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Chemotherapy-induced nausea and vomiting prophylaxis in pediatric patients at a teaching hospital: assessment of adherence to guidelines

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Abstract

Aims: Describing the adherence rate of antiemetic prophylaxis in pediatric patients using antineoplastic agents and possible associated factors. **Methods:** It is a retrospective cross-sectional study, which took place in a teaching hospital at Belo Horizonte. There were included pediatric patients that received chemotherapy at the hospital from January to June, 2022. The demographic, clinical and pharmacotherapeutic data were collected from physicians' prescriptions and patients' charts. Descriptive analysis was performed and the results were expressed by absolute and relative frequency for categorical variables and by measures of central tendency and dispersion for numeral variables. Univariate analysis was done in order to assess the association between chemotherapy induced nausea and vomiting and exposure variables. It was calculated through Pearson's chi-square test. It was considered statistically significant a p-value less than 0,05. **Results:** It was observed that the prescription practice was closer to recommendations made by guidelines of American Society of Clinical Oncology and Multinational Association of Supportive Care in Cancer | European Society of Medical Oncology with 62% of adherence, meanwhile Pediatric Oncology Group of Ontario had 4,6% of concordance. Underuse of antiemetics was the principal reason for discordance. In particular the lack of dexamethasone prescription. It was identified statistically significance association between nausea and vomiting registers and vincristine and cyclophosphamide use. **Conclusions**: This study detected high adherence to the American Society of Clinical Oncology and Multinational Association of Supportive Care in Cancer | European Society of Medical Oncology guidelines, even though, the number of observed nausea and vomiting events flag up a potential failure in the antiemetic prophylaxis. The associative analyses between nausea and vomiting registers and vincristine and cyclophosphamide use were statistically significant.

Keywords: antineoplastic guidelines; antiemetics; chemotherapy; nausea; vomiting; pediatrics.

Profilaxia para náuseas e vômitos induzidos por quimioterapia antineoplásica em pacientes pediátricos em hospital de ensino: avaliação da adesão a protocolos

Resumo

Objetivos: Descrever as taxas de adesão a protocolos institucionais quanto a profilaxia antiemética em pacientes pediátricos em uso de antineoplásicos e possíveis fatores associados. **Métodos:** Trata-se de um estudo transversal retrospectivo, realizado num hospital de ensino de Belo Horizonte. Foram incluídos pacientes pediátricos, admitidos de janeiro a junho de 2022, para realização de quimioterapia. Os dados demográficos, clínicos e farmacoterapêuticos foram coletados de prescrições médicas e prontuários clínicos. A análise descritiva dos dados foi realizada determinando frequências absolutas e relativas para as variáveis categóricas e medidas de tendência central e de dispersão para as numéricas. As associações entre náuseas e vômitos induzidos por quimioterapia e as variáveis de exposição foram verificadas por meio da análise univariada utilizando-se o teste de qui-quadrado de Pearson, sendo considerada de significância estatística um valor de p<0,05. **Resultados:** Foi identificado que a prática de prescrições na instituição se aproxima mais das recomendações disponibilizadas pelos *guidelines* da *American Society of Clinical Oncology* e da *Multinational Association of Supportive Care in Cancer | European Society of Medical Oncology* em que foi verificado 62% de conformidades, enquanto o *guideline da Pediatric Oncology Group of Ontario* apresentou 4,6% de conformidade. A subutilização de medicamentos foi a principal causa de discordância às recomendações, sendo a omissão da prescrição de dexametasona o motivo mais frequente de desacordo. Identificou-se associação estatisticamente significativa entre registro de náuseas ou vômitos e uso de vincristina e ciclofosfamida. **Conclusão:** O estudo detectou alta adesão as recomendações dos protocolos *American Society of Clinical Oncology* e da *Multinational Association of Supportive Care in Cancer | European Society of Medical Oncology*, ainda que o número de náuseas e vômitos relatados aponte para uma falha na profilaxia antiemética. A associação entre registro de náuseas e vômitos e o uso de vincristina e ciclofosfamida foi estatisticamente significativa.

Palavras-chave: protocolos antineoplásicos; antieméticos; quimioterapia; náusea; vômitos; pediatria.

