

## Original Research Article

# ASSESSMENT OF ADVERSE DRUG REACTIONS OF CISPLATIN, CARBOPLATIN AND OXALIPLATIN: A PROSPECTIVE OBSERVATIONAL STUDY

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Received : 12/02/2026  
 Received in revised form : 29/03/2026  
 Accepted : 15/04/2026

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DOI: 10.70034/ijmedph.2026.2.126

Source of Support: Nil,  
 Conflict of Interest: None declared

**Int J Med Pub Health**  
 2026; 16 (2); 734-739

**ABSTRACT**

**Background:** Platinum-based chemotherapy agents—cisplatin, carboplatin, and oxaliplatin—are widely used in the treatment of solid malignancies but are associated with varying toxicity profiles that may impact treatment outcomes.

**Materials and Methods:** This prospective observational study included 165 adult patients with histologically confirmed cancers treated at a tertiary care hospital in Chennai over one year. Patients received standard platinum-based regimens and were monitored each cycle. Toxicities were assessed using CTCAE criteria, neurotoxicity with EORTC QLQ-CIPN-20, and performance status by WHO scale. Statistical analysis was performed using ANOVA and chi-square tests.

**Results:** Carboplatin showed higher hematological toxicity, including severe anemia, leucopenia, and thrombocytopenia. Cisplatin was associated with increased nephrotoxicity and severe nausea and vomiting. Oxaliplatin demonstrated lower hematological and renal toxicity but higher incidence of peripheral neuropathy and diarrhoea. Differences were statistically significant ( $p < 0.05$ ).

**Conclusion:** Distinct toxicity profiles exist among platinum agents. Individualized selection can help minimize adverse effects and improve patient outcomes.

**Keywords:** Toxicity profile, Chemotherapy, Nephrotoxicity, Neurotoxicity, Hematological toxicity.

**INTRODUCTION**

Cancer remains one of the leading causes of morbidity and mortality worldwide, posing a significant public health burden despite continuous advances in diagnostic and therapeutic strategies.<sup>[1,2]</sup> In India, the incidence of cancer is steadily increasing, largely attributed to population growth, aging, urbanization, and lifestyle modifications.<sup>[3]</sup> Chemotherapy continues to play a central role in the management of malignancies, either as a curative modality or as part of multimodal therapy aimed at prolonging survival and improving quality of life.<sup>[4]</sup> Among the various chemotherapeutic agents, platinum-based compounds—namely cisplatin, carboplatin, and oxaliplatin—are widely utilized due to their broad-spectrum antitumor activity. These agents exert their cytotoxic effects primarily through the formation of DNA cross-links, leading to

inhibition of DNA replication and transcription, ultimately resulting in apoptosis of rapidly dividing cancer cells.<sup>[5]</sup> Owing to this mechanism, platinum compounds have become integral components in the treatment of a wide range of solid tumors, including head and neck cancers, gastrointestinal malignancies, ovarian carcinoma, and colorectal cancer.<sup>[6]</sup> Despite their therapeutic efficacy, the use of platinum compounds is often limited by their associated toxicity profiles.<sup>[7]</sup> Cisplatin, one of the earliest and most potent agents in this class, is well known for its dose-limiting adverse effects such as nephrotoxicity, severe nausea and vomiting, ototoxicity, and electrolyte imbalances.<sup>[8]</sup> Carboplatin, a second-generation platinum compound, was developed to reduce the toxicity associated with cisplatin, particularly nephrotoxicity and gastrointestinal adverse effects; however, it is more frequently associated with hematological toxicities such as

