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PREVALENCE AND PREDICTORS OF CHEMOTHERPAY-INDUCED PERIPHERAL NEUROPATHY AMONG WOMEN WITH PRIMARY BREAST CANCER

Medical Surgical Nursing

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ABSTRACT

Background: Chemotherapy-induced peripheral neuropathy is the most troublesome adverse effect of certain chemotherapeutic drugs used to treat breast cancer. **Objectives:** The objective of the study was to explore the prevalence and predictors of chemotherapy-induced peripheral neuropathy in women with breast cancer who received chemotherapy. **Materials And Methods:** This hospital-based prospective cohort study was conducted among 307 women aged 30-70 years with histopathologically confirmed breast cancer stage I–III who received chemotherapy from a Comprehensive Cancer Centre in Kerala, India. Sociodemographic and clinical variables were examined to explore predictive factors. **Findings:** The mean age of the participants was 51.57±10.12 years. Invasive ductal carcinoma was predominant (96.1%) with a majority (55.4%) in breast cancer stage II. The prevalence of chemotherapy-induced peripheral neuropathy was 77.2% (n = 237). In the univariate analysis, being widowed/divorced/separated/single, advanced anatomical stage, ER receptor status, metastasis in the ipsilateral axillary lymph nodes, sentinel lymph node biopsy, sentinel lymph node scintigraphy, adjuvant chemotherapy, number of chemotherapy cycles, paclitaxel, docetaxel, cumulative doses of paclitaxel and docetaxel, and dose reduction were significantly associated with chemotherapy-induced peripheral neuropathy ($p<0.05$). In the multivariate analysis, paclitaxel (OR = 2.597, 95% CI = 1.402-4.811, p=0.002) had higher Odds for chemotherapy-induced peripheral neuropathy than docetaxel. Being widowed/separated/divorced/single (OR = 9.271, 95% CI = 1.187-72.421, p=0.034), chemotherapy cycles (OR = 70.544, 95% CI = 3.277–1518.693, p=0.007), and metastasis to the ipsilateral lymph nodes (OR = 2.087, 95% CI = 1.056-4.111, p=0.034) were the predictors of chemotherapy-induced peripheral neuropathy. **Conclusion:** The study findings indicate that paclitaxel and number of chemotherapy cycles are major risk factors for chemotherapy-induced peripheral neuropathy. CIPN has a profound effect on patients' QOL. Early identification of risk factors and implementation of early strategic plans are essential to improve QOL.

KEYWORDS

Chemotherapy-Induced Peripheral Neuropathy, Breast Cancer, Prevalence, Predictors.

INTRODUCTION

Breast cancer is the most common cancer in women worldwide, accounted for 2.3 million new cases and 670,000 deaths globally in 2022 [1,2]. Breast cancer is the most common cancer among women in Southeast Asia [3] and India ranked highest in the estimated female breast cancer deaths (68,337) [2] and accounted for 13.6% of all new cases of cancer in 2022 [4]. Breast cancer is diagnosed at a younger age in Indian women than Western countries [5].

Various chemotherapy classes such as taxanes, platinum-based drugs, vinca alkaloids, and bortezomib, used to treat cancer produce neurotoxic effects [6]. Taxanes are most commonly used for the treatment of breast cancer. A significant proportion of patients treated with neurotoxic chemotherapeutic drugs develop chemotherapy-induced peripheral neuropathy (CIPN). Almost 71% to 96% of patients receiving chemotherapy develop CIPN within one month.[7]. The prevalence of CIPN is high upon completion of chemotherapy, which gradually declines after weeks or months [8] or persist for years or are lifelong [9]. The prevalence of CIPN varies with the chemotherapeutic agent used, its dosage, duration [7], multidrug combinations, and pre-existing disease conditions.

The exact pathophysiological mechanisms underlying CIPN remain unclear. The mechanism by which chemotherapeutics cause CIPN is multifactorial and involves microtubule disruption, oxidative stress, mitochondrial damage, altered ion channel activity, myelin sheath damage, DNA damage, immunological processes, and neuroinflammation [10,11]. CIPN causes functional impairment and can affect patients' daily activities and may require dose reduction, delay, or even discontinuation [8,12], which has a profound effect on the treatment outcome and quality of life (QOL) of patients.

