

COMPARATIVE STUDY BETWEEN MEPERIDINE, KETAMINE, AND ONDASETRON FOR PROPHYLACTIC MANAGEMENT OF POST-SPINAL SHIVERING IN PATIENTS UNDERGOING LOWER ABDOMINAL SURGERIES

By

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ABSTRACT

Background: Shivering can be very unpleasant and physiologically stressful for the patient. It can be detrimental to patients with low cardio-respiratory reserve.

Objective: The study was done to compare the effect of Meperidine, Ketamine, and Ondansetron in prevention of post-spinal shivering.

Patients and Methods: This prospective randomized single blinded controlled clinical study was conducted on 120 patients under spinal anesthesia ASA I, II, undergoing lower abdominal and lower limb surgical procedures not exceeding 60 minutes. Patients were randomized into three equal groups. Group (A) received meperidine in a dose of 0.5 mg/kg.i.v, Group(B) received ketamine in a dose of 0.25 mg/kg.iv, and Group (C) received ondansetron in a dose of 4 mg. iv . All these drugs were given after subarachnoid block. Patients were evaluated by measuring shivering grade, HR, Systolic BP every 5 minutes for 60 minutes after interthecal injection. Shivering during spinal anesthesia was determined using a scale validated by Tsai and Chu. Blood pressure, heart rate and side effects were recorded.

Results: There were statistical significant differences between Meperidine, Ketamine, and Ondansetron as Meperidine has a superior effect in prevention of shivering. No changes in systolic BP and HR.

Conclusion: Meperidine and low dose ketamine (0.25mg/kg) were significantly more effective than ondansetron for prevention of post-spinal shivering in patients undergoing lower abdominal surgeries.

Keywords: Meperidine, Ketamine, Ondansetron , sub arachnoid shivering.

INTRODUCTION

Shivering is one of the most important postoperative complications seen in clinical practice, (Morsali *et al.*, 2017). It is an important concern in patients undergoing surgery under general anesthesia as well as regional anesthesia, i.e. spinal anesthesia or epidural

anesthesia. The reported median incidence of shivering related to neuraxial anesthesia from different studies is 55% (Venkatraman *et al.*, 2018). Because of its associated discomfort, distress, aggravation of pain, increased metabolic demands, and increased oxygen consumption. Prevention and treatment of postanesthesia shivering is an important

component of perioperative management of the patient (*Bagle et al., 2016*).

To decrease the incidence and severity of post-spinal shivering many trials done either pharmacological or non-pharmacological. Non pharmacological like heavy blankets and reassurance. Pharmacological agents like clonidine, magnesium sulfate, dolasetron, ondansetron, ketamine and meperidine are used to control shivering (*Kundra et al., 2017*).

This study was designed to compare the effect of Meperidine, Ketamine, and Ondansetron in prevention of post-spinal shivering and determine which of these pharmacological interventions serves best to achieve therapeutic effect with minimal side effect.

PATIENTS AND METHODS

After approval by the local ethics committee, Faculty of Medicine, Al-Azhar University, and patients gave written consents, this prospective randomized single blinded controlled clinical study was conducted from February 2018 to May 2019 at Al-Azhar Hospital (New Dameitta) on 120 patients (21-60 years old) of both sexes ASA I, II, undergoing lower abdominal and lower limb surgeries not exceeding 60 minutes under spinal anesthesia. Exclusion criteria were ASA III, IV patients with body temperature above 38 or below 36.5, history of convulsions, neuromuscular disorders, and patients with known allergies to the studied drugs. Patients were randomized into three equal groups, Group (A) received Meperidine in a dose of 0.5 mg/kg. IV, Group (B) received Ketamine in a dose of 0.25 mg/kg. IV, and Group

(C) received Ondansetron in a dose of 4 mg. IV. All these drugs were given after subarachnoid block .

All studied patients were evaluated preoperatively by history, clinical examination, review of investigations, and premedicated with with oral diazepam (2mg) at night, and one hour before operation. Monitoring was done including electrocardiogram, SPO₂, blood pressure, temperature, and baseline reading was recorded. Subarachnoid block was performed, using 25 G disposable Quinke's spinal needle with 0.5% hyperbaric bupivacaine over 10 sec in the inter-space L4-5 in sitting position.

Operating room temperature was maintained at 24°C-25°C. Ringer Lactate solution preload (10 ml/kg/h) and was maintained at 6 ml/kg/h after spinal anesthesia.

