Intravenous dexmedetomidinevs intravenous tramadol for control of postspinal shivering in patients undergoing knee arthroscopy: a randomized double-blind placebo controlled trial

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Abstract: Background: Shivering, the rate of which in regional anaesthesia is 39%, is an undesired complication seen intra and postoperatively. **Aim:** this study aimed to compare the ability of preventing post spinal anesthesia shivering by i.v. dexmeditomedine and tramadol. **Methods:** A total of 75 patients with ASA I – II, aged 18-60 years and undergoing elective knee arthoscopy surgery under spinal anesthesia were divided into three groups randomly, before spinal anesthesia by 20 minutes 0.5 mcq/kg dexmeditomedine i.v was applied to D group (n=25), 0.5 mg tramadol i.v. was applied to T group (n=25) and 0.9% normal saline was applied to group C (n=25) in 10 minutes. The hemodynamics, oxygen saturation, axillary temperature, shivering, sedation score and side effects were evaluated and recorded intraoperatively every 5 minutes. **Results:** there was significant difference between group D and T in compare with C group as regard the incidence of shivering (p= 0.031) and there were significant differences between D group and other groups as regard grade of shivering (p=0.01), there was significant difference between D group and others as regard sedation score it was higher in D group. Nausea and vomiting was significant higher in T group in compared to other groups. **Conclusion:** The current study revealed that prophylactic i.v. dexmeditomedine 0.5 mcq/kg was effective as i.v. tramadol 0.5mg/kg in prevention post spinal shivering in patients undergoing knee arthroscopy compared to the control group.

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Key words: Arthoscopic surgery, dexmeditomedine, tramadol, shivering, spinal anesthesia.

1. Introduction

Shivering is known to be a frequent complication, reported in 40 to 70 % of patients undergoing surgery under regional anesthesia. Post-anesthetic shivering (PAS) is spontaneous involuntary, rhythmic, oscillating, thermo-like muscle hyperactivity that increases metabolic heat production up to 600 % after general or regional anesthesia [(1)].

This unpleasant and undesirable complication occurring after sub-arachnoid block (SAB) secondary to vasodilatation due to sympathetic blockade [(2)].

Shivering occurs mainly in hypothermic patients but may also occur in normothermic. Shivering leads to feelings of discomfort in the patient as well as an increase in oxygen consumption, carbon dioxide production, catecholamine release, cardiac output, intraocular pressure and complications such as tachycardia and hypertension [(3)].

In addition to this, shivering may affect accurate monitoring by causing artifacts in the monitor [(4)].

Shivering also increases intracranial pressure, and may contribute to increased wound pain, delayed wound healing [(5)], and delayed discharge from post-anesthetic care [(6)].

Dexmedetomidine, a centrally acting alpha 2 adrenergic agonist, has been used as a sedative agent and is known to reduce the shivering threshold. Various studies have been performed using dexmedetomidine in the prophylaxis of postoperative shivering [(7)].

During the last decade, tramadol has become a favored and commonly used drug for post-spinal anesthesia shivering. However, it has many adverse effects like nausea, vomiting, dizziness etc., which cause further discomfort to the patient [(8)].

Aim of the Work

The aim of the study was to compare the efficacy of Intravenous (i.v) Dexmedetomidine and i.v Tramadol in the treatment of postspinal anesthesia shivering.

2. Patients and Methods

After obtaining approval from the Research Ethical Committee of Ain Shams University, this study was conducted on 75 patients in the operating theatres of Ain Shams University Hospital. It was a randomized double-blind placebo controlled trial. Study Periodwas6 months from 1st of May to 31th of October 2018.

After obtaining institutional approval and written informed consent from all patients, the study included patients with ASA I and II patients, with ages of 18–60 years, body weight 60-100 Kg and underwent elective knee arthroscopy under spinal anesthesia.

Patients who refused to participate, patients with duration of surgery more than 90 min, hypo- or hyperthyroidism, cardiopulmonary disease, psychological disorders, cases with a need for blood transfusion during surgery, an initial body temperature >38.0C or <36.0C, a known history of alcohol or substance abuse and patients receiving vasodilators or medications likely to alter thermoregulation were excluded from the study.

