Incidence and risk factors associated with falls among women with breast cancer during taxane-based chemotherapy

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Abstract
Purpose This study aims to evaluate the falling incidence density and examine the potential risk factors associated with falling among women with breast cancer during taxane-based chemotherapy.
Methods One hundred and twenty-three women with breast cancer participated in this study. The fall incidence density, taxane-induced peripheral neuropathy (TIPN) symptoms, and physical performance tests were evaluated at five time points throughout chemotherapy treatment. A fall diary was used to record fall incidence during treatment. The fall incidence density was calculated by dividing the number of first fall occurrences by person-time at risk. The risk factors associated with time to first fall were analyzed using the Cox proportional hazards model. The Kaplan-Meier curve illustrated the probability of survival from a fall during chemotherapy treatment.

Results Over the course of treatment, 29 (23.58%) participants reported falls. The fall incidence density was 3 per 1000 person-day. This study discovered a significant link between age (adjusted HR (HRadj) = 1.07; 95% CI: 1.02–1.13) and BMI (HRadj = 1.11; 95% CI: 1.02–1.21) and falling.

Conclusions Women with breast cancer could fall for the first time at any time after starting chemotherapy until the end of the follow-up period. Furthermore, time to first fall was associated with age and BMI. Early detection of falling in women with breast cancer, particularly among older persons and those with a high BMI, may be essential to preventing falls.

Keywords Breast cancer · Fall incidence density · Physical performance test · Taxane-based chemotherapy

Introduction
Breast cancer is one of the most frequently diagnosed malignancies in the world [1]. The incidence rate of breast cancer has risen dramatically in recent years [2]. Women with breast cancer who have undergone chemotherapy and/or hormonal therapy face a significant risk of falling, falling injuries, and higher expenses for medicine and health treatment as a result [3, 4].

The most common agent suggested for early, as well as advanced, stages of treatment is taxane-based chemotherapy [5]. However, a common adverse effect of taxane-based chemotherapy treatment is taxane-induced peripheral neuropathy (TIPN) symptoms [6]. Several studies have suggested that TIPN symptoms from breast cancer treatment are associated with physical performance impairments and an increased risk of falling [7–9]. For patients with cancer undergoing chemotherapy, falling can cause severe injuries, decreases in function, and higher mortality [4, 10, 11]. The risk of falling among older adults with cancer was higher when compared to cancer-free older individuals (adjusted odds ratio 1.16; 95% CI: 1.02–1.33) [12]. Several important factors increased the risk of falling, including age, obesity, and TIPN symptoms, as well as the number of cycles in chemotherapy, balance, and poor physical performance [9, 13]. Impaired physical performance can be linked to
decreased functionality, which is associated with fall risk [14]. Many studies have shown that, in addition to having a greater risk of falls, patients undergoing neurotoxic chemotherapy are physically impaired such as mobility, endurance, and gait [15–18].

Although a recent systematic review found that several studies have investigated falls in patients with different cancers receiving neurotoxic chemotherapy drugs, the majority of the studies were retrospective [19]. There have been few prospective longitudinal studies that revealed falling risk. Further, there is a lack of evidence on fall incidence density and the risk factors for falls among patients with breast cancer who underwent taxane-based treatment. The objectives of this study were to determine the incidence density of falling among women with breast cancer who received taxane-based chemotherapy and to investigate the possible risk factors associated with the length of time for falls to occur. We expected that falling among women with breast cancer undergoing taxane-based chemotherapy would have occurred after the first treatment cycle.

Materials and methods

Design and setting

This prospective cohort study utilized convenience sampling of women with breast cancer who received taxane-based chemotherapy. The study was performed to explore the incidence density of falls and evaluate the association between patients’ characteristics, chemotherapy schedules and regimens, TIPN symptoms, and physical performances. The participants were recruited from the National Cancer Institute of Thailand, King Chulalongkorn Memorial Hospital, and Bhumibol Adulyadej Hospital in Thailand between October 2020 and July 2021.

Participants

One hundred and twenty-three women with breast cancer participated in this prospective cohort study. The study protocols were approved by the Ethics Review Committee for Research Involving Human Projects, Chulalongkorn University (COA No. 209/2020), National Cancer Institute of Thailand (COA No. 025/2020), King Chulalongkorn Memorial Hospital (COA No. 001/2021), and Bhumibol Adulyadej Hospital (under study ID: 13/63) before data collection.

