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Original Article

Assessment of Gastrointestinal Toxicity in Head and Neck Cancer (HNCS) Patients Receiving Platinum Compounds Chemotherapy at a Tertiary Care Hospital

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ABSTRACT

Background: Platinum-based chemotherapy, including cisplatin and carboplatin, is a standard treatment for head and neck cancers. However, Gastrointestinal (GI) toxicity remains a common adverse effect that may affect treatment tolerability. Comparative real-world data on GI toxicity patterns between cisplatin and carboplatin are limited. **Materials and Methods:** A prospective observational study was conducted over six months at a tertiary care hospital, enrolling 140 patients with head and neck cancer receiving platinum-based chemotherapy. Gastrointestinal adverse events were monitored during each chemotherapy cycle and graded using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Toxicity patterns were analyzed according to demographic characteristics, residential status, treatment cycles, chemotherapy regimens, and type of platinum compound. **Results:** Out of 140 patients, 123 experienced gastrointestinal toxicity, with a total of 133 toxicity events recorded. Grade 1 toxicity was most common, followed by Grade 2, while Grade 3 events were infrequent. Higher GI toxicity rates were observed among male patients, those aged 41-50 years, and rural residents. Toxicity incidence was greatest during early chemotherapy cycles (cycles 1-3). Cisplatin was predominantly associated with low-grade (Grade 1-2) GI toxicity, whereas carboplatin showed a relatively higher proportion of Grade 3 toxicity. **Conclusion:** Gastrointestinal toxicity was frequent in head and neck cancer patients receiving platinum-based chemotherapy and was influenced by both patient-related and treatment-related factors. Early identification of high-risk groups may facilitate timely supportive care and improve treatment tolerability.

Keywords: Gastrointestinal toxicity, Head and neck cancer, Platinum-based chemotherapy, Cisplatin, Carboplatin, CTCAE Scale.

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INTRODUCTION

Platinum-based chemotherapy-induced intestinal abnormalities is a usual side effect associated with a wide range of chemotherapy drugs. Actively replicating cells located in the gastrointestinal epithelium make it particularly vulnerable to the effects of these drugs. Gastrointestinal toxicity commonly presents in the form of mucositis, diarrhea, or constipation, and in many cases, it acts as a dose-limiting factor, potentially requiring interruption or discontinuation of therapy. In severe instances, it can pose a life-threatening risk (Akbarali *et al*., 2022).

Both carboplatin and oxaliplatin frequently cause mild-to-moderate nausea, vomiting, and diarrhea, and they are less emetogenic than cisplatin. However, patients who have already received cisplatin can be more likely to develop vomiting while taking carboplatin or oxaliplatin (Hartmann and Lipp, 2003). Some patients undergoing platinum-based chemotherapy may experience anorexia, characterized by a loss of appetite, which can contribute to malnutrition and weight loss during treatment, while others may experience cachexia or weight loss because of poor food consumption (Oun *et al*., 2018).

Head and Neck Cancer (HNCs), known as Head and Neck Squamous Cell Carcinoma (HNSCCs), is principally originated through squamous cells in the mouth, pharynx, and larynx (Head and Neck Cancers, 2024). HNCs are more predominant in males, with a 2:1 ratio compared to females, and are commonly analyzed in individuals over 50 years of age (www.cdc.gov.). Patients with head and neck cancer are principally treated with surgery, radiation therapy, and systemic therapies like immunotherapy, chemotherapy, and targeted therapy (Lee, 2023).

In comparison to the CBDCA arm, the CDDP-based chemotherapy is linked to higher gastrointestinal and nephrotoxicity but lower

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hematological toxicities, and gastrointestinal toxicity, mainly in the form of nausea, vomiting, and mucositis, is more prevalent in the cisplatin group (Guan *et al*., 2016; Roila *et al*., 2011). Carboplatin, a second-generation platinum derivative, is less reactive, better tolerated, and has similar therapeutic effectiveness to cisplatin. It causes milder emetic symptoms, although slight to modest hepatic damage may develop throughout treatment (Tripathi, 2018).

