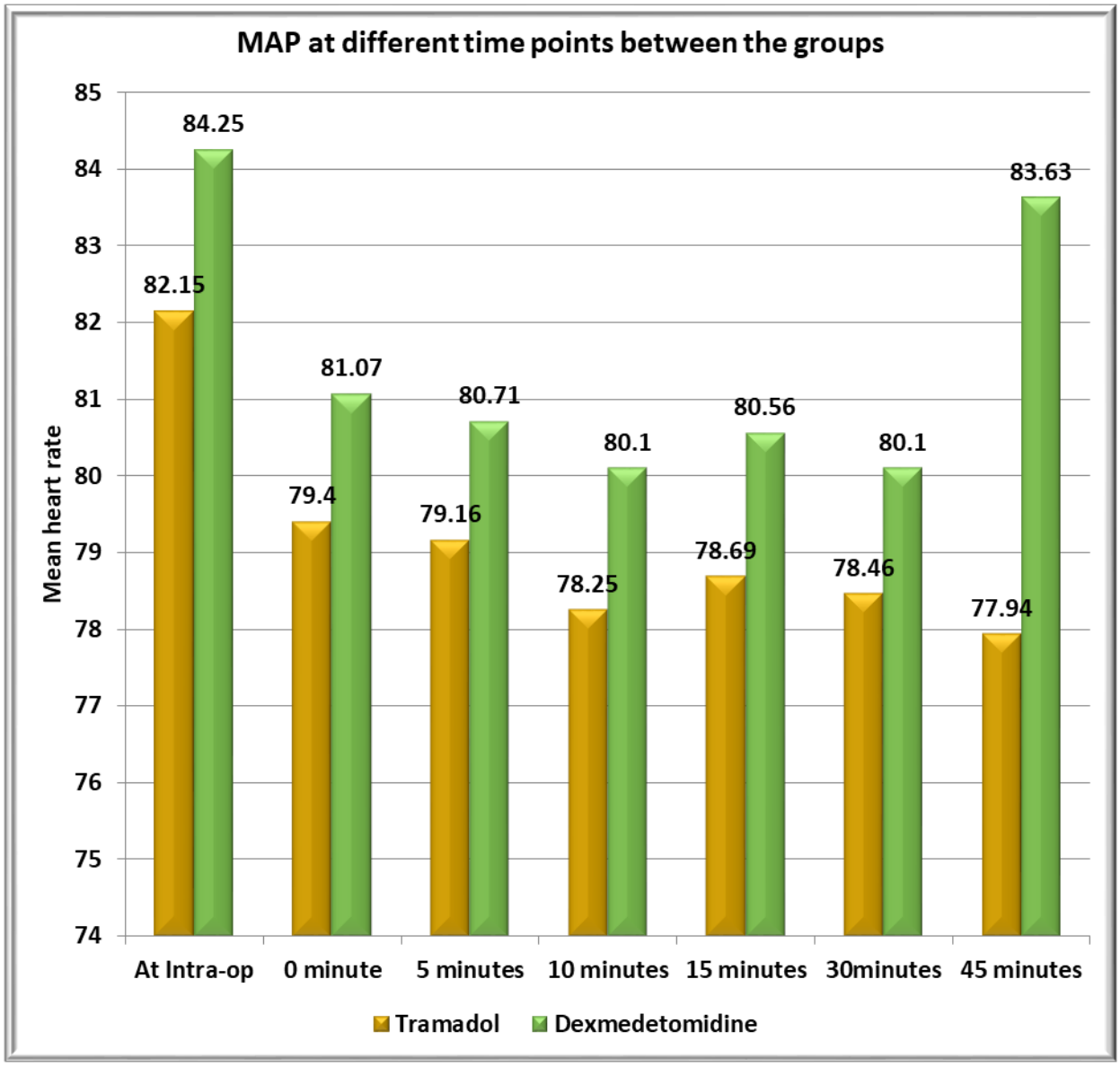


Table 1: Comparison of onset of shivering and time required for cessation of shivering