anemia, leucopenia, and thrombocytopenia.<sup>[9]</sup> Oxaliplatin, a third-generation platinum analog, has gained prominence in the treatment of colorectal cancer and is characterized by a relatively favorable renal toxicity profile but is associated with unique dose-dependent peripheral neuropathy.<sup>[10]</sup> The variability in toxicity profiles among these platinum agents is influenced by differences in their pharmacokinetics, dosing schedules, and patient-related factors such as age, nutritional status, and baseline organ function. These toxicities can significantly impact treatment adherence, necessitate dose modifications or discontinuation, and ultimately affect clinical outcomes. Therefore, a comprehensive understanding of the comparative toxicity profiles of these agents is essential for optimizing chemotherapy regimens and ensuring patient safety. Although several studies have evaluated the efficacy of platinum-based chemotherapy, there is limited comparative data focusing on their toxicity patterns in real-world clinical settings, particularly in the Indian population.<sup>[11-13]</sup> Early identification and grading of adverse drug reactions using standardized tools such as the Common Terminology Criteria for Adverse Events (CTCAE), along with assessment of functional status and quality of life, are crucial for effective management.<sup>[14-16]</sup> In this context, the present study was undertaken to prospectively evaluate and compare the toxicity profiles of cisplatin, carboplatin, and oxaliplatin in patients undergoing chemotherapy. The findings of this study aim to provide insights that may assist clinicians in selecting appropriate platinum-based regimens, minimizing treatment-related toxicities, and improving overall patient outcomes.

## MATERIALS AND METHODS

### Study Design and Setting

This study was designed as a prospective observational study conducted in the Department of Oncology at Rajiv Gandhi Government General Hospital, Chennai, in collaboration with the Institute of Pharmacology, Madras Medical College. The study was carried out over a period of one year from January 2019 to December 2019.

### Study Population

A total of 165 adult patients with histologically confirmed malignancies who were initiated on platinum-based chemotherapy were enrolled in the study. Patients were recruited consecutively based on eligibility criteria during the study period.

### Inclusion Criteria

- Patients aged between 18 and 60 years
- Both male and female patients
- Histologically confirmed diagnosis of malignancy
- Newly diagnosed cases receiving first cycle of platinum-based chemotherapy
- Patients with adequate baseline hematological, renal, and hepatic function

- Willingness to participate and provide written informed consent

### Exclusion Criteria

- Patients who had previously received chemotherapy
- Patients with pre-existing peripheral neuropathy
- Patients with chronic kidney disease
- Patients with severe comorbid conditions affecting study outcomes

### Chemotherapy Regimens

Patients received platinum-based chemotherapy as per institutional protocol. The cisplatin group received cisplatin (50–75 mg/m<sup>2</sup>) with 5-fluorouracil (750 mg/m<sup>2</sup>, Days 1–3) every 21 days for six cycles. The carboplatin group received carboplatin (400 mg/m<sup>2</sup>) with paclitaxel (175 mg/m<sup>2</sup>, Day 1) every 21 days for six cycles. The oxaliplatin group received the FOLFOX-4 regimen comprising oxaliplatin (85 mg/m<sup>2</sup>), leucovorin, and 5-fluorouracil. All patients were given premedication with dexamethasone, ondansetron, and ranitidine, along with adequate hydration.

### Data Collection Tools

Data were collected using a structured proforma. It included demographic details (age, sex, height, weight, body surface area) and clinical information (type of malignancy, staging, and treatment plan). Laboratory parameters recorded included hematological indices, renal function tests, and liver function tests.

### Assessment of Toxicity

Toxicities were graded using the Common Terminology Criteria for Adverse Events (CTCAE). Neurotoxicity was assessed using the EORTC QLQ-CIPN-20 questionnaire. Performance status was evaluated using the WHO Performance Status Scale. Adverse drug reactions were documented using the Pharmacovigilance Programme of India (PvPI) reporting form.

### Follow-Up and Monitoring

Patients were followed up at the end of each chemotherapy cycle. During each visit, clinical symptoms, adverse reactions, and laboratory parameters were recorded. Toxicity grading, performance status, and neurotoxicity assessment were performed and documented.

### Outcome Measures

The primary outcomes included hematological toxicity (anemia, leucopenia, thrombocytopenia), renal toxicity (urea and creatinine), neurotoxicity (peripheral neuropathy), gastrointestinal toxicity (nausea, vomiting, diarrhoea), and dermatological toxicity (alopecia).

