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Original Research Article

A retrospective drug utilization study in chemotherapy-induced nausea and vomiting

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ABSTRACT

Background: Chemotherapy-induced nausea and vomiting (CINV) significantly impacts patients' quality of life. Despite advancements in therapy, optimal management of CINV remains crucial. This study evaluates drug utilization patterns in CINV management in patients attending the government cancer hospital, Chhatrapati Sambhajinagar (Maharashtra). Objective were to evaluate the drug utilization patterns in CINV management amongst cancer patients.
Methods: Retrospective, cross-sectional observational study in 242 cancer patients attending the outpatient department in a government cancer hospital, Chhatrapati Sambhajinagar. The prescriptions were taken from the record section after the necessary approval of IEC and permissions. Prescriptions were evaluated as per WHO drug prescribing indicators.
Results: The 484 drugs were prescribed for CINV in 242 patients. Most patients were aged between 51-60 years (31.82%), followed by 41-50 years (26.86%). All drugs are prescribed under generic names. Three classes of drugs were identified as monotherapy or combination therapy. 5-HT3 receptor antagonists and corticosteroids were the two most frequently used classes, followed by NK1 receptor antagonists. In prescribing patterns, dual combination regimens of 5-HT3 receptor antagonists and corticosteroids were the most common (99.17%), followed by triple combination and monotherapy (0.41% each). Out of the total, 483 (99.79%) drugs were given by parenteral route and 1 (0.21%) by oral route.
Conclusions: Following standard protocols for CINV was noted. The use of 5-HT3 receptor antagonists (Granisetron) and corticosteroids (dexamethasone) in combination was common, suggesting a pattern of adherence to guidelines and improving patient care.

Keywords: Chemotherapy, Nausea, Vomiting, 5-HT3 receptor antagonists, Corticosteroids

INTRODUCTION

Chemotherapy-induced nausea and vomiting (CINV) is one of the most distressing side effects seen in cancer patients undergoing chemotherapy. It significantly impacts the quality of life, disrupts daily activities, and often leads to poor compliance with treatment regimens, ultimately affecting therapeutic outcomes.

Despite the availability of advanced antiemetic therapies, the management of CINV continues to be a challenge.

CINV is a multifaceted physiological response involving the central nervous system (CNS), gastrointestinal (GI) tract, and a variety of neurotransmitters.[1] The condition is classified into five categories: acute, delayed, anticipatory, breakthrough, and refractory, each driven by distinct mechanisms. Chemotherapeutic agents trigger nausea and vomiting primarily through the activation of the chemoreceptor trigger zone (CTZ) and stimulation of the GI system.[2]

The CTZ, located in the area postrema of the medulla, is highly sensitive to circulating toxins as it lies outside the

blood-brain barrier. Chemotherapy drugs directly stimulate the CTZ, leading to activation of the vomiting center in the medulla. Key neurotransmitters involved in this process include dopamine (D2), serotonin (5-HT3), neurokinin-1 (NK1), and substance P.[3] Simultaneously, chemotherapeutic agents damage the GI mucosa, prompting the release of serotonin from enterochromaffin cells. Serotonin binds to 5-HT3 receptors on vagal afferents, sending signals to the vomiting center through the vagus nerve. Delayed CINV, which typically manifests 24-120 hours post-chemotherapy, is driven primarily by substance P and its interaction with NK1 receptors, differentiating it from the serotonin-dominant mechanism of acute CINV.[4]

