Wiley
European Journal of Cancer Care
Volume 2025, Article ID 4229814, 7 pages
https://doi.org/10.1155/ecc/4229814

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Research Article

Exploring Chemotherapy-Induced Peripheral Neuropathy Severity Patterns in Young Adult Women With Breast Cancer Receiving Weekly or Dose Dense Paclitaxel

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Received 11 February 2025; Revised 18 August 2025; Accepted 15 September 2025

Guest Editor: Ricardo Santiago Gomez

Purpose: The purpose of this secondary analysis was to explore paclitaxel-induced peripheral neuropathy severity patterns among women with breast cancer receiving weekly or dose dense paclitaxel regimens.
Methods: Young adult women with breast cancer (18–39 years) beginning cancer treatment with dose dense (175 mg/m^2 every 14 days) or weekly (80 mg/m^2) paclitaxel completed the QLQ-CIPN20 before the first paclitaxel infusion (T1) and then at two time points during paclitaxel chemotherapy (T2: 350 mg/m^2 and T3: 700 mg/m^2). QLQ-CIPN20 scores were compared between women receiving dose dense or weekly paclitaxel across the three time points using mixed-effect linear regression models.
Results: Among women receiving dose dense paclitaxel ($n = 27$), mean QLQ-CIPN4 scores increased from 4.63 at T1 to 15.43 at T3, while among women receiving weekly paclitaxel ($n = 12$), mean QLQ-CIPN4 scores increased from 2.08 at T1 to 5.56 at T3. Similar trends were observed for changes in QLQ-CIPN20 sensory and motor subscale scores among both groups. Overall, while CIPN severity was worse at each time point among women receiving dose dense paclitaxel relative to women receiving weekly paclitaxel, there were no statistically significant differences between groups for changes in QLQ-CIPN4 ($p = 0.24$), QLQ-CIPN20 sensory ($p = 0.41$), or QLQ-CIPN20 motor score ($p = 0.68$) over time.
Conclusions: The results may be used to promote awareness among patients and clinicians regarding potential trajectories of paclitaxel-induced peripheral neuropathy for women with breast cancer.

Keywords: breast neoplasms; chemotherapy-induced peripheral neuropathy; paclitaxel; young adult

1. Introduction

Breast cancer is the leading cancer diagnosis among adolescent and young adult women in the United States [1]. Several common treatment regimens for breast cancer treatment involve the neurotoxic agent, paclitaxel [2]. Chemotherapy-induced peripheral neuropathy (CIPN) (e.g., numbness or tingling in the hands or feet) is a dose-dependent and debilitating side effect of paclitaxel as approximately 40% of women with breast cancer report moderate–severe nonpainful CIPN during paclitaxel treatment [3]. Specifically, cross-sectional data ($n = 15$) highlight that young adults (18–39 years old) with breast cancer, gastrointestinal cancer, or multiple myeloma experience moderate or greater nonpainful CIPN (46.7%) and/or CIPN interference (33.3%) per the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) [4] numbness and tingling severity and interference items during neurotoxic chemotherapy (e.g., paclitaxel, oxaliplatin, and bortezomib) [3]. Women with breast cancer who experience CIPN report difficulty in exercising, driving, opening jars, and buttoning shirts due to numbness and tingling in the hands and/or feet [3].

Paclitaxel is routinely administered in dose dense (i.e., every 2 weeks) or weekly delivery schedules [5], but it is unclear if one paclitaxel delivery schedule may lead to increased CIPN incidence or severity over the other. Prior research suggests that weekly paclitaxel dosing leads to significant neuropathy among women with breast cancer [6, 7]. For example, data demonstrate that up to 54.5% and 85.5% of women with breast cancer report numbness and tingling in the hands by 6 and 12 weeks of weekly paclitaxel treatment, respectively [7]. Furthermore, approximately 36% of women receiving weekly paclitaxel require dose reduction due to neuropathy [7]. However, few studies have directly compared CIPN severity and incidence rates among women with breast cancer receiving weekly or dose dense paclitaxel regimens.