Just after the intrathecal injection, one of the study drugs was given IV according to the group. These parameters were measured every 5 minutes for 60 minutes after intrathecal injection. Shivering incidence and grades, HR, and Systolic BP, were recorded every 5 minutes. Shivering was graded using a scale similar to that validated by *Tsai and Chu (2001)*.

Heart rate was maintained within 60 to 90 b/m. Hypotension was treated with intravenous Ringer's solution (15 ml/kg) and ephedrine (5-10 mg i.v) as needed. Bradycardia (HR < 60/ min.) was treated with atropine (0.01-0.02 mg/kg).

Statistical analysis:

Analysis of data was done by using SPSS (statistical program for social science version 16) as follows:- Qualitative data were presented as

numbers and percentages. Quantitative data were presented as mean ± standard deviation. Qualitative data were analyzed by using Chi-square test. Quantitative data were analyzed by using one way ANOVA test HR& BP were analyzed by repeated-measure ANOVA test. Significant data by

one way ANOVA test were further analyzed by post-hoc analysis (Bonferroni correction) for detection of significant group. P < 0.05 was considered significant.

RESULTS

There was no significant difference in the age, sex, weight, ASA physical status, and type of surgery between groups (table 1).

Table(1): Demographic data and type of surgery in the studied groups

Parameters		Groups			p-value
		Group (A) N=40	Group (B) N=40	Group (C) N=40	
Age (years)		40.1±13.5	43.33±11.12	47.80±10.10	0.014
Weight (Kg)		63.9±11.4	60.93±7.31	65.85±6.92	> 0.05
Sex (M/F)		20/20	25/15	22/18	> 0.05
ASA grade (1:2)		35/5	38/2	37/3	> 0.05
Type of surgery	Vaginal hysterectomy	15 patients	10 patients	10 patients	> 0.05
	Appedictomy	3 patints	5 patients	3 patients	> 0.05
	Hernioplasty	22 patients	25patients	27 patients	> 0.05

Shivering occurred in 3 (7.5 %) patients in group A, 4 (10 %) patients in group B, and 11 (27.5 %) patients in group C. So, there were significant

differences between group A,B and group C. But there was no significant difference between group A and group B (Table 2).

Table 2: Shivering grades in the studied groups

Groups Shivering grades	Group A n=40	Group B n=40	Group C n =40	P-value
After 0 min				
Grade(0)	35 (87.5%)	35(87.5%)	30 (75%)	<0.05
Grade(1)	5 (12.5%)	4 (10%)	3 (7.5%)	
Grade(2)	0 (0%)	1(2.5%)	7 (17.5%)	
Grade(3)	0 (0%)	0 (0%)	0 (0%)	
Grade(4)	0 (0%)	0 (0%)	0 (0%)	
After 5 min				
Grade(0)	28 (70%)	27(67.5%)	28 (70%)	<0.05
Grade(1)	10 (25%)	6 (15%)	5 (12.5%)	
Grade(2)	1 (2.5%)	5 (12.5%)	3 (7.5%)	
Grade(3)	1 (2.5%)	2 (5%)	4 (10%)	
Grade(4)	0 (0%)	0 (0%)	0 (0%)	
After 10 min				
Grade(0)	27 (67.5%)	27 (67.5%)	20 (50%)	<0.05
Grade(1)	9 (22.5%)	7 (17.5%)	7 (17.5%)	
Grade(2)	1 (2.5%)	3 (7.5%)	5 (12.5%)	
Grade(3)	3 (7.5%)	2 (5%)	5 (12.5%)	
Grade(4)	0 (0%)	1 (2.5%)	3 (7.5%)	
After 15 min				
Grade(0)	29 (72.5%)	27 (67.5%)	18 (45%)	<0.05
Grade(1)	8 (20%)	6 (15%)	7 (17.5%)	
Grade(2)	1 (2.5%)	3 (7.5%)	4 (10%)	
Grade(3)	1(2.5%)	2 (5%)	6 (15%)	
Grade(4)	1(2.5%)	2 (5%)	5 (12.5%)	
After 20 min				
Grade(0)	29 (72.5%)	29 (72.5%)	15(37.5%)	<0.05
Grade(1)	8 (20%)	5 (12.5%)	9 (22.5%)	
Grade(2)	0 (0%)	2 (5%)	5 (12.5%)	
Grade(3)	1 (2.5%)	2 (5%)	5 (12.5%)	
Grade(4)	2 (5%)	2 (5%)	6 (15%)	
After 25 min				
Grade(0)	29 (72.5%)	31 (77.5%)	15(37.5%)	<0.05
Grade(1)	8 (20%)	4 (10%)	7 (17.5%)	
Grade(2)	1 (2.5%)	1 (2.5%)	7 (17.5%)	
Grade(3)	1 (2.5%)	1 (2.5%)	4 (10%)	
Grade(4)	1 (2.5%)	3 (7.5%)	7 (17.5%)	
After 30 min				
Grade(0)	31 (77.5%)	31 (77.5%)	15(37.5%)	<0.05
Grade(1)	6 (15%)	4 (10%)	7 (17.5%)	
Grade(2)	1 (2.5%)	1 (2.5%)	7 (17.5%)	
Grade(3)	1 (2.5%)	1 (2.5%)	4 (10%)	
Grade(4)	1 (2.5%)	3 (7.5%)	7 (17.5%)	
After 45 min				
Grade(0)	33 (82.5%)	31 (77.5%)	15(37.5%)	<0.05
Grade(1)	3 (17.5%)	4 (10%)	7 (17.5%)	
Grade(2)	1 (2.5%)	1 (2.5%)	7 (17.5%)	
Grade(3)	1 (2.5%)	1 (2.5%)	4 (10%)	
Grade(4)	2 (5%)	3 (7.5%)	7 (17.5%)	
After 60 min				
Grade(0)	33 (82.5%)	31 (77.5%)	15(37.5%)	<0.05
Grade(1)	3 (17.5%)	4 (10%)	7 (17.5%)	
Grade(2)	1 (2.5%)	1 (2.5%)	7 (17.5%)	
Grade(3)	1 (2.5%)	1 (2.5%)	1 (2.5%)	
Grade(4)	2 (5%)	3 (7.5%)	10 (25%)	

