

Efficacy of IV Tramadol versus IV Dexmedetomidine in Shivering Following Sub Arachnoid Block

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Abstract: A Prospective, randomized study, Group T patients received inj. Tramadol 0.5mg/kg diluted in 100ml normal saline & Group D received inj. Dexmedetomidine 0.5µg/kg diluted in 100ml normal saline, both drugs were infused over a time period of 5mins before giving spinal anaesthesia. **Result:** The mean shivering score in Group D was 0.4±.21 at T0 interval, the mean shivering score in Group T was 0.13± 0.34 at T0 interval. After 2hrs the shivering score was 0.02±0.15 in Group D & 0.11±0.32 in Group T. **Conclusion:** Both drugs dexmedetomidine & tramadol were effective in preventing shivering after spinal anaesthesia.

Keywords: Tramadol, Dexmedetomidine, Shivering, Subarachnoid block, Haemodynamic stability

1. Introduction

Spinal anaesthesia is widely used as a safe anaesthetic technique for both elective and emergency operations. Shivering is one of the most common complications of the central neuraxial blockade due to impairment of thermoregulatory control, reported in 19%-33% of the patients undergoing surgery under spinal anaesthesia [1]. Post anaesthetic shivering is defined as an involuntary, spontaneous, rhythmic oscillating tremor like muscle hyperactivity that increases metabolic heat production upto 600% after general or regional anaesthesia [2]. Shivering is an important complication of hypothermia; it is a complicated response of the body that included at least three different patterns of muscular activity. The processing of thermoregulatory response has three components: Afferent thermal sensing, Central regulation & efferent responses. Together they work to maintain normal core body temperature [3]. Though hypothalamic thermoregulation remains intact during regional anaesthesia, it is associated with greater heat loss than general anaesthesia which is attributed to various reasons like abnormal heat loss due to vasodilatation, impairment of shivering in the area of block & rapid intravenous infusion of cold fluids [6]. Spinal anaesthesia impairs the thermoregulatory system by inhibiting tonic vasoconstriction, which plays important role in regulation of temperature [7].

There are various methods available to control shivering during anaesthesia which includes the non - pharmacological methods & pharmacological methods using drugs which have anti-shivering properties. The non - pharmacological methods using equipments to maintain normal temperature of the body are effective but expensive and lack practicality [8]. Pharmacological agents remain the most popular mode of treatment of shivering. Many agents have been used to

eliminate post - op shivering such as meperidine, doxapram, tramadol, ketanserin, clonidine, Propofol, physostigmine, nefopam, dexamethasone, magnesium sulfate, & fentanyl [9]

Tramadol Hydrochloride, a µ-opioid receptor agonistic drug has a modulatory effect on central monoaminergic pathways & thus inhibits the neuronal uptake of noradrenaline/serotonin & encourages 5HT₃ secretion which resets the body temperature regulating centre [10]. Dexmedetomidine, a potent α₂ adrenergic receptor agonist, has been used as a sedative agent and is known to reduce the shivering threshold. It acts by decreasing the vasoconstriction and shivering thresholds [11].

Hence the aim is to study the efficacy between dexmedetomidine and tramadol in preventing shivering post sub arachnoid block.

2. Literature Survey

Quincke in 1891 demonstrated a safe, predictable means of performing lumbar puncture. In 1898, August Bier used Quincke's technique to inject cocaine in order to produce operative anaesthesia in six patients, the first real spinal anaesthesia. The first phase in the history of spinal anaesthesia, from 1899 to 1905, was characterized using only cocaine for spinal anaesthesia. It was called "cocainization of the spinal cord". In 1905, Heinrich Braun, a German surgeon, reported the use of procaine for operative spinal anaesthesia. Means for controlling levels of anaesthesia by making procaine solutions hyperbaric by adding glucose, was first reported by Barker in 1907 or hypobaric, by adding alcohol. Synthesis of tetracaine in 1931 and its introduction into clinical practice by Sise in 1935, synthesis of dibucaine and its introduction into clinical anaesthesia was demonstrated by Lemmon in 1940 and Tuohy in 1945. In

