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ORIGINAL ARTICLE

A Comparative Study of Two Different Doses of Intravenous Ondansetron for Prevention of Post-spinal Anesthesia Shivering in Inguinal Hernia Repair Surgery

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ABSTRACT

Background: Shivering is one of the most commonly encountered problems after both general and regional anesthesia and its incidence about 40% to 50% of the patients whom undergoing surgical operation under spinal anesthesia. The aim of this work was to compare two different clinically relevant doses of ondansetron (4mg vs 8mg) in prevention of postspinal anesthesia in inguinal herniorrhaphy. **Patients and Methods:** A comprehensive sample included elective unilateral inguinal hernia in Zagazig University hospitals during period of six months from November 2018 to April 2019 (10-11 cases / month) sample will be 63 cases randomly allocated into 3 groups; group A (ondansetron 4mg IV), group B (ondansetron 8mg IV) and group C (control group). **Results:** Each dose of ondansetron 4 mg or 8 mg have the ability to decrease the incidence of postspinal anesthesia with no significant differences between the two doses. There were no significant difference regarding side effects of the two doses of ondansetron in prevention of post spinal shivering. **Conclusion:** we concluded that both doses of intravenous ondansetron 4mg and 8mg are efficient and safe in reducing the incidence and severity of shivering during spinal anesthesia.

Key words: Ondansetron, spinal anesthesia, shivering.

INTRODUCTION

Spinal anesthesia is a commonly used technique in both elective and emergency surgeries. Despite the popularity and ease of its use, this procedure is frequently associated with hemodynamic instability and shivering [1] .

Shivering is a random spontaneous and asynchronous skeletal muscle contractions that increases the basal metabolism and is characterized to be a defense mechanism for temperature regulation in adults. It is one of the most common encountered problems during perioperative period and is reported in 40%–50% of the patients whom undergoing surgical operation under spinal anesthesia. Shivering may cause serious complications such as increase of oxygen (O_2) consumption (600%), blood pressure (BP), intracranial pressure (ICP), intraocular pressure (IOP), postoperative pain and also, increase of cardiac output (COP) by five times in healthy people [2] .

The pathogenesis of shivering is unclear, it may include combination of mechanisms, such as alterations of thermoregulatory thresholds, body heat distribution, drop of body core temperature, and the effect of the cold fluids and the injected drugs into the neuraxis [3]. It occurs when the preoptic region of the anterior hypothalamus is cooled and this stimulates the motor centre of shivering which is located in the posterior hypothalamus that activates the descending shivering pathway resulting in increased spinal muscle tone manifested as shivering [3].

The neurotransmitter serotonin (5-hydroxytryptamine [5-HT3]) plays an important role in neurotransmission of

thermoregulation. According to previous studies, the serotonergic system plays an important role in the pathogenesis of peri-operative shivering [4]. Several drugs have benefits in treating or preventing post-spinal shivering (PSS), including clonidine, tramadol, ketamin, and meperidine, however, these drugs were reported many adverse effects such as sedation, nausea, vomiting, bradycardia, hypotension and respiratory depression [5]. Recently, a meta-analysis of **Wenwang et al.** [6]. was conducted to assess the prophylactic effect of 5-HT3 receptor antagonists (5-HT3RAs) on management of perioprative shivering in adults and demonstrated that 5-HT3RAs can be used perioperatively to prevent the shivering in adults under general or neuraxial anesthesia.

Ondansetron, 5-HT3 antagonists, is commonly used as antiemetic during operation. Some studies used it as anti-shivering drug following both general and neuraxial anesthesia .The mechanism of action of ondansetron as anti-shivering drug is not clearly understood and it is proposed to act centrally at the level of the pre-optic anterior hypothalamic region by inhibition of serotonin reuptake [7].

Ondansetron has a good advantage in anesthesia, due to its very low incidence of decrease in blood pressure, bradycardia, respiratory depression and sedation [8]. **Kelsaka et al.** [7]. compared ondansetron (8mg) with meperidine (0.4mg /kg) for reducing the incidence and severity of shivering during and after regional anesthesia and found that the incidence of shivering was significantly decreased to 8% in ondansetron group, meanwhile **Shakya et al.** [5]. compared ondansetron (4mg) and low doses ketamine (0.25mg/kg) and reported that ondansetron decreased the incidence of shivering to 10% in patients undergoing spinal anesthesia.

