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ORIGINAL ARTICLE

Evaluation of the Semmes–Weinstein filaments and a questionnaire to assess chemotherapy-induced peripheral neuropathy

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Abstract
Objective This study aims to assess the use of Semmes–Weinstein monofilaments (SWMs) and of the Chemotherapy-Induced Neurotoxicity Questionnaire (CINQ) in the detection of chemotherapy-induced peripheral neuropathy (CIPN).
Method It is a comparative and cross-sectional study performed in a philanthropic general hospital, located in the state of Minas Gerais, Brazil. One hundred seventeen individuals have participated in this study; they were divided into two groups: patients (n=87) treated with oxaliplatin, paclitaxel, or docetaxel and controls (n=30) without malignant disease.
Results There were statistically significant differences between groups for all symptoms assessed by means of the CINQ. Lower limbs were more severely affected. Patients had increased frequency and severity of changes in all points assessed with SWM compared with controls. In the analyses of concordance between CINQ and SWM, kappa=0.320 (p<0.001) was obtained, and there was a moderate and positive correlation (ρ=0.357; p<0.001).
Conclusion CINQ and SWM may be valid tools for diagnosing CIPN in oncology practice. SWM may identify subclinical CIPN.

Keywords Cancer · Neuropathy · Chemotherapy · Drug therapy · Adverse effects

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Introduction

Chemotherapy-induced peripheral neuropathy (CIPN) is a major dose-limiting side effect of several chemotherapeutic agents. Estimates of its prevalence can be as high as 60 % in patients receiving treatment of antineoplastic drugs. CIPN is mainly associated with the administration of taxanes and platinum derivatives which are used to treat different cancers, including breast, ovarian, lung, and intestine cancers [1–3]. The neurotoxic effects of these drugs cause sensory, motor, and autonomic nervous system impairment that may produce distressing symptoms and functional compromise [4]. Sensory neuropathy is the most common type of CIPN and often impairs activities of daily living [5, 6]. The main symptoms are numbness, burning and electric shock-like pain in hands and feet, and hypersensitivity to cold temperatures [7–9].

There are great challenges in recognizing and managing the symptoms of CIPN, which are related to limited understanding of its pathogenesis, lack of evidence-based practice for symptom management, and late recognition of the symptoms [9]. Results of a study investigating the assessment of chemotherapy-induced neurotoxicity showed that most of

the oncology nurses (75 %) were aware of the importance of detecting and monitoring CIPN but held little knowledge about the available assessment methods [10].

To assess sensory impairment in clinical practice, the use of a tuning fork has been suggested to evaluate vibratory sensation, specific tests of proprioception (sense of the relative position of neighboring parts of the body), stereognosis test, and walk-and-turn test [9]. Other structured and/or systematic assessment tools are available and have been used in patients at risk for CIPN, such as electroneuromyography (ENMG) and clinical inventories. ENMG is the gold standard tool for the evaluation of peripheral neuropathy but is expensive and can be influenced by different measurement techniques and by physiological factors. Variables like temperature of the skin and presence of unmyelinated fibers will affect the results and lead to equivocal diagnosis [11].

The National Cancer Institute Common Toxicity Criteria (NCI-CTC) is commonly used as a grading scale to classify the severity of CIPN and to assess its impact on activities of daily living [12–14]. Other scales, such as the Functional Assessment Cancer Therapy/Gynecology Group-Neurotoxicity (FACT/GOG-Ntx), the FACT-Taxane, and the QLQ-CIPN 20 are used to assess CIPN symptoms and related quality of life [15–17]. Some of the most frequently used diagnostic scales for assessing CIPN are the Total Neuropathy Score (TNS), the Patient Neurotoxicity Questionnaire (PNQ), the Chemotherapy-Induced Peripheral Neuropathy Assessment Tool (CIPNAT), the Oxaliplatin Scale, the Neuropathic Pain Scale for Chemotherapy-Induced Neuropathy (NPS-CIN), and the Chemotherapy-Induced Neurotoxicity Questionnaire (CINQ) [12, 18–23].

