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"COMPARISON OF INTRAVENOUS DEXMEDETOMIDINE AND TRAMADOL FOR CONTROL OF SHIVERING UNDER SPINAL ANAESTHESIA. A PROSPECTIVE RANDOMISED STUDY".

Anaesthesiology

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ABSTRACT

This prospective study compared intravenous dexmedetomidine and tramadol for controlling shivering during spinal anaesthesia in 70 adult patients. Primary outcomes included time for shivering resolution, with secondary outcomes covering shivering incidence, hemodynamics, adverse events, and patient satisfaction. Dexmedetomidine exhibited superior efficacy ($p < 0.05$), achieving quicker resolution and lower shivering incidence (15%) compared to tramadol (30%). Both drugs were well-tolerated, and patient satisfaction was higher with dexmedetomidine. Dexmedetomidine showed promise for perioperative shivering control, enhancing comfort and satisfaction.

KEYWORDS

Shivering, Spinal, Dexmedetomidine, Tramadol

INTRODUCTION

Spinal anaesthesia has been established as simple and safe anaesthesia technique for short to intermediate duration of infra umbilical surgeries.

It may not be very comfortable for all, especially those with intra-operative and postoperative shivering. Shivering is an oscillatory, involuntary mechanical muscular activity and a natural protective mechanism to the reduction of body temperature.[1] Shivering interferes with proper monitoring and is associated with several adverse effects, as it increases the circulating catecholamine, heart rate, cardiac output, minute ventilation, patient oxygen consumption, metabolic CO_2 production, lactic acid level, intraocular and intracranial pressure, and postoperative pain from surgical incision stretching.[2]

Shivering is not only physically distressing for the patient, but can have various other detrimental effects. It may lead to pain, patient discomfort, impede monitoring techniques, increase intraocular and intracranial pressures, double or even triple oxygen consumption and carbon dioxide production,[3] which might pose difficulties in patients with existing intrapulmonary shunts, fixed cardiac output or limited respiratory reserve.

Dexmedetomidine is a highly selective α-2 adrenoceptor agonist with potent effects on the central nervous system. Intravenous dexmedetomidine reduces both the vasoconstriction and shivering thresholds.[4]

Tramadol is an opioid analgesic with opioid effect mainly mediated via mu receptor with minimal effect on kappa and delta receptors. The anti-shivering action of tramadol is probably mediated via its opioid or serotonergic and noradrenergic activity or both. Tramadol, is an inhibitor of the re-uptake of serotonin (5- HT) and norepinephrine in the spinal cord found to influence the thermoregulatory control mechanisms. [5]

Tramadol is commonly used for the treatment of shivering in clinical practice. However, tramadol can lead to nausea and vomiting which is very distressing for the patient. Therefore, it is necessary to find a better drug with fewer side effects.

In present study, intravenous dexmedetomidine and intravenous tramadol will be compared in terms of efficacy to treat the shivering in patients subjected to various surgeries under spinal anaesthesia.

AIMS AND OBJECTIVE

To compare the safety and efficacy of intravenous dexmedetomidine or tramadol to treat the shivering in patients subjected to various surgeries under spinal anaesthesia.

MATERIAL AND METHOD

Study Area–K.D Medical College Hospital and Research Centre, Mathura
(Department of Anaesthesia and Critical Care)

Study Design- A Prospective randomised controlled study.

Study Sample Size- – 70 patients of ASA I and II undergoing lower abdomen and lower limb surgeries under spinal anaesthesia. (power of test=80%, level of significance=5%)

Sample Age Group- 18-60 years.

Study Period- One year duration from June 2023 to December 2023.