Introduction

The incidence and mortality of malignant neoplasms have grown rapidly at the global level, surpassing coronary heart disease and stroke as the leading cause of death in many countries. Above all, this fact reflects the countries' socioeconomic development in the last century, which guaranteed the necessary conditions for population growth and aging, as well as changes in the distribution of risk factors associated with cancer[1].

Given this scenario, a significant increase is noticed in chemotherapy use for the treatment of neoplasms whose adverse effects are many and common. Among them, antineoplastic-chemotherapy nausea and vomiting (CINV) stand out, which strongly affect the patients' quality of life and may result in treatment impairment due to dose reductions and therapy discontinuation[2].

According to patients, nausea and vomiting are among the most uncomfortable adverse effects associated with chemotherapy, leading to important physical consequences such as dehydration, anorexia and weight loss, as well as psychological harms, as they preclude performing common activities of daily living[3].

Bearing in mind the specificities of the pediatric population, which require oncological therapeutic schemes with higher doses sometimes administered for long periods of time and greater propensity to adverse reactions, when compared to the adult population, CINV becomes even more worrying for children, adolescents and their caregivers, being commonly reported as the main discomfort related to antineoplastic treatments, with a profound impact on their everyday lives[4–6]. It is estimated that, when adequate prophylaxis is not performed, 70% of the pediatric population undergoing antineoplastic treatments will experience CINV with 30% to 90% incidence in the first 24 hours[4,7].

Emesis can be classified as acute, delayed, anticipatory, refractory and escape. Acute emesis occurs within the first 24 hours after the stimulus, whereas late emesis begins 24 hours after the stimulus. On the other hand, anticipatory, refractory and escape emesis are not temporally related to the stimulus; the first is triggered by memory of previous events in similar situations, the second occurs recurrently whenever in the presence of a stimulus and the last manifests itself even in the face of adequate prophylactic measures[8].

The contemporary classification, defined at the Perugia Antiemetic Consensus Conference in 2004, is divided into four risk categories with categorization of the antineoplastic agents according to their emetogenic potential into high, moderate, low and minimum. Previously, the risk classification categories differed considerably across the organizations, which made it difficult to implement guidelines. Despite small differences, the various current protocols are convergent, both in relation to the categorization of antineoplastic agents and in prophylaxis recommendations[9].

The emetogenic potential of the antineoplastic regime used is notoriously the dominant factor for the occurrence of CINV; however, it is understandable that other factors, mainly associated with each patient, contribute to the occurrence of these reactions. A number of research studies have been conducted to assess possible risk factors, especially for the adult population. Publications including pediatric and adolescent patients on the topic are scarce and their results are not quite elucidating. The studies found showed that the occurrence of nausea was higher among female adolescents and children[6,10–12].

Although there are protocols in the scientific literature in the area that present robust recommendations for ensuring effectiveness and safety of CINV prophylaxis for the adult population, protocols specifically studied for the pediatric population are still scarce and limited. The objective of this study was to describe the adherence rates to institutional protocols for antiemetic prophylaxis in pediatric patients using antineoplastic drugs and the risk factors associated with reports of acute nausea and vomiting.

Methods

Study design and locus

A retrospective and cross-sectional study was carried out in a large-size public general university hospital, which serves adult and pediatric patients with medium- and high-complexity diseases through the Unified Health System, with a total installed capacity of 507 beds and located in Belo Horizonte, Minas Gerais.

Sample and selection criteria

The study included children and adolescents aged from 0 to 17 years old, admitted to the institution's pediatric inpatient unit to undergo antineoplastic chemotherapy cycles from January to June 2022. Outpatients were not included in the study, only those admitted to the institution where the study was carried out, who are high-complexity patients justifying the need for hospitalization for chemotherapy.

Inclusion was through an active search for antineoplastic prescriptions in the hospital's electronic prescription system. The exclusion criteria defined for this study corresponded to medical records with incomplete information and hospitalized patients using antineoplastic drugs administered by routes other than intravenous.

Data collection

Collection of the demographic, clinical and pharmacotherapeutic data was carried out from February to August 2022 by a single researcher, using medical prescriptions and multiprofessional evolutions recorded in institutional electronic medical charts as research source.

Study variables

The demographic data collected were age, gender and self-declared skin color. The diverse clinical information collected corresponded to the onco-hematological diagnosis, as well as to the emetogenic outcome of the first 24 hours after antineoplastic chemotherapy use; in other words, records of nausea, vomiting or reduced appetite, the latter only being considered when excluding any other possible cause for inappetence, such as mucositis.