CINQ is a structured questionnaire, capable of determining the incidence, type, and duration of neurological changes in lower and upper limbs and in oral and facial parts as well as the impact of CIPN symptoms on the person's ability to perform activities of daily living (ADLs) [18]. Recently, this tool was translated and validated into Dutch and was compared to the FACT/GOG-Ntx. Results showed a negative association between severe neuropathy symptoms and quality of life [24].

The Semmes–Weinstein monofilaments (SWMs), or an esthesiometer, is a sensitive, specific, simple, and inexpensive screening tool for identifying peripheral neuropathy in clinical setting. Developed to assess tactile point pressure sensitivity, this tool has been routinely used to detect peripheral sensory neuropathy in patients with diabetes and leprosy, but not in the oncology setting [25, 26].

Recently, the CI-PeriNomS Group [27] analyzed the validity and reliability of tools to assess CIPN. The group concluded that the tools showed discrepant results when assessing the severity of the CIPN, and there is an urgent need for more studies to determine effective assessment strategies to identify signs and symptoms of neurotoxicity. Therefore, the current study aimed to evaluate the effectiveness of the SWM examination and CINQ [18] for CIPN screening.

Methods

Sample and setting

We conducted a cross-sectional study at a large philanthropic hospital in Brazil between July 2010 and February 2011. The local ethics committee approved the study, and all patients gave written informed consent.

A sample of 117 individuals participated in the study. Subjects were allocated into control or patient groups. Subjects 18 years or older, who received at least 1 cycle of oxaliplatin, docetaxel, or paclitaxel, composed the patient group (n=87). Control group (n=30) included relatives or friends of the patients who had similar sociodemographic characteristics and who had never received antineoplastic treatment. Exclusion criteria for both groups were the presence of cognitive impairment, history of sensory or motor symptoms due to traumatic or non-traumatic neurological diseases, diabetes, and alcohol consumption more than two times a week.

Instruments

A sociodemographic questionnaire and review of medical charts were used to identify sociodemographic and clinical characteristics of the sample. Functional capacity of participants was evaluated using the ECOG Performance Status Scale, a tool developed by the Eastern Cooperative Oncology Group and validated by the World Health Organization (WHO) in 1982 [28]. CINQ and SWM were used to assess CIPN and its severity.

CINQ was translated into Portuguese and was adapted and validated after the original authors' permission [18]. Following the translation and back-translation, three specialists validated the semantic, technical, and content equivalence. Conceptual and criterion validity tests supported the cross-cultural stability of the CIPN. Test–retest reliability showed good internal consistence, with a Cronbach's alpha of 0.863. The Portuguese version of the CINQ was easily understood by the participants.

CINQ was designed to be completed by nurses to get information on peripheral neurological symptoms experienced by the patient just after a chemotherapy cycle [18]. Nine of the 29 items assess symptoms on the lower limbs, 10 assess symptoms on the upper limbs, and 10 assess oral and facial symptoms. Each item assesses the frequency of the symptom and its impact on ADL. The sum of individual items leads to a final score that categorizes the participant in a grading scale according to the presence of symptoms and

impact on ADL: 0 (no symptom), 1 (symptoms of short duration that do not interfere with function), 2 (symptoms interfering with some functions, but not with the basic activities of daily living), 3 (pain or functional impairment that interferes with activities of daily living), and 4 (persistent symptoms that are disabling or life-threatening) [13, 18].

For the SWM test, we used the Sorri® SWM kit which has six monofilaments with different colors and weight from 0.05 to 300 g. The monofilaments enable the clinician to make a map of areas with reduced pressure perception and with easy visualization and fast interpretation and diagnosis [25]. SWM test followed the protocol used in Brazil to evaluate leprosy neuropathy [29]. The testing session started using the thinnest monofilament (0.05 g, green color), as recommended by the manufacturer.

Procedures to evaluate CIPN

The research nurse collected the data during individual appointment. First, the participant was interviewed with CINQ. Then, the research nurse performed SWM test, instructing the participants to keep their eyes closed during the test. Each monofilament was used for three consecutive times on the same point, and the participants were asked to provide information about their sense of touch, including its precise location. If the participant did not feel a monofilament, the following (heavier) one was used [25, 29]. Tactile perception along the pathway of the radial, ulnar, and median nerves was assessed on seven points on each hand. Each foot had the tibial, sural, saphenous, and fibular nerves assessed on 10 points (Fig. 1) [29].

