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ORIGINAL ARTICLE

Comparative study between dexamethasone and ondansetron for prevention of shivering during spinal anaesthesia

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ABSTRACT

BackgroundShivering is one of frequent, undesirable adverse effects of spinal anaesthesia. **The aim of this study** was to compare the efficacy and safety of prophylactic intravenous administration of either 0.1mg/kg of dexamethasone or 4mg of ondansetron immediately before establishment of spinal block for prevention of shivering during spinal anaesthesia.

Patients and methods:A total of 90 patients of both gender of ASA physical status class I and II between 21 and 60 years old scheduled for elective lower body surgeries under spinal anaesthesia were randomly allocated into three groups: Control group (C group) received 10 ml normal saline; Dexamethasone group (D Group) received 0.1mg/kg dexamethasone and ondansetron group (O Group) received 4 mg ondansetron. Studied drugs were given intravenously (IV) immediately before establishment of spinal block.

Results: Dexamethasone and ondansetron significantly reduced incidence and severity of shivering during spinal anaesthesia with no statistically significant difference between both of them. No significant associated side effects occurred with dexamethasone nor ondansetron when used for prevention of shivering during spinal anaesthesia.

Conclusion: Both dexamethasone and ondansetron are efficient and safe in reducing the incidence and severity of shivering during spinal anaesthesia and no one is superior to the other.

Keywords: Ondansetron, Dexamethasone, Postoperative shivering, Spinal anesthesia**.**

1. INTRODUCTION

Shivering is one of frequent, undesirable adverse effects of both general and regional anaesthesia. It is defined as an involuntary, repetitive activity of skeletal muscles. The incidence of shivering is up to 40-60% even in regional anaesthesia **(1)**.

Shivering in surgical patients is divided into thermoregulatory and non-thermoregulatory in nature **(2)**. The adverse effects of shivering depend on its severity. Mild shivering (Grade 1-2) leads to mild rise of O2 consumption to a level comparable to light exercise. Severe shivering (Grade 3-4) leads to dramatic rise of O2 consumption and CO2 production up to 500% **(1)**, patient discomfort, aggravation of postoperative pain, hindering wound healing, rise of intracranial pressure and intraocular pressure **(3)**, impedance of monitoring (as ECG and pulse oximetry) and interference of the surgeon's work under spinal anaesthesia with subsequent prolongation of the operative time **(4)**.

There are numerous efficient drugs for preventing or stopping post-anaesthesia shivering including pethidine **(3)**, tramadol, clonidine **(5)**, ketamine, nefopam **(6)**,

ondansetron **(7)**, dexmedetomidine **(8)** and dexamethasone **(9)**. No anti-shivering drug is ideal. Sometimes more than one drug is needed for control of perioperative shivering **(2)**.

Dexamethasone is a potent, long-term acting synthetic glucocorticoid class of steroid drugs that have anti-inflammatory and immunosuppressant properties **(10)**. It is one of the most active glucocorticoids, being about 25 to 30 times as potent as hydrocortisone **(11)**. It prevents thermoregulatory shivering via its central inhibitory effect on the thermoregulatory center and prevents non thermoregulatory shivering by its anti-inflammatory activity, i.e. antagonizing the activation of the inflammatory responses and release of cytokines during surgery **(9)**.

Ondansetron is a highly potent selective 5 hydroxytryptamine receptor antagonist, which is widely used as an anti-emetic **(12)**. Its mechanism of action as anti-shivering is not clear and it is proposed to act centrally at the level of the pre-optic anterior hypothalamic region by inhibition of serotonin reuptake **(13)**.

The aim of this work was to compare the efficacy and safety of prophylactic intravenous administration of either 0.1mg/kg of dexamethasone or 4mg of ondansetron immediately before establishment of spinal block for prevention of shivering during spinal anaesthesia.

2. PATIENTS AND METHODS

After obtaining approval from the local ethics committee and written informed consent from each patient, this prospective double blinded randomized controlled clinical study was carried out at the Zagazig University Hospitals from May 2017 till February 2018. 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.

A total of 90 patients of both gender scheduled for elective lower body surgeries under spinal anaesthesia were included in this study. The age of these patients ranged from 21 to 60 years and their physical status (PS) ranged from class I to II according to American Society of Anaesthesiologists (ASA) classification. Exclusion criteria were patients refusal, patients with neurological, psychiatric, muscular disorder, coagulopathy, severe hepatic and renal impairment, history of allergy to local anaesthetics, previous back surgery, infection or mass at the site of injection and vertebral column deformity, history of peptic ulcer, diabetes mellitus and hypothyroidism or severe cardiopulmonary disease, patients taking one of the studied drugs (ondansetron or dexamethasone), having fever or hypothermia or requiring blood transfusion and operations more than two hours.

