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Research Article

Enhancing QOL in Cancer Patients: An Observational Study on the Incidence and Severity of Platinum-Induced Peripheral Neuropathy at a Single Cancer Centre in Chennai

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Abstract

Background and objectives: Chemotherapy-induced peripheral neuropathy (CIPN) is a persistent adverse effect of agents like taxanes, platinum drugs, etc. This study focuses on platinum drugs and aims to compare platinum-based regimens, regarding the incidence and severity of platinum-induced peripheral neuropathy (PIPN), to identify those with higher neurotoxic potential. A secondary objective is to assess patient-specific risk factors to improve analysis accuracy. **Methods:** A prospective observational study was conducted at a tertiary care hospital, Chennai from September 2024 to February 2025, involving 78 adult cancer patients receiving platinum-based chemotherapy. Stratified sampling ensured equal group representation (n = 26 each). Neuropathy was assessed using NCI-CTCAE criteria, with statistical analysis including chi-square/Fisher's exact tests and logistic regression. Post hoc analysis identified significant group differences. **Results:** A total of 18% of participants developed symptoms consistent with peripheral neuropathy (PN). A statistically significant association was observed between platinum-based agents and the occurrence of PN ($p = 0.032$), with carboplatin showing a comparatively higher incidence. Among the platinum-based regimens, the paclitaxel–carboplatin (PC) combination exhibited the strongest association with PN ($p = 0.049$). The majority of PN cases were mild, with grade 3 and 4 events occurring exclusively in the carboplatin group. However, no statistically significant association was observed between treatment groups and PN severity ($p > 0.05$). **Interpretation and conclusions:** The study demonstrated a significant association between the paclitaxel-carboplatin (PC) regimen and the incidence of peripheral neuropathy (PN), especially in ovarian and endometrial cancers, suggesting a possible additive neurotoxic effect of paclitaxel and carboplatin in combination. These findings highlight the need for tailored neuroprotective strategies at the initiation of treatment, especially when the PC regimen is prescribed.

Keywords: Paclitaxel-carboplatin, Paclitaxel-carboplatin induced peripheral neuropathy, Peripheral neuropathy, Platinum-induced peripheral neuropathy, PIPN.

INTRODUCTION

The cancer burden is rising relentlessly both globally and in India, making the battle against it seem far from over. In India, the incidence of cancer cases was projected to increase from 1.46 million in 2022 to 1.57 million by 2025, with lung cancer and breast cancer remaining the most common sites of cancer incidence in males and females, respectively.[1] Cancer treatment involves various approaches, including surgery, immunotherapy, hormone therapy, radiotherapy, chemotherapy, and RNA-based therapies. Though chemotherapy is effective, it often falls short of eradicating the cancer cells and is accompanied by many side effects, significantly affecting the quality of life of cancer patients.[2]

Chemotherapy-induced peripheral neuropathy (CIPN) is a serious and often persistent adverse effect of certain chemotherapeutic agents, acting as a major dose-limiting factor in many first-line treatments and affecting 20–50% of patients at standard doses and nearly all at higher doses.[3] It can lead to longer infusion times, dose reductions, or early termination of chemotherapy, negatively impacting treatment efficacy and patient survival.[4] CIPN primarily manifests as sensory, motor, and autonomic deficits, with sensory symptoms—such as numbness, tingling, and pain—being the most common, typically starting in the hands and feet. Motor symptoms, like weakness and balance issues, are less frequent but can progress to paralysis, while autonomic symptoms are rare.[5]

Platinum-based chemotherapy agents like oxaliplatin, carboplatin, and cisplatin are known to cause CIPN, and the incidence and severity of neurotoxicity may vary among different platinum drugs.[6] However, once neurotoxicity develops, the clinical presentation is generally similar for all three drugs, with only minor pattern differences.[7] Most of the existing literature indicates that, among the three agents, cisplatin and oxaliplatin exhibit a greater neurotoxic potential compared with carboplatin. This difference in neurotoxicity is attributed to the reactivity of each specific platinum drug, particularly the liability of leaving groups as they interact with various biomolecules, which determines the severity of the toxicity.[8]