As there are no recommended treatment strategies for nonpainful CIPN [8], a greater understanding of the pattern and severity of CIPN among women receiving dose dense or weekly paclitaxel is needed to promote patient-clinician communication and guide clinical decision making surrounding CIPN (e.g., provide patient education, paclitaxel dose reduction, referral to subspecialty such as physical therapy). Thus, the purpose of this secondary analysis was to explore CIPN severity patterns among women with breast cancer receiving weekly or dose dense paclitaxel regimens.

2. Materials and Methods

2.1. Design, Sample, and Setting. The present manuscript presents a secondary analysis of a single arm, prospective, longitudinal clinical trial ($N = 50$) [9]. While the primary trial recruited young adults with leukemia, lymphoma, or breast cancer receiving vincristine or paclitaxel, the aim of this secondary analysis was focused on CIPN severity among young adult women with breast cancer receiving paclitaxel. Young adults (18–39 years old) from the primary study were eligible for this analysis if they were diagnosed with breast cancer, planned to receive dose dense (four cycles [every 14 days] $\times$ 175 mg/m^2) or weekly paclitaxel (12 cycles $\times$ 80 mg/m^2), did not have neuropathy at baseline, and did not plan to receive other neurotoxic chemotherapy agents other than paclitaxel. All participants were recruited from Dana-Farber Cancer Institute and provided verbal consent to participate. Regulatory oversight was provided by the Dana-Farber/Harvard Cancer Center Office for Human Research Studies (19–862).

2.2. Measures. European Organization of Research and Treatment of Cancer Quality of Life Questionnaire-Chemotherapy-Induced Peripheral Neuropathy (QLQ-CIPN20) was used. Numbness and tingling severity was quantified using two of the measure's original subscales: (1) sensory (nine items that include symptoms such as loss of feeling, tingling, or pain in the hands and feet) and (2) motor (eight items that include symptoms such as cramping or weakness in the hands or feet). The items of each scale are transformed to a 0–100 score (higher scores = worse CIPN) [10]. As data have called into question the factor structure of the QLQ-CIPN20 subscales [11, 12], CIPN severity was also measured using the four individual numbness and tingling items of the QLQ-CIPN20. The sum-scored approach has demonstrated strong discriminate validity based on its ability to differentiate increasing Common Terminology Criteria for Adverse Events–sensory scores in patients receiving neurotoxic chemotherapy [12].

2.3. Procedures. Participants completed the patient-reported outcomes measures before the first paclitaxel infusion (T1) and then at two time points during paclitaxel chemotherapy (T2: 350 mg/m^2 and T3: 700 mg/m^2) [6]. Given that CIPN is a dose-dependent side effect of paclitaxel administration, the aim was to hold cumulative paclitaxel dose at T3 constant between women receiving weekly (12 cycles $\times$ 80 mg/m^2) or dose dense paclitaxel (4 cycles $\times$ 175 mg/m^2) [6, 7]. Thus, 700 mg/m^2 was selected for the T3 cumulative paclitaxel dose as this was the end of treatment cumulative dose for women receiving dose dense paclitaxel. For women receiving dose dense paclitaxel, T2 and T3 were completed after receiving 350 mg/m^2 (i.e., after the 2nd cycle) and 700 mg/m^2 (i.e., after the 4th cycle) of paclitaxel, respectively. For women receiving weekly paclitaxel, T2 and T3 were completed after receiving 400 mg/m^2 (i.e., after the 5th cycle) and 720 mg/m^2 (i.e., after the 9th cycle) of paclitaxel, respectively. Participants also completed a demographics questionnaire at T1 (e.g., age, sex, and ethnicity) and study staff abstracted cancer treatment-related information (e.g., cancer type and stage and cumulative paclitaxel dose) at T3.

2.4. Statistical Analyses. QLQ-CIPN20 (i.e., four numbness and tingling items, sensory subscale, and motor subscale, respectively) were described at each time point among women receiving paclitaxel 175 mg/m^2 every 14 days and women receiving paclitaxel 80 mg/m^2 weekly. QLQ-CIPN4,

QLQ-CIPN20 sensory, and QLQ-CIPN20 motor scores were compared between groups across the three time points using mixed-effect linear regression models.