All patients were divided into three groups each groups contained 25 patients: Group D: Dexmedetomidine (0.5 mcg/kg) IV (n=25 patients), Group T: Tramadol 0.5mg/kg IV (n=25 patients) and Group C: 0.9% sodium chloride (normal saline (NS)) (n=25 patients).

Blinding and Randomization

Blinding of patients and assigning them random to their groups were done by giving patients serial numbers, provided by a computer program.

Study Tools and Study Procedures:

Pre-anaesthetic examination, preoperative investigations including complete blood picture, renal function tests, liver function tests, and coagulation profile and informed written consent obtained from the participants were fulfilled.

Anesthetic Management Plan:

1-Pre-operative Settings:

Patients didn't not receive premedication. On arrival in the operating theatre, all patients had a venous cannula inserted. IV fluids were administrated at room temperature 25C. No other warming device used. Lactated Ringer's solution were administrated and infused at 10 ml/kg over 30 min before spinal anesthesia. The infusion rate was reduced to 6 ml/ kg.

2-Intra-operative Settings

Heart rate, mean arterial pressure (MAP), and peripheral oxygen saturation recorded using standard non-invasive monitors before intrathecal injection and thereafter at 5 min interval, body temperature (axillary temperature) were recorded with an axillary thermometer. The ambient temperature was measured by a wall thermometer. The ambient temperature will be maintained at 25C with constant humidity.

Supplemental oxygen (5 liter/ min) was delivered via a facemask during the operation. All patients were covered with one layer of surgical drapes over the chest, thighs, and calves during the operation and one cotton blanket over the entire body after operation. During the preoperative period, sensory block were assessed with a pinprick test at 5 min intervals.

The study drugs were diluted to a volume of 20 ml, presented as coded syringes and given over 10 minutes by an anesthesiologist who was blinded to the group allocation to patients 20 min before initiation of subarachnoid block.

Subarachnoid anesthesia was instituted at either L3/4 or L4/5 interspaces. Hyperbaric bupivacaine, 5 mg /ml, 15mg injected using a 25 G Quincke spinal needle.

The presence of shivering was observed by an observer that was blinded to the study drug administered. Shivering was graded using a scale similar to that validated by:

Tsai and Chu Scale [23]:

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 but not generalized;

4= Shivering involving the whole body.

During surgery, a shivering score was recorded at 5 min intervals. if after 15 min of spinal anesthesia and concomitant administration of a prophylactic dose of one of the study drugs, Grade 3 or 4 shivering was noted, the prophylaxis would be regarded as ineffective and meperidine 25 mg IV would be administered.

Side-effects, such as hypotension, nausea and vomiting were recorded. Hypotension defined as a decrease in MAP of more than 20% from baseline (baseline MAP was calculated from three measurements taken on the ward before surgery). This will be treated by crystalloid infusion and if necessary ephedrine 5 mg IV will be administered. The amount of ephedrine given in each group would be recorded. IV granisetron (1 mg) would be given in case of vomiting or after 2 successive episodes of nausea.

The attending anesthetist also assessed the degree of **sedation level** at the 20th min of intraoperative duration according to sedation score (Ramsay sedation scale) [9].

Ramsay sedation scale:

Score Response

1. Anxious or restless or both.
2. Cooperative, orientated and tranquil.
3. Responding to commands.
4. Brisk response to stimulus.
5. Sluggish response to stimulus.
6. No response to stimulus.

Statistical methods

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 18.0, IBM Corp., Chicago, USA, 2009.

Descriptive statistics were done for quantitative data as minimum & maximum of the range as well as mean±SD (standard deviation) for quantitative normally distributed data, while it was done for qualitative data as number and percentage.

Inferential analyses were done for quantitative variables using Shapiro-Wilk test for normality testing, independent t-test in cases of two independent groups with normally distributed data and ANOVA test with post hoc Tukey test for more than two independent groups with normally distributed data. In qualitative data, inferential analyses for independent variables were done using Chi square test for differences between proportions and Fisher's Exact test for variables with small expected numbers with post hoc Bonferroni test. Long rank test was used to compare rates. The level of significance was taken at P value < 0.050 is significant, otherwise is non-significant.

