Objective: The aim was to evaluate the reliability and the validity of the Turkish version of the chemotherapy-induced peripheral neuropathy assessment tool (CIPNAT) in cancer patients using taxane. Methods: This methodological study was carried out to evaluate the validity and the reliability of the CIPNAT. The sample cohort comprised 430 breast cancer patients who were administered taxane, a chemotherapeutic agent, between April and December 2017. Data were collected by the CIPNAT and by a demographic data form. The CIPNAT content reliability was checked after completing it in Turkish. Validity was tested after the translation as well. Cronbach’s alpha and test–retest reliability were utilized for reliability analyses. Results: Cronbach’s alpha value was 0.87 in this study. The test–retest reliability ranged between 0.90 and 0.96 for all items. No difference existed between the means of test and retest scores of the CIPNAT. A statistically significant positive relationship materialized between the item’s test and retest scores. There were statistically significant positive relationships among all levels of the CIPNAT. Factor analysis resulted in a size value higher than 1 and explained 66% of total variation. These results show that the Turkish version of the CIPNAT is a valid and reliable scale in Turkish society. Conclusions: This study showed that the CIPNAT in Turkey is a reliable and valid tool to evaluate taxane chemotherapy in breast cancer patients.

Key words: Breast cancer, peripheral neuropathy, taxane, validity–reliability

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Introduction

Chemotherapy-induced peripheral neuropathy (CIPN) is a common complication, in which chemotherapy drugs cause damage to the peripheral nerve system. The reported incidence of drug-induced peripheral neuropathy ranges from 20% to 100%. Drugs that have been identified as causes of toxic neuropathy include taxanes (paclitaxel and docetaxel), platinum-based drugs (oxaliplatin, cisplatin, and carboplatin), vinca alkaloids (vincristine, vinblastine, and vinorelbine), thalidomide, and bortezomib. These drugs affect different parts of the nervous system. Initially, CIPN affects feet and later progresses to the hands and arms. Affected patients may experience symptoms such as tingling, numbness, burning, or an electric shock sensation. These symptoms can have negative effects on patients' activities of daily living. Symptoms of CIPN may be observed at the beginning of treatment, as well as during and after treatment. The side effects of chemotherapeutic drugs are dose dependent and often manifest as sensory dysfunction. Currently, anthracyclines and taxanes are considered the most important chemotherapeutic drug regimens administered during breast cancer treatment. Taxol was first isolated from the shell of Taxus brevifolia, a plant native to the USA, in 1962. Today, taxane compounds (paclitaxel and semisynthetic derivative docetaxel) are considered the most important chemotherapeutic agents for cancer. However, the incidence of neuropathy increases with prolonged taxane treatment, ultimately leading to severe neuropathy.

Several scales have been developed to evaluate CIPN. These include the National Cancer Institute Common Terminology Criteria for Adverse Events, Reduced Total Neuropathy Score (TNSr), TNSr-Short Form, and Neuropathic Pain Scale for Chemotherapy-Induced Neuropathy.

The CIPN Assessment Tool (CIPNAT), which was developed by Tofthagen et al., evaluates both the condition of peripheral neuropathy and the daily challenges faced by patients. Kutlutürkan et al. previously studied the reliability and validity of the CIPNAT in cancer patients treated with taxanes or platinum group. By contrast, with this study, we aimed to investigate all neuropathy-related problems occurred breast cancer patients treated with taxanes.

Therefore, this study evaluated the reliability and validity of CIPNAT for peripheral neuropathy in patients receiving taxane-based chemotherapy for breast cancer.

Hypothesis

H₀: CIPNAT is not a valid or reliable tool for evaluating CIPN in breast cancer patients.

Methods

Study design and samples

This methodological study was conducted at the Ankara University School of Medicine, the Outpatient Chemotherapy Unit of Cebeci Hospital, and the Day Chemotherapy Unit of the Gülhane Training and Research Hospital.

Inclusion criteria

Patients with breast cancer were included in the study on a voluntary basis if they met the following criteria: ability to comprehend and speak the Turkish language, age older than 18 years, development of neuropathy upon taxane treatment at an oncology clinic or outpatient/daily chemotherapy unit, and nonterminal-stage cancer. Patients with diabetes and central nervous system complications that prevented questionnaire completion were excluded from the study.