3. Results

3.1. Demographic Characteristics. Of the 50 participants who completed the primary trial, 39 (78%) young adult women with breast cancer were eligible for analysis. Table 1 describes the demographic characteristics of participants who received paclitaxel 80 mg/m^2 weekly ($n = 12$, 31%) or paclitaxel 175 mg/m^2 every 14 days ($n = 27$, 69%), respectively. Participants who received paclitaxel 175 mg/m^2 every 14 days were more racially and ethnically diverse and were more likely to have completed paclitaxel before T3 in comparison to participants who received paclitaxel 80 mg/m^2 weekly.

3.2. CIPN Severity Over Time Among Women Receiving Weekly or Dose Dense Paclitaxel. Table 2 and Figure 1 describe QLQ-CIPN20 scores at each time point among women receiving dose dense paclitaxel (i.e., 175 mg/m^2 every 14 days) or weekly paclitaxel (i.e., 80 mg/m^2). Among women receiving dose dense paclitaxel, mean QLQ-CIPN4 scores increased from 4.63 at T1 to 15.43 at T3, while among women receiving weekly paclitaxel, mean QLQ-CIPN4 scores increased from 2.08 at T1 to 5.56 at T3. Similar trends were observed for changes in QLQ-CIPN20 sensory and motor subscale scores among women receiving dose dense or weekly paclitaxel. Overall, while CIPN severity was worse at each time point among women receiving dose dense paclitaxel relative to women receiving weekly paclitaxel, there were no statistically significant differences between groups for changes in QLQ-CIPN4 ($p = 0.24$), QLQ-CIPN20 sensory ($p = 0.41$), or QLQ-CIPN20 motor score ($p = 0.68$) over time.

4. Discussion

To our knowledge, this is among the first analysis to compare CIPN patterns among women with breast cancer receiving weekly or dose dense paclitaxel regimens, two of the most common paclitaxel-based adjuvant regimens. The results of this analysis demonstrated that at approximately the same cumulative dose of paclitaxel (~700 mg/m^2), dose dense paclitaxel delivery produced worse CIPN severity than weekly paclitaxel delivery among women with breast cancer. While the results were not statistically significant between groups, the mean change (10.8) in QLQ-CIPN4 score during paclitaxel treatment among women receiving dose dense paclitaxel was clinically significant. A psychometric study conducted by Li et al. demonstrated that the minimally important difference for QLQ-CIPN20 scores from baseline to end of treatment was 7.32 [13].

Our results are inconsistent with prior studies demonstrating that weekly paclitaxel administration produces severe CIPN [6, 7] as our results revealed that women receiving weekly paclitaxel experienced little CIPN. Our findings may have differed from the current literature for several reasons. First, we administered the QLQ-CIPN20 as recommended by the National Cancer Institute Clinical Trials Planning Meeting for CIPN [14] whereas past investigators have administered the Total Neuropathy Score [15] or the Functional Assessment of Cancer Therapy/Gynecologic Oncology Group–Neurotoxicity [16]. There is no gold standard CIPN measure currently [17], which makes direct comparison of CIPN severity and incidence across studies difficult [18]. Second, previous investigations were conducted among women of all ages receiving weekly paclitaxel [6, 7]. The evidence is unclear regarding how age influences CIPN severity [19–21]. Third, previous investigators measured CIPN after 12 weeks of weekly paclitaxel therapy (i.e., 892 or ~960 mg/m^2) [6, 7], not 700 mg/m^2 (~9 weeks). It is possible that worse CIPN severity may have been observed among women receiving weekly paclitaxel if CIPN was measured near the end of treatment in the present study. Of note, Timmins et al. (2021) demonstrated that approximately half of women receiving weekly paclitaxel self-reported CIPN after 6 weeks of weekly paclitaxel [7].