Parameter	**Tramadol**		**Dexmedetomidine**		**P value**
	Mean	**SD**	**Mean**	**SD**	
Onset of shivering (Minutes)	10.4	2.8	10.05	2.4	0.49
Time required for cessation of shivering (Minutes)	3.6	1.1	2.78	0.74	<0.001

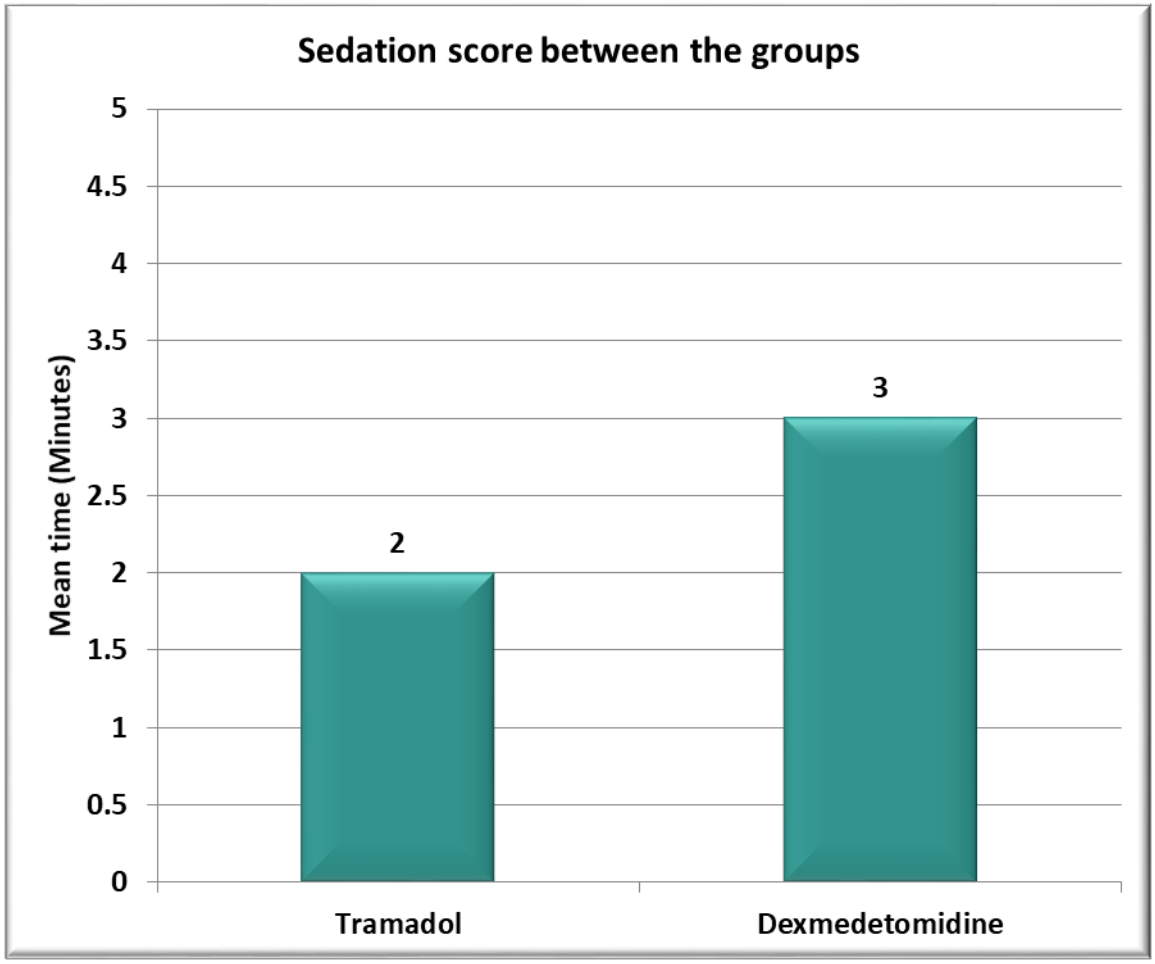
Table-2: Comparison of recurrence between the groups