According to the research work of El Bakry and Ibrahim **(9)** the percent of shivering in control group was 50% and that of group using dexamethasone was 20%. Using open EPI with power 80% and confidence interval 95% so the total sample size is 90 (30 in each group).

The selected patients were categorized randomly according to the tested drugs into three equal groups, 30 patients in each group. These groups were Control group (C group) which received 10 ml of normal saline intravenously as placebo, Dexamethasone group (D Group) which received 0.1mg/kg dexamethasone (dexamethasone 8 mg/2 ml; Medical Union Pharmaceuticals, Abu-Sultan, Ismailia, Egypt) diluted up to 10 ml volume with normal saline intravenously and ondansetron group (O Group) which received 4 mg Ondansetron (Danset 4 mg/2 ml; ADWIA Pharmaceuticals Company, 10th of Ramadan City, Egypt) diluted to up to 10 ml volume with normal saline intravenously.

For blindness, one of the authors was responsible for giving the tested drug and other one unaware of the given drug was responsible for data collection.

In the operating room, the ambient temperature was maintained at 24°C. Standard monitors (electrocardiogram, noninvasive blood pressure, and pulse oximetry) were attached to the patients. A wide bore (18 gauge) IV cannula was established. Drugs and equipments for resuscitation and airway management were available and ready before establishment of

spinal block. The study drug was coded and presented to the anaesthetist not involved in the management of the patient and administered by intravenous (IV) route immediately before establishment of spinal block. The study drugs and saline were warmed to 37°C before administering them to the patient. Normal saline was warmed by fluid warmer that was adjusted to 37 o C. From the 3 way tap of the plastic tube extension of intravenous transfusion set, a volume of warmed normal saline was withdrawn to be used either as placebo (10 ml) in control group or for diluting the tested drugs till its volume reached 10 ml and also for warming it before their administration to the other two groups.

Spinal block was then performed using a 22 gauge quincke spinal needle with stylet at L3/4 or L4/5 level in sitting position with markedly flexed back, and 3 mL of 0.5% hyperbaric bupivacaine (Sunnypivacaine; Sunny Pharmaceutical, Badr City, Egypt) was administered slowly once cerebrospinal fluid came back through the spinal needle. After removal of spinal needle and sterile dressing was applied on the site of needle insertion site, the patient was then immediately placed supine on 10 degree anti-Trendlinburg position tilt of the operating table. Supplemental Oxygen (3 L/min) was applied via nasal cannula. The level of sensory block was assessed by needle brick at 5-min intervals till there was no change in the level of anaesthesia. The upper parts of the body of all patients were covered with standard single small blanket under the sterile disposable surgical drape.

Data collection:

Demographic data of all patients were collected preoperatively included age, body mass index, sex ratio and ASA physical status classes.

The overall incidences, onset time and the various severities` levels of shivering were detected and recorded. Severity of shivering was graded by a scale validated by Tsai and Chu **(14)**: [Grade 0 = no shivering, Grade 1 = piloerection or peripheral vasoconstriction but no visible shivering, Grade 2 = muscular activity in only one muscle group, Grade 3 = muscular activity in more than one muscle group but not generalized shivering, Grade 4 = shivering involving the whole body]. Patients with mild shivering (grades 1 and 2) were treated with surface warming and patient with moderate and severe shivering (grades 3 and 4 respectively) were treated with 0.5mg/kg Pethidine IV.

The type of shivering either thermoregulatory or non-thermoregulatory was detected and recorded. For detection of thermoregulatory shivering, core body temperature monitoring was performed. Core body temperature was detected and recorded (using ear thermometer which measures tympanic membrane temperature) before spinal block (base level), 5, 10, 20, 30 and 60min after onset of spinal block, at end of surgery and every 30 min postoperatively and at recovery from spinal block. The coexistence of shivering with lowering of body temperature was detected and recorded. For detection of non-thermoregulatory shivering, pain intensity was monitored by 0-10 visual analogue scale (VAS). VAS was detected and recorded before spinal block (base level), 5, 10, 20, 30 and 60min after onset of spinal block, at end of surgery and every 30 min postoperatively and at recovery from spinal block. The coexistence of shivering with normothermia and VAS score more than 4 was detected and recorded.

