

## Comparative Study of Ondansetron, Haloperidol or Midazolam in Prevention of Post-Operative Nausea and Vomiting in Laparoscopic Gynecological Operations

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### Abstract

**Background:** Post-Operative Nausea and Vomiting (PONV) is a common, undesirable effect after surgery performed under general anesthesia.

**Aim of Study:** The aim of this study is to compare the effect of ondansetron, haloperidol or midazolam in the prevention of PONV in non-smoker females undergoing laparoscopic gynecological operations under general anesthesia.

**Patient and Methods:** This prospective randomized controlled study carried out in Tanta University Hospital for six months (from November 2016 to April 2017). This study included 90 nonsmoker female patients, aged between 18 and 60 years, ASA I & II, scheduled for laparoscopic gynecological operations under general anesthesia. The anesthetic technique, drugs, monitoring, and care were standardized in all the patients during the perioperative period. Patients were randomly allocated to one of three groups (n=30 for each group): Group I ondansetron (O) 4mg I.V ondansetron was given at the end of surgery. Group II haloperidol (H) 1mg I.V haloperidol was given at the end of surgery. Group III midazolam (M) 2mg I.V midazolam was given 30 minutes before the end of surgery. Dexamethasone 4mg was added to each study group after induction of anesthesia. For the first 24 hours after anesthesia, the presence or absences of nausea, vomiting or retching were recorded. Rescue antiemetic was given if the patient complains of PONV.

**Results:** Mean response during 0-24 hours was 86.7%, 80%, 83.3% in ondansetron, haloperidol and midazolam groups, respectively. No significant difference through the three groups was found. ( $p$ -value=0.787). Regarding rescue antiemetics, there was no statistically significant difference between the three groups. Upon arrival to PACU and after 60 minutes, there was no statistically significant difference in sedation score.

**Conclusion:** In the studied surgical population, the efficacy and toxicity of post-operative nausea and vomiting prophylaxis

with haloperidol 1mg or midazolam 2mg were not significantly different from ondansetron 4mg.

**Key Words:** Ondansetron – Haloperidol – Midazolam – Post-operative nausea and vomiting – Laparoscopic gynecological operations.

### Introduction

**POST-OPERATIVE** Nausea and Vomiting (PONV) is a common, uninvited effect after surgery performed under general anesthesia. The incidence is about 72% in women undergoing general anesthesia for major gynecological surgery [1]. General anesthesia with inhalational agents is associated with an average PONV incidence of 20-30% in surgical patients [2]. In addition to being considered a major undesirable consequence by patients, severe cases of PONV may result in post-operative complications and unintended hospital admissions [3].

The etiology of emesis is multifactorial. The factors influencing the PONV are patient factors, surgical factors and anesthesia factors. Female gender from puberty on was the strongest patient specific predictor [4]. Cholecystectomy, gynecological surgery, and laparoscopic approaches are associated with a higher incidence of PONV [5]. Volatile anesthetics use was the strongest anesthesia-related factor [6]. Balanced anti emesis, using drug combinations with different mechanisms of action is a better and valuable approach than single drug therapy [7].

Ondansetron is considered the gold standard drug compared with other antiemetics [1]. However, the high cost of ondansetron has been a major limitation in its routine prophylactic use. Also, 5-

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HT3 antagonists (ondansetron, granisetron and dolasetron) are listed among QT interval-prolonging drugs with possible risk of torsade de pointes. Moreover, several cases of cardiac dysrhythmias after administration of 5-HT3 antagonists have been reported [8]. For these reasons, the challenge to use and introduce more cost-effective drugs with fewer side effects to prevent PONV is going on. Centrally, Ondansetron binds competitively and selectively to serotonin receptors in the Chemoreceptor Trigger Zone (CTZ). It also blocks receptors in the gastrointestinal tract, which prevents the action of serotonin and inhibits emetic symptoms [9]. Haloperidol is a dopamine D2 receptor antagonist, accounting for its antipsychotic activity. Chemoreceptor trigger zone is dopamine-rich receptors, therefore the antagonism of dopamine D2 receptors by haloperidol in the CTZ is mechanism of reducing nausea and vomiting [10]. Haloperidol has antiemetic properties when used in low dose (0.5 to 2mg IM or IV) [11,12]. At these doses, sedation does not occur, and cardiac arrhythmias are not reported. The suggested mechanism of action of midazolam as an antiemetic is by decreasing dopamine input at the CTZ as well as reducing 5-hydroxytryptamine release by binding to the  $\gamma$ -aminobutyric acid benzodiazepine complex [13].

