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Original Article

Oncology Section

Assessment of the Toxicity Profile in Patients with Breast Carcinoma Receiving Paclitaxel Chemotherapy: A Prospective Observational Study

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ABSTRACT

Introduction: Paclitaxel is a commonly used chemotherapeutic agent in the management of breast carcinoma however, it is frequently associated with treatment-limiting toxicities that can adversely affect patient outcomes and quality of life.

Aim: To evaluate the toxicity profile of paclitaxel-based chemotherapy in patients with breast carcinoma and to compare toxicities between weekly and three-weekly treatment regimens.

Materials and Methods: The present prospective observational study was conducted among 40 histopathologically confirmed female patients with breast carcinoma receiving paclitaxel chemotherapy at Jawaharlal Nehru Medical College between April 2023 and March 2025, in Maharashtra, India. Toxicities were graded using the Common Terminology Criteria for Adverse Events (CTCAE) and pain was assessed using the Visual Analogue Scale (VAS). Among 40 patients, 21 patients received weekly paclitaxel (80 mg/m^2) and 19 patients received three-weekly paclitaxel (175 mg/m^2). Anaemia and neurological status were assessed before each cycle. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 22 and a p-value <0.05 was considered statistically significant.

Results: The mean age in the three-weekly and weekly groups was 51.95±8.38 years and 52.33±8.50 years, respectively, with no statistically significant difference (p=0.886). A highly significant increase in Chemotherapy-Induced Peripheral Neuropathy (CIPN) was observed, with 35 out of 40 patients (17 patients in the three-weekly and 18 patients in the weekly groups) developing neuropathy by the final cycle (p<0.0001). Pain scores increased significantly following chemotherapy (p<0.001), with a greater rise observed in the three-weekly group. Treatment-emergent toxicities included thrombophlebitis in 29 patients (72.5%), while hypersensitivity reaction, cardiac toxicity, and thrombocytopenia were observed in one patient each (2.5%).

Conclusion: Both weekly and three-weekly paclitaxel regimens were associated with a significant increase in peripheral neuropathy and pain, with a relatively higher toxicity burden observed in the three-weekly schedule.

Keywords: Anaemia, Chemotherapy-induced peripheral neuropathy, Pain, Chemotherapeutic agent

INTRODUCTION

Breast cancer remains a major global health problem, ranking as the second most common malignancy among women, with approximately 2.3 million new cases and over 620,000 deaths reported worldwide each year, accounting for nearly 25% of all cancers in females [1]. Although major progress has been made in endocrine and targeted therapies, chemotherapy continues to be a cornerstone in breast cancer management, as multiple randomised controlled trials have shown that adjuvant chemotherapy reduces recurrence and improves overall survival [2]. However, its use is frequently limited by acute and long-term toxicities, which can negatively impact adherence, treatment effectiveness, and patient outcomes [3]. Despite improvements in drug regimens and supportive care, up to 87% of patients still experience at least one adverse effect during the course of chemotherapy [4,5].

Paclitaxel and docetaxel are two taxanes commonly employed in the treatment of early-stage breast cancer, particularly in the adjuvant and neoadjuvant settings [6,7]. Paclitaxel has demonstrated efficacy against a wide range of common cancers, including non-small cell lung cancer, breast cancer, and ovarian cancer. Its mechanism of action involves promoting the polymerisation of tubulin, leading to cytotoxic effects. Clinical studies have demonstrated that incorporating taxanes into chemotherapy regimens based on anthracyclines leads to improved disease-free and overall survival rates in patients with non-metastatic breast cancer [8-10]. The standard adjuvant chemotherapy protocol for breast cancer involves four cycles of doxorubicin combined with cyclophosphamide followed by 12 weekly paclitaxel infusions. Adding trastuzumab improves outcomes in HER2-positive tumours [11]. However, paclitaxel can cause neuropathy, cardiotoxicity, and pain syndrome [12], impacting patients' well-being and potentially leading to dose delays or discontinuation [13]. Hence, the present study evaluates paclitaxel toxicity in breast cancer patients examining its relation to chemotherapy cycles.

