Natural Resources for Human Health
eISSN: 2583-1194

Original Research

Received 18 April 2026
Revised 24 May 2026
Accepted 22 June 2026

Natural Resources for Human Health 2026, Vol. 6 (5s): 1092–1099

KEYWORDS:
Antiemetics, CINV, ASCO.

# An Observational Study on the Use of Antiemetic Drugs in Clinical Practice for Chemotherapy-Induced Nausea and Vomiting Management Among Iraqi Cancer Patients

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## ABSTRACT:

**Introduction**: Chemotherapy-induced nausea and vomiting (CINV)represents a significant concern in treatment of cancer patients. CINV possesses negative impact both on patients and oncologist. Several approaches are considered in prevention and management of CINV. This study evaluates the rationale of use and efficacy of anti-emetics among cancer patients in in two Iraqi hospitals.

**Methods**: A cross-sectional observational study was conducted among Iraqi cancer patients in two hospitals in Baghdad (Baghdad teaching hospital and Oncology teaching hospital). This study included all patient receiving chemotherapy after confirmed diagnosis with any type of cancer. The emetogenicity level of different chemotherapeutic agents was classified based on ASCO 2011 classification.

**Results**: There were 109 patients, 65 females (59.6%) and 44 males (40.4%) recruited in the current study. Oral Ondansetron 8 mg was used with the highest percent (31%) followed by I.V. Ondansetron 8 mg I.V plus dexamethasone 20 mg I.V (21%). The cycle in which CINV was mainly the first cycle (80.3% of patients) followed by second cycle (9.2%) and third cycle (5.3%) of chemotherapy. CINV increased in level in female patients in about 43.1% and in male patients in only 11.4%

**Conclusion**: The practice of using antiemetic agents in Baghdad teaching hospital and oncology hospital didn't comply with ASCO guideline recommendation that was based on emetogenicity classification. In addition, high incidence of vomiting in cycle number one emphasized on the need for better approach in management of CINV.

## INTRODUCTION

Chemotherapy-induced nausea and vomiting (CINV) are among the most severe side effects of cancer treatment. These symptoms negatively affect quality of life, patients' nutritional status, and treatment compliance [1].

The etiology of CINV is mainly due to a complex interplay between different systems either neurological or non-neurological [2]. Chemotherapeutic agents, especially if they have a high emetogenic potential, like cisplatin, result in damage of the gastrointestinal mucosa and the release of enterochromaffin cells, which release 5-HT or serotonin. This activates vagal 5-

$HT_3$ receptors, which signals the chemoreceptor trigger zone (CTZ), located in postrema of brain's medulla [3]. The activation of CTZ also results from integrating signals from other neurotransmitters as dopamine, serotonin and substance P (via NK1 receptors). In addition, psychological factors, sensory stimuli, and vestibular inputs may add to the pathogenesis CINV [4].

CINV is classified clinically into five different subtypes. Acute CINV appears within the first 24 hours of chemotherapy treatment, with a peak around 5 to 6 hours. Delayed CINV is presented between 24 hours and five days post-treatment [5]. Anticipatory CINV is a pre-learned response to previous attacks of CINV. Breakthrough CINV is the resistant vomiting despite prophylactic antiemetic treatment, and it can be life threatening and necessitates immediate intervention [6]. Refractory CINV is the vomiting that persists all over the treatment course despite changing therapeutic protocols. Diagnosis of CINV is mainly clinical, depending on the duration of symptoms, treatment history, and chemotherapeutic agents'emetogenic risk [7].

The management of CINV is mainly of preventive nature relying on the emetogenic risk of the type of chemotherapy administered [8]. The American Society of Clinical Oncology (ASCO) recommends a four-drug regimen that contain a 5-$HT_3$ receptor antagonist (as ondansetron), a NK1 receptor antagonist (as aprepitant), corticosteroid (mainly dexamethasone), and olanzapine (second-generation atypical antipsychotic) [9]. Low-risk protocols usually need one therapeutic choice as dexamethasone or a 5-$HT_3$ antagonist. In case of breakthrough or refractory CINV, other choices such as metoclopramide, benzodiazepines, or cannabinoids can be considered [10]. In case of anticipatory CINV, non-pharmacological interventions as behavioral therapy, acupuncture, and dietary adjustments can be beneficial in controlling CINV in those patients [11].