Numerous studies have examined the incidence of peripheral neuropathy associated with specific chemotherapeutic classes, such as taxanes.[9] Others have focused on the overall incidence of peripheral neuropathy across specific chemotherapy regimens, and some have studied any one specific platinum drug.[10,11] However, despite the breadth of existing research on different classes of chemotherapy, there remains a notable lack of comprehensive data specifically addressing the incidence and severity of peripheral neuropathy associated exclusively with platinum-based regimens, and to identify which is most strongly associated with its development. Identifying this is crucial for developing new interventions or making early interventions aimed at improving the quality of life, particularly for cancer patients receiving a platinum-based regimen in India.

Our primary objective is to compare platinum-based regimens to evaluate the incidence and severity of peripheral neuropathy associated with each, aiming to identify regimens with higher neurotoxic potential. Additionally, as a secondary objective, we aim to address population heterogeneity by considering specific risk factors that may influence the incidence and severity of peripheral neuropathy, ensuring a more accurate and comprehensive analysis. These findings are expected to provide insights for improving prevention and management strategies in India.

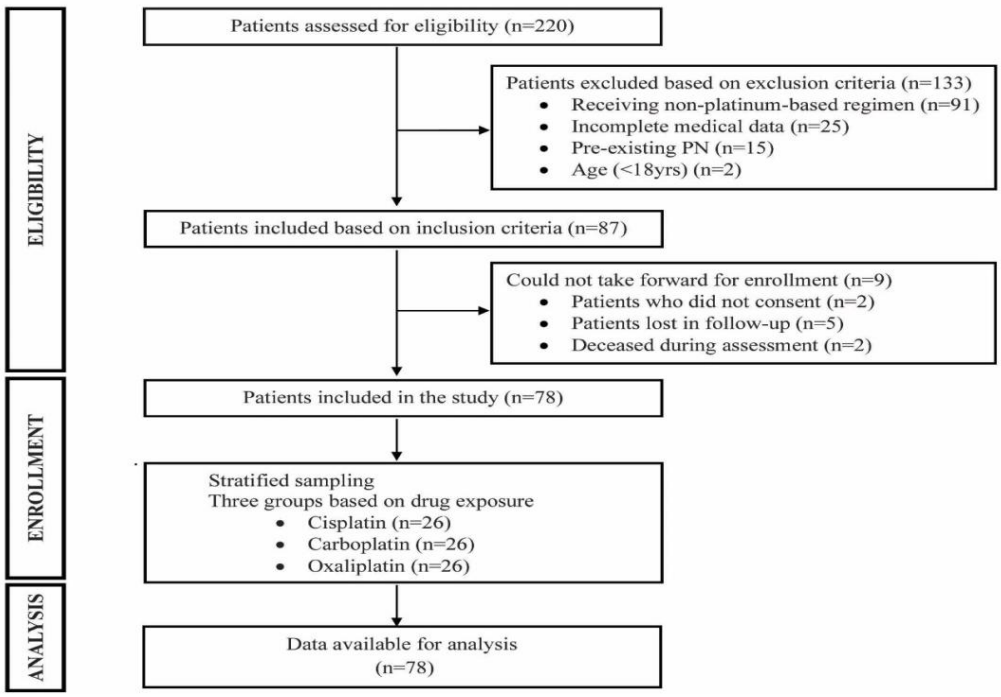
METHODS AND MATERIALS

A prospective observational study was conducted at the Department of Medical Oncology, Gleneagles Health City Chennai (GHCC), India, over the period of six months, from September 2024 to February 2025. Ethical approval was obtained from the respective Institutional Ethics Committee (Approval ID: [BMHR/2024/0090]), and the study adhered to the Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational research.

