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Falls in Persons with Chemotherapy Induced Peripheral Neuropathy

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Falls are a considerable health concern for older adults, including persons with cancer. The Centers of Disease Control report that falls are the leading cause of injury and death [1]. People who are receiving chemotherapy for cancer are more likely to fall compared to people who are not receiving cancer treatment [2]. Cancer diagnosis and treatment bring unique risks of falls. Problems associated with anemia, fatigue, pain and functional status all may contribute to fall risk [2,3].

Peripheral neuropathy is a major dose limiting side effect of many commonly used chemotherapy drugs including taxanes, platinum-based drugs, and vinca-alkaloids. The mechanisms of CIPN have not been clearly elucidated, and may vary with each neurotoxic agent [4]. Taxanes inhibit microtubule depolymerization leading to abnormalities in axonal mitochondria and acute sensory-motor neuropathies that often resolve within months after completion of chemotherapy [5,6]. Animal studies of paclitaxel related CIPN have demonstrated inflammation and vacuolation in the mitochondria of C-fibers and myelinated axons occurring as little as 7 days after paclitaxel administration [7]. Platinum based chemotherapies may be associated with the effects of oxidative stress on dorsal root ganglia [8,4,9]. Involvement of large myelinated nerve fibers results in delayed onset, predominantly sensory neuropathies [9].

Loss of sensation, loss of proprioception, and weakness in the muscles of the lower extremities are common signs and symptoms of peripheral neuropathy, regardless of etiology [10–13]. Diminished sensation and loss of neuromuscular control of the lower extremities may escalate to eventually interfere with balance and gait. Previous research has demonstrated that peripheral neuropathy is an under-recognized risk factor for falls [12]. Risk factors for falls in persons with chemotherapy induced peripheral neuropathy (CIPN) have not been previously studied. The purpose of this study is to evaluate possible risk factors for falls in a group of patients with CIPN. The following research questions guided this study:

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1. What differences in demographic and disease related characteristics, neuropathic symptoms and functional performance exist between fallers and non-fallers with CIPN?
2. What are the most significant risk factors for falls in persons with CIPN?

Review of Literature

Risk Factors for Falls in Persons Receiving Chemotherapy

Advancing age, fatigue, generalized weakness, muscle weakness and atrophy, anemia, and poor performance status increase the concern for falls in persons receiving chemotherapy [14,15]. Older adults aged 75 years and older are up to five times more likely to fall as compared to people aged 65 years or less [16]. Generalized weakness for people who are diagnosed with cancer can be influenced by factors such as anemia, fatigue, and muscle weakness. Anemia is a common complication associated with cancer and cancer treatment. Patients with anemia have less red blood cells and therefore less oxygen carrying capability resulting in tiredness or fatigue. Fatigue is related to fall risk and can be a prime factor in motivating falls [17]. Fatigue can lead to a general weakness and functional status problems which are also motivations for a fall [18].

Functional Status

Functional status is the ability to perform activities that are integral to independence [19]. An older adult who is diagnosed with cancer and is impaired in functional status has a greater risk of falls [2]. Persons who have difficulty performing activities such as bathing, dressing or transferring are more likely to fall and are more likely to be hospitalized [20] and are also more likely to become frail [21]. Functional status and not age is a reasonable indicator of cancer treatment tolerance [22]. Functional status is a valuable assessment measure that can help understand a more complete picture of health status as compared to a traditional patient assessment. Performance status is a clinical evaluation intended to provide an insight into understand how a person walks, balance, and other things such as grip strength. Performance status measures are often objective measurements such as the Timed Up & Go (TUG) Instrument [23] and grip strength measures [24]. People with poor grip are not only at risks for falls, but have an increased risk for mortality [24]. People diagnosed with cancer and undergoing cancer treatment may have occasions when performance status measures may not be as robust compared to a time when the patient was not undergoing cancer therapy. Occasions when patients are experiencing weakness resulting in problems with balance, gait or strength are prime opportunities for falls. As part of the oncology assessment, functional status concerns must be addressed in order to better predict falls and perhaps reduce the changes of serious injury in older adults receiving cancer treatment.