MATERIALS AND METHODS

The present prospective observational study was conducted at the General Surgery Department in a Tertiary care hospital and a teaching and research institute in Maharashtra, Central India, affiliated with Jawaharlal Nehru Medical College from April 2023 to March 2025. Ethical clearance for the proposed work was sought from the Institutional Ethical Committee {DMIHER(DU)/IEC/2023/964} before start of the present study. All participants were recruited from an outpatient oncology clinic or inpatient wards after obtaining informed written consent.

Inclusion and Exclusion criteria: Inclusion criteria comprised of female patients of all age groups who were histopathologically diagnosed with breast carcinoma alone and breast carcinoma with pre-existing grade I or grade II neuropathy who were planned to receive paclitaxel-based chemotherapy. Exclusion criteria comprised of pre-existing cardiac arrhythmias, patients allergic to paclitaxel,

patients with baseline neuropathy (grade III) and patients of breast carcinoma who have lost to follow-up.

Sample size calculation: The sample size was calculated using the Krejcie-Morgan formula [14] considering total no of patients in two years in Outpatient Department (OPD), which is as described:

$n=\chi^2 \times N \times P (1-P) / \{d^2 (N-1)+\chi^2 P (1-P)\}$

$n=3.84 \times 40 \times 0.5 (1-0.5) / \{0.05^2 (40-1)+3.84 \times 0.5 (1-0.5)\}$.

$n \approx 36.31$

$n=40$

where '*n*' is the required sample size, χ^2 is the Chi-square value for one degree of freedom at the 95% confidence level (3.84), *N* is the population size (40) that comprises total number of patients in two years in the OPD, *P* is the population proportion (assumed as 0.5 for maximum sample size), and *d* is the acceptable margin of error (0.05).

Study Procedure

Each enrolled patient was assigned a unique study identification number, and baseline clinical, laboratory, and imaging data were documented systematically for further follow-up.

Pre-existing neuropathy was graded using the CTCAE version 5.0 before initiating chemotherapy. The treatment protocol and chemotherapy regimen were decided as per tumour board discussion. Among 40 patients, 21 patients received weekly paclitaxel (80 mg/m^2) and 19 patients received three-weekly paclitaxel (175 mg/m^2). Breast carcinoma patients received paclitaxel 80 mg per square meter by intravenous infusion for one hour weekly for 12 doses, and paclitaxel 175 mg/m^2 by intravenous infusion for three hours every three weeks for four doses. Premedication for paclitaxel included Inj. Avil, Inj. Dexamethasone, Inj. Pantoprazole 40 mg, and Inj. Emeset.

All patients received Granulocyte-Colony Stimulating Factors (G-CSF), specifically Filgrastim 5 mcg/kg, administered subcutaneously prior to each chemotherapy cycle as a prophylactic measure to mitigate the risk of paclitaxel-induced neutropenia. Haematological toxicities, including anaemia, neutropenia, and thrombocytopenia, were evaluated prior to each chemotherapy cycle using the CTCAE version 5.0 to ensure standardised grading and monitoring of myelosuppressive effects induced by paclitaxel [15].

Assessment of bilateral lower limb pain was conducted using the VAS, a validated subjective tool for pain quantification, wherein patients were asked to rate their pain intensity on a scale ranging from 0 (no pain) to 10 (worst imaginable pain).

Infusion-related adverse events, including hypersensitivity reaction, phlebitis, and cardiac complications, were meticulously monitored and documented on daily basis in all inpatients receiving paclitaxel chemotherapy.

STATISTICAL ANALYSIS

Statistical analysis was performed using SPSS software version 22. Chi-square analysis and student's t-test was performed to find the association with variables ($p<0.05$).

RESULTS

The mean age in the 3-weekly group is 51.95±8.38 years, while in the weekly group, it is slightly higher at 52.33±8.50 years, The statistical analysis using a t-test yields a t-value of 0.144 and a p-value of 0.886 [Table/Fig-1].

Mean age (years)	N	Mean	Std. deviation	t-value	p-value
3 weekly	19	51.95	8.38	0.144	0.886
weekly	21	52.33	8.50		

[Table/Fig-1]: Comparison of mean age among subjects receiving weekly and three-weekly paclitaxel chemotherapy regimens.