Study population

The study included 78 participants (aged ≥18 years) with a confirmed diagnosis of any origin of cancer who were prescribed platinum-based chemotherapy. While some degree of heterogeneity was expected due to the inclusion of participants with comorbidities such as diabetes mellitus, hypothyroidism, infections, autoimmune diseases, and lifestyle-related factors like smoking and alcohol use, these were not excluded. This approach was adopted to reflect real-world clinical scenarios, as such conditions are common among cancer patients and may influence the incidence and severity of peripheral neuropathy (PN). Participants who did not meet the inclusion criteria, had incomplete medical records, or did not provide informed consent were excluded from the study. The participant enrolment process had been summarised in Figure 1.

Figure 1



Sample size and sampling

Based on expert opinion, assuming an outcome proportion of 20% in the study group, the sample size was calculated with a 95% confidence level, a 5% margin of error, and a 10% anticipated loss to follow-up. Using standard sample size estimation formulas for observational studies, the initial estimate was calculated to be 71 participants. After adjusting for the 10% loss to follow-up, the final sample size was determined to be 78. The sample size was determined based on a priori power analysis to ensure adequate statistical power. The study employed a stratified sampling method to ensure the representation of participants from key subgroups, namely: cisplatin, carboplatin, and oxaliplatin, with each group consisting of 26 participants.

Data collection and assessment

After obtaining informed consent, baseline data, including sociodemographic characteristics, clinical history, and chemotherapy details, were collected using a structured data collection form. The form was designed based on previous studies and literature to capture key information such as age, gender, BMI (Body Mass Index), ethnicity, social history, cancer diagnosis, stage, comorbidities, chemotherapy regimen, number of cycles, treatment plan, and the grade of PN. Neuropathy was assessed at baseline using the National Cancer Institute - Common Terminology Criteria for Adverse Events (NCI-CTCAE) criteria. Participants were monitored throughout their chemotherapy regimen, with data collected on cycles completed, dose adjustments, and any additional treatments. Neuropathy assessments were repeated at each follow-up visit to track to identify PN and changes in severity.

Ethical considerations

The study protocol was approved by the Institutional Ethics Committee (Approval ID: [BMHR/2024/0090]). Written informed consent was obtained from all participants prior to enrolment.

Data analysis

Data analysis was performed using IBM SPSS Statistics version 23. Continuous variables were summarised as mean, standard deviation (SD), median, and range, while categorical data were presented as frequencies and percentages. The chi-square test or Fisher's exact test was applied to categorical variables, and binary logistic regression was used for continuous variables. Post hoc analysis, with standardised residuals > +2 or < -2, identified significant groups.

For neuropathy severity, the chi-square test or Fisher's exact test was employed for categorical variables and ordinal regression was used for continuous exposure variables. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 78 patients who received platinum-based chemotherapy were observed and followed up for six months to assess the incidence and severity of peripheral neuropathy (PN). An incidence of 18% of participants reported symptoms consistent with peripheral neuropathy, and the severity of these symptoms was assessed. In addition to estimating incidence and severity, the study aimed to explore potential risk factors associated with peripheral neuropathy.

Participants were nearly equally distributed by gender, with a mean age of 56.38 ± 13.66 years. The association between gender and age with the development of peripheral neuropathy was assessed to explore any relation between them, which was insignificant. The mean BMI was 24.96 ± 4.62 kg/m^2, with most patients falling within normal or underweight. Due to cancer-related muscle loss, the presence of obesity was minimal in the study, allowing the study to primarily focus on other risk factors. Similarly, smoking and alcohol consumption history were evaluated with peripheral neuropathy. The study included only non-smokers and former smokers, as well as non-alcoholic and former alcoholic participants, enabling an analysis of past exposures and their potential influence on peripheral neuropathy. Although the study aimed to investigate ethnicity and family history as additional risk factors, all participants belonged to a single ethnic background (non-Chinese Asian), and none reported a family history of peripheral neuropathy. The sociodemographic, clinical, and treatment characteristics of the patients are summarised in Table I and Table II.