We considered an impaired sense of touch when the person did not perceive the green monofilament's pressure (0.05 g) at any point of the hand. Previous studies concluded that a perception up to the 0.05 g filament indicates a normal skin sense of touch, except for the plantar region, where a normal perception is up to the blue filament (0.2 g) [25, 29].

Statistical analyses

Statistical analyses were performed using SPSS software version 15.0 (SPSS, Inc., Chicago, IL, USA). Descriptive analyses provided data on sociodemographic and clinical parameters. Comparisons between patients and controls were performed using Mann–Whitney and chi-square tests for continuous and categorical variables, respectively. The effect of age and performance status in CINQ grading was controlled by a logistic regression model. According to the backward elimination procedure, variables with the highest p value in univariate analysis were progressively deleted from the model. The final model retained variables with a significance level of ≤ 0.05. The goodness of fit of the final model was tested using the Hosmer–Lemeshow method.

Spearman coefficient provided the correlation between CINQ and SWM final scores, and kappa coefficient indicated agreement between CINQ and SWM in defining impaired and non-impaired sensory function in subjects. All p values were two-tailed, and a significance level of $\alpha = 0.05$ was chosen.

Results

Sample characterization

Table 1 shows the sociodemographic and clinical characteristics of patients and controls. Age ranged from 45 to 63 years old, and the majority of participants were women and had low educational level and income. Patients demonstrated worse performance status, as assessed by ECOG functional scale, when compared to controls ($p < 0.001$). However, the majority of patients (69 %, $n = 60$) had only mild impact in performance status.

The majority of patients received paclitaxel (68.9 %, $n = 60$), an antineoplastic drug commonly used to treat breast, ovarian, and lung cancers. The number of treatment cycles varied between 2 and 14 (mean±SD; 3.2±3.09).

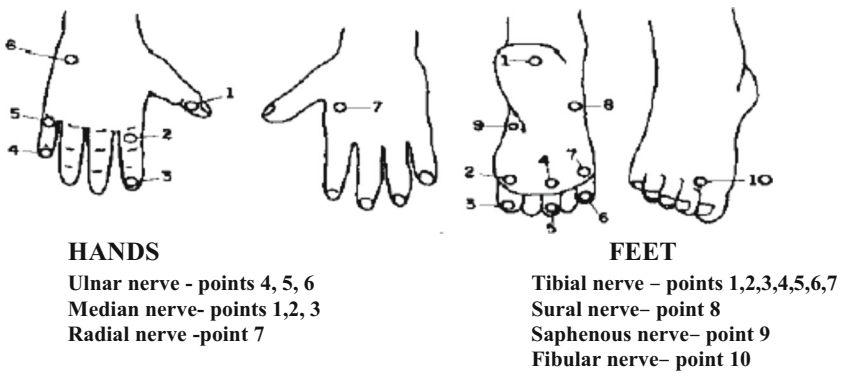

Fig. 1 Points assessed by the Semmes–Weinstein Monofilaments and their corresponding nerves

Table 1 Comparison of sociodemographic and clinical characteristics between patients (N=87) and controls (N=30)