There was statistical significant difference between groups A ,B and

group C regarding incidence of shivering (Table 3).

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Table (3): Incidence of shivering among the studied groups

Parameters \ Groups	Mepridine (A)	Ketamine (B)	Ondansetrone (C)	P-value
Shivering (No & %)	3(7.5%)	4(10%)	11(27.5%)	<0.05*

Heart rate showed no significant difference between the studied groups (Table 4).

Table (4): Heart rate (beats per minute) in studied groups

Time (minutes) \ Groups	Group (A) Mean \pm SD beat / min	Group (B) Mean \pm SD beat / min	Group (C) Mean \pm SD beat / min	P
(base line)	83.2 \pm 5.7	85.5 \pm 6.0	83.5 \pm 6.2	> 0.5
5	88.2 \pm 8.6	89.2 \pm 8.5	87.2 \pm 8.3	> 0.5
10	78.1 \pm 8.8	81.1 \pm 8.1	79.1 \pm 8.8	> 0.5
15	79.0 \pm 8.6	80.0 \pm 8.3	78.0 \pm 8.2	> 0.5
20	75.0 \pm 10.1	76.0 \pm 10	73.0 \pm 9.8	> 0.5
25	72.0 \pm 9.0	77.0 \pm 9.0	71.0 \pm 8.0	> 0.5
30	75.8 \pm 8.8	76.2 \pm 8.2	77 \pm 8.2	> 0.5
35	73.9 \pm 7.8	77.2 \pm 6.8	78.1 \pm 5.4	> 0.5
40	72.2 \pm 6.8	76.1 \pm 6.2	74.2 \pm 5.8	> 0.5
45	72.4 \pm 6.5	77.4 \pm 5.5	76.4 \pm 4.5	> 0.5
50	71.8 \pm 6.3	78.8 \pm 2.3	73.8 \pm 5.3	> 0.5
55	70.9 \pm 6.3	76.8 \pm 6.5	75.8 \pm 6.2	> 0.5
60	72.8 \pm 6.4	78.8 \pm 6.3	76.8 \pm 6.5	> 0.5

In Group A, 4 patients were treated with atropine 0.01-0.02 mg/kg as HR decreased below 60/min. In Group C, 5 patients needed treatment by atropine, and 3 patients in Group B.

Systolic blood pressure showed no significant differences between groups (Table 5).