Adverse Drug Reactions (ADRs) can occur within the terms of approved use or from off-label use, high dose, wrong use, and drug misunderstanding. Predisposing factors include polypharmacy, multiple and intercurrent diseases, age, drug characteristics, gender, race, and genetic factors (Gov.uk.). The CTCAE v5.0 (SCLAE) system is designed to be flexible and adaptable and can be used in various clinical trial settings, including phase I, II, III, and IV studies. It includes a hierarchical classification system, a list of preferred terms for each category, and guidelines for reporting harmful incidents. Through using CTCAE v5.0, researchers and clinicians can ensure consistent and accurate reporting of adverse events across different studies, facilitating effective comparison and integration of results (Uptodate.com.).

MATERIALS AND METHODS

Study Design and Setting

This study was conducted as a prospective observational study in the Department of Medical Oncology at Geetanjali Medical College and Hospital, Udaipur, Rajasthan, over a period of six months. A prospective design was adopted to enable systematic identification, documentation, and grading of Gastrointestinal (GI) toxicities associated with platinum-based chemotherapy in patients with head and neck cancers.

Ethical Approval and Consent

The study protocol was reviewed and approved by the Institutional Human Ethics Committee (Approval No: GU/HREC/EC/2024/2617). Written informed consent was obtained from all participants prior to enrollment, and the study was conducted in accordance with the principles of the Declaration of Helsinki.

Study Population

Patients diagnosed with head and neck cancer and receiving platinum-based chemotherapy (cisplatin or carboplatin) were included in the study. Both male and female patients of all age groups were eligible for inclusion. Patients with malignancies other than head and neck cancer, those receiving non-platinum chemotherapy regimens, pregnant or lactating women, and patients unwilling to provide informed consent were excluded to minimize confounding factors.

Sample Size and Sampling

The sample size was calculated using Cochran's formula, and a total of 140 patients were enrolled using a convenience sampling method based on eligibility and consent during the study period.

Data Collection

Data were collected using a structured and pre-validated data collection form, which included demographic details (age, gender, residential status), clinical characteristics, chemotherapy regimen, and treatment cycle information. Patients were followed prospectively during chemotherapy cycles for the development of gastrointestinal adverse events.

Assessment of Gastrointestinal Toxicity

Gastrointestinal toxicities such as nausea, vomiting, diarrhea, constipation, and mucositis were monitored and graded using the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, a standardized and widely accepted toxicity grading system in oncology practice. Suspected adverse drug reactions were documented and reported using the Indian Pharmacopoeia Commission (IPC) adverse drug reaction reporting form.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) software. Descriptive statistics were used to summarize baseline characteristics and toxicity profiles, expressed as frequencies and percentages. Comparative analysis between cisplatin- and carboplatin-related gastrointestinal toxicity and other subgroup variables was performed using the Chi-square test and Wilcoxon rank-sum test, as appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline characteristics of study participants

In Table 1, total number of patients included in the study was 140, of whom 80 patients received cisplatin and 60 patients received carboplatin. Age-wise distribution showed that many patients belonged to the 31-50 years age group, with 40 patients in the 31-40 years group and 43 patients in the 41-50 years group, together accounting for more than half of the study population. This was followed by the 51-60 years age group (31 patients), while very few patients were observed in the younger (18-30 years) and older (≥71 years) age categories. The age-wise distribution between the cisplatin and carboplatin groups showed a statistically significant difference (p=0.0005).

Gender-wise analysis revealed that male patients constituted the majority (107 patients), followed by female patients (33 patients). A statistically significant difference in gender distribution was

observed between the cisplatin and carboplatin treatment groups (p=0.0015).

Based on residential status, the majority of patients were from rural areas (127 patients; 90.7%), whereas only 13 patients (9.3%) belonged to urban areas, and this difference was found to be statistically significant (p<0.001).

Regarding treatment cycles, the highest number of patients received chemotherapy during cycle 1 (55 patients), followed by cycle 2 (39 patients) and cycle 3 (30 patients), with a gradual decline in subsequent cycles. The distribution of patients across treatment cycles showed a statistically significant difference (p=0.004).

Grade wise GI toxicity according to platinum compound

Among the 140 enrolled patients, gastrointestinal toxicities were observed in 123 patients, accounting for a total of 133 toxicity events.