### Causality Assessment

All adverse drug reactions were evaluated using the WHO Causality Assessment Scale and categorized accordingly.

### Statistical Analysis

Data were analyzed using appropriate statistical software. Continuous variables were expressed as mean ± standard deviation, and categorical variables

as percentages. Repeated measures ANOVA and chi-square test were applied. A p-value < 0.05 was considered statistically significant.

### Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethics Committee, Madras Medical College (IEC No: 44112018 dated 13.11.2018). The study adhered to the ethical principles outlined in the ICMR National Ethical Guidelines and the ICH-GCP guidelines. Written informed consent was obtained from all participants prior to enrollment, and confidentiality of patient data was strictly maintained.

## RESULTS

### Demographic Characteristics

The age distribution of the study participants is presented in Table 1. The mean age of patients in the Cisplatin group was  $53.38 \pm 5.83$  years, which was slightly higher compared to the Carboplatin group ( $49.8 \pm 9.13$  years) and the Oxaliplatin group ( $50.3 \pm 8.85$  years). However, the difference in mean age among the three groups was not statistically significant ( $p = 0.059$ ). This indicates that the study groups were comparable with respect to age distribution.

**Table 1: Age Distribution of Study Participants**

Group	N	Mean Age (years)	Standard Deviation	p-value
Cisplatin	55	53.38	5.83	0.059
Carboplatin	50	49.8	9.13	
Oxaliplatin	50	50.3	8.85	

The sex distribution of the study participants is summarized in Table 2. In the Cisplatin group, the majority of participants were male, accounting for 41 (74.54%), while females constituted 14 (25.46%). In contrast, the Carboplatin group had a higher

proportion of female participants, with 32 (64%) females and 18 (36%) males. The Oxaliplatin group showed a relatively balanced distribution, with 30 (60%) males and 20 (40%) females.

**Table 2: Sex Distribution**

Group	Male n (%)	Female n (%)	Total
Cisplatin	41 (74.54)	14 (25.46)	55
Carboplatin	18 (36)	32 (64)	50
Oxaliplatin	30 (60)	20 (40)	50

The distribution of cancer types among the study participants is presented in Table 3. The most common cancer observed was colon cancer, accounting for 29 cases (18.71%), followed closely by oral cancer with 28 cases (18.06%) and ovarian cancer with 27 cases (17.42%). Oesophageal cancer constituted 23 cases (14.84%), while rectal cancer

accounted for 21 cases (13.55%). Less frequently observed cancers included stomach cancer with 16 cases (10.32%), pharyngeal cancer with 7 cases (4.52%), and laryngeal cancer with 4 cases (2.58%). Overall, gastrointestinal and gynecological malignancies formed a significant proportion of the study population.

**Table 3: Distribution of Cancer Types**

Cancer Type	Frequency	Percentage (%)
Oral	28	18.06
Stomach	16	10.32
Pharynx	7	4.52
Larynx	4	2.58
Oesophagus	23	14.84
Ovary	27	17.42
Colon	29	18.71
Rectum	21	13.55

### Baseline Laboratory Parameters

The baseline hematological parameters of the study participants are presented in Table 4. The mean hemoglobin levels were comparable among the Cisplatin ( $10.1 \pm 1.2$  g/dL), Carboplatin ( $10.1 \pm 1.6$  g/dL), and Oxaliplatin ( $10.0 \pm 1.3$  g/dL) groups, with no statistically significant difference observed ( $p = 0.891$ ). Similarly, platelet counts did not differ significantly across the groups, with mean values of  $311.2 \pm 104.6$  cells/mm<sup>3</sup> in the Cisplatin group,  $303.7$

$\pm 52.9$  cells/mm<sup>3</sup> in the Carboplatin group, and  $308.5 \pm 60.9$  cells/mm<sup>3</sup> in the Oxaliplatin group ( $p = 0.884$ ). However, as shown in Table 4, the total leukocyte count demonstrated a statistically significant difference among the groups ( $p = 0.001$ ). The Cisplatin group had the highest mean total count ( $7291.6 \pm 2709$  cells/mm<sup>3</sup>), followed by the Oxaliplatin group ( $6615.7 \pm 1349$  cells/mm<sup>3</sup>), while the Carboplatin group showed comparatively lower values ( $5729 \pm 1303$  cells/mm<sup>3</sup>).