Group Allocation- - After given spinal anaesthesia patients complaining of shivering were divided into two groups by computer generated random numbers: -

1. GROUP D (n =35): received Dexmedetomidine (0.5µg/kg) intravenous for shivering in spinal anaesthesia.

2. GROUP T (n =35): received Tramadol (0.5mg/kg) intravenous for shivering in spinal anaesthesia.

Inclusion Criteria

1. Patients aged 18 to 60 years.
2. ASA grade 1 and 2.

Exclusion Criteria

1. ASA grade 3 and 4.
2. Patients with fever, drug allergic reaction, thyroid illness and neuromuscular diseases.
3. Patients suffering from any chronic pain syndrome, or having any psychiatric illness, urinary tract infection, severe diabetes or autonomic neuropathies, known history of substance or alcohol abuse.
4. Patients who had a history of known hypersensitivity to dexmedetomidine or tramadol.
5. Patients converted to general anaesthesia were excluded from study.

Method:

The present study was Prospective Randomised Controlled trial in which 70, ASA I and II patients of either sex who underwent elective

surgeries under spinal anaesthesia complaining of shivering were selected. Patients were allocated randomly into two groups D (n=35) and T (n=35).

The attending anaesthesiologist recorded the time in minutes at which shivering started after spinal anaesthesia (onset of shivering), severity of the shivering, time to the disappearance of shivering and response rate (shivering ceasing within 15 min after treatment). Shivering was graded with a score validated by Crossley and Mahajan.[6]

All the patients included in the study were preloaded with 500 ml of ringer lactate solution. After shifting to operation theatre baseline parameters and temperature were recorded using standard monitor. All patients in our study received spinal anaesthesia in lateral position using 25G Quincke needle by midline approach within L3-L4 intervertebral space under sterile precautions. After giving spinal anaesthesia patients were adequately covered with sterile drapes.

Shivering of grade 2 and 3 scale was considered to need treatment. When patients developed shivering of mentioned grades, they were randomly assigned to one of the 2 study groups.

Group D received intravenous Dexmedetomidine (0.5µg/kg) over 5 minutes.

Group T received intravenous Tramadol (0.5mg/kg) over 5 minutes.

The time from drug administration until the disappearance of shivering was noted. Patients were monitored at interval of 1 minute, 3min, 5min and hence forth 10, 15, 20 and 30 minutes until the end of shivering.

Patients were monitored for recurrence of shivering and side effects like nausea, vomiting, bradycardia, hypotension.

Bradycardia, hypotension was treated with Atropine and Mephentermine and vomiting with Metoclopramide in titrated dose when required.

Shivering score	Characteristic
0	No shivering
1	Peripheral vasoconstriction, but no visible shivering
2	Muscular activity in only one muscle group
3	Muscular activity in more than one muscle group, but not generalised
4	Shivering involving the whole body.

RESULTS AND ANALYSIS

Data analysis was done with the help of computer by using SPSS software version 26.0. Using this software, percentage, mean, standard deviation and 'p' value were calculated through one way ANOVA, and Chi square test and a P value of < 0.05 was taken as significant.

All 70 patients with ASA physical status I/II involved in study who satisfied all inclusion criteria were randomly divided into two groups:
1. GROUP D (n =35): received Dexmedetomidine (0.5µg/kg) intravenous for shivering in spinal anaesthesia.

2. GROUP T (n =35): received Tramadol (0.5mg/kg) intravenous for shivering in spinal anaesthesia.

Table - 1 Age wise distribution of Subjects

Age group (in yrs.)	Group D		Group T		P. Value
	N0.	%	N0.	%	
20-30	7	20%	11	31%	0.189
31-40	6	17%	7	20%	
41-50	8	23%	7	20%	
51-60	14	40%	10	29%	
Total	35	100%	35	100%	
Mean ±SD	44.18±12.44		41.28±11.38		

According to Table no.1, it was observed that maximum number of patients were in the group D 51-60 years age group (40%) and group T 51-60 years age group (29%). The age of patients ranged from 20-60 years, mean age ± SD of patients in Group D was 44.18±12.44 years while that of group T was 41.28±11.38 years. On comparing both group, significant difference was not found. (P. Value = 0.189).