**Significance of the Study**

Given the high burden of chemotherapy failure due to different causes, and the role that the management of CINV could play to improve cancer patients quality of life and increase the opportunity of successful cancer treatment protocols by reducing the cycle delay caused by CINV and increase patients adherence in Iraqi cancer patients, a well designed study is needed to explore the practice in Iraqi settings.

This study aimes to compare the use of antiemetics in CINV in two different Iraqi health institutes with ASCO guidelines in the past decade, and to be part of a future larger study to compare the improvement in the clinical practice in using antiemtics in order to improve Iraqi cancer patients quality of life.

## METHODS

A cross-sectional observational study was conducted among Iraqi cancer patients in two hospitals in Baghdad (Baghdad teaching hospital and Oncology teaching hospital). This study included all patient receiving chemotherapy after confirmed diagnosis with any type of cancer. No intervention was made by any means to affect the current chemotherapy protocol that patient receive. The data collected prospectively and retrospectively from patient registry and records. A case report form was developed and included the following:

a) patient's demographic characteristic (age, gender).

b) data of chemotherapy treatment: protocoland dosage, number of cycles and day of each cycle.

c) data of antiemetic agents: type, dose and its route of administration.

d) In addition, incidence and severity of nausea and vomiting before and after chemotherapy treatment in each cycle and in last cycle, incidence rates were recorded both acute (first 24 hours) and delayed (1-5 days).

In this study the emetogenicity level of different chemotherapeutic agents was classified based on ASCO 2011 classification (Table 1) in order to compare the current practice regarding the use antiemetic agent in our setting with ASCO guideline recommendations. For each patient there was a given code in order to avoid repetition of collected cases.

Natural Resources for Human Health
eISSN: 2583-1194

**Table (1):** Classification of Antineoplastic agents for their emetic properties [12]

| High risk | Moderate risk | Low risk | Minimal risk |
|---|---|---|---|
| Cisplatin<br>Mechlorethamine | Oxaliplatin Cytarabine > 1 g/m2 | Pamarubicin<br>Cytarabine 1,000 ≤ mg/m2<br>Mitoxantrone | Bevacizumab<br>Bleomycin |
| SCT ≥ 1,500 mg/m2<br>Carmustine<br>Dacarbazine<br>Dactinomycin | Pomavid® is a medicine that contains the active substance pomalidomide.The active substance in Pomavid is pomalidomide. | Drugs used to treat this type of cancer include topotecan, etoposide, pemetrexed, methotrexate, mitomycin, gemcitabine, fluorouracil, bortezomib, cetuximab, trastuzumab. | Each of these drugs is a type of chemotherapy.All of these medications are chemotherapy. |

All statistical analysis carried out by using the Statistical Package for Social Sciences (SPSS) software version 25 (SPSS Inc., Chicago, USA). Frequencies and percentages were used in demographic data, in addition to cross tabulation for certain questions and different statistical tests like Chi-square. Also, the frequency and percentage were applied in descriptive statistics. The p value of 0.05 was considered in this research for statistical significance.

**RESULTS**

In the present study, 109 patients were recruited, patients recruited from Baghdad teaching hospital were diagnosed with hematological malignancies (78%) while patients recruited from Oncology teaching hospitalwere diagnosed with solid tumor malignancies (22%).

Included patients were 65 females (59.6%) and 44 males (40.4%). About 6.4% of included patientsaged below 18 years, while 23% aged 18-30 years, and 59.6% aged 30-65 years and11%aged above 65 years (Figure 1).