The mechanism of dexamethasone antiemetic activity may involve central inhibition of prostaglandin synthesis [14], a decrease in 5-HT turnover in the central nervous system [15] or changes in the permeability of the blood CSF barrier to serum proteins [16].

There is no single cause for PONV, thus, a combination of antiemetics may be more effective than a single antiemetic. When used in combination, drugs from different classes should be selected to optimize their effects [17,18].

### Patients and Methods

This prospective randomized controlled study was carried out in Tanta University Hospital for six months. After approval from the Institutional Ethics Committee, an informed consent was taken from each patient. Ninety nonsmoker female patients, aged between 18 and 60 years, ASA I & II, scheduled for laparoscopic gynecological operations under general anesthesia were included in this study. Exclusion criteria included: Patient refusal, patients with known hypersensitivity or contraindications to study drugs, history of nausea, vomiting or retching in 24 hours before anesthesia, patients who have received antiemetic drugs or drugs with antiemetic property during 24 hours

before anesthesia, conditions requiring chronic opioids use and those suffering from gastrointestinal, liver and renal diseases. Pre-operative assessment was done by history taking, clinical examination, routine laboratory investigations including: CBC, bleeding time, clotting time, liver function tests, kidney function tests. Monitoring included ECG, pulse oximetry, noninvasive blood pressure, MAC, temperature probe and end-tidal carbon dioxide was applied to all patient. Patient induction started by pre-oxygenation for at least 3 minutes with 100% oxygen at a flow rate of 6L/min. Fentanyl at a dose of 1mcg/kg was administered followed by propofol 2mg/kg. Tracheal intubation was facilitated by administration of cisatracurium 0.1mg/kg. Ventilation was mechanically controlled and adjusted to maintain end-tidal CO<sub>2</sub> values between 30 and 35mmHg throughout the surgery. Anesthesia was maintained with isoflurane 1MAC, cisatracurium 0.02mg/kg every 30 minutes and fentanyl 1  $\mu$ g/kg/h as a bolus dose. Patients were randomly allocated by closed envelope technique to one of three groups (n=30 for each group): Group I ondansetron (O) 4mg I.V ondansetron was given at the end of the surgery.

Group II haloperidol (H) 1mg I.V haloperidol was given at the end of the surgery. Group III midazolam (M) 2mg I.V midazolam was given 30min before the end of surgery. Dexamethasone 4mg was added to each study group and given after induction. At the end of the procedure, isoflurane was discontinued, the combination of atropine 1mg and neostigmine 2.5mg were administered intravenously and the trachea was extubated after fulfilling criteria of extubation. Hemodynamics (heart rate, mean arterial pressure, peripheral capillary oxygen saturation) were recorded before giving the study drug, 15 minutes after giving the study drug and after extubation. All patients were assessed every hour for the first 6 hours, three hours for next 6 hours and sixth hours for subsequent 12 hours using the following PONV scoring system:

- Score 0-No nausea.
- Score 1-Nausea only.
- Score 2-Nausea with Retching.
- Score 3-Vomiting.

The primary outcome of the study is the absence of nausea, retching, vomiting with no requirement of rescue antiemetics for 24 hours post-operatively. While, secondary outcomes are the presence of adverse effects like headache, dizziness, sedation, hemodynamic instability and pain intensity. Sedation was assessed upon arrival to PACU and after

60min using the modified observer's assessment of alertness/sedation (OAA/S) score, whereas 5 is alert and 0 deep sleep. Data were fed to the computer and analyzed using IBM SPSS software package Version 20.0. (Armonk, NY: IBM Corp) The used tests were: Chi-square test for categorical variables, Fisher's Exact or Monte Carlo correction, F-test (ANOVA) for normally distributed quantitative variables. And Post Hoc test (LSD Least Significant Difference) for pairwise comparisons. ANOVA with repeated measures for normally distributed quantitative variables, and Post Hoc test (LSD) (Bonferroni adjusted) for pairwise comparisons. Mann Whitney test for abnormally distributed quantitative variables, to compare between two studied groups. Kruskal Wallis test for abnormally distributed quantitative variables, and Post Hoc (Dunn's multiple comparisons test) for pairwise comparisons.