Following an expert assessment, the CIPNAT retained 23 variables and first nine items consist of three parts. It was designed as a 41-point scale when collected with other residents. The sample size was calculated as 10 times by the item numbers in the questionnaire. In this context, the study was applied on 430 patients, with the evaluation of the sub items. The sub items were as follows: “How disturbing was it?,” “How emotionally upsetting was it?,” and “How frequently did you experience it?” Data from 282 individuals with neuropathy were analyzed according to the CIPNAT.

Instruments

The study data were collected using the “patient identification form for the determination of peripheral neuropathy development status in oncology patients” and CIPNAT.

Patient identification form for the determination of neuropathy development status in oncology patients

This form comprised three sections:

In the first section, the patient’s age, sex, educational status, occupation, marital status, average monthly income, number of members and children in the family, place of permanent residence, home ownership status, family history of cancer diagnosis, current status of the patient, history of smoking and alcohol use, and chronic illness status assessment were recorded.

In the second section, the patient’s primary diagnosis, date of diagnosis, and disease stage were recorded. The following information about previous treatments was also recorded: date and type, radiotherapy administration status, current treatment, chemotherapeutic drug type, cycles of chemotherapy, status of peripheral neuropathy preventive

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treatment, surgical history, and names, doses, administration routes, and duration of use of any medications.

The third section recorded information about the incidence of common symptoms and signs occurring during or after chemotherapy, including dizziness, loss of balance, falling, increased sensitivity to cold, tingling, numbness, burning sensation, dysphagia, and weakness, as well as the locations of these issues such as fingers and toes, hands, feet, legs, or other areas of the body. If any of these problems had occurred, the observations were evaluated in the context of chemotherapy in the morning, afternoon, evening, and night and the continuity or occurrence of problems at other times.

Chemotherapy-induced peripheral neuropathy assessment tool

The CIPNAT is a Likert-type scale developed by Tofthagen et al. This tool comprises two sections. The first section consists of 36 items that address the frequency, severity, and state of discomfort due to neuropathic symptoms. The second section consists of 14 items intended to evaluate patients’ daily activities. Initially, the patients were asked if they had developed any of nine symptoms after chemotherapy. If the answer to any question was “yes,” the frequency, severity, and state of discomfort associated with that symptom were scored and evaluated using a numerical scale of 0–10. A higher score indicated a high level of neuropathy due to chemotherapy.

Tofthagen et al. reported a statistically significant correlation between the Functional Assessment of Cancer Therapy/Gynecologic Oncology Group–Neurotoxicity and CIPNAT scales (r = 0.83, P < 0.001, n = 167). The total Cronbach’s alpha coefficient of the CIPNAT scale was 0.95. These study results indicate that the scale is a valid and reliable tool.

In our study, the two-part scale was prepared for preapplication after expert-level language and scope validation. The first part included questions about sensory and motor issues such as numbness, itching, burning, discomfort, sensitivity to cold, pain, weakness, and balance disorders. Each question was assigned four options, A–D, and for each “Yes” response to A (over the last week, have you experienced this), the three following questions were answered: B, How severe was it? C, How emotionally upsetting was it? and D, How frequently did you have it? Each category was scored on a scale of 0–10. Initially, this tool was evaluated on the patients who answered yes to the items. If the answers were 1 or 2, the responses were evaluated as few, and if the answers were 8, 9, or 10, the responses were evaluated as many. In the second section of the form, the problems faced by patients during activities of daily living (e.g., dressing, walking, picking up objects, holding onto objects, driving, working, participating in hobbies or leisure activities, exercising, sleeping, sexual activity, interpersonal relationships, writing, usual household chores, and enjoyment of life) were evaluated and scored on a scale of 0–10.

Data collection

The study data were collected from patients who met the inclusion criteria and visited the participating university hospital and day chemotherapy unit of an educational research hospital between April and December 2017.