Peripheral neuropathy is more common among patients with breast cancer treated with paclitaxel than with docetaxel [13]. The typical presentation of CIPN is a symmetrical stocking-glove distribution pattern. CIPN manifest primarily as sensory, motor, and autonomic symptoms. Sensory symptoms include numbness, tingling or pins-and-needle sensation, neuropathic pain, burning, cramping, sensory loss in the hands and feet, trouble handling small objects and walking [6,12,13,14]. Motor neuropathy manifests as gait instability, difficulty in maintaining balance, or impaired fine motor skills, while autonomic nerve dysfunction results in symptoms such as constipation or diarrhoea, abnormal sweating, and orthostatic dizziness [12,14]. CIPN can be mild, reversible, severe or irreversible [8].

The risk factors for peripheral neuropathy include age, body mass index (BMI), cumulative chemotherapy drug dose, physical inactivity, hypertension, depression [12,14], alcohol use, pre-existing neuropathy, diabetes mellitus [14], taxane type, chemotherapy cycles, use of β-blockers and fatigue [12]. There is a lack of literature on CIPN in patients with breast cancer in India. We believe that this study would facilitate the development of targeted interventions and guidelines, thereby enhancing patient outcomes and QOL. This study aimed to explore the prevalence and predictors of chemotherapy-induced peripheral neuropathy among women with breast cancer who had received chemotherapy.

MATERIALS AND METHODS

Study Setting And Population

The present study is a hospital-based prospective cohort study conducted in the chemotherapy unit of a Comprehensive Cancer Centre of a tertiary care centre, Kerala, India. The study was conducted among 307 women who were histopathologically confirmed with breast cancer stage I-III who received chemotherapy. The calculated sample size was 303 based on the 73.0% prevalence rate reported by Simon et al. [15]. Women aged 30-70 years who were histopathologically confirmed with breast cancer stage I–III and scheduled for first cycle of chemotherapy were included and excluded women with metastatic breast cancer, baseline neuropathy, amputation of the extremity or part of the extremity, receiving palliative care or

received prior radiation.

Data Collection Instruments And Measurements

Data were collected using sociodemographic proforma and CIPN assessment tools. The symptoms of CIPN were collected through self-reports and interviews and treatment related data from electronic medical records. Sociodemographic and clinical data were collected before the commencement of chemotherapy, while CIPN symptoms were assessed before the commencement (baseline) and on the completion of chemotherapy.

Statistical Analysis

Categorical variables were presented as frequencies and percentages, and association between the variables by chi-square. Continuous data were summarized using means and standard deviations and logistic regression was used to explore the predictive factors. Statistical significance was set at p- < 0.05.

RESULTS

The prevalence of chemotherapy-induced peripheral neuropathy is 77.2% and the data are presented into CIPN and non-CIPN group (Fig 1).

I. Sample Characteristics

Table 1: Socio-demographic And Clinical Variables

Variables	Total f (%) 307 (100.0)	Groups f (%)	
		CIPN 237 (77.2)	Non-CIPN 70 (22.8)
Age group (years) Mean ± SD)	51.57 ± 10.12		
< 50	135 (44.0)	103 (43.5)	32 (45.7)
≥ 50	172 (56.0)	134 (56.5)	38 (54.3)
BMI - Mean ± SD	26.46 ± 11.30		
Normal	105 (34.2)	80 (33.8)	25 (35.7)
Pre-obesity	154 (50.2)	120 (50.6)	34 (48.6)
Obese Class I	37 (12.1)	30 (12.6)	7 (10.0)
Obese Class II & III	11(3.5)	7 (3.0)	4 (5.7)
Histological type			
Ductal carcinoma in-situ	2 (0.7)	1 (0.4)	1 (1.4)
Invasive ductal carcinoma	295 (96.1)	229 (96.6)	66 (94.3)
Lobular carcinoma	10 (3.2)	7 (3.0)	3 (4.3)
Anatomical staging			
Stage I	37 (12.0)	24 (10.1)	13 (18.6)
Stage II	170 (55.4)	129 (54.5)	41 (58.6)
Stage III	100 (32.6)	84 (35.4)	16 (22.8)
Hormone Status			
Estrogen receptor positive	203 (66.1)	149 (62.9)	54 (77.1)
Progesterone receptor positive	200 (65.1)	152 (64.1)	48 (68.6)
Hormone receptor positive	179 (58.3)		
HER2 positive	89 (30.0)	65 (27.4)	24 (34.3)
Triple negative	66 (21.5)	56 (23.6)	10 (14.3)
Luminal B	189 (61.6)	146 (61.6)	43 (61.4)

The participants had a mean age of 51.57±10.12, majority were married (90.2%), had pre-obesity (50.2%), and 15.6% were obese. Invasive ductal carcinoma (295, 96.1%) was the predominant type of breast cancer and 55.4% had stage II breast cancer. Immunochemistry findings favoured hormone positivity (66.1% ER-positive, 65.1% PR-positive, 58.3% hormone-receptor-positive), and 68.5% were Luminal B subtype (Table 1).