Recurrence	**Tramadol**		**Dexmedetomidine**	
	n	**%**	**n**	**%**
No	46	83.6	50	90.9
Yes	9	16.4	5	9.1
Total	**55**	**100.0**	**55**	**100.0**
Chi square p value=0.25 (Not significant)				

Table-3: Sedation score

Sedation score	**Tramadol**	**Dexmedetomidine**	**P value**
	Mean	**Mean**	
Sedation score	2	3	<0.001 Significant

FIG 3: Sedation score between two study groups



DISCUSSION:

Shivering is an uncomfortable experience to the patient. The probable mechanism underlying will be impairment of central thermoregulation, internal redistribution of body heat and heat loss to the environment. The risk factors which cause hypothermia in subarachnoid blockade includes OT temperature, level of sensory block and IV fluids. Adverse effects seen are hypoxia, post operative pain, delayed wound healing along with these shivering interferes with monitoring devices. Hence it is important to treat the shivering in patients.

In this comparative, observational study we observed that intra-operative shivering could be treated with either intravenous dexmedetomidine or intravenous tramadol in patients undergoing surgeries under subarachnoid block.

Neurotransmitter pathways involved in shivering include α2 adrenergic receptors, serotonergic receptors, opioids receptors, anticholinergic receptors. Drugs that act on these receptors include opioids such as nalbuphine, pethidine, tramadol and others such as ketanserin, propofol, clonidine, ketamine were used in the controlling of shivering. However, these drugs have side effects such as hypotension, hypertension, sedation, respiratory depression, nausea and vomiting which limit their use.

Tramadol is an opioid analgesic that acts on the mu receptors and has minimal effect on kappa and delta receptors. Other receptors that tramadol acts on are monoaminergic receptors of the descending inhibitory pathway in the spine. The exact mechanism of tramadol's anti-shivering action could be its effects on serotonergic and noradrenergic or opioids or both.

Dexmedetomidine an alpha 2 adrenergic agonist, its anti-shivering effect mediated via binding to α2 receptors that reduces vasoconstriction along with this it has binding to α2 receptors that reduces vasoconstriction along with this it has thermoregulatory effects[7]. The advantages are its acts as analgesic, sedative and antihypertension. It has dual effect anti-shivering and sedation.

The interpretation of results between the two groups based on clinically significant shivering indicated a statistically significant superiority of IV dexmedetomidine over IV tramadol intraoperatively. Confirming with our results one of the study observed that the time required for cessation of shivering is markedly shorter with dexmedetomidine when compared with tramadol[8]. The results obtained supported our observation, in their study concluded that time

required for control of shivering with dexmedetomidine is significantly less when compared with the dexamethasone where in their study the drug was given prophylactically[9].

In one of the study conducted, comparison of tramadol 0.5mg/kg IV and meperidine 0.5mg/kg IV in post spinal anaesthesia shivering. Supporting our study this study concluded that both are equally effective. But tramadol offers less recurrence, rapid onset and fewer side effects compared with meperidine[10]. One of the study conducted compared 0.5µg/kg dexmedetomidine and 0.5mg/kg tramadol in 100ml NS given intravenously over 10minutes in patients who developed grade 2 shivering.[11] This study supported our study that inj dexmedetomidine is preferred than tramadol.

The other α2 agonist clonidine showed an adverse effect such as hypotension, bradycardia. But dexmedetomidine doesn't alter haemodynamics.

The results of this study indicate that the time required for cessation of shivering, recurrence of shivering is significantly less with the IV dexmedetomidine. Besides that, adverse effects such as nausea and vomiting have higher incidence with the IV tramadol when compared with dexmedetomidine. The sedation caused by dexmedetomidine showed additional advantage by providing comfort to the patient, surgeon as well as anaesthetist.

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