Heart rate, blood pressure, oxygen saturation and respiratory rate were recorded at the following intervals: baseline (before induction of spinal block), one minute after onset of spinal anaesthesia, every 10 min in the first 30min then at 60, 90, 120 min intraoperatively, 30 min postoperatively and at full recovery from spinal anaesthesia. Bradycardia was considered if the decrease in HR is more than 20% of HR. Hypotension was considered if the decrease in BP is more than 20% of BP. In case of hypotension, the patients were managed with intravenous loading with Ringer's lactate and boluses of 10 mg ephedrine IV. In case of bradycardia, the patients were managed with 0.02 mg/kg atropine IV. Respiratory depression was considered if respiratory rate is less than 10

breaths per min and oxygen saturation (SpO2) is < 92% for 30 or more seconds.

The incidences of the various associated side effects as nausea, vomiting, headache, itching etc. were detected and recorded.

Statistical analysis:

According to the research work of El Bakry and Ibrahim **(9)** the percent of shivering in control group was 50% and that of group using dexamethasone was 20%. Using open EP with power 80% and confidence interval 95%, so the total sample size is 90 (30 in each group).

Data were analyzed by using Statistical Package for Social Sciences (SPSS) software program. The values were noted as mean and standard deviation. Chi-square test and Analysis of Variance (ANOVA) were used for statistical analysis when appropriate. In all tests, P value below 0.05 was considered statistically significant.

3. RESULTS

Statistically patients demographic (Age, body mass index, sex ratio and ASA ps classes), operative data (duration of surgery and type of surgery) and spinal block data (block level and duration) of the three studied groups were comparable (P > 0.05) **(Table 1)**.

Statistically, the corresponding overall incidences of shivering in each of dexamethasone (30%) and ondansetron (40%) groups were significantly less than (P< 0.05) that in control group (66.7%). The mean times of onset of shivering were 22.3 ±17.96, 19.55 ± 17.08 and 22.2 ± 22.29 min. in control, dexamethasone and ondansetrone groups respectively with no statistical significant difference between the three groups. Statistically, severity of shivering in each of dexamethasone and ondansetron groups was significantly less (P < 0.05) than that in control group. The incidence and severity of shivering in dexamethasone and ondansetrone were comparable **(Table 2)**.

The incidence of thermoregulatory shivering was more frequent than non-thermoregulatory one in the three groups. The incidence was 90%, 88.89% and 91.67% in control, dexamethathone and ondansetrone groups respectively with no significant difference between them (P > 0.05) **(Table 3)**.

Statistically, baseline values of the core body temperature of the three groups were comparable (P > 0.05). The core body temperature of the three groups dropped significantly below the corresponding baseline values (P < 0.05) during the first 20 min after spinal block, then it rose gradually till it reached the baseline values at the end of spinal blockade. The corresponding core body temperature values of three groups at various time of measurement were statistically comparable (P > 0.05) **(Figure 1)**.

Baseline values of VAS in the three groups were equal 0. Non thermoregulatory shivering in the three groups was associated with VAS equal 4 or more.

Statistically, the incidences of occurrence of hypotension and bradycardia in the three groups were comparable (P > 0.05). Respiratory depression did not occur in the three groups. No associated side effects were detected in the three groups except only one patient developed pruritus in dexamethasone group **(Table 4)**.

Table (1): Patients' demographic, operative and spinal block data of the three studied groups

	Control group n = 30	Dexamethasone group n = 30	Ondansetron group n = 30	P
Demographic details:				
Age (Years)	40.6 ±12.24	41.8 ± 11.76	39.5 ±12.28	0.76
BMI (Kg/m^2)	28.2 ± 3.13	27.5 ± 3.27	28.2 ± 3.29	0.63
Sex ratio:				
Female	15 (50%)	14 (46.7%)	13 (43.3%)	0.87
Male	15 (50%)	16 (53.3%)	17 (56.7%)	
ASA ps classification:				
ASA ps class I	25 (83.3%)	20 (66.7%)	22 (73.3%)	0.33
ASA ps class II	5 (16.7%)	10 (33.3%)	8 (26.7%)	