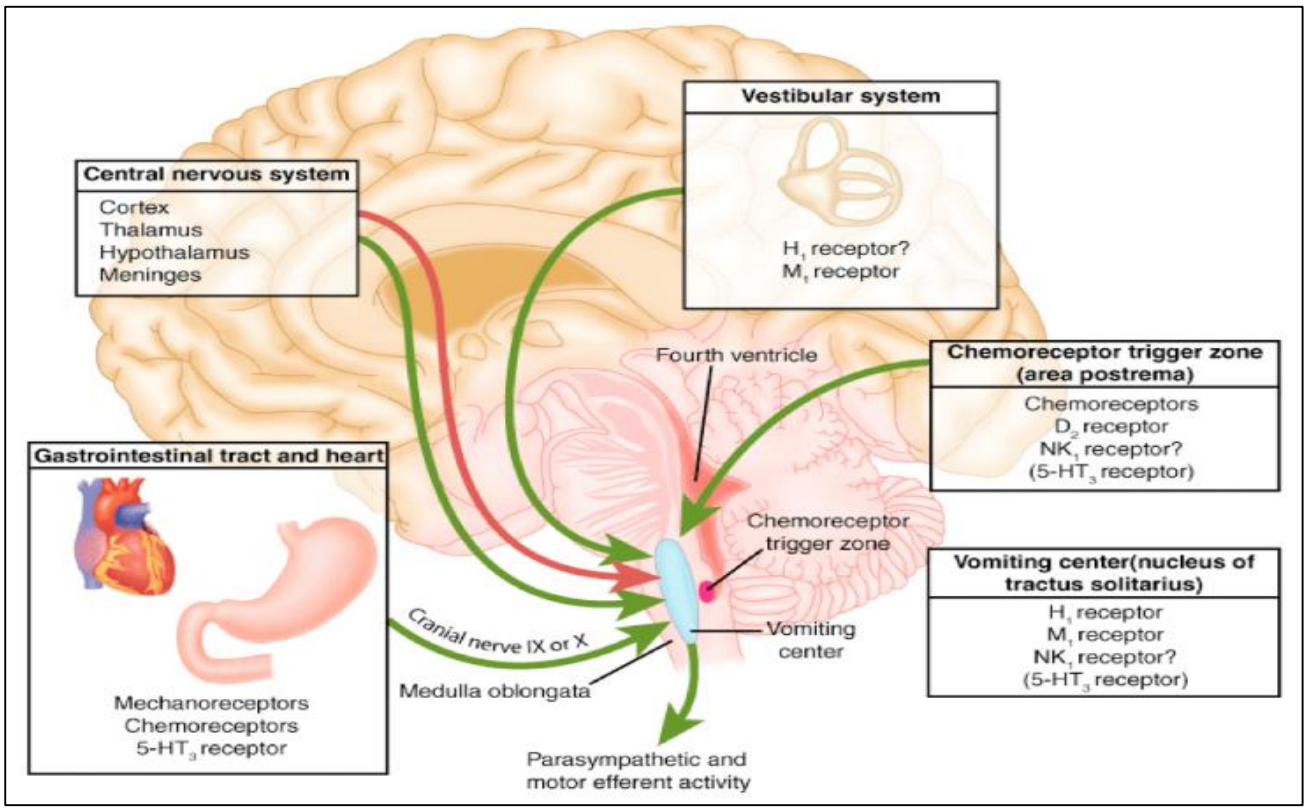

Figure 1: Pathways and receptors involved in nausea-vomiting.

The vomiting reflex is orchestrated by the vomiting center, which integrates peripheral signals from vagal and splanchnic nerves with central inputs from the CTZ and higher brain centers. This reflex involves relaxation of gastric muscles, contraction of abdominal muscles, and coordinated diaphragmatic movements. Anticipatory CINV, a learned response triggered before chemotherapy sessions, is mediated by the cerebral cortex and limbic system, with contributions from dopamine and endocannabinoid systems.[5]

Risk factors for CINV include the emetogenic potential of the chemotherapy regimen, with agents like cisplatin and cyclophosphamide being highly emetogenic. Patient-specific factors, such as younger age, female gender, a history of motion sickness, and low alcohol intake, also increase susceptibility. Therapeutic strategies for CINV target key neurotransmitter pathways. For instance, 5-HT3 receptor antagonists like ondansetron block serotonin-mediated signalling, NK1 receptor antagonists like aprepitant inhibit substance P activity, and dopamine receptor blockers like metoclopramide mitigate CTZ activation.[6]

Antiemetic protocol

In India, the management of CINV is guided by international guidelines like American society of clinical oncology (ASCO) and multinational association of supportive care in cancer (MASCC) but adapted to local needs. CINV is categorized into acute (within 24 hours of chemotherapy) and delayed (after 24 hours, lasting several days) phases. Emetogenicity levels follow the Hesketh model, ranging from very low to very high risk, with high-dose cisplatin (≥70 mg/m²) classified as very high risk.[7]

High-risk regimens, such as those involving cisplatin, often use aprepitant (days 1-3), granisetron (day 1), and dexamethasone (days 1-4). For moderate-risk regimens, combinations like granisetron, methylprednisolone, and dexamethasone are common, while low-risk regimens often include metoclopramide and dexamethasone.[4] Day 1 administration typically occurs in hospitals, while subsequent doses taken at home with follow-up support.

Variations exist due to resource constraints, with cost-effective alternatives like Granisetron replacing aprepitant

in public hospitals. Adherence to guidelines for certain regimens, such as anthracycline-cyclophosphamide, varies. Overall, tailored approaches balancing evidence-based practices and local realities are essential to improving CINV outcomes in India.