**Table 4: Baseline Hematological Parameters**

Parameter	Cisplatin (Mean ± SD)	Carboplatin	Oxaliplatin	p-value
Hemoglobin	10.1 ± 1.2	10.1 ± 1.6	10 ± 1.3	0.891
Total Count	7291.6 ± 2709	5729 ± 1303	6615.7 ± 1349	0.001
Platelets	311.2 ± 104.6	303.7 ± 52.9	308.5 ± 60.9	0.884

The baseline renal parameters of the study participants are summarized in Table 5. There was a statistically significant difference in both urea and creatinine levels among the three groups ( $p = 0.001$ ). The mean urea levels were highest in the Carboplatin group ( $38.6 \pm 25.1$  mg/dL), followed by the Cisplatin group ( $32.5 \pm 8.4$  mg/dL), and lowest in the Oxaliplatin group ( $24.5 \pm 3.9$  mg/dL). Similarly, as

shown in Table 5, serum creatinine levels also varied significantly across the groups ( $p = 0.001$ ). The Cisplatin group had the highest mean creatinine level ( $1.2 \pm 0.4$  mg/dL), followed by the Carboplatin group ( $1.0 \pm 0.1$  mg/dL), while the Oxaliplatin group showed the lowest values ( $0.7 \pm 0.1$  mg/dL). These findings indicate a significant baseline difference in renal function parameters among the study groups.

**Table 5: Baseline Renal Parameters**

Parameter	Cisplatin	Carboplatin	Oxaliplatin	p-value
Urea	32.5 ± 8.4	38.6 ± 25.1	24.5 ± 3.9	0.001
Creatinine	1.2 ± 0.4	1.0 ± 0.1	0.7 ± 0.1	0.001

The baseline liver function parameters of the study participants are presented in Table 6. A statistically significant difference was observed in all liver function tests among the three groups ( $p = 0.001$ ). The mean serum bilirubin levels were highest in the Carboplatin group ( $1.1 \pm 0.2$  mg/dL), followed by the Cisplatin group ( $0.9 \pm 0.3$  mg/dL), and lowest in the Oxaliplatin group ( $0.4 \pm 0.1$  mg/dL). Similarly, SGOT levels were higher in the Cisplatin group ( $33.4 \pm 14$  IU/L) and Carboplatin group ( $31.6 \pm 5.3$  IU/L)

compared to the Oxaliplatin group ( $23.1 \pm 3.2$  IU/L). As shown in Table 6, SGPT levels also followed a similar trend, with higher values in the Cisplatin ( $33.9 \pm 14.8$  IU/L) and Carboplatin ( $31.7 \pm 6.8$  IU/L) groups, while the Oxaliplatin group had markedly lower levels ( $16.8 \pm 6.8$  IU/L). In addition, alkaline phosphatase (ALP) levels were highest in the Carboplatin group ( $114.7 \pm 22.8$  IU/L), followed by the Cisplatin group ( $88.6 \pm 17.2$  IU/L), and lowest in the Oxaliplatin group ( $47.1 \pm 10.5$  IU/L).

**Table 6: Baseline Liver Function Tests**

Parameter	Cisplatin	Carboplatin	Oxaliplatin	p-value
Bilirubin	0.9 ± 0.3	1.1 ± 0.2	0.4 ± 0.1	0.001
SGOT	33.4 ± 14	31.6 ± 5.3	23.1 ± 3.2	0.001
SGPT	33.9 ± 14.8	31.7 ± 6.8	16.8 ± 6.8	0.001
ALP	88.6 ± 17.2	114.7 ± 22.8	47.1 ± 10.5	0.001

### Toxicity Profile

The incidence of hematological toxicity, specifically anemia of Grade  $\geq 3$  severity, is presented in Table 7. A statistically significant difference was observed among the three groups ( $p = 0.01$ ). The Carboplatin group exhibited the highest proportion of patients with severe anemia, accounting for 24%, followed by the Cisplatin group with 14%. In contrast, the

Oxaliplatin group showed the lowest incidence, with only 4% of patients experiencing Grade  $\geq 3$  anemia. These findings indicate that Carboplatin is associated with a higher risk of severe anemia, whereas Oxaliplatin demonstrates a comparatively safer hematological profile, with Cisplatin showing intermediate toxicity.