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	Control group n = 30	Dexamethasone group n = 30	Ondansetron group n = 30	P
Operative data:				
Duration of operation (min)	92.3 ±25.87	93.25 ± 26.17	85 ± 24.21	0.39
Type of surgery:				
Orthopaedic surgery	6 (20%)	7 (23.3%)	9 (30%)	0.52
General surgery	6 (20%)	6 (20%)	6 (20%)	
Urosurgery	14(46.7%)	13 (43.3%)	7 (23.3%)	
Gynaecological surgery	4 (13.3%)	4 (13.3%)	8 (26.7%)	
Spinal block data:				
Maximal block level: Range (Median)	10 (10-12)	10 (10-12)	10 (10-12)	1
Duration of spinal block (min)	144.8±19.64	145.69 ± 22.03	144.78 ± 20.37	0.98

Data expressed as mean ± SD, range (median) and number (%).
n= group number. ps= physical status.
P= Comparison between the three groups.
P> 0.05= non significant difference

Table (2): The overall incidence, onset and severity of shivering in control versus each of dexamethasone and ondansetron groups

	Control group n = 30	Dexamethasone group n = 30	Ondansetron group n = 30	P
The overall incidence of shivering:				
Yes	20 (66.7%)	9 (30%)	12 (40%)	**P = 0.01**
No	10 (33.3%)	21 (70%)	18 (60%)	**P1= 0.004** **P2= 0.04** P3= 0.42
Onset of shivering after induction (min)	22.3±17.96	19.55 ± 17.08	22.2 ± 22.29	P= 0.82
Severity of shivering:				
Grade 0	10 (33.3%)	21 (70%)	18 (60%)	**P=0.002** **P1= 0.007** **P2= 0.01** P3= 0.95
Grade 1	3 (10%)	0 (0%)	0 (0%)	
Grade 2	5 (16.7%)	4 (13.3%)	5 (16.7%)	
Grade 3	5 (16.7%)	5 (16.7%)	7 (23.3%)	
Grade 4	7 (23.3%)	0 (0%)	0 (0%)	

Data were expressed as number (%) and mean ± SD.
n= group number.
P= Comparison between the three groups.
P1= Control versus Dexamethasone group.
P2= Control versus Ondansetron group.
P3= Dexamethasone group versus Ondansetron group.
P> 0.05= non significant difference. P< 0.05= significant difference.

Table (3): The incidence of the two types of shivering in the three groups

	Control Group N= 20	Dexamethasone group N = 9	Ondansetron group N= 12	P
Thermoregulatory shivering	18 (90%)	8 (88.89%)	11 (91.67%)	0.98
Non-thermoregulatory shivering	2 (10%)	1(11.11%)	1(8.33%)	

Data were expressed as number (%).
N= total number of patients with shivering in each group.
P= Comparison between the three groups.
P> 0.05= non significant difference.

Table (4): Incidence of various side effects

	Control group n = 30	Dexamethasone group n = 30	Ondansetron group n = 30	P
Hypotension:				
Yes	9 (30%)	6 (20%)	7 (23.3%)	
No	21 (70%)	24 (80%)	23 (76.6%)	0.66
Bradycardia:				
Yes	9 (30%)	5 (16.7%)	7 (23.3%)	
No	21 (70%)	25 (83.3%)	23 (76.6%)	0.47
Respiratory depression:				
Yes	0	0	0	
No	30 (100%)	30 (100%)	30 (100%)	1
Occurrence of other side effects (only Pruritus):				
Yes	0	1 (3.3%)	0	
No	30 (100%)	29 (96.7%)	30 (100%)	0.36

Data were expressed as number (%).
n= group number.
P= Comparison between the three groups.
P> 0.05= non significant difference.

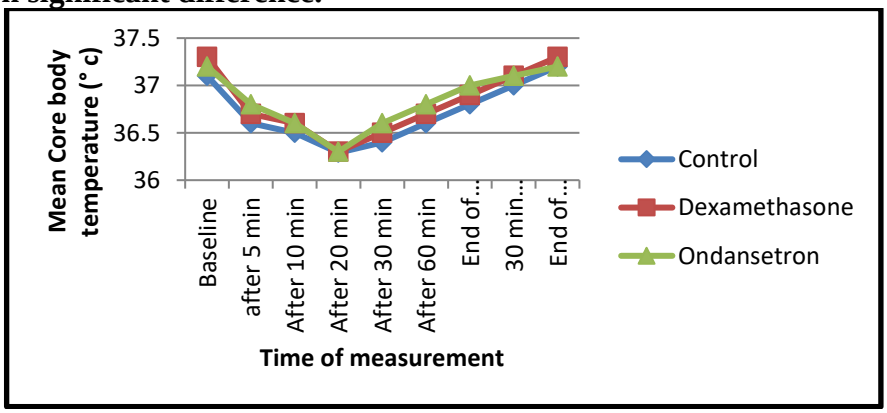

Figure (1): Core body temperature levels at various times of measurements in the three groups.