PATIENTS AND METHODS

Site of study:

This study was conducted in Zagazig University Hospital.

Sample size:

This study was carried out at the department of Anesthesia and Surgical Intensive Care, Zagazig University hospitals after review, approval by the Institutional Review Board (IRB) committee at Faculty of Medicine, Zagazig University during the period from November 2018 to May 2019. Sample was 63 cases randomly allocated into 3 groups; group A (ondansetron 4mg IV), group B (ondansetron 8mg IV) and group C (control group receivednormal saline IV). In groups A and B solution (ondansetron) was infused over 15 minutes, just before performing spinal anesthesia.

Written informed consent was obtained from all participants. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Randomization:

- Patients were randomized randomly allocated into three groups, using computer each group consist of 21 patients :

Group A: Patients received 4 mg ondansetron diluted in normal saline to 50 ml.

Group B: patients received 8 mg ondansetron diluted in normal saline to 50 ml.

Group C: patients (control group) received 50 ml normal saline.

Inclusion criteria

Age: 21-50 years old, Both sexes (male and female), Physical status: American Society of Anesthesiologists (ASA) I & II, Type of operation: elective unilateral inguinal hernia repair surgery, Body Mass Index {BMI (Kg/m2)} = 18.5 - 25., Duration of surgery not more than 90 min.

Exclusion criteria

Patient refusal, Patients with hypersensitivity to the used drugs (local anesthesia or ondansetron), Patients contraindicated with spinal anesthesia (such as hypovolemia, coagulopathy, infection at site of injection, …etc.), using of ondansetron or pethidine preoperativly, Patients with hyperthyroidism or hypothyroidism, severe cardiac disease, liver disease, neuromuscular pathology, psychological disorder, history of convulsions, addictions, pregnancy, obesity and patients receiving vasodilators or any drugs likely to alter thermoregulation, Patients whose an basal body temperature reading preoperatively of >37.5 °C or < 36.5

°C, alcoholic patients or drug abuse, Failure of regional anesthesia and conversion to general anesthesia.

Type of study:

Comparative prospective randomized double blinded controlled clinical study.

Data analysis

The data were coded, entered into a personal computer and analyzed using SPSS 20.0 software. The results are presented as rates and proportions in tables. The Chi-square test was used for comparison of the two groups. T-test was used for comparison of the two means. Statistical significance was set at p values of < 0.05 at 85% confidence levels

RESULTS

Table (1) showed that there is no significant differences in groups A regarding age **(years)** (mean age of the patients was 31.54±7.9), also there is no significant differences in group B (mean age of the patients was 34.04±8.65) and there is no significant differences in group C (mean age of the patients was 36.5±9.34). The result showed also that there are no significant differences between three groups (P> 0.05). and there is no significant differences within each group and between the three groups (P> 0.05) regarding the sex (Male/Female) { number of Male/Female in group A was 11/8 (52.4%/47.6%), number of Male/Female in group B was 12/9 (57.1%/42.9%) and number of Male/Female in group C was 13/8 (61.9%/38.1%)}., while the mean of BMI **(Kg/m^2)** was 28.2±3.29, 27.5±3.27 and 28.2±3.13 in groups A, B and C respectively with no significant differences within each group and between the three groups (P> 0.05) regarding BMI.

Table (2) showed that the mean arterial pressure **(mmhg)** was 94.68±8.36, 93.18±9.82, 82.5±10.98, 78.9±11.95, 77.59±12.18, 80.68±12.0 at zero,15.30,45,60, 90 min, respectively with no significant difference within the group (P> 0.05), while in group (B) it was 91.85±8.94, 91.42±8.69, 84.09±8.99, 79.61±8.61, 81.47±12.78, 77.7±7.36 at zero,15,30,45,60,90 min, respectively with no significant difference within the group (P> 0.05) and in group (C) it was 90.8±10.23, 89.2±7.57, 80.95±9.66, 78.6±9.27, 73.85±8.7, 78.6±9.95 at zero,15,30,45,60,90 min, respectively with no significant difference within the group (P> 0.05). Table (3), regarding heart rate **(B/min),** there was no significance difference within the group and between the three groups (P> 0.05) . Table (4), showed that there is no significance difference within the group and between the three groups (P> 0.05) according to peripheral oxygen saturation. Table (5), showed that there is no significance difference within the group and between the three groups (P> 0.05) according to Temperature. Table (6), showed that shivering occurred in group (A) in 3 patients (14.3%) and in group (B) it happened in 2 patient (9.5%) and there was no significant difference in the occurrence of shivering between group (A) and group (B) {P> 0.05} while it was significantly increased in patients of the group (C) compared to the other two groups {P< 0.05} as it happened in 8 patients (38.1%).