**Table 7: Hematological Toxicity (Anemia – Grade  $\geq 3$ )**

Group	Patients with Grade $\geq 3$ Anemia (%)	p-value
Cisplatin	14%	0.01
Carboplatin	24%	
Oxaliplatin	4%	

The occurrence of leucopenia and thrombocytopenia among the study groups is summarized in Table 8. A statistically significant difference was observed for both toxicities across the three treatment groups ( $p < 0.05$ ). As shown in Table 8, the incidence of leucopenia was highest in the Carboplatin group,

moderate in the Oxaliplatin group, and lowest in the Cisplatin group. A similar pattern was observed for thrombocytopenia, with the Carboplatin group exhibiting the highest occurrence, followed by the Oxaliplatin group, while the Cisplatin group showed the least incidence.

**Table 8: Leucopenia and Thrombocytopenia**

Toxicity	Cisplatin	Carboplatin	Oxaliplatin	p-value
Leucopenia	Low	High	Moderate	<0.05
Thrombocytopenia	Low	High	Moderate	<0.05

The comparison of major toxicities among the platinum-based chemotherapy agents is presented in Table 9. A statistically significant difference was observed for nephrotoxicity, neurotoxicity, and alopecia among the three groups. As shown in Table 9, nephrotoxicity was highest in the Cisplatin group, followed by a moderate incidence in the Carboplatin group, while the Oxaliplatin group exhibited the

lowest incidence ( $p = 0.001$ ). In terms of neurotoxicity, Oxaliplatin showed the highest levels, whereas Cisplatin demonstrated moderate neurotoxicity and Carboplatin exhibited the lowest incidence ( $p = 0.001$ ). Regarding alopecia, the Carboplatin group had the highest occurrence, while both Cisplatin and Oxaliplatin groups showed moderate incidence ( $p = 0.002$ ).

**Table 9: Comparison of Nephrotoxicity, Neurotoxicity, and Alopecia among Platinum Compounds**

Toxicity Type	Cisplatin	Carboplatin	Oxaliplatin	p-value
Nephrotoxicity	Highest incidence	Moderate incidence	Lowest incidence	0.001
Neurotoxicity	Moderate	Lowest	Highest	0.001
Alopecia	Moderate	Highest	Moderate	0.002

The gastrointestinal toxicity profile among the three treatment groups is presented in Table 10. A statistically significant difference was observed for all parameters ( $p < 0.05$ ). As shown in Table 10, nausea and vomiting were most pronounced in the Cisplatin group, where both toxicities were reported

as high. The Carboplatin group exhibited moderate levels of nausea and vomiting, while the Oxaliplatin group showed the lowest incidence of these symptoms. In contrast, diarrhoea was least common in the Cisplatin group, moderate in the Carboplatin group, and highest in the Oxaliplatin group.

**Table 10: Gastrointestinal Toxicity**

Toxicity	Cisplatin	Carboplatin	Oxaliplatin	p-value
Nausea	High	Moderate	Low	<0.05
Vomiting	High	Moderate	Low	<0.05
Diarrhoea	Low	Moderate	High	<0.05