## Results

All the 90 patients, 30 in each group were included in the study. There were no significant differences between the three groups with regard to age ( $p=0.905$ ), body mass index ( $p=0.942$ ), history of PONV ( $p=0.853$ ) and ASA physical status (1.000) as shown in (Table 1). There was no statistically significant difference between the three groups for HR, MAP or Spo2 at any time as shown in (Table 2). Between the three groups, there was no statistically significant difference in sedation score upon arrival to PACU and after 60 minutes as shown in (Table 2). There was no statistically significant difference in VAS score during 0-2 hours and 2-24 hours. Concerning adverse effects, no statistically significant difference was found among the three studied groups as shown in (Table 2).

Table (1): Patient demographic data.

Variable Mean $\pm$ SD	Control I n=30	Control II n=30	Control III n=30	
• Age (y) $\pm$ SD	27.40 $\pm$ 5.49	27.07 $\pm$ 5.58	26.77 $\pm$ 5.37	F 0.100 $p$ 0.905
• BMI kg/m <sup>2</sup>	25.33 $\pm$ 2.07	25.17 $\pm$ 1.90	25.30 $\pm$ 1.93	F 0.060 $p$ 0.942
• ASA physical status (I/II)	27/3	28/2	28/2	$\chi^2$ 0.440 MC $p$ 1.000
• History of PONV (yes/no)	9/21	8/22	10/20	$\chi^2$ 0.317 $p$ 0.853

Table (2): Patient hemodynamics.

Variable	Before administration	15min. after administration	After extubation
<b>Heart rate (beats/min.):</b>			
Mean $\pm$ SD:			
Group I	93.0 $\pm$ 10.28	92.2 $\pm$ 13.24	96.37 $\pm$ 14.87
Group II	92.20 $\pm$ 10.53	92.8 $\pm$ 13.57	97.37 $\pm$ 14.92
Group III	90.90 $\pm$ 9.59	89.17 $\pm$ 8.89	91.07 $\pm$ 8.98
	F 0.328	0.784	1.967
	$p$ 0.721	0.460	8.98
<b>Spo2 (%):</b>			
Group I	98.97 $\pm$ 1.0	98.97 $\pm$ 0.82	98.97 $\pm$ 0.87
Group II	98.90 $\pm$ 1.06	99.23 $\pm$ 0.68	99.23 $\pm$ 0.86
Group III	99.37 $\pm$ 0.72	99.47 $\pm$ 0.57	99.27 $\pm$ 0.69
	F 2.170	1.122	0.118
	$p$ 0.120	0.330	0.889
<b>MAP (mmHg):</b>			
Group I	87.07 $\pm$ 9.95	87.07 $\pm$ 10.83	87.07 $\pm$ 8.87
Group II	88.27 $\pm$ 10.49	88.70 $\pm$ 15.28	90.33 $\pm$ 13.41
Group III	87.0 $\pm$ 8.97	85.43 $\pm$ 9.89	89.43 $\pm$ 9.29
	F 0.158	0.544	0.076
	$p$ 0.854	0.582	0.927

Table (3): Patient operative characteristics.

	Group I	Group II	Group III	
<b>Sedation score (mean <math>\pm</math> SD):</b>				
Upon arrival to PACU	4.43 $\pm$ 1.33	4.10 $\pm$ 0.92	4.20 $\pm$ 1.27	H(p) 1.472 (0.479)
60min. after extubation	5 $\pm$ 0.0	5 $\pm$ 0.0	5 $\pm$ 0.0	H(p) 0.0 (1.000)
<b>VAS score: (Mean <math>\pm</math> SD)</b>				
	3.3 $\pm$ 0.6	3.0 $\pm$ 0.7	3.2 $\pm$ 0.9	F 1.265 $p$ 0.287
2-24h	2.3 $\pm$ 0.7	2.0 $\pm$ 0.5	2.2 $\pm$ 0.7	F 1.707 $p$ 0.187
Adverse effect (yes/no)	2/28	26/4	3/27	$\chi^2$ 1.731 MC $p$ 0.929

A complete response is defined as no nausea, no retching, no vomiting and no need for rescue antiemetics during the 24-h post-operative period. (Table 4) and Fig. (1) show comparison between the three studied groups according to complete response. Mean response during 0-24 hours was not significantly different through the three groups. ( $p$ -value=0.787). Table (5) shows the comparison between the three studied groups according to the incidence of rescue anti emetics taken by patients. There was no statistically significant difference between the three groups.