The inclusion criteria were (a) between 35 and 65 years of age, (b) confirmed breast cancer diagnosis, (c) plan to receive taxane-based chemotherapy or had received equal to or less than 3 cycles of taxane-based chemotherapy with no signs of TIPN, and (d) good communication skills, as well as the ability to understand the Thai language. Participants were excluded if they had a musculoskeletal or neurological condition with peripheral neuropathic signs, had received other neurotoxic chemotherapy agents, or had already fallen before the study started.

Procedures

To assess the fall incidence density and related fall factors, a longitudinal prospective study was conducted. Before participating in the study, all participants were informed of the study aims and testing procedures, after which informed consent was acquired. The fall incidence and factors associated with time to fall were measured five times: (1) before chemotherapy was initiated to create a baseline, (2–4) before each chemotherapy cycle began, and (5) within 30 days after the final chemotherapy cycle was received.

Fall incidence density

Fall incidence density was the outcome of interest in the current study. A fall was described as an occurrence that led to an inadvertent rest on the ground or any other lower level not caused by an intrinsic event (like stroke) or overwhelming threat [20]. A fall included trips and slips, as defined in previous research [21]. At the beginning, each participant and caregiver was given a detailed description of a fall. In addition, participants were given a diary and told to record their falls throughout the study period. Then, the researcher gathered the fall diary at each measuring point. Participants were prompted to always report falls in the diary by weekly telephone calls. The first time a participant fell was utilized to compute the fall incidence density [22]. In addition, the report of at least one fall was further used to classify participants into faller and non-faller subgroups.

TIPN symptoms measurement

All participants reported TIPN symptoms with the EORTC QLQ-CIPN20 questionnaire. The EORTC QLQ-CIPN20 self-reported questionnaire included 20 items that assessed chemotherapy-induced peripheral neuropathy, including TIPN symptoms. Each item was rated on a 4-point scale (1 = “not at all,” 2 = “a little,” 3 = “quite a bit,” 4 = “very much”), with higher scores indicating a higher severity of TIPN symptoms [23]. Many studies determined that the self-reported questionnaire was valid and reliable to evaluate peripheral neuropathy complications from neurotoxic agents [23–25]. In this study, participants were identified with TIPN symptoms if they reported sensations of numbness or tingling in their fingers/toes in four items [26] at any of the time points. Participants were then allocated into
two subgroups, those with and without TIPN symptoms, for further analysis.

Physical performance test

All participants were asked to complete physical performance tests, including the Romberg test, the sharpened Romberg test, the unipedal stance test, and the 30-s chair stand test after completing the self-reported questionnaire. The order of the physical performance tests was randomized by drawing lots. For the Romberg test, participants were asked to stand with their feet approximately 6–8 in. apart with their hands at their sides. Then, they were told to close their eyes and stand still for 60 s. The timer was stopped if participants opened their eyes or lost their balance [27]. For the sharpened Romberg test, participants were asked to stand in a tandem position with one leg in front of the other and their hands at their sides. Then, they were instructed to close their eyes and stand still for 60 s. Again, the timer was stopped if participants opened their eyes or lost their balance [28]. For the unipedal stance test, participants were asked to stand on a preferred leg without support and to remain still for 30 s. The timer was stopped when a raised leg touched down or balance was lost [29]. For the 30-s chair stand test, participants had to sit in the center of a chair with their arms crossed, feet flat on the floor, and back straight. When participants were instructed with “ready to go,” the participants then stood up and sat down as many times as they could in 30 s [30]. Three trials per physical performance test were conducted. The average values were used for analysis.

Data analysis

Data were analyzed using SPSS Statistics version 23 for Windows (IBM, Armonk, NY). The data were tested for normality using the Kolmogorov-Smirnov test. Demographic characteristics data were presented as frequencies, median, interquartile range, mean, and standard deviation. The differences in demographic characteristics at baseline between faller and non-faller were evaluated using t-tests and Mann-Whitney U tests for continuous data with normal and non-normal distribution, respectively. Only age, weight, height, BMI, and cumulative dose were distributed normally. In addition, the χ² test or Fisher’s exact test was used to compare the categorical data for demographic characteristics at baseline. Only the line of therapy and regimen were tested with the χ² test.