## DISCUSSION

The findings of the present study are consistent with previously published literature on the toxicity profiles of platinum-based chemotherapeutic agents. Several studies have highlighted the distinct adverse effect patterns associated with cisplatin, carboplatin, and oxaliplatin, supporting the observations made in this study. Cisplatin-induced nephrotoxicity observed in our study (Table 9) is well documented in earlier research. A study by Pabla and Dong (2008) reported that cisplatin causes dose-dependent renal tubular injury mediated by oxidative stress and inflammatory pathways, making nephrotoxicity a major dose-limiting factor.<sup>[17]</sup> Similarly, Hartmann and Lipp (2003) emphasized that despite adequate hydration and preventive strategies, cisplatin continues to exhibit significant renal toxicity, which aligns with our findings of the highest nephrotoxicity incidence in the cisplatin group.<sup>[18]</sup> The high incidence of gastrointestinal toxicity, particularly nausea and vomiting in the cisplatin group (Table 10), is also supported by prior evidence. Hesketh (2008) classified cisplatin as a highly emetogenic chemotherapeutic agent, requiring aggressive antiemetic prophylaxis.<sup>[19]</sup> Our results corroborate this, as patients receiving cisplatin experienced the highest levels of nausea and vomiting despite standard premedication. In contrast, carboplatin demonstrated a higher incidence of hematological toxicities, including anemia, leucopenia, and thrombocytopenia (Tables 7 and 8). This is in agreement with the findings of Calvert et al. (1989), who reported that carboplatin's primary dose-

limiting toxicity is myelosuppression, particularly thrombocytopenia.<sup>[20]</sup> Additionally, Lokich and Anderson (1998) observed that carboplatin is associated with significantly less nephrotoxicity compared to cisplatin but carries a higher risk of bone marrow suppression, which is consistent with our observations.<sup>[21]</sup> Oxaliplatin-related neurotoxicity, which was most prominent in our study (Table 9), has been widely reported in the literature. Gamelin et al. (2002) described oxaliplatin-induced peripheral neuropathy as a cumulative and dose-dependent toxicity, often presenting as sensory neuropathy.<sup>[22]</sup> Similarly, Grothey (2003) highlighted that neurotoxicity is the principal dose-limiting adverse effect of oxaliplatin, particularly in patients receiving prolonged treatment.<sup>[23]</sup> Our findings strongly align with these reports, as oxaliplatin showed the highest incidence of neurotoxicity among the three groups. Regarding gastrointestinal toxicity, our study found that oxaliplatin was associated with a higher incidence of diarrhoea, which is consistent with findings by de Gramont et al. (2000) in patients receiving FOLFOX regimens for colorectal cancer.<sup>[24]</sup> The authors reported that diarrhoea is a common adverse effect of oxaliplatin-based combination therapy, likely due to mucosal damage in the gastrointestinal tract. Furthermore, the relatively lower renal toxicity observed with oxaliplatin in our study is supported by Stathopoulos et al. (1990), who demonstrated that oxaliplatin has minimal nephrotoxic potential compared to cisplatin, making it a safer alternative in patients with compromised renal function.<sup>[25]</sup> Overall, the comparative toxicity patterns observed in the present study are in strong agreement with existing evidence.

However, most previous studies have evaluated these agents individually or within specific cancer types, whereas the present study provides a comprehensive, real-world comparison of all three platinum compounds within a single cohort. This adds to the existing body of literature by offering a broader perspective on toxicity profiles in routine clinical practice, particularly in the Indian population.

## CONCLUSION

This study demonstrates that cisplatin, carboplatin, and oxaliplatin exhibit distinct and clinically relevant toxicity profiles. Cisplatin was associated with a higher incidence of nephrotoxicity and severe gastrointestinal adverse effects, particularly nausea and vomiting. Carboplatin showed a greater tendency to cause hematological toxicities, including anemia, leucopenia, and thrombocytopenia, making regular monitoring essential. In contrast, oxaliplatin demonstrated comparatively lower renal and hematological toxicity but was significantly associated with peripheral neuropathy and diarrhoea, which may affect long-term treatment adherence and quality of life. The observed differences were statistically significant, emphasizing the need for careful selection of platinum agents based on individual patient characteristics, baseline organ function, and treatment goals. Early identification and appropriate management of adverse drug reactions can help minimize complications and improve therapeutic outcomes. Overall, an individualized approach to platinum-based chemotherapy is crucial to enhance safety, tolerability, and effectiveness in cancer treatment.

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