1945, Prickett and associates published their report on the neurologic safety of intrathecal epinephrine to prolong the duration of spinal anaesthesia. In 1993, Ezzat Abouleish et al, conducted study to compare the effects of adding either preservative-free morphine 0.2 mg or epinephrine 0.2 mg, or a combination of both to hyperbaric bupivacaine in parturients having elective cesarean section. The conclusion drawn was that the addition of 0.2 mg of morphine plus 0.2 mg of epinephrine to hyperbaric bupivacaine improved the intra- and postoperative analgesia without an added risk. In 1997, Laura S. Stone et al, conducted study on genetically modified mouse line expressing a point mutation (D79N) in the α_2a adrenergic receptor (α_2aAR) to investigate the role of the α_2aAR in α_2 agonist-evoked analgesia and adrenergic–opioid synergy. These results demonstrate that the α_2aAR subtype is the primary mediator of α_2 adrenergic spinal analgesia and is necessary for analgesic synergy with opioids. Thus, combination therapies targeting the α_2aAR and opioid receptors may prove useful in maximizing the analgesic efficacy of opioids while decreasing total dose requirements.

3. Methods

The study protocol, informed consent form and were submitted to the ethical committee of Kurnool Government hospital. Study was done & data was collected during the study period of 18 months . from November 2017 to April 2018. The study was conducted on patients of ASA GRADE 1 & 2 of either sex between the age group of 18-60yrs posted for elective lower abdominal & lower limb surgeries requiring sub arachnoid block .There were divided 2 groups comprising of 45 patients in each group.

Inclusion Criteria: Patient age between 18-60yrs, with ASA grade 1 & 2, whose height is in between 150cms to 175cms.

A written and informed consent for the sub arachnoid block was taken and the patients were explained that she/he is a part of the study. Patients were randomly allocated into two groups. Patients of the group T received intravenous tramadol 0.5mg/kg in 100ml saline & patients of group D received intravenous dexmedetomidine 0.5 μ g/kg in 100 ml saline 5 min prior to sub arachnoid block.

The operating room temperature was kept at 22-24°C. IV fluids are being administered at the room temperature & anaesthetic equipments and emergency drugs were kept ready at hand. Then the study drugs were injected 5mints prior to giving spinal anaesthesia.

Before starting the case, routine check of the anaesthesia machine was done. All patients are covered with 1 layer of surgical drapes over chest, thighs & calves during the operation, and then one cotton blanket over entire body post operatively. No other warming devices are used. After taking a short history from the patient, an intravenous cannula of size 18G was placed on the vein of left or right forearm. Noninvasive blood pressure, ECG leads, SpO2 monitor were placed and preoperative vitals (BP, HR, and

SpO2) were noted. Injection ranitidine 50mg intravenous and Injection metoclopramide was given intravenously to the patients as premedication.

Patients were positioned in sitting posture and after antiseptic dressing and draping, a 25G Quincke needle was inserted in L3-L4 inter-vertebral space and hyperbaric bupivacaine 0.5% 2.5ml was administered intrathecally. Thereafter patient was been placed in supine position. Blood pressure monitoring was done every 3mints by NIBP monitor.

The MAP (NIBP), HR, SPO2, Shivering, sedation score were recorded at each intervals of 0, 15, 30, 45, 60, 75, 90, 105, 120mints.

Scoring for shivering graded with 5 point scale validated by Crossly and Mahajan were;

0 = No shivering

1 = piloerection or peripheral vasoconstriction but no visible shivering

2 = muscular activity in only one muscle group

3 = muscular activity in more than one muscle group

4 = whole body shivering

Level of sedation was assessed by means of Ramsay sedation scale;

1 point = worried, agitated or unpeaceful

2 point = co-operative, oriented and calm

3 point = responds to oral warnings

4 point = snoozing, gives lively response to hitting between the eye brows or loud noise

5 point = snoozing, slowly responds to hitting between eyebrows or loud noise

6 point = snoozing, no response.

Nausea and vomiting; the presence of nausea or vomiting was measured on a 3 point scale with 1 indicating – no nausea, 2- only nausea no vomiting, 3-vomiting.

Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two groups.