3. Results

Table (1): Demographic characteristics:

Variables		D-group (N=25)	T-group (N=25)	C-group (N=25)	P
Age (years)	Mean±SD	38.6±11.5	36.9±9.8	35.5±9.7	^0.587
	Range	22.0–58.0	20.0–53.0	20.0–55.0	
Sex n. (%)	Male	13 (52.0%)	16 (64.0%)	17 (68.0%)	#0.481
	Female	12 (48.0%)	9 (36.0%)	8 (32.0%)	
Weight (kg)	Mean±SD	76.0±13.1	77.7±14.8	75.2±12.3	^0.800
	Range	46.8–98.5	52.4–112.2	51.6–103.0	
Height (cm)	Mean±SD	169±6.2	170.6±6.4	170.2±6.2	#0.203
	Range	155–177	156–179	160–178	
ASA n. (%)	I	17 (68.0%)	18 (72.0%)	20 (80.0%)	#0.620
	II	8 (32.0%)	7 (28.0%)	5 (20.0%)	
Mean sensory*	Mean±SD	T7	T8	T8	^0.528
	Range	T6-10	T4-10	T6-10	
Duration of operation (minutes)	Mean±SD	50.7±17.9	53.4±15.0	57.2±15.2	^0.359
	Range	30.0–95.0	25.0–90.0	25.0–90.0	

^ANOVA test. #Chi square test. * block at the 20th min.

There was no significant difference between the studied groups regarding demographic characteristics.

Table (2): The systolic blood pressure readings among the studied groups (mmHg):

Time		D group (N=25)	T group (N=25)	C group (N=25)	^P
Basal	Mean±SD	121.6±11.0	121.4±10.5	120.8±9.3	0.961
	Range	105.0–140.0	107.0–150.0	110.0–140.0	
Minute-5	Mean±SD	112.5±7.6	109.2±5.0	111.0±6.7	0.203
	Range	99.0–129.0	100.0–120.0	100.0–130.0	
Minute-10	Mean±SD	111.1±9.1	108.7±5.9	110.4±4.9	0.449
	Range	89.0–126.0	90.0–121.0	103.0–127.0	
Minute-15	Mean±SD	111.5±6.9	108.7±9.0	109.1±4.6	0.322
	Range	99.0–123.0	80.0–130.0	102.0–120.0	
Minute-20	Mean±SD	112.2±6.7	110.9±7.1	110.6±4.3	0.614
	Range	101.0–120.0	102.0–135.0	105.0–120.0	

^ANOVA test with post hoc Tukey test.

There was no significant difference between studied groups regarding the systolic blood pressure (SBP) readings.

Table (3): The diastolic blood pressure readings among the studied groups (mmHg):

Time		D group (N=25)	T group (N=25)	C group (N=25)	P
Basal	Mean±SD	80.8±9.3	79.0±7.9	78.8±8.6	0.677
	Range	63.0–98.0	60.0–90.0	65.0–95.0	
Minute-5	Mean±SD	73.0±9.5	71.5±6.2	70.3±6.9	0.520
	Range	50.0–90.0	60.0–80.0	60.0–90.0	
Minute-10	Mean±SD	69.3±10.5	71.6±4.7	71.0±4.3	0.595
	Range	40.0–85.0	59.0–79.0	65.0–85.0	
Minute-15	Mean±SD	72.2±8.4	70.8±5.6	70.4±5.0	0.661
	Range	60.0–90.0	55.0–80.0	65.0–90.0	
Minute-20	Mean±SD	72.4±7.0	74.1±5.3	72.1±4.8	0.352
	Range	58.0–80.0	65.0–88.0	66.0–88.0	

^ANOVA test with post hoc Tukey test.

There was no significant difference between studied groups regarding the diastolic blood pressure (DBP) readings.