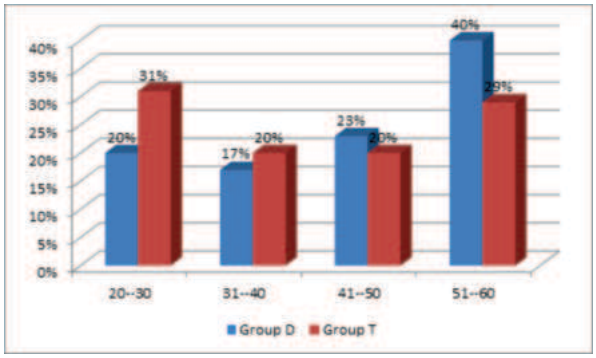
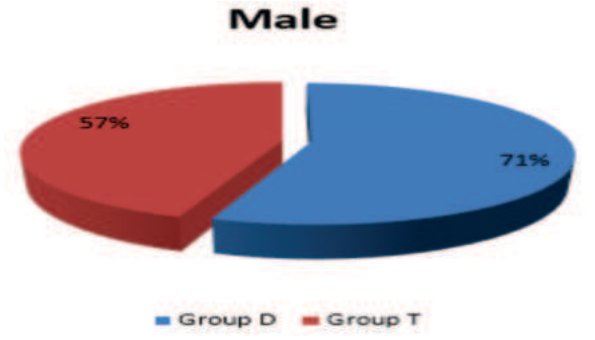


Table - 2 Gender wise distribution of Subjects

Gender	Group D		Group T		P. Value
	N0.	%	N0.	%	
Male	25	71%	20	57%	0.357
Female	10	29%	15	43%	
Total	35	100%	35	100%	



According to Table no.2 In Group D there were 25(71%) male and 10(29%) female and group T had 20 (57%) male and 15 (43%) female subjects. The P. Value is 0.357.

Table - 3 Weight distribution in groups

Weight (in kg)	Group D		Group T		P. Value
	N0.	%	N0.	%	
50--58	10	29%	3	9%	0.355
59--68	15	42%	20	57%	
69--78	10	29%	12	34%	
Total	35	100%	35	100%	
Mean±SD	63.72±6.67		65.88±4.83		

According to Table no.3, it was observed that maximum number of patients were in the group D 59-68 kg weight (42%) and group T 59-68 kg weight (57%). The weight of patients Mean±SD in Group D is 63.72± 6.67kg while that of group T is 65.88± 4.83kg. Significant difference was not found on comparing the data of both groups. (P. Value = 0.355).

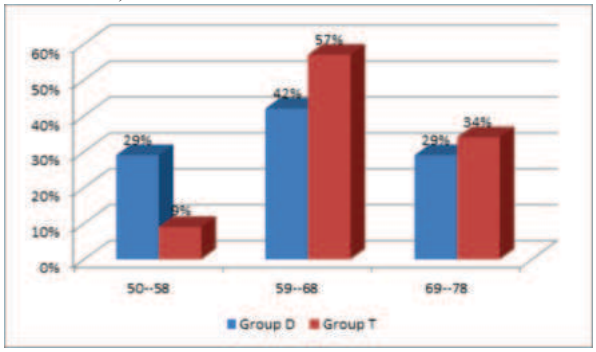
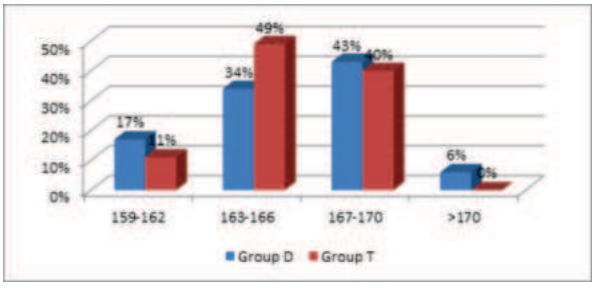