All statistical tests with P value <0.05 was taken as significant

4. Results

This present study was done on 90 patients who underwent elective lower abdominal or lower limb surgeries under spinal anaesthesia. They were divided into two groups, each group comprising of 45 patients.

Group T patients received inj. Tramadol 0.5mg/kg diluted in 100ml normal saline & Group D received inj. Dexmedetomidine 0.5 μ g/kg diluted in 100ml normal saline, both drugs were infused over a time period of 5mins before giving spinal anaesthesia.

Table 1: Comparing Age, Height, Weight among two study groups

Variable	Tramadol					Dexmedetomidine					t-value	P-value
	N	Min.	Max.	Mean	SD	N	Min.	Max.	Mean	SD		
Age (years)	45	30	57	44.5	8.3	45	28	59	41.5	8.6	1.7	0.09
Height (cms)	45	150	174	161.2	6.5	45	152	170	159.6	4.6	1.4	0.17
Weight (kg)	45	50	77	60.3	6.9	45	50	77	59.4	5.5	0.7	0.50

Independent t-test

Mean Blood Pressure

Table 2: Comparing MAP (mm Hg) in between two groups of the patients.

MAP	Group										t-value	P-value
	Dexmedetomidine					Tramadol						
	N	Min	Max	Mean	SD	N	Min	Max	Mean	SD		
at T0	45	75	102	87.29	7.00	45	74	102	86.73	6.90	-.38	.71
at T1	45	77	97	87.00	5.21	45	77	97	86.96	5.24	-.04	.97
at T2	45	75	98	87.31	4.69	45	75	98	87.36	4.67	.05	.96
at T3	45	76	98	86.22	4.16	45	76	98	86.16	4.27	-.08	.94
at T4	45	78	96	85.89	3.86	45	76	96	85.80	3.97	-.11	.91
at T5	45	79	96	86.69	3.49	45	79	96	86.69	3.49	.00	1.00
at T6	45	81	96	87.71	3.24	45	81	96	87.69	3.15	-.03	.97
at T7	45	80	93	87.58	3.63	45	80	93	87.53	3.62	-.06	.95
at T8	45	78	94	87.22	3.75	45	78	94	87.22	3.75	.00	1.00

Independent t test

Mean arterial pressure at the time of infusion was 87.29±7 and 86.73±6.90 in group D and group T respectively. As it was seen in SBP and DBP, there was a clinically and

statistically insignificant (p>0.05) change in MAP in group D i.e.87±5.21mm Hg at T1 when compared to group T which was found to be 86.96±5.24mmHg.

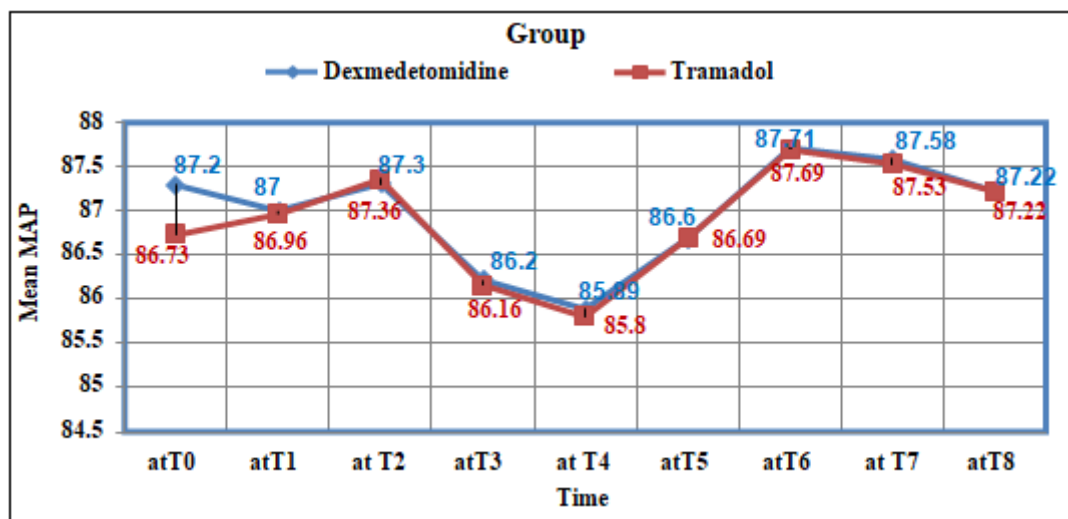


Figure 2: Distribution of MAP (mmHg)