Risk Factors for Falls in Persons with Peripheral Neuropathy

Much of what is known about peripheral neuropathy and falls comes from the literature on diabetes and the research has primarily been conducted by researchers in physical therapy and rehabilitative medicine. Conservative gait pattern with decreased walking speed and

smaller step size are compensatory mechanisms that have been documented in individuals with peripheral neuropathy[25,26].

A previous study by Macgilchrist and colleagues (2010) sought to identify risk factors for falls in diabetics with peripheral neuropathy and identified decreased walking velocity, decreases strength of ankle dorsiflexors and severity of peripheral neuropathy as significant fall predictors[27]. Reduced leading toe-obstacle clearances leading to an increased risk of tripping over obstacles has also been observed in diabetics at risk for or having peripheral neuropathy [28]. Several studies have shown that physical activity including gait, balance, and resistance training may be useful in improving balance and reducing in people with peripheral neuropathy[10,29–32].

While this information has many implications for future research, few studies have included oncology patients and little is known about assessment, or management of fall risk in individuals with chemotherapy induced peripheral neuropathy (CIPN). Clinical trials of neurotoxic chemotherapy drugs have evaluated the frequency and severity of neuropathy as a side effect but stopped short of evaluating the effects of neuropathy on patient safety or fall risk[33–35]. While several studies have examined the negative impact of CIPN on physical performance, specific risk factors for falls in persons receiving neurotoxic chemotherapy have not been adequately addressed in the literature [36–39,28]. This study is one of the first to evaluate risk factors for falls in persons with CIPN.

Methods

Design, Sample, and Setting

This prospective, descriptive study included persons receiving paclitaxel, docetaxel, oxaliplatin or cisplatin, for treatment of any cancer. The sample was accrued at two sites, a large National Cancer Institute (NCI) designated Comprehensive Cancer Center in west central Florida and a private medical oncology practice in the same geographic area. To be included in this study patients had to 1) the able to speak and understand English; and 2) be between 18 and 90 years of age. 3) report at least one neuropathic symptom on the Chemotherapy Induced Peripheral Neuropathy Assessment Tool.

Instruments

Demographic Data Form

A demographic data form was developed for this study and included age, gender, race/ethnicity, education, marital status, income, years of formal education, employment status, type of cancer, type of chemotherapy, number of cycles of chemotherapy, and cumulative dose of neurotoxic agent. Information about chemotherapy drugs and doses was obtained by the researcher from the medical record.

Chemotherapy Induced Peripheral Neuropathy Assessment Tool

Neuropathic symptoms, functional status, and incidence of falls were measured using the Chemotherapy Induced Peripheral Neuropathy Assessment Tool [40]. The CIPNAT is a fifty item instrument that contains two sets of items; symptom experience items and interference

items. The 36 symptom experience items measure severity, distress, and frequency of nine neuropathic symptoms including; numbness in the hands, numbness in the feet, tingling in the hands, tingling in the feet, sensitivity to cold temperatures, nerve pain, muscle/joint aches, muscle weakness and loss of balance. Participants are first asked whether they have developed any of the nine symptoms since receiving chemotherapy. For each symptom reported, participants are asked to rate the intensity, distress, and frequency of that symptom on a 0–10 numeric rating scale. The symptom experience item set is scored by adding the number of symptoms reported (0–9) with the severity, distress, and frequency scores for each reported symptom. Scores range from 0–279 with higher scores corresponding with higher levels of CIPN.