5-HT3 receptor antagonists are cornerstone agents in the prevention and management of CINV, particularly in the acute phase. These drugs target serotonin (5-hydroxytryptamine) released from enterochromaffin cells in the gastrointestinal tract following chemotherapy-induced damage. The serotonin binds to 5-HT3 receptors on vagal afferent nerves, transmitting signals to the vomiting center via the vagus nerve. By blocking this receptor, 5-HT3 antagonists like ondansetron, granisetron, and palonosetron effectively prevent the initiation of the emetic reflex.[8] Among these agents, palonosetron stands out for its longer half-life and enhanced efficacy in managing both acute and delayed CINV. Granisetron is widely used, where it is often preferred over costlier alternatives like aprepitant in public healthcare systems due to its affordability and efficacy.[9] These agents are frequently combined with corticosteroids such as dexamethasone and NK1 receptor antagonists like aprepitant for optimal control of high-risk regimens, such as those involving cisplatin or anthracycline-cyclophosphamide combinations.[10] The integration of 5-HT3 receptor antagonists into antiemetic protocols has significantly improved patient outcomes, reducing the burden of acute emesis and improving chemotherapy adherence. However, resource constraints in many regions necessitate the use of tailored approaches to maximize their benefits in diverse settings.

Corticosteroids, particularly dexamethasone, play a pivotal role in the prevention and treatment of CINV. Although their exact mechanism of action is not entirely understood, corticosteroids are believed to exert their antiemetic effects through multiple pathways. These include reducing inflammation in the GI tract, decreasing serotonin release by enterochromaffin cells, and modulating prostaglandin activity in the CNS.[11] Dexamethasone is commonly used in combination with other antiemetics, such as 5-HT3 receptor antagonists and NK1 receptor antagonists, to enhance their efficacy. In acute CINV, dexamethasone is administered at high doses on day 1, while lower doses are continued for delayed CINV in high-risk regimens. For instance, in cisplatin-based chemotherapy, dexamethasone is often given for four days in combination with aprepitant and granisetron.[12] The benefits of corticosteroids in CINV management are well documented, including their ability to reduce both the severity and duration of nausea and vomiting. Additionally, corticosteroids are cost-effective, making them particularly valuable in resource-limited settings like India, where access to expensive antiemetics can be challenging. However, the use of corticosteroids is not without risks, as long-term or repeated use may lead to side effects such as hyperglycaemia, immunosuppression, and insomnia.[13] Despite these challenges, corticosteroids remain an integral part of evidence-based guidelines for CINV management, including recommendations by ASCO, MASCC, and ESMO.[14] Their inclusion in combination regimens has significantly improved patient outcomes, particularly in high- and moderate-risk chemotherapy protocols.

NK1 receptor antagonists play a critical role in managing CINV, particularly in preventing delayed-phase symptoms, which are often challenging to control. Agents such as aprepitant, fosaprepitant, netupitant, and rolapitant function by blocking the binding of substance P to NK1 receptors in the brainstem, thereby inhibiting the emetic pathway. Clinical trials have consistently shown that adding an NK1 receptor antagonist to a standard regimen of a 5-HT3 receptor antagonist and dexamethasone significantly enhances antiemetic efficacy. For instance, in patients undergoing highly emetogenic chemotherapy (HEC) such as cisplatin, triple therapy including an NK1 receptor antagonist improved the complete response rate (no emesis and no use of rescue therapy) by up to 20% compared to dual therapy.[1,18] Furthermore, NK1 receptor antagonists have demonstrated efficacy in moderately emetogenic chemotherapy (MEC) regimens, such as anthracycline-cyclophosphamide combinations, where they effectively prevent both acute and delayed CINV.[16] Long-acting formulations like rolapitant offer the convenience of extended protection without the need for multiple dosing. Overall, the inclusion of NK1 receptor antagonists in antiemetic regimens has become a cornerstone of evidence-based guidelines, significantly improving patient outcomes and quality of life.[17]

Emerging therapies in CINV are advancing management of this distressing side effect, aiming to improve patient outcomes and quality of life. One promising development is the use of NK1 receptor antagonists (NK1 RAs), such as fosaprepitant and rolapitant, which demonstrate enhanced efficacy in controlling delayed CINV when combined with serotonin receptor antagonists and corticosteroids.[18] Additionally, the advent of novel drug delivery systems, such as transdermal and subcutaneous formulations of antiemetics, offers improved convenience and adherence for patients undergoing chemotherapy.[19] A significant advancement includes the FDA-approved fixed-dose combination of netupitant and palonosetron, which simplifies regimens by targeting multiple CINV pathways in a single dose, showing superior efficacy in both acute and delayed phases of CINV.[20] Emerging research also highlights the potential of cannabinoid-based therapies, which show promise in refractory CINV cases, though further studies are needed to confirm their efficacy and safety profiles.[21] These advancements underscore the importance of personalized approaches in CINV management, focusing on tailoring therapies to individual patient needs and treatment regimens.