Table (5): Systolic BP (mm Hg) in the studied groups

TIME \ Groups	Group(A) Mean \pm SD N=40	Group(B) Mean \pm SD N=40	Group(C) Mean \pm SD N=40	p
(base line)	122.3 \pm 13.3	123.3 \pm 13.3	120.3 \pm 13.3	> 0.5
5 min	120.7 \pm 10.9	120.7 \pm 10.9	121.7 \pm 10.9	> 0.5
10 min	113.3 \pm 10.7	114.3 \pm 10.7	113.3 \pm 10.7	> 0.5
15 min	110.4 \pm 5.6	118.4 \pm 5.6	110.4 \pm 5.6	> 0.5
20 min	111.7 \pm 10.1	117.7 \pm 10.1	111.7 \pm 10.1	> 0.5
25 min	117.9 \pm 8.7	117.9 \pm 8.7	117.9 \pm 8.7	> 0.5
30min	118.8 \pm 9.4	120.8 \pm 9.4	118.8 \pm 9.4	> 0.5
35 min	119.5 \pm 8.2	119.5 \pm 8.2	116.5 \pm 8.2	> 0.5
40 min	118.2 \pm 6.2	119.2 \pm 6.2	116.2 \pm 6.2	> 0.5
45 min	119.3 \pm 5.6	119.3 \pm 5.6	115.3 \pm 5.6	> 0.5
50 min	118.8 \pm 4.2	119.8 \pm 4.2	118.8 \pm 4.2	> 0.5
55 min	119.2 \pm 6.7	119.2 \pm 6.7	119.2 \pm 6.7	> 0.5
60 min	121.4 \pm 5.6	121.4 \pm 5.6	120.4 \pm 5.6	> 0.5

Diastolic blood pressure showed no significant differences between groups (Table 6).

Table (6): Diastolic BP (mm Hg) in the studied groups .

Groups TIME (MINS)	Group(A) Mean \pm SD N =40	Group(B) Mean \pm SD N=40	Group(C) Mean \pm SD N=40	P
(base line)	74.1 \pm 7.7	75.1 \pm 7.6	75.1 \pm 7.7	> 0.5
5 min	73.9 \pm 6.4	74.9 \pm 5.4	73.9 \pm 6.4	> 0.5
10 min	70.1 \pm 4.9	73.1 \pm 3.8	71.1 \pm 4.9	> 0.5
15 min	69.6 \pm 5.3	71.6 \pm 3.3	69.6 \pm 5.3	> 0.5
20 min	68.6 \pm 5.3	71.6 \pm 2.3	69.6 \pm 5.3	> 0.5
25 min	68.6 \pm 6.3	73.6 \pm 4.3	69.6 \pm 6.3	> 0.5
30 min	69.6 \pm 5.5	71.8 \pm 2.5	69.6 \pm 5.5	> 0.5
35 min	67.7 \pm 6.4	73.7 \pm 5.4	68.7 \pm 6.4	> 0.5
40 min	70.3 \pm 4.7	74.3 \pm 5.7	70.3 \pm 4.7	> 0.5
45 min	64.2 \pm 6.2	75.2 \pm 5.8	66.2 \pm 6.2	> 0.5
50 min	76.9 \pm 3.8	77.2 \pm 5.8	76.9 \pm 3.8	> 0.5
55 min	72.7 \pm 4.8	70.6 \pm 4.8	72.7 \pm 4.8	> 0.5
60 min	70.6 \pm 4.6	73.6 \pm 5.2	70.6 \pm 4.6	> 0.5

Hypotension was seen in 5 cases (12.5%) in Group A, 3 cases (7.5%) in group B and 6 cases (15%) in group C.

There was no significant difference between groups regarding hypotension, nausea, vomiting, and hallucinations,

but there was a significant difference between C group and A, B groups regarding sedation (Table 7).

Table(7): Side effects among studied groups

Groups	Group (A) (n=40)	Group (B) (n=40)	Group (C) (n=40)	P value
Side effects				
Hypotension	5	3	6	>0.05
Nausea	4	3	1	>0.05
Vomiting	3	2	1	>0.05
Sedation	37	38	0	< 0.001
Hallucinations	0	2	0	>0.05

DISCUSSION

Shivering is one of the most important postoperative complications seen in clinical practice (*Morsali et al., 2017*). It is an important concern in patients undergoing surgery under general anesthesia as well as regional anesthesia, i.e. spinal anesthesia or epidural anesthesia. The reported median incidence of shivering related to neuraxial anesthesia from different studies is 55% (*Venkatraman et al., 2018*). Because of its associated discomfort, distress,

aggravation of pain, increased metabolic demands, and increased oxygen consumption. Prevention and treatment of postanesthesia shivering is an important component of perioperative management of the patient (*Bagle et al., 2016*).