The pharmacotherapeutic variables analyzed were the antineoplastics and antiemetics used in their proper doses and prescribed dosages with confirmation of administration by the Nursing team. These data were obtained through medical prescriptions and Nursing documents. The anthropometric data – weight, height and body surface area – were used to determine doses in mg/kg or mg/m².

The antineoplastic therapies were classified according to their emetogenicity degree as high, moderate, low and minimum; and the prophylactic antiemetic regimes were categorized as compliant, partially compliant and non-compliant, according to the protocols defined for this research, considering the drugs made available by the institution's standardization. The protocols used in this study were those from the *Pediatric Oncology Group of Ontario* (POGO)[13,14], the *American Society of Clinical Oncology* (ASCO)[15] and the *Multinational Association of Supportive Care in Cancer* (MASCC) | *European Society of Medical Oncology* (ESMO)[16,17].

The prophylactic schemes were considered compliant when they followed all recommendations, including medications and dosage; partially compliant, with prophylaxis performed with the drugs indicated by the references, disregarding the dosage; and non-compliant, when the recommended drugs were not used, except for cases when the medications were not available in the institution.

Data analysis

The descriptive data analysis was performed by determining absolute and relative frequencies for the categorical variables. The associations between CINV and the exposure variables were verified through univariate analysis using Pearson's chi-square test. The association between the variables was considered statistically significant when p-value<0.05. For the univariate analysis, the independent variables selected were the following: gender, age ≥ 12 years old and < 12 years old, diagnosis, antineoplastic agent used (cyclophosphamide, cytarabine, methotrexate and vincristine) and prophylaxis compliance with the recommendations according to each protocol used.

The statistical tests were performed using the *Statistical Package for Social Sciences*® (SPSS®) statistical program, version 25.0.

Ethical considerations

This study is part of the research project entitled "Safety in the medication use process with a focus on Clinical Pharmacy in the hospital context", approved by the Research Ethics Committee of the Federal University of Minas Gerais (*Comitê de Ética em Pesquisa-Universidade Federal de Minas Gerais, COEP-MG) under number 80169717.4.0000.5149.*

Results

During the data collection period and according to the inclusion criteria, 39 patients were selected, totaling 416 chemotherapy regimens prescribed for each 24-hour period. Of these, one patient was excluded because he had an administration route other than intravenous, resulting in 415 chemotherapy regimens for analysis.

Most of the patients included in the study were male, younger than 12 years old, self-declared brown-skinned and diagnosed with hematological malignancies, as described in Table 1. According to the characteristics observed in the patients and the number of chemotherapy regimens, the following frequencies are verified: of the 415 chemotherapy regimens analyzed, 39.5% were female patients, 29.6% were aged over 12 years old and 16.9% were diagnosed with solid tumors.

Table 1. Sociodemographic and clinical characteristics of the pediatric patients (n = 38) using antineoplastics admitted to a teaching hospital in southeastern Brazil

Characteristics	n (%)
Gender	
Female	13 (34.2)
Male	25 (65.8)
Age	
< 12 years old	25 (65.8)
≥ 12 years old	13 (34.2)
Self-declared skin color	
Brown	29 (76.3)
White	5 (13.2)
Black	3 (7.9)
Not declared	1 (2.6)
Diagnosis	
Malignant hematological neoplasms	29 (76.3)
Malignant solid tumors	9 (23.7)

Source: Research data, 2022.

The most used antineoplastic agent was cytarabine, followed by vincristine, cyclophosphamide and etoposide. The least used ones were bleomycin, dacarbazine, vinblastine and cisplatin. In relation to the antiemetics, only ondansetron and dexamethasone were prescribed. The impossibility of using the aprepitant antiemetic was due to its non-standardization in the institution (Table 2).

Table 2. Antineoplastic and antiemetic drugs used by pediatric patients admitted to a teaching hospital in southeastern Brazil

Drugs	n (%)
Antineoplastics	
Asparaginase	7 (1.1)
Bleomicina	2 (0.3)
Carboplatina	15 (2.5)
Ciclofosfamida	75 (12.3)
Cisplatina	4 (0.7)
Citarabina	131 (21.4)
Dacarbazina	2 (0.3)
Daunorrubicina	38 (6.2)
Doxorrubicina	33 (5.4)
Etoposídeo	73 (11.9)
Ifosfamida	43 (7.0)
Metotrexato	43 (7.0)
Mitoxantrona	18 (2.9)
Peg-asparaginase	28 (4.6)
Topotecana	5 (0.8)
Vimblastina	2 (0.3)
Vincristina	93 (15.2)
Antiemetic prophylaxis	
Ondansetrona	380 (66.5)
Dexametasona	191 (33.5)

Source: Research data, 2022.