The assessment and management of CIPN women with breast cancer at the point of care remains challenging because there are no first-line assessment [17] or management options for nonpainful CIPN during treatment [8]. The study results may be used to provide education to women with breast cancer regarding when patients may begin to experience numbness and tingling during paclitaxel treatment. Clinicians commonly use chemotherapy dose reduction as a strategy to mitigate increasing CIPN severity during chemotherapy [22]. At this time, study results should not be used to inform dose-reduction clinical decision making for individual patients as data mainly focused on CIPN severity, but not interference. Qualitative evidence suggests that while there is not a standardized approach to chemotherapy dose reduction, clinicians are more likely to dose reduce chemotherapy when CIPN interference is high (e.g., difficulty walking or interferes with activities of daily living) [22]. Future research is needed to develop measures and/or algorithms to inform the tailoring of paclitaxel dosages at the patient level for CIPN management.

Because our study was designed to compare trajectories of CIPN during paclitaxel delivery rather than posttreatment, we were not able to evaluate chronic paclitaxel-induced peripheral neuropathy patterns. Prior research demonstrates that CIPN symptoms may persist in the months following neurotoxic chemotherapy completion [23]. Future investigations should extend follow-up beyond paclitaxel treatment completion to more fully characterize the incidence and severity of chronic CIPN in young adult women with breast cancer receiving weekly or dose dense paclitaxel.

5. Limitations

There are several limitations to this study. The external generalizability of the results to women with breast cancer is low given that the study was conducted at one site and among a homogenous patient population with regard to race and ethnicity. The study design controlled for cumulative

Table 1: Demographic characteristics of the analyzed sample at T1.

Characteristic	Paclitaxel 80 mg/m^2 Weekly ($n = 12$)	Paclitaxel 175 mg/m^2 14 days ($n = 27$)
Age at consent		
Mean (SD)	34.25 (3.02)	34.44 (4.19)
Sex		
Female	12 (100%)	27 (100%)
Race		
Asian	1 (8.3%)	5 (18.5%)
Black or African-American	0	3 (11.1%)
White	11 (91.7%)	19 (70.4%)
Ethnicity		
Hispanic or Latino	0	3 (11.1%)
Not Hispanic or Latino	12 (100%)	24 (88.9%)
Education		
Completed high school	1 (8.3%)	1 (3.7%)
Some college or technical training	1 (8.3%)	4 (14.8%)
University undergraduate degree	5 (41.7%)	10 (37%)
University post graduate degree	5 (41.7%)	12 (44.4%)
Marital status		
Single	7 (58.3%)	7 (25.9%)
Married/Partnered	5 (41.7%)	19 (70.4%)
Divorced	0	1 (3.7%)
Employment status		
Working full time	3 (25%)	12 (44.4%)
Working part-time	1 (8.3%)	0
Working at home	1 (8.3%)	0
Working, but on medical leave	5 (41.7%)	10 (37%)
Not working	1 (8.3%)	4 (14.8%)
Student	1 (8.3%)	1 (3.7%)
Cancer type		
Breast	12 (100%)	27 (100%)
Cancer stage		
Stage I	1 (8.3%)	3 (11.1%)
Stage II	7 (58.3%)	19 (70.4%)
Stage III	3 (25%)	4 (14.8%)
Metastatic	1 (8.3%)	1 (3.7%)
Cumulative dose paclitaxel (mg/m^2)		
T2 Mean (Range)	393.33 (41.19)	343.27 (34.32)[a]
T3 Mean (Range)	712 (41.22)	697.41 (13.47)
Days between last paclitaxel and T3		
Mean (Range)	NA[b]	34.19 (25.18)[c]
Neurotoxic chemotherapy dose reduction		
Yes, neuropathy related	1 (8.3%)	1 (3.7%)
Yes, other reasons[d]	4 (33.3%)	1 (3.7%)
No	7 (58.3%)	25 (92.6%)

[a]$n = 26$.
[b]Not applicable as all participants were still on treatment at the T3 time point.
[c]All participants had completed paclitaxel treatment prior to T3.
[d]Other dose reduction reasons: low neutrophil count, rash, increased liver function tests, and diarrhea.