Grading of shivering was done as follows: Grade 0: No shivering. Grade1: piloerection, peripheral vasoconstriction (VC), peripheral cyanosis without other cause, but without visible muscle activity. Grade 2: Visible muscle activity confined to one muscle group. Grade 3: Visible muscle activity in more than one muscle group. Grade 4: Gross muscle activity involving the whole body [(9)], and the results in Table (7), showed that there were no significant differences within each group and between the three groups according to the grade zero, grade I and grade II of shivering, (P> 0.05). Grade III of the shivering was higher distributed in group (C) as it happened in 5 patients (23.8 %) while in group A was in 1 patient (4,8 %) and not happened in group B, however there were no significant differences between three groups (P> 0.05) were recorded. . Table (8), showed that there were no significant differences within each group and between the three groups regarding to onset of shivering, Table (9), showed that Nausea happened in 1 patient (4.8%) in group (A) and 1 patient (4.8%) in group (B), and there was no significant differences (P> 0.05) between group (A) and (B), while it happened in 10 patients (47.6%) in group (C). However, there were significant differences in group C (P< 0.05) compared to groups (A) and (B). The vomiting was seen in 2 patients (9.5%) in

group (A), 1 patient (4.8%) in group (B) and 6 patients (28.6%) in group (C), with no significant differences within each group and between three groups (P> 0.05) were recorded.

Table 1: Age, Sex and BMI distribution among studied groups**:**

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	P
Age (years)	31.54±7.9	34.04±8.65	36.5±9.34	0.189
Sex (Male/Female)	11/10 (52.4%/47.6%)	12/9 (57.1%/42.9%)	13/8 (61.9%/38.1%)	0.82
BMI (Kg/m2)	28.2 ± 3.29	27.5 ± 3.27	28.2 ± 3.13	0.863

BMI = Body Mass Index

P > 0.05 = non significant, P < 0.05 = significant

Table 2: MAP (mmhg) distribution among studied groups at different time:

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	F	P
MAP at Zero min	94.68±8.36	91.85±8.94	90.8±10.23	1.015	0.369
MAP at 15 min	93.18±9.82	91.42±8.69	89.2±7.57	1.257	0.314
MAP at 30 min	82.5±10.98	84.09± 8.99	80.95±9.66	0.914	0.406
MAP at 45 min	78.9±11.95	79.61±8.61	78.6±9.27	0.072	0.931
MAP at 60 min	77.59±12.18	81.47±12.78	73.85±8.7	2.286	0.111
MAP at 90 min	80.68±12.0	77.7±7.36	78.6±9.95	2.456	0.098

MAP = Mean arterial pressure

P > 0.05 = non significant, P < 0.05 = significant

Table 3: HR (B/min) distribution among studied groups at different time:

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	F	P
HR at Zero min	90.59±15.65	97.33±11.44	96.5±13.52	1.552	0.220
HR at 15 min	92.63±17.54	93.63±13.85	95.6±12.01	0.241	0.787
HR at 30 min	92.9±14.33	96.71±13.75	97.9±14.63	0.714	0.494
HR at 45 min	89.13±17.39	94.04±16.68	93.3±18.18	1.178	0.315
HR at 60 min	88.13±17.74	95.47±18.8	90.8±14.06	1.978	0.147
HR at 90 min	78.09±16.05	82.9±11.73	84.6±14.95	2.087	0.133

HR = Heart rate

P > 0.05 = non significant, P < 0.05 = significant

Table 4: SpO2 distribution among studied groups at different time:

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	F	P
SPO2 at Zero nin	97.45±2.66	98.19±2.4	98.5±1.57	1.178	0.315
SPO2 at 15 min	98.91±2.21	95.74±2.3	99.1±1.12	2.695	0.076
SPO2 at 30 min	99.22±1.37	99.19±1.24	99.25±1.11	0.012	0.988
SPO2 at 45 min	99.42±1.55	99.31±1.5	98.95±1.66	2.138	0.123
SPO2 at 60 min	99.77±1.54	99.71±0.98	99.3±1.97	1.357	0.265
SPO2 at 90 min	99.86±0.75	99.84±0.84	99.8±0.89	0.101	0.905