Table - 4 Height (cm) distribution in groups

Height(cm)	Group D (n=35)		Group T (n=35)		P. Value
	No.	%	No.	%	
159-162	6	17%	4	11%	0.069
163-166	12	34%	17	49%	
167-170	15	43%	14	40%	

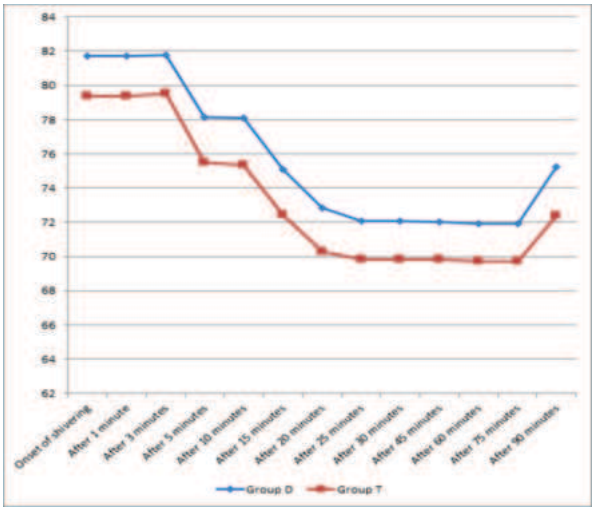
>170	2	6%	0	0%	
Total	35	100%	35	100%	
Mean ±SD	165.80±3.30		165.30±2.71		



According to Table no.4, it was observed that maximum number of patients were in the group D 167-170 (in cm) height (43%) and group T 163-166 (in cm) height (49%). The height of patients Mean±SD in Group D is 165.80±3.30 cm while that of group T is 165.30± 2.71cm. Significant difference was not found on comparing the data of both groups. (P. Value = 0.069).

Table -5 Mean Heart Rate in study Groups at different time interval

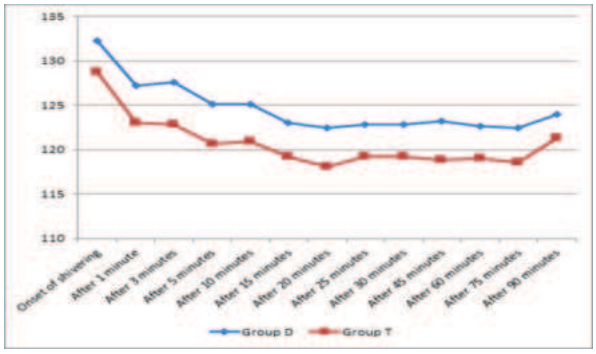
	Group D		Group T		't' test	P. Value
Time interval (in min)	N	Mean±SD	N	Mean±SD		
Onset of shivering	35	81.70±4.77	35	79.36±4.18	2.288	0.027
After 1 minute	35	81.70±4.77	35	79.36±4.18	2.288	0.027
After 3 minutes	35	81.78±4.75	35	79.50±4.08	2.242	0.030
After 5 minutes	35	78.16±4.82	35	75.48±4.23	2.620	0.012
After 10 minutes	35	78.08±4.86	35	75.34±4.36	2.656	0.011
After 15 minutes	35	75.10±4.57	35	72.42±4.41	2.713	0.009
After 20 minutes	35	72.82±4.66	35	70.26±3.96	2.603	0.012
After 25 minutes	35	72.06±4.71	35	69.84±3.88	2.282	0.027
After 30 minutes	35	72.06±4.71	35	69.84±3.88	2.282	0.027
After 45 minutes	35	72.02±4.65	35	69.84±3.88	2.268	0.028
After 60 minutes	35	71.94±4.61	35	69.70±3.85	2.347	0.023
After 75 minutes	35	71.94±4.61	35	69.70±3.85	2.347	0.023
After 90 minutes	35	75.26±4.49	35	72.38±4.07	3.031	0.004



At baseline, the mean heart rate in Group D was 81.70±4.77 beats per minute whereas in Group T, the mean value was 79.36±4.18 beats per minute showing no significant difference among groups. (P. Value = 0.027). The Heart Rate was decreased at 20 minutes-to-60-minute interval in two groups. The downward trend continued at 20 to 60 min as well. There is significant difference in group D and Group T. The mean value of heart rate remained stable.