paclitaxel dosage, age, gender, and cancer type. However, it is possible that additional variables (e.g., co-occurring symptoms that may influence CIPN severity such as anxiety, depression, fatigue, or sleep disturbance) [24, 25] may have confounded the results of the analysis pertaining to CIPN severity at T3. Similarly, although cumulative paclitaxel dose and demographics were generally balanced, imbalances in co-occurring symptoms or paclitaxel dose reductions may also have influenced observed differences between groups. These exploratory analyses were likely underpowered given the small sample size. The 700-mg/m^2 cumulative dose threshold for T3 patient-reported outcomes measurement was based on the end of treatment time point for the dose dense paclitaxel regimen. There is the possibility that we may have observed similar rates of CIPN between groups if we measured CIPN severity at the end of treatment for women receiving dose dense and weekly paclitaxel [6, 7]. The measurement of CIPN at specific cumulative doses of paclitaxel during treatment also did not allow for the tracking of late or persistent paclitaxel-induced peripheral

Table 2: Mean (SD) paclitaxel-induced peripheral neuropathy severity from T1 to T3 ($N = 39$).

Outcomes	Paclitaxel 80 mg/m^2 Weekly ($n = 12$)	Paclitaxel 175 mg/m^2 14 days ($n = 27$)
QLQ-CIPN4[a]		
T1	2.08 (5.18)	4.63 (13.54)
T2	6.25 (10.73)	19.23 (22.08)[b]
T3	5.56 (8.94)	15.43 (18.16)
QLQ-CIPN20 sensory		
T1	0.93 (2.3)	3.29 (10.24)
T2	4.32 (5.66)	12.39 (16.4)[b]
T3	3.09 (5.2)	9.05 (11.77)
QLQ-CIPN20 motor		
T1	0 (0)	2.95 (10.46)
T2	0.69 (1.62)	12.27 (22.46)[b]
T3	2.43 (4.85)	7.3 (12.91)

[a]First four items of the QLQ-CIPN20 that ask participants to rate the severity of numbness or tingling in the hands and feet, respectively.
[b]$n = 26$.