Drug utilization studies are essential tools in pharmacological research that assess prescribing patterns, rationality, and efficacy of medications in real-world

clinical practice. These studies are instrumental in identifying gaps in adherence to evidence-based guidelines, optimizing drug use, and improving overall patient outcomes. Retrospective analyses, in particular, provide a comprehensive understanding of past trends and pave way for evidence-based improvements in healthcare delivery.

Globally, the incidence of CINV varies based on the emetogenic potential of chemotherapy regimens, patient-specific factors, and the effectiveness of antiemetic protocols.[4,22] Guidelines from organizations such as the MASCC and the ASCO recommend a combination of serotonin (5-HT3) receptor antagonists, NK1 receptor antagonists, and corticosteroids as the cornerstone of CINV prevention.[7] However, studies indicate inconsistent adherence to these guidelines, with substantial variations in clinical practice.[23]

In addition, economic constraints, availability of medications, and patient-specific factors often influence prescribing patterns, particularly in resource-limited settings. For example, the use of low-cost alternatives or deviations from recommended regimens has been observed in many regions, raising concerns about suboptimal CINV management.[24]

This retrospective drug utilization study aims to analyse the prescribing patterns of antiemetic drugs for CINV in a real-world setting, focusing on adherence to guidelines, the choice of medications. By leveraging existing data, this study intends to contribute to the development of more effective, patient-centred strategies for managing CINV.

METHODS

This is a six-month retrospective observational study done between January 2024 to June 2024 at the government cancer hospital, Chhatrapati Sambhajinagar.

We included prescriptions for patients above 18 years of age with documented chemotherapy induced nausea and vomiting and received treatment for CINV with medical record available. Patient excluded age less than 18 years, Patients not experienced or been treated for CINV, Patients with incomplete medical records or missing information on antiemetic use, patients with co-existing conditions causing nausea/vomiting unrelated to chemotherapy

This study was approved by the institutional ethics committee, and necessary permission/informed consent was obtained from the head of the department for retrospective records of patients.

A data collection form was designed, and data was recorded. The data includes demographic details of patients and cancer therapy information. Another section was added to record the details of the medications for CINV given to the patient during the study duration.

We entered data in a Microsoft Excel spreadsheet and analysed it with descriptive statistics. Our data was calculated in frequency and percentage. The results were tabulated for ease of interpretation. Continuous data are expressed as mean±SD.

RESULTS

Table 1 presents age-wise distribution of patients, showing the frequency of participants across various age groups. The majority of the participants were found in 51-60 years age group, accounting for 31.82% of total population, followed by 41-50 years age group comprising 26.86%.

Table 1: Details of age distribution of patients.

Age (in years)	N	Percentage (%)
18-30	7	2.89
31-40	35	14.46
41-50	65	26.86
51-60	77	31.82
61-70	39	16.12
71-80	15	6.20
>80	4	1.65
Total	242	100

Table 2 represents the various combinations of drug used in treatment of CINV, which includes combination of dexamethasone and granisetron in majority prescription followed by dexamethasone and granisetron with aprepitant kit, granisetron alone.

In Figure 2, analysis of drug distribution revealed that the most commonly prescribed drug was granisetron, accounting for 50% of the total medications given. This was followed by dexamethasone and aprepitant kit comprising 49.79% and 0.21%, respectively.

In this study, various chemotherapeutic regimens associated with differing emetogenic potentials were administered to patients. Type and intensity of chemotherapeutic regimen significantly influenced incidence and severity of CINV; therefore, need for appropriate antiemetic prophylaxis required to emetogenic risk.