Table -6 Mean SBP in study Groups at different time interval

	Group D		Group T		't' test	P. Value
Time interval (in min)	N	Mean±SD	N	Mean±SD		
Onset of shivering	35	132.28±8.16	35	128.70±6.92	2.431	0.0019
After 1 minute	35	127.24±13.06	35	123.00±14.95	1.683	0.099
After 3 minutes	35	127.64±12.58	35	122.88±15.11	1.865	0.068
After 5 minutes	35	125.14±10.54	35	120.62±12.34	2.100	0.041
After 10 minutes	35	125.08±10.13	35	120.90±11.78	2.029	0.048
After 15 minutes	35	123.02±7.90	35	119.24±8.50	2.384	0.021
After 20 minutes	35	122.48±7.47	35	118.10±7.26	3.039	0.004
After 25 minutes	35	122.80±7.93	35	119.24±7.66	2.397	0.020
After 30 minutes	35	122.80±7.93	35	119.20±7.69	2.420	0.019
After 45 minutes	35	123.20±7.87	35	118.80±7.98	2.880	0.006
After 60 minutes	35	122.64±7.55	35	118.98±7.33	2.565	0.013
After 75 minutes	35	122.48±7.65	35	118.54±7.57	2.605	0.012
After 90 minutes	35	123.94±7.63	35	121.34±7.19	1.783	0.081



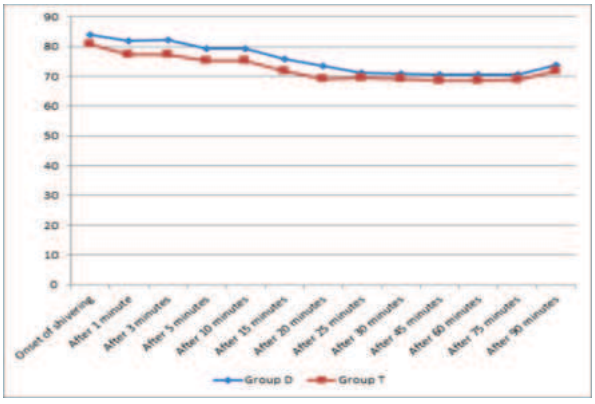
The mean basal systolic blood pressure in Group D was 132.28± 8.16mmHg and Group T was 128.70± 6.92mmHg. Mean Systolic blood pressure decreased at 20 minute-to-75-minute interval in two groups. The downward trend continued at 20 to 75 min as well. The systolic blood pressure remained stable thereafter.

Comparing the obtained data statistically it was found significant at all time interval (P < 0.05).

Table -7 Mean DBP in study Groups at different time interval

Time interval (in min)	Group D		Group T		't' test	P. Value
	N	Mean±SD	N	Mean±SD		
Onset of shivering	35	83.98±4.89	35	80.80±4.55	3.823	<0.001
After 1 minute	35	81.88±7.87	35	77.16±8.58	3.123	0.003
After 3 minutes	35	82.18±7.78	35	77.30±8.21	3.354	0.002
After 5 minutes	35	79.38±5.87	35	75.22±8.83	3.717	<0.001
After 10 minutes	35	79.38±5.87	35	75.22±5.83	3.717	<0.001
After 15 minutes	35	75.92±4.59	35	71.86±4.07	4.741	<0.001

