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COMPARISON OF THE CLINICAL EFFICACY BETWEEN ONDANSETRON AND TRAMADOL IN PREVENTING POST-ANESTHETIC SHIVERING IN CESAREAN SECTIONUNDER SPINAL ANESTHESIA

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ABSTRACT

Background: Shivering is a cause of discomfort and dissatisfaction in patients undergoing cesarean section under spinal anesthesia. For prevention of this complication, different drugs are used. Aim of study: To evaluate the efficacy ondansetron and tramadol for prevention of intra and p o s t operative shivering in patients undergoing cesarean section with spinal anesthesia. Methods: 70 patients, ASA I, females, age between (18-38), scheduled for cesarean section under spinal anesthesia, were randomly allocated to two groups, group O (received 8mg ondansetron), and group T (received 1mg/kg tramadol) as prophylactic dose after delivery of baby. Patients were evaluated regarding their heart rate, mean arterial blood pressure, oxygen saturation, core temperature, peripheral temperature and post anesthetic shivering scale. Results: The comparison between two studied groups by hemodynamic parameters of name arterial blood pressure, heart rate, oxygen saturation, there were no significant differences in all times before and after delivery of baby and drug given. In mean of core temperature, after 5, 10, 15, 20min after giving drug and inrecovery, after 30, and 60 min from recovery was significantly higher in group O than that in group T. While in mean of peripheral temperature after 10, 15, 20min after giving drug and in recovery, and 30, and 60 min after recovery swasignificantly higher in group O than that in group T In mean of post- anesthetic shivering scale, there were no significant differences in all times afterdelivery of baby and giving drugs. Conclusion: The prophylactic administration of ondansetron (8mg) or tramadol (1mg/kg) produces significant anti-shivering effect in patients undergoing cesarean sectionunder spinal anesthesia without any significant side effects. Ondansetron is significantly more effective than tramadol.

KEYWORDS: Tramadol, ondansetron, spinal anesthesia, shivering, post anesthetic shivering.

INTRODUCTION

Intrathecal and epidural anesthesia for cesarean delivery can cause significantdecrease in core temperature.[1] This is most likely due to the onset of sympathetic block and a mixing of warm blood in the body core with cooler blood in lower limbs.[2]

Hypothermia which occurs after spinal anesthesia is due to vasodilation below the level of block and redistribution of body heat from core to periphery and restriction of shivering to muscle mass above level of blockade.[3] Spinal anesthesia decrease the thresholds triggering vasoconstriction and shivering (above level of the block) approximately 0.6 °c.[4,5]

Shivering can be defined as involuntary and oscillatory muscular activities thatincrease the metabolic rate by two to three folds to maintain the core temperature, with the increment of heat production by only 200% in adults.[6]

The etiology of shivering is not clearly understood, it may involve a combination of mechanisms, including modulation of thermoregulatory thresholds, changes in body heat distribution reduction in body core temperature, and the cooling effect of the fluid injected into neuraxis.[7]

Shivering is very common after spinal anesthesia with incidence of 22%.[7] Furthermore, spinal anesthesia is not always associated with significant thermal discomfort

despite patients experiencing core hypothermia by mechanisms, thatstill remain unclear.[8]

Shivering classified to 5 grades according to Crossley and Mahajan,[9] grade

- Grade 0: No shivering.
- Grade 1: No visible muscle activity, but one or more of piloerection, peripheral vasoconstriction or peripheral cyanosis.
- Grade 2: Muscular activity in only one muscle group.
- Grade 3: Moderate muscular activity in more than one musclegroup, but not generalized shaking.
- Grade 4: Violent muscular activity that involves the entire body.
- Shivering interferes with routine intraoperative monitoring like electrocardiogram (ECG), blood pressure and pulse oximetry.[10,11] It can lead to adverse postoperative outcomes like increased wound pain and infection which leads to delayed discharge of the patient.[12]

Recent years, with increasing awareness of its undesirable aftermath, effective prevention of post-anesthesia shivering (PAS) is being imperative. It has been reported that PAS could be prevented by warming skin surface,[13] and warming theadministered fluid.[14] In addition a verity of medication are used which include meperidine,[15] 3tramadol,[16] corticosteroid,[17] ondansetron,[18] etc.

Patient and method

After obtaining the scientific council of anesthesia and intensive care unit committee approval, prospective, double blind randomized, was carried out in obstetric operation theaters of Baghdad teaching hospital, during the period from 1° of January 2018 to 1" of December 2018.