Demographic data were collected from patients who had provided written consent to participate. Information about medical characteristics was obtained from the patients’ files. Finally, patients were asked about the problems that they experienced during or after treatment and requested to complete the CIPNAT. Approximately 15–20 min was needed to complete the questionnaire. To test the comprehensibility of the data collection forms, 10 patients were included in a pre (pilot)-application between May 1 and 15, 2017. For retesting, the scale was reapplied to 27.9% (n = 122) of the sample group at 2-week intervals. Participation in retesting was also voluntary. On the 1st day of the questionnaire form application, the weekly chemotherapy treatment time duration of patients who consented to participate was recorded to enable subsequent data collection.

Statistical analysis

The data collected from the patients were evaluated using SPSSIBM® (Statistical Package for the Social Sciences for Windows), version 22.0 (IBM, Armonk, NY, USA). Numbers and percentage distributions were used to evaluate descriptive statistics.

To validate the CIPNAT, the language translation, construct, and content validity were assessed; to determine reliability, the internal consistency coefficient, substance analysis, and time-invariant were determined. The back-translation method was used to determine language validity, while a factor analysis was used for structure reliability and expert opinions were solicited to determine content validity. Internal consistency was calculated using Cronbach’s α coefficient and the item-total correlation coefficient. The test–retest method for time-invariant determination was calculated using the Pearson product moment correlation coefficient. A P < 0.05 was considered statistically significant.

Ethical approval

The authors who developed the CIPNAT scale granted permission for its use in Turkey. The Ethics Committee of the University of Ankara also granted permission for the study (number 85434274-050.04.04/5510, dated
January 23, 2017). Permission for the study was also received from the Head Physician of the Cebeci Research and Practice Hospital of Ankara University (number 5913746-663.08-4027, dated April 14, 2017). In addition, permission for the study was also received from the Head Physician of the Gülhane Research and Practice Hospital (decision number 5913746-663.08-E.1347, dated February 21, 2017). Patients provided written consent to participate after receiving an explanation of the study.

**Results**

Information about the medical and other characteristics of the 430 participating patients is presented in Tables 1 and 2, respectively.

Table 3 presents information about the signs and symptoms reported by 282 patients diagnosed with developing neuropathy.

**Language validity translation**

Initially, a request for permission to apply the CIPNAT in Turkey was sent to Tofthagen et al., the developers, via e-mail. Subsequently, the CIPNAT was translated from English into Turkish by three experts proficient in English. The resulting scale was back-translated into English by three people: a linguist and two native English speakers. In the last stage, semantic differences were avoided by equalizing the forms in both languages.15,16

**Content validity**

After making the necessary corrections, the scales were presented to a panel of 10 experts to determine the content validity. Each item was rated as “necessary,” “useful but insufficient,” or “unnecessary.”17 There were no significant differences among the experts’ opinions regarding the content validity of the scale. After obtaining expert opinions, the scale was assumed to be ready for preapplication. During the preapplication, the patients’ understanding of the scale items and the related problems were determined and the answers were recorded. As each item was understood during the preapplication, no changes were made to the scale.

**Structure reliability**

The Kaiser-Meyer-Olkin (KMO) Test and Bartlett’s Test (Chi-square test) were used to determine whether the CIPNAT was appropriate for a structural reliability analysis.15,18 The tests indicated that data obtained using this scale were sufficiently good for a factor analysis (KMO = 0.966; P = 0.0001; $\chi^2 = 40$, 306.216). A principal component analysis conducted to test the structure reliability of CIPNAT and determine the factors yielded factor powers of 0.553–0.937 [Table 4].

**Internal consistency coefficient**

Reliability indicates whether all items in a scale are or are not homogeneous. In this study, Cronbach’s $\alpha$ coefficient was used to test the internal consistency of CIPNAT.13 For each dimension of the developed scale, Cronbach’s $\alpha$ values were determined using an internal consistency analysis. Individual evaluations of the scale sub dimensions yielded the following $\alpha$ values: “How severe was it?” –0.88; “How emotionally upsetting was it?” –0.87; and “How frequently did you experience it?” –0.87. These results indicate that