Fall incidence density referred to the probability of fall occurrence among women with breast cancer during taxane-based chemotherapy treatment. The fall incidence density is the number of first fall occurrences divided by the total person-day at risk. The days of observation were computed from the day of enrolment to the date of the first fall, loss of follow-up, death, or the trial’s conclusion. The Cox proportional hazards model was performed to determine the association between the risk factors of interest and the time to first fall and then reported as an unadjusted hazard ratio (HR) with a 95% confidence interval (CI). First, the model fit time to first fall with the risk factors of interest, including personal characteristics (age and BMI), chemotheraphy condition (line of therapy and cumulative dose), number of drugs taken in 1 day, TIPN symptoms, and physical performance (measured by the Romberg test, sharpened Romberg test, unipedal stance test, and 30-s chair stand test). Age and BMI (p < 0.05), and number of drugs taken in 1 day (as known clinical relevance with fall) [31] were revealed as potential confounding factors. Next, in the multivariate analysis, a backward stepwise elimination strategy with an entry p-value of 0.05 and an exclusion p-value of 0.1 in the final model was utilized. The factors with a p-value smaller than 0.05 and factors of known clinical relevance to falls were considered potential confounding factors and used for the adjustment in the next step. In addition, time to first fall was shown as the function of time by the Kaplan-Meier (KM) curve. The log-rank test was used to compare the survival function of falls between women with breast cancer who were with and without TIPN symptoms. The significance level was set at p < 0.05.

Results

Demographic characteristics

A total of 262 women with breast cancer who received taxane-based chemotherapy were invited to enroll in this study. One hundred and twenty-seven women with breast cancer met the inclusion criteria. Four women dropped out of the study because they only attended a one-time point of measurement. Thus, one hundred and twenty-three women with breast cancer participated in the study. The median follow-up was 63 (42–93) days. Table 1 presents the demographic and clinical characteristics of participants. The results showed that 29 participants reported falls (fallers), and 94 participants did not report any falls (non-fallers) over the course of 3 months of taxane-based chemotherapy treatment. Significant differences in age, height, and BMI between faller and non-faller groups were observed at baseline. In addition, significant differences in the 30-s chair stand test results were observed between faller and non-faller groups both at baseline and at the end of the study. About two-thirds of the participants who fell did so at home (n = 21, 72.41%), with about one-third tripping on the stairs, one-fourth falling in the bedroom, and the largest percentage falling in the
bathroom. While one-third of the fallers fell outdoors, the majority of these slipped or tripped on the street (Table 2).

According to the inclusion criteria, the number of participants was different at each time of measurement, which was 79, 104, 114, 110, and 97 before the 1st, 2nd, 3rd, and 4th chemotherapy cycles, and within the 30-day follow-up, respectively. The highest percentage of participants who reported their first fall occurrence was during the 30-day follow-up (8.2%). That percentage also increased before receiving the 2nd, 3rd, and 4th chemotherapy cycles (Fig. 1a). Similarly, the percentage of participants who reported TIPN symptoms progressively increased before receiving the 2nd cycle through the 4th cycle. The greatest percentage of participants reported TIPN symptoms before receiving the 4th cycle (75.5%) (Fig. 1b). For the physical performance, a change in the median score was found for the 30-s chair stand test before receiving the 2nd, 3rd, and 4th cycles (Fig. 1c).

For severity of TIPN symptoms, participants reported the severity of TIPN symptoms using the EORTC QLQ-CIPN20 questionnaire. In the beginning, all participants reported “not at all” (100%). However, before receiving the 2nd cycle, about half of the participants indicated that their TIPN symptoms were “a little.” Before receiving the 3rd cycle and the 30-day follow-up, the TIPN symptoms worsened progressively (Fig. 2).