SPO2 = Peripheral Oxygen Saturation

P > 0.05 = non significant, P < 0.05 = significant

Table 5: Temperature distribution among studied groups at different times:

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	F	P
Temp at Zero min	37±0.64	36.99±0.51	37.17±0.55	2.017	0.123
Temp at 15 min	36.71±0.51	36.8±0.51	36.9±0.87	1.123	0.885
Temp at 30 min	36.73±0.51	37.0±0.48	36.8±0.45	1.178	0.265
Temp at 45 min	36.67±0.55	37.0±0.35	36.7±0.52	1.053	0.298
Temp at 60 min	36.44±0.32	36.9±0.47	36.7±0.55	1.317	0.211
Temp at 90 min	36.61±0.41	36.85±0.48	36.7±0.52	1.445	0.189

Temp = Temperature

P > 0.05 = non significant, P < 0.05 = significant

Table 6: Shivering distribution among studied groups:

			Groups			Total	X^2	P
			Group (A) (N=21)	Group (B) (N=21)	Group(C) (N=21)			
Shivering	**NO**	**N**	18	19	13	50	6.12	0.049 *
		%	85.7%	90.5%	61.9%	79.4%		
	YES	**N**	3	2	8	13		
		%	14.3%	9.5%	38.1%	20.6%		
Total		**N**	21	21	21	63		
		%	100.0%	100.0%	100.0%	100.0 %		

P > 0.05 = non significant, P < 0.05 = significant

Table 7: Shivering grade distribution among studied groups:

			Groups			Total	P
			Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)		
Grade	**0**	**N**	18	19	13	50	0.072
		%	85.7%	90.5%	61.9%	79.4%	
	I	**N**	0	0	0	0	
		%	0%	0%	0%		
	II	**N**	2	2	3	7	
		%	9.5%	9.5%	14.3%	11.1%	
	III	**N**	1	0	5	6	
		%	4.8%	0.0%	23.8%	9.5%	
Total		**N**	21	21	21	63	
		%	100.0%	100.0%	100.0%	100.0%	

P > 0.05 = non significant, P < 0.05 = significant

Table 8: Shivering onset distribution among studied groups:

	Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)	P
Shivering Onset (min)	**41.25±7.5**	**37.5±10.6**	**31.13±8.65**	**0.181**

P > 0.05 = non significant, P < 0.05 = significant

Table 9: Intra-operative nausea and vomiting distribution among studied groups:

			Groups			Total	P
			Group (A) (N=21)	Group (B) (N=21)	Group (C) (N=21)		
Nausea	**No**	**N**	**20**	**20**	**11**	**51**	**0.00***
		%	**95.2%**	**95.2%**	**52.4%**	**81.0%**	
	Yes	**N**	**1**	**1**	**10**	**12**	
		%	**4.8%**	**4.8%**	**47.6%**	**19.0%**	
Vomiting	**No**	**N**	**19**	**20**	**15**	**54**	**0.066**
		%	**90.5%**	**95.2%**	**71.4%**	**85.7%**	
	Yes	**N**	**2**	**1**	**6**	**9**	
		%	**9.5%**	**4.8%**	**28.6%**	**14.3%**	
Total		**N**	**21**	**21**	**21**	**63**	
		%	**100.0%**	**100.0%**	**100.0%**	**100.0 %**	

P > 0.05 = non significant, P < 0.05 = significant

DISCUSSION

Prevention and treatment of post-anesthesia shivering is an important part of postoperative patient care. The post-anesthesia shivering may cause severe complications due to sympathetic stimulation and oxygen consumption increase or increased in carbon dioxide production [7].

The best way to avoid these postoperative complications can be achieved by injection of ondansetron 8mg IV preoperatively just before performing spinal anesthesia to prevent postspinal anesthesia [3].

The mechanism of shivering after spinal anesthesia is unclear, but it may be according to the reduce in the core body temperature due to sympathetic block, peripheral vasodilatation lead to the cutaneous blood flow increase, which causing heat loss through skin, cold temperature of operation room, rapid cold IV fluids infusion and the effect of cold anesthetic drugs on the thermo sensitive receptors in spinal cord [10].