The 14 interference items assess neuropathic interference with usual activities (functional status). These items ask participants to rate how much their symptoms interfere with the following activities; dressing, walking, picking up objects, holding onto objects, driving, working, participating in hobbies or leisure activities, exercising, sexual activity, sleeping, relationships with others, writing, household chores, and enjoyment of life. A scale of 0 (not at all interfering) to 10 (completely interfering) is used. Scores on the interference item set are calculated by adding scores and range from 0–140. Higher scores on the interference item set correspond with greater neuropathic interference with usual activities (poorer functional status). Correlations with a measure of the same or similar concept ($r = .83$, $p < .001$) and differences between contrasting groups ($t = 7.66$, $p < .001$) provided evidence of construct validity. High test-retest correlations ($r = .921$, $p < .001$) and Cronbach's alpha ($\alpha = .927$) provided evidence of reliability.

Two descriptive items were added to the CIPNAT to assess whether participants had sustained any injuries as a result of neuropathic symptoms. If they answered positively, they were then asked for a description of the injury. Patients who reported falls were classified as fallers and those who reported no injury or non-fall related injuries were classified as non-fallers.

Procedures

The study was approved by the Protocol Research Monitoring Committee at the Cancer Center and the IRB of the University of South Florida. Patients were invited to participate during a regularly scheduled visit to the infusion center. The study was explained, questions answered, and the consent signed before data collection began. Patients completed the Chemotherapy Induced Peripheral Neuropathy Assessment Tool (CIPNAT) and demographic data form. Information on type of cancer, type of chemotherapy, number of cycles of chemotherapy, and cumulative dose of neurotoxic agent were obtained from the medical record.

Data analysis

For the purpose of analyzing differences in falls between classes of chemotherapy, participants receiving taxanes (paclitaxel and docetaxel) were grouped together and participants receiving platinum based chemotherapies (cisplatin and oxaliplatin) were grouped together. To analyze differences in falls between stages of disease, cancer stages I

and II were grouped together as early stage and cancer stages III, IV or extensive were grouped together as late stage.

All data was analyzed using the Software Package for the Social Sciences version 17. Demographic data are presented as frequencies and means and standard deviations. In univariate analyses, mean values of demographic, treatment, and neuropathic symptom variables were compared between fallers (n=21) and non-fallers (n=88) by use of student *t*-tests and Mann-Whitney U tests. Similarly, chi-square tests were used to compare percentages of drug class and disease stage between fallers and non-fallers. Variables identified as statistically significant in univariate analyses were used in a forward stepwise logistic regression model to identify factors independently associated with falling. A p-value of < 0.05 was used to define statistical significance for all analyses.

Results

Sample

The sample consisted of predominantly Caucasian participants with solid tumors in stage III or IV (Table 1). The majority were married (66.1%) and female (63.3%). Participants represented a diverse range of incomes. The mean age was 58.4 (SD=11.8) and participants reported a mean of 14.1(SD=2.6) years of formal education. They had received a mean of 5.6 (SD=5.1) cycles of chemotherapy with mean cumulative doses of 544.4(SD=722.7) of neurotoxic chemotherapy drug.

Differences Between Fallers and Non-Fallers

In this sample, 19.3% (n=21) of participants reported at least one fall since beginning chemotherapy. Fallers had received higher cumulative doses of chemotherapy, had a significantly higher number of neuropathic symptoms (p=.016), higher total scores on the entire CIPNAT(p=.001) as well as both the symptom experience (p=.005)and interference items of the CIPNAT (p=.001), more severe muscle weakness (p<.001) and loss of balance (p<.001), and higher interference with walking (p<.001) and driving (p=.022) (Table 2). Participants who received a taxane (paclitaxel or docetaxel) were more likely to have fallen (p=.022) than those who had received a platinum based chemotherapy drug (cisplatin or oxaliplatin) (Table 3). No significant differences between fallers and non-fallers in age, gender, stage of disease, or other demographic characteristics were detected.

Fall Predictors

In logistic regression analyses, loss of balance (odds ratio=1.45, p=0.005) and cycle number (odds ratio=1.33, p=0.04) were independently associated with falling, whereas interference with walking (odds ratio=1.28, p=0.06) and taxane drug class (odds ratio=10.14, p=0.07) were borderline significant (Table 4). The confidence interval for the estimated effect of taxane drug class (0.84 – 122.1) was very wide due to only 3 fallers in the platinum drug class group.