Table (4): The mean arterial pressure readings among the studied groups (mmHg):

Time		D-group (N=25)	T-group (N=25)	C-group (N=25)	^P
Basal	Mean±SD	94.4±9.4	93.2±8.5	92.8±8.6	0.801
	Range	78.7–112.0	76.7–110.0	80.0–110.0	
Minute-5	Mean±SD	86.1±8.1	84.1±5.4	83.8±6.3	0.414
	Range	66.3–103.0	73.3–93.3	73.3–103.3	
Minute-10	Mean±SD	83.2±9.3	84.0±4.5	84.1±4.1	0.870
	Range	56.3–98.7	69.3–89.7	78.3–99.0	
Minute-15	Mean±SD	85.3±7.4	83.5±6.5	83.3±4.7	0.458
	Range	73.0–99.3	63.3–96.7	77.3–100.0	
Minute-20	Mean±SD	85.7±6.2	86.4±5.4	84.9±4.5	0.625
	Range	73.0–93.0	77.7–98.7	79.0–98.7	

^ANOVA test with post hoc Tukey test.

There was no significant difference between studied groups regarding mean arterial pressure (MAP) readings.

Table (5): The heart rate readings among the studied groups (beats/minute):

Time		D group (N=25)	T group (N=25)	C group (N=25)	^P
Basal	Mean±SD	79.3±12.9	79.7±8.8	79.6±8.9	0.964
	Range	64.0–99.0	63.0–90.0	60.0–97.0	
Minute-5	Mean±SD	76.4±13.4	80.8±8.9	78.5±6.7	0.275
	Range	55.0–99.0	66.0–99.0	70.0–90.0	
Minute-10	Mean±SD	76.7±12.7	83.5±11.0	80.0±9.6	0.065
	Range	54.0–96.0	62.0–99.0	62.0–99.0	
Minute-15	Mean±SD	76.3±11.6	83.5±11.2	78.7±8.9	0.059
	Range	54.0–99.0	62.0–99.0	62.0–91.0	
Minute-20	Mean±SD	77.5±10.7	84.3±10.8	80.1±8.4	0.061
	Range	60.0–97.0	62.0–100.0	62.0–91.0	

^ANOVA test with post hoc Tukey test.

There was no significant difference between studied groups regarding heart rate readings.

Table (6): The O_2 saturation readings among the studied groups (%):

Time	Measures	D group (N=25)	T group (N=25)	C group (N=25)	^P
Basal	Mean±SD	97.9±0.9	98.1±1.1	97.6±1.1	0.270
	Range	96.0–100.0	96.0–100.0	96.0–100.0	
Minute-5	Mean±SD	97.9±0.9	98.2±1.0	97.7±0.9	0.115
	Range	97.0–100.0	96.0–100.0	96.0–99.0	
Minute-10	Mean±SD	98.0±0.9	98.1±1.1	98.0±0.9	0.832
	Range	96.0–100.0	96.0–100.0	97.0–100.0	
Minute-15	Mean±SD	97.7±1.0	98.0±0.9	97.5±1.0	0.274
	Range	96.0–100.0	96.0–99.0	96.0–99.0	
Minute-20	Mean±SD	97.9±0.9	98.1±1.0	97.9±1.0	0.745
	Range	96.0–100.0	96.0–100.0	96.0–100.0	

^ANOVA test

There was no significant difference between studied groups regarding O_2 saturation readings among the studied groups.

Table (7): Axillary temperature readings among the studied groups (Cº):

Time	Measures	D group (N=25)	T group (N=25)	C group (N=25)	^P
Basal	**Mean±SD**	36.4±0.1	36.4±0.1	36.4±0.1	0.387
	Range	36.3–36.5	36.3–36.5	36.3–36.5	
Minute-5	**Mean±SD**	36.3±0.1	36.4±0.1	36.3±0.1	0.146
	Range	36.2–36.5	36.2–36.5	36.2–36.4	
Minute-10	**Mean±SD**	36.3±0.1	36.3±0.1	36.3±0.1	0.284
	Range	36.2–36.4	36.2–36.4	36.2–36.4	
Minute-15	**Mean±SD**	36.3±0.1	36.3±0.1	36.3±0.1	0.580
	Range	36.1–36.4	36.1–36.4	36.1–36.4	
Minute-20	**Mean±SD**	36.2±0.1	36.3±0.1	36.2±0.1	0.131
	Range	36.1–36.4	36.1–36.4	36.1–36.3	

^ANOVA test

There was no significant difference between studied groups regarding axillary temperature readings at different times among the studied groups.