| Table 1: Sociodemographic characteristics (n=430) |  |
|---|---|
| Socio-demographic characteristics | n (%) |
| **Age (years)** | |
| 25-44 | 123 (28.61) |
| 45-59 | 195 (45.35) |
| 60 and more | 112 (26.04) |
| **Education** | |
| Illiterate | 30 (6.9) |
| Elementary school | 186 (43.3) |
| Secondary school | 38 (8.8) |
| High school | 123 (28.6) |
| University and higher | 53 (12.4) |
| **Employment** | |
| Unemployed | 324 (75.5) |
| Retired | 24 (5.5) |
| Employed | 82 (19) |
| **Marital status** | |
| Married | 352 (81.8) |
| Single | 78 (18.2) |
| **Children number** | |
| 0-2 | 264 (61.4) |
| 3 and more | 166 (38.6) |

| Table 2: Patient medical characteristics (n=430) |  |
|---|---|
| Medical characteristics | n (%) |
| **Stage of cancer** | |
| I | 8 (1.9) |
| II | 164 (38.1) |
| III | 223 (51.8) |
| IV | 35 (8.2) |
| **Prechemotherapy** | |
| Yes | 47 (10.9) |
| No | 383 (89.1) |
| **Taxane dose** | |
| 90-139 mg | 273 (63.5) |
| 140 mg and more | 157 (36.5) |
| **Received cures** | |
| 1-2 | 124 (28.8) |
| 3-6 | 157 (36.5) |
| 7 and more | 149 (34.7) |
| **Total cures** | |
| 12 | 365 (84.9) |
| > 12 | 19 (4.4) |
| < 12 | 46 (10.7) |
the scale was highly reliable. In addition, the reliability coefficient $\alpha$ of another dimension, “Over the last week, how much have the symptoms you reported interfered with daily activities?” was 0.97. For all scale items, $\alpha = 0.87$.

**Substance analysis**

A substance analysis was performed to determine the extent to which the items of CIPNAT were entirely related to the overall tool.\(^{15}\) The patients’ answers to the scale questions and the total correlations of each item with the other items were calculated [Table 4].

**Time-invariant**

The test–retest analysis is the most commonly used method to determine whether a measurement instrument is time-invariant.\(^{13}\) In the test–retest analysis of the time-invariance of CIPNAT, a very strong correlation was observed between the scores obtained from the first application of the scale and those obtained from the reapplication [Table 5].

**Discussion**

In this study, CIPNAT received significantly high results in the validity and reliability analyses when used to evaluate CIPN in patients receiving taxane-based therapy for breast cancer [Tables 4 and 5]. These results led to the rejection of the $H_0$ hypothesis, “CIPNAT is not a valid or reliable tool for evaluating CIPN in breast cancer patients.”

Currently, taxanes play an important role in the adjuvant chemotherapy treatment of breast cancer. However, CIPN is a common side effect experienced by cancer patients treated with taxane-based therapies.\(^{19}\) Accordingly, CIPNAT, which was designed to evaluate the neuropathic conditions of patients receiving taxane treatment and associated problems with activities of daily living, was systematically introduced into a Turkish language setting. This tool is expected to facilitate and simplify evaluations and records of the development of neuropathy in cancer patients treated with taxanes. In this study, the evaluation of the CIPN was conducted as recommended by the literature with respect to validity and reliability.

The evaluation of scale reliability revealed the reapplicability of CIPNAT. To determine the reliability of internal consistency, a single measuring tool is used.
to investigate whether the items consistently measure symptoms. Tools with a high level of internal consistency between items are considered reliable. A reliability coefficient >0.70 is considered desirable for a measurement tool. For multidimensional scales, the \( \alpha \) coefficient should be calculated for each factor. In this study, Cronbach’s \( \alpha \) coefficient was used to determine internal consistency. The high \( \alpha \) reliability coefficients for all scale items and each dimension (\( \alpha \geq 0.87 \)) indicated that the scale was highly reliable. This is consistent with the findings of Tofthagen et al., who reported \( \alpha \) values of 0.93, 0.91, and 0.95 for the symptom evaluation, effects on activities of daily living dimensions, and total items, respectively. Similarly, Kutlutürkan et al. reported a Cronbach’s \( \alpha \) of 0.97 for the total items. These results indicate that the scale items were consistent with each other and that the scale exhibited good internal consistency.

In reliability analysis, the between-item correlation coefficients are calculated to determine the strengths of the relationships (strong or weak) and the consistency between items. The literature suggests that an acceptable coefficient for item selection would be nonnegative and >0.20. In this study, the item-total score correlations ranged between 0.56 and 0.92. For each item, a higher correlation coefficient indicated that the focused behavior could be effectively measured.