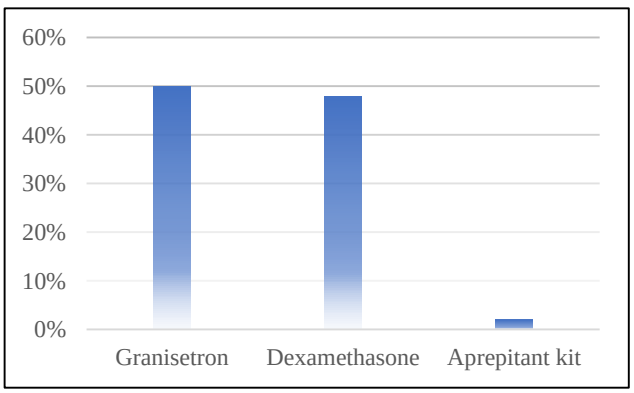

Figure 2: Drug distribution.

Table 2: Prescribes combinations in patients.

Antiemetic drugs	No. of prescriptions	Percentage (%)
Inj dexamethasone + inj. granisetron	240	99.17
Inj granisetron	1	0.41
Inj dexamethasone + inj. granisetron + aprepitant kit	1	0.41
Total	242	100

Table 3: Chemotherapy regimen used in patients.

Chemotherapy regimen	No. of prescriptions	Percentage (%)
Adriamycin + cyclophosphamide	53	21.90
Paclitaxel	44	18.18
Paclitaxel + carboplatin	41	16.94
Epirubicin + cyclophosphamide	37	15.29
Pemetrexed + carboplatin	10	4.13
Transtuzumab + paclitaxel	8	3.31
Transtuzumab	5	2.07
Transtuzumab + docetaxel + carboplatin	5	2.07
Epirubicin + cyclophosphamide + 5-FU	5	2.07
Transtuzumab + paclitaxel + carboplatin	4	1.65
Docetaxel	4	1.65
Doxorubicin + cyclophosphamide	3	1.24
Adriamycin + cyclophosphamide + 5-FU	3	1.24
Transtuzumab + docetaxel + cyclophosphamide	2	0.83
Docetaxel + carboplatin	2	0.83
Carboplatin	2	0.83
Cisplatin	2	0.83
Pemetrexed + gefitinib	2	0.83
Pemetrexed + cisplatin + gefitinib	2	0.83
Adriamycin + ifosfamide	1	0.41
Carboplatin + gemcitabine	1	0.41
Gemcitabine	1	0.41
Pemetrexed + gemcitabine	1	0.41
Gemcitabine + vinorelbine	1	0.41
Gemcitabine + cisplatin	1	0.41
Carboplatin + etoposide	1	0.41
Doxorubicin + 5-FU	1	0.41
Total	242	100

Table 4: Details of prescribed drugs for CINV.

Class of drug	Name of drug	Dose	Route	Frequency of prescribed drugs	Generic/ brand	Percentage (%)
Corticosteroid	Dexamethasone	16 mg	IV	241	Generic	49.79
5-HT3 receptor antagonists	Granisetron	3 mg	IV	242	Generic	50
NK1 receptor antagonists	Aprepitant kit	125/80 mg	Oral	1	Generic	0.21
Total				484	100	

Table 4 shows the notable drug classes included in a study like corticosteroid, 5 HT3 receptor antagonist, and neurokinin receptor 1 antagonist, which were used as part of a combination regimen.

DISCUSSION

The mean age was found to be 53±12.61 (range: 18-85) years (Table 1), as compared to the studies done in united states, where average age population was 63.3 years.[25]

Among 242 patients, nearly all the patients (100%) received 5HT3 receptor antagonists in combination with corticosteroid (99.99%) and NK1- receptor antagonists (0.41%). The frequency of antiemetics used is shown in Table 2. Table 3 shows that among the study population, the most commonly used chemotherapy regimens are adriamycin and cyclophosphamide 53 (21.90%), followed by paclitaxel 44 (18.18%) which are considered to be highly emetogenic agents.[26] Antiemetic therapy used was consistent with the standard NCCN guidelines for antiemesis.[27] Figure 1 shows the drug distribution in all CINV-treated patients. All the drugs were prescribed by generic name (100%), around 99.79% of the drug were prescribed by intravenous route followed by oral route (0.21%); among all the drugs, only dexamethasone is included in the national List of Essential Medicine, details shown in Table 4.

CINV remains one of the most debilitating side effects of cancer treatment; it significantly impacts patients undergoing cancer treatment, affecting their quality of life and adherence to therapy. A retrospective drug utilization study on CINV provides insights into prescribing patterns and guidelines followed.