In Table 2, total of 133 gastrointestinal toxicity events were recorded during the study period. The majority of toxicities were Grade 1 (86 events), followed by Grade 2 toxicity (44 events), while Grade 3 toxicity was least observed (3 events).

Among patients receiving cisplatin, 89 gastrointestinal toxicity events were reported, of which Grade 1 toxicity accounted for 56 events, followed by Grade 2 toxicity in 32 events, and Grade 3 toxicity in 1 event. In contrast, patients treated with carboplatin experienced 44 gastrointestinal toxicity events, with Grade 1 toxicity observed in 30 events, followed by Grade 2 toxicity in 12 events, and Grade 3 toxicity in 2 events.

The comparison of gastrointestinal toxicity grades between cisplatin and carboplatin showed a statistically significant difference (p=0.0015).

Gender-Wise Distribution

In Table 3, gender-wise analysis of gastrointestinal toxicity showed that male patients experienced the maximum number of toxicity events. Among males, Grade 1 toxicity observed in 68 events, followed by Grade 2 toxicity in 32 events, whereas Grade 3 toxicity was observed in only 3 events. In female patients, Grade 1 toxicity observed in 18 events, followed by Grade 2 toxicity in 12 events, while no Grade 3 toxicity was reported. The association between gender and gastrointestinal toxicity grades showed a statistically significant difference (p<0.001).

Age-Wise Distribution of Gastrointestinal Toxicity

In Table 4, age-wise distribution of gastrointestinal toxicity demonstrated variation in both frequency and severity across different age groups. A total of 133 gastrointestinal toxicity events were recorded. Patients aged 31-40 years (45 events) and 41-50 years (44 events) accounted for the highest number of toxicity events. In the 21-30 years age group, toxicity was limited to Grade 1 (1 event) and Grade 2 (2 events), with no Grade 3 toxicity observed.

In patients aged 31-40 years, Grade 2 toxicity predominated (26 events), followed by Grade 1 toxicity (19 events), whereas no Grade 3 toxicity was reported. In contrast, the 41-50 years age group showed a predominance of Grade 1 toxicity (36 events), followed by Grade 2 toxicity (7 events), with Grade 3 toxicity observed in only 1 event. Among patients aged 51-60 years, Grade 1 toxicity (17 events) was most common, followed by Grade 2 (6 events) and Grade 3 toxicity (2 events).

Patients aged 61-70 years predominantly experienced Grade 1 toxicity (13 events), with only 1 Grade 2 event and no Grade 3 toxicity. In the 71-80 years age group, toxicity was limited to Grade 2 events (2 events) only. The association between age group and gastrointestinal toxicity grades was found to be statistically significant (p=0.019).

Table 1: Baseline characteristics of study participants.

Sl. No.	Study Parameter	Total No. of Patients (n=140)	Cisplatin (n=80)	Carboplatin (n=60)	p-value
1.	**Age (in years)**				0.0005*
	18-30	4	3	1	
	31-40	40	31	9	
	41-50	43	29	14	
	51-60	31	11	20	
	61-70	17	5	12	
	71-80	3	1	2	
	81-90	2	0	2	
2.	**Gender**				0.0015*
	Male	107	69	38	
	Female	33	11	22	
3.	**Residential status**				0*
	Rural	127	73	54	
	Urban	13	7	6	
4.	**Treatment Cycle**				0.004*
	Cycle 1	55	34	21	
	Cycle 2	39	21	18	
	Cycle 3	30	14	16	
	Cycle 4	10	7	3	
	Cycle 5	5	4	1	
	Cycle 6	1	0	1	

* Statistical analysis was performed using Chi-square.
* Statistical analysis was performed using Chi-square.
* Statistical analysis was performed using Levene's test.
*Statistical analysis was performed using Two-way ANOVA.

Table 2: Grade wise GI toxicity according to platinum compound.

Sl. No.	Toxicity Grades	No. of Toxicities (*n*=133)	Cisplatin (*n*=89)	Carboplatin (*n*=44)	*p*-value
1.	Grade 1	86	56	30	0.0015*
2.	Grade 2	44	32	12	
3.	Grade 3	3	1	2	

*Statistical analysis was performed using Fisher's exact test (Freeman-Halton extension).