At all time intervals mean MAP was normal and statistically insignificant

Heart Rate

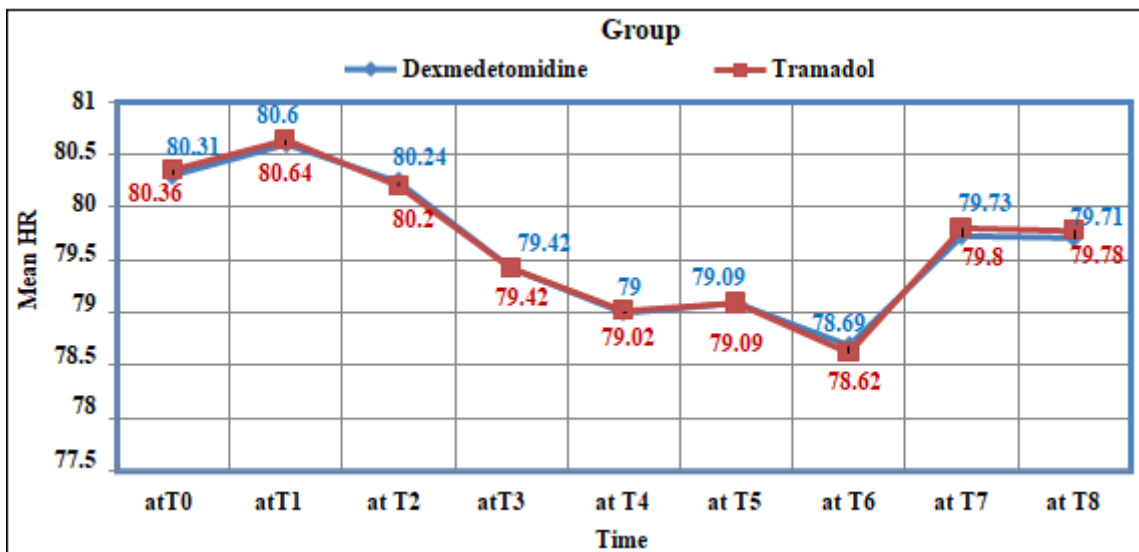
Table 3: Comparison of HR (bpm) in between two study groups

HR	Group										t-value	P-value
	Dexmedetomidine					Tramadol						
	N	Min	Max	Mean	SD	N	Min	Max	Mean	SD		
at T0	45	66	104	80.31	10.35	45	66	104	80.36	10.44	0.02	0.98
at T1	45	64	99	80.6	9.06	45	64	99	80.64	9.06	0.02	0.98
at T2	45	66	99	80.24	7.76	45	66	99	80.2	7.76	-0.03	0.98
at T3	45	68	92	79.42	6.13	45	68	92	79.42	6.14	0	1
at T4	45	67	98	79	7.31	45	68	98	79.02	7.32	0.01	0.99
at T5	45	65	91	79.09	7.4	45	65	91	79.09	7.4	0	1
at T6	45	64	92	78.69	6.69	45	64	92	78.62	6.66	-0.05	0.96
at T7	45	64	101	79.73	10.02	45	65	101	79.8	10	0.03	0.97
at T8	45	66	100	79.71	9.35	45	66	100	79.78	9.36	0.03	0.97

Independent t-test

At T0 mean heart rate in group D was found to be 80.31±10.35 and in group T 80.36±10.44. After giving SAB

there was insignificant reduction in mean heart rates at all time intervals in both groups.