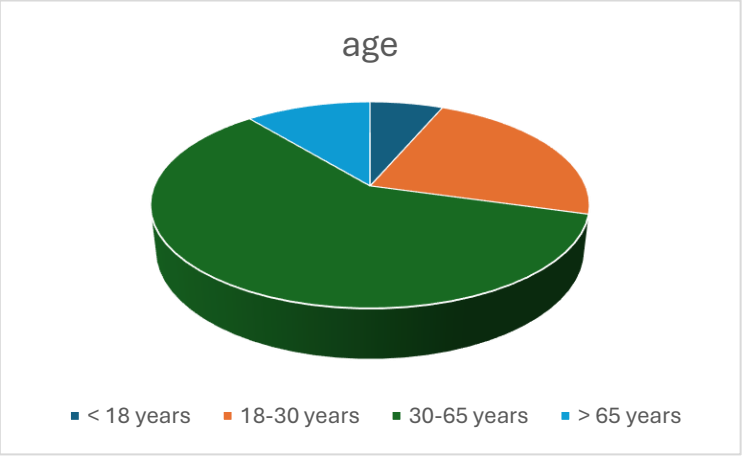


**Figure (1):** Age distribution among included patients

The emetogenic risk of chemotherapeutic agents classified according to the guidelines of ASCO is illustrated in table 2.

**Table (2):** The emetogenic risk of chemotherapeutic agents in included patients

| The emetogenic risk | No. (%) |
|---|---|
| High | 25 (22.9%) |
| Moderate | 43 (39.5%) |
| Low | 38 (34.9%) |
| Minimal | 3 (2.7%) |

The number of cycles for chemotherapy for patients ranged between 1-23 cycles with highest percentage of patients having 2 cycles (23.9%) followed by those having only one cycle (22.9%) and patients having three cycles (17.4%%).The cycle in which CINVwas mainly the first cycle (80.3% of patients)followed by second cycle (9.2%) and third cycle (5.3%) of chemotherapy.

As regards frequency of vomiting in the previouscycle,itranged from 1-7 time, with highest percent of patients (25%) suffering from at least one vomiting episode in previous cycles. Twice and third time of vomiting also showed high percentages (Figure 2).

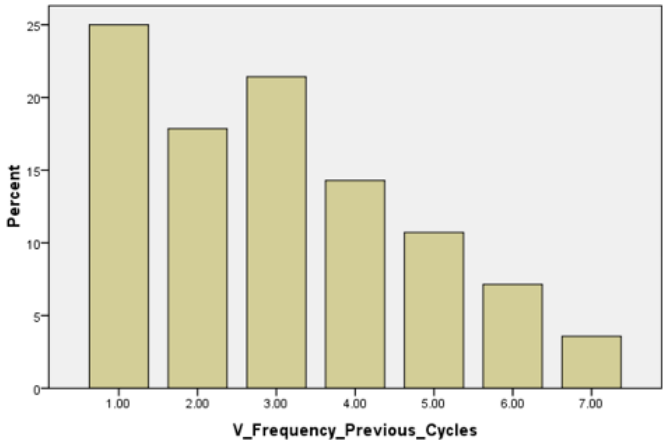


**Figure (2):**Frequency of vomiting in previous cycle

In addition, included patients reported change in level of CINV, 30.3% had increased level, 25.7% had decreased level while 11% of patients were the same and 20.2% had no vomiting (Figure 3).

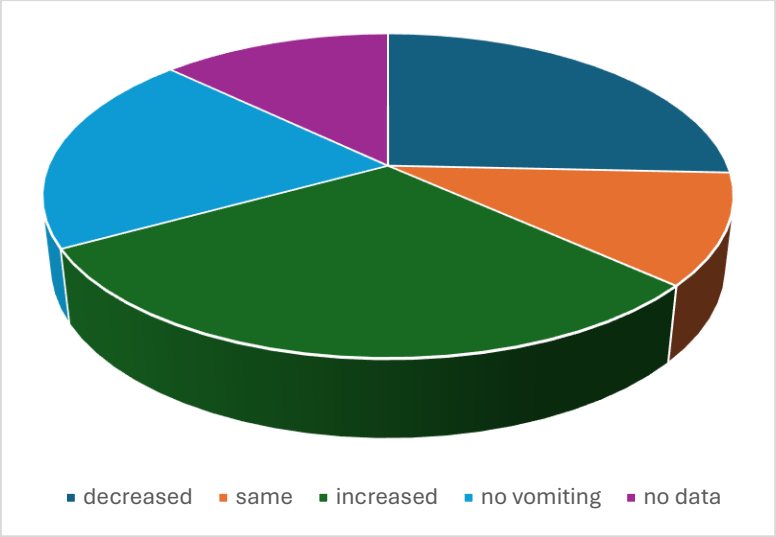


**Figure (3):** Change in level of CINV

The association between patients' gender and change in level of CINV proved high statistical significance (p=0.008), as CINV increased in level in female patients in about 43.1% and in male patients in only 11.4% (Table 3).