Rural vs. Urban Distribution

In Table 5, residential status, a total of 133 gastrointestinal toxicity events were recorded, of which 118 events occurred among rural patients and 15 events among urban patients. Among rural patients, Grade 1 toxicity was most common in 74 events, followed by Grade 2 toxicity in 41 events, while Grade 3 toxicity was observed in 3 events. In contrast, urban patients experienced Grade 1 toxicity in 12 events, followed by Grade 2 toxicity in 3 events, with no Grade 3 toxicity reported. The comparison of gastrointestinal toxicity grades between rural and urban patients did not show a statistically significant difference (p=0.059).

Gastrointestinal Toxicity Across Treatment Cycles

In Table 6, The distribution of gastrointestinal toxicity across chemotherapy cycles showed variation in both frequency and severity. The highest number of toxicity events was observed during cycle 1 (48 events), followed by cycle 3 (47 events) and cycle 2 (29 events). During cycle 1, Grade 1 toxicity predominated (32 events), followed by Grade 2 toxicity (16 events), with no Grade 3 toxicity observed. In cycle 2, Grade 1 (13 events) and Grade 2 toxicity (14 events) were comparable, while Grade 3 toxicity was observed in 2 events. In cycle 3, Grade 1 toxicity remained most frequent (35 events), followed by Grade 2 (11 events) and Grade 3 toxicity (1 event). Toxicity events during later cycles were fewer and were limited to Grade 1 and Grade 2 toxicity. The distribution of gastrointestinal toxicity across treatment cycles showed a statistically significant difference (p=0.013).

Comparison Between Cisplatin and Carboplatin

In Table 7, comparison between platinum compounds, 89 gastrointestinal toxicity events were reported in patients receiving cisplatin, whereas 44 events were observed in those treated with carboplatin. Among cisplatin-related toxicities, Grade 1 toxicity was most common 56 events, followed by Grade 2 toxicity 32 events, with Grade 3 toxicity observed in 1 event. In contrast, carboplatin-related toxicities showed Grade 1 toxicity in 30 events, followed by Grade 2 toxicity in 12 events, and Grade 3 toxicity in 2 events. The comparison between cisplatin and carboplatin demonstrated a statistically significant difference in gastrointestinal toxicity grades (p=0.001).

Table 3: Gender-Wise Distribution.

Gender	No. of Toxicities (*n*=133)	Grade 1	Grade 2	Grade 3	*p*-value
Male	103	68	32	3	0.001*
Female	30	18	12	0	

*Statistical analysis was performed using Fisher's exact test (Freeman-Halton extension).

DISCUSSION

Platinum-based chemotherapy is a key component in the management of head and neck cancers; however, Gastrointestinal (GI) toxicity remains a major concern affecting treatment tolerability. In the present prospective observational study, GI toxicity was commonly observed, with Grade 1 toxicity predominating, followed by Grade 2 events, while Grade 3 toxicity was infrequent. This pattern is consistent with earlier reports indicating that platinum compounds predominantly cause mild to moderate GI adverse effects rather than severe toxicity in most patients (Akbarali *et al.*, 2022; Hartmann and Lipp, 2003).

A clinically relevant finding of this study was the difference in GI toxicity profiles between cisplatin and carboplatin. Cisplatin-treated patients experienced a higher proportion of Grade 1-2 GI toxicity, whereas carboplatin-treated patients showed a comparatively higher proportion of Grade 3 toxicity. Cisplatin is known for its high emetogenic potential due to enhanced serotonin release and stimulation of the chemoreceptor trigger zone, leading to frequent nausea and vomiting (Hartmann and Lipp, 2003; Roila *et al.*, 2011). Similar observations have been reported by Hartmann and Lipp, who described greater GI intolerance with cisplatin compared to other platinum agents (Hartmann and Lipp, 2003).

Comparative evidence from previous studies supports these findings. A meta-analysis by Guan *et al.* comparing cisplatin- and carboplatin-based chemotherapy in head and neck squamous cell carcinoma reported higher GI toxicity with cisplatin, while carboplatin demonstrated better overall tolerability but was still associated with occasional severe adverse events (Guan *et al.*, 2016). The findings of the present study are in agreement with this literature, highlighting distinct toxicity patterns between the two platinum compounds.