Shivering Score

Table 4: Comparison of shivering score in between two study drugs

Shivering score	Group										Z-value	P-value
	Dexmedetomidine					Tramadol						
	N	Min	Max	Mean	SD	N	Min	Max	Mean	SD		
at T0	45	0	1	0.04	.21	45	0	1	.13	.34	-1.47	0.14
at T1	45	0	1	0.16	.37	45	0	1	.16	.37	0.00	1.00
at T2	45	0	1	0.16	.37	45	0	1	.16	.37	0.00	1.00
at T3	45	0	3	0.20	.63	45	0	1	.16	.37	-0.47	0.64
at T4	45	0	2	0.09	.36	45	0	1	.18	.39	-1.54	0.12
at T5	45	0	1	0.11	.32	45	0	1	.11	.32	0.00	1.00
at T6	45	0	1	0.02	.15	45	0	1	.07	.25	-1.02	0.31
at T7	45	0	1	0.02	.15	45	0	1	.09	.29	-1.37	0.17
at T8	45	0	1	0.02	.15	45	0	1	.11	.32	-1.68	0.09

Independent t-test

The mean shivering score in Group D was 0.4±.21 at T0 interval whereas the mean shivering score in Group T was 0.13± 0.34 at T0 interval. At the end of time of observation i.e. after 2hrs the shivering score was

0.02±0.15 in Group D & 0.11±0.32 in Group T. The variations in shivering score was insignificant in between the groups of Tramadol & Dexmedetomidine i.e. at T8, P= 0.09.

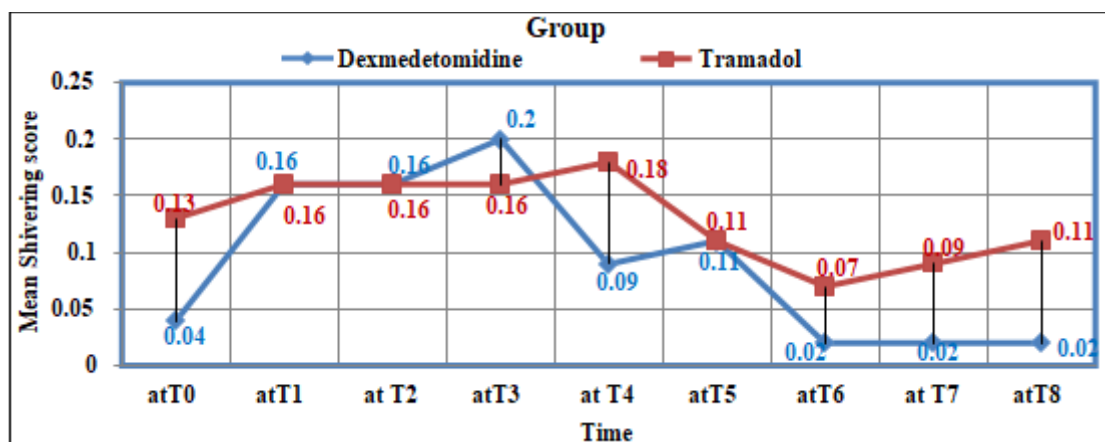


Figure 4: Distribution of shivering score at various time intervals in both the groups

Sedation Score

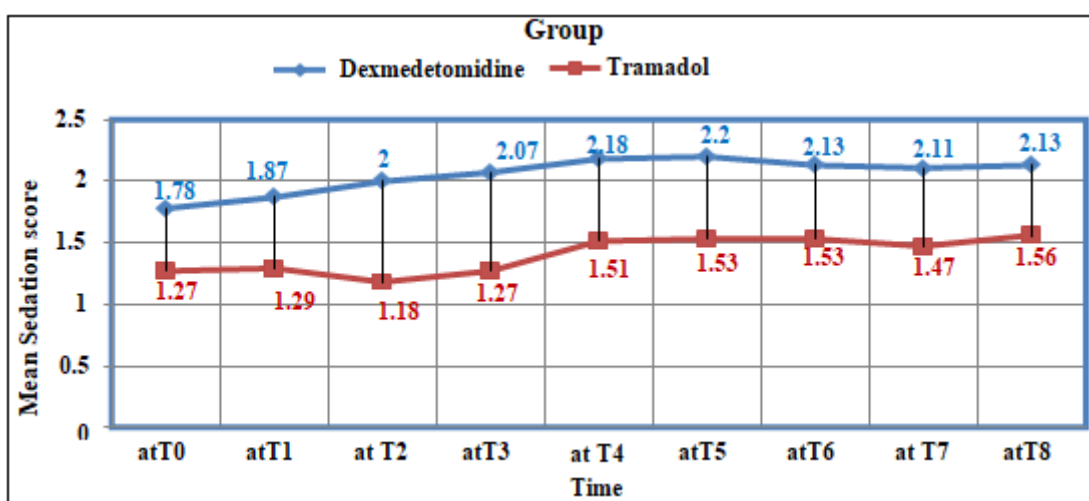
Table 5: Comparison of Sedation score in between two study groups