**Table (3):** Association between patients' gender and change in level of CINV

| Changein level of CINV | Males No. 44 | Females No. 65 | P value |
|---|---|---|---|
| Decreased | 16 (36.4%) | 12 (18.5%) | **0.008** |
| Same | 5 (11.4%) | 7 (10.8%) | |
| Increased | 5 (11.4%) | 28 (43.1%) | |
| No vomiting | 10 (22.7%) | 12 (18.5%) | |
| Unknown | 8 (18.2%) | 6 (9.2%) | |

Different antiemetic agents and combinations were used in different classes of emetogenicity as a prevention of CINV.Oral Ondansetron8 mg was used with the highest percent (31%) followed by I.V. Ondansetron 8 mg I.V plus dexamethasone 20 mg I.V (21%) (Figure 4).

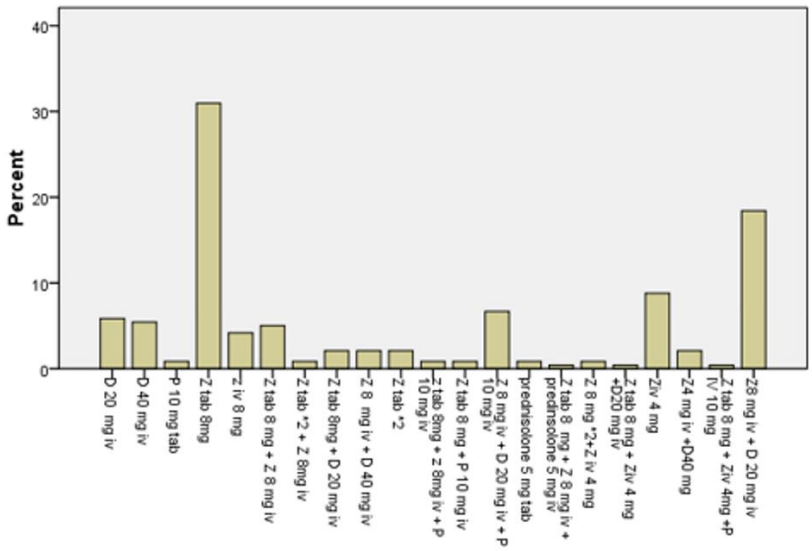


**Figure (4):** Percentage of antiemetic agents and combinations used as prevention of CINV, Z (ondansetron), D (dexamethasone), P (metoclopromide).

Concerning the distribution of antiemetic agents and combinations as regards different classes of chemotherapy emetogenicity, table 4 provides detailed analysis of such distribution. It should be noted that for minimal emetogenicity no antiemeticswererequired for prevention of CINV except for dexamethasone (20 mg i.v).

**Table (4):** Distribution of antiemetic agents and combinations by classes of chemotherapy emetogenicity

| | High | Moderate | low |
|---|---|---|---|
| Ondansetron (8 mg oral) | 41.4% | 20% | 40.5% |
| Ondansetron 8 mgi.v and dexamethasone 20 mg i.v. | 6.9% | 29% | 14.9% |
| Ondansetron 4 mg i.v. plus dexamethasone 20 mg i.v. | - | 2% | 4.1% |
| Ondansetron (4 mg i.v) | 15.5% | 12% | - |
| Ondansetron 8mg i.v. plus dexamethasone 20mg i.v. plus | 15.5% | 4% | 4.1% |

| | | | |
|---|---|---|---|
| metoclopramide 10mg i.v. | | | |
| Ondansetron (8mg oral and 8mg I.V.) | 1.7% | 11% | - |
| Ondansetron (8 mg oral) + dexamethasone (20 mg i.v) | - | 1% | 5.4% |
| Ondansetron 8 mg oral twice | 1.7% | 1% | 4% |
| Dexamethasone(20 mg i.v) | - | 1% | 10.8% |

## DISCUSSION

CINV is one of the most important and most detrimental factors on the quality of life, therapy compliance and clinical response of patients. It can cause more than just physical discomfort, often leading to nutritional deficiencies and psychological stress and a failure to follow treatment [13]. Current therapeutic approaches encompass the utilization of 5-$HT_3$ receptor antagonists, $NK_1$ receptor antagonists, corticosteroids, and novel medicines such as olanzapine, frequently administered in combination to enhance efficacy [14].