II. Prevalence Of Chemotherapy-Induced Peripheral Neuropathy

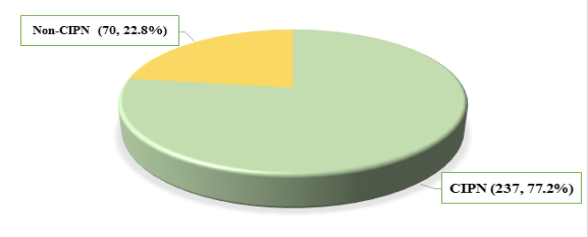

Fig 1: Prevalence of Chemotherapy-induced peripheral neuropathy among patients with breast cancer received Chemotherapy

The majority (182, 76.8%) of the patients who developed CIPN developed it between 4 and 8 weeks with a mean time of 5.063±1.439 weeks (Fig 2).

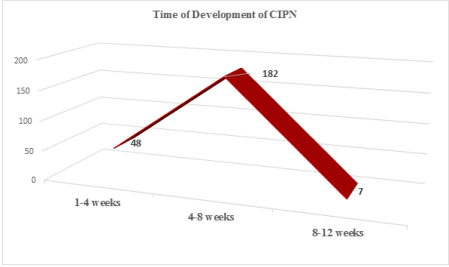

Fig 2: Development of CIPN in weeks

III. Association of Chemotherapy-Induced Peripheral Neuropathy with Sociodemographic and Clinical Variables

Table 2: Association of chemotherapy-induced peripheral neuropathy with sociodemographic variables

Variables	CIPN group (n = 237)	Non-CIPN (n= 70)	df	Chi square	p- value
Age (years)					
< 50	103	32	1	0.111	0.738
≥ 50	134	38			
Marital status					
Single/widowed/ separated/divorced	28	2	1	4.917	0.027*
Married	209	68			
BMI (Kg/m^2) [n= 306]					
< 25	78	25	1	0.264	0.607
≥ 25	159	44			

Table 3: Association Of Chemotherapy-induced Peripheral Neuropathy With Clinical Variables

Variables	CIPN group (n = 237)	Non-CIPN (n= 70)	df	Chi square	p-value
Anatomical stage					
Early stage (I, II)	153	54	1	3.897	0.048*
Advanced stage (III)	84	16			
ER- receptor status					
ER- negative	88	16	1	4.915	0.027*
ER- Positive	149	54			
PR- receptor status					
PR- Negative	85	22	1	0.468	0.494
PR- positive	152	48			
Axillary symptom					
No	215	56	1	5.996	0.020*
Yes	22	14			
Metastasis, IALN					
No	70	35	1	9.602	0.002**
Yes	163	35			
Metastasis, IMLN					
No	212	67	1	2.557	0.110
Yes	25	3			
Lymph Node Assessment					
SLNB					
No	152	34	1	8.202	0.004**
Yes	85	38			
SLSG					
No	168	37	1	7.202	0.007**
Yes	69	32			
Previous breast surgery					
No	99	17	1	7.029	0.008*
Yes	138	53			

ER – Estrogen receptor, PR – Progesterone receptor, LN – Lymph node, IMLN - Internal mammary lymph node; IALN –Ipsilateral

axillary lymph node, SLNB – Sentinel lymph node biopsy, SLSG – Sentinel Lymph Node Scintigraphy

Chemotherapy-induced peripheral neuropathy was significantly associated with marital status, anatomical stage, ER-receptor status, axillary symptoms, metastasis in the ipsilateral axillary lymph nodes, lymph node assessments sentinel lymph node biopsy and sentinel lymph node scintigraphy and prior breast surgery (Tables 2 and 3).