Gender-wise analysis showed a higher incidence of GI toxicity among male patients, which may reflect the higher prevalence of head and neck cancers and greater treatment intensity in males (Head and Neck Cancers, 2024; www.cdc.gov.). Age-wise analysis indicated increased toxicity among patients aged 41-50 years, possibly due to aggressive treatment regimens and cumulative drug exposure. Additionally, GI toxicity was more frequently observed during early chemotherapy cycles, particularly cycle 2, emphasizing the importance of early monitoring and appropriate

Table 4: Age-Wise Distribution of Gastrointestinal Toxicity.

Age group	No. of Toxicities (*n*=133)	Grade 1	Grade 2	Grade 3	*p*-value
21-30	3	1	2	0	0.019*
31-40	45	19	26	0	
41-50	44	36	7	1	
51-60	25	17	6	2	
61-70	14	13	1	0	
71-80	2	0	2	0	

*Statistical analysis was performed using Chi-square.

Table 5: Rural vs. Urban Distribution.

Residential	No. of Toxicities (*n*=133)	Grade 1	Grade 2	Grade 3	*p*-value
Rural	118	74	41	3	0.059*
Urban	15	12	3	0	

*Statistical analysis was performed using F Test.

Table 6: Gastrointestinal Toxicity Across Treatment Cycles.

Treatment cycle	No. of Toxicities (*n*=133)	Grade 1	Grade 2	Grade 3	*p*-value
Cycle 1	48	32	16	0	0.013*
Cycle 2	29	13	14	2	
Cycle 3	47	35	11	1	
Cycle 4	6	3	3	0	
Cycle 5	2	2	0	0	
Cycle 6	1	1	0	0	

*Statistical analysis was performed using Friedman Test.

Table 7: Comparison Between Cisplatin and Carboplatin.

Drugs	No. of Toxicities (*n*=133)	Grade 1	Grade 2	Grade 3	*p*-value
Cisplatin	89	56	32	1	0.001*
Carboplatin	44	30	12	2	

*Statistical analysis was performed using Fisher's exact test (Freeman-Halton extension).

supportive care. This observation aligns with guideline-based evidence that early-cycle toxicities can influence patient compliance and outcomes (Roila *et al.*, 2011).

Overall, the results of this study are consistent with existing literature and underscore the need for individualized toxicity monitoring, especially in patients receiving cisplatin and during initial treatment cycles.

CONCLUSION

The present study demonstrates that gastrointestinal toxicity is a frequent adverse effect in head and neck cancer patients receiving platinum-based chemotherapy. The severity and occurrence of GI toxicity were influenced by type of platinum agent, treatment cycle, age, and gender.

Cisplatin was associated with a higher incidence of mild to moderate GI toxicity, whereas carboplatin showed a comparatively higher proportion of severe toxicity events. Early chemotherapy cycles emerged as a critical period for toxicity development, highlighting the need for vigilant monitoring and timely supportive interventions.

Understanding the distinct toxicity profiles of cisplatin and carboplatin can assist clinicians in optimizing regimen selection and implementing preventive strategies to improve treatment tolerability and patient outcomes. Further large-scale, multicenter studies are recommended to confirm these findings.

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ABBREVIATIONS

HNC/HNCs: Head and Neck Cancer(s); **HNSCCs:** Head and Neck Squamous Cell Carcinoma; **SCCHN:** Squamous cell carcinoma of head and neck; **GI:** Gastrointestinal; **ADRs:** Adverse Drug Reactions; **CDDP:** Cisplatin; **CBDCA:** Carboplatin; Assessment Tools and Regulatory Bodies; **CTCAE:** Common Terminology Criteria for Adverse Events, a standardized system used to grade the severity of adverse events in oncology; **IPC:** Indian Pharmacopoeia Commission, which provides forms for reporting suspected adverse drug reactions; **SPSS:** Statistical Package for the Social Sciences, a software used for statistical data analysis; **ANOVA:** Analysis of Variance, specifically used in the sources as "Two-way ANOVA" for statistical analysis.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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