Discussion

This study identifies potential risk factors for falls in persons with chemotherapy induced peripheral neuropathy including cumulative dose and cycle number, severity of loss of balance, severity of muscle weakness, self reported interference with walking or driving, number of neuropathic symptoms, severity of CIPN, and performance status. Patients receiving taxanes may be at higher risk for falls during chemotherapy than patients receiving platinum based chemotherapy drugs.

Significant differences in muscle weakness and loss of balance existed between fallers and non-fallers. Patient reported loss of balance was a significant predictor of falls in this study. Muscle weakness and loss of balance are frequently overlooked symptoms of CIPN that should be routinely assessed in individuals receiving neurotoxic chemotherapy. Patients in this study provided self-report of neuropathic symptoms and interference with activities. Asking patients about muscle weakness and loss of balance may be useful methods for assessing for fall risk and should be combined with objective measures of strength and balance such as gait observation, Romberg testing, Timed Up & Go, and grip strength testing. This study used self-report to measure functional status. Objective measures of functional status should be incorporated into future studies evaluating fall risk in persons with CIPN.

Previous studies have demonstrated that the risk of developing neuropathy increases with escalating cumulative doses and cycles of chemotherapy [41–43]. This study suggests that the risk of falls increases with cumulative doses and chemotherapy cycles and that persons with higher peripheral neuropathy scores are at higher risk of falls. Fallers scored significantly higher on the CIPNAT, including number of symptoms, symptom experience items, and interference items than did non-fallers. Assessment of CIPN using a reliable and valid self-report tool may be helpful in identifying patients at risk for falls.

The majority of patients in this study had advanced stages of cancer, which may have contributed to the insignificant difference in disease stage between fallers and non-fallers. Future studies should include larger sample sizes and include more patients with early stage disease. The lack of significant differences in age between fallers and non-fallers suggest that older individuals may tolerate neurotoxic chemotherapy as well as younger ones. This supports the findings of previous research demonstrating that older adults have a similar risk of developing CIPN than their younger counterparts and among those that do develop neuropathy, the severity levels are similar between older and younger patients [44].

Finally this study suggests that patients receiving taxanes may be at a higher risk of falling during chemotherapy than patients receiving platinum based drugs. CIPN symptoms may vary based upon which neurotoxic chemotherapy drug(s) are given [45]. The sample size did not allow for comparison by neurotoxic drug alone. Future research should include comparisons between individual drugs, especially because neuropathic symptoms vary according to both drug class and individual drug being used.

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Table 1

Frequencies and percentages of demographic variables (n=109)

Variable	Frequency	Percentage
Gender		
Female	69	63.3
Male	40	36.7
Marital Status		
Married	72	66.1
Divorced	13	11.9
Single	11	10.1
Widowed	10	9.2
Separated	3	2.8
Income		
Less than 25,000 yr.	24	22.0
25–50,000 yr	24	22.0
50–75,000 yr	16	14.7
Over 75,000 yr	24	22.0
Prefer not to answer	21	19.3
Race or Ethnicity		
White/Caucasian	92	84.4
Hispanic	7	6.4
African American	6	5.5
Asian	2	1.8
American Indian/Alaska Native	2	1.8
Cancer Type		
Breast	24	22.0
Colon	31	28.4
Lung	16	14.7
Ovarian	8	7.3
Prostate	7	6.4
Pancreatic	4	3.7
Esophageal	2	2.8
Other	15	13.8
Cancer Stage		
1	4	3.7
2	11	10.1
3	30	27.5
4	56	51.4
Extensive	2	1.8
missing	6	5.5
Employment status		
Full-time	21	19.3

Variable	Frequency	Percentage
Part-time	4	3.7
On leave of absence	13	11.9
Retired	39	35.8
Disabled	25	22.9
Unemployed	5	4.6
Self-employed	1	0.9
Full-time student	1	0.9