Table 4: Association Between Chemotherapy-induced Peripheral Neuropathy And Chemotherapy Related Variables

Variables	CIPN (n = 237)	Non-CIPN (n= 70)	df	χ^2	p-value
Line of chemotherapy					
Neo adjuvant	100	17	1	7.35	0.007**
Adjuvant	137	53			
No. of chemotherapy cycles					
Four	31	23	3	18.83	0.0003**
Six	54	17			
Eight	142	25			
Twelve	10	5			
No	87	40	1	9.30	0.002**
Yes	150	30			
Docetaxel					
No	147	30	1	8.13	0.004**
Yes	90	40			
Cumulative dose of					
Paclitaxel					
No paclitaxel	87	40	2	9.33	0.009**
≤ 1120	78	15			
> 1120	72	15			
Docetaxel					
No docetaxel	147	30	2	9.87	0.007**
≤ 540	44	22			
> 540	46	18			
Dose delay					
No	183	60	1	2.37	0.124
Yes	54	10			
Dose reduction					
No	117	61	1	11.03	0.0009**
Yes	60	9			

Chemotherapy-induced peripheral neuropathy was significantly associated with line of chemotherapy, number of cycles of chemotherapy received, paclitaxel, docetaxel, cumulative doses of paclitaxel and docetaxel and chemotherapy dose reduction. Variables with p<0.2 were retained and subjected to further analysis by multivariate logistic regression to explore predictors of CIPN.

IV. Predictors of Chemotherapy-Induced Peripheral Neuropathy

Table 5: Predictors of chemotherapy-induced peripheral neuropathy in Breast Cancer

Variables	OR	95% CI for OR		p- value
		Lower	Upper	
Paclitaxel	2.597	1.402	4.811	0.002**
Widowed/divorced/ separated/single	9.271	1.187	72.421	0.034*
No. of cycles of chemotherapy				0.057
Four	1.352	0.505	3.622	0.548
Six	70.544	3.277	1518.693	0.007**
Eight	3.970	0.735	21.442	0.109
Metastasis, ipsilateral axillary LN	2.087	1.059	4.111	0.034*
Neoadjuvant	0.433	0.198	0.944	0.035*

Paclitaxel (OR = 2.597, 95% CI 1.402-4.811), being widowed/separated/divorced/single (OR = 9.271, 95% CI 1.187-74.421, p=0.034), number of chemotherapy cycles (OR = 70.544, 95% CI 3.277–1518.693, p=0.007 for six cycles), and metastasis in the ipsilateral axillary lymph nodes (OR = 2.087, 95% CI 1.059-4.111, p=0.034) emerged as the most significant risk factors for CIPN. Paclitaxel had higher risk for CIPN than docetaxel and neoadjuvant chemotherapy had a lower risk of CIPN than did adjuvant chemotherapy in these patients.

DISCUSSION

CIPN affects a significant proportion of patients treated with chemotherapy, especially with taxanes and platinum agents. Various recent studies reported a higher prevalence of CIPN ranging from 60 to 87% [7, 8, 16, 17, 18, 19]. A narrative review reported the incidence of CIPN that varied from 11% to 85% [13]. The current study reports a prevalence as high as 77.2% in these women which is consistent with report of various studies. We performed a multivariable logistic regression analysis to determine the predictors of CIPN. The multivariable logistic regression identified that paclitaxel, being widowed/separated/divorced/single, an increase in the number of chemotherapy cycles, and metastasis to the ipsilateral axillary lymph nodes were strong independent predictors or risk factors for CIPN in breast cancer.

Studies reported factors such as the cumulative dose of chemotherapy [19], cumulative chemotherapy cycles [12] chemotherapy dose [14,19,20], diabetes[13,14,19], previous neuropathies, treatment schedule [19]were strongly associated with CIPN. In addition, taxane type [12,19,21], age [13,15,17, 20,21,22], obesity or elevated BMI [20,21,24], hypertension, physical activity level, and depression [13,14] were significantly associated with CIPN [14]. Smoking [19,22], inactivity [22], and pretreatment anaemia [13] also increased the risk for CIPN. There is no gold standard for evaluating the severity of CIPN symptoms [21]. A combination of objective, subjective, and clinical assessment methods are used for diagnosis. Several instruments are available and have been used to assess CIPN.

Limitation Of The Study

This was a single-centre study that included patients receiving different cycles of chemotherapy which might limit the generalizability of the results.

Future Consideration

Future studies are needed to develop and evaluate CIPN prevention and management strategies. Potential biomarkers must be identified to diagnose and predict CIPN.

CONCLUSION

Chemotherapy-induced peripheral neuropathy is a common and devastating adverse effect of chemotherapy which has a detrimental effect on the quality of life of patients with breast cancer. Various patient-, disease-, and treatment-related risk factors have contributed to its development. Therefore, early identification of risk factors will help to design further preventive and therapeutic strategies and enhance the QOL of patients.

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