This table evaluates the presence of neuropathy before the commencement of treatment. In the 3-weekly group, 89.5% of patients had no pre-existing neuropathy, while 10.5% did. In the weekly group, all patients (100%) were free of pre-existing neuropathy [Table/Fig-2].

Pre-existing neuropathy	3 Weekly		Weekly	
	Frequency	Percent	Frequency	Percent
No	17	89.5	21	100.0
Yes	2	10.5	0	0

[Table/Fig-2]: Distribution of study subjects with pre-existing neuropathy among weekly and three-weekly paclitaxel chemotherapy groups.

[Table/Fig-3a] presents the development of anaemia among patients undergoing paclitaxel chemotherapy across treatment cycles. Initially, 30 patients were classified as having normal haemoglobin levels, while 10 were anaemic. By the final chemotherapy cycle, the number of patients with normal levels decreased to 23, and those with anaemia increased to 17. The Chi-square test value is 2.73 with a p-value of 0.09, suggesting that while there is a visible trend toward increased anaemia, the change is not statistically significant at the conventional 0.05 threshold.

	Normal	Anaemia	Chi-square value, p-value
First cycle	30	10	2.73;0.09
Last cycle	23	17	

[Table/Fig-3a]: Progression of anaemia following paclitaxel chemotherapy administration.

[Table/Fig-3b] reveals the subset analysis looks at patients receiving chemotherapy every three weeks. The number of normal cases increased slightly from 13 to 14, while anaemic cases decreased from 6 to 5. The Chi-square value is 0.12 and the p-value is 0.720, indicating no significant change in anaemia status in this subgroup.

	Normal	Anaemia	Chi-square value, p-value
First cycle	13	6	0.12; 0.720
Last cycle	14	5	

[Table/Fig-3b]: Progression of anaemia following administration of three-weekly paclitaxel chemotherapy.

[Table/Fig-3c] reveals that in patients treated weekly, a decrease in normal cases from 17 to 14 and an increase in anaemic cases from four to seven are observed. The Chi-square value is 1.10 and the p-value is 0.292, indicating that these changes are not statistically significant.

	Normal	Anaemia	Chi-square value, p-value
First cycle	17	4	1.10; 0.292
Last cycle	14	7	

[Table/Fig-3c]: Progression of anaemia following weekly paclitaxel chemotherapy

[Table/Fig-3d] reveals that patients were divided based on pre-chemotherapy anaemia status. Among the 30 initially non-anaemic patients, seven developed anaemia, whereas five of the 10 already anaemic patients worsened. The Chi-square value is 2.53 with a p-value of 0.11, which again indicates no statistically significant difference between the two groups.

Pre-chemotherapy status	Developed/worsened anaemia after chemotherapy	Did not develop/ worsen	Chi-square value, p-value
Normal (n=30)	7	23	2.53; 0.11
Anaemia (n=10)	5	5	

[Table/Fig-3d]: Comparative analysis of post-chemotherapy anaemia development in patients with and without baseline anaemia.

[Table/Fig-3e] shows the severity of anaemia progression. Among the 30 patients without baseline anaemia, one developed Grade I anaemia and six developed Grade II anaemia. In contrast, those with Grade II anaemia before treatment showed progression, with one patient

advancing to Grade III. The p-value of 0.345 suggests no statistically significant difference in anaemia grading post-chemotherapy.

Pre-Chemotherapy status	Grade I Anaemia	Grade II Anaemia	Grade III Anaemia	Chi-square value, p-value
No Anaemia (n=30)	1	6	0	2.12; 0.345
Anaemia Grade II (n=10)	0	4	1	

[Table/Fig-3e]: Progression of Anaemia Grades (as per CTCAE) in patients receiving paclitaxel chemotherapy.

[Table/Fig-4a] highlights a stark increase in neuropathy after chemotherapy. At the first cycle, 38 patients were without neuropathy, and only two presented symptoms. By the last cycle, only five remained free of neuropathy, while 35 had developed it. The Chi-square value is 45.75 with a p-value of 0.000, indicating a highly significant rise in neuropathy over the course of treatment.