The distributions found in the emetogenic classification of antineoplastic agents, according to each reference, as well as compliance with their recommendations, are shown in Table 3. It was observed that, for all references, most of the antineoplastic regimes were of moderate risk, whereas those classified as high-risk were the minority, with the exception of POGO, where this classification was the second most recurrent.

Table 3. Descriptive analysis of the emetogenic risk classification, compliance of the prophylaxis schemes with the recommendations and causes of disagreements observed, by selected protocol, of the pharmacotherapy of pediatric patients using antineoplastics hospitalized in a teaching hospital from southeastern Brazil.

Variable	Institutional protocols selected n (%)		
	POGO	ASCO	MASCC/ESMO
Emetogenic potential			
High	112 (28.4)	21 (5.4)	21 (5.4)
Moderate	162 (41.0)	204 (52.4)	204 (52.4)
Low	95 (24.1)	144 (37.0)	144 (37.0)
Minimum	26 (6.6)	20 (5.1)	20 (5.1)
Compliance of the prophylaxis			
Compliant	18 (4.6)	241 (62.0)	241 (62.0)
Partially compliant	209 (52.9)	42 (10.8)	42 (10.8)
Non-compliant	168 (42.5)	106 (27.2)	106 (27.2)
Cause of disagreement			
Underuse	225 (60.2)	100 (67.6)	100 (67.6)
Excessive use	132 (35.3)	37 (25.0)	37 (25.0)
Use not recommended	17 (4.5)	11 (7.4)	11 (7.4)

Source: Research data, 2022.

In relation to compliance of the antiemetic prophylaxis regimes with the recommendations provided by the selected guidelines, an identical profile was observed for the ASCO and MASCC/ESMO protocols, with predominance of prophylaxis in compliance with the recommendations (62.0%). With regard to POGO, predominance corresponded to partial compliance (52.9%) and a reduced profile of compliance (4.6%).

The causes of disagreements with the recommendations are presented in Table 3. Antiemetics underuse – cases of underdoses, delays shorter than recommended and non-prescription of drugs recommended for prophylaxis – proved to be the main cause of disagreements for all references. The POGO protocol showed 65.2% underuse of recommended antiemetics, whereas the percentage was 67.6% for ASCO and MASCC/ESMO. Prophylaxis schemes performed with more drugs than recommended or in doses and schedules higher than those recommended were classified as excessive use. Dexamethasone was the main drug involved in underutilization of drugs in the prophylaxis schemes evaluated. Ondansetron was the agent most often involved in overuse or non-recommendation cases, for all references.

It was observed that 35% of the patients evaluated reported some CINV-related event. It was verified that there was no significance in the associations between CINV and the gender, age and diagnosis variables; however, it was found that, there were proportionally more events (37.5%) in the male population than among females (30.5%). In relation to age, it was noticed that, among the population aged at least 12 years old, the occurrence of events was also proportionally higher (37.4%), whereas 33.6% of the population aged under the age of 12 reported some event. With regard to the diagnosis variable, there was greater proportionate reporting of events in the group diagnosed with solid tumors (41.4%), whereas only 33.3% had an event in the group with hematologic malignancies. When associating the antineoplastic drugs and the occurrence of events, significance was observed for cyclophosphamide and vincristine, with the Odds Ratio (OR) found for the first one evidencing more chances of events with its use, whereas the chance of occurrence of events was lower with its use for the second. Considering the association of compliance of the prophylaxis schemes proposed with the selected recommendations, no significant value was verified, as presented in Table 4.

Table 4. : Univariate analysis of the factors associated with the recording of events in pediatric patients using antineoplastics admitted to a teaching hospital in southeastern Brazil.