Here, a correlation coefficient closer to +1 is thought to indicate higher reliability. To evaluate time-invariance, the scale in this study was reapplied to 122 patients after a 2-week interval from the first application. The coefficients of invariance \( r \) between two applications of the scale at the 2-week interval were 0.93, 0.96, 0.96, and 0.90 for the dimensions of “How severe was it?,” “How emotionally upsetting was it?,” “How frequently did you experience it?,” and “Over the last week, how much had the symptoms you reported interfered with daily activities?,” respectively. These results demonstrate a significant and positive correlation between the test and retest scores among patients in this study. Similarly, Tofthagen et al. reapplied the original scale to 30 patients to determine the test–retest reliability. Therefore, the symptom evaluation and activities of daily living dimensions received \( r \) values of 0.897 and 0.932, respectively. These results indicate that the scale is time-invariant, with a statistically high level of reliability.

Validity can be described as the degree of measurement of a property measured by a measurement tool. Content validity is assessed to determine whether each item in the scale, as well as the total scale, represents the area to be measured. In the content validity analysis of CIPNAT, the opinions of 10 experts did not differ significantly. Subsequently, a preapplication involving 10 patients revealed that the scale was understood. Accordingly, the expressions used in the Turkish-translated scale appear to have an understandable language structure and content. Finally, a factor analysis is conducted to determine whether the scale items could or could not be grouped under different sizes. This study included explanatory factor analyses. The literature suggests that factors with positive values exceeding 0.32 should be included. Kutlutürkan et al. reported factor powers of 0.498 and 0.948, consistent with our factor powers of 0.553–0.937. These powers explain 66.6% of the variance in a single factor.

CIPNAT was found to be a valid and reliable tool for application in Turkish settings.

**Limitations**

This study is limited by the fact that CIPNAT was developed only for taxane-treated breast cancer patients.

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**Conflicts of interest**

There are no conflicts of interest.

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Appendix: Chemotherapy-Induced Peripheral Neuropathy Assessment Tool

| Over the last week, have you experienced | How severe is it? | How distressing (emotionally upsetting) is it? | How frequently do you have it? |
|------------------------------------------|------------------|---------------------------------------------|-------------------------------|
| A                                        | B                | C                                           | D                            |
|------------------------------------------|------------------|---------------------------------------------|-------------------------------|
| Numbness in fingers/hands?               | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Numbness in toes/feet?                  | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Tingling in fingers/hands?              | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Tingling in toes/feet?                  | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Discomfort in fingers/ hands or toes/feet? | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Sensitivity to cold temperature?        | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Muscle or joint aches?                  | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Weakness in arms or legs?               | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |
| Trouble with your balance?              | No               | 0 1 2 3 4 5 6 7 8 9 10                      |                               |

Over the last week, how much have the symptoms you reported interfered with:

| Activity                      | Not at all | Completely |
|-------------------------------|------------|------------|
| Dressing (buttoning, zipping, etc.) | 0 1 2 3 4 5 6 7 8 9 10 |
| Walking                       | 0 1 2 3 4 5 6 7 8 9 10 |
| Picking up objects            | 0 1 2 3 4 5 6 7 8 9 10 |
| Holding onto objects          | 0 1 2 3 4 5 6 7 8 9 10 |
| Driving                       | 0 1 2 3 4 5 6 7 8 9 10 |
| Working                       | 0 1 2 3 4 5 6 7 8 9 10 |
| Participating in hobbies or leisure activities | 0 1 2 3 4 5 6 7 8 9 10 |
| Exercising                    | 0 1 2 3 4 5 6 7 8 9 10 |
| Sleeping                      | 0 1 2 3 4 5 6 7 8 9 10 |
| Sexual activity               | 0 1 2 3 4 5 6 7 8 9 10 |
| Relationships with other people | 0 1 2 3 4 5 6 7 8 9 10 |
| Writing                       | 0 1 2 3 4 5 6 7 8 9 10 |
| Usual household chores        | 0 1 2 3 4 5 6 7 8 9 10 |
| Enjoyment of life             | 0 1 2 3 4 5 6 7 8 9 10 |