	Normal	Neuropathy	Chi-square value, p-value
First cycle	38	2	45.75; 0.0001*
Last cycle	5	35	

[Table/Fig-4a]: Comparative analysis of neuropathy in patients receiving paclitaxel chemotherapy.

[Table/Fig-4b] reveals that neuropathy also increased significantly. Initially, 17 patients had no neuropathy and two had symptoms. By the end of the treatment, the numbers reversed dramatically, with only two remaining symptom-free and 17 experiencing neuropathy. The Chi-square value of 23.68 and p-value of 0.000 indicate a strong, statistically significant relationship between the 3-weekly schedule and increased neuropathy incidence.

	Normal	Neuropathy	Chi-square value, p-value
First cycle	17	2	23.68; 0.0001*
Last cycle	2	17	

[Table/Fig-4b]: Comparative analysis of Chemotherapy-Induced Peripheral Neuropathy (CIPN) in patients receiving three-weekly paclitaxel chemotherapy regimen.

[Table/Fig-4c] reveals that among patients on the weekly schedule, none had neuropathy at baseline (21 normal). By the last cycle, only three remained normal, and 18 developed neuropathy. The Chi-square value of 31.5 with a p-value of <0.0001 reflects a highly significant progression of neuropathy in this group.

	Normal	Neuropathy	Chi-square value, p-value
First cycle	21	0	31.5, <0.0001
Last cycle	3	18	

[Table/Fig-4c]: Comparative analysis of Chemotherapy-Induced Peripheral Neuropathy (CIPN) in patients receiving weekly paclitaxel chemotherapy regimen.

[Table/Fig-4d] explores the severity of neuropathy. Of the 38 patients who had no neuropathy before treatment, 16 developed Grade I, 14 developed Grade II, and three progressed to Grade III. Among the two patients who already had neuropathy, both progressed to Grade II. The Chi-square value of 2.51 and p-value of 0.283 indicate that although neuropathy increased, the distribution across grades was not statistically significant.

Pre- Chemotherapy status	Post-chemotherapy status				Chi-square value, p-value
	No Neuropathy	Grade I	Grade II	Grade III	
No neuropathy n=38	5	16	14	3	2.51; 0.283
Pre-existing Neuropathy n=2 (grade I)	-	0	2	0	

[Table/Fig-4d]: Progression of neuropathy from pre-chemotherapy to post-chemotherapy according to CTCAE grading

[Table/Fig-5] reveals that in patients receiving chemotherapy every three weeks, the mean pain score increased from 5.05 to 6.36.

Pain score	Pre-chemotherapy	Post-chemotherapy
3 weekly	5.05	6.36
Weekly	4.38	5.90

[Table/Fig-5]: Comparison of mean pain scores between weekly and three-weekly chemotherapy schedules- pre- and post-chemotherapy analysis.

For those on the weekly schedule, it increased from 4.38 to 5.90. Although pain increased in both groups post-treatment, the rise was slightly more pronounced in the 3-weekly group, possibly due to cumulative neurotoxicity from higher intermittent doses.

A total of 29 incidences of thrombophlebitis events were documented among these patients. Additionally, one patient (2.5%) manifested cardiac toxicity, presenting clinically during treatment. The cardiac events were managed as per institutional protocols, with close monitoring and supportive care. Furthermore, hypersensitivity reactions related to paclitaxel infusion were documented in one patient (2.5 %). These infusion-related reactions were promptly identified and treated with appropriate premedication and symptomatic management, preventing further complications [Table/Fig-6].

Toxicity	Number of Patients (n)	Percentage (%)
Thrombophlebitis	29	72.5
Thrombocytopenia	1	2.5
Cardiac toxicity	1	2.5
Hypersensitivity reaction	1	2.5
No toxicity	8	20

[Table/Fig-6]: Treatment-emergent toxicities in paclitaxel chemotherapy for breast carcinoma.

DISCUSSION

The present study highlights the toxicity profiles of weekly and 3-weekly paclitaxel regimens in breast carcinoma patients. Both regimens showed significant increases in neuropathy, with a slightly higher incidence in the 3-weekly group. Anaemia rates remained unchanged, while pain scores increased in both groups, more pronounced in the 3-weekly group. These findings emphasise the need to carefully consider regimen choice to balance efficacy and toxicity, ensuring optimal treatment outcomes for breast cancer patients receiving paclitaxel chemotherapy.