	Patient (n=87) n (%)	Control (n=30) n (%)	p value[a] (p<0.05)
Age (years)	53±11.9	44±12.7	*0.035*[a]
Gender			0.306[b]
Female	67 (77.0)	26 (86.7)	
Male	20 (23.0)	4 (13.3)	
Marital status			0.558[b]
Single/divorced	22 (25.3)	8 (26.7)	
Married	56 (64.4)	21 (70)	
Widowed	9 (10.3)	1 (3.3)	
Schooling			0.140[b]
Illiterate	8 (9.2)	3 (10.0)	
Elementary school	46 (52.9)	11 (36.7)	
High school	24 (27.6)	8 (26.6)	
Higher education	9 (10.2)	8 (26.6)	
Smoking			0.777[b]
Yes	13 (14.9)	5 (16.7)	
No	74 (85.1)	25 (83.3)	
Alcohol consumption			1.000[b]
Yes	22 (25.3)	8 (26.7)	
No	65 (74.7)	22 (73.3)	
ECOG Performance Status (PS) Index			*<0.001*[c]
0	03 (3.4)	29 (96.7)	
1	60 (69.0)	01 (3.3)	
2	21 (24.1)	00 (0)	
3	03 (3.4)	00 (0)	
Adopted chemotherapy protocol			
Paclitaxel	60 (68.9)	–	–
Oxaliplatin	25 (28.7)	–	–
Docetaxel	2 (2.3)	–	–
Number of chemotherapy cycles			
2–3 cycles	46 (52.8)	–	–
4–6 cycles	26 (29.8)	–	–
7–9 cycles	08 (9.2)	–	–
11–14 cycles	07 (7.9)	–	–
Type of cancer			
Breast	41 (47.1)	–	–
Colon/rectum	24 (27.6)	–	–
Ovary	08 (9.2)	–	–
Lung	6 (6.9)	–	–
Others	5 (5.7)	–	–
Type of chemotherapy			
Neoadjuvant	17 (19.5)	–	–
Adjuvant	32 (36.8)	–	–
Palliative	36 (41.4)	–	–
Concomitant	02 (2.3)	–	–

[a] Mann–Whitney U test (p<0.05)

[b] Chi-square test

[c] Fisher's exact test

Use of CINQ to detect sensory changes

Almost all patients (96.6 %, n=84) manifested at least one of the 20 symptoms investigated by CINQ, and among the controls, 19 (79 %) exhibited one or more symptoms (p<0.001). When comparing each CINQ subscale (lower limbs, upper limbs, oral/facial) between patients and controls, there were also significant differences in the presence of paresthesia or dysesthesias as shown in Table 2.

Lower limb paresthesia was more frequent than dysesthesia in the group of patients, with predominance of tingling (50.6 %) and numbness (49.4 %) in feet. Dysesthesia on lower limbs was reported as sensation of heavy legs (59.7 %), burning sensation, or hypersensitivity to cold (25.3 %). Symptoms on upper limbs were mainly tingling (49.4 %), numbness (46 %), and cold hypersensitivity of the hands (29.9 %). Oral and facial symptoms most reported by patients were drooping eyelids (37.9 %), tingling mouth (23 %), throat discomfort (37.9 %), eye discomfort (43.7 %), and shock-like pain (34.5 %).

When categorized according to CINQ grading, 47 % (n=41) of patients were classified in grades 1 to 3, mainly in grade 1 (28.7 %, n=25) (Table 3). Therefore, the majority of patients reporting CIPN symptoms present only mild interference in their ADLs.

In the logistic regression analysis including six independent variables (gender, age, nicotine use, alcohol use, performance status, and grades of CIPN evaluated by CINQ), CINQ grading (OR, 7.22; 95 % CI, 1.86–28.03) was retained in the final model.

Use of the SWM to detect chemotherapy-induced sensory changes

Over 80 % of the patients had at least one point with sensory change, while most controls (60 %) showed no change (p<0.001) (Table 4).

Table 2 Paresthesias and dysesthesias detected by the Chemotherapy-Induced Neurotoxicity Questionnaire (CINQ) in patients and controls

	Patient (n=87) n (%)	Control (n=24)[a] n (%)	p value[b] (p<0.05)
Lower limb paresthesia or dysesthesia	72 (82.8)	13 (54.2)	*<0.001*
Upper limb paresthesia or dysesthesia	65 (74.7)	10 (41.7)	*<0.001*
Oral and facial paresthesia or dysesthesia	70 (80.5)	13 (54.2)	*<0.001*

[a] Six controls did not answer the CINQ

[b] Chi-square test

Table 3 Classification of patients and controls on Chemotherapy-Induced Neurotoxicity Questionnaire (CINQ) grading

	Patient (N=87) n (%)	Control (N=30[a]) n (%)	p value[b]
CINQ grades			*<0.001*
0	46 (52.9)	29 (96.7)	
1	25 (28.7)	0	
2	15 (17.2)	1 (3.3)	
3	1 (1.1)	0	

[a] Six controls did not answer CINQ

[b] Chi-square (p<0.05)

Patients exhibited hand sensory loss starting with 0.2 g pressure (blue monofilament) until 4 g pressure (red monofilament), indicating a large spectrum of sensory changes, i.e., from mild sensory reduction to loss of protective sensation with an increased risk for lesions [30]. Controls showed milder changes in point pressure sensitivity. The largest difference between the groups was found in the point 5 of the right hand, which corresponds to ulnar nerve territory. Sensory changes in each hand point ranged from 50.6 to 70.1 % in patients and from 13.3 to 30 % in controls.