Table (4): Complete response.

Complete response (yes/no)	1st 6 hours	2nd 6 hours	2nd 12 hours	Mean response (0-24h)	
0-2h	26/4	25/5	25/5	26/4	$\chi^2$ 0.480
Group II (N=30)	24/6	24/6	25/5	24/6	$p$ 0.787
Group III (N=30)	24/6	25/5	26/4	25/5	

Table (5): Rescue antiemetics.

Rescue anti emetics (yes/no)	1st 6 hour	2nd 6 hour	2nd 12 hour
Group I	4/26	5/25	5/25
Group II	6/24	6/24	5/25
Group III	5/24	5/25	4/26
$\chi^2$	0.608	0.152	0.255
$p$	0.738	0.927	$FEP=1.000$

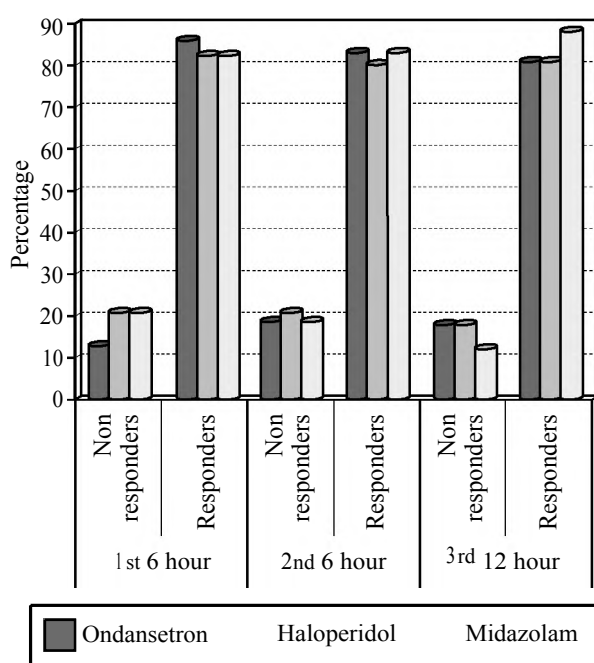


Fig. (1): Complete response.

### Discussion

Post-Operative Nausea and Vomiting (PONV) is a common complication of laparoscopic procedures. Those most at risk are patients who are young, female, and nonsmokers; patients with fewer co morbidities; and those undergoing laparoscopic gynecologic procedures [18]. However, in our study, care was taken to ensure that the treatment groups were comparable in terms of type of patient, demographics, surgical procedures, anesthetics administered, and analgesics used after the

operation (other than the study medication). Therefore, the difference in the incidence of PONV between the study groups can be attributed to the differences between the agents tested. The three groups were comparable with respect to demographic characteristics, history of PONV, ASA physical status, the mean sedation score at arrival to PACU and 60 minutes after extubation and the mean post-operative pain scores (VAS). There was no statistically significant difference between the three groups for MAP, HR or Spo<sub>2</sub> at any time. Mean response during 0-24 hours was 86.7%, 80%, 83.3% in ondansetron, haloperidol and midazolam groups, respectively. No significant difference between the three groups was found. ( $p=0.787$ ) Regarding rescue antiemetics, during 1st 6 hours, 2nd 6 hours and 2nd 12 hours there was no statistically significant difference between the three groups. Our study showed that ondansetron had preventive effects on PONV similar to midazolam or haloperidol in high-risk patients after gynecological laparoscopic surgery. In agreement, Yi Lee et al., [19] found no significant difference between ondansetron and haloperidol on prophylaxis of PONV. Po Kai Wang et al., [20] conducted a study comparing the effect of dexamethasone with ondansetron or haloperidol for prevention of patient-controlled analgesia related PONV. No significant difference was found between both groups. In contrast, the study conducted by Aouad MT et al., [21], the prophylactic administration of 1mg intravenous haloperidol or 4mg ondansetron, in female patients undergoing gynecological surgery, did not improve the overall incidence of nausea and/or vomiting vs. Placebo (2-24h). The difference can be explained by the combination of using nitrous oxide by Aouad et al., during anesthesia in gynecological surgery which is considered as 2 components of high-risk group for PONV while using single drug therapy. In agreement, a study conducted by Y. Lee et al., [22] comparing between ondansetron 4mg and midazolam 2mg for preventing post-operative nausea and vomiting showed that; the proportions of patients who did not experience post-operative nausea and vomiting in the first 24h were similar in the two groups. Another study comparing the effect of haloperidol, midazolam and their combination was done by Azim Honarmand et al., [23].