TABLE I- CHARACTERISTICS OF STUDY PARTICIPANTS

Socio-Demographic Characteristics of Study Participants		
Variables	**Categories**	**Frequency n(%) N=78**
Gender	Male	32(41)
	Female	46(59)
Ethnicity	Non-Chinese Asian	78(100)
	Chinese	-
	Caucasian	-

Age in years, Mean ± SD		56.38 ±13.66
BMI, Mean ± SD		24.96 ± 4.62
Family history of PN	Yes	-
	No	78(100)
Smoking	Non-Smoker	74(94.9)
	Ex-Smoker	4(5.1)
	Smoker	-
Alcohol consumption	Alcoholic	-
	Non-Alcoholic	74(94.9)
	Ex-Alcoholic	4(5.1)
Clinical Characteristics of Study Participants		
Co-Morbidities	Diabetes mellitus	26(56.5)
	Hypothyroidism	10(21.7)
	Infection	4(8.7)
	Autoimmune disease	2(4.3)
	DM + Hypothyroidism +Infection	4(8.7)
Stages of cancer	Stage 1	8(10.3)
	Stage 2	20(25.6)
	Stage 3	22(28.2)
	Stage 4	28(35.9)

TABLE II - CHEMOTHERAPY REGIMEN AND TREATMENT CHARACTERISTICS

Variables	**Categories**	**Frequency n (%) N=78**
Regimens	Nab-Paclitaxel + Carboplatin (Nab-PC)	4(5.1)
	Paclitaxel + Carboplatin (PC)	12(15.4)
	Gemcitabine + Carboplatin(GemCarbo)	3(3.8)
	Docetaxel + Carboplatin +Trastuzumab (DCH)	5(6.4)
	Pemetrexed + Carboplatin	2(2.6)
	Capecitabine + Oxaliplatin (CAPOX)	14(17.9)
	5-Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel (FLOT)	5(6.4)
	5-Fluorouracil + Leucovorin + Oxaliplatin + Irinotecan (FOLFIRINOX)	4(5.1)
	Oxaliplatin	3(3.8)
	Gemcitabine + Cisplatin (GC)	4(5.1)
	Cisplatin	15(19.2)
	Bleomycin + Etoposide + Cisplatin (BEP)	4(5.1)
	Doxorubicin + Cisplatin	2(2.6)
	Paclitaxel + Ifosfamide + Cisplatin(TIP)	1(1.3)
Platinum drugs	Carboplatin	26(33.33)
	Oxaliplatin	26(33.33)

	Cisplatin	26(33.33)
Other Neurotoxic Drugs in the Study Regimen	Nab-Paclitaxel	5(6.5)
	Paclitaxel	13(16.9)
	Docetaxel	8(10.4)
	Drugs considered non-neurotoxic [a]	51(66.2)
Duration of chemotherapy	<1 months	7(9)
	<3 months	28(35.9)
	<6 months	43(55.1)
Neuroprotective agents	Mylin Plus	17(22.1)
	Pregabalin	4(5.2)
	Renerve plus	3(3.9)
	Mylin Plus + Pregabalin	9(11.7)
	Mylin Plus + Renerve Plus	1(1.3)

[a]It includes Gemcitabine, Docetaxel, Trastuzumab, Pemetrexed, Capecitabine, 5-Fluorouracil, Leucovorin, Irinotecan, Bleomycin, Etoposide, Doxorubicin, Ifosfamide

The primary objective of the study was to assess the incidence of peripheral neuropathy (PN) in relation to different platinum-based chemotherapy agents. A statistically significant association was observed between platinum drugs and PN (Fisher's Exact test, p = 0.032). Post hoc analysis using standardised residuals indicated a higher-than-expected incidence of PN with carboplatin (residual = +2.1).

A significant association was also found between the primary site of cancer and PN incidence (Fisher's Exact test, p = 0.03). Post hoc analysis showed elevated standardised residuals for endometrial cancer (+3.3) and ovarian cancer (+2.4), suggesting these sites were major contributors to the observed association. The association between chemotherapy regimens and PN was significant (Fisher's Exact test, p = 0.049), with the paclitaxel + carboplatin regimen contributing most prominently in post hoc analysis. Additionally, a significant relationship was identified between neurotoxic agents in the regimen and PN (Fisher's Exact test, p = 0.001). Among these, paclitaxel showed the highest standardised residual, indicating a strong association with the occurrence of PN. Additionally, a statistically significant association was observed between comorbidities and the incidence of peripheral neuropathy (Fisher's Exact test, $p < 0.05$). However, post hoc analysis did not identify any specific comorbidity as significantly contributing to this association. The statistical results have been summarised in Table III.