Seventy patients have been enrolled in this study. Al patients scheduled to have elective cesarean section under spinal anesthesia. Written informed consent wasobtained from all patients before enrolling them in the study.

Included criteria

- Age: 18-38 years old.
- ASA class II.
- Wt.: BMI <35 kg/m^2.
- Elective cesarean delivery under spinal anesthesia.

Excluded criteria

- Patients refusal.
- Patients with significant cardiovascular, neurological disease or othercontraindication to spinal anesthesia.
- Patients with hypersensitivity to tramadol or ondansetron.
- Patients with diabetes or thyroid disease.

Data collected using pre-constructed form sheet and detailed history was taken from each patient, information about patients age, weight, height and medical history. A clinical examination was performed by general examination and vital signs measurement. Patients were divided into two groups (ondansetron group n=35& tramadol group n=35).

The operating room temperature was maintained at 22-24 °C. Heart rate, mean arterial blood pressure and peripheral oxygen saturation with core and peripheral temperature through (forehead & ear thermometer) were monitored before intrathecal injection,3 min after intrathecal injection, and every 5min after injected the drug of study and every 30 min in recovery room for I hr.

The presence of shivering was observed by an observer anesthesiologist blinded to the drug administered. The intensity of post-anesthetic shivering may be graded using the scale described by Crossley and Mahajan. Side-effects such as nausea, vomiting, hypotension, bradycardia, skin rash and headache, fi present, were recorded.

The data analyzed using Statistical Package for Social Sciences (SPSS) version

25. The data presented as mean, standard deviation and ranges. Categorical data presented by frequencies and percentages. Independent t-test (two tailed) was used to compare the continuous variables among studied groups accordingly. A level of P- value less than 0.05 was considered significant.

RESULTS

Studied patient's age were ranging from 18 to 38 years with a mean of 26.69 yearsand standard deviation (SD) of ±4.59 years. The highest proportion of study patients was aged <30 years (78.6%).

Concerning BMI level, the highest proportion of studied patients were obese class I(72.9%).

In this study, mean of core temperature was significantly higher in group O than that in group T after 15 min. of delivery and drug administration. No significant difference (P≥ 0.05) in mean of core temperature before and at delivery of the babyand giving drug between study groups. And as shown in the table.

Time of record	Core Temp. (ºC)		P-value
	Group T Mean ± SD	Group O Mean ± SD	
Baseline	36.21 ± 0.26	36.14 ± 0.3	0.122
After spinal anesthesia	36.8 ± 0.48	36.69 ± 0.45	0.21
3 min after spinal anesthesia	36.7 ± 0.37	36.56 ± 0.49	0.181
6 min after spinal anesthesia	36.49 ± 0.46	36.37 ± 0.63	0.089
9 min after spinal anesthesia	36.58 ± 0.48	36.48 ± 0.43	0.225
At delivery of baby (giving drug)	35.91 ± 0.3	36.04 ± 0.37	0.135
After 5 min	35.8 ± 0.38	36.0 ± 0.28	0.022
After 10min	35.69 ± 0.48	35.96 ± 0.27	0.005
After 15 min	35.69 ± 0.46	36.02 ± 0.33	0.001
After 20min	35.68 ± 0.38	36.09 ± 0.33	0.001
In recovery	35.69 ± 0.39	36.13 ± 0.34	0.001
After 30 min of recovery	35.73 ± 0.39	36.14 ± 0.43	0.001
After 60 min of recovery	35.73 ± 0.39	36.21 ± 0.41	0.001

In this study, mean of peripheral temperature after 10, 15, 20min after giving drug and in recovery, 30, and 60 min after recovery was significantly higher in group O than that in group T36.88 versus 36.64, =P 0.026; 36.88 versus 36.60, =P 0.019; 36.96 versus 36.65, =P 0.002; 37.08 versus 36.73, =P 0.001; 37.05 versus 36.81, =P 0.035; and 37.08 versus 36.81, =P 0.002 respectively). No significant difference (P >0.05) in mean of peripheral temp before after given drugs and after 5mints of given drugs between studiedgroups.