Patients were divided into 4 groups and received haloperidol 2mg i.v. (group H); midazolam 2mg i.v. (group M); haloperidol 2mg plus midazolam 2mg i.v. (group HM); saline i.v. (group C). Complete prophylactic rate in group H was 20%, in group M was 45%, in group HM was 70% and in group C was 20%. Prophylactic rate was higher in

midazolam group than in haloperidol group which had no benefit over saline. In agreement, Yi Lee et al., [22] in his study found no difference in sedation score between haloperidol 2mg and ondansetron 4mg. In agreement, Azim Honarmand [24] conducted a study to compare the effect of midazolam and ondansetron in PONV prophylaxis. That study showed that midazolam did not prolong PACU and extubation time. It was due to using sub hypnotic dose midazolam for prevention of PONV. In agreement, in a meta-analysis conducted by Eun Jin Ahn et al., [25] fifteen of the 16 relevant studies reported that there were no significant differences between midazolam and control groups. Among 3 studies in which midazolam was administered continuously, [26-28] only 1 study [28] reported that the incidence of mild sedation in the midazolam group was higher than levels in the control group.

### Conclusion:

In the studied surgical population, PONV prophylaxis with haloperidol 1mg or midazolam 2mg, both combined with dexamethasone 4mg, is comparable to ondansetron 4mg combined with dexamethasone 4mg as regarding the efficacy and complications. Haloperidol and midazolam have similar safety and efficacy for PONV prophylaxis as ondansetron in patients undergoing gynecologic laparoscopic surgeries without increasing recovery time and the level of sedation. Haloperidol or midazolam can be used as an alternative to ondansetron, which is considered the gold standard for PONV prophylaxis.

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## دراسة مقارنة بين عقار أوندانسيترون، هالوبريدول أو كيدازولام في الوقاية من الغثيان والقيء ما بعد الجراحي في عمليات أمراض النساء بالمنظار

الهدف من الدراسة هو إمكانية إستبدال العلاج الرئيسى المضاد للقيء (أوندانسيترون) متلافيا بعض الآثار الجانبية له وكذلك إرتفاع سعره نسبيا. حيث تم مقارنة كل من أوندانسيترون وهالوبريدول وميدازولام مع إضافة ديكساميثازون إلى كل منهم. لم يتم العثور على فرق إحصائي واضح بين المجموعات الثلاث فيما يتعلق بالبيانات الديموغرافية، والتاريخ المرضى للغثيان والقيء ما بعد الجراحة والحالة الصحية للمرضى. وفيما يتعلق بالعلامات الحيوية (نبضات القلب، متوسط ضغط الدم ومستوى الأكسجين بالدم)، لم تظهر أى تغييرات ذات دلالة إحصائية بين مجموعات الدراسة. متوسط الإستجابة لعقاقير الدراسة خلال ٢٤ ساعة كانت كالآتي: ٨٦.٧٪ و ٨٠٪ و ٨٣.٣٪ فى أوندانسيترون وهالوبريدول وميدازولام، على التوالى والذي لم يظهر أى تغيرات ذات دلالة إحصائية. لم تظهر أى تغييرات ذات دلالة إحصائية بين مجموعات الدراسة بالنسبة لمضادات القيء العلاجية التى تم إعطائها خلال ٢٤ ساعة وكذلك متوسط مستوى النعاس والأعراض الجانبية ومتوسط مستوى الألم خلال ٢٤ ساعة بعد العملية. بالرغم من أن أوندانسيترون يعد الدواء الرئيسى للوقاية من الغثيان والقيء ما بعد العمليات الجراحية، يعد كلا من عقارى هالوبريدول أو ميدازولام مضافا إليهما ديكساميثازون بديلا له من حيث الوقاية الجيدة من القيء والغثيان فى ما بعد جراحات المنظار لأمراض النساء وكلاهما يعمل بكفاءة مقارنة بالدواء الرئيسى (أوندانسيترون).