It was found that Paclitaxel chemotherapy significantly increased neuropathy incidence, with the number of patients without neuropathy decreasing from 38 to 5, while those with neuropathy rose from two to 35 (p<0.001). Both 3-weekly and weekly treatment groups showed significant increases in neuropathy, with p-values of 0.0001 and <0.0001, respectively. In consistent to present study, Costa MS et al., reported neurotoxicity as the most prevalent significant finding among the incidence of taxane toxicity [16]. Another concordant study by Guo Q et al., found that duration of chemotherapy and priority of albumin-bound paclitaxel (nab-PTX) based chemotherapy were potential risk factors for CIPN in breast cancer patients treated with nanonab-PTX [17]. Patients receiving nab-PTX for over four weeks or as first-line chemotherapy had higher CIPN rates, highlighting the need for further research to mitigate these risks and improve patient outcomes. Other comparable study by Timmins HC et al., showed significant neuropathy development by six weeks of weekly paclitaxel treatment, persisting up to 12 months and this study also found that dose reduction did not lead to more favourable neuropathy outcomes, suggesting that individual risk factors play a crucial role in neuropathy development [18]. A study by Shenoy PK et al., observed that among the patients who completed the planned 12 cycles of weekly paclitaxel, significant grade 3/4 toxicities were observed with peripheral neuropathy among 12%

of cases whereas the present study found a significant increase in neuropathy incidence (%), with 35 out of 40 patients developing neuropathy [11].

In the present study, the rise in pain scores suggests that paclitaxel treatment may contribute to increased sensory discomfort or pain, possibly related to neuropathy. Similarly, a study by Loprinzi CL et al., found that 20% of patients experienced significant pain (scores 5-10/10) after the first dose, with numbness and tingling being more prominent symptoms than shooting or burning pain [19].

Hypersensitivity reactions are primarily attributed to Cremophor EL, the solvent used in paclitaxel formulation, which can activate mast cells and complement pathways, leading to severe allergic responses [20].

Cardiac toxicity was also observed in one patient (2.5%), manifesting during the chemotherapy course. Though relatively rare, paclitaxel-induced cardiotoxicity, including arrhythmias and ischemic changes, has been previously reported, particularly in patients with existing cardiovascular co-morbidities [21]. One case (2.5%) of isolated Grade I thrombocytopenia was noted between chemotherapy cycles despite administrating G-CSF (Filgrastim) before each cycle. A retrospective review by Markman M et al., also reported mild thrombocytopenia in 2-3 % of patients receiving standard paclitaxel doses [22]. Collectively, these findings reinforce the necessity for comprehensive toxicity monitoring protocols during paclitaxel therapy.

Limitation(s)

The present study was conducted at a single centre with relatively small sample size (n=40), which may limit the generalisability of the findings. Although, comorbid conditions such as diabetes mellitus and vitamin B12 deficiency were part of the predefined inclusion criteria, the study was not specifically powered to evaluate their independent impact on toxicity profiles. This may have confounded the interpretation of certain adverse effects like neuropathy. Pain assessment was done using the VAS, a validated tool; however, as it relies on subjective self-reporting, there exist potential for reporting bias due to inter-individual variability in pain perception. Additionally, while the present study documents toxicity profile under predefined dosing regimens, no dose reduction or modifications were undertaken or assessed, which may not reflect real-world clinical scenarios where dose adjustment is often guided by toxicity severity. Finally, the relatively short follow-up period may have limited the detection late-onset or cumulative toxicities.

CONCLUSION(S)

Both 3-weekly and weekly treatment groups showed significant increases in neuropathy. Anaemia rates remained unchanged in both groups, indicating that paclitaxel chemotherapy may not have a significant impact on anaemia in breast cancer patients. These findings emphasise the need to carefully consider the choice of paclitaxel regimen to balance efficacy and toxicity, taking into account individual patient factors and medical histories, to ensure optimal treatment outcomes for breast cancer patients receiving paclitaxel chemotherapy.

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