Table (8): The incidence of shivering among the studied groups:

Variables		D-group (N=25)	T-group (N=25)	C-group (N=25)	P
Shivering n. (%)		2 (8.0%)a	3(12.0%)a	9 (36.0%)a	**& 0.031***
Grade of shivering ***at the 20th min***	**≤ 2**	23 a	22 a	16 a	**& 0.031***
	> 2	2 a	3 a	9 a	

^Independent t-test. & Fisher's Exact test with post hoc Bonferroni test (homogenous groups had the same letter "a, b". *Significant. Homogenous groups have the same letter NS not significant

There were significant differences between D group and T group compared to C group regarding the incidence of shivering. There was no significant difference between the D group and T group as regard the incidence of shivering and the grade of shivering after 20 minutes of the intrathecal injection.

Table (9): The side effects among the studied groups:

Variables	D group (N=25)	T group (N=25)	C group (N=25)	& P
Sedation score at20th min intraoperative	4(1-3) a	2(1-2) b	1(1-2) b	**0.001***
Nausea	1 (4.0%) a	6 (24.0%) b	1 (4.0%) a	**0.043***
Vomiting	0 (0.0%) a	6 (24.0%) b	0 (0.0%) a	**0.001***
Bradycardia	2 (8.0%)	0 (0.0%)	0 (0.0%)	0.324
Hypotension	2 (8.0%)	1 (4.0%)	2 (8.0%)	1.000

& Fisher's Exact test. *Significant. Homogenous groups have the same letter, data presented is median (Minimum-Maximum)

There were significant differences between T group and the other groups as regard the incidence of **Nausea and vomiting.** There was no significant difference between the studied groups regarding the incidence of **bradycardia and hypotension.** There was a significant difference between D group and the other groups as regard **Sedation score** after 20 minutes of the intrathecal injection.

4. Discussion

In the current study, administration of 0.5 mcq/kg i.v dexmeditomidine and, Administration of 0.5 mg/kg i.v tramadol were significant reducing the incidence of shivering during spinal anesthesia in patients undergoing knee arthroscopy compared to the control group.

As regard demographic characters, mean arterial pressure, heart rate, oxygen saturation and body temperature, these results were not significant and these results were supported by the results of the studies carried on dexmeditomidine by ***Megalla et al*** [(10)]***, Botros et al*** [(11)]***, Ameta et al*** [(12)]***, Bajwa et al.*** [(13)]***, Arora et al.*** [(14)] and studies carried on Tramadol by

Billotta et al. [15]**,** ***Dhimar et al.*** [16], ***Vilayudha and Chiruvella*** [17]**.**

In contrast to the results of the current study, the study of ***Usta*** [7] and his colleagues, 2011**,** found that the HR was significant lower in the D group when compared with the C group from the 5th minute of infusion until the end of the blockade.

According to the incidence of shivering, these results were supported by the results of the studies carried on dexmediomedine by ***Megalla et al*** [10]**,** ***Botros et al*** [11]**,** ***Ameta et al*** [12]**,** ***Bajwa et al.*** [13]**,** ***Arora et al.*** [14] and studies carried on Tramadol by ***Billotta et al.*** [15]**,** ***Dhimar et al.*** [16], ***Vilayudha and Chiruvella*** [17]**.**

According to the incidence of shivering, these results were supported by the studies of ***Botros*** [11] and his colleagues, **2018**, who compared between prophylactic dexmedetomidine and ondansteron for patients under spinal anaesthesia under going elective surgical procedures in the lower half of the body (orthopedic, general or gynecological surgeries) where they administrated dexmeditomedine 0.5 mcq/kg and there was significant difference between D group in comparison to control group regards the incidence of shivering was (27.5% versus 57.5%) respectively.

Also these results were supported by the studies of ***Bicer*** and his colleagues [18], that compared between prophylactic dexmedetomidine and mepridine in patients who scheduled for elective abdominal or orthopaedic surgery under general anaesthesia and found the incidence of postanaesthetic shivering was significant in D group in comparison to the placebo group and the meperidine group.