TABLE III - STATISTICAL ANALYSIS OF INCIDENCE OF PERIPHERAL NEUROPATHY

Factor	Univariate regression			Multivariate regression		
	OR	95% CI	p-value	OR	95% CI	p-value
Platinum Drugs, Carboplatin (All other groups)[a]	6.353	(1.216, 33.191)	0.032*	0.033	(0.002, 10.369)	0.023*
Gender, Male (Female)	1.944	(0.551, 6.857)	0.301	4.637	(0.968, 22.207)	0.055
Age	0.965	(0.919, 1.014)	0.160	0.949	(0.9, 1.0)	0.52
BMI	1.067	(0.926, 1.228)	0.371	1.135	(0.960, 1.342)	0.139
Smoking, Smoker (All other groups)[a]	1.564	(0.151, 16.254)	0.708	0.177	(0.009, 3.569)	0.259
Alcohol consumption, Alcoholic (All other groups)[a]	0.639	(0.062, 6.644)	0.716	0.348	(0.020, 6.072)	0.470
Primary site of cancer, Ovary (All Other Groups)[a]	2.561	(1.896, 2.759)	0.03*	5.741	(0.567, 58.093)	0.139
Stage of Cancer, Stage 4 (All Other Groups)[a]	0.567	(0.132, 2.426)	0.444	0.104	(0.006, 1.652)	0.109

Comorbidities, Diabetes mellitus (All other groups)[a]	16.5	(1.353, 201.29)	0.017*	0.060	(0.003, 1.403)	0.08
Regimen, PC (All other groups)[a]	0.924	(0.846, 0.956)	0.049*	0.078	(0.008, 1.596)	0.09
Cumulative Dose - Carboplatin	0.996	(0.994, 0.999)	0.009	0.999	(0.998, 1.0)	0.123
Cumulative Dose - Oxaliplatin	1.003	(0.995, 1.011)	0.476	1.0	(0.998, 1.002)	0.787
Cumulative Dose - Cisplatin	1.017	(0.989, 1.045)	0.244	0.999	(0.998, 1.001)	0.748
Other Neurotoxic Drugs in the Study Regimen, Paclitaxel (All other groups)[a]	2.874	(1.585, 5.210)	0.001*	2.448	(2.154, 4.925)	0.048*
Duration of chemotherapy, Less than 1 month (All other groups)[a]	0.558	(0.202, 1.538)	0.259	0.033	(0.006, 10.376)	0.246
Neuroprotective agents, Mylin Plus (All other groups)[a]	0.486	(0.189, 2.125)	0.411	0.126	(0.086, 0.569)	0.579

*p-value of <0.05 considered significant

[a] Reference variable groups are indicated in parentheses. The phrase 'all other groups' refers to the combined reference group, where multiple categories are merged into a single group for comparison against the case group.

While platinum drugs and several clinical factors were significantly associated with the incidence of PN, no statistically significant relationship was found with the **severity** of neuropathy. Severity was assessed using the National Cancer Institute's Common Terminology Criteria for Adverse Events (NCI-CTCAE v5.0), but no significant differences were observed across drug types, regimens, or other variables ($p > 0.05$). Though not significant, the patients receiving oxaliplatin and cisplatin showed only grade 1 and grade 2, while patients receiving carboplatin showed severity of all grades, and details are presented in Table IV.

TABLE IV - SEVERITY OF PERIPHERAL NEUROPATHY

Variables	Categories	Frequency n (%) N=14	p-value
Severity of Peripheral Neuropathy	Grade 1	4(28.5)	0.664*
	Grade 2	5(35.7)	
	Grade 3	3(21.4)	
	Grade 4	2(14.2)	

*A p-value > 0.05 indicating no statistically significant association between platinum-based drugs and the severity of peripheral neuropathy.