The present study was conducted on 63 patients underwent elective surgery under spinal anesthesia, to compare the efficacy and safety of prophylactic ondansetron 4mg IV versus ondansetron 8mg IV in prevention of post spinal shivering.

Ondansetron is a specific 5-HT3 receptor antagonist. The mechanism of action of ondansetron as anti-shivering drug is not clearly understood as it is proposed to act centrally at the level of the pre-optic anterior hypothalamic region by inhibition of serotonin reabsorption [7]. **Sharma et al.** [11]. evaluated the effect of prophylactic administration of ondansetron to prevent the incidence of shivering during regional anesthesia, and concluded that prophylactic administration of ondansetron significantly reduced the incidence of shivering in patients under regional anesthesia without occurrence of side effects.

In this study, the shivering incidence rate in the group (C) {control group} without using ondansetron was 38.1% while with

ondansetron 4 mg in the group (A) this rate was reduced to 14.3% and with ondansetron 8 mg in the group (B) the rate was reduced to 9.5%. Thus, shivering was significantly increased in group (C) compared to groups (A) and (B). Meanwhile no significant difference between group (A) and group (B) was found.

Powell and Buggy [12]**.,** also compared the effect of prophylactic administration of ondansetron 8 mg with normal saline on the incidence of postoperative shivering, and the results showed that incidence of postoperative shivering was 57% in the saline group, which was reduced to 33% in the ondansetron 8 mg group**.**

Kelsaka et al. [7] compared in their study between meperidine 0.4 mg/kg and ondansetron 8 mg in reducing shivering after spinal anesthesia. The incidence of shivering was reduced from 36% in control to 8% in meperidine group and 8% in ondansetron group. No significant difference was found between the two groups of meperidine and ondansetron.

Shakya et al. [5] reported that the administration of 4 mg ondansetron before induction of spinal block can significantly reduce the incidence of postoperative shivering to 10% of patients compared with 42.5% of patients in the control group.

In this study, grade III of shivering was high in the control group (C) 23.8% compared with ondansetron 4 mg group (A) 4.8% and ondansetron 8 mg group (B) 0%, with no significant differences between ondansetron 4 mg and ondansetron 8 mg groups. These findings were in agreement with **Badawy and Mokhtar** [(13)] who reported that the severity of shivering was significantly high in the control group comparing to patients group whom receiving ondansetron 8 mg. These results were consistent with a previous study by **Kelsaka et al.** [7] who compared between ijection IV ondansetron 8 mg with meperidine 0.4 mg/kg for preventing shivering in patients undergoing spinal anesthesia and they reported that the shivering incidence was reduced from 36% in control group to 8% in meperidine 0.4 mg/kg group and 8% in ondansetron 8 mg group and the shivering can occur without occurrence of hypothermia.

The shivering may be occur in normothermic patients undergoing regional anesthesia [14].

In the present study, regarding Nausea, there were significant differences in group C ($P< 0.05$) compared to groups (A) and (B). Regarding vomiting there was significant differences within each group and between three groups ($P> 0.05$). This finding was in agreement with the study of **Rai et al.** [15] who reported that nausea and vomiting was observed in 19/40 patients (47.5%) in the normal saline group, while in the ondansetron 8 mg group it was in 2/40 patients (5%).

In our study, there were no significant differences between the three groups as regard haemodynamic. These results were in consistent with previous studies of **Kelsaka et al.** [7] who compared between ondansetron 8 mg with meperidine 0.4 mg/kg for prevention of shivering in patients undergoing spinal anesthesia and **Shakya et al.** [5] who compared prophylactic small dose of ketamine 0.25 mg/kg with ondansetron 4 mg for prevention of shivering after spinal anesthesia.

Limitation of this study:

One of the limitations of the present study was the economic cost of ondansetron which limits its use to the therapeutic role rather than routine premedication. Another limitation was that we did not use a standard anti-shivering drug like meperidine as a control group as we considered it the rescue medication for all patients if the ondansetron failed to pre-limitation of this study.

Conclusion: From our study, we can conclude that the injection of both doses of ondansetron 4mg and 8mg intravenous are efficient and safe, but it is better to use the small dose of ondansetron 4mg to reduce the severity and incidence of shivering during spinal anesthesia.

Recommendation:

Intravenous administration of 4 mg of ondansetron before spinal block is recommended for reduction of the incidence and severity of shivering during spinal anesthesia

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