In a study by ***Usta*** [7] and his colleagues, **2011,** supported our results as regard the incidence of shivering in spinal anesthesia, there was significant difference between D group and placebo group, **prophylactic** i.v dexmedetomidine reduced the incidence of shivering (10% versus 56.7%) without significant difference in incidence of hypothermia compared with the control group.

This study was also supported by study of ***Arora*** and his colleagues, [14]**,** who compared between **prophylactic** tramadol and dexmedetomidine injection and found that there was no significant difference between the T group (1 mg/kg) and in the D group (0.5 mcq/kg) during spinal anaesthesia as regards the incidence of shivering.

This study was supported also by ***Ameta*** [12] and his colleagues in **2018**, who reported that administration of **prophylactic** 0.5 mcq/kg dexmeditomedine was effective in prevention of shivering with patients undergoing lower abdominal or lower limb surgeries under spinal anaesthesia where the incidence of shivering was 24% and in control group was 42%.

The study results were supported with the findings of ***Megalla*** and colleagues [10]**,** who found that there was significant difference between D group patients who received i.v dexmedetomidine 1 mcq/kg in comparison with nalbuphine group and the placebo group as a **treatment** for post spinal shivering.

These results were supported by ***Lakhe et al.*** [19], who carried a study to evaluate the efficacy of tramadol compared to ketamine and ondansetron in prevention of shivering under spinal anesthesia, all drugs was given as **prophylactic**, and found that there was a significant difference between T group in comparison to Placebo group that was 10% in comparison to control 56%.

These results were supported also by the studies done by ***Hidayah et al*** [20], who compared between prophylactic ketamine i.v 0.5 mg/kg (K Group), tramadol i.v 0.5 mg/kg (T Group) and normal saline in prevention of shivering during spinal anaesthesia, and found that there was a significant difference between groups as the incidence of shivering was 8% in (K Group), 16% in (T Group) and 24% in control group.

These results were supported by the studies ***Mohta*** *and* his colleagues [21] compared pethidine with different doses of tramadol as **prophylactic** post general anaesthesia shivering after abdominal surgery. The study showed that the number of patients that experienced shivering was significant highest in the normal saline group where 14 out of 33 (42%) patients shivered, compared to three (9%), two (6%), one (3%) and four (12%) patients shivered in groups Tramadol (1mg/kg), Tramadol (2mg /kg), Tramadol (3mg /kg) and pethidine (0.5mg /kg) respectively.

These results also were supported by the studies by ***Wason*** and his colleagues [22]**,** that compared between prophylactic ketamine, clonidine and tramadol as prophylactic to the incidence of shivering under neuraxialanaesthesia and found that there was a significance that the study results were (14/50) people did not shiver at all in the control group, while 82% patients (41/50) in the ketamine group, 94% patients (47/50) in the clonidine group and 88% patients (44/50) in the tramadol group did not shiver at all.

In the current study there was no significant difference between dexmeditomidine and tramadol as regards the incidence of shivering and grade of shivering.

The current study according to **sedation score,** there was significant difference between D group followed by T group in comparison to control group. These results were supported by ***Bicer et al.***, [18]**,** ***Megalla et al*** [10]**,** ***Usta et al.,*** [7] **and** ***Ameta et al.,*** [12]**.**

The results of these study were supported by the results of ***Botros et al*** study [11] revealed the sedation scores were significant in D group than those of both Saline group and ondesteron group.

In contrast to the current study, the study carried by ***Velayudha and Chiruvella,*** [17]**,** who showed that sedation was more common in the tramadol group compared to the clonidine group with no significant difference.

In the current study dexmeditomidine, tramadol and normal saline were comparable as regards the incidence of nausea and vomiting. There was a significant difference between T group in comparison to other groups according to nausea and vomiting and these results were supported by the results of the studies carried by ***Megalla et al*** [10]**, *Botros et al*** [11]**, *Bilotta et al*** [15]**.** Also, these results supported by the results of the studies carried by ***Billotta et al*** [15].

Conclusion

The current study revealed that prophylactic i.v dexmeditomedine 0.5 mcq/kg was effective as i.v tramadol 0.5mg/kg in prevention post spinal shivering in patients undergoing knee arthroscopy compared to the control group.

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