### Table 1 Demographic and clinical characteristics of the participants

| Characteristics                          | Total (n = 123) | Fallers (n = 29) | Non-fallers (n = 94) | p-value |
|------------------------------------------|-----------------|-----------------|----------------------|---------|
| **Baseline**                             |                 |                 |                      |         |
| Age (years), mean (SD)                   | 50.11 (9.04)    | 54.00 (7.09)    | 48.91 (9.27)         | 0.01*   |
| Weight (kg), mean (SD)                   | 60.67 (12.17)   | 62.04 (11.80)   | 60.24 (12.32)        | 0.48    |
| Height (cm), mean (SD)                   | 155.76 (6.47)   | 152.81 (4.84)   | 156.66 (6.66)        | 0.001*  |
| BMI (kg/m²), mean (SD)                   | 24.94 (4.39)    | 26.49 (4.37)    | 24.46 (4.30)         | 0.03*   |
| Line of therapy, n (%)                   |                 |                 |                      | 0.06    |
| Adjuvant                                 | 94 (76.40)      | 26 (89.65)      | 68 (72.34)           |         |
| Neoadjuvant                              | 29 (23.60)      | 3 (10.35)       | 26 (27.66)           |         |
| Number of drugs taken in 1 day, n (%)    |                 |                 |                      | 0.10    |
| None                                     | 76 (61.80)      | 13 (44.83)      | 63 (67.02)           |         |
| 1                                        | 22 (17.90)      | 6 (20.70)       | 16 (17.01)           |         |
| 2                                        | 17 (13.80)      | 8 (27.59)       | 9 (9.56)             |         |
| 3                                        | 6 (4.90)        | 1 (3.44)        | 5 (5.31)             |         |
| 4                                        | 2 (1.60)        | 1 (3.44)        | 1 (1.10)             |         |
| TIPN symptoms, n (%)                     | 0 (0.0)         | 0 (0.0)         | 0 (0.0)              | 1.00    |
| **Physical performance, median (interquartile range)** |
| Romberg test                             | 60 (60–60)      | 60 (60–60)      | 60 (60–60)           | 1.00    |
| Sharpened Romberg test                   | 60 (60–60)      | 60 (32.75–60)   | 60 (60–60)           | 0.29    |
| Unipedal stance test                     | 30 (30–30)      | 30 (30–30)      | 30 (30–30)           | 0.65    |
| 30-s chair stand test                    | 16 (13–20)      | 14 (10–16)      | 17 (13.25–20)        | 0.03*   |
| **End of the study**                     |                 |                 |                      |         |
| Cumulative dose (mg), mean (SD)          | 1125.34 (278.56)| 1199.51 (278.07)| 1102.46 (276.17)     | 0.11    |
| TIPN symptoms, n (%)                     | 110 (89.43)     | 26 (89.65)      | 84 (89.36)           | 0.96    |
| No-TIPN                                  | 13 (10.57)      | 3 (10.35)       | 10 (10.64)           |         |
| **Physical performance, median (interquartile range)** |
| Romberg test                             | 60 (60–60)      | 60 (60–60)      | 60 (60–60)           | 0.06    |
| Sharpened Romberg test                   | 54 (30–60)      | 45 (22.50–60)   | 56 (33–60)           | 0.12    |
| Unipedal stance test                     | 30 (27–30)      | 30 (16–30)      | 30 (28–30)           | 0.09    |
| 30-s chair stand test                    | 12.67 (10.67–15.50)| 11.33 (10–14.13)| 13.13 (11–15.85)     | 0.04*   |

*Statistically significant
Incidence density of falls

Out of the total number of 123 participants, 29 participants (23.58%) reported falls. Moreover, the fall incidence density was 3 per 1000 person-day, or 3 per 1000 persons who fell in the course of 1 day of observation.

Risk factors associated with time to first fall

The results demonstrated a significant association between time to first fall and potential fall risk factors, including age, BMI, and number of drugs taken in 1 day. Finally, after adjustment for potential fall risk factors, the results demonstrated a significant association between time to first fall and age and BMI (HRadj = 1.07; 95% CI: 1.02–1.13, \( p = 0.01 \) and HRadj = 1.11; 95% CI: 1.02–1.21, \( p = 0.01 \)) (Table 3).