Variables	Event recording* N (%)		Total	OR (95% CI)	p-value
	Yes	No			
Gender					
Male	94 (37.5)	157 (62.5)	251	1.37 (0.90 - 2.08)	0.145
Female	50 (30.5)	114 (69.5)	164		
Age					
≥ 12 years old	46 (37.4)	77 (62.6)	123	1.18 (0.76 - 1.83)	0.453
< 12 years old	98 (33.6)	194 (66.4)	292		
Diagnosis					
Solid tumors	29 (41.4)	41 (58.6)	70	1.41 (0.84 - 2.39)	0.195
Hematologic neoplasms	115(33.3)	230 (66.7)	345		
Antineoplastics					
Cyclophosphamide	34 (45.3)	41 (54.7)	75	1.73 (1.04 - 2.88)	0.033
Cytarabine	49 (37.4)	82 (62.6)	131	1.19 (0.77 - 1.83)	0.432
Methotrexate	33 (76.7)	10 (23.3)	43	0.54 (0.26 - 1.13)	0.011
Vincristine	22 (23.7)	71 (76.3)	93	0.51 (0.30 - 0.86)	0.096
Compliance of the prophylaxis					
POGO					
Compliant	4 (22.2)	14 (77.8)	18	1.98 (0.64 - 6.12)	0.230
Partially compliant + Non-compliant	136 (36.1)	241 (63.9)	377		
ASCO					
Compliant	86 (35.7)	155 (64.3)	241	0.98 (0.64 - 1.50)	0.912
Partially compliant + Non-compliant	52 (35.1)	96 (64.9)	148		
MASCC/ESMO					
Compliant	86 (35.7)	155 (64.3)	241	0.98 (0.64 - 1.50)	0.912
Partially compliant + Non-compliant	52 (35.1)	96 (64.9)	148		

Source: Research data, 2022. *Records of nausea, vomiting or reduced appetite were considered as events. OR: Odds Ratio; CI: Confidence Interval; POGO: Pediatric Oncology Group of Ontario; ASCO: American Society of Clinical Oncology; MASCC/ESMO: Multinational Association of Supportive Care in Cancer/European Society of Medical Oncology.

Discussion

This study obtained two important findings referring to agreement of the antiemetic prophylaxis schemes with the recommendations, in which quite varied results were found between the selected references and in relation to the cause of the disagreements observed. It was also possible to verify trends related to risk factors, although the association analyses did not present significant results.

For the ASCO and MASCC/ESMO references, prophylaxis compliance with the recommendations was over 60%. This finding presents more expressive results than those obtained by Bun et al. in a study carried out at a Japanese teaching hospital in 2019, whose classification was performed based on the ASCO protocol, showing that only 21.5% of the patients under the age of 18 received appropriate antiemetic prophylaxis[18].

Evaluating the prophylaxis schemes used through the POGO protocol, there was total compliance with the recommendations in almost 5% and, partial compliance in almost 53%. These results are compared to the findings by McKinnon et al. in a study conducted at four Canadian institutions in 2018, where the results showed that only 2% of the patients received prophylaxis according to the POGO protocol and 29% received prophylaxis partially according to the POGO protocol[4]. Given this scenario, the conformities found in this study were higher, although still quite low when compared to the expected total compliance.

The differences observed across the selected references, both in the emetogenic classification of drugs and in compliance of the prophylaxis schemes with their recommendations, can be explained by the specificity of POGO in relation to the pediatric population, as its classification of emetogenicity of the antineoplastics and prophylaxis recommendations were elaborated considering the particularities of the population[14]

From the analysis performed, it was verified that the main cause for disagreements for the POGO, ASCO and MASCC/ESMO references was medication underuse, with the absence of dexamethasone prescriptions as the main item observed. Other studies reached the same result, which evidences the controversy in the use of corticosteroids as antiemetics in Pediatrics. Despite having proven efficacy, this class of medications is still underutilized due to its safety profile, which is highly associated with the development of adverse reactions[19,20]. Other factors that may lead pediatric oncologists to avoid using dexamethasone are the possibility of interference with antitumor immunity, the risk of infections) especially fungal ones) and modification of the blood-brain barrier, which can cause alterations in the distribution of antineoplastic drugs in central nervous tissues[18].

In a study carried out by McKinnon et al. it was observed that, after implementing the POGO guideline, which recommends high dexamethasone doses associated with other classes of antiemetics for the prophylaxis of drugs with high and moderate emetogenicity, there was an increase in adverse reactions associated with corticosteroids, such as hyperglycemia, insomnia and dyspepsia. These findings resulted in the elaboration of an institutional protocol with a reduction of doses and frequencies of dexamethasone administration[4].