Sedation Score	Group										Z-value	P-value
	Dexmedetomidine					Tramadol						
	N	Min.	Max	Mean	SD	N	Min	Max	Mean	SD		
at T0	45	1	2	1.78	0.42	45	1	2	1.27	0.45	-4.83	<0.001
at T1	45	1	3	1.87	0.59	45	1	2	1.29	0.46	-4.59	<0.001
at T2	45	1	3	2.00	0.52	45	1	2	1.18	0.39	-6.53	<0.001
at T3	45	1	3	2.07	0.33	45	1	2	1.27	0.45	-6.92	<0.001
at T4	45	2	3	2.18	0.39	45	1	2	1.51	0.51	-5.71	<0.001
at T5	45	2	3	2.20	0.40	45	1	2	1.53	0.50	-5.64	<0.001
at T6	45	2	3	2.13	0.34	45	1	2	1.53	0.50	-5.48	<0.001
at T7	45	2	3	2.11	0.32	45	1	2	1.47	0.50	-5.84	<0.001
at T8	45	2	3	2.13	0.34	45	1	2	1.56	0.50	-5.34	<0.001

Independent t-test

The mean sedation score at time interval T1 was recorded as 1.87 ± 0.59 in Group D & the mean in Group T was recorded as 1.29 ± 0.46 . There was significant variation in

sedation score in between the groups ($p < 0.05$) i.e. 0.001. 3 was the maximum score seen in of Dexmedetomidine group.

**Figure 6:** Distribution of sedation score of both the study groups at various time intervals**5. Discussion**

Shivering is known to be a frequent complication in patients undergoing surgery under neuraxial anesthesia. The possible mechanisms of shivering during spinal anaesthesia include impairment of central thermoregulation, heat loss to the environment & internal redistribution of body heat. Potential risk factors for hypothermia in spinal anaesthesia include level of sensory block, Ageing, IV solutions and temperature of the operation theatre.

In this study it was found that 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 electivesurgeries.

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. In our study incidence of shivering was maximum at T1 & T2 in Group D whereas the incidence of shivering was maximum at T4 in Group T with no significance difference between the two group at any point of time ($P > 0.05$). Similar

findings was seen in the study by Neeharika Arora,^[12] Bozgeyik et al^[13].

Kundra et al ^[15] concluded that there was no statistically significant variation with respect to SBP/DBP among groups of tramadol and dexmedetomidine which was similar to my study where variation in SBP/DBP among both groups was statistically insignificant ($P > 0.05$). In the contrary Jinguo Wang study found dexmedetomidine was associated with higher incidence of hypotension (RR = 2.50; 95%CI [1.24, 5.03], $P = 0.01$, $I^2 = 0\%$), and bradycardia (RR = 4.78; 95%CI [1.76, 13.00], $P = 0.002$, $I^2 = 0\%$).

Lim fern ^[14] have found there was significant incidence of bradycardia and hypotension in dexmedetomidine group, which was not found in my study and this variation could be explained by small sample size.

In study conducted by Jinguo Wang ^[16], the incidence of sedation of dexmedetomidine was significantly higher than that of tramadol (RR = 2.48; 95% CI [1.32, 4.65], $P = 0.005$, $I^2 = 82\%$) In my study only the patients who were in Group D remained cooperative, orientated, tranquil and could respond to commands, in contrast to Group T where the

patients were not significantly sedated and these findings were similar to the results obtained in the study conducted by Elvan et al, Lim Fern et al [14]. The highest incidence of sedation was found to be 88% in this study which is almost similar to the finding of study done by Maheshwari et al. Postoperative nausea and vomiting (PONV) is a very unpleasant experience for the patient. Postoperative vomiting/retching can lead to rare but serious medical complications, such as aspiration of gastric contents, suture dehiscence, esophageal rupture, subcutaneous emphysema, or pneumothorax. PONV may delay discharge from PACUs and can be the leading cause of unexpected hospital admission after ambulatory anesthesia.