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Table 2

Differences between fallers and non-fallers

Variable	Group	N	Mean	SD	t	p																																																																																																												
Age	Non-fallers	88	58.3	11.4	-2	.860																																																																																																												
	Fallers	21	58.9	13.3			Cycle number	Non-fallers	85	4.7	2.9	N/A	.074	Fallers	16	10.4	9.7	Cumulative dose	Non-fallers	85	473.9	668.0	N/A	.045*	Fallers	18	877.1	887.2	Number of Neuropathic Symptoms	Non-fallers	88	4.4	2.2	-2.5	.016*	Fallers	21	5.6	1.9	CIPNAT score	Non-fallers	87	99.1	62.5	6.7	.001*	Fallers	21	166.7	69.9	-3.8	Total Interference (CIPNAT)	Non-fallers	87	29.0	24.2		.001*	Fallers	21	55.5	29.1	Total Symptom Experience (CIPNAT)	Non-fallers	88	70.0	45.7	-3.0	.005*	Fallers	21	106.1	50.2	Muscle Weakness (severity)	Non-fallers	88	2.3	3.0	-4.4	<.001*	Fallers	21	6.0	3.6	Loss of Balance (severity)	Non-fallers	88	1.7	2.4	-5.2	<.001*	Fallers	21	5.8	3.4	Interference with walking	Non-fallers	87	2.2	3.1	-5.9	<.001*	Fallers	21	6.1	2.6	Interference with driving	Non-fallers	87	1.5	2.8	-2.4	.022*	Fallers
Cycle number	Non-fallers	85	4.7	2.9	N/A	.074																																																																																																												
	Fallers	16	10.4	9.7			Cumulative dose	Non-fallers	85	473.9	668.0	N/A	.045*	Fallers	18	877.1	887.2	Number of Neuropathic Symptoms	Non-fallers	88	4.4	2.2	-2.5	.016*	Fallers	21	5.6	1.9	CIPNAT score	Non-fallers	87	99.1	62.5	6.7	.001*	Fallers	21	166.7	69.9	-3.8	Total Interference (CIPNAT)	Non-fallers	87	29.0	24.2		.001*	Fallers	21	55.5	29.1	Total Symptom Experience (CIPNAT)	Non-fallers	88	70.0	45.7	-3.0	.005*	Fallers	21	106.1	50.2	Muscle Weakness (severity)	Non-fallers	88	2.3	3.0	-4.4	<.001*	Fallers	21	6.0	3.6	Loss of Balance (severity)	Non-fallers	88	1.7	2.4	-5.2	<.001*	Fallers	21	5.8	3.4	Interference with walking	Non-fallers	87	2.2	3.1	-5.9	<.001*	Fallers	21	6.1	2.6	Interference with driving	Non-fallers	87	1.5	2.8	-2.4	.022*	Fallers	21	3.9	4.3								
Cumulative dose	Non-fallers	85	473.9	668.0	N/A	.045*																																																																																																												
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Table 3

Chi-square for differences between fallers and non-fallers in chemotherapy type and disease stage.

	Non-Fallers	Fallers	Total	Sig.
Drug Class				
Platinum Drugs (cisplatin and oxaliplatin)	38	3	41	.022*
Taxanes (paclitaxel and docetaxel)	50	18	68	
Disease Stage				
Early stage (Stage 1 or 2)	14	1	15	.292
Late Stage (Stage 3, 4, or extensive small cell lung cancer)	69	19	88	

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Table 4

Summary of Bivariate Regression Analysis of Fall Prediction

Variable	Adjusted Odds Ratio	95% CI	P value
Cycle number	1.33 (per 1 unit)	1.01–1.75	.04*
Loss of Balance	1.45 (per 1 unit)	1.12–1.88	.005*
Interference with walking	1.28 (per 1 unit)	.99–1.64	.057
Drug class	10.14 (taxane vs. platinum)	.84–122.13	.068

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