The rate of participants who were non-faller overall and according to TIPN symptoms

Figure 3 demonstrates the probability of first fall occurrence during 3 months of chemotherapy treatment among participants, with and without TIPN symptoms. Based on the survival analysis and KM curve, the overall rate of participants who were non-faller was 76.4%. In addition, the overall rates of participants with or without TIPN symptoms were 74.5% and 85.7%, respectively. There were no statistically significant differences in the probability of fall occurrence between participants who had TIPN symptoms and those without TIPN symptoms (\( p < 0.17 \)).

Discussion

This study was the first to evaluate the fall incidence density among women with breast cancer treated with taxane-based chemotherapy. The results showed that 29 participants (23.58%) reported falls over the course of 3 months. The fall incidence density was 3 per 1000 person-day over the course of taxane-based chemotherapy treatment. Significantly, age and BMI were found to be relevant factors in fall incidence density.

Another important finding is that the initial fall occurred after the first round of taxane-based chemotherapy and continued throughout treatment. The possible cause might be related to an alteration in postural stability. However, no association between the Romberg and sharpened Romberg tests and falls was found in the current study. These findings were in contrast to previous studies that evaluated postural stability among women with breast cancer using laboratory testing for postural control, such as the sensory organization test (SOT) and center of pressure (COP) [16, 32]. Those results showed that women with breast cancer who had taxane-based treatment would have problems controlling their postural stability. One possible explanation for this might be that the static balance tests used in the current study may be insufficiently sensitive and specific to assess the changes in postural stability in women with breast cancer who were in the chemotherapy program. Previously, the postural stability assessments with computerized devices such as center of pressure (COP) [33], as well as the more complex use of sensory organization, have been recommended for assessing decreased postural control in patients with various conditions [34, 35]. In addition, the previous study suggested that individuals with severe TIPN symptoms had a lower Romberg test score [27, 36].

Previous research revealed that there was a link between the unipedal stance test and the 30-s chair stand test [29, 37]. In the current investigation, however, no link was discovered between the unipedal stance test and the 30-s chair stand test and falling. The severity of TIPN symptoms could be one explanation for these findings. The majority of the participants in this study had mild to moderate symptoms, with none reporting severe symptoms. A high-severity neuropathy symptom has been associated to poor physical performance, disability, and a higher risk of falling [18].

Our results found no statistically significant differences in the probability of fall occurrence between participants who had TIPN symptoms and those without TIPN symptoms. One possible explanation for these results may be whether TIPN symptoms were detected when individuals reported sensory neuropathy symptoms in their fingers/toes but did
Fig. 1 The percentage of participants who reported (a) the first fall, and (b) TIPN symptoms, as well as the median scores of (c) 30-s chair stand test before the 1st, 2nd, 3rd, and 4th chemotherapy cycles, and within the 30-day follow-up.

Fig. 2 The severity of TIPN symptoms among women with breast cancer before each chemotherapy cycle.
not report motor neuropathy symptoms. Motor neuropathy appears to be linked to a higher chance of falling [11].

The present study also found that most fall patients fell at home compared to outside; falls at home usually involved stairs and bathrooms. Our results were consistent with a previous study that suggested most patients with cancer (75%) who fell did so at home [38]. However, the results differed from the previous study where it suggested that the fall rate in older patients with cancer was similar in the home and outside [39]. The difference in results may relate to participant gender since the majority of the participants in the latter study were males engaging in intense physical activities such as hiking, tennis, and running, therefore increasing the risk of outdoor falls.

Moreover, a systematic review study suggested that home assessment and home modification interventions were linked to reduced fall risks [40]. Similar to previous studies, the causes of falls in most patients who had undergone neurotoxic chemotherapy included tripping or slipping while walking, muscle weakness, and loss of balance [4, 38]. These findings indicated that healthcare providers should be educated concerning basic hazards in home environments.