This suggests that while certain agents and factors increase the likelihood of developing PN, they may not influence the grade or clinical severity of symptoms as per NCI-CTCAE classification.

DISCUSSION

In our study, the incidence of peripheral neuropathy (PN) was found to be 18%, demonstrating both clinical relevance and statistical significance. Compared to previous studies, the incidence observed in our study was lower.[12] Our findings also revealed significant variation in the incidence of peripheral neuropathy among different platinum-based drugs. Notably, carboplatin showed a higher association with PN compared to oxaliplatin and cisplatin. This finding contrasts with earlier reports, such as the study by *Feng G et al.,* which identified oxaliplatin as the primary contributor to PN.[13] Following a closer analysis, this discrepancy may not be solely due to carboplatin itself, but rather to the combination of drugs used in the chemotherapy regimens. Many regimens in our study included multiple anti-cancer drugs, some of which are known to be neurotoxic, making it important to consider the contribution of each component. When the individual associations of other neurotoxic agents in the regimen with PN were examined, paclitaxel was found to have a stronger association with increased incidence of PN compared to other drugs. This is consistent with existing literature, including studies by *Sun S et al.,* which highlight the substantial neurotoxicity associated with paclitaxel alone.[14]

Further evaluation revealed that the paclitaxel-carboplatin (PC) regimen, in particular, was significantly associated with both the incidence and severity of PN

which was similar in reporting of the study by *Guastalla JP et al*.[15] These findings suggest that the higher neuropathy rates observed with the PC regimen may be due to a combined or additive neurotoxic effect of both paclitaxel and carboplatin, rather than carboplatin alone. This may explain why carboplatin was more significantly associated with neuropathy in our study.

Moreover, the frequent use of the paclitaxel + carboplatin regimen, especially in gynaecological cancers, may therefore explain the higher incidence of PN noted in patients with endometrial and ovarian cancer in our study.[16] While comorbid conditions as a group were found to be associated with PN, no single comorbidity appeared to significantly influence the outcome individually, suggesting a more complex interplay of general health status and treatment response.

In our study, the severity of PN, as assessed by NCI-CTCAE grading, did not differ significantly among the platinum agents, treatment regimens, or other variables analyzed. Though insignificant, our study revealed a higher number of mild cases (Grades 1 and 2) of peripheral neuropathy. This result is consistent with the study conducted by *Ashok V. Kalidindi et al.,* which also reported that most cases of peripheral neuropathy were of mild severity.[17]

The predominance of mild severity could be due to the shorter period of our study. The absence of long-term follow-up is a crucial limitation, particularly given that peripheral neuropathy is often a long-term side effect of chemotherapy. The study's six-month follow-up period was insufficient to capture the full scope of the long-term effects of chemotherapy on peripheral neuropathy. The study's findings are also limited by its single-centre design, as the research was carried out at only one clinical site.

Overall, our study highlights the increased risk of PN with combination regimens containing carboplatin and paclitaxel, especially in patients with ovarian and endometrial cancers. These findings underline the importance of careful monitoring and early preventive measures in cancer patients.

CONCLUSION

The study explored and analysed both the incidence and severity of peripheral neuropathy (PN) in patients receiving platinum-based chemotherapy. It was concluded that in the study population, the paclitaxel + carboplatin (PC) regimen was significantly associated with an increased incidence of PN, particularly in female patients with ovarian and endometrial cancers. These findings underscore the importance of implementing tailored neuroprotective strategies from the start of the chemotherapy cycle, particularly when prescribing the paclitaxel and carboplatin (PC) regimen. Early initiation of neuroprotective measures, coupled with vigilant monitoring of high-risk patients, can help mitigate the development of peripheral neuropathy. Additionally, establishing a stewardship framework to systematically document symptoms and facilitate timely interventions will further enhance patient outcomes and quality of life during and after chemotherapy.

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