After 20 minutes	35	73.36±4.82	35	69.06±4.17	5.473	<0.001
After 25 minutes	35	71.14±5.33	35	69.56±5.31	1.754	0.086
After 30 minutes	35	70.86±5.24	35	69.24±4.92	1.821	0.075
After 45 minutes	35	70.54±5.03	35	68.68±4.29	2.178	0.034
After 60 minutes	35	70.54±5.03	35	68.68±4.29	2.178	0.034
After 75 minutes	35	70.66±4.99	35	68.84±4.23	2.142	0.037
After 90 minutes	35	73.90±4.62	35	71.86±4.07	2.376	0.021



The mean basal diastolic blood pressure in Group D was 83.98± 4.89 mmHg and Group T was 80.80± 4.55mm Hg and was statistically significant. Mean diastolic blood pressure started decreasing at 20-minute-to 75 minutes interval post spinal anaesthesia.

The downward trend at after 20 minutes to 75 min as well. The mean diastolic blood pressure remained stable thereafter in Group D and Group T.

Comparing the obtained data statistically it was found significant difference was found in all intervals. The P. value is <0.05 between the two groups.

Table -8 Mean MAP in study Groups at different time interval

	Group D		Group T		't' test	P. Value
Time interval (in min)	N	Mean±SD	N	Mean±SD		
Onset of shivering	35	100.10±4.90	35	96.70±4.55	3.776	<0.001
After 1 minute	35	96.98±9.11	35	92.46±10.20	2.552	0.014
After 3 minutes	35	97.36±8.72	35	92.48±10.14	2.804	0.007
After 5 minutes	35	94.66±6.76	35	90.30±7.55	3.193	0.002
After 10 minutes	35	94.68±6.59	35	90.44±7.26	3.205	0.002
After 15 minutes	35	91.62±4.97	35	87.70±4.65	3.989	<0.001
After 20 minutes	35	87.70±4.55	35	85.40±4.29	5.146	<0.001
After 25 minutes	35	88.36±5.09	35	86.08±5.33	2.440	0.018
After 30 minutes	35	88.20±4.99	35	86.10±5.37	2.127	0.038
After 45 minutes	35	88.10±4.64	35	85.38±4.57	3.235	0.002
After 60 minutes	35	87.97±4.26	35	85.40±4.54	2.965	0.005
After 75 minutes	35	87.92±4.65	35	85.34±4.40	3.049	0.004
After 90 minutes	35	90.56±4.51	35	88.40±4.24	2.436	0.019

The mean basal MAP in Group D was 100.10± 4.90mmHg and Group T was 96.70± 4.55mmHg. Mean MAP decreased at 1 minute- to-75-minutes interval in two groups. The downward trend continued to 1 - to- 75 minutes in two groups.

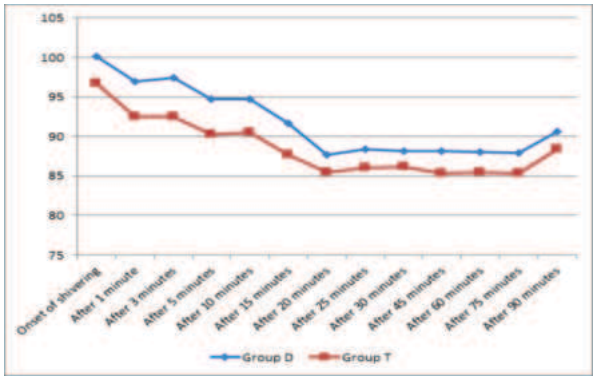
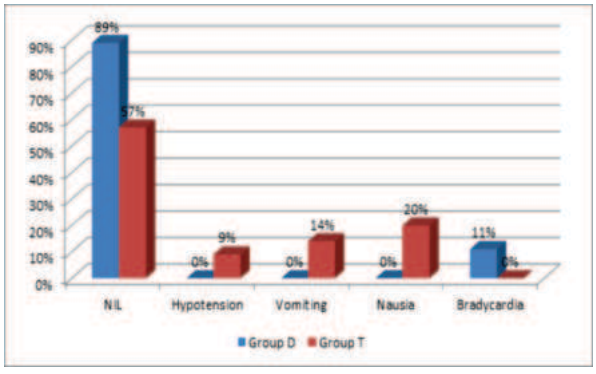