The retrospective analysis underscores the prominence of key antiemetic classes, including serotonin (5-HT3) receptor antagonists (e.g., ondansetron, granisetron), NK1 receptor antagonists (e.g., aprepitant, fosaprepitant), and corticosteroids (e.g., dexamethasone). These drugs are often prescribed in combination to enhance efficacy, particularly in patients receiving HEC regimens. The widespread use of such combinations aligns with evidence suggesting superior control of both acute and delayed CINV compared to monotherapy.[28]

A key metric in assessing the quality of antiemetic therapy is adherence to established guidelines, such as those by the ASCO, the national comprehensive cancer network (NCCN), and the MASCC. Studies have reported that there are deviations from these guidelines in certain clinical settings, attributed to factors such as resource constraints, clinician preferences, or patient-specific considerations. Non-adherence to recommended prophylactic regimens for delayed CINV, particularly in MEC, was notable. Such deviations may compromise optimal symptom control and adversely affect patient outcomes.[1,19] It was noted, In the present study that CINV was treated as per current guidelines.

The analysis provides real-world evidence on the efficacy of various antiemetic regimens. While serotonin receptor antagonists effectively manage acute CINV, their role in delayed CINV is less robust, necessitating adjunctive therapy with NK1 receptor antagonists and corticosteroids. The combination of these agents has been shown to significantly reduce the incidence of both acute and delayed symptoms, contributing to improved patient outcomes.[29]

The study highlights the influence of demographic and clinical factors, such as age, gender, type and stage of cancer, and chemotherapy regimen, on drug utilization patterns. Additionally, patients undergoing HEC regimens, such as those containing cisplatin, require more aggressive prophylactic measures. The role of pharmacogenetics, particularly polymorphisms affecting drug metabolism (e.g., CYP2D6 or CYP3A4), also emerges as a critical factor in explaining inter-patient variability in cancer drug efficacy and their adverse effect profiles.[28,29]

Cost-effectiveness is a significant consideration in the choice of antiemetic therapy, particularly in low and middle-income countries. While newer agents such as rolapitant and netupitant have demonstrated superior efficacy, their higher costs may limit widespread adoption. The study underscores the preference for generics over branded drugs in resource-constrained settings, highlighting the need for balancing clinical efficacy with economic feasibility.[32]

The ultimate goal of antiemetic therapy is to preserve the quality of life (QoL) by minimizing the physical and emotional burden of CINV. The study emphasizes that effective symptom control translates to better patient-reported outcomes, including reduced distress, improved appetite, and greater ability to maintain daily activities. QoL assessments should be routinely integrated into CINV management to provide a more holistic view of therapeutic success.[33]

Like all retrospective studies, this analysis is subject to inherent limitations. The reliance on historical medical records introduces risks of incomplete or inconsistent data. Additionally, the lack of randomized allocation in drug regimens limits the ability to establish causality. Patient-reported outcomes, often absent from retrospective data, represent another critical gap. Future studies should consider incorporating prospective designs to address these limitations and enhance data reliability.[34]

This study has certain limitations that should be considered while interpreting the findings. The study was conducted at a single tertiary care hospital, which may not reflect prescribing trends and treatment patterns in other healthcare settings, including rural or private institutions. The limited sample size may restrict the generalizability of the findings to other settings with different prescribing patterns. Data on patient adherence to antiemetic therapy and over-the-counter medication use were not assessed. The assessment of the prescription of drug treatment based on the severity of CINV was not analysed, which could impact the result of this study.

This study provides valuable insights into the real-world management of CINV, revealing strengths in current practices. Adherence to evidence-based guidelines, the adoption of personalized approaches, and a focus on cost-effective strategies are essential to optimizing CINV management.

CONCLUSION

The study investigated the patterns of antiemetic utilization for CINV among cancer patients receiving chemotherapy and they are treated with HEC or MEC regimens, both of which are associated with a significant risk of CINV.

The commonly prescribed antiemetic regimen was therapy, consisting of a 5-HT 3 receptor antagonist and a corticosteroid (typically dexamethasone). This combination is recommended by international guidelines for managing CINV. Following this, monotherapy and triple regimens comprising 5HT3-receptor antagonists and a combination of 5HT3-receptor antagonists, a corticosteroid (dexamethasone), and a NK1 receptor antagonist, respectively, were used for CINV.

The findings underline the importance of increasing adherence to guideline-directed antiemetic prophylaxis, particularly in high-risk patients, and exploring new strategies to address delayed-phase CINV better. Moreover, the study also explores the need for routine assessment of patient-specific factors by clinicians, such as age, gender, and chemotherapy regimen, which can influence the risk of CINV and the efficacy of antiemetic treatment.

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