| Table 3 Cox multivariate model for factors associated with falls |
|---------------------------------|-----------------|-----------------|-----------------|
|                                 | Unadjusted HR (95% CI) | p-value | Adjusted HR (95% CI) | p-value |
| Age                             | 1.06 (1.01–1.11) | 0.01* | 1.07 (1.02–1.13) | 0.01* |
| BMI                             | 1.10 (1.01–1.20) | 0.02* | 1.11 (1.02–1.21) | 0.01* |
| Line of therapy                 | 0.33 (0.09–1.01) | 0.07 | - | - |
| Cumulative dose                 | 1.01 (1.00–1.01) | 0.22 | - | - |
| Number of drugs taken in 1 day  | 1.30 (0.96–1.77) | 0.09 | - | - |
| TIPN symptoms                   | 0.80 (0.24–2.63) | 0.71 | - | - |
| Romberg test                    | 0.94 (0.90–1.08) | 0.09 | - | - |
| Sharpened Romberg test          | 0.99 (0.97–1.01) | 0.38 | - | - |
| Unipedal stance test            | 0.98 (0.95–1.01) | 0.28 | - | - |
| 30-s chair stand test           | 0.89 (0.71–1.02) | 0.08 | - | - |

*aStatistically significant

Fig. 3 A Kaplan-Meier curve of time to first fall among participants during received taxane-based chemotherapy. (a) Total participants (n = 123). (b) Participants with TIPN and without TIPN symptoms (n = 110, 30, respectively)
and help patients to evaluate and modify their homes for hazards to reduce the risk of fall, especially among patients with TIPN symptoms.

The results of the current study demonstrated a significant link between age and BMI and time to fall. There were several risk factors related to falls in the elderly, including physiological, musculoskeletal, and functional decline [41]. Aging is associated with a decline in peripheral nervous system structure and function, including a decline in the number of sensory and motor neurons and the impairment of sensorimotor integration capacity [41, 42]. Many studies have found an association between age and the risk of TIPN symptoms [8, 43, 44]. Elderly people with neuropathy symptoms seem to have an abnormal gait, muscle weakness, and functional decline, which increases the risk of falls [15, 18, 45]. In addition, the literature indicated that patients with neuropathy symptoms have an increased risk of falls [46]. Furthermore, one previous study explored the association between overweight and obese individuals and the risk of falls. The results suggested that obese individuals have an increased risk of falls [47]. The possible reason might be related to the levels of physical function and activity in a person with a high BMI. A person with a high BMI had an increased risk of functional limitation [48]. Patients with cancer who had undergone neurotoxic chemotherapy agents and had functional limitations seemed to be at an increased risk of fall [18]. Therefore, early screening falling among women with breast cancer should be performed during taxane-based chemotherapy, particularly in older women with a high BMI.

A few limitations need to be considered. Only the fall incidence density throughout the treatment period and within a 30-day follow-up was provided in the current study. It was unable to express the fall incidence density over a longer period. Another flaw in this study was the use of a self-reported assessment to evaluate the TIPN symptoms, which failed to observe motor neuropathy. Moreover, our findings suggested that the fall incidence density and risk factors associated with time to fall might be unique to women with breast cancer aged 35 to 65 and could not be extended to other age groups. Hence, the results of the current study may not be able to be extrapolated to other cancer populations. More research should be done on the sensory and motor neuropathy screening activity using a combination of patient self-reported and objective evaluation techniques, as well as computerized postural stability examinations. In addition, future research should also be conducted concerning fall incidence density continuing for at least 6–12 months after finishing chemotherapy treatment.

The results of this study help us to better understand that the first fall for women undergoing taxane-based chemotherapy treatment occurs after the first cycle of treatment and then falls continue throughout the course of treatment, with the highest percentage occurring during the 30-day follow-up. Furthermore, the results demonstrated a significant association between time to first fall and age and BMI. These findings imply that early detection of falling among older persons and those with a high BMI may be essential to preventing falls. Moreover, this study supports the idea that the education of patients on the modification of their homes for hazards could reduce the risk of fall as the results demonstrated that most patients fell at home.

Author contribution All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Nida Rattanakrong. The first draft of the manuscript was written by Nida Rattanakrong and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethics approval This study was performed in line with the principles of the Declaration of Helsinki. The study protocols were approved by the Ethics Review Committee for Research Involving Human Projects, Chulalongkorn University (COA No. 209/2020), National Cancer Institute of Thailand (COA No. 025/2020), King Chulalongkorn Memorial Hospital (COA No. 001/2021), and Bhumibol Adulyadej Hospital (under study ID: 13/63) before data collection.

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

Consent for publication Not applicable.

Code availability Not applicable.

Conflict of interest The authors declare no competing interests.

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