Shivering considered significant when the patient shivered at least to grade 3 after 15 minutes of spinal anesthesia (*Tsai and Chu, 2001*). From this concept, we tried in this study to clarify the antishivering effect of Mepridine, Ketamine and Ondanstron. In our study, regarding significant shivering, it occurred

in 7.5 % of patients of group A, 10 % of patients of group B, and 27.5 % of patients of group C. So, there was significant difference between group A, B and group C. There was no significant difference between group A and group B. This agreed with *Shakya et al. (2010)* who showed that low-dose ketamine and ondansetron are effective in the prevention of shivering compared with placebo. In this study, ketamine was significantly more effective than ondansetron in controlling shivering after spinal anesthesia that, can be partly confirming the results of our study. Our study also agreed with The study done by *Browning et al. (2013)* who found no significant difference in the incidence of post spinal shivering between ondansetron or saline administered before establishing combined spinal/epidural anesthesia in parturient underwent cesarean section. Our study agreed with *Badawy and Mokhtar (2017)* who studied the role of ondansetron in prevention of post-spinal shivering (PSS) in obstetric patients. They found that there was a statistically significant higher incidence of shivering in group (B), compared to group (C). So, there was nearly the same percent of shivering in group (C).

Our study did not agree with *Safavi and Colleagues (2014)* who stated that midazolam is effective in preventing shivering after spinal anesthesia. This disagreement may be due to their larger dose of ondansetron

As regard HR, in group (A), 4 patients treated with atropine (0.01-0.02 mg/kg) as HR decreased below 60/min. In group (C), 5 patients needed treatment, and 3 patients in group (C).

As regard side effects, hypotension was seen in 12.5% in group (A), 7.5% in group (B) and 15% in group (C). Mild sedation was seen in 95% in group (B), 92.5% in group (A), and none in group (C) most of them were sedated to grade 1& 2 and not reach grade 3. It was obvious that there was no sedation seen in ondansetron. *Shakya et al., (2010)* stated that hallucinations were not noted in Ketamine group.

Nausea was seen in 4 patients in group (A), 3 in group (B) and 1 patient in group (C). Vomiting was seen in 3 patients in group (A), 2 in group (B) and 1 patient in group (C). Such patients were administered i.v. metoclopramide 10 mg.

CONCLUSION

Meperidine and low dose of ketamine were more effective than ondansetron for prevention of post-spinal shivering with minimal hemodynamic effects, but more sedation in patients undergoing lower abdominal surgeries.

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مقارنة بين الميبريدين والكيثامين والأوندانسيترون للوقاية من الارتجاج الحاد نتيجة التخدير النصفي بالمرضى الخاضعين لعمليات جراحية أسفل البطن

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يعتبر الارتجاج الناتج عن التخدير النصفي أحد العيوب التي تؤرق المريض والطبيب. وهناك العديد من التداخلات المادية والدوائية لخفض الإصابة والحد من الارتجاج الناتج عن التخدير النصفي.

الهدف من البحث: المقارنة بين تأثير عقار الميبريدين والكيثامين والأوندانسيترون لمنع الارتجاج الناتج عن التخدير النصفي.

المرضى وطرق البحث: تم اجراء هذه الدراسة على (120) مريض ، و تم تقسيم المرضى بشكل عشوائي إلى ثلاث مجموعات متساوية:

- المجموعة الأولى : خضعت للحقن من الميبريدين (0.5مجم/كجم).
- المجموعة الثانية : خضعت للحقن من الكيثامين (0.25 مجم/كجم).
- المجموعة الثالثة : خضعت للحقن من الأوندانسيترون (4 مجم).

وتم استبعاد المرضى الذين يعانون من الأمراض العصبية والعضلية والحساسية المعروفة لأي من الأدوية المستخدمة، او المرضى الذين يعانون من إرتفاع او إنخفاض في درجات الحرارة. وأجريت مقابلات مع جميع المرضى قبل الجراحة بيوم واحد، كما تم عمل التحاليل الروتينية قبل إجراء التخدير النصفي. وبعد اعطاء التخدير النصفي للمرضى تم اعطاء أحد الأدوية علي حسب نوع المجموعة وتم قياس درجات الارتجاج والنبض وضغط الدم والأثار الجانبية للأدوية مثل إنخفاض ضغط الدم والغثيان والقيء والهلوسة.

نتائج البحث: تعتبر نسبة الارتجاف أقل في مجموعتي الميبريدين والكيثامين عن مجموعة الأوندانسيترون، كما أن إنخفاض درجة الحرارة كان أكثر في مجموعة الأوندانسيترون عن مجموعتي الميبريدين والكيثامين. كما أن نسبة الآثار الجانبية أقل في مجموعة الأوندانسيترون.

الاستنتاج: يعتبر حقن كلاً من عقاري الميبريدين والكيثامين أكثر فعالية من عقار الأوندانسيترون للحد من الارتجاف الناتج عن التخدير النصفي.