In lower limbs, the severity of sensory loss was worse in the group of patients, varying from the violet monofilament (2 g) up to the black mark (not perceiving any of the filaments), with great vulnerability to lesions. Sensory loss in each feet point varied from 26.4 to 88.5 % in patients group and from 6.7 to 83 % in the control group (p<0.05).

Correlation between CINQ and SWM final scores

The analysis of agreement between the instruments showed a weak but statistically significant kappa value (κ=0.320, p<0.001). Furthermore, Spearman correlation showed a positive correlation between SWM and CINQ (ρ=0.357, p<0.001) in the patient group, but there was no significant correlation in the control group.

Discussion

Significant CIPN symptoms were reported by 47 % of the patients when assessed by CINQ, while 80 % of the patients exhibited sensory changes in SWM test. There is no consensus about CIPN prevalence. Studies have reported very divergent numbers, with the frequency varying from 10 to 100 % [19, 31]. This large variability may be due to differences in methods to assess CIPN and sample characteristics [31]. This is exemplified by the current study in which, depending on the sensitivity of the assessment method, the frequency of CIPN can vary. As our sample is mainly composed of patients who have already been exposed to at least three cycles of chemotherapy [32], this may contribute to explain the elevated number of CIPN described.

Table 4 Sensitivity changes detected by the Semmes–Weinstein monofilaments in patients and controls

	Patient (n=87) n (%)	Control (n=30) n (%)	Total (N=117) n (%)	p value[a] (p<0.05)
Left foot				
Point 1	75 (86.2)	25 (83.0)	100 (85.5)	*0.034*
Point 2	63 (72.4)	10 (33.3)	73 (62.4)	*0.005*
Point 3	61 (70.0)	11 (36.7)	72 (61.5)	*0.045*
Point 4	67 (77.0)	8 (26.7)	75 (64.1)	*<0.001*
Point 5	57 (65.5)	7 (23.3)	64 (54.7)	*0.007*
Point 6	56 (64.4)	8 (26.7)	64 (54.7)	*0.014*
Point 7	68 (78.2)	7 (23.3)	75 (64.1)	*<0.001*
Point 8	69 (79.3)	15 (50.0)	84 (71.8)	*0.045*
Point 9	59 (67.6)	8 (26.7)	67 (57.3)	*0.004*
Point 10	25 (28.6)	2 (06.7)	27 (23.1)	*0.022*
Right foot				
Point 1	77 (88.5)	24 (80.0)	101 (86.3)	*0.037*
Point 2	63 (72.4)	8 (26.7)	71 (60.7)	*<0.001*
Point 3	58 (66.7)	10 (33.3)	68 (58.1)	*0.040*
Point 4	59 (68.0)	8 (26.7)	67 (57.3)	*0.005*
Point 5	55 (63.2)	9 (30.0)	64 (54.7)	*0.050*
Point 6	54 (62.0)	9 (30.0)	63 (53.8)	*0.050*
Point 7	60 (69.0)	18 (60.0)	78 (66.7)	*0.037*
Point 8	65 (74.7)	14 (46.7)	79 (67.5)	*0.040*
Point 9	57 (65.5)	10 (33.3)	67 (57.3)	*0.006*
Point 10	23 (26.4)	3 (10.0)	26 (22.2)	0.067
Left hand				
Point 1	53 (60.9)	4 (13.3)	57 (48.7)	*<0.001*
Point 2	48 (55.2)	5 (16.7)	53 (45.3)	*0.002*
Point 3	45 (51.7)	8 (26.7)	53 (45.3)	*0.015*
Point 4	45 (51.7)	9 (30.0)	65 (55.6)	*0.045*
Point 5	47 (54.4)	6 (20.0)	53 (45.3)	*<0.001*
Point 6	51 (58.6)	7 (23.3)	58 (49.6)	*0.007*
Point 7	46 (52.9)	7 (23.3)	53 (45.3)	*0.045*
Right hand				
Point 1	59 (67.8)	7 (23.3)	66 (56.4)	*<0.001*
Point 2	57 (65.5)	8 (26.7)	65 (55.6)	*<0.001*
Point 3	55 (63.2)	9 (30.0)	64 (54.7)	*<0.001*
Point 4	54 (62.0)	8 (26.7)	62 (53.0)	*<0.000*
Point 5	61 (70.1)	6 (20.0)	67 (57.3)	*<0.001*
Point 6	57 (65.5)	8 (26.7)	65 (55.6)	*<0.001*
Point 7	44 (50.6)	7 (23.3)	51 (43.6)	*0.025*