From the relationship between CINV and the various exposure variables, no significant results were mostly observed, which precludes inferring possible risk factors associated with CINV. The only significant results observed were for the use of cyclophosphamide and vincristine. These results corroborate the emetogenic classifications of these drugs, as high-dose cyclophosphamide is classified as of moderate to high emetogenic risk and vincristine is an antineoplastic with minimum emetogenicity risk, which presented an inexpressive rate of adverse events[9,14,15,17].

There were no significant results for the other drugs analyzed, which can be explained by the wide variation in doses of medications such as cytarabine and methotrexate and by the various associations of drugs with different emetogenic potentials, as in the case of etoposide when associated with antineoplastic agents of greater emetogenic potential. In these cases, it would be necessary to evaluate the therapeutic regimes in order to obtain statistically significant results that are clinically relevant.

The few studies carried out to identify patient-associated risk factors for CINV found that adolescents, female children, diagnoses of solid tumors, and non-white ethnicity can be associated with an increased risk for CINV[11,12]. Although the association results obtained in this study were not significant, they were able to show that there were more reports of events in the male gender, in patients aged at least 12 years old and in those diagnosed with solid tumors. It is to be noted that various factors can be associated with reports of nausea and vomiting events, such as prognosis, neoplasm staging and disease severity, factors that were not considered in this analysis.

In relation to prophylaxis compliance with the references, in addition to not having observed significant results, quite inconsistent results were verified. The occurrence of events was relatively lower among patients who used prophylaxis as recommended only for POGO. The other references showed results with no difference between events reported in compliant and non-compliant prophylaxis schemes. This fact can be explained by the reduced number and heterogeneity of the sample and by limitations of the retrospective research model, which precludes acquiring information about the occurrence of events more effectively, such as direct contact with the patients to prove such occurrence.

This study presents some limitations, such as the fact that the institution's standardization of drugs precludes complying with all the referenced recommendations, as neurokinin-1 antagonist drugs, recommended by all protocols for prophylaxis of antineoplastic chemotherapy with high emetogenic potential and by some protocols for moderate emetogenicity, are not available for use in the hospital under study.

The size of the sample population was not calculated and was quite limited in number of patients (38), as well as quite heterogeneous, precluding data generalization. In addition to that, other limiting factors for the study were identified, such as underreporting of emesis in medical records by health professionals. Other study limitations were not excluding patients undergoing some non-pharmacological treatment to control emesis and not having differentiated patients in initial treatment from those in treatment continuation or relapse. However, this study is innovative because it identifies the adherence rates to protocol recommendations regarding use of antiemetics in pediatric patients on antineoplastics. It is worth noting the importance of identifying the need for updated national references that consider the characteristics and reality of the Brazilian pediatric population. The national literature found corresponded to a 2004 article by the Brazilian Society of Clinical Oncology[21] and the 2011 Brazilian Association of Palliative

Care Nausea and Vomiting Consensus[22], both without specific recommendations for the pediatric population. In addition to that, the study results can stimulate institutional actions that lead to elaboration of a protocol and standardization of the medical courses of action for better quality and safety in the treatment of pediatric patients affected with onco-hematological diseases.

Conclusion

Through this study, we were able to show that the prescriptions of antiemetics for prophylaxis in the chemotherapy protocols for pediatric patients at the institution are close to the recommendations proposed by the ASCO and MASCC/ESMO protocols. We also concluded that the development of an institutional protocol, with standardization of prescriptions, would result in improved care, with a reduction in excessive and unnecessary medication use. Finally, the need for further studies to assess the risk factors for CINV in the pediatric population becomes clear, as well as for greater detail and assessment of the antiemetic prophylactic needs of this population segment, in order to define the best prophylactic regime with adequate antiemetic drug recommendations in their doses and frequencies and for each category of emetogenic classification.

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Collaborators

SRA, IHC and CSL participated in conception and design; SRA, IHC, CSL, RCGV and GCO took part in data analysis and interpretation; and SRA, IHC, CSL, RCGV, GCO and CC participated in writing and critical review of the intellectual content. All authors approved the final version of the article.

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Declaration of conflict of interests

The authors declare that there are no conflicts of interest regarding this article.

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