4. DISCUSSION

In this study the shivering incidence rate in the control group was 66.7% while in the dexamethasone group this rate was reduced to 30% and in the ondansetron group to 40%.

In the present study, the relatively higher incidence of shivering that was detected in the control group (66.7%) was in disagreement with other workers reported findings. The reported incidence of shivering in the control group in Bilotta et al. **(15)** was

57%, in Kelsaka et al. **(16)** was 36%, in Sagir et al. **(17)** it was 55% and in Shakya et al. **(7)** it was 42.50%. The relatively low incidence of shivering in the control group of the other workers may be attributable to the use of diazepam for premedication which has anti-shivering property as in the study of Kelsaka et al. **(16)**, and Shakya et al. **(7)**, and different types of patients, anaesthesia and operations in other workers.

From the present study, the detected efficient effects of prophylactic IV administration of each of dexamethasone and ondansetron immediately before establishment of spinal block, on reducing the incidence of shivering was in agreement with other workers. Shakya et al. **(7)** reported that administering 4 mg/kg ondansetron before induction of spinal block can significantly reduce the incidence of shivering (10% compared with 42.5% of control group). El Bakry and Ibrahim **(9)** reported that, the incidence of shivering was significantly low in dexamethasone group (20%) compared with of control group (50%).

In the present study, the onset of shivering in the unblocked part of the body was about 20 min after spinal block in each group with no statistically significant difference among the three groups ($P > 0.05$). These findings are similar to Luggya et al. **(18)** who found that mean time of shivering was between 15 to 25 minutes with majority of the shivering occurring at 20 minutes. In contrast, Koay et al. **(19)** found that the time of onset of shivering was about 10 minutes in each group.

In the present study, severity of shivering was significantly higher ($P < 0.05$) in the control group than in other groups, with no statistically significant difference between dexamethasone and ondansetron groups ($P > 0.05$). These findings were in agreement with other workers findings. El Bakry and Ibrahim **(9)** reported that, the severity of shivering was significantly higher ($P< 0.05$) in the control group than in dexamethasone group. Badawy and Mokhtar **(13)** reported that the severity of shivering was significantly higher ($P< 0.05$) in the control group than in ondansetron group.

In the present study, drop of core temperature coexisted with the majority and pain after recovery from spinal block coexisted with the minority of shivered patients in the three groups. This indicates that, drop of core temperature is the cause of thermo-regulatory shivering and pain is the cause of non-thermoregulatory shivering.

In the present study, there was no difference between the three groups in relation to haemodynamic parameters. These findings were consistent with previous studies by Kelsaka et al. **(16)**, Shakya et al. **(7)** and El Bakry and Ibrahim **(9)** who found that there was no difference between the groups regarding haemodynamic values.

Despite the effect of dexamethasone on inhibition of release of vasodilator inflammatory mediators which may affect MABP **(20)**, in the present study the drop in the MABP that occurred in the three groups was not statistically significant and may be attributed to block of sympathetic by spinal anaesthesia with subsequent vasodilatation in the blocked part of the body.

In the present study, respiratory depression was not detected in the patients of the three studied groups. This finding was in agreement with El Bakry and Ibrahim **(9)** finding. They reported that, prophylactic IV administration of dexamethasone for the prevention of postoperative shivering during transurethral resection of the prostate under spinal anaesthesia was not associated with respiratory depression.

In the present study, no associated side effects were detected in the three groups except only one patient developed pruritus in dexamethasone group. This finding was in agreement with some workers and in disagreement with others. El Bakry and Ibrahim **(9)** had no cases of pruritus with dexamethasone. No cases of nausea or vomiting were found in this study. El Bakry and Ibrahim **(9)** reported three cases of nausea and two cases of vomiting with dexamethasone. Badawy and Mokhtar **(13)** had two cases of vomiting with ondansetron.

The cause of controversy between the present study finding and other workers findings may be attributed to the different

group sizes, use of different drug doses, different administration times and different operation types and durations.

The limitations of the present study were that population of the present study was limited to ASA physical status class I and II and to adult patients. Also, only one fixed dose of the various tested drugs was evaluated.

5. CONCLUSION

Both dexamethasone and ondansetron are efficient and safe in reducing the incidence and severity of shivering during spinal anaesthesia and no one is superior to the other.

Conflicts of interest: The authors report no conflicts of interest.

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