In hands, points 1, 2, and 3 correspond to the median nerve; 4, 5, and 6 to the ulnar nerve; and 7 to the radial nerve. In feet, points 1, 2, 3, 4, 5, 6, and 7 correspond to the tibial nerve; 8 to the sural nerve; 9 to the saphenous nerve; and 10 to the fibular nerve

[a] Chi-square (p<0.05)

CINQ and SWM were demonstrated to be suitable to assess sensory changes associated with the use of different neurotoxic antineoplastic agents, which is in line with previous studies that used these two instruments independently [18, 24, 27, 33]. Nevertheless, the agreement between CINQ and SWM was modest. This can be partially explained by the rationale underlying each instrument (structured interview×standardized clinical evaluation). Moreover, when answering CINQ, factors like memory bias and fear of reporting symptoms that could impact on therapeutic plan may influence patients' response, underestimating the frequency and severity of CIPN [9, 14, 20, 31]. To minimize this, the clinician must be careful in CINQ application, for instance, assuming an empathic posture, making sure that the patient clearly understood the questions, and trying not to direct or influence the subject's answer [34]. Another caution is to observe whether respondents have a correct appraisal of their symptoms, as they tend to be inattentive when symptoms do not interfere with ADL.

SWM identified sensory loss not reported by the patients when answering CINQ, notably in lower limbs. Previous studies considered SWM as an effective assessment tool to detect sensory changes, enabling the clinician to map them, determining their extension and severity [29, 30, 34]. The results of the current study corroborate the value of the SWM test in identifying sensory changes in the oncology setting. Future studies must establish reference values for the SWM test in oncology patients after chemotherapy and how these values impact on ADL.

In the current study, most patients reporting significant CIPN symptoms exhibited only mild to moderate impact on ADL. This contrasts with previous studies suggesting that CIPN strongly affects the patient's quality of life [5, 18, 20, 24]. Sample characteristics (e.g., age, chemotherapy plan) and cultural aspects may explain this.

Regarding the distribution of CIPN symptoms, they usually start in lower limbs with progression to upper limbs and cranial segment [18, 19]. Accordingly, sensory symptoms were more frequently observed in lower limbs by both CINQ and SWM. SWM test revealed more severe sensory loss along tibial nerve territory, suggesting that the plantar region may be more susceptible to the consequences of CIPN than other areas. The damage of the tibial nerve with the consequent impairment of superficial (sense of touch, pressure, pain, and temperature) and deep (sense of vibration and proprioception) sensations in the feet predisposes the subject to be susceptible to foot injuries and falls [29].

Some of the limitations of this study include its cross-sectional design and the lack of comparison of the results with ENMG, which is considered as the gold standard test in the evaluation of peripheral neuropathies. Both CINQ and SWM do not measure neuropathic pain, which is an essential component in assessing patients treated with potentially neurotoxic antineoplastic drugs.

CINQ and SWM seem to be valid tools in oncology practice. SWM can identify subclinical CIPN, while CINQ can assess the impact of CIPN symptoms on the activities of daily living (ADLs). The need for subclinical CIPN detection among patients cannot be overemphasized. It can guide chemotherapy dose adjustment or even changes in the chemotherapy protocol. The systematic use of assessment tools such as the CINQ and SWM may provide important information, which will contribute for the control of neurotoxicity, thus preventing impact on ADL and decrease in the patient's quality of life. Future studies are warranted to support the role of these instruments in CIPN evaluation and management.

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Conflict of interest None

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