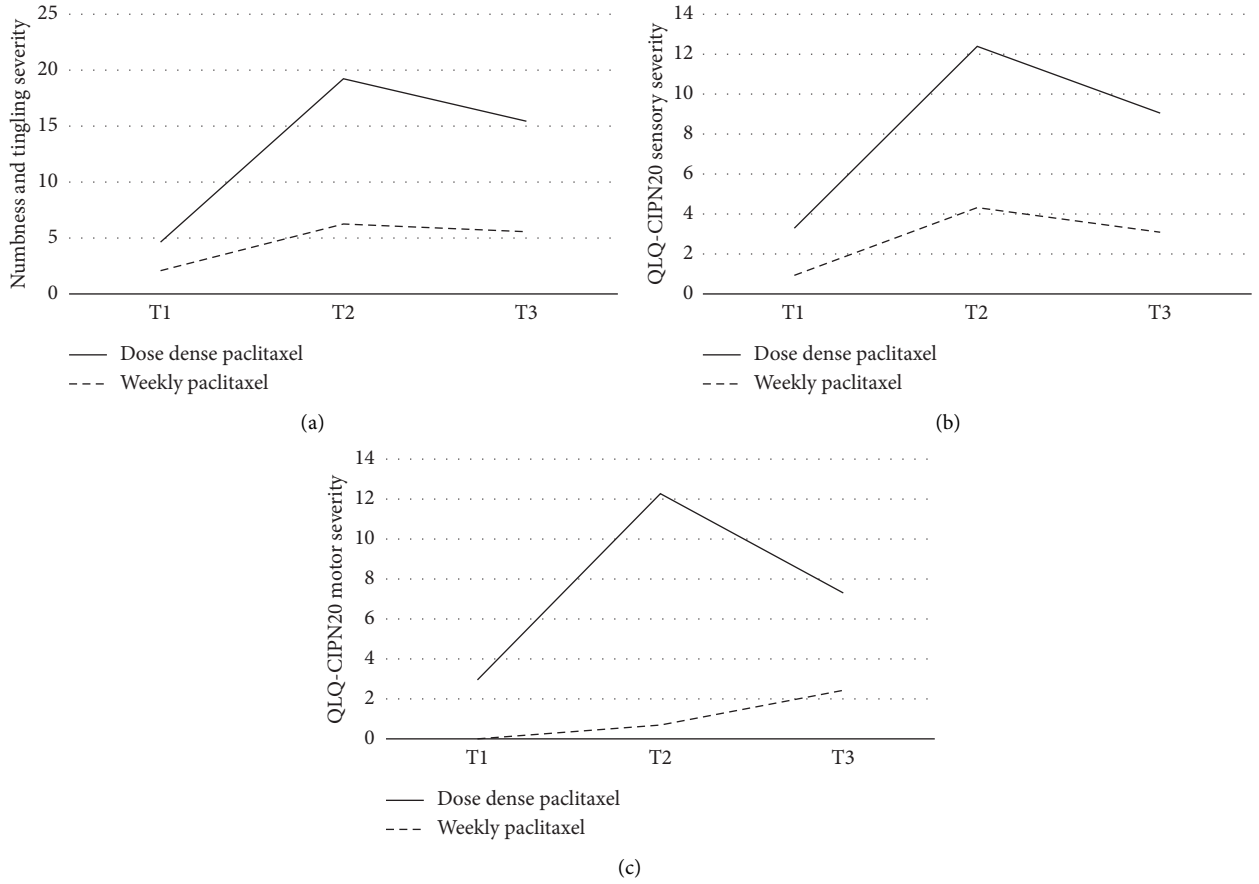

Figure 1: Chemotherapy-induced peripheral neuropathy severity scores among individuals receiving dose dense paclitaxel ($n = 27$) or weekly paclitaxel ($n = 12$) from T1 to T3. Figure 1 describes CIPN4 (panel (a)), QLQ-CIPN20 Sensory Subscale scores (panel (b)), and QLQ-CIPN20 Motor subscale scores (panel (c)) among individuals receiving dose dense paclitaxel or weekly paclitaxel from T1 to T3.

neuropathy severity beyond the end of treatment. Finally, body mass index (BMI) was not collected as part of this analysis. Given prior evidence suggesting that higher BMI may increase the risk of developing CIPN [26], future studies may include BMI as a potential covariate when examining neuropathy trajectories.

6. Conclusion

Study results demonstrated that women with breast cancer who received dose dense paclitaxel experienced greater CIPN severity than women receiving weekly paclitaxel, although the results were not statistically significant. The

results may be used to promote awareness among patients and clinicians regarding potential trajectories of CIPN symptoms during dose dense or weekly paclitaxel for women with breast cancer, but not guide treatment decisions. Overall, future research measuring CIPN using multiple subjective and objective measures and throughout paclitaxel administration in a larger sample of women with breast cancer is needed to further support our findings.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethics Statement

Study oversight and institutional review board approval was provided by the Dana-Farber/Harvard Cancer Center Office for Human Research Studies (19–862).

Consent

Informed consent was obtained from all individual participants included in the study.

Disclosure

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest

Robert Knoerl has received personal fees from the Comprehensive and Integrative Medicine Institute. Marlise R. Luskin has received research funding from Novartis and Abbive and serves on advisory boards for Pfizer, Novartis, and Jazz. The other authors declare no conflicts of interest.

Author Contributions

Robert Knoerl: investigation, methodology, formal analysis, writing–original draft, project administration, and funding acquisition; Emanuele Mazzola: formal analysis; Marilyn Hammer and Donna Berry: supervision. All authors contributed to writing–review and editing and conceptualization of the study.

Funding

Research reported in this publication was supported by the National Institute of Nursing Research of the National Institutes of Health (K23NR018689).

Acknowledgments

The authors would like to acknowledge Erica Fox, Barbara Halpenny, and Anna Tanasijevic for their assistance with participant screening and recruitment, data collection, and/or study management.

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