The study done by Mahesh Sharma, Kalpana Kharbuja, Bikash Khadka [17], regarding the side effects of tramadol concluded that tramadol group had significant number of nausea or vomiting episodes ($P=0.001$) which was similar in my study where $P=0.001$.

The study by Kundra et al [15], had found that the incidence of nausea was highly significant in tramadol group compared to the dexmedetomidine group ($P < 0.001$). Similarly, the incidence of vomiting was significantly higher in the tramadol group compared to dexmedetomidine group ($P = 0.041$). Tramadol had more nausea or vomiting when compared to dexmedetomidine.

Similarly in a study conducted by Jinguo Wang, Zaitang Wang, Junyan Liu & Na Wang 4 out of 332 patients receiving dexmedetomidine experienced nausea, and 80 out of 332 patients receiving tramadol experienced nausea. There were 342 patients receiving dexmedetomidine (1 with vomiting) and 342 patients receiving tramadol (41 with vomiting). Dexmedetomidine had lower incidences of nausea and vomiting than tramadol (Nausea: RR = 0.10; 95% CI [0.05, 0.19], $P < 0.00001$, $I^2 = 48\%$; Vomiting: RR = 0.13; 95% CI [0.06, 0.30], $P < 0.00001$, $I^2 = 0\%$), which was similar finding in my study where the mean nausea & vomiting score of Group D at T1 was measured as 1 ± 0.00 & nausea & vomiting score of Group T was recorded as 1.20 ± 0.40 . Nausea & vomiting score was statistically significant in between the study groups (< 0.05). Hence incidence of nausea and vomiting was significantly higher in the tramadol group compared to dexmedetomidine group in my study.

Thus from my study we can say that both the study drugs i.e. dexmedetomidine & tramadol were effective in preventing shivering after spinal anaesthesia as long as side effects & cost effectiveness and availability is kept in mind.

6. Conclusion

Spinal anaesthesia or sub arachnoid block is the anaesthesia of choice worldwide in emergent or non-emergent surgeries, owing to its ease of administration and the avoidance of several side effects of giving general anaesthesia to a patient. Shivering is one of the concerned side effects of spinal anaesthesia which could be prevented by using many non-pharmacological & pharmacological measures. Among the various pharmacological drugs. In this study we compared the efficacy of tramadol & dexmedetomidine to prevent

shivering in patients after giving spinal anaesthesia. Even though the maximum incidence of shivering was less in Group D at a particular time interval, the difference between the two groups were statistically insignificant. There was no significant variation in the haemodynamics of both the groups. Patients in the dexmedetomidine group remained more sedated without respiratory depression having p value as 0.001 at all-time intervals whereas patients in the tramadol group had more incidence of nausea and vomiting which was statistically significant with the p value of 0.001. Therefore we can conclude that both the study drugs i.e. dexmedetomidine & tramadol were effective in preventing shivering after spinal anaesthesia as long as side effects & cost effectiveness and availability is kept in mind.

7. Future Scope/ Our Limitations of the Study

Study has been done in a single centre with limited patient input study group. The limitations of this study were small sample size, and selection of medium duration surgeries as the chance of developing core hypothermia are more in long duration surgeries. Tympanic membrane temperature probe and mid esophagus temperature probe could not be used to measure core body temperature because it causes patient discomfort who is awake under spinal anaesthesia. Axillary temperature couldn't be monitored because of unavailability at the study site. Recurrence rate of shivering was not calculated. Our results provided evidence to extend the clinical value of dexmedetomidine beyond its routine usage for sedation and analgesia. As long as cost is not a barrier, dexmedetomidine having less side effects and less recurrence of shivering compared to tramadol, is more beneficial. Both drugs are effective in preventing shivering without haemodynamic instability.

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