Time of record	Peripheral Temp. (ºC)		P-value
	Group T Mean ± SD	Group O Mean ± SD	
Baseline	36.44 ± 0.32	36.38 ± 0.4	0.152
After spinal anesthesia	36.68 ± 0.48	36.62 ± 0.32	0.112
3 min after spinal anesthesia	36.31 ± 0.41	36.39 ± 0.44	0.162
6 min after spinal anesthesia	36.81 ± 0.52	36.77 ± 0.54	0.23
9 min after spinal anesthesia	36.42 ± 0.57	36.48 ± 0.47	0.472
At delivery of baby (giving drug)	35.8 ± 0.45	36.9 ± 0.42	0.348
After 5 min	35.67 ± 0.26	36.86 ± 0.45	0.267
After 10min	36.64 ± 0.48	36.88 ± 0.4	0.026
After 15 min	36.6 ± 0.49	36.88 ± 0.45	0.019
After 20min	36.65 ± 0.4	36.96 ± 0.41	0.002
In recovery	36.73 ± 0.36	37.08 ± 0.43	0.001
After 30 min of recovery	36.81 ± 0.42	37.05 ± 0.51	0.035
After 60 min of recovery	36.81 ± 0.41	37.08 ± 0.51	0.02

In this study, there were no significant differences (P ≥0.05) between studied groups in means of PAS in al times after delivery of baby and giving the drug.

Time of record	PAS scale		P-value
	Group T	Group O	
At delivery of baby (giving drug)	0	0.08 ± 0.28	0.083
After 5 min	0.05 ± 0.23	0.08 ± 0.5	0.78
After 10min	0.2 ± 0.84	0	0.154
After 15 min	0.14 ± 0.7	0.08 ± 0.5	0.678
After 20min	0.2 ± 0.17	0	0.314
In recovery	0	0	-
After 30 min of recovery	0	0.22 ± 0.94	0.161
After 60 min of recovery	0	0	-

DISCUSSION

Post anesthetic shivering is one of the unwanted and common complications. The exact mechanism of shivering under spinal anesthesia has not been fully established. The possible mechanisms of shivering during SA in parturient result from central thermoregulation. Pharmacologic drugs remain the most popular agents for treatment and prevention of shivering.

In our study, were hemodynamic parameters like oxygen

saturation, heart rate, and mean arterial pressure were monitored every 3min after spinal anesthesia and every 5min after baby delivered and study drug giving throughout intraoperative period.

There was no difference among the two groups.

These results were consistent with previous studies by Sagir et al,[19] and Kelsaka et al,[20] In their study also there was no difference among the groups regarding hemodynamic values.

In our study, we found that there were no significant differences ($P \geq 0.05$) between study group in means of PAS in al times after delivery of baby and giving drug.

The comparison between study groups in mean of peripheral temperature is shown: mean of peripheral temperature after 10, 15, 02 mints. after giving drug and in recovery, 30, and 60 min after recovery was significantly higher in group O than that in group T, while No significant difference ($P > 0.05$) in mean of peripheral temperature after giving drug and after 5 min of giving drug between study groups.

In the study done by Kelsaka et al,[20] core temperature was preserved in group's ondansetron (8mg) and pethidine (0.4mg kg') with respect to control group during intraoperative period after spinal anesthesia. Which was the similar prophylactic dose of ondansetron in our study, in which mean of core temperature at ,5 10, 15, 20 min after giving drug and in recovery period for 1 hr. was significantly higher in ondansetron group than that in tramadol group.

Mathew et al,[21] used tramadol 1mg/kg for treating post operating shivering and no undesirable side effects (nausea and vomiting) were noted which is comparable with our study. In addition, in other studies,[22,23] tramadol had no effect on blood pressure, arterial oxygen saturation percentage and body temperature. Therefore, these results are all in agreement with our findings.

In our study, there was one patient from 35 pt. of group O and 2 patients from 35 pt. of group T were developing shivering in recovery room after 30 min. which resolved by giving pethidine 50mg, and warm fluid, in which the pt. recover within few minutes and consider as rescue cases.

There was one patient dropped occur, she was prepared and had all feature of included criteria with tramadol group, after 2min from induction of spinal anesthesia developed shivering grade 4 with sever hypotension, so we gave her ephedrine 5mg 1st bolus dose and increase rate of fluid so the case not consider inour data.

CONCLUSION

We suggest that the prophylactic administration of ondansetron (8mg) or tramadol (1mg/kg) produces significant anti-shivering effect in patients undergoing cesarean section during spinal anesthesia without any significant side effects. Ondansetron is significantly more effective than tramadol.

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