The current study revealed that in included cancer patients, the cycle in which CINV occurred mainly 1st cycle 80.3% and decrease 2nd cycle 9.2%. This high prevalence of CINV in the first cycle highlighted poor approach in prevention CINV. Possible explanation can be owed to the administration of ondansetron was wrong because it was given directly by intravenous bolus rather than intravenous infusion and not waiting half an hour before giving chemotherapy this may lead to ineffective response and drug-drug interaction occur in some cases especially with cyclophosphamide so that patient complained from nausea and vomit after cycle of chemotherapy because the prevention was ineffective due to wrong administration of antiemetic agent.

Risk-based antiemetic regimens based on the emetogenic potential of the chemotherapy and patient-specific factors were highlighted by ASCO [14]. In cases of high emetogenic chemotherapy, the ASCO guidelines suggest using a 4-drug chemotherapy treatment strategy consisting of a $NK_1$ receptor antagonist, 5-$HT_3$ receptor antagonist, dexamethasone, and olanzapine. It has been shown to be more effective in clinical trials [15] and is effective during the acute and delayed stages of CINV. A single 5-$HT_3$ receptor antagonist plus dexamethasone will usually suffice for chemotherapy with moderate emetogenicity (MEC) and in the case of carboplatin use an $NK_1$ receptor antagonist is also required [16].

In the present study, the correlation between gender and level of CINV was highly significant ($p=0.008$) with an increase in the level of CINV in females patients (43.1%) and 11.4% in male patients. There have been consistent clinical evidence of gender differences in CINV, with female subjects being much more susceptible than male subjects. One potential explanation is hormonal effects, such as estrogen, that have been shown to affect neurotransmitter systems, such as serotonin and dopamine, and thus make individuals more vulnerable to emetogenic cues [17].

There is also a discrepancy in neurophysiological factors. Women have more visceral sensitivity and better autonomic responses that can further suggest and amplify the feeling of nausea [17].

Oral Ondansetron 8 mg was administered with the highest percent (31%) in the present study followed by I.V. Ondansetron 8 mg I.V (dexamethasone 20 mg I.).V (21%). Ondansetron is a must-have for the treatment and utility of CINV. Ondansetron works by blocking signals in the gastrointestinal tract and central nervous system that are triggered by serotonin and are important pathways that cause nausea and vomiting during chemotherapy. The oral formulation is particularly effective for the treatment of acute CINV (occurring within the first 24 hours after treatment) and has performed well in many clinical settings in comparison to intravenous treatment [18].

## CONCLUSION

A high rate of vomiting in the first cycle of chemotherapy highlights the need for improved treatment of CINV to improve adherence to therapy and quality of life. For the institutions included, current use of antiemetic drugs within the institutions was not consistent with the recommendations of the ASCO guideline in terms of emetogenicity classification. Giving ondansetron to patients who receive low emetogenic chemotherapy should not be done, and is a case of the wrong treatment.

## RECOMMENDATIONS

The current study findings recommend that emetogenic risk for each patient should be evaluated by chemotherapy regimen, history of prior CINV, as well as other factors which include age and gender. For moderate to highly emetogenic chemotherapy, the use of antiemetic agents, such as 5-$HT_3$ receptor antagonists, NK1 receptor antagonists and corticosteroids is recommended as a prophylactic treatment.Also, there is a need to inform patients of the significance of adherence with the recommended schedule of antiemetic administration, to screen for late onset CINV and to emphasize the use of nonpharmacologic interventions, including dietary measures and behavioral therapy.

### Conflict of interest

The authors didn't declare any conflict of interest.

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