Table - 9 Side effect

Side effect	Group D		Group T	
	N0.	%	N0.	%
NIL	31	89%	20	57%
Hypotension	0	0%	3	9%
Vomiting	0	0%	5	14%
Nausea	0	0%	7	20%
Bradycardia	4	11%	0	0%
Total	35	100%	35	100%

P. Value = 0.023

The vomiting was observed more frequently in the tramadol group with 5 patients, hypotension 3 patients and nausea 7 patients, The bradycardia was observed in in the dexmedetomidine in 4 patients. The P value is significant. (P value= 0.023)



DISCUSSION

The shivering is a protective response occurring as part of a centrally mediated thermoregulatory defense mechanism to hypothermia.[7] The shivering is a frequent complication under regional anaesthesia occurring either as a result of a decrease in core body temperature or mis information from receptors.[8] The shivering under anaesthesia not only increases the oxygen consumption but also causes tachycardia, hypertension and interferes with the monitoring of pulse oximeter, electrocardiogram and blood pressure. Inspite of the availability of numerous drugs to treat shivering, there is no consensus drug that effectively controls shivering without any side effects.

The shivering was controlled faster in the dexmedetomidine group and it stayed for a longer time than tramadol group. Mittal et al. performed a study on the comparison of dexmedetomidine and tramadol for post spinal anaesthesia shivering. They concluded that dexmedetomidine in a dose of 0.5 mcg.kg−1 had a faster onset to control shivering in 2.52 ± 0.44 min.[9] Usta et al. conducted a study on dexmedetomidine infusion for the prevention of shivering during spinal anaesthesia. They observed that dexmedetomidine infusion of $0.4 mcg.kg^{-1}.h^{-1}$ was effective in preventing shivering and providing sedation for minor surgical procedures.[10]

At baseline, the mean heart rate in Group D was 81.70±4.77 beats per minute whereas in Group T, the mean value was 79.36±4.18 beats per minute showing no significant difference among groups. (P. Value = 0.027). The Heart Rate was decreased at 20 minutes-to-60-minute interval in two groups. The downward trend continued at 20 to 60 min as well. There is significant difference in group D and Group T. The mean value of heart rate remained stable.

Similar finding was observed by MD Shawagfeh et al in his study.

The mean basal systolic blood pressure in Group D was 132.28± 8.16 mmHg and Group T was 128.70± 6.92 mmHg. Mean Systolic blood pressure decreased at 20 minute-to-75-minute interval in two groups. The downward trend continued at 20 to 75 min as well. The Systolic blood pressure remained stable thereafter. Comparing the obtained data statistically it was found significant at all time intervals ($P < 0.05$).

The mean basal diastolic blood pressure in Group D was 83.98± 4.89 mmHg and Group T was 80.80± 4.55 mm Hg and was statistically significant. Mean diastolic blood pressure started decreasing at 20-minute-to -75 minutes interval post spinal anaesthesia. The downward trend continued at 20 minutes to 75 min as well. The mean diastolic blood pressure remained stable thereafter in Group D and Group T. Comparing the obtained data statistically it was found significant difference in all intervals. The P. value is <0.05 between the two groups.

The mean basal MAP in Group D was 100.10± 4.90mmHg and Group T was 96.70± 4.55mmHg. Mean MAP decreased at 1 minute- to-75-minutes interval in two groups. The downward trend continued to 1 -to- 75 minutes in two groups.

The vomiting was observed more frequently in the tramadol group with 5 patients, hypotension 3 patients and nausea 7 patients, The Bradycardia was observed in in the dexmedetomidine in 4 patients. The P value is significant. (P value= 0.023).

CONCLUSION

We conclude that dexmedetomidine is more effective than tramadol. The complications reported with dexmedetomidine were easily treatable and did not have much clinical impact.

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